Anthem

Clinical UM Guideline

Subject: Treatment of Osteochondral Defects
Guideline #: CG-SURG-67 **Publish Date:** 12/27/2017
Status: New **Last Review Date:** 11/02/2017

Description

This document addresses treatment of osteochondral defects of the knee, ankle and other joints using the following procedures or devices:

- Autologous chondrocyte transplant (ACT);
- Minced cartilage repair;
- Osteochondral allograft;
- Osteochondral autograft (OATS/mosaicplasty);
- Resorbable synthetic bone filler materials.

Note: Please see the following related document(s) for additional information:

- SURG.00011 Allogeneic, Xenographic, Synthetic and Composite Products for Wound Healing and Soft Tissue Grafting
- CG-SURG-69 Meniscal Allograft Transplantation of the Knee

Clinical Indications

Medically Necessary:
Note: *Members must meet the disease specific criteria as well as the general criteria as set forth in this document for the specific procedure to be considered medically necessary.*

Autologous chondrocyte transplantation (ACT), also known as autologous chondrocyte implantation (ACI), to treat cartilaginous defects of the knee is considered **medically necessary** when **all** of the following criteria are met:

1. Inadequate response to prior surgical therapy to correct the defect; **and**
2. Size of the cartilage defect is greater than or equal to 1.5 square cm (i.e. length x width)* in total area; **and**
3. The defect involves only the cartilage and not the subchondral bone, unless ACT is being used to treat osteochondritis dissecans associated with a bony defect 10 mm or less in depth which has failed prior conservative treatment. Lesions due to osteochondritis dissecans associated with a bony lesion greater than 10 mm in depth must also undergo corrective bone grafting; **and**
4. No known history of allergy to the antibiotic Gentamicin; **and**
5. No known sensitivities to bovine cultures; **and**
6. Condition involves a focal, full thickness, (grade III or IV) isolated defect of the knee involving the weight bearing surface of the medial or lateral femoral condyles or trochlear region (trochlear groove of the femur) caused by acute or repetitive trauma; **and**
7. All criteria listed in the “General Criteria” section below are met.

Osteochondral allograft transplantation to treat cartilaginous defects of the knee is considered **medically necessary** when **all** of the following criteria are met:

1. Arthroscopic or magnetic resonance imaging (MRI) examination results which detail the size, location and type of osteochondral defect; **and**
2. Size of the cartilage defect is greater than or equal to 2 square cm (i.e. length x width)* in total area; **and**
3. Condition involves a focal, full thickness, (grade III or IV) isolated defect of the weight bearing surface of the medial or lateral femoral condyles or trochlear region (trochlear groove of the femur) caused by acute or repetitive trauma; **and**
4. All criteria listed in the “General Criteria” section below are met.

Osteochondral autograft transplantation, either osteochondral autograft transplant (OATS) or autologous mosaicplasty to treat cartilaginous defects of the knee is considered **medically necessary** when **all** of the following criteria are met:

1. Arthroscopic or magnetic resonance imaging (MRI) examination results which detail the size, location and type of osteochondral defect; **and**
2. Size of the cartilage defect is between 1.0 to 2.5 square cm (i.e. length x width)* in total area; **and**
3. Condition involves a focal, full thickness, (grade III or IV) isolated defect of the knee involving the weight bearing surface of the medial or lateral femoral condyles or trochlear region (trochlear groove of the femur) caused by acute or repetitive trauma; **and**
4. All criteria listed in the “General Criteria” section below are met.

** Note: Square centimeters (square cm) is equal to the total surface area (length x width). Square centimeters measurement can be calculated by multiplying the length in centimeters by the width in centimeters.*

General Criteria
For **all** procedures listed above, **all** of the General Criteria listed below must be met:

1. Skeletally mature adolescent with documented closure of growth plates or adult; **and**
2. Persistent symptoms of disabling localized knee pain for at least 6 months, which have failed to respond to conservative treatment; **and**
3. The lesion must be discrete, single and unipolar (involving only one side of the joint. “Kissing lesions” are an exclusion); **and**
4. The lesion is largely contained with near normal surrounding articular cartilage and articulating cartilage, (grades 0, 1, 2); **and**
5. A normal joint space is present; **and**
6. No active infection is present; **and**
7. No inflammation or osteoarthritis is present in the joint; **and**
8. The knee is stable, with functionally intact menisci and ligaments and normal alignment. Corrective procedures, e.g. ligament or tendon repair, osteotomy for realignment, meniscal allograft transplant or repair may be performed in combination with or prior to transplantation; **and**
9. Individual is willing and able to comply with post-operative weight-bearing restrictions and rehabilitation; **and**
10. No history of cancer in the bones, cartilage, fat or muscle of the affected limb; **and**
11. Body Mass Index (BMI) less than or equal to 35.

Not Medically Necessary:
Use of autologous chondrocyte transplantation, osteochondral allograft transplantation, or osteochondral autograft transplantation (OATS/mosaicplasty) for joints other than the knee is considered not medically necessary, including but not limited to the ankle (talus).

Use of autologous chondrocyte transplantation, osteochondral allograft transplantation, and osteochondral autograft transplantation (OATS/mosaicplasty) is considered **not medically necessary** when the criteria cited above are not met.

Non-autologous mosaicplasty using resorbable synthetic bone filler materials (including but not limited to plugs and granules) to repair osteochondral defects of the knee or ankle is considered **not medically necessary.**

Use of minced articular cartilage (whether synthetic, allograft or autograft) to repair osteochondral defects of the knee or ankle is considered **not medically necessary.**

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage or these services as it applies to an individual member.

Autologous chondrocytes, osteochondral allografts and autografts

CPT

27412	Autologous chondrocyte implantation, knee
27415	Osteochondral allograft, knee, open [when specified as osteochondral allograft]
27416	Osteochondral autograft(s), knee, open (eg, mosaicplasty) includes harvesting of autograft[s])
29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (eg, mosaicplasty) (includes harvesting of the autograft)
29867	Arthroscopy, knee, surgical; osteochondral allograft (eg, mosaicplasty)

HCPCS

J7330	Autologous cultured chondrocytes, implant
S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)

ICD-10 Procedure

For the following codes when specified as autologous chondrocyte implantation, osteochondral autograft, or osteochondral allograft:

0SUC07Z-0SUD47Z	Supplement knee joint with autologous tissue substitute [right or left, by approach; includes codes 0SUC07Z, 0SUC47Z, 0SUD07Z, 0SUD47Z]
0SUC0KZ-0SUD4KZ	Supplement knee joint with nonautologous tissue substitute [right or left, by approach; includes codes 0SUC0KZ, 0SUC4KZ, 0SUD0KZ, 0SUD4KZ]

ICD-10 Diagnosis

M23.000-M23.92	Internal derangement of knee
M92.50-M92.52	Juvenile osteochondrosis of tibia and fibula
M93.261-M93.269	Osteochondritis dissecans knee
M93.861-M93.869	Other specified osteochondropathies lower leg
M94.8X6	Other specified disorders of cartilage lower leg

Other procedures

CPT

27599	Unlisted procedure, femur or knee [when specified as implantation of minced cartilage chondral autograft or allograft of the knee, or the use of resorbable synthetic bone filler materials (including but not limited to plugs and granules) to repair osteochondral defects of the knee]
28446	Open osteochondral autograft, talus (includes obtaining graft[s])
28899	Unlisted procedure, foot or toes [when specified as autologous chondrocyte implantation or osteochondral allograft of the ankle (talus), or the use of resorbable synthetic bone filler materials (including but not limited to plugs and granules) to repair osteochondral defects of the ankle (talus)]
29892	Arthroscopically aided repair of large osteochondritis dissecans lesion, talar dome fracture, or tibial plafond fracture, with or without internal fixation [when code used to describe arthroscopic osteochondral talus graft]
29999	Unlisted procedure, arthroscopy [when specified as autologous chondrocyte implantation, osteochondral autograft, osteochondral allograft or the use of resorbable synthetic bone filler

materials (including but not limited to plugs and granules) to repair osteochondral defects of other joints]

