# Protocol

# Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

(70178)

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| **Medical Benefit** | | **Effective Date**: 10/01/18 | **Next Review Date**: 07/21 |
| **Preauthorization** | No | **Review Dates**: 03/07, 05/08, 03/09, 01/10, 01/11, 09/11, 09/12, 09/13, 07/14, 07/15, 07/16, 07/17, 07/18, 07/19, 07/20 | |

***Preauthorization is not required.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

**RELATED PROTOCOLS**

Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions

Meniscal Allografts and Other Meniscal Implants

| Populations | Interventions | Comparators | Outcomes |
|---|---|---|---|
| Individuals:<br>• With full-thickness articular cartilage lesions of the knee | Interventions of interest are:<br>• Osteochondral autograft | Comparators of interest are:<br>• Marrow stimulation<br>• Autologous chondrocyte implantation | Relevant outcomes include:<br>• Symptoms<br>• Functional outcomes<br>• Quality of life<br>• Treatment-related morbidity |
| Individuals:<br>• With full-thickness articular cartilage lesions of the knee when autografting would be inadequate | Interventions of interest are:<br>• Fresh osteochondral allograft | Comparators of interest are:<br>• Marrow stimulation | Relevant outcomes include:<br>• Symptoms<br>• Functional outcomes<br>• Quality of life<br>• Treatment-related morbidity |
| Individuals:<br>• With primary full-thickness articular cartilage lesions of the ankle <1.5$cm^2$ | Interventions of interest are:<br>• Osteochondral autograft | Comparators of interest are:<br>• Marrow stimulation | Relevant outcomes include:<br>• Symptoms<br>• Functional outcomes<br>• Quality of life<br>• Treatment-related morbidity |
| Individuals:<br>• With large (>1.5 $cm^2$) or cystic (>3.0 $cm^3$) full-thickness articular cartilage lesions of the ankle | Interventions of interest are:<br>• Osteochondral autograft | Comparators of interest are:<br>• Marrow stimulation | Relevant outcomes include:<br>• Symptoms<br>• Functional outcomes<br>• Quality of life<br>• Treatment-related morbidity |
| Individuals:<br>• With osteochondral lesions of the ankle that have failed primary treatment | Interventions of interest are:<br>• Osteochondral autograft | Comparators of interest are:<br>• Marrow stimulation | Relevant outcomes include:<br>• Symptoms<br>• Functional outcomes<br>• Quality of life<br>• Treatment-related morbidity |

| Populations | Interventions | Comparators | Outcomes |
|---|---|---|---|
| Individuals:<br>• With primary full-thickness articular cartilage lesions of the ankle <1.5 $cm^2$ | Interventions of interest are:<br>• Fresh osteochondral allograft | Comparators of interest are:<br>• Marrow stimulation | Relevant outcomes include:<br>• Symptoms<br>• Functional outcomes<br>• Quality of life<br>• Treatment-related morbidity |
| Individuals:<br>• With large (>1.5 $cm^2$) or cystic (>3.0 $cm^3$) cartilage lesions of the ankle when autografting would be inadequate | Interventions of interest are:<br>• Fresh osteochondral allograft | Comparators of interest are:<br>• Osteochondral autograft | Relevant outcomes include:<br>• Symptoms<br>• Functional outcomes<br>• Quality of life<br>• Treatment-related morbidity |
| Individuals:<br>• With revision osteochondral lesions of the ankle when autografting would be inadequate | Interventions of interest are:<br>• Fresh osteochondral allograft | Comparators of interest are:<br>• Osteochondral autograft | Relevant outcomes include:<br>• Symptoms<br>• Functional outcomes<br>• Quality of life<br>• Treatment-related morbidity |
| Individuals:<br>• With full-thickness articular cartilage lesions of the elbow | Interventions of interest are:<br>• Fresh osteochondral autograft | Comparators of interest are:<br>• Marrow stimulation | Relevant outcomes include:<br>• Symptoms<br>• Functional outcomes<br>• Quality of life<br>• Treatment-related morbidity |
| Individuals:<br>• With full-thickness articular cartilage lesions of the shoulder | Interventions of interest are:<br>• Osteochondral autograft | Comparators of interest are:<br>• Marrow stimulation | Relevant outcomes include:<br>• Symptoms<br>• Functional outcomes<br>• Quality of life<br>• Treatment-related morbidity |
| Individuals:<br>• With full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder | Interventions of interest are:<br>• Autologous or allogeneic minced or particulated articular cartilage | Comparators of interest are:<br>• Marrow stimulation<br>• Autologous chondro-cyte implantation | Relevant outcomes include:<br>• Symptoms<br>• Functional outcomes<br>• Quality of life<br>• Treatment-related morbidity |
| Individuals:<br>• With full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder | Interventions of interest are:<br>• Decellularized osteochondral allograft plugs | Comparators of interest are:<br>• Marrow stimulation | Relevant outcomes include:<br>• Symptoms<br>• Functional outcomes<br>• Quality of life<br>• Treatment-related morbidity |
| Individuals:<br>• With full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder | Interventions of interest are:<br>• Reduced osteochondral allograft discs | Comparators of interest are:<br>• Marrow stimulation | Relevant outcomes include:<br>• Symptoms<br>• Functional outcomes<br>• Quality of life<br>• Treatment-related morbidity |

