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Mechanical Testing of Absorbable Suture Anchors

ABSTRACT & COMMENTARY

Synopsis: *Even if absorbable suture anchors offer advantages in term of complications, they may be the weakest link in the fixation of soft tissue to bone.*

Source: Meyer DC, et al. Mechanical testing of absorbable suture anchors. *Arthroscopy*. 2003;19(2):188-193.

ABSORBABLE SUTURE ANCHORS ARE ATTRACTIVE IMPLANTS because there is little risk of mechanical complications. Few data are available to help the surgeon choose an appropriate anchor. Bench testing was performed for most of the available absorbable anchors with attention to eyelet design and effects on suture. Mechanical properties were correlated to their design and weight.

Twelve absorbable anchor models were tested: Panalok 3.5 mm and Panalok RC (Mitek), Bio Roc EZ 2.8 mm and 3.5 mm (Innova-sive), Rotorloc (Acufex), Bio-FASTak (Arthrex), Bio-Anchor (Livantek), Biophase (Biomet Merck), Tag Wedge 3.7 mm and Tag Rod II (Acufex), BioStatak (Zimmer), and BioCorkscrew 5.0 mm (Arthrex). All were loaded with No. 2 Ethibond suture.

Anchors were tested in a 37°C water-bath by insertion into polyurethane test bone. Mechanical testing included pull-out testing in line of the anchor axis, as well as time to failure under a constant 100 N load. Drawing the suture through the eyelet 25 times assessed the effects of suture abrasion on strength.

Mechanical testing revealed that the anchor fixation was not the weakest link. Load to failure ranged from 124 to 244 N (5 failed by eyelet cutout and 6 by suture breakage). Static loading at 100 N revealed widely varying time to failure ranging from 0.1 to more than 300 hours. Eight failed from eyelet cutout, while the same anchor (Tag Wedge 3.7 mm) was the only one to pull out of bone, and 3 did not fail after 300 hours. Mechanical strength under both conditions correlated with anchor weight but not with crystallinity. Unlike metal anchors, suture abrasion did not seem to be a major problem for absorbable anchors.

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■ COMMENT BY J.P. WARNER, MD, AND
PHILLIPE CLAVERT, MD

Few data about absorbable anchors are available. The major finding of this study was that the anchors failed predominantly by cut-through at their eyelet. As the properties of absorbable polymers may differ as a function of temperature, the experiments were performed at 37°C. This is a major strength of this paper. Absorbable polymer strength is increased by high crystal content, which may lead to inflammatory foreign-body reactions during absorption. No correlation of mechanical performance between both tensile strength or static loading and crystallinity was found. The weight of the anchors had a significant, but not decisive, influence on the mechanical performance of the anchor. Meyer and colleagues recommend designing absorbable implants as small as possible but with sufficient mechanical strength, to create a small drill hole, and to implant as little absorbable material as possible.

Double-loaded anchors failed in tensile load at only slightly higher load than the breaking strength of a single suture loop. Absorbable suture anchors are sensitive to permanent load: They creep under static tension. In 6 of

12 anchors, the initial breaking strength of the suture anchor was lower than the tensile strength of the suture material. Compared to metal anchors, the suture anchor eyelet allows suture gliding without relevant abrasion (except for 2 of them).

Development of absorbable suture anchors is increasing because of potential risks of metallic injury to the glenoid cartilage, loosening, and migration. This paper gives us a lot of new considerations about these anchors. It would be interesting for Meyer et al to have studied the cyclic load of these anchors until the failure of the eyelet or the suture because during the passive rehabilitation time after surgery, repairs are cycled and sutures may have to slide in the eyelet. ■

Dr. Clavert is a Fellow at Harvard Medical School.

PCL Deficiency is Bad to the Bone

ABSTRACT & COMMENTARY

Synopsis: PCL insufficiency is associated with early and continuous cartilage degeneration of the medial femoral condyle and patella.

Source: Strobel MJ, et al. Arthroscopic evaluation of articular cartilage lesions in posterior cruciate ligament-deficient knees. *Arthroscopy*. 2003;19(3):262-268.