ICD-10 Procedure

	For the following codes when specified as use of resorbable synthetic bone filler materials:
0SUC0JZ-0SUD4JZ	Supplement knee joint with synthetic substitute [right or left, by approach; includes codes 0SUC0JZ, 0SUC4JZ, 0SUD0JZ, 0SUD4JZ]
	For the following codes when specified as osteochondral autograft, autologous chondrocyte implantation or osteochondral allograft, or the use of resorbable synthetic bone filler materials:
0RUJ07Z-0RUK47Z	Supplement shoulder joint with autologous tissue substitute [right or left, by approach; includes codes 0RUJ07Z, 0RUJ47Z, 0RUK07Z, 0RUK47Z]
0RUJ0JZ-0RUK4JZ	Supplement shoulder joint with synthetic substitute [right or left, by approach; includes codes 0RUJ0JZ, 0RUJ4JZ, 0RUK0JZ, 0RUK4JZ]
0RUJ0KZ-0RUK4KZ	Supplement shoulder joint with nonautologous tissue substitute [right or left, by approach; includes codes 0RUJ0KZ, 0RUJ4KZ, 0RUK0KZ, 0RUK4KZ]
0RUL07Z-0RUM47Z	Supplement elbow joint with autologous tissue substitute [right or left, by approach; includes codes 0RUL07Z, 0RUL47Z, 0RUM07Z, 0RUM47Z]
0RUL0JZ-0RUM4JZ	Supplement elbow joint with synthetic substitute [right or left, by approach; includes codes 0RUL0JZ, 0RUL4JZ, 0RUM0JZ, 0RUM4JZ]
0RUL0KZ-0RUM4KZ	Supplement elbow joint with nonautologous tissue substitute [right or left, by approach; includes codes 0RUL0KZ, 0RUL4KZ, 0RUM0KZ, 0RUM4KZ]
0RUN07Z-0RUP47Z	Supplement wrist joint with autologous tissue substitute [right or left, by approach; includes codes 0RUN07Z, 0RUN47Z, 0RUP07Z, 0RUP47Z]
0RUN0JZ-0RUP4JZ	Supplement wrist joint with synthetic substitute [right or left, by approach; includes codes 0RUN0JZ, 0RUN4JZ, 0RUP0JZ, 0RUP4JZ]
0RUN0KZ-0RUP4KZ	Supplement wrist joint with nonautologous tissue substitute [right or left, by approach, includes codes 0RUN0KZ, 0RUN4KZ, 0RUP0KZ, 0RUP4KZ]

0SU907Z-0SUB47Z	Supplement hip joint with autologous tissue substitute [right or left, by approach; includes codes 0SU907Z, 0SU947Z, 0SUB07Z, 0SUB47Z]
0SU90JZ-0SUB4JZ	Supplement hip joint with synthetic substitute [right or left, by approach; includes codes 0SU90JZ, 0SU94JZ, 0SUB0JZ, 0SUB4JZ]
0SU90KZ-0SUB4KZ	Supplement hip joint with nonautologous tissue substitute [right or left, by approach; includes codes 0SU90KZ, 0SU94KZ, 0SUB0KZ, 0SUB4KZ]
0SUF07Z-0SUG47Z	Supplement ankle joint with autologous tissue substitute [right or left, by approach; includes codes 0SUF07Z, 0SUF47Z, 0SUG07Z, 0SUG47Z]
0SUF0JZ-0SUG4JZ	Supplement ankle joint with synthetic substitute [right or left, by approach; includes codes 0SUF0JZ, 0SUF4JZ, 0SUG0JZ, 0SUG4JZ]
0SUF0KZ-0SUG4KZ	Supplement ankle joint with nonautologous tissue substitute [right or left, by approach; includes codes 0SUF0KZ, 0SUF4KZ, 0SUG0KZ, 0SUG4KZ]

ICD-10 Diagnosis

Note: the procedures listed above are considered Not Medically Necessary for all indications

All diagnoses

Discussion/General Information

Identification of Osteochondral Defects

The gold standard for the diagnosis of osteochondral defects of the knee is arthroscopy. However, with advances in imaging techniques, MRI has become an acceptable method to characterize osteochondral defects and enable treatment planning (Galea, 2009; Ramappa, 2007; Sanders 2001).

Autologous Chondrocyte Transplantation (ACT)

The majority of the literature concerning autologous chondrocyte transplantation (ACT) for the knee consists mostly of small uncontrolled case series with individuals whose lesions varied greatly in size, type and location. As part of a post-approval commitment required by the U.S. Food and Drug Administration (FDA), Genzyme conducted a prospective, longitudinal, multi-center Study of the Treatment of Articular Repair (STAR). This study assessed the effectiveness of autologous chondrocyte implantations in individuals who had failed prior treatments for articular cartilage defects of the knee (Zaslav 2008). A total of 154 participants who had failed previous treatment for articular cartilage defects of the knee (medial condyle, lateral condyle, or trochlea) received autologous chondrocyte transplantation. Failed prior surgical procedures included debridement, subchondral drilling, osteochondral autograft, microfracture and abrasion arthroplasty. Follow-up period was 48 months. Outcome measures included change in baseline knee function, knee pain, quality of life and general health using standardized measurement tools (Modified Cincinnati Overall Knee Score,

visual analog scale [VAS], Knee Injury and Osteoarthritis Outcome Scale [KOOS], Short Form [SF] 36). The duration of the benefit of the autologous chondrocyte transplantation was compared with the benefit duration of the prior failed non-autologous chondrocyte transplantation procedure using an independent observer and objective criteria for treatment failure. The mean age for the cohort was 34.5 ± 8.1 years, and mean BMI was 27.9 ± 4.6. The chondral defect(s) size in this cohort was moderate to large. Only 12% had defects less than 2 cm² while 51% were greater than or equal to 4 cm² with a mean lesion size at implant of 4.6 cm². One limitation of this study is its lack of a concurrent, randomized controlled comparison with other therapies.

A total of 126 participants (82%) completed the protocol and 28 participants (18%) discontinued the study prior to completion. The majority of individuals (76%) reported significant improvements in knee function and symptoms, including activities of daily living and recreational activities. Seventy-six percent of the study participants were deemed a treatment success, while 24% were considered treatment failures. Mean improvements for all outcome measures were observed from baseline to all time points ($p<0.001$). No significant difference was noticed between individuals whose primary surgery had been a marrow-stimulating procedure and those whose primary procedure had been a debridement alone. The median difference in the duration of benefit between the failed prior non-autologous chondrocyte transplantation treatment and the autologous chondrocyte transplantation was 31 months ($p<0.001$). Seventy-six participants (49%) had subsequent surgical procedures(s), most were arthroscopic. Researchers concluded that individuals with moderate to large chondral lesions with failed prior cartilage treatments can expect sustained and clinically significant improvement in pain and function after autologous chondrocyte transplantation.

