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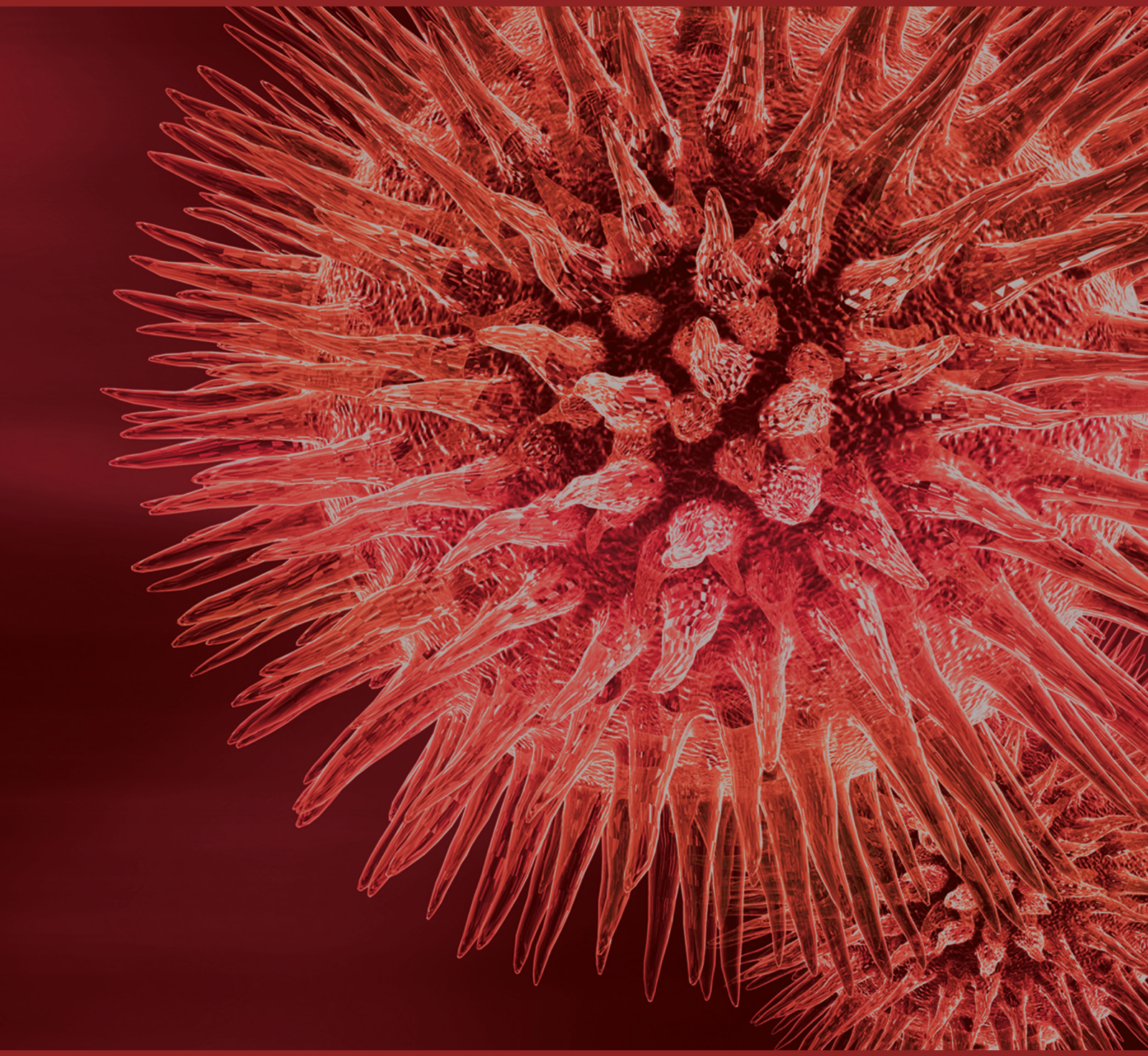
Guest Editors: Jau-Ching Wu, Patrick C. Hsieh, Praveen V. Mummaneni, and Michael Y. Wang



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Hindawi Publishing Corporation
BioMed Research International
Volume 2015, Article ID 372502, 3 pages
http://dx.doi.org/10.1155/2015/372502

Editorial

Spinal Motion Preservation Surgery

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Received 3 December 2015; Accepted 16 December 2015

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The principals of spinal surgery include decompression of neural elements, stabilization of motion segments, and balancing the vertebral alignment. Common operations involve resection of the herniated disc or removal of osteophytes and sometimes stabilization of spondylolisthesis. In extreme cases, for example, correction of scoliosis, fixation of multiple spinal segments and intended bone fusion are often necessary and inevitable, because only arthrodesis can maintain the surgical outcomes for a prolonged time. However, arthrodesis inevitably causes a loss in the range of physiological motion of the spinal segments and consequently may lead to multiple problems, including stiffness, junctional kyphosis, and increased risk of adjacent segment disease (ASD). In the area of spinal surgery during the last decade, much attention therefore has been directed to motion preservation. There are multiple techniques and devices aimed at preserving the segmental range of motion in the treated spine, including disc or facet arthroplasty, laminoplasty, pedicle based dynamic stabilization, and interspinous devices [1–7].

To date, among these innovative surgical approaches to preserve spinal motion, cervical disc arthroplasty (CDA) has the most data on its use and effectiveness. Several multicenter, prospective, randomized, and controlled clinical trials have demonstrated equivalent or superior clinical results of CDA when compared with standard anterior cervical discectomy and fusion (ACDF) [8–11]. Most of the implanted artificial discs have functioned well to maintain a physiological range of motion at the indexed levels [12–14]. However, there has not been enough evidence for the theoretical benefit of CDA on decreasing ASD. Even the true incidence of ASD or its etiologies remain elusive. A study of a cohort of 19,385 patients who underwent ACDF estimated the annual incidence of ASD to be 0.8%, and the accumulative reoperation rate after ACDF was 5.6% in ten years [15]. Although motion preservation surgery of the spine avoids the compensatory increase in the work load at the adjacent levels after spinal arthrodesis surgery, whether ASD can be decreased or postponed by spinal motion preservation surgery remains uncertain. Due to the relatively low incidence rate of ASD, more studies with a larger number of patients and longer term follow-up are required to clarify the outcomes and effects of surgery that preserves spinal motion.

Surgery aiming to preserve motion of the lumbar spine has generated much attention and concern. The lumbar spine inherently endures more weight than the cervical spine and thus makes stabilization as well as preservation of motion even more challenging. Lumbar disc arthroplasty (LDA), in several clinical trials, demonstrated similar improvement in clinical outcomes to spinal fusion surgery [16, 17]. However, there were not sufficient data to support the reduction of ASD after LDA. Moreover, there was less evidence of satisfactory long term outcomes from LDA than has been shown with cervical disc replacement. As there were additional problems related to the approach and difficulty in retrieval, LDA did not gain similar popularity to CDA in the past decade [18].

Others tried pedicle based dynamic stabilization devices since they reportedly provided limited segmental motion and decreased stiffness, but some of these pedicle screws became

loose during follow-up [2, 5, 7]. A few studies demonstrated satisfactory clinical outcomes of these dynamic pedicle screws in lumbar degenerative disc disease (DDD) and mild spondylolisthesis [1, 2, 5, 7]. However, the role of lumbar dynamic devices is still debated and is not well accepted.

Another attempt at nonfusion fixation in the lumbar spine was the use of interspinous devices. However, interspinous devices typically led to postoperative focal kyphosis with various degrees of stability provided, depending on its design [19].

The major concerns of these lumbar dynamic devices are the indications for surgery and the durability of the surgery. There are still many debates on the best candidates for such kinds of motion preservation surgery on the lumbar spine. Patients with DDD were the most commonly proposed candidates for these dynamic devices. Nonetheless, it is uncertain if these devices are effective not only for those with DDD but also for others who suffer from disc herniation, hypertrophic ligaments, facet arthropathy, spondylolisthesis, and scoliosis. Such dynamic devices inevitably have wearing problems and lack long term results.

Furthermore, the spinal-pelvic alignment has not been well studied for motion preservation surgery in the lumbar spine. The importance of sagittal balance learned from fusion surgery for deformity has not been translated to or not corroborated for dynamic devices.

In this special issue, there are five papers addressing these state-of-art applications of spinal motion preservation surgery. The papers cover review of material science of CDA, new assessment of three-dimensional movements in lumbar facet joints and vertebrae in patients who underwent LDA, long term (up to almost 9 years) outcomes of cervical laminoplasty in the elderly, comparison of vertebral body stapling and bracing for patients with idiopathic scoliosis, and analysis of lumbar lordosis on screw loosening in Dynesys dynamic stabilization. Although many of these technologies have been on the market for years, more studies are necessary to investigate the long term effects and address the avoidance of associated complications before greater expansion of their utilization.

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Hindawi Publishing Corporation
BioMed Research International
Volume 2015, Article ID 152435, 8 pages
http://dx.doi.org/10.1155/2015/152435

Clinical Study

The Effect of Lumbar Lordosis on Screw Loosening in Dynesys Dynamic Stabilization: Four-Year Follow-Up with Computed Tomography

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Received 19 August 2015; Revised 10 November 2015; Accepted 11 November 2015

Academic Editor: Panagiotis Korovessis

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Introduction. This study aimed to evaluate the effects of Dynesys dynamic stabilization (DDS) on clinical and radiographic outcomes, including spinal pelvic alignment. *Method*. Consecutive patients who underwent 1- or 2-level DDS for lumbar spondylosis, mild degenerative spondylolisthesis, or degenerative disc disease were included. Clinical outcomes were evaluated by Visual Analogue Scale for back and leg pain, Oswestry Disability Index, and the Japanese Orthopedic Association scores. Radiographic outcomes were assessed by radiographs and computed tomography. Pelvic incidence and lumbar lordosis (LL) were also compared. *Results*. In 206 patients with an average follow-up of 51.1 ± 20.8 months, there were 87 screws (8.2%) in 42 patients (20.4%) that were loose. All clinical outcomes improved at each time point after operation. Patients with loosened screws were 45 years older. Furthermore, there was a higher risk of screw loosening in DDS involving S1, and these patients were more likely to have loosened screws if the LL failed to increase after the operation. *Conclusions*. The DDS screw loosening rate was overall 8.2% per screw and 20.4% per patient at more than 4 years of follow-up. Older patients, S1 involvement, and those patients who failed to gain LL postoperatively were at higher risk of screw loosening.

1. Introduction

Sciatica, neurogenic claudication, and lower back pain are common symptoms of degenerative lumbar spondylolisthesis. Although many patients who experience these can be managed with medication or rehabilitation, spondylolisthesis with spinal stenosis at L4/5 is not uncommon in the elderly and sometimes requires surgery [1, 2]. The surgical options usually include decompression and stabilization if there is segmental instability. Moreover, during the past several decades, various surgical corridors have been developed, including anterior [3], posterior [4, 5], and lateral [6], via traditional open, minimally invasive [4, 5, 7], or endoscopic [8] approaches.

In the last decade, there has been an emerging option of spinal motion preservation surgery (SMPS) for lumbar spondylosis. Unlike fusion, preservation of motion of the indexed spinal segments after surgical decompression intuitively allows movements similar to one's physiology motion. As long as adequate spinal stability is achieved, it theoretically provides favorable outcomes and eliminates the development of adjacent segment disease (ASD) after arthrodesis [9]. However, the actual benefits of these SMPS still require further studies to corroborate.

In 1994, Dr. Dubois first used the Dynesys dynamic stabilization (DDS, Zimmer Spine, Minnesota) [10]. The pedicle screw based system was intended to provide mobile stabilization, controlling motion in all three planes (flexion/extension, axial rotation, and lateral bending). Its safety and efficacy have been demonstrated by several case series for the management of degenerative disc disease (DDD), lumbar spondylosis, and spondylolisthesis [10–15]. On the other hand, restoration of sagittal balance, lumbar lordosis (LL), and pelvic incidence (PI) were reportedly correlated with clinical improvement after fusion of the thoracolumbar spine [16, 17]. Nevertheless, the true effect of stabilization for patients with slight to mild disability remains uncertain. Furthermore, there is a paucity of the literature addressing these spinal pelvic parameters, including sagittal balance, LL, and PI, in patients with spondylolisthesis who were managed with dynamic stabilization. Therefore, this study aimed to investigate the clinical outcomes of DDS and its correlation to the radiological parameters in the setting of spondylolisthesis.

2. Methods

2.1. Patient Population. Consecutive patients who underwent posterior decompression and Dynesys dynamic stabilization (DDS) in the authors' institute from 2006 to 2010 were included. All their medical records, radiological studies, and clinical evaluations were retrospectively reviewed.

The inclusion criteria were symptomatic lumbar spinal stenosis, Meyerding grade one spondylolisthesis, recurrent disc herniation, and degenerative disc disease causing symptoms such as neurogenic claudication, back pain, leg pain, or any combination of the above. All patients failed at least 12 weeks of conservative management, including medication, traction, local injection, or physical therapy. The exclusion criteria were multiple level disc disease, spondylolisthesis of Meyerding grade two or higher, degenerative scoliosis, the presence of vertebral fracture, infection, tumor, or loss of follow-up. Every patient was evaluated by anteroposterior radiograph, lateral dynamic (i.e., flexion and extension) radiographs, computed tomography (CT), and magnetic resonance imaging (MRI) prior to the operation.

2.2. Surgical Technique. Patients were placed under general anesthesia in a prone position with adequate cushioning. Standard total laminectomies were performed cautiously with preservation of the facet joints. Subdermal dissection was made through the same midline skin incision, which allowed another two fascial incisions, one on each side, for the Wiltse approach. The Dynesys titanium alloy screws without hydroxyapatite coating were then placed transpedicularly through the Wiltse plane without destruction of the facet joints. The DDS constructs, polycarbonate-urethane spacers, and polyethylene-terephthalate cords (Sulene-PET) were assembled under appropriate tension, measured by the standard instrument, without specific attempt to reduce the spondylolisthesis intraoperatively. Lateral fluoroscopy was routinely used to assure optimal positioning of the screws at the end of surgery.

2.3. Clinical and Radiographic Evaluations. All medical records and radiological images were retrospectively reviewed. Functional outcomes were evaluated by Visual Analogue Scale (VAS) for back and leg pain, Oswestry Disability Index (ODI), and clinical symptom scores of the Japanese Orthopaedic Association (JOA) by special nurses under the guidance of attending surgeons during clinical visits according to the designated time schedule. The patients themselves completed a questionnaire preoperatively and regularly at 6, 12, 18, and 24 months postoperatively.

Lateral standing lumbar radiographs were taken for every patient preoperatively and at the last follow-up. Lumbar lordosis (LL) was defined as the angle measured between the superior endplate of L1 and the superior endplate of S1. Pelvic incidence (PI) was defined as the angle subtended by a line drawn between the center of the two femoral heads and the sacral endplate and a line drawn perpendicular to the sacral endplate. Screw position was defined by postoperative computed tomography (CT) examination. Screw loosening was defined as the presence of a "halo zone sign" or "double halo sign" on anteroposterior radiographs during follow-up. In cases of equivocal findings of screw loosening by the radiographs, multidetector CT scans with two-dimensional reformatted images were used to determine questionable screw loosening.

2.4. Statistical Analysis. Data are presented as the average ± standard deviation for continuous variables and as frequency and percentages for categorical variables. All statistical tests were two-tailed, and $p < 0.05$ was considered statistically significant by independent t-test or chi-square test. All statistical analyses were performed using MedCalc Software (Ostend, Belgium).

3. Results

3.1. Patients' Demographic Data. From 2007 to 2010, a total of 291 consecutive patients who underwent 1- or 2-level DDS were included in the present study. Among them there were 206 patients (71%), in whom 1064 screws were placed and who completed the clinical and radiological evaluations for more than 2 years postoperatively and were thus analyzed.

Of these 206 patients, there were 115 men (55.8%) and 91 women (44.2%), and the mean age was 61.0 ± 12.9 years at the time of surgery. The mean clinical follow-up duration was 51.1 ± 20.8 months, and the mean radiological follow-up duration was 40.7 ± 19.7 months. Of the 206 patients, 86 (41.7%) underwent 1-level surgery, and 120 (58.3%) underwent 2-level surgery. The distributions of indexed levels are presented in Table 1.

3.2. Clinical Outcomes. The clinical outcomes were measured by VAS score of back and leg pain and ODI and JOA scores. When compared to the preoperative status, all the outcome

Table 1: Demographic and clinical characteristics.

Characteristic	Value
Number of patients	206
Sex	
Male	115 (55.8%)
Female	91 (44.2%)
Age (year)*	61.0 ± 12.9
Months of follow-up*	
Imaging	40.7 ± 19.7
Clinical	51.1 ± 20.8
Number of instrumented levels	
1 level	86 (41.7%)
L2-3	2
L3-4	7
L4-5	61
L5-S1	16
2 levels	120 (58.3%)
L2-3-4	4
L3-4-5	86
L4-5-S1	30

*Values are presented by mean ± SD.

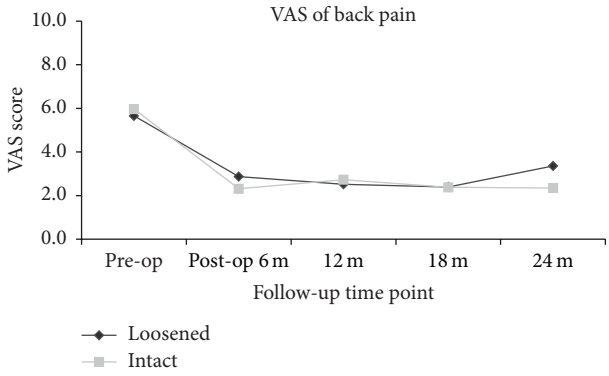


Figure 1: Clinical outcomes measured by VAS for back pain at different time points, suggestive of significant improvement postoperatively. No statistical differences were present between patients with and without screw loosening at each time point.

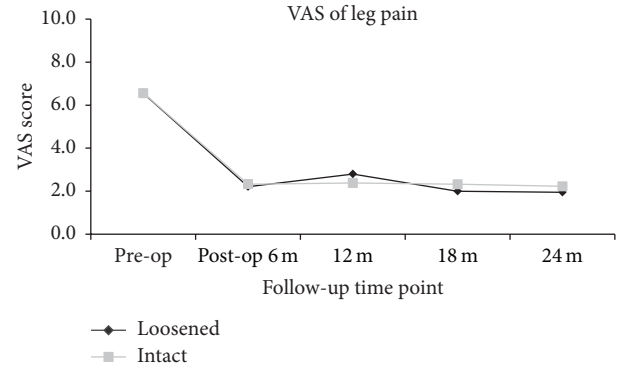


Figure 2: Clinical outcomes measured by VAS for leg pain at different time points, suggestive of significant improvement postoperatively. No statistical differences were present between patients with and without screw loosening at each time point.

