

## Clinical Study

# Early Clinical Outcomes Associated with a Novel Osteochondral Allograft Transplantation System in the Knee

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**Background.** Osteochondral defects of the knee are a common finding at the time of arthroscopic intervention. *Purpose/Hypothesis.* To report our outcomes after utilizing a new technique of osteochondral allograft transplantation for focal cartilage defects. *Study Design.* Case series. *Methods.* All patients treated with osteochondral allograft transplantation with a Zimmer Chondrofix plug (Zimmer Inc., Warsaw, IN) for focal cartilage defects over a 12-month period were followed up at a minimum of 24 months. Failures were documented and radiographs were evaluated. *Results.* 61 knees (58 patients) underwent grafting. Three cases were lost to follow-up. In the remaining 58 cases the average age was 40 (range 18–59). At a mean follow-up of 28 months (range 24–36), there were 5 failures requiring further surgery. Mean KOOS scores in the Pain, Symptoms, ADL, Sports, and Quality of Life dimensions were 82, 79, 84, 66, and 58, respectively. Radiographs demonstrated maintenance of the subchondral bone without graft absorption or subsidence. *Conclusions.* Our observations suggest that osteochondral allograft transplantation leads to a satisfactory activity level and function at early follow-up while avoiding the inherent complexities associated with other cartilage restoration techniques. Longer follow-up is warranted to monitor the subchondral bone, articular surface, and patient outcome measures.

## 1. Introduction

Each year it is estimated that chondral defects of the knee affect more than 900,000 people in the United States and result in more than 200,000 procedures [1]. In 34% of all knee arthroscopies, one or more focal full-thickness or nearly full-thickness cartilage defects are seen [2–4]. It is also estimated that 36% of all athletes have a cartilage defect in the knee [5]. Human articular cartilage has limited ability to self-repair, so damage to the articular cartilage in the knee is a potential risk factor in the development of early-onset osteoarthritis and can result in loss of movement and pain [6–8].

Full-thickness articular cartilage defects, defined as Outerbridge grades III–IV [9], are likely to progress to early

degenerative wear and become increasingly symptomatic [10]; thus surgical treatment is recommended [11]. A variety of surgical options exist for the treatment of full-thickness chondral defects in the knee such as debridement, microfracture, osteochondral autograft transfer (OAT), osteochondral allograft transplantation (OCA), and autologous chondrocyte implantation (ACI). Each of these techniques presents its own unique set of limitations.

Microfracture is the most common method employed for cartilage restoration in the knee [12]. It relies on marrow stimulation and the influx of marrow products into the cartilage defect. The mature fibrocartilage formed is less durable than native type II collagen, resulting in some degradation over time [13]. Some surgical algorithms use approximately 2 cm<sup>2</sup>

as the upper threshold for microfracture and beyond this move onto more advanced cartilage restoration techniques [14–16].

OATS and mosaicplasty are techniques involving the transport of osteochondral plugs from another area of the knee to the defect. Disadvantages associated with these techniques include leaving an articular cartilage defect in another location of the knee, progression of osteoarthritic changes at the donor site, the relative size limitation of  $<20\text{ mm}^2$  [17], and the fact that an arthrotomy may be required. As larger areas of OATs are required, more donor site complaints and symptoms occur [18].

OCA eliminates the donor site complications and size limitations of OATS by obtaining the donor tissue from a cadaver. It allows treatment of both cartilage and underlying bony defects to a greater degree than ACI. This technique has shown promising results at long-term follow-up [19]. Limitations to OCA involve the need for donor tissue and the timing of transplantation, which is best achieved between 14 and 28 days to allow testing of the tissue, without the significant loss of cell viability that occurs over time [20].

As first proposed in 1994 ACI allows the treatment of large cartilage defects in the knee. Unfortunately, it is expensive, costing approximately 66,000 dollars per case [21]. The technique requires a 2-stage procedure (harvesting and implantation) and is less successful with bone loss at the base of the lesion [22].