Bentley and colleagues (2003) reported the findings of a prospective randomized clinical trial comparing autologous chondrocyte implantation (also known as autologous chondrocyte transplantation [ACT]) and mosaicplasty. A total of 100 participants with a mean age of 31.3 years (16 to 49) and with a symptomatic lesion of the articular cartilage in the knee suitable for cartilage repair were randomized to undergo either ACT or mosaicplasty. Of the 100 knees, 46 (46%) had post-traumatic defects, 19 (19%) had osteochondritis dissecans, 14 (14%) had chondromalacia patellae and 21 (21%) had lesions of unknown etiology which were probably posttraumatic. The lesions were on the medial femoral condyle in 53 knees (53%), the patella in 25 (25%), the lateral femoral condyle in 18 (18%), the trochlea in 3 (3%) and the lateral tibial plateau in 1 (1%). There were 58 participants who underwent ACT and 42 participants who underwent mosaicplasty. The mean age at the time of surgery of 31.6 years (20 to 48) for those who underwent mosaicplasty and 30.9 years (16 to 49) for those who underwent ACT. The mean size of the defect was 4.66 cm² (1 to 12.2). The mean duration of symptoms was 7.2 years and the mean number of previous operations, excluding arthroscopy, was 1.5. After a mean follow-up of 19 months, functional assessment using objective clinical assessment and the modified Cincinnati and Stanmore scores demonstrated that 88% had excellent or good results after autologous chondrocyte implantation compared with 69 % after mosaicplasty. All five patellar mosaicplasties failed. The authors concluded that both mosaicplasty and ACT provide encouraging clinical results after a mean period of 1 year, but that mosaicplasty appears to deteriorate with time. Limitations of the study include the study being unblinded and a lack of long-term follow-up.

Pascual-Garrido and colleagues (2009) reported outcomes from 62 subjects (who underwent ACI of the patellofemoral joint. The mean defect size was 4.2 cm^2. In addition to ACI of the patella, 67% of participants had concomitant procedures performed, including anteromedialization (n=28), lateral release (n=4), lateral meniscal transplant (n=2), and osteochondral autograft (n=1). Outcomes were assessed using questionnaires which were administered preoperatively, 6 months and 1 year postoperatively, and then annually. At an average follow-up of 4 years (range, 2 to7), the participants demonstrated significant improvement based on established outcome scales (the Lysholm [37 to 63], the International Knee Documentation Committee [31 to 57], the KOOS which includes the five categories of pain, symptoms, activities of daily living, sport, and quality of life, the Cincinnati [43 to 63], Tegner [4 to 6], and SF-12 Physical [38 to 41]). The participants reported the overall condition of their knee as excellent, very good, or good in 71% of the cases; 81% of the participants were satisfied with the procedure. There were 4 failures (8%), defined as poor clinical outcome accompanied by evidence of graft failure or need for conversion to knee arthroplasty or osteochondral allograft. The authors concluded that ACT is a viable treatment option for chondral defects of the patellofemoral joint and that ACT combined with anteromedialization improves outcomes more than autologous chondrocyte implantation alone.

Genzyme has provided an unpublished subset analysis of the Zaslav study examining the outcome of those individuals with BMI greater than or equal to 30. Based on the information provided for the 113 participants for whom BMI data and 4 year follow-up data was available, the results suggest that there is no significant difference in the magnitude of improvement between the participants with a BMI less than 30 and those with a BMI equal to or greater than 30.

The Washington State Department of Labor and Industries (2004) published recommendations for review criteria of knee surgery based on evidence in the medical literature, with expert opinion and community-based practicing physicians. Their criterion for consideration of osteochondral autograft (mosaicplasty or OATS procedure) and ACI included the recommendation that these procedures be performed on individuals with a body mass index (BMI) of less than 35. The rationale for the inclusion of this criterion was stated as follows:

> Medical literature indicates that patients with a Body Mass Index (BMI) greater than 35 are more likely to have a pre-existing history of cardiac disease or diabetes; are more likely to have post operative complications including infections, wound dehiscence, deep vein thrombosis, pulmonary embolism, cardiac arrhythmias, myocardial infarction, ileus, prolonged hospitalization; and were more likely to be discharged to a rehabilitation facility.

Peterson and colleagues (2003) conducted a study to assess the intermediate to long-term results of ACT in individuals with osteochondritis dissecans (OCD). Between 1987 and 2000, 58 participants with documented OCD of the knee underwent treatment with ACT. The individuals were evaluated annually using five scoring systems: (1) a modified Lysholm score; (2) the modified Cincinnati (Noyes) knee score; (3) the overall Cincinnati knee-rating score; (4) the Wallfgren-Tegner activity score; and (5) the overall Brittberg clinical grading score. An arthroscopic assessment of graft integrity was also completed. MRI was carried out only in the second half of the study period and included a total of 15 individuals undergoing MRI evaluation (4 receiving both preoperative and postoperative evaluation, and 11 receiving postoperative evaluation only.) Twenty-two participants consented to arthroscopic second-look evaluation of graft integrity. Radiographic examinations were completed on all 58 individuals with 27 receiving both preoperative and a 2 year postoperative exam. The defect was located on the medial femoral condyle in 39 of the individuals and on the lateral femoral condyle in 19 individuals. The mean lesion size was 5.7 cm^2 (range, 1.5 to 12.0 cm^2), and the mean defect depth was 7.8 mm (range, 4 to 15 mm). Only those lesions deeper than 10 mm were treated with simultaneous bone-grafting. After a mean duration of follow-up of 5.6 years, 91% of the participants had a good or excellent overall rating on the basis of a clinician evaluation and 93% had improvement on the self-assessment questionnaire. The Tegner-Wallgren, Lysholm, and Brittberg-Peterson VAS scores all showed improvement. The macroscopic quality of graft integrity averaged 11.2 on a 12-point scale, with only 1 graft having a score of less than 9 points. Two participants had a failure of treatment in the early postoperative period. A single individual had a good or excellent rating at 2 years but then reported a decline in clinical status at the time of the latest follow-up. The researchers concluded that the two early failures occurred in association with graft delamination due to early return to impact sports in the first 2 years postoperatively and that the graft delaminations occurred in deep defects. The researchers also concluded that repair of defects deeper than 8 to 10 mm may be improved by simultaneous bone-graft and cartilage-grafting with ACT.

Researchers have also been investigating the use of ACT for osteochondral defects of the ankle. A review of the peer-reviewed scientific literature did not reveal any published controlled trials that compared the efficacy and safety of ACT for the repair of osteochondral defects of the ankle with standard therapies including subchondral drilling or microfracture. Schafer (2003) reviewed the literature and identified four case series reports which totaled 40 subjects treated for cartilage lesions of the ankle joint with chondrocyte transplant. Results of these case series were promising although follow-up was limited (18 to 33 months) and outcome measures were varied. It was concluded that given the limited number of individuals studied, it was not possible to define indications for ACT of the talus and no conclusions could be made with regard to which specific type and size of defect would be appropriate for cartilage repair of the ankle with chondrocyte transfer.

Two prospective case series using ACI to treat chondral lesions of the talus have been published. Baums et al (2007) published a small prospective case series in Germany in which 12 individuals with a mean age of 29.7 years and a focal cartilage lesion (mean size 2.3 cm^2) of the talus were treated with ACI. Follow-up at a mean of 63 months showed significant improvement in the American Orthopedic Foot and Ankle Society (AOFAS) 0-100 scale; mean score 88.4 compared with 43.5 points preoperatively. Nam et al (2009) published a small prospective case series of 11 subjects

with talar chondral lesions (mean size 2.7 cm^2), the majority of whom had failed non-surgical and prior surgical treatments including debridement, drilling, pinning, or abrasion arthroplasty. The authors describe the study as the first prospective U.S. study of ACI for talar chondral lesions. Follow-up at a mean of 38 months (range, 24-60 months), revealed that 10 of the 11 participants were judged to be improved by the procedure using standardized measures including the AOFAS ankle hindfoot scale which increased to 84 from 47 preoperatively.

