

Knee Joint Preservation With Autologous Cartilage Implantation

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With an increasingly younger population participating in competitive sports and with participation in recreational activities at an all time high for men and women of all ages, primary cartilaginous lesions and resulting post-traumatic arthritis are being seen more frequently than ever before.¹ Cartilaginous lesions, if large enough and left untreated, may progress to complete joint degeneration in patients at a very young age. Joint injuries and the resultant articular damage in older adults often progresses to osteoarthritis.² Knee damage results from

- sports-related injuries 28% of the time,
- injuries related to falls 25% of the time, and
- injuries resulting from daily activities 22% of the time.

The remaining incidences of knee damage

are a result of miscellaneous injuries.³ Patients who present with articular damage often complain of pain, swelling, and inability to perform activities of daily living.

For more than 200 years, physicians have noted that articular cartilage tissue has a limited capacity to heal and repair itself.¹ With better understanding of cartilage biology and function and an improved ability to identify treatable injuries, surgeons are increasingly able to treat these cartilage injuries and restore joint function.¹

In the 1950s, options to treat cartilage injuries included drilling the subchondral bone and joint debridement. In the 1970s, more treatment options became available, including the use of cadaveric transplantation to repair articular damage. The 1980s witnessed enormous developments in molecular biology and biomaterials along with medical discoveries regarding the growth factor.² In 1987, Lars Peterson, MD, PhD, of Sweden, pioneered a procedure called autologous cartilage implantation (ACI) for articular damage after numerous animal studies were performed with promising results. With publication of the autologous chondrocyte transplantation technique in 1994,³ research and emphasis on cartilage repair and regeneration became a topic of renewed interest in the

ABSTRACT

DAMAGE TO THE BODY'S JOINT CARTILAGE is becoming a disabling problem for Americans as they live longer and remain active.

TRADITIONALLY, ARTICULAR DAMAGE has been treated with arthroscopic debridement and microfracture, abrasion arthroplasty, and osteochondral autograft. Orthopedic surgeons now can offer patients a new option: autologous cartilage implantation (ACI), in which cultured autologous cartilage cells are used to repair and promote growth in cartilage defects.

USE OF ACI PRESERVES the articular surfaces of the knee in patients with early onset osteoarthritis, decreases pain, maintains patients' quality of life, and delays possible total joint replacement. *AORN J* 86 (October 2007) 550-558.

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field of orthopedic surgery and sports medicine.¹ In 1995, Tom Minas, MD, director of the Cartilage Repair Center, Chestnut Hill, Massachusetts, was one of the first orthopedic surgeons in the United States to perform ACI surgery. In June 2006, Dr Minas performed his 400th cartilage transplant at Brigham and Women's Hospital, Boston, Massachusetts.

ANATOMY

The bones of the knee consist of the femur, tibia, and patella. The knee joint's soft tissue consists of ligaments and tendons that help maintain the alignment and provide stabilization. Articular cartilage covers the ends of bones at the joint surfaces. It is a smooth, glistening, white, near-frictionless, mechanically hard tissue that lacks nerve endings or a blood supply.⁴ Disruption of one or more of these structures (eg, bones, ligament, tendons, articular cartilage) can lead to malalignment and cartilage damage. Damage to the articular cartilage exposes the nerve endings in the subchondral surfaces and can lead to pain and discomfort and, eventually, osteoarthritis.⁴

CARTILAGE REPAIR OPTIONS

Repair of articular cartilage loss can be achieved only by surgical means. Pharmaceutical means used to date (eg, shark cartilage, chondroitin sulfate, glucosamine, injectable visco-supplements) do not repair or regenerate cartilage. They may provide pain relief or maintain cartilage health, but even these claims have not been scientifically proven.⁴ Articular damage can be treated with marrow stimulation procedures, such as

- arthroscopic debridement and microfracture,
- abrasion arthroplasty, and
- osteochondral autograft.⁵

Osteochondral autograft is analogous to a hair-plug transfer, which essentially is a harvesting technique. The surgeon removes a small section of the patient's own cartilage with the underlying bone plug from a nonweight-bearing area and then transfers it to the defect on the weight-bearing surface.⁶

These traditional treatments primarily violate the integrity of the underlying subchondral bone plate by drilling, abrasion, or microfracture. These techniques, however, lead to the

