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Revisiting Open Bankarts

ABSTRACT & COMMENTARY

Synopsis: To Magnusson and colleagues' surprise, they found an unacceptably high rate of recurrent instability of 17% with long-term follow-up from open Bankart procedures.

Source: Magnusson L, et al. Revisiting the open Bankart experience. A four- to nine-year follow-up. *Am J Sports Med.* 2002;30(6):778-782.

TRAUMATIC ANTERIOR DISLOCATIONS ALMOST ALWAYS RESULT IN detachment of the anterior inferior glenohumeral ligament and labral complex, termed a Bankart lesion. Historically, these have been fixed with an open reattachment of the capsulolabral complex with some degree of capsular shift to tighten any stretch in the capsule. A couple of frequently quoted papers by Rowe and Hovelius have recurrence rates of less than 5% with this open Bankart reconstruction.^{1,2} Unfortunately, it has been difficult for others to reproduce these results.

Magnusson and colleagues from Sweden critically looked at their results with open Bankart reconstructions in 54 patients. A standard open approach was used to reattach the capsule and labrum with about a 1-cm imbrication or shift of the capsule. These were fixed with standard suture anchor techniques to the front of the glenoid with the arm in 20° of external rotation.

All of the patients were evaluated by 3 experienced therapists who were not part of the surgical team, and, therefore, not at risk for surgeon observer bias by putting patients in a position in which they want to please their surgeons with good reports. Surprisingly, they found a high rate of recurrent instability, with 5 patients redislocating and 3 subluxating for a total recurrent instability rate of 17%. Some of these events first occurred several years after surgery. The minimum follow-up for this study was 4 years with a mean of nearly 6 years. Magnusson et al conclude that longer-term follow-up is needed with other studies to elicit a true recurrence rate with any stabilization procedure.

The patients also were noted, as other studies have found, to have

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decreased external rotation with an average loss of approximately 10°. However, 7 patients experienced a loss of much more motion than that. In addition to the loss of motion, the Constant shoulder scores and strength of rotation were significantly better on the noninjured side, and the activity level of patients decreased significantly. Magnusson et al conclude that they could not validate their hypothesis that an open Bankart would render a stable, well-functioning shoulder over the long term.

■ COMMENT BY DAVID R. DIDUCH, MS, MD

With the increasing popularity of arthroscopic Bankart reconstruction and a steady decrease in recurrence rate as techniques improve, it is helpful to see a critically performed study such as this that gives another look at the open Bankart experience. Magnusson et al are to be congratulated for trying to eliminate surgeon and observer bias in an otherwise retrospective study design. They can also be congratulated for following the patients over the long term and making a strong point for that in future studies. Several of the episodes of instability did not occur until 4-7 years after the index procedure. They also make a strong point to include subluxations as surgical failures.

The recurrent instability rate of 17% was unacceptably high for Magnusson et al to feel that the Bankart procedure predictably restores stability and a well-functioning shoulder. This certainly would be compounded by the loss of motion and recurrent pain reflected in the low Constant scores in these patients. It would be helpful to see similar long-term follow-up in the future as our arthroscopic experience grows with the newer techniques. I think this paper certainly heats up the debate of whether arthroscopic or open procedures are best. The long-held assumption that an open procedure would be better indicated for higher-demand contact athletes might not hold true if the recurrence rates are this high. ■

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Meniscal Allograft Replacement: Does it Work?

A B S T R A C T & C O M M E N T A R Y

Synopsis: This study demonstrates significant early to mid-term improvements in pain, function, and activity level following meniscal allograft replacement in properly selected individuals.

Source: Ryu RK, et al. Meniscal allograft replacement: A 1-year to 6-year experience. *Arthroscopy*. 2002;18(9):989-994.

THE NATURAL HISTORY OF COMPLETE MENISCECTOMY is well established. Total lateral meniscectomy in particular can result in rapid and relentless progression of arthrosis. What can be done about it? Well, as we all have learned, meniscal repair should be accomplished whenever possible and minimal meniscectomy when it is not. Nevertheless, total or near-total meniscectomy is an unfortunate consequence of certain knee injuries. When this occurs in very young patients, it can have devastating consequences. It seems reasonable, therefore, to consider meniscal replacement in this patient population—but how well does it work? This paper gives us some insight into this critical question.

