MEDICAL POLICY

CARTICEL AUTOLOGOUS CULTURED CHONDROCYTES

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By: Roger Hinkson, M.D., MPH
Consulting Medical Director

POLICY

- The procedure is useful in the treatment of an isolated osteochondral defect without degenerative osteoarthritis (Osteoarthritis can cause bony changes that prevent successful reimplantation).
- The procedure is recommended as second line therapy after failure of conservative care and typically surgery.
- In the procedure cartilage is removed from a less weight-bearing area and the chondrocytes are isolated. The chondrocytes are then grown in vitro until there are enough to reimplant in the damaged area.

ALL THE FOLLOWING CRITERIA MUST BE MET PRIOR TO CONSIDERATION:

1. Conservative Care:
Failure of conservative therapy (minimum of 2 months of physical therapy). PLUS

2. Subjective Clinical Findings:
Presence of disabling pain and/or knee locking. PLUS

3. Objective Clinical Findings:
A) Failure of established surgical interventions (i.e., microfraction, drilling, abrasion) (diagnostic arthroscopy, lavage, or debridement is not considered adequate to meet this criterion). Note: The procedure may be reasonable prior to other surgery for larger lesions (>1.5-2.0 sq cm). AND

B) Focal articular cartilage defect down to but not through the subchondral bone on a load bearing surface of the femoral condyle (medial, lateral, trochlear) (not in the patella). AND

C) Single, clinically significant, lesion that measures between 1 to 10 sq cm in area that affects a weight-bearing surface of the medial femoral condyle or the lateral femoral condyle. AND

D) Procedure is not being done for treatment of degenerative arthritis (osteoarthritis). AND
E) Stable knee with intact meniscus and normal joint space on X-ray. AND

F) Full-thickness lesion [*Modified Outerbridge Grade III-IV] that involves only cartilage. AND

G) Knee is stable with intact, fully functional menisci and ligaments. AND

H) Normal knee alignment. AND

I) Patient is less than 60 years old. AND

L) Body Mass Index of less than 35.

4. Imaging Clinical Findings:
Chondral defect on the weight-bearing surface of the medial or lateral femoral condyle on: MRI. OR Arthroscopy.

ACI Exclusion Criteria:
ACI is definitely not recommended in the following circumstances: Lesion that involves any portion of the patellofemoral articular cartilage, bone, or is due to osteochondritis dissecans; A "kissing lesion" or Modified Outerbridge Grade II, III, or IV exists on the opposite tibial surface; Mild to severe localized or diffuse arthritic condition that appears on standing x-ray as joint space narrowing, osteophytes, or changes in the underlying bone; Unhealthy cartilage border; the synovial membrane in the joint may be used as a substitute border for up to 1/4 of the total circumference; Prior total meniscectomy of either compartment in the affected knee (Must have at least 1/3 of the posterior meniscal rim.); History of anaphylaxis to gentamycin or sensitivity to materials of bovine origin; Chondrocalcinosis is diagnosed during the cell culture process.

DOCUMENTATION

Recommended as a second-line therapy after failure of initial arthroscopic or surgical repair. Recent studies have confirmed the success of this technically demanding technique when done by experienced practitioners. (Zaslav, 2009) (Schindler, 2009) (Saris, 2009) In recent years the

surgical implantation of healthy cartilage cells (autologous condrocyte implantation [ACI]) into damaged areas has been seen as an alternative option and a potential improvement over the current strategies for the management and treatment of articular cartilage defects. A 2002 Cochrane review concluded that there is not enough evidence to make a determination that would influence current practice and determined that ACI must currently be considered as a technology under investigation with an effectiveness that is yet to be determined. (Wasiak-*Cochrane*, 2002) (Bentley, 2003) (Horas, 2003) (Blue Cross Blue Shield, 2003) A 2006 updated review concluded that the use of ACI and other chondral resurfacing techniques is becoming increasingly widespread, but there was no evidence of significant difference between ACI and other interventions. (Wasiak-*Cochrane*, 2006) (Ruano-Ravina, 2005) (Ruano-Ravina, 2006) There is insufficient evidence at present to say that ACI is cost-effective. (Clar, 2005) Autologous chondrocyte implantation (ACI) is being used to treat patients with cartilaginous defects of the femoral condyle. The ACI process involves obtaining healthy chondrocyte cells from a patient's knee, culturing the cells through a process termed Carticel (Genzyme), and implanting the cultured chondrocytes back into the patient via a surgical procedure. The revised FDA labeling suggests a more restricted use of autologous chondrocytes, i.e., as a second-line therapy after failure of initial arthroscopic or surgical repair. When no improvement has been achieved using all available alternative treatments that can be performed arthroscopically, only alternatives requiring open arthrotomy and major knee surgery are available. It is possible in this case that ACI might be a reasonable consideration, particularly in cases when osteochondral allograft is not technically feasible or available to the patients and when total knee replacement is not a clinically acceptable alternative. (Regence BlueCross BlueShield, 2004) Autologous chondrocyte implantation (ACI) is a viable approach for cartilage repair of the knee, according to a recent systematic review. ACI has long been regarded as the youngest and the most complicated new procedure in a round of three (ACI, osteochondral cylinders and microfracture), and has been frowned upon as too technological and expensive by many. The study had three conclusions: (1) ACI is at least as effective as other treatments in the short term; (2) it is the only treatment with true potential for tissue regeneration, the key to satisfying long term effects; & (3) if long-term results turn out to be good, that would counterbalance the higher initial costs and result in superior cost-effectiveness. ACI was compared with osteochondral allografting in 4 studies, subchondral marrow stimulation in 5 studies, and with abrasion in the remaining study. Ultimately, outcomes with the various approaches were generally similar. For example, one study showed that rates of good and excellent clinical results were 88% after ACI compared to 69% after osteochondral autograft transfer. Another study reversed the order, with 88% recovering completely after osteochondral grafts and 68% with ACI. (Vavken, 2010) The benefits of ACI last well into the second decade, and in over three-fourths of patients 10-20 years after the implantation it appears to provide reduced pain and increased function. The emerging consensus favors osteoarticular allograft transplants (OATs) and microfracture techniques for relatively small lesions and ACI or osteochondral allografting for larger ones. Because age of the tissue damage can impact treatment efficacy, ACI may be preferred as a first-line treatment. ACI is especially used in young, active individuals who participate in "cut-and-run" sports such as football, soccer, and tennis. The total process requires both technical proficiency on the part of the surgeon and patience on the part of the patient, who must undergo two surgeries and then cannot put weight on the treated joint for up to three or four months. (Vasiliadis, 2010) For articular cartilage injuries, ACI provides more durable results, but microfracture offers a faster recovery, according to a cohort study. ACI offers good results over time and should delay further

joint degeneration, but the disadvantage of the regenerative approach to cartilage injury treatment is long recovery time. (Kon, 2011) Young patients with osteoarthritic knees have generally poor outcomes from matrix-assisted autologous chondrocyte transplantation (MACT) as a salvage procedure in cartilage lesions, and there was significantly poorer outcome in knees with previous meniscectomy procedures. (Filardo, 2012)

REFERENCES

OFFICIAL DISABILITY GUIDELINES, KNEE CHAPTER, 2013