Medical Policy Reference Manual
Medical Policy

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

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Focal chondral defects of the knee, either due to trauma or other conditions such as osteochondritis dissecans, often fail to heal on their own and may be associated with pain, loss of function, disability and the long-term complication of osteoarthritis. Various methods of cartilage resurfacing have been investigated including marrow-stimulation techniques such as subchondral drilling, microfracture, and abrasion arthroplasty, all of which are considered standard therapies and all of which attempt to restore the articular surface by inducing the growth of fibrocartilage into the chondral defect. However, fibrocartilage does not share the same biomechanical properties as hyaline cartilage, and thus various strategies for chondral resurfacing with hyaline cartilage have been investigated, such as autologous chondrocyte implantation *(see Medical Policy 7.01.048, Autologous Chondrocyte Implantation)* and osteochondral graftings.

Both allogenic and autologous osteochondral grafts have been investigated. Both fresh and cryopreserved allogenic osteochonodral grafts have been used with some success, although cryopreservation decreases the viability of cartilage cells, and fresh allografts may be difficult to obtain and create concerns regarding infectious diseases. For these reasons, 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 and autografts for smaller lesions. In an effort to extend the amount of the available donor tissue, investigators have used multiple, small osteochondral cores harvested from non-weight-bearing sites in the knee, for treatment of full-thickness chondral defects. Several systems are available for performing this procedure, the Mosaicplasty System (Smith and Nephew), the Osteochondral Autograft Transfer System (OATS®, Arthrex, Inc.), and the COR™ and COR2™ systems (DePuy-Mitek). Although mosaicplasty and OATS may use different instrumentation, the underlying principle is similar; i.e., the use of multiple osteochondral cores harvested from a non-weight-bearing region of the femoral condyle and autografted into the chondral defect. While osteochondral autografting is primarily performed on the femoral condyles of the knee, osteochondral grafts have also been used to repair chondral defects of the patella, tibia and ankle.

Policy

Osteochondral allografting is considered **medically necessary** as a technique to repair large full-thickness chondral defects of the knee.

Osteochondral autografting is considered **medically necessary** for the treatment of symptomatic full-thickness cartilage defects of the knee.

Osteochondral allografting or autografting for all other joints, including, but not limited to, patellar and talar (27899, 28446, 28899), is considered **experimental / investigational** as it does not meet TEC criteria # 2-5

Policy Guidelines

Rationale (2009):

Osteochondral allografting for lesions of the knee has been done for a while using fresh or cryopreserved grafts. Osteochondral autografting has been investigated as an option to increase the survival rate of the grafted cartilage and to eliminate the risk of disease transmission which may occur with allografts. Controlled studies for osteochondral autografting in the treatment of focal articular cartilage of the knee demonstrate similar benefit to other cartilage resurfacing procedures in appropriately selected patients. A number of uncontrolled studies indicate that osteochondral autografts can improve symptoms in some patients with full-thickness lesions of the femoral condyle who have had inadequate response to a prior arthroscopic or other surgical repair procedure, who otherwise have limited options.

Overall, there is a scarcity of published evidence regarding patient outcomes in osteochondral allografts or autografts for osteochondral defects of the ankle and other joints. Although these procedures have been used more successfully in repairs of the knee joint, this technique has not been performed nearly as much for the ankle, due to the special considerations of the dynamics involved with the ankle joint, and the steep learning curve required to perform the surgery. Expert reviews published on the subject label the technique a "promising" alternative, but suggest further studies. The currently available evidence is inadequate to permit conclusions regarding health outcomes for osteochondral autografts and allografts for joints other than the knee.

Rationale (2007) - Osteochondral Allograft Repair of the Ankle (former title of policy):

1. The technology must have final approval from the appropriate government regulatory bodies:

Osteochondral allograft repair is a surgical procedure, not subject to regulation by the Food and Drug Administration. Bone and tissue banks where allografts may originate are subject to statutes enforceable by the FDA.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