THE LONG-TERM EFFECTS OF PCL (POSTERIOR CRUCIATE Ligament) deficiency on the articular cartilage of the medial femoral condyle and patella are well recognized.^{1,2} The present paper, however, suggests that these changes occur much more rapidly than we have previously believed. In this retrospective study Strobel and associates reviewed almost 600 cases of patients with a PCL injury (documented with stress radiography) treated at their institution between 1993 and 1999. From this group, they selected 181 patients who underwent arthroscopy without PCL or ACL reconstruction. Most of these arthroscopies were performed immediately prior to PCL reconstruction. Groups were stratified based upon the duration of PCL deficiency, whether they had combined PCL-PLC (posterolateral corner) deficiency (characterized by posterior tibial displacement with more than 12-mm side-to-side difference on stress radiography), and based upon prior medial meniscal surgery.

The overall incidence of degenerative articular cartilage lesions (Outerbridge grade II-IV) in the study was

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67.4%. Almost half of the study group had degenerative lesions on the medial femoral condyle and one-third had changes on the patella. These changes significantly increased with chronicity of PCL deficiency—especially on the medial femoral condyle. Degenerative changes were also more common in patients with combined PCL-PLC deficiency and those patients with prior partial medial meniscectomy.

■ COMMENT BY MARK D. MILLER, MD

This paper is retrospective and has some potential problems with conflicting variables that make proper statistical analysis difficult. As Strobel et al point out, there may also have been at least some selection bias because they performed arthroscopy only on patients who were symptomatic (about half of their entire group of PCL-deficient patients). Nevertheless, it provides another piece to the puzzle regarding the long-term effects of PCL deficiency. It is critical that Strobel et al have considered the degree of instability (based on stress radiography) in their results. It has only recently been recognized (at least in the United States) that increased posterior tibial displacement of greater than 12 mm on stress radiographs is associated with a combined PCL-PLC injury. In fact, combined PCL-PLC injuries have only been well characterized within the last decade. Of course, these patients will also have external rotation asymmetry at 30° and 90° of knee flexion, but stress radiographs allow critical objective evaluation of these injuries.

Natural history studies of PCL-deficient knees are extremely limited in the current literature. The few studies that have been done reported the results of radiographic degenerative changes and did not address combined injuries and prior partial meniscectomy.^{1,2} The present study, based on arthroscopic evaluation, suggests that chondral degeneration occurs much earlier (often within 5 years) than the prior studies have suggested (20 years or more). It is not surprising that prior medial meniscectomy and increased laxity are associated with more rapid progression of degenerative changes in the medial compartment. The effect of meniscectomy and PCL deficiency on contact pressures in vitro have been well characterized. Increased laxity and rotational instability associated with combined PCL-PLC injury markedly alters the contact areas of the medial femoral condyle and medial tibial plateau. The present in vivo study suggests that these alterations in contact result in chondral changes—and much earlier than previously thought. This has important implications regarding surgical indications for PCL reconstruction, especially in patients with combined PCL-PLC injuries. ■

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The Function of the Meniscomfemoral Ligaments

ABSTRACT & COMMENTARY

Synopsis: *The true function of the meniscomfemoral ligaments remains unclear, but it may have profound implications for treatment of PCL-deficient knees and lateral meniscal tears.*

Source: Gupte CM, et al. A review of the function and biomechanics of the meniscomfemoral ligaments. *Arthroscopy.* 2003; 19(2):161-171.

PRECISE DEFINITION OF THE ROLE OF THE MENISCOMFEMORAL ligaments (MFLs) continues to be elusive. This article summarizes the available information about the MFLs by presenting a comprehensive review of the literature, beginning with the initial description of the ligaments by Humphrey in 1858 and suggests future studies to conclusively define their function.

The MFLs originate from the posterior horn of the lateral meniscus. The anterior meniscomfemoral ligament (aMFL) of Humphrey passes anterior to the posterior cruciate ligament (PCL) to insert on the femur between the distal margin of the femoral attachment of the PCL and the edge of the condylar articular cartilage. The posterior meniscomfemoral ligament (pMFL) of Wrisberg passes posterior to the PCL to insert at the proximal margin of the femoral attachment of the PCL.

