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Corporate Medical Policy

Osteochondral Allograft Transplantation and Autograft Transfer System (OATS/mosaicplasty) in the Treatment of Articular Cartilage Lesions

File name: Osteochondral Allograft Transplantation and Autograft Transfer System (OATS/Mosaicplasty in the Treatment of Articular Cartilage Lesions)
Last Review: 05/2011
Next Review: 05/2012
Effective Date: 07/01/2011

Description

Focal chondral defects of the knee, either due to trauma or other conditions such as osteochondritis dissecans, often fail to heal on their own and may be associated with pain, loss of function, disability, and the long-term complication of osteoarthritis. The ideal resurfacing technique would eliminate symptoms, restore normal biomechanics of the knee joint, and prevent the long-term emergence of osteoarthritis and the necessity for total knee arthroplasty. Various methods of cartilage resurfacing have been investigated including marrow-stimulation techniques such as subchondral drilling, microfracture, and abrasion arthroplasty, all of which are considered standard therapies and all of which attempt to restore the articular surface by inducing the growth of fibrocartilage into the chondral defect. However, fibrocartilage does not share the same biomechanical properties as hyaline cartilage, and thus various strategies for chondral resurfacing with hyaline cartilage have been investigated. Autologous chondrocyte implantation involves the harvesting of normal chondrocytes from normal non-weight-bearing articular surfaces, which are then cultured and expanded in vitro and then transplanted back into the patient. Autologous chondrocyte implantation is considered separately in policy No. 7.01.48.

Osteochondral grafts have also been investigated. Both fresh and cryopreserved allogenic osteochondral grafts have been used with some success, although cryopreservation decreases the viability of cartilage cells, and fresh allografts may be difficult to obtain and create concerns regarding infectious diseases. For these reasons, autologous osteochondral grafts have been investigated as an option to increase the survival rate of the grafted cartilage and to eliminate the risk of disease transmission. Autologous grafts are limited by the small number of donor sites; thus allografts are typically used for larger lesions. In an effort to extend the amount of the available donor tissue, investigators have used multiple, small osteochondral cores harvested from non-weight-bearing sites in the knee, for treatment of full-thickness chondral defects. Several systems are available for performing this procedure, the Mosaicplasty System (Smith and Nephew), the Osteochondral Autograft Transfer System (OATS, Arthrex, Inc.), and the COR and COR2 systems (DePuy-Mitek). Although mosaicplasty and OATS may use different instrumentation, the underlying principle is similar; i.e., the use of multiple osteochondral cores harvested from a non-weight-bearing region of the femoral condyle and autografted into the chondral defect. These terms have been used interchangeably to describe the procedure. In contrast to autologous chondrocyte implantation (ACI), in which separate surgical procedures are required to harvest and then transplant the cultured chondrocytes, with osteochondral autografting the harvesting and transplantation can be performed during the same surgical procedure.

Preparation of the chondral lesion involves debridement and preparation of recipient tunnels. Multiple individual osteochondral cores are harvested from the donor site, typically from a peripheral non-weight-bearing area of the femoral condyle. Donor plugs range from 6 mm to 10 mm in diameter. The grafts are press fit into the lesion in a mosaic-like fashion into the same-sized tunnels. The resultant surface consists of transplanted hyaline articular cartilage and fibrocartilage, which is thought to provide "grouting" between the individual autografts. Mosaicplasty may be performed with either an open approach or arthroscopically. Osteochondral autografting has also been investigated as a treatment of unstable osteochondritis dissecans lesions using multiple dowel grafts to secure the fragment. While osteochondral autografting is primarily performed on the femoral condyles of the knee, osteochondral grafts have also been used to repair chondral defects of the patella, tibia, and ankle.

Policy

Benefits are subject to all terms, limitations and conditions of the subscriber contract.

Prior approval may be required subject to all terms, limitations and conditions of the subscriber contract.

For New England Health Plan (NEHP) members an approved referral authorization is required.

Federal Employee Program (FEP) members may have different benefits that apply. For further information please contact FEP customer service.

When service or procedure is covered

Osteochondral allografting may be considered **medically necessary** as a technique to repair large (e.g., 10 cm^2) full-thickness chondral defects caused by acute or repetitive trauma.