This study evaluated the results of 29 meniscal replacements in 28 patients. Twenty-five patients with 26 meniscal replacements were evaluated at 1- to 6-year follow-up. Twenty-three allografts were evaluated with complete office evaluation and an additional 3 with telephone interviews. Study instruments included a visual analog scale, Lysholm II survey, Tegner and IKDC activity ratings, and a subjective scale. Results demonstrated that pain was significantly reduced and function was improved. Function improved in 17 out of 25, and overall satisfaction was 83%. Patients with grade IV chondrosis did worse, with functional improvement in only 3 out of 7. Workers' compensation patients also fared worse. Combined ACL reconstruction, gender, and medial vs lateral replacement did not affect results.

■ COMMENT BY MARK D. MILLER, MD

Ryu and colleagues' results are encouraging, especially in light of the fact that these patients have no other reasonable alternative. Ryu et al point out the flaws of their retrospective group without a control, but they have done an excellent job of following their cohort carefully. They describe their ideal candidate as younger than 45 years old with normal mechanical alignment, minimal (grade I or II) chondrosis, intact ACL, and some pain. Unfortunately, pain often heralds a knee in which arthrosis has progressed too far to make the patient a reasonable candidate for an allograft replacement; herein lies the dilemma. Additionally, it is still extremely difficult to get pre-authorization to perform these procedures in certain parts of the country and with certain carriers. Hopefully, with additional studies like the present one, and longer follow-up, we can turn this around. ■

Timing of ACL Reconstruction in Pediatric Patients

ABSTRACT & COMMENTARY

Synopsis: Delays in ACL reconstruction in patients younger than 14 years old results in more unreparable meniscus injuries.

Source: Millett PJ, Willis AA, Warren RF. Associated injuries in pediatric and adolescent anterior cruciate ligament tears: Does a delay in treatment increase the risk of meniscal tear? *Arthroscopy*. 2002;18(9):955-959.

THE EFFECT OF DELAYING ACL SURGERY ON THE occurrence of meniscus injury in pediatric patients is

not well studied. Therefore, the purpose of this article was to evaluate the effect of a delay of ACL surgery on the occurrence of meniscus injuries in children. This paper is a retrospective review of 39 patients (30 girls, 9 boys) with an average age of 13.6 years (range, 10-14 years) who underwent ACL surgery. The mean duration from injury until ACL surgery was 101 days (range, 7-696 days). The surgical procedures varied, including ACL repairs (3), ACL repairs plus hamstring augmentation (8), and ACL reconstructions (hamstrings [7], bone patella tendon bone [21]). Two groups were compared—acute (17), if surgery was performed within 6 weeks of injury and chronic (22), if surgery was performed after 6 weeks from injury. The associations between medial and lateral meniscus injuries, the time from injury to ACL surgery, and the pattern of meniscus injury were compared.

The results identified 25 meniscus injuries (10 medial tears, 15 lateral tears). The association between the time from injury to ACL surgery and number of medial meniscus tears was highly statistically significant ($P = .02$). However, no significance between the incidence of lateral meniscus tears and surgery time was made. Medial meniscus tears were more common in the chronic group and required surgical repair or removal more often than in the acute group.

■ COMMENT BY JAMES R. SLAUTERBECK, MD

ACL injury is more prevalent in children than sports physicians would like. The reconstructions in this age group, when the growth plates are open, carry some risk. Permanent growth abnormalities may alter knee mechanics for life and may counter all our efforts to return these younger athletes to sports. On the other hand, meniscus injuries resulting from a delay in ACL reconstruction also carry some risk. Since loss of significant amounts of the meniscus is associated with arthritis, delaying treatment may also poorly affect outcome.

This study identified that in those athletes treated with delayed ACL surgery, a greater number of meniscus injuries were identified. Additionally, the greater number of medial meniscus injuries resulted in meniscectomy instead of repair.