The MFLs are variably present in each knee, and the incidence of the MFLs is the subject of many anatomical studies. Gupte and associates propose explanations as to why considerable variation of reported incidences exist, including variations in techniques of isolation of the ligaments, differences in criteria for defining an MFL, or even variability of incidence between races. An anterior dissection approach may underestimate the incidence of the pMFL, and misidentification of the oblique fibers of the PCL for fibers of the pMFL may result in an overestimation.

In an effort to elucidate the incidence of the MFLs,

Gupte et al combine the results of the incidence data presented in the anatomical studies. This summary concludes that the overall incidence of at least 1 MFL is 91%. In the knees demonstrating at least 1 structure, the incidence of an aMFL is 48.2% and a pMFL is 70.4%. The incidence of both ligaments coexisting in 1 knee is 31.8%.

The general consensus is that the pMFL is a more substantial structure than the aMFL. The pMFL may be up to 50%, and the aMFL is often less than 33% of the PCL diameter. However, very little biomechanical research has been performed regarding the structural or material properties of the MFLs.

■ **COMMENTS BY JOHN P. GOLDBLATT, MD, AND JOHN C. RICHMOND, MD**

The strength of this review is the comprehensive review of published studies to date, as well as the presentation of several suggestions for future studies that would serve to conclusively define the role of the MFLs. A number of theories regarding the functional role of the MFLs are summarized. One theory is that they serve a stabilizing, constraining, and possibly proprioceptive role, much like the ACL and PCL. Another idea is that they control the motion of the lateral meniscus, thereby enhancing the role of the meniscus in load distribution, while at the same time protecting the meniscus from injury. These theories are largely conjecture, and Gupte et al suggest several means to accurately prove the theories, such as a selective-cutting study. In addition, a histological examination in search of mechanoreceptors in human specimens would support the theory of proprioception.

Interestingly, one conclusion of this review suggests that precise knowledge of the function of the MFLs may result in a paradigm shift in how we treat the PCL-deficient knee. Many researchers propose that the MFLs are an integral part of the PCL complex. However, studies regarding the clinical consequence of PCL rupture fail to mention the status of the MFLs. It is possible to have complete rupture of the PCL with intact MFLs. PCL-deficient knees with intact MFLs may have a more favorable prognosis when treated nonoperatively. Clear definition of the role of the MFLs may have profound implications. PCL reconstruction may be averted if the MFLs remain intact. Or, reconstruction may be carried out in a manner to preserve the remaining fibers of the MFLs. Gupte et al conclude that a prospective clinical study examining the prognosis of PCL injuries in relation to MFL integrity would be of value.

It is suggested that the clarification of the role of the MFLs may also influence the operative approach to lat-

eral meniscus injury. Techniques for treating posterior horn lateral meniscus tears may change, and meniscal transplantation techniques may be altered. ■

Dr. Goldblatt is a Fellow at Tufts University School of Medicine.

Graft Choice in ACL Surgery

ABSTRACT & COMMENTARY

Synopsis: *Although both grafts yielded acceptable results in a large literature meta-analysis, patellar tendon grafts tended to result in slightly more stable knees with a lower failure rate but at the expense of higher complications and anterior knee pain.*

Source: Freedman KB, et al. Arthroscopic anterior cruciate ligament reconstruction: A meta-analysis comparing patellar tendon and hamstring tendon autografts. *Am J Sports Med.* 2003;31(1):2-11.

AUTOGRAFT PATELLAR OR HAMSTRING TENDONS ARE the most common choices of graft for ACL reconstructions, and both have been used with good success. Although some prospective, randomized studies comparing the 2 grafts are emerging, as follows this paper in the same journal issue, numbers of patients tend to be too small to draw meaningful conclusions. As Freedman and colleagues found in the present meta-analysis of the 2 methods covering 34 years and involving 1348 patellar tendon patients and 628 hamstring patients, it would take nearly 1200 patients in a randomized trial to have sufficient power given the differences they observed between groups.

Therefore, Freedman et al performed a literature review analyzing ACL reconstruction using either autograft with a minimum patient follow-up of 2 years. They found the patellar tendon graft patients had more stable knees (< 3mm side-to-side difference on KT-1000 was 79% patellar vs 73.8% hamstring) and a lower failure rate (1.9% patellar vs 4.9% hamstring). However, this came with a price, as the patellar group had a higher complication rate for manipulation or lysis of adhesions (6% vs 3%) and more anterior knee pain (17% vs 11%). Yet, hardware removal was more common in the hamstring group.

