The Effectiveness of Autologous Chondrocyte Implantation for Treatment of Full-Thickness Articular Cartilage Lesions in Workers’ Compensation Patients

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Abstract

This prospective longitudinal analysis evaluated the effectiveness of autologous chondrocyte implantation in 24 workers’ compensation patients with articular cartilage injuries >2 cm². Mean lesion size was 4.7 cm² (range: 2-10 cm²). Nineteen lesions were on the distal femur and 5 were on the patella. Clinical assessment scores improved from a mean of 3.2 at baseline to 6.8 one year postoperatively, with 78% rated good or excellent. Among patients with >1-year follow-up, 63% returned to unrestricted work status at a mean of 7 months; an additional 22% returned to modified work.

Articular cartilage injuries remain a medical challenge, which is magnified as the lesions become larger. These lesions have a low capacity for healing, and larger lesions are at higher risk for breaking down and progressing.

Treatment options for patients with large chondral injuries are limited. Traditional methods involve drilling or microfracture and are based on stimulation of marrow stem cells to create a repair tissue in the defect. The repair tissue formed by these stem cells is fibrocartilage. Bone marrow stimulation techniques are effective in smaller lesions that are well-shouldered and protected. However, as the diameter of the lesion increases, the fibrocartilage repair tissue is subjected to higher radial forces and shear stresses. This repair tissue is mechanically inadequate to withstand physiologic loads, resulting in premature failure and subsequent intervention.

Another treatment option is osteochondral plugs. This technique involves harvesting one or more osteochondral plugs from an uninvolved, nonweight-bearing area of the affected knee. Its usefulness is limited by defect size. Experts in using this technique, Bobic et al. recommend osteochondral plugs for smaller (<2 cm²) lesions only. Treating larger lesions with osteochondral plugs has been shown by Hangody to be more technically challenging and have higher rates of adverse events.

It has been speculated that the durability of a cartilage repair may be directly related to the degree to which it mimics normal hyaline cartilage. Brittberg et al. demonstrated that autologous chondrocyte implantation produces a hyaline-like repair tissue. To be successful, a repair should produce tissue that is capable of withstanding the mechanical stresses of activities of daily living, as well as the added stress of heavy manual labor. To gain general acceptance, the procedure must be reproducible as well.

Autologous chondrocyte implantation is entering its second decade. Although still controversial to some, the data collected on autologous chondrocyte implantation represent a consistent and reproducible outcome in lesions >2 cm², a finding not demonstrated with other treatment options.

The long-term Swedish experience demonstrates an overall success rate of 85% in patients with femoral lesions. This correlates with the results of a 4-year US multicenter experience, which demonstrated improvement in 85% of patients with lesions of the medial or lateral condyles or trochlea.

This study determined the outcome of autologous chondrocyte implantation in workers’ compensation patients. Of the patients involved in this multicenter series, 40% were workers’ compensation patients. A major treatment goal is return to work, and economic and psychosocial factors common in these patients makes this goal difficult to achieve.
Several studies have shown that results of surgical procedures vary between workers' compensation and nonworkers' compensation patients. Noyes and Barber-Westin\textsuperscript{10} demonstrated that workers' compensation patients remained out of work significantly longer following arthroscopic anterior cruciate ligament (ACL) reconstructions than nonworkers' compensation patients. Fulkerson\textsuperscript{11} reported only 40% of workers' compensation patients returned to work following an anterior medialization procedure.

Results of surgery in workers' compensation patients have been reported in the literature. Misamore et al\textsuperscript{12} reported worse outcomes in rotator cuff repairs in workers' compensation patients, and Bray et al\textsuperscript{13} reported lower postoperative scores following arthroscopic lateral releases in this population.

Atlas et al\textsuperscript{14} reported 200 workers' compensation patients with significantly inferior results with surgical treatment regarding back and leg pain relief, function, and satisfaction with overall health compared to nonworkers' compensation patients. Weber\textsuperscript{15} and Bosacco et al\textsuperscript{16} reported the return to work rate in the workers' compensation population to be <35% in patients with a minimum of 2-year follow-up after lumbar disk surgery.