This study gives us some new information but has some limitations because the study is retrospective, missing some documentation (MRI) or exam findings at initial visit that would identify meniscus pathology, not consistent at using specific criteria to determine the surgical treatment of the torn meniscus, and lacking standardization of ACL surgical treatment. Although the limitations of this study are real, this is

probably the best study to date defining potential consequences of delaying ACL injury. All treatment of ACL injury in young children carries risk. We as sports physicians need to identify in a prospective long-term study which treatments, operative or nonoperative, carry the least risk and then advocate appropriate treatment. ■

Development of Dynamic Knee Stability after Acute ACL Injury

ABSTRACT & COMMENTARY

Synopsis: By using a perturbation training regimen, Chmielewski and colleagues were able to alter muscle contraction patterns in a way beneficial to coping with an ACL-deficient knee.

Source: Chmielewski TL, et al. Development of dynamic knee stability after acute ACL injury. *J Electromyogr Kinesiol.* 2002;12(4):267-274.

ACL-INJURED SUBJECTS WHO FUNCTION AT HIGH levels are termed "copers."¹ "Non-copers," who do not function well during high-level sports, demonstrate decreased knee motion and extensor moment, increased soleus activity, altered gastrocnemius and hamstring timing, and use significantly more co-contraction.

Chmielewski and colleagues state that no single muscle activation strategy has been determined to be optimal to produce dynamic knee stability (DNS) in all patients. Therefore, rehabilitation should involve activities that challenge knee stability. Chmielewski et al reference the force feed-back hypothesis: When perturbing force is applied to a joint, muscles that resist the perturbation are stretched and activated to resist that force. By using a perturbation training regimen, Fitzgerald et al² were able to get a 93% return to high level with perturbation, strength, and agility training, compared to only 50% return to high level with strength and agility alone. The purpose of this present study was to determine if perturbation training predictably alters muscle activation patterns.

Chmielewski et al screened for those patients with "good potential for nonoperative management." They used a very small sample of 9 subjects (7 males, 2 females). Though they were all injured during athletics, it was not clear that they were currently involved in the same level of sport. The screening testing included

objective quadriceps index (isometric quadriceps strength on the involved relative to the noninvolved side), timed 1-legged hop tests, subjective knee outcome survey-ADL scale (KOS-ADL), and global rating self-report of function questionnaire. Objective gait analysis with EMG, kinetic, and kinematic measures was also used.

Perturbations incorporated 3 basic exercises: rollerboard, rockerboard, and rollerboard with stationary platform. These exercises require that the subject either resists the force or regains balance. The protocol progressed from a focus on sagittal plane and predictable perturbations with verbal cues to random challenges in all planes of greater intensity. During the last 5 treatments, the perturbations were presented while subjects performed sport-specific tasks.

The quadriceps index and the mean timed hop were the same pre- vs post-training. KOS-ADL (92-97%) and global rating (84-94%) scores both significantly increased. Gait assessment demonstrated that the vastus lateralis (VL) integral EMG significantly increased after perturbation training, and the time to peak VL activity correlated to both soleus onset and the integrated EMG activity of the lateral hamstrings. These correlations didn't exist before training or on the uninjured side.

■ COMMENT BY TIMOTHY E. HEWETT, PhD

This is a good study of the effects of conservative treatment on high-functioning patients with ACL deficiency. Chmielewski et al report that perturbation training in these high-functioning "copers" alters muscle activity in the affected limb. They recommend perturbation training in athletes who pass a screening examination that includes objective and subjective assessments. The study results are limited only to this high-functioning population. In addition, Chmielewski et al may have over-interpreted their findings in the discussion.

They carefully selected their study population, which might have led to a selection bias in their results. This fact and the small sample size make it difficult to generalize the applicability of the findings of this study. Five of the 9 patients went on to ACL reconstruction. It is a bit concerning that the objective scores didn't change post-training but the subjective did (perhaps subjects were told the perturbation training was good for them). There was no control group to study this effect.

The integral of the quadriceps activity increased after training, though the quadriceps can destabilize the knee. Chmielewski et al explain this by pointing out that hamstrings and soleus activation predicted quadriceps activity. However, the data showing differences in the timing of muscle activity pre- and post-training are not very con-

vincing. The amount of soleus and gastrocnemius activity did not increase, the changes in onset appear small, and they don't appear to be altered much relative to quadriceps activity. Other questions include: Why did Chmielewski et al test EMG during gait? They didn't train gait? Why not test while doing a more training-specific activity?