■ **COMMENT BY DAVID R. DIDUCH, MS, MD**

No question about it—both patellar tendon and ham-

string autografts work fine for ACL reconstruction. However, each of us has our preferences as do our patients. Freedman et al make an excellent point through which we should interpret other papers to follow: It would take prohibitively huge numbers of patients to detect any meaningful differences between the 2 groups in a prospective study given how well both groups do.

Although there are definite weaknesses to a meta-analysis and we are cautioned to reading too much into the results, the study does reinforce differences between the groups that I believe are real and which we can share with our patients at decision time. Patellar tendon grafts are slightly tighter and have a slightly lower failure rate. It is important to remember that hamstring fixation has evolved much more than the tried and true interference screw for the patellar tendon grafts. It would be interesting to do a similar meta-analysis covering only the past 3-5 years with more modern fixation methods. Nevertheless, given the constant improvements in fixation methods, it is safe to conclude that both grafts are acceptable.

For me, then, the decision with the patient tends to involve the presence of pre-existing anterior knee pain (prefer hamstring), concerns about the size of the scar, the need for the tightest knee possible and early return to sports (patellar graft), or an early return to work (hamstring graft). At some level, the surgeon also needs to factor in what they can do best, although in 2003 it is probably best that a surgeon routinely doing ACLs be competent in both techniques. ■

A Possible Explanation for Perceived Knee Laxity in ACL-Deficient Athletes Wearing Braces

ABSTRACT & COMMENTARY

Synopsis: ACL braces were least effective in controlling abnormal knee laxity during the transition from non-weight bearing to weight bearing.

Source: Beynnon BD, et al. The effect of anterior cruciate ligament deficiency and functional bracing on translation of the tibia relative to the femur during non-weight bearing and weight bearing. *Am J Sports Med.* 2003;31(1):99-105.

MANY AUTHORS REPORT ON THE EFFICACY OF functional bracing of the knee during unweighted or weight-bearing conditions. However, little is known

about the transition between these positions. The purpose of this study was to quantify the amount of tibia motion in the anterior cruciate ligament (ACL)-deficient knee during nonweight bearing, throughout the transition to weight bearing, and during weight bearing. Nine subjects with chronic ACL tears were studied with and without knee braces. Anterior/posterior shear and compressive loads were applied to the knee, simulating weight-bearing, nonweight-bearing and transitional weight-bearing conditions. Anterior laxity of the tibia relative to the femur was measured with the Vermont Knee Laxity Device.

Anterior/posterior tibial motion was significantly reduced in the braced anterior cruciate ligament-deficient knee to a level within the limits of the normal knee motion during nonweight-bearing and weight-bearing conditions. However, during the transition phase from nonweight bearing to weight bearing, the anterior translation of the tibia was 3.5 times greater than in the normal knee, and bracing did not significantly reduce the translation.

Beynnon and associates concluded that bracing the chronic ACL-deficient knee was effective in significantly reducing abnormal anterior/posterior laxity during nonweight-bearing and weight-bearing conditions. However, braces were not effective in reducing the abnormal translations produced during the transition phase.

■ COMMENT BY JAMES R. SLAUTERBECK, MD

It is important to understand if knee braces control anterior knee laxity in both loaded and unloaded conditions. However, the transition phase between the loaded and the unloaded condition is very dynamic and may be the point where high shear forces are likely the greatest. Studying the knee during weight-bearing transition may identify higher than expected anterior tibia translation as a result of quadriceps and hamstring torques applied to their respective insertion sites. The knee likely experiences the high change in torque many times during running and cutting. Under these dynamic conditions, the effects of bracing could be diminished if the femur is significantly anterior to the expected position from a resulting anterior shear force. This unexpected anterior position could lead to a sensation of abnormal laxity that would not be measured under static conditions of weight bearing or nonweight bearing.

The strengths of this study are that it is performed in humans in a well-controlled setting. This study uses a device, which applied a compressive and anterior-based force to the knee. This combination of applied loads simulates weight bearing, nonweight bearing and a transi-

tion phase between the 2 over a functional range of motion. This is a unique article and may help explain why some athletes perceive increased laxity in a properly fitting brace during running and cutting. ■

Articular Cartilage Defects— Plug it or Cell it?