Osteochondral autografting, using 1 or more cores of osteochrondral tissue, may be considered **medically necessary** for the treatment of small symptomatic full-thickness cartilage defects caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior surgical procedure, when all of the following have been met:

- Adolescent patients should be skeletally mature with documented closure of growth plates (e.g., 15 years or older). Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., younger than 55 years)
- Focal, full-thickness (grade III or IV) uni-polar lesions on the weight-bearing surface of the femoral condyles or trochlea that are between 1 and 2.5 cm^2 in size
- Documented minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge Grade II or less),and normal-appearing hyaline cartilage surrounding the border of the defect
- Normal knee biomechanics, or alignment and stability achieved concurrently with osteochondral grafting
- Absence of meniscal pathology

When service or procedure is not covered

Osteochondral allografting or autografting for all other joints, including patellar and talar, and any indications other than those listed above, is considered **investigational**.

Policy Guidelines

If debridement is the only prior surgical treatment, consideration should be given to marrow-stimulating techniques before osteochondral grafting is performed.

Severe obesity, e.g., body mass index (BMI) greater than 35 kg/m^2, may affect outcomes due to the increased stress on weight-bearing surfaces of the joint.

Misalignment and instability of the joint are contraindications. Therefore additional procedures, such as repair of ligaments or tendons or creation of an osteotomy for realignment of the joint, may be performed at the same time.

Rationale

At the time this policy was created, the available evidence consisted of single institution case series focusing on chondral lesions of the knee using osteochondral autografts. (1-3) The case series included heterogeneous populations of patients, some of whom were undergoing treatment for additional abnormalities, such as ligament or meniscal repair, and the chondral defect may only have been identified incidentally. The available case series were both small in number, contained heterogeneous patients, and lacked complete follow-up to permit conclusions. There was also no long-term follow-up regarding potential morbidity related to the multiple donor sites. In addition, no studies compared the results of osteochondral autografting with other established therapies such as lavage or various marrow-stimulation techniques, including microfracture, subcondral drilling, or abrasion arthroplasty.

Additional case series and 1 randomized trial were identified in a literature search of the MEDLINE database for the period of 2001 through June 2005. (4-13) Case series on osteochondral autografting for the knee, talus, elbow, and shoulder were considered inadequate to permit scientific conclusions. (4-12) An additional search of the literature at this time focused on the use of allografts. Although osteochondral allografts were described in patients with large chondral defects, no published literature was identified in which osteochondral allografts were used to resurface focal chondral defects. A search of the MEDLINE database for the period of May 2005 through December 2006 identified 3 additional randomized trials. (14-16) These trials provided some data on efficacy and morbidity associated with various resurfacing procedures in a small number of selected patients; however, additional studies with larger sample sizes were needed.

A search of the MEDLINE database for the period of January 2007 through March 2008 identified a number of small case series (5–30 patients) describing use of osteochondral autografts for cartilage defects of the knee, elbow, and ankle. (17,18) Additional review of the evidence was conducted in September 2008, subsequent to input from physician specialty societies and academic medical centers (see below). The literature was found to consist primarily of uncontrolled case series with limited (e.g., 2 years or less) follow-up.

A 2008 systematic review by Magnussen et al assessed whether “advanced” cartilage repair techniques (osteochondral transplantation or autologous chondrocyte transplantation) showed superior outcomes in comparison with traditional abrasive techniques for the treatment of isolated articular cartilage defects. (19) Finding a total of 5 randomized controlled trials and 1 prospective comparative trial that met their selection criteria, Magnussen and colleagues concluded that no one technique had been shown to produce superior clinical results for treatment of articular cartilage defects. They stated that, “any differences in outcome based on the formation of articular rather than fibrocartilage in the defect may be quite subtle and only reveal themselves after many years of follow-up. Similarly, complications such as donor site morbidity in OAT may be late in their presentation and thus not be detected at short follow-up.” Relevant studies are described below. (20-23)

