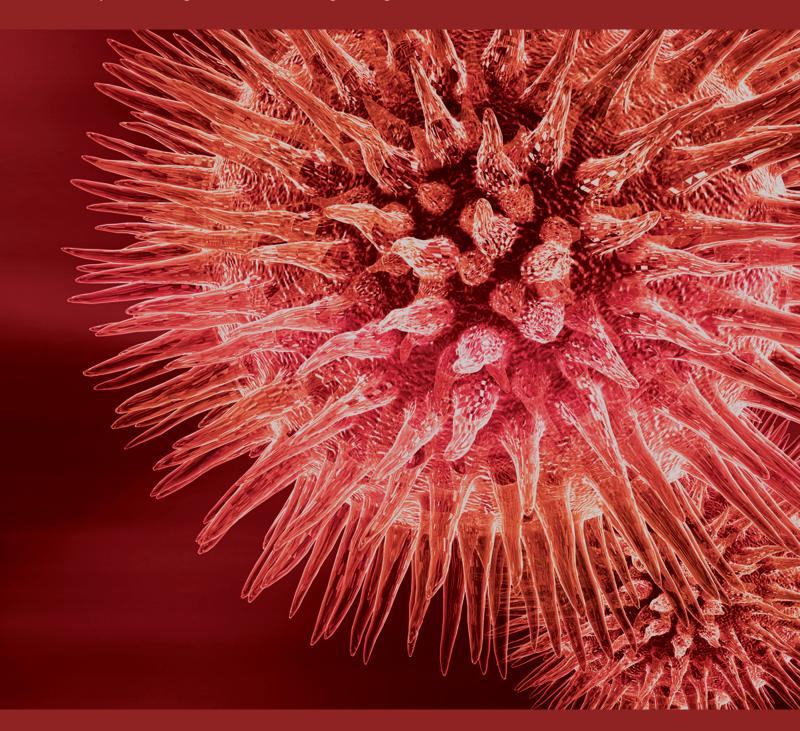
# The State of the Art in Minimally Invasive Spine Surgery

Guest Editors: Tsung-Jen Huang, Ki-Tack Kim, Hiroaki Nakamura, Anthony T. Yeung, and Jiancheng Zeng



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#### **Editorial**

### The State of the Art in Minimally Invasive Spine Surgery

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Received 9 February 2017; Accepted 9 February 2017; Published 28 February 2017

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In the past two decades, minimally invasive spine (MIS) surgery has been increasingly applied and drawn much attention in the treatment of spinal disorders [1–12]. To date, there has been a higher demand in patients' request to conduct this surgery, and the traditional open spine surgery has gradually been replaced with MIS surgery. According to the reports, the number of MIS instrumented surgeries conducted in 2010 accounted for 1/6 of the total number of all spine surgeries in the United States and 1/3 in 2016, which is anticipated to be more than 1/2 in 2020 [13].

With the aids of modern diagnostic and navigation technology, innovative spinal devices, and optical and improved MIS instruments, MIS surgery does show its merits including a smaller skin incision, less trauma to paravertebral soft tissues, reduced blood loss during operation, and a faster functional recovery in these patients. However, at present, whether MIS surgery can really achieve the expected results as in open surgery with fewer comorbidities is still debatable. However, the merits and demerits of these techniques in treating patients with spinal diseases have been systemically reviewed and critically analyzed [13–17]. The detailed information on why these techniques have low tissue invasiveness to the patient's body [18–21] and the same or even better outcome compared to traditional open spine surgery is still

very limitedly elucidated. However, we are glad to see that these changes might lead to better patient surgical outcomes and reduce the economic burden [22] for the medical cost related to postoperative hospital stay or complications.

Over the past 10 years, the important role of percutaneous full endoscopic interlaminar/transforaminal surgery has been reassessed in patients with degenerative lumbar disc diseases or stenosis [23–27]. This technique has been proven to work satisfactorily as other procedures even in patients with complex spinal degeneration or mild to moderate deformity that is usually considered a reason for fusion surgery in most of our past surgeries. Furthermore, the full endoscopic interlaminar/transforaminal surgery has become a daily surgical practice in many spine centers around the world. We have seen the potentiality in these procedures which could be like the laparoscopic cholecystectomy in general surgery developed in 1987, which now has already replaced traditional open cholecystectomy. In this way, we can preserve the fusion as a fallback procedure rather than prematurely fusing the spine and we can provide our patients first with an option of nonfusion surgery.

In this special issue, 12 papers were accepted for publication after a carefully blinded review by experts in MIS or spine field.

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C.-Y. Lee et al. reported a register-based case-control study of 187 patients undergoing video-assisted thoracoscopic (VATS, 111) or minimal access spine surgery (MASS, 76) in a single center. A systemic review of the literature including 625 VATS and 399 MASS patients was analyzed. The authors highlighted the notion that MASS is associated with reduced operative time, approach-related complications, and the thoracotomy conversion rate.

W. Kong et al. demonstrated nicely the surgical strategy of percutaneous full endoscopic interlaminar or extraforaminal, not transforaminal, approach for 62 patients with lumbar disc herniation. Two patients were converted to open surgery at initial procedures, with at least 1-year follow-up. The good to excellent rate of surgical result was 91.6%. The authors claimed that, based on the main location of the herniated disc and its relationship with the compressed root, percutaneous full endoscopic discectomy through 3 different puncture techniques is feasible and safe to remove the herniated disc.

M.-H. Chen and J.-Y. Chen reported on novel nonpedicular screw-based fixation in 39 patients with grade 1 lumbar spondylolisthesis with a mean follow-up of 1 year. The authors had used an interspinous fusion device (IFD) and two PLIF cages for each patient. There were no major complications noted. Interestingly, in the series, there were no spinous process fractures or migration of the IFD, however, in 5 patients having early retropulsion of the PLIF cages at the earlier weeks after surgery. They advocated that further study is mandatory for proposing a novel anatomic and radiological scoring system to identify which patients are suitable for this treatment modality and avoid postoperative complications.

P. D. Nunley et al. reported on an expanding treatment option, the Superion® spacer, an FDA approved device, for lumbar spinal stenosis at 2-, 3-, and 4-year follow-up. Certainly, this is a minimally invasive implantation procedure employing this stand-alone interspinous spacer that functions as an extension blocker to avoid compression of nerve root without direct surgical excision of tissue adjacent to it. They concluded that no inferiority was found compared with the open laminectomy group at each time period of follow-up.

M.-H. Wu et al. reported the outcome of using of the intraoperative computed tomography- (iCT-) guided navigation to operate on eight patients suffering from infectious spondylitis with simultaneous minimally invasive anterior and posterior approach. In their patients, the follow-up period was at least 2 years. They demonstrated that the application of iCT-guided navigation can provide good intraoperative 3D orientation and visualization of anatomic structures. It also offers a high pedicle screw placement accuracy in the patient's lateral decubitus position. In addition, the fact that all operation room staffs were free from the radiation exposure during operation under the iCT-guided navigation was a great advantage.

C.-L. Tai et al. performed a nicely designed research to analyze the applicability of bone cement for percutaneous vertebroplasty. The authors modified bone cement by combining polymethylmethacrylate (PMMA) with three different volume fractions of castor oil (5%, 10%, and 15%). It was found that increasing castor oil content and precooling treatment

effectively decreased the peak polymerization temperatures and increased the period to reach the peak polymerization temperature. They concluded that the addition of castor oil to PMMA followed by precooling may create ideal modified bone cement with a low modulus, low polymerization temperature, and long handling time, therefore enhancing its applicability and safety for vertebroplasty.

A.-M. Wu et al. performed a systemic review and metaanalysis to investigate the outcomes of minimally invasive versus open posterior approach spinal fusion in the treatment of lumbar spondylolisthesis. They concluded that the minimally invasive posterior approach had less estimated blood loss and hospital stay than open fusion; however, the minimally invasive approach required more operative time. They also highlighted the notion that both approaches had similar results in pain and functional outcomes, complication, fusion rate, and secondary surgery.

P. H. Chou et al. made a systemic review on the "topping-off" technique by applying the hybrid stabilization device (HSD), or interspinous process device (IPD), aiming to avoid adjacent segment disease (ASD) proximal to the fusion construct. Based on their review, the incidences of radiographic ASD at index level were 12.6%, 10.2%, and 52.6% in HSD, IPD, and fusion alone, respectively. They also claimed that the application of "topping-off" technique with HSD or IPD above fusion to avoid ASD still has no good evidence. Therefore, prospective randomized clinical trials should be conducted to further elucidate the role of topping-off techniques.

W.-S. Choi et al. reported and was the first to use an endoscopic radiofrequency ablation of the sacroiliac joint complex to treat 17 patients with chronic low back pain. The clinical result was a satisfactory rate of 88.6%. With a small incision at lower posterior sacral skin after C-arm localization, then introducing the endoscope upwardly can see and ablate the branches of posterior sacral nerve effectively. Their preliminary results confirmed the feasibility and efficacy of this novel technique.

L. Kuang et al. reported a new miniopen anterolateral lumbar interbody fusion (ALLIF) with self-anchored stand-alone polyetheretherketone (PEEK) cage in 22 patients receiving lumbar revision surgery. The mean blood loss was 85.4 mL. All patients achieved solid fusion at a mean of 2-year follow-up. They found that 4 patients with 4 operated levels had cage subsidence without clinical symptoms. Significant differences were observed between the pre- and postoperation status for the VAS and ODI scores, foraminal height, and disc height. The authors advocated that this approach can lessen access-related trauma and provide good clinical results.

J. Akhgar et al. had performed an excellent investigation on the location of the common iliac veins (CIVs), with 1 mm CT-myelography slices of 504 patients, at the level of the promontorium and together with a meticulous dissection in 20 human cadavers. The authors advocated that the transarticular sacral screw trajectory is safe as long as the screw does not penetrate the anterior cortex of S1. The level of the inferior vena cava formation can help to predict the distance between the right and left CIVs at the level of the

promontorium. The CIVs do not have a uniform anatomical location; therefore, preoperative computed tomography is necessary to confirm their location.

Z. Li et al. reported a series of 38 patients, 31 ipsilateral and 7 contralateral, with a recurrent lumbar disc herniation at the primary discectomy level. All the patients were treated with unilateral pedicle screws and transforaminal lumbar interbody fusion cage. The patients were followed up for a mean of 52.2 months, regardless of the laterality of the recurrence of herniation, and the authors had found no differences in clinical parameters between the two groups at follow-up except for the length of operating time. They concluded that miniopen TLIF with unilateral pedicle screw fixation can be an alternate option for single level reherniation regardless of ipsilateral or contralateral reherniation.

Thus far, we may say that MIS surgery is still in its evolving stage. Issues such as the learning curves, the need of training in anterior spine surgery when conversion to open surgery is necessary, costs and benefits, and potential complications still require constant analyses. Moreover, radiation exposure continues to be a major concern to the staffs in the operation room in MIS surgery. We hope the readers could get some inspirations from the published articles in this special issue and continue to improve our spine services.

Tsung-Jen Huang Ki-Tack Kim Hiroaki Nakamura Anthony T. Yeung Jiancheng Zeng

#### References

- [1] P. C. McAfee, P. Geis, I. L. Fedder et al., "The incidence of complications in endoscopic anterior thoracolumbar spinal reconstructive surgery- a prospective multicenter study comprising the first 100 consecutive cases," *Spine*, vol. 20, no. 14, pp. 1624–1632, 1995.
- [2] T.-J. Huang, R. W.-W. Hsu, H.-P. Liu, Y.-S. Liao, and H.-N. Shih, "Technique of video-assisted thoracoscopic surgery for the spine: new approach," *World Journal of Surgery*, vol. 21, no. 4, pp. 358–362, 1997.
- [3] J.-C. Le Huec, C. Tournier, S. Aunoble, K. Madi, and P. Leijssen, "Video-assisted treatment of thoracolumbar junction fractures using a specific distractor for reduction: prospective study of 50 cases," *European Spine Journal*, vol. 19, supplement 1, pp. S27–S32, 2010.
- [4] L. Cuddihy, A. J. Danielsson, P. J. Cahill et al., "Vertebral body stapling versus bracing for patients with high-risk moderate idiopathic scoliosis," *BioMed Research International*, vol. 2015, Article ID 438452, 7 pages, 2015.
- [5] A. T. Yeung, "Minimally invasive disc surgery with the Yeung endoscopic spine system (YESS)," *Surgical Technology International*, vol. 8, pp. 267–277, 1999.
- [6] A. T. Yeung and P. M. Tsou, "Posterolateral endoscopic excision for lumbar disc herniation: surgical technique, outcome, and complications in 307 consecutive cases," *Spine*, vol. 27, no. 7, pp. 722–731, 2002.
- [7] S. Ruetten, M. Komp, and G. Godolias, "A new full-endoscopic technique for the interlaminar operation of lumbar disc herniations using 6-mm endoscopes: prospective 2-year results of 331

- patients," *Minimally Invasive Neurosurgery*, vol. 49, no. 2, pp. 80–87, 2006.
- [8] T.-J. Huang, R. W.-W. Hsu, Y.-Y. Lee, and S.-H. Chen, "Videoassisted endoscopic lumbar discectomy," *Surgical Endoscopy*, vol. 15, no. 10, pp. 1175–1178, 2001.
- [9] M. J. Perez-Cruet, K. T. Foley, R. E. Isaacs et al., "Microendoscopic lumbar discectomy: technical note," *Neurosurgery*, vol. 51, no. 5, pp. 129–136, 2002.
- [10] T.-J. Huang, R. W.-W. Hsu, S.-H. Chen, and Y.-Y. Lee, "Minimal access surgery in managing anterior lumbar disorders," *Clinical Orthopaedics and Related Research*, no. 387, pp. 140–147, 2001.
- [11] H. M. Mayer, "A new microsurgical technique for minimally invasive anterior lumbar interbody fusion," *Spine*, vol. 22, no. 6, pp. 691–700, 1997.
- [12] T.-J. Huang, R. W.-W. Hsu, Y.-Y. Li, and C.-C. Cheng, "Minimal access spinal surgery (MASS) in treating thoracic spine metastasis," *Spine*, vol. 31, no. 16, pp. 1860–1863, 2006.
- [13] F. M. Phillips, I. Cheng, Y. R. Rampersaud et al., "Breaking through the 'glass ceiling' of minimally invasive spine surgery," *Spine*, vol. 41, S8, pp. S39–S43, 2016.
- [14] M. J. Perez-Cruet, R. G. Fessler, and N. I. Perin, "Review: complications of minimally invasive spinal surgery," *Neurosurgery*, vol. 51, no. 5, pp. S26–S36, 2002.
- [15] C. Silvestre, J.-M. Mac-Thiong, R. Hilmi, and P. Roussouly, "Complications and morbidities of mini-open anterior retroperitoneal lumbar interbody fusion: oblique lumbar interbody fusion in 179 patients," *Asian Spine Journal*, vol. 6, no. 2, pp. 89–97, 2012.
- [16] T.-J. Huang, R. W.-W. Hsu, C.-W. Sum, and H.-P. Liu, "Complications in thoracoscopic spinal surgery: a study of 90 consecutive patients," *Surgical Endoscopy*, vol. 13, no. 4, pp. 346–350, 1999.
- [17] D. K. Bateman, P. W. Millhouse, N. Shahi et al., "Anterior lumbar spine surgery: a systematic review and meta-analysis of associated complications," *Spine Journal*, vol. 15, no. 5, pp. 1118– 1132, 2015.
- [18] T.-J. Huang, R. W.-W. Hsu, Y.-Y. Li, and C.-C. Cheng, "Less systemic cytokine response in patients following microendoscopic versus open lumbar discectomy," *Journal of Orthopaedic Research*, vol. 23, no. 2, pp. 406–411, 2005.
- [19] R. Sasaoka, H. Nakamura, S. Konishi et al., "Objective assessment of reduced invasiveness in MED. Compared with conventional one-level laminotomy," *European Spine Journal*, vol. 15, no. 5, pp. 577–582, 2006.
- [20] K.-T. Kim, S.-H. Lee, K.-S. Suk, and S.-C. Bae, "The quantitative analysis of tissue injury markers after mini-open lumbar fusion," *Spine*, vol. 31, no. 6, pp. 712–716, 2006.
- [21] T.-J. Huang, Y.-J. Weng, Y.-Y. Li, C.-C. Cheng, and R. W.-W. Hsu, "Actin-free gc-globulin after minimal access and conventional anterior lumbar surgery," *Journal of Surgical Research*, vol. 164, no. 1, pp. 105–109, 2010.
- [22] C. L. Goldstein, F. M. Phillips, and Y. R. Rampersaud, "Comparative effectiveness and economic evaluations of open versus minimally invasive posterior or transforaminal lumbar interbody fusion," *Spine*, vol. 41, supplement 8, pp. s74–s89, 2016.
- [23] A. T. Yeung and C. A. Yeung, "Minimally invasive techniques for the management of lumbar disc herniation," *Orthopedic Clinics* of *North America*, vol. 38, no. 3, pp. 363–372, 2007.
- [24] S. Ruetten, M. Komp, H. Merk, and G. Godolias, "Full-endoscopic interlaminar and transforaminal lumbar discectomy versus conventional microsurgical technique: a prospective,

- randomized, controlled study," *Spine*, vol. 33, no. 9, pp. 931–939, 2008.
- [25] X. Wang, J. Zeng, H. Nie et al., "Percutaneous endoscopic interlaminar discectomy for pediatric lumbar disc herniation," *Child's Nervous System*, vol. 30, no. 5, pp. 897–902, 2014.
- [26] A. T. Yeung, "Moving away from fusion by treating the pain generator: the secrets of an endoscopic master," *Journal of Spine*, vol. 4, no. 6, 2015.
- [27] H.-F. Nie, J.-C. Zeng, Y.-M. Song et al., "Percutaneous endoscopic lumbar discectomy for L5-S1 disc herniation via an interlaminar approach versus a transforaminal approach: a prospective randomized controlled study with 2-year follow-up," *Spine*, vol. 41, supplement 19, pp. B30–B37, 2016.

Hindawi Publishing Corporation BioMed Research International Volume 2017, Article ID 4385620, 13 pages http://dx.doi.org/10.1155/2017/4385620

#### Review Article

## Could the Topping-Off Technique Be the Preventive Strategy against Adjacent Segment Disease after Pedicle Screw-Based Fusion in Lumbar Degenerative Diseases? A Systematic Review

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Received 25 July 2016; Accepted 10 November 2016; Published 22 February 2017

Academic Editor: Jiancheng Zeng

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The "topping-off" technique is a new concept applying dynamic or less rigid fixation such as hybrid stabilization device (HSD) or interspinous process device (IPD) for the purpose of avoiding adjacent segment disease (ASD) proximal to the fusion construct. A systematic review of the literature was performed on the effect of topping-off techniques to prevent or decrease the occurrence of ASD after lumbar fusion surgery. We searched through major online databases, PubMed and MEDLINE, using key words related to "topping-off" technique. We reviewed the surgical results of "topping-off" techniques with either HSD or IPD, including the incidence of ASD at two proximal adjacent levels (index and supra-adjacent level) as compared to the fusion alone group. The results showed that the fusion alone group had statistically higher incidence of radiographic (52.6%) and symptomatic (11.6%) ASD at the index level as well as higher incidence (8.1%) of revision surgery. Besides, the HSD (10.5%) and fusion groups (24.7%) had statistically higher incidences of radiographic ASD at supra-adjacent level than the IPD (1%). The findings suggest that the "topping-off" technique may potentially decrease the occurrence of ASD at the proximal motion segments. However, higher quality prospective randomized trials are required prior to wide clinical application.

#### 1. Introduction

Fusion surgery has been shown to improve functional outcomes in appropriately selected symptomatic patients with various degenerative lumbar disorders [1, 2]. However, adjacent segment disease (ASD) is still a significant problem following rigid spinal fixation [3, 4]. Fusion surgery aims to relieve symptom from degenerative or unstable motion segments. There is increase in range of motion and stress at the upper adjacent level after rigid fixation [3, 5], which is one of many factors, contributing to the development of ASD.

The incidence of radiographic ASD ranges from 5.2% to 100%, depending on patient population, follow-up duration, the imaging used for evaluation, and definition of ASD [4].

The symptomatic ASD ranged from 5.2% to 18.5% as reported by Park et al. [4]. Ghiselli et al. [3] reported the rate of symptomatic ASD following either decompression or fusion was predicted to be 16.5% at 5 years and 36.1% at 10 years.

Generally, symptomatic ASD in patients who failed in conservative treatment needs revision surgery to relieve symptoms. However, some studies reported relatively modest results in patients who received revision surgery for symptomatic ASD [6, 7]. Regarding the location of ASD, Aota et al. [8] demonstrated that ASD occurred in 24.6% of the cases proximal to lumbar fusion and 2.6% of the cases distal to fusion and a similar trend, reported by Etebar and Cahill [9]. It is important for surgeons to carefully evaluate the proximal adjacent disc above fusion levels before surgery in order to

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lower the occurrence of ASD. The "topping-off" technique with either hybrid stabilization device (HSD) or interspinous process devices (IPD) might be one of the solutions.

This "topping-off" technique refers to application of hybrid dynamic pedicle screw construct or interspinous process device above the fused segments. This technique provides a transitional zone between caudal rigid fused construct and cephalad mobile/unfused segments, which may decrease the incidence of ASD [10, 11]. The rationale of this technique is that the semirigid zone provides a gradual transition from the rigid to mobile segments to lessen stress concentration at the adjacent level. Khoueir et al. [12] classified posterior dynamic stabilization devices into three categories: (1) hybrid stabilization device with pedicle screw/rod construct such as DTO® and Dynesys (we defined it as HSD in this manuscript); (2) interspinous process devices (IPD) such as Wallis, X-STOP, DIAM, and Coflex; (3) total facet replacement system. Because of the lack of evidence in the literature on total facet implants, we focused on the former two devices of HSD and IPD in our literature reviews.

To our knowledge, systematic review investigating the "topping-off" technique with HSD or IPD to prevent ASD following lumbar fusion surgery has not been done. This manuscript reviews the surgical results of "topping-off" techniques and compares the incidence of ASD at proximal two adjacent levels among HSD, IDP, and fusion alone group.

#### 2. Materials and Methods

We followed the methodological guidelines outlined by the Transparent Reporting of Systematic Reviews and Meta-Analyses (PRISMA) [19, 20] to conduct this systematic review.

- 2.1. Literature Search and Selection. A literature review of clinical studies published from January 2007 to December 2015 was conducted. The articles written in English were included. We completed a search into National Center for Biotechnology Information databases using PubMed/ MEDLINE, with keywords and Boolean operators. The search strategy for publications was of "Topping-off", "hybrid stabilization", "hybrid stabilization device", "hybrid stabilisation", "hybrid fixation", and "interspinous process device" AND "fusion", "lumbar spine", "adjacent segment disease", and "adjacent segment degeneration". Editorials and commentaries from major neurosurgical and orthopaedic journals were also reviewed to gather further information on this topic. Furthermore, we searched and reviewed the relevant articles on the reference list for further information. We only included studies published in SCI (scientific citation index) journals.
- 2.2. Methodological Quality Assessment. Full-text versions of all included articles were downloaded and assessed for potential bias by two independent reviewers (PC & CL). The National Heart Lung and Blood Institute (NIH) quality assessment tool for case series studies [21] was used to assess the methodological quality of the selected studies. This categorises studies as either good, fair, or poor. Encountering

any disagreement, we made a consensus by discussion within the review team.

2.3. Article Selection and Data Extraction. We collected clinical trials studying the effect of hybrid stabilization or proximal IPD implantation to prevent ASD after lumbosacral fusion surgery. Many clinical studies were initially selected including prospective, retrospective studies or case series with or without comparison group (fusion alone). The problems adjacent to fusion levels or ASD were considered as primary outcomes. After reviewing the titles and abstracts of collected studies, we then determined if the content of the studies was suitable for retrieval. The studies in which the average patient follow-up time was less than 24 months or the number of patients was less than 20 were not considered.

Two authors independently extracted data from the articles. We contacted the authors of the studies for the uncertain details. The following data were extracted: (1) participant demographics; (2) indication for surgeries; (3) adjacent segment degeneration; (4) radiographical and clinical outcomes; (5) implant-related complications and other outcomes. Details of ASD following fusion surgery and required revision surgery were further analyzed among the three groups. Only ASD that were specifically stated as having occurred or not having occurred in the articles were used in the analysis. ASD were not assumed to be absent just because they were not discussed (Table 4).

2.4. Statistical Analysis. For statistical analysis, quantitative data are described by the mean, range, and standard deviation if available; qualitative data are described as counts and percentages. We used chi-square test with the Yates continuity correction to evaluate the incidence or proportion in the comparative groups in the parameters. A p value of < 0.05 indicated statistical significance. All statistical computation has been performed with the SPSS for Windows statistical package (version 21.0, Chicago, Illinois).

#### 3. Results

- 3.1. Identified Trials. A flow chart describing the procedure of study selection is shown in Figure 1. The search yielded 393 articles of prospective or retrospective case series. No additional studies were found manually. All studies had abstracts screened and assessed for eligibility. Thirteen full-text articles were retrieved and appraised for eligibility. Eventually 366 patients from 6 articles, 2 prospective [12, 14] and 4 retrospective [13, 15–17], were included in our systematic review. The methodological quality as measured by the NIH quality assessment tool was high with all studies assessed as good. The level of evidence for these selected articles was also analyzed (Table 1).
- 3.2. Study Characteristics and Outcomes. The relevant characteristics for each included study are summarized in Table 1. Regarding the level of evidence, there were two papers of level II [14, 18], three papers of level III [15, 16, 22], and one paper of level IV [13]. Every particular indication

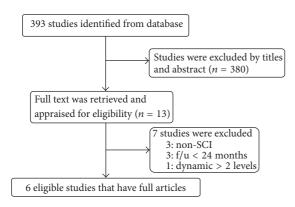


FIGURE 1: The flow chart for manuscript selection.

for "topping-off" surgery was reported in all studies. Some degree of adjacent disc degeneration was the main reason for dynamic stabilization above fusion construct in most (5/6) studies. Location for topping-off stabilization was illustrated in 5 studies, located from L1/2 to L4/5. The methodology for evaluating radiographic and clinical results was not consistent in all studies. The evaluation tools and results in each study are summarized in Tables 2 and 3, respectively, for radiographic parameters and functional outcomes. The radiographic evaluation tools used in these studies are disc height, foraminal height, and UCLA grade obtained from plain radiography and Pfirrmann's classification and Modic grade obtained from MRI images. It is difficult to compare the radiographic results among these studies because of the inconsistency of evaluation tools (Table 2). The clinical outcome was evaluated with visual analogue score (VAS) for back or leg, Oswestry Disability Index (ODI), and short form (36) health survey (SF-36). Ultimately, all studies revealed that the clinical outcomes improved significantly postoperatively (Table 3).

- 3.3. Adjacent Segment Disease. The demographic data and results of ASD for the topping-off techniques and fusion alone group were listed in Table 4. There were 95 patients in HSD group, 98 patients in IPD group, and 173 patients in fusion alone group with a mean age of 62.7, 64.9, and 60.5, respectively. The number of fused vertebrae was 2 in HSD group, 3.4 in IPD group, and 2.5 in fusion alone group. The mean follow-up time was 42.8, 47.2, and 50.4 months in each group. The details of adjacent segment disease for topping-off techniques and fusion alone group are shown in Tables 5 and 6, respectively. The definitions of "index level" and "supra-adjacent level" were illustrated in Figure 2.
- 3.3.1. ASD at the Index Level. The index level was defined as the level of HSD or IPD or the adjacent level above fusion. The difference in the incidence of radiographic or symptomatic ASD at the index level was statistically significant among the three groups. The fusion group presented statistically higher percentage of symptomatic ASD (11.6% or probably higher as some papers defined ASD requiring revision surgery for symptomatic ASD) and radiographic ASD (52.6%) as well as

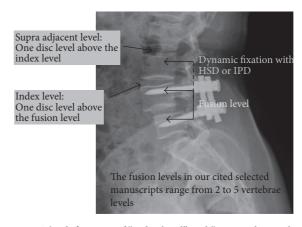


FIGURE 2: The definitions of "index level" and "supra-adjacent level" in our manuscript. "Index level" represents the disc level just above the fusion construct. "Supra-adjacent level" represents one disc level above the index level. The fusion levels in selected manuscripts ranged from 2 to 5 vertebrae levels, which were not, respectively, presented herein.

revision surgery for ASD (8.1%) as compared to "topping-off" groups (p = 0.003, p < 0.001, and p = 0.008 resp.).

- 3.3.2. ASD at Supra-Adjacent Level. The supra-adjacent level was defined as the level above index level. Interestingly, the HSD (10.5%, 7 out of 95 patients) and fusion groups (24.7%, 20 out of 81 patients) had higher incidences of radiographic ASD at supra-adjacent level than in the IPD (1%, 1 out of 98 patients) (p < 0.001). The fusion alone group still had a higher incidence of ASD at supra-adjacent level as compared to HSD (p < 0.05).
- 3.4. Implants-Related Complications in HSD or IPD. No implant-related complication was reported in all IPD group. Regarding the HSD group, a patient needed revision surgery after 26 months because of a clinically symptomatic dislocation of the Dynesys screws. This patient was excluded from further analysis because dynamic stabilization was removed during revision surgery.

#### 4. Discussion

Accelerated degeneration at adjacent segments above or below lumbar spinal fusion site has been a significant problem in clinical practice. In this review, we focused on the cephalad "topping-off" techniques either HSD or IPD and compared with the fusion alone groups, as these newer techniques are controversial. Our review revealed the potential of these "topping-off" techniques in decreasing the incidence of ASD after fusion surgery.

4.1. The Mechanism of ASD. While rigid fixation improves the fusion rate and functional outcomes [1, 2], many studies have reported the increased prevalence of adjacent motion segment degeneration following lumbar fusion [3, 4, 7].

TABLE 1: Clinical reported hybrid stabilization device and interspinous process device in the lumbar degenerative surgery.

Reported clinical outcomes	VAS (back, leg) ODI	VAS (back) ODI	JOA score	VAS (back, leg) ODI
Reported radiographic outcomes	X-ray (DH/VBH) MRI (Pfirrmann)	MRI (Modic)	X-ray (middle DH) MRI (Pfirrmann)	MRI (Pfirrmann)
Level for dynamic device	L23 L34 L45	L34 L45	L34	L12 L23 L34
Fused vertebrae numbers	7	7	7	4
Exclusion criteria for the study	(1) Idiopathic or deg. scoliosis (2) Gr. 3-4 listhesis (3) Failed back syndrome (4) Sagittal imbalance (LL < P1-5°) (5) BMI> 35 (6) Clinical contraindication to surgery*	(1) Symptomatic proved by discography (2) Positive disc analgesia analgesia (3) Severe facet joints arthropathy (4) Spine deformity (5) Destructive process (6) Previous surgery	(1) ≥4 mm listhesis at L3 (2) Severe DD at L34 (Pfirrmann's V) (3) Deg. scoliosis ≥ 10° (4) Severe instability	NA
Indications for index level instrumentation	Hybrid stabilization device (HSD)  Pfirrmann I to III	Asymptomatic but radiographic DD (Modic grade I)	No instability	Interspinous process device (IPD)  (I) DH ≤ 50% with/without segmental F/E mobility 48 (2) No segmental F/E mobility and the status of the discs was suitable
Max. F/u (months)	brid stabilizati 24	16	NA	erspinous pro
Min. F/u (months)	Hy 24	09	NA	74 Thi
Mean F/u (months)	24	76.4	42	41.2
Patients numbers	38	22	35	49
Study (level of evidence)	Retrospective series cases (IV)	Prospective randomized, nonblind comparative (11)	Retrospective comparative (III)	Retrospective (III)
Implant type	CD HORIZON BalanC™ System (Medtronic Minnesota, USA)	Allo Spine™ Dynesys Transition System (Zimmer, Winterthur,	Natural Neutral Concept Rod (Howa Co. Ltd.)	DIAM (Device for Intervertebral Assisted Motion) (Medtronic Sofamor Danek)
Authors, years	Formica et al. [13], 2015	Putzier et al. [14], 2010	Imagama et al. [15], 2009	Lu et al. [16], 2015

TABLE 1: Continued.

Reported clinical outcomes	VAS (back, leg) ODI	VAS (back) ODI SF-36
Reported radiographic outcomes	Х-гау (FH)	X-ray (ant./post. DH) (UCLA)
Level for dynamic device	L23 L34 L45	NA
Fused vertebrae numbers	2	3.5
Exclusion criteria for the study	NA	(1) Severe osteoporosis (2) Loss lumbar lordosis (3) Previous lumbar surgery (fracture) (4) Ankylosis (5) UCLA > II in index level (6) Spinous process insufficiency
Indications for index level instrumentation	(1) Pfirrmann Gr. II-III (2) MRI: facet deg. or effusion (3) Mild to moderate spinal or foraminal stenosis	(1) UCLA Gr. I or II (no listhesis or IV (no listhesis or lyticlesion) (2) Degenerative (listhesis spinal stenosis, loss of segmental lordosis) (3) 2 to 4 vertebral fusions
Max. F/u (months)	97	NA A
Min. F/u (months)	24	NA
Mean F/u (months)	46.8	09
Patients numbers	25	24
Study (level of evidence)	Retrospective (III)	Prospective controlled (II)
Implant type	DIAM (Device for Intervertebral Assisted Motion) (Medtronic Sofamor Danek)	Wallis
Authors, years	Lee et al. [17], 2013	Korovessis et al. [18], 2009

NA: not available, min.: minimum, max.: maximum, f/u: follow-up, PSs: pedicle screws, FH: foraminal height, ant.: anterior, post.: posterior, deg.: degenerative, F/E: flexion/extension, ASD: adjacent segment disease, ODI: Oswestry Disability Index, VAS: visual analogue scale, JOA: Japanese Orthopaedic Association, DH: disc height, and VBH: vertebral body height.

\* Other clinical contraindications were including (1) long-term medication of steroid or NSAID (chronic pain Gerbershagen Gr. ≥ 2); (2) liver or kidney diseases; (3) malignant tumor; (4) pregnancy; (5) chronic nicotine, alcohol, or drug abuse.

TABLE 2: Reported radiographic parameters in the hybrid stabilization device and interspinous process device groups.

Piecop Digaching   Activativative   Activativate   Activativate						idy	-	*	-			-			-					-	
MRI   Piccop   Post-op   Final   Piccop   Post-op   Piccop   Pic	Authors,	Pre-op D.	D grading	A-ray at dynami	DH ic level	MIKI g. at dynan	rading nic level	A-ray one	disc height evel above	at	lumb	عامbaا ar lordosis		Instr lumba	umented tr lordosis		Segmental at index	motion level	at	Segmental mot supra-adjacent	ion level
Phirmann         Lo III         0.278         0.269         49.56         56.57         56.9           Modic         1	years	X-ray	MRI	Pre-op Post		Pre-op	Final	Pre-op		Final	Pre-op			re-op 1		Final	Pre-op Post			e-op Post-op	Final
Modic         1         Progressed Figure Seed         44         42         45         45         46         67           Pfirrmann (2.1)         (2.3)         III to V grade in 4pts         (1.6)         (2.2)         (15)         (14)         (4.3)         46         6.7           Pfirrmann 16, Ir Shrimed height (4.1)         1.6, II. 6, II. 7, I. 4         40.6         36.2         8.2         18/10 (17)         4.9         18/10 (17)         18/10 (17)         4.9         18/10 (17)         4.9         4.9         4.0	Formica et al. [13], 2015	DH/VBH	Pfirrmann			I to III				0.269			-		56.57 (7.34)	56.9 (7.21)					
Pfrymann         10         98         III to Voicesed Appts         94         42         45         79         46         67           Pfrrmann         2.1)         Acan Appts	Putzier et al. [14], 2010		Modic			н															
Mean   Gr. 29   S67.2   According to the properties of the prope	magama et al. [15], 2009	Middle	Pfirrmann	10 (2.1)	9.8 (2.3)		Progressed one grade in 4 pts	9.9 (1.6)		9.4 (2.2)	42 (15)		45 (14)				7.9 (4.3)	(3.5)		7. (7.	7.2 (3.1)
Foraminal height   Examinal height   Examinated from figures)   Examinate	Lu et al. [16], 2015		Pfirrmann			Mean Gr. 2.9 I: 6, II: 16 III: 16, IV: 14					40.6	36.2					35/49 (7 maintained F/E mo	12%) 1 pre-op tion			
11.9   13.8   12   (ant. DH)   (1yr)   12   24.8   (1yr)   (	ee et al. 17], 2013	Foraminal height		Foraminal 21.3 24															6		
	Korovessis tt al. [18], 1009	DH (ant.) DH (post.) UCLA <sup>+</sup>	3	13.8 (1yr) 8.2 (post- 7. op) 1 from figures)	5. 6.						39.7 (Esti fi	40.9 (1 yr) mated fron gures)	42.8						S		

Blank in the each column meant not mentioned by the authors. UCLA<sup>+</sup>: University of California at Los Angeles (UCLA) grading scale. The values in the parentheses were standard deviation, deg.: degenerative, pre-op: pre-op: prostoperative, post-op: postoperative, post.: posterior, DH: disc height, VBH: vertebral body height, and pt: patients.

TABLE 3: Reported functional outcomes in the hybrid stabilization device and interspinous process device groups.

		,		-	( )		-				-		76
Authors,	Dationte	Mean	Visua	Visual analogue scale (back)	(back)	Visua	Visual analogue scale (leg)	(leg)	Osw	Oswestry Disability Index	ndex		SF-36
years	ı atıcılış	n/J	f'u Pre-op	Post-op	Final	Pre-op	Pre-op Post-op	Final	Pre-op	Post-op	Final	Pre-op	Final Pre-op Post-op Final
Formica et al. [13], 2015	38	24	24 7.87 (1.39) 1.98 (	1.98 (1.04)	0.42 (0.53)	4.77 (1.98)	(1.04) 0.42 (0.53) 4.77 (1.98) 1.87 (1.55) 0.37 (0.9) 62.18 (13.1)	0.37 (0.9)	62.18 (13.1)		18.11 (4.78)		
D., tzi or of ol [14] 2010		16.4	8	4	4				70	30 (1 yr)	35		
r utziei et al. [14], 2010	77	4.0/ 77	(Est	(Estimated from figures)	ures)				(Est	(Estimated from figures)	ıres)		
										JOA			
Imagama et al. [15], 2009 35	35	42							11.8 (6.2)	11.8 (6.2) 25.2 (3.7)			
Lu et al. [16], 2015	49	41.2	7.1 (1.4)	1.3 (2 yrs) (2.3)	1.5 (2.4)	7.2 (1.3)	1.4 (2 yrs) (2.5)	1.4 (2.3)	27.7 (3.8)	49 41.2 7.1 (1.4) 1.3 (2 yrs) (2.3) 1.5 (2.4) 7.2 (1.3) 1.4 (2 yrs) (2.5) 1.4 (2.3) 2.77 (3.8) 14.6 (2 yrs) (3.4) 14.1 (3.9)	14.1 (3.9)		
Lee et al. [17], 2013	25	46.8	25 46.8 7.2	4.3 (1 yr)	3.9	6.9	3.8 (1 yr) 3.7 (2 yr) 26.1	3.7 (2 yr)	26.1	17.4 (1 yr) 16.3 (2 yrs)	16.3 (2 yrs)		
7 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	,		72 (21)	(0) (					34	8	6	F	5
NOI OVESSIS Et al. [10], 2009 24	77		00 /.2 (2.1)	2 (7)					(Est	(Estimated from figures)	res)	Π	60 10

The values were presented as mean, the values in the parentheses were standard deviation, and blank in the each columns meant not mentioned in the manuscript. JOA: Japanese Orthopaedic Association Score; SF-36: short form-36 questionnaires.

TT 4 D 4 1 1	1 1 1 1 1 1 1 1 1 1 1 1		1 . 1
LARIE 4. Data in the h	whrid stabilization devi	ce intereninglis process	device, and fusion groups.
IADLE I. Data III tile II	.y bi ia stabilization ac vi	ec, interspinous process	device, and rasion groups.

	Hybrid stabilization device	Interspinous process device	Fusion	p value
Numbers of patients	95	98	173	NA
$Age (y/o)^+$	62.7	64.9	60.5	NA
Male/female	NA	NA	NA	NA
Numbers of fused vertebrae	2	3.4	2.45	NA
Follow-up (months)	42.8	47.2	50.4	NA
Adjacent segment disease (ASD)				
Symptomatic ASD at index level	0	5 (5.1%)	20 <sup>++</sup> (11.6%)	0.003
Radiographic ASD at index level	12 (12.6%)	10 (10.2%)	91 (52.6%)	< 0.001
Symptomatic ASD at supra-adjacent level	0	0	0	_
Radiographic ASD at supra-adjacent level	7 (10.5%)	1 (1%)	20/81* (24.7%)	< 0.001
Revision surgery for ASD	0	3 (3%)	14 (8.1%)	0.008

The bold numbers in the p values indicated statistical significance. NA indicates not available.

Although clinical studies investigated risks factors predisposed in the progression of ASD [5, 8, 9, 23-30], the exact pathogenesis of ASD remains uncertain. Biomechanical and clinical studies have suggested the compensatory loading transfer [31] and increased range of motion [3, 5] at upper adjacent level after rigid fixation. Regarding the intradiscal pressure (IDP) at proximal adjacent disc (PAD) following rigid fixation, Cunningham et al. [32] reported an increase of IDP up to 45% on axial compression and anterior flexion loading motion in comparison to normal disc. Weinhoffer et al. [33] also reported a significant increase of IDP at PAD following instrumentation in a simulated fusion model. The authors mentioned increased IDP may alter the metabolic status and further play an important role in the pathogenesis of ASD. However, there are several clinical studies suggesting that ASD is part of a normal degenerative process rather the altered biomechanical stress on the adjacent disc [34, 35].

4.2. The Risk Factors for ASD. There are many papers on the risks factors for ASD. These risk factors include patient's age [8, 9, 24], postmenopausal status [9], sagittal mal-alignment [5, 25, 26], multiple level fusion [23, 28, 29], posterior interbody fusion [24], iatrogenic injury to the facets of the adjacent segment [8, 30], and preexisting disc degeneration [36]. There are other papers in the literature supporting or contradicting these risk factors [4]. Kumar et al. [37] reported that gender, different types of fusion (posterior fusion versus combined posterolateral and posterior interbody fusion), and fusion level (fusions extending down to the sacrum versus fusions stopped at short of the sacrum) are not risk factors for ASD. In addition, Rahm and Hall [24] reported a negative correlation between sagittal alignment and incidence of ASD. The inconsistent conclusions are as a result of retrospective selection bias, limited follow-up time, or different methodology evaluating ASD. The progression of ASD following lumbar spine fusion is obviously multifactorial, and further research can help identify and quantify the contributing risk factors for ASD.

4.3. Intervals from Fusion Surgery to Revision Surgery for Symptomatic ASD. Based on Lee et al. [22], Kumar et al. [5], and Aota et al. [8], the mean interval from fusion to revision surgery for ASD is approximately 51 months, ranging from 41.3 to 62.4 months. We excluded studies with limited follow-up time less than 24 months and the occurrence of ASD is greater with longer follow-up.

4.4. Biomechanical Characteristics in Dynamic Devices on Spine Range of Motion (ROM) and Intradiscal Pressure (IDP). Schmoelz et al. [38] reported Dynesys does not change IDP at proximal adjacent disc after fixation under moment-controlled mode, while Cabello et al. [39] reported Dynesys decreases 50% of the IDP at instrumented level and increases 10% of the IDP at supra-adjacent level under load-controlled mode. Different controlled modes in biomechanical testing may explain these diverse results [40]. Moreover, Schmoelz et al. [38] reported Dynesys is more flexible than rigid fixation, but spine ROM was still limited.

Lafage et al. [41] reported that the Wallis decreases the disc stress and ROM and increases the spinous process loading at instrumented level. Bellini et al. [31] reported that DIAM in vitro decreases ROM and IDP at instrumented level. The Wallis and DIAM both decrease but preserve some degree of ROM [31, 41], which can decrease the stresses at the adjacent level.

4.5. Rationale of "Topping-Off" Technique and Clinical Application. The "topping-off" technique provides a transitional zone between caudal rigid fused segment and cephalad mobile unfused spines, which may decrease the incidence of ASD [10, 11]. Based on posterior dynamic stabilization system reported by Khoueir et al. [12], the Dynesys construct belongs to hybrid stabilization device; Wallis and DIAM belong to posterior interspinous device. Similar biomechanical characteristics include decreased IDP and limited [31, 38, 39, 41, 42] but still preserve some ROM at HSP/IPD instrumented level.

<sup>&</sup>lt;sup>+</sup>The authors did not exclude those who lost follow-up in the demographic results. The mean age was just estimated.

<sup>&</sup>lt;sup>++</sup>Two papers only mentioned numbers of revision surgeries for symptomatic ASD but did not mention numbers of symptomatic ASD. (The result might be underestimated.)

<sup>\*</sup>Only 3 cited manuscripts reported their results.

TABLE 5: Adjacent segment disease and implant-related complications in hybrid stabilization device and interspinous process device.

	`	4				
Authors	Symptomatic ASD at	Radiographic ASD at	Criteria for	Dynamic implant-	Reasons for revision	vision
Wears	index level or	index level or	radiographic ASD	related	Symptomatic	Implant
years	supra-adjacent level	supra-adjacent level	iaciogiapino iron	complications	ASD	failure
Formica et al. [13], 2015	0 pts: index level 0 pts: supra-adjacent level	0 pts: index level 0 pts: supra-adjacent level	NA	No	No	No
Putzier et al. [14], 2010	0 pts: index level 0 pts: supra-adjacent level	2 pts.: index level I: fusion, I: instability 2 pts: supra-adjacent level 2: progressive DD	<ul> <li>(1) Fusion</li> <li>(2) Disc degeneration Modic &gt; 1</li> <li>(3) Facet arthritis, Fujiwara &gt; Gr. 1</li> <li>(4) &lt; 25% pre-op disc height</li> <li>(5) Instability signs such as traction spurs</li> </ul>	1 pt: dynamic PSs dislocation at 26 months Removed implant (the pt was excluded in the study)	°Z	+-
Imagama et al. [15], 2009	0 pts: index level 0 pts: supra-adjacent level	10 pts: index level (7 pts by MRI) (3 pts diagnosed by X-ray*) 5 pts: supra-adjacent level (2 pts by MRI) (3 pts diagnosed by X-ray*)	(1) DD (Pfirrmann) progression ≧1 grade (2) Spinal stenosis progression ≧ 1 grade	No	No	No
Lu et al. [16], 2015	3 pts: index level 0 pts: supra-adjacent level	3 pts: index level 0 pts: supra-adjacent level	(1) Anterolisthesis (2) Retrolisthesis due to hypermobility on flexion/extension (3) Loss of disc height and sclerosis along endplate (DD)	Spinous process fr.: no Implant failure: no	П	N <sub>o</sub>
Lee et al. [17], 2013	2 pts: index level NA: supra-adjacent level	6 pts: index level NA: supra-adjacent level	(1) Collapsed disk space (Pfirrmann Gr. V) (2) Spondylolisthesis (translation ≥3 mm) (3) Proximal junctional kyphosis Cobb angle ≥10° (4) Compression fr. at adjacent segments	Spinous process fr.: no Implant failure: NA	2	NA
Korovessis et al. [18], 2009	0 pts: index level 0 pt: supra-adjacent level	1 pt: index level 1 pt: supra-adjacent level	<ul> <li>(1) Listhesis</li> <li>(2) Disc collapse</li> <li>(3) ↑segmental range of motion (ROM)</li> <li>(4) &gt;grade II of modified UCLA grade</li> </ul>	Spinous process fr.: no Implant failure: NA	0	NA
MA: not original Mumbous	oncomment of the forth of the comment of the contract of the c	confidence and constraint				

NA: not available. Numbers: occurrence of patients numbers. Pre-op: preoperative.

\*Radiographic ASD defined as one of the following criteria in X-ray: (1) disc height decrease ≤ 50%; (2) listhesis ≥ 3 mm (neutral position); (3) disc angle decrease (at flexion) ≥5°.

ASD: adjacent segment disease, pts: patients, PSs: pedicle screws, DD: disc degeneration, DIAM: Device for Intervertebral Assisted Motion, f/u: follow-up, and fr:: fracture. <sup>+</sup>1 pt. suffered clinically symptomatic dislocation of dynamic pedicle screws and needed revision surgery of implant removal at 26 months f/u and was excluded in the study.

TABLE 6: Adjacent segment disease in the fusion alone groups in these cited manuscripts.

	Patients numbers	Mean age (Y/O)	Pre-op status at index level*	Radiographic ASD at index level	Symptomatic ASD at index level	Revision surgery for ASD	Radiographic ASD at supra-adjacent level
Formica et al. [13], 2015			No comparative fusion group in the manuscript	e manuscript			
Putzier et al. [14], 2010	25	44.6	(1) Asymptomatic bur radiographic DD (Modic grade I)	9	П	П	0
			(1) No instability				
Imagama et al. [15], 2009	35	64	(2) Pfirrmann Gr. II–IV	35	No	No	14
			(3) None, mild, or moderate spinal stenosis				
			(1) DH ≤ 50% with/without segmental F/E mobility				
Lu et al. [16], 2015	42	59	(2) No segmental F/E mobility and the status of disc	20	6	3	NA
			was suitable				
			(1) Pfirrmann Gr. II-III				
Lee et al. [17], 2013	50	62.9	(2) MRI: facet degeneration or effusion	24	7+	7	NA
			(3) Mild to moderate spinal or foraminal stenosis				
			(1) UCLA Gr. I or II (no listhesis or lytic lesion)				
Korovessis et al. [18],	10	7	(2) Degenerative (listhesis, spinal stenosis, loss of	4	+	"	y
2009	17	£0	segmental lordosis)	o	o	0	o
			(3) 2 to 4 vertebral fusions				

DH: disc height; F/E: flexion/extension. +The authors only mentioned numbers of revision surgeries for symptomatic ASD but did not mention numbers of symptomatic ASD. The numbers of symptomatic ASD might be underestimated.