ABSTRACT & COMMENTARY

Synopsis: *A randomized, prospective study found equivalent clinical outcomes for articular cartilage defects treated with either osteochondral plug grafts or autologous chondrocyte implantation (ACI). ACI improvement took longer, and the histology revealed mainly fibrocartilage, calling into question any advantage to this technique.*

Source: Horas U, et al. Autologous chondrocyte implantation and osteochondral cylinder transplantation in cartilage repair of the knee joint. *J Bone Joint Surg Am.* 2003;85-A(2):185-192.

IT IS WELL ESTABLISHED THAT ARTICULAR CARTILAGE defects lack the intrinsic ability to heal. What is less established is the ideal treatment for larger, symptomatic lesions. Horas and colleagues of this study from Germany prospectively randomized 20 patients each to treatment with either osteochondral plug autografts (also called OATS or mosaicplasty) or autologous chondrocyte implantation.

Each patient had a single, symptomatic, moderate-sized lesion (average about 3.7 cm²) involving the weight-bearing region of the femoral condyle. ACI involved a cartilage biopsy procedure followed 3 weeks later by open implantation of the culture-expanded cells beneath a periosteal patch, cambium layer down. The osteochondral plug group had grafts taken from the superior-medial trochlear ridge first and posterior condyles second, depending on how many were needed, and implanted simultaneously via an open approach. Both groups underwent an identical, conservative rehab course that gradually progressed weight bearing and activity over 12 weeks. Patients were evaluated at 6, 12, and 24 months following surgery, with arthroscopy and biopsies obtained in about one-quarter of patients in each group. Immunohistochemical staining was performed for collagens type I, II, III, VI, and X, and aggrecan and protein S-100.

No clinical differences were discernable between

groups by Tegner activity scores or Meyers score at 2 years. Using Lysholm knee scores, the ACI group took longer to improve with slightly lower scores at all time points. More importantly, the light microscopy, scanning electron microscopy, and immunohistochemistry results all demonstrated the repair tissue for ACI was almost entirely fibrocartilage, with rare areas that were hyaline-like upon review by blinded pathologists. Another concern on EM was that the ACI regenerate tissue had many missing cells, raising the possibility of early cell death of the transplanted chondrocytes. On the contrary, the autologous plugs were both microscopically and biochemically identical to surrounding normal cartilage, with the only possible problem being persistent clefts separating the plug from adjacent intact cartilage. Horas et al recommend waiting for longer-term results before performing ACI on larger numbers of patients.

■ COMMENT BY DAVID R. DIDUCH, MS, MD

This represents the first paper that is both randomized and prospective regarding these 2 commonly used treatments for cartilage lesions. More importantly, it also is the first paper to report ACI results by investigators not directly linked to ACI commercially, and for these reasons, this is a most welcome addition to the literature. Their results for ACI are concerning for several reasons, including the regenerate tissue being basically fibrocartilage, having almost no biochemical or histological makeup of hyaline cartilage, and being devoid of cells in many areas. They conclude with a warning to hold the procedure before using it on large numbers of patients.

The osteochondral plug results, on the other hand, were quite encouraging. The transplanted cartilage had no discernable differences from the surrounding native cartilage even at 2 years. The clefts around the plugs probably do not matter clinically as they were quite small and showed no signs of progressing in size. Perhaps performing an abrasion chondroplasty at the time of transplantation would encourage fibrocartilage to fill these spaces better between plugs. The details of number of plugs and location of harvest are somewhat sketchy, but Horas et al's general approach is fewer plugs of larger diameter.

That the osteochondral plugs were able to treat the same size defects as the ACI technique—with much better histology, a quicker recovery, 1 fewer operation, and a dramatic fraction of the cost—should bolster the use of plug transfer as an established technique. The creation of the Tracking or “T” codes has given the insurance industry unwarranted license to treat this procedure as “exper-

imental.” Papers like this will help to justify its use. On the contrary, papers like this call into question the value of ACI and further question in my mind whether the expensive transplanted cells do anything of substance as compared to the periosteal patch. ■

Back Pain in Rowers

ABSTRACT & COMMENTARY

Synopsis: *Rowers with pre-existing back pain prior to college were more likely to develop back pain in college but less likely to miss practice or end their careers because of it than rowers without pre-existing back pain.*

Source: O’Kane JW, et al. Effect of pre-existing back pain on the incidence and severity of back pain in intercollegiate rowers. *Am J Sports Med.* 2003;31(1):80-82.

