

# **Coverage Policy Manual**

Policy #: 2006006 Category: Surgery

Initiated: February 2006 Last Review: September 2018

# Osteochondral Allograft and/or Mosaicplasty for Osteochondral Defects of the Knee

## **Description:**

Chondral and osteochondral grafts are used in repair of full-thickness chondral defects involving the joint. In the case of osteochondral autografts, one or more small osteochondral plugs are harvested from non-weight-bearing sites in the knee and press fit into a prepared site in the lesion. Osteochondral allografts are typically used for larger lesions to reduce donor site morbidity. Autologous or allogeneic minced cartilage is also being evaluated as a treatment of articular cartilage lesions.

#### **Background**

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.

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.

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). Multiple cylinders may be used to fill a larger defect in a manner similar to OATS or mosaicplasty.

ProChondrix is a cellular 3D fresh cartilage matrix available through AlloSource for use in articular cartilage repair.

Filling defects with minced articular cartilage (autologous or allogeneic), is another single-stage procedure that is being investigated for cartilage repair. The Cartilage Autograft Implantation System (CAIS, Johnson and Johnson, Phase III trial) harvests cartilage and disperses chondrocytes on a scaffold in a single-stage treatment. BioCartilage® (Arthrex) consists of a micronized allogeneic cartilage matrix that is intended to provide a scaffold for microfracture. DeNovo NT Graft (Natural Tissue Graft) and DeNovo® ET Live Chondral Engineered Tissue Graft (Neocartilage) are produced by ISTO Technologies with exclusive distribution rights by Zimmer. DeNovo NT consists of manually minced cartilage tissue pieces obtained from juvenile allograft donor joints. The tissue fragments are mixed intra-operatively with fibrin glue before implantation in the prepared lesion. It is thought that mincing the tissue helps both with cell migration from the extracellular matrix and with fixation. As there is no use of chemicals and minimal manipulation, the allograft tissue does not require FDA approval for marketing. DeNovo® ET graft (Neocartilage) uses juvenile allogeneic cartilage cells engineered by ISTO Technologies. The FDA approved ISTO's Investigational New Drug (IND) application for Neocartilage in 2006, which allowed them to pursue Phase III clinical trials of the product in humans.

Autologous chondrocyte implantation (ACI) is another method of cartilage repair involving the harvesting of normal chondrocytes from normal non-weight-bearing articular surfaces, which are then cultured and expanded in vitro and implanted back into the chondral defect. ACI techniques are discussed in policy No. 1997014.

Autologous osteochondral grafts for the treatment of osteochondral defects of the knee is handled in policy No. 1998142.

# Policy/ Coverage:

## **Effective September 2018**

## Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

Osteochondral allografting as a technique to repair large full-thickness chondral defects of the knee caused by acute or repetitive trauma meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in patients who meet the following criteria:

- Defect size is greater than 2.5cm<sup>2</sup>; and
- BMI is less than 35; and
- Knee must be stable and aligned (Additional procedures for realignment and stability may be performed concurrently).

## Does Not Meet Primary Coverage Criteria Or Is Investigational For Contracts Without Primary Coverage Criteria

Osteochondral allografting for all other joints does not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes.

For members with contracts that do not have primary coverage criteria, osteochondral allografting for all other joints is considered investigational. Investigational services are considered specific contract exclusions in most member benefit certificates of coverage.

Treatment of focal articular cartilage lesions with allogeneic minced or particulated cartilage does not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes.

For members with contracts without primary coverage criteria, treatment of focal articular cartilage lesions with allogeneic minced or particulated cartilage is considered investigational. Investigational services are specific contract exclusions in most member benefit certificates of coverage.

## Effective July 2013 - August 2018

# Meets Primary Coverage Criteria Or Is Covered For Contracts Without Primary Coverage Criteria

Osteochondral allografting as a technique to repair large full-thickness chondral defects of the knee caused by acute or repetitive trauma meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness

in patients who meet the following criteria:

- Defect size is greater than 2.5cm<sup>2</sup>; and
- o BMI is less than 35; and
- Knee must be stable and aligned (Additional procedures for realignment and stability may be performed concurrently).

## Does Not Meet Primary Coverage Criteria Or Is Investigational For Contracts Without Primary Coverage Criteria

Osteochondral allografting for all other joints does not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes.