Non-copers may account for approximately two-thirds of the ACL-injured population and Chmielewski et al categorized them as similar to "quadriceps avoiders." Berchuck et al³ speculated that quadriceps avoidance was a positive adaptation. This paper says they are non-copers. This discrepancy is interesting and more research needs to be performed to determine if non-copers and quadriceps avoiders are truly one and the same.

I would recommend this study for those physicians who desire to keep their high-level athletes who suffer an ACL injury functioning through the remainder of their sports season in order that reconstruction can be deferred to the off-season. ■

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Comparing Tibial Fixation Methods for Hamstring Grafts

A B S T R A C T & C O M M E N T A R Y

Synopsis: *The type of fixation device used in an anterior cruciate ligament reconstruction determines the strength and stiffness of a tendon in a bone tunnel following implantation.*

Source: Singhatat W, et al. How four weeks of implantation affect the strength and stiffness of a tendon graft in a bone tunnel. *Am J Sports Med.* 2002;30(4):506-513.

A TENDON GRAFT MUST HEAL TO THE BONE TUNNEL In order to function as an anterior cruciate ligament.

The present study evaluates the difference in strength and stiffness of a tendon graft fixed with either a biore sorbable interference screw or a WasherLoc device.

In 32 skeletally mature sheep, the long digital extensor tendon was transplanted into a 30-mm hole drilled into the tibial metaphysis. Fixation was performed with a bioabsorbable interference screw (Bio-Interference Screw, Arthrex Inc., Naples, Fla) in 16 sheep, and a WasherLoc (Arthrotek, Inc., Warsaw, Ind), a spiked washer compressed onto the tendon graft by a cortical screw, in the other 16 sheep. After 4 weeks of implantation, the animals were sacrificed and both limbs harvested. A tendon transplantation performed in the contralateral leg at the time of harvest was used as a control for the strength and stiffness of the complex at the time of implantation. For each fixation device, the strength and stiffness of the complex at the tendon-bone interface were determined by incrementally loading the specimens to failure while mounted on a materials testing machine (Instron 5566, Instron Corp., Canton, Mass).

At implantation, all of the fixation complexes failed by pulling the tendon out from the tunnel. After 4 weeks of implantation, all complexes with the bioresorbable screw and 6 of the 8 complexes (75%) fixed with the WasherLoc failed the same way. The remaining 2 WasherLoc complexes failed by rupture of the tendon outside the tunnel.

The strength (down 63%) and stiffness (down 40%) of the complex with the bioresorbable interference screw decreased significantly 4 weeks after implantation. With WasherLoc fixation, 4 weeks of implantation did not significantly change the strength of the complex; however, it significantly increased the stiffness of the complex by 136%. With the bioresorbable interference screw fixation, the strength and stiffness of the tendon-bone interface developed relatively slowly; whereas, development occurred relatively rapidly with WasherLoc fixation.

■ COMMENT BY BRIAN J. COLE, MD, MBA, AND NINA SHERVIN, MS

Although numerous studies measuring the strength and stiffness of various fixation methods have been conducted, the present study sought to evaluate the performance of the fixation complex during the first few weeks following implantation. The results of this study indicate that the strength and stiffness of the bioresorbable interference screw deteriorated after 4 weeks of implantation and that the development of the tendon-bone interface was slow. On the other hand, the WasherLoc fixation complex had either maintained or improved its strength and stiffness after implantation and resulted in a more rapid development of the tendon-bone interface.

Given the large discrepancy between 2 commonly used fixation devices, Singhatat and associates suggest that clinical studies be used to determine the effectiveness of fixation devices as opposed to in vitro studies in animal or human cadaveric bone. These findings should also be considered by a clinician when deciding whether to use aggressive rehabilitation after reconstruction of a knee with a torn anterior cruciate ligament. This study confirms the findings of other biomechanical studies that imply that the use of bioabsorbable screws used alone to fix soft tissue grafts in tibial tunnels may be biomechanically insufficient to tolerate aggressive rehabilitation protocols. ■

Preventing Tibial Stress Fracture With Custom Shoe Orthoses

A B S T R A C T & C O M M E N T A R Y

Synopsis: Custom biomechanical orthoses are beneficial in reducing the risk of stress fracture for walking, especially in army boots; however, these orthoses are not helpful in activities that involve running or when athletes are already wearing standard running shoes.