COLLEGE ROWERS OFTEN COMPLAIN OF BACK PAIN. IT is not known if rowers with a history of back pain before college have more significant back pain during their college rowing careers. This study was set up to determine whether pre-existing back pain is a significant risk factor for back pain in intercollegiate rowers. For those rowers with pre-existing back pain and back pain during college, the study examined if they were able to effectively participate in college rowing.

Surveys were sent to 4680 rowing athletes from 5 strong university programs. A total of 2165 were answered. Survey responders older than 45 years, coxswain, and those without back pain during college were excluded, leaving 1829 surveys for the study. The survey included questions concerning back pain before the rower’s college career, during intercollegiate rowing, number of missed practices, time lost from college rowing because of back pain, and career-ending back pain. The definition for back pain was pain lasting longer than 1 week.

Athletes with pre-existing back pain (57.1%) developed back pain during their college-rowing career more often than athletes without pre-existing back pain (36.6%). In the athletes with pre-existing pain, 55% missed practice and 8% ended their college rowing careers because of back pain. A total of 78.8% missed less than 1 week, and 5.9% missed more than 1 month. In athletes without pre-existing back pain, 62% missed practice and 17% ended their college rowing careers because of back pain. A total of 61.9% missed less than 1 week, and 18.1% missed more than 1 month. O’Kane

and associates concluded that rowers with pre-existing back pain are more likely to have back pain in college but are less likely to miss extended periods of practice time or end their college rowing careers because of back pain.

■ COMMENT BY JAMES R. SLAUTERBECK, MD

Often a pre-existing injury may dissuade a coach from taking an athlete into the program. For many injuries, like pre-existing ACL injury, one might hold off on scholarship choice until successful treatment. Additionally, an athlete with a pre-existing injury may ask a physician, coach, or himself if the athlete can effectively participate in sports at a higher level. Many rowers have back pain, and it is not known if pre-existing back pain is associated with inability to participate in their sport.

This data appear to support the idea that rowers with pre-existing back pain have a higher incidence of back pain in college but miss less time than their peers who do not have pre-existing pain. This suggests that those with back pain have learned how to cope with their pain and continue to perform.

The data collected from this study carry the bias of all retrospective surveys in that information obtained was based on recollection. Additionally, only approximately 50% of the surveys were answered, presenting a significant selection bias. However, this study provides O’Kane et al a base of which to begin a prospective study to better answer these questions. Additionally, with a scarcity of information on this topic, we now have some information to begin to discuss with rowers with back pain. ■

CME Questions

28. Compared to metal anchors, absorbable suture anchors:

- have mechanical properties that do not change with temperature.
- tend to fail mostly by suture breakage.
- tend to fail mostly by suture cutout through the anchor eyelet.
- have more problems with abrasion of the suture at the eyelet.
- have mechanical properties independent of anchor weight.

29. Which of the following statements regarding the association of PCL deficiency with the development of degenerative articular cartilage injuries in the knee is true?

- There is no association.
- PCL deficiency may lead to chronic (20 years) changes.
- PCL deficiency may lead to changes within 5 years, especially in patients with combined PCL-PLC injuries and prior partial medial meniscectomy.
- PCL deficiency may lead to changes within 5 years. Combined injuries and partial medial meniscectomy had no effect on the development of these changes.

30. Which of the following is true concerning the meniscofemoral ligaments?

- a. They provide 33-50% of the restraining force to posterior tibial translation.
- b. Absence results in instability of the lateral meniscus.
- c. They provide restraint to the lateral meniscus, thus explaining why the amount of translation seen by the lateral meniscus is less than the medial meniscus during knee flexion.
- d. The exact functional role in knee biomechanics remains to be determined.
- e. They are both present in no more than 15% of knees.

