

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



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DESCRIPTION

An osteochondral defect is any type of damage to articular cartilage and underlying subchondral bone due to traumatic injury or degenerative changes (e.g., osteochondritis dissecans (OCD), osteonecrosis or osteoarthritis). Due to the inability of the articular cartilage to heal itself efficiently, surgical procedures have been developed to stimulate new cartilage growth such as osteochondral autograft and allografts. The use of osteochondral autografts using 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.

Damaged articular cartilage can be associated with pain, loss of function, and disability, and can lead to debilitating osteoarthritis 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. Osteochondral autografts and allografts are used to repair full-thickness chondral defects involving a joint.

Treatment

There are two main goals of conventional therapy for individuals 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: debridement (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 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.

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 individuals 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 are 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 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 debridement and preparation of recipient tunnels. Multiple individual osteochondral cores are harvested from the donor site, typically from a peripheral non-weight-bearing area of the femoral condyle. Donor plugs range from 6 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 autologous osteochondral transplantation 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.

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 autologous osteochondral transplantation 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.

Note: 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 medical policy [07.01.64 Autologous Chondrocyte Implant for Focal Articular Cartilage Lesions](#)

Osteochondral Autograft (OATS/Mosaicplasty) for Articular Cartilage Lesions of the Knee

Clinical Context and Therapy Purpose

The purpose of osteochondral autograft (OATS/mosaicplasty) in individuals with full-thickness focal articular cartilage lesions (osteochondral defects) of the knee is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is individuals with full-thickness articular cartilage lesions (osteochondral defects) of the knee.

Interventions

The therapy being considered is autologous autograft. The injured area of cartilage and underlying bone are removed and replaced with a graft of cartilage and bone harvested from another area. It is hypothesized that the implanted graft's chondrocytes retain

features of hyaline cartilage that are similar in composition and property to the original articulating surface of the joint, thereby restoring the hyaline cartilage surface.

Comparators

To restore articular surface, standard therapies of marrow stimulation currently in use include microfracture, abrasion arthroplasty, and drilling. Microfracture involves debridement of the damaged area and puncturing of the underlying bone to allow bleeding of the bone, stimulating the formation of new joint surface cartilage.

Autologous chondrocyte implantation may also be considered as an option see medical policy [07.01.64 Autologous Chondrocyte Implant for Focal Articular Cartilage Lesions](#).

Outcomes

The general outcomes of interest are improvements in symptoms, functional outcomes, quality of life, and treatment-related morbidity. Symptom improvements in the knee can be detected using the Lysholm Knee Scale, which consists of 8 items: pain, instability, locking, swelling, limp, stair climbing, squatting, and need for support.

For long-term outcomes, 5- to 15-year follow-up is recommended.

Review of Evidence

Zamborsky et. al. (2020) completed a systematic review and network meta-analysis that evaluated the most appropriate surgical interventions for patients with knee articular cartilage defects. The authors included a total of 21 articles (from 12 RCTs) in their analysis with a total population of 891 patients. Follow-up varied widely among the included studies, ranging from 12 months to 15 years. Of the surgical interventions evaluated, microfracture was associated with significantly higher failure rates compared to autologous chondrocyte implantation at 10 years of follow-up (relative risk [RR], 0.12; 95% confidence interval [CI]; 0.04 to 0.39). No significant differences in failure rates were seen between microfracture and osteochondral autograft transplantation, matrix-induced autologous chondrocyte implantation, or characterized chondrocyte implantation at 2, 5, and 10 years of follow-up. Osteochondral autograft transplantation was associated with significantly more excellent or good results at >3 years of follow-up as compared to microfracture, whereas microfracture was associated with significantly poorer results as compared to autologous chondrocyte implantation and matrix-induced autologous chondrocyte implantation. No significant differences between the interventions were noted regarding reintervention, biopsy types, or adverse events. Based on efficacy and safety, autologous chondrocyte implantation was ranked as the best intervention for failure outcome at 10 years of follow-up, followed by osteochondral autograft transplantation, then microfracture. Microfracture was consistently ranked worse than cartilage repair techniques for other outcomes including quality of tissue repair and return-to-activity rates.

Gracitelli et. al. (2016) wrote a Cochrane review evaluating surgical interventions (microfracture, drilling, autologous osteochondral transplantation, allograft

transplantation) for the treatment of isolated cartilage defects of the knee in adults. Three RCTs compared autologous osteochondral transplantation with microfracture for isolated cartilage defects. The evidence was considered of very low quality with high or unclear risk of bias.

Pareek et. al. (2016) found, in a mid-term meta-analysis that included 5 randomized controlled trials (RCTs), that Tegner Activity Scale scores were higher, and failure rates lower, with autologous osteochondral transplantation than with microfracture. In a subgroup analysis, activity scores were higher in the subset of patients treated with autologous osteochondral transplantation who had lesions greater than 3 cm² at mid-term follow-up.

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

Section Summary

Several systematic reviews of RCTs have evaluated autologous osteochondral transplantation for cartilage repair of the knee in the short- and mid-term. The randomized controlled trials (RCTs) are not high quality, and not all reviews found a benefit compared with abrasion techniques. However, compared with abrasion techniques (e.g., microfracture, drilling), there is evidence that autologous osteochondral transplantation 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 the improved 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 autologous osteochondral transplantation 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

Clinical Context and Therapy Purpose

The purpose of fresh osteochondral allografts in individuals with full-thickness focal articular cartilage lesions (osteochondral defects) of the knee is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is individuals with full-thickness articular cartilage lesions (osteochondral defects) of the knee.

Interventions

The therapy being considered is fresh or frozen osteochondral allograft. The injured area of cartilage and underlying bone are removed and replaced with a graft of cartilage and bone harvested from a donor.

Comparators

To restore articular surface, standard therapies of marrow stimulation currently in use include microfracture, abrasion arthroplasty, and drilling.

Outcomes

The general outcomes of interest are improvements in symptoms, functional outcomes, quality of life, and treatment-related morbidity. Symptom improvements in the knee can be detected using the Lysholm Knee Scale, which consists of 8 items: pain, instability, locking, swelling, limp, stair climbing, squatting, and need for support.

For long-term outcomes, 5- to 15-year follow-up is recommended.

Review of Evidence

Systematic Reviews

A systematic review by Kunze et. al. (2022) focused solely on potential risk factors for failure after osteochondral allograft transplantation of the knee. They included 16 studies consisting of 1401 patients who received an allograft transplant. The pooled prevalence of overall failure was 18.9%. Of the risk factors identified, bipolar chondral defects (odds ratio [OR], 4.20; 95% CI, 1.17 to 15.08; $p=.028$) and male sex (OR, 2.04; 95% CI, 1.17 to 3.55; $p=.012$) were significant risk factors for failure after allograft transplant. Older age (mean difference [MD], 5.06 years; 95% CI, 1.44 to 8.70; $p=.006$) and greater body mass index (MD, 1.75 kg/m²; 95% CI, 0.48 to 3.03; $p=.007$) at the time of surgery were also significant risk failures for failure. There was no statistical significance to support that concomitant procedures, lesion size, or lesion location were associated with an increased risk of failure.