Although such claims have not been scientifically proven, pharmaceutical means used to date (eg, shark cartilage, chondroitin sulfate, glucosamine, injectable visco-supplements) may provide pain relief or maintain cartilage health. They do not repair or regenerate cartilage.

formation of fibrous scar tissue that is notably less durable than the cartilage tissue it was intended to replace.⁵

During the ACI procedures, the surgeon harvests the patient's own cartilage cells (ie, chondrocytes), and a biotechnology company grows them in a culture, increasing them tenfold. The surgeon then replants these chondrocytes into the cartilage defect and covers them with a ceiling of native tissue (ie, periosteum). The cells grow to fill the defect and resurface areas of cartilage loss with hyaline-like cartilage.⁷

When osteoarthritis is severe, the usual treatment is replacement of the articular surface with an artificial prosthesis. Total knee replacement most commonly is performed to treat this problem in people older than 60 years. Joint replacement in younger patients (ie, younger than 50 years) is more troublesome because prostheses have a limited life expectancy.⁸ The results from one study suggest that ACI yields long-term improvement in function and symptoms and may be a viable and optimal treatment for young to middle-aged adult athletes or patients whose lifestyles are very physically demanding.⁹ In addition, an earlier study showed that ACI not only produces a hyaline-like repair tissue but also results in improved efficacy, lower costs, good

long-term outcomes, and the ability to resume participation in sports.⁹

PATIENT SELECTION

The ACI procedure is an option for some patients as young as 15 years of age to 55 years of age who have symptomatic articular cartilage defects and who are experiencing pain and swelling that compromises their ability to perform activities of daily living. These patients have relatively healthy joints and are of a reasonable weight. Often, the patients selected for this surgical treatment have had failed marrow stimulation procedures, such as abrasion, drilling, and microfracture.¹⁰

CONTRAINDICATIONS AND PRECAUTIONS. Specific contraindications to ACI include the use of tobacco and medications that may impair cell proliferation, such as nonsteroidal anti-inflammatory drugs (NSAIDs) and immunosuppressive medications. Patients with systemic inflammatory disease also are excluded.¹¹ Precautions should be taken when performing ACI in patients with a known anaphylaxis to gentamicin because, currently, gentamicin is used to allow for sterility control in the biopsy transport medium (Leslie Wolfe, clinical account executive, Genzyme Biosurgery, e-mail communication, August 27, 2007). Some patients may have a sensitivity to gentamicin and not be aware of it, so the gentamicin is removed from the final product. A small residual level of antibiotic, however, still remains in the final product from the cell culture processing.

EDUCATING THE PATIENT. Before ACI can be offered as an option to a selected patient, health care practitioners must thoroughly educate the patient regarding treatment options and contraindications. Furthermore, health care practitioners must ensure that the patient fully understands the procedure, rehabilitation process, and possible complications and has realistic expectations of the procedure outcomes. Many patients who need this procedure will be undergoing what is considered to be an extremely complicated salvage procedure. If ACI does not fit the patient's needs, health care practitioners should discuss with the patient other treatment options (eg, unicompartmental knee arthroplasty, patellofemoral arthroplasty).¹¹

SURGICAL MANAGEMENT

The principal goals for surgical management of symptomatic chondral and osteochondral defects are to

- reduce symptoms,
 - improve joint congruence by restoring the joint surface with the best available tissue, and
 - prevent additional cartilage degeneration.¹²
- Ultimately, patients seek surgical intervention to improve their quality of life.

ASSESSING ARTICULAR DAMAGE. Candidates for ACI will undergo two surgical procedures. The first is a knee arthroscopy, a minimally invasive procedure during which the surgeon assesses the knee joint directly. The surgeon notes the size, number, and location of cartilage defects. If the areas of damage are localized rather than generalized (ie, like fixing potholes, rather than paving a road) then the surgeon may consider the patient's knee to be suitable for cartilage repair by ACI. The surgeon measures the defect areas to determine how many vials of cells need to be cultured and obtains the tissue biopsy from which the cells will be grown.⁴

SURGICAL REPAIR. During the second procedure, a knee arthrotomy, the surgeon implants the cultured cells and covers them with a periosteal graft. A minimum of two weeks is necessary for adequate chondrocyte culture;¹¹ but the average length of time between obtaining the biopsy and implantation is approximately one to two months. This allows time for the patient to obtain insurance approval before scheduling the cartilage implant portion of the procedure and allows adequate time for the patient to rehabilitate from the arthroscopic procedure.