## DESCRIPTION

Osteochondral grafts are used to repair full-thickness chondral defects involving a joint. In the case of osteochondral autografts, one or more small osteochondral plugs are harvested from non-weight-bearing sites, usually from the knee, and press fit into a prepared site in the lesion. Osteochondral allografts are typically used

for larger lesions. Autologous or allogeneic minced cartilage, decellularized osteochondral allograft plugs, and reduced osteochondral allograft discs are also being evaluated as a treatment of articular cartilage lesions.

**SUMMARY OF EVIDENCE**

The following conclusions are based on a review of the evidence, including but not limited to published evidence and clinical expert opinion, solicited via BCBSA's Clinical Input Process.

KNEE LESIONS

For individuals who have full-thickness articular cartilage lesions of the knee who receive an osteochondral autograft, the evidence includes randomized controlled trials (RCTs), systematic reviews of RCTs, and longer term observational studies. The relevant outcomes are symptoms, functional outcomes, quality of life (QOL), and treatment-related morbidity. Several systematic reviews have evaluated osteochondral autografting for cartilage repair in the short- and mid-term. Compared with abrasion techniques (e.g., microfracture, drilling), there is evidence that osteochondral autografting decreases failure rates and improves outcomes in patients with medium-size lesions (e.g., 2-6 $cm^2$) when measured at longer follow-up. This is believed to be due to the higher durability of hyaline cartilage compared with fibrocartilage from abrasion techniques. There appears to be a relatively narrow range of lesion size for which osteochondral autografting is most effective. The best results have also been observed with lesions on the femoral condyles, although treatment of lesions on the trochlea and patella may also improve outcomes. Correction of malalignment is important for the success of the procedure. The evidence suggests that osteochondral autografts may be considered an option for moderate-sized symptomatic full-thickness chondral lesions of the femoral condyle, trochlea, or patella. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have full-thickness articular cartilage lesions of the knee when autografting would be inadequate due to lesion size, location, or depth who receive a fresh osteochondral allograft, the evidence includes case series. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Due to the lack of alternatives, this procedure may be considered a salvage operation in younger patients for full-thickness chondral defects of the knee caused by acute or repetitive trauma when other cartilage repair techniques (e.g., microfracture, osteochondral autografting, autologous chondrocyte implantation) would be inadequate due to lesion size, location, or depth. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

