BlueCross BlueShield of Alabama

Medical and Drug Policies

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

Policy Number: MP-248

Latest Review Date: June 2018

Category: Surgery

Policy Grade: B

Description of Procedure or Service:

Osteochondral grafts are used in repair of 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 in 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.

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. Talar lesions are reported to be about 4% of osteochondral lesions.

Treatment

There are 2 main categories 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: abrasion arthroplasty, microfracture, and drilling, all of which are considered standard therapies.

Microfracture

Efficacy of the microfracture technique for articular cartilage lesions of the knee was examined in a 2009 systematic review. Twenty-eight studies (total N=3122 patients) were selected; 6 studies were randomized controlled trials (RCTs). 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. The size of the lesion has also been shown to have an effect on outcomes following marrow stimulation procedures.

Abrasion

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, although 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 and 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, 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. At an average 47-month follow-up (range, 7-77 months), 5 patients were rated as having an excellent Lysholm Knee Scale score (95-100 points), 2 as good (84-94 points), and 4 as poor (≤64 points). Reported knee problems were instability in daily activities, pain after walking 1 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 2 to 7 years after AOT.

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 (CAIS; Johnson and 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 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 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) 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 (7-15mm). 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 2 years. The osteochondral discs are typically inserted after microfracture and secured in place with fibrin glue and/or sutures.

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. These techniques are discussed in policy #156 Autologous Chondrocyte Implantation for Focal Articular Cartilage Lesions.

Policy:

Effective for dates of service on or after July 12, 2017:

Osteochondral Allografting

Osteochondral allografting may be **considered medically necessary** as a technique to repair the following:

1. 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 size, location, or depth of the lesion
2. 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.
3. 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 **not medically necessary** and **investigational**.

Osteochondral Autografting

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

1. 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., younger than 55 years);
    - Focal, full-thickness (Grade III or IV) unipolar lesions on the weight-bearing surface of the femoral condyles, trochlea or patella that are between 1 and 2.5cm^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.
2. Large (area >1.5 cm^2) or cystic (volume >3.0 cm^3) osteochondral lesions of the talus.
3. 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 not medically necessary** and **investigational.**

Meniscal Allograft Transplant

Meniscal allograft transplantation may be considered medically necessary when performed concurrently or sequentially with osteochondral allografting or osteochondral autografting.

Treatment of focal articular cartilage lesions with autologous minced or particulated cartilage is considered **not medically necessary** and **investigational**.

Treatment of focal articular cartilage lesions with allogeneic minced or particulated cartilage is considered **not medically necessary** and **investigational**.

Treatment of focal articular cartilage lesions with decellularized osteochondral allograft (e.g., Chondrofix) **is considered not medically necessary** and **investigational.**

Treatment of focal articular cartilage lesions with reduced osteochondral allograft discs (e.g., ProChondrix, Cartiform) **is considered not medically necessary** and **investigational.**

Effective for dates of service March 12, 2017 through July 11, 2017:

Osteochondral Allografting

Osteochondral Allografting as a technique to repair **large 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 size, location, or depth of the lesion may be **considered medically necessary**.

Osteochondral Allografting for all other joints is considered **not medically necessary** and **investigational**.

Osteochondral Autografting

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., younger than 55 years);
- Focal, full-thickness (Grade III or IV) unipolar lesions on the weight-bearing surface of the femoral condyles, trochlea or patella that are between 1 and 2.5cm^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.

Osteochondral autografting for all other joints, including talar, and any indications other than those listed above **is considered not medically necessary** and **investigational.**

Treatment of focal articular cartilage lesions with autologous minced cartilage is considered **not medically necessary** and **investigational**.

Treatment of focal articular cartilage lesions with allogeneic minced cartilage is considered **not medically necessary** and **investigational**.

Treatment of focal articular cartilage lesions with decellularized osteochondral allograft (e.g., Chondrofix) is considered **not medically necessary** and **investigational**.

Treatment of focal articular cartilage lesions with reduced osteochondral allograft discs (e.g., ProChondrix, Cartiform) is considered **not medically necessary** and **investigational**.

Meniscal Allograft Transplant

Meniscal allograft transplantation may be considered medically necessary when performed concurrently or sequentially with osteochondral allografting or osteochondral autografting.

Effective for dates of service on or after June 30, 2015 through March 11, 2017:

Osteochondral Allografting

Osteochondral Allografting as a technique to repair **large 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 size, location, or depth of the lesion may be **considered medically necessary**.

Osteochondral Allografting for all other joints is considered **not medically necessary** and **investigational**..

Osteochondral Autografting

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., younger than 55 years);

- Focal, full-thickness (Grade III or IV) unipolar lesions on the weight-bearing surface of the femoral condyles, trochlea or patella that are between 1 and 2.5cm^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.

Osteochondral autografting for all other joints, including talar, and any indications other than those listed above **is considered not medically necessary and investigational.**.

Treatment of focal articular cartilage lesions with autologous minced cartilage is considered **not medically necessary** and **investigational**..

Treatment of focal articular cartilage lesions with allogeneic minced cartilage is considered **not medically necessary** and **investigational**.

Meniscal Allograft Transplant

Meniscal allograft transplantation may be considered medically necessary when performed concurrently or sequentially with osteochondral allografting or osteochondral autografting.