Hangody, who first reported use of the mosaicplasty technique in humans in 1992, has authored a number of summaries and case series. (1, 2, 20) It is likely that these reports contain overlapping populations of patients, and few details are reported. In a 1997 article, Hangody and colleagues refer to a 1992–1994 comparison study of mosaicplasty and abrasion arthroplasty. No details of this study are provided, except to note that the mosaicplasty patients had significantly improved Hospital for Special Surgery (HSS) knee scores, compared to those undergoing abrasion arthroplasty. (1) A 2008 summary paper includes descriptions of a prospective multicenter comparison of 413 resurfacing procedures and follow-up from 1,097 mosaicplasties at the author's institution. (20) Although the authors report that the comparative study found hyaline-like resurfacing to result in a better clinical outcome than other techniques, the cited study is not available as a publicly available peer-reviewed publication. For the retrospective analysis, Hangody and colleagues reported 789 implantations on the femoral condyles, 147 in the patellofemoral joint, 31 on the tibia condyles, 98 on talar domes, 8 on the capitulum humeric, 3 on humeral heads, and 11 on femoral heads. About two thirds of the patients were reported to have had a localized cartilage lesion, and the remainder underwent surgery because of osteochondral defects. In 81% of patients concomitant surgical interventions were performed; these included reconstruction of the anterior cruciate ligament (ACL) realignment osteotomies, meniscus surgery, and patellofemoral realignment procedures. Clinical scores found good to excellent results in 92% of patients with femoral condylar implantations, 87% of tibial resurfacings, 74% of patellar and/or trochlear mosaicplasties, and in 93% of talar procedures. Moderate and severe donor-site disturbances were reported in 3% of patients. Ninety-eight second-look arthroscopies were done for persistent or recurrent pain, swelling or postoperative intraarticular bleeding (31 patients at 2 months to 11 years), second trauma (26 patients at 1–9 years) or to evaluate recovery in professional athletes (41 patients, 4–7 months). Although at least 57 (58%) second-look arthroscopies were associated with clinical symptoms, the report indicates that 81 (83%) of the evaluations indicated good gliding surfaces, histologically proven survival of the transplanted hyaline cartilage, and acceptable fibrocartilage covering of the donor sites. Slight or severe degenerative changes were seen at the recipient and/or donor sites in 17 cases (17%). The association between clinical symptoms and histological results was not discussed. Painful hemarthroses were observed in 56 (5%) of patients. The authors note that although these results are encouraging for use of autologous osteochondral mosaicplasty as an alternative treatment for small- and medium-sized focal defects, postoperative bleeding from the empty donor tunnels represents a possible postoperative complication, and donor-site morbidity remains an open question. Based on their extensive experience with this procedure, Hangody and colleagues consider the optimal indications to be a lesion size of 1–4 cm^2, patient age of 50 years or younger (due to decreased repair capacity with aging), and correction of instability, malalignment, and meniscal or ligamental tears. (20)

Osteochondral autografts in comparison with microfracture

One study from Lithuania was a well-controlled and blinded comparison of mosaic osteochondral autologous transplantation (OAT) versus microfracture for lesions of the femoral condyle (1–4 cm^2) in 60 athletes between 15 and 40 years of age (mean, 24.3 years). (14) Follow-up on 95% of the athletes for up to 3 years following surgery showed that more athletes returned to sports activities (mean, 6.5 months) following OAT (93% vs. 52%), and fewer required revision (1of 28 vs. 9 of 29). Overall, 96% of patients treated by OAT had an excellent or good result compared with 52% treated by microfracture. At 1 year follow-up, scores on the International Cartilage Repair Society (ICRS) cartilage grading system improved from a baseline of 51 to 86 in the OAT group and 76 in the microfracture group. At 3-year follow-up, scores from Hospital for Special Surgery questionnaires improved from a baseline of 77 to 91 in the OAT group and 81 in the microfracture group. No donor-site morbidity was observed. Blinded arthroscopic and histological assessment in a subset of patients showed hyaline cartilage of normal appearance following transplantation, whereas microfracture was frequently observed to result in surface fibrillation and soft fibroelastic tissue.

Another group from Italy randomized 32 patients with osteochondral lesions of the talus to chondroplasty, microfracture, or OAT. (15) This small study found similar improvements (approximately 40 points) for the 3 treatment groups as measured by the American Orthopaedic Foot and Ankle Society Ankle-Hindfoot Score (baseline score of 31 to 37) and the Subjective Assessment Numeric Evaluation (baseline score of 35 to 36). Complication rates were also similar, with persistent pain reported by 1 patient following chondroplasty, by 2 patients following microfracture, and by 2 patients following OAT. Postoperative pain, measured by Numeric Pain Intensity Scores, was greater following OAT (5.25) than chondroplasty (3.3) or microfracture (3.4).

Osteochondral autografts in comparison with chondrocyte implantation

Horas and colleagues reported 2-year follow-up on a study of 40 patients (between 18 and 42 years of age) with an articular lesion of the femoral condyle (range of 3.2 to 5.6 cm^2) who were randomly assigned to undergo either autologous chondrocyte implantation or osteochondral autografting. (13) Eleven (28%) had received prior surgical treatment. The authors reported that both treatments resulted in an improvement in symptoms (85% of each group), although those in the osteochondral autografting group responded more quickly. Histomorphological evaluation of 5 biopsy specimens at 2 years or less after transplantation indicated that the osteochondral cylinders had retained their hyaline character, although the investigators noted a persistent interface between the transplant and the surrounding original cartilage. Evaluation of autologous chondrocyte implants indicated a rigid, elastic tissue, with partial roughening and the presence of fibrocartilage.