For members with contracts that do not have primary coverage criteria, osteochondral allografting for all other joints is considered investigational. Investigational services are considered specific contract exclusions in most member benefit certificates of coverage.

Treatment of focal articular cartilage lesions with allogeneic minced cartilage does not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes.

For members with contracts without primary coverage criteria, treatment of focal articular cartilage lesions with allogeneic minced cartilage is considered investigational. Investigational services are specific contract exclusions in most member benefit certificates of coverage.

# Effective July 2011 - June 2013

Osteochondral allografting as a technique to repair large full-thickness chondral defects of the knee caused by acute or repetitive trauma meets member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in patients who meet the following criteria:

- Defect size is greater than 2.5cm<sup>2</sup>; and
- BMI is less than 35; and
- Knee must be stable and aligned (Additional procedures for realignment and stability may be performed concurrently).

Osteochondral allografting for all other joints does not meet member benefit certificate primary coverage criteria that there be scientific evidence of effectiveness in improving health outcomes.

For members with contracts that do not have primary coverage criteria, osteochondral allografting for all other joints is considered investigational. Investigational services are considered specific contract exclusions in most member benefit certificates of coverage.

## **Effective Prior to July 2011**

Osteochondral allograft meets primary coverage criteria for effectiveness and is covered as a technique to repair focal chondral defects of the femur in patients who meet the following criteria:

- Symptomatic cartilaginous defect in the medial, lateral, trochlear or patellar area of the femoral condyle
- Clinically significant symptoms, acute cartilage injury

- Defect size is greater than 2.5 cm2
- Patient is less than 40 years of age
- Knee must be stable and aligned
- No evidence of more than mild osteoarthritis or inflammatory disease
- BMI is less than 30

Any other use of osteochondral allograft or mosaicplasty for osteochondral defects of the knee does not meet Primary Coverage Criteria that there be scientific evidence of effectiveness.

For contracts without Primary Coverage Criteria, any other use of osteochondral allograft or mosaicplasty for osteochondral defects of the knee is considered investigational and is not covered. Investigational services are an exclusion in the member benefit certificate.

### **Rationale:**

Gross and colleagues reported on 60 patients who received fresh femoral condylar grafts in young active patients. Kaplan-Meier survivorship showed 95% graft survival at 5 years and 85% at 10 years. If allograft incorporation does occur, the procedure is associated with improved pain, function, range of motion, and a low risk of progressive arthritis (case series, Jamali and associates).

Literature suggests that outcomes are improved with the use of fresh osteochondral allografts but this is complicated by the generalized abbreviated timeline from death until implantation. Chondrocyte survivability is best when fresh but infection screening incubation time may be too long. Human osteochondral allografts stored for approximately 3 weeks undergo decreases in cell viability in the superficial zone whereas matrix and biomechanical characteristics appear preserved.

# 2008 Update

Gross and associates (Gross AE, 2008) examined histologic features of 35 allograft specimens retrieved at the time of subsequent graft revision or other knee surgery. Graft survival time ranged from 1 to 25 years. Given chondrocyte viability, long-term allograft survival depends on graft stability by rigid fixation of host bone to graft bone.

Little clinical information has been available on the outcome of patients who have been treated with fresh allografts stored for several weeks or more. A study (Williams RJ, 2007) analyzed the clinical outcome and graft morphology in 19 patients with symptomatic chondral and osteochondral lesions of the knee who were treated with fresh allografts between 1999 and 2002. Grafts were obtained commercially, with mean storage time 30 days (17 to 42 days). The mean lesion size was 602 mm(2). Quality of Life was measured using the ADL scale and the Short Form-36. Morphology was evaluated using MRI. At mean follow-up duration of 48 months, the ADL scale increased from 56 to 70 (p<0.05) and the mean Short form-36 score increased from 51 to 66 (p<0.005). At 25 months, cartilage-sensitive MRI showed that normal articular cartilage thickness was preserved in 18 grafts, and allograft cartilage signal properties were similar to normal cartilage in 8 of the 18 grafts. Osseous trabecular incorporation of the allograft was complete or partial in 14 patients and poor in 4 patients. Trabecular incorporation correlated positively with Short Form-36 scores at follow-up. Conclusion: Fresh allografts which had been hypothermically stored for the tested duration were effective in the short term, both structurally and functionally.

# 2011 Update

A literature search was conducted through June 2011. The identified published literature is summarized below.