Based on this systematic review, the incidences of radiographic ASD at index level were 12.6%, 10.2%, and 52.6% in HSD, IPD, and fusion alone, respectively. With the "toppingoff" technique, the incidence of ASD seems to decrease significantly at mid-term follow-up. These devices might possibly alleviate the degenerative progression above the fusion level. Regarding the incidence of radiographic ASD at supra-adjacent level, there were 1%, 10.5%, and 24.7% in IPD, HSD, and fusion alone, respectively. The IPD has the best result in delayed progression of ASD at supra-adjacent level. From the biomechanical view, we assumed that the HSD was more rigid than IPD but less rigid than the instrumented fusion, which may be one of the explanations for the results. Another possible reason for higher incidence of ASD at supra-adjacent level in HSD comparing to IPD is that iatrogenic facet joints surface might jeopardize when placing proximal pedicle screws [8, 43]. More in vitro biomechanical and high-quality prospective randomized studies are needed for further clarification on the issue.

4.6. Implants- (HSD or IPD) Related Complications. The incidence of broken pedicle screws in treatment of degenerative lumbar disease ranged from 2.2% to 12.4% [44–46] based on either total pedicle screws or patient numbers. In our results, 2 broken dislodged dynamic screws in 1 patients (0.98%, 1 out of 102 patients) in HSD group were observed, which was much lower than traditional pedicle screws fixation. This result could be different if more studies were to be analyzed or if follow-up was longer.

After Wallis being implanted, there is a change in the stress distribution of the spine, especially the spinous process [41]. Moreover, application of the tension band construct significantly increases the stress of the contact surface between the spinous process and the implant. Significant bone resorption was observed in more than 50% of the patients with Wallis implantation as reported by Wang et al. [47] and by Miller et al. [48]. The possible reasons to explain spinous process fracture or resorption are as follows: (1) the downward conduction of stress in the lumbar spine at greatest force at L5 spinous process [49]; (2) continuous motion at implanted level. Nevertheless, neither bone resorption nor spinous fracture was observed in this review.

4.7. Can Preoperative Disc Degeneration Affect the Incidence of ASD after Fusion? Park et al. [4] reported that the preoperative condition of adjacent disc for further implication in ASD following fusion is still elusive. Ghiselli et al. [3] reported the correlation between ASD and preoperative disc degeneration status at the time of surgery is not significant in 215 patients based on UCLA disc degeneration grading with mean 7-year follow-up. Nakai et al. [36] and Liang et al. [50] reported the preoperative disc degeneration correlates with the progression of ASD at adjacent fusion level based on the disc height and pre-MRI Pfirrmann's grading, respectively. All these studies did not perform the postoperative MRI image to evaluate the disc degenerative status as final follow-up.

Preoperative disc degeneration with Pfirrmann grade ≧ III [50, 51] has a higher chance of developing symptomatic ASD. Regarding relative risks (RR) for developing ASD after

fusion surgery, Ghiselli et al. [3] reported L4-5 poses a high risk, T12-L1, L1-2, and L3-4 have the intermediate risks, and L2-3 has the lower relative risks. Liang et al. [50] reported disc bulge in preoperative CT examination may serve as reasonable prediction for symptomatic ASD. Sénégas [52] reported that Wallis can be used for disc degeneration of Pfirrmann's classification grades II, III, and IV above the fusion level.

Taken together, surgeons should be more aware of preoperative adjacent disc condition. The reasonable indications for "topping-off technique" might be (1) Pfirrmann Gr. ≧ III, (2) budged disc, and (3) high risk (L4-5) disc level and relative intermediate risk disc levels (T12-L1, L1-2, and L3-4). However, we found inconclusive surgical indications for topping-off fixation in this systematic review. We still need more evidence to support this conclusion by prospective randomized controlled study. Nevertheless, we suggest surgeons to pay more attention to the preoperative adjacent disc degenerative status, correlating between radiographic findings and patients' symptoms. The patient should be informed on the controversial nature and unpredictable outcomes when inserting these devices. More importantly, surgeons could improve their surgical techniques, such as maintaining the lordosis at the instrumented levels [5, 25, 26], no violation of the proximal adjacent facet joints [53, 54] when placing pedicle screws at the most upper levels, and no excessive distraction of disc for interbody fusion [55]. These techniques will likely lessen the development of ASD.

4.8. Limitations. Several major drawbacks or limitations were found in this systematic review. First, a small number of enrolled patients and short follow-up time do not lead to a definitive conclusion. Second, there could be selection bias. Third, the criteria of radiographic parameters for ASD were not consistent in these cited studies. We suggest using MRI images combined with flexion-extension radiography to diagnose ASD if feasible. Based on our literature review, the application of "topping-off" technique with HSD or IPD above fusion to avoid ASD still lacks good evidence, and therefore prospective randomized clinical trials should be conducted to further elucidate the role of topping-off techniques.

#### 5. Conclusion

Although the evidence is weak, the "topping-off" technique with HSD or IPD might decrease the incidence of proximal ASD both radiographically and symptomatically as compared to the fusion group. At the index level, the effects of HSD or IPD for decreasing ASD were similar. At supra-adjacent level, IPD seems to have the better effect of avoiding ASD. In conclusion, the "topping-off" technique might be considered as a possible solution for postfusion ASD, but further research is needed prior to wide application. The patient selection and choices of stabilizing implants should be assessed with more level I clinical studies. Based on our literatures review, the preventive strategy of ASD with application of "topping-off" technique above fusion is still elusive, and prospective randomized trials with higher quality are still required for

further elucidating the effect of topping-off technique for prevention of ASD.

#### **Competing Interests**

The authors declare that there is no conflict of interests regarding the publication of this paper.

#### References

- [1] K. K. Lingutla, R. Pollock, E. Benomran et al., "Outcome of lumbar spinal fusion surgery in obese patients: a systematic review and meta-analysis," *The Journal of Bone & Joint Surgery—British Volume*, vol. 97, no. 10, pp. 1395–1404, 2015.
- [2] L. Y. Carreon, S. D. Glassman, and J. Howard, "Fusion and nonsurgical treatment for symptomatic lumbar degenerative disease: a systematic review of Oswestry Disability Index and MOS Short Form-36 outcomes," *Spine Journal*, vol. 8, no. 5, pp. 747–755, 2008.
- [3] G. Ghiselli, J. C. Wang, N. N. Bhatia, W. K. Hsu, and E. G. Dawson, "Adjacent segment degeneration in the lumbar spine," *The Journal of Bone and Joint Surgery A*, vol. 86, no. 7, pp. 1497–1503, 2004.
- [4] P. Park, H. J. Garton, V. C. Gala, J. T. Hoff, and J. E. McGillicuddy, "Adjacent segment disease after lumbar or lumbosacral fusion: review of the literature," *Spine*, vol. 29, no. 17, pp. 1938–1944, 2004.
- [5] M. Kumar, A. Baklanov, and D. Chopin, "Correlation between sagittal plane changes and adjacent segment degeneration following lumbar spine fusion," *European Spine Journal*, vol. 10, no. 4, pp. 314–319, 2001.
- [6] F. M. Phillips, G. D. Carlson, H. H. Bohlman, and S. S. Hughes, "Results of surgery for spinal stenosis adjacent to previous lumbar fusion," *Journal of Spinal Disorders*, vol. 13, no. 5, pp. 432–437, 2000.
- [7] W. J. Chen, P. L. Lai, C. C. Niu, L. H. Chen, T. S. Fu, and C. B. Wong, "Surgical treatment of adjacent instability after lumbar spine fusion," *Spine*, vol. 26, no. 22, pp. E519–E524, 2001.
- [8] Y. Aota, K. Kumano, and S. Hirabayashi, "Postfusion instability at the adjacent segments after rigid pedicle screw fixation for degenerative lumbar spinal disorders," *Journal of Spinal Disorders and Techniques*, vol. 8, no. 6, pp. 464–473, 1995.
- [9] S. Etebar and D. W. Cahill, "Risk factors for adjacent-segment failure following lumbar fixation with rigid instrumentation for degenerative instability," *Journal of Neurosurgery*, vol. 90, no. 4, pp. 163–169, 1999.
- [10] H.-Y. Liu, J. Zhou, B. Wang et al., "Comparison of toppingoff and posterior lumbar interbody fusion surgery in lumbar degenerative disease: a retrospective study," *Chinese Medical Journal*, vol. 125, no. 22, pp. 3942–3946, 2012.
- [11] Z. Zhu, C. Liu, K. Wang et al., "Topping-off technique prevents aggravation of degeneration of adjacent segment fusion revealed by retrospective and finite element biomechanical analysis," *Journal of Orthopaedic Surgery and Research*, vol. 10, article no. 10, 2015.
- [12] P. Khoueir, K. A. Kim, and M. Y. Wang, "Classification of posterior dynamic stabilization devices," *Neurosurgical focus*, vol. 22, no. 1, 2007.
- [13] M. Formica, L. Cavagnaro, M. Basso, A. Zanirato, L. Felli, and C. Formica, "Is it possible to preserve lumbar lordosis after hybrid

- stabilization? Preliminary results of a novel rigid–dynamic stabilization system in degenerative lumbar pathologies," *European Spine Journal*, vol. 24, pp. 849–854, 2015.
- [14] M. Putzier, E. Hoff, S. Tohtz, C. Gross, C. Perka, and P. Strube, "Dynamic stabilization adjacent to single-level fusion: part II. No clinical benefit for asymptomatic, initially degenerated adjacent segments after 6 years follow-up," *European Spine Journal*, vol. 19, no. 12, pp. 2181–2189, 2010.
- [15] S. Imagama, N. Kawakami, Y. Matsubara, T. Kanemura, T. Tsuji, and T. Ohara, "Preventive effect of artificial ligamentous stabilization on the upper adjacent segment impairment following posterior lumbar interbody fusion," *Spine*, vol. 34, no. 25, pp. 2775–2781, 2009.
- [16] K. Lu, P.-C. Liliang, H.-K. Wang et al., "Reduction in adjacent-segment degeneration after multilevel posterior lumbar inter-body fusion with proximal DIAM implantation," *Journal of Neurosurgery: Spine*, vol. 23, no. 2, pp. 190–196, 2015.
- [17] C.-H. Lee, S.-J. Hyun, K.-J. Kim, T.-A. Jahng, S. H. Yoon, and H.-J. Kim, "The efficacy of lumbar hybrid stabilization using the DIAM to delay adjacent segment degeneration: an intervention comparison study with a minimum 2-year follow-up," *Neurosurgery*, vol. 73, no. 2, pp. ons224-ons232, 2013.
- [18] P. Korovessis, T. Repantis, S. Zacharatos, and A. Zafiropoulos, "Does Wallis implant reduce adjacent segment degeneration above lumbosacral instrumented fusion?" *European Spine Journal*, vol. 18, no. 6, pp. 830–840, 2009.
- [19] N. Panic, E. Leoncini, G. De Belvis, W. Ricciardi, and S. Boccia, "Evaluation of the endorsement of the preferred reporting items for systematic reviews and meta-analysis (PRISMA) statement on the quality of published systematic review and meta-analyses," PLOS ONE, vol. 8, Article ID e83138, 2013.
- [20] L. Shamseer, D. Moher, M. Clarke et al., "Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation," *BMJ*, vol. 349, Article ID g7647, 2015.
- [21] "The National Heart Lung and Blood Institute Quality assessment tool for case series studies," https://www.nhlbi.nih.gov/health-pro/guidelines/in-develop/cardiovascular-risk-reduction/tools/case\_series.
- [22] C. S. Lee, C. J. Hwang, S. W. Lee et al., "Risk factors for adjacent segment disease after lumbar fusion," *European Spine Journal*, vol. 18, article 1637, 2009.
- [23] A. F. Mannion, G. Leivseth, J.-I. Brox, P. Fritzell, O. Hägg, and J. C. T. Fairbank, "ISSLS prize winner: long-term follow-up suggests spinal fusion is associated with increased adjacent segment disc degeneration but without influence on clinical outcome: results of a combined follow-up from 4 randomized controlled trials," Spine, vol. 39, no. 17, pp. 1373–1383, 2014.
- [24] M. D. Rahm and B. B. Hall, "Adjacent-segment degeneration after lumbar fusion with instrumentation: a retrospective study," *Journal of Spinal Disorders*, vol. 9, no. 5, pp. 392–400, 1996.
- [25] J. D. Schlegel, J. A. Smith, and R. L. Schleusener, "Lumbar motion segment pathology adjacent to thoracolumbar, lumbar, and lumbosacral fusions," *Spine*, vol. 21, no. 8, pp. 970–981, 1996.
- [26] S. Umehara, M. R. Zindrick, A. G. Patwardhan et al., "The biomechanical effect of postoperative hypolordosis in instrumented lumbar fusion on instrumented and adjacent spinal segments," *Spine*, vol. 25, no. 13, pp. 1617–1624, 2000.
- [27] H.-J. Wilke, P. Neef, M. Caimi, T. Hoogland, and L. E. Claes, "New in vivo measurements of pressures in the intervertebral disc in daily life," *Spine*, vol. 24, no. 8, pp. 755–762, 1999.

[28] C. Wimmer, H. Gluch, M. Krismer, M. Ogon, and R. Jesenko, "AP-translation in the proximal disc adjacent to lumbar spine fusion," *Acta Orthopaedica Scandinavica*, vol. 68, no. 3, pp. 269– 272, 1997.

- [29] J. Y. Yang, J. Lee, and H. Song, "The impact of adjacent segment degeneration on the clinical outcome after lumbar spinal fusion," *Spine*, vol. 33, no. 5, pp. 503–507, 2008.
- [30] L. L. Wiltse, S. E. Radecki, H. M. Biel et al., "Comparative study of the incidence and severity of degenerative change in the transition zones after instrumented versus noninstrumented fusions of the lumbar spine," *Journal of Spinal Disorders*, vol. 12, no. 1, pp. 27–33, 1999.
- [31] C. M. Bellini, F. Galbusera, M. T. Raimondi, G. V. Mineo, and M. Brayda-Bruno, "Biomechanics of the lumbar spine after dynamic stabilization," *Journal of Spinal Disorders & Techniques*, vol. 20, no. 6, pp. 423–429, 2007.
- [32] B. W. Cunningham, Y. Kotani, P. S. McNulty, A. Cappuccino, and P. C. McAfee, "The effect of spinal destabilization and instrumentation on lumbar intradiscal pressure: an *in vitro* biomechanical analysis," *Spine*, vol. 22, no. 22, pp. 2655–2663, 1997
- [33] S. L. Weinhoffer, R. D. Guyer, M. Herbert, and S. L. Griffith, "Intradiscal pressure measurements above an instrumented fusion a cadaveric study," *Spine*, vol. 20, no. 5, pp. 526–531, 1995.
- [34] M. F. Hambly, L. L. Wiltse, N. Raghavan, G. Schneiderman, and C. Koenig, "The transition zone above a lumbosacral fusion," *Spine*, vol. 23, no. 16, pp. 1785–1792, 1998.
- [35] M. Penta, A. Sandhu, and R. D. Fraser, "Magnetic resonance imaging assessment of disc degeneration 10 years after anterior lumbar interbody fusion," *Spine*, vol. 20, no. 6, pp. 743–747, 1995.
- [36] S. Nakai, H. Yoshizawa, and S. Kobayashi, "Long-term follow-up study of posterior lumbar interbody fusion," *Journal of Spinal Disorders*, vol. 12, no. 4, pp. 293–299, 1999.
- [37] M. N. Kumar, F. Jacquot, and H. Hall, "Long-term follow-up of functional outcomes and radiographic changes at adjacent levels following lumbar spine fusion for degenerative disc disease," *European Spine Journal*, vol. 10, no. 4, pp. 309–313, 2001.
- [38] W. Schmoelz, J. F. Huber, T. Nydegger, Dipl-Ing, L. Claes, and H. J. Wilke, "Dynamic stabilization of the lumbar spine and its effects on adjacent segments: an in vitro experiment," *Journal* of Spinal Disorders and Techniques, vol. 16, no. 4, pp. 418–423, 2003.
- [39] J. Cabello, J. M. Cavanilles-Walker, M. Iborra, M. T. Ubierna, A. Covaro, and J. Roca, "The protective role of dynamic stabilization on the adjacent disc to a rigid instrumented level. An in vitro biomechanical analysis," *Archives of Orthopaedic and Trauma Surgery*, vol. 133, no. 4, pp. 443–448, 2013.
- [40] P. Strube, S. Tohtz, E. Hoff, C. Gross, C. Perka, and M. Putzier, "Dynamic stabilization adjacent to single-level fusion: part I. Biomechanical effects on lumbar spinal motion," *European Spine Journal*, vol. 19, no. 12, pp. 2171–2180, 2010.
- [41] V. Lafage, N. Gangnet, J. Sénégas, F. Lavaste, and W. Skalli, "New interspinous implant evaluation using an in vitro biomechanical study combined with a finite-element analysis," *Spine*, vol. 32, no. 16, pp. 1706–1713, 2007.
- [42] H.-J. Wilke, J. Drumm, K. Häussler, C. MacK, W.-I. Steudel, and A. Kettler, "Biomechanical effect of different lumbar interspinous implants on flexibility and intradiscal pressure," *European Spine Journal*, vol. 17, no. 8, pp. 1049–1056, 2008.
- [43] B. He, L. Yan, H. Guo, T. Liu, X. Wang, and D. Hao, "The difference in superior adjacent segment pathology after lumbar

- posterolateral fusion by using 2 different pedicle screw insertion techniques in 9-year minimum follow-up," *Spine*, vol. 39, no. 14, pp. 1093–1098, 2014.
- [44] N. Boos and J. K. Webb, "Pedicle screw fixation in spinal disorders: a European view," *European Spine Journal*, vol. 6, pp. 2–18, 1997.
- [45] P. C. Jutte and R. M. Castelein, "Complications of pedicle screws in lumbar and lumbosacral fusions in 105 consecutive primary operations," *European Spine Journal*, vol. 11, no. 6, pp. 594–598, 2002.
- [46] J. E. Lonstein, F. Denis, J. H. Perra, M. R. Pinto, M. D. Smith, and R. B. Winter, "Complications associated with pedicle screws," *The Journal of Bone & Joint Surgery—American Volume*, vol. 81, no. 11, pp. 1519–1528, 1999.
- [47] K. Wang, Z. Zhu, B. Wang, Y. Zhu, and H. Liu, "Bone resorption during the first year after implantation of a single-segment dynamic interspinous stabilization device and its risk factors," BMC Musculoskeletal Disorders, vol. 16, article no. 117, 2015.
- [48] J. D. Miller, M. C. Miller, and M. G. Lucas, "Erosion of the spinous process: a potential cause of interspinous process spacer failure—report of 2 cases," *Journal of Neurosurgery: Spine*, vol. 12, no. 2, pp. 210–213, 2010.
- [49] L. M. Schulte, J. R. O'Brien, L. E. Matteini, and W. D. Yu, "Change in sagittal balance with placement of an interspinous spacer," *Spine*, vol. 36, no. 20, pp. E1302–E1305, 2011.
- [50] J. Liang, Y. Dong, and H. Zhao, "Risk factors for predicting symptomatic adjacent segment degeneration requiring surgery in patients after posterior lumbar fusion," *Journal of Orthopaedic Surgery and Research*, vol. 9, article 97, 2014.
- [51] H. Ishihara, M. Kanamori, Y. Kawaguchi, H. Nakamura, and T. Kimura, "Adjacent segment disease after anterior cervical interbody fusion," *The Spine Journal*, vol. 4, no. 6, pp. 624–628, 2004.
- [52] J. Sénégas, "Mechanical supplementation by non-rigid fixation in degenerative intervertebral lumbar segments: the wallis system," *European Spine Journal*, vol. 11, supplement 2, pp. S164– S169, 2002.
- [53] S. M. Jones-Quaidoo, M. Djurasovic, R. K. Owens III, and L. Y. Carreon, "Superior articulating facet violation: percutaneous versus open techniques," *Journal of Neurosurgery: Spine*, vol. 18, no. 6, pp. 593–597, 2013.
- [54] D. Lau, S. W. Terman, R. Patel, F. L. Marca, and P. Park, "Incidence of and risk factors for superior facet violation in minimally invasive versus open pedicle screw placement during transforaminal lumbar interbody fusion: a comparative analysis: clinical article," *Journal of Neurosurgery: Spine*, vol. 18, no. 4, pp. 356–361, 2013.
- [55] T. Kaito, N. Hosono, Y. Mukai, T. Makino, T. Fuji, and K. Yonenobu, "Induction of early degeneration of the adjacent segment after posterior lumbar interbody fusion by excessive distraction of lumbar disc space: clinical article," *Journal of Neurosurgery: Spine*, vol. 12, no. 6, pp. 671–679, 2010.

Hindawi Publishing Corporation BioMed Research International Volume 2017, Article ID 2302395, 7 pages http://dx.doi.org/10.1155/2017/2302395

### Clinical Study

## Application of Intraoperative CT-Guided Navigation in Simultaneous Minimally Invasive Anterior and Posterior Surgery for Infectious Spondylitis

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Received 6 August 2016; Revised 18 December 2016; Accepted 26 January 2017; Published 16 February 2017

Academic Editor: George Babis

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This study was aimed at evaluating the safety and efficacy of using intraoperative computed tomography- (iCT-) guided navigation in simultaneous minimally invasive anterior and posterior surgery for infectious spondylitis. Nine patients with infectious spondylitis were enrolled in this study. The average operative time was 327.6 min (range, 210–490) and intraoperative blood loss was 407 cc (range, 50–1,200). The average duration of hospital stay was 48.9 days (range, 11–76). Out of a total of 54 pedicle screws employed, 53 screws (98.1%) were placed accurately. A reduced visual analog scale on back pain (from 8.2 to 2.2) and Oswestry disability index (from 67.1% to 25.6%) were found at the 2-year follow-up. All patients had achieved resolution of spinal infection with reduced average erythrocyte sedimentation rate (from 83.9 to 14.1 mm/hr) and average C-reactive protein (from 54.4 to 4.8 mg/dL). Average kyphotic angle correction was 10.5° (range, 8.4°–12.6°) postoperatively and 8.5° (range, 6.9°–10.1°) after 2 years. In conclusion, the current iCT-guided navigation approach has been demonstrated to be an alternative method during simultaneous minimally invasive anterior and posterior surgery for infectious spondylitis. It can provide a good intraoperative orientation and visualization of anatomic structures and also a high pedicle screw placement accuracy in patient's lateral decubitus position.

#### 1. Introduction

In recent years, many approaches for anterior spinal surgery have been developed to correct and treat injuries or lesions by providing adequate decompression and debridement, maintenance, and reinforcement of the stability [1, 2]. However, these anterior approaches faced the potential complications like vessel or nerve injuries due to a large incision and extensive anatomical dissection [3]. Furthermore, in order to overcome these limitations, posterior approaches were also developed which later were found to be associated with

graft collapse or nonunion [4]. The drawback associated in these conventional methods has attracted attention towards minimally invasive spinal surgery (MISS) which provides minimized damage to paraspinal soft tissues and musculature thereby preserving tissue structures with highly reduced surgical complications. However, MISS may limit visualization and identification of anatomical landmarks during surgery due to smaller incisions and reduced soft tissue dissections that might lead to more severe complications. Therefore, in order to improve the identification of anatomic structure and the accuracy of pedicle screws placement, the intraoperative

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Table 1: Demographics of simultaneous minimally invasive anterior and posterior spinal surgery for infectious spondylitis.

Sex		
Male		4
Female		5
Age		71 (50–79)
ASA classification		
2		2
3		6
4		1
Surgical level		
T10-T11		2
T11-L1		3
L1-L2		4
Causative pathogens		
Staphylococcus aureus		4
Candida albicans		1
Candida tropicalis		1
Mycobacterium tuberculosis		1
Salmonella enterica, serotype D		2
Laboratory tests	Pretreatment	Posttreatment
CRP (mg/dL)	54.4 (25–78)	4.8 (1.3–11)
ESR (mm/hr)	83.9 (30–150)	14.1 (5–24)
Functional scales	Preoperative	Postoperative (2 yr)
Visual analog scale	8.2 (7–10)	2.2 (1–3)
Oswestry disability index	67.1 (54.3–88.9)	25.6 (11–40)
·	Postoperative	Postoperative (2 yr)
Kyphotic angle correction	10.5° (8.4°-12.6°)	8.5° (6.9°–10.1°)

ASA: American Society of Anesthesiologists; CRP: C-reactive protein; ESR: erythrocyte sedimentation rate.

computed tomography- (iCT-) guided navigation has been developed and may play a significant role in MISS [5]. Webb et al. had a cadaveric study using a fluoroscopy-based navigation for minimally invasive direct lateral interbody fusion in which the navigation system had provided a high accuracy up to less than 1 mm over L2–L5 and largely reduced radiation exposure for surgeons [6]. This feasibility study had demonstrated the benefits and safety of navigation in the anterior spinal surgery. However, up to date, there is scarcity of data on simultaneous anterior and posterior minimally invasive approach using iCT-guided navigation. In this study, we aimed to evaluate the safety and efficacy by using iCT-guided navigation in simultaneous minimally invasive anterior and posterior surgery for infectious spondylitis.

#### 2. Materials and Methods

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2.1. Study Design and Patient Population. This retrospective cohort study included 9 patients (5 females, 4 males) with infectious spondylitis (Table 1). All the patients underwent simultaneous minimally invasive anterior and posterior surgery with iCT-guided navigation between May 2011 and May 2014. This study was approved by the institutional review

board (IRB number 102-3501B). All demographic and perioperative data were collected from chart reviews and prospectively recorded preoperatively, postoperatively, and after 2-year follow-up in institutional Spine Operation Registry, including the following factors: sex, age, ASA classification, diagnosis, surgical level, operative time, blood loss, neurologic status as American Spinal Injury Association (ASIA) impairment scale, back pain score (visual analog scale, VAS), functional scale (Oswestry disability index, ODI), radiographic examination (kyphotic correction angle immediately after surgery and 2-year follow-up), inflammatory markers, and radiation dose.

2.2. Surgical Technique. A preoperative examination of patients including plain radiographs and magnetic resonance imaging (MRI), blood and urine cultures, and inflammatory status (erythrocyte sedimentation rate and C-reactive protein) was done and then simultaneous anterior and posterior spinal surgery was undertaken. Pedicle screw was first inserted with the aid of iCT-guided navigation in the lateral decubitus position followed by simultaneous minimal access spinal surgery (MASS) for anterior decompression and

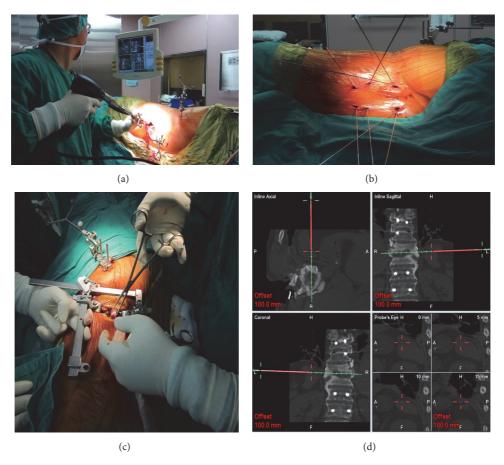


FIGURE 1: Intraoperative image demonstrating simultaneous anterior minimal access spinal surgery (MASS) and minimally invasive posterior spinal surgery. The trajectories of pedicle screws can be made by a registered drill guide and the iCT-guided navigation (a). The guidewire facilitates cannulated pedicle screw insertion (b). The consecutive anterior spinal surgery can be performed at the same position (c). The intraoperative navigation for MASS approach showing the site of infectious spondylitis and paraspinal structures (d).

reconstruction. Finally, the connecting rods were inserted and anchored in pedicle screw heads to achieve stabilization.

As demonstrated in Figure 1, patient was placed in the lateral decubitus position to allow simultaneous approaches to the anterior and posterior spine. The entire lateral thoracoabdominal region was included in the operative field, including the iliac crest for autograft harvest when needed. The reference array was fixed to the iliac crest just above anterior superior iliac spine away from the planned bone graft harvest site. A registration CT scan was then performed and the image was transferred to the navigation system. CT images before and after screw insertion were reviewed for screw position accuracy. The radiation dose from CT was noted as effective dose from converting the total dose length product with a conversion factor for the trunk region (0.015) [7]. We started the surgery from posterior instrumentation using percutaneous MISS approach. After identifying the pedicle entry, the screw tracks were then prepared with a registered drill guide. Guide wires were inserted into the tracks as guides. After all the pedicle screw tracks were prepared, cannulated pedicle screws of sufficient length and diameter were placed in the planned screw track to the optimal depth by the assistance of the navigation system. After the screw had been inserted, a

confirmatory CT scan was immediately done as a second registration CT scan for anterior MASS. If screw malposition was seen on the confirmation CT, then the malpositioned screws were immediately removed. The final definite fixation with rods was done after anterior reconstruction with bone graft. MASS techniques had previously been described in detail [8, 9]. A summary of the MASS for the treatment of target lesion included curettage and debridement of the lesion site, obtaining tissue specimens, decompression of the epidural space, and placement of autogenous bone struts from the ilium or excised rib into the intervertebral space. After the completion of decompression and reconstruction, a second confirmatory CT scan was again performed to determine the correct placement of the bone graft. With MASS, there are three primary ways to access anterior spine lesions localized by iCT-guided navigation perioperatively, and all use a 2- to 3-inch skin incision for both thoracic and lumbar lesions. For thoracic spine lesions, a transthoracic anterolateral approach can be performed after an underlying rib is resected. A 28- or 32-French chest tube was placed at the end of surgery. For the thoracic-lumbar junction, a retropleural and retroperitoneal approach with only diaphragmatic crural detachment and no take-down procedure was used. A chest tube was needed instead of a postoperative Hemovac drainage if air leakage is present during normal saline filling of the retropleural space following the resumption of two-lung ventilation [8]. For the lumbar spine, exposure to the anterior lumbar spine is through a retroperitoneal method, and the wound was closed after insertion of a 1- and 8-inch Hemovac drain (Figure 2). The postoperative drain was removed when the drainage was <50 mL per 8 hours [9].

2.3. iCT-Guided Navigation System and Evaluation of Screw Positioning. The navigation system (Spine & Trauma iCT Navigation SW, Brainlab AG, Feldkirchen, Germany) consisted of a sliding gantry 24-slice CT scanner (SOMATOM Sensation, Siemens, Munich, Germany) with the following specifications: 120 peak tube voltage (kVp), rotation time of 1 second, multiplanar reconstructions with slice thickness and increment of 1.5 mm, and a frameless infrared-based navigation station (VectorVision Sky, Brainlab AG, Munich, Germany). Postoperative iCT images were reviewed for screw position using digital image measurements (Centricity PACS 3.0, GE Healthcare, Fairfield, CT, USA). The assessment used a measurement scale in the digital image system as described by Gertzbein and Robbins [10]. The pedicle encroachment with ≤2 mm was considered within safe zone while >2 mm was regarded as malpositioned and potentially unsafe. The malposition of the screw was evaluated by Kast criteria [11].

#### 3. Results

The average operative time in the simultaneous anterior and posterior surgery was 327.6 minutes (range 210–493). The average blood loss during surgery was 407 cc (range, 50–1,200). The average duration of hospital stay was 48.9 days (range, 11–76). Furthermore, the average effective dose of radiation exposure during surgery was 15.4 millisieverts (mSv) (range, 19.4–26.8). The screw placement accuracy in this approach showed that, out of 54 pedicle screws employed, 53 screws were placed correctly (98.1%). The malpositioned screw was major breach as medial perforation with narrowing of the vertebral channel more than 25%.

Furthermore, following the surgery, the infection was controlled among all 9 patients treated with antibiotics, while one patient suffered from pneumonia, a major postoperative complication, and another patient was kept under extensive observation under intensive care unit due to delayed recovery from anaesthesia. We then evaluated the pain score on VAS which was 8.2 before surgery and 2.2 after 2-year follow-up. Besides, we also recorded the ODI score, a measure of functional improvement and recovery. The average preoperative ODI was 67.1 (range: 54.3–88.9) versus 25.6 (range: 11–40) postoperatively. As measured from radiograph, the average preoperative Cobb's kyphotic angle was 10.5° (range, 8.4°-12.6°) which decreased significantly to 8.5° (range, 6.9°–10.1°) after 2 years. The surgery also improved clinical and neurologic status according to ASIA impairment scale in which 4 patients showed improvement (Table 2). The posttreatment examination of the blood tests showed that the inflammatory markers including CRP and ESR were significantly reduced

TABLE 2: Preoperative and postoperative evaluation of improvement in American Spinal Injury Association (ASIA) impairment scale. Table showing change in the ASIA impairment scale between the preoperative status (vertical) and postoperative status at 2-year follow-up (horizontal).

Pre		P	Post	
Pre	В	С	D	E
В	0**	2***	0***	0***
C	0*	0**	1***	0***
D	0*	0*	1**	1***
E	0*	0*	0*	4**

<sup>\*</sup>Poor; \*\* similar; \*\*\* improved.

to 4.8 mg/dL (1.3–11) and 14.1 mm/hr (5–24) from preoperative value of 54.4 mg/dL (25–78) and 83.9 mm/hr (30–150) respectively.

In our study, 2 patients were identified with epidural abscess; one had psoas muscle abscess while the other one had lung empyema. With the aid of iCT-guided navigation, location of infected tissues can be accurately visualized which could help in debridement of infected tissues and draining of abscess.

#### 4. Discussion

The major aims of surgical treatment in spinal infection are removal of infected tissues, reduction in kyphotic deformity, and pain thereby providing spinal stability [12, 13]. For the treatment of spinal disorders, the anterior approach has commonly been used as it provides an excellent decompression of the spinal cord; however, it often does not allow the adequate stabilization of the thoracic spine due to the normal kyphotic curvature. The anterior surgical approach in vertebral infection has also been reported to provide direct access to debride infected tissues [14]. However, only partial spinal stability can be achieved through anterior approach. Therefore, the addition of posterior approach may be helpful to correct kyphotic deformity and hence the spinal stability. Besides, both the anterior and posterior surgical approach have been reported with increased rate of misplaced screws [15] and vascular complications [16].

Based on this clinical study on surgical treatment of infectious spondylitis, we suggest that a simultaneous anterior and posterior MISS with iCT-guided navigation may overcome the limitations posed in either anterior or posterior approach and rendering complete circumferential decompression and stabilization. In the cadaveric study by Webb et al., the use of fluoroscopy-guided navigation for the anterior spinal surgery was feasible with an accuracy of less than 1 mm for L2-L5 [6]. Furthermore, the pedicle screw placement through the intraoperative cone-beam CT-guided navigation had been reported with higher accuracy than under fluoroscopic guidance in a prospective comparison study [17]. The iCT-guided navigation used in this approach also provided potential benefit to surgeon in avoiding radiation exposure which could not be possible in fluoroscopically assisted spinal surgery [18]. In a report, Ozturk et al. had also documented that

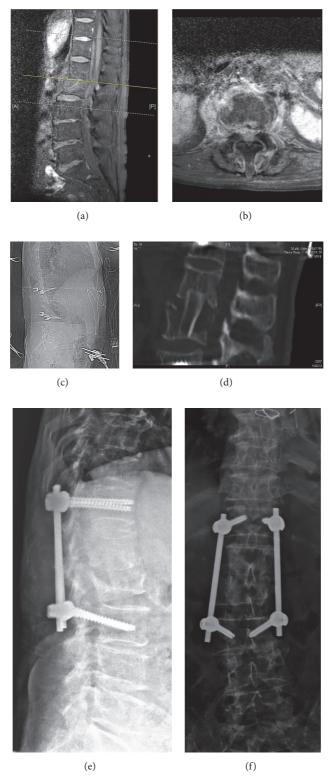


FIGURE 2: L1-L2 infectious spondylitis accompanied with epidural abscess treated with simultaneous minimally invasive anterior and posterior surgery using the iCT-guided navigation. Preoperative MRI demonstrated L1-L2 vertebral osteomyelitis and epidural abscess with obvious canal compromise (a, b). Intraoperative CT image obtained following simultaneous anterior and posterior spinal surgery (c, d) showing the spinal decompression and reconstruction. Partial resection of the L2 vertebra with reconstruction of L1-L2 with a percutaneous pedicle screw-rod construct and interbody iliac strut bone grafting (e, f).

simultaneous anterior and posterior spinal fusion surgery is faster with lesser blood loss and fewer complications when compared to sequential one-stage combined anterior and posterior spinal surgery [19]. This technique can be performed with the patients kept in the lateral decubitus position and can also facilitate the identification of anatomic structure and the screw implantation with a higher accuracy [5]. Moreover, the trajectory of the screw can also be analyzed immediately along with the length and position through confirmatory intraoperative CT scan [20]. Of note, the intraoperative localization of abscesses in epidural space and psoas muscles is still a challenge especially in minimally invasive spinal surgery [21]; however, iCT-guided navigation used in our study enabled localization of epidural and psoas muscle abscesses which were drained off and infected tissue was thoroughly debrided. So, the real-time visualization of vital organs and vessels through iCT-guided navigation during surgical process offers high safety. Based on overall treatment outcomes, we demonstrated that iCT-guided navigation could be applied safely during simultaneous minimally invasive anterior and posterior surgery for infectious spondylitis.

The limitations of this study include limited case numbers, a single surgeon experience, heterogeneous pathogens, and no comparative study. Furthermore, this report only included thoracic and lumbar spinal infections. However, the further detailed investigations by increasing number of cases and pathogen-based comparative study are needed to elucidate the potential benefits of this approach in spinal infections.

#### 5. Conclusion

The current iCT-guided navigation approach has been demonstrated to be an alternative method during simultaneous minimally invasive anterior and posterior surgery for infectious spondylitis. It can provide a good intraoperative orientation and visualization of anatomic structures and also a high pedicle screw placement accuracy in patient's lateral decubitus position.

#### **Competing Interests**

All authors declare that they have no conflict of interests.

#### Acknowledgments

The authors greatly appreciate the contribution of Mr. Chu-Hsiang Hsu (MSRS) for the assistance in operating CT scan. The authors also thank the Research Committee of Chang Gung Memorial Hospital, Taiwan, for the assistance (no. CMRPG6A0211-2) in the Spine Operation Registry.

#### References

[1] B. Garg, P. Kandwal, B. Upendra, A. Goswami, and A. Jayaswal, "Anterior versus posterior procedure for surgical treatment of thoracolumbar tuberculosis: a retrospective analysis," *Indian Journal of Orthopaedics*, vol. 46, no. 2, pp. 165–170, 2012.

- [2] R.-M. Lin, K.-Y. Huang, and K.-A. Lai, "Mini-open anterior spine surgery for anterior lumbar diseases," *European Spine Journal*, vol. 17, no. 5, pp. 691–697, 2008.
- [3] K. Weiss, R. Kramar, and P. Firt, "Cranial and cervical nerve injuries: local complications of carotid artery surgery," *Journal* of Cardiovascular Surgery, vol. 28, no. 2, pp. 171–175, 1987.
- [4] A. D. Steffee and D. J. Sitkowski, "Posterior lumbar interbody fusion and plates," *Clinical Orthopaedics and Related Research*, no. 227, pp. 99–102, 1988.
- [5] C.-Y. Lee, M.-H. Wu, Y.-Y. Li et al., "Intraoperative computed tomography navigation for transpedicular screw fixation to treat unstable thoracic and lumbar spine fractures: clinical analysis of a case series (CARE-compliant)," *Medicine*, vol. 94, no. 20, article e757, 2015.
- [6] J. E. Webb, G. J. Regev, S. R. Garfin, and C. W. Kim, "Navigation-assisted fluoroscopy in minimally invasive direct lateral interbody fusion: a cadaveric study," SAS Journal, vol. 4, no. 4, pp. 115–121, 2010.
- [7] S. Ulzheimer, C. Leidecker, and H. Endt, "Dose parameters and advanced dose management on SOMATOM scanners," White Paper, Siemens Medical Solutions, Forchheim, Germany, 2011, https://static.healthcare.siemens.com/siemens\_hwem-hwem\_ ssxa\_websites-context-root/wcm/idc/groups/public/@us/@imaging/documents/download/mdaw/ndq2/~edisp/low\_dose\_session\_27\_v2-00308413.pdf.
- [8] T.-J. Huang, R. W.-W. Hsu, Y.-Y. Li, and C.-C. Cheng, "Minimal access spinal surgery (MASS) in treating thoracic spine metastasis," *Spine*, vol. 31, no. 16, pp. 1860–1863, 2006.
- [9] T.-J. Huang, R. W.-W. Hsu, S.-H. Chen, and Y.-Y. Lee, "Minimal access surgery in managing anterior lumbar disorders," *Clinical Orthopaedics and Related Research*, no. 387, pp. 140–147, 2001.
- [10] S. D. Gertzbein and S. E. Robbins, "Accuracy of pedicular screw placement in vivo," *Spine*, vol. 15, no. 1, pp. 11–14, 1990.
- [11] E. Kast, K. Mohr, H.-P. Richter, and W. Börm, "Complications of transpedicular screw fixation in the cervical spine," *European Spine Journal*, vol. 15, no. 3, pp. 327–334, 2006.
- [12] V. Hegde, D. S. Meredith, C. K. Kepler, and R. C. Huang, "Management of postoperative spinal infections," World Journal of Orthopaedics, vol. 3, no. 11, pp. 182–189, 2012.
- [13] N. Miyakoshi, M. Hongo, T. Kobayashi, T. Abe, E. Abe, and Y. Shimada, "Improvement of spinal alignment and quality of life after corrective surgery for spinal kyphosis in patients with osteoporosis: a comparative study with non-operated patients," Osteoporosis International, vol. 26, no. 11, pp. 2657–2664, 2015.
- [14] W.-H. Chen, L.-S. Jiang, and L.-Y. Dai, "Surgical treatment of pyogenic vertebral osteomyelitis with spinal instrumentation," *European Spine Journal*, vol. 16, no. 9, pp. 1307–1316, 2007.
- [15] G. Li, G. Lv, P. Passias et al., "Complications associated with thoracic pedicle screws in spinal deformity," *European Spine Journal*, vol. 19, no. 9, pp. 1576–1584, 2010.
- [16] Z. Klezl, G. N. Swamy, T. Vyskocil, J. Kryl, and J. Stulik, "Incidence of vascular complications arising from anterior spinal surgery in the thoraco-lumbar spine," *Asian Spine Journal*, vol. 8, no. 1, pp. 59–63, 2014.
- [17] M.-H. Shin, J.-W. Hur, K.-S. Ryu, and C.-K. Park, "Prospective comparison study between the fluoroscopy-guided and navigation coupled with O-arm-guided Pedicle Screw Placement in the Thoracic and Lumbosacral Spines," *Journal of spinal disor*ders & techniques, vol. 28, no. 6, pp. E347–E351, 2015.
- [18] Y. R. Rampersaud, K. T. Foley, A. C. Shen, S. Williams, and M. Solomito, "Radiation exposure to the spine surgeon during

- fluoroscopically assisted pedicle screw insertion," *Spine*, vol. 25, no. 20, pp. 2637–2645, 2000.
- [19] C. Ozturk, U. Aydinli, R. Vural, A. Sehirlioglu, and M. Mutlu, "Simultaneous versus sequential one-stage combined anterior and posterior spinal surgery for spinal infections (outcomes and complications)," *International Orthopaedics*, vol. 31, no. 3, pp. 363–366, 2007.
- [20] M.-H. Wu, T.-J. Huang, Y.-Y. Li, C.-C. Cheng, K.-C. Huang, and R. W.-W. Hsu, "Comparison of the accuracies of transpedicular screw insertion during computed tomography-free, -based, and intraoperative computed tomography spinal surgeries," Formosan Journal of Musculoskeletal Disorders, vol. 3, no. 2, pp. 39– 42, 2012.
- [21] K. Rosc-Bereza, M. Arkuszewski, E. Ciach-Wysocka, and M. Boczarska-Jedynak, "Spinal epidural abscess: common symptoms of an emergency condition. A case report," *Neuroradiology Journal*, vol. 26, no. 4, pp. 464–468, 2013.

Hindawi Publishing Corporation BioMed Research International Volume 2017, Article ID 5619350, 6 pages http://dx.doi.org/10.1155/2017/5619350

### Clinical Study

### A Novel Nonpedicular Screw-Based Fixation in Lumbar Spondylolisthesis

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Received 5 August 2016; Accepted 21 December 2016; Published 10 January 2017

Academic Editor: Jiancheng Zeng

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Objective. The authors present the clinical results obtained in patients who underwent interspinous fusion device (IFD) implantation following posterior lumbar interbody fusion (PLIF). The purpose of this study is investigating the feasibility of IFD with PLIF in the treatment of lumbar spondylolisthesis. *Methods*. Between September 2013 and November 2014, 39 patients underwent PLIF and subsequent IFD (Romeo®2 PAD, Spineart, Geneva, Switzerland) implantation. Medical records of these patients were retrospectively reviewed to collect relevant data such as blood loss, operative time, and length of hospital stay. Radiographs and clinical outcome were evaluated 6 weeks and 12 months after surgery. *Results*. All 39 patients were followed up for more than one year. There were no major complications such as dura tear, nerve injuries, cerebrospinal fluid leakage, or deep infection. Both interbody and interspinous fusion could be observed on radiographs one year after surgery. However, there were 5 patients having early retropulsion of interbody fusion devices. *Conclusion*. The interspinous fusion device appears to achieve posterior fixation and facilitate lumbar fusion in selected patients. However, further study is mandatory for proposing a novel anatomic and radiological scoring system to identify patients suitable for this treatment modality and prevent postoperative complications.

#### 1. Introduction

Lumbar arthrodesis with decompression of the neural structures is an effective surgical management for degenerative spondylolisthesis with stenosis. The current methods for lumbar arthrodesis include posterolateral fusion, posterior interbody fusion (PLIF), and transforaminal lumbar interbody fusion (TLIF) with pedicle screw instrumentation. However, these treatment modalities involving the pedicle screw-based fixation have several drawbacks. The most common complications associated with pedicle screw fixation included unrecognized screw misplacement, fracturing of the pedicle, and iatrogenic cerebrospinal fluid leak. Consequently, mechanical failure, transient neurapraxia, or permanent nerve root injury could happen [1, 2]. In addition, postoperative back pain

could result from wide muscle dissection and long operative times for pedicular screw fixation.

Recently, interspinous spacers have been developed to satisfy the requirements of minimally invasive procedures, decrease the morbidity associated with pedicle screw instrumentation, and prevent the overload on adjacent vertebral segments. As the growing applications of interspinous devices, the surgical indications have been extended, ranging in degenerative stenosis, discogenic low back pain, herniated intervertebral disc diseases, and low-grade instability [3]. Interspinous process devices can be categorized by design as static, dynamic, or fusion devices. The intention of all these implants is designed to maintain certain distraction between the spinous processes. Nevertheless, the development of interspinous fusion devices (IFD) is intended to

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TABLE 1: Demogra	phic data in	patients	undergoing	PLIF wit	n IFD.
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Patients	IFD
Number	39
Sex (male: female)	6:33
Age	52-79 (mean 66.0)
Spondylolisthesis level	Number of cases
L3-4	9
L4-5	27
L3-4-5	2
L2-3 and L4-5	1

be an alternative to pedicle screw fixation system and to aid in the stabilization of the spine with interbody fusion. Theoretically, using IFD instead of pedicle screw fixation inherits the advantages of other interspinous process devices such as delivery through a single incision, reduced disruption of paraspinal musculature, and reduced risk of nerve injuries [4]. In addition, adjacent segmental degeneration (ASD) resulted from pedicle screw [5-7] and rod fixation may be prevented by less rigid fixation provided by IFD. When IFD are used in combination with interbody fusion devices, they potentially offer a biomechanically circumferential fusion comparable or improved outcomes compared to traditional pedicle screw and rod instrumentation. Therefore, in this study, we retrospectively reviewed our experience with 39 patients who underwent the interspinous fusion devices (IFD) combined with posterior lumbar interbody fusion (PLIF) for grade I lumbar spondylolisthesis.

#### 2. Materials and Methods

Between September 2013 and November 2014, 39 patients with grade I lumbar spondylolisthesis underwent posterior IFD (Romeo 2 PAD, Spineart, Geneva, Switzerland) and posterior lumbar interbody fusion (Juliet®OL, Spineart, Geneva, Switzerland). The demographic data of the patients is listed on Table 1.

The study group included 39 patients, 6 males and 33 females, who ranged in age from 52 to 79 years (mean 66.0 years) at the time of surgery. All patients included in this study presented with radicular pain and/or intermittent claudication and required laminoforaminotomy for neural decompression. Levels of lumbar spondylolisthesis in this study were as follows: L3-4 in 9 patients, L4-5 in 27 patients, L3-4-5 in 2 patients, and L2-3 and L4-5 in 1 patient. L4-5 spondylolisthesis was most common. Patients with advanced spondylolisthesis (≥grade II spondylolisthesis) were excluded from this study. Other exclusion criteria included (1) osteoporosis; (2) disabling leg from compression fracture, metabolic neuropathy, or vascular claudication; (3) previous surgery at the intended treatment level.