Source: Ekenman I, et al. The role of biomechanical shoe orthoses in tibial stress fracture prevention. *Am J Sports Med.* 2002;30(6):866-870.

THE TIBIA IS THE MOST COMMON LOCATION FOR STRESS fractures, thought to occur from repetitive loading of the bone with high strains or, especially, high-strain rates. If orthotics could reduce the rate of stress fractures without the need to alter any other training parameters, this would be a major advantage to athletes. Simple over-the-counter, soft, shock-absorbing inserts have been found not to affect the overall incidence of stress fractures. However, one study has shown clinically a 50% reduction in stress fractures when custom biomechanical shoe orthoses were worn in army boots for marching.¹ The hypothesis of the present study was that these custom biomechanical shoe orthoses would reduce strain and strain rates when athletes wore them in either army boots or running shoes.

Nine athletically fit members of the special forces unit of the Swedish Police served as "volunteers." It is somewhat amazing what these subjects endured. They had an open surgical procedure on the morning of testing with just local anesthesia to insert a pair of 16-mm bone sta-

ples equipped with strain gauges into their tibias at 2 locations. The wounds were left open and just covered with gauze dressing as they then performed the study, having the staples removed at the conclusion of the day and the wounds closed with sutures.

Each of the subjects was custom fitted with biomechanical orthoses of 2 types. One was a semi-rigid, three-quarter length polypropylene orthosis with a thin fabric cover, and the other was a soft, full-length biomechanical orthosis, which was made of 3 different densities of polyurethane. Subjects were issued Nike Air Max running shoes as well as Israeli Army infantry boots 1 month ahead so that they could break in their shoes and orthoses. Measurements were then made during treadmill walking and during serial 2-km treadmill runs at 13 km/h with running shoes, with and without the orthoses, and during serial 1-km runs with army boots, with and without the orthoses. Measurements during walking after the runs were made to look at the possibility of fatigue-induced changes in strain rates.

Ekenman and colleagues found that the addition of both types of orthoses to army boots significantly lowered peak strains while walking, but only the soft orthoses lowered the strain rates with the boots. During running, however, the semi-rigid orthoses significantly increased the strain rates when worn with the boots. There was no advantage to the soft orthoses with the boots during running.

The peak strains were significantly lower when athletic shoes were worn compared to boots. The addition of the orthoses to the boots brought the strains to roughly equivalent levels with athletic shoes. The addition of the orthoses to the running shoes offered no benefit whatsoever during running activities. In fact, the semi-rigid orthoses caused a slight increase in strain and strain rates. They conclude that biomechanical orthoses, either soft or semi-rigid, offer no benefit to running shoes. They do recommend soft orthoses for activities that involve primarily walking in army boots.

■ COMMENT BY DAVID R. DIDUCH, MS, MD

Ekenman et al have shown with a very carefully designed study and noble volunteers that custom orthoses offer no benefit with either running shoes or military boots for activities that involve mainly running. Semi-rigid orthoses were actually found to increase strain rates when used together with military boots with running. They conclude that custom biomechanical shoe orthoses have no place in stress fracture prevention in sports in which running is a primary activity. Indeed, semi-rigid orthoses in runners may be even contra-indicated because of increased strain rates during running.

They do, however, find benefit to custom orthoses for walking in military boots, just as other authors have demonstrated with a 50% reduction in stress fracture incidence.¹

Differences in the biomechanics between walking and running, in particular involving hind foot mechanics and time of heel contact, likely account for the differences in Ekenman et al's findings between running and walking activities. As such, there are very different recommendations based on the activity encountered. Military recruits in army boots who primarily perform marching activities can benefit from custom full-length, soft, biomechanical orthoses. Semi-rigid, three-quarter length orthoses should be avoided as they actually increase the risk of stress fracture with any running in army boots. Athletes wearing standard running shoes would have no benefit from custom orthoses for stress fracture prevention and may actually see a slight increase in strain rates with the semi-rigid orthoses. Given that other studies have shown no benefit for noncustom, over-the-counter orthoses used as shock absorbers, it is safe to recommend to our athletes that the simple choice of good shoes is sufficient. ■

Reference

1. Finestone A, et al. Prevention of stress fractures using custom biomechanical shoe orthoses. *Clin Orthop.* 1999;360:182-190.