Merkely et. al. (2021) conducted a systematic review of clinical outcomes after osteochondral allograft transplantation for large chondral defects of the knees. Their review compared patients receiving a primary allograft transplant ($n=13$) and those receiving allograft transplant as a revision after a failed autologous implant ($n=13$). All patients demonstrated significant improvement in all functional scores after allograft transplant, and there were no significant differences between groups. Authors concluded that revision of prior failed autologous implant with allograft transplant is a viable treatment option with similar clinical outcomes as primary allograft transplant.

Gracitelli et. al. (2016) published a Cochrane review on surgical interventions (microfracture, drilling, mosaicplasty, and allograft transplantation) for treating cartilage defects of the knees and did not identify any randomized controlled trials (RCTs) on fresh allograft transplantation.

De Caro et. al. (2015) included in their systematic review 11 articles that had at least 10 patients and were published in the previous 5 years. Articles included a total of 374 knees in 358 patients treated with fresh osteochondral allografting. The size of the lesions ranged from 1 to 27 cm. 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 graft survival rates of 82% at 10 years and 66% at 20 years. Although bony integration was usually achieved, cartilage integration was limited.

Chui et. al. (2015) stated in their review of indications, techniques, and outcomes that fresh osteochondral allografting would be indicated for lesions greater than 2 cm² for which other techniques such as microfracture, autologous osteochondral transplantation, and autologous chondrocyte implantation are inadequate due to lesion size, location, or depth. 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 1 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.

Gracitelli et. al. (2015) reported on fresh osteochondral allografting for patellar cartilage injury. Of 28 knees (27 patients) that had osteochondral transplantation, 8 (28.6%) were considered failures and 9 (45%) required further surgery. Allograft survival 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 (71.4%) knees with intact grafts.

Section Summary

The evidence on fresh osteochondral allografts for articular cartilage lesions of the knee includes case series and systematic reviews of case series. Due to the lack of alternatives, this fresh allograft procedure may be considered as 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, autologous osteochondral transplantation, autologous chondrocyte implantation) would be inadequate due to lesion size, location, or depth.

Osteochondral Autograft for Articular Lesions of the Ankle Less Than 1.5cm²

Clinical Context and Therapy Purpose

The purpose of autologous osteochondral transplantation in patients with primary full-thickness focal articular cartilage lesions of the ankle (talus) <1.5 cm² is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is patients with primary full-thickness focal articular cartilage lesions of the ankle (talus) <1.5 cm².

Interventions

The therapy being considered is autologous osteochondral transplantation. The injured area of cartilage and underlying bone are removed and replaced with a graft of cartilage and bone harvested from another area.

Comparators

To restore articular surface, standard therapies of marrow stimulation currently in use include microfracture, abrasion arthroplasty, and drilling. Microfracture involves debridement of the damaged area and puncturing of the underlying bone to allow bleeding of the bone, stimulating the formation of new joint surface cartilage.

Outcomes

The general outcomes of interest are improvements in symptoms, functional outcomes, quality of life, and treatment-related morbidity. There are several symptom measurements for the ankle, such as the Foot and Ankle Ability Measures, in which the patient indicates the ability to perform various walking activities on a scale from "no difficulty" to "unable to do," as well as the American Orthopaedic Foot & Ankle Society Score, and the Foot and Ankle Outcome Score; quality of life can be measured using the Short-Form 12-item (SF-12) or SF-36.

Based on the available literature, follow-up should be 6 months or longer, but longer-term follow-up is recommended.

Review of Evidence

Osteochondral lesions of the talus are typically associated with an ankle sprain or fracture but comprise a relatively small proportion of lesions (~4%) compared with cartilage lesions of the knee joint. Therefore, randomized controlled trials (RCTs) on autologous osteochondral transplantation for ankle (talar) lesions may be limited.

Systematic Reviews

Zengerink et. al. (2010) published a systematic review on the treatment of osteochondral lesions of the talus. Fifty-one nonrandomized and 1 randomized trial (Gobbi et. al. [2006]) 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 autologous chondrocyte implantation. Because of the high cost of autologous chondrocyte implantation and the knee morbidity seen with autologous osteochondral transplantation, reviewers concluded that bone marrow stimulation is the treatment of choice for primary osteochondral talar lesions. However, the analysis was not conducted to assess the relation between lesion characteristics and success rates, limiting the interpretation of these results.

Section Summary

For the use of autologous osteochondral transplantation for repair of articular cartilage lesions of the ankle that are less than 1.5 cm² in area, a systematic review found similar improvements in outcomes following microfracture and autologous osteochondral transplantation. However, 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 autologous osteochondral transplantation as a primary treatment for smaller ankle lesions.

Osteochondral Autograft for Larger Lesions of the Ankle (Talus) or Lesions of the Ankle (Talus) that have Failed a Prior Procedure

The following sections review the evidence for ankle (talar) lesions that have failed a prior arthroscopic procedure, and for larger lesions, defined as at least 1.5 cm² 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 cm² in area have lower success rates than for those for smaller lesions. For lesions less than 1.5 cm² in size, multiple studies have shown high success rates with marrow stimulation alone. Because of the increase in morbidity with autologous osteochondral transplantation, 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. A series reported by Choi et al (2009) also estimated that failure rate following marrow stimulation was 10.5% for lesions less than 1.5 cm²; whereas 80% of lesions at least 1.5 cm² failed after a marrow stimulation procedure.

In 2017, the BCBS Association obtained clinical input to help determine whether the use of autografts and allografts for individuals with focal articular cartilage lesions of the talus (ankle) would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. Input obtained in 2017 supports the following indications:

- Use of osteochondral autograft for:
 - Primary treatment of large (area >1.5 cm²) or cystic (volume >3.0 cm³) 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 cm²) or cystic (volume >3.0 cm³) 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.

Osteochondral Autograft for the Treatment of Large (Area > 1.5 cm²) or Cystic (Volume >3.0 cm³) Articular Cartilage Lesions of the Ankle

Clinical Context and Therapy Purpose

The purpose of autologous osteochondral transplantation in individuals with large (area >1.5 cm²) or cystic (volume >3.0 cm³) full-thickness articular cartilage lesions of the ankle (talus) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is individuals with large (area >1.5 cm²) or cystic (volume >3.0 cm³) full-thickness articular cartilage lesions of the ankle (talus).

Interventions

The therapy being considered is autologous osteochondral transplantation. The injured area of cartilage and underlying bone are removed and replaced with a graft of cartilage and bone harvested from another area.

Comparators

To restore articular surface, standard therapies of marrow stimulation currently in use include microfracture, abrasion arthroplasty, and drilling. Microfracture involves debridement of the damaged area and puncturing of the underlying bone to allow bleeding of the bone, stimulating the formation of new joint surface cartilage.