Key Points:

This evidence review has been updated periodically with searches of the MEDLINE database. The most recent literature update was performed through February 5, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Osteochondral Autograft for Articular Cartilage Lesions of the Knee

The evidence on osteochondral autograft transplantation surgery (AOT) for articular cartilage lesions of the knee includes systematic reviews and a number of RCTs that compare outcomes from AOT with marrow stimulation or ACI.

Systematic Reviews

A 2016 Cochrane review by Gracitelli et al evaluated surgical interventions (microfracture, drilling, osteochondral autografts, and allograft transplantation) for the treatment of isolated cartilage defects of the knee in adults. Three RCTs selected compared AOT to microfracture for isolated cartilage defects. The evidence was considered of very low quality with high or unclear risk of bias.

In a 2008 systematic review by Magnussen et al, at short-term follow-up, neither of the "advanced" cartilage repair techniques (osteochondral transplantation or autologous chondrocyte transplantation) showed superior outcomes compared with traditional abrasive techniques. Based on evidence from 5 RCTs and 1 prospective comparative trial, reviewers concluded that no single technique produced superior clinical results for treatment of articular cartilage defects, however, "any differences in outcome based on the formation of articular rather than fibrocartilage in the defect may be quite subtle and only reveal themselves after many years of follow-up. Similarly, complications such as donor-site morbidity in AOT may be late in their presentation and thus not be detected at short follow-up."

However, in a mid-term meta-analysis that included 5 RCTs, Pareek et al (2016) found that Tegner Activity Scale (TAS) scores were higher and failure rates lower with AOT compared to microfracture. In subgroup analysis, activity scores were higher in the subset of patients treated with AOT who had lesions greater than 3 cm^2 at midterm follow-up.

In a 2011 systematic review, Harris et al evaluated whether outcomes from cartilage repair/restoration techniques remained successful if combined with meniscal allograft. Six level IV studies (case series) with 110 patients were included in the review. Patients underwent meniscal allograft transplantation with either ACI (n=73), osteochondral allograft (n=20), osteochondral autograft (n=17), or microfracture (n=3). All studies showed improved clinical outcomes at final follow-up compared with the preoperative condition. Outcomes were also compared with historical outcomes of each procedure performed in isolation. Four of the 6 studies found outcomes equivalent to procedures performed in isolation, suggesting that the combined procedures did not result in poorer outcomes.

While observational studies do not provide evidence of efficacy or comparative efficacy, they may provide information about the durability of any observed improvements and potential impacts of patient selection factors. Observational studies have reported longer term outcomes and an impact of sex, age, and size and location of the lesion.

Hangody, who first reported use of the mosaicplasty technique in humans in 1992, has coauthored a number of summaries and case series. Based on their experience with this procedure, Hangody et al considered the optimal indications to be lesions 1 to 4 cm^2 in diameter, patients 50 years of age or younger (due to decreased repair capacity with aging), and correction of instability, malalignment, and meniscal or ligamental tears. Solheim et al (2010, 2013) reported 5- to 9-year (N=69) and 10- to 14-year (N=73) follow-up from patients treated for 1 to 5 cm^2 in area. The LKS score improved from 49 at baseline to 72 at mid-term and long-term follow-up. The Lysholm Knee Scale scores and visual analog scale (VAS) scores for pain improved at mid-term follow-up and long-term follow-up. However, a poor outcome, defined as a Lysholm score of 64 or less or subsequent knee replacement, was observed in 40% of the patients by 10 to 14 years. Factors associated with a poor outcome were patient age (≥40 years at the time of surgery), female sex, and articular cartilage defects of 3 cm^2 or more. The failure rate was 83% for females 40 years or older with a defect area of 3 cm^2 or more compared to 12.5% for males younger than 40 years old with an articular cartilage defect less than 3 cm^2.

The importance of concomitant realignment procedures is addressed by other studies. Marcacci et al (2007) described 7-year follow-up for 30 patients treated with AOT for symptomatic grade III to IV chondral lesions (average, 1.9 cm; range, 1.0-2.5 cm). Nineteen patients received other procedures (anterior cruciate ligament reconstruction, meniscectomy, medial collateral ligament repair) at the same time. Magnetic resonance imaging (MRI) at 7 years showed complete bone integration in 96% of patients, complete integration of the grafted cartilage in 75% of cases, complete filling of the cartilage defect in 63%, and congruency of the articular surface in “some” patients.

Other publications have reported on improved outcomes following AOT for patellar lesions. For example, a prospective study by Astur et al (2014) analyzed 33 patients with symptomatic patellar lesions (diameter, 1-2.5 cm) treated with AOT. At a minimum 2-year follow-up (range, 24-54 months), all patients were reported to have significant improvements in functional scores, as measured by the Lysholm Knee Scale, Kujala, and

Fulkerson scores and the 36-Item Short-Form Health Survey quality of life score. In a series of 22 patients (mean lesion size, 1.6 cm2). Nho et al (2008) reported that both the International Knee Documentation Committee Subjective Knee Evaluation Form (IKDC) and the activity of daily living scores increased significantly from preoperatively to 29-month follow-up following patellar resurfacing.