All patients underwent PLIF with a poly-ether-ether-ketone (PEEK) cage (Juliet OL, Spineart, Geneva, Switzerland) and interspinous fusion with an IFD composed of two titanium plates with 30 degrees' polyaxiality and a PEEK

central core (Romeo 2 PAD, Spineart, Geneva, Switzerland). A 4-5 cm midline skin incision was made at the intended fusion level overlying the spinous processes. Exposure of the rostral and caudal spinous processes was done by routine subperiosteal dissection with preservation of the supraspinous ligament for later anatomical closure. Dissection was carried out down to the lumbar lamina. Decompression with insertion of an interbody cage was done over the symptomatic side using standard PLIF procedures. Both autograft harvested from laminoforaminotomy and artificial bone graft were packed in the interbody cage and adjacent to the cage in the disc space to provide larger contact area for bone fusion. The interspinous ligament was removed to facilitate implantation of IFD. A small portion of the edge of rostral and caudal spinous processes was removed to expose cancellous bone. The central PEEK core of IFD was filled with autologous bone fragments harvested from the decompression procedures before implantation of IFD. Trial spacers of different sizes were inserted in the interspinous space to select IFD of optimal size. Once the two plates of selected IFD were inserted with one plate on each side of the spinous processes, the easy one-step locking mechanism allowed us to compress, fix, and lock the implant between the rostral and caudal portions of spinous processes. The supraspinous ligament was secured to the spinous processes for anatomical restoration (Figure 1). Finally, the wound was closed using standard multilayered methods without drainage. All patients were asked to wear orthosis for three months after surgery and avoid bending and lifting heavy objects.

Medical records of 39 patients were reviewed to collect data such as estimated blood loss (EBL), operative time, and length of hospital stay. The clinical outcome including back pain and sciatica was measured using the visual analogue scale (VAS). All outcome measures were assessed on the day after surgery for the immediate postoperative outcome and 6 weeks and 12 months after surgery. Postoperative radiographs including plain anteroposterior and flexion-extension views were evaluated at 6 weeks and 12 months after surgery.

#### 3. Results

There were a total of 6 men and 33 women in the study. The mean operative time for interspinous fusion and posterior interbody fusion ranged from 65 to 105 minutes, which was considerably less than that in the open pedicle screw fixation. The mean estimated blood loss ranged from 120 ml to 150 ml in all 39 patients. The average length of hospital stay was 5.5 days in average. There were no intraoperative complications such as dura tear and nerve injury in all 39 patients.

The follow-up duration was over one year in all 39 patients. Immediately postoperatively, all patient experienced improvement in both sciatica and back pain. Except for 5 patients developing early migration of interbody devices, the remaining patients had favorable outcome in sciatica and back pain during one-year follow-up. Mean leg pain (VAS) decreased from 7.2 to 3.1 and 2.2, 6 weeks and 12 months after surgery, respectively. Interbody fusion was observed in 34 patients one year after surgery. Interestingly, interspinous fusion could also be observed in anteroposterior radiographs

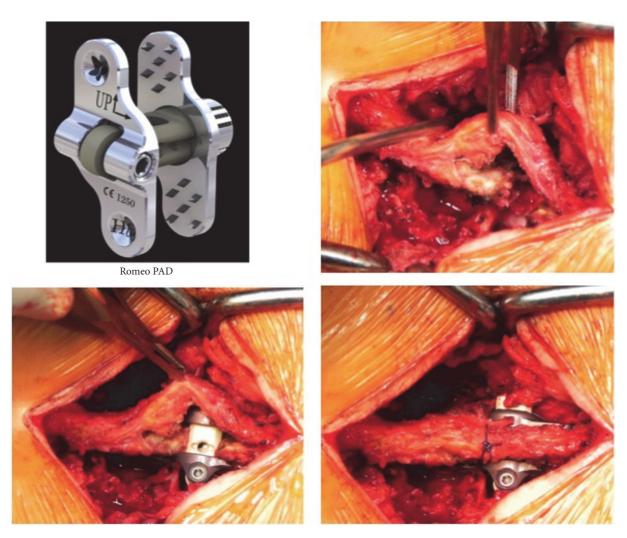


FIGURE 1: Implantation of interspinous fusion devices (Romeo 2 PAD, Spineart, Geneva, Switzerland).

(Figure 2). There was no adjacent segment degeneration in our patients.

There were five patients (3 female, 2 male, age ranged from 52 to 79 years) suffering from early retropulsion of interbody devices. Figure 3 showed an illustrative 57-year-old woman of early retropulsion of IFD. However, fracture of the spinous processes or migration of interspinous devices did not happen in any patient. There was no major surgery-related complication such as deep infection, nerve root injury, and CSF leakage in our patients.

#### 4. Discussion

The aim of interspinous process devices is to neutralize excessive movement in flexion and extension associated with distraction of the spinal segments to opening of the foramens [8]. Development of various IPD was attempted to reduce the risks associated with the pedicle screw fixation. 4% cerebrospinal fluid leakage, 2% transient neurapraxia, 2% permanent nerve root injury, 4-5% deep infection, and 3–12% hardware failure have been reported for the pedicle

screw fixation technique [1, 2]. In addition, superior segment facet violation has recently shown to cause the adjacent level destabilization in pedicle screw fixation [9]. In this study, IFD implants were placed on only the spinous processes and presented no risk of dural or neural injury and cerebrospinal fluid leakage. Furthermore, the operative time for IFD implantation was shorter than that for the pedicle screw fixation. Additionally, smaller incision, minimal bone exposure, and less muscle retraction/dissection decreased the blood loss for IFD implantation. Because many patients receiving lumbar fusion surgery are elderly, lowering the blood loss during surgery indicates reduced surgical risks and better postoperative recovery.

Although previous study showed that range of motion (ROM) at the instrumented level was significantly decreased in both the IFD and pedicle screw fixation compared with the preoperative state [10], 12.8% of our patients (5 in 39 patients) developed posterior migration of the interbody cage during the early postoperative period (6 weeks). This result necessitates the reexamination of biomechanical characteristics of the interspinous devices. Hartmann et al. evaluated

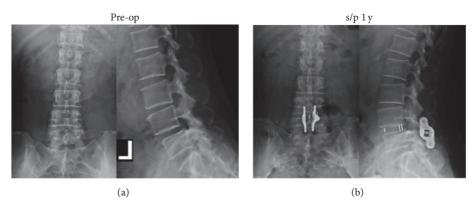


FIGURE 2: Imaging studies obtained in a 59-year-old female who presented with grade I spondylolisthesis (a). The patient underwent interspinous fusion device implantation following PLIF. One year after surgery, anteroposterior and lateral radiographs confirmed the position of the IFD and cage and showed both interbody and interspinous bone fusion (b).



FIGURE 3: An illustrative 59-year-old female case demonstrated grade I spondylolisthesis on preoperative image studies. Radiographs 2 days after surgery showed IFD and interbody cage in appropriate positions. However, early migration of interbody cage was noted on the lateral radiograph 6 weeks after surgery.

biomechanical effect of different interspinous devices on lumbar spinal range of motion. The results showed that interspinous devices led to a significant reduction in ROM during flexion-extension but to a significant increase in ROM during lateral bending and rotation [11]. A biomechanical study using human cadaver spines conducted by Techy et al. also demonstrated no statistically significant difference in the ROM in flexion-extension among the stand-alone interspinous devices and unilateral and bilateral pedicle fixation constructs. However, in both lateral bending and

axial rotation, the unilateral and bilateral pedicle screw fixation constructs were significantly more rigid than the IPD alone and the interbody device combination [12]. Contrarily, Wang and associates reported interspinous devices (Spire SPP; Medtronic, Minneapolis, MN, USA) could limit axial rotation and lateral bending ROM as well as unilateral pedicle screw and rod fixation [13]. Another in vitro biomechanical study suggested that both bilateral pedicle screw fixation and IFD provided equivalent flexion-extension and axial rotation stability in a posterior lumbar interbody fusion

model with posterior expandable cages [14]. Without doubt, a stand-alone interbody device allows facet sliding which can potentially prevent spinal arthrodesis. It is preferred to include posterior augmentation to simulate 360-degree stability. However, the exact amount of stiffness and ROM required to promote arthrodesis is ambiguous. Besides, the stability provided by instrumentation must cross an unknown threshold, varying from patient to patient, to ensure fusion. In spite of the increasing use of interspinous implants, the 2011 clinical guidelines from the NASS (North American Spine Society) suggested that there is insufficient evidence to support the net benefit for long-term outcomes for the placement of an interspinous process device [15, 16]. In addition, complications associated with interspinous process device implantation for lumbar spine degenerative disease included fracture of the spinous process, implant dislocation, and dura tear with cerebrospinal fluid (CSF) leakage. An European multicenter study revealed the complication rate was 7.8%. The ultimate failure rate requiring additional surgery was 9.6% [3]. Compared with IPD, clinical experience for IFD to date is limited; a previous report suggested the results of IFD investigations were promising in posterior lumbar interbody fusion models compared to select cases of bilateral pedicle screw fixation [10]. Wang et al. compared a small group (21 patients) with an interspinous device (Spire SPP; Medtronic, Minneapolis, MN, USA) used to supplement interbody fusion to 11 patients with bilateral pedicle screws. They demonstrated less blood loss and shorter operative time, without an increase in the rate of pseudarthrosis or hardware failure in the interspinous device group [17]. However, there was a high extrusion/expulsion rate of interbody devices in our patients. Interestingly, in our series, there was no incidence of cage subsidence, which has been frequently reported in stand-alone cage implantation [18]. Therefore, interspinous fusion devices as a posterior augmentation for spinal stability may contribute to the avoidance of cage subsidence in our study. Nevertheless, a deliberate preoperative anatomic and radiologic scoring system should be developed for patient selection to avoid migration of interbody cage. Because there was no consensus that had been reached on defining or classifying spondylolisthesis with respect to its stability, we were not able to determine the causes of posterior migration of the interbody cages from our cases. However, a degenerative lumbar spondylolisthesis instability classification (DSIC) proposed by Simmonds et al. [19] including the analysis of disc angle, presence of joint effusion, and signs of restabilization may provide preoperative evaluations for better patient selection for this IFD treatment modality in the future.

#### 5. Conclusion

Bilateral pedicle screw stabilization with interbody body fusion is still considered the gold standard in lumbar arthrodesis. Posterior interspinous fusion device for onelevel fusion is associated with minimal operative risk of dura and nerve injuries, shortens operative time, and decreases intraoperative blood loss. The interspinous fusion device also appears to achieve posterior fixation and facilitate lumbar fusion in selected patients. However, it is not a panacea for all patients with lumbar spondylolisthesis. Future study for preoperative evaluation and analysis of anatomic/radiological pitfalls and tips is mandatory for proposing a novel scoring system to identify patients suitable for this treatment modality and prevent postoperative complications.

#### **Competing Interests**

The authors declare that they have no competing interests.

#### References

- [1] S. I. Esses, B. L. Sachs, and V. Dreyzin, "Complications associated with the technique of pedicle screw fixation: a selected survey of abs members," *Spine*, vol. 18, no. 15, pp. 2231–2239, 1993.
- [2] P. C. Jutte and R. M. Castelein, "Complications of pedicle screws in lumbar and lumbosacral fusions in 105 consecutive primary operations," *European Spine Journal*, vol. 11, no. 6, pp. 594–598, 2002.
- [3] R. Gazzeri, M. Galarza, M. Neroni et al., "Failure rates and complications of interspinous process decompression devices: A European Multicenter Study," *Neurosurgical Focus*, vol. 39, no. 4, article E14, 2015.
- [4] J. F. Zucherman, K. Y. Hsu, C. A. Hartjen et al., "A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results," *Spine*, vol. 30, no. 12, pp. 1351–1358, 2005.
- [5] J. L. West, J. W. Ogilvie, and D. S. Bradford, "Complications of the variable screw plate pedicle screw fixation," *Spine*, vol. 16, no. 5, pp. 576–579, 1991.
- [6] T.-H. Kim, B. H. Lee, S.-H. Moon, S.-H. Lee, and H.-M. Lee, "Comparison of adjacent segment degeneration after successful posterolateral fusion with unilateral or bilateral pedicle screw instrumentation: a minimum 10-year follow-up," *The Spine Journal*, vol. 13, no. 10, pp. 1208–1216, 2013.
- [7] S. Okuda, M. Iwasaki, A. Miyauchi, H. Aono, M. Morita, and T. Yamamoto, "Risk factors for adjacent segment degeneration after PLIF," *Spine*, vol. 29, no. 14, pp. 1535–1540, 2004.
- [8] A. Landi, "Elastic resistance of the spine: why does motion preservation surgery almost fail?" *World Journal of Clinical Cases*, vol. 1, no. 4, pp. 134–139, 2013.
- [9] M. J. Cardoso, A. E. Dmitriev, M. Helgeson, R. A. Lehman, T. R. Kuklo, and M. K. Rosner, "Does superior-segment facet violation or laminectomy destabilize the adjacent level in lumbar transpedicular fixation?: an *in vitro* human cadaveric assessment," *Spine*, vol. 33, no. 26, pp. 2868–2873, 2008.
- [10] H. J. Kim, K. H. Bak, H. J. Chun, S. J. Oh, T. H. Kang, and M. S. Yang, "Posterior interspinous fusion device for one-level fusion in degenerative lumbar spine disease: comparison with pedicle screw fixation—preliminary report of at least one year follow up," *Journal of Korean Neurosurgical Society*, vol. 52, no. 4, pp. 359–364, 2012.
- [11] F. Hartmann, S.-O. Dietz, H. Hely, P. M. Rommens, and E. Gercek, "Biomechanical effect of different interspinous devices on lumbar spinal range of motion under preload conditions," *Archives of Orthopaedic and Trauma Surgery*, vol. 131, no. 7, pp. 917–926, 2011.

[12] F. Techy, P. Mageswaran, R. W. Colbrunn, T. F. Bonner, and R. F. McLain, "Properties of an interspinous fixation device (ISD) in lumbar fusion constructs: a biomechanical study," *Spine Journal*, vol. 13, no. 5, pp. 572–579, 2013.

6

- [13] J. C. Wang, D. Spenciner, and J. C. Robinson, "SPIRE spinous process stabilization plate: biomechanical evaluation of a novel technology. Invited submission from the joint section meeting on disorders of the spine and peripheral nerves, March 2005," *Journal of Neurosurgery: Spine*, vol. 4, no. 2, pp. 160–164, 2006.
- [14] S. A. Gonzalez-Blohm, J. J. Doulgeris, K. Aghayev, W. E. Lee III, A. Volkov, and F. D. Vrionis, "Biomechanical analysis of an interspinous fusion device as a stand-alone and as supplemental fixation to posterior expandable interbody cages in the lumbar spine," *Journal of Neurosurgery: Spine*, vol. 20, no. 2, pp. 209–219, 2014
- [15] R. Chou, J. D. Loeser, D. K. Owens et al., "Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American pain society," *Spine*, vol. 34, no. 10, pp. 1066–1077, 2009.
- [16] R. Chou, J. Baisden, E. J. Carragee, D. K. Resnick, W. O. Shaffer, and J. D. Loeser, "Surgery for low back pain: a review of the evidence for an American Pain Society Clinical Practice Guideline," *Spine*, vol. 34, no. 10, pp. 1094–1109, 2009.
- [17] J. C. Wang, R. W. Haid Jr., J. S. Miller, and J. C. Robinson, "Comparison of CD HORIZON SPIRE spinous process plate stabilization and pedicle screw fixation after anterior lumbar interbody fusion: invited submission from the joint section meeting on disorders of the Spine and Peripheral Nerves, March 2005," *Journal of Neurosurgery: Spine*, vol. 4, no. 2, pp. 132–136, 2006.
- [18] K. R. Cho, S. Lee, E. S. Kim, and W. Eoh, "Mid-term clinical outcomes of stand-alone posterior interbody fusion with rectangular cages: a 4-year-minimum follow-up," *Korean Journal of Spine*, vol. 10, no. 3, pp. 126–132, 2013.
- [19] A. M. Simmonds, Y. R. Rampersaud, M. F. Dvorak, N. Dea, A. D. Melnyk, and C. G. Fisher, "Defining the inherent stability of degenerative spondylolisthesis: a systematic review," *Journal of Neurosurgery: Spine*, vol. 23, no. 2, pp. 178–189, 2015.

Hindawi Publishing Corporation BioMed Research International Volume 2017, Article ID 8423638, 9 pages http://dx.doi.org/10.1155/2017/8423638

#### Review Article

# The Outcomes of Minimally Invasive versus Open Posterior Approach Spinal Fusion in Treatment of Lumbar Spondylolisthesis: The Current Evidence from Prospective Comparative Studies

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Received 4 August 2016; Accepted 4 December 2016; Published 5 January 2017

Academic Editor: Jiancheng Zeng

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Purpose. To investigate the evidence of minimally invasive (MI) versus open (OP) posterior lumbar fusion in treatment of lumbar spondylolisthesis from current prospective literatures. *Methods*. The electronic literature database of Pubmed, Embase, and Cochrane library was searched at April 2016. The data of operative time, estimated blood loss and length of hospital stay, visual analog scale (VAS) of both lower back pain and leg pain, Oswestry disability index (ODI), SF-36 PCS (physical component scores) and SF-36 MCS (mental component scores), complications, fusion rate, and secondary surgery were extracted and analyzed by STATA 12.0 software. *Results*. Five nonrandom prospective comparative studies were included in this meta-analysis. The meta-analysis showed that the MI group had a significantly longer operative time than OP group, less blood loss, and shorter hospital stay. No significant difference was found in back pain, leg pain, ODI, SF-36 PCS, SF-36 MCS, complications, fusion rate, and secondary surgery between MI and OP groups. *Conclusion*. The prospective evidence suggested that MI posterior fusion for spondylolisthesis had less EBL and hospital stay than OP fusion; however it took more operative time. Both MI and OP fusion had similar results in pain and functional outcomes, complication, fusion rate, and secondary surgery.

#### 1. Introduction

With the help of radiographic and endoscopic system and special surgical tools, the minimally invasive posterior lumbar surgery was developed and worldwide popularly in last decades [1, 2]. It was reported the minimally invasive spinal surgery techniques had advantages of shorter skin wound incision, less muscle trauma, less blood loss, and hospital stay [3–5].

Currently, the minimally invasive (MI) lumbar spinal fusion techniques including MI posterior lumbar interbody fusion [6], MI transforaminal lumbar interbody fusion [7,

8], MI posterolateral lumbar fusion, MI lateral lumbar fusion [9], MI oblique lumbar interbody fusion, and MI anterior lumbar interbody fusion. The posterior approach permits the decompression and discectomy directly and does not have complications of vessel, hypogastric sympathetic plexus, and ureter injury, which may be caused by anterior approach [10–12], and is most widely used nowadays [13].

And the previous systematic review and meta-analysis in literatures showed that MI transforaminal lumbar interbody fusion appears similar safety and efficacy to open transforaminal lumbar interbody fusion and associated with

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lower blood loss and infection rates for general degenerative lumbar disease patient [14, 15].

However, spondylolisthesis is one of the most lumbar spinal disorders and may be caused by isthmic or degeneration. The symptoms of spondylolisthesis include low back pain and leg pain, decreasing walk ability, and neurogenic claudication. Surgical interventions were recommended when the symptoms could not be relieved by conservative treatment [16-18]. The difference of spondylolisthesis to other degenerative lumbar diseases (such as lumbar stenosis without spondylolisthesis and lumbar disc herniated) is that in spondylolisthesis patients the vertebrae will be slipped anteriorly. The traditional open spinal fusion, which performed laminectomy to completely decompression the spinal canal and nerve root, was recognized as one of the "gold standard" methods in treatment of spondylolisthesis and had credible pain relief and function improvement [19, 20]. MI technique may be hard to achieve completely decompression because of the limited vision; therefore, the clinical efficacy and safety of minimally invasive posterior spinal fusion in treatment of lumbar spondylolisthesis are still controversial. In this study, we aim to provide the best evidence from current prospective comparative studies for surgeons and researchers.

#### 2. Methods

This systematic review and meta-analysis was done according to the preferred reporting items for systematic review and meta-analyses (PRISMA) guidelines (Checklist S1 in Supplementary Material available online at https://doi.org/10.1155/2017/8423638) [21]. No primary personal data will be collected; therefore no additional ethical approval needs to be obtained.

- 2.1. Search Strategy. Two authors (Chun-Hui Chen and Zhi-Hao Shen) independently searched the electronic literature database of Pubmed, Embase, and Cochrane library, without language limitation at April 2016. The key words were used as follows: posterior lumbar interbody fusion, transforaminal lumbar interbody fusion, posterolateral lumbar fusion, posterior lumbar fusion, posterior lumbar arthrodesis, minimally invasive lumbar fusion, minimally invasive fusion, spondylolisthesis, isthmic spondylolisthesis, and degenerative spondylolisthesis. One of search strategy developed with comprehensive use of keywords performed in Pubmed was showed in Table S1. Related articles and reference lists were searched to avoid original miss.
- 2.2. Eligibility Criteria. The study was included in this metaanalysis if it was (1) prospective randomized controlled trial (RCT) or nonrandomized prospective comparative study; (2) it compared the clinical outcomes of minimally invasive posterior approach lumbar fusion versus traditional open posterior approach lumbar fusion; (3) the participants were spondylolisthesis (including isthmic and degenerative spondylolisthesis); (4) it was with a follow-up term of at least 12 months.

Exclusion criteria were as follows: (1) respective studies, case series, case report, and review articles; (2) follow-up

of less than 12 months; (3) duplicated publications from the same hospital or research center.

- 2.3. Selection of Literature. We used the PRISMA flow diagram to select the included studies (Figure 1); the results of literature search were imported into the software Endnote X4. Two authors (Zhen-Hua Feng and Wan-Qing Weng) independently assessed the potentially eligible studies. Firstly, the titles and abstracts were screened to exclude the duplicated and apparently irrelevant ones or those that do not meet our inclusion criteria. After then, the remaining potential studies were full-text downloaded and reviewed. Any disagreement between two above authors was sent and discussed with the third independent author (Ai-Min Wu).
- 2.4. Data Extraction. Two reviewers (Chun-Hui Chen and Shu-Min Li) independently extracted data, and the third reviewer (Wen-Fei Ni) checked the consistency between them. A standard form was used; the extracted items included the following: (1) the general study information, for example, the authors, publishing date, country, name of investigate site, study design, sample size, age, gender, index levels, follow-up term; (2) perioperative parameters, including operative time, estimated blood loss, X-ray exposure, and length of hospital stay; (3) clinical outcomes, including visual analog scale (VAS) of both lower back pain and leg pain, Oswestry disability index (ODI), SF-36 PCS (physical component scores), and SF-36 MCS (mental component scores); (4) complications, nonfusion rate, and secondary surgery; the complications included dural tear, wound infection, screw or rod fracture, graft dislodgement, epidural hematoma, and adjacent disc disease. For continuous outcomes, we extracted the mean and SD (standard deviation) and participant number will be extracted. For dichotomous outcomes, we extracted the total numbers and the numbers of events of both groups. The data in other forms was recalculated when possible to enable pooled analysis.
- 2.5. Quality Assessment of Included Studies. The methodological index for nonrandomized studies (MINORS) was used to assess the quality of the included studies [22, 23]. Twelve items were scored as "0" (not reported), "1" (reported but inadequate), or "2" (reported and adequate). Two reviewers (Ai-Min Wu and Yong-Long Chi) independently assessed the quality of the included studies.
- 2.6. Statistical Analysis. The data was collected and input into the STATA software (version 12.0; StataCorp, College Station, TX) for meta-analysis. Random-effects model was used to combine the data from individual studies. Relative risk (RR) was calculated for dichotomous outcomes such as complications, nonfusion, and secondary surgery. Standard mean difference (SMD) was calculated for continuous outcomes such as operative time, estimated blood loss, length of hospital stay, and clinical parameters. Heterogeneity was assessed using the  $x^2$  and  $I^2$ . We defined the acceptable heterogeneity by p value of  $x^2$  test > 0.10 and  $I^2$  < 50%. For heterogeneity data, sensitivity analysis was involved to

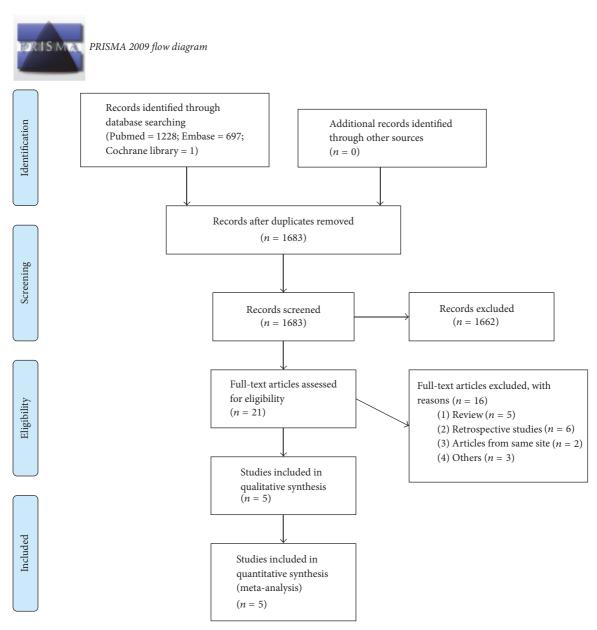


FIGURE 1: Flowchart of the study selection process. From [21]. For more information, visit http://www.prisma-statement.org/.

remove one study and evaluate whether the other results would be markedly affected.

#### 3. Results

3.1. Included Studies. A total 1926 potential records were identified through Medline (n=1228), Embase (n=697), and Cochrane library (n=1). The list of articles were input into software endnote X4, and then 243 duplicate articles were excluded, after titles and abstracts screened, leaving 21 full-text articles to be assessed for eligibility, and 16 were excluded for reasons of "the papers were review or retrospective studies or from same investigation site" and some other reasons (details were showed in Figure 1). Finally, five nonrandom prospective comparative studies [24–28] were included in

this meta-analysis. The procedure of literatures selection was showed in Figure 1 (PRISMA flow diagram).

3.2. Characteristics and Qualifications of Included Studies. The characteristics of all five included studies were summarized and shown in Table 1. All the five included studies [24–28] were prospective comparative studies without random. They were from five different countries (Australia, China, Germany, Japan, and USA) and all of them were published after 2010. Total of 184 participants in MI group and 182 in OP group were included in this meta-analysis. The methodological quality assessment of the five included studies was summarized in Table 2. The scores ranged from 18 to 20 with a median value of 19. The summary of outcomes of included studies was shown in Table 3.

TABLE 1: The characteristics of the included studies.

Authors	Ghahreman et al.	Wang et al.	Archavlis and Carvi y Nievas	Kotani et al.	Parker et al.
Year	2010	2010	2013	2012	2014
Study design	PCT	PCT	PCT	PCT	PCT
Country	Australia	China	Germany	Japan	USA
Age (years)	MI: 53 (40-61) OP: 60 (48-63)	MI: $47.9 \pm 8.5$ OP: $53.2 \pm 10.6$	MI: $67 \pm 8$ OP: $68 \pm 7$	MI: $63 \pm 9$ OP: $66 \pm 9$	MI: $53.5 \pm 12.5$ OP: $52.6 \pm 11.6$
Number of participants	MI: 25 OP: 27	MI: 42 OP: 43	MI: 24 OP: 25	MI: 43 OP: 37	MI: 50 OP: 50
Gender					
Male	MI: 12; OP: 13	MI: 13; OP: 16	MI: 14; OP: 10	MI: 14; OP: 12	MI: 16; OP: 18
Female	MI: 13; OP: 14	MI: 29; OP: 27	MI: 17; OP: 8	MI: 29; OP: 25	MI: 34; OP: 32
Index levels					
L3-4	MI: 0; OP: 2	MI: 3; OP: 3	MI: 2; OP: 1	4	MI: 4; OP: 3
L4-5	MI: 11; OP: 10	MI: 21; OP: 23	MI: 16; OP: 17	76	MI: 32; OP: 30
L5-S1	MI: 11; OP: 15	MI: 18; OP: 17	MI: 6; OP: 7	_	MI: 14; OP: 17
L4-S1	MI: 3; OP: 0	_	_	_	_
Follow-up term (months)	12	26 (13–35)	24	MI: 32 (24–49); OP: 40 (24–60)	24

MI: minimally invasive TLIF group; OP: open TLIF group; PCT: prospective comparative trials.

Table 2: Quality assessment of five included studies.

Methodological item for nonrandomised studies	Ghahreman et al.	Wang et al.	Archavlis and Carvi y Nievas	Kotani et al.	Parker et al.
(1) A clearly stated aim	2	2	2	2	2
(2) Inclusion of consecutive patients	1	2	2	1	1
(3) Prospective collection of data	2	2	2	2	2
(4) Endpoints appropriate to the aim of the study	2	2	2	2	2
(5) Unbiased assessment of the study end point	0	0	0	0	0
(6) Follow-up period appropriate to the aim of the study	1	1	2	2	2
(7) Loss to follow-up less than 5%	2	2	2	2	2
(8) Prospective calculation of the study size	0	0	0	0	0
(9) An adequate control group	2	2	2	2	2
(10) Contemporary groups	2	2	2	2	2
(11) Baseline equivalence of groups	2	2	2	2	2
(12) Adequate statistical analyses	2	2	2	2	2
Total scores	18	19	20	19	19

3.3. Perioperative Parameters. All five studies [24–28] reported the operative time data of both groups; the meta-analysis showed that the MI group had a significantly longer operative time than OP group, with SMD = 0.36 (95% CI: 0.08, 0.64). Four studies [25–28] reported the data of estimated blood loss; the meta-analysis showed that the MI

group had a significantly less blood loss than the OP group, with SMD = -1.42 (95% CI: -2.64, -0.20). Three studies [24, 25, 27] reported the length of hospital stay; the meta-analysis showed that the MI group had a significantly shorter hospital stay than the OP group, with SMD = -1.04 (95% CI: -1.48, -0.59) (Figure 2). Heterogeneity was observed in data

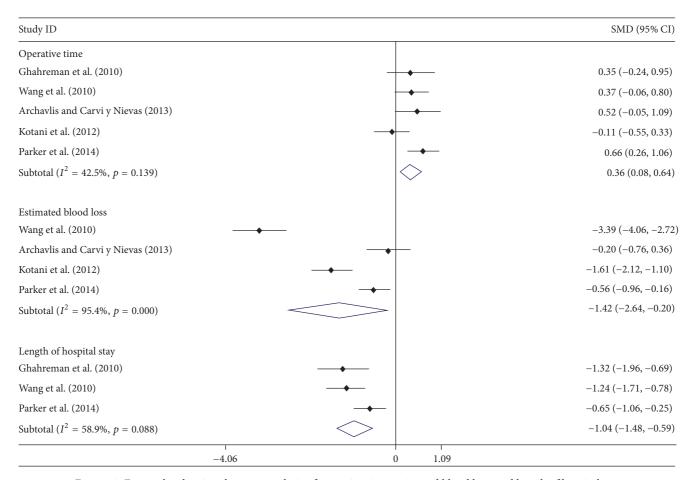


FIGURE 2: Forest plot showing the meta-analysis of operative time, estimated blood loss, and length of hospital stay.

of estimated blood loss ( $I^2 = 95.4\%$ , p = 0.000) and length of hospital stay ( $I^2 = 58.9\%$ , p = 0.088); sensitivity analysis found that there was no significant change when any study was omitted (Figures S1 and S2).

3.4. Clinical Outcomes. Three studies [24, 25, 28] reported the data of back pain and two studies [24, 28] reported leg pain; the meta-analysis showed there was no significant difference between both MI and OP groups, SMD of back pain = -0.11 (95% CI: -0.39, 0.17) and SMD of leg pain = 0.03 (95% CI: -0.29, 0.35). Three studies [25, 27, 28] reported the data of ODI, and the meta-analysis showed that there was no significant difference between both MI and OP groups, with SMD of ODI = -0.91 (95% CI: -1.91, 0.09). Two studies [24, 28] reported SF-36 PCS and MCS, the meta-analysis showed that there was no significant difference between both MI and OP groups, SMD of SF-36 PCS = 0.24 (95% CI: -0.08, 0.56) and SMD of SF-36 MCS = 0.21 (95% CI: -0.12, 0.53) (Figure 3). Heterogeneity was observed in data of ODI, with  $I^2 = 88.4\%$ , p = 0.000; sensitivity analysis found that there was no significant change when any study was omitted (Figure S3).

3.5. Adverse Events. Four studies [24–26, 28] reported the data of complications; the meta-analysis showed that there was no significant difference between both MI and OP groups, with RR = 0.96 (95% CI: 0.50, 1.83). Four studies [24–27] reported the data of nonfusion rate; the meta-analysis showed that there was no significant difference between both MI and OP groups, with RR = 1.29 (95% CI: 0.32, 5.17). And three studies [25, 26, 28] reported the data of secondary surgery; the meta-analysis showed that there was no significant difference between both MI and OP groups, with RR = 1.01 (95% CI: 0.33, 3.11) (Figure 4). No obvious heterogeneity was observed in data of complications, nonfusion, and secondary surgery.

#### 4. Discussion

The technique of posterior/posterolateral lumbar fusion had more than 100 years' history [29], there are many different kinds of lumbar fusion now, and they are widely used in treatment of lumbar disc herniation, lumbar instability, and spondylolisthesis [13, 30–32]. To reduce the operative trauma [33, 34], Foley et al. reported using the miniopen tubule

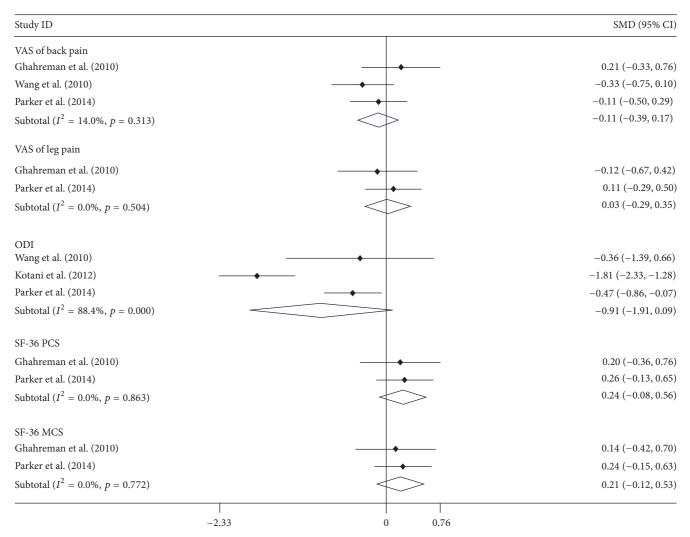


FIGURE 3: Forest plot showing the meta-analysis of visual analogue scale (VAS) scores for low back pain and leg pain, the Oswestry disability index, SF-36 PCS (physical component scores), and SF-36 MCS (mental component scores).

microsurgical approach with percutaneous pedicle screw fixation to achieve lumbar arthrodesis [1, 35]. The minimally invasive technique was modified and widespread in last decades.

Khan et al. [15] performed a meta-analysis of MI-TLIF versus open TLIF and found that the MI-TLIF can significantly reduce the blood loss, length of hospital stay, and complications; however, the fusion rate and operative time was similar. Another meta-analysis [14] found that the MI-TLIF not only reduced the blood loss more than open TLIF but also had significantly lower VAS of back pain and ODI scores.

In our this meta-analysis, only the spondylolisthesis patients were included, and we found that the MI technique can significantly reduce the estimated blood loss and length of hospital stay; however, it took more operative time. The decompression process of lumbar spondylolisthesis may need more time because of the limited space and vision, and the minimally invasive technique also needs a longer learning curve for surgeons [36, 37]. Another inconsistency to Phan

et al.' meta-analysis that we did not find significant difference in VAS of back pain and ODI scores between MI and OP groups. The patients with spondylolisthesis had the similar results in back and leg pain, ODI, and SF-36 scores, as well as complications, fusion rate, and secondary surgery between MI and OP groups.

Currently, MI lumbar fusion is mainly used in treatment of lower grade spondylolisthesis [25, 38]. Whether the MI lumbar fusion can be used in treatment of high-grade spondylolisthesis is still a controversial subject. Quraishi and Rampersaud reported that they use the minimally invasive bilateral transforaminal lumbar interbody fusion to treat high-grade isthmic spondylolisthesis [39], with estimated blood loss less than 100 ml, and about 150 minutes' operating time. The slip percentage improved from 68% preoperatively to 28% postoperatively. Because the estimated blood loss is more than 1000 ml when high-grade spondylolisthesis patients underwent traditional open TLIF [40], they suggested the MI technique may have more advantage in blood

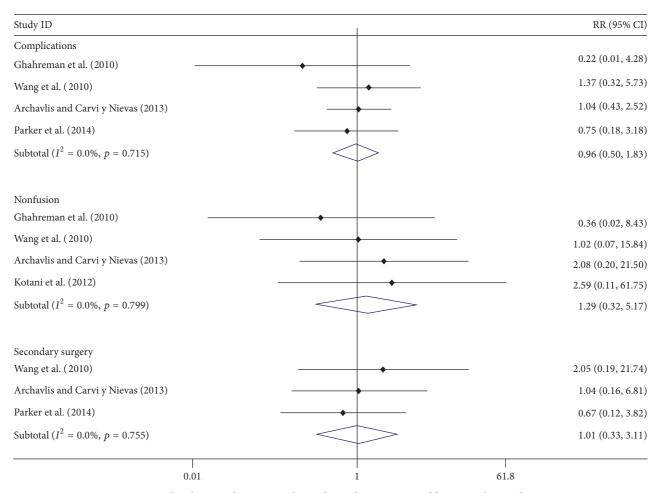


FIGURE 4: Forest plot showing the meta-analysis of complications, rate of fusion, and secondary surgery.

loss in high-grade spondylolisthesis. The evidence that MI fusion is better for high-grade spondylolisthesis still needs further research.

Strength and Limitation of This Study. This study had many strengths; all of the included studies in this meta-analysis were prospective studies, which therefore overcomes the shortcomings of recall or selection bias in retrospective studies [41]. The methodological index for nonrandomized studies (MINORS) was used to assess the quality of the included studies, which had minimized scores of 18, the score range of 18 to 20.

However, there were still some limitations of present study, none of them was randomized control trials, the sample size was not very large, and the duration of follow-up was less than 5 years. Therefore, we suggested further long-term, larger sample size, and randomized control trials to be conducted.

#### 5. Conclusions

In summary, our present meta-analysis base prospective comparative studies suggested that MI posterior fusion for spondylolisthesis had less EBL and hospital stay than OP fusion; however it took more operative time. Both MI and OP fusion had similar results in pain and functional outcomes, complication, fusion rate, and secondary surgery.

#### **Disclosure**

The funders had no role in the design, execution, or writing of the study.

#### **Competing Interests**

All authors declare that they have no conflict of interests.

#### **Authors' Contributions**

Ai-Min Wu, Wen-Fei Ni, and Yong-Long Chi conceived and designed the experiments. Ai-Min Wu, Chun-Hui Chen, Zhi-Hao Shen, Zhen-Hua Feng, Wan-Qing Weng, and Shu-Min Li performed the experiments. Ai-Min Wu, Chun-Hui Chen, Li-Hui Yin, and Wen-Fei Ni analyzed the data. Ai-Min Wu, Wen-Fei Ni, and Yong-Long Chi contributed reagents/ materials/analysis tools. Ai-Min Wu and Wen-Fei Ni wrote the paper.

Authors	Ghahreman et al.	Wang et al.	Archavlis and Carvi y Nievas	Kotani et al.	Parker et al.
Operative time (mins)	MI: 236 ± 68 OP: 213 ± 67	MI: 156 ± 32 OP: 145 ± 27	MI: 220 ± 48 OP: 190 ± 65	MI: 172 ± 33 OP: 176 ± 37	MI: 284 ± 95 OP: 230 ± 67
EBL	_	MI: $264 \pm 89$ OP: $673 \pm 145$	MI: $185 \pm 140$ OP: $255 \pm 468$	MI: $184 \pm 36$ OP: $453 \pm 243$	MI: $233 \pm 229$ OP: $383 \pm 305$
Hospital stay	MI: $4 \pm 1.58$ OP: $6.67 \pm 2.36$	MI: $10.6 \pm 2.5$ OP: $14.6 \pm 3.8$	_	_	MI: $3 \pm 1.53$ OP: $4 \pm 1.53$
Back pain VAS	MI: $2.67 \pm 3.14$ OP: $2 \pm 3.13$	MI: $0.92 \pm 0.5$ OP: $1.1 \pm 0.6$	_	_	MI: $3.3 \pm 2.9$ OP: $3.6 \pm 2.8$
Leg pain VAS	MI: $1.33 \pm 2.36$ OP: $1.67 \pm 3.13$	_	_	_	MI: $3 \pm 3$ OP: $2.7 \pm 2.6$
ODI	_	MI: $10.8 \pm 3.3$ OP: $12.2 \pm 3.9$	_	MI: $12.8 \pm 13.3$ OP: $36.5 \pm 12.9$	MI: $11 \pm 9.4$ OP: $15.6 \pm 10.3$
SF-36 PCS	MI: 64.33 ± 40.98 OP: 56.67 ± 35.37	_	_	_	MI: 44.3 ± 11.2 OP: 41.3 ± 11.8
SF-36 MCS	MI: 76.67 ± 18.87 OP: 72.67 ± 36.16	_	_	_	MI: $54.5 \pm 10.8$ OP: $52 \pm 10.1$
Complications	MI: 0/25 OP: 2/27	MI: 4/42 OP: 3/43	MI: 7/24 OP: 7/25	_	MI: 3/50 OP: 4/50
Nonfusion	MI: 0/25 OP: 1/27	MI: 1/42 OP: 1/43	MI: 2/24 OP: 1/25	MI: 1/43 OP: 0/37	_
Secondary Surgery	_	MI: 2/42 OP: 1/43	MI: 2/24 OP: 2/25	_	MI: 2/50 OP: 3/50

TABLE 3: The summary of outcomes of included studies.

MI: minimally invasive surgery group; OP: open surgery group; EBL: estimated blood loss; VAS: visual analog scale; ODI: Oswestry disability index; SF-36 PCS: Short Form-36 physical component scores; SF-36 MCS: Short Form-36 mental component scores.

#### Acknowledgments

This work was funded by Wenzhou Science and Technology Project (Y20160369) and the National Natural Science Foundation of China (81501933, 81301563).

#### References

- [1] K. T. Foley, L. T. Holly, and J. D. Schwender, "Minimally invasive lumbar fusion," *Spine*, vol. 28, no. 15, supplement, pp. S26–S35, 2003.
- [2] T. T. Kim, J. P. Johnson, R. Pashman, and D. Drazin, "Minimally invasive spinal surgery with intraoperative image-guided navigation," *BioMed Research International*, vol. 2016, Article ID 5716235, 7 pages, 2016.
- [3] S. Fan, Z. Hu, F. Zhao, X. Zhao, Y. Huang, and X. Fang, "Multifidus muscle changes and clinical effects of one-level posterior lumbar interbody fusion: minimally invasive procedure versus conventional open approach," *European Spine Journal*, vol. 19, no. 2, pp. 316–324, 2010.
- [4] N.-F. Tian, Y.-S. Wu, X.-L. Zhang, H.-Z. Xu, Y.-L. Chi, and F.-M. Mao, "Minimally invasive versus open transforaminal lumbar interbody fusion: a meta-analysis based on the current evidence," *European Spine Journal*, vol. 22, no. 8, pp. 1741–1749, 2013.
- [5] H. Nie, J. Zeng, Y. Song et al., "Percutaneous endoscopic lumbar discectomy for L5-S1 disc herniation via an interlaminar approach versus a transforaminal approach: a prospective randomized controlled study with 2-year follow up," *Spine*, vol. 41, supplement 19, pp. B30–B37, 2016.

- [6] G. S. Sidhu, E. Henkelman, A. R. Vaccaro et al., "Minimally invasive versus open posterior lumbar interbody fusion: a systematic review," *Clinical Orthopaedics and Related Research*, vol. 472, no. 6, pp. 1792–1799, 2014.
- [7] I. O. Karikari and R. E. Isaacs, "Minimally invasive transforaminal lumbar interbody fusion: a review of techniques and outcomes," *Spine*, vol. 35, no. 26S, pp. S294–S301, 2010.
- [8] W. Choi, J. Kim, K. Ryu, J. Hur, and J. Seong, "Minimally invasive transforaminal lumbar interbody fusion at L5-S1 through a unilateral approach: Technical feasibility and outcomes," *Bio-Med Research International*, vol. 2016, Article ID 2518394, 8 pages, 2016.
- [9] B. M. Ozgur, H. E. Aryan, L. Pimenta, and W. R. Taylor, "Extreme lateral interbody fusion (XLIF): a novel surgical technique for anterior lumbar interbody fusion," *Spine Journal*, vol. 6, no. 4, pp. 435–443, 2006.
- [10] V. Goz, J. H. Weinreb, F. Schwab, V. Lafage, and T. J. Errico, "Comparison of complications, costs, and length of stay of three different lumbar interbody fusion techniques: an analysis of the Nationwide Inpatient Sample database," *Spine Journal*, vol. 14, no. 9, pp. 2019–2027, 2014.
- [11] S.-D. Jiang, J.-W. Chen, and L.-S. Jiang, "Which procedure is better for lumbar interbody fusion: anterior lumbar interbody fusion or transforaminal lumbar interbody fusion?" *Archives of Orthopaedic and Trauma Surgery*, vol. 132, no. 9, pp. 1259–1266, 2012.
- [12] J. K. Baker, P. R. Reardon, M. J. Reardon, and M. H. Heggeness, "Vascular injury in anterior lumbar surgery," *Spine*, vol. 18, no. 15, pp. 2227–2230, 1993.

[13] H. Yoshihara and D. Yoneoka, "National trends in the surgical treatment for lumbar degenerative disc disease: United States, 2000 to 2009," *Spine Journal*, vol. 15, no. 2, pp. 265–271, 2015.