ANKLE LESIONS

For individuals who have primary full-thickness articular cartilage lesions of the ankle less than 1.5 $cm^2$ who receive an osteochondral autograft, the evidence includes observational studies and a systematic review of these studies. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. A systematic review found similar improvements in outcomes following microfracture and autologous osteochondral transplantation (AOT). Given the success of marrow stimulation procedures for smaller lesions (<1.5 $cm^2$) and the increase in donor-site morbidity with graft harvest from the knee, current evidence does not support the use of AOT as a primary treatment for smaller articular cartilage lesions of the ankle. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have large (area >1.5 $cm^2$) or cystic (volume >3.0 $cm^3$) full-thickness articular cartilage lesions of the ankle who receive an osteochondral autograft, the evidence includes an RCT and several observational studies. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. An RCT in patients with large lesions found similar efficacy for AOT, marrow stimulation, and arthroplasty at two-year follow-up. Longer term results were not reported in the RCT. However, observational studies with longer term follow-up (four to five years) have shown favorable results for patients with large or cystic lesions

receiving osteochondral autograft transplantation. Limitations of the published evidence preclude determining the effects of the technology on health outcomes. Evidence reported through clinical input supports that the use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. Studies on the standard treatment for ankle lesions, marrow stimulation, have reported positive outcomes for patients with small lesions of the ankle (<1.5 $cm^2$) but have generally reported high failure rates for patients with large (>1.5 $cm^2$) lesions. Because the standard treatment has been shown to be less effective on larger lesions, there is support in the clinical community for osteochondral autografts in patients with large lesions of the ankle. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have osteochondral lesions of the ankle that have failed primary treatment who receive an osteochondral autograft, the evidence includes two nonrandomized comparative trials and several case series. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. The best evidence for revision AOT comes from a nonrandomized comparative study that found better outcomes with AOT than with repeat marrow stimulation. This finding is supported by case series that have indicated good-to-excellent results at mid-term and longer term follow-up with revision AOT. The published evidence supports a meaningful improvement in the net health outcome. Evidence reported through clinical input further supports that this use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have primary full-thickness articular cartilage lesions of the ankle less than 1.5 $cm^2$ who receive a fresh osteochondral allograft, there is little evidence. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Because microfracture is effective as a primary treatment for lesions less than 1.5 $cm^2$ and AOT is effective as a revision procedure, use of allograft for small primary cartilage lesions has not been reported. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have large (area >1.5 $cm^2$) or cystic (volume >3.0 $cm^3$) cartilage lesions of the ankle when autografting would be inadequate who receive a fresh osteochondral allograft, the evidence includes a small number of patients in an RCT, case series, and a systematic review of case series. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. The majority of patients in the RCT were patients with revision osteochondral lesions, so conclusions about the few patients with primary lesions could not be made. The systematic review of case series reported improvements in ankle scores and decreases in pain scores, though 25% of patients needed additional surgery and 13% experienced either graft nonunion, resorption, or symptom persistence. Limitations of the published evidence preclude determining the effects of the technology on health outcomes. Evidence reported through clinical input supports that the use provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. For particularly large lesions, marrow stimulation techniques have been found to be ineffective and obtaining an adequate volume of autograft may cause significant morbidity. For these reasons, osteochondral allografts may be a considered option for large lesions of the ankle. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have revision osteochondral lesions of the ankle when autografting would be inadequate who receive a fresh osteochondral allograft, the evidence includes an RCT. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Most of the patients in the RCT had failed a prior microfracture. The RCT found that outcomes were statistically similar with osteochondral allografts compared with autografts. However, failure rates due to nonunion were higher in patients in the allograft group compared with patients in the autograft group. Limitations of the published evidence preclude determining the effects of the technology on health outcomes. Evidence reported through clinical input supports that the use

provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice. For particularly large lesions, marrow stimulation techniques have been found to be ineffective and obtaining an adequate volume of autograft may cause significant morbidity. For these reasons, osteochondral allografts may be a considered option for revision of large lesions of the ankle. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

ELBOW LESIONS

For individuals who have full-thickness articular cartilage lesions of the elbow who receive an osteochondral autograft, the evidence includes a meta-analysis of case series. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Osteochondritis dissecans of the elbow typically occurs in patients who play baseball or do gymnastics. The literature on osteochondral autografts for advanced osteochondritis dissecans of the elbow consists of small case series, primarily from Europe and Asia, and a systematic review of case series. Although the meta-analysis suggested a benefit of osteochondral autographs compared with débridement or fixation, RCTs are needed to determine the effects of the procedure with greater certainty. The evidence is insufficient to determine the effects of the technology on health outcomes.