Subsection Summary: Systematic Reviews

Several systematic reviews of RCTs have evaluated AOT for cartilage repair of the knee in the short and mid-term. The RCTs are not high quality, and not all reviews found a benefit compared with abrasion techniques. However, compared with abrasion techniques (eg microfracture, drilling), there is evidence that AOT decreases failure rates and improves outcomes in patients with medium-size lesions (e.g., 2-6 cm2) when measured at longer follow-up. This is believed to be due to better durability of the natural hyaline cartilage compared with the fibrocartilage that is obtained with abrasion techniques. Factors shown to affect success in observational studies are younger male patients with lesions smaller than 3 cm2. Thus, there is a relatively narrow range of lesion size for which AOT is most effective. In addition, the best results have been observed with lesions on the femoral condyles, although treatment of trochlea and patella lesions also improves outcomes. Correction of malalignment is important for the success of the procedure.

Fresh Osteochondral Allograft for Articular Cartilage Lesions of the Knee

Systematic Reviews

The 2016 Cochrane review by Gracitelli et al did not identify any RCTs on fresh allograft transplantation.

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. There were a combined total of 374 knees in 358 patients treated with fresh osteochondral allografting. The size of the lesions ranged from 1 to 27 cm^2. 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 (2015) state that fresh osteochondral allografting is indicated for lesions greater than $2cm^2$ 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. Reviewers also considered fresh osteochondral allografting to be a salvage procedure for previously failed restoration treatments of the knee.

Observational Studies

Nielsen et al (2017) identified 149 knees in 142 patients who had participated in a sport or recreational activity before a cartilage injury. 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.

Fresh osteochondral allografting for patellar cartilage injury was reported by Gracitelli in 2015. Of 28 knees (27 patients) that had osteochondral transplantation, eight (28.6%) were considered failures and nine (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.

Section Summary: Fresh Osteochondral Allograft for Articular Cartilage Lesions of the Knee

The evidence on fresh osteochondral allografts for articular cartilage lesions includes case series and systematic reviews of case series. Due to the lack of alternatives, this fresh allograft 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, ACI) would be inadequate due to the size, location, or depth.

Osteochondral Autografting for Articular Cartilage Lesions of the Ankle

Osteochondral Autograft for Articular Cartilage Lesions of the Ankle Less Than 1.5 cm^2

Osteochondral lesions of the talus are typically associated with ankle sprain or fracture, but comprise a relatively small proportion of lesions (~4%) compared to cartilage lesions of the knee joint. Therefore, RCTs on AOT for talar lesions may be limited. One RCT with 32 patients, case series, and a systematic review of these studies have been identified on AOT for lesions of the talus.

Zengerink et al (2010) published a systematic review of treatment of osteochondral lesions of the talus. Fifty-one nonrandomized and 1 randomized trial were included. Studies described a variety of lesion sizes, some cystic, some as primary treatment, and some after a failed arthroscopic procedure, with follow-up of at least 6 months. Success rates averaged 85% for bone marrow stimulation, 87% for osteochondral autografting, and 76% for ACI. Because of the high cost of ACI and the knee morbidity seen with osteochondral autografting, the review concluded that bone marrow stimulation is the treatment of choice for primary osteochondral talar lesions. However, analysis was not conducted to assess the relation between lesion characteristics and success rates, limiting interpretation of these results.

The following sections review the evidence for lesions that have failed a prior arthroscopic procedure, and for larger lesions, defined as at least 1.5 cm^2 in size. This size threshold is derived from studies that have determined bone marrow stimulation procedures for articular cartilage lesions of the talus that are at least 1.5 cm^2 in area have lower success rates than for those for smaller lesions. For lesions less than 1.5 cm^2 in size, multiple studies have shown high success rates with marrow stimulation alone. Because of the increase in morbidity with AOT, marrow stimulation would be the most appropriate treatment for small primary lesions. Of the relatively small number of talar osteochondral lesions, about 20% will be considered too large for marrow stimulation. This series reported by Choi et al (2009) also estimated that failure rate following marrow stimulation was 10.5% for lesions less than 1.5 cm^2; whereas 80% of lesions at least 1.5 cm^2 failed after a marrow stimulation procedure.

Subsection Summary: Osteochondral Autograft for Articular Cartilage Lesions of the Ankle Less Than 1.5 cm^2

For the use of osteochondral autograft for repair of articular cartilage lesions of the ankle that are less than 1.5 cm^2 in area, a systematic review found similar improvements in outcomes following microfracture and AOT. However, 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 ankle lesions.

Osteochondral Autograft for the Primary Treatment of Large (>1.5 cm^2) or Cystic Articular (>3.0 cm^3) Cartilage Lesions of the Ankle

Randomized Controlled Trials

The sole RCT identified on AOT for articular cartilage lesions of the talus is by Gobbi et al (2006). The study included 32 patients with large (mean, ≈4 cm2; range, 1-8 cm^2) lesions randomized to chondroplasty, microfracture, or AOT. Assessment at 24-month follow-up showed similar improvements (≈40 points) for the 3 treatment groups, as measured by the American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hindfoot score (baseline score, 31-37; an AOFAS score of 90 to100 is considered excellent, 80-89 is good, 70-79 is fair, <70 is poor) and the Subjective Assessment Numeric Evaluation (baseline score, 35-36). Complication rates were also similar. Postoperative pain, measured by numeric pain intensity scores, was greater following AOT (5.25) than after chondroplasty (3.3) or microfracture (3.4). Although authors reported following subjects through a mean of 53 months (range, 24-199 months), durability results after 24 months was not reported. Thus any potential differences between hyaline and fibrocartilage at longer term follow-up cannot be determined from this study.