- [14] K. Phan, P. J. Rao, A. C. Kam, and R. J. Mobbs, "Minimally invasive versus open transforaminal lumbar interbody fusion for treatment of degenerative lumbar disease: systematic review and meta-analysis," *European Spine Journal*, vol. 24, no. 5, pp. 1017–1030, 2015.
- [15] N. R. Khan, A. J. Clark, S. L. Lee, G. T. Venable, N. B. Rossi, and K. T. Foley, "Surgical outcomes for minimally invasive vs open transforaminal lumbar interbody fusion: an updated systematic review and meta-analysis," *Neurosurgery*, vol. 77, no. 6, pp. 847– 874, 2015.
- [16] P. G. Matz, R. Meagher, T. Lamer et al., "Guideline summary review: an evidence-based clinical guideline for the diagnosis and treatment of degenerative lumbar spondylolisthesis," *The Spine Journal*, vol. 16, no. 3, pp. 439–448, 2016.
- [17] H. N. Herkowitz and L. T. Kurz, "Degenerative lumbar spondylolisthesis with spinal stenosis: a prospective study comparing decompression with decompression and intertransverse process arthrodesis," *Journal of Bone and Joint Surgery*, vol. 73, no. 6, pp. 802–808, 1991.
- [18] P. C. McAfee, J. G. DeVine, C. D. Chaput et al., "The indications for interbody fusion cages in the treatment of spondylolisthesis: analysis of 120 cases," *Spine*, vol. 30, no. 6, pp. S60–S65, 2005.
- [19] X. Liu, Y. Wang, G. Qiu, X. Weng, and B. Yu, "A systematic review with meta-analysis of posterior interbody fusion versus posterolateral fusion in lumbar spondylolisthesis," *European Spine Journal*, vol. 23, no. 1, pp. 43–56, 2014.
- [20] J.-H. Min, J.-S. Jang, and S.-H. Lee, "Comparison of anteriorand posterior-approach instrumented lumbar interbody fusion for spondylolisthesis," *Journal of Neurosurgery: Spine*, vol. 7, no. 1, pp. 21–26, 2007.
- [21] D. Moher, A. Liberati, J. Tetzlaff, and D. G. Altman, "Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement," *Physical Therapy*, vol. 6, no. 7, Article ID e1000097, 2009.
- [22] K. Slim, E. Nini, D. Forestier, F. Kwiatkowski, Y. Panis, and J. Chipponi, "Methodological index for non-randomized studies (MINORS): development and validation of a new instrument," ANZ Journal of Surgery, vol. 73, no. 9, pp. 712–716, 2003.
- [23] X. Zeng, Y. Zhang, J. S. W. Kwong et al., "The methodological quality assessment tools for preclinical and clinical studies, systematic review and meta-analysis, and clinical practice guideline: a systematic review," *Journal of Evidence-Based Medicine*, vol. 8, no. 1, pp. 2–10, 2015.
- [24] A. Ghahreman, R. D. Ferch, P. J. Rao, and N. Bogduk, "Minimal access versus open posterior lumbar interbody fusion in the treatment of spondylolisthesis," *Neurosurgery*, vol. 66, no. 2, pp. 296–304, 2010.
- [25] J. Wang, Y. Zhou, Z. F. Zhang, C. Q. Li, W. J. Zheng, and J. Liu, "Comparison of one-level minimally invasive and open transforaminal lumbar interbody fusion in degenerative and isthmic spondylolisthesis grades 1 and 2," *European Spine Journal*, vol. 19, no. 10, pp. 1780–1784, 2010.
- [26] E. Archavlis and M. Carvi y Nievas, "Comparison of minimally invasive fusion and instrumentation versus open surgery for severe stenotic spondylolisthesis with high-grade facet joint osteoarthritis," *European Spine Journal*, vol. 22, no. 8, pp. 1731– 1740, 2013.
- [27] Y. Kotani, K. Abumi, M. Ito, H. Sudo, Y. Abe, and A. Minami, "Mid-term clinical results of minimally invasive decompression

- and posterolateral fusion with percutaneous pedicle screws versus conventional approach for degenerative spondylolisthesis with spinal stenosis," *European Spine Journal*, vol. 21, no. 6, pp. 1171–1177, 2012.
- [28] S. L. Parker, S. K. Mendenhall, D. N. Shau et al., "Minimally invasive versus open transforaminal lumbar interbody fusion for degenerative spondylolisthesis: comparative effectiveness and cost-utility analysis," *World Neurosurgery*, vol. 82, no. 1-2, pp. 230–238, 2014.
- [29] R. A. Hibbs, "An operation for progressive spinal deformities," New York Medical Journal, vol. 93, pp. 1013–1016, 1911.
- [30] K.-T. Kim, S.-H. Lee, Y.-H. Lee, S.-C. Bae, and K.-S. Suk, "Clinical outcomes of 3 fusion methods through the posterior approach in the lumbar spine," *Spine*, vol. 31, no. 12, pp. 1351– 1358, 2006.
- [31] F. M. Phillips, P. J. Slosar, J. A. Youssef, G. Andersson, and F. Papatheofanis, "Lumbar spine fusion for chronic low back pain due to degenerative disc disease: a systematic review," *Spine*, vol. 38, no. 7, pp. E409–E422, 2013.
- [32] Q. Zhang, Z. Yuan, M. Zhou, H. Liu, Y. Xu, and Y. Ren, "A comparison of posterior lumbar interbody fusion and transforaminal lumbar interbody fusion: a literature review and meta-analysis," *BMC Musculoskeletal Disorders*, vol. 15, article 367, 8 pages, 2014.
- [33] K.-T. Kim, S.-H. Lee, K.-S. Suk, and S.-C. Bae, "The quantitative analysis of tissue injury markers after mini-open lumbar fusion," *Spine*, vol. 31, no. 6, pp. 712–716, 2006.
- [34] D.-Y. Kim, S.-H. Lee, S. K. Chung, and H.-Y. Lee, "Comparison of multifidus muscle atrophy and trunk extension muscle strength: percutaneous versus open pedicle screw fixation," *Spine*, vol. 30, no. 1, pp. 123–129, 2005.
- [35] K. T. Foley, S. K. Gupta, J. R. Justis, and M. C. Sherman, "Percutaneous pedicle screw fixation of the lumbar spine," *Neuro*surgical Focus, vol. 10, no. 4, article E10, 2001.
- [36] K. H. Lee, W. Yeo, H. Soeharno, and W. M. Yue, "Learning curve of a complex surgical technique: minimally invasive transforaminal lumbar interbody fusion (MIS TLIF)," *Journal of Spinal Disorders and Techniques*, vol. 27, no. 7, pp. E234–E240, 2014.
- [37] S. V. Nandyala, S. J. Fineberg, M. Pelton, and K. Singh, "Minimally invasive transforaminal lumbar interbody fusion: one surgeon's learning curve," *Spine Journal*, vol. 14, no. 8, pp. 1460–1465, 2014.
- [38] W. A. Sulaiman and M. Singh, "Minimally invasive versus open transforaminal lumbar interbody fusion for degenerative spondylolisthesis grades 1-2: patient-reported clinical outcomes and cost-utility analysis," *Ochsner Journal*, vol. 14, no. 1, pp. 32–37, 2014.
- [39] N. A. Quraishi and Y. R. Rampersaud, "Minimal access bilateral transforaminal lumbar interbody fusion for high-grade isthmic spondylolisthesis," *European Spine Journal*, vol. 22, no. 8, pp. 1707–1713, 2013.
- [40] N. Goyal, D. W. Wimberley, A. Hyatt et al., "Radiographic and clinical outcomes after instrumented reduction and transforaminal lumbar interbody fusion of mid and high-grade isthmic spondylolisthesis," *Journal of Spinal Disorders and Techniques*, vol. 22, no. 5, pp. 321–327, 2009.
- [41] P. L. Jia, P. F. Zhang, H. D. Li, L. H. Zhang, Y. Chen, and M. M. Zhang, "Literature review on clinical decision support system reducing medical error," *Journal of Evidence-Based Medicine*, vol. 7, no. 3, pp. 219–226, 2014.

Hindawi Publishing Corporation BioMed Research International Volume 2016, Article ID 2834259, 8 pages http://dx.doi.org/10.1155/2016/2834259

# Clinical Study

# Endoscopic Radiofrequency Ablation of the Sacroiliac Joint Complex in the Treatment of Chronic Low Back Pain: A Preliminary Study of Feasibility and Efficacy of a Novel Technique

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Received 2 August 2016; Accepted 3 November 2016

Academic Editor: Tsung-Jen Huang

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Background. Radiofrequency ablation (RFA) is a less invasive technique for treatment of sacroiliac joint (SIJ) pain. Objective. To evaluate the feasibility and efficacy of endoscope-guided RFA for the treatment of CLBP from the SIJ complex. Methods. In this retrospective study, the medical records of 17 patients who underwent endoscope-guided RFA of the SIJ complex were reviewed. A bipolar radiofrequency probe was used to lesion the posterior capsule of the SIJ as well as the lateral branches of S1, S2, S3, and the L5 dorsal ramus in multiple locations. We visualized the ablation area using endoscope. We assessed visual analogue scale (VAS) and the Oswestry disability index (ODI) preoperatively, immediately postop, and at 1-, 3-, and 6-month postop outpatient clinic visits. Patient satisfaction of the procedure was assessed in percentages. Results. The mean duration of operation was 20 to 50 minutes. The mean VAS and the ODI scores decreased significantly immediately after the procedure and were kept significantly lower than baseline levels during the follow-up periods. No complications occurred perioperatively and during the follow-up periods. 88.6% of patients were satisfied with the procedure. Conclusions. Our preliminary results suggest that endoscope-guided RFA may be alternative option to treat CLBP secondary to SIJ complex.

#### 1. Introduction

Chronic low back pain (CLBP) that lasts for six months or longer is estimated to occur in 60–80% of the general population in their lifetime [1] and is associated with substantial healthcare costs. The sacroiliac joint (SIJ) complex is one of the major sources of chronic low back pain, accounting for around 10–33% of the total number of CLBP cases [1–5]. The SIJ complex consists of the joint capsule, various muscular and ligamentous structures overlying the joint, and neural structures that innervate the SIJ [6]. Current treatment options for SIJ complex-mediated CLBP include intraarticular and periarticular steroid injections, SIJ fusion, and radiofrequency ablation of the neural structures innervating the SIJ. Intra-articular injection of the joint using a mixture

of steroids and local anesthetics is a simple procedure and provides quick pain relief, but the effect is short-lived [7]. In addition, SIJ fusion is an invasive surgical procedure that should be reserved for cases refractory to nonoperative measures [8, 9]. On the other hand, radiofrequency ablation (RFA) of the SIJ complex offers longer-lasting effects and has gained wide attention in the last decade [10], with increasing numbers of reports advocating for its efficacy [7, 11–14]. RFA is usually performed under fluoroscopic guidance. The target structures are the lateral branches of the sacral rami, the dorsal ramus of L5, and the ligamentous structures overlying the joint. However, variations in the pattern of innervation exist between individuals, which provides a challenge for surgeons [15]. Due to these variations, different RFA target locations and techniques have been proposed to overcome

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this difficulty [16, 17]. Endoscopic radiofrequency ablation has been utilized in the treatment of facetogenic CLBP in a number of clinical reports with favorable results [18–20], but to our knowledge, the efficacy of this technique when applied to SIJ-associated CLBP has not been reported. In this study, we utilized endoscopy for the precise ablation of potential pain generators associated with the SIJ and evaluated the clinical efficacy of this new technique.

#### 2. Materials and Methods

The institutional review board at our institution approved this study. The medical records of 17 consecutive patients who underwent RFA of the SIJ for CLBP between April 2011 and December 2015 were reviewed. The inclusion criteria for treatment were as follows: patients with a chief complaint of CLBP with signs and symptoms of SIJ involvement on physical examination and radiological tests such as computed tomography (CT), unresponsive to conservative therapy including oral analgesics and physical therapy, persistent CLBP despite previous lumbosacral operation or pain procedures, and minimum follow-up period of 6 months.

SIJ complex pathology as the main cause of CLBP is difficult to diagnose due to overlapping patterns with other sources of CLBP and varying patterns of pain between individuals [7, 21]. CT findings of arthropathy or erosion of the SIJ, while not specific, may suggest SIJ based pathology in patients with clinical suspicion [22]. While numerous physical examination methods have been suggested, provocative test was reported to have more reliability in numerous reports [23, 24]. In order to confirm the SIJ pain as the main source of CLBP, two separate diagnostic intra-articular and multisite lateral sacral branch blocks of the SIJ complex were performed at least 2 weeks apart. If patient experienced 50% or higher improvement in pain from the baseline according to visual analogue scale (VAS) after each block, SIJ complex was considered to be the main pain generator, and endoscopic RFA was scheduled. Patients with tumors of the SIJ, concern for secondary gain, previous surgery of the SIJ such as SIJ fusion, or other severe comorbid medical conditions were excluded. All patients were followed for a minimum of six months after the procedure in outpatient clinics. Endoscopic RFA of the SIJ complex was performed in the operating room. Patients were discharged the day after the procedure. All patients were followed up at the outpatient clinic at 1, 3, and 6 months after the procedure and annually thereafter.

2.1. Surgical Techniques. All subjects were placed in the prone position on chest rolls on a radiolucent Jackson table. Before beginning the procedure, patients were fully informed of the procedure details. Patients were monitored and maintained communication with the surgeon throughout the procedure.

After sterile prepping and draping, an anteroposterior fluoroscopic view was obtained using a C-arm. A transducer was tilted cephalad approximately 10–15 degrees and was tilted oblique 10–15 degrees contralaterally to optimally visualize the posterior aspect of the SIJ. The skin entry point was positioned at the inferior aspect of the posterior SIJ, and local anesthetic was injected into the entry point. An 18-gauge

needle was docked onto the interosseous ligament overlying the posterior SIJ. Then, a guide wire was advanced through the needle, the needle was removed, and a 0.5 cm skin incision was made at the entry site. A cannulated obturator was inserted along the guide wire through the skin incision, and a beveled or nonbeveled working cannula of 7.9 mm diameter was advanced along the obturator until the cannula reached the posterior SIJ. After removing the obturator, the endoscope (6.9 mm  $\times$  5.6 mm) was introduced through the cannula. The final position of the cannula was confirmed with fluoroscopy.

Under endoscopic visualization, the posterior sacroiliac ligament and its overlying soft tissue were ablated using a Trigger-Flex bipolar probe (Elman International, Inc.) that was introduced through the working channel of the endoscope. First, we ablated perforating branches that innervate the posterior capsule of the SIJ. After visual confirmation of the long posterior sacroiliac ligament, we proceeded with RFA along the course of the ligament in the cranial direction to the level of the posterior superior iliac spine (Figure 1). The fluoroscope was then adjusted to obtain an anteroposterior view. Next, using the wanding maneuver of the cannula, the cannula tip was moved along the subcutaneous plane toward the region lateral to the S1-S3 sacral foramina, and a linear multidepth lesion was made along the line connecting the lateral margins of the S1-3 sacral foramina (Figure 2). When uncertain about the position of the RF probe tip, we checked the tip position with the fluoroscope. We attempted to visually confirm the lateral branches exiting the sacral foramina and the branches coursing toward the SIJ when possible to ensure accurate nerve lesioning. Throughout the procedure, we maintained constant communication with the patient to assess the level of pain associated with each stimulus and to identify which stimulus area caused the most pain. Continuous saline irrigation was maintained throughout the procedure to minimize thermal injury to the surrounding structures. After ablation of the target points, the endoscope and cannula were removed. One-point suture with Nylon was used, and sterile dressing was applied.

2.2. Clinical Assessment. Patients were instructed to visit the outpatient clinic at 1, 3, 6, and 12 months after the procedure. Pain intensity and functional disability were assessed via questionnaires with outcome measurements before the procedure, immediately after the procedure, and at each follow-up outpatient visit. All clinical assessments were performed by a single coresearcher. At each follow-up visit, back and leg pain intensity was assessed using the visual analogue scale (VAS) and the Oswestry disability index (ODI). Additionally, all patients were asked to express their degree of satisfaction with the procedure on a percentage scale.

2.3. Statistical Analysis. Mean VAS scores for back and ODI scores immediately after the procedure, three and six months after, and one year after the procedure were compared to the scores recorded before the procedure. Statistical significance was assessed using paired Student's *t*-tests. *p* values less than 0.05 were considered to be statistically significant. All statistical analyses were performed using SPSS version 18 (SPSS Inc.).

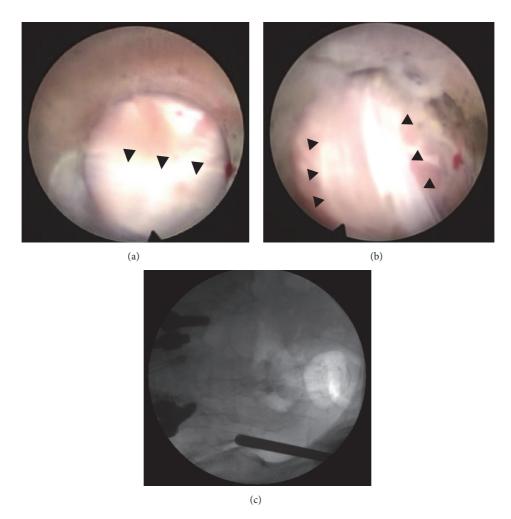


FIGURE 1: ((a) and (b)) Long posterior ligament (black arrowheads) overlying the posterior capsule of the SIJ. (c) Corresponding position of the cannula tip in the anteroposterior fluoroscopic image.

#### 3. Results

In this study, there were 2 male and 15 female patients whose age ranged from 37 to 81 years (mean age 61.9  $\pm$  11.8 years). On preoperative lumbosacral MRI, herniated nucleus pulposus was identified in eight patients, spondylolisthesis in four patients, and spinal stenosis in five patients. On CT scan of the pelvis, arthropathy of the SIJ was observed in 11 patients (64.7%).

Before the RFA procedure, ten patients (58.8%) had undergone operation or pain procedure on the lumbosacral spine. Four patients (23.5%) underwent lumbar or lumbosacral interbody fusion and posterior fixation, four (23.5%) underwent discectomy or laminectomy, and two (11.8%) underwent medial branch RFA. Seven patients (41.2%) underwent nerve block procedures including caudal block, medial branch block, root block, and transforaminal epidural block. All of the ten patients experienced persistent CLBP despite these procedures. Patient demographic data are summarized in Table 1.

RFA was performed on the right side only in eight patients (47.1%), on the left side only in five patients (29.4%), and

on both sides in four patients (23.5%). The mean duration of operation from the time of local anesthetic injection to wound closure was  $26.6 \pm 22.5 (20-50)$  mins per side. All patients were discharged the next day, without perioperative complications such as hematoma collection, wound discharge, or development of acute neurological deficit. The mean VAS scores for back pain decreased from  $6.7 \pm 1.41$ preoperatively to 3.6  $\pm$  1.28, 3.2  $\pm$  1.06, 2.8  $\pm$  1.14, and  $3.1 \pm 1.78$  immediately postoperatively, and at 1, 3, and 6 months' follow-up visits, respectively. All of the follow-up VAS scores were significantly lower than the baseline (p <0.005). The mean ODI score preoperatively was 22.2  $\pm$  3.36 and decreased to  $14.1 \pm 3.35$ ,  $13.1 \pm 4.05$ ,  $12.9 \pm 4.32$ , and  $12.0 \pm 4.69$  immediately postop and at the 3, 6, and 12-month follow-up visits, respectively. All of the follow-up ODI scores were significantly lower than baseline (p < 0.001). Mean patient satisfaction rate was 86.6% (70-100). These results are summarized in Table 2.

3.1. Example Case. A 69-year-old female presented with chronic low back pain and left buttock pain for the last five years. She had undergone L4-5 and L5-S1 fusion at another

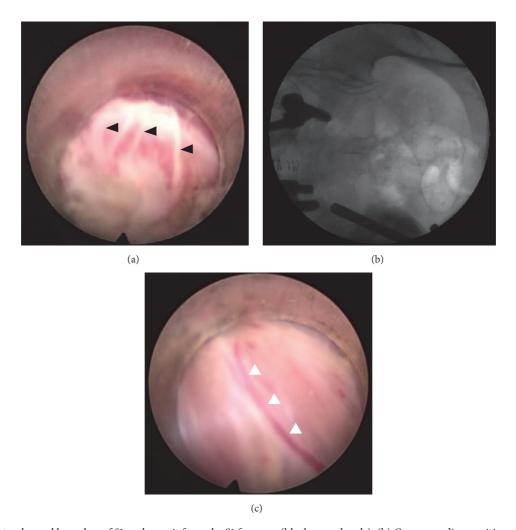


FIGURE 2: (a) Lateral sacral branches of S1 as they exit from the S1 foramen (black arrowheads). (b) Corresponding position of the endoscope cannula. (c) Small arteries or veins can often be seen coursing along the nerve branches (white arrowheads), which can help with identification of thin nerve branches.

institution in 2008. She had remained asymptomatic for two years, but in 2010, she started feeling left-sided buttock pain. Conservative treatment with oral analgesics and four separate root blocks and epidural blocks at a local pain clinic were ineffective. CT scan of the pelvis revealed bilateral SIJ arthropathy. Her initial VAS for back pain and her ODI scores were 7 and 40, respectively, and downward pressure on the sacrum with the patient in the prone position elicited severe pain (VAS 8). After two diagnostic SIJ complex injections, her VAS score dropped to 2 points on both occasions. Endoscopeguided RFA was performed one month later.

Local analgesics were applied to the entry point of the skin, which was about 1 cm above where the buttock pain was elicited. Buttock pain was elicited when the long posterior sacroiliac ligament overlying the posterior articular capsule was stimulated with the RF probe in short bursts (Figures 1(a), 1(b), and 1(c)). While maintaining continuous saline irrigation, the painful areas along the length of ligament were coagulated with the RF probe to the level of the posterior superior iliac spine. Next, using the wanding maneuver, the

tip of the cannula was gently mobilized in the subcutaneous plane and repositioned next to the lateral margin of the S1 neural foramen. The S1 lateral sacral branches were identified and coagulated in the same manner (Figures 2(a), 2(b), and 2(c)). Ablation of a targeted area was stopped when no further pain was elicited upon additional stimulation. The S2 and S3 lateral branches were ablated in a similar manner (Figure 3).

#### 4. Discussion

The SIJ complex is increasingly being recognized as a major source of CLBP, and, yet, the exact pain generating mechanisms and anatomical properties of the SIJ complex have not been fully established. The literature surrounding the treatment of SIJ complex-mediated pain is still quite sparse. Diagnosing SIJ complex pain remains largely a diagnosis of exclusion. In SIJ complex pain, patients tend to complain of buttock pain, but many experience lower leg pain on the involved side as well, which can be confused with radiculopathy or referred pain from other low back structures

TABLE 1: Patient demographic data.

Patient number	Age	Gender	Follow-up period (months)	Side of procedure	Other diagnoses	Previous operations/procedures
1	56	F	49	Right	HNP, L4-5, Lt.	Root block, L4, 5, Lt.
2	70	F	37	Left	Extraforaminal HNP, L5-S1, Lt.	Transforaminal epidural block, L5-S1, Lt.
3	74	F	36	Both	HNP, L3-4, 4-5, 5-S1	Caudal block medial branch block, L3-4, 4-5, 5-S1, both
4	73	F	35	Both	Spinal stenosis, L3-4, 4-5	Medial branch block, L3-4, 4-5, both
5	76	F	35	Left	HNP, L4-5, Rt.	(1) Decompressive hemilaminectomy, L4, Rt. (2005) (2) Medial branch RFA, L4, 5, Rt. (2006)
6	81	F	22	Right	Spinal stenosis, L3-4, 4-5	PLIF, L3-4, 4-5 (2008)
7	37	F	22	Right	Spinal stenosis, L4-5, L5-S1	Root block, L4, 5, Rt.
8	72	F	21	Left	Spinal stenosis, L5-S1	PLIF, L5-S1 (2001)
9	61	F	15	Left	Spondylolisthesis, L4-5	2014.10.8 MIS TLIF 45 (post-procedure)
10	57	F	13	Right	Spinal stenosis, L4-5	PLIF, L4-5 (2012)
11	48	F	13	Right	HNP, L3-4, Rt.	Transforaminal epidural block, L3-4, Rt.
12	58	F	12	Right	Spondylolisthesis, L3-4	Caudal block, epidural block, L3-4 Trigger point injection of paravertebral muscles
13	56	F	12	Left	HNP, L5-S1, Rt.	Discectomy, L5-S1, Rt. (2013)
14	58	F	10	Both	Facet arthropathy, L4-5, Lt.	Medial branch RFA, L4, 5, Lt. (2013)
15	60	F	9	Both	Spondylolisthesis, L4-5	PLIF, L4-5 (2013)
16	47	M	9	Right	HNP, L5-S1, Lt.	Discectomy, L5-S1, Lt. (2013)
17	69	F	8	Right	Spondylolisthesis, L4-5, L5-S1	PLIF, L4-5, 5-S1 (2008)

TABLE 2: Preoperative and postoperative clinical data.

	Mean preoperative scores	Mean immediate postoperative scores	Mean 1-month follow-up scores	Mean 3-month follow-up scores	Mean 6-month follow-up scores
VAS	$6.7 \pm 1.41$	$3.6 \pm 1.28$	$3.2 \pm 1.06$	$2.8 \pm 1.14$	$3.1 \pm 1.78$
ODI	$22.2 \pm 3.36$	$14.1 \pm 3.35$	$13.1 \pm 4.05$	$12.9 \pm 4.32$	$12.0 \pm 4.69$

[25]. There is no single reliable test that can identify the SIJ complex as the main pain generator in CLBP, and, in the majority of cases, there are a number of possible pain generators that are equally likely to contribute to the CLBP. For these reasons, accurate diagnosis and successful treatment of SIJrelated pain provide a challenge for surgeons, often causing delay in recognition of SIJ complex as the main source of CLBP. Recognizing the SIJ as the main pain generator takes time and effort, since SIJ complex pain is often only diagnosed after all other modalities fail to treat the patient's CLBP. In our case series, all 17 patients had competing pathologies of the lumbar spine, including herniated lumbar disks, spinal stenosis, spondylolisthesis, and facet joint arthropathy that may have contributed to their symptoms. All had received one or more pain procedures at the lumbar level, including root blocks, epidural blocks, epidural neurolysis, facet joint blocks, and medial branch blocks/neurotomy with minimal or unsatisfactory results. Of the 17 patients, 7 (41.1%) had

previously undergone some form of surgical procedure at the lumbar level, including five cases of interbody fusion and two cases of discectomy, which did not satisfactorily alleviate their CLBP. The average duration of symptoms prior to the diagnosis of SIJ complex pain was  $2.8 \pm 6.5$  years (6 months–10 years).

The SIJ complex consists of an articular region, a posterior ligamentous region, and a dorsal ligamentous region, which support the joint [26]. Neural innervations are found in both the posterior capsule of the joint and in the posterior sacroiliac and interosseous ligaments [6]. Although many studies have used intra-articular injections both to provide relief and to identify the origin of the SIJ pain, results from recent studies indicate that periarticular ligamentous structures may contribute more to SIJ pain than the articular region itself [27, 28], suggesting that the periarticular ligamentous structures are better targets for treatment. Dreyfuss et al. demonstrated that multisite, multidepth lateral sacral branch blocks are

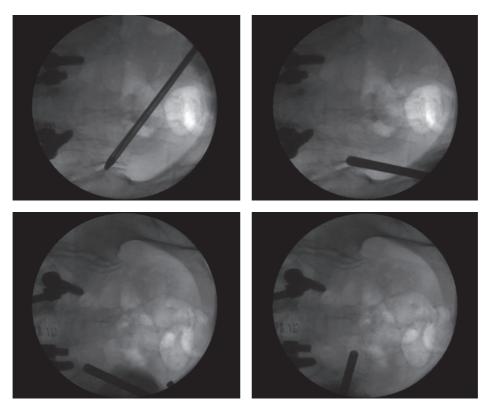


FIGURE 3: Fluoroscopic view of the endoscopic cannula tip in various positions during the procedure. The cannula tip can be moved in the subcutaneous plane and can be repositioned without causing much discomfort. If patients did experience discomfort, an additional lidocaine injection was applied.

more reliable than intra-articular injections for identifying the SIJ complex as the main pain generator, and a recent systemic review by King et al. also supports this view. When performing diagnostic blocks, we targeted the intra-articular joint itself as well as the lateral sacral branches of S1–3 and the L5 dorsal ramus, since these will be the targets for RFA. Additionally, compared to intra-articular injection alone, relief after injection of these structures would be a better predictor of favorable outcomes after RFA.

The lateral branches of L5-S4, especially the branches of S1-S3 innervating the sacroiliac joint, are quite variable between individual patients in their course, branches, and location. To ablate all pain generators, a large lesion area would be required [16, 17]. Current techniques to accomplish these lesions include a periforaminal approach and a lateral sacral crest approach. The periforaminal approach involves making a series of lesions around the lateral border of the S1-S3 sacral foramina using a monopolar or bipolar RF probe. However, as described by Roberts et al. [17], it is often difficult to achieve a clear view of the foramina under fluoroscopy. The lateral sacral technique involves creating a lesion strip along the lateral sacral crest at regular intervals, effectively ablating the fine plexus of lateral branches overlying this region. This technique also has disadvantages in that the lateral crest is not easy to identify under fluoroscopy alone.

For both the periforaminal approach and the lateral sacral crest approach, multiple skin punctures are made in

order to place the RF probe, which can result in patient discomfort. Because the cannula for the endoscope is considerably thicker and more rigid than the RF probe itself, it was possible to reach the periforaminal regions of the S1-3 sacral foramina through a single incision using the endoscope wanding maneuver. Notably, the wanding maneuver did not cause the patients more discomfort. If the procedure was uncomfortable, we offered the patient light sedation with midazolam. With the aid of the endoscope, we achieved better visualization of bony landmarks as well as the lateral branches of S1-S3 when possible. The branches of the posterior rami of S1-S3 travel deep to the long posterior sacroiliac and sacrotuberous ligaments. According to a cadaveric study by Roberts et al. [17], the diameter of the S1–S3 branches ranges from 0.21 to 1.51 mm, and in many cases, the lateral branches could not be identified with certainty. If gentle stimulation of the suspected lateral branch with the RF probe elicited pain, we ablated the branch. Except for one patient, all procedures were performed with the patient under local anesthesia or light sedation, and communication with the patient was maintained throughout the procedure.

Another advantage of direct visualization with the endoscope is that it affords us the ability to identify areas that have already been ablated. This allows us to avoid damaging the soft tissue with excessive lesioning of the same region. Avoiding repeated lesioning helped curb complications such as postprocedural pain and dysesthesia (Figure 4).



FIGURE 4: Under endoscopic view, it is possible to clearly discern areas that have already been ablated (surrounded by arrows) and which areas have not. It is also possible to gauge the depth of the ablation.

Our study has several limitations. First, this is a retrospective study with a limited number of cases. Second, no direct comparison was made with conventional fluoroscopic-guided RFA method in the clinical results and perioperative parameters. Third, patients were not categorized by their VAS and ODI scores before the procedure or previous operation or procedure, and clinical effects of endoscopic RFA procedure could be confounded by other variables. We plan to conduct a randomized clinical trial comparing conventional RFA and endoscopic RFA in the future.

#### 5. Conclusions

Our preliminary results suggest that endoscope-guided RFA may be alternative option to treat CLBP secondary to SIJ complex pain with favorable clinical outcomes, including a long-term pain-free period and improved physical function with minimal complications.

#### **Competing Interests**

The authors declare that there is no conflict of interests regarding the publication of this paper.

#### References

- [1] M. V. Boswell, A. M. Trescot, S. Datta et al., "Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain," *Pain Physician*, vol. 10, no. 1, pp. 7–111, 2007
- [2] A. C. Schwarzer, C. N. Aprill, and N. Bogduk, "The sacroiliac joint in chronic low back pain," *Spine*, vol. 20, no. 1, pp. 31–37, 1995.
- [3] F. D'Orazio, L. M. Gregori, and M. Gallucci, "Spine epidural and sacroiliac joints injections—when and how to perform," *European Journal of Radiology*, vol. 84, no. 5, pp. 777–782, 2015.
- [4] J.-Y. Maigne, A. Aivaliklis, and F. Pfefer, "Results of sacroiliac joint double block and value of sacroiliac pain provocation tests in 54 patients with low back pain," *Spine*, vol. 21, no. 16, pp. 1889–1892, 1996.

[5] J. N. Sembrano and D. W. Polly, "How often is low back pain not coming from the back?" *Spine*, vol. 34, no. 1, pp. E27–E32, 2009.

- [6] V. Bowen and J. D. Cassidy, "Macroscopic and microscopic anatomy of the sacroiliac joint from embryonic life until the eighth decade," *Spine*, vol. 6, no. 6, pp. 620–628, 1981.
- [7] S. P. Cohen, Y. Chen, and N. J. Neufeld, "Sacroiliac joint pain: a comprehensive review of epidemiology, diagnosis and treatment," *Expert Review of Neurotherapeutics*, vol. 13, no. 1, pp. 99–116, 2013.
- [8] J. M. Buchowski, K. M. Kebaish, V. Sinkov, D. B. Cohen, A. N. Sieber, and J. P. Kostuik, "Functional and radiographic outcome of sacroiliac arthrodesis for the disorders of the sacroiliac joint," *Spine Journal*, vol. 5, no. 5, pp. 520–529, 2005.
- [9] K. A. Giannikas, A. M. Khan, M. T. Karski, and H. A. Maxwell, "Sacroiliac joint fusion for chronic pain: a simple technique avoiding the use of metalwork," *European Spine Journal*, vol. 13, no. 3, pp. 253–256, 2004.
- [10] R. C. Cox and J. D. Fortin, "The anatomy of the lateral branches of the sacral dorsal rami: implications for radiofrequency ablation," *Pain Physician*, vol. 17, no. 5, pp. 459–464, 2014.
- [11] W. Stelzer, M. Aiglesberger, D. Stelzer, and V. Stelzer, "Use of cooled radiofrequency lateral branch neurotomy for the treatment of sacroiliac joint-mediated low back pain: a large case series," *Pain Medicine (United States)*, vol. 14, no. 1, pp. 29– 35, 2013
- [12] P. Vanelderen, K. Szadek, S. P. Cohen et al., "13. Sacroiliac joint pain," *Pain Practice*, vol. 10, no. 5, pp. 470–478, 2010.
- [13] S. M. Aydin, C. G. Gharibo, M. Mehnert, and T. P. Stitik, "The role of radiofrequency ablation for sacroiliac joint pain: a metaanalysis," PM & R, vol. 2, no. 9, pp. 842–851, 2010.
- [14] F. M. Ferrante, L. F. King, E. A. Roche et al., "Radiofrequency sacroiliac joint denervation for sacroiliac syndrome," *Regional Anesthesia and Pain Medicine*, vol. 26, no. 2, pp. 137–142, 2001.
- [15] S. P. Cohen and S. Abdi, "Lateral branch blocks as a treatment for sacroiliac joint pain: A Pilot Study," *Regional Anesthesia and Pain Medicine*, vol. 28, no. 2, pp. 113–119, 2003.
- [16] K. Y. Ho, M. A. Hadi, K. Pasutharnchat, and K. H. Tan, "Cooled radiofrequency denervation for treatment of sacroiliac joint pain: two-year results from 20 cases," *Journal of Pain Research*, vol. 6, pp. 505–511, 2013.
- [17] S. Roberts, R. Burnham, K. Ravichandiran, A. Agur, and E. Loh, "Cadaveric study of sacroiliac joint innervation: implications for diagnostic blocks and radiofrequency ablation," *Regional Anesthesia and Pain Medicine*, vol. 39, no. 6, pp. 456–464, 2014.
- [18] Z.-Z. Li, S.-X. Hou, W.-L. Shang, K.-R. Song, and W.-W. Wu, "Evaluation of endoscopic dorsal ramus rhizotomy in managing facetogenic chronic low back pain," *Clinical Neurology and Neurosurgery*, vol. 126, pp. 11–17, 2014.
- [19] S. Y. Jeong, J. S. Kim, W. S. Choi, J. W. Hur, and K. S. Ryu, "The effectiveness of endoscopic radiofrequency denervation of medial branch for treatment of chronic low back pain," *Journal* of Korean Neurosurgical Society, vol. 56, no. 4, pp. 338–343, 2014.
- [20] A. Yeung and S. Gore, "Endoscopically guided foraminal and dorsal rhizotomy for chronic axial back pain based on cadaver and endoscopically visualized anatomic study," *International Journal of Spine Surgery*, vol. 8, pp. 23–23, 2014.
- [21] N. C. Nacey, J. T. Patrie, and M. G. Fox, "Fluoroscopically Guided Sacroiliac Joint Injections: comparison of the Effects of Intraarticular and Periarticular Injections on Immediate and Short-Term Pain Relief," *American Journal of Roentgenology*, vol. 207, no. 5, pp. 1055–1061, 2016.

- [22] H. Elgafy, H. B. Semaan, N. A. Ebraheim, and R. J. Coombs, "Computed tomography findings in patients with sacroiliac pain," *Clinical Orthopaedics and Related Research*, no. 382, pp. 112–118, 2001.
- [23] M. Laslett and M. Williams, "The reliability of selected pain provocation tests for sacroiliac joint pathology," *Spine*, vol. 19, no. 11, pp. 1243–1249, 1994.
- [24] P. Van Der Wurff, R. H. M. Hagmeijer, and W. Meyne, "Clinical tests of the sacroiliac joint. A systematic methodological review. Part 1: reliability," *Manual Therapy*, vol. 5, no. 1, pp. 30–36, 2000.
- [25] J. D. Fortin, A. P. Dwyer, S. West, and J. Pier, "Sacroiliac joint: pain referral maps upon applying a new injection/arthrography technique part i: asymptomatic volunteers," *Spine*, vol. 19, no. 13, pp. 1475–1482, 1994.
- [26] L. Kapural, F. Nageeb, M. Kapural, J. P. Cata, S. Narouze, and N. Mekhail, "Cooled radiofrequency system for the treatment of chronic pain from sacroiliitis: the first case-series," *Pain Practice*, vol. 8, no. 5, pp. 348–354, 2008.
- [27] A. Vleeming, H. B. Albert, H. C. Östgaard, B. Sturesson, and B. Stuge, "European guidelines for the diagnosis and treatment of pelvic girdle pain," *European Spine Journal*, vol. 17, no. 6, pp. 794–819, 2008.
- [28] E. Murakami, Y. Tanaka, T. Aizawa, M. Ishizuka, and S. Kokubun, "Effect of periarticular and intraarticular lidocaine injections for sacroiliac joint pain: prospective comparative study," *Journal of Orthopaedic Science*, vol. 12, no. 3, pp. 274–280, 2007.

Hindawi Publishing Corporation BioMed Research International Volume 2016, Article ID 6808507, 9 pages http://dx.doi.org/10.1155/2016/6808507

# Clinical Study

# Video-Assisted Thoracoscopic Surgery and Minimal Access Spinal Surgery Compared in Anterior Thoracic or Thoracolumbar Junctional Spinal Reconstruction: A Case-Control Study and Review of the Literature

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Received 31 July 2016; Revised 16 November 2016; Accepted 1 December 2016

Academic Editor: William B. Rodgers

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There are no published reports that compare the outcomes of video-assisted thoracoscopic surgery (VATS) and minimal access spinal surgery (MASS) in anterior spinal reconstruction. We conducted a retrospective case-control study in a single center and systematically reviewed the literature to compare the efficacy and safety of VATS and MASS in anterior thoracic (T) and thoracolumbar junctional (TLJ) spinal reconstruction. From 1995 to 2012, there were 111 VATS patients and 76 MASS patients treated at our hospital. VATS patients had significantly (p < 0.001) longer operating times and significantly (p < 0.022) higher thoracotomy conversion rates. We reviewed 6 VATS articles and 10 MASS articles, in which there were 625 VATS patients and 399 MASS patients. We recorded clinical complications and a thoracotomy conversion rate from our cases and the selected articles. The incidence of approach-related complications was significantly (p = 0.021) higher in VATS patients. The conversion rate was 2% in VATS patients and 0% in MASS patients (p = 0.001). In conclusion, MASS is associated with reduction in operating time, approach-related complications, and the thoracotomy conversion rate.

#### 1. Introduction

Video-assisted thoracoscopic surgery (VATS) and minimal access spinal surgery (MASS) have been considered primarily as minimally invasive surgery (MIS) for anterior thoracic (T) and thoracolumbar junction (TLJ) spine surgery [1]. VATS was first described by Mack et al. in 1993 [2]; it allows for biopsy, anterior release, abscess drainage, and discectomy [3, 4]. VATS has been used to treat anterior thoracic diseases at our hospital since 1995. Over the next 10 years, we used VATS in many spinal procedures: decompression, corpectomy, reconstruction, and stabilization. The microsurgical miniopen anterolateral approach was first introduced in 1997 by

Mayer [5] for minimally invasive anterior lumbar interbody fusion. Kossmann et al. [6] reported in 2001 that the anterior column of the thoracic spine could easily be assessed and reconstructed using a minithoracotomy and a table-mounted retractor. At that time, we developed a new VATS approach [7–10], which we called the "extended manipulating channel method." It allowed us to use a combination of conventional spinal instruments and VATS to enter the chest cavity and to manipulate those instruments as we would for standard open surgical procedures. Furthermore, at our hospital, a refined MASS has been evolving since 2000 from our extended manipulating channel method without VATS [11, 12]. MASS has been used to treat vertebral metastasis, osteomyelitis, and

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fractures. It is generally believed that because MASS allows direct three-dimensional vision of the surgical field, which seems to make the procedure familiar to spine surgeons used to standard open surgical procedures, it has become more popular than VATS. Thus, we compared the outcomes of MASS in anterior T and TLJ spinal reconstruction and fusion with those of VATS.

#### 2. Patients and Methods

2.1. Patients. We identified, in our hospital's Spine Operation Registry, all patients who underwent VATS (Figures 1 and 2) and MASS (Figure 3). We previously published reports which described both VATS [7, 8, 10, 13] and MASS [12, 14] techniques for anterior T or TLJ spinal reconstruction between 1995 and 2012 and retrospectively reviewed their records. The inclusion criteria were anterior intervertebral fusion after a discectomy with a partial or a total corpectomy for treating spinal fractures, vertebral malignancy, infectious spondylitis, thoracic disc herniation, and degenerative spinal diseases. Patients with pediatric scoliosis, a discectomy without fusion, or a biopsy were excluded from the study. All included patients had undergone minimally invasive anterior spine reconstruction performed by one senior surgeon (T. J. Huang). We reviewed the patients' medical records and recorded data on operating time, estimated blood loss, need for intensive care, conversion to standard open thoracotomy, and complications in patients with T and TLJ spinal disorders. Approval for this study was obtained from the Ethics Committee and Institutional Review Board of our hospital (IRB number 101-1238B).

2.2. Review of Published Literature. The English language literature published between 1995 and 2012 was systematically reviewed. The Cochrane Review Database, EMBASE, Medline, PubMed, and Google Scholar were searched. The reference lists of the selected articles were checked. Search terminology included miniopen, MASS, VATS, anterior T spinal surgery, TLJ (T11-L2) spinal surgery, and anterior spinal fusion. We excluded studies associated with pediatric spine surgery, disc excision without fusion, and anterior lumbar surgery (L3-L5). Technical notes, case reports, anatomical descriptions, or a combined surgery of thoracoscopic surgery and thoracotomy was not included. The articles were screened and selected by two independent reviewers (Y. Y. Li and C. C. Cheng) based on the inclusion and exclusion criteria. Disagreements were resolved by discussion or by a consultation with a third reviewer (Ching-Yu Lee). The data of the selected articles were extracted and analyzed in detail by two independent reviewers (M. H. Wu and Chien-Yin Lee). Because data on the surgical complications were going to be analyzed, the interrater agreement about these data was analyzed using the kappa statistic. Disagreements were resolved by discussion or by a consultation with a senior spine surgeon (T. J. Huang).

2.3. Data Analysis. The perioperative parameters of our included sample were operating time, estimated blood loss, complications, conversion to standard thoracotomy, and the

need for postoperative admission to the intensive care unit. They were recorded and compared between our VATS and MASS patients. The perioperative data of the selected articles were average operating time, average estimated blood loss, complication rates, and conversions to thoracotomy.

Data of clinical complications and conversions to standard thoracotomy, which were recorded from our cases and the selected articles, were compared between VATS and MASS patients. A minor complication was defined as a minor risk event with no treatment, with medical treatment, or with intraoperative repair but without long-term sequelae. A major complication was defined as a life-threatening or irreversible event requiring invasive treatment or revision surgery. Death was mortality because of associated perioperative complications

An approach-related complication was defined as *inter-costal neuralgia*, *pleural effusion*, or *air leakage causing subcutaneous emphysema or pneumothorax* [15, 16].

#### 3. Statistical Methods

All statistical analyses were done using SPSS 12.0 for Windows. An independent Student t-test was used for numerical data. An  $\chi^2$  analysis or a Fisher exact test was used for categorical data. Significance was set at p < 0.05. The observed interrater agreement for the data extracted from the selected publications was analyzed using the kappa statistic.

#### 4. Results

We reviewed the medical records of 187 patients who had undergone minimally invasive surgery (MIS) for anterior T or TLJ spinal fusion at our hospital between 1995 and 2012. VATS was used in 111 patients, and MASS was used in the other 76 patients (Table 1). Operating time was longer in the VATS group than in the MASS group (p < 0.001). There was a significantly higher incidence of conversion to standard open thoracotomy in the VATS group than in the MASS group (p = 0.022). There were no significant differences in average blood loss or the need for postoperative admission to the intensive care unit (ICU).

#### 5. Literature-Reported Results

There were 16 articles about MIS for anterior T/TLJ spinal fusion (Table 2): 6 VATS articles [17–22] and 10 MASS articles [6, 23–31]. Of the 6 VATS articles, the median average operating time was 223 minutes (range: 155–347 minutes), the median average estimated blood loss was 585 mL (range: 310–1117 mL), the median complication rate was 25.9% (range: 9.4–34%), and the median conversion rate was 0.5% (range: 0–6.2%). Of the 10 MASS articles, the median average operating time was 170 minutes (range: 101–210 minutes), the median average estimated blood loss was 423 mL (range: 290–912 mL), the median complication rate was 14.9% (range: 0–33%), and there were no conversions to standard open procedure.

Perioperative complications were collected from 187 patients of our institute and 1024 patients of the 16 selected

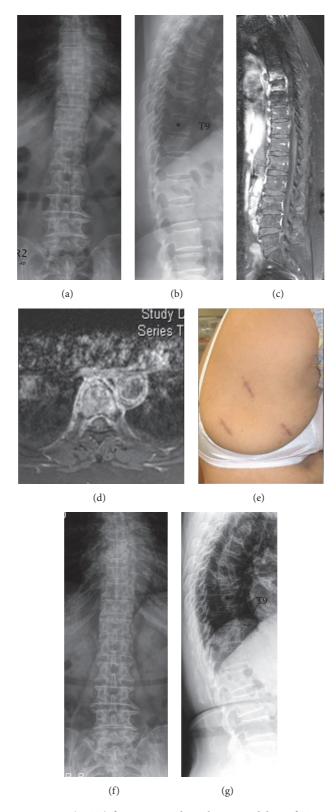


FIGURE 1: Video-assisted thoracoscopic surgery (VATS) for treating tuberculous spondylitis of T7-8 in a 74-year-old woman. (a) and (b) Vertebral destruction and collapse in T8. (c) and (d) Gadolinium-enhanced magnetic resonance imaging (MRI) shows osteomyelitis in T7-8 vertebral bodies and anterior epidural abscess spreading under the anterior longitudinal ligament. (e) The incisional wound was 2.5–3.0 cm long to allow a three-portal video-assisted thoracoscopic debridement, curettage, and harvested tricortical iliac strut bone graft for anterior spinal reconstruction on T7-8. (f) and (g) Solid bone fusion was noticed on T7-8 at the 2-year follow-up.

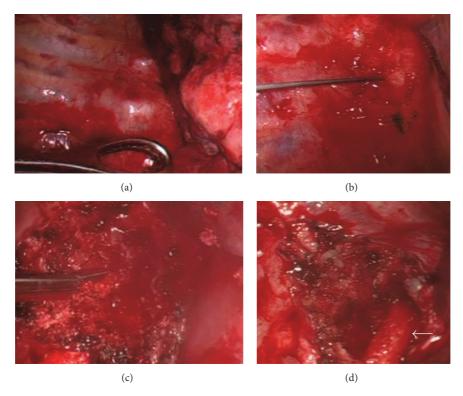


FIGURE 2: Video-assisted thoracoscopic surgery (VATS) spinal approach to tuberculous spondylitis of T7-8. (a) and (b) The lesion site was identified using fluoroscopy and was displayed on the video monitor. The lesion site was initially covered with the visceral pleura because of inflammation. (c) The infected vertebral body and soft tissue were removed using pituitary rongeurs and elongated curettes. (d) Column reconstruction with intervertebral fusion was initiated using an autogenous tricortical iliac strut graft (white arrow).

TABLE 1: MIS for anterior T and TLJ spinal reconstruction in 187 patients at our Institution.

	VATS	MASS	p value
Number of patients	111	76	
Male/female	68/43	39/37	0.177
Mean age (year)	57.1 ± 14.5	$60.4 \pm 14.8$	0.133
Number of pathologic regions			0.085
T	59 (53)	50 (66)	
TLJ	52 (47)	26 (34)	
Number of pathologic types			0.253
Fracture	25 (23)	9 (12)	
Infectious spondylitis	31 (28)	24 (32)	
Spinal malignancy	49 (44)	36 (47)	
Disc herniation or degeneration	6 (5)	7 (9)	
Perioperative data			
Operating time <sup>#</sup> (mins)	$224.5 \pm 68.6$	$183.5 \pm 33.2$	<0.001*
Estimated blood loss <sup>#</sup> (ml)	$916.0 \pm 660.3$	$933.8 \pm 847.6$	0.879
Conversion to standard thoracotomy	8 (7)	0	$0.022^*$
Need for postoperative ICU care	9 (8)	4 (5)	0.565

Data are expressed as mean  $\pm$  standard deviation or number (%). \* p < 0.05.

MIS: minimally invasive surgery; VATS: video-assisted thoracoscopic surgery; MASS: minimal access spinal surgery; T: thoracic; TLJ: thoracolumbar junction; ICU: intensive care unit.

<sup>&</sup>lt;sup>#</sup>Patients undergoing conversion thoracotomy were not included.

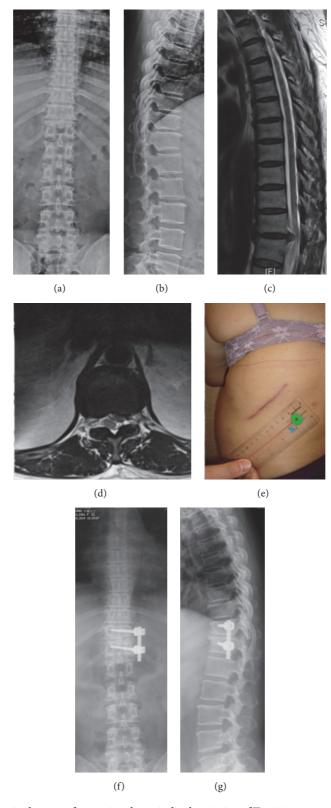


FIGURE 3: Anterior minimal access spinal surgery for treating thoracic disc herniation of T11-12 in a 41-year-old woman. (a) and (b) Narrowing disc space with endplate sclerosis on T11-12 level was noticed. (c) and (d) Magnetic resonance imaging (MRI) shows left paracentral disc herniation on T11-12 level. (e) A 7 cm skin incision in the patient's left lateral thoracic cage. (f) and (g) Anterior retropleural and retroperitoneal approach for thoracic discectomy and fusion was performed using a double-barreled rib strut graft and anterior vertebral instrumentation. No intraoperative one-lung ventilation, a postoperative chest tube, or ICU care was given. Solid bone fusion on T11-12 was noticed at the 2-year follow-up.