Conversely, a report from Johns Hopkins on total hip arthroplasty in workers' compensation patients indicated that workers' compensation did not negatively influence the clinical outcome.\textsuperscript{17}

This study is a prospective longitudinal analysis of 24 workers' compensation patients with large full-thickness chondral lesions who were treated with autologous chondrocyte implantation between 1995 and 1999. This series assessed the effectiveness of autologous chondrocyte implantation in patients returning to work. End points measured were return to partial or complete work status. The emphasis of this analysis focuses on those patients with a minimum of 1-year follow-up who have returned to complete work status.

**MATERIALS AND METHODS**

**Patient Population**

Twenty-four patients (19 men and 5 women) with workers' compensation insurance were studied. Average patient age was 38 years (range: 25-52 years). Of the 24 patients, 18 were involved in physically demanding jobs such as construction, heavy equipment operation, or firefighting. The 6 remaining patients were employed in less physically demanding jobs. The average size lesion was 4.74 cm\textsuperscript{2} (range: 2-10 cm\textsuperscript{2}). Nineteen lesions were in the weight-bearing portion of the medial femoral condyle and 5 were centrally located patella lesions.

In addition to the isolated lesions, one patient underwent concomitant ACL reconstruction at implantation. One patient had multiple lesions, one on the medial femoral condyle and one on the patella. Patients had variable symptoms, but pain was the predominant complaint.

The duration of symptoms prior to autologous chondrocyte implantation varied. Eleven patients had pain for >2 years, 4 patients had pain between 1 and 2 years, and 8 patients experienced pain for <1 year. Fifteen patients had 38 previous surgical procedures, an average of 2.7 procedures per patient. Average time lost from work as estimated from patient charts was approximately 12 months. Most patients experienced decreased levels of activities of daily living secondary to knee pain.

**Clinical Assessment**

Patients were reviewed at 6 and 12 months and annually thereafter. At follow-up, the patient and physician reported results using the Modified Cincinnati Knee Rating Scale.\textsuperscript{18} Each patient also was assigned a clinical assessment grade (poor, fair, good, or excellent) based on the overall clinical result as judged by the physician and based on the Modified Cincinnati Knee Rating Scale. Because this scale is based on return to specific level of sports activity, an inherent weakness exists in its use. However, its emphasis on physical capability seems appropriate in the context of this study.

This scale has two components. The first is an overall subjective assessment of the patient's activity level. A score of 6 indicates return to sports with some limitations, 8 indicates return to sports with only minor limitations, 9 indicates minor symptoms following sports, and 10 indicates complete return to sports with no symptoms. A score of 9 or 10 is considered excellent, 6-8 good, 4-5 fair, and 0-3 poor.

The second component of this scale is a clinical assessment of the patient's knee, which measures range of motion, presence of effusion, alignment, and points of tenderness.

For the purpose of this study, "out of work" is defined as patients receiving workers' compensation benefits due to a work-related physical injury and released by a physician. "Partial work" is defined as returning to work but with accompanying medical orders that restrict certain activities. "Complete work" is defined as having no activity restrictions specified by medical orders. Defining "work" is important in interpreting the results of the study. Most patients were manual laborers, placing significant demands on the repair grafts.

**RESULTS**

**Clinical Outcomes**

A clinical assessment grade was given based on physical evaluation. At baseline, 92% of patients were rated fair to poor according to the Modified Cincinnati Knee Rating Scale. The baseline scores for the 24 patients showed an average value of 3.6 for the clinician and 3 for the patient. The clinical assessment scores at baseline rated 2 patients as good, 16 as fair, and 6 as poor.