Better Stability for Proximal Humeral Hemiarthroplasty

ABSTRACT & COMMENTARY

Synopsis: A biomechanical study of tuberosity reattachment in hemiarthroplasty after 4-part humeral head fractures found that cerclage wiring provided optimal stability.

Source: Frankle MA, et al. Stability of tuberosity attachment in proximal humeral hemiarthroplasty. *J Shoulder Elbow Surg.* 2002;11(5):413-420.

HEMIARTHROPLASTY IS AN ESTABLISHED TREATMENT for 4-part proximal humerus fractures, especially with significant displacement or poor-quality bone. This study evaluates 5 different techniques for tuberosity attachment in an attempt to analyze interfragmentary stability.

In the control group, the tuberosities were attached to

the humeral shaft with nylon strap ties, and the rotator interval was closed. The second group added the attachment of the tuberosities to each other. The third group added attachment to the anterior fin. The fourth, fifth, and sixth groups included the addition of a circumferential cerclage to the previous 3. A robotic arm was used to test the reconstruction at 10°/s from 0° to 60°. Three cycles were performed for each reconstruction and interfragmentary displacements were measured at 15°, 30°, and 50° of external rotation. Using analysis of variance, Frankle and associates did not determine a difference within the cerclage or noncerclage groups. Therefore, the similar groups were combined and compared to the control and to each other for statistical analysis.

This study demonstrated that cerclage containing repairs had significantly lower displacements and strains ($P < 0.05$) than those without cerclages. Incorporation of the anterior fin did not enhance fixation when cerclage was used. The noncerclage groups allowed 45° of external rotation before reaching 100% strain, whereas the cerclage-containing groups allowed an additional 15° (total of 60° ER). Strain at the fracture site measured 200% at only 50° ER without the use of cerclage.

■ COMMENT BY COL PATRICK ST. PIERRE, MD

This is a well-done biomechanical study of tuberosity fixation in the treatment of a 4-part proximal humerus fracture by hemiarthroplasty. Frankle et al were recognized for their efforts by winning the Neer Award for 2001. They quite nicely tried to control as many factors in their experimental design as possible while testing the one question of whether cerclage fixation of the tuberosities brings increased fixation strength. Although it appears that the original design was to test several reconstruction techniques, they were able to combine similar designs and increase the power of their study.

Frankle et al recognized several limitations to their study. First, they acknowledged that they created perfect fracture lines with a saw, allowing for anatomic reduction of the fragments. Second, they only tested in rotation, while in the postoperative setting there would be forward flexion and abduction forces. Third, they only tested one prosthesis design, and variable designs may decrease the effect of cerclage fixation. Because these limitations affected both test groups equally, they do not invalidate their conclusions.

One major concern about the study design was that they used as the control a method that did not attach the tuberosities to each other. This would not be standard practice and may have had an effect on the statistical analysis. However, based on the information provided, Frankle et al demonstrate enough difference between the

2 combined groups to make their conclusions valid.

They should be commended on their study and their critical evaluation of tuberosity fixation in hemiarthroplasty. This is a preliminary study to what should be a more extensive evaluation of this technique using different prostheses and additional motion planes. However, even with just this study, surgeons should consider the use of cerclage when performing this operation in order to maximize fixation strength. ■