THE PREOPERATIVE ASSESSMENT

Although patient safety is always a collaborative effort of a multidisciplinary team, the primary responsibilities of the perioperative nurse are ensuring patient safety; maintaining the sterile field; ensuring communication occurs between all perioperative team members and with the patient; providing supplies; and making sure that, overall, the procedure is uneventful. As with all surgical patients, the perioperative nurse should protect the patient by checking the patient's identification band, surgical consent, and correct site marking and making sure that the patient has a

general understanding of what the surgeon plans to do. The initial interview, although brief, allows the nurse to build a relationship with the patient and ask pertinent questions about the patient's previous surgical and medical history; allergies; and any medical, surgical, or anesthetic difficulties the patient may have had in the past. Communication is the key to a successful surgical procedure, so this is a good time for the perioperative nurse to answer any questions the patient may have. After performing the preoperative evaluation, the nurse communicates with the surgeon, anesthesia care provider, and implant coordinator about any special provisions or equipment needed for a successful surgical experience.

THE INITIAL PROCEDURE— KNEE ARTHROSCOPY

The circulating nurse and scrub person set up for a basic knee arthroscopy procedure. After gathering appropriate knee arthroscopic instruments and supplies, the circulating nurse and scrub person add an arthroscopic gouge, small mallet, and pituitary rongeur with which the surgeon will obtain a cartilage biopsy from a non-weight-bearing surface (eg, medial or lateral superior edge of the femoral condyle or intercondylar notch).

The circulating nurse transports the patient to the OR suite via a stretcher and helps the patient move onto the OR bed in the supine position. After securing the safety strap and placing the arm boards on the bed, the circulating nurse initiates the surgical time out with the active participation of all surgical team members. The circulating nurse remains with the patient and assists the anesthesia care provider throughout induction of anesthesia. The surgeon then places a tourniquet over cotton cast padding on the upper thigh of the patient's surgical leg and secures the patient's leg into position using a thigh post or leg holder. The nurse performs the surgical skin prep, after

which the scrub person and surgeon drape the patient in the usual fashion.

The surgeon takes a full-thickness biopsy that includes a small sample of bone.¹³ The surgeon places the biopsy in the biopsy tube from the cartilage biopsy transport kit. The commercially prepared cartilage biopsy kit is stored in a tissue refrigerator at 2° C to 8° C (36° F to 46° F) before and after the biopsy is taken.

The surgeon may debride and trim suspicious areas in the knee joint in an effort to provide the patient with some relief of pain, swelling, and joint locking. When the surgery is complete, the circulating nurse and surgeon place an elastic bandage wrap or antiembolism stocking, controlled compression cryotherapy device, and knee immobilizer on the patient. The anesthesia care provider and circulating nurse then transport the patient to the day surgery unit for recovery. The circulating nurse provides a report to the postanesthesia care unit (PACU) nurse using a hand-off communication checklist. The PACU nurse discharges the patient to home later that day.

After the procedure, the surgeon completes the paperwork describing the number and size

of the defects and identifies the number of cells needed to repair those defects. A transport person then transports the cells to the biotechnology company.

CULTURING AND GROWING THE CELLS. When the biopsy arrives at the biotechnology facility, a technologist extracts the chondrocytes and cultures them through a primary phase. For storage, the technologist cryopreserves the chondrocytes cells and biopsy in the vapor phase of a liquid nitrogen tank. The technologist uses a specialized cryoprotectant solution for the freezing process to assure cell viability and growth upon thawing. When the surgeon schedules an elective surgical date with the patient for the implantation procedure

After performing the preoperative evaluation, the nurse communicates with the surgeon, anesthesia care provider, and implant coordinator about special provisions or equipment needed for a successful outcome.

and determines the appropriate number of cell vials needed, a technologist thaws the cells from cryostorage and plates them into cell culture flasks for another proliferation stage. It is cells from the growing stage of the culture that are used for final product assembly. The final product is shipped in a specialized container that has been designed by the biotechnology company for this purpose. The correct temperature of the cells and container has been extensively studied and validated to meet the needs for the chondrocyte cells and to assure product quality upon delivery. The product should be stored in the validated shipping box until use (Leslie Wolfe, clinical account executive, Genzyme Biosurgery, e-mail communication, August 27, 2007). The chondrocytes must be used within 72 hours. The original biopsy tissue, however, may be stored for up to 18 months.⁴