Outcomes

The general outcomes of interest are improvements in symptoms, functional outcomes, quality of life, and treatment-related morbidity. There are several symptom measurements for the ankle, such as the Foot and Ankle Ability Measures, in which the individual indicates the ability to perform various walking activities on a scale from "no difficulty" to "unable to do," as well as the American Orthopaedic Foot & Ankle Society Score, and the Foot and Ankle Outcome Score; quality of life can be measured using the SF-12 or SF-36.

Based on the available literature, follow-up should be 6 months or longer, but longer-term follow-up is recommended.

Review of Evidence

Randomized Controlled Trials

Gobbie et. al. conducted the single randomized controlled trial (RCT) identified on autologous osteochondral transplantation for articular cartilage lesions of the talus. The study included 32 patients (33 ankles) with large (mean, 4 cm²; range, 1-8 cm²) lesions randomized to chondroplasty (n=11 ankles), microfracture (n=10 ankles), or autologous osteochondral transplantation (n=12 ankles). Assessment at 24-month follow-up showed

similar improvements for the 3 treatment groups, as measured by the American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale score (mean baseline scores ranging 31 to 37 and mean 24-month scores ranging from 83 to 85). An AOFAS score of 90 to 100 is considered excellent, 80 to 89 is good, 70 to 79 is fair, and <70 is poor. The Subjective Assessment Numeric Evaluation scores also improved significantly in all treatment groups, from baseline scores of 35 to 36 to 24-month scores of 78 to 82. Complication rates were also similar. Postoperative pain, measured by numeric pain intensity scores, was greater following autologous osteochondral transplantation (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 were not reported. Thus, any potential differences between hyaline and fibrocartilage at longer-term follow-up cannot be determined from this study.

Observational Studies

Shimozono et. al. (2018) conducted a retrospective analysis comparing patients receiving autologous osteochondral transplantation (n=25) with patients receiving osteochondral allografts (n=16) for lesions of the ankle. Patients in the autograft group had significantly better outcomes as measured by the Foot and Ankle Outcome Score, the Magnetic Resonance Observation of Cartilage Repair Tissue score, and the SF-12 Health Survey. The rate of secondary procedures was also higher in the allograft group (25%) compared with the autograft group (0%).

Haleem et. al. (2014) reported on a minimum 5-year follow-up for autologous osteochondral transplantation for larger lesions of the talus. Fourteen patients who had a double-plug graft for a larger lesion (mean, 208 mm²) 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 mm²). Both groups had significant improvements in the Foot and Ankle Outcome Score and SF-12 Health Survey scores, with no significant difference between the single-plug and double-plug groups. In the single-plug group, Foot and Ankle Outcome Score improved from 51.6 at baseline to 87.1 at final follow-up, while in the double-plug group the Foot and Ankle Outcome Score improved from 49.5 to 86.2.

Section Summary

The evidence on autologous osteochondral transplantation for the treatment of large or cystic articular cartilage lesions includes a randomized controlled trial (RCT) that found similar efficacy results for autologous osteochondral transplantation, marrow stimulation, and chondroplasty at 2-year follow-up. Longer-term results were not reported in this RCT. However, several observational studies with longer-term follow-up (4 to 5 years) have shown favorable results for patients with large or cystic lesions receiving autologous osteochondral transplantation. Studies on the standard treatment for ankle lesions (marrow stimulation), have reported positive outcomes for patients with small lesions of the ankle (<1.5 cm²) but have generally reported high failure rates for patients with large (>1.5 cm²) lesions.

Osteochondral Autograft for treatment of Osteochondral Lesions of the Ankle that have Failed a Prior Marrow Stimulation Procedure

Clinical Context and Therapy Purpose

The purpose of autologous osteochondral transplantation in individuals with osteochondral lesions of the ankle (talus) that have failed a prior marrow stimulation procedure is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is patients with osteochondral lesions of the ankle that have failed a prior marrow stimulation procedure.

Interventions

The therapy being considered is autologous osteochondral transplantation. The injured area of cartilage and underlying bone are removed and replaced with a graft of cartilage and bone harvested from another area.

Comparators

To restore articular surface, standard therapies of marrow stimulation currently in use include microfracture, abrasion arthroplasty, and drilling. Microfracture involves debridement of the damaged area and puncturing of the underlying bone to allow bleeding of the bone, stimulating the formation of new joint surface cartilage.

Outcomes

The general outcomes of interest are improvements in symptoms, functional outcomes, quality of life, and treatment-related morbidity. There are several symptom measurements for the ankle, such as the Foot and Ankle Ability Measures, in which the patient indicates the ability to perform various walking activities on a scale from "no difficulty" to "unable to do," as well as the American Orthopaedic Foot & Ankle Society Score, and the Foot and Ankle Outcome Score; quality of life can be measured using the SF-12 or SF-36.

Based on the available literature, follow-up should be at least 6 months, but longer-term follow-up is recommended.

Review of Evidence

Nonrandomized Comparative Trials

Yoon et. al. (2014) compared outcomes for 22 patients who underwent autologous osteochondral transplantation with outcomes for 22 patients who underwent repeat arthroscopy using 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%) patients treated with autologous osteochondral transplantation compared with 12 (54.5%) patients who received repeat marrow stimulation ($p=.021$). All patients showed initial improvement in visual analog scale and AOFAS scores 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 autologous osteochondral transplantation (18 [81.8%]) achieved excellent or good results over a mean follow-up of 48 months, and none required further revisions.

Observational Studies

Georgiannos et al. (2016) 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 had improved from 55 to 90, and the median visual analog scale score improved from 52/100 to 91. All grafts had incorporated, and osteotomy sites healed, although 5 patients underwent subsequent surgery for osteophytes.

Section Summary

The evidence for autologous osteochondral transplantation in patients with articular cartilage lesions of the ankle (talus) that have failed a prior marrow stimulation procedure includes nonrandomized comparative trials and observational studies. One nonrandomized comparative study has suggested improved outcomes with autologous osteochondral transplantation compared with repeat marrow stimulation. Observational studies have consistently indicated good-to-excellent results of autologous osteochondral transplantation at mid-term follow-up.

Fresh Osteochondral Allograft for Articular Cartilage Lesions of the Ankle

Use of autologous osteochondral transplantation is limited by the number of cores that can be taken from the non-weight-bearing part of the ankle (talus) or ipsilateral knee. Autologous osteochondral transplantation may also be inadequate due to lesion depth or location, such as on the talar shoulder. For osteochondral lesions for which autologous osteochondral transplantation would be inadequate due to lesion size, depth, or location, the use of fresh osteochondral allografts has been investigated. 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 randomized controlled trial (RCT) was identified that

compared autologous osteochondral transplantation with allograft plugs for recurrent cartilage lesions.

The following 3 sections assess the evidence for fresh osteochondral allograft for specific indications involving articular cartilage lesions of the ankle (talus).