Harris and colleagues published a systematic review of combined meniscal allograft transplantation and cartilage repair/restoration in 2010 (Harris, 2011). Six level IV studies (case series) with a total of 110 patients were included in the review. Patients underwent meniscal allograft transplantation with either autologous chondrocyte implantation (ACI, n=73),

osteochondral allograft (n=20), osteochondral autograft (n=17) or microfracture (n=3). All studies showed improvement in clinical outcomes at final follow-up compared to the preoperative condition. Outcomes were also compared with historical outcomes of each individual procedure performed in isolation. Four of the 6 studies found outcomes equivalent to procedures performed in isolation, while 2 studies found that outcomes with combined surgery were not as good as the historical controls. Across the 6 studies, 13 failures (12%) were reported; these included 11 isolated meniscal allograft transplantation failures, 1 combined meniscal allograft and ACI failure, and 1 isolated ACI failure. Three knees with failed meniscal allograft transplantation were converted to total knee arthroplasty. Nearly 50% of the patients underwent 1 or more subsequent surgeries after combined meniscal allograft transplantation and cartilage repair/restoration procedures.

Long-term outcomes with osteochondral allografting have been reported in case series. Emmerson et al. reported mean 7.7 year follow-up (range 2-22 years) from 66 knees of 64 patients who underwent fresh osteochondral allografting for the treatment of osteochondritis dissecans of the femoral condyle (Gudas, 2005). All patients had undergone previous surgery, with an average of 1.7 prior surgeries on each knee. The mean allograft size was 7.5 cm2. One knee was lost to follow-up. Of the remaining 65 knees, 10 patients (15%) underwent reoperation, 47 (72%) were rated good to excellent and 8 (13%) were rated fair to poor. Kaplan-Meier survival analysis demonstrated 91% graft survival at 5 years and 76% graft survival at 10 and 15 years. The mean D'Aubigne and Postel score improved from 13.0 (fair) preoperatively to 16.4 (good) at the most recent follow-up. Subjective knee function improved from a mean of 3.4 to 8.4 on a 10-point scale.

Gross and colleagues reported minimum 5-year follow-up on series of 60 patients who received femoral condylar grafts and 65 patients who received tibial plateau grafts for knee defects (Gross, 2005). Eligible recipients of allografts were younger than 60 years and had traumatic unipolar osteochondral defects of at least 3 cm in diameter and 1 cm deep. If the meniscus was also significantly damaged, it was resected and replaced with allograft meniscus. Realignment of the involved leg was also performed to unload the graft. Patients were assessed preoperatively and postoperatively using the modified Hospital for Special Surgery (HSS) score. If there was no outcome data in the database within the last 12 months, the patients were contacted and a follow-up visit was arranged or a questionnaire was administered by telephone. Referring physicians were also contacted to obtain recent radiographs of the knee. Follow-up was obtained on 86% of patients who received a femoral graft (average of 10 years) and 97% of patients with a tibial graft (average of 11.8 years). For the femoral grafts, 12 failed and required graft removal or conversion to total knee replacement. At the end of the study period, 48 of the 60 femoral grafts (80%) were in situ with an average HSS score of 83 out of 100. Kaplan-Meier survival analysis showed 95% graft survival at 5 years, 85% at 10 years, and 74% at 15 years. For the tibial grafts, 21 failed at a mean interval of 9.7 years. At the end of the study, 44 of 65 tibial grafts (68%) were in situ and functioning with an HSS score > 70 points. Survival analysis revealed 95% graft survival at 5 years, 80% at 10 years, and 65% at 15 years.

## Allografts for Use in Large Defects of the Talus

Use of allografts for large defects of the talus has been reported in small case series. For example, Raikin published results from a series of 15 patients who underwent fresh matched osteochondral allograft transplantation for talar lesions with a volume > 30 cm3 (Nho, 2008). At an average 54 months after surgery (minimum of 2 years), mean visual analog scores (VAS) for pain had improved from 8.5 to 3.3 and the mean AOFAS Ankle-Hindfoot score had improved from 38 to 83 points. Two ankles had undergone conversion to fusion. Radiographic analysis revealed some evidence of collapse or resorption in 10 of the 15 ankles (67%). Gortz et al. reported on a series of 11 patients (12 ankles) who underwent fresh osteochondral allografting for unipolar lesions of the talus (Emmerson, 2007). Patients had undergone an average of 1.8 prior surgeries (range, 1 to 5). The average graft size was 3.6 cm2, which was an average of 40.5% of the talar surface. At a mean 38 month follow-up (range, 24 to 107 months) 2 of the ankles had failed and undergone revision or fusion. For the remaining 10 patients, the mean Olerud-Molander Ankle Score (OMAS) improved from a score of 28 to 71. Outcomes were categorized at good to excellent in 5 ankles (42%), fair in 3 (25%), and poor in 2 (17%). All patients demonstrated radiographic union by 6 months, with an overall graft survival rate of 83%.