Giannini and colleagues (2008) conducted a single-center case series study of 46 subjects who underwent autologous chondrocyte implantation for repair of type II or IIA post-traumatic talar dome lesions from 2001-2004. Researchers investigated the outcome of autologous chondrocyte implantation using laboratory expanded autologous chondrocytes grown on a hyaluronan-based scaffold (Hyalograft C®, Fidia Advanced Biopolymers, Abano Terme, Italy). During the first phase of the surgery, ankle arthroscopy was performed and cartilage was harvested from the detached osteochondral fragment or from the margins of the lesion. Lesions deeper than 5 mm were first filled with autologous cancellous bone. Chondrocytes were then cultured using the Hyalograft C scaffold. In a second surgical procedure, the lesion was arthroscopically implanted with the Hyalograft C cultured chondrocyte patch. The AOFAS score was used to clinically evaluate the participants preoperatively and at 12 and 36 months after surgery. At a mean time interval of 18 months, the first 3 subjects underwent a second-look arthroscopy with cartilage harvested from the implant and histological examination. Preoperatively, the mean AOFAS rating was 57.2 ± 14.3. At the 12-month follow-up, the mean AOFAS rating was 86.8 ± 13.4 ($p<0.0005$), compared to 89.5 ± 13.4 ($p<0.0005$) at 36 months after surgery. Clinical results varied based on the age of participants and previous operations for cartilage repair. Histological examination in the first 3 subjects implanted revealed the regeneration of hyaline-like cartilage.

Filardo and colleagues (2014) explored the outcomes of individuals who had undergone implantation of the Hyalograft C for the repair of trochlear or patellar lesions. Other procedures conducted at the same time included trochleoplasty, ACL reconstruction, lateral release, realignment or meniscectomy. Study participants were followed for 5 years and evaluated every year using the EuroQoL VAS, IKDC subjective score, Kujala score, and Tegner score. Failure was defined as the need for additional surgery due to symptoms related to the primary defect. Both cohorts demonstrated significant improvements in outcomes. Although neither group reached the preinjury sports activity level, individuals with trochlear lesions demonstrated more improvement than those with patellar lesions. At the time of this review, the Hyalograft C implant had not been approved by the FDA for marketing the United States.

Zengerink and colleagues (2010) completed a systematic review comparing the effectiveness of several treatments for osteochondral defects of the talus. Of the 52 studies which met the inclusion criteria, there were 4 studies related to autologous chondrocyte transplantation as a treatment of osteochondral defects of the talus. After calculating the proportion of the population treated successfully and weighted success rates, the authors reported a success percentage for ACI of 76%. While the results of this systematic review and these small case series are promising, there currently is insufficient evidence to evaluate the efficacy of ACI in the treatment of articular cartilage lesions of the talus or joints other than the knee.

Minced Cartilage Repair

Disadvantages of osteochondral autograft transplantation include donor site morbidity, technical difficulty in matching the joint contour, limitation of defect size which can be treated, residual gaps between plugs and the risk of cartilage and bone collapse. Osteochondral allogeneic transplants are limited by graft availability, technical difficulty, and potential for disease transmission. There is interest in the use of advanced tissue engineering technologies to create a single-stage procedure for chondral repair using chondrocytes and a scaffold delivery mechanism. Minced cartilage repair is considered a second generation technique that does not require in vitro cell expansion and is described as a single-staged minimally invasive procedure. The procedure uses minced pieces of cartilage seeded over a scaffold which allows for even distribution of the chondrocytes to expand within the defect providing structural and mechanical protection. By applying minced cartilage techniques, the same amount of donor tissue that would be used in ACI (200-300 mg) can be used to treat a 10 cm^2 lesion (McCormick 2008).

The first clinical application of the minced cartilage technique was the cartilage autograft implantation system (CAIS) developed by DePuy Mitek (Raynham, MA). The CAIS scaffold implant is a resorbable copolymer foam reinforced with

a mesh that is fastened in place with resorbable CAIS staples. The fixation technique used eliminates the need for suturing and the use of morselized cartilage fragments obtained intraoperatively eliminates a second procedure and cell expansion (ACI) techniques. The CAIS bone fixation staple device obtained FDA 510(K) market clearance in 2008. A randomized open label active control trial comparing CAIS to micro-fracture at 24 months as a treatment of cartilage defects of the knee was begun in July 2010 and is estimated to be completed in December 2016 (Advanced Technologies and Regenerative Medicine, 2010). Long-term randomized human studies have not been published. Further clinical study is needed to establish the safety and durable outcome benefit of this technique over standard methods of cartilage repair.

A second technology, DeNovo NT Graft ("Natural Tissue Graft"; Zimmer Inc., Warsaw, IN/ISTO Technologies Inc. St Louis, MO), is another application for cartilage regeneration using minced donated juvenile (less than 12 years of age) fresh allograft cartilage tissue obtained from human cadavers. During implantation, the minced cartilage tissue is mixed in a fibrin glue adhesive. This cartilage-fibrin construct is then implanted into the defect with an additional thin fibrin adhesive layer. Because of the minimal manipulation of the tissue, DeNovo NT graft is classified as a 361hTC/P product not requiring FDA premarket approval (McCormick 2008). A post market study of the outcome of the DeNovo NT Graft procedure in 25 individuals with articular cartilage defects of the knee (NCT00791245) was begun in 2006. Information on the clinicaltrial.gov website indicates the study was completed in August 2012. Another ongoing study, the DeNovo NT Longitudinal Data Collection (LDC) Knee Study (NCT01329445) seeks to evaluate the long-term outcomes of DeNovo NT for the repair of cartilage damage in the knee and is expected to be completed in 2018. A third study, the DeNovo NT Ankle LDC Study (NCT01347892) is a post-market clinical study to collect long-term outcomes for DeNovo NT Graft treatment of articular cartilage lesions in 250 individuals. As of June 2015, this study was actively ongoing but not recruiting participants and is expected to be completed in 2019.

Kruse and colleagues (2012) reported the outcomes of a single individual who underwent implantation of the DeNovo NT juvenile allograft cartilage to repair a posterio-medial talar osteochondral defect. At the 6-month follow-up visit, the individual had returned to full activity, and at 24 months, she remained completely pain free.

Farr and colleagues (2012) reviewed the scientific literature as well as discussed the indications, contraindications and surgical technique for the CAIS and DeNovo NT graft implantation as treatment options for focal articular cartilage defects in the knee. The authors concluded that both the CAIS and DeNovo NT systems may be viable future treatments options for individuals with symptomatic osteochondral defects and prospective randomized controlled studies are necessary to refine the indications and contraindications for both CAIS and DeNovo NT. Coetzee and colleagues (2013) reported the results of a cohort case series that collected outcomes in 23 subjects (24 ankles) treated with the DeNovo NT tissue graft between 2009-2011 with at least a 12 month post-operative visit. The average lesion size was 125 ± 75 mm^2 and average depth was 7 ± 5 mm. In addition to the juvenile chondrocyte treatment, 9 (38%) ankles had one concomitant procedure and 9 (38%) had more than one concomitant procedure. Clinical evaluations were completed with an average follow-up of 16.2 months. The authors reported good to excellent AOFAS functional outcomes in 78% of participants. Limitations of the study include the absence of a control group, limited size, short follow-up period, and retrospective enrollment which limits comparison of the preoperative clinical values.