Fresh Osteochondral Allograft for Primary Full-Thickness Articular Cartilage Lesions of the Ankle Less Than 1.5cm²

Clinical Context and Therapy Purpose

The purpose of fresh osteochondral allograft in individuals with primary full-thickness articular cartilage lesions of the ankle (talus) <1.5 cm² is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is individuals with primary full-thickness articular cartilage lesions of the ankle (talus) <1.5 cm².

Interventions

The therapy being considered is fresh osteochondral allograft: The injured area of cartilage and underlying bone are removed and replaced with a graft of cartilage and bone harvested from a donor.

Comparators

To restore articular surface, standard therapies of marrow stimulation currently in use include microfracture, abrasion arthroplasty, and drilling. Microfracture involves debridement of the damaged area and puncturing of the underlying bone to allow bleeding of the bone, stimulating the formation of new joint surface cartilage.

Outcomes

The general outcomes of interest are improvements in symptoms, functional outcomes, quality of life, and treatment-related morbidity. There are several symptom measurements for the ankle, such as the Foot and Ankle Ability Measures, in which the individual indicates the ability to perform various walking activities on a scale from "no difficulty" to "unable to do," as well as the American Orthopaedic Foot & Ankle Society Score, and the Foot and Ankle Outcome Score; quality of life can be measured using the SF-12 or SF-36.

Based on the available literature, follow-up should be at least 6 months, but longer-term follow-up is recommended.

Review of Evidence

The literature on fresh allograft for the treatment of small lesions of the ankle (talus) 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 cm² and autologous osteochondral transplantation 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.

Section Summary

There is little evidence on fresh osteochondral allografts for the primary treatment of full-thickness articular cartilage lesions of the ankle (talus) <1.5 cm². Because microfracture is effective as a primary treatment in lesions less than 1.5 cm², autologous osteochondral transplantation is typically considered a revision procedure. Due to the high failure rate of allografts, use of allografts for small primary cartilage lesions is not appropriate.

Fresh Osteochondral Allograft for Large (Area Greater than 1.5 cm²) or Cystic (Volume Greater Than 3.0 cm³) Cartilage Lesions of the Ankle

Clinical Context and Therapy Purpose

The purpose of fresh osteochondral allograft in individuals with large (area >1.5 cm²) or cystic (volume >3.0 cm³) cartilage lesions of the ankle (talus) for which autografting would be inadequate is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is individuals with large (area >1.5 cm²) or cystic (volume >3.0 cm³) cartilage lesions of the ankle for which autografting would be inadequate.

Interventions

The therapy being considered is fresh osteochondral allograft. The injured area of cartilage and underlying bone is removed and replaced with a graft of cartilage and bone harvested from a donor.

Comparators

The comparator of interest is fresh osteochondral transplantation: The injured area of cartilage and underlying bone are removed and replaced with a graft of cartilage and bone harvested from another area.

Outcomes

The general outcomes of interest are improvements in symptoms, functional outcomes, quality of life, and treatment-related morbidity. There are several symptom measurements for the ankle, such as the Foot and Ankle Ability Measures, in which the individual indicates the ability to perform various walking activities on a scale from "no difficulty" to "unable to do," as well as the American Orthopaedic Foot & Ankle Society Score, and the Foot and Ankle Outcome Score; quality of life can be measured using the SF-12 or SF-36.

Based on the available literature, follow-up should be at least 3 to 5 years.

Review of Evidence

Systematic Reviews

Pereira et. al. (2021) published a systematic review including 12 studies (7 retrospective case series and 5 prospective case series) in 191 patients who received a fresh osteochondral allograft for osteochondral lesions of the talus (n=194 ankles; mean lesion size range, 1.21 to 3.8 cm²). The average patient follow-up was 56.8 months (range, 6 to 240 months). Results revealed that aggregate mean preoperative and postoperative AOFAS scores (n=8 studies) were 49.6 (range, 38-61) preoperatively and 80.4 (range, 72.8-84) postoperatively. All studies reporting both pre- and postoperative AOFAS scores showed significant improvements from the preoperative values (p<.05). Five studies evaluated the visual analog scale pain score, with significant decreases pre- to postoperatively (p<.05). Overall, 21.6% of patients required subsequent surgical interventions such as arthroscopic debridement and hardware removal. The overall graft survival rate was 86.6%; 26 graft failures were recorded across the included studies.

Van Tienderen et. al. (2017) included in a systematic review, 5 studies with a total of 90 patients (91 ankles) who received a fresh osteochondral allograft for large or cystic osteochondral lesions of the talus. Studies selected reported at least 1 outcome of interest, including AOFAS score, Foot Functional Index score, visual analog scale score, reoperation rate, or rate of allograft collapse. The mean lesion volume was 3.7 cm³ (range, 1.0-10.9 cm³) and the number of prior procedures ranged from 1 to 4. At a mean follow-up of 45 months (range, 6-91 months), mean AOFAS scores of the combined studies improved from 48 to 80 and mean visual analog scale scores of the combined studies 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.

Randomized Controlled Trials

Ahmad and Jones (2016) conducted a randomized controlled trial (RCT) comparing autologous osteochondral transplantation 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. The majority of the study participants had recurrent osteochondral lesions. Only 5 patients with large primary osteochondral lesions were in the autograft treatment group, and 4 patients with large primary osteochondral lesions were in the allograft treatment group. Subgroup analyses on these patients with primary lesions were not conducted.

Section Summary

The evidence for fresh osteochondral allografts for the treatment of large (area >1.5 cm²) or cystic (volume >3.0 cm³) osteochondral lesions of the ankle includes a small number of patients in a randomized controlled trial (RCT) and systematic reviews of case series. 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 reviews 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 in 1 systematic review. Also, the use of allografts may have a negative impact on any future arthroplasty or arthrodesis. 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.

Fresh Osteochondral Allograft for Revision of Osteochondral Lesions of the Ankle

Clinical Context and Therapy Purpose

The purpose of fresh osteochondral allograft as a revision procedure in individuals with recurrent osteochondral lesions of the ankle (talus) for which autografting would be inadequate is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is individuals with recurrent osteochondral lesions of the ankle (talus) for which autografting would be inadequate.

Interventions

The therapy being considered is fresh osteochondral allograft. The injured area of cartilage and underlying bone is removed and replaced with a graft of cartilage and bone harvested from a donor.

Comparators

The comparator of interest is autologous osteochondral transplantation: The injured area of cartilage and underlying bone are removed and replaced with a graft of cartilage and bone harvested from another area.

Outcomes

The general outcomes of interest are improvements in symptoms, functional outcomes, quality of life, and treatment-related morbidity. There are several symptom measurements for the ankle, such as the Foot and Ankle Ability Measures, in which the patient indicates the ability to perform various walking activities on a scale from "no difficulty" to "unable to do," as well as the American Orthopaedic Foot & Ankle Society Score, and the Foot and Ankle Outcome Score; quality of life can be measured using the SF-12 or SF-36.

Based on the available literature, follow-up should be 5 years or longer.

