**Name of Policy:**
Autografts and Allografts in the Treatment of Focal Articular Cartilage Lesions

Policy #: 248
Category: Surgery

**Background/Definitions:**
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

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

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

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

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:

Chondral and osteochondral autografts and allografts are used in repair of full-thickness chondral defects involving the joint. In the case of osteochondral autografts, one or more small osteochondral plugs are harvested from non-weight-bearing sites in the knee and press fit into a prepared site in the lesion. Osteochondral allografts are typically used for larger lesions to reduce donor site morbidity. Autologous or allogeneic minced cartilage is also being evaluated as a treatment of articular cartilage lesions.

Focal chondral defects of the knee, 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. 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 allogenic 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; 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. These terms have been used interchangeably to describe the procedure.

Preparation of the chondral lesion involves debridement and preparation of recipient tunnels. Multiple individual osteochondral cores are harvested from the donor site, typically from a peripheral non-weight-bearing area of the femoral condyle. Donor plugs range from 6-10 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 osteochondritis dissecans lesions using multiple dowel grafts to secure the fragment. While osteochondral autografting is primarily performed on the femoral condyles of the knee, osteochondral grafts have 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 (7-15mm). Multiple cylinders may be used to fill a larger defect in a manner similar to OATS or mosaicplasty.

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 III 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 owned and distributed 100% by Zimmer, and DeNovo® ET Live Chondral Engineered Tissue Graft (Neocartilage) is produced by ISTO Technologies. The Zimmer DeNovo NT consists of manually minced cartilage tissue pieces obtained from juvenile allograft donor joints. The tissue fragments are mixed intra-operatively 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 FDA approval for marketing. The ISTO engineered DeNovo® ET graft (Neocartilage) uses juvenile allogeneic cartilage cells. The FDA approved ISTO’s Investigational New Drug (IND) application for Neocartilage in 2006, which allowed them to pursue Phase III clinical trials of the product in humans.

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. Filling defects with minced articular cartilage (autologous or allogeneic) is another single-stage procedure that is being investigated for cartilage repair. These techniques are discussed in policy #156 Autologous Chondrocyte Transplantation for Focal Articular Cartilage Lesions.

**Policy:**
**Effective for dates of service on or after June 27, 2014:**
Osteochondral Allografting
Osteochondral Allografting as a technique to repair large full thickness chondral defects of the knee caused by acute or repetitive trauma meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

Osteochondral Allografting for all other joints does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.
Osteochondral Autografting

Osteochondral autografting, using one or more cores of osteochondral tissue meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and may be considered medically necessary for the treatment of symptomatic full-thickness cartilage defects of the knee caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior surgical procedure, when all of the following have been met.

- Adolescent patients should be skeletally mature with documented closure of growth plates (e.g., 15 years or older). Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., younger than 55 years);
- Focal, full-thickness (Grade III or IV) unipolar lesions on the weight-bearing surface of the femoral condyles, or trochea or patella that are between 1 and 2.5cm² in size;
- Documented minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge Grade II or less), and normal-appearing hyaline cartilage surrounding the border of the defect;
- Normal knee biomechanics, or alignment and stability achieved concurrently with osteochondral grafting.

Osteochondral autografting for all other joints, including patellar and talar, and any indications other than those listed above does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Treatment of focal articular cartilage lesions with autologous minced cartilage does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is therefore considered investigational.

Treatment of focal articular cartilage lesions with allogeneic minced cartilage does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is therefore considered investigational.

Meniscal Allograft Transplant

Meniscal allograft transplantation meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when performed concurrently or sequentially with osteochondral allografting or osteochondral autografting.

Effective for dates of service on or after June 13, 2013 through June 26, 2014:

Osteochondral Allografting

Osteochondral Allografting as a technique to repair large full thickness chondral defects of the knee caused by acute or repetitive trauma meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.
Osteochondral Allografting for all other joints does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Osteochondral Autografting
Osteochondral autografting, using one or more cores of osteochondral tissue meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and may be considered medically necessary for the treatment of symptomatic full-thickness cartilage defects of the knee caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior surgical procedure, when all of the following have been met.

- Adolescent patients should be skeletally mature with documented closure of growth plates (e.g., 15 years or older). Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., younger than 55 years);
- Focal, full-thickness (Grade III or IV) unipolar lesions on the weight-bearing surface of the femoral condyles or trochlea that are between 1 and 2.5cm2 in size;
- Documented minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge Grade II or less), and normal-appearing hyaline cartilage surrounding the border of the defect;
- Normal knee biomechanics, or alignment and stability achieved concurrently with osteochondral grafting.

Osteochondral autografting for all other joints, including patellar and talar, and any indications other than those listed above does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Treatment of focal articular cartilage lesions with autologous minced cartilage does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is therefore considered investigational.

Treatment of focal articular cartilage lesions with allogeneic minced cartilage does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is therefore considered investigational.

Meniscal Allograft Transplant
Meniscal allograft transplantation meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when performed concurrently or sequentially with osteochondral allografting or osteochondral autografting.

Effective for dates of service on or after September 6, 2011 and prior to June 13, 2013:
Osteochondral Allografting as a technique to repair large full thickness chondral defects of the knee caused by acute or repetitive trauma meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.
Osteochondral Allografting for all other joints does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Osteochondral Autografting

Osteochondral autografting, using one or more cores of osteochondral tissue meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and may be considered medically necessary for the treatment of symptomatic full-thickness cartilage defects of the knee caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior surgical procedure, when all of the following have been met.

- Adolescent patients should be skeletally mature with documented closure of growth plates (e.g., 15 years or older). Adult patients should be too young to be considered an appropriate candidate for total knee arthroplasty or other reconstructive knee surgery (e.g., younger than 55 years);
- Focal, full-thickness (Grade III or IV) unipolar lesions on the weight-bearing surface of the femoral condyles or trochlea that are between 1 and 2.5cm² in size;
- Documented minimal to absent degenerative changes in the surrounding articular cartilage (Outerbridge Grade II or less), and normal-appearing hyaline cartilage surrounding the border of the defect;
- Normal knee biomechanics, or alignment and stability achieved concurrently with osteochondral grafting.