CME Questions

8. **Early to mid-term results of meniscal allograft replacement:**
 - a. are universally bad.
 - b. are encouraging for lateral meniscal replacements, but unsatisfactory for medial meniscal replacements.
 - c. are encouraging for medial meniscal replacements, but unsatisfactory for lateral meniscal replacements.
 - d. are encouraging for medial and lateral meniscal replacements in properly selected individuals.
9. **The problem with having a surgeon perform evaluations of post-operative patients is known as:**
 - a. patient bias.
 - b. observer bias.
 - c. study bias.
 - d. statistical bias.
10. **Delaying ACL surgery in children younger than age 14:**
 - a. carries no risk of additional lateral meniscus injury.
 - b. carries no risk of additional medial meniscus injury.
 - c. carries increased risk of additional lateral meniscus injury.
 - d. carries increased risk of additional medial meniscus injury.
11. **Four weeks following an ACL reconstruction in an ovine model, which of the following is *false*?**
 - a. The use of a bioresorbable interference screw results in both decreased strength and stiffness of the tendon-fixation device-bone complex.
 - b. The use of WasherLoc results in no decrease in strength and increased stiffness of the tendon-fixation device-bone complex.
 - c. The development of the tendon-bone interface is slower with a bioresorbable interference screw than with WasherLoc.
 - d. There is no difference between a bioresorbable interference screw and WasherLoc as fixation devices in the strength and stiffness of a tendon in a bone tunnel.
12. **Non-copers demonstrate which of the following?**
 - a. Decreased knee motion and extensor moment
 - b. Increased soleus activity
 - c. Altered gastrocnemius and hamstring timing
 - d. Significantly more co-contraction
 - e. All of the above

13. **Custom full-length, biomechanical, soft orthoses were found to reduce strain rates in:**

- a. walking with running shoes.
- b. walking with army boots.
- c. running with running shoes.
- d. running with army boots.

14. **The addition of cerclage when performing hemiarthroplasty in the treatment of 4-part proximal humerus fractures increased the amount of rotation tolerated until 100% strain was noted at the fracture site by an additional:**

- a. 0°.
- b. 5°.
- c. 10°.
- d. 15°.
- e. 20°.



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PHARMACOLOGY WATCH

FDA Issues 'Black Box' Warning Based on WHI Study

The FDA has mandated a "Black Box" warning for all estrogen and estrogen/progestin products for use by postmenopausal women. The new warnings are based on analysis of data from the Women's Health Initiative (WHI) study that was published July 2002. The box warning emphasizes that these drugs have been associated with increased risks for heart disease, heart attacks, strokes, and breast cancer and that they are not approved for heart disease prevention. Wyeth Pharmaceuticals, the manufacturer of Premarin, Prempro, and Premphase, products that were used in the WHI study, are also required to change their indications to: treatment of severe vasomotor symptoms, vulvar and vaginal atrophy associated with menopause, prevention of postmenopausal osteoporosis, and should only be used when the benefit clearly outweighs the risk. The labeling will also be required to include consideration of other therapies for the atrophy and osteoporosis indications, and to recommend use of the lowest dose for the shortest duration possible. While Wyeth's products are the focus of this initial press release and FDA action, all estrogen products will be subject to new labeling. The FDA is also recommending future research to answer questions regarding the risks of lower-dose estrogen products and if other types of estrogens and progestins are associated with lower risk of CVD and breast cancer. The complete press release can be viewed at www.fda.gov.

ALLHAT: Thiazide for Hypertension Treatment

Thiazide diuretics should be considered first-line therapy for hypertension, according to the authors of the ALLHAT study published in

December. In a finding that surprised nearly everyone (especially the sponsors of the study) in patients with hypertension and at least one other cardiovascular risk factor, the diuretic chlorthalidone was associated with better cardiovascular outcomes at less cost and with equal tolerability compared to a calcium channel blocker or an ACE inhibitor. ALLHAT enrolled more than 33,000 patients from 623 centers in the United States, Canada, and the US Virgin Islands. Patients were randomized to the calcium channel blocker amlodipine, the angiotensin-converting enzyme inhibitor lisinopril, or chlorthalidone. Mean follow-up was 4.9 years with the primary outcome being combined fatal CHD or nonfatal MI. Secondary outcomes included all-cause mortality, stroke, combined CHD, and combined cardiovascular disease (CVD). The 6-year rate of the primary outcome and all-cause mortality was virtually identical for all 3 drugs. Chlorthalidone was superior to amlodipine in preventing heart failure (10.2% vs 7.7%, RR, 1.38, 95% CI, 1.25-1.52) and was superior to lisinopril for lowering blood pressure and in 6-year rates of combined cardiovascular disease including stroke (6.3% vs 5.6%) and heart failure (8.7% vs 7.7%). With improved cardiovas-

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cular outcomes, lower cost, and equal tolerability, the study concludes that thiazide-type diuretics are superior in preventing one or more forms of CVD and that they should be the preferred agent in antihypertensive therapy, and should be included in all multidrug regimens (*JAMA*. 2002;288:2981-2997). An accompanying editorial calls ALLHAT "one of the most important trials of antihypertensive therapy" and suggests that national guidelines should be changed to emphasize use of thiazide diuretics as initial therapy (*JAMA*. 2002;288:3039-3042).