The published evidence in the peer-reviewed literature comes from small case-series studies and retrospective reviews of mostly short-term outcomes. Kim and colleagues (2002) describe results of seven patients who underwent tibiotalar allografts for post-traumatic arthropathy through an average follow-up period of 148 months. The failure rate of this small series was 42%. Subjective results in the form of ankle score and SF-12 survey both showed increases, but the increases did not appear to be significant. Overall, although the authors concluded that osteochondral autografting may provide a viable alternative for post-traumatic ankle arthrosis in selected individuals, the study was too small to permit conclusions regarding health outcomes. Myerson et al (2005) in a retrospective review of 75 operations performed at a single facility reported that healing occurred after a mean of 4 months post-surgery in 92% of their cases. Once the graft was integrated, there was no evidence of graft resorption or subsidence at a mean of 3.5 years post-surgery. The review addresses issues such as successful grafting and complications, but did not focus on outcomes measures such as symptom relief, physical ability, or overall quality of life, and did not describe details of the patient population other than an average age. Meehan and colleagues (2005) reported on the results of 11 patients in a prospective series. Diagnoses included post-traumatic arthritis (n=7), osteoarthritis (n=2), and osteochondral defects (n=2). At a minimum follow-up of 24 months, 6 patients had successful grafts. Of the five failed grafts, 3 had successful second attempts, one underwent total ankle arthroplasty, one had no additional surgery. Subjective measures of pain, gait, walking scores, and AOFAS scores were significantly improved. The authors noted that the serum of 10 patients tested positive for cytotoxic HLA antibodies postoperatively. The authors concluded that osteochondral allografting is a "promising" alternative to arthrodesis and prosthetic ankle joint replacement. Gross et al (2001) reported on experience with 9 cases of osteochondral allograft for lesions of the talus. Six grafts remained in situ over a range of 4-19 years follow-up. The remaining three cases required arthrodesis due to resorption and fragmentation of the graft.

Overall, there is a paucity of published evidence regarding patient outcomes in osteochondral allografts for osteochondral defects of the ankle. Although osteochondral allografts have been used more successfully in repairs of the knee joint, this technique has not been performed nearly as much for the ankle, due to special considerations of the dynamics involved with the ankle joint, and the steep learning curve required to perform the surgery. Expert reviews published on the subject label the technique a "promising" alternative, but suggest further studies. The

experts do seem to agree that osteochondral grafting for ankle defects may end up being the preferred treatment approach for patients who are younger and more active.

3. The technology must improve the net health outcome:

The currently available evidence is inadequate to permit conclusions regarding health outcomes. Significant rates of failed grafts in small case series suggest that there is likewise inadequate evidence to determine that the technology improves net health outcomes. Furthermore, as one study documented the presence of cytotoxic HLA antibodies in 10/11 patients in the series, there is also a suggestion osteochondral allografts may not be as non-immunogenic as had originally been thought, and perhaps deserves further study. This sentiment was voiced recently in an article wherein the commentator (Kadakia) stated, "The bone graft and cartilage were initially thought to be immunoprotected...but there's a lot of thinking that this is not the case and there is some sort of 'rejection' of the grafts."

4. The technology must be as effective as any established alternatives:

For patients presenting with osteochondral defects, osteoarthritis, or arthritis of the ankle secondary to traumatic injury, the physician's options include conservative management, autografting (mosaicplasty), allografting, arthrodesis, or prosthetic joint replacement. There are no studies that have directly compared outcomes of the different surgical approaches. It has been voiced that allografting is reserved for larger defects, especially in younger, active patients.

5. The improvement must be attainable outside the investigational settings:

There is inadequate evidence to permit conclusions regarding health outcomes from investigational settings. Therefore, there is insufficient data to determine if improvement in health outcomes can be expected outside of the investigational settings.

Update 2011:

A search of the peer-reviewed literature was performed from May 2009 through May 2011. Findings in the literature do not change the medically necessary indications for osteochondral autografts and allografts in the treatment of focal articular cartilage lesions. Therefore, the policy is unchanged.

Update 2013:

A search of the peer-reviewed literature was performed from June 2011 through June 2013. Findings in the literature do not change the medically necessary indications for osteochondral autografts and allografts in the treatment of local articular cartilage lesions. Therefore, the policy is unchanged.

Update 2015:

A search of the peer-reviewed literature was performed from July 2013 through July 2015. Findings in the literature do not change the medically necessary indications for osteochondral autografts and allografts in the treatment of local articular cartilage lesions. Therefore, the policy is unchanged.

Update 2017:

A search of the peer-reviewed literature was performed from August 2015 through September 2017. Findings in the literature do not change the medically necessary indications for osteochondral autografts and allografts in the treatment of focal articular cartilage lesions. Therefore, the policy is unchanged.

Cross References to Related Policies and Procedures

Autologous Chondrocyte Implantation, Medical Policy 7.01.048
Collagen Meniscus Implant, Medical Policy 7.01.112
Meniscal Allograft Transplantation, Medical Policy 7.01.015

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own, and may or may not be in agreement with those of CareFirst.

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