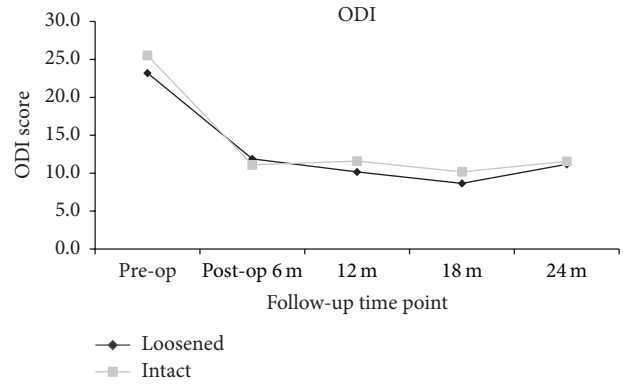


Figure 3: Clinical outcomes demonstrated by ODI at different time points, suggestive of significant improvement postoperatively. No statistical differences were present between patients with and without screw loosening at each time point.

scores had significantly improved at 6, 12, 18, and 24 months after surgery ($p < 0.05$). Whether screw loosening was evident or not, the scores of VAS back and leg pain (Figures 1 and 2), ODI (Figure 3), and JOA (Figure 4) all improved when compared to that of preoperation.

At the 24-month follow-up time point, all clinical scores of patients with screw loosening had significant improvement when compared to that of preoperation (VAS back: 3.4 ± 2.8 versus 5.7 ± 3.3; $p < 0.01$; VAS leg: 2.0 ± 2.9 versus 6.6 ± 3.0; $p < 0.01$; ODI: 11.2 ± 9.6 versus 23.2 ± 9.2; $p < 0.01$; and JOA: 10.1 ± 3.0 versus 5.7 ± 3.4; $p < 0.01$). For patients with intact (i.e., no loosening) screws, all clinical scores at 24 months after operation had significant improvement when compared to that of preoperation (VAS back: 2.3 ± 2.7 versus 6.0 ± 3.1; $p < 0.01$; VAS leg: 2.2 ± 2.9 versus 6.6 ± 2.9; $p < 0.01$; ODI: 11.6 ± 10.3 versus 25.5 ± 9.2; $p < 0.01$; and JOA: 10.7 ± 8.9 versus 5.2 ± 3.0; $p < 0.01$). There were no significant differences between the 2 groups at all evaluation time points ($p > 0.05$) (Figures 1–4).

3.3. Screw Loosening and Involvement of S1 Segment. Among the 1064 screws inserted into 206 patients, radiographic evidence of screw loosening was demonstrated in 87 screws (8.2%) of 42 patients (20.4%) (Figure 5). The mean age of patients with screw loosening was significantly older than that of intact screws (64.6 ± 11.6 versus 60.1 ± 13.1; $p = 0.03$). There were no differences in sex distribution ($p = 0.99$), mean body mass index ($p = 0.22$), diabetes mellitus ($p = 0.47$), hypertension ($p = 0.47$), cigarette smoking ($p = 0.92$), and levels of instrumentation ($p = 0.48$) (Table 2).

Between the two groups of patients (with and without screw loosening), there were no differences in PI, LL, or S1 involvement (all $p > 0.05$). The screw loosening was distributed from L2 to S1, and the highest percentage of screw loosening was found in S1 (16.3%).

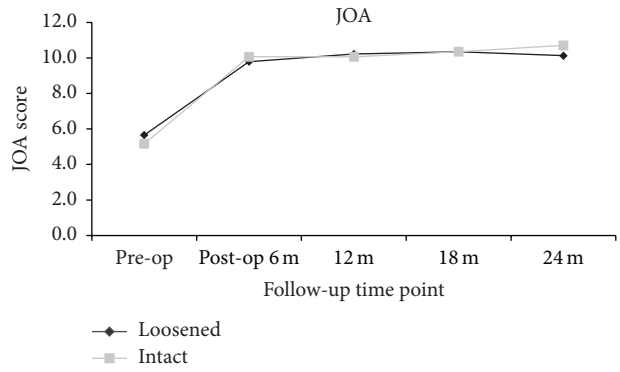


Figure 4: Clinical outcomes demonstrated by JOA score at different time points, suggestive of significant improvement postoperatively. No statistical differences were present between patients with and without screw loosening at each time point.

Table 2: Comparison of patients with and without screw loosening.

Characteristic	Screw loosening		p value
	Yes	No	
Number of patients	42 (20.4%)	164 (79.6%)	
Age (year)*	64.6 ± 11.6	60.1 ± 13.1	**0.03**
Sex (F : M)			0.99
Male	23	92	
Female	19	72	
BMI*	24.6 ± 3.2	25.6 ± 3.8	0.22
DM	11/42	30/164	0.47
HTN	16/42	75/164	0.47
Smoke	3/42	15/164	0.92
Instrumentation			0.48
1 level	15/42	71/164	
2 levels	27/42	135/164	
Blood loss (mL)*	822.6 ± 521.6	703.6 ± 544.5	0.22
Number of screws	87 (8.2%)	977 (91.8%)	
Screw distribution			
L2	0 (0%)	12 (100%)	
L3	16 (8.1%)	182 (91.9%)	
L4	24 (6.4%)	352 (93.6%)	
L5	32 (8.3%)	354 (91.7%)	
S1	15 (16.3%)	77 (83.7%)	

*Values are presented by mean ± SD.
BMI = body mass index; DM = diabetes mellitus; and HTN = hypertension.

Among the 46 patients whose DDS construct involved S1, radiologically evident screw loosening was found in 10 (28.8%) patients (Table 3). In this subgroup analysis, there were no differences in PI and LL (both $p > 0.05$) between the two groups of patients (with and without screw loosening). Although the differences did not reach significance, there was a trend toward higher delta LL (postoperation minus that of preoperation) in patients with screws loosening and S1 involvement. (9.3 ± 12.8 versus 0.4 ± 12.5, $p = 0.07$). Moreover, in patients who gained LL through the DDS surgery, the rate of screw loosening was significantly lower than in those who had decreased LL (12.1% versus 46.1%, $p = 0.03$) (Table 4).

Table 3: Comparison of radiographic measurements in patients with S1 involvement.

Characteristic	Screw loosening		p value
	Yes	No	
Number of patients	10 (28.8%)	36 (71.2%)	
PI*	40.8 ± 12.1	41.6 ± 9.9	0.84
LL*			
Pre-op	29.9 ± 12.2	26.6 ± 9.9	0.45
Post-op	30.3 ± 11.9	35.9 ± 11.3	0.20
Delta (post-op minus pre-op)	0.4 ± 12.5	9.3 ± 12.8	0.07
PI − LL	10.9 ± 13.2	15.0 ± 12.1	0.39

*Values are presented by mean ± SD.
PI = pelvic incidence; LL = lumbar lordosis.

Table 4: Rate of screw loosening in Dynesys dynamic stabilization involving S1.

	Screw loosening (Number of patients)		Rate of loosening	p value
	Yes	No		
Delta LL ≥0	4	29	12.1%	**0.03**
Delta LL <0	6	7	46.1%	
Total	10	36		

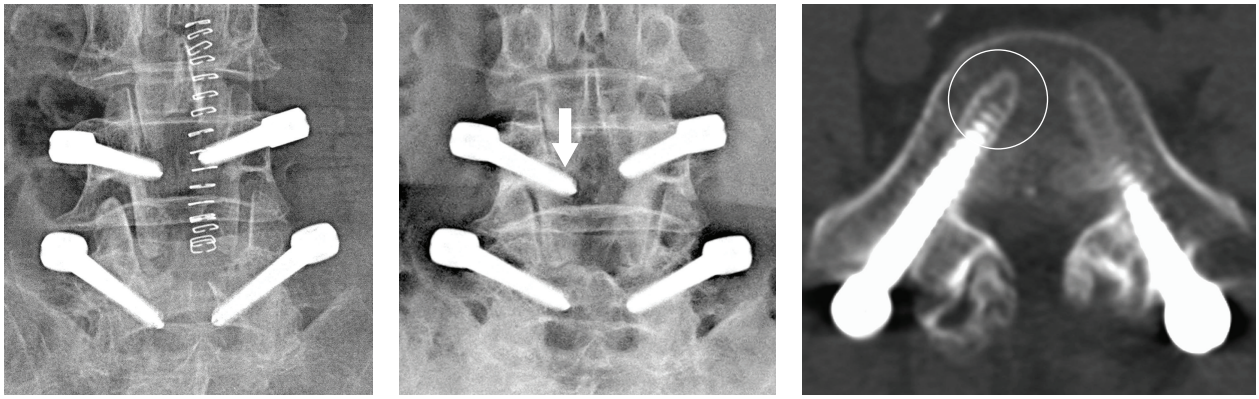
Delta LL (lumbar lordosis) was defined as postoperative LL minus preoperative LL.

3.4. Further Management. Among the 87 loosened screws found in 42 patients, there were 4 screws broken (0.4%), which were found in 4 patients (1.9%). In the serial follow-up of these patients, there were few clinically significant symptoms. One patient who had a loosened screw later received secondary revision surgery due to progressive spondylolisthesis at the adjacent level, which was treated with transforaminal lumbar interbody fusion.

In the current series, there were no malpositioned screws that caused neurological symptoms which required revision surgery, although postoperative CTs demonstrated several breaches of the pedicles. There were 2 patients who had postoperative infection and received secondary surgery for the removal of implants within 2 years after the primary surgery.

4. Discussion

This study analyzed 1064 Dynesys screws used for dynamic stabilization in 206 patients with lumbar spondylosis. During a mean follow-up period of 51 months, 87 screws (8.2%) in 42 patients (20.4%) became loose. Interestingly, the clinical outcomes equally improved whether screw loosening was evident or not. Most of the patients with screw loosening were asymptomatic, and screw loosening was identified only radiographically during regular follow-ups, except one patient who actually received secondary surgery of fusion



(a) (b) (c)

Figure 5: Postoperative images obtained from a 69-year-old female patient who underwent dynamic stabilization at the level of L4/5. (a) Plain radiograph on postoperative day 3. (b) Postoperative plain radiograph 6 months after surgery documented the halo sign (arrow) which was indicative of screw loosening. (c) CT scan performed 19 months after surgery documented the presence of screw loosening (circle).

for spondylolisthesis at an adjacent level. The study demonstrated that quite a proportion of patients who received DDS actually had screw loosening, but this did not affect the clinical improvement over an average of 4 years. Furthermore, the present report indicated that older patients, construct involving S1, and those who had flat back (failed to gain LL) postoperatively were more likely to have screw loosening. This finding raised the concern of longer-term adverse events of this pedicle-based dynamic stabilization system. To date, this was the largest series of DDS with emphasis on screw loosening, clinical outcomes, and spinal pelvic alignment. The results could be reasonably anticipated because of the tendency of osteopenia in the elderly, structural characteristics of the S1 vertebra, and the importance of restoration of LL in lumbar spine surgery.

The problem of screw loosening is a concern in the dynamic stabilization system. Wu et al. [15] studied retrospectively 658 screws in 126 patients who underwent DDS for a mean follow-up of 37.0 months: 4.7% of screws in 19.8% patients had screw loosening. Ko et al. [14] studied retrospectively 71 patients who underwent decompression using DDS for 1- or 2-level lumbar spondylosis. Screw loosening in 19.7% of patients and 4.6% of screws was noted. In a series by Payer et al. [2] of 30 patients who had single-level degenerative lumbar disease with stenosis and who underwent DDS, screw loosening was found in 2 cases. Segura-Trepichio et al. [12] also reported on 22 patients who underwent DDS. A total of 4 (18%) patients had signs of loose screws. The rate of screw loosening in our report seems to be similar with previous studies.

In a previous report by Wu et al., patients of older age or those with diabetes were noted to have higher rates of screw loosening [15]. A large series published previously described decreased bone mineral density (BMD) associated with age [18, 19]. Decreased bone mineral density, especially in patients with osteoporosis, is indicative of a high risk of screw loosening. On the other hand, there was no statistically significant change of screw loosening rates in patients with diabetes mellitus (DM) between the groups in our present study. For patients with type 2 DM, some authors have reported an elevated BMD [20–22], while other studies have reported a decreased BMD [23, 24], and some have reported unaltered bone density [20, 25]; some cross-sectional studies have even found normal BMD [26, 27]. The effect of DM on BMD or screw loosening is controversial.

From a biomechanical viewpoint, the lumbosacral junction has a high mechanical demand and short, wide, cancellous pedicles at L5 and S1 [28]. The lumbosacral junction and the disc level of L4/5 contribute the most to the formation of lumbar lordosis when compared to other disc levels. Bicortical fixation with S1 screws has been recommended to achieve adequate fixation at the lumbosacral junction [29]. The bridged segments of the lumbosacral junction is a close linkage system. In patients with lumbosacral fusion, distraction instrumentation would cease lumbar lordosis and cause flat back syndrome [30]. Kostuik and Hall [31] reviewed the cases of 45 adult patients in whom fusion was performed on the sacrum for scoliosis. Of those patients, 22 (49%) were noted to have lost lumbar lordosis. Thirteen (29%) underwent corrective osteotomies, with improvement in their pain. In our present study, all patients had clinical improvement in their VAS scores of the back and leg. Loss of lumbar lordosis with instrumentation presented no sign of flat back syndrome, but a higher screw loosening rate. We supposed that loss of lumbar lordosis in dynamic stabilization would cause a higher rate of screw loosening.

Pelvic incidence (PI), a spinal pelvic parameter, plays an important role in spinal sagittal balance. It is considered as a constant value decided by the individual anatomical position of the pelvis [32]. This parameter strongly correlates with lumbar lordosis by statistical analysis. The lower value of PI implies a flattened lordosis. For example, Boulay et al. in 2006 conducted a study about the correlation between PI and lordosis [33]. The mean PI in adults is measured as

Table 5: The comparison outcome of total patients and patients over 2-year follow-up.

	Number of patients	Follow-up (months)		Rate of loosening per patient (%)	Rate of loosening per screw (%)
		Clinical	Radiological		
All patients	291	46.4 ± 22.7	32.6 ± 21.2	21.3	8.4
Follow-up >2 years	206	51.1 ± 20.8	40.7 ± 19.7	20.4	8.2

53 ± 9 degrees. A low PI value is considered as less than 44 degrees, which would lead to a flattened lordosis. A high PI (more than 62 degrees) would lead to more pronounced lordosis. Theoretically, a flattened lordosis contributes to a worse sagittal balance of the spine, and the standing position of an individual with inadequate LL would not be in the condition of efficient biomechanical economy.

In the current study, the screw loosening did not directly correlate with PI or lordosis ($p > 0.05$). However, it was correlated with the difference between pre- and postoperative lordosis. If the lumbar lordosis is flattened postoperatively, the screw loosening rate will increase significantly. The ideal positive or negative difference between PI and lordosis should be within 11 degrees [34]. The postoperative flattened lordosis would lead to a discordant balance to PI. Though this finding does not have clinical impact, the biomechanical effect cannot be ignored in the long run.

There are limitations to the current study. First, it is a retrospective study and inevitably had some loss during follow-up. However, all the patients in the series were treated by the same group of surgeons under a uniform management strategy. Thus, there was little selection bias between the patients involved in the current study. With a mean follow-up of more than 4 years (51 months), over one thousand Dynesys screws were followed up in more than 70% of the patients (>200 patients). This was the largest series to date specifically focused on Dynesys screw loosening. An additional analysis included all 291 patients of the current series and demonstrated that overall 21.3% of patients had screw loosening at a mean follow-up of 32.6 months. This comprehensive rate of screw loosening was similar to that analyzed from those patients who had more than 24 months of follow-up (i.e., 20.4% of patients at 40.7 months). The overall rate of loosening per screw, 8.4% at 32.6 months, was similar to that of 206 patients who had follow-up more than two years (i.e., 8.2% of screws at 40.7 months) (Table 5). Therefore, the data were not skewed when only patients with more than two years of follow-up were analyzed. The report reasonably reflected the actual clinical scenario.

Second, the determination of screw loosening was not ideal. The current method of identification of loosened Dynesys screws was dependent on the observer, radiologists, and neurosurgeons interpreting the image studies and thus could be arbitrary. The true identification of screw loosening should involve surgical exploration and pathological examination for confirmation of the weakened bone-screw interface. Nevertheless, the current study incorporated CT scans in conjunction with the dynamic radiographs. Although this assessment of screw loosening was not perfect, it was the best currently available evidence and also clinically practical. There were no comparable studies of such a scale in the literature assessing DDS with CTs and radiographs. Furthermore, the spinal pelvic parameters were seldom addressed in previous reports of DDS. It was reasonable to infer that PI and LL were critically important in motion preservation surgery of the lumbar spine. Also, this study did not demonstrate the actual timing of occurrence of the screw loosening, which could happen earlier than that caught on imaging studies due to clinical silence. These issues would require future studies with longer follow-up to clarify.

5. Conclusion

In patients who underwent DDS, the screw loosening rate was overall 8.2% of screws and 20.4% of patients, at a mean follow-up of more than 4 years. Older patients, S1 involvement, and those who failed to gain LL postoperatively were at higher risk of screw loosening. Although the screw loosening was not symptomatic, this raised a concern about its long-term clinical effects.

Abbreviations

ASD: Adjacent segment disease
BMD: Bone mineral density
BMI: Body mass index
CT: Computed tomography
DDD: Degenerative disc disease
DDS: Dynesys dynamic stabilization
DM: Diabetes mellitus
HTN: Hypertension
JOA: The Japanese Orthopaedic Association (JOA) scores
LL: Lumbar lordosis
MRI: Magnetic resonance image
ODI: Oswestry Disability Index
PI: Pelvic incidence
SMPS: Spinal motion preservation surgery
VAS: Visual Analogue Scale.

Conflict of Interests

The authors report no conflict of interests concerning the materials or methods used in this study or the findings specified in this paper.