Osteochondral autografting for all other joints, including patellar and talar, and any indications other than those listed above does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Meniscal Allograft Transplant

Meniscal allograft transplantation meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when performed concurrently or sequentially with osteochondral allografting or osteochondral autografting.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members’ contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.
Key Points:
The most recent update for this policy was performed for the period of April 2012 through May 2014. Following is a summary of key references to date.

A 2008 systematic review by Magnussen et al assessed whether “advanced” cartilage repair techniques (osteochondral transplantation or autologous chondrocyte transplantation) showed superior outcomes in comparison with traditional abrasive techniques for the treatment of isolated articular cartilage defects. Finding a total of five randomized controlled trials (RCTs) and one prospective comparative trial that met their selection criteria, Magnussen and colleagues concluded that no one technique had been shown to produce superior clinical results for treatment of articular cartilage defects. They stated that, “any differences in outcome based on the formation of articular rather than fibrocartilage in the defect may be quite subtle and only reveal themselves after many years of follow-up. Similarly, complications such as donor site morbidity in OAT [osteochondral autograft transfer] may be late in their presentation and thus not be detected at short follow-up.”

Harris and colleagues published a systematic review of combined meniscal allograft transplantation and cartilage repair/restoration in 2010. Six level IV studies (case series) with a total of 110 patients were included in the review. Patients underwent meniscal allograft transplantation with either autologous chondrocyte implantation (ACI, n=73), osteochondral allograft (n=20), osteochondral autograft (n=17), or microfracture (n=3). All studies showed improvement in clinical outcomes at final follow-up compared to the preoperative condition. Outcomes were also compared with historical outcomes of each individual procedure performed in isolation. Four of the six studies found outcomes equivalent to procedures performed in isolation, while two studies found that outcomes with combined surgery were not as good as the historical controls. Across the six studies, 13 failures (12%) were reported; these included 11 isolated meniscal allograft transplantation failures, one combined meniscal allograft and ACI failure, and one isolated ACI failure. Three knees with failed meniscal allograft transplantation were converted to total knee arthroplasty. Nearly 50% of the patients underwent one or more subsequent surgeries after combined meniscal allograft transplantation and cartilage repair/restoration procedures.

Hangody, who first reported use of the mosaicplasty technique in humans in 1992, has authored a number of summaries and case series. It is likely that these reports contain overlapping populations of patients, and few details are reported. In a 1997 article, Hangody and colleagues refer to a 1992–1994 comparison study of mosaicplasty and abrasion arthroplasty. No details of this study are provided, except to note that the mosaicplasty patients had significantly improved Hospital for Special Surgery (HSS) knee scores, compared to those undergoing abrasion arthroplasty. A 2008 summary paper includes descriptions of a prospective multicenter comparison of 413 resurfacing procedures and follow-up from 1,097 mosaicplasties at the authors’ institution. Although the authors report that the comparative study found hyaline-like resurfacing to result in a better clinical outcome than other techniques, the cited study is not available as a publicly available peer-reviewed publication. For the retrospective analysis, Hangody and colleagues reported 789 implantations on the femoral condyles, 147 in the patellofemoral joint, 31 on the tibia condyles, 98 on talar domes, eight on the capitulum humeri, three on humeral heads, and 11 on femoral heads. About two thirds of the patients were reported
to have had a localized cartilage lesion, and the remainder underwent surgery because of osteochondral defects. In 81% of patients concomitant surgical interventions were performed; these included reconstruction of the anterior cruciate ligament (ACL) realignment osteotomies, meniscus surgery, and patellofemoral realignment procedures. Clinical scores found good to excellent results in 92% of patients with femoral condylar implantations, 87% of tibial resurfacings, 74% of patellar and/or trochlear mosaicplasties, and in 93% of talar procedures. Moderate and severe donor-site disturbances were reported in 3% of patients. Ninety-eight second-look arthroscopies were done for persistent or recurring pain, swelling, or postoperative intra-articular bleeding (31 patients at two months to 11 years); second trauma (26 patients at one to nine years); or to evaluate recovery in professional athletes (41 patients at four to seven months). Although at least 57 (58%) second-look arthroscopies were associated with clinical symptoms, the report indicates that 81 (83%) of the evaluations indicated good gliding surfaces, histologically proven survival of the transplanted hyaline cartilage, and acceptable fibrocartilage covering of the donor sites. Slight or severe degenerative changes were seen at the recipient and/or donor sites in 17 cases (17%). The association between clinical symptoms and histological results was not discussed. Painful hemarthroses were observed in 56 (5%) patients. The authors note that although these results are encouraging for use of autologous osteochondral mosaicplasty as an alternative treatment for small- and medium-sized focal defects, postoperative bleeding from the empty donor tunnels represents a possible postoperative complication, and donor-site morbidity remains an open question. Based on their extensive experience with this procedure, Hangody and colleagues consider the optimal indications to be a lesion size of 1–4 cm², patient age of 50 years or younger (due to decreased repair capacity with aging), and correction of instability, malalignment, and meniscal or ligamental tears.

Osteochondral Autografts and Allografts for Focal Articular Cartilage Lesions of the Knee Comparative Trials

Osteochondral Autografts in Comparison with Microfracture

Three randomized controlled trials from the same group of investigators and one retrospective comparative trial have been identified that compared outcomes following osteochondral autografting or microfracture.

