Medical Policy

Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

Effective Date: January 1, 2018
Revised: November 21, 2017
Reviewed: November 21, 2017

Description

Focal chondral defects of the knee, either due to trauma or other conditions such as osteochondritis dissecans (OCD), often fail to heal on their own and may be associated with pain, loss of function, disability, and the long-term complication of osteoarthritis. The ideal resurfacing technique would eliminate symptoms, restore normal biomechanics of the knee joint, and prevent the long-term emergence of osteoarthritis and the necessity for total knee arthroplasty. Various methods of cartilage resurfacing have been investigated including marrow-stimulation techniques such as subchondral drilling, microfracture, and abrasion arthroplasty, all of which are considered standard therapies and all of which attempt to restore the articular surface by inducing the growth of fibrocartilage into the chondral defect. However, fibrocartilage does not share the same biomechanical properties as hyaline cartilage, and thus various strategies for chondral resurfacing with hyaline cartilage have been investigated.

Both fresh and cryopreserved allogeneic osteochondral grafts have been used with some success, although cryopreservation decreases the viability of cartilage cells, and fresh allografts may be difficult to obtain and create concerns regarding infectious diseases. As a result, autologous osteochondral grafts have been investigated as an option to increase the survival rate of the grafted cartilage and to eliminate the risk of disease transmission. Autologous grafts are limited by the small number of donor sites; thus allografts are typically used for larger lesions. In an effort to extend the amount of the available donor tissue, investigators have used multiple, small osteochondral cores harvested from non-weight-bearing sites in the knee for treatment of full-thickness chondral defects. Several systems are available for performing this procedure, the Mosaicplasty System (Smith and Nephew), the 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 (ie, use of multiple osteochondral cores harvested from a non-weight-bearing region of the femoral condyle and autografted into the chondral defect). These terms have been used interchangeably to describe the procedure.

Preparation of the chondral lesion involves débridement and preparation of recipient tunnels. Multiple individual osteochondral cores are harvested from the donor site, typically from a peripheral non-weightbearing 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 may be performed with either an open approach or arthroscopically. Osteochondral autografting

has also been investigated as a treatment of unstable OCD 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 also been used to repair chondral defects of the patella, tibia, and ankle. With osteochondral autografting, the harvesting and transplantation can be performed during the same surgical procedure. Technical limitations of osteochondral autografting are difficulty in restoring concave or convex articular surfaces, incongruity of articular surfaces that can alter joint contact pressures, short-term fixation strength and load-bearing capacity, donor site morbidity, and lack of peripheral integration with peripheral chondrocyte death associated with graft harvesting and insertion

Recently, a minimally processed osteochondral allograft (Chondrofix®; Zimmer) has become available for use. Chondrofix® is composed of decellularized hyaline cartilage and cancellous bone and can be used "off the shelf" with precut cylinders (7-15 mm). Multiple cylinders may be used to fill a larger defect in a manner similar to OATS or mosaicplasty.

Autologous chondrocyte implantation (ACI) is another method of cartilage repair involving the harvesting of normal chondrocytes from normal non-weight-bearing articular surfaces, which are then cultured and expanded in vitro and implanted back into the chondral defect.

REGULATORY STATUS
Filling defects with minced articular cartilage (autologous or allogeneic), is another single-stage procedure that is being investigated for cartilage repair. The Cartilage Autograft Implantation System (CAIS; Johnson and Johnson; phase 3 trial) harvests cartilage and disperses chondrocytes on a scaffold in a single-stage treatment. BioCartilage® (Arthrex) consists of a micronized allogeneic cartilage matrix that is intended to provide a scaffold for microfracture. DeNovo NT Graft (Natural Tissue Graft) is produced by ISTO Technologies with exclusive distribution rights by Zimmer. DeNovo NT consists of manually minced cartilage tissue pieces obtained from juvenile allograft donor joints. The tissue fragments are mixed intraoperatively with fibrin glue before implantation in the prepared lesion. It is thought that mincing the tissue helps both with cell migration from the extracellular matrix and with fixation. As there is no use of chemicals and minimal manipulation, the allograft tissue does not require U.S. Food and Drug Administration (FDA) approval for marketing. DeNovo® ET Live Chondral Engineered Tissue Graft (Neocartilage) is marketed by ISTO Technologies outside of the United States. DeNovo® ET graft uses juvenile allogeneic cartilage cells engineered by ISTO Technologies. FDA approved ISTO's Investigational New Drug application for Neocartilage in 2006, which allowed them to pursue phase 3 clinical trials of the product in humans.

Policy/Criteria

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

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

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

- For the treatment of symptomatic full-thickness cartilage defects of the knee caused by acute or repetitive trauma in patients who have had an inadequate response to a prior surgical procedure, when all of the following have been met:
    - Adolescent patients should be skeletally mature with documented closure of growth plates (eg, ≥15 years). Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (eg, ≤55 years)
    - Focal, full-thickness (grade III or IV) unipolar lesions on the weight-bearing surface of the femoral condyles, trochlea, or patella that are between 1 and 2.5 cm2 in size
    - Documented minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge grade II or less), and normal-appearing hyaline cartilage surrounding the border of the defect
    - Normal knee biomechanics, or alignment and stability achieved concurrently with osteochondral grafting.
- Large (area >1.5 cm2) or cystic (volume >3.0 cm3) osteochondral lesions of the talus.
- Revision surgery after failed marrow stimulation for osteochondral lesion of the talus.

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

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

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

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

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

POLICY GUIDELINES

If débridement is the only prior surgical treatment, consideration should be given to marrow-stimulating techniques before osteochondral grafting is performed.

Severe obesity (eg, body mass index greater than 35 kg/m2) 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.

Members must consult their applicable benefit plans or contact a Member Services representative for specific coverage information.

Billing and Coding

Search:

CPT	
27415	Osteochondral allograft, knee, open

CPT	
27416	Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])
28446	Open osteochondral autograft, talus (includes obtaining graft(s))
29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (e.g., mosaicplasty) (includes harvesting of the autograft(s)
29867	Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)
ICD-10-PCS	ICD-10-PCS codes are only used for inpatient services.
0SQC0ZZ – 0SQDXZZ	Surgical, lower joints, repair, knee, code by approach (open, percutaneous, percutaneous endoscopic)

Practice Guidelines and Position Statements

American Academy of Orthopaedic Surgeons
In 2010 guidelines, which remain available on the American Academy of Orthopaedic Surgeons (AAOS) website in 2017, on the diagnosis and treatment of osteochondritis dissecans (OCD), AAOS was unable to recommend for or against a specific cartilage repair technique in symptomatic skeletally immature or mature patients with an unsalvageable OCD lesion.

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

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence conducted a 2005 review of mosaicplasty for knee cartilage defects. The corresponding guidance, released in 2006, stated that “There is some evidence of shortterm efficacy, but data on long-term efficacy are inadequate.”

Source

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