Autologous chondrocyte implantation

Background

Autologous chondrocyte implantation (ACI) repairs articular cartilage damage in the knee. Patients with damaged cartilage suffer pain, immobility, and locking of the joint. Many have already undergone surgery to fix the cartilage but are still experiencing pain.

The surgeon first performs an arthroscopic biopsy of the knee, collecting knee cartilage cells. These cells are sent to the only laboratory in the United States with FDA approval to culture chondrocytes, Genzyme Corp. (wholly-owned subsidiary of sanofi-aventis) in Cambridge, MA (several other laboratories are currently conducting investigational studies to support their bids for FDA approval to provide ex vivo autologous chondrocyte cultures). The laboratory cultures chondrocytes from the biopsy, growing a culture of 11–12 million cells from the hundreds of thousands that were harvested in the biopsy. This process takes four to six weeks. When a culture is mature, the lab sends it back to the surgeon, who implants it in the patient’s knee.

The ACI technique requires an open knee approach. The first step of the surgery is to trim the defect to a stable rim and clean the base of the bone. A template of the defect is made from sterile paper and used to trace out the desired cut for harvesting a periosteal graft patch, which is taken from the shinbone just below the knee. The patch is applied to the lesion and microsutured to the articular cartilage margins of the lesion so that it forms a watertight seal. The surgeon uses fibrin glue to cement the seal, and then injects the cultured chondrocytes under the patch.

The FDA approved autologous chondrocyte cultures for injection into the knee in 1997. The procedure is indicated for a relatively small segment of patients: adults under 55 suffering from articular cartilage lesions of the femur (medial and lateral femoral condyles and trochlea) in knees with normal alignment that have failed standard first line treatments. The patient must have minimal degenerative change in the surrounding area (arthritis is a contraindication for ACI), have normal knee biomechanics or alignment, and stability can be achieved concurrently with the ACI procedure. The patient must be too young to be a candidate for a total knee replacement.

Involved specialties

Orthopedic surgeons
Positions of specialty boards

**ABOS**

The American Board of Orthopaedic Surgery (ABOS) offers specialty certification for orthopedic surgeons. According to the ABOS 2012 Rules and Procedures for Residency Education Part I and Part II Examinations, in order to sit for the certification exam, candidates must:

- Complete a 60-month residency in an accredited orthopedic surgery program
- Hold a valid, unrestricted license to practice medicine
- Be continuously and actively engaged in orthopedic surgery practice, which includes hospital admitting and surgical privileges, in a single location for a period of at least 20 months immediately prior to taking the oral portion of the certification exam,
- Perform at least 14 documented surgical cases in a six-month period that begins on April 1 preceding the oral examination
- Be able to demonstrate competence and adherence to ethical standards, including advertising standards

According to the ABOS, postgraduate training in orthopedic surgery should include a minimum of four years of specialty training. For physicians whose specialty training took place prior to July 1, 2000, the first year may be fulfilled by any accredited residency program that involves patient care.

For physicians training after July 1, 2000, the first year of postgraduate training must include:

- Six months of structured surgical rotation, including multisystem trauma, plastic surgery/burn care, surgical intensive care, and vascular surgery
- One month of training in at least three of the following: emergency medicine, medical/cardiac intensive care, rheumatology, anesthesiology, musculoskeletal imaging, and rehabilitation
- No more than three months of orthopedic surgery

The subsequent years of study must include:

- 12 months of adult orthopedics
- 12 months of fractures/trauma
- Six months of children’s orthopedics
- Six months of basic and/or clinical specialties

Orthopedic surgery residency programs must include education on:

- Children’s orthopedics.
- Diagnosis and care of disorders affecting the bones, joints, and soft tissues of the upper and lower extremities, including the hand and foot; the entire spine, including intervertebral discs; and the bony pelvis.
- Diagnosis and both operative and nonoperative care of acute trauma (including athletic injuries), infectious disease, neurovascular impairment,
Autologous chondrocyte implantation and chronic orthopedic problems, including reconstructive surgery, neuromuscular disease, metabolic bone disease, benign and malignant tumors, and rehabilitation.