Bentley and colleagues randomized 100 consecutive patients with symptomatic lesions of the knee (average 4.7 cm^2, range of 1 to 12 cm^2) to ACI or mosaicplasty. (21) Seventy-four percent of lesions were on the femoral condyle, and 25% of lesions were on the patella. Ninety-four patients had undergone previous surgical interventions and the average duration of symptoms before surgery was 7 years. Clinical assessment at 1g year showed excellent or good results in 98% of the ACI patients and 69% of the mosaicplasty patients. The mosaicplasty plugs showed incomplete healing of the spaces between the grafts, fibrillation of the repair tissue, and disintegration of the grafts in some patients. This finding may be related to both the relatively large lesion size and the unusual prominent placement of the plugs in this study, which was intended to allow contact with the opposite articular surface,

Dozin et al reported results from a multicenter randomized clinical trial in which ACI was compared to mosaicplasty (22). Forty-four individuals (61% male, 39% female) age 16–40 years (mean 28.7 ± 7.8), who had a focal, symptomatic chondral injury of Outerbridge grade III or IV with no previous surgical treatment, were randomly assigned to ACI or mosaicplasty 6 months after undergoing arthroscopic debridement. The average lesion size was 1.9 cm. Only 12 of 22 (54%) in the ACI group and 11 of 22 (50%) of the mosaicplasty group actually underwent the assigned procedure. Dropouts comprised 14 patients (32%) who reported spontaneous improvement following arthroscopy and did not undergo subsequent surgery, 5 who did not show up at the presurgery examination and could not be further traced, and 2 who refused surgery for personal reasons. Because of the substantial dropout rate, the original primary outcome measure, the mean Lysholm Knee Scoring Scale (LKSS) assessed 12 months post-surgery was converted into a scale in which improvement was categorized by proportions of responders (LKSS < 60, LKSS 60-90, LKSS 90-100). With this scale, and including 10 patients who were cured by debridement (intention-to-treat analysis) the percentages of patients who achieved complete success were 89% (16 of 18 evaluable cases) in the mosaicplasty arm versus 68% (13 of 19 evaluable cases) in the ACI arm (test for trend P = 0.093). The high rate of spontaneous improvement after simple debridement raises questions about the appropriateness of additional surgical intervention in patients with small lesions similar to those included in this trial.

Longer-term follow-up

Laprell and colleagues reported 6–12 year follow-up from 29 of 35 patients (83%) with severe osteochondral defects (77% with osteochondritis dissecans) who were treated by autologous osteochondral transplantation. (23) The average age of the patients at the time of surgery was 26 years. Clinical evaluation at an average 8 years after the procedure found 12 patients (41%) to be normal, 14 (48%) as nearly normal, and 3 (10%, all of whom refused correction of malalignment) as abnormal. No patient was assessed as severely abnormal. In contrast, no patients considered their functional status to be normal, 3 (10%) considered function to be nearly normal, 20 (69%) thought their function abnormal, and 6 (21%) considered their functional status to be severely abnormal.

Another report described 7-year follow-up on 30 patients who had been treated with autologous osteochondral transplantation for symptomatic grade III to IV chondral lesions (average 1.9 cm, range of 1.0 to 2.5 cm). (17) Nineteen patients received other procedures (ACL reconstruction, meniscectomy, medial collateral ligament repair) at the same time, and it is therefore not possible to assess the contribution of the osteochondral transplantation to the functional results reported. Magnetic resonance imaging at 7 years showed complete bone integration in 96% of patients, complete integration of the grafted cartilage in 75% of cases, complete filling of the cartilage defect in 63% of the patients, and congruency of the articular surface in “some” patients. Subchondral bone changes (edema or sclerosis) were noted in 71% of patients. The donor sites were filled with a tissue of different density than the surrounding bone, presumed to be fibrous tissue. No patients reported anterior knee pain. Non-painful patellar crepitus was observed in 3 (10%) patients.

Adverse Events

One study reported donor site morbidity in 11 patients (of 15) who had undergone graft harvest from the knee (mean of 2.9) for treatment of osteochondral lesions of the talus. (18) At an average 47-month follow-up (7–77 month range), 5 patients were rated as having an excellent Lysholm score (95–100 points), 2 as good (84–94), and 4 as poor (64 or less). Reported knee problems were instability in daily activities, pain after walking a mile or more, having a slight limp, and difficulty squatting.