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Hindawi Publishing Corporation
BioMed Research International
Volume 2015, Article ID 438452, 7 pages
http://dx.doi.org/10.1155/2015/438452

Clinical Study

Vertebral Body Stapling versus Bracing for Patients with High-Risk Moderate Idiopathic Scoliosis

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Received 6 June 2015; Revised 23 September 2015; Accepted 12 October 2015

Academic Editor: Jau-Ching Wu

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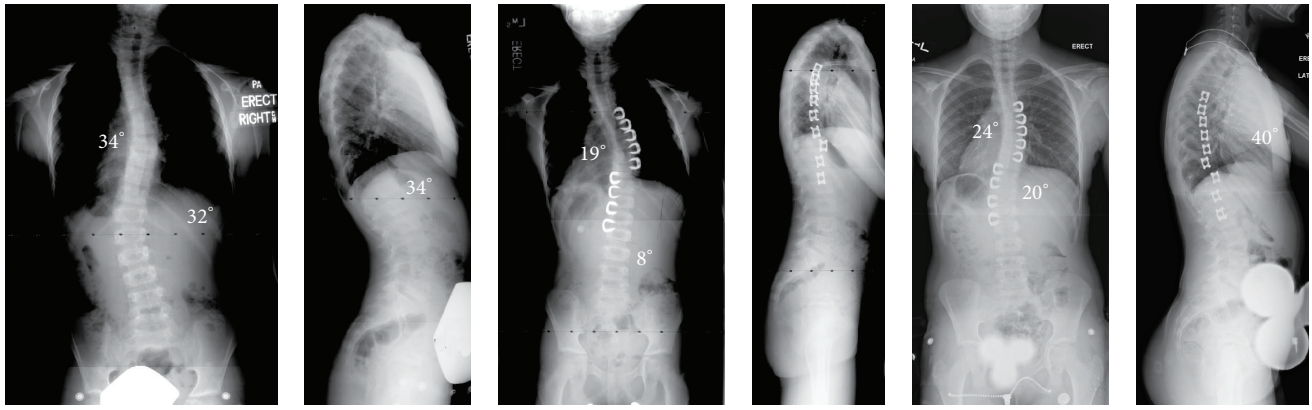
Purpose. We report a comparison study of vertebral body stapling (VBS) versus a matched bracing cohort for immature patients with moderate (25 to 44°) idiopathic scoliosis (IS). *Methods*. 42 of 49 consecutive patients (86%) with IS were treated with VBS and followed for a minimum of 2 years. They were compared to 121 braced patients meeting identical inclusion criteria. 52 patients (66 curves) were matched according to age at start of treatment (10.6 years versus 11.1 years, resp. [$P = 0.07$]) and gender. *Results*. For thoracic curves 25–34°, VBS had a success rate (defined as curve progression <10°) of 81% versus 61% for bracing ($P = 0.16$). In thoracic curves 35–44°, VBS and bracing both had a poor success rate. For lumbar curves, success rates were similar in both groups for curves measuring 25–34°. *Conclusion*. In this comparison of two cohorts of patients with high-risk (Risser 0-1) moderate IS (25–44°), in smaller thoracic curves (25–34°) VBS provided better results as a clinical trend as compared to bracing. VBS was found not to be effective for thoracic curves ≥35°. For lumbar curves measuring 25–34°, results appear to be similar for both VBS and bracing, at 80% success.

1. Introduction

The available nonsurgical treatment methods for moderate juvenile and adolescent idiopathic scoliosis (IS) are observation and bracing. Bracing has been the subject of great debate in recent years. The previously performed Scoliosis Research Society (SRS) brace study from the early 1980s attempted to prove effectiveness of conservative treatment of adolescent IS (AIS) [1]. A more recent follow-up of some of these patients showed that a meticulously performed brace regimen did hinder progression, with no need for subsequent surgical correction [2]. However, Dolan and Weinstein [3] conducted a systematic review of the available clinical studies for bracing and observation and compared surgical rates after observation and bracing for AIS. They concluded that there was not enough evidence to recommend bracing over observation, as the pooled surgical rate for bracing was 23%, and for observation it was 22%. Following this review, a randomized trial addressing the effect of bracing was conducted [4]. They were able to show that bracing is effective in decreasing the progression of high-risk [5] curves to the threshold for surgery.

There are other issues than the effectiveness associated with bracing, particularly the psychosocial ramifications of brace wear. Compliance with brace wear is certainly an issue, particularly for boys [6], and poor compliance has



(a) (b) (c) (d) (e) (f)

Figure 1: (a and b) This is an 8-year-old girl who presented with a double major curve (right thoracic: 34°, left thoracolumbar: 32°). The lateral X-ray shows a normal sagittal contour, with kyphosis from T5 to T12 of 34°. (c and d) Following VBS, the first erect PA and lateral films show the staples to be intact. There is excellent correction of both curves, with the thoracic curve correcting to 19° and the lumbar to 8°. (e and f) Films from 2-1/2 years postoperatively show successful maintenance of the thoracic curve (now measuring 24°) and the lumbar curve (now measuring 20°). The lateral film from 2 years postoperatively shows a 40° kyphosis from T5 to T12.

been associated with poor results [4, 7]. Furthermore, most children will have to wear the brace for an average of 2.9 years [8] but maybe for as long as 6 to 8 years, depending upon the patient's age at the start of bracing.

Vertebral body stapling (VBS) has been presented as an alternative treatment strategy for immature patients with IS (Figures 1 and 2). Preliminary results of VBS cohorts have been published [9, 10]. This current study reports a retrospective comparison study of VBS versus bracing alone for patients with moderate (25 to 44°) idiopathic scoliosis using identical inclusion criteria.

2. Materials and Methods

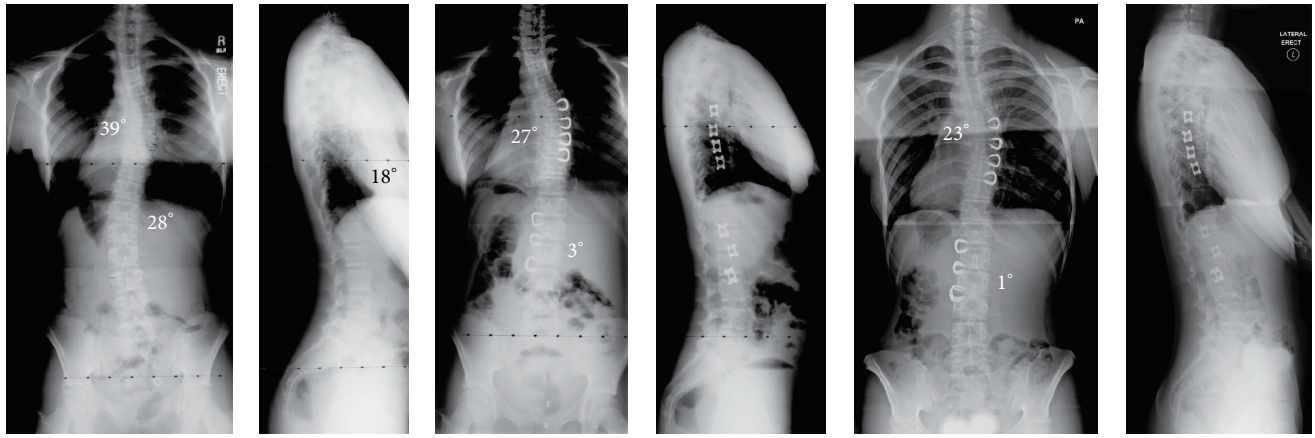
After obtaining IRB approval as well as informed consent for inclusion in research studies, we retrospectively reviewed our medical records from 2002 to 2007 and found a total of 83 patients who underwent VBS with proportional staples. The staple design was changed in 2002 to shorten the tines according to the disc height. Each staple had the correct proportional tine length as opposed to an earlier generation with a fixed tine length for all staples, which prevented the tines from being inserted close to the growth plate as was possible with the proportional staples. This study includes only patients having had surgery with proportional staples.

We identified 49 consecutive patients with 57 curves who met our inclusion criteria of (1) diagnosis of idiopathic scoliosis; (2) age at least 8 years at time of surgery or bracing; (3) curve measuring 25 to 44° at first visit; (4) Risser sign of 0 or 1 at the time of surgery; and (5) minimum 2-year follow-up after surgery. Of the 49 patients identified, 42 (86%) patients were available for this review. Seven patients had follow-up of less than 2 years, and further follow-up could not be obtained. VBS was performed on the largest curve, thoracic or lumbar, and the second curve was stapled if ≥25° and if the apex crossed the midline.

Data collection included patient age at the time of index procedure, gender, surgery/start of bracing date, and complications, if any. For the VBS group, measurements were made on preoperative posteroanterior (PA), lateral, and supine bending films at first erect and 2 years or longer recent follow-up. At each visit, standing PA and lateral radiographs were obtained. On the PA views, the Cobb angle and Risser grade were obtained. In addition, all radiographs were evaluated for signs of staple loosening, breakage, or dislodgment. This would include radiographic changes such as haloing around the staple prongs or subtle radiographic changes such that the staples are not in the exact same location from X-ray to X-ray.

The bracing cohort consisted of a consecutive series of patients derived from the Gothenburg Scoliosis Database which contains information about all patients with scoliosis ($n = 2655$) seeking advice or treatment at the Department of Orthopaedics at Sahlgren University Hospital in Gothenburg, Sweden, between 1963 and 1994. This database, previously used for other studies on patients who had been treated with brace or surgery for AIS [2, 11], was chosen as the source for a control group due to the ability to obtain a large control group with complete follow-up data. Most importantly, since it was an active database, it could be queried for identical inclusion criteria and for success criteria. Patients meeting identical inclusion criteria as the VBS group (curves < 45°) who had undergone brace treatment were sought for comparison. From this database, 154 curves in 121 patients treated between 1965 and 1990 were identified who met our inclusion criteria as outlined above. Until 1974, patients were treated with a Milwaukee brace (cervicothoracolumbosacral orthosis, or CTLSO) and then after 1974 a Boston brace (thoracolumbosacral orthosis, or TLSO). Patients were braced for at least 12 months, and the brace was recommended to be worn 22 to 24 hours per day until skeletal maturity.

Children in the braced group were found to be significantly older at start of bracing than the VBS group at surgery, 12.8 years versus 10.5 years, respectively ($P < 0.0001$). In



(a) (b) (c) (d) (e) (f)

Figure 2: (a and b) This is an 11-year-old girl who presents with a 39° right thoracic curve and a 28° left lumbar curve. The lateral film shows 18° of kyphosis (normal sagittal contour) from T5 to T12. (c and d) Following VBS, the thoracic curve corrected to 27° and the lumbar curve to 3°. (e and f) Now at age 14, 2-1/2 years post-op, the patient is now Risser 4. The thoracic curve measures 23° and the lumbar 1°. The lateral film shows 21° of kyphosis from T5 to T12.

order to make comparisons reliable, a subgroup from the Gothenburg database was constructed as a matched group based on the following matching criteria: initial Cobb angle, age at start of treatment, and Risser sign. This resulted in 52 patients with 66 curves in the braced group for comparison, and the age at the start of bracing was now not statistically significantly different between the two groups.

Patients with double curves, where one of the curves was included but the other one was too large for inclusion (i.e., >45°), were excluded from both the VBS and bracing groups.

A study by Katz and colleagues [12] examined the natural history and effectiveness of brace treatment for curves <45°. In this study, there seemed to be a significant division of results above or below 35°; therefore, 35° was chosen as the variable for curve severity subanalysis in our study of thoracic curves treated with VBS.

Each curve (thoracic or lumbar) was analyzed separately and grouped according to location of the curves, either thoracic (vertex down to T11) or thoracolumbar/lumbar (vertex from T11-T12 downward). "Improvement" was defined as improvement in the pretreatment Cobb angle of >10° measured on the final follow-up radiograph. "No change" was defined as a +10 to −10° change (both values inclusive) in the pretreatment Cobb angle. "Progression" was defined as worsening of the curve >10°. "Success" was defined as either "improvement" or "no change" on the final follow-up Cobb angle. Ten degrees was chosen so as to be clearly outside the range of possible measurement error due to radiographs being obtained and measured at different locations. In addition, based on a previous study comparing various types of braces [13], 10° was chosen to represent a clinically significant change in curve size.

If a curve progressed to posterior spinal fusion (PSF), this was considered a "failure" of treatment regardless of curve type. For example, if a patient had a double major curve pattern and then progressed to fusion, even if the lumbar curve had not progressed >10°, it was still considered a "failure." This allows for the most conservative measurements for success of treatment and remains consistent with previous articles on bracing for scoliosis [1, 12, 14].

Statistical analysis was performed using the Statistical Analysis Systems (SAS) version 9.2 (SAS Institute, Cary, NC). GEE (Generalized Estimating Equation) was used to assess the occurrence of failure with regard to Cobb angle at the time of final measurement. The Wilcoxon two-sample test was used to assess demographic differences among the two groups. A P value of ≤ 0.05 was considered statistically significant.

2.1. Surgical Technique: VBS. While under general anesthesia, the patient is positioned in the lateral decubitus position with the convex side of the curve facing up. An axillary roll is used underneath the concave side above the curve so as to allow the curve to correct slightly. All vertebral bodies in the Cobb angle of the curve are instrumented. Single-lung ventilation and carbon dioxide (CO_2) insufflation are used for better visualization. At this point, vertebral bodies are identified using biplanar fluoroscopy. The thoracoscope is placed through the anterior portal. Intercostal portals for staple insertion are placed close to the posterior axillary line. After incision, nasal speculum dilators are used to enlarge the portals. Under fluoroscopic control, a trial is used at every level to gauge the size of the staple. Optimal placement requires that the tines of the staple are close to the vertebral endplate. In the sagittal profile, the staple is placed anterior to the rib head. In patients with hypokyphosis, more anterior position is desired. In the lumbar spine, the staple is placed in the posterior half of the vertebral body. The tines of the trial are used to make pilot holes. The trial device can be used to push on the apex of the curve, thus improving the correction. Care is taken to protect the segmental vessels. After the holes are made, a staple of appropriate size (range, 3–8 mm wide in a 2- or 4-pronged design) is selected and its tines straightened using a distracter. Staples are placed in ice

Table 1: Demographics and distribution of curves among included patients.

Criterion	Vertebral body stapling ($N = 42$)	Bracing ($N = 52$)	P values
Avg. age at start of treatment (years)	10.6 (8–14)	11.1 (8.4–11.5)	0.07
Avg. curve size at start of treatment (°)	31.5 (25–44)	31.3 (25–44)	0.82
Time of brace treatment (months)	—	40.8 (13–103)	—
Avg. follow-up after surgery/maturity (mos)	40.8 (23–75)	105 (46–185)	<0.0001
Number of females	52	60	
Number of males	5	6	
Thoracic curves 25–34°	26 (3M)*	36 (2M)	
Thoracic curves 35–44°	11 (2M)	12 (3M)	
Lumbar curves 25–34°	15	16 (1M)	
Lumbar curves 35–44°	5	2	

*M = Males.

to keep the tines open. Then the trial is removed and the staple is quickly inserted using a specially made insertion device. Tines of the staple are matched with the pilot holes. Optimal position of the staple is reconfirmed fluoroscopically, and the staple is impacted into the vertebral body. After removal of the inserter, if the staple is not flush with the disc, an impactor is used to further drive the staple into the vertebral body. It is important to obtain optimal correction of the spine before impacting the trial or the inserter. If the spine is not straight, then an additional inserter can be placed in the previously inserted staple adjacent to the staple to be inserted and used to push on the spine (translation) to obtain curve correction.

In the lumbar spine, we have used a direct lateral, retroperitoneal approach with a minimal open incision [15]. Staples are placed at 3 to 4 levels. During the approach, the psoas is usually retracted posteriorly. As an alternative, one can gently separate the psoas muscle longitudinally directly over the posterior half of the disc under electromyographic control [15].

At the end of the procedure, position of the staples is reconfirmed using fluoroscopy. A chest tube drain is inserted under thoracoscopic guidance through the anterior portal.

In these patients, the chest tube was usually removed on the first postoperative day. Initially, a noncorrecting soft corset brace was prescribed for lumbar curves for 6 weeks to help with stabilization of the staples by decreasing the patients' motion. Activity restrictions were lifted after 6 weeks. Patients were observed radiographically every 3 to 4 months until skeletal maturity and then every 6 months thereafter.

3. Results

Demographics and radiographic appearance of the spinal deformity were compared in the two cohorts (Table 1). There were no significant differences between the two groups in terms of age and curve size at start of treatment. In the VBS group, of the 49 patients who met the inclusion criteria, 42 (86%) were located and data updated specifically for this study. The mean age at the time of surgery was 10.6 years (range, 8–14 years). The mean preoperative curve size was 31.5° (32° thoracic and 31° lumbar). Average follow-up was 40.8 months. There were 57 curves in 42 patients, with 15 patients having both thoracic and lumbar curves. For the bracing group, there were 66 curves in 52 patients, with 12 patients having both thoracic and lumbar curves and 2 patients having a double thoracic curve. The mean age at the start of treatment was 11.1 years. The curve size before start of bracing measured a mean of 31.3°. Average follow-up was 105 months (±37.8 months) after end of bracing; that is, at maturity.

Table 2: Results of treatment of patients with AIS treated with either VBS (57 curves) or bracing (66 curves).

	No change/ improvement (%)	Progression (%)	P value
Thoracic curves 25–34°			
VBS ($N = 26$)	81	19	0.16
Bracing ($N = 36$)	61	39	
Thoracic curves 35–44°			
VBS ($N = 11$)	18	82	0.19
Bracing ($N = 12$)	50	50	
Lumbar curves 25–34°			
VBS ($N = 15$)	80	20	1.0
Bracing ($N = 16$)	81	19	
Lumbar curves 35–44°			
VBS ($N = 5$)	60	40	0.43
Bracing ($N = 2$)	0	100	

For thoracic curves measuring between 25 and 34°, VBS had a success rate of 81% versus 61% for bracing ($P = 0.16$, Table 2). In thoracic curves measuring 35 to 44°, VBS had a very poor success rate of 18% versus 50% for bracing ($P = 0.19$). For lumbar curves, success rates were not different; for curves measuring from 25 to 34°, the success rate of VBS versus bracing was 80% versus 81%, respectively ($P = 1.0$),

and for lumbar curves from 35 to 44°, the success rate was 60% versus 0%, respectively ($P = 0.43$). In the latter group, however, the numbers were low; only 5 patients underwent stapling, and 2 were braced.

We also examined the number of female versus male patients and determined that the small number of male patients (5 for VBS and 6 for the brace group) would not significantly alter our conclusions.

Complications were divided into 3 categories: major, minor, and insignificant [16]. There were no major complications in this series of patients. Minor complications in the VBS group consisted of 1 new postoperative foot dystonia that resolved within 3 months. One patient had 1 lumbar staple removed secondary to "backing out," but it had not completely dislodged. Three broken staples were noticed, none of which required removal. All patients who started bracing were able to complete the treatment except for two who could not tolerate the bracing regimen due to psychosocial factors. The curves of both these patients progressed before maturity, and they were therefore surgically treated.

4. Discussion

Treatment options for moderate IS have long been limited to bracing and observation. The former commits the child either to 16–23 hours per day of brace wear or brace wear during the night. Either way, bracing is hot and uncomfortable, which is a particular concern in warmer climates and during summer months everywhere. Brace treatment typically lasts for 3 to 5 years but could be much longer for a patient who starts wearing a brace, say, at age 8. Serious self-image issues often accompany brace wear but have yet to be fully described in an objective manner. It has been shown that previously braced patients in their adulthood felt that their body asymmetry was worse than nontreated scoliosis patients, despite similar curve sizes, possibly an effect of long-term bracing before maturity [17, 18]. Furthermore, compliance with prescribed wearing schedules is also a factor that decreases the efficacy of brace treatment [7] (Karol LA et al.: "The effect of compliance monitoring on brace use and success in patients with AIS." Paper presented at the POSNA Annual Meeting 2013, Toronto, Canada). Observation involves periodic radiographs and the anxiety associated with the possibility of progression.