➤ Musculoskeletal imaging procedures, use and interpretation of clinical laboratory tests, prosthetics, orthotics, physical modalities and exercises, neurological and rheumatological disorders, and medical ethics

➤ Clinical and/or laboratory research.

➤ Instruction in anatomy, biochemistry, biomaterials, biomechanics, microbiology, pathology, pharmacology, physiology, and other basic sciences related to orthopedic surgery. The resident must have the opportunity to apply these basic sciences to all phases of orthopedic surgery.

Twelve months of the orthopedic surgery residency program may be spent on services consisting partially or entirely of:

➤ Additional experience in general adult or children’s orthopedics or fractures/trauma

➤ An orthopedic clinical specialty

➤ Orthopedics-related research

➤ Experience in a graduate medical education program whose educational content is preapproved by the director of the orthopedic surgery residency program

**AOBOS**

The American Osteopathic Board of Orthopaedic Surgery (AOBOS) offers a board certification examination to osteopathic physicians who perform orthopedic surgery. In order to sit for the examination, candidates must:

➤ Be a graduate of a college of osteopathic medicine that has been accredited by the American Osteopathic Association (AOA)

➤ Hold an unrestricted license to practice medicine

➤ Conform with the AOA Code of Ethics

➤ Complete an AOA-accredited residency program in orthopedic surgery (a four-year program for surgeons who began training prior to July 1, 2008; a five-year program for surgeons who began training after July 1, 2008)

➤ Provide documentation verifying that they have performed at least 200 major procedures over 12 consecutive months

➤ Practice orthopedics for at least 12 consecutive months after completion of the residency program

**Positions of societies, academies, colleges, and associations**

**AAOS**

The American Academy of Orthopaedic Surgery (AAOS) does not publish criteria specific to the delineation of privileges or competency regarding ACI. However, the organization publishes a position statement, *Delineation of Privileges in Orthopaedic Surgery*, which was reviewed in 2007.
According to this statement:

*Orthopaedic surgeons who have successfully completed a residency program accredited by the Residency Review Committee for Orthopaedic Surgery have met educational requirements in the areas of diagnosis and care of disorders affecting the bones, joints, and soft tissues of the upper and lower extremities, including the hand and foot; the entire spine, specifically including intervertebral disks; and the bony pelvis. Further, orthopaedic education includes experience with all patient age groups, acute and chronic care, related clinical subjects including musculoskeletal imaging procedures, use and interpretation of clinical laboratory tests, use of prosthetics, orthotics, physical modalities and exercises, treatment of certain neurological and rheumatological disorders, and administration of local, regional, or spinal anesthesia.*

Another AAOS document, *Information Statement on Tissue-Engineered and Cell-Based Medical Products*, explains that regulation of biological products is evolving and that products may come to the market before a physician is familiar with them. The statement cautions orthopedic surgeons to fully understand the risks and benefits of these products before working with them to treat patients, and admonishes orthopedic surgeons to keep current with developments in products and technologies that may benefit the orthopedic surgery patient.

**ACGME**

The Accreditation Council for Graduate Medical Education (ACGME) publishes *ACGME Program Requirements for Graduate Medical Education in Orthopaedic Surgery*. Orthopedic residency programs are five years in length. Regarding patient care and medical knowledge, residents must:

➤ Handle clinical problems of sufficient variety and volume to afford them adequate experience in the diagnosis and management of adult and pediatric orthopedic disorders.

➤ Have clinical experience that includes adult orthopedic surgery, including joint reconstruction; pediatric orthopedic surgery, including pediatric trauma; trauma, including multisystem trauma; surgery of the spine, including disk surgery, spinal trauma, and spinal deformities; hand surgery; foot surgery in adults and children; athletic injuries, including arthroscopy; metastatic disease; and orthopedic rehabilitation, including amputations and postamputation care.

➤ Develop competence in the preadmission care, hospital care, operative care, and follow-up care (including rehabilitation) of patients. Opportunities for resident involvement in all aspects of care of the same patient should be maximized.