In summary, only 1 relatively small randomized controlled trial from Europe has demonstrated improved clinical outcomes when compared with microfracture. Data regarding the long-term viability of the transplanted osteochondral hyaline cartilage is also limited. However, controlled studies demonstrate similar benefit to other cartilage resurfacing procedures in appropriately selected patients, and a number of uncontrolled studies indicate that osteochondral autografts can improve symptoms in some patients with lesions of the femoral condyle who have failed prior surgical treatment. These patients have limited options. Therefore, based on the clinical input received and additional literature reviewed, it is concluded that osteochondral autografts may be considered an option for symptomatic full-thickness chondral lesions of the femoral condyle caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure. Evidence is currently insufficient to evaluate the efficacy of osteochondral autografts in comparison with other surgical repair procedures as a primary treatment of small lesions, or to evaluate the efficacy of osteochondral autografts for joints other than the knee. Questions also remain about the natural history of asymptomatic lesions found incidentally during other surgical procedures. Additional controlled trials with longer follow-up are needed to demonstrate that use of osteochondral autografts as a primary treatment results in improved clinical outcomes in comparison with traditional marrow-stimulating procedures.

Physician Specialty Society and Academic Medical Center Input

In response to requests, 5 inputs were received from 1 physician specialty society and 3 academic medical centers while this policy was under review. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input

received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. After review, the Practice Committee of the American College of Rheumatology (ACR) declined to comment, providing the explanation that because they do not do this procedure they are not in a position to comment for or against. All 5 reviewers agreed that osteochondral autografts and allografts are considered reasonable for patients with full-thickness chondral defects who meet specific criteria.

Other Guidelines

The Interventional Procedures Advisory Committee of the United Kingdom's National Institute for Health and Clinical Excellence (NICE) conducted a 2005 review of mosaicplasty for knee cartilage defects. (24) The corresponding NICE Guidance on mosaicplasty, released in 2006 (25), is in agreement with conclusions listed above, stating that "There is some evidence of short-term efficacy, but data on long-term efficacy are inadequate."

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Eligible Providers:

Orthopedic surgeons (MD or DO)

Billing and Coding Information:

See Attachment I

Policy Implementation/Update Information:

2006: New Policy

2007: Minor wording changes; Reviewed by the CAC July 2007

2008: Policy completely revised to correspond to BCBS of Massachusetts Medical Policy for benefit consistency with the New England Health Plan and the Vermont legal definition of medical necessity, based upon expert medical opinion and generally accepted practice parameters in New England. Reviewed by CAC 09/2008.

07/2009: Policy revised to follow Blue Cross and Blue Shield Association Medical Policy guidelines and rationale, which previously considered OATS as investigational, but now has established medical necessity criteria. BCBSVT developed specific criteria was changed to those of the BCBSA, which are less restrictive. Reviewed by CAC 09/15/2009.

05/2011 – Minor wording changes made

Approved by BCBSVT Medical Policy Committee: Date Approved

Antonietta L. Sculimbrene, MD, MHA
Chairman, Medical Policy Committee

Attachment I
OATS/Mosaicplasty

CPT Coding:

27415	Osteochondral allograft, knee, open	Prior Approval required.
27416	Osteochondral autograft(s), knee, open (eg, mosaicplasty) (includes harvesting of autograft[s])	Prior Approval required.
28446	Open osteochondral autograft, talus	Prior Approval required.
29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (e.g., mosaicplasty) (includes harvesting of the autograft[s])	Prior Approval required.
29867	Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)	Prior Approval required.

ICD-9 Procedure	81.47	Other repair of knee
ICD-9 Diagnosis	715.16	Osteoarthrosis, localized, primary, lower leg
	715.26	Osteoarthrosis, localized, secondary, lower leg
	715.36	Osteoarthrosis, localized, not specified whether primary or secondary, lower leg
	715.96	Osteoarthrosis, unspecified whether generalized or localized, lower leg
	716.16	Traumatic arthropathy, lower leg
	718.06	Articular cartilage disorder, lower leg
	718.86	Other joint derangement, lower leg
	719.86	Other specified disorders of joint, lower leg
	732.7	Osteochondritis dissecans
	733.90	Other unspecified disorder of bone and cartilage
	959.7	Injury, knee, leg, ankle, and foot