Bleazey and colleagues (2012) conducted a retrospective review of 7 individuals with osteochondral lesions of the talus who were treated with the DeNovo NT graft along with sponge allograft. All of the participants had failed conservative therapy and 4 of the participants had failed microfracture. The participants were evaluated using the VAS for pain and activity at 6 month follow-up. All of the participants showed clinically significant improvement. At 6 months follow-up, pain scores associated with walking decreased from an average of 7.7 at baseline to 1.9 at 6 months and the ability to walk 4 blocks improved from a score of 4.8 to 9.2.

Farr and colleagues (2014) reported the results of a case series evaluating individuals with articular cartilage lesions in the knee that were treated with DeNovo NT graft. The 25 participants had a mean lesion size of 2.7 ± 0.8 cm^2. Each individual was assessed preoperatively with a knee examination and surveys including the International Knee Documentation Committee (IKDC) subjective knee form, 100-mm VAS for pain, and Knee injury and Osteoarthritis Outcome Score (KOOS). The study participants were followed at predetermined time points postoperatively through 2 years. MRI was performed at baseline and at 3, 6, 12, and 24 months. At 2 years, the participants were given the

option of undergoing voluntary diagnostic arthroscopic surgery with cartilage biopsy to assess the histological appearance of the cartilage repair including safranin O staining for proteoglycans and immunostaining for type I and II collagen. During the 24-month follow-up period, the IKDC score increased from a mean of 45.7 to 73.6, KOOS-pain score from 64.1 to 83.7, KOOS-symptoms score from 64.6 to 81.4, KOOS-activities of daily living score from 73.8 to 91.5, KOOS-sports and recreation score from 44.6 to 68.3, and KOOS-quality of life score from 31.8 to 59.9. The MRI results indicated that T2-weighted scores were reverting to a level approximating that of normal articular cartilage by 2 years. Histologically, the repair tissue in biopsy samples from 8 participants was composed of a mixture of hyaline and fibrocartilage; immunopositivity for type II collagen was generally higher than for type I collagen, and there appeared to be integration of the transplanted tissue with the surrounding native articular cartilage. There were no reoperations other than the elective biopsies, and one graft delamination was reported at 24 months.

While the studies investigating the use of minced cartilage repair as a treatment of osteochondral defects of the ankle and knee appear promising, larger studies are needed to confirm these findings. Randomized trials comparing this technique with standard methods of cartilage repair and long-term studies involving larger populations are needed to establish its safety and a durable outcome benefit.

Osteochondral Allograft

Osteochondral allografting has been investigated as a treatment of osteochondral defects of both the knee and the ankle. The current medical literature regarding osteochondral allografting of the knee shows that this procedure has demonstrated acceptable long-term results measured by reduction in pain, improved physical function, and sustained osteochondral graft viability. Several long-term studies have demonstrated long-term donor osteochondral grafts viability up to 10 years and one as long as 14 years with a success rate reported at 63%. Shorter term studies have reported success rates of between 75-80%. The evidence indicated that osteochondral allografting has been highly successful in individuals with chondral defects resulting from trauma or osteochondritis dissecans, but less so in individuals with osteonecrosis or steroid induced lesions. Finally, the literature is unanimous in emphasizing the importance of proper individual selection including adequate joint stability and alignment.

Researchers have also investigated the long-term survival of concurrent meniscus allograft transplantation and repair of the articular cartilage (Stone 2010). In this prospective 2-12 year follow-up report, 119 meniscal allograft transplantations were carried out in conjunction with articular cartilage repair in 115 individuals with severe articular cartilage damage. At the time of surgery, 53 (46.1%) of the study participants were over the age of 50. The mean follow-up period was 5.8 years (2 months-12.3 years.) Twenty-five (20.1%) of the procedures failed at a mean of 4.6 years (2 months-10.4 years). Of the failed procedures, 18 progressed to knee replacement at a mean of 5.1 (1.3-10.4) years. The researchers found that the survival of the transplant was not affected by gender, axial alignment, the severity of cartilage damage, the degree of narrowing of the joint space or medial versus lateral allograft transplantation. With regard to the subjective outcome measures of the study (pain, activity and function), the researchers reported the study participants experienced significant improvements at all periods of follow-up, with the exception of the 7 year Tegner Index Score. The authors concluded that meniscal allograft transplantation carried out in conjunction with articular cartilage repair provides lasting pain relief and improved function in individuals with severe articular cartilage damage.

Several small case series, totaling 28 individuals, have reported on osteochondral allografts for talar cartilage defects (Gross, 2001; Kim, 2002; Tontz, 2003). The results reported from these small case series using varied outcome measures have been mixed and do not permit conclusions with respect to the efficacy, durability and safety of osteochondral allografts in the treatment of osteochondral defects of the ankle.

El-Rashidy and colleagues (2011) reported on fresh osteochondral allograft transfers in 42 subjects with a symptomatic, refractory osteochondral lesion of the talus. Postoperative follow-up was completed in 38 (90%) of the participants. Postoperative MRI scans were used to access the ankle for osteoarthritis, graft incorporation and stability. Clinical evaluation was accomplished with the use of the American Orthopaedic Foot & Ankle Society ankle-hindfoot score and a VAS pain scale. All scores were obtained from either direct participant interview or retrospective chart review. All participants were also asked about their subjective satisfaction with the procedure. The average duration of follow-up post osteochondral allograft transplantation was 37.7 months. Graft failure occurred in 4 of the participants, resulting in

an overall failure rate of 10.5%. All 4 of the participants with graft failure had undergone a prior operation consisting of arthroscopy with microfracture (3 subjects) and arthroscopy with microfracture followed by a failed osteochondral autograft transfer (1 subject.). One individual also had preoperative evidence of a kissing lesion on the distal tibial articular surface, which the authors concluded may have contributed to the procedure failing. When the scores before revision for those with graft failure were included, the mean VAS pain scale score improved from 8.2 to 3.3 points, and the mean American Orthopaedic Foot & Ankle Society ankle-hindfoot score improved from 52 to 79 points. Patient-reported satisfaction with the outcome was rated as excellent, very good, or good by 28 of the 38 participants and as fair or poor by 10 individuals. Of the 15 postoperative MRI scans, most showed minimal graft subsidence, reasonable graft stability, and persistent articular congruence. The authors concluded that fresh osteochondral allograft is a viable and effective method for the treatment of osteochondral lesions of the talus as evidenced by improvements in pain and function. The authors also acknowledge that limitations of the study include its retrospective design, the lack of comparative controls, 4 (10%) individuals lost to follow-up, and the relatively short duration of follow-up. The authors also acknowledge that only a limited number of postoperative MRI scans were completed and do not suggest that MRI findings be used as evidence to support the effectiveness of the technique. The authors suggest that the next step in the evaluation of ostechondral allograft transplantation of the talus would be a prospective randomized controlled trial comparing this surgical technique with other similar surgical techniques designed to restore the articular cartilage of the talar dome.

More recently, there has been interest in the use of Cartiform® (Osiris Therapeutics, Inc. Columbia, MD), a cryopreserved viable chondral allograft developed to augment marrow stimulation for articular cartilage repair. The Cartiform chondral allograft consists of native viable chondrocytes, chondrogenic growth factors, and extracellular matrix proteins within the superficial, transitional, and radial zones of hyaline cartilage. It has been theorized that the product provides a means for host mesenchymal stem cells to infiltrate the graft from the underlying bone marrow following marrow stimulation resulting in the optimal microenvironment to undergo chondrogenesis. Information from the manufacturer indicates that Cartiform is regulated by the FDA under 21 CFR Part 1271 Human Cells, Tissues and Cellular and Tissue-based Products (HCT/Ps). Cartiform is manufactured and distributed by Osiris Therapeutics, Inc. and offered through Arthrex®.