At baseline, 24 patients receiving workers' compensation benefits had full-thickness cartilage lesions treated with autologous chondrocyte implantation. Of these 24 patients, 18 had a minimum of 12-month follow-up. Three patients had <3-month follow-up, and were considered too early to assess. Two patients failed treatment within the
first 6 months due to graft delamination. One patient was killed in a motor vehicle accident 3 months postoperatively. The inclusion of the treatment failures, as well as the deceased patient, provides an intent to treat analysis.

At 1 year, for the 18 remaining patients, the clinician-reported Modified Cincinnati Knee Rating Scale score average was 6.8, an increase of 3.2 over baseline. Patient-reported scores averaged 6.2, also representing an increase of 3.2 over baseline (Figure 1). Clinical assessment scores for the first year showed that 78% of patients received a rating of excellent to good (Figure 2). Five patients were rated excellent, 9 were good, 3 were fair, and 3 were poor. Both measurement tools demonstrated substantial improvement after the first year.

Fifteen patients underwent 2-year follow-up. The Modified Cincinnati Knee Rating Scale clinician scores remained constant at 6.8; however, the patient scores dropped to 5.6. Clinical assessment scores demonstrated that 80% were rated as having an excellent to good result. Five patients were rated excellent, seven were rated good, one was rated fair, and two were rated poor. This represents a significant difference between clinician-reported scores and patient self-assessment. One patient considered a clinical failure at this point due to continuous symptoms.

At 3-year follow-up, 11 patients were assessed. The clinician scores increased to 7.3 and the patient scores increased to 6.7. Clinical assessment scores rated 3 patients as excellent, 5 as good, and 3 as fair.

At 4-year follow-up, 10 patients were assessed. Modified Cincinnati Knee Rating Scale scores for the clinician and patient continued to improve. Clinician scores were 7.8 and patient scores were 7.2. All 10 patients were involved in high physical demand jobs. Clinical assessment scores showed 6 excellent ratings, 2 good, and 2 fair.

The Table illustrates the time frame when patients were able to return to various levels of work. At 1-year postoperatively, 18 (75%) of 24 patients had returned to partial work with limitations on physical activity, as specified by medical orders. Of these 24 patients, 3 patients had <1-year follow-up. Excluding these 3 patients, 85% of the remaining patients returned to partial work status.

The effect of lesion location on return to work was studied. Medial femoral condyle lesions were present in 16 patients with at least 1-year follow-up. Fifteen (94%) of 16 patients returned to partial work. In patients with patella lesions, 3 (60%) of 5 patients returned to partial work status.

Time to return to partial work for all patients was approximately 5 months after implantation. In patients with medial femoral condyle lesions average return time was 4.1 months, and in patients with patella lesions average return time was 5.3 months.

Of the total 24 patients studied, 13 (54%) returned to full work with no restrictions at 1-year follow-up. In patients with >1-year follow-up, 13 (62%) of 21 patients returned to unrestricted work status. Seven (33%) of 21 patients returned to work with no

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**TABLE**

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<th>Complete (mos)</th>
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**Abbreviation:** UPS = United Parcel Service.
symptoms and no restrictions. Six (29%) patients reported mild symptoms after strenuous work, but none significant enough to discontinue work.

Return to work rates were analyzed by lesion location. Eleven (69%) of 16 patients with medial femoral condyle lesions and >1-year follow-up returned to complete work status. In patients with patella lesions, 63% returned to complete work status at 4 years. The average time to return to complete work status for patients with medial femoral condyle lesions was 7 months and 6.5 months for patient with patella lesions.

In this series, 10 patients had >4-year follow-up; 100% are working without limitations. Seven (70%) of 10 are asymptomatic, and 3 (30%) of 10 report mild symptoms following heavy exertion. The patient satisfaction level was >90%.

**Acute Versus Chronic Injuries**

Patients with acute lesions (<12 months postinjury) and patients with chronic lesions (>12 months postinjury) were compared (Figure 3). In the 8 patients with <1 year from initial injury to implantation, 75% returned to partial work and 63% achieved complete work status. In the subgroup, where the initial injury occurred between 1 and 2 years before implantation, only 50% returned to partial and 25% to complete work. Patients with >2 years from injury to surgery had the highest return to work rates; 73% returned to partial work and 65% to complete work status.