Candesartan Effective Against Migraines

The angiotensin II receptor blocker candesartan is effective in preventing migraine headaches, according to a new study. Norwegian researchers looked at 60 patients age 18-65 with 2-6 migraines per month. Patients were randomized in a double-blind placebo-controlled crossover study with the main outcome being number of days with headache. Secondary outcomes included use of pain medications and triptans, hours with headache, headache severity, and days lost from work. During the 12-week study, the mean number of days with headache was 18.5 with placebo vs 13.6 with candesartan ($P = .001$) in the intention to treat analysis ($n = 57$). Patients were considered a candesartan responder if they noted a reduction of 50% or more of days with headache (18 of 57 patients, 31.6%) or days with migraine (23 of 57 patients, 40.4%). Although this represented a minority of patients, those who did respond benefited from effective migraine prophylaxis. Candesartan's tolerability profile was comparable with placebo (*JAMA*. 2003;289:65-69).

Cough! No Cold Relief from Echinacea

Echinacea offers no benefit in treating the common cold according to a study from the University of Wisconsin. A total of 148 college students with recent onset colds were randomized to an encapsulated mixture of unrefined Echinacea (*E purpurea* herb and root and *E angustifolia* root) 6 times a day on the first day of illness and 3 times a day on the subsequent days up to a total of 10 days. The main outcome was the severity and duration of self-reported symptoms of URI. No statistically significant differences were detected between Echinacea and placebo groups for any of the measured outcomes, which included trajectories of severity over time or mean cold duration. No significant

side effects were noted with Echinacea. The study concludes that no detectable benefit or harm could be found with Echinacea treatment for the common cold (*Ann Intern Med.* 2002;137:939-946).

COX-2 Inhibitors and GI Benefits Could Be Overrated

Could the GI benefits of COX-2 inhibitors be overrated? A new study suggests that the COX-2 inhibitor celecoxib is no safer than a combination of diclofenac plus omeprazole with regard to ulcer risk in patients with a history of peptic ulcer disease and arthritis. Researchers from Hong Kong recruited patients with arthritis and NSAID-related bleeding ulcers. After their ulcers had healed, 287 patients who were negative for *Helicobacter pylori*, were randomly assigned to receive celecoxib 200 mg twice a day plus placebo, or diclofenac 75 mg twice a day plus 20 mg of omeprazole for 6 months. Recurrent bleeding ulcer occurred in 7 patients receiving celecoxib and 9 receiving diclofenac/omeprazole (4.9% vs 6.4%). Renal adverse events including hypertension, peripheral edema, and renal failure occurred in 24.3% of patients receiving celecoxib and 30.8% of those receiving diclofenac/omeprazole. The authors suggest that neither regimen offered effective protection against recurrent ulcer complications or renal adverse effects (*N Engl J Med.* 2002;347:2104-2110).

FDA Actions

Pfizer's new anti-migraine drug, eletriptan (Relpax) has been approved by the FDA for marketing. The drug that is available in 20-mg and 40-mg tablets has been shown to be effective in aborting migraine headaches within 2 hours. The company is marketing a 80-mg tablet in Europe, but the FDA refused to approve the higher dose due to an increase in adverse events.

Montelukast (Singulair), Merck's leukotriene inhibitor, has been approved by the FDA for the treatment of seasonal allergic rhinitis. The drug has been on the market since 1998 for the treatment of asthma in adults and children. This new indication is the first for a leukotriene inhibitor, and creates a new, nonantihistamine treatment modality for this indication. Montelukast was approved for symptoms of seasonal allergic rhinitis in adults and children aged 2 years and older. It is available in 10 mg strength for adults, and a chewable 4 mg or 5 mg strength for children. ■