In an effort to avoid the individual complications and limitations associated with each of these techniques, we have been using a relatively new technique of osteochondral allograft transplantation, Chondrofix® Osteochondral Allograft (Zimmer Inc., Warsaw, IN). These allografts consist of decellularized hyaline cartilage and cancellous bone that maintain the mechanical properties of unprocessed osteochondral grafts.

Similar to OCA, Chondrofix transplantation is single-stage and guarantees an immediate reliable tissue transfer of an osteochondral unit; however the grafts are readily available on the shelf, thus eliminating the narrow timing aspects to OCA. The aim of this study was to evaluate the results of this technique retrospectively in a selected group of patients with the goal of analyzing patient outcomes and understanding which factors could influence the clinical outcome in order to clarify the correct indication of this treatment option.

## 2. Methods

This study was approved by our Health System Institutional Review Board. All patients between the ages of 18 and 60 who had received a Chondrofix plug in the twelve-month period between February 2012 and February 2013 were retrospectively included in the study.

The procedures were performed by one of two fellowship-trained, board-certified orthopaedic surgeons. Inclusion criteria included a symptomatic full-thickness cartilage lesion identified preoperatively by advanced imaging or prior arthroscopy, though the size of the lesion was consistently underestimated. Patients with inflammatory arthritis

TABLE 1: Primary diagnosis.

DJD	27
PF DJD	15
ACL tear	5
OCD lesion	4
PF instability	3

DJD: degenerative joint disease; PF: patellofemoral; ACL: anterior cruciate ligament; OCD: osteochondritis dissecans.

or significant uni- or tricompartmental arthritis were not considered candidates for transplantation.

A tourniquet was used, and the knee was examined arthroscopically. Once the final decision to perform osteochondral allograft transplantation was taken, the lesion was sized, prepared, and grafted with instrumentation provided in the Chondrofix set. One or more plugs were placed depending on the size and shape of the lesion. The instrumentation was introduced through an appropriately sized accessory portal, and the procedure was visualized arthroscopically. An arthrotomy was employed only in the case of a patellar lesion, allowing the patella to be everted for perpendicular preparation and grafting of the defect.

Postoperatively all patients were allowed to weight-bear as tolerated and encouraged to progress to full range of motion. A brace was only used if required due to an associated procedure (e.g., cruciate ligament reconstruction). Patients were instructed to avoid high impact activities for 6 weeks. Follow-up visits occurred at 3 weeks, 6 weeks, 3 months, 6 months, and yearly thereafter. Radiographs of the knee were obtained (weight bearing anteroposterior, lateral, and skyline) at the 3-week, six-month, and yearly follow-ups.

Clinical evaluation included range of motion (ROM), presence of an effusion, and radiographic changes. They completed the Tegner score [23], and the Knee Injury and Osteoarthritis Outcome Score (KOOS) patient-derived outcome tool [24]. Patients who were unable to be evaluated in person completed the scores over the telephone.

## 3. Results

61 cases in 58 patients were eligible for inclusion. The average age was 40.0 (range 18–59) and 59% of cases were in male patients. The primary diagnoses (Table 1) were degenerative joint disease (DJD) in 27 cases, patellofemoral (PF) DJD in 15 cases, anterior cruciate ligament (ACL) tear and resultant instability in 5 cases, osteochondritis dissecans (OCD) lesion in 4 cases (Figures 1(a) and 1(b)), and PF instability and DJD in 3 cases.

Procedures performed concomitantly (Table 2) include arthroscopic partial meniscectomy in 18 cases, ACL reconstruction in 5 cases, open proximal realignment and lateral release in 4 cases, arthroscopic lateral release in 4 cases, microfracture in 2 cases, and lateral meniscus repair, patellofemoral arthroplasty in 1 case each. Four knees had undergone prior ACL reconstruction, 1 knee had prior arthroscopic lateral release, and 1 knee had previous open osteochondral allografting.

