

OSTEOCHONDRAL GRAFTING OF KNEE

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COVERAGE RATIONALE

Osteochondral autograft transplantation is proven for treatment of a symptomatic focal full-thickness articular cartilage defect of the knee when all of the following are present:

- Adult who has achieved mature skeletal growth
- Considered unsuitable candidate for total knee replacement
- Presence of debilitating symptoms that significantly limit ambulation
- Absence of inflammatory joint disease or steroid-induced cartilage or bone disease
- Normal alignment or correctable varus or valgus deformities
- Minimal to absent degenerative changes in surrounding articular cartilage (Outerbridge Grade II or less)

Osteochondral allograft transplantation using human cadaver tissue is proven for the treatment of a symptomatic focal full-thickness articular cartilage defect of the knee when all of the following are present:

- Adult who has achieved mature skeletal growth
- Considered unsuitable candidate for total knee replacement

- Presence of debilitating symptoms that significantly limit ambulation
- Absence of inflammatory joint disease
- Normal alignment or correctable varus or valgus deformities
- Minimal to absent degenerative changes in surrounding articular cartilage (Outerbridge Grade II or less)

Minced articular cartilage repair (allograft or autograft) is unproven for the treatment of osteochondral defects of the knee.

Randomized trials that compare the outcomes of minced articular cartilage repair with standard methods have not been published. Clinical studies are needed to establish the safety and outcome benefit of this technique over standard methods of cartilage repair.

Information Pertaining to Medical Necessity Review (When Applicable)

In addition to the criteria listed above, osteochondral autograft and allograft transplantation of the knee is medically necessary in patients who meet all of the following criteria:

- Failed conventional medical treatment (including physical therapy and/or bracing techniques) and/or prior surgical treatment
- Willingness to comply with extensive period of rehabilitation following surgery

BACKGROUND

Damage to cartilage may result from either traumatic injury or from degenerative conditions (e.g., osteochondritis dissecans, osteonecrosis or osteoarthritis).

Cartilage healing and repair are affected by factors such as age, the degree and depth of damage, associated joint instability, the underlying cause, previous meniscectomy, misalignment and genetic factors. Only in limited situations can the damaged articular cartilage remodel and rebuild itself. Undisplaced lesions in skeletally immature individuals generally heal with immobilization; however, in skeletally mature individuals, surgery is often indicated as it is widely accepted that a symptomatic cartilage lesion is likely to persist or worsen without treatment.

Chondral defects of the knee due to trauma or other conditions such as osteochondritis dissecans often fail to heal on their own and may be associated with chronic pain and disability. Nonsurgical treatment options for damage to articular cartilage include weight loss, physical therapy, braces, orthotics, and pain management. Total joint replacement is not advised for younger patients because implants might not withstand the higher levels of physical activity for an extended period of time. A number of surgical options short of total joint replacement are available, including: stimulation of bone marrow through subchondral drilling or debridement, abrasion chondroplasty, or microfracture; fixation with pegs, wires, screws, or bioabsorbable implants; grafts of perichondrium or periosteum; autologous chondrocyte transplantation; and osteochondral allografting or autografting.

Allograft

Osteochondral allografting involves transplantation of a piece of articular cartilage and attached subchondral bone from a cadaver donor to a damaged region of the articular surface of a joint. The goal of this procedure is to provide viable chondrocytes and supporting bone that will be sufficient to maintain the cartilage matrix and thereby relieve pain and reduce further damage to the articular surface of the joint. Allografts often are used as a salvage treatment when other cartilage repair procedures have failed. For extensive loss of bone, reconstruction with bulk allograft replacement may be an option. Fresh allografts may be difficult to obtain and creates concerns regarding a small risk of infectious disease transmission. For these reasons, autologous osteochondral grafts have been investigated.

Recently, a minimally processed osteochondral allograft (Chondrofix®, Zimmer) has become available for use. Chondrofix® is composed of decellularized hyaline cartilage and cancellous bone and can be used “off the shelf” with precut cylinders (7-15 mm).

Autograft

Osteochondral autologous transplant involves the placement of viable hyaline cartilage grafts obtained from the individual into a cartilage defect. The grafts are harvested from a nonweight-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.

The advantages of using autograft include graft availability, the absence of possible disease transmission risk, and that the procedure is a single-stage procedure. Disadvantages reported include donor site morbidity and limited available graft volume. In addition, tissue may have to be harvested from two different donor sites in order to provide enough material for a large defect without compromising the donor site.