Authors	Years	PT no.	Study design	AOT (min)	ABL (ml)	CR (%)	TCR (%)
Dickman et al.	1996	17	VATS for reconstruction in T spine	347	1117	29.4	0
Khoo et al.	2002	371	VATS in treating T or TL spinal fractures	240	650	9.7	1.1
Kapoor et al.	2005	16	VATS in treating TB spondylitis	223	497	31.2	6.2
Le Huec et al.	2010	50	VATS for treating TLJ fractures	155	620	20.0	0
Lü et al.	2012	50	VATS in treating thoracic TB spondylitis	210	550	34.0	0
Wait et al.	2012	121	VATS for discectomy and fusion in T spine	NA	310	22.3	1.7
Kossmann et al.	2001	58	MASS for reconstruction in $T/TLJ(58) + L(7)$	170	912	7.7%	0
El Saghir	2002	21	MASS for reconstruction in TL spine	101	724	33%	0
Scheufler	2007	38	MASS for reconstruction in T/TLJ spine	167	652	18%	0
Payer and Sottas	2008	37	MASS for reconstruction in TL spine	181	632	16.2%	0
Smith et al.	2010	52	MASS in treating TLJ fractures	128	300	13.5%	0
Uribe et al.	2010	21	MASS in treating T spinal tumor	117	291	4.8%	0
Khan et al.	2012	20	MASS for reconstruction in $T/TLJ(20) + L(4)$	188	423	0	0
Deviren et al.	2011	12	MASS for reconstruction in T spine	210	400	16.7%	0
Baaj et al.	2012	80	MASS for reconstruction in TL spine	NA	NA	12.5%	0
Uribe et al.	2012	60	MASS for discectomy and fusion in T spine	182	290	25%	0

MIS: minimally invasive surgery; T: thoracic; TLJ: thoracolumbar junction; PT no.: patient number; AOT: average operating time; ABL: average estimated blood loss; CR: complication rate; TCR: thoracotomy conversion rate; VATS: video-assisted thoracoscopic surgery; MASS: minimal access spinal surgery.

publications (Table 3). The assessment score agreement between the reviewers was good (kappa statistic: 0.62, p <0.001). There were 126 (17%) perioperative complications in VATS patients and 71 (15%) in MASS patients (p =0.317): there was not significantly different distribution of no, minor, and major complication (p = 0.567). Revision surgery was the most common major complication in both groups: 11 VATS patients and 8 MASS patients. There were 6 mortalities in this study, 3 in each cohort of VATS and MASS: 1 with pneumonia, 1 with acute thromboembolism, and 1 with intraoperative arrhythmia and acute cardiac infarction in VATS patients; 1 with pneumonia and 2 with acute thromboembolism in MASS patients. The incidence of approach-related complications was significantly higher in VATS patients than MASS patients (p = 0.011). There was no significant difference in the prevalence of pulmonary infection or iatrogenic cardiovascular injury between both surgical procedures.

The overall conversion rate from MIS to standard thoracotomy in VATS patients was 2% (n=15) and 0% in MASS patients (p=0.001) (Table 4). The most common cause for unplanned conversion to standard open thoracotomy was severe intrathoracic adhesion (40%), followed by iatrogenic cardiovascular injury (20%) and excessive uncontrollable bleeding from cancellous bone or soft tissue (20%).

#### 6. Discussion

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VATS and MASS are well-known MIS methods for anterior spinal surgeries [1]. It is generally believed that using VATS for spinal surgery entails a learning curve more difficult to negotiate than does using MASS [19]; however, few studies focus on analyzing the advantages and disadvantages of using VATS and MASS to treat anterior spinal disorders. In this study, VATS required longer operating time and a higher

incidence of conversion to standard open thoracotomy than did MASS at our hospital. Similarly, our review of the VATS and MASS literature for anterior T and TLJ spinal reconstruction showed that VATS was more likely to need operating time and to increase blood loss. In addition, Molina et al. [32], in a systematic review of MIS in the management of metastatic spine disease, reported that VATS was associated with longer operating time, a longer length of stay in the hospital, and more blood loss than was MASS. We found that since MASS seems more familiar to most surgeons it yields faster and safer decompression, stabilization, and reconstruction than does VATS.

We found that the overall MIS complication rate for anterior T and TLJ spinal reconstruction in the 1211 patients analyzed in the selected articles and in our hospital was 16.2%: 126 perioperative complications in VATS patients (17%) and 71 complications in MASS patients (15%). VATS and MASS patients had similar minor and major complication rates; however, VATS is more associated with approach-related complications. Consistent with the results of previous case series [3, 16, 19, 33], approach-related complications are most common in patients undergoing VATS. This might be true because trocar placement sometimes injures an intercostal nerve or pleural membrane, which leads to intercostal neuralgia, pleural effusion, pneumothorax, or subcutaneous emphysema [15]. Hence, the first thoracoscopic portal, which is not made using endoscopic visualization, is created using a minithoracotomy to make a 1.5 cm skin incision that precludes blind trocar insertion [16, 34, 35].

Conversion to standard open thoracotomy occurred more frequently in VATS patients than in MASS patients in our hospital and in the selected literature. Consistent with our findings, other studies [35, 36] have reported that VATS is restricted because of severe pleural adhesion, poor tolerance of one-lung ventilation, and difficulty with

TABLE 3: A summary of perioperative complications in MIS for anterior T and TLJ spinal surgery.

	VATS $(n = 736)$	MASS $(n = 475)$	р
Number of patients			
Complications in authors' institute	27	11	0.263
Complications in review articles	99	60	
A total number of complications	126 (17)	71 (15)	0.317
No complication	610	404	0.567
Minor complication	102	59	
Major complication	24	12	
Minor complication	102 (80)	59 (83)	0.708
Pleural effusion, pneumothorax, and intercostal neuralgia	52	18	
Superficial wound infection	12	3	
Incidental durotomy	8	15	
Pulmonary infection s/p medical treatment	8	3	
Lung atelectasis or poor pulmonary function	7	4	
Hypesthesia or transient motor dysfunction	3	5	
Paralytic ileus	0	5	
Laceration of lung parenchyma s/p repair	4	0	
Deep vein thrombosis	0	4	
Pharyngeal pain	3	0	
Subcutaneous emphysema	2	0	
Implant malposition	1	1	
Splenic contusion	1	0	
Iatrogenic rib fracture	1	0	
Urinary tract Infection	0	1	
Major complication	24 (20)	12 (17)	
Revision	11	8	
Graft dislodgment or implant failure or pseudoarthrosis	7	5	
Incomplete decompression (residual disc herniation)	3	2	
Wrong level	1	0	
Dehiscent muscular layers in the flank	0	1	
Pneumonia with requiring intubation	4	0	
Iatrogenic cardiovascular injury	3	0	
Deep wound infection	1	1	
Permanent neurogenic deterioration	1	0	
Postoperative acute myocardial infarction	1	0	
Death	3	3	
Pneumonia	1	1	
Intraoperative arrhythmia	1	0	
Acute thromboembolism	1	2	
Specific complications in MIS for anterior T and TLJ spinal Surgery			
Approach-associated complications	54	18	$0.011^{*}$
Pulmonary infections	13	4	0.218
Iatrogenic cardiovascular injury	3	0	0.284

Data are expressed as mean  $\pm$  standard deviation or number (%). \* p < 0.05.

MIS: minimal ly invasive surgery; VATS: video-assisted thoracoscopic surgery; MASS: minimal access spinal surgery; T: thoracic; TLJ: thoracolumbar junction.

endoscopic control of bleeding. In addition, the conversion rate from VATS to standard open thoracotomy was 7.2% in our hospital and 1.1% in the selected articles. Metastatic vertebral tumors and infectious spondylitis occurred in most of our VATS patients whereas vertebral fracture and herniation of intervertebral disc were the majority of spinal

disorders in VATS patients from the selected articles. Chronic inflammation, infection, and metastatic tumor are well-known causes of intrathoracic adhesion [37], which might explain the relatively higher incidence of conversion to open thoracotomy in our VATS patients than in the patients in the reviewed literature. Severe pleural adhesion encountered in

	VATS (n = 736)	MASS (n = 475)	Р
Conversion to standard open procedure	15 (2)	0	0.001*
Severe intrathoracic adhesion	6	0	
Iatrogenic cardiovascular injury	3	0	
Excessive uncontrollable bleeding	3	0	
Poor tolerance of one-lung ventilation	2	0	
Extremely narrow intercostal space	1	0	

TABLE 4: Causes of conversion thoracotomy in MIS for anterior spinal surgery.

Data are expressed as mean  $\pm$  standard deviation or number (%). \* p < 0.05.

MIS: minimally invasive surgery; VATS: video-assisted thoracoscopic surgery; MASS: minimal access spinal surgery.

metastatic chronically infected diseases of the thoracic spine, but thoracoscopic adhesiolysis is a technically demanding procedure that must be done by an expert thoracic surgeon. Besides, intraoperative bleeding was more directly and easily controlled using cauterization, hemoclips, or suture ligation in MASS. Therefore, MASS is a reasonable MIS method for treating anterior T and TLJ spinal reconstruction and fusion, especially for metastatic and infectious spinal diseases.

This study has some limitations. First, this is a retrospective study. To minimize the statistical bias, we included patients who had undergone MIS spinal surgery done by the same surgeon (T. J. Huang) at our hospital. Second, the evidence level of the systemic review in this study is low. This is because there is still a paucity of reports that a meta-analysis needs, those that show comparative data of VATS and MASS for treating anterior spinal diseases. Additional comparative VATS and MASS studies that focus on treating anterior spinal diseases are required.

In conclusion, VATS and MASS are effective MIS methods for treating anterior T and TLJ spinal reconstruction, and they have equivalent complication rates. MASS requires less operating time and has fewer approach-related complications. VATS is more likely to have a higher conversion rate from MIS to standard open thoracotomy when severe pleural adhesion and difficulty in endoscopically controlling bleeding are encountered.

#### **Competing Interests**

All authors declare that they have no conflict of interests regarding the publication of this paper.

#### Acknowledgments

The authors thank Chia-Hao Chang, Ph.D., who is specialized in statistics, for statistical assistance. The authors also thank the Research Committee of Chang Gung Memorial Hospital, Taiwan, for assistance (no. CMRPG6F0131) in the Spine Operation Registry.

#### References

[1] O. Ofluoglu, "Minimally invasive management of spinal metastases," *Orthopedic Clinics of North America*, vol. 40, no. 1, pp. 155–168, 2009.

- [2] M. J. Mack, J. J. Regan, W. P. Bobechko, and T. E. Acuff, "Application of thoracoscopy for diseases of the spine," *The Annals of Thoracic Surgery*, vol. 56, no. 3, pp. 736–738, 1993.
- [3] M. J. Mack, J. J. Regan, P. C. McAfee, G. Picetti, A. Ben-Yishay, and T. E. Acuff, "Video-assisted thoracic surgery for the anterior approach to the thoracic spine," *The Annals of Thoracic Surgery*, vol. 59, no. 5, pp. 1100–1106, 1995.
- [4] J. J. Regan, M. J. Mack, and G. D. Picetti, "A technical report on video-assisted thoracoscopy in thoracic spinal surgery: preliminary description," *Spine*, vol. 20, no. 7, pp. 831–837, 1995.
- [5] H. M. Mayer, "A new microsurgical technique for minimally invasive anterior lumbar interbody fusion," *Spine*, vol. 22, no. 6, pp. 691–700, 1997.
- [6] T. Kossmann, D. Jacobi, and O. Trentz, "The use of a retractor system (SynFrame) for open, minimal invasive reconstruction of the anterior column of the thoracic and lumbar spine," *European Spine Journal*, vol. 10, no. 5, pp. 396–402, 2001.
- [7] T.-J. Huang, R. W.-W. Hsu, H.-P. Liu, Y.-S. Liao, and H.-N. Shih, "Technique of video-assisted thoracoscopic surgery for the spine: new approach," *World Journal of Surgery*, vol. 21, no. 4, pp. 358–362, 1997.
- [8] T. J. Huang, R. W. W. Hsu, H. P. Liu et al., "Video-assisted thoracoscopic treatment of spinal lesions in the thoracolumbar junction," *Surgical Endoscopy*, vol. 11, no. 12, pp. 1189–1193, 1997.
- [9] T.-J. Huang, R. W.-W. Hsu, H.-P. Liu, Y.-S. Liao, K.-Y. Hsu, and H.-N. Shih, "Analysis of techniques for video-assisted thoracoscopic internal fixation of the spine," *Archives of Orthopaedic* and Trauma Surgery, vol. 117, no. 1-2, pp. 92–95, 1998.
- [10] T.-J. Huang, R. W.-W. Hsu, H.-P. Liu et al., "Video-assisted thoracoscopic surgery to the upper thoracic spine," *Surgical Endoscopy*, vol. 13, no. 2, pp. 123–126, 1999.
- [11] T. J. Huang, R. W. Hsu, S. H. Chen, and Y. Y. Lee, "Minimal access surgery in managing anterior lumbar disorders," *Clinical Orthopaedics and Related Research*, no. 387, pp. 140–147, 2001.
- [12] T.-J. Huang, R. W.-W. Hsu, Y.-Y. Li, and C.-C. Cheng, "Minimal access spinal surgery (MASS) in treating thoracic spine metastasis," *Spine*, vol. 31, no. 16, pp. 1860–1863, 2006.
- [13] T.-J. Huang, R. W.-W. Hsu, S.-H. Chen, and H.-P. Liu, "Video-assisted thoracoscopic surgery in managing tuberculous spondylitis," *Clinical Orthopaedics and Related Research*, no. 379, pp. 143–153, 2000.
- [14] C.-Y. Lee, T.-J. Huang, Y.-Y. Li, C.-C. Cheng, and M.-H. Wu, "Comparison of minimal access and traditional anterior spinal surgery in managing infectious spondylitis: a minimum 2-year follow-up," *Spine Journal*, vol. 14, no. 7, pp. 1099–1105, 2014.
- [15] K. M. Cheung and S. Al Ghazi, "Approach-related complications of open versus thoracoscopic anterior exposures of the thoracic

- spine," Journal of Orthopaedic Surgery, vol. 16, no. 3, pp. 343–347, 2008
- [16] D. H. Kim, T. A. Jahng, R. S. V. Balabhadra, M. Potulski, and R. Beisse, "Thoracoscopic transdiaphragmatic approach to thoracolumbar junction fractures," *Spine Journal*, vol. 4, no. 3, pp. 317–328, 2004.
- [17] C. A. Dickman, D. Rosenthal, D. G. Karahalios et al., "Thoracic vertebrectomy and reconstruction using a microsurgical thoracoscopic approach," *Neurosurgery*, vol. 38, no. 2, pp. 279–293, 1996.
- [18] S. K. Kapoor, P. N. Agarwal, B. K. Jain Jr., and R. Kumar, "Videoassisted thoracoscopic decompression of tubercular spondylitis: clinical evaluation," *Spine*, vol. 30, no. 20, pp. E605–E610, 2005.
- [19] L. T. Khoo, R. Beisse, and M. Potulski, "Thoracoscopic-assisted treatment of thoracic and lumbar fractures: a series of 371 consecutive cases," *Neurosurgery*, vol. 51, no. 5, pp. S104–S117, 2002.
- [20] J.-C. Le Huec, C. Tournier, S. Aunoble, K. Madi, and P. Leijssen, "Video-assisted treatment of thoracolumbar junction fractures using a specific distractor for reduction: prospective study of 50 cases," *European Spine Journal*, vol. 19, S1, pp. S27–S32, 2010.
- [21] G. Lü, B. Wang, J. Li, W. Liu, and I. Cheng, "Anterior debridement and reconstruction via thoracoscopy-assisted mini-open approach for the treatment of thoracic spinal tuberculosis: minimum 5-year follow-up," *European Spine Journal*, vol. 21, no. 3, pp. 463–469, 2012.
- [22] S. D. Wait, D. J. Fox Jr., K. J. Kenny, and C. A. Dickman, "Thoracoscopic resection of symptomatic herniated thoracic discs: clinical results in 121 patients," *Spine*, vol. 37, no. 1, pp. 35– 40, 2012.
- [23] A. A. Baaj, E. Dakwar, T. V. Le et al., "Complications of the mini-open anterolateral approach to the thoracolumbar spine," *Journal of Clinical Neuroscience*, vol. 19, no. 9, pp. 1265–1267, 2012.
- [24] V. Deviren, F. A. Kuelling, G. Poulter, and M. Pekmezci, "Minimal invasive anterolateral transthoracic transpleural approach: a novel technique for thoracic disc herniation. A review of the literature, description of a new surgical technique and experience with first 12 consecutive patients," *Journal of Spinal Disorders and Techniques*, vol. 24, no. 5, pp. E40–E48, 2011.
- [25] H. El Saghir, "Extracoelomic mini approach for anterior reconstructive surgery of the thoracolumbar area," *Neurosurgery*, vol. 51, no. 5, supplement, pp. S118–S122, 2002.
- [26] S. N. Khan, T. Cha, J. A. Hoskins, M. Pelton, and K. Singh, "Minimally invasive thoracolumbar corpectomy and reconstruction," *Orthopedics*, vol. 35, no. 1, pp. e74–e79, 2012.
- [27] M. Payer and C. Sottas, "Mini-open anterior approach for corpectomy in the thoracolumbar spine," *Surgical Neurology*, vol. 69, no. 1, pp. 25–31, 2008.
- [28] K.-M. Scheufler, "Technique and clinical results of minimally invasive reconstruction and stabilization of the thoracic and thoracolumbar spine with expandable cages and ventrolateral plate fixation," *Neurosurgery*, vol. 61, no. 4, pp. 798–808, 2007.
- [29] W. D. Smith, E. Dakwar, T. V. Le, G. Christian, S. Serrano, and J. S. Uribe, "Minimally invasive surgery for traumatic spinal pathologies: a mini-open, lateral approach in the thoracic and lumbar spine," *Spine*, vol. 35, pp. S338–S346, 2010.
- [30] J. S. Uribe, E. Dakwar, T. V. Le, G. Christian, S. Serrano, and W. D. Smith, "Minimally invasive surgery treatment for thoracic spine tumor removal: a mini-open, lateral approach," *Spine*, vol. 35, no. 26S, pp. S347–S354, 2010.

[31] J. S. Uribe, W. D. Smith, L. Pimenta et al., "Minimally invasive lateral approach for symptomatic thoracic disc herniation: initial multicenter clinical experience: clinical article," *Journal of Neurosurgery: Spine*, vol. 16, no. 3, pp. 264–279, 2012.

- [32] C. A. Molina, Z. L. Gokaslan, and D. M. Sciubba, "A systematic review of the current role of minimally invasive spine surgery in the management of metastatic spine disease," *International Journal of Surgical Oncology*, vol. 2011, Article ID 598148, 9 pages, 2011.
- [33] A. Imperatori, N. Rotolo, M. Gatti et al., "Peri-operative complications of video-assisted thoracoscopic surgery (VATS)," *International Journal of Surgery*, vol. 6, no. 1, pp. S78–S81, 2008.
- [34] P. C. McAfee, J. R. Regan, T. Zdeblick et al., "The incidence of complications in endoscopic anterior thoracolumbar spinal reconstructive surgery. A prospective multicenter study comprising the first 100 consecutive cases," *Spine*, vol. 20, no. 14, pp. 1624–1632, 1995.
- [35] M. J. Perez-Cruet, R. G. Fessler, and N. I. Perin, "Review: complications of minimally invasive spinal surgery," *Neurosurgery*, vol. 51, no. 5, pp. S26–S36, 2002.
- [36] P. Latham and K. K. Dullye, "Complications of thoracoscopy," Anesthesiology Clinics of North America, vol. 19, no. 1, pp. 187– 200, 2001.
- [37] J. T. Huggins and S. A. Sahn, "Causes and management of pleural fibrosis," *Respirology*, vol. 9, no. 4, pp. 441–447, 2004.

Hindawi Publishing Corporation BioMed Research International Volume 2016, Article ID 1457219, 9 pages http://dx.doi.org/10.1155/2016/1457219

#### Research Article

# Anatomical Location of the Common Iliac Veins at the Level of the Sacrum: Relationship between Perforation Risk and the Trajectory Angle of the Screw

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Received 4 August 2016; Revised 8 November 2016; Accepted 21 November 2016

Academic Editor: Ayhan Cömert

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Purpose. To determine the safety of transarticular surface screw (TASS) insertion and the anatomical location of the common iliac veins (CIVs) at the level of the promontorium. Materials and Methods. The locations of the CIVs on 1 mm computed tomographymyelography slices of 50 patients at the level of the promontorium and 20 human cadavers were investigated. Results. Among the patients, the left CIV was closer to the S1 anterior wall than the right CIV (mean distance:  $5.0 \pm 3.0$  and  $7.0 \pm 4.2$  mm, resp.). The level of the inferior vena cava (IVC) formation varied among the cadavers. The mean distance between the IVC formation and promontorium tip was  $30.2 \pm 12.8$  mm. The height of the IVC formation and distance between the right and the left CIVs at the level of the promontorium were significantly correlated (P < 0.001). Conclusion. The TASS trajectory is safe as long as the screw does not penetrate the anterior cortex of S1. The level of the IVC formation can help to predict the distance between the right and the left CIVs at the level of the promontorium. The CIVs do not have a uniform anatomical location; therefore, preoperative computed tomography is necessary to confirm their location.

#### 1. Introduction

Placement of screws in the sacrum is essential to ensure rigid fixation during instrumentation of the lumbosacral spine. Despite the availability of various screw implantation techniques for the sacrum, failure to achieve a safe, strong screw trajectory continues to be a significant clinical problem. Our center recently developed and implemented a novel sacral screw trajectory for S1 called transarticular surface screw (TASS) implantation. This technique can be combined with an L5 cortical bone trajectory screw and L5 pedicle screw for L5-S1 instrumentation and fusion (Figure 1).

A variety of techniques for sacral screw insertion to provide enhanced screw purchase have been described such as the cortical bone trajectory technique [1], the penetrating S1 endplate screw technique [2], bicortical and tricortical purchase [3], and the technique described by Luk et al. [4].

However, the safest S1 screw trajectory with which to obtain sacral fixation remains the main concern during screw implantation in the sacrum. Screw insertion toward the tip of the promontorium and S1 endplate to enhance screw strengthening is a cornerstone in many types of S1 screw implantation techniques [1, 3–8], including TASS implantation. However, one of the obstacles to safe screw insertion at this level is the close relationship of arteries, veins, and nerves with the anterior wall of the S1 vertebral body.

A thorough understanding of the anatomy of the structures at risk is a key to safe, successful implantation of screws in this region. Injury to the common iliac veins (CIVs) during S1 screw insertion is not a common complication, but it is serious and may be fatal [9, 10]. The close relationship of the CIVs with the anterior wall of the S1 vertebral body makes these veins susceptible to iatrogenic injury during S1 screw insertion [2, 9, 11]. The aim of the present study was to

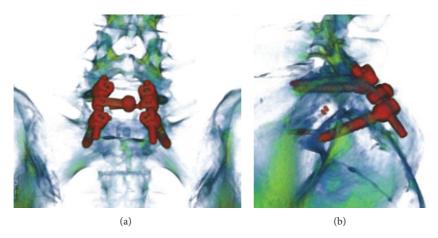


FIGURE 1: (a) Reconstructed coronal computed tomography image shows a combination of L5 cortical bone trajectory and S1 transarticular surface screw. (b) Reconstructed sagittal computed tomography image in the same patient.

TABLE 1: Demographic characteristics of patients and cadavers.

Characteristics	CT images $n = 50$	Cadavers $n = 20$
Age		
Mean	67.3	83.8
SD	±13.7	±9.1
Minimum	16	68
Maximum	90	103
Sex		
Female	24 (48%)	11 (55%)
Male	26 (52%)	9 (45%)

determine the anatomical location of the CIVs in front of the S1 vertebral body on reconstructed computed tomography-myelography (CTM) images and in human cadavers to determine the safest trajectory during TASS insertion.

#### 2. Materials and Methods

After obtaining institutional ethics approval for this study, we investigated the anatomical location of the CIVs around the sacrum on 1-mm slices of reconstructed CTM images in 50 patients and 20 human formalin-embalmed cadavers to confirm the safety of TASS insertion (Table 1).

2.1. First Part of Study. Reconstructed CTM images of 50 patients (26 males and 24 females; mean age: 67.3 years; age range: 16–90 years) who underwent spine surgery in our institution were collected and analyzed by two investigators who used the same method and were blinded to each other's results.

Two axial slices were meticulously prepared and printed by an expert spine surgeon; one slice was taken from the tip of the promontorium, and the other was taken 1 cm caudal to the tip of the promontorium, parallel to the SI endplate (both slices included the TASS entry point). All measurements were performed on the above-mentioned printed axial slices (Figures 2 and 3).

#### 2.2. Measurements

- (a) The locations of the bilateral CIVs were determined in two planes. One plane included the TASS entry point (one-third the distance from the medial aspect of the superior articular process of S1 in axial and caudal level of pedicle, in sagittal location which is located within the articular surface and promontorium), and the other plane was parallel to the S1 endplate and included the TASS entry point (Figures 2 and 3).
- (b) The angles of the CIVs from the insertion point of the TASS were measured.
- (c) The shortest distance from the anterior wall of the S1 vertebra to the nearest wall of the CIV on both the right and the left sides was measured (Figures 2(c) and 2(d)).
- (d) The distance from the insertion point of the TASS toward the promontorium and anterior wall of the S1 vertebra was measured in two planes and at three different angles  $(10^{\circ}, 0^{\circ}, \text{and} 10^{\circ})$ .
- (e) The height and body weight of each patient were measured to determine the presence of any correlation of the patient's height and weight with the distance of the right and left CIVs or any other parameters.
- 2.3. Second Part of Study. Twenty human embalmed cadavers (9 males and 11 females; mean age at time of death: 83.8 years; range: 63–103 years) that had been donated for medical education and research were used in the present study.

Each cadaver was placed in the supine position, and the abdomen was opened with a midline incision. All abdominal and pelvic organs were moved away.

To locate the center of the promontorium, we measured the width of the L5 vertebra with a digital caliper and divided

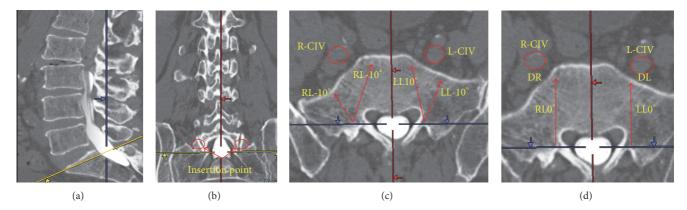


FIGURE 2: (a) Sagittal computed tomography image. The yellow line indicates the transarticular surface screw trajectory. (b) The red circle indicates the insertion point of the TASS in the coronal view. (c) R-CIV: right common iliac vein; L-CIV: left common iliac vein; RL10: trajectory 10° lateral to the insertion point; RL-10: trajectory 10° medial to the insertion point on the right side. LL10 and LL-10 are consistent with the same definitions on the left side. (d) RL0 trajectory straight and perpendicular to a horizontal line from the insertion point. DR and DL indicate the distance between the nearest wall of the CIV and the anterior wall of the S1 vertebra on the right and left side, respectively.

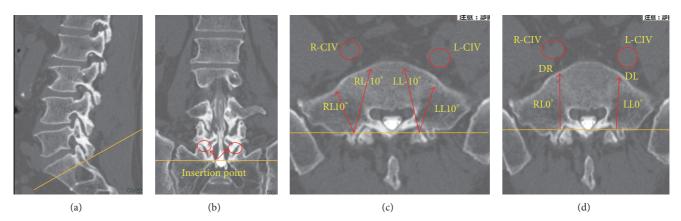


FIGURE 3: Sagittal coronal and axial computed tomography images from the trajectory parallel to S1 endplate. Abbreviations are as defined in Figure 2.

it into two (Figure 4(a)). The center of the promontorium was then marked with a tiny needle.

#### 2.4. Measurements

- (a) The distance between the formation of the inferior vena cava (IVC) and the center of the promontorium was measured (Figure 4(b)).
- (b) The distance between the center of the promontorium and the right and left CIVs was also measured (Figure 4(c)).

Upon completion of the measurements, the location of the IVC formation was marked and plain anteroposterior and lateral radiographs were taken of each cadaver to verify the location of the IVC radiographically.

The diameter of the median sacral vein was measured to identify cadavers with a dilated median sacral vein. The median sacral vein is an unpaired vein located at the medial aspect of the sacrum and accompanies the middle sacral artery to receive blood from the sacral venous plexus,

emptying into the left common iliac vein. The median sacral vein was considered dilated when its diameter measured  $\geq 2 \text{ mm } [9]$ .

2.5. Statistical Analyses. The mean and standard deviation were calculated for each measurement. Statistical analysis was performed using computer software (SPSS version 17; Chicago, IL, USA). A P value of <0.05 was considered statistically significant.

#### 3. Results

3.1. CT Images. At the level of the promontorium, the left CIV was closer to the S1 anterior wall than was the right CIV (mean distance:  $5.00 \pm 3.00$  versus  $7.00 \pm 4.28$  mm, resp.; P = 0.016) (Table 2).

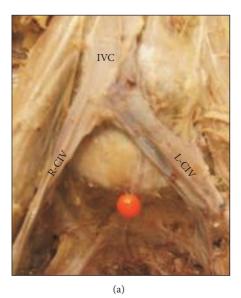
The average angle of the left and right CIVs ranged from  $6^{\circ}$  to  $22^{\circ} \pm 7.0^{\circ}$  and  $2^{\circ}$  to  $20^{\circ} \pm 11.85^{\circ}$ , respectively (Table 3).

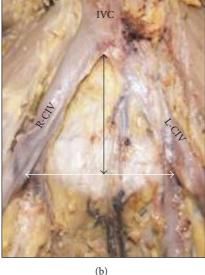
The right CIV was located farther laterally from the center of the promontorium than was the left CIV (24.00  $\pm$  4.65 versus 19.00  $\pm$  6.44 mm, resp.; P = 0.001) (Table 4).

	Toward tip of S1 endplate (mm)		Parallel to S1 endplate (mm)	
	Mean	ICC (95% CL)	Mean	ICC (95% CL)
DR	8 ± 4.03	0.82 (0.71–0.89)	6 ± 3.71	0.81 (0.70-0.88)
DL	$5 \pm 3.01$	0.84 (0.74-0.90)	$5 \pm 2.51$	0.84 (0.74-0.90)
P value	0.016		0.0763	

TABLE 2: Distance between the anterior wall of S1 vertebral body and the nearest wall of common iliac veins on the right and left sides.

DR: distance between the right CIV and anterior wall of SI vertebral body on the right side; DL: distance between the left CIV and anterior wall of SI vertebral body on the left side.





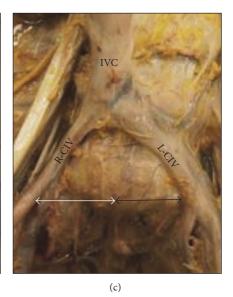


FIGURE 4: (a) Locations of the common iliac veins (CIVs) and inferior vena cava (IVC). The pin indicates the center of the promontorium. (b) The vertical arrow indicates the distance between the level of the IVC formation and tip of the promontorium. The horizontal arrow indicates the distance between the right and left CIVs. (c) The white arrow indicates the distance between the center of the promontorium and the medial wall of the right CIV (R-CIV), and the black arrow indicates the distance between the center of the promontorium and the medial wall of the left CIV (L-CIV).

The mean distance between the right and left CIVs at the level of the promontorium was  $43.00 \pm 8.74$  mm.

The average screw length in the TASS plane (trajectory toward the tip of the S1 cranial endplate) at three different angles ( $10^{\circ}$ ,  $0^{\circ}$ , and  $-10^{\circ}$ ) was equal on the right and left sides, and the overall screw length in the TASS plane at three different angles was longer than the trajectory parallel to the S1 endplate. However, the difference was not statistically significant (P > 0.05) (Table 5).

The mean height and weight of the patients were 159 cm and 60 kg, respectively. No correlation of the height and weight of the patients with the distance of the right and left CIVs at the level of the promontorium was found.

*3.2. Cadavers.* The CIVs lie within the connective tissues immediately in front of the S1 and L5 vertebral bodies.

The left CIV was located closer to the center of the promontorium than was the right CIV. The IVC formation was located cranial to the promontorium in all cadavers.

Among the 20 cadavers, the IVC formation was located at the level of the L5-S1 disc space or L5 caudal endplate in 10 cadavers, at the level of the L5 vertebral body in 5 cadavers,

and at the level of the L4-L5 intervertebral disc or L4 vertebral body in 5 cadavers (Figures 5 and 6).

The level of the IVC formation varied among the different cadavers and by sex. A low location of the IVC formation was more common in female than in male cadavers (7 versus 3, resp.; P < 0.005) (Figure 6). The mean distance between the IVC formation and the center of the promontorium in male and female cadavers was 35.5 mm and 25.8 mm, respectively, and the mean distance from the center of the promontorium to the left CIV in male and female cadavers was 23.2 mm and 17.0 mm, respectively (P < 0.001) (Figure 7).

There was a statistically significant correlation between the location of the IVC formation and the distance between the right and left CIVs at the level of the promontorium. In cadavers with a medium to high location of the IVC formation, the distance between the two CIVs at the level of the promontorium was wider than in cadavers with a low location of the IVC formation (P < 0.05) (Figure 8).

The mean distance from the right and left CIVs to the center of the promontorium was  $21.7 \,\mathrm{mm}$  and  $19.3 \,\mathrm{mm}$ , respectively (P < 0.018) (Figure 9).

A dilated median sacral vein was observed in 4 of 20 cadavers (20%).

e e			•
Trajectory toward tip of promontorium (°)		Trajectory parallel to S1 endplate (°)	
Mean ± SD	ICC (95% CL)	Mean ± SD	ICC (95% CL)

 $9.00 \pm 8.38$ 

 $3.00 \pm 8.51$ 

 $3.00 \pm 8.51$ 

 $19.00 \pm 9.28$ 

Table 3: Locations of the right and left common iliac veins based on vertical insertion screw trajectory.

0.74(0.58-0.84)

0.79(0.66 - 0.88)

0.78(0.64 - 0.87)

0.92 (0.87-0.95) AIR°: angle between vertical line (passing from insertion point toward anterior wall of SI) and medial border of the right common iliac vein; A2R°: angle between vertical line and lateral border of the right common iliac vein; AlL° and A2L°: same definitions but on the left side; SD: standard deviation.

Table 4: Distance between the right and left common iliac veins at the level of the promontorium.

Distance	Level of S1 cranial endplate (mm)	1 cm caudal to S1 cranial endplate (mm)	P value
R-CIV/L-CIV	$43.00 \pm 8.73$	$47.00 \pm 15.90$	0.015
R-CIV/P	$24.00 \pm 4.61$	$26.00 \pm 8.12$	1.091
L-CIV/P	$19.00 \pm 6.46$	$21.00 \pm 7.14$	0.018
P value (R-CIV/P versus L-CIV/P)	0.001	0.003	

Data are presented as mean ± standard deviation. R-CIV and L-CIV: distance between the right and left common iliac veins; R-CIV/P: distance between the right common iliac vein and the center of promontorium; L-CIV/P: distance between the left common iliac vein and the center of promontorium.

TABLE 5: Length of transarticular surface screw, toward promontorium and parallel to S1 endplate at three different angles.

	Toward tip of S	Toward tip of S1 endplate (mm)		Parallel to S1 endplate (mm)		
	Mean $\pm$ SD	ICC (95% CL)	Mean $\pm$ SD	ICC (95% CL)	P value	
RL10°	$31.00 \pm 3.87$	0.79-0.87	$31.00 \pm 3.56$	0.79-0.87	>0.05	
RL0°	$36.00 \pm 3.93$	0.76-0.86	$33.00 \pm 4.15$	0.76-0.86	>0.05	
RL-10°	$40.00 \pm 4.45$	0.71-0.83	$35.00 \pm 4.74$	0.71-0.83	>0.05	
LL10°	$32.00 \pm 3.88$	0.88-0.93	$31.00 \pm 3.67$	0.88-0.93	>0.05	
LL0°	$36.00 \pm 4.23$	0.72-0.83	$34.00 \pm 4.54$	0.72-0.83	>0.05	
LL-10°	$41.00 \pm 4.23$	0.84-0.91	$35.00 \pm 4.54$	0.84-0.91	>0.05	

RLO: screw length from insertion point of transarticular surface screw toward anterior wall of SI at an angle perpendicular to horizontal line passing through the facet joint on an axial computed tomography image; RL10: length of screw at 10° lateral trajectory toward anterior wall of S1 from insertion point on the right side; RL-10: length of screw at 10° medial trajectory toward anterior wall of S1 from insertion point on the right side; LL0, LL10, and LL-10 indicate the same information on the left side.

#### 4. Discussion

A1(R)°

A2(R)°

A1(L)°

A2(L)°

The CIVs and internal iliac veins are located posterior and lateral to their corresponding arteries. The veins lie in the connective tissue immediately in front of the sacral ala, at the level of the first and second sacral vertebrae [12–14]. This is a typical anatomical location of these vessels (in front of the sacral bone). However, to describe the location of the CIVs and IVC formation based on their relationship with the center of the promontorium, a single acceptable location for the CIVs and IVC formation is needed, and such a location is difficult to define.

 $6.00 \pm 6.58$ 

 $22.00 \pm 7.01$ 

 $2.00 \pm 9.73$ 

 $20.00 \pm 11.85$ 

Iatrogenic injury to major vascular structures is a recognized complication of spine surgery [10, 15-18]. Such complications occur during posterior instrumentation of the spine in <1 of every 2000 operations [18, 19]. Injury to the aorta and iliac vessels can carry a mortality rate as high as 61% [19, 20].

In this study, the anatomical location of the CIVs, location of IVC formation, and distance between right and left CIVs

varied in each individual (Table 6). Additionally, statistically significant differences in the correlation of the right and left CIVs with the center of the promontorium were observed between males and females. The existence of all of these differences is one of the main obstacles to designing a safe screw trajectory for S1.

0.74 (0.58-0.84)

0.79(0.66-0.88)

0.78(0.64 - 0.87)

0.92(0.87-0.95)

The area between the right and left CIVs at the level of the promontorium seems to be safe if the tip of the screw penetrates the anterior wall of S1, but this distance is not uniform in all humans. We found a statistically significant correlation of the distance of the right and left CIVs at the level of promontorium with the location of the IVC formation. Therefore, we classified the IVC formation into three main groups: low formation (at the level of the L5-S1 disc space or L5 caudal endplate), medium formation (at the level of the L5 vertebral body), and high formation (at the level of the L4-L5 disc space and L4 vertebral body). In the low IVC formation group, the distance between the right and left CIVs at the level of the promontorium was significantly shorter than that in the high IVC formation group. This

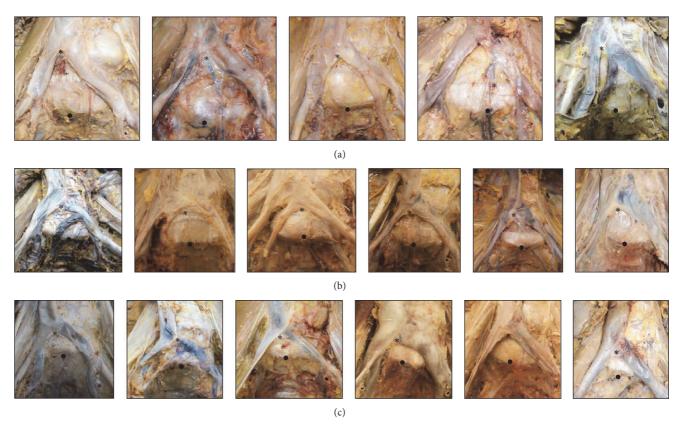


FIGURE 5: Three different levels of the inferior vena cava (IVC) formation ((a) high, (b) medium, and (c) low). \*Level of IVC formation. • Tip of promontorium.

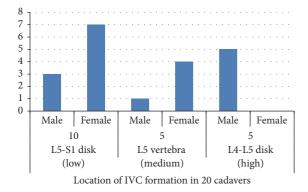


FIGURE 6: Distance between the level of inferior vena cava (IVC) formation and the promontorium in males and females.

indicates that if the tip of the screw penetrates the anterior cortex of the sacrum during screw insertion, the chance of a CIV injury is higher in the presence of a low IVC formation than a high IVC formation.

In tricortical S1 pedicle screw purchase, Matsukawa et al. [3] recommend a screw orientation trajectory located as medially as possible in relation to the sacral midline. In this method, the anterior cortex of S1 is penetrated to achieve tricortical enhancement. We found that penetration of the

SI anterior cortex in each trajectory before evaluation of the location of the CIVs and IVC formation increases the chance of iatrogenic vessel injury because the location of these structures is not uniform in all humans.

Esses et al. and Ergur et al. strongly recommended avoiding anterior cortex penetration because of the risk of neurovascular injury [2, 9]. Our findings support those of other studies that recommended prevention of anterior cortex penetration during SI screw insertion.

Mirkovic et al. [13] defined two safe zones for S1 screw placement: a medial safe zone and a lateral safe zone. The medial safe zone is bordered laterally by the sacroiliac joint, and its medial border is delineated by the lumbosacral trunk. The second zone lies between the sacral promontory medially and the internal iliac vein laterally. In the present study, the medial safe zone in female and low IVC formation was very narrow. Additionally, we found a dilated median sacral vein passing from the medial safe zone in 20% of cadavers, and this vein is highly susceptible to injury if the anterior cortex of S1 is penetrated by a screw.

Therefore, we strongly recommend avoiding penetration of the anterior wall of the S1 vertebra during S1 screw insertion in any trajectory, even in the center of the promontorium, because of the variable locations of the CIVs and dilated median sacral vein.

The risk of CIV injury is higher on the left than on the right side if the anterior cortex of S1 is accidently penetrated

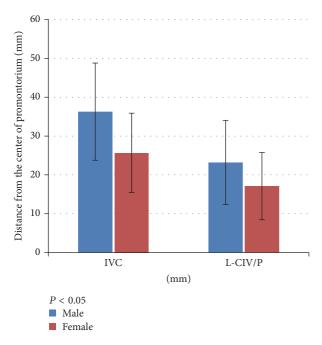


FIGURE 7: Location of the inferior vena cava (IVC) formation and the left common iliac vein (LCIV) from the center of the promontorium in males and females.

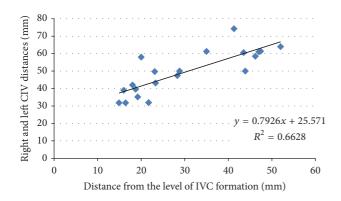


FIGURE 8: Correlation between level of inferior vena cava (IVC) formation and distance of right and left common iliac veins (CIVs) at the level of the promontorium.

during the operation. Moreover, the risk of both right and left CIV injury during S1 screw implantation is higher in females than in males. The risk of CIV injury on either side is greater in patients with a low IVC formation than in those with high IVC formation.

Based on the findings of the present study, we present the following tips for safe TASS implantation:

- (a) The tip of the screw should not penetrate the anterior cortex of the S1 vertebra.
- (b) The length of the screw should range from 32 to 35 mm.
- (c) A maximum screw length and low-risk trajectory can be achieved by insertion of screw at -10° toward the

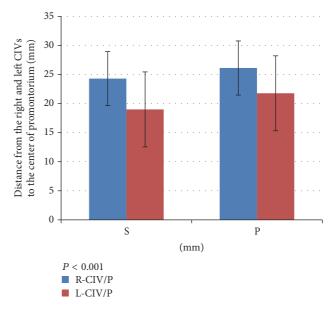


FIGURE 9: Distance from right and left common iliac veins (CIVs) to the center of the promontorium. S: level of the S1 cranial endplate; P: 1 cm caudal to the cranial S1 endplate.

tip of the promontorium (directed 10° medially from the insertion point).

(d) CT evaluation before screw insertion is recommended to check the location of the CIVs, the level of the IVC formation, and selection of the appropriate screw length based on the axial and sagittal planes.

The information provided in this study will be useful for prevention of iatrogenic CIV injury during S1 screw implantation. Additionally, the mini-open anterior approach for L5-S1 fusion and instrumentation involves implantation of a cage between L5 and S1; therefore, a wide distance between the right and left CIVs is safer than a narrow distance. Spine surgeons can detect high-risk patients by checking the level of the IVC formation and distance of the right and left CIVs at the level of the promontorium based on the preoperative CT.

Some limitations of this study require acknowledgment. We used CTM images, which are less sensitive than CT angiography for detection of the CIVs. Additionally, embalmed specimens were used for this study, and we cannot exclude potential artifacts resulting from the embalming processes. The specimens were of relatively advanced age; thus, integrant spine scoliosis, anterior longitudinal ligament ossification, and other degenerative changes may have been present and might have changed some features of the CIV structures. Finally, we used Japanese cadavers, and our results might not be applicable to other races.

#### 5. Conclusion

The TASS trajectory is safe as long as the anterior cortex of the SI vertebra is not penetrated by the screw. The level of the IVC formation is a good indicator with which to predict the

Table 6: Locations of common iliac veins and inferior vena cava formation in 20 cadavers.

Cadaver	R-CIV/P (mm)	L-CIV/P (mm)	R-CIV/L-CIV (mm)	IVC/P (mm)
1	37.1	27.3	64.2	52.3
2	33.3	28.4	61.3	47.4
3	19.2	20.1	39.4	16.3
4	40.2	18.3	58.2	20.6
5	19.1	23.2	42.3	18.3
6	29.3	2.8	31.8	14.9
7	32.8	14.6	47.4	28.3
8	30.6	30.8	61.4	47.4
9	36.1	24.7	61.3	35.2
10	28.9	16.3	43.2	23.3
11	26.3	23.7	50.3	43.9
12	24.2	36.4	60.6	43.5
13	26.1	5.8	31.9	21.7
14	32.5	7.1	39.6	18.7
15	27.2	31.5	58.5	46.2
16	42.3	32.3	74.3	41.3
17	24.3	6.6	31.8	16.4
18	21.8	13.3	35.2	19.2
19	38.3	11.4	49.7	23.1
20	27.1	23.5	50.2	28.8
Mean	29.7	19.8	49.5	30.2
Minimum	19.1	2.8	31.8	14.9
Maximum	42.3	36.4	74.3	52.3
SD	±6.66	±9.86	±12.46	±12.83

R-CIV/P: distance between the right common iliac vein and the center of promontorium; L-CIV/P: distance between the left common iliac vein and the center of promontorium; R-CIV/L-CIV: distance between the right common iliac vein and the left common iliac vein; IVC/P: distance between the level of inferior vena cava formation and the tip of promontorium; SD: standard deviation.

distance between the right and left CIVs at the level of the promontorium. The CIV does not have a uniform anatomical location; therefore, preoperative CT evaluation for confirmation of the CIV location is necessary.

#### **Ethical Approval**

This study protocol was reviewed and approved by the institutional ethics committee of Osaka City University Graduate School of Medicine (Approval no. 2882). The submitted manuscript does not contain any information about medical drugs.

#### **Competing Interests**

The authors declare that there are no competing interests regarding the publication of this paper.

#### Acknowledgments

The authors would like to thank the individuals who donated their bodies for medical research as well as the Department of Anatomy at Osaka City University for their kind cooperation and support.

#### References

- [1] B. J. Morse, N. A. Ebraheim, and W. T. Jackson, "Preoperative CT determination of angles for sacral screw placement," *Spine*, vol. 19, no. 5, pp. 604–607, 1994.
- [2] S. I. Esses, D. J. Botsford, R. J. Huler, and W. Rauschning, "Surgical anatomy of the sacrum: a guide for rational screw fixation," *Spine*, vol. 16, no. 6S, pp. S283–S288, 1991.
- [3] K. Matsukawa, Y. Yato, T. Kato, H. Imabayashi, T. Asazuma, and K. Nemoto, "Cortical bone trajectory for lumbosacral fixation: penetrating S-1 endplate screw technique: technical note," *Journal of Neurosurgery: Spine*, vol. 21, no. 2, pp. 203–209, 2014.
- [4] K. D. K. Luk, L. Chen, and W. W. Lu, "A stronger bicortical sacral pedicle screw fixation through the S1 endplate: an in vitro cyclic loading and pull-out force evaluation," *Spine*, vol. 30, no. 5, pp. 525–529, 2005.
- [5] G. D. Carlson, J. J. Abitbol, D. R. Anderson et al., "Screw fixation in the human sacrum. An in vitro study of the biomechanics of fixation," *Spine*, vol. 17, no. 6, supplement, pp. S196–S203, 1992.
- [6] N. Ebraheim, F. F. Sabry, Y. Nadim, R. Xu, and R. A. Yeasting, "Internal architecture of the sacrum in the elderly. An anatomic and radiographic study," *Spine*, vol. 25, no. 3, pp. 292–297, 2000.
- [7] T. L. Halvorson, L. A. Kelley, K. A. Thomas, T. S. Whitecloud, and S. D. Cook, "Effects of bone mineral density on pedicle screw fixation," *Spine*, vol. 19, no. 21, pp. 2415–2420, 1994.

[8] R. A. Lehman Jr., T. R. Kuklo, P. J. Belmont Jr., R. C. Andersen, and D. W. Polly Jr., "Advantage of pedicle screw fixation directed into the apex of the sacral promontory over bicortical fixation: a biomechanical analysis," *Spine*, vol. 27, no. 8, pp. 806–811, 2002.