This group also had the highest level of overall patient satisfaction. Thus, no relationship appears to exist between length of preoperative symptoms and return to work rates.

**Adverse Events**

No serious or deep infections occurred. Complications that delayed patients’ ability to return to work occurred. Eight (33%) patients had severe quad atrophy following surgery that delayed their rehabilitation progress. Four (17%) patients had flexibility restrictions that required manipulation.

Three patients required reoperation for lysis of adhesions. Two patients had patellar lesions and one had a medial femoral condyle lesion. All three patients failed treatment. Two patella lesions failed within the first year. In one case, the graft delaminated and the other showed incomplete defect fill. In the medial femoral condyle defect that failed, repair tissue had filled the defect with good integration in host cartilage at 2 years; however, the patient reported significant symptoms and was considered a failure for that reason.

Three (13%) patients suffered traumatic falls following implantation. In each case, the patient returned to partial work status but was delayed from returning full time. Two of three patients still experience minor symptoms after working but have good range of motion and no effusion.

**CASE REPORTS**

**Case 1**

A 26-year-old fireman was injured and underwent an abrasion procedure 1 year later for a 2 cm² medial femoral condyle chondral lesion. Due to persistent symptoms and a reduction in physical capability, he was placed on workers’ compensation approximately 1 year postoperatively.

The patient underwent arthroscopy with a cartilage biopsy, and subsequent autologous chondrocyte implantation. Two months postoperatively, he returned to light duty, and by 5 months postoperatively he returned to work full-time. Four years postimplantation, the patient is symptom-free.

**Case 2**

A 25-year-old construction worker slipped on a metal rod and injured his right knee. One year after injury, ACL reconstruction and debridement were performed for a medial femoral condyle chondral lesion.

Due to continuous pain and absence from work, he was rescoped 1 year postoperatively and had a cartilage biopsy harvested. Autologous chondrocyte implantation was performed.

Six months postoperatively, the patient returned to light duty. At 9 months postoperatively, he returned to full duty with the exception of shoveling. At 14 months he was working with no limitations, full range of motion, and without swelling or slight pain after heavy work.

Two years later, he twisted his knee. Magnetic resonance imaging was negative, and a second-look scope showed an intact, well incorporated autologous chondrocyte implantation graft. A small cleft was noted between the anterior portion of the repair graft and the host cartilage, but was not clinically significant. The repair tissue was judged comparable to the host cartilage with respect to stiffness. Four months after presentation, the patient was still experiencing discomfort after heavy work but no limitations.

**DISCUSSION**

Several factors made treatment of these patients challenging. First, all patients had large lesions, measuring >2 cm². Second, the 18 chronic lesions had failed an average of 2 prior procedures. Third, all 24 patients were receiving workers’ compensation.

Clinically, this group matched the outcomes that were reported in a general population in a large, United States multicenter study. In the first year, a significant increase was noted on patient assessment, increasing overall scores from a baseline of 3.2 to 6.2. An increase of 2 increments on the
Modified Cincinnati Knee Rating Scale represents a significant improvement in functional activities.

In the second year, patient assessment declined. This could be a reflection of the maturation process of the repair tissue, as described by Minas and Peterson. These patients returned to physically demanding jobs at an average of 7 months postoperatively. It is possible the tissue was not mature enough to distribute mechanical loads off the repair tissue. Even with this decline at 2 years, these patients were able to continue working. In years 3 and 4, the physician and patient scores improved. These increases may reflect the maturation process of the repair tissue.

The Swedish originators of the autologous chondrocyte implantation technique have reported improvement 2-3 years following implantation. In the present series, improvements were noted to continue through the fourth year. Because of this maturation process, only those patients with a minimum of 1-year follow-up were included in this review.