The results of this study suggest that patients with some types of high-risk moderate scoliosis of 25 to 44° can be treated successfully with VBS. The best results were seen in thoracic curves measuring 25 to 34°, where VBS had a success rate of 81%, and in lumbar curves measuring 25 to 34°, where 80% of the patients were successfully treated with only few complications.

Treatment of larger thoracic curves measuring 35 to 44° at the start of treatment was not successful in any of the groups (18% for VBS versus 50% of the braced group). In the lumbar curves measuring 35 to 44°, we do not think that any conclusions can be drawn because the numbers of curves and patients were not large enough.

Results of bracing for idiopathic scoliosis are very dependent on the patient's age at discovery and at initiation of treatment. A recent review by Katz and colleagues [19] of 100 patients suggests that bracing over 12 hours per day was effective in 82%. All of the patients in Katz's study were over 10 years of age, and 10 of them were at Risser 2. Katz and colleagues' cohort was much more mature than the patients undergoing VBS in this current series (average age of 10.6 years). The recently published report by Weinstein and colleagues [4] included more mature patients, all of whom were older than 10 years of age, with a Risser degree of 0, 1, or 2. In contrast, Charles and colleagues [5] reported on a group of patients with juvenile idiopathic scoliosis who were treated with bracing. They found that for curves >30°, 100% of the patients required a fusion, and for those with curves 21–30°, 75% progressed to fusion despite bracing.

The negative aspects of brace wear are also often overlooked. Misterska and colleagues [20] have reported increased stress levels in patients and parents when bracing is utilized. Katz and colleagues [19] reported that the best results occurred when the patients wore the brace in the daytime and after school, a time when middle school students are often least likely to want to wear a brace. One of the indications for stapling thoracic curves measuring <35° or lumbar curves measuring 25 to 44° is when the child is distraught at having to wear the brace at school.

For this review, thoracic and lumbar curves were analyzed separately because each type of curve responds differently to both VBS and bracing. There were not enough patients to subanalyze the data by curve pattern (thoracic versus thoracolumbar/lumbar versus double major). Betz and colleagues [21] have demonstrated the feasibility, safety, and utility of the Nitinol staples in AIS. In another study, Betz and colleagues [9] reported results in 39 patients, in whom 87% of curves demonstrated coronal stability at a minimum 1-year follow-up. Betz and colleagues [10] have also reported a minimum 2-year follow-up for patients showing coronal stability of approximately 78% in all lumbar curves and thoracic curves <35°. Poor results were seen in thoracic curves >35° consistently in all the reviews.

This current paper shows similar results of failure with thoracic curves >35° with longer follow-up and more patients. This failure in thoracic curves >35° has led the senior authors to change strategies for VBS as a treatment option for thoracic curves >35°. One fusionless option to consider would be to use staples along with some kind of posterior growing system. The downside of this approach is the necessity to lengthen the posterior construct every 6 months. Maybe in the future, with noninvasive posterior lengthening systems, this may be a viable option. However, the authors' current strategy is to perform anterior vertebral body tethering alone for thoracic curves >35°.

We also now further understand the importance of maximizing correction on the OR table in that our best results (>80%) were seen when the first erect radiograph showed the curve reduced to <20° [10]. We now use intraoperative techniques to maximize correction (coronal and axial) of each curve segment before stapling each disc space. An example of this effort is maintaining sustained apical

translation correction with the staple holder (inserter) as the more proximal levels are stapled. Because of the trend we have seen in obtaining correction, we now offer patients with significant growth remaining (Sanders digital score [22] <5) VBS as a corrective option and not just a means to hold the curve as an alternative to bracing. In addition, for a curve that does not measure <20° on the first post-op erect film, the patient should wear a nighttime corrective brace until the curve measures <20° or skeletal maturity is reached [10].

In evaluating the results of this study, both strengths and limitations must be taken into account. Two groups with identical inclusion criteria that were consecutive, had at least two years of follow-up, and were evaluated using the same methods constitute an ideal setting for a comparative study. A limitation of the study is that the average age at start of treatment of the patients in both groups was statistically different (10.6 years for VBS and 12.8 years for bracing; $P < 0.001$) when the groups were first compared. The statistician modified the braced patients included in the analysis in order to obtain a match in the average age of the patients. All patients were Risser 0 or 1 at start of treatment, which is only a rough estimation of skeletal maturity and proxy for the potential for scoliosis progression. Another limitation was that the control group was a historical group, that is, previously treated. However, being the only known way of achieving a large control group that had been meticulously followed and documented through the whole treatment period and with a sufficient follow-up time, this drawback had to be accepted. The VBS group was also limited in that the follow-up was only for 2 years, and the group was not followed to skeletal maturity. Minor changes in the results would be expected and will be the subject of a future study. Furthermore, we did not have hand X-rays for bone age or Sanders digital score. This would have been a much better comparison than age and Risser score but was not in use when treatment of these groups started. The coauthors currently use Sanders digital score <5 as an indication for recommending stapling.

For future study, genetic testing (when available) may also help with patient selection in further refining the subset of patients whose curves will definitely progress. Furthermore, genetic testing such as the Scoliscore may identify patients with curves that are likely to be refractory to bracing [23, 24]. Unfortunately, the positive predictive value of the Scoliscore has yet to be proven; therefore, this clinically available test is not yet helpful for predicting VBS as a desirable treatment for a genetically diagnosed high-risk curve.

Based on this review, the authors performing VBS currently use the following indications for recommending stapling to patients: (1) age <13 years in girls and <15 years in boys; (2) Sanders digital score <5; (3) thoracic curves ≤35° and lumbar coronal curves ≤45°; and (4) sagittal thoracic curve <40°. If the thoracic curve measures 35 to 45° and/or a thoracic curve measure <35° but does not bend below 20°, then vertebral body tethering is considered [25–28]. Also, if the curve on first erect film does not measure <20° after VBS, the patient should wear a corrective nighttime brace until it does.

5. Conclusion

In this comparison of two cohorts of patients with high-risk (Risser 0-1) moderate idiopathic scoliosis (measuring 25 to 44°), the results of treatment of smaller thoracic curves (25 to 34°) show VBS to have a better result by clinical trend but not statistically different results versus bracing (81% versus 61%, resp., $P = 0.16$). For lumbar curves measuring 25 to 34°, results appear to be similar for both VBS and bracing. These results suggest that VBS could be used as an alternative or adjunct to bracing for patients with these curve ranges who are struggling with the ramifications of brace wear. For thoracic curves measuring 35 to 44°, the number of patients in this group was too small for statistical evaluation.

Ethical Approval

The study was approved by the Human Research Ethical Committee at the Medical Faculty of Gothenburg University, Sweden, and the Institutional Review Board of Temple University School of Medicine, Philadelphia, PA.

Conflict of Interests

Laury Cuddihy, Aina J. Danielsson, Harsh Grewal, John M. Richmond, M. J. Mulcahey, and M. Darryl Antonacci have nothing to disclose. Patrick J. Cahill is a paid consultant for DePuy Synthes Spine, Ellipse Technologies, Globus Medical, Medtronic. Amer F. Samdani is a paid consultant for DePuy Synthes Spine, Globus Medical, Stryker, Zimmer. John P. Gaughan received honorarium for statistical consulting. Randal R. Betz is a paid consultant for DePuy Synthes Spine, Globus Medical, Medtronic, Abyrx, SpineGuard, and Zimmer. He received royalties from DePuy Synthes Spine and Medtronic. He is on the speakers' bureau of DePuy Synthes Spine and is an unpaid consultant for Advanced Vertebral Solutions and Orthobond. He received stocks/options from Advanced Vertebral Solutions, MiMedx, Orthobond, Abyrx, SpineGuard, and MiMedx. He received research support from DePuy Synthes Spine and publishers' royalties from Thieme.

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Hindawi Publishing Corporation
BioMed Research International
Volume 2015, Article ID 260703, 9 pages
http://dx.doi.org/10.1155/2015/260703

Clinical Study

A New CT Method for Assessing 3D Movements in Lumbar Facet Joints and Vertebrae in Patients before and after TDR

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Received 1 June 2015; Revised 22 September 2015; Accepted 5 October 2015

Academic Editor: Jau-Ching Wu

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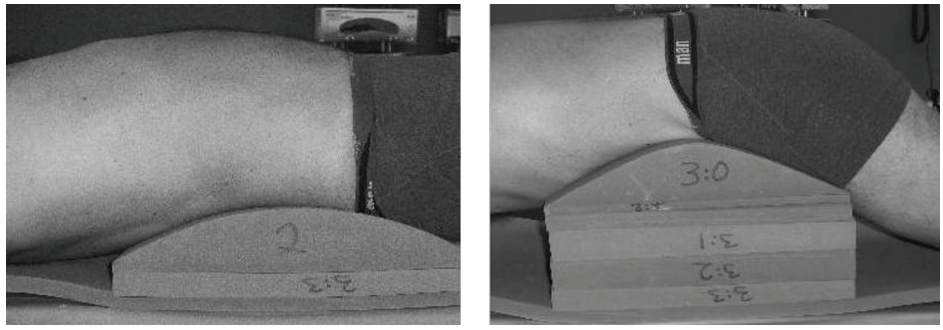
This study describes a 3D-CT method for analyzing facet joint motion and vertebral rotation in the lumbar spine after TDR. Ten patients were examined before and then three years after surgery, each time with two CT scans: provoked flexion and provoked extension. After 3D registration, the facet joint 3D translation and segmental vertebral 3D rotation were analyzed at the operated level (L5-S1) and adjacent level (L4-L5). Pain was evaluated using VAS. The median (±SD) 3D movement in the operated level for the left facet joint was 3.2 mm (±1.9 mm) before and 3.5 mm (±1.7 mm) after surgery and for the right facet joint was 3.0 mm (±1.0 mm) before and 3.6 mm (±1.4 mm) after surgery. The median vertebral rotation in the sagittal plane at the operated level was 5.4° (±2.3°) before surgery and 6.8° (±1.7°) after surgery and in the adjacent level was 7.7° (±4.0°) before and 9.2° (±2.7°) after surgery. The median VAS was reduced from 6 (range 5–8) to 3 (range 2–8) in extension and from 4 (range 2–6) to 2 (range 1–3) in flexion.

1. Introduction

Common chronic low back pain (CLBP) which causes individual suffering and high societal costs [1–3] often results from painful degenerative disc disease (DDD). However, DDD is not the full explanation [4–7]. Patients often present a history of mechanical CLBP varying with different body positions, movements, and loads. The "gold standard" for treating patients failing conservative treatment is spinal fusion; however, treatment with current fusion techniques alters the biomechanics and physiological function, promoting degenerative changes in adjacent segments of the spine [8, 9]. Total disc replacement (TDR) is an alternative [10, 11].

Methods for *in vivo* analysis of TDR patients are primarily based on a two-dimensional (2D) radiographic examination where manual measurements on conventional radiographs have a precision of 2–4 mm for translation and 2–4° for rotations (depending on technique) [11–16]. Computer assisted analysis of these lateral radiographs has increased the precision to ~2° in the lumbar spine, for example, by beam distortion compensation [17, 18]. Two popular methods are distortion compensated roentgen analysis (DCRA) and quantitative motion analysis (QMA) [19]. Three-dimensional (3D) movements of a lumbar segment are provided by biplane radiography with [20] or without [21] radiostereometric analysis (RSA) and by computed tomography (CT) scans. RSA techniques with implantation of tantalum beads are an invasive method but currently the most precise method [20].

In this paper we use a noninvasive CT based method for detecting 3D movement with a radiation dose comparable to the above mentioned radiographic exam [22–24]. Four earlier studies from our group validated this method for the spine on phantom and healthy subjects and on patients with cervical



(a) (b)

Figure 1: A person lying on the jig in extension provocation (a) and in flexion provocation (b).

total disk replacement (CTDR) and reported an accuracy of 0.6 mm and 1.0° in all cardinal planes [25–28]. This study aims to assess and compare 3D movement of individual facet joints and the segmental rotation of the vertebrae in the operated level (L5-S1) and in the adjacent level (L4-L5) in patients prior to TDR surgery and at three years after surgery.

2. Material and Methods

Ten patients with DDD were selected for this feasibility study (five men and five women). Median age at inclusion was 45 years (25–53). The patients meeting the criteria described below were consecutively selected from a larger randomized controlled study. Patients with a body mass index (BMI) above 35 were excluded as were patients with multilevel surgery or surgery in levels other than the L5-S1 segment. The median time of onset of back pain before surgery was 3 years (1–10). Magnetic resonance imaging (MRI) showed degeneration of the disc at the L5-S1 level with slight to moderate facet joint arthrosis. Three of these patients had done discography before surgery. Each patient signed an informed consent form which was approved by the Regional Ethics Committee (Dnr. 03-663). Three different prostheses, Prodisc (Synthes Spine, West Chester, PA, USA; $n = 5$), Charité (DePuy Spine, Raynham, MA, USA; $n = 3$), and Maverick (Medtronic, Memphis, TE, USA; $n = 2$), were used in this study.

Each patient was examined before and three years after surgery. No additional medication was given before the examinations. Each examination comprised two CT scans, one in provoked flexion and the other in provoked extension. The patients were placed on a customized jig (OT-Center, Danderyds, Sweden), incorporating different blocks for provoking the lumbar spine into extension and flexion. Provocation of the spine for extension occurred in supine position and for flexion occurred in prone position (as shown in Figure 1). Low back pain during examination was assessed using the visual analog scale (VAS) which measures pain intensity on a one-dimensional scale [29]. Patients were gradually provoked in the jig up to maximal extension or flexion but stopped if the low back pain was over 8 on the 10-level VAS scale or if in prone position the space between the top of the CT scanner tunnel and the patient's spine was too small.

The patients were examined using a clinical CT scanner (Light Speed QX/i, General Electric Medical Systems, Waukesha, WI, USA). Images were acquired from the L4 to S1 vertebra with 1.25 mm collimation, a pitch of 3 (0.75 mm/rotation), a tube tension of 120 kV, and a tube current of 250 mA. The volumes were reconstructed with an x-y matrix size of 512 × 512 into approximately 230 slices. The x-y pixel size was approximately 4 mm and the slice spacing was 0.5 mm. The radiation dose was calculated to be 0.68 mSv per scan.

Spatial registrations of CT data, and subsequent measurement of vertebrae movement, were performed using a semiautomated 3D volume registration tool described in our previous publications [25–27, 30–32]. This tool maps the "target" volume (the one to be registered) into the "reference" (the fixed) volume coordinate system. This is accomplished through selectable transformations with varying degrees of freedom, automatically generated from manually selected landmarks picked in the target and reference volumes through a graphical user interface. The registration produces two CT data volumes, the transformed target volume and the original reference volume. A more detailed technical description is given in the appendix.

The CT data volumes for extension and flexion were registered by using the L5 vertebra. Nine cohomologous landmarks were placed in the L5 vertebra in both CT volumes. To create an accurate registration, care was taken to spread the landmarks throughout the vertebrae in 3D, and a rigid body transformation was generated. Figure 2 shows the placing of one landmark on L5 in all three orthogonal planes. When a landmark is chosen, the software automatically displays it on all three orthogonal planes and optionally on the 3D isosurface. Both visual and numeric analyses were used to determine how well the vertebra was registered. For the visual analysis, the registered and the reference vertebra were superimposed in 2D and in 3D as isosurfaces. For the numerical analysis the difference (in distance) between the transformed target landmarks and the reference landmarks was calculated. Ideally, this difference should be zero. In both volumes, the L5 vertebra registration was within 2 CT voxels (1.4 mm), now in a single coordinate system defined by the CT scanner with the origin at the center of the CT volume. All further rotations

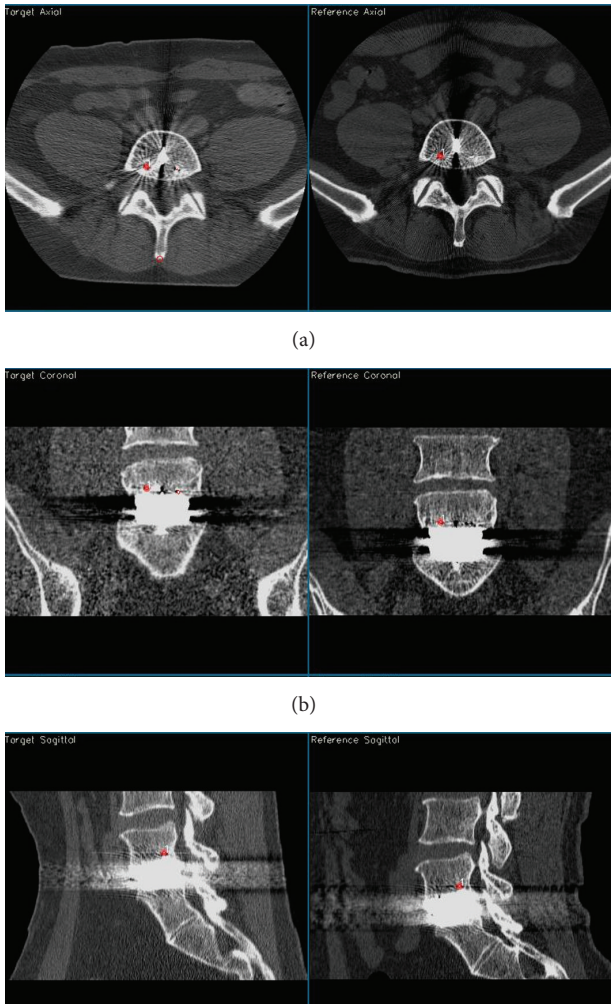


Figure 2: Example in 2D of choosing landmarks on L5 ((a) axial view, (b) coronal view, and (c) sagittal view).

and translations are calculated in this "L5-registered" coordinate system. In this study the analysis was performed by one observer who was an experienced orthopaedic surgeon who was very familiar with this method. In a previous study in the cervical spine, we tested this method with regard to inter- and intraobserver difference [26].

Movement in the spine between the extension and flexion examinations was assessed by measuring (1) segmental 3D rotation and (2) facet joint 3D translation between both L4-L5 and L5-S1. These measurements utilized the 3D volume registration tool to create rigid body transformations based on sets of landmarks (as described below).

For the segmental 3D rotation, the L5-registered flexion and extension volumes were registered twice, once with respect to L4 and once with respect to S1, using landmarks placed in each of L4 and S1 exactly as was done for L5. These two registrations generated rigid body transformation matrices that corresponded to the movement between L4-L5 and L5-S1, respectively. These rotation matrices were decomposed into Euler angles to obtain the cardinal axes of the vertebra L4 and S1 in relation to L5. The following rotational order was used: $R_z R_y R_x$, where R_x is the rotation about the x-axis (i.e., the sagittal plane) and this rotation was applied first.