- [9] I. Ergur, O. Akcali, A. Kiray, C. Kosay, and H. Tayefi, "Neurovascular risks of sacral screws with bicortical purchase: an anatomical study," *European Spine Journal*, vol. 16, no. 9, pp. 1519–1523, 2007.
- [10] P. C. Jutte and R. M. Castelein, "Complications of pedicle screws in lumbar and lumbosacral fusions in 105 consecutive primary operations," *European Spine Journal*, vol. 11, no. 6, pp. 594–598, 2002.
- [11] G. O. Chong, Y. H. Lee, D. G. Hong, Y. L. Cho, and Y. S. Lee, "Anatomical variations of the internal iliac veins in the presacral area: clinical implications during sacral colpopepxy or extended pelvic lymphadenectomy," *Clinical Anatomy*, vol. 28, no. 5, pp. 661–664, 2015.
- [12] C. S. Ramesh Babu, R. Lalwani, and I. Kumar, "Right double inferior vena cava (IVC) with preaortic iliac confluence case report and review of literature," *Journal of Clinical and Diagnostic Research*, vol. 8, no. 2, pp. 130–132, 2014.
- [13] S. Mirkovic, J. J. Abitbol, J. Steinman et al., "Anatomic consideration for sacral screw placement," *Spine*, vol. 16, no. 6, supplement, pp. S289–S294, 1991.
- [14] T. Nagashima, J. Lee, K. Andoh et al., "Right double inferior vena cava: report of 5 cases and literature review," *Journal of Computer Assisted Tomography*, vol. 30, no. 4, pp. 642–645, 2006.
- [15] S. Anda, S. Aakhus, K. O. Skaanes, E. Sande, and H. Schrader, "Anterior perforations in lumbar discectomies. A report of four cases of vascular complications and a CT study of the prevertebral lumbar anatomy," *Spine*, vol. 16, no. 1, pp. 54–60, 1991.
- [16] J. E. Lonstein, F. Denis, J. H. Perra, M. R. Pinto, M. D. Smith, and R. B. Winter, "Complications associated with pedicle screws," *Journal of Bone and Joint Surgery—A*, vol. 81, no. 11, pp. 1519– 1528, 1999.
- [17] S. Papadoulas, D. Konstantinou, H. P. Kourea, N. Kritikos, N. Haftouras, and J. A. Tsolakis, "Vascular injury complicating lumbar disc surgery. A systematic review," *European Journal of Vascular and Endovascular Surgery*, vol. 24, no. 3, pp. 189–195, 2002.
- [18] D. H. Szolar, K. W. Preidler, H. Steiner et al., "Vascular complications in lumbar disk surgery: report of four cases," *Neuroradiology*, vol. 38, no. 6, pp. 521–525, 1996.
- [19] S. A. Loh, T. S. Maldonaldo, C. B. Rockman et al., "Endovascular solutions to arterial injury due to posterior spine surgery," *Journal of Vascular Surgery*, vol. 55, no. 5, pp. 1477–1481, 2012.
- [20] H. Bingol, F. Cingoz, A. T. Yilmaz, M. Yasar, and H. Tatar, "Vascular complications related to lumbar disc surgery," *Journal of Neurosurgery*, vol. 100, no. 3, pp. 249–253, 2004.

Hindawi Publishing Corporation BioMed Research International Volume 2016, Article ID 7261027, 6 pages http://dx.doi.org/10.1155/2016/7261027

# Clinical Study

# Miniopen Transforaminal Lumbar Interbody Fusion with Unilateral Fixation: A Comparison between Ipsilateral and Contralateral Reherniation

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Received 8 June 2016; Revised 30 September 2016; Accepted 11 October 2016

Academic Editor: Hiroaki Nakamura

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The aim of this study was to evaluate the risk factors between ipsilateral and contralateral reherniation and to compare the effectiveness of miniopen transforaminal lumbar interbody fusion (TLIF) with unilateral fixation for each group. From November 2007 to December 2014, clinical and radiographic data of each group (ipsilateral or contralateral reherniation) were collected and compared. Functional assessment (Visual Analog Scale (VAS) score and Japanese Orthopaedic Association (JOA)) and radiographic evaluation (fusion status, disc height, lumbar lordosis (LL), and functional spine unit (FSU) angle) were applied to compare surgical effect for each group preoperatively and at final followup. MacNab questionnaire was applied to further evaluate the satisfactory rate after the discectomy and fusion. No difference except pain-free interval was found between ipsilateral and contralateral groups. There was a significant difference in operative time between two groups. No differences were found in clinical and radiographic data for assessment of surgical effect between two groups. The satisfactory rate was decreasing in both groups with time passing after discectomy. Difference in pain-free interval may be a distinction for ipsilateral and contralateral reherniation. Miniopen TLIF with unilateral pedicle screw fixation can be a recommendable way for single level reherniation regardless of ipsilateral or contralateral reherniation.

#### 1. Introduction

Recurrent lumbar disc herniation (rLDH) refers to disc herniation occurring at the ipsilateral or contralateral side of previous operation level and causes clinical symptoms after more than six months of "painless" period from primary surgery [1–3]. Many risk factors have been reported to be associated with rLDH, including age, gender, traumatic history, and disc degeneration [1, 4]; however, most risk factors are focused on ipsilateral reherniation, and only a few articles pay attention to the contralateral reherniation. Evidences show that different pathogenic mechanism may exist in those two kinds of reherniation [5, 6].

Recurrent lumbar herniation has become a common reason for revision surgery, and the optimal surgical treatment for rLDH is still controversial. Some authors propose that repeat discectomy is the treatment of choice, which could

achieve satisfactory clinical outcome comparable to the primary procedure, and some spine surgeons believe that fusion is a reasonable choice as repeated discectomy requires more removal of disc materials, which would potentially affect the segmental stability; besides, the presence of scar tissue may increase the risk of nerve injury or dural tear [5, 7, 8]. Several articles have reported that TLIF with bilateral fixation is a recommendable choice for rLDH with satisfied surgical effect [8, 9]. Sonmez and Xue analyzed patients who underwent unilateral percutaneous instrumentation plus TLIF for rLDH and compared them with bilaterally instrumented group. Both groups had a significant decrease in VAS and JOA scores after surgery, while unilateral instrumented group had some advantages in operation time, blood loss, and economic cost [10, 11]. Up to now, no articles have been concerned with the difference which may exist between ipsilateral and contralateral reherniation after fusion. The aim of this

study is to evaluate the risk factors between ipsilateral and contralateral reherniation and to compare the effectiveness of miniopen transforaminal lumbar interbody fusion (TLIF) with unilateral fixation for ipsilateral reherniation with those for contralateral ones.

#### 2. Materials and Methods

2.1. Patient Group. From November 2007 to December 2014, 38 patients who were treated with unilateral pedicle screw instrumented TLIF were included in this study; among them, 31 patients with ipsilateral reherniation were set as group I and 7 patients with contralateral reherniation were set as group II. The inclusion criteria were (1) recurrent disc herniation nonresponse to conservative treatment of more than 3 months; (2) over 6 months of pain-free period after primary discectomy; (3) ipsilateral or contralateral disc herniation observed on imaging at the same level as the primary discectomy. Patients with pathological vertebral fracture, severe osteoporosis of the spine, active infection, or spinal metastasis were excluded. All patients developed back/leg pain, leg numbness, or intermittent claudication after an initial painfree interval, which was averaged 63.3 months (range 6-228 months) following discectomy. All cases were single level recurrent herniation with imaging confirmed (Figure 1).

2.2. Risk Factors Evaluation. The patients were divided into ipsilateral or contralateral group based on the orientation of the reherniation. Demographic and clinical data including age, gender, pain-free interval, LDH types, and traumatic history were compared between two groups. Radiographic factors including disc height (DH), lumbar lordosis (LL), and functional spine unit (FSU) angle were compared; two experienced spine surgeons who were blind to the clinical data took the measurement of radiographic value. DH, LL, and FSU angle were measured as the figure showed (Figure 2).

2.3. Surgical Procedure. All operations were conducted by the same surgeon in a single center. After successful general anesthesia, the patient was placed in a prone position, and the surgical level was confirmed with the help of a C-arm machine. A paramedian longitudinal incision about 4 cm long was made on the reherniation side. Paraspinal muscle was split and retracted to expose the articular process, transverse process, and lamina. According to the surface location and anatomic marker, two pedicle screws were placed, and then the inferior and superior articular processes, part of lamina, and ligamentum flavum were removed, to decompress the nerve root, A complete discectomy and end-plate preparation were performed; thereafter, a suitable cage filled with autologous bone, which came from the resected bones, was placed obliquely across the disc space, and then connecting rod was installed, followed by the fluoroscopy confirmation. After washing the wound with saline, a drainage tube was placed, and the incision was sutured by layers.

2.4. Surgical Outcome Evaluation. Perioperative parameters of both groups including incision length, intraoperative blood loss, drainage volume, operative time, hospital stay,

TABLE 1: Risk factors data analysis.

	G	roup	
Parameters	Ipsilateral (31)	Contralateral (7)	
Age (years)	51.9 ± 11.4	46.3 ± 11.1	0.258
Gender (male/female)	19:12	3:4	0.425
Pain-free interval (months)	$54.3 \pm 51.2$	$102.9 \pm 79.0$	0.048
Fused segment			
L4-L5	20	2	0.108
L5-S1	11	5	0.106

Data presented as mean  $\pm$  SD. P < 0.05 was considered to be significant.

and postoperative complications were obtained from hospital records and compared. Visual Analog Scale (VAS) score and Japanese Orthopaedic Association (JOA) were applied to assess the pain and functional outcome for each group preoperatively and at final followup. The patients were examined with X-ray films at 2, 6, and 12 months and annually thereafter after surgery. Three-dimensional CT (3DCT) scan was performed at 6 months and yearly to assess the fusion status accurately. Solid fusion was defined as bone bridging the disk space without lucency according to the 3DCT with sagittal and coronal reconstruction [12]. MacNab questionnaire was applied to further evaluate the satisfactory rate after the discectomy and fusion for each group.

2.5. Data Analysis. Statistical analysis was performed with SPSS 20.0 (SPSS, Inc., Chicago, IL, USA). The data of ipsilateral and contralateral groups were compared by two independent sample t-test and Fisher's exact test. A P value < 0.05 was considered to be significant.

#### 3. Results

The 38 patients were followed up for a mean duration of 52.2 months, ranging from 12 to 93 months. Risk factors evaluation was shown in Table 1; there was no statistical significance for the two groups in age, gender, and traumatic history. Painfree interval had significant difference between two groups and contralateral group has longer time of pain-free interval compared to that of ipsilateral group. Protruded and extruded type were more common in ipsilateral reherniation while extruded type except one protruded patient makes up the majority of contralateral reherniation group before the first surgery. Both groups have no sequestered patient. After the discectomy, the ratio of those types has no significant statistic difference (Table 2).

Perioperative parameters including incision length, blood loss, drainage volume, operative time, and hospital time were shown in Table 3. There was no statistical significant difference existing between the ipsilateral and contralateral group regarding the perioperative parameters except the operative time. One patient in ipsilateral group had superficial wound infection after surgery. The situation was under control after several dressing changes. No other complications such as dural tear were observed among these patients during the perioperative period. For radiographic data, DH, LL, and FSU angle and fused segment have no statistical difference for two

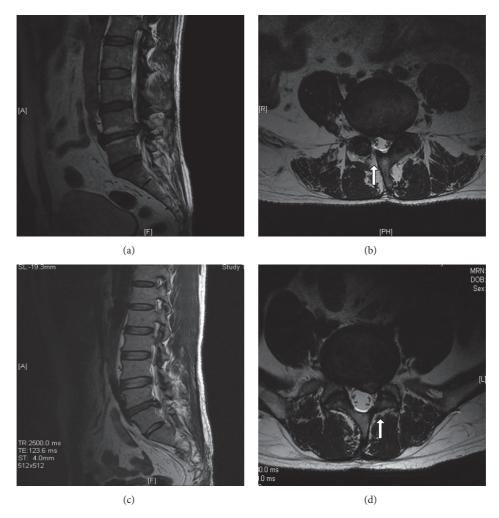


FIGURE 1: T2 sagittal (a) and axial (b) MRI show contralateral reherination; T2 sagittal (c) and axial (d) MRI show ipsilateral reherination. The arrow reflecting the laminectomy defect due to previous surgery.

Table 2: Types of lumbar disc herniation distribution of two groups before and after discectomy.

Para	meters		Groups	
	LDH types	Ipsilateral (31)	Contralateral (7)	P
	Protruded- type	18	1	
Before discectomy	Extruded- type	13	6	0.09
	Sequestered- type	0	0	
	Protruded- type	14	3	
After discectomy	Extruded- type	17	4	1.00
	Sequestered- type	0	0	

Data presented as mean  $\pm$  SD. P < 0.05 was considered to be significant.

groups before and after discectomy and after fusion with unilateral fixation TLIF (Table 4). Compared with preoperative

Table 3: Perioperative parameters in patients undergoing unilateral fixation TLIF for the treatment of recurrent herniation.

Variable	Ipsilateral (31)	Contralateral (7)	P
Incision length (cm)	$4.0 \pm 0.3$	$4.1 \pm 0.2$	0.408
Intraoperative blood loss (mL)	$119.5 \pm 78.4$	$75.7 \pm 36.5$	0.161
Drainage volume (mL)	$118.6 \pm 82.6$	174.3 ± 111.7	0.139
Operative time (minutes)	$86.8 \pm 18.9$	$70.0 \pm 17.3$	0.038
Hospital time (days)	$9.7 \pm 3.1$	$9.3 \pm 1.7$	0.713

Data presented as mean  $\pm$  SD. P < 0.05 was considered to be significant.

values, the lumbar JOA scores of last followup were obviously improved. The postoperative VAS score was obviously lower than that of preoperative. Both groups showed no statistical significance in preoperative and postoperative score and fusion rate (Table 5). The satisfactory rates were decreasing in





FIGURE 2: Preoperative and 3-day postoperative anterior-posterior X-ray images showing unilateral pedicle screw instrumented TLIF on L4-5 level. The angle of lumbar lordosis was measured between the superior endplate of L1 and S1. The functional spine unit was measured between the superior endplate and inferior endplate of fusion segment. The mean disc height was defined as the arithmetic mean between anterior and posterior disc height.

TABLE 4: Radiographic evaluation before and after discectomy and after fusion with unilateral fixation TLIF for the treatment of recurrent herniation.

		Gro		
Period	Parameters	Ipsilateral (31)	Contralateral (7)	P
	Disc height	$11.2\pm1.0$	$10.6\pm1.2$	0.211
Before discectomy	Functional spine unit	$16.8 \pm 4.9$	$13.6 \pm 2.9$	0.113
	Lumbar lordosis	$34.2 \pm 8.1$	$36.6 \pm 4.9$	0.468
After discectomy	Disc height	$11.1\pm2.1$	$11.8\pm1.5$	0.404
	Functional spine unit	$16.5 \pm 4.8$	$15.0 \pm 5.9$	0.472
	Lumbar lordosis	$34.8 \pm 9.2$	$38.5 \pm 5.9$	0.322
After fusion	Disc height	$12.4\pm1.8$	$13.5\pm1.9$	0.170
	Functional spine unit	$17.0 \pm 5.8$	$12.5 \pm 3.4$	0.054
	Lumbar lordosis	$35.6 \pm 10.5$	$33.3 \pm 7.5$	0.590

Data presented as mean  $\pm$  SD. P < 0.05 was considered to be significant.

both groups with time passing. After 6 months from the first surgery, the satisfactory rate was 93.5% (excellent and good according to the Macnab criteria) in ipsilateral group, while in contralateral group the rate was 100% and the rate decreased at 2 years after the discectomy (58.1% in ipsilateral group and 71.4% in contralateral group) and was lower at 4 years after

Table 5: Clinical evaluation before and after unilateral fixation TLIF for the treatment of recurrent herniation.

Variable	Ipsilateral (31)	Contralateral (7)	P
Preoperative			
Back pain VAS score	$6.3 \pm 1.5$	$6.8 \pm 1.4$	0.403
Leg pain VAS score	$7.7 \pm 0.7$	$8.0 \pm 0.4$	0.280
JOA score	$9.0 \pm 1.7$	$8.4 \pm 1.4$	0.367
Last followup			
Back pain VAS score	$1.0\pm0.7$	$1.1\pm0.7$	0.709
Leg pain VAS score	$1.2 \pm 0.9$	$1.4\pm0.5$	0.473
JOA score	$26.2 \pm 1.3$	$26.0 \pm 0.6$	0.614
Fusion rate	90.3%	85.7%	1.000

Data presented as mean  $\pm$  SD, P < 0.05 was considered to be significant.

TABLE 6: Satisfactory rate for two groups after the discectomy and fusion.

Satisfactory	Time	Groups		
rate	111110	Ipsilateral (31)	Contralateral (7)	
After the discectomy	6 months	93.5%	100%	
	2 years	58.1%	71.4%	
	4 years	41.9%	57.1%	
After the	6 months	100%	100%	
fusion	Last followup	96.8%	100%	

surgery (41.9% in ipsilateral group and 57.1% in contralateral group) (Table 6).

#### 4. Discussion

Recurrent lumbar herniation has become a common reason for revision surgery. The incidence of rLDH ranges from 5% to 11% and increases over time [13]. Many risk factors have been reported to be associated with rLDH. Suk et al. reported that young age, male gender, smoking, and traumatic history may be the risk factors for recurrent herniation after conventional open discectomy [1]. In another report, Choi et al. conducted a study which showed that long pain-free interval and mild disc degeneration could differentiate the development of contralateral reherniation from that of ipsilateral reherniation [5]. In our study, pain-free period of contralateral group was significantly longer than that of ipsilateral group as Choi et al. reported. Besides, a longer painfree time may indicate a high satisfactory rate to some extent. Contralateral reherniation may have a different pathology mechanism from that of ipsilateral. The extruded type was more common in contralateral group, for this type of herniation requires more removal of disc materials which may reduce the rate of rLDH in a short time; however, it may also potentially affect the segmental stability and accelerate the disc degeneration. As a result, rLDH will be induced, and it may play more important role in contralateral reherniation.

Surgical treatment for rLDH has been controversial and can be broadly categorized as revision discectomy alone

or revision discectomy with fusion; however, some authors argued that repeat discectomy would weaken the stability of the involved spine and increased the risk of rLDH. Österman et al. in a large retrospective study revealed that patients undergoing multiple revisions after lumbar discectomy got markedly reduced risk for subsequent operations if the first procedure was a spinal fusion [14]. Therefore, it appears to be a reasonable choice for fusing the index level in cases of rLDH. There are many fusing choices including PLF, PLIF, ALIF, and TLIF, the latter of which has been a well-accepted procedure [15]. The use of unilateral pedicle screw fixation with TLIF for rLDH was also reported in some study and the clinical effect was satisfied [10, 11]. Our study demonstrated that JOA and VAS score improved significantly after surgery. Postoperative radiographic result showed a good fusion rate which indicated the effect of this surgical technical. Besides, a miniopen paramedian approach about 4 cm long was applied, which can provide a greater surgical field, and miniopen TLIF required shorter time to learn compared to minimally invasive TLIF [16].

Perioperative parameters data showed no difference between ipsilateral and contralateral group except the operative time, even though the paramedian TLIF can provide a facilitated pathway through the unscarred tissue. However, more attention is still needed to avoid dural rupture or root injury, and this may illustrate the reason for more time in ipsilateral group. Preoperative and postoperative functional evaluation including JOA and VAS had no statistical difference between two groups; the fusion rate was comparable to that of other studies [11, 17]. Satisfactory rate after fusion was quite good at last followup. Taken together, miniopen TLIF with unilateral pedicle screw fixation can be a recommendable way for single level rLDH regardless of ipsilateral or contralateral reherination.

There are some limitations in this study. Firstly, it is a retrospective case-control study, which inevitably has selection and recall bias, despite the fact that we collected and analyzed the data meticulously. Secondly, the number of patients included in this study is relatively small and the followup time is relatively short in some patients. Thus, a randomized controlled study with enough samples is needed to further confirm the safety and effectiveness of this surgical technology.

#### 5. Conclusion

Difference in pain-free interval may be a distinction for ipsilateral and contralateral reherination. Unilateral pedicle screw instrumented TLIF via a miniopen paramedian incision can provide a safe, effective, and less invasive way for the treatment of rLDH regardless of ipsilateral or contralateral reherination.

#### **Competing Interests**

The authors declare that they have no competing interests.

#### **Authors' Contributions**

Zheng Li and Fubing Liu contributed equally to this study.

#### References

- [1] K.-S. Suk, H.-M. Lee, S.-H. Moon, and N.-H. Kim, "Recurrent lumbar disc herniation: results of operative management," *Spine*, vol. 26, no. 6, pp. 672–676, 2001.
- [2] C.-C. Niu, L.-H. Chen, P.-L. Lai, T.-S. Fu, and W.-J. Chen, "Single cylindrical threaded cage used in recurrent lumbar disc herniation," *Journal of Spinal Disorders and Techniques*, vol. 18, no. 1, pp. S65–S72, 2005.
- [3] M. J. McGirt, G. L. Garcés Ambrossi, G. Datoo et al., "Recurrent disc herniation and long-term back pain after primary lumbar discectomy: review of outcomes reported for limited versus aggressive disc removal," *Neurosurgery*, vol. 64, no. 2, pp. 338– 344, 2009.
- [4] M. Shimia, A. Babaei-Ghazani, B. E. Sadat, B. Habibi, and A. Habibzadeh, "Risk factors of recurrent lumbar disk herniation," *Asian Journal of Neurosurgery*, vol. 8, no. 2, pp. 93–96, 2013.
- [5] K. B. Choi, D. Y. Lee, and S.-H. Lee, "Contralateral reherination after open lumbar microdiscectomy: a comparison with ipsilateral reherination," *Journal of Korean Neurosurgical Society*, vol. 44, no. 5, pp. 320–326, 2008.
- [6] G. Cinotti, S. Gumina, G. Giannicola, and F. Postacchini, "Contralateral recurrent lumbar disc herniation: results of discectomy compared with those in primary herniation," *Spine*, vol. 24, no. 8, pp. 800–806, 1999.
- [7] S. Ozgen, S. Naderi, M. M. Ozek, and M. N. Pamir, "Findings and outcome of revision lumbar disc surgery," *Journal of Spinal Disorders*, vol. 12, no. 4, pp. 287–292, 1999.
- [8] Z. Li, J. Tang, S. Hou et al., "Four-year follow-up results of transforaminal lumbar interbody fusion as revision surgery for recurrent lumbar disc herniation after conventional discectomy," *Journal of Clinical Neuroscience*, vol. 22, no. 2, pp. 331–337, 2015.
- [9] Z. Chen, J. Zhao, A. Liu, J. Yuan, and Z. Li, "Surgical treatment of recurrent lumbar disc herniation by transforaminal lumbar interbody fusion," *International Orthopaedics*, vol. 33, no. 1, pp. 197–201, 2009.
- [10] E. Sonmez, I. Coven, F. Sahinturk, C. Yilmaz, and H. Caner, "Unilateral percutaneous pedicle screw instrumentation with minimally invasive tlif for the treatment of recurrent lumbar disk disease: 2 years follow-up," *Turkish Neurosurgery*, vol. 23, no. 3, pp. 372–378, 2013.
- [11] H. Xue, Y. Tu, and M. Cai, "Comparison of unilateral versus bilateral instrumented transforaminal lumbar interbody fusion in degenerative lumbar diseases," *Spine Journal*, vol. 12, no. 3, pp. 209–215, 2012.
- [12] L. Hackenberg, H. Halm, V. Bullmann, V. Vieth, M. Schneider, and U. Liljenqvist, "Transforaminal lumbar interbody fusion: a safe technique with satisfactory three to five year results," *European Spine Journal*, vol. 14, no. 6, pp. 551–558, 2005.
- [13] P. Gaston and R. W. Marshall, "Survival analysis is a better estimate of recurrent disc herniation," *Journal of Bone and Joint Surgery—Series B*, vol. 85, no. 4, pp. 535–537, 2003.
- [14] H. Österman, R. Sund, S. Seitsalo, and I. Keskimäki, "Risk of multiple reoperations after lumbar discectomy: a populationbased study," *Spine*, vol. 28, no. 6, pp. 621–627, 2003.
- [15] T. E. Mroz, D. Lubelski, S. K. Williams et al., "Differences in the surgical treatment of recurrent lumbar disc herniation among spine surgeons in the United States," *Spine Journal*, vol. 14, no. 10, pp. 2334–2343, 2014.

[16] W.-L. Lo, C.-M. Lin, Y.-S. Yeh et al., "Comparing miniopen and minimally invasive transforaminal interbody fusion in singlelevel lumbar degeneration," *BioMed Research International*, vol. 2015, Article ID 168384, 5 pages, 2015.

[17] K. S. Suk, H. M. Lee, N. H. Kim, and J. W. Ha, "Unilateral versus bilateral pedicle screw fixation in lumbar spinal fusion," *Spine*, vol. 25, no. 14, pp. 1843–1847, 2000.

Hindawi Publishing Corporation BioMed Research International Volume 2016, Article ID 1758352, 9 pages http://dx.doi.org/10.1155/2016/1758352

### Clinical Study

## Applying the Mini-Open Anterolateral Lumbar Interbody Fusion with Self-Anchored Stand-Alone Polyetheretherketone Cage in Lumbar Revision Surgery

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Received 23 May 2016; Revised 4 September 2016; Accepted 28 September 2016

Academic Editor: Hiroaki Nakamura

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The author retrospectively studied twenty-two patients who underwent revision lumbar surgeries using ALLIF with a self-anchored stand-alone polyetheretherketone (PEEK) cage. The operation time, blood loss, and perioperative complications were evaluated. Oswestry disability index (ODI) scores and visual analog scale (VAS) scores of leg and back pain were analyzed preoperatively and at each time point of postoperative follow-up. Radiological evaluation including fusion, disc height, foraminal height, and subsidence was assessed. The results showed that the ALLIF with a self-anchored stand-alone PEEK cage is safe and effective in revision lumbar surgery with minor surgical trauma, low access-related complication rates, and satisfactory clinical and radiological results.

#### 1. Introduction

Posterior approaches, such as posterior lumbar interbody fusion (PLIF) and transforaminal lumbar interbody fusion (TLIF), are commonly used in revision lumbar surgery partially because of their advantage of directly removing problematic implants and fractured screws and rods [1, 2]. Solid lumbar fusion requires internal fixation to help achieve immobilization. However, these approaches also increase the risk of damaging the posterior muscular elements, leading to long-term back pain [1]. In addition, extensive adjacentlevel facet joint violations have been reported with posterior revision surgery, which theoretically leads to instability of the upper adjacent level and may accelerate adjacent segment degeneration (ASD) [3, 4]. Significantly higher incidental durotomy rates have been found in posterior revision surgery than in primary surgery due to scar tissue adhesion [5]. Anterior lumbar interbody fusion (ALIF) is an alternative approach when dealing with ASD, recurrent disc herniation, cage migration, and pseudarthrosis. It provides direct access to the vertebral column and allows more extensive decompression of the disc space and better end plate preparation for arthrodesis, while simultaneously restoring disc height and correct lumbar kyphosis [6]. Moreover, ALIF avoids posterior

muscle trauma, adjacent-level facet joint violation, and acceleration of ASD [6, 7]. Nevertheless, access-related complications have been documented, such as urethral injury, bowel perforation, incisional hernia, neurological injury, ileus, and retrograde ejaculation in men, with vascular injury being the most disastrous [2, 7–11]. The transpoas exposure of extreme lateral interbody fusion (XLIF) reduces manipulation of the aorta and vena cava; hence, the incidence of vascular injury is lower [12–15]. However, this approach is associated with access-related thigh symptoms, such as numbness, pain, and weakness, resulting from injury of the lumbar plexus or motor nerves, especially when the L4/5 level is involved [16].

Minimally invasive lumbar surgery techniques were first described by Mayer in 1997, which were advocated as an alternative to anterior or posterior approaches for lumbar fusion with less surgical trauma and quicker recovery [17]. This approach used a psoas-preserving access to the lumbar spine via the anterior oblique retroperitoneal approach, but with less invasion of the psoas muscle and lumbar plexus than XLIF. To distinguish this new technique from other minimally invasive ALIF, Silvestre et al. renamed it the oblique lumbar interbody fusion (OLIF) [13]. However, the L5/S1 level can only be achieved through transperitoneal approaches, which provides only indirect decompression. It is

still not possible to treat conditions such as recurrent lumbar disc herniation without subsequent posterior surgery, which inevitably increases the surgical trauma.

The recently developed mini-open OLIF allows psoas-preserving access to the lumbar spine via the anterior oblique retroperitoneal approach with less invasion of the psoas muscle and a reduced incidence of lumbar plexus and motor nerve injury [18]. However, this approach allows only a limited operative field, and direct decompression is hard to achieve. Although it has been reported that spinal stenosis could be resolved successfully by indirect decompression, posterior fixation cannot be avoided [18]. In this study, for the first time, an ALLIF using a self-anchored standalone polyetheretherketone (PEEK) cage was used to increase the visual field and to facilitate direct decompression. The safety and efficacy of this procedure were also evaluated to investigate whether it could serve as a new alternative to anterior revision surgery after posterior lumbar surgery.

#### 2. Materials and Methods

2.1. Study Population. Between April 2012 and April 2014, a total of 22 patients who underwent the ALLIF revision surgery and met the following criteria were recruited: (1) initial posterior surgery for lumbar degenerative disc disease or lumbar spondylolisthesis, (2) age between 18 and 65 years, (3) patients with back and/or leg pain after initial surgery who were unresponsive to appropriate conservative treatment, (4) having conditions such as recurrent disc herniation, pseudarthrosis, adjacent segment degeneration, or cage migration confirmed by computed tomography (CT) or magnetic resonance imaging (MRI), and (5) having 24 months or more of follow-up data. Patients with the following criteria were excluded: (1) previous abdominal or anterior lumbar surgery history, (2) posterior scarred adhesion compressing the nerve structure confirmed by medical history or physical or radiological examination, (3) abdominal aortic aneurysm or severe peripheral vascular disease, (4) obesity with BMI  $\geq$  28 kg·m<sup>2</sup>, and (5) severe osteoporosis. The characteristics of these included patients were listed in Table 1. The mean follow-up time was  $24.6 \pm 6.7$  months. All procedures were performed by the same surgeon (Lü), who has rich experience with anterior lumbar surgery and laparoscopic lumbar surgery for lumbar degenerative disease, deformity, tumor, and infection.

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in this study.

2.2. Surgical Procedure. Patients were placed in the supine position. A transverse skin incision of 4 to 6 cm was made on the lateral wall of abdomen, parallel to the projection of the affected disc level (Figure 1). The external oblique, internal oblique, and transverse abdominal muscles were

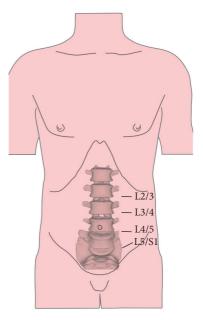


FIGURE 1: A transverse or oblique 4 to 6 cm skin incision was made on the lateral wall of the abdomen, parallel to the projection of the affected disc level.

then bluntly dissected. The peritoneal content was mobilized inwardly. Headlights were used to illuminate the operation field. The lateral edges of the iliac artery and the iliac vein were bluntly separated from the spine using gentle, peanut sponge, and fingertip dissection. A hand-held abdominal retractor was placed on the anterolateral part of the spine with vessels and the peritoneal contents retracted medially. For operations at and above L4/L5, the psoas muscle and lumbar plexus were identified and mobilized. Another hand-held abdominal retractor was placed on the lateral side of the spine gently retracting the psoas muscle and sympathetic nerves posteriorly. The intervertebral disc was exposed between the psoas muscle and aorta. For operations at L5/S1, exposure was carried out below the aortic bifurcation or over the shoulder of the aortic bifurcation (between the psoas muscle and left iliac artery) according to the relationship of aorta and the L5/S1 disc, assessed by CTA or MR preoperatively (Figure 2). The operation levels were identified fluoroscopically. After discectomy, a nerve hook was used to explore the lateral recess and posterior edge of the vertebra to confirm complete decompression. Endplate preparation was performed using curettes. The disc space was distracted using a parallel distractor. A proper-sized self-anchored PEEK cage (ROI-A® Oblique, LDR Médical, Troyes, France) (Figure 2(c)) was determined by trials under fluoroscopy. Cages were inserted obliquely into intervertebral space using fluoroscopy after filling with porous bioceramic artificial bone (Dragonbio®, Hubei, China). Once the position of the cage was optimal, two self-guided anchoring plates were inserted into the adjacent vertebrae under fluoroscopy.

2.3. Clinical Outcome Measurements. Operative time, blood loss, and intra- and postoperative complications were noted.

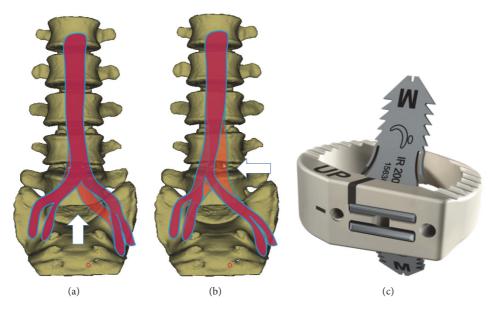


FIGURE 2: (a) The access to L5/S1 when the aortic bifurcation is high. (b) The access to L5/S1 when the aortic bifurcation is low. (c) The self-anchored PEEK cage we used in the study (ROI-A Oblique, LDR Médical, Troyes, France).

Clinical outcomes including the Oswestry low back pain disability index (ODI) and visual analog scale (VAS) for back pain and leg pain were measured preoperatively and postoperatively at 3, 6, 12, and 24 months.

2.4. Radiological Outcome Measurements. Fusion was identified by the presence of continuous bridging trabeculae at the graft and end plate junction on radiographs or CT scans [19]. Pseudarthrosis was defined when assessment failed to meet the fusion criteria at the last follow-up. Other radiological outcomes (foraminal height, disc height, and subsidence) were measured preoperatively and at 2 days and 3, 6, 12, and 24 months postoperatively. Disc height was defined as the mean value of the anterior disc height and posterior disc height. The foraminal height was determined as the longest distances between the craniocaudal dimensions of the foramen [20]. Subsidence was defined as any compromise of either vertebral endplate visible on CT scan or X-ray [21].

2.5. Statistical Analysis. All statistical analyses were conducted using SPSS version 19.0 software (SPSS Inc., Chicago, IL, USA). Comparisons between the preoperative and post-operative parameters within the groups were performed using a paired t-test. A p value < 0.05 was considered statistically significant.

#### 3. Results

Patient characteristics including age, gender, primary surgery, primary operation levels, reasons for revision surgery, and revision levels are summarized in Table 1. There were 13 females and 9 males aged between 48 and 63 years with a total of 27 segments enrolled in this study. There were 7 patients excluded for meeting the exclusion criteria. The

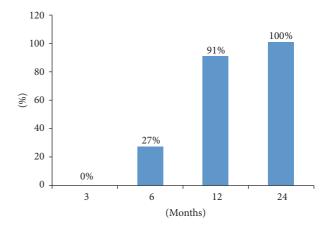


FIGURE 3: A column diagram demonstrating the fusion rate of the patients at each time point.

average age was  $55.4\pm5.5$  years. Of all these 22 patients, 19 had posterior instrumentation in their previous surgery. And 7 of them experienced the failure of the posterior instrumentation before the revision surgery. The single-level cases included 9 cases at L4/5, 2 cases at L3/4, and 6 cases at L5/S1; 5 cases were with two levels. Only one patient suffered from peritoneal rupture during the exposure. No other perioperative complications were found. Four patients with 4 operated levels suffered cage subsidence without clinical symptoms (Table 1). Fusion was achieved in all patients (Figure 3).

The average operating time was  $68.6 \pm 22.9$  minutes, and the average estimated blood loss was  $85.4 \pm 34.7$  mL. As shown in Table 2, the VAS back pain score decreased from  $5.8 \pm 1.5$  preoperatively to  $2.2 \pm 0.9$ ,  $2.4 \pm 1.0$ ,  $2.4 \pm 0.8$ , and  $2.3 \pm 0.9$  postoperatively at 2 weeks and 3, 6, 12, and 24 months, respectively (p < 0.05). The average VAS leg pain score also

TABLE I: Characteristics of 22 patients who underwent revision lumbar surgery using ALLIF with self-anchored stand-alone PEEK cage.

		•		· ·		o	
Patient number	Gender	Age	Primary surgery	Reasons for revision surgery	Operation levels	Posterior fixation	Cage subsidence
1	Female	56	TLIF for L4/5 LDH	Implant migration	L4/5	Intact	No
2	Male	61	TLIF for L3/L4, L4/5 LDH	Implant migration	L3/4, L4/5	Intact	No
3	Female	61	TLIF for L4/5, L5/S1 LDH	Pseudarthrosis	L4/5, L5/S1	Breakage of the screw	L4/5
4	Female	49	PLIF for L4/5 LDH	ASD	L5/S1	Intact	No
5	Female	57	TLIF for L5/S1 LDH	ASD	L4/5	Intact	No
9	Female	50	PLIF for L5/S1 LDH	ASD	L4/5	Intact	No
7	Male	52	TLIF for L5/S1 LDH	ASD	L4/5	Intact	No
8	Female	63	TLIF for L4/5 LDH	ASD	L5/S1	Intact	No
6	Male	53	TLIF for L3/L4, L4/5 LDH	Pseudarthrosis	L3/4, L4/5	Breakage of the rod	L4/5
10	Male	48	L5/S1 discectomy	Recurrent disc herniation	L5/S1	None	No
11	Female	42	L4/5 discectomy	Recurrent disc herniation	L4/5	None	No
12	Male	62	L4/5 discectomy	Recurrent disc herniation	L4/5	None	
13	Female	55	TLIF for L5 spondylolisthesis	ASD	L4/5	Intact	No
14	Female	28	Decompression and PLF for L5/S1 LDH	Recurrent disc herniation	L5/S1	Intact	No
15	Male	99	TILF for L4/5 LDH	Pseudarthrosis	L4/5	Breakage of the rod	No
16	Male	09	Decompression and PLF for L4/5 LDH	Recurrent disc herniation	L4/5	Intact	No
17	Female	59	TLIF for L5 spondylolisthesis	Pseudarthrosis at L5/S1 and ASD at L4/5	L4/5, L5/S1	Breakage of the rod	L4/5
18	Female	63	TLIF for L4 spondylolisthesis	ASD	L5/S1	Intact	No
19	Male	52	TLIF for L5 spondylolisthesis	Pseudarthrosis	L5/S1	Screw loosening	L5/S1
20	Female	57	PLIF for L3/4, L4/5 LDH	Pseudarthrosis	L3/4	Intact	No
21	Female	50	TLIF for L3/4, L4/5 LDH	Pseudarthrosis at L4/5 and ASD at L5/S1	L4/5, L5/S1	Intact	No
22	Male	54	PLIF for L3/4, L4/5, L5/S1 LDH	Pseudarthrosis at L4/5	L4/5	Breakage of the rod	No
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PLIF: posterior lumbar interbody fusion, PLF: posterolateral lumbar fusion, TLIF: transforaminal lumbar interbody fusion, LDH: lumbar disc herniation, and ASD: adjacent segment degeneration.

TABLE 2: Clinical outcomes measured by VAS and ODI scor	Table 2: Clinical	outcomes measured	d bv '	VAS	and	ODI score
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	Preop	3 months	6 months	12 months	24 months
VAS back pain	$5.8 \pm 1.5$	$2.2 \pm 0.9^*$	$2.4 \pm 1.0^*$	$2.4 \pm 0.8^*$	$2.3 \pm 0.9^*$
VAS leg pain	$5.3 \pm 1.6$	$2.0 \pm 1.3^*$	$2.2 \pm 1.3^*$	$2.3 \pm 1.0^*$	$2.1 \pm 1.1^*$
ODI	$42.7 \pm 12.6\%$	$25.5 \pm 8.5\%^*$	$23.8 \pm 6.8^*$	$23.4 \pm 6.1\%^*$	$24.0 \pm 6.5\%$

<sup>\*</sup>Statistically significant compared with preoperation (p < 0.05).

Preop: preoperatively, 3 months: 3 months postoperatively, 6 months: 6 months postoperatively, and 12 months: 12 months postoperatively.

TABLE 3: Radiological outcome measured by disc height and foraminal height (mm).

	Preop	Postop	3 months	6 months	12 months	24 months
Disc height	$8.6 \pm 2.5$	$12.3 \pm 1.5^*$	$11.8 \pm 2.2^*$	$11.6 \pm 2.3^*$	$11.3 \pm 2.3^*$	11.0 ± 2.0*
Foraminal height	$15.8 \pm 3.4$	$19.4 \pm 2.8^*$	$19.0 \pm 3.1^*$	$18.7 \pm 2.7^*$	$18.5 \pm 2.5^*$	$18.2 \pm 2.7^*$

<sup>\*</sup>Statistically significant compared with preoperation (p < 0.05).

Preop: preoperatively, postop: postoperatively, 3 months: 3 months postoperatively, 6 months postoperatively, and 12 months: 12 months: 12 months postoperatively.

decreased from  $5.3 \pm 1.6$  preoperatively to  $2.0 \pm 1.3$ ,  $2.2 \pm 1.3$ ,  $2.3 \pm 1.0$ , and  $2.1 \pm 1.1$  at 3, 6, 12, and 24 months, respectively (p < 0.05). The average preoperative ODI score was  $42.7 \pm 12.6\%$ . Similarly, at 3, 6, 12, and 24 months after surgery, the postoperative ODI scores were significantly decreased to  $27.5 \pm 8.2\%$ ,  $25.5 \pm 8.5\%$ ,  $23.8 \pm 6.8\%$ , and  $23.4 \pm 6.1\%$ , respectively (p < 0.05).

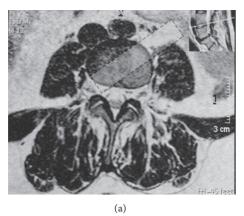
The average foraminal height was  $15.8 \pm 3.4$  mm before surgery and increased postoperatively to  $19.4 \pm 2.8$  mm at 2 days,  $19.0 \pm 3.1$  mm at 3 months,  $18.7 \pm 2.7$  mm at 6 months,  $18.5 \pm 2.5$  at 12 months, and  $18.2 \pm 2.7$  mm at 24 months (p < 0.05). The average disc height also increased from  $8.6 \pm 2.5$  mm preoperatively to  $12.3 \pm 1.5$  mm,  $11.8 \pm 2.2$  mm,  $11.6 \pm 2.3$  mm,  $11.3 \pm 2.3$  mm, and  $11.0 \pm 2.0$  at 2 days and 3, 6, 12, and 24 months after surgery, respectively (p < 0.05). The results are summarized in Table 3.

#### 4. Discussion

Anterior lumbar spinal surgery has been commonly used in conditions that include disc degeneration, trauma, infection, deformity, and tumor with approaches such as ALIF, XLIF, and OLIF [7]. Recently, these anterior approaches were adopted in lumbar revision surgery [5, 22]. Mamuti et al. retrospectively reviewed 35 patients who underwent mini-open retroperitoneal anterior lumbar interbody fusion using selfanchored cage device for the treatment of recurrent lumbar disc herniation following primary posterior instrumentation [23]. Their result showed good clinical and radiological outcomes without complications related to surgical technique and cage device. Furthermore, Mobbs et al. recommended that anterior lumbar interbody fusion could be a salvage technique for pseudarthrosis following posterior lumbar fusion surgery when the chronic low back pain raised by pseudarthrosis was nonresponsive to conservative management [24]. Anterior lumbar interbody fusion could provide a wider implant bed and more meticulous preparations of endplates for arthrodesis, which lead to the high fusion rate theoretically.

The approach-related complications concern most researchers. Bateman et al. performed a systematic review

to identify the types and incidence rates of complications associated with various approaches to anterior lumbar spine surgery. The results showed that the overall complication rate was 14.1% with intraoperative and postoperative complication rates of 9.1% and 5.2%, respectively. The most common complications reported were venous injury (3.2%), retrograde ejaculation (2.7%), neurologic injury (2%), prosthesis-related (2%), postoperative ileus (1.4%), superficial infection (1%), and complications classified as "others" (1.3%). Laparoscopic and transperitoneal procedures were associated with higher complication rates, whereas lower complication rates were observed in patients receiving mini-open techniques. A study by Fujibayashi et al. evaluated twenty-eight patients who underwent OLIF for lumbar degeneration disease [18]. Two cases of hip flexor weakness and 6 cases of thigh pain/numbness that resolved spontaneously within 3 months after operation were observed. In our study, no major approach-related complications, such as vascular injuries, ureteral injuries, visceral complication (bowel perforation), ileus, incisional hernia, or retrograde ejaculation, were observed. This suggested that the ALLIF technique is a relatively safe procedure. Other factors attributing to a low complication rate should also be considered. All procedures were performed by skilled surgeons with extensive anterior spinal surgery experience. Preoperative CT angiography was taken to evaluate difficulties in the exposure because vascular injuries were prone to occur in presence of anatomical variation, or with surrounding scar tissue [25]. Because micromotion in the bone-graft interface is believed to be one of the main reasons for pseudarthrosis and cage subsidence [1, 26], additional pedicle screws have been used to provide sufficient primary stability after mini-open OLIF [18]. However, the self-anchored PEEK cage we used (ROI-A Oblique, LDR Médical, Troyes, France) has two integrated self-locking clips bridging the index levels which was designed to provide stronger lumbar stability, avoid the motions between the adjacent vertebral bodies, and promote solid fusion. A biomechanical test revealed that the self-locking stand-alone cage could provide immediate stability that was equivalent to that with anterior plate or posterior pedicle screw fixation [27]. Clinical studies have also demonstrated that a high



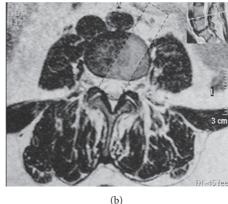


FIGURE 4: (a) Only indirect decompression can be achieved in OLIF because of the limited operation angle and field. (b) A wider operation angle and space can be provided for direct decompression in ALLIF with the skin incision placed closer to the middle line of the abdomen.

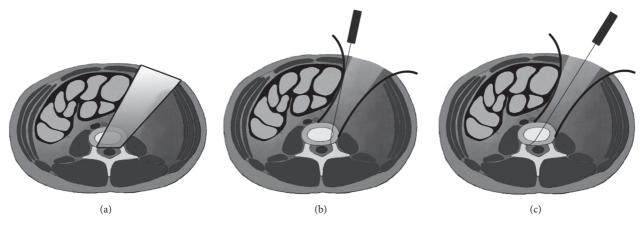


FIGURE 5: (a) The ideal operation field for direct decompression. ((b) and (c)) The operation field of the ALLIF.

fusion rate (90.6% to 97.3%) with good clinical results could be achieved using these self-anchored designed stand-alone cages [3, 25, 28]. In our study all patients achieved solid fusion at the last follow-up which supported the hypothesis that these self-anchored stand-alone cages could provide immediate stability after surgery and reach high fusion rate.

In our ALLIF, a transverse skin incision placed closer to the middle line of the abdomen was made on the lateral wall at the outer rim of abdominal rectus muscle, compared with the typical incision for OLIF. This slight adjustment provides a wider visual and operative field (Figure 4). All discectomy procedures could be performed under direct visualization, which made it possible to decompress the neurological structure bilaterally without damaging the nerve element or dural sac, thus avoiding posterior decompression surgery. A nerve hook could be used to explore the lateral recess and posterior edge of the vertebra to confirm complete and thorough decompression, which could not be achieved in the OLIF because of the operation angle (Figure 5). The indirect decompression in OLIF is achieved by disc distraction and not by the removal of the compressing element. The better operation angle in ALLIF also makes it possible to access

every L5/S1 level, even in patients with a high-riding pelvis, which may not be possible in OLIF. Moreover, the cage was easily inserted obliquely along this access angle, which largely reduced the manipulation of the aorta and vena cava, decreasing the risk of vascular injury compared with ALIF. Retraction of vascular structures throughout an entire procedure was blamed for the increase in vessel injuries and thrombotic events in OLIF [7, 29]. Therefore, we used handheld abdominal retractors instead of self-retaining retractors to expose the discs, for they could be released intermittently to minimize the risk of vascular thrombosis. Besides, in the traditional OLIF, the access to disc of L5/S1 was below the aortic bifurcation. In our ALLIF, the access to L5/S1 disc could be below the aortic bifurcation or over the shoulder of the aortic bifurcation (between the psoas muscle and left iliac artery) according to the vascular windows at L5/S1 disc assessed by CTA or MR preoperatively. In an anatomy study by Molinares et al., 31% of MR images of patients (31/100) showed no anterior access to L5/S1 disc. However, in 4 (12.9%) of these 31 MR images, an oblique access to L5/S1 disc was found between the psoas muscle and iliac artery. We also adopted the muscle-splitting approach in our study as the

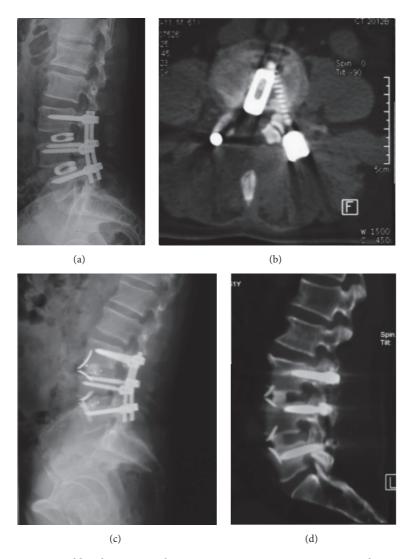


FIGURE 6: Case presentation. A 61-year-old male patient with previous PLIF surgery at L3-L5 10 months ago was admitted because of the recurrence of back and leg pain. Cage migration was confirmed by both radiograph and CT scan ((a) and (b)). ALLIF revision surgery using a self-anchored cage was performed. Good position of cage levels and satisfactory alignment of the lumbar spine were achieved (c). Fusion was achieved at 12-month follow-up (d).

so-called "sliding window" technique described by Mayer [17]. Thus, we could easily expose two discs with a slight increase in skin incision length.