Review of Evidence

Randomized Controlled Trial

Ahmad and Jones (2016; discussed above) included in their study 9 large and 27 recurrent osteochondral lesions of the talus. Most patients had failed a prior microfracture. The study randomized 20 patients to autologous osteochondral transplantation and 20 patients to plugs taken from a size-matched donor talus. Four patients from the allograft group had significant damage to the shoulder of the talar dome. These 4 received a hemi-talus allograft and were subsequently excluded from the study. Comparative analyses combined the patients with primary and recurrent lesions. Foot and Ankle Ability Measures and visual analog scale 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 visual analog scale 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 differences were not statistically significant. However, 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).

Observational Study

Gaul et al (2019) presented a case series of 19 patients (20 ankles) who received osteochondral allografts for osteochondral lesions of the ankle, 19 of which had prior surgical procedures (drilling, osteotomy, microfracture). Five of the 20 ankles required further surgery, 3 of which were considered allograft failures. The mean time to failure was 3.5 years. Of the 17 nonfailed ankles, the median follow-up was 9.7 years. Mean Olerud-Molander Ankle Score improved significantly following the procedure. Of the 15 patients who answered the follow-up survey, 14 reported less pain and better function.

Section Summary

The evidence on fresh osteochondral allografts for revision of osteochondral lesions of the ankle includes a RCT that compared outcomes between patients receiving autografts versus allografts. Most of the patients 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. 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 an option for revision of large lesions of the ankle.

Osteochondral Autograft and Fresh Osteochondral Allograft for Treatment of Articular Cartilage Lesions of Elbow and Shoulder

Clinical Context and Test Purpose

The purpose of autologous and fresh osteochondral transplantation in individuals with full-thickness articular cartilage lesions of the elbow and shoulder is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is individuals with full-thickness articular cartilage lesions of the elbow and shoulder.

Interventions

Therapy being considered is osteochondral autograft and fresh osteochondral allograft. The injured area of cartilage and underlying bone is removed and replaced with a graft of cartilage and bone harvested from another area or from a donor.

Comparators

To restore articular surface, standard therapies of marrow stimulation currently in use include microfracture, abrasion arthroplasty, and drilling.

Outcomes

The general outcomes of interest are improvements in symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Based on the available literature, follow-up should be 6 months or longer, or until the patient can return to their previous activity level, but longer-term follow-up is recommended.

Review of Evidence

Systematic Reviews

A systematic review of 71 case series or case reports (N=934) by Sayani et. al. (2021) investigated patient-reported functional outcomes, range of motion, and return to sports after treatment (autologous osteochondral transplantation [n=427], fixation [n=141], debridement and microfracture [n=136], and nonsurgical or nonoperative management [n=230]) for osteochondritis dissecans of the capitulum. Subgroup analysis according to treatment type was possible for 30 studies, including 14 studies on autologous osteochondral transplantation. Autologous osteochondral transplant groups demonstrated significant improvements in postoperative functional scores and range of motion, but when standardized, there was no significant differences between treatment types (debridement, fixation, or autograft transplant) in magnitude of outcomes. The overall return to sports was 94% of patients treated surgically. In larger lesions, there was a significantly lower return to sports rate when nonoperative treatment was used compared to surgical intervention (20% vs. 96.3%, respectively; n=114; p<.001). There was no significant difference in return to sports rates between baseball and gymnastics for lesions managed surgically. The highest proportion of return to sports rates was with debridement (100%), followed by autologous osteochondral transplantation (95.9%), and then fixation (83.1%).

Kirsch et. al. (2017) conducted a systematic review of the literature through July 2016 of case series evaluating return to play after autologous osteochondral transplantation for the treatment of osteochondritis dissecans of the capitellum. Seven case series (N=126) met the inclusion criteria and were rated as moderate quality using the Methodological Index

for Non-Randomized Studies. A total of 119 (94%) of the patients undergoing autologous osteochondral transplantations successfully returned to competitive sports. The mean time to unrestricted return was 5.6 months (range, 3 to 14 months).

Westermann et al (2016) included in their systematic review 24 case series (N=492 patients) that assessed return to sports after operative treatment (autologous osteochondral transplantation [n=164], microfracture and debridement [n=236], and fixation [n=92]) for osteochondritis dissecans of the capitulum.⁴⁵ The most common primary sport was baseball (371/464) followed by gymnastics (35/464). Quality of the evidence was assessed using the Grading of Recommendations Assessment, Development, and Evaluation system. None of the studies were randomized or controlled, but rather mostly level 4 evidence, retrospective, and from single institutions. The overall return to sports rate was 86% at a mean of 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 at any level after autologous osteochondral transplantation (0.95; 95% CI, 0.89 to 0.99) compared with debridement and microfracture (0.62; 95% CI, 0.46 to 0.77; p<.001) or fixation with pins, wires, or screws (0.72; 95% CI, 0.51 to 0.89; p=.01). Grafts were taken from the lateral femoral condyle or ribs. The percentages returning to their preoperative sport at their previous level were 94% (autologous osteochondral transplantation), 71% (microfracture and debridement), and 64% (fixation). Adverse events from the surgical procedures were rare; however, patients considering autologous osteochondral transplantation need to consider donor site morbidity.

Observational Study

Sato et. al. (2018) presented a case series of 72 patients receiving autologous osteochondral transplantation for advanced (stage III and IV) osteochondritis dissecans of the humeral capitellum in young athletes, who were followed for at least 3 years.⁴⁷ The Timmerman and Andrews clinical rating score, which incorporates subjective measures (such as pain, swelling, and activity level) and objective measures (such as flexion and arc of elbow motion) improved significantly from 101 to 190 following the procedure. Seventy of the patients returned to their sport without restrictions by 5.8 months. Subsequent surgeries included additional grafting (n=2), delayed medial ligament reconstruction (n=1), and arthroscopic removal of loose bodies (n=2).

Donor-Site Morbidity

Bexkens et. al. (2017) conducted a meta-analysis of case series that assessed donor-site morbidity after autologous osteochondral transplantation for osteochondritis dissecans 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 patients 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

Osteochondritis dissecans of the elbow typically occurs in patients who play baseball or do gymnastics. The literature on autologous osteochondral transplantation for advanced osteochondritis dissecans of the elbow consists of case series, primarily from Europe and Asia, and systematic reviews of case series. Although a meta-analysis suggested a benefit of autologous osteochondral transplantation compared with debridement or fixation, additional prospective comparative studies are needed to determine the effects of the procedure with greater certainty.

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

Minced or Particulated Cartilage for Articular Cartilage Lesions

Clinical Context and Therapy Purpose

The purpose of autologous or allogeneic minced or particulated articular cartilage transplantation in individuals with full-thickness articular cartilage lesions of the knee, ankle (talus), elbow, or shoulder is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is individuals with full-thickness articular cartilage lesions of the knee, ankle (talus), elbow, or shoulder.

Interventions

The therapy being considered is autologous or allogeneic minced or particulated articular cartilage transplantation. In these procedures, pieces of cartilage are mechanically minced into 1- to 2-mm pieces, allowing chondrocytes to be released from the extracellular matrix, migrate to surrounding tissues, and form a new cartilage tissue matrix.