One study from Lithuania was a well-controlled and blinded comparison of mosaic OAT versus microfracture for lesions of the femoral condyle (1–4 cm²) in 60 athletes between 15 and 40 years of age (mean, 24.3 years). Follow-up on 95% of the athletes for up to three years following surgery showed that more athletes returned to sports activities (mean, 6.5 months) following OAT (93% vs. 52%), and fewer required revision (1 of 28 vs. 9 of 29 – both respectively). Overall, 96% of patients treated by OAT had an excellent or good result compared with 52% treated by microfracture. At one year follow-up, scores on the International Cartilage Repair Society (ICRS) cartilage grading system improved from a baseline of 51 to 86 in the OAT group and 76 in the microfracture group. At three-year follow-up, scores from HSS questionnaires improved from a baseline of 77 to 91 in the OAT group and 81 in the microfracture group. No donor-site morbidity was observed. Blinded arthroscopic and histological assessment in a subset of patients showed hyaline cartilage of normal appearance following transplantation, whereas microfracture was frequently observed to result in surface fibrillation and soft fibroelastic tissue. At ten-year follow-up there were four failures (14%) in the OAT group and 11 failures (38%) in the microfracture group. The Tegner scores decreased in both groups over time, but remained
significantly better following OAT than microfracture. In the subgroup of patients who were less than 25 years of age at the time of surgery, 15 of 20 patients (75%) in the OAT group and eight of 22 patients (37%) in the microfracture group maintained the same level of activity (competitive athletes or frequently sporting) as before the injury. The level of sporting activity was reported to decrease in older patients because of age or other reasons not related to their knee.

Another report by Gudas and colleagues was a comparison of mosaicplasty versus microfracture or debridement. One hundred and two patients with lesions associated with anterior cruciate ligament (ACL) injury were randomized to one of the three procedures in association with ACL repair. A matched control group of 34 patients with ACL injury but no articular cartilage lesion was included for comparison. The postoperative rehabilitation protocol was the same for the three treatment groups. At a mean 36.1 month follow-up, patients were evaluated with the International Knee Documentation Committee (IKDC) score, Tegner activity score, and clinical assessment. All groups showed a significant improvement in the IKDC score compared to before surgery. Patients without cartilage lesions had IKDC subjective scores that were significantly better than patients with cartilage lesions. For the three groups of patients with cartilage lesions, the mosaicplasty group’s IKDC subjective knee evaluation was significantly better than the microfracture or debridement groups, although the differences between the groups were modest. Tegner activity scores were similar for the mosaicplasty and microfracture groups (7.1 and 6.9, respectively), and slightly lower for the debridement group (6.2).

In 2009, Gudas and colleagues published a randomized clinical trial of osteochondral transplantation (n=25) versus microfracture (n=25) in children 12 to 18 years of age (mean of 14.3 years). Only children with Grade 3 or 4 osteochondritis dissecans (OCD) defects of the femoral condyles were included in the study. The OCD defects were between 2 and 4cm² in area, and the mean duration of symptoms was 24 months. Follow-up was obtained in 94% of patients. After one year, the proportion of excellent to good outcomes was similar for the two groups (92% for osteochondral transplantation vs. 86% for microfracture). However, after a mean 4.2 years of follow-up (range three to six years), the microfracture group showed nine failures (41% of 22). In comparison, there were no failures in the osteochondral transplantation group, and good to excellent outcomes were obtained in 83% of the children. Magnetic resonance imaging (MRI) at a mean 18 months after the operation showed no evidence of graft loosening or migration with excellent or good repair in 19 of 21 children (91%). In comparison, blinded evaluation showed excellent or good repair in 10 of 18 children (56%) after microfracture.

Krych et al reported a retrospective comparison of 96 patients treated with either mosaicplasty or microfracture for articular cartilage defects of the knee. Outcomes were measured annually at one, two, three, and five years. At the latest follow-up, there was no significant difference between the two groups in the SF-36 physical component, the Knee Outcome Survey activities of daily living or IKDC scores. The mosaicplasty group showed a greater improvement in the Marx Activity Rating Scale at the two, three, and five-year follow-up.

Osteochondral Autografts in Comparison with Autologous Chondrocyte Implantation

There are several randomized controlled trials that compare outcomes following treatment with osteochondral autografts or ACI.
Bentley and colleagues randomized 100 consecutive patients with symptomatic lesions of the knee (average 4.7cm², range of 1 to 12cm²) to ACI or mosaicplasty. Seventy-four percent of lesions were on the femoral condyle, and 25% of lesions were on the patella. Ninety-four patients had undergone previous surgical interventions, and the average duration of symptoms before surgery was seven years. Clinical assessment at one year showed excellent or good results in 98% of the ACI patients and 69% of the mosaicplasty patients. The mosaicplasty plugs showed incomplete healing of the spaces between the grafts, fibrillation of the repair tissue, and disintegration of the grafts in some patients. This finding may be related to both the relatively large lesion size and the unusual prominent placement of the plugs in this study, which was intended to allow contact with the opposite articular surface. With six patients lost to follow-up at a minimum ten years after the index surgery, repair was found to have failed in 17% of patients treated with ACI and 55% of patients treated with mosaicplasty.

Dozin et al reported results from a multicenter randomized clinical trial in which ACI was compared to mosaicplasty. Forty-four individuals (61% male, 39% female) age 16–40 years (mean 28.7 ± 7.8), who had a focal, symptomatic chondral injury of Outerbridge Grade III or IV with no previous surgical treatment, were randomly assigned to ACI or mosaicplasty six months after undergoing arthroscopic debridement. The average lesion size was 1.9 cm. Only 12 of 22 (54%) in the ACI group and 11 of 22 (50%) of the mosaicplasty group actually underwent the assigned procedure. Dropouts comprised 14 patients (32%) who reported spontaneous improvement following arthroscopy and did not undergo subsequent surgery, five who did not show up at the presurgery examination and could not be further traced, and two who refused surgery for personal reasons. Because of the substantial dropout rate, the original primary outcome measure, the mean Lysholm Knee Scoring Scale (LKSS) assessed 12 months post-surgery was converted into a scale in which improvement was categorized by proportions of responders (LKSS <60, LKSS 60-90, LKSS 90-100). With this scale, and including ten patients who were cured by debridement (intention-to-treat analysis), the percentages of patients who achieved complete success were 89% (16 of 18 evaluable cases) in the mosaicplasty arm versus 68% (13 of 19 evaluable cases) in the ACI arm (test for trend P=0.093). The high rate of spontaneous improvement after simple debridement raises questions about the appropriateness of additional surgical intervention in patients with small lesions similar to those included in this trial.