SHOULDER LESIONS

For individuals who have full-thickness articular cartilage lesions of the shoulder who receive an osteochondral autograft, the evidence includes a case series. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. Evidence on osteochondral autografting for the shoulder is very limited. The evidence is insufficient to determine the effects of the technology on health outcomes.

KNEE, ANKLE, ELBOW, OR SHOULDER LESIONS

For individuals who have full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder who receive autologous or allogeneic minced or particulated articular cartilage, the evidence includes a small RCT and small case series. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. The evidence on autologous minced cartilage includes a small RCT. The evidence on allogeneic juvenile minced cartilage includes a few small case series. The case series have suggested an improvement in outcomes compared with preoperative measures but there is also evidence of subchondral edema, nonhomogeneous surface, graft hypertrophy, and delamination. For articular cartilage lesions of the knee, further evidence, preferably from RCTs, is needed to evaluate the effect on health outcomes compared with other procedures. There are fewer options for articular cartilage lesions of the ankle. However, further study in a larger number of patients is needed to assess the short- and long-term effectiveness of this technology. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder who receive decellularized osteochondral allograft plugs or reduced osteochondral allograft discs, the evidence includes small case series. The relevant outcomes are symptoms, functional outcomes, QOL, and treatment-related morbidity. The case series on decellularized osteochondral allograft plugs reported delamination of the implants, and high failure rates. Evidence on reduced osteochondral allograft discs consists only of case reports and very small case series. The evidence is insufficient to determine the effects of the technology on health outcomes.

Clinical input obtained in 2017 supports that the following indications provide a clinically meaningful improvement in the net health outcome and are consistent with generally accepted medical practice.

- Use of osteochondral autograft for:
  - Primary treatment of large (area >1.5 $cm^2$) or cystic (volume >3.0 $cm^3$) osteochondral lesion of the talus.
  - Revision surgery after failed marrow stimulation for osteochondral lesion of the talus.

- Use of fresh osteochondral allograft for:
  - Primary treatment of large (area >1.5 $cm^2$) or cystic (volume >3.0 $cm^3$) osteochondral lesion of the talus when autografting would be inadequate due to lesion size, depth, or location.
  - Revision surgery for osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth, or location.

Thus, the above indications may be considered medically necessary considering the suggestive evidence and clinical input support.

However, the clinical input does not support whether the following indication provides a clinically meaningful improvement in the net health outcome or is consistent with generally accepted medical practice.

- Use of osteochondral grafts in the elbow.

Thus, the above indication may be considered investigational.

**POLICY**

Fresh osteochondral allografting may be considered **medically necessary** as a technique to repair:

- Full-thickness chondral defects of the knee caused by acute or repetitive trauma when other cartilage repair techniques (e.g., microfracture, osteochondral autografting or autologous chondrocyte implantation) would be inadequate due to lesion size, depth or location.
- Large (area >1.5 $cm^2$) or cystic (volume >3.0 $cm^3$) osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth, or location.
- Revision surgery after failed prior marrow stimulation for large (area >1.5 $cm^2$) or cystic (volume >3.0 $cm^3$) osteochondral lesions of the talus when autografting would be inadequate due to lesion size, depth or location.

Osteochondral allografting for all other joints is considered **investigational**.

Osteochondral autografting, using one or more cores of osteochondral tissue, may be considered **medically necessary:**

- For the treatment of symptomatic full-thickness cartilage defects of the knee 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., 55 years of age or younger)
  - Focal, full thickness (grade III or IV) unipolar lesions on the weight-bearing surface of the femoral condyles, trochlea, or patella that are between one 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.
- Large (area >1.5 $cm^2$) or cystic (volume >3.0 $cm^3$) osteochondral lesions of the talus.

