

# INTRACORP MEDICAL NECESSITY GUIDELINES

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**Subject: Osteochondral Autograft  
Transplant (Mosaicplasty/OATS®)  
Number: 0197**

**Effective Date: 10/15/2005**

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**Osteochondral autograft transplant (i.e., mosaicplasty, OATS®) for the treatment of articular cartilage defects because is considered experimental, investigational or unproven.**

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## **General Background**

Osteochondral autologous transplant involves the placement of viable hyaline cartilage grafts into a cartilage defect. The grafts are harvested from a non-weight-bearing region of the joint during an open or arthroscopic procedure and then transplanted into a cartilage defect to restore the articular surface of the bone. Osteochondral autologous transfers are performed mainly to treat small and medium-size focal chondral and osteochondral defects of the weight-bearing surfaces of the knee joint, but have also been used in the ankle, patella and tibia.

Normal function of the knee joint requires a smooth-gliding, articular cartilage surface, called the hyaline cartilage. Lesions involving the articular or hyaline cartilage interfere with the smooth gliding motion and may lead to severe pain, instability and joint stiffness. Damage to the hyaline cartilage may result either from traumatic injury or from degenerative conditions (e.g., osteochondritis dissecans, osteonecrosis or osteoarthritis). Osteoarthritis or degenerative arthritis is the most common form of arthritis in the United States and is characterized by erosion of the articular cartilage. As the disorder progresses, the matrix becomes more irregular, and in the final stages, only small bits of cartilage remain attached to the subchondral bone.

Damaged articular cartilage can remodel and rebuild itself in limited circumstances. The healing process for cartilage repair can be affected by factors such as the age of the patient, the degree and depth of the damage, associated joint instability, underlying cause, previous meniscectomy, misalignment and genetic factors. Despite most standard surgical treatments, the cartilage remains weakened, and the patient continues with pain and limited joint mobility. In the elderly population, treatment usually consists of a total knee arthroplasty. Because of problems with loosening of the prosthesis due to increased activity, total knee arthroplasty is not indicated for younger patients. Treatment options in this group consist of penetration of subchondral bone to stimulate new tissue growth, periosteal grafting, autologous chondrocyte cell transplantation, and osteochondral autografts or allografts. This Coverage Position focuses on osteochondral autograft transplantation.

The goal of osteochondral transplantation is to re-establish the cartilage matrix with chondrocytes and supporting bone to improve joint function and decrease pain. Both fresh and cryopreserved allogeneic osteochondral grafts have been used with some success, although cryopreservation may decrease the viability of the cartilage cells, and fresh allografts may be difficult to obtain. Allogeneic grafts also entail a concern of disease transmission. As a result, there has been ongoing interest in the use of autologous osteochondral grafts as an option to increase the survival rate of the cartilage while decreasing the possibility of infection. Autologous grafts have been limited by the small number of available donor sites. Single grafts have been harvested from the patella, femoral condyle and proximal part of the fibula. More recently, investigators have used small, multiple plugs of osteochondral cartilage from non-weight-bearing sites to extend the availability of donor-site grafts. There are two forms of osteochondral grafting: mosaicplasty and the osteochondral autograft transplantation system (OATS®) procedure.

Repairing articular cartilage damaged by trauma or degenerative processes may alleviate pain, swelling and joint dysfunction. The evaluation of clinical outcomes for osteochondral autograft procedures vary

widely across studies. Several scoring and grading systems appear in the literature; some authors use International Cartilage Repair Society (ICRS) scores and label outcomes excellent/good/fair/poor. Other authors evaluate outcomes according to Cincinnati and Stanmore scores. Histological evaluation of the donor and recipient site should include survival of the transplanted hyaline cartilage and the formation and ingrowth of fibrocartilage from the defect. Other reported outcomes seen in the literature include improved range of motion, return to sports, reduction of pain and swelling, and improved patient satisfaction.

While patient selection is not well-defined in the literature, the upper age limit most often recommended for this type of transplant has been documented at age 50 because of an observed decrease in the quality of surrounding articular cartilage in the fifth decade of life. Normal surrounding hyaline cartilage reduces boundary shear and improves outcomes. Authors propose that the ideal candidate for this procedure is one who has chondral defects with sharp, definite borders surrounded by normal-appearing hyaline cartilage, and a defect from 1-4 cm<sup>2</sup> in extent, requiring only 4-6 grafts. The medical literature, however, reports that lesions as large as 16 cm<sup>2</sup> have been treated successfully with autografts.

While mosaicplasty and OATS procedures may provide favorable results in some cases, less favorable outcomes and complications have been reported and include fracture of the osteochondral plug, postoperative hematoma, risk of surface incongruity, donor-site morbidity and insufficient stability of the graft.