31. Compared to patellar tendon grafts, hamstring autografts were found in a meta-analysis to:

- a. be tighter.
- b. have a lower failure rate.
- c. have more anterior knee pain.
- d. require more manipulations to restore motion.
- e. require hardware removal more frequently.

32. ACL knee braces cannot control anterior tibial translation relative to the femur during conditions of:

- a. standing.
- b. nonweight bearing.
- c. weight bearing.
- d. transition from nonweight bearing to weight bearing.

33. Compared to osteochondral plug transfer, the regenerate tissue from autologous chondrocyte implantation:

- a. was often devoid of cells.
- b. was more fibrocartilaginous.
- c. had better integration at the margins of the defect.
- d. was slower to show clinical improvement.
- e. All of the above

34. A survey of nearly 2000 college rowers determined that:

- a. Rowers with pre-existing back pain had back pain that ended their college rowing careers more frequently than those without pre-existing back pain.
- b. Rowers without pre-existing back pain had pain that ended their college rowing careers less frequently than those with back pain before college.
- c. Rowers with pre-existing back pain miss more days of rowing in college than those without pre-existing back pain.
- d. Rowers with pre-existing back pain miss less days of rowing in college than those without pre-existing back pain.

Answers: 28(c); 29(c); 30(d); 31(e); 32(d); 33(e); 34(d)

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PHARMACOLOGY WATCH



Counterfeit Procrit Uncovered by FDA Surveillance

In one of the more bizarre stories of the year, the FDA has uncovered files of counterfeit Procrit (epoetin alfa—Johnson & Johnson) in routine surveillance. To make matters worse, the fake vials have been contaminated with bacteria and many contain no active ingredient. Johnson & Johnson is sending out a “Dear Doctor” letter to warn health care professionals about the counterfeit vials including the lot numbers of the suspected counterfeits. Fake Procrit was also discovered last summer in United States. At that time, counterfeiters apparently purchased 2000 U/mL vials and labeled them as the higher priced 40,000 U/mL vials. More information is available at the Johnson & Johnson/Ortho Biotech web site including pictures of the counterfeit vials.

Pharmaceutical Marketing Campaigns in Full Swing

Love ‘em or hate ‘em, direct-to-consumer (DTC) advertisements of pharmaceuticals are big business. The Kaiser Family foundation reports that spending on DTC ads increased nearly 10-fold in 10 years, from \$260 million to \$2.5 billion in 2000. More than 80% of respondents report seeing or hearing a drug ad in the last 3 months according to an FDA survey, and the Kaiser study reports that one third of patients have asked their doctor about an ad they saw on TV or in print. Unfortunately, drug ads are increasingly unregulated. The FDA is tasked with reviewing DTC ads for false or misleading statements, but according to a recent review in *Consumer Reports*, the agency has only 30 reviewers to handle 30,000 submissions each year. By the time false or misleading ads are pulled from the airways, they have often run their lifespan, with new ads appearing in their place. But are the pharmaceutical companies getting \$2.5 billion of value from these ads?

Apparently. A recent FDA survey of physicians revealed that when patients initiate a discussion about a prescription drug they’ve seen advertised, they asked for a prescription more than 50% of the time. Some 66% of physicians said they were not pressured to prescribe a drug in that situation. However, when a specific brand name drug was requested, physicians felt pressured to prescribe it more than 50% of the time. Despite this, physicians are split on the effect of DTC ads on their patients and practice, with 32% feeling negative about the ads, 40% feeling positive, and 28% feeling that DTC advertising has no effect on the practice (www.fda.gov/cder/ddmac/presentations.htm).

Ambulatory Antibiotic Reduction: Take the Good with the Bad

The national campaign to reduce antibiotic use in ambulatory practice seems to be working, but there is good news and bad news. Researchers from UCSF and Harvard reviewed the rates of overall antibiotic use in the National Ambulatory Medical Care Survey between 1991-1992, and compared those rates to usage between 1998-1999. The use of antibiotics decreased in the latter time period especially for the treatment of respiratory tract infections such as the common cold and pharyngitis (visits with a