Comparators

To restore articular surface, standard therapies of marrow stimulation currently in use include microfracture, abrasion arthroplasty, and drilling. Microfracture involves debridement of the damaged area and puncturing of the underlying bone to allow bleeding of the bone, stimulating the formation of new joint surface cartilage.

Autologous chondrocyte implantation may also be considered as an option and is discussed in medical policy [07.01.64 Autologous Chondrocyte Implant for Focal Articular Cartilage Lesions](#).

Outcomes

The general outcomes of interest are improvements in symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Based on the available literature, follow-up should be 1 to 2 years or longer.

Review of Evidence

Autologous Minced Cartilage

Randomized Controlled Trials

Cole et. al. (2011) reported on a multicenter trial with 29 patients (of 582 screened) randomized in a 1:2 ratio to microfracture or Cartilage Autograft Implantation System. In the single-stage Cartilage Autograft Implantation System procedure, autologous hyaline cartilage was harvested, minced, affixed to 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, International Cartilage Repair Society 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 follow-up, there were differences reported. The International Knee Documentation Committee Form score was significantly higher in the Cartilage Autograft Implantation System 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 Knee injury and Osteoarthritis Outcome Score symptoms and stiffness, pain, activities of daily living, sports and recreation, knee-related quality of life were significantly increased at 24 months in the Cartilage Autograft Implantation System group compared with microfracture patients. Qualitative analysis of MRI at 3 weeks and 6, 12, and 24 months showed no differences in the fill of the graft bed, tissue integration, or presence of subchondral cysts. Adverse events were similar for the groups.

Allogeneic Juvenile Minced Cartilage

Knee

Case Reports and Series

A retrospective review by Dawkins et. al. (2021) included 34 patients (36 knees) who received particulated juvenile allograft to the patellofemoral joint. Return to sport rate among patients who participated in a sport preoperatively was 100% (n=30 patients, 31 knees). After allograft, independent MRI assessment concluded that 67% of patients achieved an overall grade of normal or nearly normal. In terms of defect fill, 78% had majority defect fill. Primary graft failure occurred in 2 cases and 1 patient experienced surgical complication.

Evidence on the efficacy of DeNovo NT is limited to case reports and small case series. Farr et. al. (2014) conducted an industry-sponsored prospective study, the largest

series identified, 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 cm² and 5 cm² (mean, 2.7 cm²; range 1.2-4.6 cm²). 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, International Knee Documentation Committee examination, and completion of questionnaires. Outcomes included the Knee injury and Osteoarthritis Outcome Score, International Knee Documentation Committee, Marx Activity Scale, and 100-mm visual analog scale score for pain. International Knee Documentation Committee score improved over the 24 months of follow-up. At 24 months, International Knee Documentation Committee score had improved from 45.7 preoperatively to 73.6 of 100. There were also significant improvements in Knee injury and Osteoarthritis Outcome Score subscores ($p < .001$) and visual analog scale pain score (from 43.7/100 at baseline to 11.1 at 24 months; $p < .001$). 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.

Tompkins et. al. (2013) included in their study 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.

Systematic Reviews

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

Case Reports and Series

DiSandis et. al. (2018) reported on a series of 46 patients receiving particulated juvenile cartilage allograft transplantation and autologous bone marrow aspirate concentration for osteochondral lesions of the talus. Only 24 patients had pre- and post-Foot and Ankle Outcome Score and SF-12 Health Survey data. Almost all subscale scores were significantly improved after the procedure; however, MRI showed inhomogeneous repair tissue structure, persistent bone marrow edema, and moderately hyperintense tissue.

Dekker et. al. (2018) conducted a retrospective review of patients receiving particulated juvenile cartilage allograft transplantation for osteochondral lesions of the talus (N=15). Twelve of the 15 patients had undergone a prior microfracture procedure and 3 patients received the transplant as a primary procedure. A successful procedure was defined as an improvement in pain and no subsequent cartilage procedures. After at least 1 year of follow-up, 9 (60%) cases were considered successful, with 3 patients needing additional cartilage procedures and 3 reporting continued pain. Predictors of failure were larger lesions and male sex.

Saltzman et. al. (2017), in addition to their systematic review of the literature, 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 mm². Two of the 6 patients underwent a medial malleolar osteotomy to access the lesion. Implantation procedures included debridement, 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 MRIs between 3 months and 2 years postoperatively, there was persistent subchondral edema and nonuniform chondral surface.

Coetzee et. al. (2013) published a preliminary report that described 24 ankles (23 patients) with osteochondral lesions of the talus (mean lesion size, 125 mm²) that 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 Scale score, with a final mean visual analog scale 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.

Section Summary

The evidence on autologous minced or particulated cartilage includes a small randomized controlled trial (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, nonuniform 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 the interpretation of its results. Randomized comparisons with microfracture in patients who have not received prior treatment would permit greater certainty about the effectiveness of this procedure.

Decellularized Osteochondral Allograft Plugs

Clinical Context and Therapy Purpose

The purpose of decellularized osteochondral allograft plugs in individuals with full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is individuals with full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder.

Interventions

The therapy being considered is decellularized osteochondral allograft plugs. For decellularized osteochondral allograft plugs, allografts undergo a procedure that extracts lipids. The graft is then inactivated and sterilized in order to extend shelf life.

Comparators

To restore articular surface, standard therapies of marrow stimulation currently in use include microfracture, abrasion arthroplasty, and drilling. Microfracture involves debridement of the damaged area and puncturing of the underlying bone to allow bleeding of the bone, stimulating the formation of new joint surface cartilage.

Outcomes

The general outcomes of interest are improvements in symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Based on the available literature, follow-up should be 1 to 2 years or longer.

Review of Evidence

Case Series

Case series have suggested high failure rates for decellularized osteochondral allograft plugs (Chondrofix). Farr et al (2016) reviewed records of 32 patients and 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=.005).

Section Summary

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

Reduced Osteochondral Allograft Discs

Clinical Context and Therapy Purpose

The purpose of reduced osteochondral allograft discs in individuals with full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations

The relevant population of interest is individuals with full-thickness articular cartilage lesions of the knee, ankle, elbow, or shoulder.

Interventions

The therapy being considered is reduced osteochondral allograft discs. For reduced osteochondral allograft discs, the discs are laser etched and contain hyaline cartilage with chondrocytes, growth factors, and extracellular matrix proteins.

Comparators

To restore articular surface, standard therapies of marrow stimulation currently in use include microfracture, abrasion arthroplasty, and drilling. Microfracture involves debridement of the damaged area and puncturing of the underlying bone to allow bleeding of the bone, stimulating the formation of new joint surface cartilage.

Outcomes

The general outcomes of interest are improvements in symptoms, functional outcomes, quality of life, and treatment-related morbidity.

Literature describing appropriate follow-up is not available, but based upon other allograft procedures, a minimum of 1 to 2 years would be considered appropriate.