### **Mosaicplasty**

The mosaicplasty procedure consists of harvesting cylindrical bone-cartilage grafts and transplanting them into focal chondral or osteochondral defects in the knee. After excision of the chondral lesion, an abrasion arthroplasty is performed to refresh the base of the defect. The grafting procedure involves collecting grafts from the posterior aspect of the femoral condyle and implanting the grafts in a mosaic-like pattern that will contribute to regeneration and repair the articular surface (Hayes, 2005). A recipient tunnel is created and sized with a drill bit slightly larger than the length of the graft. The harvested graft is placed in the tunnel by a press-fit method. All subsequent grafts are inserted in a similar pattern. Each core transfer should be completed before proceeding, in order to prevent fracture of the tunnel wall. Donor sites are routinely left open; they fill with cancellous bone and fibrocartilage within 4-8 weeks. Authors claim that mosaicplasty reduces the possibility of donor-site morbidity and produces a more even surface (Scapinelli, et al., 2002).

### **OATS**

The OATS procedure is similar to mosaicplasty, involving the use of a larger, single plug that usually fills an entire defect. It is often performed to graft chondral defects that are also associated with anterior cruciate ligament (ACL) tears. This method allows arthroscopic access to both the ACL and the chondral defect for the performance of a repair and the grafting procedure. Authors have reported increased donor-site morbidity with the use of larger, single plugs.

### **Literature Review**

Some clinical studies suggest that joint function and symptoms may improve as a result of osteochondral autografting (Jakob, et al., 2002; Bobic, 1996; Outerbridge, et al., 1995). Nevertheless, a review of the published scientific literature yields few randomized controlled clinical trials to support the use of osteochondral autografting as a treatment for chondral defects. Most of the published studies are small, retrospective case series lacking evaluation of long-term outcomes.

Outerbridge et al. (1995) performed autologous grafts in ten patients to repair osteochondral defects of the weight-bearing surface of the femoral condyle. Follow-up evaluation was conducted post-operatively for an average of six and one-half years. The results were evaluated on the basis of a questionnaire, the clinical history, a physical exam and radiographs of the knee. The authors reported that function was improved and pain reduced in all patients, although four still had mild pain in the anterior part of the knee with strenuous or prolonged activity, and two had flexion deformities.

Bobic (1996) investigated the OATS procedure, studying 12 cases of arthroscopic osteochondral autograft transplantation in conjunction with ACL reconstruction. The chondral lesions ranged in size from 10-22 mm in diameter. Three to five osteochondral cylinders, 10-15 mm long, were harvested in each

case from the donor site. The author reported promising uniform results in 10 of 12 cases (83%) at two years' follow-up.

Jakob et al. (2002) used mosaicplasty to treat more than 110 patients with cartilage defects of the knee, hip and ankle, 52 of whom specifically underwent mosaicplasty of the knee. The average follow-up was 37 months (range 24-56). Cartilage defects were classified preoperatively as International Cartilage Repair Society Grade III lesions in 23 patients and Grade IV lesions in 29 patients. Two years post-surgery, improved knee function was observed in 92% of the patients. In four patients, graft failure necessitated reoperation. Complications and reoperation were related to large surface lesions. The authors concluded that autologous transplantation is a valid option for the treatment of full-thickness osteochondral defects, but that the method is limited by the defect size and the number of plugs to be taken at the donor site. This retrospective study lacks a control or comparison group and evaluation of long-term outcomes.

In a more recent publication, Bentley et al. (2003) compared autologous chondrocyte implantation (ACI) to mosaicplasty. A total of 100 patients were randomized to undergo either ACI or mosaicplasty. Fifty-eight patients underwent ACI, while 42 underwent mosaicplasty. The mean size of the defect was 4.66 cm<sup>2</sup>. The mean follow-up was 19 months; it consisted of evaluation using modified Cincinnati and Stanmore scores and objective clinical assessment. The study revealed excellent or good results in 88% of patients after ACI repairs, compared to 69% for mosaicplasty. Arthroscopy at one year demonstrated excellent or good repairs in 82% after ACI and only 34% after mosaicplasty. In summary, the authors stated that the results for ACI are comparable to those in other studies, but that continued use of mosaicplasty is of dubious value. Blinding was not reported in this study.

Hangody reported on the mosaicplasty procedure in several articles. Most recently, his group reported on a total of 10 years of clinical experience with mosaicplasty. Clinical scores, imaging techniques, control arthroscopies, histological examination of biopsy samples, and cartilage stiffness measurements were used to evaluate clinical outcomes and quality of the transplanted cartilage in a total of 831 patients. According to the authors' investigations, femoral condylar implantations had good-to-excellent results in 92% of patients, tibial resurfacing in 87%, patellar and/or trochlear mosaicplasties in 79%, and talar procedures in 94%. The Bandi score showed long-term donor-site disturbances in 3% of patients. Sixty-nine of 83 control arthroscopies had congruent gliding surfaces, histologically proven survival of the transplanted hyaline cartilage, and fibrocartilage covering of the donor-site. The authors concluded that autologous osteochondral mosaicplasty is a viable alternative in treating small to medium-sized focal chondral and osteochondral defects of the weight-bearing surfaces of the knee and other weight-bearing synovial joints (Hangody, et al., 2004).