➤ Have adequate experience in nonoperative outpatient diagnosis and care, including all orthopedic anatomic areas and patients of all age groups. Each week residents must have at least one half day and should have two half days of outpatient clinical experience in physician offices or hospital clinics with a minimum of 10 patients per session on all clinical rotations.
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➤ Be directly supervised by faculty and instructed in pre- and postoperative assessment as well as the operative and nonoperative care of general and subspecialty orthopedic patients.

➤ Have the opportunity to assume increasing responsibility for patient care, under direct faculty supervision (as appropriate for each resident’s ability and experience), as they progress through a program. Inpatient and outpatient experience with all age groups is necessary.

➤ Have instruction in basic motor skills, including proper use of surgical instruments and operative techniques. Evaluation of new or experimental techniques and/or materials should be emphasized. The application of basic motor skills must be integrated into daily clinical activities, especially in the operating room.

To meet the medical knowledge competency, residents must:

➤ Have basic science education in anatomy, biomechanics, pathology, and physiology. The basic science program must also include resident education in embryology, immunology, pharmacology, biochemistry, and microbiology.

➤ Have instruction in anatomy that includes study and dissection of anatomic specimens by the residents, as well as and lectures or other formal sessions;

➤ Have instruction in pathology that includes correlative pathology in which gross and microscopic pathology are related to clinical and roentgenographic findings.

➤ Have instruction in biomechanics presented in seminars or conferences emphasizing principles, terminology, and application to orthopedic surgery.

➤ Have organized instruction in the basic medical sciences integrated into the daily clinical activities by clearly linking the pathophysiologic process and findings to the diagnosis, treatment, and management of clinical disorders.

➤ Have organized instruction in the appropriate use and interpretation of radiographic and other imaging techniques.

➤ Have education that includes orthopedic oncology, rehabilitation of neurologic injury and disease, spinal cord injury rehabilitation, orthotics and prosthetics, and the ethics of medical practice.

➤ Demonstrate an investigatory and analytic thinking approach to clinical situations

➤ Know and apply the basic and clinically supportive sciences that are appropriate to orthopedic surgery

AOA

The AOA also offers a residency program in orthopedic surgery. According to the AOA publication Basic Standards for Training in Orthopaedic Surgery, effective July 2009, osteopathic physicians completing orthopedic surgery residencies must complete a five-year program. Residents in the first postgraduate year must complete rotations as follows:

➤ Two months or rotations of internal medicine

➤ One month or rotation of emergency medicine
Three months or rotations of general orthopedic surgery
➤ One month or rotation of family practice
➤ Two months or rotations of non-orthopedic surgery or vascular, general trauma, basic wound/burn/plastics, and urology
➤ Two months of electives, which may include general orthopedic surgery, foot and ankle, hand, hip and knee, shoulder and elbow, spine, sports medicine, pediatrics or pediatric orthopedics, anesthesiology, radiology, pain management, neurology, neurosurgery, and physical medicine and rehabilitation

Study in years two to five includes:
➤ Surgical anatomy of common orthopedic procedures
➤ Children’s orthopedics to include congenital deformities, osteochondroses, fractures, and acquired deformities
➤ Tumors of the musculoskeletal system
➤ Three months each or 100 documented cases in each of the following fields: hand, spine, and trauma under a surgeon who is specifically trained in the subspecialty by fellowship or experience
➤ Six months or 100 documented cases in the field of pediatrics under a surgeon who is specifically trained in the subspecialty by fellowship or experience
➤ Adult practice in spinal problems, fractures, amputations and prostheses, reconstructive procedures, pain management, neuromuscular disease, peripheral vascular problems, and problems in other fields associated with orthopedic surgery
➤ Direct participation in case management, both nonsurgical and surgical, pre-and postoperative, as well as operating room management
➤ Use of orthopedic surgical instruments, operating room techniques, and conduct as well as the proper application of all orthopedic appliances and maintenance of these appliances while in use
➤ Review of musculoskeletal imaging studies in conference with the radiologist and/or other orthopedic surgeons
➤ Participation in emergency room coverage, supervision, and other outpatient services