## Summary

Evidence is sufficient to consider osteochondral allografting as a technique to repair large (e.g., 10 cm2) full-thickness chondral defects of the knee caused by acute or repetitive trauma. Use of allografts for large defects of the talus has been reported in small case series. Evidence is insufficient to evaluate the effect of osteochondral allografting of the talus, or other joints, on health outcomes. Therefore, osteochondral allografts for joints other than the knee are considered investigational. Recent evidence indicates that osteochondral grafting combined with meniscal allograft results in outcomes similar to either procedure performed alone; therefore the coverage statement has been changed to include combined procedures.

## 2012 Update

A literature search was conducted through June 2012. There was no new information identified that would prompt a change in the coverage statement. A summary of the relevant information is included below.

In 2011, Berlet et al. reported a prospective study with minimum follow-up of 2 years in 12 patients who had received an osteochondral allograft for talar defects (Berlet, 2011). In another patient, the graft had failed and was not included in the analysis. All patients had failed at least one prior surgical treatment and had a mean lesion size of 1.5 cm2. At follow-up (mean 3.3 years), AOFAS Ankle-Hindfoot scores improved from 61 at baseline to 79. There was a trend toward improvement in the physical or mental health components of the Short-form (SF)-12 Health Survey, although the study was underpowered to detect a significant difference. Radiographs and MRI performed yearly showed radiolucencies in 3 grafts (25%), edema in 4 (33%), and failure to incorporate for 1 graft.

El-Rashidy et al. reported a retrospective review of 38 of 42 total patients who were treated with osteochondral allografts (El-Rashidy, 2011). All patients had failed conservative management and had a mean lesion size of 1.5 cm2. Grafts were harvested from a similar anatomic location on the donor talus to match the contour and surface anatomy of the recipient bed. The average duration of follow-up was 38 months. Including scores from 4 patients (10.5%) in whom graft failure occurred, the AOFAS Ankle-Hindfoot score improved from 52 to 79 points and VAS improved from 8.2 to 3.3 points. Patient satisfaction with the outcome was rated as excellent, very good, or good by 28 of the 38 patients (74%) and as fair or poor by 10 patients (26%). Of the 15 patients who had postoperative MRI, 5 (33%) had signs of graft instability.

A search of the online site <a href="www.clinicaltrials.gov">www.clinicaltrials.gov</a> in May 2012 identified an industry-sponsored Phase IV (post-marketing) trial with Chondrofix® (NCT01410136). The study has an estimated enrollment of 50 patients who may have up to 2 cartilage lesions, each measuring less than 8 cm2, of the femoral condyle or trochlea. The study will follow patients through 60 months and has an estimated completion date of 2017.

# 2013 Update

A literature search conducted through June 2013 did not reveal any new information on the use of osteochondral allografts for the treatment defects of the knee, that would prompt a change in the coverage statement.

One study on the use of allogeneic minced cartilage was identified. Bleazey and Brigado conducted a retrospective review of 7 patients who were treated with juvenile minced cartilage (DeNovo NT) together with sponge allograft (Bleazey, 2012). All patients had failed conservative therapy (walking boot and physical therapy) and 4 patients had failed microfracture. Patients were evaluated with VAS for pain and activity at 6 month follow-up. All patients showed clinically significant improvement. Pain during walking decreased from an average of 7.7 at baseline to 1.9 at 6 months. Ability to walk 4 blocks improved from a score of 4.8 to 9.2. A statement was added to the coverage statement addressing the use of allogeneic minced cartilage.

# 2014 Update

A literature search conducted using the MEDLINE database was conducted through July 2014. There was no new information identified that would prompt a change in the coverage statement. The key identified literature is summarized below.