For the facet joint 3D translation, the L5-registered flexion and extension volumes which had the individual facet joints in the same coordinate system were used. These volumes were registered twice, once with respect to L4 and once with respect to S1. To accomplish the registration, four landmarks were designated in each individual joint at the L4-L5 and L5-S1 levels. These four landmarks were placed in the two volumes as follows, for each facet joint: one each in the most cranial point, the most caudal point, the most anterior point, and a posterior point in the periphery. The volumes were then registered with respect to the L4-L5 landmarks and then again with respect to the L5-S1 landmarks. Using the translation matrix generated from the rigid body transformation the 3D translation of the left and right facet joints (as viewed from the anterior) in L4-L5 and L5-S1 was calculated. More detailed information about this method can be found in [25, 27].

The vertebral and facet joint data were tested for being a normal (Gaussian) distribution by histograms, box, density, and quantile-quantile plots. Though the data were almost normal a paired Wilcoxon signed rank test was used to evaluate the difference in motion before and after TDR. The tests for a normal distribution were applied to the pain (VAS) scores before and after TDR where data were found to be not normal. Therefore a paired Wilcoxon signed rank test was used to evaluate the difference in pain before and after TDR. The level of significant was chosen to be $p < 0.05$. The open source statistical package R version 3.0.2 was used for all statistical calculations [33].

3. Results

All patients were able to extend and flex their spine in the jig before and three years after surgery without exceeding the pain level of 8 on the VAS scale. The space in the CT-tunnel was sufficient for maximal provocation of all patients. Patient 7 had severe pain during extension provocation both before and after surgery but it did not exceed the chosen pain level of 8 on the VAS score. Volume registration of the vertebrae was successful in all cases. In the numeric analysis, the mean value for error of all the landmarks in the human vertebrae was 0.73 mm (0.41–0.93 mm). The visual analysis of the registration of L5 is exemplified in Figure 3. With the exception of Patient 8 (see Section 4), in all other patients there were no other abnormalities nor were there any bone bridges between the vertebrae indicating spontaneous fusion.

3.1. Operated Level (L5-S1). The main segmental vertebral movement was in the sagittal plane (flexion/extension), with a median (±SD) of 5.4° (±2.3°) before surgery (range 2.9–9.5°) and 6.8° (±1.7°) after surgery (range 3.8–9.6°). In all preoperative examinations, there were only small coronal and transverse plane rotations, whereas in the postoperative examinations there were some cases where the coronal rotation improved. The median (±SD) movement in the coronal plane was 0.4° (±0.2°) before (range 0.1–0.5°) and 0.8°

Table 1: Individual patient's movement and facet joint magnitude at L5-S1 level before and after surgery.

Patient	Rotation (degrees)						3D facet translation (mm)			
	Sagittal		Coronal†		Transverse		Right		Left	
	Before	After	Before	After	Before	After	Before	After	Before	After
1	9.3	9.6	0.4	0.7	0.0	0.9	4.8	3.5	5.7	6.7
2	9.5	8.6	0.5	0.5	0.1	1.0	5.0	7.6	5.0	3.7
3	3.7	3.8	0.1	0.2	0.4	0.0	2.5	2.6	1.7	1.7
4	5.5	5.3	0.5	3.2	0.9	0.5	3.7	3.0	1.4	0.3
5	8.2	5.9	0.1	0.8	0.1	0.2	3.8	3.5	4.1	3.4
6	4.3	7.4	0.5	1.9	0.5	0.6	1.7	4.0	5.8	3.1
7	2.9	6.6	0.2	0.8	0.1	0.6	2.7	4.0	0.6	4.4
8	6.1	6.9	0.2	2.7	0.6	0.3	3.1	2.6	1.9	4.1
9	4.3	5.0	0.5	0.2	0.8	0.4	2.7	3.7	4.7	4.6
10	5.3	7.4	0.4	0.4	0.8	0.0	2.8	3.6	2.3	2.5
Median (±SD)	5.4 (±2.3)	6.8 (±1.7)	0.4 (±0.2)	0.8 (±1.1)	0.5 (±0.3)	0.5 (±0.3)	3.0 (±1.0)	3.5 (±1.4)	3.2 (±1.9)	3.7 (±1.7)
Minimum	2.9	3.8	0.1	0.2	0.0	0.0	1.7	2.6	0.6	0.3
Maximum	9.5	9.6	0.5	3.2	0.9	1.0	5.0	7.6	5.8	6.7

†Significantly different before and after operation ($p = 0.03$).

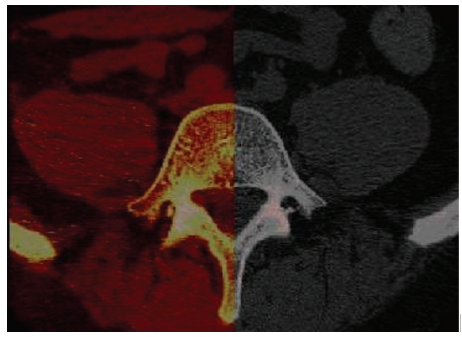


Figure 3: 2D overlay projection of the L5 vertebra in axial plane. The red part is the transformed vertebra superimposed on the reference vertebrae. One can see that it is an almost perfect match.

(±1.1°) after surgery (range 0.2–3.2°) which was statistically significant ($p = 0.03$). In the transverse plane the movement was virtually unchanged. The 3D movement of the right facet joint had a median (±SD) magnitude of 3.0 mm (±1.0 mm) before (range 1.7–5.0 mm) and 3.6 mm (±1.4 mm) after surgery (range 2.6–7.6 mm). The median movement of the left joint was 3.2 mm (±1.9 mm) before (range 0.6–5.8 mm) and 3.6 mm (±1.7 mm) after surgery (range 0.3–6.7 mm). There were some asymmetric movements between the right and left facet joint both before and after surgery. Data for the individual patients are presented in Table 1. There was no significant difference found before or after surgery except in the coronal plane as already noted.

3.2. The Adjacent Level (L4-L5). As in the operated level, the main movement occurred in the sagittal plane with a median (±SD) of 7.7° (±4.0°) before (range 2.2–15.2°) and 9.2° (±2.7°) after surgery (range 5.4–12.7°). In the coronal and transverse planes there were only small rotations in all patients before and after surgery. The 3D movement of the right facet joint had a median (±SD) of 3.4 mm (±2.1 mm) before (range 1.0–8.1 mm) and 3.6 mm (±1.7 mm) after surgery (range 2.5–6.9 mm). The median movement in the left facet joint was 4.0 mm (±1.9 mm) before (range 1.2–7.1 mm) and 4.5 mm (±1.8 mm) after surgery (range 2.2–7.2 mm). There were some asymmetric movements between the right and left facet joint both before and after surgery. Table 2 presents the data for the individual patients for the adjacent L5-L4 level. There was no significant difference found before or after surgery.

3.3. VAS Results. Table 3 presents the VAS during the provocations of the patient. For patient 3 the pain scale was not recorded at the time of the three-year examination; therefore the pain results are based only on 9 patients. Using the Wilcoxon signed rank test, the pain during provocation in both extension and flexion three years after surgery was found to be significantly lower ($p = 0.01$ extension; $p = 0.03$ flexion) than before surgery. The median VAS in extension went from 6 before surgery (range 5–8) to 3 after surgery (range 2–8) and from 4 before surgery (range 2–6) to 2 after surgery (range 1–3) in flexion.

4. Discussion

This study used a method that enabled both quantitative and qualitative evaluation of motion of the vertebral segment in the lumbar spine. Detailed information was obtained about the movement of the vertebral segment, including the individual facet joint movement magnitude, before and after TDR. These patients had around 50% of the range of motion (ROM) when compared with the healthy subjects investigated previously [27]. This corresponds well with other studies contrasting the difference in mobility between healthy subjects and patients after modern TDR [18, 34]. As patients had less pain after surgery, one might expect that postoperatively

Table 2: Individual patient's movement and facet joint magnitude at L4-L5 level *before* and *after* surgery.

Patient	Rotation (degrees)						3D facet translation (mm)			
	Sagittal		Coronal		Transverse		Right		Left	
	Before	After	Before	After	Before	After	Before	After	Before	After
1	7.1	6.8	0.3	1.0	0.3	0.2	3.4	2.6	3.3	2.2
2	11.6	12.7	1.4	0.8	0.0	0.3	3.2	3.7	4.5	5.8
3	2.2	9.6	0.8	0.8	0.4	0.4	1.0	5.6	1.2	6.6
4	3.8	6.5	1.1	0.4	0.2	0.3	1.9	3.4	2.0	3.8
5	15.2	12.4	0.2	1.1	0.7	0.4	8.1	6.9	7.1	6.7
6	5.9	8.8	0.6	0.5	0.9	0.9	2.8	3.2	3.1	3.9
7	3.2	5.4	0.6	1.4	0.8	0.9	3.4	2.5	3.4	2.7
8	9.8	8.7	0.2	2.2	1.1	1.3	4.6	2.9	6.1	3.0
9	9.2	12.7	0.8	1	0.8	0.4	3.9	4.9	4.6	5.1
10	8.2	10.3	1.2	0.9	0.2	0.3	6.2	6.7	5.9	7.2
Median (±SD)	7.7 (±4.0)	9.2 (±2.7)	0.7 (±0.4)	1.0 (±0.5)	0.6 (±0.4)	0.4 (±0.4)	3.4 (±2.1)	3.6 (±1.7)	4.0 (±1.9)	4.5 (±1.8)
Minimum	2.2	5.4	0.2	0.4	0.0	0.2	1.0	2.5	1.2	2.2
Maximum	15.2	12.7	1.4	2.2	1.1	1.3	8.1	6.9	7.1	7.2

Table 3: The visual analogue scale (VAS) for pain before and three years after surgery during provocation in extension and flexion. Patient number three was excluded because there were no scores at three-year examination.

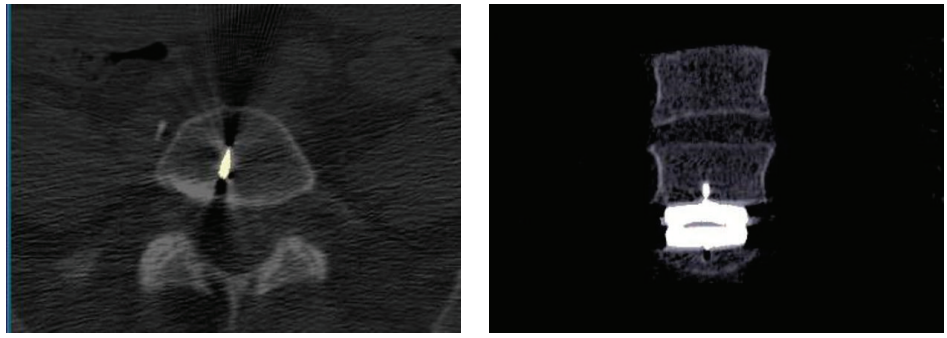
Patient	VAS extension†		VAS flexion†	
	Before	After	Before	After
1	5	2	3	2
2	6	5	4	3
3	Missing value	Missing value	Missing value	Missing value
4	6	3	4	2
5	6	3	3	3
6	7	3	6	3
7	8	8	5	3
8	5	2	2	2
9	7	4	2	2
10	6	3	4	1
Median	6	3	4	2
Minimum	5	2	2	1
Maximum	8	8	6	3
p value		0.01		0.03

†Significantly different before and after surgery.

patients would have a greater ROM. However, all the patients returned to almost the same ROM after surgery, and considering the large difference in ROM between the patients preoperatively, preoperative ROM might be the most important factor in predicting postoperative ROM [35]. A lateral view (2D X-ray) only presents one cardinal axis. Even though there are some methods to calculate the other two axes, it is not a truly three-dimensional method. This method is a true three-dimensional method and we know that the segmental movement is a three-dimensional movement and not just a 2-dimensional movement in the sagittal plane. Additionally, we did not note any ossification between the endplates of the vertebrae in the operating level or at the adjacent levels in the follow-up CT scans after three years. No major complication had occurred to any of the patients after three years.

This evaluation was based upon passive provocation; thus, the muscle contraction was less in the lumbar spine with this provocation than it would be if the patients were provoked in a standing position. Some studies have shown that passive provocation has an increased ROM compared to active muscle provocation [13]. However, with passive provocation the motion of the facet joints might better reflect the relationship between implant and facet joint than the facet joints' actual motion pattern. In our provocations, we encountered two practical problems. First, as the duration of patient provocation increased, the risk of motion artefacts increased. However, with present day CT scanners this is much less of an issue. Second, prone flexion provocation can be limited by the CT-tunnel (although this did not occur in this study). It was important to place the jig in the correct position in relationship to the pelvis so that maximum provocation in both extension and flexion would be in the lower lumbar spine. Extension provocation was easy to perform in this study, with all patients able to be fully extended.

The radiation exposure from CT examinations is, in general, higher than that from conventional radiographic examinations. However, with modern CT scanners the protocol can be optimized to reduce the effective radiation dose. In this study the CT scan protocol was adjusted to reduce the effective radiation dose to as low as 0.68 mSv/CT scan, which is almost equal to that of conventional 2D radiographic examination [36, 37]. Future development of CT scanners will further reduce the amount of radiation and thus increase the possibility to improve the accuracy of this method by allowing higher resolution with the same radiation exposure. Additionally, metal artefacts have been decreasing in CT scans because the manufacturer's software has been increasingly handling them better.



(a) (b)

Figure 4: Patient 1: 2D projections where the prosthesis is visualized as towards the right of the midline. In the left axial view, the keel of the prosthesis is partly visualized. In the right coronal view it is shown that the prosthesis was placed slightly to the right of the midline.

Proponents argue that TDR preserves/restores segmental motion and might reduce the risk of adjacent segment degeneration (ASD). Some studies support the argument that ASD is prevented after TDR [38–40], while others show ASD after TDR only with the first type of disc prosthesis that was used [41, 42]. This could be the result of the DDD progressing by itself to multiple levels; it might be a consequence of increased stress on adjacent levels generated from nonphysiological motion, or lack of motion in the disc prosthesis [41].

Prostheses that fail to adequately replicate the physiologic kinematics of the lumbar spine may predispose the patient to facet joint degeneration at the treated segment or in adjacent segments. The distance and angle after TDR are reproducibly obtained with CT after surgery. We have done a number of studies with double examinations where this is shown to be true. For instance, see [26]. Therefore, we believe that it is important to analyze if any changes occur in the individual mobility pattern of facet joints at both operated and adjacent segments after TDR [43]. Analysis of 3D movement and evaluation of the individual facet joints before and after surgery can reveal how the disc prosthesis affects the motion pattern of the segment.

The present study was a small study with only ten patients in which the same experienced orthopaedic surgeon inserted all the prosthesis. The intended position of the implant was all the way towards the posterior longitudinal ligament, since that would place the center of rotation in the physiological anterior-posterior position. To avoid irregular mobility and load that could over time affect either facet joint, the implant was positioned as close to the midline as possible. When this study was undertaken, implants were higher than today, which is why sometimes the treated segment might have been "overstuffed," but in general the lowest implants available were used [44]. Further, X-rays were taken shortly after surgery, which showed that the prosthesis was correctly aimed and positioned with regard to the size and height of the devise. The aim was to establish the possibility to detect rotation and facet joint movement. In this regard it was interesting to look at the quality of motion, as in the following examples.

Patient 1 had a Maverick prosthesis in the L5-S1 level. The rotation after surgery was about the same as before surgery, but the magnitude of the facet joint movement was different: the movement in the left joint was 6.7 mm and in the right facet joint was 3.5 mm. Visual analysis showed that the prosthesis was placed slightly to the right of the midline of the vertebra (Figure 4).

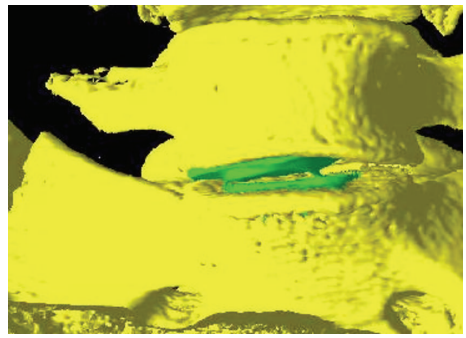


Figure 5: 3D isosurface illustrating the subsidence of the prosthesis (green) into the endplate of the L5 vertebra on Patient 8.

In Patient 8, the Charité prosthesis had subsided into the L5 vertebra and caused a coronal plane rotation and a different movement in the facets joints (Figure 5). The asymmetric facet joint movement might indicate that the facet joint with more stress might degenerate sooner with the possible recurrence of low back pain.

In Patient 4 the left facet joint was more degenerated with osteophytes in the CT scans three years after surgery than the right facet joint, and it clearly induced a large difference in the coronal rotation in addition to there being a large asymmetry between the movement of the left and right facet joint (Figure 6).

This method is a truly 3D method that is easy to use, is noninvasive, and can be performed routinely in a clinical setting using any modern CT scanner, with an effective radiation dose comparable to radiographs. It takes five to ten minutes to complete the registration of the L5 vertebra. It then takes another five to ten minutes to choose landmarks on the L4 and S1 vertebrae and a comparable time for landmark choice on the facet joints. Then the analysis proceeds automatically

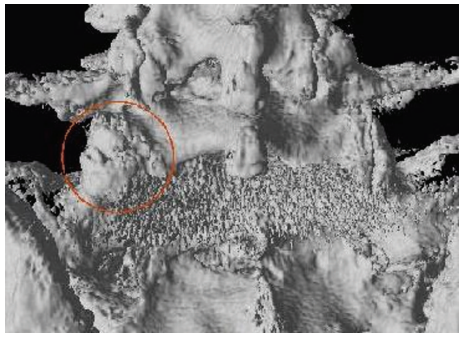


Figure 6: 3D isosurface for Patient 4 viewed from behind the L5-S1 vertebrae. In the left joint of L5-S1 (red circle) the osteoarthritis is severe with visually displayed osteophytes in this view. Below the joint there are artefacts from the prosthesis in L5-S1 level.

and completes in under a minute. The data found in this small pilot study suggests that TDR preserves the motion in the lumbar segment even after three years which might cause less adjacent level problems.

5. Conclusion

It has been shown that this method is suitable to study patients operated on in the lumbar spine. This truly 3D method can be performed in a relatively short time at low effective radiation dose. Detailed information about kinematics was obtained. This method of detecting movement in the spine is useful in research to confirm the correct positioning of disc prostheses, in the future development of TDR designs, and for clinical use.