Osteochondral autograft transfer system (OATS) and mosaicplasty are two types of osteochondral autografting.

- **Mosaicplasty** – A technique that consists of removing small osteochondral cylinders from low weight-bearing surfaces of the affected joint or another joint in the same patient and transplanting them in a mosaic-like formation into focal chondral or osteochondral defects in the knee. It is usually utilized to treat larger defects.
- **Osteochondral Autograft Transfer System (OATS) procedure** – This procedure is similar to mosaicplasty; however, it involves the use of a larger, single plug that usually fills an entire defect (e.g., those associated with anterior cruciate ligament (ACL) tears).

These techniques are limited by the amount of donor tissue available in the joint. Donor site morbidity increases as more tissue is harvested. Treatment of small lesions may be performed arthroscopically, while treatment of larger lesions is typically performed through an open arthrotomy.

Minced cartilage repair is considered a second generation technique that does not require in vitro cell expansion and is described as a single-staged minimally invasive procedure. The procedure uses minced pieces of cartilage seeded over a scaffold which allows for even distribution of the chondrocytes to expand within the defect providing structural and mechanical protection. The first clinical application of the minced cartilage technique was the cartilage autograft implantation system (CAIS) developed by DePuy Mitek. A second technology, DeNOVO NT Graft ("Natural Tissue Graft"; Zimmer Inc, Warsaw, is another application for cartilage regeneration using minced donated juvenile.

DeNovo NT Graft is a tissue based articular cartilage graft that is processed from healthy donors less than 13 years of age and greater than 6 lbs. in weight. Donors are sourced through appropriate Organ and Tissue Procurement Organizations (OTPOs).

CLINICAL EVIDENCE

Osteochondral Autograft Transplantation of the Knee

Bentley et al. (2003) randomized 100 consecutive patients with symptomatic lesions of the knee (average 4.7 cm², range of 1 to 12 cm²) to autologous chondrocyte implantation (ACI) or mosaicplasty. Clinical assessment at 1 year showed excellent or good results in 98% of the ACI patients and in 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 the unusual prominent placement of the plugs in this study, which was intended to allow contact with the opposite articular surface.

Horas et al. (2003) reported 2-year follow-up on a study of 40 patients (18 - 42 years of age) with an articular lesion of the femoral condyle (size range of 3.2 to 5.6 cm²). The patients were randomly assigned to undergo either autologous chondrocyte transplant or osteochondral autografting. The investigators reported that both treatments resulted in a decrease in symptoms. However, the improvement provided by the autologous chondrocyte implantation lagged behind that provided by the osteochondral cylinder transplantation.

Dozin et al. (2005) reported results from a multicenter randomized clinical trial in which ACI (mean lesion size 1.97 cm²) was compared to osteochondral autografting (mean lesion size 1.88 cm²) in 47 patients. Patients underwent arthroscopic debridement of the lesion at the time of enrollment. They were called for surgery 6 months after the initial debridement. Fourteen patients (31.8%) experienced substantial improvement following the initial debridement and, being clinically cured, received no further treatment. Seven patients (15.9%) were lost to follow-up. Among the 23 patients (52.3%) who could effectively be evaluated, a complete recovery was observed upon clinical examination in 88% of the mosaicplasty-treated patients and in 68% of the ACI-treated ones.

In a prospective randomized clinical study Gudas et al. (2006) compared the outcomes of mosaic type autologous osteochondral transplantation (OAT) and microfracture (MF) procedures for the treatment of the articular cartilage defects (mean lesion size 2.8 cm²) of the knee joint in 57 athletes. There were 28 athletes in OAT group and 29 in MF group. According to the modified Hospital for Special Surgery (HSS) and International Cartilage Repair Society (ICRS) scores, functional and objective assessment showed that 96% had excellent or good results after OAT compared with 52% after MF procedure. In 12, 24 and 36 months after the operations, the HSS and ICRS showed statistically significantly better results in the OAT group.