Allogeneic Juvenile Minced Cartilage for Use in the Knee: Evidence on the efficacy of DeNovo NT is limited to case reports and small case series. The largest series, reported in 2013 to 2014, included 13 patients (15 knees) who received particulated juvenile allograft to the patella (Tompkins, 2013). Ten of the 15 knees underwent concomitant procedures, limiting interpretation of functional outcomes. Cartilage repair assessed at a mean of 28.8 months was reported to be nearly normal in 73% of knees while 27% of knees had evidence of graft hypertrophy. Currently available evidence is insufficient to evaluate the effect of this technology on health outcomes.

Allogeneic Juvenile Minced Cartilage for Use in the Ankle: Use of DeNovo NT for the talus has been reported in small case series. The largest series is from a preliminary report of a larger study (Coetzee, 2013). The full multicenter study has a targeted enrollment of 250 patients with 5-year follow-up. In the preliminary report, 24 ankles (23 patients) with osteochondral lesions of the talus were treated with DeNovo NT. Fourteen of the ankles (58%) had failed at least 1 prior bone marrow stimulation procedure. At an average follow-up of 16.2 months, 78% of ankles had good to excellent scores on the AOFAS Ankle-Hindfoot scale with a final mean VAS of 24/100. However, 18 ankles (76%) had at least 1 concomitant procedure (hardware removal and treatment for impingement, synovitis, instability, osteophytes, malalignment), limiting interpretation of the functional results. There was 1 treatment failure caused by partial graft delamination. Bleazey and Brigado conducted a retrospective review of 7 patients who were treated with juvenile minced cartilage (DeNovo NT) together with sponge allograft.(44) All patients had failed conservative therapy (walking boot and physical therapy), and 4 patients had failed microfracture. Patients were evaluated with VAS for pain and activity at 6-month follow-up. All patients showed clinically significant improvement. Pain during walking decreased from an average of 7.7 at baseline to 1.9 at 6 months. Ability to walk 4 blocks improved from a score of 4.8 to 9.2.

# 2015 Update

A literature search conducted using the MEDLINE database through July 2015 did not identify any new information that would prompt a change in the coverage statement. The following is a summary of the key identified literature.

A 2015 systematic review by De Caro et al included 11 articles that had at least 10 patients and were published in the previous 5 years.25 There were a combined total of 374 knees in 358 patients treated with osteochondral allografting. The size of the lesions ranged from 1 to 27 cm2. Different outcome measures were used, but overall results showed improvement in objective and subjective clinical scores, a high rate of return to some level of sport or active duty, and a graft survivorship rate of 82% at 10 years and 66% at 20 years. Although bony integration was usually achieved, cartilage integration was limited. In a 2015 review of indications, techniques, and outcomes, Chui et al state that osteochondral allografting is indicated for lesions greater than 2 cm2 for which other techniques such as microfracture, osteochondral autograft transplantation, and autologous chondrocyte implantation are inadequate due to the size, location, or depth of the lesion.26 These authors also consider osteochondral allografting to be a salvage procedure for previously failed restoration treatments of the knee.

Osteochondral allografting for patellar cartilage injury was reported by Gracitelli in 2015.29 Of 28 knees (27 patients) that had osteochondral transplantation, 8 (28.6%) were considered failures and 9 (45%) required further surgery. Allograft survivorship was estimated to be 78.1% at 10 years and 55.8% at 15 years. The mean follow-up duration was 9.7 years (range, 1.8-30.1 years) for the 20 knees (71.4%) with intact grafts.

Evidence on the efficacy of DeNovo NT is limited to case reports and small case series. The largest series identified was an industry-sponsored prospective study by Farr et al, which included 25 patients with cartilage lesions of the femoral condyle or trochlea (NCT00791245).30 Patients had symptomatic, focal, contained chondral lesions of the femoral condyles or trochlea with defect areas ranging between 1 and 5 cm2 (mean, 2.7 cm2; range 1.2-4.6 cm2). The mean number of prior surgeries was 1.1, with 18 patients reporting prior débridement and/or microfracture. Patients returned for follow-up at 3, 6, 12, 18, and 24 months for radiographs, IKDC examination, and completion of questionnaires. Outcomes included the KOOS, IKDC, Marx Activity Scale, and 100-mm VAS for pain. The IKDC improved over the 24 months of follow-up. At 24 months IKDC had

improved from 45.7 preoperatively to 73.6 of 100. There were also significant improvements in KOOS subscores (p<0.001) and VAS pain score (from 43.7/100 at baseline to 11.1 at 24 months, p<0.001). MRI showed a mean lesion fill of 109.7% with mild graft hypertrophy identified in 20.7% of patients. Of 11 elective second look arthroscopies at 24 months, 2 grafts (18%) showed either partial or complete delamination. Histology from 8 patients with biopsy showed a mixture of hyaline and fibrocartilage; areas with hyaline cartilage were variable across the sections. There was good integration with the surrounding native cartilage.