The patients in our study showed significant improvement in disc height and foraminal height compared with the preoperation status at each time point (Figure 6). In addition, the VAS and ODI scores decreased significantly after surgery compared to baseline. Studies by Siepe et al. [3] and Allain et al. [28] have shown similar results with significant improvement in disc height and foraminal height and decrease in VAS and ODI scores at each time point of follow-up after surgery. Subsidence of the implant into the vertebral endplate may lead to progressive lumbar deformity and recurrence of foraminal stenosis and neurological symptoms, which have been of concern to researchers. The subsidence rate has varied in different studies using a self-anchor stand-alone cage without posterior fixation. In the

study by Allain et al., 1 out of 51 analyzed cases experienced subsidence at a 12-month follow-up using cages similar to those we used [28]. Behrbalk et al. reported that 16% (5/32) of cases of subsidence were observed with ALIF using another kind of self-anchor stand-alone cage (SynFix-LR) without posterior instrumentation [30, 31]. A decreased bone mineral density, an increased number of fused segments, damage of the endplate, overdistraction of the surgical segment, and use of oversized cages are thought to contribute to subsidence [32-34]. Beutler and Peppelman Jr. found that most of the subsidence cases happen in the first 3 months postoperatively [32]. Besides, they demonstrated that the cage subsidence is usually accompanied by the appearance of the pseudarthrosis. The long-term micromotion at the nonfused segment damaged the endplate and absorbed the cancellous bone underneath. In the present study, 18.2% (4/22) of patients suffered subsidence and all cases of subsidence were observed before the first 6-month follow-up. Nevertheless, all cases of subsidence reached solid fusion at the last follow-up. Study showed that although the subsidence was not uncommon, the rate of symptomatic subsidence is relatively low. In the study of Le et al., radiographical subsidence occurred in 14.3% (20/140) and the symptomatic subsidence was noted only in 2.1% (3/140) of all patients [33]. In our series, all patients with cage subsidence had no clinical symptoms. Researches demonstrated that the caudal endplate is weaker than the cranial one [33, 34]. Thus the caudal endplate is at higher risk of injury with the stronger cranial endplate usually remaining intact. Similarly, in our series, the damage of caudal endplate was found in all cases with only one case of cranial endplate damage.

This study has several potential limitations. It was a non-controlled study with a relatively small number of patients, and the inclusion criteria were restrictive. Patients with osteo-porosis or with risk factors of access-related complication were excluded, which may have led to an underestimation of the rates of nonunion, subsidence, and access-related complications.

#### 5. Conclusion

The ALLIF using a self-anchored stand-alone PEEK cage is a relatively new surgical technique for lumbar revision that provides a wide visual field for operations such as direct decompression. This technique is a safe and effective method in revision lumbar surgery with only limited surgical trauma, low access-related complication rates, and satisfactory clinical and radiological results. The decreased incidence in nonunion and cage subsidence observed may be attributed to the delicate design of this self-anchored PEEK cage.

#### **Competing Interests**

The authors declare that they have no conflict of interests. None of the authors has received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article.

#### References

- [1] P. Strube, E. Hoff, T. Hartwig, C. F. Perka, C. Gross, and M. Putzier, "Stand-alone anterior versus anteroposterior lumbar interbody single-level fusion after a mean follow-up of 41 months," *Journal of Spinal Disorders and Techniques*, vol. 25, no. 7, pp. 362–369, 2012.
- [2] A. J. Talia, M. L. Wong, H. C. Lau, and A. H. Kaye, "Comparison of the different surgical approaches for lumbar interbody fusion," *Journal of Clinical Neuroscience*, vol. 22, no. 2, pp. 243– 251, 2015.
- [3] C. J. Siepe, K. Stosch-Wiechert, F. Heider et al., "Anterior standalone fusion revisited: a prospective clinical, X-ray and CT investigation," *European Spine Journal*, vol. 24, no. 4, pp. 838– 851, 2015.
- [4] Z. Li, J. Tang, S. Hou et al., "Four-year follow-up results of transforaminal lumbar interbody fusion as revision surgery

- for recurrent lumbar disc herniation after conventional discectomy," *Journal of Clinical Neuroscience*, vol. 22, no. 2, pp. 331–337, 2015
- [5] S. I. Tafazal and P. J. Sell, "Incidental durotomy in lumbar spine surgery: incidence and management," *European Spine Journal*, vol. 14, no. 3, pp. 287–290, 2005.
- [6] K. D. Than, A. C. Wang, S. U. Rahman et al., "Complication avoidance and management in anterior lumbar interbody fusion," *Neurosurgical Focus*, vol. 31, no. 4, article E6, 2011.
- [7] D. K. Bateman, P. W. Millhouse, N. Shahi et al., "Anterior lumbar spine surgery: a systematic review and meta-analysis of associated complications," *Spine Journal*, vol. 15, no. 5, pp. 1118– 1132, 2015.
- [8] E. Escobar, E. Transfeldt, T. Garvey, J. Ogilvie, J. Graber, and L. Schultz, "Video-assisted versus open anterior lumbar spine fusion surgery: a comparison of four techniques and complications in 135 patients," *Spine*, vol. 28, no. 7, pp. 729–732, 2003.
- [9] J. D. Schwender, M. T. Casnellie, J. H. Perra et al., "Perioperative complications in revision anterior lumbar spine surgery: incidence and risk factors," *Spine*, vol. 34, no. 1, pp. 87–90, 2009.
- [10] C.-H. Flouzat-Lachaniette, W. Delblond, A. Poignard, and J. Allain, "Analysis of intraoperative difficulties and management of operative complications in revision anterior exposure of the lumbar spine: a report of 25 consecutive cases," *European Spine Journal*, vol. 22, no. 4, pp. 766–774, 2013.
- [11] A. A. Gumbs, N. D. Bloom, F. D. Bitan, and S. H. Hanan, "Open anterior approaches for lumbar spine procedures," *The American Journal of Surgery*, vol. 194, no. 1, pp. 98–102, 2007.
- [12] B. D. Grimm, D. P. Leas, S. C. Poletti, and D. N. Johnson, "Postoperative complications within the first year after extreme lateral interbody fusion: experience of the first 108 patients," *Clinical Spine Surgery*, vol. 29, no. 3, pp. E151–E156, 2016.
- [13] C. Silvestre, J.-M. Mac-Thiong, R. Hilmi, and P. Roussouly, "Complications and morbidities of mini-open anterior retroperitoneal lumbar interbody fusion: oblique lumbar interbody fusion in 179 patients," *Asian Spine Journal*, vol. 6, no. 2, pp. 89–97, 2012.
- [14] R. Q. Knight, P. Schwaegler, D. Hanscom, and J. Roh, "Direct lateral lumbar interbody fusion for degenerative conditions: early complication profile," *Journal of Spinal Disorders and Techniques*, vol. 22, no. 1, pp. 34–37, 2009.
- [15] W. B. Rodgers, E. J. Gerber, and J. Patterson, "Intraoperative and early postoperative complications in extreme lateral interbody fusion: an analysis of 600 cases," *Spine*, vol. 36, no. 1, pp. 26–32, 2011.
- [16] K. S. Cahill, J. L. Martinez, M. Y. Wang, S. Vanni, and A. D. Levi, "Motor nerve injuries following the minimally invasive lateral transpsoas approach: clinical article," *Journal of Neurosurgery: Spine*, vol. 17, no. 3, pp. 227–231, 2012.
- [17] H. M. Mayer, "A new microsurgical technique for minimally invasive anterior lumbar interbody fusion," *Spine*, vol. 22, no. 6, pp. 691–699, 1997.
- [18] S. Fujibayashi, R. A. Hynes, B. Otsuki, H. Kimura, M. Takemoto, and S. Matsuda, "Effect of indirect neural decompression through oblique lateral interbody fusion for degenerative lumbar disease," *Spine*, vol. 40, no. 3, pp. E175–E182, 2015.
- [19] J. W. Brantigan and A. D. Steffee, "A carbon fiber implant to aid interbody lumbar fusion: two-year clinical results in the first 26 patients," *Spine*, vol. 18, no. 14, pp. 2106–2117, 1993.

- [20] T. Hasegawa, H. S. An, V. M. Haughton, and B. H. Nowicki, "Lumbar foraminal stenosis: critical heights of the intervertebral discs and foramina. A cryomicrotome study in cadavera," *Journal of Bone and Joint Surgery—Series A*, vol. 77, no. 1, pp. 32–38, 1995.
- [21] J. H. Lee, D.-W. Jeon, S.-J. Lee, B.-S. Chang, and C.-K. Lee, "Fusion rates and subsidence of morselized local bone grafted in titanium cages in posterior lumbar interbody fusion using quantitative three-dimensional computed tomography scans," *Spine*, vol. 35, no. 15, pp. 1460–1465, 2010.
- [22] S. A. Brau, R. B. Delamarter, M. A. Kropf et al., "Access strategies for revision in anterior lumbar surgery," *Spine*, vol. 33, no. 15, pp. 1662–1667, 2008.
- [23] M. Mamuti, S. Fan, J. Liu et al., "Mini-open anterior lumbar interbody fusion for recurrent lumbar disc herniation following posterior instrumentation," *Spine*, vol. 41, no. 18, pp. E1104– E1114, 2016.
- [24] R. Mobbs, K. Phan, G. Thayaparan, and P. Rao, "Anterior lumbar interbody fusion as a salvage technique for pseudarthrosis following posterior lumbar fusion surgery," *Global Spine Journal*, vol. 6, no. 1, pp. 14–20, 2016.
- [25] V. Saraph, C. Lerch, N. Walochnik, C. M. Bach, M. Krismer, and C. Wimmer, "Comparison of conventional versus minimally invasive extraperitoneal approach for anterior lumbar interbody fusion," *European Spine Journal*, vol. 13, no. 5, pp. 425–431, 2004.
- [26] J. Li, M. L. Dumonski, Q. Liu et al., "A multicenter study to evaluate the safety and efficacy of a stand-alone anterior carbon I/F Cage for anterior lumbar interbody fusion: two-year results from a Food and Drug Administration investigational device exemption clinical trial," *Spine*, vol. 35, no. 26, pp. E1564–E1570, 2010.
- [27] M. B. Kornblum, A. W. L. Turner, G. B. Cornwall, M. A. Zatushevsky, and F. M. Phillips, "Biomechanical evaluation of stand-alone lumbar polyether-ether-ketone interbody cage with integrated screws," *Spine Journal*, vol. 13, no. 1, pp. 77–84, 2013.
- [28] J. Allain, J. Delecrin, J. Beaurain, A. Poignard, T. Vila, and C.-H. Flouzat-Lachaniette, "Stand-alone ALIF with integrated intracorporeal anchoring plates in the treatment of degenerative lumbar disc disease: a prospective study on 65 cases," *European Spine Journal*, vol. 23, no. 10, pp. 2136–2143, 2014.
- [29] J. K. Czerwein Jr., N. Thakur, S. J. Migliori, P. Lucas, and M. Palumbo, "Complications of anterior lumbar surgery," *Journal of the American Academy of Orthopaedic Surgeons*, vol. 19, no. 5, pp. 251–258, 2011.
- [30] E. Behrbalk, O. Uri, R. M. Parks, R. Musson, R. C. C. Soh, and B. M. Boszczyk, "Fusion and subsidence rate of stand alone anterior lumbar interbody fusion using PEEK cage with recombinant human bone morphogenetic protein-2," *European Spine Journal*, vol. 22, no. 12, pp. 2869–2875, 2013.
- [31] C. H. Kim, C. K. Chung, T. Jahng, S. B. Park, S. Sohn, and S. Lee, "Segmental kyphosis after cervical interbody fusion with standalone polyetheretherketone (PEEK) cages," *Journal of Spinal Disorders and Techniques*, vol. 28, no. 1, pp. E17–E24, 2015.
- [32] W. J. Beutler and W. C. Peppelman Jr., "Anterior lumbar fusion with paired BAK standard and paired BAK proximity cages: subsidence incidence, subsidence factors, and clinical outcome," *Spine Journal*, vol. 3, no. 4, pp. 289–293, 2003.
- [33] T. V. Le, A. A. Baaj, E. Dakwar et al., "Subsidence of polyetheretherketone intervertebral cages in minimally invasive lateral retroperitoneal transpsoas lumbar interbody fusion.," *Spine*, vol. 37, no. 14, pp. 1268–1273, 2012.

[34] G. M. Malham, R. M. Parker, C. M. Blecher, and K. A. Seex, "Assessment and classification of subsidence after lateral interbody fusion using serial computed tomography," *Journal of Neurosurgery: Spine*, vol. 23, no. 5, pp. 589–597, 2015.

Hindawi Publishing Corporation BioMed Research International Volume 2016, Article ID 3267307, 5 pages http://dx.doi.org/10.1155/2016/3267307

#### Research Article

# **Interspinous Process Decompression: Expanding Treatment Options for Lumbar Spinal Stenosis**

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Received 6 August 2016; Accepted 19 September 2016

Academic Editor: Anthony T. Yeung

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Interspinous process decompression is a minimally invasive implantation procedure employing a stand-alone interspinous spacer that functions as an extension blocker to prevent compression of neural elements without direct surgical removal of tissue adjacent to the nerves. The Superion® spacer is the only FDA approved stand-alone device available in the US. It is also the only spacer approved by the CMS to be implanted in an ambulatory surgery center. We computed the within-group effect sizes from the Superion IDE trial and compared them to results extrapolated from two randomized trials of decompressive laminectomy. For the ODI, effect sizes were all *very large* (>1.0) for Superion and laminectomy at 2, 3, and 4 years. For ZCQ, the 2-year Superion symptom severity (1.26) and physical function (1.29) domains were *very large*; laminectomy effect sizes were *very large* (1.07) for symptom severity and *large* for physical function (0.80). Current projections indicate a marked increase in the number of patients with spinal stenosis. Consequently, there remains a keen interest in minimally invasive treatment options that delay or obviate the need for invasive surgical procedures, such as decompressive laminectomy or fusion. Stand-alone interspinous spacers may fill a currently unmet treatment gap in the continuum of care and help to reduce the burden of this chronic degenerative condition on the health care system.

#### 1. Introduction

Lumbar spinal stenosis is a classic neural compression syndrome where spine extension causes constriction of the nerve roots exiting the spinal column. Stenotic arthritic encroachment reduces the foraminal aperture resulting in the primary patient complaint of intermittent neurogenic claudication [1]. A simple postural solution to resolve these symptoms is to move the spine into flexion thereby decompressing the nerve roots. The "gold standard" surgical option, laminectomy, decompresses the neural structures by directly removing

impinging ligament and bone [2]. Over 175,000 surgeries are performed to treat spinal stenosis annually in the US, making it the number one reason for spine surgery in the elderly population [3].

As an alternative, interspinous process decompression is a minimally invasive procedure that builds on the concept that back extension is a seminal factor in the causative chain that instigates neurogenic claudication. This procedure involves the implantation of a stand-alone interspinous spacer that functions by serving as a lumbar vertebral joint extension blocker to prevent compression of neural elements

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FIGURE 1: The Superion interspinous spacer.

in extension. The spacer blocks the extension motion without exposure or removal of tissue adjacent to the dura or exiting nerves [4].

On 20 May 2015, the US Food and Drug Administration (FDA) approved the Superion Interspinous Decompression System (VertiFlex, San Clemente, CA, USA) for commercial distribution. Not requiring concomitant surgical decompression, this second generation stand-alone interspinous device is the only spacer commercially available to physicians in the US (Figure 1). Following US regulatory approval, the Superion achieved a number of consequential and significant regulatory and clinical milestones. First, the AMA CPT® Editorial Panel approved the addition of Category I CPT codes to describe one- and two-level insertion of standalone interspinous spacers at their October 2015 meeting. Effective January 1, 2017, the new Category I codes will replace the existing Category III CPT codes that applied to first generation spacers. Second, the Centers for Medicare and Medicaid Services (CMS) added the insertion of interspinous spacers to their list of approved surgical procedures in Ambulatory Surgery Centers, effective January 1, 2016. Additionally, several peer reviewed publications of the Superion Investigational Device Exemption (IDE) trial have documented the large, statistically significant improvements achieved in condition-specific, pain, and functional clinical outcomes following device implantation at 6 months, 2 years, and 3 years [7-10]. Accomplishing this series of milestones substantiates the graduation of the Superion device from a concept with potential to an acceptable and practical clinical modality for the treatment of intermittent symptoms of neurogenic claudication secondary to moderate spinal stenosis.

#### 2. Materials and Methods

The Superion is indicated to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (intermittent neurogenic claudication) secondary to a diagnosis of moderate degenerative lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, confirmed by X-ray, MRI, and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. The Superion is indicated for those patients

with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain, and who have undergone at least 6 months of nonoperative treatment. The Superion may be implanted at one or two adjacent lumbar levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5 (Figure 2).

For this intended use, moderate degenerative lumbar spinal stenosis is defined as follows:

- (i) 25% to 50% reduction in the central canal and/or nerve root canal (subarticular, neuroforaminal) compared to the adjacent levels on radiographic studies, with radiographic confirmation of any one of the following:
  - (a) Evidence of thecal sac and/or cauda equina compression
  - (b) Evidence of nerve root impingement (displacement or compression) by either osseous or non-osseous elements
  - (c) Evidence of hypertrophic facets with canal encroachment
- (ii) Also associated with the following clinical signs:
  - (a) Present with moderately impaired physical function (PF) defined as a score of ≥2.0 of the Zurich Claudication Questionnaire (ZCQ)
  - (b) Ability to sit for 50 minutes without pain and to walk 50 feet or more.

To gauge the practical clinical significance of the published Superion IDE findings, we computed the within-group (i.e., Superion arm only) effect size at each annual postoperative interval compared to baseline for each clinical outcome separately through 4 years using Cohen's formula and thresholds [11, 12]. The effect size is computed as the standardized difference between two means or, simply put, the mean score (preop) – mean score (follow-up)/standard deviation of the change. Effect sizes are typically reported in the range from 0.0 (no effect) to >1.0 (very large effects) with the following thresholds: 0.2 (small effect), 0.5 (medium effect), 0.8 (large effect), and >1.0 (very large effect). The effect size calculation provides some normalization for baseline and distribution imbalances.

We identified two published laminectomy studies that included at least one of the same outcomes as the Superion IDE trial and included sufficient data to compute corresponding effect sizes. First, the Superion IDE results were compared with published findings for decompressive laminectomy by extrapolating within-group 4-year effect sizes for the Oswestry Disability Index (ODI) from the published report of the NIH-sponsored SPORT trial, the largest study of surgical and nonsurgical management of lumbar stenosis [5, 13]. Similarly, we estimated the 2-year effect size for Zurich Claudication Questionnaire (ZCQ) symptom severity and physical function domains for decompressive laminectomy based on the published report of Strömqvist et al. [6].

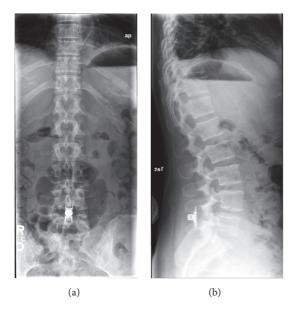


FIGURE 2: Anteroposterior (a) and lateral (b) plain radiographic images showing proper anatomical positioning of the Superion spacer in situ.

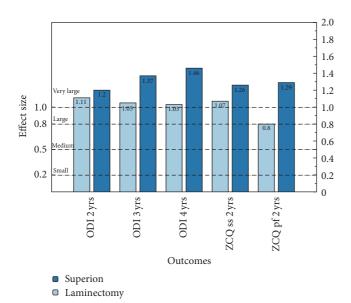


FIGURE 3: Within-group effect sizes calculated from the Superion IDE trial in contrast with comparable effect size extrapolated from the SPORT trial [5] for ODI outcomes at 2, 3, and 4 years of follow-up and from Strömqvist et al. [6] for ZCQ symptom severity (ss) and physical function (pf) at 2 years of follow-up.

#### 3. Results

The comparative within-group effect sizes for Superion and laminectomy treatments are provided in Figure 3. For back function, the ODI results consistently showed *very large* effect size estimates for both treatments at all follow-up intervals. Superion ODI effect sizes were particularly robust. For condition-specific impairment, the 2-year ZCQ results were similarly robust for Superion treatment with *very large* effect sizes for both the symptom severity and physical function

domains. In contrast, while laminectomy resulted in a *very large* effect size for symptom severity, the physical function domain result just met the threshold for a *large* effect size. Overall, the effect sizes for Superion were uniformly higher than those reported for the "gold standard" treatment and did not exhibit worsening with time.

#### 4. Discussion

The Superion is the second "stand-alone" interspinous spacer approved by the FDA and the only one currently available on the US market. Importantly, the implantation procedure does not cause substantial alterations or disruptions to the spinal anatomy adjacent to neural structures. Specifically, the epidural space is not surgically exposed during spacer insertion, whereas laminectomy decompression directly opens the epidural space. The surgical exposure of the epidural space is known to routinely produce epidural scar, adhesions, and tethering around the dural sac and exiting nerve roots, which can cause symptomatic problems [14, 15]. Additionally, if subsequent surgical procedures are necessary to address progressive degenerative changes and/or reemergence of symptoms, the avoidance of the epidural space in the Superion placement reduces the complexity of future surgical options compared to starting with a laminectomy procedure. Also, if device removal is required, the implant can be explanted via the same minimally invasive access as the original implantation procedure. This suggests that interspinous spacers may be considered a reasonable "first line" option in the continuum of care for the treatment of moderate lumbar spinal stenosis (Figure 4).

The minimization of iatrogenic insult associated with implantation of interspinous spacers significantly reduces the risk of operative adverse events. In a recent review of spinal devices in the Medicare population, higher perioperative complication rates were found in decompression surgeries

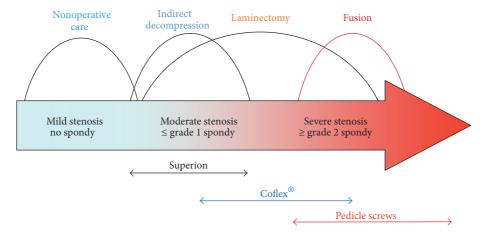


FIGURE 4: The continuum of care of treatment for lumbar spinal stenosis. Superion represents the "first line" option for minimally invasive surgical treatment.

compared to interspinous spacers [16]. Because of the minimally invasive nature of the surgery, implantation of spacers can be accomplished under local anesthesia in an ambulatory surgical setting or with conscious sedation.

Lauryssen et al. [17] documented consistently similar clinical improvements in back and leg pain, back function, and condition-specific impairment for both the Superion and decompressive laminectomy at 2 years postoperatively. Herein, we found robust effect sizes (>1.0) at each postoperative follow-up interval for ODI and ZCQ with Superion treatment, uniformly higher than comparable effect sizes with laminectomy, and the magnitude of the effect size was durable through 4 years of follow-up. While estimates of the practical clinical significance of the Superion compare favorably with published results for laminectomy, enthusiasm should be tempered by the known limitations of using historical controls. Nevertheless, these results are encouraging and support the use of the Superion as an effective treatment option for lumbar spinal stenosis.

#### 5. Conclusions

Interspinous spacers fill a distinct treatment gap in the continuum of care for patients with moderate degenerative lumbar spinal stenosis. These patients have exhausted conservative care but may be inappropriate candidates for or unwilling to undergo surgical decompressive laminectomy. Because spacers are implanted in a minimally invasive fashion without anatomical disruption, they can be easily removed and converted to laminectomy if symptoms reemerge. This study corroborates previous reports that found similar clinical benefit provided by both spacers and laminectomy, providing the patient with a minimally invasive surgical option without compromising the extent or time duration of the symptom relief.

#### **Competing Interests**

Dr. Block received support from VertiFlex to assist in manuscript development. Dr. Blumenthal serves as Medical

Director at VertiFlex. All other authors declare that there is no conflict of interests regarding the publication of this paper.

#### Acknowledgments

The authors thank Terry Meredith for graphical assistance.

#### References

- [1] J. N. Katz and M. B. Harris, "Clinical practice. Lumbar spinal stenosis," *The New England Journal of Medicine*, vol. 358, no. 8, pp. 818–825, 2008.
- [2] G. M. Overdevest, W. Jacobs, C. Vleggeert-Lankamp, C. Thomé, R. Gunzburg, and W. Peul, "Effectiveness of posterior decompression techniques compared with conventional laminectomy for lumbar stenosis," *Cochrane Database of Systematic Reviews*, vol. 3, Article ID CD010036, 2015.
- [3] R. A. Deyo, S. K. Mirza, B. I. Martin, W. Kreuter, D. C. Goodman, and J. G. Jarvik, "Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults," *The Journal of the American Medical Association*, vol. 303, no. 13, pp. 1259–1265, 2010.
- [4] V. Loguidice, W. Bini, S. Shabat, L. E. Miller, and J. E. Block, "Rationale, design and clinical performance of the Superion® Interspinous Spacer: a minimally invasive implant for treatment of lumbar spinal stenosis," *Expert Review of Medical Devices*, vol. 8, no. 4, pp. 419–426, 2011.
- [5] J. N. Weinstein, T. D. Tosteson, J. D. Lurie et al., "Surgical versus nonoperative treatment for lumbar spinal stenosis four-year results of the spine patient outcomes research trial," *Spine*, vol. 35, no. 14, pp. 1329–1338, 2010.
- [6] B. H. Strömqvist, S. Berg, P. Gerdhem et al., "X-stop versus decompressive surgery for lumbar neurogenic intermittent claudication: randomized controlled trial with 2-year followup," *Spine*, vol. 38, no. 17, pp. 1436–1442, 2013.
- [7] L. E. Miller and J. E. Block, "Interspinous spacer implant in patients with lumbar spinal stenosis: preliminary results of a multicenter, randomized, controlled trial," *Pain Research and Treatment*, vol. 2012, Article ID 823509, 10 pages, 2012.
- [8] V. V. Patel, P. D. Nunley, P. G. Whang et al., "Superion® Interspinous spacer for treatment of moderate degenerative lumbar

- spinal stenosis: durable three-year results of a randomized controlled trial," *Journal of Pain Research*, vol. 8, pp. 657–662, 2015.
- [9] V. V. Patel, P. G. Whang, T. R. Haley et al., "Superion interspinous process spacer for intermittent neurogenic claudication secondary to moderate lumbar spinal stenosis: two-year results from a randomized controlled FDA-IDE pivotal trial," *Spine*, vol. 40, no. 5, pp. 275–282, 2015.
- [10] V. V. Patel, P. G. Whang, T. R. Haley et al., "Two-year clinical outcomes of a multicenter randomized controlled trial comparing two interspinous spacers for treatment of moderate lumbar spinal stenosis," *BMC Musculoskeletal Disorders*, vol. 15, no. 1, article 221, 2014.
- [11] L. E. Kazis, J. J. Anderson, and R. F. Meenan, "Effect sizes for interpreting changes in health status," *Medical Care*, vol. 27, no. 3, supplement, pp. S178–S189, 1989.
- [12] G. M. Sullivan and R. Feinn, "Using effect size-or why the P value is not enough," *Journal of Graduate Medical Education*, vol. 4, no. 3, pp. 279–282, 2012.
- [13] J. N. Weinstein, T. D. Tosteson, J. D. Lurie et al., "Surgical versus nonsurgical therapy for lumbar spinal stenosis," *The New England Journal of Medicine*, vol. 358, no. 8, pp. 794–810, 2008.
- [14] P. Fransen, "Prevention of scar tissue formation in spinal surgery: state of the art and review of the literature," *Journal of Neurosurgical Sciences*, vol. 55, no. 3, pp. 277–281, 2011.
- [15] D. E. Jamison, E. Hsu, and S. P. Cohen, "Epidural adhesiolysis: an evidence-based review," *Journal of Neurosurgical Sciences*, vol. 58, no. 2, pp. 65–76, 2014.
- [16] R. A. Deyo, B. I. Martin, A. Ching et al., "Interspinous spacers compared with decompression or fusion for lumbar stenosis: complications and repeat operations in the medicare population," *Spine*, vol. 38, no. 10, pp. 865–872, 2013.
- [17] C. Lauryssen, R. J. Jackson, J. M. Baron et al., "Stand-alone interspinous spacer versus decompressive laminectomy for treatment of lumbar spinal stenosis," *Expert Review of Medical Devices*, vol. 12, no. 6, pp. 763–769, 2015.

Hindawi Publishing Corporation BioMed Research International Volume 2016, Article ID 7901562, 8 pages http://dx.doi.org/10.1155/2016/7901562

#### Research Article

## Modification of Mechanical Properties, Polymerization Temperature, and Handling Time of Polymethylmethacrylate Cement for Enhancing Applicability in Vertebroplasty

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Received 25 June 2016; Accepted 14 September 2016

Academic Editor: Ki-Tack Kim

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Polymethylmethacrylate (PMMA) bone cement is a popular bone void filler for vertebroplasty. However, the use of PMMA has some drawbacks, including the material's excessive stiffness, exothermic polymerization, and short handling time. This study aimed to create an ideal modified bone cement to solve the above-mentioned problems. Modified bone cements were prepared by combining PMMA with three different volume fractions of castor oil (5%, 10%, and 15%). The peak polymerization temperatures, times to achieve the peak polymerization temperature, porosities, densities, modulus and maximum compression strengths of standard (without castor oil), and modified cements were investigated following storage at ambient temperature ( $22^{\circ}$ C) or under precooling conditions ( $3^{\circ}$ C). Six specimens were tested in each group of the aforementioned parameters. Increasing castor oil content and precooling treatment effectively decreased the peak polymerization temperatures and increased the duration to achieve the peak polymerization temperature (P < 0.05). Furthermore, the mechanical properties of the material, including density, modulus, and maximum compression strength, decreased with increasing castor oil content. However, preparation temperature (room temperature versus precooling) had no significant effect (P > 0.05) on these mechanical properties. In conclusion, the addition of castor oil to PMMA followed by precooling created an ideal modified bone cement with a low modulus, low polymerization temperature, and long handling time, enhancing its applicability and safety for vertebroplasty.

#### 1. Introduction

Osteoporosis is common in aging populations. In the US, the prevalence of osteoporosis is 10.3% in adults 50 years and older; women in the same age group have a higher prevalence at 15.4% [1]. The rate of compression fractures is 20% in people 70 years and older and 16% in postmenopausal women [2]. A study by Johnell and Kanis also found that osteoporosis causes more than 8.9 million fractures each year and that osteoporotic fractures occur every 3 seconds [3]. Thus, it is very important to determine how to treat and prevent osteoporotic vertebral compression fractures. In general, vertebroplasty is suggested to treat vertebral

compression fractures to increase the rigidity, supporting force and recovery height of the collapsed spinal vertebrae.

Vertebroplasty is a well-established, common treatment for acute osteoporotic vertebral compression fractures. Vertebroplasty can reduce pain and allows for rapid rehabilitation [4–6]; however, secondary vertebral compression fractures after vertebroplasty with polymethylmethacrylate (PMMA) bone cement augmentation often occur [7], at rates ranging from 12% to 52% [8, 9]. The inherent characteristics of PMMA, such as its excessive stiffness, exothermic polymerization, and short handling time, are considered the main factors leading to surgery failure, particularly for patients with osteoporosis [9–12].

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PMMA bone cement is widely used in vertebroplasty because of its low cost and high stability. However, PMMA has various disadvantages. First, PMMA may cause thermal injury [13, 14], as PMMA polymerizes via an exothermic reaction that can cause necrosis in tissues close to the treatment location. Second, PMMA has high Young's modulus (*E*) and high compressive strength ( $\sigma_c$ ). The Young modulus of PMMA ranges from 2,000 to 3,000 MPa, which is much higher than the Young modulus of spongy bone, which ranges from 50 to 800 MPa [15, 16]. This large difference in material properties increases the risk of secondary fracture [17, 18]. Finally, the handling time of PMMA is short and may be not sufficiently long for clinical use. This is a dangerous factor for patients. In recent years, calcium phosphate cement (CPC) has been designed to resolve the above-listed limitations of PMMA [19]. CPC has low E, low  $\sigma_c$ , low reacting temperature, and established biological activities [20, 21]; however, the lower initial E and the absorption of CPC can lead to other issues. For instance, the initial mechanical strength of CPC may be not sufficient for some osteoporosis cases [22]. The absorption of CPC may lead to collapse of the augmented vertebrae. CPC is also less economical than PMMA and suffers from a lack of clinical studies; thus, methods of improving PMMA for use in hospitals and as a biomaterial are needed.

2

Various methods of improving PMMA have been reported. It has been demonstrated that the addition of castor oil to PMMA can change its mechanical properties by lowering its Young's modulus, compressive strength, and reacting temperature [23, 24]. In our recent study [25], precooling raw PMMA material effectively slowed its polymerization reaction and thus lengthened its handling time in vertebroplasty [25]. Precooling and the addition of castor oil are simple and inexpensive methods of enhancing the applicability of PMMA for clinical settings. However, how PMMA changes following such treatments is currently unknown. Therefore, in the current study, two groups of PMMA samples were investigated: one stored at room temperature and the other stored under precooling conditions. Each group was composed of four different PMMA sample types, created by mixing PMMA with different volumes of castor oil.

#### 2. Materials and Methods

2.1. Sample Preparation. In this study, the commercially available acrylic bone cement Simplex® P (Stryker, Kalamazoo, MI, USA) and castor oil (Hubei Ketian Pharmaceutical Co., Taiwan) were employed. The package of bone cement is composed of 40 g PMMA polymer powder and 20 cc liquid monomer. PMMA samples were divided into two major groups: a normal temperature group (NTG) and a precooling group (PCG). In the NTG, PMMA polymer powder and liquid monomer were maintained at 22°C for 24 hours; in the PCG, they were maintained at 3°C for 24 hours through the use of thermostatic controlling equipment. The two major groups were then divided into four subgroups: one control group and three experimental groups. In the control group, the PMMA polymer powder and liquid monomer were

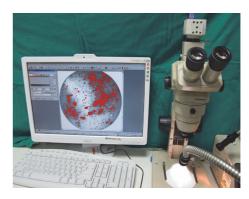


FIGURE 1: Photograph showing the porosity observation. Cavities on the sample surface were observed using an optical microscope. Following an image of the sample was captured, the image was analyzed using Image-Pro Plus 7.0 software.

mixed for 1 minute, and no castor oil was added. This group was designated "M0." For the experimental groups, liquidphase PMMA samples were mixed with castor oil at 5%, 10%, and 15% (wt%) volumes and denoted as "M5," "M10," and "M15," respectively. A maximum content of castor oil of 15 wt% was chosen because, in our pilot study, we found it difficult to achieve a uniform mixing of castor oil when the content of castor oil was up to 20 wt%. This leads to a severely uneven distribution of porosities and also difficulty for injection of the mixture. Unevenly distributed porosity may provide imbalanced support to a vertebral body after vertebroplasty, which may increase the risk of refracture at the weaker side. In the experimental groups, the PMMA polymer powder and liquid monomer were roughly mixed prior to the addition of castor oil. Then, the mixture was blended with castor oil for 1 minute, and the viscosity was measured for 10 seconds after waiting for 1 minute [26]. All of the samples were then divided into eight groups: NTG-M0, NTG-M5, NTG-M10, NTG-M15, PCG-M0, PCG-M5, PCG-M10, and PCG-M15. Blending cement was added to a forming syringe, and the samples were allowed to solidify for 48 hours [27]. Following this, the solidified samples were cut into cylinders with a diameter of 13 mm and a height of 26 mm (by ASTM D695 standard), after which they were subjected to three tests. The size of each sample was verified using Vernier calipers (Mitutoyo, 200 mm/0.02 mm), and a precision balance (HXB 300 g/0.01 g) was used to measure the weight of each sample. Then, the density of each sample was calculated.

2.2. Porosity Observation. Six samples in each subgroup were used to assess porosity. Each sample was polished, and carbon dust was evenly spread on the polished surface to aid in visualizing the porosity. Then, cavities on the sample surface were observed using an optical microscope (SZ-PT, Olympus Co., Japan), and an image of the sample was captured. The image was analyzed using Image-Pro Plus 7.0 software (Image-Pro; Media Cybernetics Inc., Bethesda, MD, USA). Porosity observation using an optical microscope was shown in Figure 1.



FIGURE 2: Photograph showing the compression test of cement sample. The specimen was prepared in a cylindrical shape with a 13 mm diameter and 26 mm height. A 20 mm diameter cylindrical rod was used as a plunger and clamped to the upper side of the wedge grip, connecting to an actuator.

2.3. Compression Test. Compressive testing was conducted according to ASTM D695 guidelines. Six samples in each group were tested to failure under axial compression using an MTS testing machine (Bionix 858, MTS Corp., MN, USA). Each specimen was prepared in a cylindrical shape with a 13 mm diameter and 26 mm height. A 20 mm diameter cylindrical rod was used as a plunger and clamped to the upper side of the MTS wedge grip, connecting to an actuator. Compressive force was applied at a constant crosshead rate of 1.5 mm/min to test the ultimate compression strength of each prepared PMMA specimen. The ultimate compression strength was defined as the measured ultimate compressive force divided by the area of the PMMA sample's radial surface. The instantaneous relationships between the applied force, displacement, and reaction time were simultaneously recorded in increments of 0.05 mm using MTS TestStar II software. The compression test of cement sample was shown in Figure 2.

2.4. Measurement of Temperature Profile. A cylindrical syringe with a diameter of 16 mm was cut to a height of 30 mm and used as a container to hold PMMA for measuring temperature profiles. The prepared samples were divided into two major groups, NTG and PCG, with four subgroups (six samples in each subgroup). PMMA was prepared following the same process described above. After the polymer powder and liquid monomer were mixed, the mixture was added to the cavity of the syringe up to 20 mm in height (Figure 3(a)). A height of 20 mm was chosen because it was determined to be similar to that of the vertebral body. Then, a thermocouple (DTM319, Tecpel Co., Taiwan) was inserted into the bone cement to a depth of 10 mm (Figure 3(b)). The temperature change in the center of each sample was measured, and the setting temperature ( $T_{\rm set}$ ) was calculated using the equation  $T_{\text{set}} = (T_{\text{max}} + T_{\text{amb}})/2$  following ASTM-F451 specifications ( $T_{\rm amb}$ : ambient room temperature, 22°C) [23]. The handling time (HT) was defined as the duration from the start of mixing to  $T_{\rm set}$ .

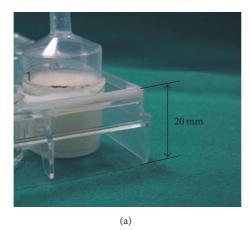
2.5. Statistical Analysis. All of the measurements were collected in six trials and are expressed as the mean  $\pm$  standard deviation (SD). Nonparametric Mann–Whitney U test was performed to evaluate difference among groups. Differences were considered significant at P < 0.05.

#### 3. Results

3.1. Maximum Polymerization Temperature and Handling Time. The average maximum polymerization temperatures  $(T_{\text{max}})$  and handling times (HT) for the samples with various contents of castor oil in the NTG and the PCG are shown in Figures 4 and 5. The results showed that the maximum polymerization temperature decreased with increasing castor oil content (Figure 4). In the normal temperature group (NTG-M0 to NTG-M15), the maximum temperature  $(T_{\text{max}})$ decreased by 35.82% between the NTG-M0 (102.18  $\pm$  3.87°C) and NTG-M15 (65.58  $\pm$  2.76°C) samples (P < 0.05). In the precooling group, a similar trend was observed. Between the PCG-M0 (93.28  $\pm$  13.91°C) and PCG-M15 (60.28  $\pm$  2.79°C) samples,  $T_{\text{max}}$  declined by 35.4%. However, there were no significant declines between the M5 and M10 groups in either the NTG or the PCG (P > 0.05). The handling time (HT) was prolonged in all groups (Figure 5). Further analysis of the NTG and the PCG showed that the HT significantly increased as the castor oil content increased. There was a 121.6% increase (P < 0.05) between the NTG-M15 (12.10  $\pm$  0.61 min) and the NTG-M0 (5.46  $\pm$  0.03 min) samples. Similarly, HT exhibited a 94.4% increase between the PCG-M15 (14.40  $\pm$ 0.52 min) and the PCG-M0 (28.03  $\pm$  1.22 min) samples (P < 0.05). Furthermore, the precooling treatment group exhibited an even greater increase in HT. The increase in time ranged from 1.89-fold in the PCT-M5 (16.53  $\pm$  0.85 min) and NTG-M5 (8.74  $\pm$  0.31 min) samples to 2.64-fold in the PCG-M0  $(14.40 \pm 0.52 \,\text{min})$  and NTG-M0  $(5.46 \pm 0.03 \,\text{min})$  samples. The handling time increased from 5.45 min (NTG-M0) to 28.03 min (PCG-M15).

Precooling treatment also reduced  $T_{\rm max}$ .  $T_{\rm max}$  declined by 11.79% between the NTG-M0 (102.18±4.77°C) and PCG-M0 (90.15±7.01°C) samples (P < 0.05). However, no significant differences were found in the other groups following the addition of castor oil (M5, M10, or M15) (P < 0.05). The typical temperature profiles corresponding to the samples with various concentrations of castor oil in the NTG and the PCG are shown in Figure 6. Overall, it was demonstrated that the addition of castor oil and the use of a precooling procedure could decrease  $T_{\rm max}$  and increase HT.

3.2. Biomechanical Evaluation. The average densities, Young's moduli, and compressive strengths for the samples with varying contents of castor oil in the NTG and the PCG are shown in Figure 7 and Table 1. PMMA density decreased with increasing castor oil content. There was an 8.4% decline (P < 0.05) between the NTG-M15 (1,017  $\pm$  24.6 kg/m³)



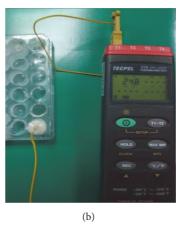


FIGURE 3: Photograph showing the measurement of temperature profile of cement sample. (a) A cylindrical syringe was cut to a height of 30 mm and used as a container to hold PMMA for measuring temperature profiles. The prepared cement mixture was added to the cavity of the syringe up to 20 mm in height. (b) Then, a thermocouple was inserted into the bone cement to a depth of 10 mm.

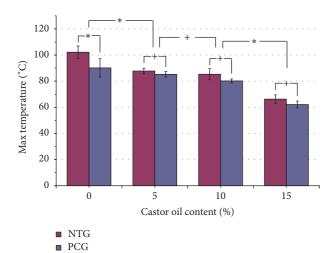


FIGURE 4: Average maximum polymerization temperature ( $T_{\rm max}$ ) for bone cement samples with various contents of castor oil in the NTG and the PCG. The maximum polymerization temperature decreased with increasing castor oil content. However, for a given castor oil concentration (M5, M10, or M15), no significant differences were found between the PCG and the NTG, except for the standard PMMA samples (M0). \*P < 0.05. \*P > 0.05.

and NTG-M0  $(1,112\pm15.9\,{\rm kg/m^3})$  samples; similar results were observed in the PCG samples. However, no significant differences were noted between the NTG and the PCG in terms of densities at varying castor oil concentrations. Thus, preparation temperature had no effect on PMMA density.

In regard to the Young modulus (E) and the compressive strength ( $\sigma_c$ ) of each sample, no significant differences were noted between the PCG and the NTG at any castor oil percentage (P > 0.05). The precooling treatment had no effect on E or  $\sigma_c$  in any of the castor oil groups. Conversely, as the castor oil percentage increased, E and  $\sigma_c$  clearly decreased. E showed a 72.7% decline (P < 0.05) between the NTG-M15 (1,739  $\pm$  128 MPa) and NTG-M0 (474  $\pm$  35 MPa) samples.

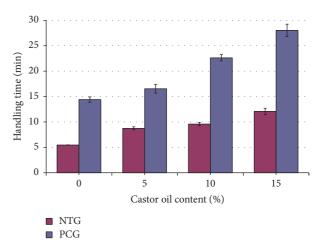


FIGURE 5: Average HT for bone cement samples with various contents of castor oil in the NTG and the PCG. The HT significantly increased as the castor oil content increased for both the NTG and the PCG. The precooling treatment group exhibited an even greater increase in HT. Significant differences (P < 0.05) were found among the groups.

Similarly, there was a 71.7% decrease (P < 0.05) between the PCG-M15 (1, 749  $\pm$  137 MPa) and PCG-M0 (495  $\pm$  30 MPa) samples. The results from the compression test also showed large declines in both the NTG and the PCG. For the NTG, the compressive strength decreased by 77.3% between the NTG-M15 and NTG-M0 (P < 0.05) samples, whereas the compressive strength decreased by 75.3% between the PCG-M15 and PCG-M0 samples in the PCG (P < 0.05).

The porosity distributions and average porosity percentages of the bone cement samples containing varying concentrations of castor oil in the NTG and the PCG are shown in Figures 8(a) and 8(b), respectively. The porosity of PMMA significantly increased as the concentration of castor oil increased in both the NTG and the PCG. In the NTG, the porosity in the NTG-M15 samples  $(43.4 \pm 4.7\%)$  increased

TABLE 1: Biomechanical prop	perties of bone cement mixed v	ith varying concentrations	of castor oil (0%, 5%, 10%, and 1	5%) at 25°C and 3°C.
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Gro	oup		Biomechanical	properties	
Treatment	Castor oil (%)	Density (kg/m³)	Porosity (%)	E (MPa)	$\sigma_c$ (MPa)
	0%	1112.4 ± 15.9	$1.3 \pm 0.5$	1739.4 ± 128.2	$75.3 \pm 5.0$
Normal (22°C)	5%	$1077.6 \pm 10.9$	$16.5 \pm 1.8$	$1306.1 \pm 48.8$	$51.2 \pm 4.4$
	10%	$1044.8 \pm 8.9$	$25.8 \pm 3.5$	$763.3 \pm 116.6$	$33.6 \pm 4.8$
	15%	$1016.8 \pm 24.6$	$43.4 \pm 4.7$	$474.0 \pm 35.3$	$17.2 \pm 1.9$
Precooling (3°C)	0%	1111.3 ± 7.7	$2.0 \pm 0.4$	1749.1 ± 137.4	$77.4 \pm 4.6$
	5%	$1075.4 \pm 11.7$	$15.8 \pm 2.8$	$1255.4 \pm 144.1$	$51.1 \pm 5.3$
	10%	$1046.8 \pm 10.4$	$26.2 \pm 3.6$	$795.3 \pm 145.5$	$29.3 \pm 3.0$
	15%	$1015.1 \pm 21.6$	$45.8 \pm 6.9$	$495.4 \pm 30.1$	$19.1 \pm 2.9$
Ref. data for cand	cellous bone [16]			325 ± 145	$2.5 \pm 1.5$

E: Young's modulus.

 $<sup>\</sup>sigma_c$ : compression strength.

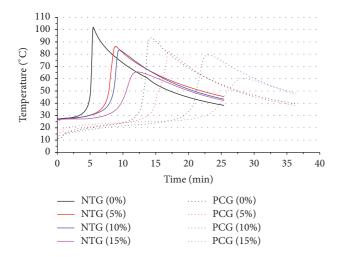


FIGURE 6: Typical temperature profiles for bone cement samples with various contents of castor oil in the NTG and the PCG. Increasing castor oil content and precooling treatment effectively decreased the peak polymerization temperatures and increased the duration to achieve the peak polymerization temperature.

by 33.4-fold (P < 0.05) compared with that in the NTG-M0 samples (1.3 ± 0.5%), whereas the porosity in the PCG-M15 samples (45.8 ± 6.9%) was 22.9 times (P < 0.05) greater than that in the PCG-M0 samples (2.0 ± 0.4%). Similar to the results of the above studies on biomechanical properties, no significant differences in terms of porosity were observed in relation to castor oil content in either the NTG or the PCG.

#### 4. Discussion

In this study, the addition of castor oil to PMMA significantly altered the biomechanical properties of PMMA. The addition of castor oil changed all of the measured properties in PMMA, leading to a lower E, a lower  $\sigma_c$ , a lower  $T_{\rm max}$ , a longer HT, and a higher porosity. In contrast, precooling treatment resulted in a lower  $T_{\rm max}$  and a longer HT but had no effect

on the mechanical properties of PMMA, including E,  $\sigma_c$ , and porosity.

Obtaining reduced E and  $\sigma_c$  in PMMA is an important aim in vertebroplasty. Some studies have indicated that the high E of PMMA leads to a risk of causing secondary fractures in neighboring vertebral bodies [17, 18]. The rigidity of traditional PMMA induces local peak stress concentrated near neighboring vertebral bodies after vertebroplasty. This phenomenon may increase the risk of secondary fracture [15, 28]. Although this has not been conclusively proven, it is still a point worth noting. Low-modulus PMMA can more closely match the properties of cancellous bone and exhibits a rigidity similar to that of vertebral bodies after vertebroplasty, as was shown in the NTG-M15 and PCG-M15 samples. However, recent studies have indicated that the target E value after vertebroplasty should be closer to that of healthy bone rather than to that of cancellous bone [29]. Thus, in PMMA, having *E* that is similar to that of cancellous bone is not sufficient. Therefore, the properties of the samples created in this study should be compared to those of healthy vertebral bone. In this study, reductions in E and  $\sigma_c$  had a linear relationship with the volume of added castor oil. Thus, the E and  $\sigma_c$  values of PMMA can be controlled. When a surgeon treats a patient with a vertebral fracture, using the techniques described here, the surgeon could theoretically customize E of PMMA to match the bone mineral density of the patient. This process may reduce the risk of secondary fracture after vertebroplasty. In addition, the porosity of the created PMMA samples was also dependent on the amount of castor oil used. The PMMA exhibited higher porosity as higher concentrations of castor oil were used. In a previous study, reduced porosity was observed to produce higher E and  $\sigma_c$  values. The porosity resulting from the mixing process used might lead to minor fissures in PMMA. These fissures cause the PMMA less rigid, which may reduce the risk of refracture at the weaker side [28].