Horas and colleagues reported two-year follow-up on a study of 40 patients (between 18 and 42 years of age) with an articular lesion of the femoral condyle (range of 3.2 to 5.6cm²) who were randomly assigned to undergo either autologous chondrocyte implantation or osteochondral autografting. Eleven (28%) had received prior surgical treatment. The authors reported that both treatments resulted in an improvement in symptoms (85% of each group), although those in the osteochondral autografting group responded more quickly. Histomorphologic evaluation of five biopsy specimens at two years or less after transplantation indicated that the osteochondral cylinders had retained their hyaline character, although the investigators noted a persistent interface between the transplant and the surrounding original cartilage. Evaluation of autologous chondrocyte implants indicated a rigid, elastic tissue, with partial roughening and the presence of fibrocartilage.
**Autologous Minced Cartilage**

In 2011, Cole et al reported a multicenter trial with 29 patients (out of 582 screened) randomized in a 1:2 ratio to microfracture or Cartilage Autograft Implantation System (CAIS). In the single-stage CAIS procedure, autologous hyaline cartilage was harvested, minced, affixed on a synthetic absorbable scaffold, and then fixed on the lesion site with absorbable staples. At baseline, there were no significant differences between groups in the duration of symptoms, International Cartilage Repair Society (ICRS) grade, and area and depth of the chondral defect. There was a difference in the gender and work status of the two groups. At three weeks and six months follow-up, there were no significant differences in outcomes between the two groups, but at later time points there were differences reported. The IKDC score was significantly higher in the CAIS group compared to the microfracture group at both 12 (73.9 vs. 57.8) and 24 (83.0 vs. 59.5) months. All subdomains of the KOOS (Symptoms and Stiffness, Pain, Activities of Daily Living, Sports and Recreation, Knee-related Quality of Life) were significantly increased at 24 months in the CAIS group compared with microfracture patients. Qualitative analysis of magnetic resonance imaging (MRI) at three weeks, and 6, 12, and 24 months showed no differences in fill of the graft bed, tissue integration, or presence of subchondral cysts. Adverse events were similar for the two groups.

**Observational Studies**

There are a number of observational studies that provide additional information on outcomes, including longer follow-up, following treatment with osteochondral autografts and allografts and factors (i.e., patient age at the time of surgery, size and location of lesion) associated with good or poor outcomes.

**Osteochondral Autografts**

Ollat et al reported a retrospective multicenter study from the French Society of Arthroscopy that included 142 patients and a mean follow-up of eight years. (The authors comment that this technique has been used extensively in France due to restrictive legislation on restoration techniques, including chondrocyte transfer.) The mean size of the lesion was 2.29cm², and the most common etiologies were osteochondral fractures (n=79) and OCD (n=61). The mean number of plugs was four (range, 1-14). Postoperative complications occurred in 19 patients (13%). Most patients (81.8%) were satisfied or very satisfied with the functional outcomes. There was a significant improvement in the ICRS, International Knee Documentation Committee (IKDC) function, and Hughston scores at follow-up. The factors for a good prognosis were found to be: male gender, location of the defect in the medial femoral condyle, OCD, deep, small defects, and a short interval before surgery. Obesity, smoking, work-related accidents, the level of sports practiced, the percentage of coverage of the defect, the number of plugs, and associated lesions did not have a statistically significant effect on the functional results in the final follow-up.

Solheim and colleagues reported five- to nine-year (n=69) and 10 to 14 year (n=73) follow-up from patients treated for articular cartilage defects of the femoral condyle, patella or trochlea. Exclusion criteria were joint space narrowing, axial malpositioning, ligament instabilities, or inability to follow the rehabilitation protocol. A median of four grafts (range, 1-11) were used to treat lesions that ranged in size from 1 to 5cm². The Lysholm score improved from 49 at baseline to 72 at mid-term follow-up and remained at 72 at the 10- to 14-year follow-up. Visual
analog scale (VAS) score for pain improved from 58 at baseline to 27 at mid-term follow-up and 33 at long-term follow-up. Poor outcome, defined as a Lysholm score of 64 or less or subsequent knee replacement, was observed in 40% of the patients by 10 to 14 years after osteochondral autografting. Factors associated with a poor outcome were patient age of 40 years or older at the time of surgery, female gender, and articular cartilage defects of 3cm² or more. The failure rate was 83% for females 40 years or older with a defect area of 3cm² or more, compared with a failure rate of 12.5% for males younger than 40 years-old with an articular cartilage defect less than 3cm². The location of the lesion (patella-femoral vs condylar) was not a significant factor for good versus poor outcome.

Other reports have focused on osteochondral transplantation for treating patellar lesions. In 2014, Astur et al reported a prospective study of 33 patients with symptomatic patellar lesions (1-2.5 cm in diameter) treated with osteochondral autografting. Patients were excluded if they had a patellar tilt abnormality, a patella alta, or a patella baja, a greater than 15-mm distance of the tibial tubercle and trochlear groove, ACL injury, or a meniscal tear. A single osteochondral plug was used in 85% of cases. At a minimum two-year follow-up (range, 24-54 months), all patients were reported to have significant improvement in functional scores, as measured by the Lysholm, Kujala, and Fulkerson scores and the SF-36 life quality score. MRI at two years showed full bone-plug integration into the patella. Nho et al reported average 29-month follow-up following patellar resurfacing with osteochondral autografts in 22 patients. Indications for surgery were patellofemoral malalignment, isolated cartilage lesion, OCD, or patellar dislocation. Concomitant procedures, including patellar realignment, were performed according to surgeon preference. The mean lesion size was 1.6cm², filled with an average 1.8 plugs per defect. The International Knee Documentation Committee (IKDC) score improved from 47 preoperatively to 74 at follow-up. The activity of daily living score increased from 60 preoperatively to 85 at follow-up.