In addition, residents must complete the following mandatory courses:
➤ Orthopedic pathology (minimum of 20 academic hours)
➤ Basic fracture course equivalent to the AO Trauma Course or the Orthopedic Fracture Association Course prior to the start of the third year of the residency program
➤ An advanced trauma life support course prior to the start of the third year of the residency program
Positions of subject matter experts

Jack Farr, MD

Jack Farr, MD, is the medical director of the Cartilage Restoration Center of Indiana, with a specialty in orthopedic treatment of sports injuries. He has been performing ACI since the procedure was approved in 1997. Farr is currently conducting research with two European laboratory consortia, Zimmer/ISTO and Depuy/Mitak/Johnson & Johnson, which have applied for FDA approval to provide ex vivo chondrocyte cultures. Farr reports that there is a third laboratory, Histogenics, that is also conducting clinical investigations at this time.

According to Farr, Genzyme is still the only source of training for ACI. The training program includes didactic lectures on the procedure, indications, contraindications, and postoperative programs. Participants perform the procedure on an animal knee, typically a cow. When performing live cases, a company representative is present to advise and assist.

Farr notes, “The technique is straightforward: The defect prep is the same as a microfracture that all surgeons are familiar with. Suturing on a patch is straightforward suturing that all surgeons do all the time. The cell suspension is then injected under the patch; again, this is not something that requires a new skill. The procedure is tedious in light of the small 6-0 sutures placed at 3–4 mm intervals to form a watertight seal. But the real skills are patient selection, treating comorbidities, and surgical approach.”

Farr states that the patient population that can benefit from ACI is relatively small, so most knee specialists perform only a few of the procedures annually. Insurance companies often require a surgeon to have performed five or six ACI procedures in order to be eligible for reimbursement.

Farr believes that appropriate patient selection and skill in treating comorbidities are the most important indicators of a surgeon’s competence to perform ACI. “Patients must be motivated and capable of committing to rehab. If they don’t approach rehab with a positive attitude, you won’t get a good result, even if you performed the procedure perfectly,” he says. Assessing the patient’s attitude and setting clear expectations are critical components of the procedure, Farr says.

Furthermore, there are three main comorbidities that ACI patients most often suffer, and any surgeon who performs ACI must be skilled at treating those comorbidities. Thus, Farr advises that when assessing a surgeon’s competence to perform ACI, reviewers should simultaneously address the surgeon’s competence to perform knee realignment and ligament reconstruction, osteotomies, and miniscus transplants.
Positions of accreditation bodies

**CMS**

CMS has no formal position concerning the delineation of privileges for ACI. However, the CMS *Conditions of Participation (CoP)* define a requirement for a criteria-based privileging process in §482.22(c)(6) stating, “The bylaws must include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.”

§482.12(a)(6) states, “The governing body must assure that the medical staff bylaws describe the privileging process. The process articulated in the bylaws, rules or regulations must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers:

- Individual character
- Individual competence
- Individual training
- Individual experience
- Individual judgment

The governing body must ensure that the hospital’s bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.”

Specific privileges must reflect activities that the majority of practitioners in that category can perform competently and that the hospital can support. Privileges are not granted for tasks, procedures, or activities that are not conducted within the hospital, regardless of the practitioner’s ability to perform them.

Each practitioner must be individually evaluated for requested privileges. It cannot be assumed that every practitioner can perform every task, activity, or privilege specific to a specialty, nor can it be assumed that the practitioner should be automatically granted the full range of privileges. The individual practitioner’s ability to perform each task, activity, or privilege must be individually assessed.

CMS also requires that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

CMS’ *CoPs* include the need for a periodic appraisal of practitioners appointed to the medical staff/granted medical staff privileges (§482.22[a][1]). In the absence of a state law that establishes a time frame for the periodic appraisal, CMS recommends that an appraisal be conducted at least every 24 months. The purpose of the periodic appraisal is to determine whether clinical
privileges or membership should be continued, discontinued, revised, or otherwise changed.