Observational Studies

In 2014, Haleem et al reported on a minimum 5-year follow-up for AOT for larger lesions of the talus. Fourteen patients who had a double plug graft for a larger lesion (mean, 208 mm^2; SD=54) were matched by age and sex to a cohort of 28 patients who had a single plug graft for a smaller osteochondral lesion (mean, 74 mm^2; SD=26). Both groups had significant improvements in the Foot and Ankle Outcome Score (FAOS) and 12-

Item Short-Form Health Survey scores, with no significant difference between the single-plug and double-plug groups. In the single-plug group, FAOS improved from 51.6 (SD=10.2) at baseline to 87.1 (SD=5.1) at final follow-up, while in the double-plug group the FAOS improved from 49.5 (SD=12.1) to 86.2 (SD=6.5).

In the 2008 report (described above), Hangody et al reported on a series AOT for knee and ankle and included 98 talar lesions 23 Good-to-excellent results were reported for 93% of the talar procedures, including durable results over a mean 4.2-year period (range, 2-7 years).The average size of the grafts was 1 cm^2, and an average of 3 osteochondral cores (range, 1-6 cm^2) were used.

Subsection Summary: Osteochondral Autograft for the Primary Treatment of Large (>1.5 cm2) or Cystic Articular (>3.0 cm3) Cartilage Lesions of the Ankle

The evidence on AOT for the treatment of large or cystic articular cartilage lesions includes an RCT that found similar efficacy results for AOT, marrow stimulation, and arthroplasty at 2-year follow-up. Longer term results were not reported. For the alternative of marrow stimulation, observational studies have generally reported worse outcomes and high failure rates for large lesions. Thus, there is a rationale for use of osteochondral autograft for larger lesions. This is supported by an observational study that showed good improvement on the FOAS through at least 5-year follow-up using 2 AOT plugs.

Osteochondral Autograft for Treatment of Osteochondral Lesions of the Ankle That Have Failed a Prior Marrow Stimulation Procedure

Nonrandomized Comparative Trials

In 2014, Yoon et al compared outcomes for 22 patients who underwent AOT to outcomes for 22 patients who underwent repeat arthroscopy with marrow stimulation after failed treatment of osteochondral lesions of the talus. The treatment was selected by the patient after discussion with the surgeon about the risks and benefits of the 2 procedures, including possible nonunion of the osteotomy site, donor-site morbidity, and the recovery period. The study included consecutive patients who met study criteria and had failed primary marrow stimulation. Exclusion criteria were diffuse arthritic changes or diffuse fibrillated articular cartilage or axial malalignment or chronic ankle instability. These 44 patients were among 399 patients who received arthroscopic marrow stimulation during the study period, indicating that, for about 90% of patients, primary marrow stimulation was effective. The 2 groups were comparable at baseline. Independent and blinded evaluation showed an excellent or good outcome on AOFAS scores (≥80) in 19 (86.4%) of patients treated with AOT compared to 12 (54.5%) of patients who received repeat marrow stimulation (p=0.021). All patients showed initial improvement in the VAS and AOFAS score after 6 months, but, over a mean follow-up of 50 months, only 7 (31.8%) in the repeat marrow stimulation group achieved excellent or good results and 14 (63.6%) of this group underwent further revisions. For patients with large lesions who were treated with repeat microfracture, 100% underwent a subsequent procedure. Conversely, a significantly higher proportion of the group treated with AOT 18 (81.8%) achieved excellent or good results over a mean follow-up of 48 months and none required further revisions.

In 2011, Imhoff et al retrospectively evaluated 26 AOT procedures (25 patients) of the talus at a mean follow-up of 7 years (range, 53-124 months); 9 of the patients had failed a prior marrow stimulation procedure. Two additional patients had undergone a revision procedure and were not included in the follow-up data. The lesion size was less than 3 cm2 and an average of 1.5 cylinders was grafted. From baseline to follow-up, AOFAS scores improved from 50 to 78 points ($p<0.01$), Tegner Activity Scale (TAS) scores from 3.1 to 3.7 ($p<0.05$), and VAS scores for pain from 7.8 to 1.5 ($p<0.01$). However, outcomes were significantly worse in patients who had undergone a prior marrow stimulation procedure (see Table 1).

Table 1. Results at 7-Year Follow-Up

Outcomes	AOFAS Score (SD)	Tegner Activity Scale Score (SD)	VAS Score (SD)
Repeat procedure	62.0 (16.4)	2.0 (1.9)	3 (3.2)
Initial procedure	87.0 (15.0)	4.6 (2.2)	0.6 (1.1)
P value	<0.01	<0.01	<0.01

AOFAS: American Orthopedic Foot & Ankle Society; VAS: visual analog scale.

Observational Studies

Osteochondral autografting for OCD was reported by Hangody et al (2001) for 36 consecutive patients. Most patients had previous surgical interventions and presented with stage III or IV lesions (completely detached or displaced fragment). The average size of the defect was 1 cm, and the average number of grafts per patients was 3 (range, 1-6). At mean follow-up of 4.2 years, ankle function measured by the Hannover scoring system showed good-to-excellent results in 34 (94%) cases. Examination by radiograph, computed tomography (CT), and MRI showed incorporation into the recipient bed and congruency of the articular surface.