Gudas et al (2009) compared the outcomes of the arthroscopic mosaic-type osteochondral autologous transplantation (OAT) and microfracture (MF) procedures for the treatment of osteochondritis dissecans (OCD) defects of the femoral condyles of the knee joint in 50 children (mean age of 14.3 years) in a prospective randomized clinical trial. Inclusion criteria included the following: 1) grades 3-4 OCD lesion; 2) OCD defects between 2 and 4cm squared in area; and 3) age less than 18 years. Forty-seven patients (94%) were available for follow-up. There were 25 patients in the OAT group and 22 patients in the MF group. The mean follow-up was 4.2 years. After 1 year, both groups had significant clinical improvement and the ICRS functional and objective assessment showed that 92% patients had excellent or good results after OAT compared with 86% after MF, but 83% after OAT and only 63% after MF procedure maintained excellent or good results after 4.2 years. There were 41% failures in the MF group, and none in the OAT group. Magnetic resonance imaging evaluation according to the ICRS evaluation system showed excellent or good repairs in 91% after OAT compared with 56% after MF. According to the investigators, this study showed significant superiority of the mosaic-type OAT over MF for the treatment of osteochondritis dissecans defects in the knee.

Hangody and Fules (2003) described the results after ten years of clinical experience with autologous osteochondral mosaicplasty in 831 patients. According to these investigations, good-to-excellent results were achieved in 92% of the patients treated with femoral condylar implantations, 87% of those treated with tibial resurfacing, 79% of those treated with patellar and/or trochlear mosaicplasties, and 94% of those treated with talar procedures. The investigators noted slightly diminished result for trochlear and tibial plateau lesions and a 3% overall incidence of donor site morbidity. According to the investigators, autologous osteochondral mosaicplasty appears to be an alternative for the treatment of small and medium-sized focal chondral and osteochondral defects of the weight-bearing surfaces of the knee and other weight-bearing synovial joints.

Hangody et al. (2010) evaluated if mosaicplasty is effective in returning elite athletes to participation in sports. The results of mosaicplasty were prospectively evaluated at 6 weeks, 3 months, 6 months, and yearly in 354 patients. Good to excellent results were found in 91% of femoral mosaicplasties, 86% of tibial, and 74% of patellofemoral; 92% of talar mosaicplasties had similar results. The investigators concluded that despite a higher rate of preoperative osteoarthritic changes in the athletic patients, clinical outcomes of mosaicplasty in this group demonstrated a success rate similar to that of less athletic patients. Higher motivation resulted in better subjective evaluation. Slight deterioration in results occurred during the 9.6-year follow-up. The authors stated that autologous osteochondral mosaicplasty may be a useful alternative for the treatment of 1.0- to 4.0 cm² focal chondral and osteochondral lesions in competitive athletes.

According to National Institute for Health and Clinical Excellence (NICE), the current evidence suggests that there are no major safety concerns associated with mosaicplasty for knee cartilage defects. There is some evidence of short-term efficacy, but data on long-term efficacy are inadequate. In view of the uncertainties about the efficacy of the procedure, it should not be used without special arrangements for consent and audit or research (NICE 2006).

Evidence from the peer-reviewed published scientific literature, textbook and some professional societies support short to intermediate-term efficacy of osteochondral autograft transplant of the knee in specific patient subgroups.

Osteochondral Allograft Transplantation of the Knee

There is evidence from several studies suggesting that osteochondral allografting of the knee is a successful alternative to autograft and provides relief of pain and improved joint function for select patients.

Ghazavi et al. (1997) used fresh small-fragment osteochondral allografts to reconstruct post-traumatic osteochondral defects in 126 knees of 123 patients with a mean age of 35 years. At a mean follow-up of 7.5 years (2 to 20), 108 knees were rated as successful (85%) and 18 had failed (15%). The factors related to failure included age over 50 years, bipolar defects, and malaligned knees with overstraining of the grafts. The investigators concluded that fresh small-fragment osteochondral allografts are indicated for unipolar post-traumatic osteochondral defects of the knee in young active patients.

Gross et al. (2008) examined histologic features of 35 fresh osteochondral allograft specimens retrieved at the time of subsequent graft revision, osteotomy, or total knee arthroplasty (TKA). Histologic features of early graft failures were lack of chondrocyte viability and loss of matrix cationic staining. Histologic features of late graft failures were fracture through the graft, active and incomplete remodeling of the graft bone by the host bone, and resorption of the graft tissue by synovial inflammatory activity at graft edges. Histologic features associated with long-term allograft survival included viable chondrocytes, functional preservation of matrix, and complete replacement of the graft bone with the host bone. Given chondrocyte viability, long-term allograft survival depends on graft stability by rigid fixation of host bone to graft bone. According to the investigators, with the stable osseous graft base, the hyaline cartilage portion of the allograft can survive and function for 25 years or more.