THE SECOND PROCEDURE— KNEE ARTHROTOMY

The circulating nurse meets and identifies the patient in the preoperative area. After reviewing the patient's medical record, the circulating nurse asks the patient to state his or her name, date of birth, and what the surgeon plans to do and then checks that the surgeon and patient have cooperatively marked the surgical site. The circulating nurse asks the patient about his or her past medical and surgical history, medical conditions, and any medications the patient is taking. The nurse also determines that the patient has had nothing to eat or drink as instructed preoperatively.

After completing the preoperative assessment, the perioperative nurse ensures that the cells have been delivered to the facility before the patient enters the surgical suite. When the cells arrive, the circulating nurse and surgeon verify that the pa-

tient's name and identification number on the certificate of analysis (ie, a technical data sheet with detailed specifications for the processed cells) match the patient's name and identification number on the shipping box, transport cylinder, and vials and that this information matches the information on the patient's identification band and medical record (Figure 1).

The circulating nurse and scrub person obtain the basic orthopedic instrument set and other applicable knee arthrotomy instruments. They obtain ring curettes in a few sizes, small sharp elevators, small fine needle holders, and smooth Adson forceps to add to the basic arthrotomy instrument kit (Figure 2). This surgical procedure requires additional specialty items, such as fibrin glue to ensure a watertight seal on the suture

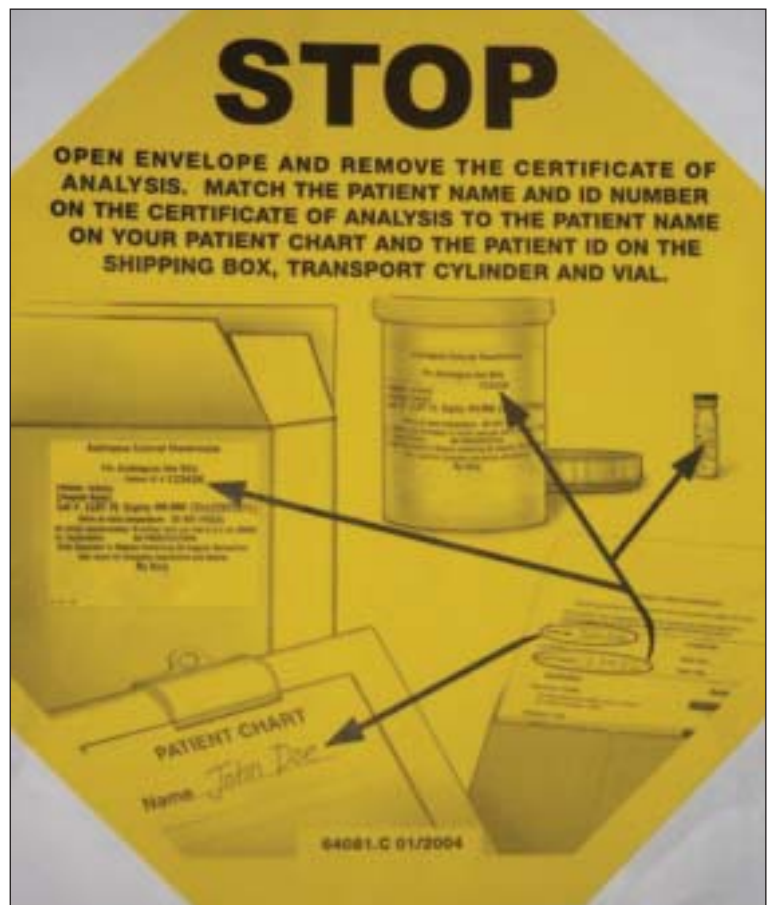


Figure 1 • The circulating nurse is responsible for verifying that the patient's name and identification number match the information on the certificate of analysis. Illustration of courtesy of Genzyme Biosurgery, Cambridge, MA.

line, mineral oil to lubricate the polyglactin suture, thrombin mixed with epinephrine for hemostasis, and 1-inch-by-3-inch compressed rayon cotton strips to apply the thrombin and epinephrine to bleeding surfaces. The biotechnology kit that is commercially prepared for this procedure contains special 6-0 polyglactin suture, extra marking pens, #18 gauge catheter tips with needles, and tuberculin syringes.