Hoffman and colleagues (2014) report the 9-month postoperative histological results of a single individual repair of a trochlear defect using marrow stimulation augmented with the Cartiform chondral allograft. At 9 months, the individual demonstrated complete resolution of pain and improvement in function. Based on histological findings, the repair tissue consisted of 85% hyaline cartilage. For comparison, a biopsy obtained from another individual 8.2 months after treatment with marrow stimulation alone contained only 5% hyaline cartilage. The researchers concluded that the results suggest that augmenting marrow stimulation with the viable chondral allograft may eliminate pain and improve outcomes, compared with marrow stimulation alone.

Researchers have also been exploring BioCartilage® (Arthrex, Naples, FL), a micronized allogeneic cartilage matrix that is intended to provide a scaffold for microfracture (Shin, 2014). A single case report was identified which described an individual who underwent an all-arthroscopic surgical technique consisting of debridement and marrow stimulation with application of BioCartilage (Desai, 2014). According to information received from the manufacturer, BioCartilage is regulated by the FDA under 21 CFR Part 1271 Human Cells, Tissues and Cellular and Tissue-based Products (HCT/Ps).

Osteochondral Autograft Transplantation (OATS/Mosaicplasty)

The medical literature regarding osteochondral autograft transplant (OATS) and mosaicplasty of the knee consists mostly of single-institution case series focusing on chondral lesions of the knee. These studies include heterogeneous populations of individuals, some of whom are undergoing treatment for additional abnormalities such as ligament or meniscal repair. Therefore, it is not known whether improvement in symptoms can be attributed to the osteochondral autografting or other components of the surgery. In addition, there are very few studies currently available comparing the results of osteochondral autografting with other established therapies. However, there is a large collection of small studies demonstrating that osteochondral autografting procedures, including mosaicplasty, confer significant benefit in terms of both functional improvement and pain relief in a population where alternative therapies are limited. Several

studies have evaluated the long-term viability of osteochondral autografts with histological examinations at up to 3 years post-transplant. The vast majority of these studies report finding stable hyaline cartilage at the operative site. In almost all articles published, individuals with misalignment, arthritis, unstable knees, and missing or compromised meniscus, were excluded from the studies due to concerns regarding suitability for the procedures. Finally, there is little agreement on any limitations regarding the size of chondral defects that are appropriate for these procedures. The medical literature suggests that mosaicplasty might be appropriate for lesions ranging from as little as 1.5 cm^2 to as large as 16 cm^2. Most recent evidence supports the position that the larger the chondral defect, the higher the complication rate and rates of donor site morbidity. Thus, at this time it may be appropriate to limit these procedures to small to moderate lesions, between 1.1 and 2.5 cm^2, until further evidence is available to fully evaluate this issue.

Researchers have investigated using osteochondral surgical procedures as a treatment of osteochondritis dissecans (OCD). Gudas and colleagues (2005) carried out a prospective randomized clinical study which investigated the outcomes of mosaic-type OATS and microfracture for the treatment of articular cartilage defects in young athletes. Sixty athletes participating in competitive sports at the regional or national levels, ranging in ages ranged from 15-40 years (mean age of 24.3 years) and who had a symptomatic localized cartilage or osteochondral defect of the knee, were randomized to undergo either an OATS or a microfracture procedure. Twenty-eight participants were assigned to the OATS group and 29 participants to the microfracture group. The inclusion criteria included (1) articular cartilage defects of the medial or lateral femoral condyle, (2) articular cartilage knee joints defects between 1 and 4 cm^2 in diameter, (3) competitive or well-trained athletes before injury (based on the ICRS) and (4) participants under the age of 40 years. None of the participants had prior surgical interventions to the affected knee. The mean duration of symptoms was 21.32 ± 5.57 months. Study participants were evaluated using modified Hospital for Special Surgery (HSS) and International Cartilage Repair Society (ICRS) scores, radiograph, magnetic resonance imaging (MRI), and clinical assessment. An independent observer performed a follow-up examination after 6, 12, 24, and 36 months. At 12.4 months postoperatively, arthroscopy with biopsy for histologic evaluation was completed. Fifty-seven participants (95%) were available for follow-up and the mean follow-up period was 37.1 months (range, 36 to 38 months). Of the 57 knees included in the study, 32 (56%) had post-traumatic full-thickness articular cartilage lesions, and 25 (44%) had OCD defects. The mean defect size in the OATS group was 2.8 ± 0.65 cm^2 and 2.77 ± 0.68 cm^2. Of the 28 subjects with lesions treated by OATS 27 (96%) had excellent or good results compared with 15 of the 29 (52%) treated by microfracture. The average HHS score increased to 80.060 ± 4.55 in the microfracture group and 91.08 ± 4.15 in the OATS group. Modified HHS evaluation showed better results in the OATS group 12, 24 and 36 months after surgery. The last follow-up done at 37.1 months postoperatively, showed deterioration in the microfracture group. Twelve months postoperatively, there was an increase in the ICRS scores in both groups but the OATS group showed more improvement at 12, 24 and 36 months postoperatively. There was no MRI evidence of graft loosening or migration during the study, however, the harvest sites showed mild surface irregularity in the majority of participants, with a few cases demonstrating moderate to marked surface irregularity. However, the degree of surface irregularity did not correspond with lower clinical outcome scores. The authors concluded OATS is superior to microfracture for the repair of articular cartilage defects in the knee. The authors acknowledged that MRI examinations over a longer follow-up period would be useful to study further the congruity of the articular surface over time. Limitations of the study include the small sample size and the short follow-up period.

The same investigators, Gudas and colleagues (2009), reported the results of a prospective randomized clinical trial comparing the outcomes of the arthroscopic mosaic-type OATS and microfracture procedures for the treatment of OCD defects of the femoral condyles of the knee joint in children under the age of 18 years. Fifty children ranging in age from 12 to 18 years (a mean age of 14.3 years) with symptomatic lesions of osteochondritis dissecans in the femoral condyle of the knee were randomized to undergo either the OATS or the microfracture procedure. Included in the study were children with grade 3 or 4 (OCD) in the medial or lateral femoral condyle according to the ICRS and OCD defects between 2 and 4 cm^2 in area. Twenty-five participants were assigned to the OATS group and 22 participants to the microfracture group. None of the subjects had prior surgical interventions to the affected knee and all were evaluated using ICRS score, x-rays, magnetic resonance imaging, and second-look arthroscopies. Forty-seven of the original 50 participants (94%) were available for follow-up, with a mean follow-up time of 4.2 years. After 1 year, both groups had significant clinical improvement ($p<0.05$) and the ICRS functional and objective assessment demonstrated that 23 of 25 (92%) participants had excellent or good results after OATS compared with 19 of 22 (86%) after microfracture.

However, only 19 of 23 (83%) of the OATS group and 12 of 19 (63%) after microfracture procedure sustained excellent or good results after 4.2 years. The microfracture group demonstrated significant deterioration over the 4.2 years follow-up, but still had significant clinical improvement compared with pretreatment evaluation. There were 9 of 22 (41%) failures in the microfracture group, and none in the OATS group. Magnetic resonance imaging evaluation according to the ICRS evaluation system showed excellent or good repairs in 19 of 21 participants (91%) after OATS compared with 10 of 18 (56%) after microfracture. The authors concluded that the mosaic-type OATS procedure showed significant superiority over microfracture for the treatment of osteochondritis dissecans defects of the knee. Limitations of this study include a small sample size and the short follow-up period. While the few studies investigating the OATS procedure as a treatment of OCD appear promising, larger studies are needed to confirm these findings.