Laprell and Petersen reported six- to 12-year follow-up from 29 of 35 patients (83%) with severe osteochondral defects (77% with OCD) who were treated by autologous osteochondral transplantation. The average age of the patients at the time of surgery was 26 years. Clinical evaluation at an average eight years after the procedure found 12 patients (41%) to be normal, 14 (48%) as nearly normal, and three (10%, all of whom refused correction of malalignment) as abnormal. No patient was assessed as severely abnormal. In contrast, no patients considered their functional status to be normal, three (10%) considered function to be nearly normal, 20 (69%) thought their function abnormal, and six (21%) considered their functional status to be severely abnormal. Another report described seven-year follow-up on 30 patients who had been treated with autologous osteochondral transplantation for symptomatic grade III to IV chondral lesions (average, 1.9cm; range, 1.0-2.5cm). Nineteen patients received other procedures (ACL reconstruction, meniscectomy, medial collateral ligament repair) at the same time. Magnetic resonance imaging (MRI) at seven years showed complete bone integration in 96% of patients, complete integration of the grafted cartilage in 75% of cases, complete filling of the cartilage defect in 63% of the patients, and congruency of the articular surface in “some” patients. Subchondral bone changes (edema or sclerosis) were noted in 71% of patients. The donor sites were filled with a tissue of different density than the surrounding bone, presumed to be fibrous tissue.
Osteochondral Allografts

Long-term outcomes with osteochondral allografting have been reported in case series. Emmerson et al reported mean 7.7 year follow-up (range 2-22 years) from 66 knees of 64 patients who underwent fresh osteochondral allografting for the treatment of OCD of the femoral condyle. All patients had undergone previous surgery, with an average of 1.7 prior surgeries on each knee. The mean allograft size was 7.5cm². One knee was lost to follow-up. Of the remaining 65 knees, ten patients (15%) underwent reoperation, 47 (72%) were rated good to excellent and eight (13%) were rated fair to poor. Kaplan-Meier survival analysis demonstrated 91% graft survival at five years and 76% graft survival at ten and 15 years. The mean D'Aubigne and Postel score improved from 13.0 (fair) preoperatively to 16.4 (good) at the most recent follow-up. Subjective knee function improved from a mean of 3.4 to 8.4 on a 10-point scale.

Gross and colleagues reported minimum five-year follow-up on a series of 60 patients who received femoral condylar grafts and 65 patients who received tibial plateau grafts for knee defects. Eligible recipients of allografts were younger than 60 years and had traumatic unipolar osteochondral defects of at least 3cm in diameter and 1cm deep. If the meniscus was also significantly damaged, it was resected and replaced with allograft meniscus. Realignment of the involved leg was also performed to unload the graft. Patients were assessed preoperatively and postoperatively using the modified HSS score. If there was no outcome data in the database within the last 12 months, the patients were contacted and a follow-up visit was arranged or a questionnaire was administered by telephone. Referring physicians were also contacted to obtain recent radiographs of the knee. Follow-up was obtained on 86% of patients who received a femoral graft (average of ten years) and 97% of patients with a tibial graft (average of 11.8 years). For the femoral grafts, 12 failed and required graft removal or conversion to total knee replacement. At the end of the study period, 48 of the 60 femoral grafts (80%) were in situ with an average HSS score of 83 out of 100. Kaplan-Meier survival analysis showed 95% graft survival at five years, 85% at ten years, and 74% at 15 years. For the tibial grafts, 21 failed at a mean interval of 9.7 years. At the end of the study, 44 of 65 tibial grafts (68%) were in situ and functioning with an HSS score greater than 70 points. Survival analysis revealed 95% graft survival at five years, 80% at ten years, and 65% at 15 years.

Allogeneic Juvenile Minced Cartilage

Evidence on the efficacy of DeNovo NT is limited to case reports and small case series. The largest series, reported in 2013 to 2014, included 13 patients (15 knees) who received particulated juvenile allograft to the patella. Ten of the 15 knees underwent concomitant procedures, limiting interpretation of functional outcomes. Cartilage repair assessed at a mean of 28.8 months was reported to be nearly normal in 73% of knees while 27% of knees had evidence of graft hypertrophy. Currently available evidence is insufficient to evaluate the effect of this technology on health outcomes.

Ankle

One small randomized controlled trial and several retrospective series have been identified on osteochondral autografting for lesions of the talus. The literature on osteochondral allografts for lesions of the talus consists of small case series.
Osteochondral Autografts

Zengerink et al published a systematic review of treatment of osteochondral lesions of the talus in 2010. Fifty-one nonrandomized and one randomized trial were included in the review. Success rates averaged 85% for bone marrow stimulation, 87% for osteochondral autografting, and 76% for ACI. Because of the high cost of ACI and the knee morbidity seen with osteochondral autografting, the authors concluded that bone marrow stimulation is the treatment of choice for primary osteochondral talar lesions. A 2009 report examined the association between defect size and outcomes following marrow stimulation techniques in 120 ankles. Eight ankles subsequently underwent osteochondral transplantation and 22 ankles were considered clinical failures (American Orthopaedic Foot and Ankle Society [AOFAS] Ankle-Hindfoot score <80). Linear regression suggested a cutoff defect size of 1.5cm$^2$ for marrow stimulation techniques, with an 80% failure rate compared to a 10.5% failure rate for ankles with a defect size less than 1.5cm$^2$. Three of 58 ankles (5.2%) with a defect area less than 1cm$^2$ showed clinical failure, while seven of 37 ankles (18.9%) with a defect area between 1.0 and 1.5cm$^2$ had failed.

The sole controlled trial that has been identified randomized 32 patients with osteochondral lesions of the talus to chondroplasty, microfracture, or OAT. This study found similar improvements (approximately 40 points) for the three treatment groups as measured by the AOFAS Ankle-Hindfoot Score (baseline score of 31 to 37) and the Subjective Assessment Numeric Evaluation (baseline score of 35 to 36). Complication rates were also similar, with persistent pain reported by one patient following chondroplasty, by two patients following microfracture, and by two patients following OAT. Postoperative pain, measured by Numeric Pain Intensity Scores, was greater following OAT (5.25) than chondroplasty (3.3) or microfracture.