## 2017 Update

A literature search conducted through August 2017 did not reveal any new information that would prompt a change in the coverage statement.

## 2018 Update

A literature search was conducted through August 2018. There was no new information identified that would prompt a change in the coverage statement. The key identified literature is summarized below.

#### **Observational Studies**

Nielsen et al identified 149 knees in 142 patients who had participated in a sport or recreational activity before a cartilage injury (Nielsen, 2017). Following treatment with one or more osteochondral allografts (mean size, 8.2 cm2), 112 (75.2%) patients had returned to the sport. Allograft survival was 91% at 5 years and 89% at 10 years; 14 knees (9.4%) were considered failures.

#### OSTEOCHONDRAL AUTOGRAFT FOR ARTICULAR CARTILAGE LESIONS OF THE ELBOW

## **Donor-Site Morbidity**

Bexkens et al conducted a meta-analysis of case series that assessed donor-site morbidity after AOT for OCD of the capitulum (Bexkens, 2017). Reviewers included 11 studies with 190 patients (range, 11-33 patients per series); most patients were adolescents. Grafts were harvested from the femoral condyle in 8 studies and from the costal-osteochondral junction in 3 studies. With donor-site morbidity defined as persistent symptoms of at least 1 year or that required intervention, morbidity was reported in 10 (7.8%) of 128 patients from the knee-to-elbow group and 1 (1.6%) of 62 in the rib-to-elbow group. A limitation of this meta-analysis was its incomplete assessment and reporting of outcomes for the donor site in the primary publications.

#### DECELLULARIZED OSTEOCHONDRAL ALLOGRAFT

Case series have suggested high failure rates for decellularized osteochondral allograft plugs (Chondrofix). A review of records for 32 patients treated by Farr et al identified failure in 23 (72%) patients when failure was defined as structural damage of the graft identified by MRI or arthroscopy, or any reoperation resulting in the removal of the allograft. Johnson et al examined records from an institutional registry of 34 patients who, following discussion of alternative cartilage repair options, chose treatment with a decellularized osteochondral allograft plug (Johnson, 2017). Patient-reported outcomes along with MRI results were recorded at 6 months, 1 year, and 2 years by independent observers. At a mean follow-up of 15.5 months (range, 6-24 months), 10 (29%) patients required revision surgery with removal of the implant. Failure rates were higher for females and larger lesions (hazard ratio, 1.9 per 1 cm2 increase; 95% CI, 1.2 to 3.1; p=0.005).

## Section Summary: Decellularized Osteochondral Allograft

The evidence on decellularized osteochondral allograft plugs has reported delamination of the implants and high failure rates.

**CPT/HCPCS:** 27415 Osteochondral allograft, knee, open

29867 Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)

## **References:**

Allen RT, Robertson CM, et al.(2005) Analysis of stored osteochondral allografts at the time of surgical implantation. Am J Sports Med 2005; 33:1479-84.

Berlet GC, Hyer CF, Philbin TM et al. (2011) Does fresh osteochondral allograft transplantation of talar osteochondral defects improve function? Clin Orthop Relat Res 2011; 469(8):2356-66.

Bexkens R, Ogink PT, Doornberg JN, et al.(2017) Donor-site morbidity after osteochondral autologous transplantation for osteochondritis dissecans of the capitellum: a systematic review and meta-analysis. Knee Surg Sports Traumatol Arthrosc. Jul 2017;25(7):2237-2246. PMID 28391550

Caldwell PE, Shelton WR.(2005) Indications for allografts. Orthop Clin N Am 2005; 36:459-67.

Coetzee JC, Giza E, Schon LC et al. (2013) Treatment of osteochondral lesions of the talus with particulated juvenile cartilage. Foot Ankle Int 2013; 34(9):1205-11.