Studies of the use of autografts in the treatment of osteochondral lesions of the talus are largely case series in design. Hangody et al (2001) reported the clinical outcome of 36 consecutive participants followed for 2 to 7 years after autologous transplantation mosaicplasty from a non-weight bearing portion of the knee to the ipsilateral ankle talus. The average size of the defects treated was one centimeter. Individuals with osteoarthritis were excluded from the study. Most participants (29 of the 34) had previous surgical intervention(s) including arthroscopic debridement, loose body removal, drilling, curettage and/or microfracture. All participants achieved full range of motion within 8 weeks following surgery. Average follow-up for the entire series was 4.2 years (2-7 years). Five individuals were followed to 7 years. At the end of follow-up, none of the participants showed loosening of the graft. Using a standardized scoring tool (Hannover), results of 28 cases were rated “excellent”, 6 were rated “good”, and 2 “moderate”. There were no cases with long term donor site morbidity.

Scranton (2006) published a retrospective case series study of the outcomes of 53 consecutive individuals with Type-V talar osteochondral defects treated with autograft plugs harvested arthroscopically from the ipsilateral knee. The type V lesions treated were confined to those with a diameter of 8 mm to 20 mm confirmed by CT or MRI. The majority of participants (32 or 64%) had previously undergone one or more prior ankle surgical procedures including debridement, curettage, drilling, internal fixation or grafting. A total of 40 subjects had symptoms for more than 1 year. The majority of individuals had also received at least 6 months of prior conservative treatment which included rest, immobilization and physiotherapy without improvement. Two subjects were lost to follow-up and 1 participant died of unrelated cause 1 year following the procedure. Of the 50 participants evaluated at a mean follow-up of 36 months (24-83), 45 (90%) achieved “good” to “excellent” score in the Karlsson-Peterson Ankle questionnaire and were satisfied with the outcome. The outcome questionnaire used was a standardized assessment of eight functional outcome measures of ankle stability, pain, swelling, stiffness, activities of daily living (ADL), stair climbing, running and use of ankle supports (Karlsson 1991). Although each subject had presented with what were described as disabling symptoms of swelling, catching or pain with activity refractory to conservative therapies, baseline Karlsson-Peterson Ankle scores were not measured.

Kreuz et al (2006) reported a prospective case series of 35 individuals with Stage III or IV (cystic) (Loomer 1993) osteochondral talar lesions treated with mosaicplasty using autologous grafts harvested from a low weight bearing area of the ipsilateral talar articular facet. All participants had previously failed surgery on the same ankle which included drilling, removal of loose body, or abrasion arthroplasty. Mean lesion size was 6.3 mm in diameters (4 mm - 10 mm). Twenty individuals required either a malleolar or tibial wedge osteotomy to access the lesion, while 15 had either an anterior or postero-lateral approach without osteotomy. The AOFAS) Ankle-Hindfoot survey was administered before the procedure and at the end of follow-up. Mean follow-up period was 49 months. The AOFAS Ankle-Hindfoot survey is a recognized method of reporting the clinical status of the ankle and foot. This tool incorporates both subjective and objective clinical measures of pain, function, range of motion, and alignment. In this case series, the mean preoperative AOFAS score was 54.5 of 100 points (47-60). Overall improvement between pre-operative and follow-up (mean 49 months) AOFAS scores was 35.4 points (26-48) with a mean follow-up score of 89.9 ($p \leq 0.017$). AOFAS score in individuals not requiring osteotomy rose by 39 points ($p=0.0001$), with malleolar osteotomy by 30.1 points ($p=0.017$), with tibial wedge osteotomy by 34.9 points ($p=0.0002$), and with postero-lateral approach by 32 points (p not reported).

A randomized controlled trial comparing the outcomes of chondroplasty, microfracture, and osteochondral autograft transplantation (OAT) in 32 individuals with osteochondral lesions of the talus was reported (Gobbi 2006). Subjects with Ferkel class 2b, 3, and 4 osteochondral lesions of the talus were randomized to one of the three treatments and

outcomes measured with the AOFAS scale and a subjective assessment numeric evaluation tool (SANE) rating. Eleven participants had chondroplasty, 9 participants had microfracture, and 12 participants had OAT. Mean time to follow-up was 53 months (24-119). There were no differences at 12 and 24 months in AOFAS scores or in SANE ratings at the end of follow-up between the three groups of individuals studied. This recent study is limited by size, but is one of the few which used a randomized, prospective design with comparison of the varied treatment options available for the treatment of osteochondral lesions of the talus. The study did not include a non-surgical control group.

Valderrabano et al (2009) reported a case series of 21 subjects with osteochondral lesions of the talus treated with knee-to ankle autologous mosaicplasty. Eight individuals were lost to follow-up and a ninth subject had insufficient follow-up. Only 12 participants of the original 21 were available for last follow-up at a mean of 72 months (range, 43-91). Of the 12 participants available to measure outcomes, 5 subjects had reoperations (knee arthroscopy, ankle arthroscopy, implant removal). Donor site morbidity (knee pain) was reported in 6 (50%) of the participants. Mean AOFAS ankle score increased from 45.9 preoperatively (24-66) to 80.2 (35-100). Recurrent lesions were found radiologically (MRI, SPECT-CT) in 10 of 10 cases examined at last follow-up. The authors offered caution in selecting individuals for this procedure since only moderate outcome benefit was suggested by this small case series and considerable donor-site morbidity was found.

Non-autologous Bone Filler Products

Researchers have explored the use of the PolyGraft® material (polylactide-co-glycolide (PLG) copolymer, calcium sulfate, polyglycolide (PGA) fibers and surfactant) to repair osteochondral defects. The only published, peer-reviewed scientific literature found on PolyGraft consisted of seven small studies carried out on animals. There were no published peer-reviewed clinical trials on humans. Therefore, there is insufficient scientific evidence to allow conclusions regarding the safety and efficacy of the use of this technology in humans at this time.

Treatment of Osteochondral Defects in Joints other than the Ankle and the Knee

Elbow

Bilsel and colleagues (2010) reported the outcomes of a 17 year old individual who had an osteochondral defect in the medial third of the capitellum which was treated with an osteochondral graft harvested from the lateral femoral condyle. Postoperative radiologic controls showed that the defect was entirely filled by the graft with appropriate graft height. At 12 months follow-up, the individual did not have any complaint about his elbow, and had no limitation of movement compared to the left elbow. Magnetic resonance imaging demonstrated that the graft was successfully adapted to the recipient site without any sign of loosening. At 40 months postoperatively, the surface of the articular cartilage appeared normal. The range of elbow motion was preserved and the individual reported no restriction in daily and sports activities.

In another study investigating treatment of osteochondral defects of the elbow, Ansah and colleagues (2007) presented the findings of 7 individuals with osteochondral lesions of the capitellum humeri (n=5), trochlea (n=1), or radial head (n=1) who were treated with cylindrical osteochondral autografts, which were harvested from the non-weight-bearing area of the proximal aspect of the lateral femoral condyle. The participants were evaluated preoperatively to assess the defect and postoperatively to assess the ingrowth and viability of the graft. The ipsilateral knee was examined for donor-site morbidity. The average follow-up period was 59 months. The authors concluded that the osteochondral autograft procedure provides the opportunity to retain viable hyaline cartilage for the repair of osteochondral lesions in the elbow while restoring joint congruity and function and perhaps reducing the risk of osteoarthritis.