Appendix

Technical Note

The user interface of the volume registration tool can simultaneously present, for any pair of volumes, arbitrary 2D slices from any orthogonal plane (axial, sagittal, and coronal) as well as 3D isosurfaces. The slices can be viewed in two larger display windows representing one orthogonal plane for each volume or six smaller windows representing all three orthogonal planes for each volume. A number of color, black and white, and gray scales are available. For CT volume viewing, one or two window width/level settings can be used as desired. For example, a lower window can be used for viewing skeletal structure or soft tissue, while a higher window can be used for simultaneously viewing metal or other high attenuating structures. The 3D isosurfaces can be viewed in large or small formats and can be zoomed, rotated, and viewed from any arbitrary direction, with various surface types (e.g., opaque or translucent).

Landmarks are chosen on concurrently viewed slices or directly on 3D isosurfaces which display the same physiological structure and are recorded as true 3D coordinates (automatically mapped to closest slices for display). Landmarks can be chosen as simple 3D points or with the aid of a 3D sphere. The sphere landmark superimposes contours of a 3D sphere that, when designated, returns the 3D coordinates of the sphere's center as the landmark point. When a landmark is chosen, the view of the slices is updated in all three orthogonal planes, the corresponding point in the 3D volume is recorded in units of mm (rather than voxel coordinates), and a sequence number is generated.

The 3D paired landmarks are used to generate the eigenvalues of the transformation matrix of coefficients. For nonrigid registration the eigenvalues are generated by employing a weighted least square linear regression followed by a Gauss-Jordan matrix inversion. For rigid body registration singular value decomposition is employed. Either method limits the effect of mismatched landmarks and generates transform coefficients for arbitrary volume data sets. At present, the x, y, and z-coordinates are given equal weight in the transformation, although there normally is a finer resolution in the x and y directions when compared with the z direction. It is possible to weight the linear regression or the singular value decomposition to compensate for this difference, but presently this is not done. There is also the possibility to use a completely manual affine transformation. The tool also offers a nonaffine transformation in the form of a first- and second-degree transformation which does not preserve the original voxel coordinate grid. Finally, a transformation is performed.

Once the new transformed volume has been created from the original, untransformed data set, this transformed volume may be resliced and evaluated side by side with the original volume in any of the three planes or superimposed on the original slices. An isosurface of the transformed volume may be displayed in 3D, superimposed with an isosurface from the original volume and/or the untransformed volume for comparison. Landmarks can also be utilized with the transformed volume together with the original volume either to create a better match or to generate a numeric estimate of the registration error.

The application in the present study used a rigid body transform. This type of transformation preserves the spatial integrity of the structures involved. Landmarks were chosen on the registered transformed and original volumes to generate numeric values for the correlation of the L4 and S1 vertebral rotations and facet joint translational movement.

Conflict of Interests

The authors report no conflict of interests concerning the materials or methods used in this study or the findings specified in this paper.

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Hindawi Publishing Corporation
BioMed Research International
Volume 2015, Article ID 713952, 7 pages
http://dx.doi.org/10.1155/2015/713952

Clinical Study

Long-Term Outcomes of Cervical Laminoplasty in the Elderly

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Received 6 May 2015; Revised 26 July 2015; Accepted 11 August 2015

Academic Editor: Jau-Ching Wu

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Incidences of cervical laminoplasty in the elderly are increasing; the influence of other age-related complications and neurological status must be considered for justifying surgery. This study identified the aforementioned influence on long-term outcomes of cervical laminoplasty in patients aged ≥75 years. Thirty-seven of 38 consecutive patients aged ≥75 years who underwent cervical laminoplasty were retrospectively evaluated. Minimum 5-year follow-up was acceptable if patients were complication-free. Follow-up was terminated when neurological evaluation was not possible, owing to death or other serious complications affecting activities of daily living (ADL). Postoperative neurological changes and newly developed severe complications were investigated. Postoperatively, one patient died of acute pneumonia, one remained nonambulatory owing to cerebral infarction, and 35 were ambulatory and were discharged. At a mean follow-up of 78 months, three patients died and nine developed serious complications severely affecting ADL. Of the 25 remaining patients, 23 remained ambulatory at mean follow-up of 105 months. Cox proportional hazard analysis revealed that postoperative motor upper and lower extremities JOA scores of ≤2 and ≤1, respectively, were risk factors for mortality or other severe complications. Postoperative neurological status can be maintained in the elderly if they remain complication-free. Poorer neurological status significantly affected their ADL and mortality.

1. Introduction

Laminoplasty, a motion preservation surgical procedure for cervical myelopathy, has become popular as a safe and effective treatment for cervical myelopathy with few reported complications and relatively good long-term outcomes [1–6]. Laminoplasty can be employed in patients with multiple-level spinal cord compression as it is suitable for elderly patients with cervical compression myelopathy [7, 8]. Further, this technique is particularly suitable for elderly patients because the incidence of airway complications is less than that occurring in anterior surgery [9, 10]. As the population continues to age, spine surgeons are expected to encounter an increased number of patients with cervical compression myelopathy. Although the neurological recovery rate (RR) in elderly patients may be inferior to that in younger patients, significant clinical improvement shortly after cervical decompression surgeries has been reported in previous reports as well [7, 11–15]. However, long-term outcomes of cervical decompression surgery in elderly patients remain uncertain.

One possible problem in interpreting long-term surgical outcomes in elderly patients is the consideration of the influence of other age-related diseases, such as cerebral infarction, dementia, and severe osteoarthritis. As patients age, the prevalence of such comorbidities increases, complicating the neurological evaluation of cervical myelopathy. Furthermore, patients with severe complications tend to discontinue outpatient treatment because they may no longer visit the hospital; thus, only patients with relatively better activities of daily living (ADL) are typically enrolled in this type of a study. Therefore, a higher follow-up rate is required for accurately evaluating long-term postoperative status, particularly among elderly patients.

Here, we report the long-term prognostic course of elderly patients after cervical laminoplasty, with a follow-up rate of 97%. This study aimed to investigate the long-term outcomes of cervical laminoplasty in terms of the neurological status and age-related comorbidities among patients aged ≥75 years.

Table 1: Demographic data of patients.

Number of patients	37
Age (years)	79 (75–86)
Sex (male/female)	22/15
Mean follow-up (months)	78 (0–140)
JOA score	
Preoperative*	9.3 (4–14)
Postoperative*	10.9 (4–15)
Recovery rate*	21% (−67 to 78)

*Six months after surgery, excluding one patient who died 2 weeks after surgery.

Table 2: Perioperative complications.

Death (pneumonia)	1
Transient ischemic attack	1
Acute cardiac failure	1
Uncontrollable high blood pressure	1
Urinary tract infection	2
Delirium	4
Severe depression	1
Surgical site infection	1
C5 palsy	2
Total	14 (35%)

2. Materials and Methods

We retrospectively reviewed medical records of 235 consecutive patients who underwent laminoplasty for cervical compression myelopathy owing to cervical spondylotic myelopathy (CSM) or ossification of the longitudinal ligament (OPLL) between 1998 and 2004 and identified 38 patients, with a mean age of 78 (75–86) years, at the time of surgery. Patients with rheumatoid arthritis, disc herniation, tumor, trauma, or previous surgery were not included. The study protocols were approved by the institutional review board of the authors' institution. Cervical laminoplasty was performed using autograft bones as spacers. Of these, one patient was excluded because he dropped out as an outpatient within 6 months for unknown reasons. Therefore, 37 patients (97%; 23 men and 14 women; Table 1) for whom the final neurological status or ADL could be investigated were included in this study. The underlying diseases in this cohort comprised CSM ($n = 30$) and OPLL ($n = 7$). Follow-up was terminated when a neurological evaluation was no longer possible, owing to patients' death or other serious complications affecting ADL. All patients underwent thorough cardiac and pulmonary function examinations before surgery. Moreover, postoperative neurological status and complications were investigated. The Japanese Orthopaedic Association (JOA) score was used for assessing the neurological ability:

(1) Upper extremity motor function:

0: impossible to eat with chopsticks or spoon.
1: possible to eat with spoon but not with chopsticks.
2: possible to eat with chopsticks, but to a limited degree.
3: possible to eat with chopsticks, awkward.
4: no disability.

(2) Lower extremity motor function:

0: cannot walk.
1: needs cane or aid on flat ground.
2: needs cane or aid only on stairs.
3: can walk without cane or aid but slowly.
4: no disability.

(3) Sensory function:

(A) Upper extremity.

0: apparent sensory loss.
1: minimal sensory loss.
2: normal.

(B) Upper extremity (same as A).
(C) Trunk (same as A).

(4) Bladder function:

0: complete retention.
1: severe disturbance.
2: mild disturbance.
3: normal.

RR based on the JOA score was evaluated using a previously described formula [16]:

$$\text{RR} = \left[\frac{(\text{postoperative JOA score} - \text{preoperative JOA score})}{(17 - \text{preoperative JOA score})} \times 100\%\right]. \quad (1)$$

2.1. Statistical Analysis. SPSS 18 (SPSS, Inc., Chicago, IL, USA) was used for all statistical analyses, and a probability (p) value of <0.05 was considered significant. Nonparametric analyses were performed using the Mann-Whitney U test. Categorical variables were analyzed using the chi-square test. Univariate Cox proportional hazard analysis was used for identifying relevant risk factors. Kaplan-Meier survival analysis was used for evaluating the postoperative period without serious complications.

3. Results

We aimed for a minimum 5-year follow-up as long as the patient had no serious complications. During postoperative hospitalization, one patient died of acute pneumonia, while one remained nonambulatory even after surgery. The remaining 35 patients remained ambulatory and were eventually discharged (Table 2). C5 palsy with an MMT grade of 2

Table 3: Postoperative course and complications.

	Preop	Postop			
		6 months	24 months	60 months	Final (105 months)
Pts. without severe complications	37 (100%)	36 (97%)	34 (92%)	29 (78%)	25 (68%)
Ambulating	29	35	32	27	23
Nonambulating	8	1	2	2	2
Pts. with severe complications (including death)	0 (0%)	1 (3%)	3 (8%)	8 (22%)	12 (32%)
Death	0	1	1	2	3
Dementia	0	0	2	5	5
Parkinsonism	0	0	0	1	1
Schizophrenia	0	0	0	0	1
Cerebral infarction	0	0	0	0	1
Subarachnoid hemorrhage	0	0	0	0	1

occurred in two patients within 2 weeks after surgery, which spontaneously improved in three months. The mean pre- and postoperative total JOA scores at 6 months of the 36 surviving patients were 9.3 and 10.9, respectively, with a mean JOA score RR of 21% (as shown in the Japanese Orthopaedic Association score). The postoperative motor JOA scores of the upper extremities (U/E) (preoperative, 2.0, versus postoperative, 2.6; $p < 0.001$) and lower extremities (L/E) (preoperative, 1.2, versus postoperative, 1.9; $p < 0.001$) were significantly high. Six months after surgery, 51% and 49% of patients revealed improvement of at least one level in the U/E or L/E JOA scores.

During the postoperative follow-up of two years, one patient died and two patients developed severe dementia. The mean pre- and postoperative total JOA scores at 2 years of the 34 patients whose neurological examination was possible were 9.3 and 11.0, respectively, with a mean JOA score RR of 19%. Pre- and postoperative radiographic examinations were performed for the surviving 36 patients. The mean pre- and postoperative C2–7 lateral Cobb angles were 16 degrees (range: −3–37 degrees) and 14 degrees (range: −10–41), respectively ($p = 0.50$). Similarly, the mean pre- and postoperative range of motion were 32 (range: 6–47) and 21 (range: 7–52), respectively ($p = 0.001$).

The neurological status of 29 patients could be evaluated 5 years postoperatively; however, it could not be determined in eight patients, owing to the death of two patients, severe dementia in five patients, and severe Parkinsonism in one patient. The mean pre- and postoperative total JOA scores at 5 years of the 29 patients whose neurological examination was possible were 9.4 and 10.6, respectively, with a mean JOA score RR of 15%. Finally, at a mean follow-up of 78 (0–140) months, three patients died and nine developed serious complications that severely affected ADL (Table 3). Therefore, of the surviving patients, 25 (68%) had no other serious complications, and 23 (92%) of them remained ambulatory at a mean follow-up of 105 (60–140) months.

We compared the outcomes of 25 patients for whom a neurological examination was possible (Figure 1) with the 12 patients who died or developed severe complications during follow-up (Figure 2) and found significant differences in postoperative (6 months) motor U/E JOA scores and both pre- and postoperative (6 months) motor L/E JOA scores (Table 4). Furthermore, Cox proportional hazard analysis revealed that a postoperative motor U/E JOA score of ≤2 (hazard ratio (HR): 5.64) and a motor L/E score of ≤1 (HR: 3.47) were risk factors for mortality or other serious complications over a long period (Table 5). According to Kaplan-Meier analysis, 82% of patients with a postoperative L/E JOA score of ≥2 survived and had no severe complications at a mean postoperative follow-up of 78 months, while the rate decreased to 61% among those with a postoperative (6 months) L/E JOA score of ≤1 (Figure 3).

4. Discussion

We aimed to clarify factors associated with long-term prognosis after laminoplasty in elderly patients and found that neurological function can be maintained for prolonged periods, unless patients develop severe complications. In contrast, 12 of the 37 patients developed severe comorbidities or died during follow-up, while poorer neurological status significantly affected ADL and mortality.

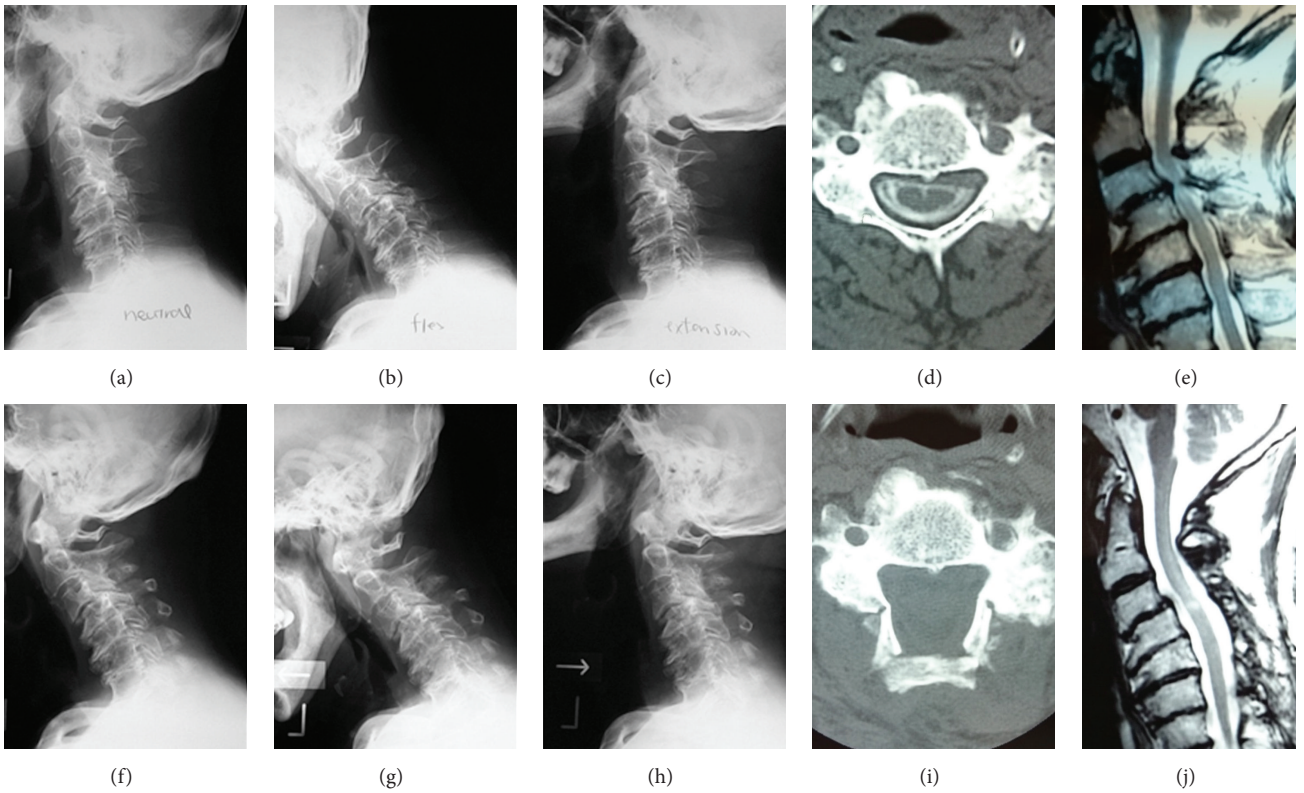
Several previous reports have indicated that outcomes of cervical laminoplasty in elderly patients may be inferior to those in younger patients [3, 11, 14, 17–19], while others found comparable surgical outcomes [7, 13, 15]. However, the definition of the term "elderly" varied from ≥65 years to ≥80 years, which may explain the inconsistencies in the reported surgical outcomes. As life expectancy has surpassed 80 years in many developed countries, patients aged 65 years are not necessarily considered elderly. Therefore, we defined elderly patients as ≥75 years.

Several studies have reported the surgical outcomes of cervical laminoplasty among an elderly population of ≥75 years. Of these, Matsuda et al. [14] have reported that the JOA score RR was inferior in 17 patients aged >75 years at a mean follow-up of 56 months. In contrast, Nagashima et al. [15] have investigated 37 patients with cervical spondylotic myelopathy aged ≥80 years at a mean follow-up of 15.9 months and reported results similar to those in younger patients. Moreover, Machino et al. [13] have reported that surgical outcomes of 90 patients with cervical myelopathy

Table 4: Comparison between patients with or without severe complications at the final follow-up period (average 105 months).

Baseline factors	Without severe complications $n = 25$	With severe complications or dead $n = 12$	p value
Age at surgery	76.9 ± 2.2	78.4 ± 3.6	0.20
Sex (male : female)	18 : 7	5 : 7	0.15
Diagnosis (CSM : OPLL)	21 : 4	9 : 3	0.66
Preop C2–7 Cobb angles*	18 ± 8	16 ± 10	0.53
Postop C2–7 Cobb angles*	15 ± 12	12 ± 9	0.39
Preop ROM*	33 ± 11	31 ± 11	0.69
Postop ROM*	20 ± 10	21 ± 16	0.59
Pretotal JOA**	9.5 ± 2.8	8.5 ± 3.3	0.39
Posttotal JOA**	11.4 ± 2.7	9.9 ± 2.7	0.14
Premotor JOA (U/E)	2.1 ± 0.9	1.7 ± 0.9	0.20
Postmotor JOA (U/E)**	2.8 ± 0.8	2.2 ± 0.5	0.02
Premotor JOA (L/E)	1.4 ± 0.9	0.8 ± 0.7	0.03
Postmotor JOA (L/E)**	2.1 ± 0.7	1.4 ± 0.8	0.02

CSM: cervical spondylotic myelopathy; OPLL: ossification of the longitudinal ligament; Preop: preoperative; Postop: postoperative; ROM: range of motion; U/E: upper extremities; L/E: lower extremities.
*Two years after surgery, excluding one patient who died 2 weeks after surgery.
**Six months after surgery, excluding one patient who died 2 weeks after surgery.