Clinical scores correlated well with patients' ability to return to work. Overall, 63% returned to unrestricted physical activities. Return to work rates varied by anatomic lesion location. Patients with medial femoral condyle defects did well, with 68% returning to complete work status. Patients with patella lesions did not fare as well. Of the two patients who failed, one had graft delamination and went on to a patellectomy, and the other had an incomplete defect fill and went on to permanent disability. Of the patella patients, 60% (3 of 5) returned to complete work status.

Review of the five patella patients revealed that all had large, centralized lesions with no adjunctive procedures performed. Current knowledge suggests that such lesions may be best treated with autologous chondrocyte implantation and mechanical decompression. Maltracking must be corrected as well.

In the initial Swedish study, only 2 of 7 patients with large central patellar lesions did well; however, of the subsequent 19 patients with patella lesions, 70% improved. All underwent procedures to decompress the patella femoral joint, correct any maltracking, or both. Early motion is critical to the success of autologous chondrocyte implantation. Three of four treatment failures developed adhesions that required a second operative procedure. Peterson et al. stated that lack of motion might negatively impact the durability of the repair tissue.

This series demonstrates that autologous chondrocyte implantation produces a repair tissue that allows patients with large lesions to return to strenuous occupations. The repair tissue is durable enough to sustain heavy loads over 4 years. It is significant that 70% of patients returned to physically demanding occupations that place significant force on the repair tissue.

Return to work is considered an important indicator of success in the treatment of workers' compensation patients, particularly by third-party payers. The results of autologous chondrocyte implantation compare favorably with those of commonly performed orthopedic procedures in this population. The current series has shown a higher return to work rate than lumbar discectomy. It has been shown that <50% of patients return to full work capacity following lumbar discectomy and fusion.

For an internal comparison, records were reviewed to find workers' compensation patients with comparably sized lesions, as well as similar history and occupations. Five patients treated with a bone marrow stimulating procedure (e.g., abrasion, drilling, microfracture) prior to 1995 were found. Two (40%) of 5 patients returned to complete work status; however, this is not statistically significant.

For an external comparison, the results of this series were compared to those of the Swedish experience with patients on sick leave. The Swedish experience (57 patients implanted between November 1987 and February 1996) demonstrated that 77%, as monitored by the Swedish government, returned to work and no longer receive financial support from the Swedish welfare system. This compared to 85% of patients in this study who were able to return to partial work status or 63% to complete work status.

The failure rate in this series was 12%. Two were defined as treatment failures based on second-look arthroscopy, which showed graft delamination or incomplete defect fill. One patient was considered a clinical failure based on ongoing symptoms.

Determining failure of a surgical procedure solely on subjective complaints in the workers' compensation population can be difficult. One patient with a medial femoral condyle defect was deemed a clinical failure at 20 months postimplantation due to persistent symptoms. This failed patient was seen 4 years after implantation and 1 year after settlement of the workers' compensation case. Clinical evaluation found no effusion, full range of motion, and no limp.

To determine what, if any, effect settlement date might have on a patient's reported outcomes, an attempt was made to correlate patient reported results with workers' compensation settlement dates. Thirteen patients returned to complete work status prior to receiving their financial settlements. Conversely, only two patients failing to return to work did not receive their financial settlement. In this series, it does not appear that financial settlements had a significant bearing on outcome. These patients were motivated and desired return to work. In treating workers' compensation patients with autologous chondrocyte implantation, patient selection is a critical factor in assuring the success of this treatment.

In retrospect, the two patients with patella lesions who failed may have developed degenerative disease. Autologous chondrocyte implantation is not indicated for treatment of established degenerative arthritis. Also, preopera-
tive psychological evaluation may be a valuable planning tool in selecting appropriate candidates for autologous chondrocyte implantation.

Lastly, patient follow-up is essential. The majority of patients in this series were prudent with their activity levels and followed the rehabilitation protocol. Communication was good and patient follow-up was >90%. The ability to gather long-term outcome measurement data is helpful to the individual surgeon as well as the worldwide autologous chondrocyte implantation database.