In 2006, Kreuz et al reported on outcomes from a prospective series of 35 patients who underwent osteochondral grafting from the ipsilateral talar articular facet following failed bone marrow stimulation. Mean lesion diameter was 6.3 mm. At a mean follow-up of 49 months (range, 33-77 months), the AOFAS Ankle-Hindfoot Score had improved from 54.5 points (range, 47-60 points) to 89.9 points (range, 80-100 points).

In 2016, Georgiannos et al reported on 5- to 7-year follow-up for a prospective cohort of 46 patients who had failed a prior marrow stimulation procedure. Osteochondral plugs, which ranged from 4.75 to 8 mm in diameter, were taken from the talar facet. A temporary block of bone was removed to provide access to the talar dome. At a median follow-up of 5.5 years (range, 52-75 months), AOFAS score (standard deviation) had

improved from 55 (4.2) to 90 (5.8), and the median VAS score improved from 52/100 (6.6) to 91 (8.2). All grafts had incorporated and osteotomy sites healed, although 5 patients underwent subsequent surgery for osteophytes.

Subsection Summary: Osteochondral Autograft for Articular Cartilage Lesions of the Ankle That Have Failed a Prior Marrow Stimulation Procedure

The evidence for AOT in patients with articular cartilage lesions of the talus that have failed a prior marrow stimulation procedure includes 2 nonrandomized comparative trials and case series. A nonrandomized comparative study has suggested improved outcomes with AOT compared to repeat marrow stimulation. However, another study has suggested that outcomes may be diminished when AOT is used for a revision procedure compared to primary treatment. Case series have indicated good-to-excellent results of AOT at mid-term follow-up.

Fresh Osteochondral Allograft for Articular Cartilage Lesions of the Ankle

Use of AOT is limited by the number of cores that can be taken from the non-weight-bearing part of the talus or ipsilateral knee. AOT may also be inadequate due to lesion depth or location, such as on the talar shoulder. For osteochondral lesions for which AOT would be inadequate due to lesion size, depth, or location, the use of fresh osteochondral allografts has been reported. Use of fresh allografts for defects of the talus has been reported mainly in case series and a systematic review of these series. Due to the relatively rare occurrence of this condition, most series have fewer than 20 patients. One RCT was identified that compared AOT to allograft plugs for recurrent cartilage lesions.

Systematic Reviews

In a 2017 systematic review, VanTienderen et al included 5 studies with a total of 90 patients (91 ankles) who received a fresh osteochondral allograft for osteochondral lesions of the talus. Studies selected reported at least 1 outcome of interest, including AOFAS score, Foot Functional Index score, VAS score, reoperation rate, or rate of allograft collapse. The mean lesion volume was 3.7 cm^3 (range, 1.0-10.9 cm^3) and the number of prior procedures ranged from 1 to 4. At a mean follow-up of 45 months (range, 6-91 months), AOFAS scores improved from 48 to 80 and VAS scores improved from 7.1 to 2.7. However, some failures occurred: 23 (25.3%) patients required at least 1 reoperation and 12 (13.2%) patients were considered failures, defined as postoperative graft nonunion or resorption or persistence of symptoms leading to arthrodesis or arthroplasty.

In addition to the failure rate of osteochondral allograft transplantation, van Dijk (2017) noted that an osteochondral allograft can compromise a future arthrodesis or arthroplasty by failure of bony ingrowth since the bulk of the graft will consist of dead bone.

Primary Full-Thickness Articular Cartilage Lesions of the Ankle Less Than 1.5 cm^2

Literature on fresh allograft for the treatment of small lesions of the ankle is very limited because this treatment is considered only when there are no other options available to delay arthrodesis or arthroplasty. Because microfracture is effective as a primary treatment in lesions less than 1.5 cm^2 and AOT is effective as a revision procedure, use of allograft for small lesions has not been reported. Note that other allograft products, such as minced juvenile cartilage and reduced allograft discs, are described in other sections.

Large (Area >1.5 cm^2) or Cystic (Volume >3.0 cm^3) Cartilage Lesions of the Ankle

In 2016, Ahmad and Jones compared osteochondral autograft with fresh allograft plugs for the treatment of large (area >1.5 cm2, n=9) or recurrent (volume >3.0 cm3; n=27) cartilage lesions of the talus. Because they only treated 5 patients with large lesions with autograft and 4 patients with large lesions with allograft, comparing treatments in this trial is limited.

Revision of Large (Area >1.5 cm2) or Cystic (Volume >3.0 cm3) Osteochondral Lesions of the Ankle

Randomized Trials

The 2016 study by Ahmad and Jones included 9 large and 27 recurrent osteochondral lesions of the talus. Most patients had failed a prior microfracture. The study randomized 20 patients to AOT and 20 patients to plugs taken from a size-matched donor talus. Four patients from the allograft group had significant damage of the shoulder of the talar dome. These 4 received a hemi-talus allograft and were excluded from the study. Foot and Ankle Ability Measures and VAS scores were similar in the 2 groups. In the allograft group, the mean Foot and Ankle Ability Measures score increased from 55.2 to 80.7 and the mean VAS score decreased from 7.8 to 2.7 at final follow-up. These outcomes were reported as being lower than those reported for the autograft group, but the difference was not statistically significant (numerical results were reported separately for anterior and medial approach). More patients in the allograft group had graft nonunion (3/16 [18.8%] patients vs the autograft group (2/20 [10%] patients), consistent with the systematic review by VanTienderen et al (2017; described above).