(a) (b) (c) (d) (e)

(f) (g) (h) (i) (j)

Figure 1: A 76-year-old man who underwent C3–7 laminoplasty for cervical spondylotic myelopathy. Pre- (a–e) and postoperative (f–j) radiographs, CT, and MRI images are shown. Pre/postoperative C2/7 Cobb angles and range of motion were 0/−7 and 33/25 degrees, respectively. Although slight kyphosis progressed after surgery, the patient underwent a good clinical course. Pre- and postoperative (96 months) JOA scores were 9 and 11, respectively.

Table 5: Predictive factors for severe complications or death at the final follow-up period (average 105 months).

Baseline factors	*n*	Hazard ratio	95% CI	*p* value
Age at surgery				
80≤	6	1.22	0.26–5.59	0.80
≤79	31	1.00		
Sex				
Male	23	0.39	0.12–1.23	0.11
Female	14	1.00		
Preop motor JOA (U/E)				
≤2	25	1.41	0.38–5.21	0.60
3≤	12	1.00		
Postop motor JOA (U/E)*				
≤2	14	5.64	1.51–21.0	0.01
3≤	22	1.00		
Preop motor JOA (L/E)				
≤1	14	3.16	0.69–14.4	0.13
2≤	23	1.00		
Postop motor JOA (L/E)*				
≤1	11	3.47	1.09–10.97	0.03
2≤	25	1.00		

Preop: preoperative; Postop: postoperative; ROM: range of motion; U/E: upper extremities; L/E: lower extremities.
*Six months after surgery, excluding one patient who died 2 weeks after surgery.

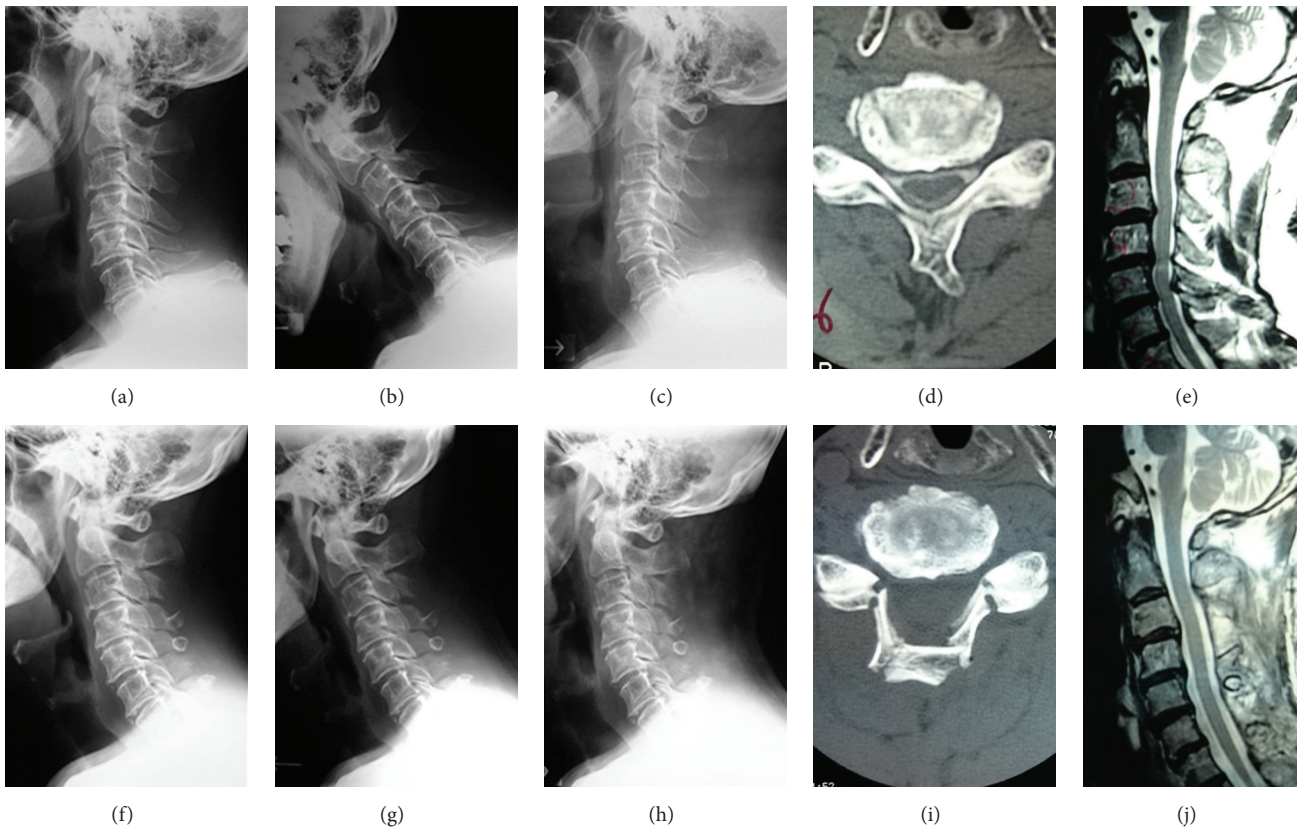


Figure 2: A 79-year-old man who underwent C4–7 laminoplasty for cervical spondylotic myelopathy. Pre- (a–e) and postoperative (f–j) radiographs, CT, and MRI images are shown. Pre/postoperative C2/7 Cobb angles and range of motion were 17/15 and 46/32 degrees, respectively. This patient was not able to walk before surgery but got managed to walk after surgery. However, he developed severe dementia and died 4 years after surgery. Pre- and postoperative (24 months) JOA scores were 5 and 7, respectively.

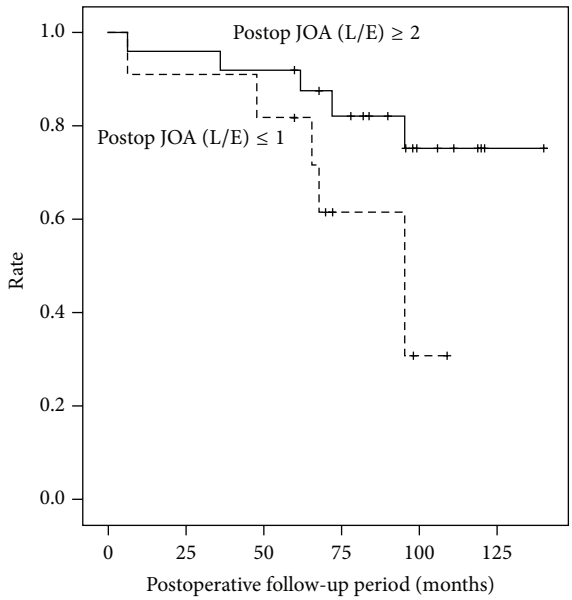


Figure 3: Kaplan-Meier analysis showing the rate of surviving patients without severe complications.

aged ≥75 years at a mean follow-up of 29 months were as good as those reported in younger patients. Although surgical outcomes of cervical laminoplasty in elderly patients remain controversial, almost all previous studies have shown positive surgical outcomes in elderly patients, at least to some extent, with varying improvement in the JOA recovery rates. However, follow-up was not very long, and the follow-up rate was not very high or unknown. The patients in this study revealed a follow-up rate of 97%, with a mean follow-up of 78 months. Moreover, we could assess the neurological status at a mean follow-up of 105 months, with the exception of patients who developed severe complications or died, which is a considerably long period among elderly patients. To our knowledge, this study reports the longest follow-up in this population.

One possible problem associated with the use of the JOA score RR is that it can be affected by the preoperative JOA score [7, 13, 20]. Instead, the use of the achieved JOA scores may be more suitable for adequately evaluating the surgical effect in elderly patients as the preoperative JOA score is generally lower in this population. As a motor L/E JOA score of 1 is believed to be satisfactory in elderly patients, we should focus on maintaining a long-term ambulatory ability. Hence, we focused on motor JOA scores, particularly those of L/E, instead of the total JOA score RR. In the present study, 92% of patients without severe complications during the postoperative follow-up period remained ambulatory at a mean follow-up of 105 (60–140) months, indicating that the neurological status was also well maintained over a relatively long period.

It is reasonable to speculate that the ambulatory ability will significantly influence mortality and ADL. Indeed, the motor L/E JOA scores significantly affected the incidence of mortality and severe complications. Considering that postoperative neurological status will gradually deteriorate in the future, patients should consider surgical intervention while motor functions are maintained as long as their preoperative comorbidities are not severe. Jiang et al. [5] have reported that the duration of symptoms and severity of stenosis significantly affected surgical outcomes of laminoplasty in elderly patients, supporting the importance of early surgical intervention in elderly patients before irreversible changes to the spinal cord develop. Once patients become bedridden, they will suffer from such complications as pneumonia and coronary diseases. To reduce the risk for becoming bedridden, the importance of physical therapy has been advocated. Recently, the relationship between locomotive functions and health-related quality of life (HRQOL) has been shown [21, 22]. Spreading the need for checking locomotive function in the elderly will not only lead to early detection of myelopathy and osteoarthritis but also reduce the risk for becoming bedridden and severe complications.

During the perioperative period, no patient showed severe neurological deterioration, although two patients suffered C5 palsy. One concern regarding surgical treatment among elderly patients is the higher prevalence of complications. In this study, patients with serious preoperative comorbidities were not considered for surgery; thus, the complication rate was comparable with that in previous reports. Although most complications were temporary, we should consider that one patient died of acute pneumonia shortly after surgery.

Finally, the relationship between poorer neurological status and complications is not limited to the elderly, although poor ADL will lead to severe complications and death more often in the elderly. Indeed, the influences of comorbidity on surgical outcomes are also reported, as measured by such indices as the Charlson Comorbidity Index [23] and the Self-Administered Comorbidity Questionnaire [24]. We may predict adverse events and postoperative HRQOL by using these indices before surgical intervention.

There are several limitations to this study. First, there was no control group. Second, the number of enrolled patients was rather small. Third, no patient-reported outcomes were utilized. Nevertheless, this study had a long follow-up period with a mean of 77 months, which we believe is considerably long in a cohort aged ≥75 years. Because severe complications after cervical laminoplasty are less frequent in younger populations, we feel it would not be informative to compare the prognostic course of elderly patients to those of younger patients.

In conclusion, postoperative neurological status can be maintained over a long period in elderly patients who do not develop severe complications. However, as postoperative neurological status will gradually worsen and a poorer postoperative course will lead to serious comorbidities in the future, we propose that patients without serious preoperative complications should undergo surgical intervention before the neurological status worsens, regardless of age.

Ethical Approval

The study approval was given by the institutional review board of the Clinical Research Support Center of the University of Tokyo Hospital.

Disclosure

The paper submitted does not contain information about medical device(s)/drug(s).

Conflict of Interests

No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this paper.

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Hindawi Publishing Corporation
BioMed Research International
Volume 2015, Article ID 719123, 9 pages
http://dx.doi.org/10.1155/2015/719123

Review Article

Material Science in Cervical Total Disc Replacement

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Received 31 July 2015; Accepted 17 September 2015

Academic Editor: Nicholas Dunne

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Current cervical total disc replacement (TDR) designs incorporate a variety of different biomaterials including polyethylene, stainless steel, titanium (Ti), and cobalt-chrome (CoCr). These materials are most important in their utilization as bearing surfaces which allow for articular motion at the disc space. Long-term biological effects of implanted materials include wear debris, host inflammatory immune reactions, and osteolysis resulting in implant failure. We review here the most common materials used in cervical TDR prosthetic devices, examine their bearing surfaces, describe the construction of the seven current cervical TDR devices that are approved for use in the United States, and discuss known adverse biological effects associated with long-term implantation of these materials. It is important to appreciate and understand the variety of biomaterials available in the design and construction of these prosthetics and the considerations which guide their implementation.

1. Introduction

Total disc replacement (TDR) was initially developed as an alternative to fusion with the aim of preserving segmental motion. Cervical TDR has been used following an anterior discectomy for the treatment of radiculopathy or myelopathy. Although the anterior cervical discectomy and fusion (ACDF) has been successful with regard to overall outcome, fusion does lead to increased biomechanical stress at adjacent segments that may then accelerate degeneration at these levels [1–5]. Arthroplasty preserves the motion at the operated level and should reduce the rate of adjacent level pathology as well as avoid any complications associated with pseudoarthrosis.

The past several years have seen the continued research and development of suitable materials for arthroplasty. Current cervical TDR designs constitute a wide range of biomaterials available for their construction. The most common design used includes metallic endplates which are fixed to the vertebral bodies above and below, with one or more articulations that involve metal-on-metal or metal-on-polymer bearing surfaces at the central core [6]. A broad range of materials are used in the cervical spine and include polyethylene, cobalt-chrome (CoCr) alloys, stainless steel, titanium (Ti) alloys, polyurethanes, and Ti alloy-ceramic composites. The choice of biomaterials utilized in these prosthetic implants centers around their sufficient durability, biocompatibility, and resistance to mechanical loading during physiologic use [7].

In this paper, we provide a review of the biomaterials used in cervical TDR devices, describe the type of bearing designs and their material considerations, review the construction of the seven current cervical TDR prosthetic implants that are approved for use in the United States by the Food and Drug Administration (FDA), and describe known adverse biological effects associated with the implantation of these materials.

2. Materials

The choice of materials used in a prosthesis takes into consideration those used in the articulation surfaces as well as outer surfaces of the prosthesis that interface with the endplates of the vertebral bodies themselves. The bearing surfaces must be made of materials to tolerate loading without fatigue or fracture, minimize friction, have superior wear characteristics, and minimize the generation of wear debris [8].

Articular surfaces may use components made from polymers such as ultrahigh molecular weight polyethylene

(UHMWPE). Metals also play a key role in implant design and creation. Metallic components have been utilized which may wear more slowly than UHMWPE and include stainless steel, titanium (Ti), and cobalt-chrome (CoCr) alloy.

Although the initial stability of an artificial disc depends on soft tissue tensioning and implant design and geometry, long-term fixation depends on bony ingrowth into the surface of the prosthesis. Surface coatings have been used to improve this type of bony ingrowth and include titanium wire mesh, plasma-sprayed titanium, porous CoCr, and bioactive materials such as hydroxyapatite and calcium phosphate [4, 9].

2.1. Polyethylene. The use of polyethylene polymer is based on its prior extensive use and support in knee and hip arthroplasties [7, 10, 11]. Polyethylene itself is a thermoplastic polymer consisting of long hydrocarbon chains with excellent chemical resistance. Ultrahigh molecular weight polyethylene (UHMWPE) has extremely long chains with a molecular mass usually between 2 and 6 million units. The longer chains allow for more effective load transfers to the polymer backbone, resulting in a very high impact strength. UHMWPE was first used clinically in 1962 by Sir Charnley in which he incorporated a UHMWPE acetabular cup against a stainless steel femoral head for use as a total hip replacement [12].

Over the past several decades, highly cross-linked UHMWPE materials have been introduced and have become the standard of care for hip arthroplasty [7, 10]. Cross-linking of polyethylene improves wear resistance and the risk of osteolysis in the hip but comes with some concomitant decrease in mechanical properties [11].

2.2. Stainless Steel. Steels are alloys of iron and other elements, primarily carbon. Stainless steel is a steel alloy with a minimum of 10.5% chromium content by mass. As such, it does not readily corrode, rust, or stain as ordinary steel. Marine grade stainless 316 steel is a molybdenum-alloyed steel that is negligibly responsive to magnetic fields and is the preferred grade steel for medical implantation due to its immunity from sensitization [13].

The use of stainless steel as a material for cervical arthroplasty can be traced to the original Bristol/Cummins disc used in 1991. In the 1980s, British neurosurgeon Brian Cummins was intent on developing a solution to adjacent segment disease and collaborated with a medical engineer to create a ball-and-socket prosthetic for use in the cervical spine. This became the Bristol/Cummins disc, manufactured from 316 stainless steel at his hospital's machine shop. In all, 22 devices were implanted in a total of 20 patients and long-term follow-up out to 12 years postoperatively demonstrated these devices to still be functional [14–16].

Though stainless steel has long been used as surgical implants for many orthopedic applications, it may not always be preferred in cervical arthroplasties because of its inferior mechanical properties [4]. Newer metals such as titanium (Ti) and cobalt-chrome alloy (CoCr) have improved yield strengths and are less prone to corrosion and fatigue failure [17].

2.3. Titanium. Titanium is a low-density transition metal with high strength and is highly resistant to corrosion. Titanium can be alloyed with multiple other metals such as iron, aluminum, vanadium, and molybdenum to create strong, lightweight alloys for use in a variety of industries. Because of its biocompatibility, it is an ideal substance for medical implantation of prosthetics and is often alloyed with 4–6% aluminum and 4% vanadium [18].

Titanium has an inherent ability for osseointegration which stems from its lower modulus of elasticity (Young's modulus) to more closely match that of bone for greater mechanical compatibility [18]. Studies have shown the capacity for bone to bond directly with pure titanium without need for an intervening membrane or scaffold [19–21]. This observation has led to the development of porous titanium spray-coatings on the outer surfaces of cervical prosthetic implants for long-term bony fixation in the cervical spine. This effect is even more significant when hydroxyapatite is applied as well [18, 21].

Titanium alloys have not been used in arthroplasty articulating components due to their poor wear characteristics [4, 18, 22, 23]. Laboratory studies have shown that implanted titanium used as a bearing surface wears down at a higher rate than either stainless steel or cobalt-chrome because of its poor abrasion resistance qualities [17, 24, 25]. The generation of polyethylene wear debris is also the greatest with titanium, and the least with cobalt-chrome [17, 24, 26–28]. Titanium is more prone to abrasive wear due to its surface oxide layer; treating the surface of titanium with nitride or diamond-like carbon, however, improves hardness and wear characteristics while still offering the same MRI imaging compatibility [4, 29, 30]. Even with this supplementation, however, its wear properties still remain inferior to cobalt-chrome or ceramic surfaces [18].

2.4. Cobalt-Chrome. Cobalt-chrome (CoCr) is a metal alloy of cobalt and chromium with a very high specific strength and approximately twice the stiffness of titanium [18]. The alloy composition used to make prosthetics for surgical implantation typically contains 5–7% molybdenum and is therefore sometimes referenced as being made of cobalt-chromium-molybdenum (CoCrMo). Due to their corrosion resistance and excellent biocompatibility, CoCr alloys pose little risk of irritation, allergic reaction, or immune response [31, 32]. This is in part due to the spontaneous formation of a chromium-oxide surface film during its synthesis which renders it biocompatible with physiological environments.