Review of Evidence

Case Reports and Case Series

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

Section Summary

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

Summary of Evidence

Summary of Evidence for Osteochondral Autografts for Articular Cartilage Lesions of Knee, Ankle (Talus), Elbow or Shoulder

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. 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 cm²) 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 an 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 and systematic reviews of case series. 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 an improvement in the net health outcome.

Ankle (Talar) Lesions

For individuals who have primary full-thickness articular cartilage lesions of the ankle (talus) < 1.5 cm² who receive an osteochondral autograft, the evidence includes observational studies and a systematic review of these studies. A systematic review found similar improvements in outcomes following microfracture and autologous osteochondral transplantation. 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 autologous osteochondral transplantation as a primary treatment for smaller articular cartilage lesions of the ankle. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have large (area >1.5 cm²) or cystic (volume >3.0 cm³) full-thickness articular cartilage lesions of the ankle (talus) who receive an osteochondral autograft, the evidence includes a randomized controlled trial (RCT) and several observational studies. A RCT in patients with large lesions found similar efficacy for autologous osteochondral transplantation, marrow stimulation, and arthroplasty at 2-year

follow-up. Longer-term results were not reported in the RCT. However, observational studies with longer-term follow-up (4-5 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. Studies on the standard treatment for ankle lesions, marrow stimulation, have reported positive outcomes for patients with small lesions of the ankle ($<1.5 \text{ cm}^2$), but have generally reported high failure rates for patients with large ($>1.5 \text{ cm}^2$) lesions. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have osteochondral lesions of the ankle (talus) that have failed primary treatment who receive an osteochondral autograft, the evidence includes 2 nonrandomized comparative trials (RCTs) and several case series. The best evidence for revision autologous osteochondral transplantation comes from a nonrandomized comparative study that found better outcomes with autologous osteochondral transplantation 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 autologous osteochondral transplantation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have primary full-thickness articular cartilage lesions of the ankle (talus) $< 1.5 \text{ cm}^2$ who receive a fresh osteochondral allograft, there is little evidence. Because microfracture is effective as a primary treatment for lesions $< 1.5 \text{ cm}^2$ and autologous osteochondral transplantation is effective as a revision procedure, use of allograft for small primary cartilage lesions has not been reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have large (area $>1.5 \text{ cm}^2$) or cystic (volume $>3.0 \text{ cm}^3$) cartilage lesions of the ankle (talus) when autografting would be inadequate, who receive a fresh osteochondral allograft, the evidence includes a small number of patients in a randomized controlled trial (RCT) and systematic reviews of case series. 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 reviews 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 in 1 systematic review. 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 an improvement in the net health outcome.

For individuals who have revision osteochondral lesions of the ankle (talus) when autografting would be inadequate, who receive a fresh osteochondral allograft, the evidence includes a randomized controlled trial (RCT). 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. 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 considered an option for revision of large lesions of the ankle. The evidence is sufficient to determine that the technology results in an 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. Osteochondritis dissecans of the elbow typically occurs in patients who play baseball or do gymnastics. Although the meta-analysis suggested a benefit of osteochondral autografts compared with debridement or fixation, randomized controlled trials (RCTs) are needed to determine the effects of the procedure with greater certainty. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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. Evidence on osteochondral autografting for the shoulder is very limited. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Summary of Evidence for Minced or Particulated Cartilage, Decellularized Osteochondral Allograft Plus and Reduced Osteochondral Allograft Discs for Articular Cartilage Lesions of Knee, Ankle (Talus), Elbow or Shoulder

For individuals who have full-thickness articular cartilage lesions of the knee, ankle (talus), elbow, or shoulder who receive autologous or allogeneic minced or particulated articular cartilage, the evidence includes a small randomized controlled trials (RCT) and small case series. 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 that the technology results in an improvement in the net health outcome.

For individuals who have full-thickness articular cartilage lesions of the knee, ankle (talus), elbow, or shoulder who receive decellularized osteochondral allograft plugs, the evidence includes small case series. The case series reported delamination of the implants

and high failure rates. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have full-thickness articular cartilage lesions of the knee, ankle (talus), elbow, or shoulder who receive reduced osteochondral allograft discs, the evidence includes very small case series. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons (AAOS)

In 2010 and 2012 the American Academy of Orthopaedic Surgeons (AAOS) issued a clinical practice guideline on the diagnosis and treatment of osteochondritis dissecans (OCD) which included the following recommendations:

- We are unable to recommend for or against a specific cartilage repair technique in symptomatic skeletally immature patients with an unsalvageable OCD lesion.
- We are unable to recommend for or against a specific cartilage repair technique in symptomatic skeletally mature patients with an unsalvageable OCD lesion.

According to the American Academy of Orthopaedic Surgeons (AAOS), most candidates eligible for articular cartilage restoration are young adults with a single injury or lesion. Older individuals, or those with many lesions in one joint, are less likely to benefit from osteochondral autograft transplantation.

The American Orthopaedic Foot and Ankle Society (AOFAS)

In 2018, the American Orthopaedic Foot and Ankle Society issued a position statement on the use of osteochondral transplantation for the treatment of osteochondral lesions of the talus. In the statement, the Society "endorses the use of osteochondral autograft and allograft transplantation for the treatment of osteochondral lesion of the talus, especially large diameter lesions, cystic lesions, and those that have failed previous surgical treatment. AOFAS does not consider these procedures to be experimental in a patient population that has failed nonoperative management."

International Consensus Group on Cartilage Repair of the Ankle

In 2017, the International Consensus Group on Cartilage Repair of the Ankle convened to review the best available evidence and develop consensus statements to guide management of patients needing cartilage repair of the ankle. The Consensus Group, consisting of 75 experts from 25 countries, acknowledged that evidence in the field of cartilage repair of the ankle is both low quality and at low levels, one topic addressed by the Consensus Group was the use of osteochondral allografts. Through a process based on the Delphi method of achieving consensus, the following recommendations were issued:

- Osteochondral allograft plugs may be preferred over autografts in the following conditions: lesions >1.5 cm; knee osteoarthritis; history of knee infection; patients

expressing concern of donor site morbidity of the knee. (Grade of evidence: prospective cohort study)

- The source of osteochondral allograft plugs for the ankle should come from the ankle, not the knee. (Grade of evidence: basic science)
- There is an absence of clinical evidence and clinical experience for the use of decellularized osteochondral allograft plugs.
The preferred type of allograft for the ankle is fresh, not frozen. (Grade of evidence: basic science)

National Institute of Health and Care Excellence (NICE)

In 2018, the National Institute for Health and Care Excellence issued a new guidance on mosaicplasty for symptomatic articular cartilage defects of the knee (IPG607).

- The guidance states that the evidence for safety and efficacy of mosaicplasty for knee cartilage defects is adequate to support the use of the procedure.

Regulatory Status

The U.S. Food and Drug Administration (FDA) 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 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.

PRIOR APPROVAL

Not applicable.

POLICY

See Related Medical Policy:

- [07.01.64 Autologous Chondrocyte Implant for Focal Articular Cartilage Lesions](#)

Fresh Osteochondral Allografting

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; microfracture, osteochondral autografting, or autologous chondrocyte implantation would be inadequate due to lesion size, location or depth.