Researchers have also endeavored to clarify the surgical efficacy of mosaicplasty for teenage athletes with advanced lesions of capitellar OCD (Iwasaki, 2009). Between 2001 and 2006, 19 teenage male individuals with advanced lesions of capitellar OCD underwent mosaicplasties. The participants were evaluated clinically and radiographically at a mean of 45 months postoperatively. At the end of the study, 18 of the participants were free from elbow pain, and 1 had occasional mild pain. The mean total arc of elbow motion and standard deviation increased significantly from 112 degrees ± 17 degrees preoperatively to 128 degrees ± 12 degrees postoperatively ($p<0.005$). The mean clinical score

described by Timmerman and Andrews (with a maximum of 200 points) improved significantly from 131 ± 23 points preoperatively to 191 ± 15 points postoperatively ($p<0.0001$). All of the participants with the exception of 1 individual had an excellent or good clinical result. All donor knees were graded as excellent on the basis of the Lysholm knee scoring system. All individuals except 2 returned to a competitive level of the sport they had previously played. Neither loose-body formation nor secondary osteoarthritic changes were found in any of the participants.

Hip

Researchers are also investigating the treatment of osteochondral defects of the hip. Evans and colleagues (2010) report on a case of an individual with a symptomatic osteochondral defect of the femoral head secondary to trauma that underwent subsequent treatment using a fresh-stored osteochondral allograft via a trochanteric osteotomy. At the end of 1 year, the individual was symptom free with near-complete incorporation of the graft radiographically. The researchers acknowledged that data from the results of a single individual provides limited information and long-term results from multiple cases are needed to establish the appropriateness of the approach.

Nousiainen and colleagues (2010) provided a review of a single case study involving the use of frozen osteochondral allograft to reconstruct a femoral head fracture-dislocation in an 18 year old individual. Clinical and diagnostic imaging follow up at 46 months revealed that despite MRI and radiographic evidence of progressive arthrosis in the hip, including subchondral cystic change in the femoral head and localized cartilage loss in the acetabulum and femoral head, the participant experienced excellent function with no complications (Harris hip score 100, hip dysfunction and osteoarthritis outcome score 62, musculoskeletal function assessment score 22, SF-36 score 81). The authors concluded that an osteochondral allograft may serve as a useful tool in the treatment of an unreconstructable femoral head fracture-dislocation.

Shoulder

Kircher and colleagues (2009) describe the outcomes of 7 individuals who underwent osteochondral autologous transplantation for full-thickness cartilage defects of the shoulder between 1998 and 2000. The individuals were evaluated using MRI, the Constant shoulder score and the Lysholm knee score to assess any donor-site morbidity. None of the participants required any further surgery on the shoulder. The mean Constant score improved significantly until the final follow-up ($p=0.018$). The Lysholm score remained excellent throughout. There was a significant progression of osteoarthritic changes from the initial surgery to the first and final follow-up but this did not appear to be related to the size of the defect, the number of cylinders required or the Constant score ($p=0.016$). The MRIs revealed, with the exception of 1 individual, a congruent joint surface at the defect with full bony integration of all osteochondral cylinders.

In another study, researchers reported the results of eight osteochondral autologous transplantations from the knee joint to the shoulder (Scheibel, 2004). All the participants (6 men, 2 women; mean age 43.1 years) were documented prospectively. In each subject, the stage of the osteochondral lesion was Outerbridge grade IV with a mean size of the affected area of 150 mm^2. All of the study participants were assessed by using the Constant score for the shoulder and the Lysholm score for the knee. Standard radiographs, MRIs and second-look arthroscopy were used to assess the presence of glenohumeral osteoarthritis and the integrity of the grafts. After a mean of 32.6 months (8 to 47), the mean Constant score increased significantly. With the exception of 1 subject, the MRIs revealed good osseointegration of the osteochondral plugs and congruent articular cartilage at the transplantation site. Second-look arthroscopy performed in two cases revealed a macroscopically good integration of the autograft with an intact articular surface. The researchers concluded that osteochondral autologous transplantation in the shoulder appears to offer good clinical results for treating full-thickness osteochondral lesions of the glenohumeral joint, but the development of osteoarthritis and the progression of pre-existing osteoarthritic changes cannot be altered by this technique.

Shin and colleagues (2014) describe the arthroscopic implantation of a micronized allogeneic cartilage scaffold (BioCartilage) to treat an isolated osteochondral lesion of the glenoid. The authors concluded that utilizing the BioCartilage product is a safe single-stage solution that can be performed arthroscopically. The authors acknowledge that ongoing clinical studies are needed in order to determine the effectiveness of this microfracture product.

The peer-reviewed scientific literature regarding the treatment of osteochondral defects in joints other than the knee is limited. Additional studies are needed to establish the appropriateness of the treatment of osteochondral defects of the ankle, elbow, hip or shoulder with these interventions (autologous chondrocyte transplantation, minced cartilage repair, osteochondral allograft, osteochondral autograft transplantation, non-autologous moasaicplasty or non-autologous bone filler products).

Definitions

Arthroscopic surgical repair: A surgical procedure using specialized video-guidance and instruments to operate on a joint without opening the surgical area in the traditional manner.

Articulating cartilage: A tough, spongy material that covers the ends of bones and may be present in the areas between bones (joints) to protect the bones and act as a shock absorber.

Autologous chondrocyte transplantation (ACT): Also known as autologous chondrocyte implantation (ACI); this is a surgical procedure where cartilage cells are removed from an individual and grown in a lab to create more cells; these cells are then implanted into the knee at areas where there are cartilage defects, in the hope that the transplanted cells take hold and heal the defects.

BMI (body mass index): The weight in kilograms, divided by height in meters squared. *Note: to convert pounds to kilograms, multiply pounds by 0.455, to convert inches to meters, multiply inches by 0.0254.

Femoral condyle: The end of the thigh bone nearest the knee.

Meniscus: A piece of cartilage, a tough, spongy material that lies in the knee joint, between the ends of the bones which acts as a shock absorber.

Minced cartilage repair: A single surgical procedure which uses pieces of cartilage which are affixed to a scaffold delivery system and implanted in the damaged knee. Depending on the particular procedure performed, either autologous or allogeneic cartilage is used.

Mosaicplasty (autologous): A surgical procedure where one or several plugs of bone, along with its articular cartilage, is taken from one area of the knee of an individual and transplanted to another part of the knee on the same individual.

Mosaicplasty (non-autologous): A surgical procedure where one or several plugs of defective bone, along with its articular cartilage, is removed and replaced with synthetic material.

Osteoarthritis: A degenerative condition of the cartilage in the joints resulting in loss of motion and pain.

Osteochondral allograft transplantation: A surgical procedure where a portion of bone, along with its articular cartilage, is taken from another person and transplanted into another person.

Osteochondral autograft transplant (OATS): A surgical procedure where a portion of bone, along with its articular cartilage, is taken from one area of an individual and transplanted to another location on the same individual.

Osteochondritis dissecans: A condition where a loss of the blood supply to an area of bone underneath a joint surface results in the affected bone and its covering of cartilage gradually loosening and causing pain.

Subchondral bone: Bone that lies directly underneath articulating cartilage.

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MAS
Minced cartilage repair
Mosaicplasty
OATS
OsteoBiologics Inc. (OBI) Implants
Osteoarthritis
Osteochondral Autograft Transplant
Transplant, Chondrocyte
TruFit
TruGraft

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
New	11/02/2017	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development. Moved content of SURG.00093 to new clinical utilization management guideline document with the same title.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan’s or line of business’s members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.