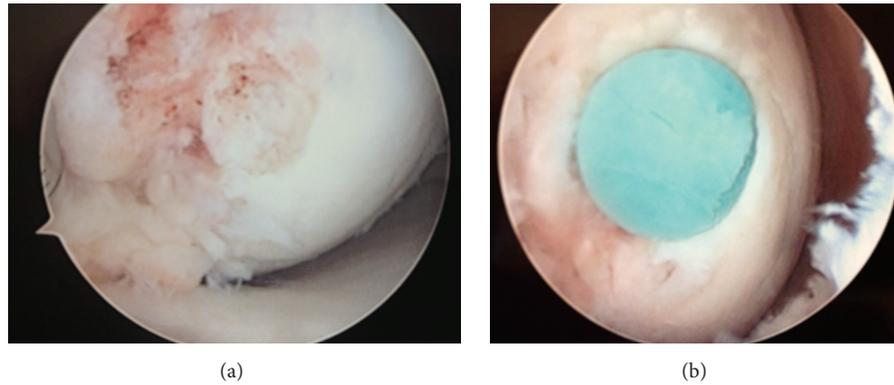


FIGURE 1: Failed OATS for a MFC OCD lesion revised to a Chondrofix plug.

TABLE 2: Other procedures.

Concomitant procedures	
Partial meniscectomy	18
ACLR	5
PRLR	4
Arthroscopic lateral release	4
Microfracture	2
Lateral meniscus repair	1
PFA	1
Prior procedures	
ACL	4
Arthroscopic lateral release	1
Open osteochondral allograft	1

ACLR: anterior cruciate ligament reconstruction; PRLR: proximal realignment and lateral release; PFA: patellofemoral arthroplasty.

Graft placement was in the medial femoral condyle (MFC) in 19 cases, the trochlea in 15 cases, the patella in 9 cases, the lateral femoral condyle in 4 cases, and multiple locations in 18 cases. Thirty-one of the cases utilized only one Chondrofix graft; 2 were used in 23 cases, 3 in 3 cases, and 4 in 4 cases. The sizes of the plugs used in the 31 cases with one plug are also listed, providing a reasonable estimate to the size of the lesions treated (Table 3).

Follow-up was achieved in 95% of cases (58 of 61). Mean follow-up was 28 months (range 24–36 months). Average Tegner activity level was 4 (range 1–7). The mean KOOS Pain, Symptom, Activities of Daily Living (ADL), Sports, and Quality of Life (QoL) domains were 82, 79, 84, 66, and 58, respectively (Table 4). Average ROM was 0 to 129 degrees. No patients were noted to have a persistent postoperative effusion. Radiographs demonstrated maintenance of the subchondral bone without any obvious graft absorption or subsidence.

Five clinical failures were noted to have gone on to subsequent surgery during the follow-up period. Three patients with DJD required conversion to arthroplasty, 1 required conversion to a total knee arthroplasty (TKA), 1 required

TABLE 3: Location, number, and size of graft plugs.

Location of lesions	
MFC	19
Multiple	18
Trochlea	15
Patella	9
LFC	4
Number of plugs	
1	31
2	23
3	3
4	4
Size of individual plugs (mm)	
7	2
9	11
11	11
15	7

MFC: medial femoral condyle; LFC: lateral femoral condyle.

TABLE 4: KOOS scores.

Domain	Mean	SD
Pain	82	±22
Symptoms	79	±18
ADLs	84	±21
Sports	66	±33
QoL	58	±29

conversion to a unicompartmental knee arthroplasty (UKA) (Figures 2(a) and 2(b)), and one patient who had a PFA at the same time as her grafting required conversion to a TKA. One 34-year-old patient with patellofemoral disease saw another surgeon and had a revision cartilage procedure, and another had a revision of one of two trochlear plugs. There were no infections. Three cases were lost to follow-up.