- Revision surgery after failed marrow stimulation for osteochondral lesion of the talus.

Osteochondral autografting for all other joints, and any indications other than those listed above, is considered **investigational**.

Treatment of focal articular cartilage lesions with autologous minced or particulated cartilage is considered **investigational**.

Treatment of focal articular cartilage lesions with allogeneic minced or particulated cartilage is considered **investigational**.

Treatment of focal articular cartilage lesions with decellularized osteochondral allograft plugs (e.g., Chondrofix) is considered **investigational**.

Treatment of focal articular cartilage lesions with reduced osteochondral allograft discs (e.g., ProChondrix, Cartiform) is considered **investigational**.

## POLICY GUIDELINES

If débridement is the only prior surgical treatment, consideration should be given to marrow-stimulating techniques before osteochondral grafting is performed, particularly for lesions less than 1.5 $cm^2$ in area or 3.0 $cm^3$ in volume.

Severe obesity (e.g., body mass index 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. In addition, meniscal allograft transplantation may be performed in combination, either concurrently or sequentially, with osteochondral allografting or osteochondral autografting.

## BACKGROUND

ARTICULAR CARTILAGE LESIONS

Damaged articular cartilage can be associated with pain, loss of function, and disability, and can lead to debilitating osteoarthrosis over time. These manifestations can severely impair an individual's activities of daily living and quality of life. The vast majority of osteochondral lesions occur in the knee with the talar dome and capitulum being the next most frequent sites. The most common locations of lesions are the medial femoral condyle (69%), followed by the weight-bearing portion of the lateral femoral condyle (15%), the patella (5%), and trochlear fossa.[1] Talar lesions are reported to be about 4% of osteochondral lesions.[2]

Treatment

There are two main goals of conventional therapy for patients who have significant focal defects of the articular cartilage: symptom relief and articular surface restoration.

First, there are procedures intended primarily to achieve symptomatic relief: débridement (removal of debris and diseased cartilage) and rehabilitation. Second, there are procedures intended to restore the articular surface. Treatments may be targeted to the focal cartilage lesion, and most such treatments induce local bleeding, fibrin clot formation, and resultant fibrocartilage growth. These marrow stimulation procedures include microfracture, abrasion arthroplasty, and drilling, all of which are considered standard therapies.

*Microfracture*

Microfracture is an arthroscopic procedure in which a small pick creates a network of holes at the base of the articular cartilage lesion, allowing blood into the injured area to form clots and subsequent fibrocartilage growth. Efficacy of the microfracture technique for articular cartilage lesions of the knee was examined by Mithoefer et al (2009) in a systematic review.[3] Twenty-eight studies (total n=3122 patients) were selected; six studies were randomized controlled trials. Microfracture was found to improve knee function in all studies during the first 24 months after the procedure but the reports on durability were conflicting. A prospective longitudinal study of 110 patients by Solheim et al (2016) found that, at a mean of 12 years (range, 10-14 years) after microfracture, 45.5% of patients had poor outcomes, including 43 patients who required additional surgery.[4] The size of the lesion has also been shown to affect outcomes following marrow stimulation procedures.

*Abrasion and Drilling*

Abrasion and drilling are techniques to remove damaged cartilage. Instead of a drill, high speed burrs are used in the abrasion procedure.

Fibrocartilage is generally considered to be less durable and mechanically inferior to the original articular cartilage. Thus, various strategies for chondral resurfacing with hyaline cartilage have been investigated. Alternatively, treatments of very extensive and severe cartilage defects may resort to complete replacement of the articular surface either by osteochondral allotransplant or artificial knee replacement.

*Osteochondral Grafting*

Autologous or allogeneic grafts of osteochondral or chondral tissue have been proposed as treatment alternatives for patients who have clinically significant, symptomatic, focal defects of the articular cartilage. It is hypothesized that the implanted graft's chondrocytes retain features of hyaline cartilage that is similar in composition and property to the original articulating surface of the joint. If true, the restoration of a hyaline cartilage surface might restore the integrity of the joint surface and promote long-term tissue repair, thereby improving function and delaying or preventing further deterioration.