A prospective, uncontrolled study of 32 patients who underwent open osteochondral autografting of the talus for osteochondritis dissecans was reported in 2012. The osteochondral grafts were harvested from the ipsilateral knee and placed in the talus after medial malleolar osteotomy. At baseline, the average AOFAS score was 59.1. At a mean 16.8 months follow-up (range, 12 to 24 months), the AOFAS score had improved to 87.9. All patients showed an improvement of at least 20 points. The Lysholm score, used to assess donor site morbidity, was 88 points at six weeks postoperatively and 98 points at six months. Two patients had persistent knee pain at the last follow-up.

In 2006, Scranton et al reported a study of 50 consecutive patients with a type-V cystic talar defect who were treated with a single osteochondral graft (15mm) taken from the ipsilateral knee. Patients with larger lesions in which multiple allograft plugs were used were excluded from analysis. Thirty-two patients (64%) had undergone a previous surgical procedure on the ankle; further surgery was required in 17 patients (34%). When contacted at a mean of 36 months (range, 24 to 83) after the index procedure, 45 patients (90%) had a good to excellent score on the Karlsson-Peterson Ankle Score questionnaire. Two patients had severe degenerative changes and underwent arthrodesis.

In 2006, Kreuz et al reported outcomes from a series of 35 patients who underwent osteochondral grafting from the ipsilateral talar articular facet (with or without osteotomy)
following failed bone marrow stimulation. Six of the patients had previously undergone osteochondral or cancellous bone grafting of the defect area. The mean lesion size was 6.3 mm. At a mean follow-up of 49 months (range 33 to 77 months), the AOFAS Ankle-Hindfoot score had improved from 54.5 (range 47–60) to 89.9 points (range 80-100).

In 2011, Imhoff and colleagues reported a retrospective review with long-term outcomes following osteochondral autografts of the talus in 28 consecutive patients. The osteochondral grafts were harvested from the femoral condyles and malleolar osteotomies were performed whenever the osteochondral defect could not be reached from the anterior incision. One patient was lost to follow-up, and two patients had a revision operation on the ankle. For 16 of the remaining 25 patients (64%), the autograft was the first line of treatment, and in nine patients (36%), it was a second surgical intervention. Between baseline and average seven years’ follow-up (range, 53-124 months), the AOFAS score increased from 50 to 78 points, the Tegner score increased from 3.1 to 3.7, and the VAS for pain decreased from 7.8 to 1.5. Patients who had transplant as a second procedure had significantly worse AOFAS (62 vs. 87) and Tegner scores (2.0 vs. 4.6) and higher VAS scores (3 vs. 0.6 – all respectively).

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

In 2011, Liu et al reported osteochondral autografting in 16 patients for acute osteochondral fractures of the talar dome associated with an ankle fracture. Ankle radiographs were taken at two, six, and twelve weeks postoperatively and every three months after fracture healing. MRI was performed after 12 months and at the latest follow-up. At an average 36-month follow-up (range, 21–48 months), the AOFAS score was 95.4 (range, 86-100). At the latest follow-up, there was no radiographic evidence of post-traumatic arthritis, and MRI showed bony integration and articular congruity of the talar dome in 93.7% of the osteochondral grafts.

**Donor Site Morbidity**

One study evaluated donor-site morbidity in 11 of 15 patients who had undergone graft harvest from the knee (mean of 2.9 plugs) for treatment of osteochondral lesions of the talus. At an average 47-month follow-up (7–77 month range), five patients were rated as having an excellent Lysholm score (95–100 points), two as good (84–94), and four as poor (64 or less). Reported knee problems were instability in daily activities, pain after walking one mile or more, having a slight limp, and difficulty squatting. Hangody et al reported that some patients had slight or moderate complaints with physical activity during the first postoperative year, but there was no long-term donor site pain in a series of 36 patients evaluated two to seven years after osteochondral autografting. A 2009 report from Europe described osteochondral autografting for lesions of the talus in 200 patients, 112 of whom had been followed up for a minimum of two years. The focus of this study was to determine factors contributing to donor-site morbidity in
the knee, rather than outcomes for the talus. The number of grafts, size of the transplanted plugs, and patient age were not related to donor-site morbidity. Body mass index (BMI) was found to be significantly associated with knee scores, with a decrease in Lysholm score by one point (1%) for each point increase in BMI. Interpretation of these results is limited by the lack of preoperative assessment of knee pain and function.

**Osteochondral Allografts**

Use of allografts for large defects of the talus has been reported in case series. Due to the relatively rare occurrence of this condition, most series have fewer than 20 patients.

The largest series is from Bugbee et al., who reviewed outcomes of 86 ankles (82 patients) treated with bipolar fresh osteochondral allografts for arthritis of the tibiotalar joint. All patients had declined arthrodesis. Patients who did not present for follow-up were contacted via telephone and/or mail to obtain subjective outcomes. At a mean follow-up of 5.3 years (range, 2 to 11), 36 ankles (42%) had undergone additional surgery. Twenty-five ankles (29%) were considered clinical failures (i.e., revision allograft, conversion to total ankle arthroplasty, arthrodesis, or amputation) and 11 ankles (13%) had undergone operations that did not involve graft removal. Radiographic evaluation categorized 29 of 63 ankles (46%) as failures, with graft collapse observed in 11 of the 29 (38%). Survivorship of the osteochondral allograft estimated by Kaplan-Meier analysis was 76% at five years and 44% at ten years. For patients who did not undergo additional surgery, 62% were classified as having excellent to good results, 26% as fair, and 12% as poor.

In 2012, Haene et al reported a prospective study of fresh talar osteochondral allografts in 16 patients (17 ankles) with large osteochondral lesions of the talus. All but one of the ankles had previously undergone single or multiple procedures. Computed tomography (CT) at an average follow-up of 4.1 years (range, two to six years) identified failure of graft incorporation in two ankles, osteolysis in five, subchondral cysts in eight, and degenerative changes in seven ankles. Clinically, five ankles (29%) were considered failures, and two (12%) had poor outcomes requiring additional surgery. Ten ankles (59%) had good to excellent results based on validated outcome scores and clinical history.