Economic considerations also are important in treating workers' compensation patients. The current cost for culturing the chondrocytes is $11,500. In 1998, Minas and Peterson published the cost-effectiveness of autologous chondrocyte implantation using the quality-adjusted life year as its measuring factor. The quality-adjusted life year is an accepted method to assess changes in overall quality of life, and can be used to compare outcomes across medical conditions and treatments. The study found the estimated cost per quality-adjusted life year of autologous chondrocyte implantation to be $6791. Minas emphasized that autologous chondrocyte implantation was more cost effective than lumbar disectomy for the treatment of herniated intervertebral disks, which had a cost per quality-adjusted life year of $33,900. Autologous chondrocyte implantation and total knee arthroplasty were similar in cost at $11,560.

Richardson reported similar findings in a health economic study that was conducted by the Swedish government, which examined the cost benefits of 57 patients treated with autologous chondrocyte implantation between November 1987 and February 1996. The government calculated that 77% of patients returned to work and the savings to the social welfare system were >$800,000. In the current series, 85% of patients were able to return to at least partial work status, exempting them from receiving workers' compensation benefits. Evaluation of the direct and indirect costs, plus indemnity costs associated with a workers' compensation patient indicates that autologous chondrocyte implantation is a cost-effective treatment option.

REFERENCES


EDITORIAL DISCUSSION

ORTHOPEDICS: This article illustrates the potential clinical success of autologous chondrocyte implantation in the treatment of articular cartilage injuries in workers' compensation patients. Are physicians biased against this population of patients based on a preconceived notion that they will not perform as well postoperatively compared to nonworkers' compensation patients?

Yates: Historically, concerns existed regarding possible outcome differences between workers' compensation patients and nonworker's compensation patients. The literature has shown variable results, with some studies demonstrating a clear difference, whereas others were unable to detect any differences. Data regarding outcomes in patients undergoing autologous chondrocyte implantation, although limited, are similar. Data obtained from Genzyme Biosurgery's (Cambridge, Mass.) data-

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base of follow-up indicates that 38% of patients who received workers’ compensation had poorer outcomes overall. Outcomes in patients in the present study, however, did not appear to be affected by workers’ compensation status.

Patient selection is critical in the success of autologous chondrocyte implantation. Patients must understand the procedure and postoperative rehabilitation plan, and have expectations to return to work.

ORTHOPEDICS: Does the financial compensation from third-party payers influence the treatment of this patient population, leading to more aggressive measures rather than conservative treatment?

Yates: In this series, the majority of patients had failed at least one prior procedure, and in most cases, two. Each patient was provided with different treatment options and the decision to perform autologous chondrocyte implantation was made by the patient. During the study period, the same amount of biopsies were harvested in nonworkers’ compensation patients, indicating no procedure bias in workers’ compensation patients.

ORTHOPEDICS: Was “return to work” encouraged in each case?

Yates: Based on the initial condition of these patients and the ultimate outcomes, the results are encouraging. Seventy-five percent of patients were able to return to work, although some had restrictions. Eighteen of 24 patients no longer relied on workers’ compensation and returned to a productive lifestyle, achieving their individual goals.

ORTHOPEDICS: Are these results reproducible in the community setting? Is autologous chondrocyte implantation a procedure that can be performed by all community orthopedists, or is it reserved for surgeons with specialty training?

Yates: To date, >4500 patients have been treated with autologous chondrocyte implantation in the United States. The majority of treating physicians have been community-based surgeons, with an 80% success rate. This procedure requires meticulous technique and attention to detail. Excellent training in the technical aspects of the procedure, as well as follow-up and documentation of outcomes, is available from the company providing the cell culture service. Patient counseling regarding realistic expectations from the surgery is vital, as well as follow-up during the rehabilitation process, which might be more easily accomplished in the community setting.