- Large (area >1.5 cm²) or cystic (volume >3.0 cm³) osteochondral lesions of the ankle (talus) when osteochondral autografting would be inadequate due to lesion size, depth, or location.
- Revision surgery after failed prior marrow stimulation (e.g., microfracture, drilling) for large (area >1.5 cm²) or cystic (volume >3.0 cm³) osteochondral lesions of the ankle (talus) when osteochondral autografting would be inadequate due to lesion size, depth or location.

Fresh osteochondral allografting not meeting the above criteria and for all other joints is considered **investigational** because the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Osteochondral Autografting (OATS/Mosaicplasty) of the Knee

Osteochondral autografting (OATS/mosaicplasty) using 1 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 individuals who have had an inadequate response to a prior surgical procedure, when **ALL** the following criteria are met:

- A focal, full-thickness Outerbridge Grade III or Grade IV unipolar lesion(s) on the weight bearing surface of the femoral condyles, trochlea or patella that are between 1 and 2.5 cm² in size; **and**
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); **and**
- Adolescent individual is skeletally mature with documented closure of the growth plates; **or**
- Adult individual is not a candidate for total knee arthroplasty or other reconstructive knee surgery; **and**
- Function-limiting pain (pain is at least 3 out of 10 in intensity *and* is associated with an impact to activities of daily living [ADLs]) for at least 3 months which has failed to respond to conservative treatment to include any of the following:
 - Physical therapy (PT) (exception to the physical therapy requirement in unusual circumstances (for instance, intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record
 - Home exercise program
 - Anti-inflammatory medications and analgesics
 - Adjunctive medications such as nerve membrane stabilizers (antidepressants or anticonvulsants) or muscle relaxants
 - Intraarticular corticosteroid injection(s).

Osteochondral autografting using 1 or more cores of osteochondral tissue may be considered **medically necessary** for the treatment of symptomatic full-thickness cartilage defects of the ankle (talus) caused by acute or repetitive trauma in individuals who have

had an inadequate response to a prior surgical procedure, when **ALL** the following criteria are met:

- Large (area $>1.5 \text{ cm}^2$) or cystic (volume $>3.0 \text{ cm}^3$) osteochondral lesion(s) of the ankle (talus); **or**
- Revision surgery after failed marrow stimulation (microfracture, drilling) for osteochondral lesion(s) of the ankle (talus); **and**
- The individual is skeletally mature with documented closure of the growth plates; **and**
- Absence of inflammatory arthritis or other systemic disease affecting the joints; **and**
- Function- limiting pain (pain is at least 3 out of 10 in intensity *and* is associated with an impact to activities of daily living [ADLs]) for at least 3 months which has failed to respond to conservative treatment to include any of the following:
 - Physical therapy (PT) (exception to the physical therapy requirement in unusual circumstances (for instance, intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record
 - Home exercise program
 - Anti-inflammatory medications and analgesics
 - Adjunctive medications such as nerve membrane stabilizers (antidepressants or anticonvulsants) or muscle relaxants
 - Intraarticular corticosteroid injection(s).

Osteochondral autografting not meeting the above criteria and for all other joints is considered **investigational** because the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Investigational

Osteochondral autografts and allografts for the treatment of focal cartilage lesions using the following is considered **investigational** because the evidence is insufficient to determine that the technology results in an improvement in the net health outcomes:

- Autologous minced or particulated cartilage
- Allogeneic minced or particulated cartilage
- Decellularized osteochondral allograft plugs (e.g., Chondrofix)
- Reduced osteochondral discs (e.g., Prochondrix, Cartiform)

Policy Guidelines

- If debridement 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 $>35 \text{ kg/m}^2$) 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.

The Kellgren-Lawrence Grading System

Is a radiographic grading system that has been developed for describing osteoarthritic changes to the tibial-femoral joint of the knee, when used, the radiographic findings on plain x-rays are typically reported within one of the following categories:

- Grade 0 – No radiographic features of osteoarthritis are present
- Grade I – Doubtful narrowing of joint space and possible osteophytic lipping
- Grade II – Definite osteophytes and possible narrowing of joint space
- Grade III – Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis, and possible deformity of bone contour
- Grade IV – Large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone contour

Kissing Lesion

Is an articular cartilage defect on opposing joint surfaces of the knee and that are in contact either between the patella and distal femur or the distal femur and tibia (e.g., bipolar lesion).

The Modified Outerbridge Classification

Is a system that has been developed for judging articular cartilage injury to the knee. This system allows delineation of varying areas of chondral pathology, based on the qualitative appearance of the cartilage surface as viewed on MRI, and can assist in identifying those injuries that are suitable for repair techniques. The characterization of cartilage in this system is as follows:

- Grade I – Softening with swelling
- Grade II – Fragmentation and fissuring less than one square centimeter (1 cm²)
- Grade III – Fragmentation and fissuring greater than one square centimeter (1 cm²)
- Grade IV – Subchondral bone exposed

The Outerbridge Classification

Is a system that has been developed for judging articular cartilage injury to the knee. This system allows delineation of varying areas of chondral pathology, based on the qualitative appearance of the cartilage surface as viewed by direct visualization intraoperatively, and can assist in identifying those injuries that are suitable for repair techniques. The characterization of cartilage in this system is as follows:

- Grade I – Softening with swelling
- Grade II – Fragmentation and fissuring less than one square centimeter (1 cm²)
- Grade III – Fragmentation and fissuring greater than one square centimeter (1 cm²)
- Grade IV – Subchondral bone exposed

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 24999 Unlisted procedure, humerus, or elbow
- 27415 Osteochondral allograft, knee, open
- 27416 Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])
- 27899 Unlisted procedure, leg or ankle
- 28446 Open osteochondral autograft, talus (includes obtaining graft[s])
- 29866 Arthroscopy, knee, surgical; osteochondral autograft(s) (e.g., mosaicplasty) (includes harvesting of the autograft[s])
- 29867 Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)
- 29885 Arthroscopy, knee, surgical; drilling for osteochondritis dissecans with bone grafting, with or without internal fixation (including debridement of base of lesion)
- 29892 Arthroscopically aided repair of large osteochondritis dissecans lesion, talar dome fracture, or tibial plafond fracture, with or without internal fixation (includes arthroscopy)
- 29999 Unlisted procedure, arthroscopy

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POLICY HISTORY

Date	Reason	Action
August 2022	Annual Review	Policy Revised
August 2021	Annual Review	Policy Revised
August 2020	Annual Review	Policy Revised
August 2019	Annual Review	Policy Revised

August 2018	Annual Review	Policy Revised
August 2017	Annual Review	Policy Revised
August 2016	Annual Review	Policy Revised
September 2015	Annual Review	Policy Revised
October 2014	Interim Review	Policy Revised
May 2014		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
 Medical Policy Analyst
 PO Box 9232
 Des Moines, IA 50306-9232

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