Harold Bohlman is credited with designing the first corrosion-resistant cobalt-chrome alloy femoral head replacement for use as a femoral head prosthetic in 1937 [33]. Since then, CoCr alloys have shown excellent wear characteristics as successfully demonstrated through their wide utilization in joint arthroplasties. Multiple studies have demonstrated CoCr's high resistance to wear especially as compared with titanium alloy [17, 27, 28]. These alloys have seen extensive use as bearing surfaces due to these proven properties [4]. CoCr is also particularly favored as a bearing surface due to reports of reduced amount of metal and polyethylene debris when compared with titanium [17, 22, 23, 34–39].

2.5. MRI Characteristics. All TDR designs are safe and compatible for the magnetic field of MRI scans. Their greatest effect on MRI, however, is in the potential imaging interference that they may cause from any magnetic properties of their constituent metals [40]. The interference artifact in patients with metallic implants is due to the large differences in magnetic properties of human tissue and implanted metals [41, 42]. Depending on the ferromagnetic properties of the metal, these alloys can produce a significant amount of this distortion artifact that may confound interpretation of important anatomic structures near the TDR device such as the spinal canal, neural foramen, disc spaces, vertebral bodies, and paraspinal tissues.

The polyethylene component of a cervical TDR produces no artifact due to its nonmetallic thermoplastic polymer composition. However, the more common metal components of stainless steel, titanium, and cobalt-chrome will all produce varying degrees of magnetic susceptibility artifact. Prior craniomaxillofacial studies have found titanium to be superior to both CoCr alloy and stainless steel with regard to distortion artifact in the face, head, and neck, but it was unclear if these conclusions would be applicable to spinal anatomy [43–45]. Knott et al. investigated the differences in magnetic and radiographic imaging artifact in posterior spinal instrumentation containing stainless steel, titanium, or CoCr alloy [46]. They found that stainless steel implants produced the most artifact but that there were no significant differences in diagnostic evaluation between titanium and CoCr alloy as evaluated by a radiologist and orthopedic surgeon using a 3.0 Tesla magnetic resonance scanner.

3. Bearing Types

Most TDR designs utilize bearings that are configured with ball-and-socket surfaces which then articulate with each other to provide motion. The mechanical load transfer through this joint, however, leads to friction which can lead to implant fixation failure as well as the generation of wear debris [8, 47]. The choice of materials for these TDR bearing surfaces then continues to be an area of extreme importance to minimize the friction between the two bearing surfaces and decrease these risks [47, 48]. The type of bearing used in the majority of TDRs currently is either that of a metal-on-polymer design or that of a metal-on-metal design [7].

3.1. Metal-on-Polymer. Bearing surface technology for total joint arthroplasties traces their origins to the hip and has evolved over decades of major industrial and scientific advancement [10, 49]. Sir Charnley developed the initial hip arthroplasty which used a metal femoral head that articulated with a high-density polyethylene cup inserted into the acetabulum [47, 50]. This allowed for his idea of a "low friction arthroplasty" to counteract what he saw as unacceptable levels of frictional torque of existing metal-on-metal articular designs of that time. The standard contemporary total hip arthroplasty bearings now are based on a metal-on-polymer design utilizing a CoCr alloy femoral head which articulates with a UHMWPE acetabular socket.

Metal-on-polymer articulations have the foundation of extensive clinical experience and literature support as a bearing surface for multiple joints [10, 49]. The majority of cervical TDR implants that are FDA-approved for use in the United States incorporate iterations of metal alloy-based superior and inferior prosthetic endplates which articulate with a central polymer core.

3.2. Metal-on-Metal. Metal-on-metal articulation designs were initially thought to be a viable alternative to metal-on-polymer devices to reduce long-term wear. These bearing designs also generate less friction on movement which can lower the volume of wear debris as compared to polyethylene type articulations, potentially reducing local inflammation and osteolysis [6].

The metal-on-metal bearing design was first widely used in the early 1960s with total hip arthroplasty via the McKee-Farrar prosthesis. This first generation total hip replacement utilized cobalt-chrome metal bearing surfaces on both the femoral and acetabular components [51]. Although early results were favorable, this design became unpopular due to possible metal hypersensitivities and ion toxicities [49, 52–54]. Newer contemporary metal-on-metal hip articulations were subsequently developed with different CoCr alloys, but these have also come under recent scrutiny due to unexpected failures and accelerated wear [6, 38, 55–57].

Because the biomechanical forces seen in the hip joint differ than those in the spine with regard to load as well as bearing surface conformational constraints, it is still unclear how these metal-on-metal designs will truly translate with long-term use in the cervical compartment [49].

4. Cervical Prosthetic Devices

There are currently seven cervical artificial disc replacements that are approved for use in the United States by the Food and Drug Administration (FDA). Their materials and bearing types will be discussed further here (Table 1).

4.1. Medtronic Prestige ST/Prestige LP. The original Medtronic Prestige ST (Medtronic Sofamor Danek, Memphis, TN, USA) artificial disc utilizes a superior stainless steel convex ball that articulates with an inferior stainless steel concave trough. This design built upon and refined the original Bristol/Cummins artificial disc, replacing the inferior hemispherical cup with a shallow ellipsoidal saucer to permit more translation. Since that metal-on-metal original design, the product has undergone multiple evolutions with the FDA recently approving the Prestige LP device in 2014 for use here in the United States. The Prestige LP retains the same ball-and-trough socket design but the implant itself utilizes a proprietary titanium-ceramic composite material. A plasma-spray titanium coating on the outer surface encourages bony growth into the device.

4.2. Depuy-Synthes ProDisc-C. The Depuy-Synthes ProDisc-C (Synthes Spine, Paoli, PA, USA) prosthesis is an adaptation using the same design as the lumbar total disc replacement

Table 1: Cervical artificial disc replacements FDA-approved for use in the United States.

Device	Manufacturer	Bearing type	Materials	Year FDA-approved
Prestige ST	Medtronic	MoM	Stainless steel	2007
ProDisc-C	Depuy-Synthes	MoP	CoCr, UHMWPE	2007
Bryan	Medtronic	MoP	Ti, PCU	2009
SECURE-C	Globus	MoP	CoCr, UHMWPE	2012
PCM	NuVasive	MoP	CoCr, UHMWPE	2012
Mobi-C	LDR	MoP	CoCr, UHMWPE	2013
Prestige LP	Medtronic	MoM	Ti-ceramic	2014

FDA: Food and Drug Administration; MoM: metal-on-metal; MoP: metal-on-polymer; CoCr: cobalt-chromium alloy; UHMWPE: ultrahigh molecular weight polyethylene; Ti: titanium alloy; PCU: polycarbonate urethane.

ProDisc-L created by the same company. The articular surfaces used include a UHMWPE inlay ball locked into the inferior endplate which articulates with a CoCr alloy socket in the superior endplate. The outer coating incorporates a porous plasma-sprayed titanium coating to encourage bony growth for long-term stability.

4.3. Medtronic Bryan. The Medtronic Bryan (Medtronic Sofamor Danek, Memphis, TN, USA) artificial disc consists of a pair of superior and inferior identical titanium (Ti) shells that conform to and articulate with a central polycarbonate urethane (PCU) core. A flexible polyether urethane (PEU) sheath then surrounds the core to prevent tissue ingrowth into the articulating surfaces.

Titanium alloy seal plugs help to retain a sterile saline lubricant. Long-term stability of the implant within the cervical spine is achieved with bony growth into porous-coated titanium alloy end plates.

4.4. LDR Mobi-C. The LDR Mobi-C cervical artificial disc (LDR USA, Austin, TX, USA) uses a three-piece design with CoCr alloy superior and inferior endplates which encase a UHMWPE mobile bearing core insert. The endplates themselves are coated with a plasma-sprayed titanium and hydroxyapatite coating for long-term fixation within the cervical spine.

4.5. Globus SECURE-C. The Globus SECURE-C prosthesis (Globus Medical, Audubon, PA, USA) also uses a three-piece design with two CoCr alloy endplates. The UHMWPE central core articulates with the superior CoCr endplate via a spherical surface and interfaces with the inferior CoCr endplate through a cylindrical surface. The outer portions of the CoCr alloy endplates use a titanium plasma-spray coating for bony ongrowth.

4.6. NuVasive PCM. The PCM (porous-coated motion) cervical artificial disc was initially developed by Cervitech (Cervitech, Rockaway, NJ, USA) and subsequently acquired by NuVasive (NuVasive, San Diego, CA, USA). The PCM disc replacement's superior and inferior endplates are made entirely of CoCr alloy while a UHMWPE central core is locked into the inferior endplate for articulation with the superior endplate. The articulating surface extends across the entire bearing and allows for a larger radius of movement and increased translation during the rotational arc. A titanium calcium phosphate coating is electrochemically applied to the outer surface of the superior and inferior CoCr alloy endplates to allow for bony growth by the vertebral bodies into the prosthesis.

5. Adverse Biologic Effects

Although all cervical prosthetics are constructed with materials that are biocompatible for implantation, the long-term effects of these materials have become more clinically relevant as more follow-up has been achieved. Wear debris is generated over time as the articulating surfaces move against each other, and this debris can subsequently lead to multiple adverse effects including inflammatory hypersensitivity reactions, pseudotumor formation, osteolysis, and implant loosening.

5.1. Wear Debris. Generation of wear debris in artificial joints has been shown to be the primary source of implant degradation, and the subsequent tissue and inflammatory reaction to the debris significantly limits the longevity of the prosthesis [4]. This debris has been associated with osteolysis, implant loosening, and subsequent prosthesis failure [4, 37, 38]. Polyethylene-on-metal provides a low friction surface contact but generates polyethylene wear debris that in the literature has been established as a cause of hip and knee arthroplasty failure. Cross-linking with gamma irradiation has been used to improve those properties in ultrahigh molecular weight polyethylene but with some effect to its mechanical properties [58, 59]. Metal-on-metal articulations lower wear rates dramatically but still generate a lower volume through higher quantity of smaller particle debris. Metal-on-metal designs also provide less shock absorption than metal-on-polyethylene [4].

Host reaction to wear debris is related to particle shape, quantity, volume, and concentration [49, 60]. Metal-on-metal articulations produce a predominance of needle-shaped particles which have been associated with greater inflammation from prior observations in polyethylene debris [61–64]. Wear debris from metal-on-metal bearings can also form corrosion products and molecular complexes [49, 65, 66]. Wear debris particles are readily phagocytosed by inflammatory cells, which in turn trigger proinflammatory cascades and oxidative stress. An individual patient's response to this debris

is also unpredictable, with some tolerating it well and others poorly [67, 68]. All bearing surfaces will produce wear debris, but poorly positioned or otherwise compromised prosthetics may produce further pathologic wear [49, 69, 70].

5.2. Immune Response. Polyethylene materials have been used for decades and have since become the standard of care in hip arthroplasty [10]. However, it has long been known that wear debris can have an effect on the local periprosthetic tissue. In one of the only long-term studies of retrieved explanted TDR tissue, Kurtz et al. noted a chronic inflammatory response in the periprosthetic fibrous tissues from 15 of 16 patients who had undergone revision lumbar surgery for removal of the TDR prosthetic. Examination of this tissue demonstrated lymphocytes, macrophages, and giant cells, which all had ingested small polyethylene particles. Greater implantation time was associated with greater presence of wear debris and giant cells, accompanied by inflammatory cytokines. Innervation and vascularization were also noted in the tissue, suggestive of the development of neuroinflammatory-induced pain in these TDR patients [7, 48]. They concluded that wear debris from TDR initiated a complex interaction within the periprosthetic tissue of the spine and pointed to the subsequent inflammatory cascade as a potential etiology of postoperative intractable pain even out to 16 years from implantation.

Veruva et al. recently reviewed the literature with regard to biomaterials that can affect wear on performance on TDR [6]. They focused on implant wear and any periprosthetic tissue inflammation as a response to implantation of the prosthetic device. In their review of papers describing devices and tissues after explanation, they found that wear-associated complications may be specific to the biomaterial selection for TDR. For metal-on-polymer prosthetics in the cervical spine, small and large polymeric debris was generated which triggered an innate immune response with nearby tissue activation of macrophages and giant cells. For total hip arthroplasties (THA), polyethylene wear and its subsequent innate inflammatory response have been associated with osteolysis, aseptic loosening, and clinical failure [6, 10, 38]. In the spine, vertebral osteolysis seems to be a rare event [71]. This is even after Punt et al. observed on the order of 1 billion polyethylene particles per gram of explanted periprosthetic tissues from TDR patients [7, 72]. Metal-on-metal prosthetics created small metallic wear debris which triggered an adaptive immune response of activated lymphocytes. This wear process poses the risk of metallosis, pseudotumors, aseptic vasculitis, and metal hypersensitivity [6, 49, 73, 74]. Fretting and corrosion products were seen in some metal-on-metal cervical TDR but their clinical effect was unclear [7, 75].

A tremendous soft tissue reaction has been observed to occur in rare occasions with metal-on-metal implants. Termed a pseudotumor, this adverse reaction can cause significant mass effect on neighboring structures and in the hip arthroplasty literature has been shown to cause pain, nerve palsy, joint dislocation, metal hypersensitivity reactions, and osteolysis [49, 76–78]. One case report on a cervical device implanted investigationally described the formation of pseudotumor at the C4-5 disc space extending ventrally down to the midbody of C6 [73]. On explanation of the implant, a large yellowish necrotic mass was discovered extending down into the ventral spinal canal. Histology demonstrated a large area of necrotic debris with prominent lymphocytic infiltrate. The Medtronic Prestige ST artificial disc is currently the only FDA-approved cervical TDR device that utilizes a metal-on-metal design using stainless steel.

Metal hypersensitivity reactions after metal-on-metal bearing device implantations are presumed to be due to type IV-delayed hypersensitivities based on their immunohistochemical features [56]. The inflammatory response seen is chronic and composed of mononuclear phagocytes, without an acute inflammatory character due to very few neutrophils observed in the tissue. Some reports exist to suggest that hypersensitivity to the metal-on-metal wear debris is the underlying pathophysiology of failed implantation, though evidence is conflicting [57, 79, 80]. Metal degradation wear debris has not been noted so far to have been associated with necrosis or tissue degeneration in the spine [7, 72].

5.3. Osteolysis. Long-term complications such as wear debris-induced osteolysis are well documented in the large joint arthroplasty literature [81–83]. Periprosthetic bone loss following hip arthroplasty placement accounted for over 75% of patients undergoing revision hip surgery in one study and in many other studies accounts for greater than the sum of all other complications [84, 85]. In most series beyond 10 years, the reported prevalence of aseptic osteolysis of hip implants is between 32 and 62% [51, 86–89].

There is also evidence to support this complication in the cervical spine. The available literature at this time of osteolysis in cervical TDR has not been robust enough to draw conclusions for a predicted incidence of this long-term condition beyond just several reported cases, both infectious and aseptic [7, 83]. Hacker et al. reported 4 patients with either the Bryan or Prestige LP discs who experienced periprosthetic bone loss after a minimum of 4 years of follow-up [83]. In one patient who was presumed to have an infection, there was marked loss of vertebral body bone with deformity. Review of the explanted device and tissue was suggestive of a low virulence bacterial infection based on the appearance of macrophages, but no agent was identified and all cultures had resulted negative. Although they did not identify any convincing evidence for osteolysis as a cause for the bone loss in these patients, they acknowledged that its potential must exist based on prior experience with arthroplasty devices. Tumialán and Gluf also reported a case of osteolysis with the ProDisc-C device in a patient who developed progressive neck pain at 9 months of follow-up [71]. Imaging at 9 and 15 months demonstrated a progressive osteolytic process which prompted explanation and conversion to an arthrodesis. Further follow-up after the arthrodesis showed resolution of the osteolytic process and radiographic fusion.

The most widely accepted mechanism of osteolysis involves implant particulate wear debris of any material which then promotes inflammation that causes long-term tissue damage and bone erosion leading to implant loosening [87, 90]. At the cellular level, proosteoclastic inflammatory

mediators stimulate differentiation of osteoclasts which subsequently mediate bone resorption leading to failure of the prosthesis [67].

5.4. Adverse Events. The current literature is fairly sparse with regard to dedicated reports of adverse events after cervical TDR that could be directly attributable to material wear, immune response hypersensitivity, or osteolysis. Hacker et al. reported on two patients who presented with neck pain due to periprosthetic bone loss around their Bryan discs but could not conclude definitively that the bone loss was from osteolysis instead of another etiology [83]. Neither patient required further intervention and one patient clinically improved at 1-year follow-up. Guyer et al. reported on one case of a patient, implanted with a Kineflex-C (Spinal Motion Inc, Mountainview, CA) cervical arthroplasty device, who was subsequently found on CT-myelography to have a soft-tissue mass causing canal stenosis [74]. The implant required a reoperation for implant removal, arthrodesis, and soft tissue mass resection. Analysis of the soft tissue mass suggested a delayed-type hypersensitivity to metal that resulted in the chronic inflammatory pseudotumor. Tumialán and Gluf reported on one patient who was found to have progressive vertebral body osteolysis after implantation of a ProDisc-C that resulted in persistent radicular and axial neck pain and required reoperation with removal of the implant and arthrodesis at that level [71]. The patient's pain improved postoperatively and the authors concluded that the osteolysis was likely due to an immune-mediated metal hypersensitivity response which resolved upon removal of the implant. Zigler et al., however, reported on the 5-year results of 103 patients treated with the ProDisc-C and found no adverse events related to polyethylene wear, osteolysis, or material failure [91]. Likewise, Sasso et al. reported on the 4-year results of 242 patients treated with the Bryan disc and similarly found that no arthroplasty device required removal for wear or wear-related failure [92]. The existing literature would suggest that adverse events related to material wear are suitably rare, although further research and follow-up are needed to better delineate the risks of these occurrences.

5.5. Clinical Evaluation. Maintaining a high level of clinical suspicion for the adverse biological effects of material wear is important for diagnosis and treatment. The proinflammatory cascade that results from significant wear debris may result in a type of neuroinflammatory-induced pain at the site of the prosthesis that may be severe enough to necessitate removal of the implant. This inflammatory process may also cause pseudotumor formation that, if large enough, can lead to the clinical spectrum and manifestations of cervical radiculopathy or myelopathy. Both pseudotumor and osteolysis can cause implant loosening and hardware failure, which will possibly lead to segmental instability and axial mechanical pain. Persistent postoperative neck or arm pain should prompt further evaluation with dynamic radiographs, CT, or MRI to allow for further workup of these material-related complications. Knowledge of these potential clinical findings in routine follow-up will assist the surgeon in capturing these complications early for further management and surgical treatment as needed.

6. Conclusion

Cervical TDR is a motion-sparing operation that provides a surgical alternative to fusion for selecting patients with cervical radiculopathy or myelopathy. Knowledge and understanding of the variety of biomaterials available will ensure the continued development of safe and effective prosthetics with increased longevity and decreased biological effects over a lifetime. An appreciation of material wear characteristics will help the surgeon maintain a high clinical suspicion of postoperative clinical manifestations of material-related biological effects.

Conflict of Interests

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

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