Marcacci et al. (2005) prospectively evaluated mosaicplasty for treatment of femoral chondral cartilage lesions in young (< age 50) active patients. Thirty-seven patients, all who practiced sports, with full thickness lesions (Outerbridge Grade IV) were treated arthroscopically. The size of the lesion was less than 2.5cm<sup>2</sup>. Two-year clinical evaluation consisted of return to sports, computed tomography or magnetic resonance imaging, and the International Cartilage Repair Society (ICRS) form. Second-look arthroscopy was performed in some cases. The results were encouraging with 78.3% good and excellent ICRS scores. Reported outcomes were better in the patients with lateral condyles compared to medial and in the younger age group compared to the older patients. The authors concluded mosaicplasty can give reliable results for small lesions in young patients. This study is flawed by lack of a control/comparison group, evaluation of long-term durability or survival of the graft. In addition, the study was limited to a population of patients who were active in sports and had small lesions, and does not allow for generalizability of the results.

Karataglis et al. (2005) evaluated mid and long-term functional outcome of the treatment of osteochondral defects of the knee joint with autologous osteochondral transplantation with the OATS technique. The group studied 42 patients who underwent 43 procedures with the OATS technique. Thirty-six patients were available for follow-up. The average area of the lesion covered was 2.73 cm<sup>2</sup>. The diameter ranged from 6-10mm, and 1-8 grafts were used to cover >90 % of the lesion area. The average length of follow-up was 36.9 months. Thirty-two patients reported improvement of their pre-operative symptoms. All but five patients had returned to previous day-to-day activities and occupation. Nine patients had a second-look arthroscopy 7-13 months following the initial surgery. The grafts were found to be stable, well

incorporated and with satisfactory chondrocyte survival in all but two cases, where they were loose and were therefore revised. The authors concluded from this small study that osteochondral autograft transplantation is a successful treatment option for focal osteochondral defects of the knee.

There are few published studies evaluating the viability of the osteochondral plug. Authors have suggested that chondrocyte viability at the plug edge is likely to be a determinant of long-term graft success (Huntley, et al., 2005). An absence of the matrix-producing cells in the cartilage-to-cartilage interface results in lack of cartilage repair, leading to degeneration of tissues and ultimately graft failure (Redman, et al., 2005; Huntley, et al., 2005).

Osteochondral autografting involves removing plugs of osteochondral tissue from non-load bearing regions of articular cartilage and transplanting plugs to the defect. There is insufficient published data to determine whether tissues derived from non-load bearing sources can withstand the stress of a load-bearing area and the degree of donor site morbidity (Redman, et al., 2005).

A recent technology assessment of mosaicplasty was conducted by Hayes (2005). The studies reviewed consisted of six retrospective case series, two prospective case series, and one randomized comparative trial. The results of the reviewed studies indicated that mosaicplasty can improve symptoms and joint function, especially for small lesions of the femoral condyle. However, there was no data regarding the efficacy of mosaicplasty for joints other than the knee or ankle, and the studies did not report follow-up beyond 2-4 years. Hayes concluded, "The efficacy of mosaicplasty compared with other alternative treatments remains to be determined."

The American College of Rheumatology (ACR) Recommendations for the Medical Management of Osteoarthritis of the Hip and Knee has noted that significant advances such as autologous chondrocyte transplantation, cartilage repair using mesenchymal stem cells and autologous osteochondral plugs are being investigated; however, they do not recommend those procedures for the treatment for patients with osteoarthritis (ACR, 2000).

### Summary

Overall, the results of the literature are encouraging; however, additional well-designed, randomized, clinical studies with long-term follow-up are required to support the use of osteochondral autografting procedures. Few clinical studies are available that compare the results of osteochondral autografting with those of other established therapies. Most of the literature supports the position that the larger the defect, the higher the complication rate. Finally, there is minimal documentation to support patient selection criteria regarding the size of chondral defects that are appropriate for this procedure. At present, insufficient evidence exists in the peer-reviewed, published scientific literature to evaluate the efficacy of osteochondral autograft transplant for the knee and other areas, such as the ankle, tibia, hip and trochlea.

## Coding/Billing Information

**Note: This list of codes may not be all-inclusive.**

### Experimental/Investigational/Unproven:

CPT®* Codes	Description
29866	Arthroscopy, knee, surgical; osteochondral autograft(s)(eg, mosaicplasty) (includes harvesting of the autograft)

HCPCS Codes	Description
	No specific codes

ICD-9-CM Diagnosis	Description

Codes	
717.7	Chondromalacia of patella
732.7	Osteochondritis dissecans
733.90	Disorder of bone and cartilage, unspecified

**\*Current Procedural Terminology (CPT®) ©2004 American Medical Association: Chicago, IL.**

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