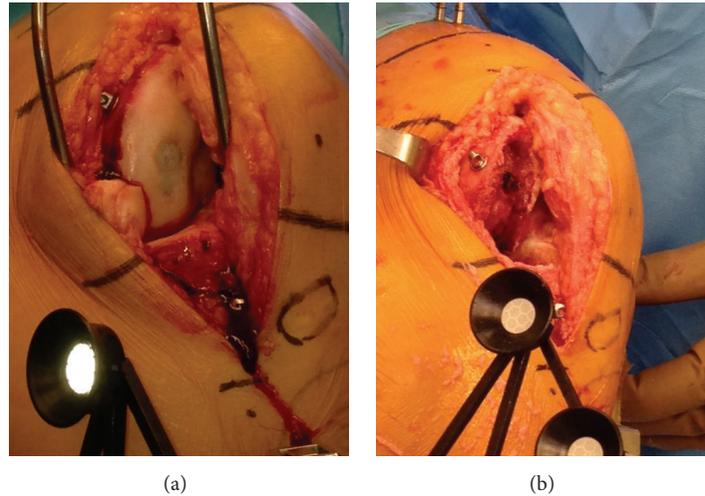


FIGURE 2: (a) Intact Chondrofix plugs in the MFC at the time of UKA. (b) Stable underlying bony integration of the bony portion of the plug for femoral component seating.

#### 4. Discussion

A number of arthroscopic repair or reconstructive techniques can be performed in the setting of full-thickness cartilage defects in the knee. Various materials, such as allografts, autografts, synthetic polymers, and periosteal and perichondral flaps, have been proposed, but the 4 techniques that have gained widespread use and interest during the last decade in North America are microfracture, OCA, OATS, and ACI procedures.

Currently, the important step of determining the area of the defect is accomplished either by attempting to interpret radiographic images prior to surgery or by using mechanical instrumentation during an arthroscopic diagnostic examination. Unfortunately, the sensitivity of conventional magnetic resonance imaging (MRI) is still limited. Improved diagnostic performance has been seen with 3-Tesla (T) MRIs compared with 1.5 T protocols [25, 26]. In a study comparing 3 T MRI to arthroscopy, the ability of MRI to predict articular cartilage lesions was examined. When using the Outerbridge classification the values for sensitivity, specificity, and accuracy were 57%, 71%, and 63%, respectively [27]. It is particularly difficult to determine the depth of the lesion [28]. Therefore, surgeons cannot rely on preoperative imaging to accurately determine treatment choice, leaving much of the decision-making process to the arthroscopic evaluation of the defect grade and size.

Thus both the complexity of existing techniques and the difficulty in predicting the size of the lesion lead us to consider this novel Chondrofix option. We were fairly familiar with this technique, having used it with Tru-Fit plugs for the preceding five years [29]. With the Chondrofix system, multiple graft sizes (7–15 mm) are available for off-the-shelf use. Single-stage implantation using an arthroscopic approach with a small incision for graft insertion can be used for all lesions with the exception of the patella, where a miniarthrotomy is required for access.



FIGURE 3: MRI evaluation of a Chondrofix plug at 3 months after implantation.



FIGURE 4: MRI evaluation of a plug at 8 months after implantation with further bony incorporation.