Berlet et al reported a 2011 prospective study with minimum follow-up of two years in 12 patients who had received an osteochondral allograft for talar defects. In another patient, the graft had failed and was not included in the analysis. All patients had failed at least one prior surgical treatment and had a mean lesion size of 1.5cm². At follow-up, (mean 3.3 years), AOFAS Ankle-Hindfoot scores improved from 61 at baseline to 79. There was a trend toward improvement in the physical or mental health components of the Short-form (SF)-12 Health Survey, although the study was underpowered to detect a significant difference. Radiographs and MRI performed yearly showed radiolucencies in three grafts (25%), edema in four (33%), and failure to incorporate for one graft.

El-Rashidy et al reported a retrospective review of 38 of 42 total patients who were treated with osteochondral allografts. All patients had failed conservative management and had a mean lesion size of 1.5cm². Grafts were harvested from a similar anatomic location on the donor talus to match the contour and surface anatomy of the recipient bed. The average duration of follow-
up was 38 months. Including scores from four patients (10.5%) in who graft failure occurred, the AOFAS Ankle-Hindfoot score improved from 52 to 79 points and VAS improved from 8.2 to 3.3 points. Patient satisfaction with the outcome was rated as excellent, very good or good by 28 of the 38 patients (74%) and as fair or poor by ten patients (26%). Of the 15 patients who had postoperative MRI, five (33%) had signs of graft instability.

Raikin published results from a series of 15 patients who underwent fresh matched osteochondral allograft transplantation for talar lesions with a volume greater than 30cm³. At an average 54 months after surgery (minimum of two years), mean VAS for pain had improved from 8.5 to 3.3 and the mean AOFAS Ankle-Hindfoot score had improved from 38 to 83 points. Two ankles had undergone conversion to fusion. Radiographic analysis revealed some evidence of collapse or resorption in 10 of the 15 ankles (67%).

Gortz et al reported on a series of 11 patients (12 ankles) who underwent fresh osteochondral allografting for unipolar lesions of the talus. Patients had undergone an average of 1.8 prior surgeries (range, 1 to 5). The average graft size was 3.6cm², which was an average of 40.5% of the talar surface. At a mean 38-month follow-up (range, 24 to 107 months) two of the ankles had failed and undergone revision or fusion. For the remaining ten patients, the mean Olerud-Molander Ankle Score (OMAS) improved from a score of 28 to 71. Outcomes were categorized at good to excellent in five ankles (42%), fair in three (25%), and poor in two (17%). All patients demonstrated radiographic union by six months, with an overall graft survival rate of 83%.

Allogeneic Juvenile Minced Cartilage
Use of DeNovo NT for the talus has been reported in small case series. The largest series is from a preliminary report of a larger study. The full multicenter study has a targeted enrollment of 250 patients with five-year follow-up. In the preliminary report, 24 ankles (23 patients) with osteochondral lesions of the talus were treated with DeNovo NT. Fourteen of the ankles (58%) had failed at least one prior bone marrow stimulation procedure. At an average follow-up of 16.2 months, 78% of ankles had good to excellent scores on the AOFAS Ankle-Hindfoot scale with a final mean VAS of 24/100. However, 18 ankles (76%) had at least one concomitant procedure (hardware removal and treatment for impingement, synovitis, instability, osteophytes, malalignment), limiting interpretation of the functional results. There was one treatment failure caused by partial graft delamination. Bleazey and Brigado conducted a retrospective review of seven patients who were treated with juvenile minced cartilage (DeNovo NT) together with sponge allograft. All patients had failed conservative therapy (walking boot and physical therapy) and four patients had failed microfracture. Patients were evaluated with VAS for pain and activity at six-month follow-up. All patients showed clinically significant improvement. Pain during walking decreased from an average of 7.7 at baseline to 1.9 at six months. Ability to walk four blocks improved from a score of 4.8 to 9.2.

Osteochondritis Dissecans (OCD) of the Elbow
Osteochondral Autografts
OCD of the elbow is an uncommon condition that in its early stages can be treated nonoperatively or with simple fragment removal. The literature on osteochondral autografts for advanced OCD of the elbow consists of small case series, primarily from Europe and Asia.
Iwasaki et al reported minimum two-year follow-up after osteochondral mosaicplasty for OCD of the elbow in 19 teenage athletes (mean age of 14 years) in Japan. Preoperative symptoms consisted of pain with sports activities (n=19) patients, limited range of motion (n=5), and elbow catching (n=3). Indications for surgery included failure of more than six months of conservative treatment or evidence on plain radiographs and MRI of unstable lesions, such as displaced (n=7) or detached (n=12) fragments. The mean defect size was 1.5cm² (range, 0.5 to 3.0cm²). Two independent observers assessed clinical findings at a mean of 45 months (range, 24–87 months); the radiologist was blinded to the clinical outcomes. Graft incorporation was observed in all patients, with nearly normal surface integrity of the articular cartilage and underlying bone in 18 patients. Eighteen of the 19 patients were classified with good to excellent results and were free from elbow pain. One patient was classified as fair with mild pain. Seventeen of the 19 patients, including all pitchers, returned to a competitive level of baseball. Mild donor site pain in the knee was reported in one patient.

Yamamoto et al reported minimum two-year follow-up (range, 24-63 months) from 18 juvenile baseball players with OCD of the elbow who were treated with osteochondral autografts. Most of the patients had failed conservative management at another hospital in Japan. For Grade 3 lesions (separated but in situ), one or two osteochondral plugs from the femoral condyle or patellofemoral joint were used to restore the articular surface or fix unstable OCD lesions. For Grade 4 lesions (displaced fragment), one to three plugs were used to restore the articular surface. For the nine patients with a Grade 3 lesion, the subjective score was increased (from 75.0 to 95.6), but the objective score (from 88.3 to 88.3) did not change. For the nine patients with a Grade 4 lesion, both subjective (from 65.6 to 88.9) and objective scores (from 72.8 to 88.3) were increased significantly. At six months after surgery, all patients but one could throw a ball without pain.