**The Joint Commission**

The Joint Commission has no formal position concerning the delineation of privileges for ACI. However, in its *Comprehensive Accreditation Manual for Hospitals*, The Joint Commission states, “The hospital collects information regarding each practitioner’s current license status, training, experience, competence, and ability to perform the requested privilege” (MS.06.01.03).

In the introduction for MS.06.01.03, The Joint Commission states that there must be a reliable and consistent system in place to process applications and verify credentials. The organized medical staff must then review and evaluate the data collected. The resultant privilege recommendations to the governing body are based on the assessment of the data.

The Joint Commission introduces MS.06.01.05 by stating, “The organized medical staff is responsible for planning and implementing a privileging process.” It goes on to state that this process typically includes:

- Developing and approving a procedures list
- Processing the application
- Evaluating applicant-specific information
- Submitting recommendations to the governing body for applicant-specific delineated privileges
- Notifying the applicant, relevant personnel, and, as required by law, external entities of the privileging decision
- Monitoring the use of privileges and quality-of-care issues

MS.06.01.05 further states, “The decision to grant or deny a privilege(s) and/or to renew an existing privilege(s) is an objective, evidence-based process.”

The EPs for standard MS.06.01.05 include several requirements as follows:

- The need for all licensed independent practitioners who provide care, treatment, and services to have a current license, certification, or registration, as required by law and regulation
- Established criteria as recommended by the organized medical staff and approved by the governing body with specific evaluation of current licensure and/or certification, specific relevant training, evidence of physical ability, professional practice review data from the applicant’s current organization, peer and/or faculty recommendation, and a review of the practitioner’s performance within the hospital (for renewal of privileges)
- Consistent application of criteria
- A clearly defined (documented) procedure for processing clinical privilege requests that is approved by the organized medical staff
- Documentation and confirmation of the applicant’s statement that no health problems exist that would affect his or her ability to perform privileges requested
- A query of the NPDB for initial privileges, renewal of privileges, and when a new privilege is requested
- Written peer recommendations that address the practitioner’s current medical/clinical knowledge, technical and clinical skills, clinical judgment, interpersonal skills, communication skills, and professionalism
- A list of specific challenges or concerns that the organized medical staff must evaluate prior to recommending privileges (MS.06.01.05, EP 9)
- A process to determine whether there is sufficient clinical performance information to make a decision related to privileges
- A decision (action) on the completed application for privileges that occurs within the time period specified in the organization’s medical staff bylaws
- Information regarding any changes to practitioners’ clinical privileges, updated as they occur

The Joint Commission further states, “The organized medical staff reviews and analyzes information regarding each requesting practitioner’s current licensure status, training, experience, current competence, and ability to perform the requested privilege” (MS.06.01.07).

In the EPs for standard MS.06.01.07, The Joint Commission states that the information review and analysis process is clearly defined and that the decision process must be timely. The organization, based on recommendations by the organized medical staff and approval by the governing body, develops criteria that will be considered in the decision to grant, limit, or deny a request for privileges. The criteria must be consistently applied and directly relate to the quality of care, treatment, and services. Ultimately, the governing body or delegated governing body has the final authority for granting, renewing, or denying clinical privileges. Privileges may not be granted for a period beyond two years.

Criteria that determine a practitioner’s ability to provide patient care, treatment, and services within the scope of the privilege(s) requested are consistently evaluated.

The Joint Commission further states, “Ongoing professional practice evaluation information is factored into the decision to maintain existing privilege(s), to revise existing privileges, or to revoke an existing privilege prior to or at the time of renewal” (MS.08.01.03).

In the EPs for MS.08.01.03, The Joint Commission says there is a clearly defined process facilitating the evaluation of each practitioner’s professional practice, in which the type of information collected is determined by individual departments
and approved by the organized medical staff. Information resulting from the ongoing professional practice evaluation is used to determine whether to continue, limit, or revoke any existing privilege.