The circulating nurse transports the patient to the OR suite via a stretcher and helps the patient move onto the OR bed in the supine position. After securing the safety strap and placing the arm boards on the bed, the circulating nurse initiates the surgical time out including verifying that the cultured chondrocyte cells are available.

The circulating nurse remains with the patient and assists the anesthesia care provider throughout induction of anesthesia. The surgeon places a tourniquet over cotton cast padding on the patient's upper thigh and places a lateral thigh post and foot rest on the OR bed to aid in positioning the patient's leg during surgery. The circulating nurse then performs the surgical skin prep, after which the scrub person and surgeon drape the patient in the usual fashion.

The surgeon cleans and debrides the cartilage defects down to the subchondral bone plate, often using the ring curettes or possibly a burr. It is important for the surgeon to ensure that the subchondral bone plate is completely intact and free of fibrous tissue and bleeding and that the cartilage surrounding the defect is healthy, with sharp, vertical walls surrounding the entire defect.¹³ This helps the surgeon suture the periosteum and contain the implanted cells. The surgeon also places fibrin glue on the suture line for a watertight seal. Epinephrine is recommended as a first-line hemostatic agent to control bleeding through the subchondral plate.¹³ A 1-inch-by-3-inch compressed rayon cotton strip soaked with a mixture of thrombin and epinephrine is applied to the area.



Figure 2 • Additional instruments are required for the autologous cartilage implantation procedure.

The surgeon measures the defect at its widest point and adds 2 mm to both the vertical and horizontal measurements.¹³ The surgeon makes a sterile paper template of the defect and takes a periosteal graft from the proximal medial anterior tibia or from the lateral distal femur if the periosteum from the tibia has been taken before this surgery. The periosteal graft acts as a cover for the damaged cartilage area. The scrub person ensures that the periosteal graft is kept moist at all times by wrapping it in a 4 x 8 sponge moistened with saline. The scrub person ensures that the 6-0 polyglactin 910 suture is kept lubricated by soaking the suture in a small cup of mineral oil. Lubricating the suture allows it to pass through the cartilage and periosteal graft more smoothly.

If it was not done previously, the surgeon corrects any ligament damage for instability issues and corrects any malalignment the patient may demonstrate. There is a greater chance that the cartilage grafts will not take if these issues are not corrected.

The circulating nurse records the lot number, expiration date, and corresponding manufacturer's number of the implanted cells on the OR record under implanted items. After surgery, the certificate of analysis becomes part of the OR record and is maintained with the chart.

One of the most important advances in the treatment of musculoskeletal injuries has come from the understanding that controlled, early resumption of activity promotes restoration of function and that treatment of injuries with prolonged bed rest may delay recovery and adversely affect normal tissue.

The anesthesia care provider and circulating nurse then transport the patient to the PACU for recovery. The circulating nurse reports to the PACU nurse using a hand-off communication checklist.

POSTOPERATIVE CARE AND REHABILITATION

The evening after surgery, the patient remains on bed rest to allow the cartilage cells to attach to the defect surfaces before movement begins.⁴ The physical therapist places the patient in a continuous passive motion (CPM) machine on the first day after surgery. Anti-inflammatory agents, such as NSAIDs, cannot be used for at least six to nine months after surgery because of their adverse effect on cartilage growth.⁴

Criteria for discharge to home are based on

- the patient's safety at home;
- good pain management on oral medications;
- an absence of fever;
- a wound that appears healthy;
- good mobility as determined by the therapist and nurses (eg, the patient is able to get in and out of bed, on and off the toilet, in and out of the shower);
- good walking skills as demonstrated with

crutches or a walker; and

- the ability to climb as many stairs as are required at home.⁴

This usually is achieved within two to three postoperative days. The patient usually is discharged with a light compression dressing, controlled compression cryotherapy device, and knee immobilizer that is used until the patient can do a straight leg raise and demonstrate quadriceps control (Figures 3 and 4).