In 2011, Ovesen et al reported mean 30-month follow-up from ten patients (age, 13-27 years) treated with osteochondral autografts from the lateral patellofemoral joint for advanced OCD of the elbow. Eight of the patients (80%) were pain-free postoperatively. The Mayo Elbow Performance Score improved from a preoperative mean of 71 points to 93.5 points postoperatively. This compared to a score of 100 points for the non-operated elbows. The Constant functional elbow score averaged 92.5 points for the operated elbow and 100 for non-operated elbows. Postoperative radiographs and MRI/computed tomography showed incorporation and a normal contour of the subchondral cortex in all patients. No problems were observed regarding donor site pain.

**Donor Site Morbidity**
Nishimura et al evaluated recovery of the donor knee after osteochondral autograft harvesting for capitellar OCD in 12 young athletes (age range, 12 to 17 years). Pain and function were assessed at 1, 2, 3, 6, 12, and 24 months after the surgery. Knee joint effusion persisted in seven of the 12 patients at one month, but none of the patients had effusion at three months. At three months, muscle power of the knee extensor was reduced in eight patients compared to the preoperative level. At 12 months, 11 patients had reached preoperative knee extensor muscle strength. All patients were pain-free at the donor site by six months (mean Lysholm score of 100) and returned to the previous competitive level of their sport.
Shoulder

Osteochondral Autograft

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

Summary

Evidence is sufficient to consider osteochondral allografting medically necessary as a technique to repair large (e.g., 10cm²) full-thickness chondral defects of the knee caused by acute or repetitive trauma. Use of allografts for large defects of the talus has been reported in small case series. Evidence is insufficient to evaluate the effect of osteochondral allografting of the talus, or other joints, on health outcomes. Therefore, osteochondral allografts for joints other than the knee are considered investigational.

For osteochondral autografting, only three relatively small randomized controlled trials from Europe have demonstrated improved clinical outcomes with osteochondral autografting of the knee when compared with microfracture. However, controlled studies demonstrate similar benefit to other cartilage resurfacing procedures in appropriately selected patients, and a number of uncontrolled studies indicate that osteochondral autografts can improve symptoms in some patients with lesions of the femoral condyle who have failed prior surgical treatment. These patients have limited options. Therefore, based on the clinical input received and additional literature reviewed, it is concluded that osteochondral autografts may be considered an option for symptomatic full-thickness chondral lesions of the femoral condyle, trochlea or patella caused by acute or repetitive trauma, in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure. Recent evidence indicates that osteochondral grafting combined with meniscal allograft results in outcomes similar to either procedure performed alone; therefore combined procedures may be considered medically necessary.

Evidence is currently insufficient to evaluate the efficacy of osteochondral autografts for joints other than the knee, or to evaluate the efficacy of osteochondral autografts in comparison with other surgical repair procedures as a primary treatment of small lesions. Questions also remain about the natural history of asymptomatic lesions found incidentally during other surgical procedures. Controlled trials with longer follow-up are needed to demonstrate that use of osteochondral autografts as a primary treatment results in improved clinical outcomes in comparison with traditional marrow-stimulating procedures.

Minced cartilage techniques are in the early stages of development and testing and/or not approved in the U.S. Of the case series evaluated, sample sizes were small with short term follow-ups and had critical study limitations documented to this point. Therefore, treatment by autologous and allogeneic minced cartilage methods is considered investigational.
Practice Guidelines and Position Statements
In a 2010 and 2012 clinical practice guideline on the diagnosis and treatment of osteochondritis dissecans (OCD), the American Academy of Orthopaedic Surgeons (AAOS) was unable to recommend for or against a specific cartilage repair technique in symptomatic skeletally immature or mature patients with an unsalvageable osteochondritis dissecans lesion.

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

Key Words:
Osteochondral allograft transplantation, osteochondral autograft transplantation, OATS, OAT, mosaicplasty, articular cartilage, hyaline cartilage, fibrocartilage, CAIS, Chondrofix®, Neocartilage, DeNovo NT Graft, DeNovo® ET Graft

Approved by Governing Bodies:
Not applicable

Benefit Application:
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

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

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


75. Rapp SM. Art of achieving an optimal cartilage repair depends on surgeon, technique. Orthopedics Today 2007; 27: 32.


Policy History:
Medical Policy Group, September 2005 (3)
Medical Policy Administration Committee, October 2005
Available for comment September 26-November 9, 2005
Medical Policy Group, October 2007 (1)
Medical Policy Administration Committee, October 2007
Available for comment October 5-November 19, 2007
Medical Policy Group, January 2009 (3)
Medical Policy Group, July 2011 (3): Updated Policy section, Key Points, & References
Medical Policy Administration Committee July 2011
Available for comment July 21 through September 5, 2011
Medical Policy Group, July 2012 (3): 2012 Updates – Description, Key Points & References
Medical Policy Administration Committee July 2012
Medial Policy Group, May 2013 (2): Deleted lesion size for allografts, Description and Key Points shortened, Deleted all web references that are no longer available.
Medical Policy Administration Committee, May 2013
Medical Policy Panel, June 2013
Medical Policy Group, June 2013 (3): 2013 Updates to Title, Description, Policy statement (adding treatments of focal articular cartilage lesions with autologous and allogeneic minced cartilage as investigational from policy #156), Key Points, References, and Key Words.
Medical Policy Administration Committee, July 2013
Available for comment July 9 through August 28, 2013
Medical Policy Group, September 2013 (3): Ad hoc update to add information to Key Points and References; no change in policy statement
Medical Policy Panel, June 2014
Medical Policy Group, June 2014 (3): 2014 Updates to Key Points & References; updated policy statement for osteochondral autografting to include patella in coverage criteria
Medical Policy Administration Committee, July 2014
Available for comment July 9 through August 25, 2014

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

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