**HFAP**

The Healthcare Facilities Accreditation Program (HFAP) has no formal position concerning the delineation of privileges for ACI. The bylaws must include the criteria for determining the privileges to be granted to the individual practitioners and the procedure for applying the criteria to individuals requesting privileges (03.01.09). Privileges are granted based on the medical staff’s review of an individual practitioner’s qualifications and its recommendation regarding that individual practitioner to the governing body.

It is also required that the organization have a process to ensure that practitioners granted privileges are working within the scope of those privileges.

Privileges must be granted within the capabilities of the facility. For example, if an organization is not capable of performing open-heart surgery, no physician should be granted that privilege.

In the explanation for standard 03.01.13 related to membership selection criteria, HFAP states, “Basic criteria listed in the bylaws, or the credentials manual, include the items listed in this standard. (Emphasis is placed on training and competence in the requested privileges.)”

The bylaws also define the mechanisms by which the clinical departments, if applicable, or the medical staff as a whole establish criteria for specific privilege delineation.

Periodic appraisals of the suitability for membership and clinical privileges is required to determine whether the individual practitioner’s clinical privileges should be approved, continued, discontinued, revised, or otherwise changed (03.00.04). The appraisals are to be conducted at least every 24 months.

The medical staff is accountable to the governing body for the quality of medical care provided, and quality assessment and performance improvement (03.02.01) information must be used in the process of evaluating and acting on re-privileging and reappointment requests from members and other credentialed staff.

**DNV**

DNV has no formal position concerning the delineation of privileges for ACI. MS.12 Standard Requirement (SR) #1 states, “The medical staff bylaws shall include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to those individuals that request privileges.”
The governing body shall ensure that under no circumstances is medical staff membership or professional privileges in the organization dependent solely upon certification, fellowship, or membership in a specialty body or society.

Regarding the Medical Staff Standards related to Clinical Privileges (MS.12), DNV requires specific provisions within the medical staff bylaws for:

➤ The consideration of automatic suspension of clinical privileges in the following circumstances: revocation/restriction of licensure; revocation, suspension, or probation of a DEA license; failure to maintain professional liability insurance as specified; and noncompliance with written medical record delinquency/deficiency requirements

➤ Immediate and automatic suspension of clinical privileges due to the termination or revocation of the practitioner’s Medicare/Medicaid status

➤ Fair hearing and appeal

The Interpretive Guidelines also state that core privileges for general surgery and surgical subspecialties are acceptable as long as the core is properly defined.

DNV also requires a mechanism (outlined in the bylaws) to ensure that all individuals provide services only within the scope of privileges granted (MS.12, SR.4).

Clinical privileges (and appointments or reappointments) are for a period as defined by state law or, if permitted by state law, not to exceed three years (MS.12, SR.2).

Individual practitioner performance data must be measured, utilized, and evaluated as a part of the decision-making for appointment and reappointment. Although not specifically stated, this would apply to the individual practitioner’s respective delineation of privilege requests.

**CRC draft criteria**

The following draft criteria are intended to serve solely as a starting point for the development of an institution’s policy regarding this procedure.

**Minimum threshold criteria for requesting privileges for ACI**

**Basic education:** MD or DO

**Minimal formal training:** The applicant must have completed an ACGME- or AOA-accredited residency training program in orthopedic surgery. In addition, the applicant must have completed a Genzyme advanced training course, which included proctored cases.

**Required current experience:** The applicant must be able to demonstrate that he or she has performed at least five ACI procedures as the primary surgeon.
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over the past 12 months. In addition, the applicant should maintain privileges in osteotomy, knee realignment and ligament reconstruction, and miniscus transplant to be considered for privileges in ACI.

References

If the applicant is recently trained, a letter of reference should come from the director of the applicant’s training program. Alternatively, a letter of reference may come from the applicable department chair and/or clinical service chief at the facility where the applicant most recently practiced.

Reappointment

Reappointment should be based on unbiased, objective results of care according to a hospital’s quality assurance mechanism.

Applicants must be able to demonstrate that they have maintained competence by showing evidence that they have performed at least 10 ACI procedures as primary surgeon in the past 24 months.

In addition, continuing education related to ACI should be required.

For more information

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