The principles of physical therapy are simple and based on common sense:

- ensure motion,
- prevent ACI graft overload and damage, and
- encourage muscle tone.⁴

One of the most important advances in the treatment of musculoskeletal injuries has come from the understanding that controlled, early resumption of activity promotes restoration of function and that treatment of injuries with prolonged bed rest may delay recovery and adversely affect normal tissue.¹⁴ Rehabilitation is a four-phase protocol, consisting of

- an early phase (ie, day one through week 12);
- a transition phase (ie, week 13 through month six);
- a mid-phase (ie, month seven through month nine); and
- a final phase (ie, month 10 through month 18).¹³

Key principles for ACI rehabilitation involve range of motion training with the use of a CPM machine and protection of the graft. Patients should not bear weight and should ambulate only with crutches for a minimum of two weeks after surgery, after which the patient may ambulate with partial weight bearing. The patient should not progress to full weight bearing for a total of six weeks after surgery.⁴ Strengthening requires early quadriceps control, which is gained by performing straight leg raises. When quadriceps control is mastered, the patient begins progressive strengthening by doing closed chain exercises in an isometric fashion. Closed chain exercises require that the distal segment of the foot be fixed by maintaining contact with a surface such as a pedal, a platform, or the ground. Examples of closed chain exercises include leg presses, squats, lunges, and weight-bearing

exercises.¹⁵ A technically excellent surgical repair requires the active cooperation of the patient and physical therapist to achieve maximum outcomes, the goal of which is for the patient to be comfortable performing activities of daily living and possibly returning to pre-injury sports activities.

ADVANTAGES AND DISADVANTAGES OF ACI

Advantages of ACI include that there is no risk for disease transmission and there is no limitation in the supply of chondrocytes available for transplant. Disadvantages of the procedure include the initial learning curve for surgeons in sewing the periosteal patch onto the defect and the length of time it takes for the graft area to mature so that it can withstand high-impact activities such as tennis or basketball (ie, approximately 12 to 15 weeks).¹ Another disadvantage is that when the date has been set for surgical implantation and the biotechnology company has grown the chondrocytes, surgery must be performed within 72 hours or the cells will expire. The chondrocytes are grown from the original biopsy. The biopsy itself is good for 18 months; however, after the cells are prepared for surgery, the cells themselves have a short life expectancy.

All surgeries have risks. When a patient signs a surgical consent, it is understood that the surgeon has explained possible risks and complications. Common risks associated with ACI include

- that 20% to 25% of patients experience graft overgrowth after four months;
- knee stiffness; and
- failure of treatment, which is defined as no pain improvement from preoperative assessment after two years and numbness occurring routinely to the lateral portion of the surgical incision as a result of cutting the sensory nerves during surgery.⁴

Graft overgrowth usually causes painful “catching” that had not been experienced before surgery. Frequently, this disappears with additional physical therapy exercises; if not, the surgeon may recommend a magnetic resonance imaging scan to document the appearance of the ACI graft and to determine whether partial or complete graft failure has occurred. At this point, the surgeon may recommend a follow-up arthroscopic procedure to assess the graft and debride any



Figures 3 • A controlled compression cryotherapy device is essential for decreasing swelling and controlling pain.



Figure 4 • The patient is discharged with a knee immobilizer and drain in place.

overgrowth tissue; this will resolve the catching and allow the graft to heal without further delay.⁴ Typically, most sensation returns by six to 12 months, but loss of sensation may be permanent.⁴

CONTINUING DEVELOPMENT

Currently, orthopedic surgeons are learning how to perform the ACI procedure in workshop formats that incorporate both didactic and clinical information. These workshops are provided by the biotechnology company that cultures and grows the cells from the biopsy. Since its inception, the number of surgeons seeking to learn this procedure has grown. Nationwide, approximately 200 to 400 physicians are being trained each year (Roland Deangelis, clinical account executive, Genzyme Biosurgery, e-mail communication, August 27, 2007). Informed patients now are asking their surgeons for this type of cartilage repair for their painful knees. More community hospitals now are performing ACIs, expanding the type and number of facilities capable of performing this surgery beyond large teaching institutions.

The future of ACI and other innovative knee repair surgical options is promising. Soon, the cartilage cells may be grown on a graft material that will eliminate the need to take a periosteal graft to cover the implanted cells. This will shorten the length of the procedure, and the graft material will be more uniform and easier to handle. The goal of the ACI procedure is to give many younger patients time and improved quality of life before their probable need for a total knee replacement. — **AORN** —

Acknowledgement: *The author acknowledges Tom Minas, MD, director of the Cartilage Repair Center, Chestnut Hill, Massachusetts, for his help and guidance in preparing this manuscript.*

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