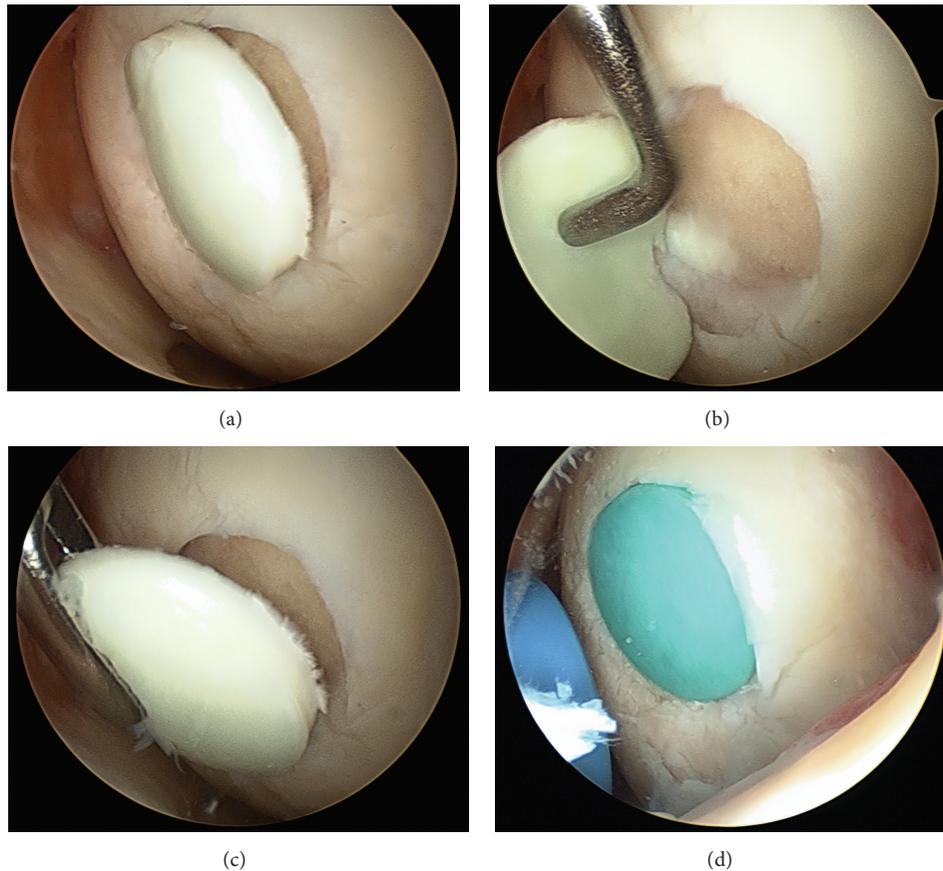


FIGURE 5: Cartilage surface delamination of a plug overlying a stable bony base with successful revision to a similarly sized plug.

Our primary concerns with this new graft option were with respect to its incorporation and durability as the grafts are acellular and treated in a novel fashion, prior to implantation. Our radiographic review did not demonstrate any significant changes. A more sensitive MRI evaluation was available for two cases that had follow-up imaging for new injuries to the knee. The first (Figure 3) was performed at 3 months and the second (Figure 4) at 8 months. They both demonstrate incorporation of the bony portion of the graft, with some changes to the overlying cartilage surface, which will have to be followed up carefully over the longer-term.

Outside the cohort in this paper, we have seen one novel failure mechanism. In this case the cartilage surface delaminated from the underlying bone on the plug. It occurred in a labourer during a squat at lift of a 100 lb piece of equipment. Arthroscopic evaluation demonstrated a well-incorporated bone base separated from the overlying cartilage (Figures 5(a)–5(d)). A successful revision to a new plug was performed, and the patient has done well to a year following revision.

The failures in this series were evaluated. Four of the five failures had two plugs in a single compartment. The plugs used were all at least 9 mm, consistent with larger defects. Thus the failure rate was 1/31 for single-plug cases and 4/23 for two-plug cases. Interestingly, none of the even larger 3- and 4-plug cases failed. Location of the lesion did not predict

failure, with 3 failures in MFC lesions and 2 in trochlear lesions.

## 5. Conclusions

While it is generally accepted that focal chondral lesions often progress towards osteoarthritis, a review of the literature presents compelling evidence that between 10 and 40% of all patients aged <40 years undergoing arthroscopic surgery for other reasons have treatable chondral injuries that will remain unaddressed [2–4]. The current study demonstrates a simple, arthroscopic, off-the-shelf solution that appears to provide reasonable clinical outcomes at short-term follow-up.

There are a number of obvious limitations to this study: it is a short-term retrospective follow-up; preoperative scores were not obtained; there were a number of different diagnoses and concomitant procedures performed; and there was no comparative group. In the future, we are planning more comprehensive and rigorous prospective comparative studies involving both preoperative and postoperative evaluations with advanced imaging, to better compare outcomes with these cartilage lesions. Based on this study, Chondrofix plugs appear to be a reasonable on-demand option for addressing full-thickness cartilage lesions encountered at the time of arthroscopy, with acceptable short-term patient satisfaction and function.

## Competing Interests

The authors declare that they have no competing interests.

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