De Caro F, Bisicchia S, Amendola A, et al.(2015) Large Fresh Osteochondral Allografts of the Knee: A Systematic Clinical and Basic Science Review of the Literature. Arthroscopy. Apr 2015;31(4):757-765. PMID 25660010

El-Rashidy H, Villacis D, Omar I et al. (2011) Fresh osteochondral allograft for the treatment of cartilage defects of the talus: a retrospective review. J Bone Joint Surg Am 2011; 93(17):1634-40.

Emmerson BC, Gortz S, Jamali AA et al.(2007) Fresh osteochondral allografting in the treatment of osteochondritis dissecans of the femoral condyle. Am J Sports Med 2007; 35(6):907-14.

Farr J, Tabet SK, Margerrison E, et al.(2014) Clinical, Radiographic, and Histological Outcomes After Cartilage Repair With Particulated Juvenile Articular Cartilage: A 2-Year Prospective Study. Am J Sports Med. Am J Sports Med. Apr 9 2014;42(6):1417-1425. PMID 24718790

Gracitelli GC, Meric G, Briggs DT, et al.(2015) Fresh osteochondral allografts in the knee: comparison of primary transplantation versus transplantation after failure of previous subchondral marrow stimulation. Am J Sports Med. Apr 2015;43(4):885-891. PMID 25817190

Gross AE, et al. (2008) Fresh osteochondral allografts for posttraumatic knee defects: long-term followup. Clin Orthop Relat Res. 2008; 446:1863.

Gross AE, Shasha N, Aubin P.(2005) Long-term followup of the use of fresh osteochondral allografts for posttraumatic knee defects. Clin Orthop Relat Res 2005; (435):79-87.

Gross AE, Shasha N, Aubin P.(2005) Long-term followup of the use of fresh osteochondral allografts for posttraumatic knee defects. Clin Orthop Relat Res 2005; Jun:79-87.

Gudas R, Kalesinskas RJ, Kimtys V et al.(2005) A prospective randomized clinical study of mosaic osteochondral autologous transplantation versus microfracture for the treatment of osteochondral defects in the knee joint in young athletes. Arthroscopy 2005; 21(9):1066-75.

Harris JD, Cavo M, Brophy R et al. (2011) Biological Knee Reconstruction: A Systematic Review of Combined Meniscal Allograft Transplantation and Cartilage Repair or Restoration. Arthroscopy 2011; 27(3):409-18.

Jamali AA, Emmerson BC, et al. (2005) Fresh osteochondral allografts. Clin Orthop Relat Res 2005; Aug: 176-85.

Johnson CC, Johnson DJ, Garcia GH, et al.(2017) High short-term failure rate associated with decellularized osteochondral allograft for treatment of knee cartilage lesions. Arthroscopy. Dec 2017;33(12):2219-2227. PMID 28967543

Karataglis D, Learmonth DJ.(2005) Management of big osteochondral defects of the knee using osteochondral allografts with the MEGA-OATS technique. Knee 2005; 12:389-93.

Nho SJ, Foo LF, Green DM et al.(2008) Magnetic resonance imaging and clinical evaluation of patellar resurfacing with press-fit osteochondral autograft plugs. Am J Sports Med 2008; 36(6):1101-9.

Nielsen ES, McCauley JC, Pulido PA, et al.(2017) Return to sport and recreational activity after osteochondral allograft transplantation in the knee. Am J Sports Med. Jun 2017;45(7):1608-1614. PMID 28375642

Raikin SM.(2009) Fresh osteochondral allografts for large-volume cystic osteochondral defects of the talus. J Bone Joint Surg Am 2009; 91(12):2818-26.

Scopp JM, Mandelbaum BR.(2005) A treament algorithm for the management of articular cartilage defects. Orthop Clin N Am 2005; 36:419-26.

Shasha N, Aubin PP, et al.(2002) Long-term clinical experience with fresh osteochondral allografts for articular knee defects in high demand patients. Cell Tissue Bank 2002; 3:175-82.

Tompkins M, Hamann JC, Diduch DR et al.(2013) Preliminary results of a novel single-stage cartilage restoration technique: particulated juvenile articular cartilage allograft for chondral defects of the patella. Arthroscopy 2013; 29(10):1661-70.

Treatment of articular cartilage defects. DeLee & Drez's Orthopedic Sports Medicine, 2nd edition 2003.

Williams RJ, et al.(2007) Fresh stored allografts for the treatment of osteochondral defects of the knee. J Bone Joing Surg Am 2007; 89:718.

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