The addition of castor oil and the use of a precooling treatment can significantly reduce the temperature of polymerization and prolong the curing time of a sample. In the present study, the maximum reduction in  $T_{\rm max}$  was a 41.01% decrease, from 102.18  $\pm$  3.87°C in the NTG-M0 samples to

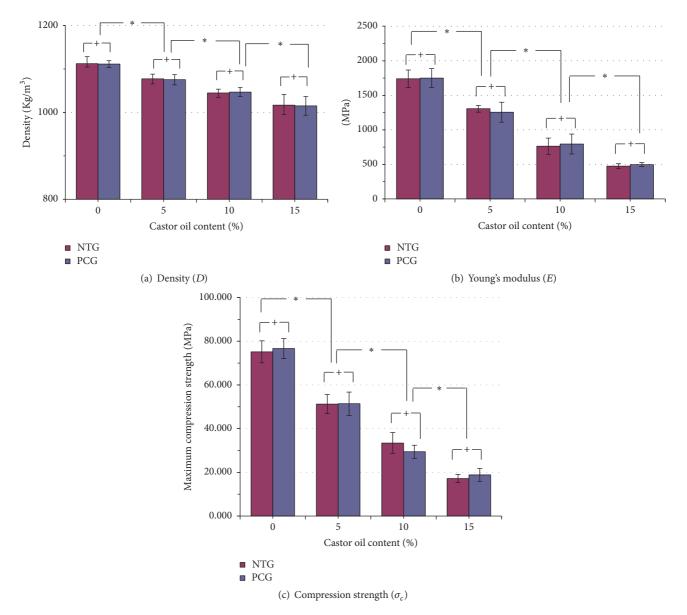


FIGURE 7: Average (a) density, (b) Young's modulus, and (c) maximum compressive strength for bone cement samples with various contents of castor oil in the NTG and the PCG. The listed properties decreased with increasing castor oil content. However, preparation temperature (room temperature or precooling) had no significant effect (P > 0.05) on these properties. \*P < 0.05. \*P > 0.05.

 $60.28 \pm 2.79^{\circ}$ C in the PCG-M15 samples (Figure 4). A lower  $T_{\rm max}$  can reduce the risk of thermal injury to neighboring tissues. However, for castor oil concentrations of M5, M10, or M15, no significant differences were found between the PCG and the NTG. This was not true for the standard PMMA samples (M0), as the castor oil in the PCG was not cooled prior to the experiments; thus, the results were not influenced. For the given concentrations of castor oil, although no significant differences were noted in  $T_{\rm max}$  between the PCG and the NTG (except in the M0 samples), HT was significantly prolonged between the groups (Figures 5 and 6). These results demonstrated that the precooling treatment had a greater effect than the addition of castor oil with regard to HT. However, for a given concentration of castor oil, the precooling treatment had little impact on the reduction of

 $T_{
m max}$ . Achieving a prolonged HT is important because it provides surgeons with additional time during vertebroplasty. Vertebroplasty can thus be completed more carefully, and further complications can be avoided. In contrast to previous studies [24, 25], our experiments showed that precooling only affects the  $T_{
m max}$  and HT of PMMA. Precooling had no influence on the other biomechanical properties tested and produced a synergistic effect when castor oil was added. Thus, physicians can independently control the biomechanical properties of PMMA by selecting the appropriate castor oil volume and can alter the precooling temperature to achieve the required handling time. Overall, our results demonstrated that precooling has a more powerful effect on  $T_{
m max}$  and HT than the addition of castor oil. Thus, surgeons can control handling time and decrease potential thermal injury using

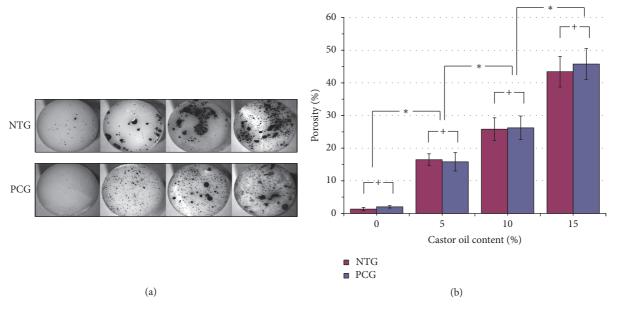


FIGURE 8: Photograph showing (a) the porous distributions in the bone cement samples and (b) the average porosities for the bone cement samples with various contents of castor oil in the NTG and the PCG. The porosity content increased with increasing castor oil content. However, preparation temperature (room temperature or precooling) had no significant effect (P > 0.05) on porosity. P < 0.05.

precooling treatment alone. Furthermore, the presence of porosity was shown to be the main determinant of E and  $\sigma_c$  for PMMA. Thus, increasing the porosity of PMMA in a controlled manner is important. The porosity of PMMA could be increased using different mixing techniques and via the addition of different substances. Therefore, future experiments evaluating different methods of increasing porosity via different mixing techniques while the percentage of castor oil is kept constant are warranted.

Our study has limitations. First, specimens prepared under a laboratory environment do not necessarily represent real clinical circumstances. The cement was cured in air without the perfusion of blood, and the environment that PMMA was exposed was not the same as that of living human vertebrae. The possible effects of the variations in the above-mentioned factors were not considered. Second, only one type of bone cement was used. PMMA from different manufacturers may have varying thermal and mechanical properties. Third, our measurements did not take into account the irregular geometry of actual human vertebrae, which may have an impact on the results of all measured parameters. Finally, only static loading (compression tests on bone cement) was used; other types of physiological loading were not considered. In actual clinical situations, PMMA is subjected to dynamic multidirectional loading. Although our loading mode did not necessarily represent actual physiological loading conditions, all of the specimens were prepared and tested in a uniform and reproducible manner, and we believe that this study provides information that could be useful for orthopedic surgeons who perform vertebroplasty. Further investigation into the effects of other loading methods, such as dynamic fatigue testing, might be necessary in the future.

#### 5. Conclusion

In the current study, the addition of castor oil and the use of a precooling treatment enabled the creation of PMMA samples with improved biomechanical properties, including lower  $T_{\rm max}$ , longer HT, lower E, and lower  $\sigma_c$  values as well as increased porosity. These properties were similar to those of healthy bone; thus, the modified PMMA samples are more suitable for use in vertebroplasty. However, further research is required regarding the use of these PMMA mixtures and their effects on rates of secondary fracture in clinical settings.

#### **Competing Interests**

The authors declare that there is no conflict of interests regarding the publication of this paper.

#### **Acknowledgments**

The authors would like to acknowledge the financial grant from the Ministry of Science and Technology, Taiwan (NSC-102-2221-E-182-014-MY2).

#### References

- [1] N. C. Wright, A. C. Looker, K. G. Saag et al., "The recent prevalence of osteoporosis and low bone mass in the united states based on bone mineral density at the femoral neck or lumbar spine," *Journal of Bone and Mineral Research*, vol. 29, no. 1, pp. 2520–2526, 2014.
- [2] T.-H. Lim, G. T. Brebach, S. M. Renner et al., "Biomechanical evaluation of an injectable calcium phosphate cement for vertebroplasty," *Spine*, vol. 27, no. 12, pp. 1297–1302, 2002.

- [3] O. Johnell and J. A. Kanis, "An estimate of the worldwide prevalence and disability associated with osteoporotic fractures," *Osteoporosis International*, vol. 17, no. 12, pp. 1726–1733, 2006.
- [4] M. E. Jensen, A. J. Evans, J. M. Mathis, D. F. Kallmes, H. J. Cloft, and J. E. Dion, "Percutaneous polymethylmethacrylate vertebroplasty in the treatment of osteoporotic vertebral body compression fractures," *American Journal of Neuroradiology*, vol. 18, no. 10, pp. 1897–1904, 1997.
- [5] J. D. Barr, M. S. Barr, T. J. Lemley, and R. M. McCann, "Percutaneous vertebroplasty for pain relief and spinal stabilization," *Spine*, vol. 25, no. 8, pp. 923–928, 2000.
- [6] J. Blasco, A. Martinez-Ferrer, J. MacHo et al., "Effect of vertebroplasty on pain relief, quality of life, and the incidence of new vertebral fractures: a 12-month randomized follow-up, controlled trial," *Journal of Bone and Mineral Research*, vol. 27, no. 5, pp. 1159–1166, 2012.
- [7] A. A. Uppin, J. A. Hirsch, L. V. Centenera, B. A. Pfiefer, A. G. Pazianos, and S. Choi, "Occurrence of new vertebral body fracture after percutaneous vertebroplasty in patients with osteoporosis," *Radiology*, vol. 226, no. 1, pp. 119–124, 2003.
- [8] Y.-A. Li, C.-L. Lin, M.-C. Chang, C.-L. Liu, T.-H. Chen, and S.-C. Lai, "Subsequent vertebral fracture after vertebroplasty: incidence and analysis of risk factors," *Spine*, vol. 37, no. 3, pp. 179–183, 2012.
- [9] Y.-J. Rho, W. J. Choe, and Y. I. Chun, "Risk factors predicting the new symptomatic vertebral compression fractures after percutaneous vertebroplasty or kyphoplasty," *European Spine Journal*, vol. 21, no. 5, pp. 905–911, 2012.
- [10] O. Lamy, B. Uebelhart, and B. Aubry-Rozier, "Risks and benefits of percutaneous vertebroplasty or kyphoplasty in the management of osteoporotic vertebral fractures," *Osteoporosis International*, vol. 25, no. 3, pp. 807–819, 2014.
- [11] D. G. Lee, C. K. Park, C. J. Park, D. C. Lee, and J. H. Hwang, "Analysis of risk factors causing new symptomatic vertebral compression fractures after percutaneous vertebroplasty for painful osteoporotic vertebral compression fractures: a 4-year follow-up," *Journal of Spinal Disorders & Techniques*, vol. 28, no. 10, pp. E578–E583, 2015.
- [12] A. Polikeit, L. P. Nolte, and S. J. Ferguson, "The effect of cement augmentation on the load transfer in an osteoporotic functional spinal unit: finite-element analysis," *Spine*, vol. 28, no. 10, pp. 991–996, 2003.
- [13] S. Toksvig-Larsen, R. Johnsson, and B. Strömqvist, "Heat generation and heat protection in methylmethacrylate cementation of vertebral bodies—a cadaver study evaluating different clinical possibilities of dural protection from heat during cement curing," *European Spine Journal*, vol. 4, no. 1, pp. 15–17, 1995.
- [14] C.-K. Park, M. J. Allen, J. Schoonmaker, P. Yuan, B. Bai, and H. A. Yuan, "Gelfoam as a barrier to prevent polymethylmethacrylate-induced thermal injury of the spinal cord: in vitro and in vivo studies in pigs," *Journal of Spinal Disorders*, vol. 12, no. 6, pp. 496–500, 1999.
- [15] P. F. Heini, U. Berlemann, M. Kaufmann, K. Lippuner, C. Fankhauser, and P. Van Landuyt, "Augmentation of mechanical properties in osteoporotic vertebral bones—a biomechanical investigation of vertebroplasty efficacy with different bone cements," *European Spine Journal*, vol. 10, no. 2, pp. 164–171, 2001
- [16] X. Banse, T. J. Sims, and A. J. Bailey, "Mechanical properties of adult vertebral cancellous bone: correlation with collagen intermolecular cross-links," *Journal of Bone and Mineral Research*, vol. 17, no. 9, pp. 1621–1628, 2002.

- [17] J. P. Kolb, R. A. Kueny, K. Püschel et al., "Does the cement stiffness affect fatigue fracture strength of vertebrae after cement augmentation in osteoporotic patients?" *European Spine Journal*, vol. 22, no. 7, pp. 1650–1656, 2013.
- [18] A. Boger, M. Bohner, P. Heini, S. Verrier, and E. Schneider, "Properties of an injectable low modulus PMMA bone cement for osteoporotic bone," *Journal of Biomedical Materials Research—Part B Applied Biomaterials*, vol. 86, no. 2, pp. 474–482, 2008.
- [19] B. Bai, L. M. Jazrawi, F. J. Kummer, and J. M. Spivak, "The use of an injectable, biodegradable calcium phosphate bone substitute for the prophylactic augmentation of osteoporotic vertebrae and the management of vertebral compression fractures," *Spine*, vol. 24, no. 15, pp. 1521–1526, 1999.
- [20] M. Nakano, N. Hirano, M. Zukawa et al., "Vertebroplasty using calcium phosphate cement for osteoporotic vertebral fractures: study of outcomes at a minimum follow-up of two years," *Asian Spine Journal*, vol. 6, no. 1, pp. 34–42, 2012.
- [21] C.-H. Tsai, R.-M. Lin, C.-P. Ju, and J.-H. Chern Lin, "Bioresorption behavior of tetracalcium phosphate-derived calcium phosphate cement implanted in femur of rabbits," *Biomaterials*, vol. 29, no. 8, pp. 984–993, 2008.
- [22] A. J. Ambard and L. Mueninghoff, "Calcium phosphate cement: review of mechanical and biological properties," *Journal of Prosthodontics*, vol. 15, no. 5, pp. 321–328, 2006.
- [23] E. Unosson, Mechanical Properties and Spreading Characteristics of Bone Cement for Spinal Applications, Luleå University of Technology, Luleå, Sweden, 2010.
- [24] A. López, A. Hoess, T. Thersleff, M. Ott, H. Engqvist, and C. Persson, "Low-modulus PMMA bone cement modified with castor oil," *Bio-Medical Materials and Engineering*, vol. 21, no. 5-6, pp. 323–332, 2011.
- [25] P.-L. Lai, C.-L. Tai, I.-M. Chu, T.-S. Fu, L.-H. Chen, and W.-J. Chen, "Hypothermic manipulation of bone cement can extend the handling time during vertebroplasty," *BMC Musculoskeletal Disorders*, vol. 13, article 198, 2012.
- [26] J. R. De Wijn, "Poly(methyl methacrylate)—aqueous phase blends: in situ curing porous materials," *Journal of Biomedical Materials Research*, vol. 10, no. 4, pp. 625–635, 1976.
- [27] KD. Kühn, Bone Cements: Up-To-Date Comparison of Physical and Chemical Properties of Commercial Materials, Springer, Berlin, Germany, 2000.
- [28] K. Sun and M. Liebschner, "Optimization of bone cement properties in vertebral reinforcement," in *Proceedings of the 13th Interdisciplinary Research Conference on Biomaterials (GRIBOI* '03), Poster No 1020, Boston, Mass, USA, April 1020.
- [29] S. M. Belkoff, J. M. Mathis, E. M. Erbe, and D. C. Fenton, "Biomechanical evaluation of a new bone cement for use in vertebroplasty," *Spine*, vol. 25, no. 9, pp. 1061–1064, 2000.

Hindawi Publishing Corporation BioMed Research International Volume 2016, Article ID 4702946, 9 pages http://dx.doi.org/10.1155/2016/4702946

### Clinical Study

## The Strategy and Early Clinical Outcome of Percutaneous Full-Endoscopic Interlaminar or Extraforaminal Approach for Treatment of Lumbar Disc Herniation

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Received 24 April 2016; Revised 8 July 2016; Accepted 1 August 2016

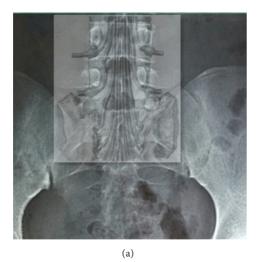
Academic Editor: Anthony T. Yeung

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Objective is to analyze the surgical strategy, safety, and clinical results of percutaneous full-endoscopic discectomy through interlaminar or extraforaminal puncture technique for LDH. Preoperative CT and MRI were analyzed, which were based on the main location of the herniated disc and its relationship with compressed nerve root. Sixty-two patients satisfied the inclusion criteria during the period from August 2012 to March 2014. We use percutaneous full-endoscopic discectomy through different puncture technique to remove the protrusive NP for LDH. Sixty patients completed the full-endoscopic operation successfully. Their removed disc tissue volume ranged from 1.5 mL to 3.8 mL each time. Postoperative ODI and VAS of low back and sciatica pain were significantly decreased in each time point compared to preoperative ones. No nerve root injury, infection, and other complications occurred. The other two patients were shifted to open surgery. No secondary surgery was required and 91.6% of excellent-to-good ratio was achieved on the basis of Macnab criteria at postoperative 12 months. Acquired benefits are fewer complications, rapid recovery, complete NP removal, effective nerve root decompression, and satisfactory cosmetic effect as well. This is a safe, effective, and rational minimally invasive spine-surgical technology with excellent clinical outcome.

#### 1. Introduction

The spinal endoscopic technique is designed to protect spinal stiffness and dynamic structure as well as to reduce and avoid traditional open surgery-related complications [1, 2]. Endoscopic surgery has some advantages, including clear visualization, less damage to the paraspinal muscle and other normal tissues, good cosmetic effect, and reduced patient morbidity with early return to work [3, 4]. Posterolateral working channel of transforaminal endoscopic discectomy is a popular endoscopic technique [5, 6]. But it has several disadvantages, including that it can not effectively deal with lumbar disc herniation located mainly in spinal canal, complicated puncture techniques, overexposure to X-rays, and insufficient treatment of L5S1 disc protrusion [3, 6]. Another method, introduced by Ruetten et al., uses interlaminar approach into the canal; this procedure preserves the classical posterior pathway and is easy to perform, thus avoiding the insufficient treatment of L5S1 by posterolateral transforaminal approach [7]. With the development of various pathway techniques, the full-endoscopic spinal technique has become an important treatment method in intervertebral lumbar disc herniation (LDH) [3, 6-8]. Proper surgical indications and good working channel position are important for successful percutaneous endoscopic lumbar discectomy [9]. Due to limited microscopic operation space, it is necessary to obtain an accurately planted operation channel, which should approach the protrusive disc as much as possible to complete the operation. As a result, a fully exposed outstanding intervertebral disc can be viewed in limited space. We classify the primary position of the protrusive disc with compressed nerve root into the axillary type, shoulder type, and extreme lateral type. Various percutaneous targeted puncture techniques for excision of protrusive NP tissue are successful in directly decompressing the nerve root. From August 2012 to March 2014, we performed the percutaneous full-endoscopic discectomy through interlaminar or extraforaminal puncture technique to treat 62 patients with single segmental intervertebral lumbar disc herniation (LDH). The effectiveness was achieved within a clinical follow-up of more than 12 months.



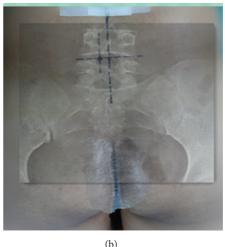


FIGURE 1: (a) Theoretical positions between the protrusive disc and the nerve root. (b) Actual puncture points on the body surface.

#### 2. Patients and Methods

2.1. General Data. Among the 62 patients, 38 were males and 24 were females. The average age was 51.6 years (18-73 years). Patients had symptoms for 1 to 18 months (3.6 months on average) and were subjected to conservative treatments for at least one month. Patients with no obvious symptom alleviation and reoccurrence were selected for the operation with our protocols. The location of the protrusive disc was L3/4 (1 case), L4/5 (33 cases in total, 19 cases on the left side, and 14 cases on the right-side), and L5S1 (28 cases in total, 16 cases on the left, and 12 cases on the right). All cases were subjected to examination of the lumbar positive and lateral X-ray films, CT, and MRI. CT and MRI were requested to distinguish the position of protrusive disc and its relationship with compressing nerve root (Figure 1(a)). The results were divided into protrusive disc of the L4 nerve root shoulder type (1 case), L5 nerve root shoulder type (8 cases), L5 nerve root axillary type (22 cases), S1 nerve root shoulder type (8 cases), axillary type (20 cases), and extreme lateral type (4 cases: 3 cases of L4/5 and 1 case of L5SI). Inclusion criteria were as follows: (1) different degrees of lumbago and unilateral obvious sciatica; (2) no signs of improvement or aggravation through conservative treatment for more than 4 weeks; (3) CT and MRI revealing a single segment of lumbar intervertebral disc herniation that was not associated with bony stenosis in ipsilateral recess; and (4) lumbar anteroposterior radiographs showing that the diameter of the interlaminar window was more than 8 mm [4, 7] (see Figure 2). All patients signed the minimally invasive surgical treatment approval consent established by our hospital ethics committee after full explanation. Exclusion criteria were as follows: (1) central lumbar disc herniation; (2) local skin condition being poor and laboratory examination showing signs of infection; (3) imaging studies suggesting infection, tumor, lumbar spinal stenosis, lumbar spine deformity, and lumbar spondylolisthesis or instability [4, 8, 10]; (4) surgical history with corresponding segmental sites; and (5) abnormal blood coagulation function.



FIGURE 2: The diameter of the interlaminar window was measured as the sagittal distance between the superior edge of lower laminar bone and inferior edge of upper laminar bone and the horizontal distance between the medial of inferior facet and lateral edge of spinous process.

2.2. Surgical Instruments. The spinal endoscope system (SPINENDOS Co., Germany) comprised 4.3 mm working channel, 7 mm outer sheath diameter, and 30-degree angled scope with continuous water irrigation system.

We also used low-temperature radiofrequency ablation system (ArthroCare Co., USA).

2.3. Surgical Technique. All operations were performed under continuous epidural anesthesia. The patients were placed on a radiolucent orthopedic surgery bed allowing the lumbar spine to be flexed as much as possible to widen the interlaminar space. Position of the fluoroscope and the height of the operating table should be checked for convenience for the operating team. After routine sterile preparation and draping, accurate level of the incision was verified under fluoroscope, and the needle was placed with respect to the established surface piercing point (Figure 3(b)).

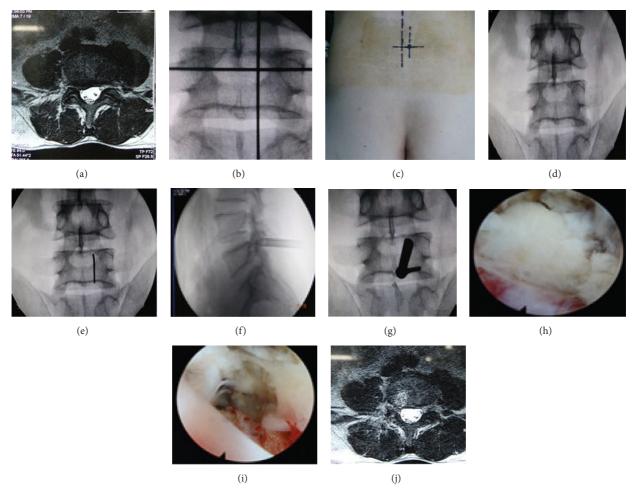


FIGURE 3: Images of patient with right-side L4/5 LDH.

2.3.1. Surgery of Nerve Root Shoulder (Figure 3). The target position of puncture was located on the paracentral foraminal part of the interlaminar window and near the tip of the joints (Figure 3(d)). The needle was inserted at the piercing point stepwise to target in the spinal canal under fluoroscope guidance. A small skin incision along needle was made approximately 7 mm just enough to pass through working channel; a tapered cannulated dilator was then inserted gently along the needle to the lateral edge of the interlaminar window. The working sheath was then inserted through dilator with its beveled opening toward the spinous processes. The depth and the location of the working sheath were confirmed by fluoroscopy. We moved the dilator and placed the endoscope. Sometimes, it is difficult to perform full-endoscopic interlaminar discectomy at L4/5 or higher levels because of narrow interlaminar windows. If the anatomic osseous diameter of the interlaminar window less than 8 mm does not allow direct access into the spinal canal through the ligamentum flavum, a high-speed burr or deep laminectomy rongeur was used to resect little partial laminar bone as needed. The procedure was performed under direct visualization with normal saline irrigation at a constant rate. The ligamentum flavum was incised about

3-5 mm to enable entry into the spinal canal, so we can differentiate the vertebral canal contents. Sometimes, for ease of decompressing nerve root, it is necessary that a little bone shaving might be needed according to the position of the migrated disc. Radiofrequency (RF) probing was used to process part of the adipose tissue and blood vessels. Thereafter, by taking advantage of work channel leverage effect, we adjusted the endoscope outwards, up, or down to recognize the nerve root [4, 7-10]. The lateral recess was then enlarged by clamps. With nerve agent hook or splitting rods to probe the nerve root shoulder, the neural structures were then retracted medially and protected by rotating the beveled opening inwards 180°. We exposed the disc clearly and avoided the nerve root injury [11]. By using clamps with different angles, protrusive disc tissues were removed. Afterwards, we adjusted the endoscopic view up and down to avoid any disc residuals. The nerve root was thus fully decompressed. The ablation of nonprotrusive disc nucleus pulposus tissues and the formation of a fibrous ring due to thermosetting shrinkage were achieved with the RF cauter [8, 10]. Before end of the operation, the operation field was checked carefully to ensure that there was no dural sac damage, significant free disc organization, or active bleeding.

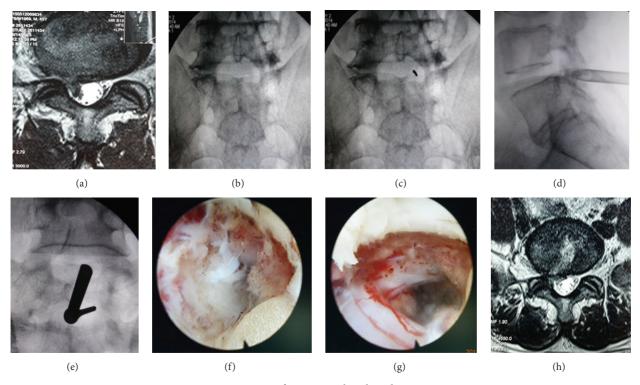


FIGURE 4: Images of patients with right-side L5S1 LDH.

Concurrently, good relaxation of nerve root was ensured when the nerve root could be easy mobilized from lateral to medial position. The operating system was removed, and the incised skin was sutured and covered with sterilized dressing. There was minimal blood loss and drainage was not necessary.

2.3.2. Surgery of Nerve Root Axillary (Figure 4). The position of the vertebral plate gaps was pinpointed under C-arm fluoroscopy. The preparation of patients position was the same as previously stated. The needle was placed based on the established surface piercing point (Figure 3(b)). The target was located at the center of the interlaminar window (Figure 4(b)). After routine sterile preparation and draping, the needle was guided from the surface into the targeted points of the spinal canal, the processes of inserting dilator and a working sheath were the same as that of shoulder type stated above. After incision of the ligamentum flavum, we can expose the nerve root and its axilla. Sometimes, we can directly view the protrusive disc tissue, removing a portion of the sequestrated disc was necessary before mobilizing the nerve root, and the beveled opening of the working sheath was placed on the herniated disc with the nerve root pushed laterally or with the dura sac pushed medially. If the protrusive disc tissue is close to the center, by taking advantage of work channel leverage effect, thecal sac was pushed more medially and disclosed the protrusive disc tissue. Despite the existence of lumbar lordosis or secondary degeneration, we can adjust the endoscope to outer upper quadrant or lower outer quadrant of interlaminar bone and can recognize the nerve root, if protrusive disc tissue mildly

migrated upward or downward. Bipolar electrocautery was used to obtain meticulous hemostasis and to release the soft tissue along the lateral recess. The neural structures were then retracted and protected by rotating the beveled opening inwards. The disc fragment was exposed and was resected using micropituitary instruments. The remaining procedures were the same as those for the nerve root shoulder type described in Section 2.3.1.

2.3.3. Surgery of Extreme Lateral Type (Figure 5). Using extraforaminal puncture, the body piercing point was above and outside the transverse process on the same side (Figures 5(b) and 5(c)). The targeted sites were outer edge of inferior endplate under C-arm fluoroscopy. The side targeted point was located at posterior inferior margin of upper vertebral endplate (Figures 5(d) and 5(e)). A needle was guided from the surface piercing point along the trajectory of extraforaminal to the targets. The skin entry point was closer and the angle of needle insertion was steeper than those of transforaminal approach (Figure 5(h)). A small incision was made in the skin at the entry site, a tapered cannulated dilator was inserted gently into the extraforaminal, and a beveled opening working cannular was inserted along the dilator. Normally, the working channel is positioned in a superiorposterior position for visualization of the nerve root. And endoscope allowed direct viewing of the protrusive disc and compressed exiting nerve root. Forceps can be used to remove protrusive NP and decompressed nerve root. Afterwards, we adjusted the endoscopic view inwards, up, and down to avoid any disc residuals. The nerve root was decompressed fully. The ablation of nonprotrusive disc nucleus pulposus tissues

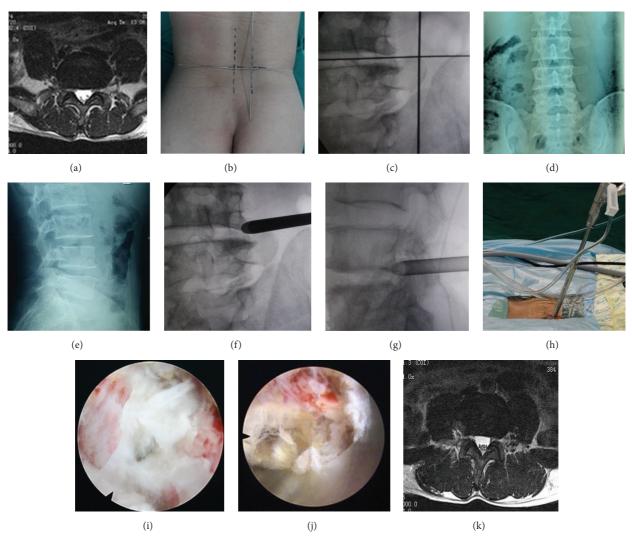


FIGURE 5: Images of patients with right-side L4/5 LDH, with symptoms in the lower and anterior side of the right thigh, knee, and medial anterior side of right leg.

and the formation of a fibrous ring due to thermosetting shrinkage were achieved with the RF cauter. There was minimal blood loss and drainage was not necessary. A sterile dressing was applied with one-point suture.

- 2.4. Postoperative Rehabilitation. The patients are usually given 8 to 24 hours' bed rest after operation and allowed to ambulate independently with lumbar support. They were discharged within 48 h to 96 h. Nonlaborious work was allowed after 2 weeks. Daily activities could be gradually resumed in accordance with their personal capabilities.
- 2.5. Curative Effectiveness Evaluation. A total of 60 patients received the postoperative follow-up more than 12 months by telephone interviews or outpatient review. Postoperative evaluation was conducted at 1 day, 1 month, 3 months, and final follow-up. Clinical data included perioperative parameters such as operative time, blood loss, removed disc tissue volume, and length of hospital stay. MRI was reexamined to evaluate the resection completeness of protrusive disc tissue.

Visual Analogue Scale (VAS) was used to evaluate patient waist and leg pain; ODI criteria were used to evaluate the patients' daily lives. The Macnab criteria were applied to evaluate clinical curative effectiveness at 12 months.

2.6. Statistical Analysis. Microsoft Excel was used for data entry and formatting. SPSS 18.0 was used to study data for statistical analysis. The paired-samples t-test was applied to compare groups on measured data. The paired-samples  $\chi^2$  test was applied to compare groups on count data. Data are presented as mean  $\pm$  standard deviation. A two-sided P < 0.05 was statistically significant.

#### 3. Results

Forty-two were axillary type, sixteen were shoulder type, and four were extreme lateral type. Two patients were shifted to open surgery at initial time. Sixty patients completed the fullendoscopic operation successfully. The operation time was

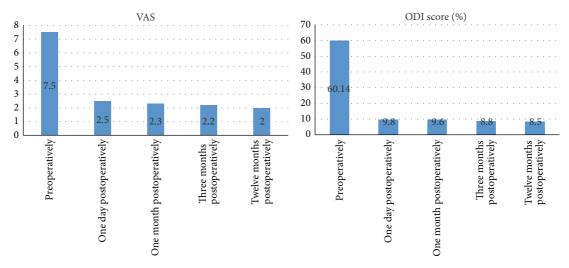


FIGURE 6: Comparison of pre- and postoperative VAS and ODI scores. Note that they decreased the most during early time of postoperative period.

50 min to 130 minutes (78 min on average) and there was no measurable intraoperative blood loss. The removed disc tissue volume was measured using a syringe ranged from 1.5 mL to 3.8 mL (2.4 mL on average). The time until the patient walked out of bed was 8 h to 24 h (16 h on average). The length of hospital admission after the operation was 48 h to 96 h (64 h on average). After operation, one patient of shoulder type suffered from lower limb hyperalgesia with burning sensation and five (2 cases of shoulder type and 3 cases of axillary type) had numbness of the proximal tibial side, which may be the results of thermal injury of nerve root surface by radiofrequency heat coagulation or excessive traction of nerve root. And the above symptoms acquired improvement with conservative treatment. No other blood vessel complication, bowel injury, cerebrospinal fluid leakage, or infection of intervertebral disc was discovered.

These 60 patients were followed up for at least 12 months. Lumbago recurrence was observed in 2 patients 1.5 months after operation due to lumbar weight, and two patients showed leg pain during long squatting 2 months after operation. The conditions of the above 4 patients were improved with conservative treatment, and no secondary surgery was required. The preoperative VAS score was  $7.5 \pm 1.04$  and ODI score was  $60.14 \pm 6.56$ . Twelve months after surgery, the VAS score was  $2.0 \pm 0.05$  and ODI score was  $8.5 \pm 3.26$  (both significant at P < 0.05) (Figure 6). Curative effectiveness was evaluated using the Macnab criteria after 12 months; the following results were obtained: 47 cases were excellent, 8 cases were good, 5 cases were fair, and 0 cases were poor. The excellent-to-good ratio was 91.6% (55/60) (Table 1).

#### 4. Discussion

Traditional lumbar intervertebral disc excision is the standard treatment of LDH, but it entails the removal of 1/3 of the joint and the ligament flavum to fully expose the nerve tissue and protrusive disc tissues, which may inevitably lead to iatrogenic instability, epidural scar adhesion, large

TABLE 1: Grade distribution 12-month postsurgical effect.

Indicator	Cases	Excellent	Good	Fair	Poor
Modified Macnab criteria	60	47 (78.3%)	8 (13.3%)	5 (8.5%)	0

trauma, bleeding, long postoperative bed time, and slow recovery [4, 6]. With the assistance of full-endoscopy, the iatrogenic injury has been significantly decreased [10, 12]. The full-endoscopic technique for treatment of LDH has two accesses, transforaminal (TF) and interlaminar (IL). The fullendoscopic lumbar discectomy was first applied in the treatment of LDH using the YESS system via the posterolateral transforaminal approach [13]. Most symptomatic lumbar disc herniations, such as partial intraspinal canals and lateral disc herniations, can be successfully treated with this procedure [6, 10, 13]. However, the factors of the high-riding iliac crest (notably at L4/5 and L5S1) and the hyperplastic facet joints block the low lumbar segments. The other disadvantages include limitations in neural manipulation, the very limited foraminal working space and complicated puncture techniques, and high radiation exposure to both the surgeons and the patients. The applications of transforaminal approach are limited to removing protrusions of all intervertebral discs [6, 10]. Meanwhile, according to the anatomy study, the distance between the edge of L5 vertebral plate and L5 vertebral endplate varies from 3.0 mm to 8.5 mm; the distance between S1 vertebral plate edge and the S1 vertebral endplate is relatively constant with an average of about 13.9 mm [14]. Compared with the upper lumbar vertebral plate gap, L5S1 vertebral plate gap is very big, with an average of 31 mm (21–40 mm) [14], which makes the operation of percutaneous full-endoscopic through interlaminar discectomy very practicable. Choi et al. reported that a full-endoscopic technique through interlaminar approach could treat L5S1 disc herniation [9], and Ruetten et al. presented good effectiveness with the fullendoscopic technique through interlaminar approach for

L5S1 disc herniation [10,12]. In our study it was demonstrated that protrusive disc tissues can be safely, effectively, and adequately removed using the percutaneous full-endoscopic discectomy via targeted puncture with minimal intraoperative blood loss; there were no damage to joints and no iatrogenic instability and no infections and other complications occurrence. Excellent surgical outcomes include significant pain relief, fewer complications, minimizing soft tissue injury, and faster rehabilitation.

The applications of all types of minimally invasive technology are focused on disease tissues or other specific goals. Because the locations of the protrusive disc sites are not identical, it is difficult for single puncture approach to treat all types of protrusive disc [6, 15]. Therefore, we analyzed preoperative CT and MRI of patients, based on the main location of the herniated disc and its relationship with compressed nerve root; the site of protrusive disc was divided into shoulder type, axillary type, and extreme lateral type. We performed percutaneous full-endoscopic discectomy through center puncture of interlaminar bone, paracentral foraminal puncture of interlaminar bone, and extraforaminal puncture technique for LDH, respectively. This strategy facilitates working channel placement at the location of intervertebral disc herniation and complete disclosure of protrusive NP tissue under the endoscopic visualization. Furthermore, this acquires good nerve root decompression and achieves good effectiveness with fewer complications.

CT and MRI scan are preferred diagnostic methods for LDH. These methods can clearly show the protrusive intervertebral disc shape and location and the relationship of protrusive disc with dural sac or nerve root [15, 16]. Given patient's protrusive disc reference, different classifications were devised. With the reference from the middle line of the vertebral canal, the results can be divided into central, paracentral, and lateral types. Type of relationship with intervertebral foramen can be divided into the transforaminal and extraforaminal type. The relationship with compressed nerve root can be divided into nerve root shoulder, axillary region, and extreme lateral type [14, 16, 17]. The patients who need surgical treatment with main symptoms are caused by protrusive disc compressing corresponding nerve root. Therefore, we classified the site according to the relationship with compressed nerve root. Before operation, CT and MRI image data were carefully analyzed. We distinguished that the type of protrusive disc was either nerve root shoulder, axillary, or extreme lateral type, which provided an important reference of puncture trajectory to the position of disc herniated. Forty-two patients were axillary protrusion using center puncture of interlaminar bone, which accounted for 67.7% of this series. The location of the protrusive intervertebral disc was equivalent to the middle area of the vertebral plate gap under C-arm fluoroscopy. Therefore, the interlaminar center was a place for targeting the operation channel. The channel tip was placed into the vertebral canal and could be positioned directly at the location of the herniated intervertebral disc. This method obtained an accurate display of the protrusive disc tissue and reduced the difficulty of detecting by adjusting the channel direction, which provided a wide field of vision that was adequate for

the removal of the protrusive disc tissues. Sixteen cases were of the shoulder type using paracentral foraminal puncture of interlaminar bone, accounting for 25.8% of this series. The location of the outstanding intervertebral disc was equivalent to the inner side of the lower articular process tip under C-arm fluoroscopy. Furthermore, the anatomical marks of paracentral foraminal puncture could be used as a shoulder type piercing target and direct the channel tip into the spinal canal. Subsequently, the lateral recess could be expanded with clamps. These marks could also show the protrusive intervertebral disc. Ruetten et al. applied a full-endoscopic technique through interlaminar approach for lumbar disc herniation, and the fine rate was 89.7%, with a two-year postoperative recurrence rate similar to the traditional technique [10, 12]. The postoperative recovery time was significantly reduced compared with the traditional method [17]. According to literature research of lumbar anatomy, width and height of lamina gap at L3/L4 were 13.10  $\pm$  1.8 mm and 8.46  $\pm$ 0.65 mm, respectively, at L4/L5 were 13.80  $\pm$  1.30 mm and  $8.86 \pm 0.85 \, \mathrm{mm}$ , respectively, and at L5S1 were 15.64  $\pm$ 1.73 mm and 10.30  $\pm$  1.2 mm, respectively [18]. Compared with L5S1 vertebral plate gap, the upper lumbar vertebral plate gap was relatively narrow. Sometimes, it is difficult to perform full-endoscopic interlaminar discectomy at L4/5 or higher levels because of narrow interlaminar windows. If the anatomic osseous diameter of the interlaminar window less than 8 mm does not allow work channel direct access into the spinal canal, a high-speed burr or deep laminectomy rongeur was used to resect a little partial laminar bone as needed. The lateral type only accounted for 4 cases, or 6.5%. We used extraforaminal puncture and acquired good results. Previous applications of Yeung's approach into the needle point were still relatively interior, and more vertical access technology was applied in the treatment of intervertebral foramen appearance in 41 patients with lumbar disc prolapse, leading to a success rate of 92% [6, 14, 19].

Sixty cases successfully completed the full-endoscopic surgery. The amount of NP removed intraoperatively had different volumes due to individual differences. The removed disc tissue volume was measured using a syringe ranged from 1.5 mL to 3.8 mL (2.4 mL on average), which completely relieved the nerve root compression. Afterwards, postoperative sciatica symptoms disappeared. No obvious recurrence was reported within one-year follow-up, and the fine rate reached 91.6%. Two patients were shifted to open surgery at initial time. The reason in one case was dural sac rupture due to excessive depth of the implanted working channel; the reason for the other case was that the protruding NP tissue could not be completely removed due to the inappropriate position of the work channel. Thus, a good working channel position is important for successful full-endoscopic surgery with proper surgical indications. Meanwhile, the percutaneous full-endoscopic targeted techniques should be specifically designed to remove the disc protrusions in various types of LDH [12, 20]. As our result demonstrated, this technique is feasible and repeatable as Ruetten proposed; targeted approach was developed to overcome lumbar disc herniation located mainly in spinal canal or extraforaminally [12, 17]. With the surgical devices and the possibility of selecting

interlaminar or posterolateral to extraforaminal procedure, we can sufficiently remove the lumbar disc herniations inside and outside the spinal canal using the full-endoscopic technique. We view percutaneous full-endoscopic interlaminar or extraforaminal approach as a safe and sufficient supplementation to microsurgical procedures [21, 22]. Spine surgeons are more familiar with interlaminar approach to relieve lumbar degenerated disease. The full-endoscopic technology through interlaminar approach is easier to learn and master and reduces the steep learning curve of mastered full-endoscopic technique compared to transforaminal approach. Nonetheless, it must be remembered that difficulties can never be ruled out during the learning progress. But some preparations are necessary, such as training in an experienced spine center, and attending the cadaveric workshops could be meaningful; and "simple" cases with big interlaminar window should be operated on to begin with, in which difficulties could not be avoided thanks to manipulation technique and the anatomic situation, if problems are encountered intraoperatively and switched to a standard procedure [1, 12, 17, 21].

#### 5. Conclusion

Based on the main location of the herniated disc and its relationship with compressed nerve root, we used percutaneous full-endoscopic discectomy through different puncture technique to remove the protrusive NP for LDH. Acquired benefits are fewer complications, rapid recovery, complete NP removal, effective nerve root decompression, and satisfactory cosmetic effect as well, which is a safe, effective, and rational minimally invasive spine-surgical technology with excellent clinical outcome.

#### **Competing Interests**

No conflicting financial interests exist.

#### **Acknowledgments**

This work was supported by Science and Technology Foundation of Guizhou Province, Qian Ke He J Zi [2012] 07.

#### References

- Z. Li, S. Hou, W. Shang, K. Song, and H. Zhao, "The strategy and early clinical outcome of full-endoscopic L5/S1 discectomy through interlaminar approach," *Clinical Neurology and Neuro*surgery, vol. 133, pp. 40–45, 2015.
- [2] Y. Zhou, H. Wang, J. Wang et al., "Learning curve for percutaneous endoscopic lumbar discectomy depending on the surgeon's training level of minimally invasive spine surgery," *Clinical Neurology and Neurosurgery*, vol. 115, no. 10, pp. 1987– 1991, 2013.
- [3] K. Wang, X. Hong, B.-Y. Zhou et al., "Evaluation of transforaminal endoscopic lumbar discectomy in the treatment of lumbar disc herniation," *International Orthopaedics*, vol. 39, no. 8, pp. 1599–1604, 2015.
- [4] B. Wang, G. Lü, W. Liu, I. Cheng, and A. A. Patel, "Full-endoscopic interlaminar approach for the surgical treatment of

- lumbar disc herniation: the causes and prophylaxis of conversion to open," *Archives of Orthopaedic and Trauma Surgery*, vol. 132, no. 11, pp. 1531–1538, 2012.
- [5] R. S. Gupta, X.-T. Wu, X. Hong, and A. Sinkemani, "Technique of percutaneous transforaminal endoscopic discectomy for the treatment of lumbar disc herniation," *Open Journal of Orthopedics*, vol. 5, no. 7, pp. 208–216, 2015.
- [6] A. T. Yeung and P. M. Tsou, "Posterolateral endoscopic excision for lumbar disc herniation: surgical technique, outcome, and complications in 307 consecutive cases," *Spine*, vol. 27, no. 7, pp. 722–731, 2002.
- [7] S. Ruetten, M. Komp, and G. Godolias, "A new full-endoscopic technique for the interlaminar operation of lumbar disc herniations using 6-mm endoscopes: prospective 2-year results of 331 patients," *Minimally Invasive Neurosurgery*, vol. 49, no. 2, pp. 80– 87, 2006.
- [8] S. Lee, S.-K. Kim, S.-H. Lee et al., "Percutaneous endoscopic lumbar discectomy for migrated disc herniation: classification of disc migration and surgical approaches," *European Spine Journal*, vol. 16, no. 3, pp. 431–437, 2007.
- [9] G. Choi, S.-H. Lee, A. Bhanot, P. P. Raiturker, and Y. S. Chae, "Percutaneous endoscopic discectomy for extraforaminal lumbar disc herniations: extraforaminal targeted fragmentectomy technique using working channel endoscope," *Spine*, vol. 32, no. 2, pp. E93–E99, 2007.
- [10] K. Martin, S. Ruetten, and G. Godolias, "Full-endoscopic discectomy for lumbar disc herniations: a prospective 12-months outcome study of patients treated with new endoscopes and instruments," *The Spine Journal*, vol. 5, no. 4, p. S120, 2005.
- [11] T. Hoogland, M. Schubert, B. Miklitz, and A. Ramirez, "Transforaminal posterolateral endoscopic discectomy with or without the combination of a low-dose chymopapain: a prospective randomized study in 280 consecutive cases," *Spine*, vol. 31, no. 24, pp. E890–E897, 2006.
- [12] S. Ruetten, M. Komp, H. Merk, and G. Godolias, "Full-en-doscopic interlaminar and transforaminal lumbar discectomy versus conventional microsurgical technique: A Prospective, Randomized, Controlled Study," *Spine*, vol. 33, no. 9, pp. 931–939, 2008.
- [13] A. T. Yeung, "Minimally invasive disc surgery with the Yeung endoscopic spine system (YESS)," *Surgical Technology International*, vol. 8, pp. 267–277, 1999.
- [14] S. W. Suh, V. U. Shingade, S. H. Lee, J. H. Bae, C. E. Park, and J. Y. Song, "Origin of lumbar spinal roots and their relationship to intervertebral discs: a cadaver and radiological study," *The Journal of Bone & Joint Surgery—British Volume*, vol. 87, no. 4, pp. 518–522, 2005.
- [15] C. Chaichankul, S. Poopitaya, and W. Tassanawipas, "The effect of learning curve on the results of percutaneous transforaminal endoscopic lumbar discectomy," *Journal of the Medical Association of Thailand*, vol. 95, supplement 10, pp. S206–S212, 2012.
- [16] M. He, G.-B. Wang, and J.-S. Wang, "The clinical research of the relation between the pain and the disc herniation type," *China Journal of Orthopaedics and Traumatology*, vol. 24, no. 7, pp. 578–581, 2011.
- [17] S. Lee, J. H. Kang, U. Srikantha, I.-T. Jang, and S.-H. Oh, "Extraforaminal compression of the L-5 nerve root at the lumbosacral junction: clinical analysis, decompression technique, and outcome," *Journal of Neurosurgery: Spine*, vol. 20, no. 4, pp. 371–379, 2014.

[18] Y. Jia, G. Hou, D. Si et al., "Anatomic measurement and clinical significance of lumbar vertebral plate gap," *Journal of Hebei United University (Health Science)*, vol. 17, no. 5, pp. 92–93, 2015.

- [19] S. Ruetten, M. Komp, H. Merk, and G. Godolias, "Use of newly developed instruments and endoscopes: full-endoscopic resection of lumbar disc herniations via the interlaminar and lateral transforaminal approach," *Journal of Neurosurgery: Spine*, vol. 6, no. 6, pp. 521–530, 2007.
- [20] S. Ruetten, U. Komp, H. Merk, and G. Godolias, "A new full-endoscopic technique for cervical posterior foraminotomy in the treatment of lateral disc herniations using 6.9-mm endoscopes: prospective 2-year results of 87 patients," *Minimally Invasive Neurosurgery*, vol. 50, no. 4, pp. 219–226, 2007.
- [21] K.-C. Choi, J.-H. Lee, J.-S. Kim et al., "Unsuccessful percutaneous endoscopic lumbar discectomy: a single-center experience of 10 228 cases," *Neurosurgery*, vol. 76, no. 4, pp. 372–380, 2015.
- [22] G. Choi, N. Prada, H. N. Modi, N. B. Vasavada, J.-S. Kim, and S.-H. Lee, "Percutaneous endoscopic lumbar herniectomy for high-grade down-migrated L4–L5 disc through an L5-S1 interlaminar approach: a technical note," *Minimally Invasive Neurosurgery*, vol. 53, no. 3, pp. 147–152, 2010.