In a prospective nonrandomized study, 60 patients with an average followup of 10 years received femoral condylar grafts. Twelve grafts failed, requiring removing of the graft in three patients and conversion to total knee replacement in nine patients. Kaplan-Meier survivorship showed 95% graft survival at 5 years and 85% at 10 years. Sixty-five patients received fresh osteochondral allografts to reconstruct the tibial plateau with an average followup of 11.8 years. In this group of patients, conversion to total knee arthroplasty was done in 21 patients at a mean interval of 9.7 years. Survival analysis revealed 95% survival at 5 years, 80% at 10 years, and 65% at 15 years. According to the investigators, this study confirms the value of fresh osteochondral allografts to reconstruct articular defects of the knee in the young active patient (Gross et al., 2005).

Emmerson et al. (2007) evaluated 66 knees in 64 patients who underwent fresh osteochondral allografting for the treatment of osteochondritis dissecans. Mean follow-up was 7.7 years (range, 2-22 years). There were 45 men and 19 women with a mean age of 28.6 years (range, 15-54 years). All patients had undergone previous surgery. Forty-one lesions involved the medial femoral condyle, and 25 involved the lateral femoral condyle. All were osteochondritis dissecans type 3 or 4. The mean allograft size was 7.5 cm(2). One knee was lost to follow-up. Of the remaining 65 knees, 47 (72%) were rated good/excellent, 7 (11%) were rated fair, and 1 (2%) was rated poor. Ten patients (15%) underwent reoperation. The authors concluded that with greater than 70% good or excellent results, fresh osteochondral allograft transplantation is a successful surgical treatment for osteochondritis dissecans of the femoral condyle.

Gortz et al. (2010) evaluated osteochondral allografts for treatment of steroid-associated osteonecrosis in 22 patients (28 knees). Patient average age was 24.3 years (range, 16-44 years). The mean graft surface area was 10.8 cm(2). The minimum followup was 25 months (mean, 67 months). Five knees failed. The graft survival rate was 89% (25 of 28). According to the authors, osteochondral allografting is a reasonable salvage option for osteonecrosis of the femoral condyles. Total knee arthroplasty (TKA) was avoided in 27 of the 28 of knees at last followup.

Fresh osteochondral allografts were used to repair articular defects in the distal femur in 72 patients. Sixty patients were available for long-term followup (mean, 10 years) to determine graft survivorship and patient outcomes. Twelve of 60 grafts failed with three having graft removal alone and nine being converted to total knee replacement. Kaplan-Meier survivorship analysis showed 85% graft survival at 10 years and 74% survival at 15 years. Patients with surviving grafts had good function, with a mean Hospital for Special Surgery score of 83 points at 10 years followup. Ten patients (17%) required meniscal transplantation whereas 41 (68%) required realignment osteotomy done simultaneously with the osteochondral allograft. Radiographs were available for 38 patients. These radiographs showed that 18 (48%) patients had no or mild arthritis, 10 (26%) had moderate, and 10 (26%) had severe arthritis. Late osteoarthritic degeneration as seen on radiographs was associated with outcomes, with patients with more severe arthritis having lower Hospital for Special Surgery scores. According to the investigators, osteochondral allograft transplantation is a valuable treatment option in patients with large osteochondral defects in the distal femoral articular surface (Aubin et al. 2001).

Several other case series (n= 9 to 25 patients) have demonstrated encouraging early results with osteochondral allograft transplantation of the knee (LaPrade et al. 2009 (n=23); Williams et al. 2007 (n=19); McCulloch et al., 2007 (n=25); Davidson et al., 2007 (n=10); et al. 2003 (n=17); Sammarco and Makwana, 2002 (n=12)). However, these were small, non-comparative studies.

