

**Washington State Health Care Authority, HTA Program
Final Key Questions****Osteochondral Allograft Transplantation and Autograft Transfer System
(OATS/mosaicplasty)****Introduction**

HTA has selected Osteochondral Allograft Transplantation and Autograft Transfer System (OATS/mosaicplasty) to undergo a health technology assessment where an independent vendor will systematically review the evidence available on its safety, efficacy, and cost-effectiveness. HTA originally posted the topic as Osteoarticular Transfer System Cartilage Surgery (OATS), now modified to the more generic title above, and gathered public input on all available evidence. HTA published the Draft Key Questions to gather public input about the key questions and any additional evidence to be considered in the evidence review. Key questions guide the development of the evidence report. HTA seeks to identify the appropriate topics (e.g. population, indications, comparators, outcomes, policy considerations) to address the statutory elements of evidence on safety, efficacy, and cost effectiveness relevant to coverage determinations.

Osteoarticular Autograft Transfer System cartilage surgery (OATS) is an open joint or arthroscopic procedure used to repair localized cartilage injuries, usually caused by trauma or acquired defect of a joint (knee, ankle, hip, shoulder, elbow), such as an anterior cruciate ligament (ACL) deficiency. In the procedure, one (or more) plugs of healthy cartilage are harvested from a less important area of the cartilage within the same joint or from preserved cadaver tissue, and inserted into the center the damaged area, with the idea that surrounding cartilage will grow over the edges of the insert without the reduction of quality to fibrocartilage cells found in other cartilage repair procedures (sub-chondral bone marrow stimulation by drilling or microfracture, abrasion arthroplasty).

Draft Key Questions

When used in patients with cartilage damage:

1. What is the case definition of a patient suitable for OATS/mosaicplasty surgery, and are there measures of reliability and validity for case identification?
 - a. What are the maximum, minimum, and optimum size (volume) of the damage that is suitable for repair using OATS/mosaicplasty?
 - b. What are the maximum and optimum number of lesions that can be repaired in a single OATS/mosaicplasty procedure?
 - c. Are there other considerations that make OATS/mosaicplasty suitable or unsuitable (age, mobility, comorbidities, BMI).
 - d. Is there a distinction between OATS and mosaicplasty, and a related case definition difference between the two?

- e. Is there a distinction between cases where autograft vs. allograft OATS/mosaicplasty is preferable?
 - f. Of the joints where OATS/mosaicplasty has used (knee, ankle, hip, shoulder, elbow), are any more or less suitable to this procedure?
 2. What are the expected treatment outcomes of OATS/mosaicplasty, and are there validated instruments and scores to measure clinically meaningful improvement?
 3. What is the evidence of efficacy and effectiveness of OATS/mosaicplasty (open or arthroscopic)? Including consideration of short term and long term:
 - a. Delay or avoidance of progression to osteoarthritis
 - b. Impact on function, pain, range of motion, quality of life, activities of daily living and return to work
 - c. Longevity of treatment effect
 - d. Need for continuing and/or subsequent intervention
 - e. Need for extended or continuing physical therapy
 - f. Recovery time considering harvest site recovery issues
 - g. Differential results from multiple versus single grafts, patterning for multiple grafts (linear arrangement vs. circular arrangement)
 - h. Differential results between allograft and autograft procedures
 - i. Differential results between open and arthroscopic procedures
 - j. Differential results in centers of excellence
 4. What is the evidence of the safety of OATS surgery? Including consideration of:
 - a. Adverse events type and frequency (peri-operative, cartilage plug detachment, cartilage rejection, graft fit, harvest site issues, development of fibrocartilage, mortality, other major morbidity such as DVT, deep infection, and excessive intraarticular bleeding)
 - b. Revision/re-operation rates (if not addressed in efficacy)
 5. What is the evidence that OATS surgery has differential efficacy or safety issues in sub populations? Including consideration of:
 - a. Gender
 - b. Age
 - c. Psychological or psychosocial co-morbidities
 - d. Baseline functional status: e.g. type of injury or lesion, extent of cartilage damage, specific damage site size, number of damage sites
 - e. Other patient characteristics or evidence based patient selection criteria, especially comorbidities of diabetes and high BMI
 - f. Provider type, setting or other provider characteristics
 - g. Payor/ beneficiary type: including worker's compensation, Medicaid, state employees
 6. What is the evidence of cost implications and cost-effectiveness for OATS/mosaicplasty? Including consideration of:
 - a. Costs (direct and indirect) and cost effectiveness
 - b. Short term and long term

Policy Context:

Injury or damage to cartilage can be resistant to healing due to low vascularization, and in joints, may lead to pain and loss of function. The resulting irritation and inflammation of the joint may also be associated with further degeneration and osteoarthritis. Treatments for injured cartilage include arthroscopic removal of damaged cartilage, stimulation of the underlying bone to encourage cartilage growth, injection of chondrocytes to encourage repair, and/or grafts of cartilage from other parts of the joint or from preserved cadaver tissue. Advanced joint degeneration is treated with other approaches, such as the injection of cushioning material (hyaluronic acid), bone shaping to reduce wear and joint replacement.

Injuries suitable for repair using OATS/mosaicplasty often occur in young, athletic individuals. Treatment that allows a continued healthy lifestyle and avoids long term joint damage and eventual more invasive procedures is of great benefit. Though definite causes for osteoarthritis have not been identified, there are indications that minor joint damage followed by years of continuous wear may be the major cause.

Technology Description:

Osteochondral Autograft Transfer System surgery is a graft procedure that uses one or more “plugs” of healthy cartilage to fill in damaged areas. It can be done as an open or arthroscopic procedure, and is sometimes combined with other joint operations such as arthroscopic debridement or ACL repair. The grafted cartilage is harvested from another area within the joint, and the harvest site as well as the repair site need to heal properly, so a period of physical therapy is required after the operation.

Osteochondral Allograft Transplant Surgery is a graft procedure similar to Osteochondral Autograft Transfer System, but using graft material from preserved cadaver cartilage. There is some indication that allograft cartilage does not integrate as well, and transplantation involves some risk of infection. However, adequate healthy cartilage tissue is not always available within the joint under repair.

Mosaicplasty is a more generic term that covers either Osteochondral autograft or allograft, open or arthroscopic.

Issues:

Significant questions remain about the safety, efficacy and effectiveness, and cost effectiveness of OATS/mosaicplasty cartilage surgery. The choice of suitable patients for OATS/mosaicplasty surgery is controversial because the size and number of damage sites for which it is functional are not well defined, because the harvesting of cartilage from another site or cadaver tissue adds risk and healing issues, and because other, less invasive procedures may be equally effective in the short term (autologous chondrocyte injection). Effectiveness questions particularly center on whether the potential beneficial outcomes of long term pain and functional improvement, prevention of osteoarthritis or further joint deterioration occur with this surgical intervention.