Section Summary: Fresh Osteochondral Allograft for Articular Cartilage Lesions of the Ankle

The evidence on osteochondral allografts for articular cartilage lesions of the ankle includes an RCT, case series and a systematic review of case series.

There is little evidence on fresh osteochondral allografts for the primary treatment of full-thickness articular cartilage lesions of the ankle less than 1.5 cm^2. Because microfracture is effective as a primary treatment in lesions less than 1.5 cm^2, AOT is effective as a revision procedure, and allografts have a high failure rate, use of allograft for small primary cartilage lesions is not appropriate.

The evidence on fresh osteochondral allografts for the treatment of large (area >1.5 cm^2) or cystic (volume >3.0 cm^3) osteochondral lesions of the ankle includes a small number of patients in an RCT, case series, and a systematic review of case series. The systematic review found a high failure rate with osteochondral allografts for talar lesions. In addition, use of allografts may have a negative impact on any future arthroplasty or arthrodesis.

The evidence on fresh osteochondral allografts for revision of large (area >1.5 cm^2) or cystic (volume >3.0 cm^3) osteochondral lesions of the ankle includes an RCT. The RCT found that outcomes were slightly, but not significantly, worse with osteochondral allografts compared to autografts. However, failure rates due to nonunion were higher in the allograft group, consistent with other findings.

Osteochondral Autograft for Articular Cartilage Lesions of the Elbow

Systematic Reviews

A 2016 systematic review by Westermann et al included 24 case series (total N=492 patients) that assessed return to sports after operative treatment for OCD of the capitulum. The most common primary sport was baseball (371/464) followed by gymnastics (35/464). The overall return to sports was 86% at a mean 5.6 months. Average lesion size was similar for the different treatments among 8 studies with information available. Among all 24 studies, patients were more likely to return to their preoperative sport after AOT (0.95; 95% CI, 0.89 to 0.99) compared with debridement or microfracture (0.62; 95% CI, 0.46 to 0.77; $p<0.001$) or fixation with pins, wires, or screws (0.72; 95% CI, 0.51 to 0.89; $p=0.01$). Grafts were taken from the lateral femoral condyle or ribs.

Donor Site Morbidity

Bexkens et al (2017) conducted a meta-analysis of case series that assessed donor-site morbidity after AOT for OCD of the capitulum. 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.

Section Summary: Osteochondral Autograft for Articular Cartilage Lesions of the Elbow

OCD of the elbow typically occurs in patients who play baseball or do gymnastics. The literature on SOT for advanced OCD 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 AOT compared to debridement or fixation, RCTs are needed to determine the effects of the procedure with greater certainty.

Osteochondral Autograft for Articular Cartilage Lesions of Shoulder

A 2009 European study by Kircher et al reported on 9-year follow-up after AOT for cartilage defects of the shoulder in 7 patients. One additional patient was reported to have had donor-site morbidity at the knee and chose not to return for follow-up. All plugs showed full integration with the surrounding bone, and 6 of 7 patients showed a congruent joint surface. The Constant score improved from 76 points preoperatively to 90 points at 33 months and remained at 91 points at the 9-year follow-up. Subscores for pain and activities of daily living showed significant improvement at 33-month follow-up, with a very slight nonsignificant decline at 9-year follow-up. None of the patients required additional shoulder surgery.

Section Summary: Osteochondral Autograft for Articular Cartilage Lesions of Shoulder

The evidence on osteochondral autografting for the shoulder is very limited and does not conclusions about the efficacy of this treatment.

Minced Cartilage for Articular Cartilage Lesions

Autologous Minced Cartilage

In 2011, Cole et al reported a multicenter trial with 29 patients (of 582 screened) randomized in a 1:2 ratio to microfracture or Cartilage Autograft Implantation System (CAIS). In the single-stage CAIS procedure, autologous hyaline cartilage was harvested, minced, affixed on a synthetic absorbable scaffold, and fixed on the lesion site with absorbable staples. At baseline, there were no significant differences between groups in the duration of symptoms, ICRS grade, and area and depth of the chondral defect. There was a difference in the sex and work status of the 2 groups. At 3-week and 6-month follow-ups, there were no significant differences in outcomes between the 2 groups, but, at later time points, there were differences reported. The IKDC score was significantly higher in the CAIS group compared with the microfracture group at both 12 (73.9 vs 57.8) and 24 (83.0 vs 59.5) months. All subdomains of the KOOS symptoms and stiffness, pain, activities of daily living, sports and recreation, knee-related quality of life were significantly increased at 24 months in the CAIS group compared with microfracture patients. Qualitative analysis of MRI at 3 weeks and 6, 12, and 24 months showed no differences in fill of the graft bed, tissue integration, or presence of subchondral cysts. Adverse events were similar for the groups.