Patient selection criteria for osteochondral allografting in the knee have not been definitively established. However, the available scientific evidence and medical consensus supports the use of osteochondral allografting in patients who fulfill all of the following criteria (Ghazavi et al., 1997; Bugbee and Convery, 1999):

- Have symptomatic and debilitating focal chondral lesions of an articular surface of the knee
- Failed conventional medical and surgical treatments
- Are not considered suitable candidates for total knee replacement
- Are willing to comply with extensive period of nonweightbearing and rehabilitation following surgery
- Do not have an inflammatory joint disease
- Do not have steroid-induced cartilage or bone disease
- Do not have extensive osteoarthritis
- Do not have uncorrected joint instability or malalignment

Professional Societies

Osteochondral Grafting of Knee: Medical Policy (Effective 11/01/2013)

American Academy of Orthopaedic Surgeons (AAOS): In a Clinical Practice Guideline for the diagnosis and treatment of osteochondritis dissecans, the AAOS states that they are unable to recommend for or against a specific cartilage repair technique in symptomatic skeletally immature patients with unsalvageable fragment (AAOS 2010).

An AAOS advisory statement for use of musculoskeletal tissue allografts indicates that the AAOS believes that for appropriate patients musculoskeletal allografts represent a therapeutic alternative. These tissues should be acquired from facilities that demonstrate compliance, use well-accepted banking methodology and follow Food and Drug Administration (FDA) Good Tissue Practices. The AAOS urges all tissue banks to follow rigorous national guidelines and standards and recommends the use of tissue from banks that are accredited by the American Association of Tissue Banks (AAOS 2006).

There is also sufficient evidence to support the use of osteochondral allograft of the knee in patients who are physically active, have failed standard medical and surgical treatments, and are considered too young for total knee arthroplasty.

Minced Cartilage Repair

A randomized open label active control trial comparing the Cartilage Autograft Implantation System (CAIS) to micro-fracture at 24 months as a treatment of cartilage defects of the knee was begun in July 2010 and is estimated to be completed in December 2016. No published randomized trials evaluating this technology have been identified. See the following Web site for more information: <http://clinicaltrials.gov/ct2/show/NCT00881023?term=CAIS&rank=1> Accessed September 11, 2013.

A post market study of the outcome of the DeNOVO NT Graft procedure in 25 individuals with articular cartilage defects of the knee was begun in 2006 and is estimated to be completed in December 2013 (ECRI, 2009). No published clinical trials evaluating this technology have been identified.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Transplantation of osteochondral autografts is a surgical procedure and, as such, is not subject to regulation by the FDA. However, the FDA does regulate manufacturing practice requirements applicable to drugs and devices. Devices used for mosaicplasty procedures may be classified under GEY (motor, surgical instrument, AC-powered); HRX (arthroscope); or HWE (instrument, surgical orthopedic, AC-powered motor and accessory/attachment). Note that devices listed under product codes GEY and HWE are 510(k) exempt. Although manufacturers may voluntarily submit product information via the 510(k) process, it is not a requirement. All manufacturers are, however, required to register their establishment and submit a "Device Listing" form; these records can be viewed in the [Registration and Listing Database](#) (search by product code, device, or manufacturer name). 510(k) clearance documentation for devices listed under product code HRX can be found in the [510\(k\) database](#).

Transplantation of osteochondral allografts is a surgical procedure, and as such, is not subject to regulation by the FDA. However, the FDA does regulate certain aspects of tissue banking, and tissues are subject to FDA requirements for good tissue practices, and infectious disease screening and testing, as well as to the good manufacturing practice requirements applicable to drugs and devices. See the following Web site for additional information: <http://www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm> Accessed September 11, 2013.

DeNovo NT is classified as "minimally manipulated" allograft tissue and as such is not subject to U.S. Food and Drug Administration (FDA) premarket approval or clearance processes. Minimally manipulated human tissues and transplantation of such tissues are regulated by FDA's Center for Biologics

Minced Cartilage Technique: The CAIS bone fixation staple device obtained FDA 510(K) market clearance in 2008. See the following Web site for more information:
http://www.accessdata.fda.gov/cdrh_docs/pdf7/K073281.pdf Accessed September 11, 2013.

Additional Products

Mosaicplasty System (Smith and Nephew), Osteochondral Autograft Transfer System (OATS, Arthrex, Inc.), and the COR and COR2 systems (DePuy-Mitek)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have National Coverage Determination (NCD) for osteochondral grafting of the knee. Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for [Non-Covered Services](#). (Accessed September 11, 2013)

APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

CPT [®] Code	Description
29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (e.g., mosaicplasty) (includes harvesting of the autograft[s])
29867	Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)
27415	Osteochondral allograft, knee, open
27416	Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
11/01/2013	<ul style="list-style-type: none"> Updated description of services to reflect most current clinical evidence, FDA information and references; no change to coverage rationale or list of applicable codes Archived previous version 2013T0537C