Both fresh and cryopreserved allogeneic osteochondral grafts have been used with some success. However, cryopreservation decreases the viability of cartilage cells and fresh allografts may be difficult to obtain and create concerns regarding infectious diseases. As a result, 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 & Nephew), the OATS (Osteochondral Autograft Transfer System; Arthrex), and the COR and COR2 systems (DePuy Mitek). Although mosaicplasty and autologous osteochondral transplantation (AOT) may use different instrumentation, the underlying mode of repair is similar (i.e., 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.

Preparation of the chondral lesion involves débridement 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 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 or AOT 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 been used to repair chondral defects of the patella, tibia, and ankle. With osteochondral autografting, the harvesting and transplantation can be performed during the same surgical procedure. Technical limitations of osteochondral autografting are difficulty in restoring concave or convex articular surfaces, the incongruity of articular surfaces that can alter joint contact pressures, short-term fixation strength and load-bearing capacity, donor-site morbidity, and lack of peripheral integration with peripheral chondrocyte death.

Reddy et al (2007) evaluated donor-site morbidity in 11 of 15 patients who had undergone graft harvest from the knee (mean, 2.9 plugs) for treatment of osteochondral lesions of the talus.[5] At an average 47-month follow-up (range, seven-77 months), five patients were rated as having an excellent Lysholm Knee Scale score (95-100 points), two as good (84-94 points), and four as poor (≤64 points). The reported knee problems were instability in daily activities, pain after walking one mile or more, slight limp, and difficulty squatting. Hangody et al (2001) reported that some patients had slight or moderate complaints with physical activity during the first postoperative year but there was no long-term donor-site pain in a series of 36 patients evaluated two to seven years after AOT.[6]

Filling defects with minced or particulated articular cartilage (autologous or allogeneic) is another single-stage procedure being investigated for cartilage repair. The Cartilage Autograft Implantation System (Johnson & Johnson) harvests cartilage and disperses chondrocytes on a scaffold in a single-stage treatment. The Reveille Cartilage Processor (Exactech Biologics) has a high-speed blade and sieve to cut autologous cartilage into small particles for implantation. BioCartilage (Arthrex) consists of a micronized allogeneic cartilage matrix that is intended to provide a scaffold for microfracture. DeNovo NT Graft (Natural Tissue Graft) is produced by ISTO Technologies and distributed by Zimmer. DeNovo NT consists of manually minced cartilage tissue pieces obtained from juvenile allograft donor joints. The tissue fragments are mixed intraoperatively 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.

A minimally processed osteochondral allograft (Chondrofix; Zimmer) is now available. Chondrofix is composed of decellularized hyaline cartilage and cancellous bone; it 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 AOT or mosaicplasty.

ProChondrix (AlloSource) and Cartiform (Arthrex) are wafer-thin allografts where the bony portion of the allograft is reduced. The discs are laser etched or porated and contain hyaline cartilage with chondrocytes, growth factors, and extracellular matrix proteins. ProChondrix is available in dimensions from 7 to 20 mm and is stored fresh for a maximum of 28 days. Cartiform is cut to the desired size and shape and is stored frozen for a maximum of two years. The osteochondral discs are typically inserted after microfracture and secured in place with fibrin glue and/or sutures.

Autologous chondrocyte implantation 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. Autologous chondrocyte implantation techniques are discussed in the Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions Protocol.

**REGULATORY STATUS**

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation, title 21, parts 1270 and 1271. Osteochondral grafts are included in these regulations.

DeNovo® ET Live Chondral Engineered Tissue Graft (Neocartilage) is marketed by ISTO Technologies outside of the United States. The Food and Drug Administration approved ISTO's investigational new drug application for Neocartilage in 2006, which allowed ISTO to pursue phase 3 clinical trials of the product in human subjects. However, ISTO's clinical trial for Neocartilage was terminated due to poor enrollment as of August 31, 2017.

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Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

**REFERENCES**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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