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prescription decreased from 13% to 10% in adults, and from 33% to 22% among children). The use of broad-spectrum antibiotics increased over the same time span; however, including the macrolides azithromycin and clarithromycin, quinolones, amoxicillin-clavulanate, and second- and third-generation cephalosporins. The use of these antibiotics increased from 24% to 48% of all antibiotic prescriptions among adults and from 23% to 40% among children. An accompanying editorial reiterates the CDC's Campaign for Appropriate Antibiotic Use in the Community, which encourages prescribing antimicrobials only when they are likely to be beneficial to the patient, selecting agents that will target the likely pathogen, and using these agents in the correct dose and for the proper duration. The editorial suggests that we have been effective at decreasing the overall use of antibiotics, but less successful at promoting targeted therapy, ie, using narrow spectrum antibiotics whenever appropriate to reduce the likelihood of resistance in a population (*Ann Intern Med.* 2003;138:525-533,605-606).

Nefazodone Under Attack Once Again

Public Citizen, the national nonprofit watchdog organization, has petitioned the FDA to remove the antidepressant nefazodone (Serzone—Bristol-Myers Squibb) from the US market. The petition is based on evidence of liver toxicity associated with the drug including liver failure and death. Nefazodone was recently pulled from the European market after reports of a worldwide total of 28 cases of liver failure of which 18 patients died. The move in Europe was voluntary on the part of Bristol-Myers Squibb because of the call for increased liver enzyme monitoring requirements in several European countries. In this country, the FDA has required a black box warning on nefazodone since January 2002. Despite these concerns, nefazodone, which is a SSRI antidepressant, continues to be relatively popular, with more than 4 million prescriptions written last year. Bristol-Myers Squibb has no plans to withdraw the drug in this country at present.

Lindane Receives Black Box Warning

The FDA has issued a Public Health Advisory concerning the use of lindane for the treatment of scabies and lice. The boxed warning is the result of concern of potential neurotoxicity especially in children. The new advisory states that lindane is a second-line treatment and updates information about its potential risk in children and adults who weigh less than 110 pounds. The advisory also states that reapplication of lindane lotion or sham-

poo is not appropriate even if itching continues after the single treatment. The FDA is also requiring package sizes to be limited to 1 and 2 oz in order to minimize the potential for product access in a single treatment. Lindane, also known as gamma benzene hexachloride, is an industrial pesticide, has been in use for decades, and has been banned in several countries. Neurologic side effects include dizziness, seizures, and even death. The drug is currently approved for the treatment of lice and scabies in patients who have failed or are intolerant of other therapies. First-line agents for scabies include permethrin cream (Nix, Elimite, Acticin) and malathion lotion (Ovide) and for lice pyrethrum with piperonyl butoxide shampoo and cream rinse permethrin cream rinse (Nix and Rid).

Aspirin Could Help Reduce Colorectal Adenomas

Two different studies in the same issue of the *New England Journal of Medicine* suggest that daily doses of aspirin reduce the risk of colorectal adenomas. In the first study, 635 patients with previous colorectal cancer were randomized to receive either 325 mg of aspirin per day or placebo. The study was terminated early when a significant reduction in colorectal adenomas was shown during the planned interim analysis. After an average of 12.8 months of follow-up, 1 or more adenomas were found in 17% of patients in the aspirin group and 27% patients in the placebo group ($P = 0.004$). The mean number of adenomas was lower in the aspirin group ($P = 0.003$) and the time to detection of the first adenoma was longer in the aspirin group than in the placebo group ($P = 0.022$). In the second study, 1121 patients with a recent history of adenomas were randomized to placebo (372 patients), 81 mg of aspirin (377 patients), or 325 mg of aspirin (372 patients). Follow-up colonoscopy was done approximately 3 years after randomization. The incidence of 1 or more adenomas was 47% placebo group, 38% in the 81 mg aspirin group, and 45% in the 325 mg aspirin group (global $P = 0.04$). The risk of larger polyps including adenomas measuring > 1 cm or with tubulovillous or villous, or severe dysplasia was also lowest in the 81 mg aspirin group. An accompanying editorial suggests that inhibition of COX-2 may prevent inflammation, increased cell proliferation and angiogenesis. The author also cautions that prophylactic aspirin is not a substitute for colorectal cancer screening (*N Engl J Med.* 2003; 348:883-890, 891-899,879-880). ■