Allogeneic Juvenile Minced Cartilage

Knee

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 (2014), which included 25 patients with cartilage lesions of the femoral condyle or trochlea. Patients had symptomatic, focal, contained chondral lesions of the femoral condyles or trochlea with defect areas ranging between 1 cm^2 and 5 cm^2 (mean, 2.7

cm^2; range 1.2-4.6 cm^2). Mean number of prior surgeries was 1.1, with 18 patients reporting prior debridement 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 score for pain. IKDC score improved over the 24 months of follow-up. At 24 months, IKDC score 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 varied across sections. There was good integration with the surrounding native cartilage.

A study by Tompkins et al (2013) included 13 patients (15 knees) who received particulated juvenile allograft to the patella. 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.

Ankle

One proposed advantage of particulated articular cartilage for osteochondral lesions of the talus is that it is not always necessary to perform an osteotomy to access the lesion. At this time, use of DeNovo NT for the talus has been reported in case reports, small case series, and a systematic review of these studies.

In 2017, Saltzman et al reported a descriptive systematic review of the published case reports and case series. Included were data on 33 ankles from 2 case reports, a series of 7 patients by Bleazy and Brigido (2012) and a series of 24 ankles by Coetzee et al (2013), described next.

The largest series is from a preliminary report of a larger study by Coetzee et al. In this preliminary report, 24 ankles (23 patients) with osteochondral lesions of the talus (mean lesion size, 125 mm^2); SD=75) were treated with DeNovo NT. Fourteen (58%) of the ankles 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 score, with a final mean VAS score of 24 out of 100. However, 18 (76%) ankles had at least 1 concomitant procedure (hardware removal and treatment for impingement, synovitis, instability, osteophytes, malalignment), limiting interpretation of the functional results. One treatment failure was caused by partial graft delamination.

In addition to their systematic review of the literature, Saltzman et al (2017) also reported on 6 patients who had been treated at their institution with particulated juvenile articular cartilage for articular cartilage lesions of the talus. Lesion size ranged from 96 to 308 mm^2. Two of the 6 patients underwent a medial malleolar osteotomy to access the lesion. Implantation procedures included débridement, marrow stimulation, and

fixation of the particulated cartilage with fibrin glue. At a mean 13-month follow-up, all 6 patients reported subjective improvements in pain and function. However, for all 3 patients who had MRI between 3 months and 2 years postoperatively, there was persistent subchondral edema and non-uniform chondral surface.

Section Summary: Minced Cartilage for Articular Cartilage Lesions

The evidence on autologous minced cartilage includes 1 small RCT from 2011. The evidence on allogeneic minced cartilage includes case reports and case series. The case series have suggested an improvement in outcomes compared with baseline, but there is also evidence of subchondral edema, non-uniform chondral 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 available procedures. For articular cartilage lesions of the ankle, there are few treatment options and, in the largest case series, over half of the patients had failed prior marrow stimulation. However, the concomitant procedures performed in that study limited interpretation of its results. A randomized comparison with microfracture in patients who have not received prior treatment would permit greater certainty about conclusions on the effectiveness of this procedure.

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 (2016) 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 (2017) 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. 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.

Reduced Osteochondral Allograft Discs

The evidence on reduced osteochondral allograft discs is limited to case reports and very small case series with 2 to 3 patients.

Section Summary: Reduced Osteochondral Allograft Discs

The evidence on reduced osteochondral allograft discs consists only of patients and is insufficient to draw conclusions about treatment efficacy.

Summary of Evidence

Knee Lesions

For individuals who have full-thickness articular cartilage lesions of the knee who receive osteochondral autografts, the evidence includes randomized controlled trials (RCTs), systematic reviews of RCTs, and longer term observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Several systematic reviews have evaluated osteochondral autografting for cartilage repair in the short and mid-term. Compared to 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 to 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 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 fresh osteochondral allografts, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, 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 cm2 who receive an osteochondral autograft, the evidence includes observational studies and a systematic review of these studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A systematic review found similar improvements in outcomes following microfracture or autologous osteochondral transplantation (AOT) Given the success of marrow stimulation procedures for smaller lesions (<1.5 cm2) 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 2 observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. An RCT in patients with large lesions found similar efficacy for AOT, marrow stimulation, and arthroplasty at 2-year follow-up. Longer term results were not reported. Because observational studies of marrow stimulation in the talus have generally reported worse outcomes and high failure rates for large lesions, there is a strong rationale for using autografts. However, there is limited evidence that osteochondral autografts lead to better outcomes than microfracture at longer follow-up. The strongest evidence is derived from 1 observational study that showed good improvement on the Foot and Ankle Outcome Score through at least 5-year follow-up using AOT in both larger (2 plugs) and smaller (1 plug) lesions. Additional study is needed to evaluate the durability of AOT in larger lesions. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have osteochondral lesions of the ankle that have failed primary treatment who receive an osteochondral autograft, the evidence includes 2 nonrandomized comparative trials and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, 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 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. Relevant outcomes are symptoms, functional outcomes, quality of life, 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. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review found a significant failure rate with osteochondral allografts for talar lesions. Although there is a potential to delay or avoid arthrodesis or total ankle arthroplasty in younger patients, use of an allograft may be detrimental to future treatments. Additional study is needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

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. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The RCT found that outcomes were slightly, but not significantly, worse with osteochondral allografts than with autografts. However, failure due

to nonunion was higher in the allograft group, consistent with other reports. The evidence is insufficient to determine the effects of the technology on health outcomes.

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. Relevant outcomes are symptoms, functional outcomes, quality of life, 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 to 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 osteochondral autografts, the evidence includes a case series. Relevant outcomes are symptoms, functional outcomes, quality of life, 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 articular cartilage, the evidence includes a small RCT and small case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence on autologous minced cartilage includes 1 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, non-homogenous 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 1 small case series. Relevant outcomes are symptoms, functional outcomes, quality of life, 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.

Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons

In 2010 guidelines, which remain available on the American Academy of Orthopaedic Surgeons (AAOS) website in 2018, on the diagnosis and treatment of osteochondritis dissecans (OCD), AAOS was unable to recommend for or against a specific cartilage repair technique in symptomatic skeletally immature or mature patients with an unsalvageable osteochondritis dissecans lesion.

A 2010 AAOS review of articular cartilage restoration methods states that "osteochondral autografting is generally used for smaller focal lesions of the femoral condyle no greater than 1.5 to 2 cm."

National Institute for Health and Clinical Excellence

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

U.S. Preventive Services and Task Force Recommendations

Not Applicable.

Key Words:

Osteochondral allograft transplantation, osteochondral autograft transplantation, OATS, OAT, mosaicplasty, articular cartilage, hyaline cartilage, fibrocartilage, CAIS, Chondrofix®, Neocartilage, DeNovo NT Graft, DeNovo® ET Graft, ProChondrix, Cartiform, AOT

Approved by Governing Bodies:

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. FDA 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.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Coding:

CPT Codes:

27415	Osteochondral allograft, knee, open
27416	Osteochondral autograft(s), knee, open (e.g. mosaicplasty) (includes harvesting of autograft[s])
28446	Open osteochondral autograft, talus (includes obtaining graft[s])
29866	Arthroscopy, knee, surgical: osteochondral autografts(s) (e.g., mosaicplasty) (includes harvesting of the autografts[s])
29867	Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)

There is no CPT code specific to osteochondral allograft of the talus.

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Policy History:

Medical Policy Group, September 2005 **(3)**

Medical Policy Administration Committee, October 2005

Available for comment September 26-November 9, 2005

Medical Policy Group, October 2007 **(1)**

Medical Policy Administration Committee, October 2007

Available for comment October 5-November 19, 2007

Medical Policy Group, January 2009 **(3)**

Medical Policy Group, July 2011 **(3):** Updated Policy section, Key Points, & References

Medical Policy Administration Committee July 2011

Available for comment July 21 through September 5, 2011

Medical Policy Group, July 2012 **(3):** 2012 Updates – Description, Key Points & References

Medical Policy Administration Committee July 2012

Medial Policy Group, May 2013 **(2):** Deleted lesion size for allografts, Description and Key Points shortened, Deleted all web references that are no longer available.

Medical Policy Administration Committee, May 2013

Medical Policy Panel, June 2013

Medical Policy Group, June 2013 **(3):** 2013 Updates to Title, Description, Policy statement (adding treatments of focal articular cartilage lesions with autologous and allogeneic minced cartilage as investigational from policy #156), Key Points, References, and Key Words.

Medical Policy Administration Committee, July 2013

Available for comment July 9 through August 28, 2013

Medical Policy Group, September 2013 **(3):** Ad hoc update to add information to Key Points and References; no change in policy statement

Medical Policy Panel, June 2014

Medical Policy Group, June 2014 **(3):** 2014 Updates to Key Points & References; updated policy statement for osteochondral autografting to include patella in coverage criteria

Medical Policy Administration Committee, July 2014

Available for comment July 9 through August 25, 2014

Medical Policy Panel, June 2015

Medical Policy Group, June 2015 – 2015 Updates to Key Points and References; updated policy statement - Osteochondral Allografting as a technique to repair large 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 size, location, or depth of the lesion" may be is considered medically necessary Medical Policy Administrative Committee, July 2015

Available for comment July 1 through August 14, 2015

Medical Policy Panel, December 2016

Medical Policy Group, December 2016 **(7)**: Updates to Description, Policy Statement- adding treatments of focal articular cartilage lesions with decellularized osteochondral allograft and reduced osteochondral allograft discs as investigational; deleted policy statement 'effective for dates of service on or after September 6, 2011 and prior to June 13, 2013'; Key Points, Approved by Governing Bodies and References.

Medical Policy Administration Committee, February 2017

Available for comment January 26 through March 11, 2017

Medical Policy Panel, June 2017

Medical Policy Group, June 2017 **(7)**: 2017 Updated Key Points, Key Words, Coding Section and References. Policy Statement updated to include coverage for osteochondral allografts and autografts for osteochondral lesions of the talus; removed previous policy statement from June 2014.

Medical Policy Administration Committee, July 2017

Medical Policy Panel, April 2018

Medical Policy Group, June 2018 (**7**): Removed policy statements effective for dates of service on or after June 27, 2014 through June 29, 2015:

Medical Policy Panel, April 2018

Medical Policy Group, June 2018 **(7)**: Updates to Description, Policy, Key Points, Approved by Governing Bodies, and References. No change to policy statement. Added "or particulate" to policy IV statements related to the treatment of focal articular cartilage lesions with allogeneic or autologous cartilage. No change in policy intent.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.

The plan does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. The plan administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

As a general rule, benefits are payable under health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and

2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and

3. Not primarily for the convenience of the patient, physician or other health care provider; and

4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.