

New Concepts in Knee Surgery Enhance Practice Performance and Patient Outcomes

Written by Maria Vinal

During a session on knee surgery sponsored by the Arthroscopy Association of North America, specialists discussed new concepts in diagnosis and treatment in arthroscopic practice, with a special emphasis on surgical methods and technical pearls that enhance practice performance and patient outcomes. The session opened with a presentation on identifying and treating posterior root tears of the medial meniscus (MM), followed by a discussion of the difference between lateral meniscus (LM) and MM root tears and the different approaches to repair. These practical topics were followed by a discussion of whether clinical practice guidelines (CPGs) have led to lost opportunity for some procedures. The session closed with discussions on the use and regulation of stem cells in orthopedics.

ANATOMIC REPAIR OF POSTERIOR MM ROOT TEARS

Anatomic repair of posterior MM root tears produces near-intact contact area and minimizes increases in mean and peak contact pressures compared with nonanatomic repair [LaPrade CM et al. *Am J Sports Med.* 2015]. According to Robert F. LaPrade, MD, PhD, Steadman Philippon Research Institute, Vail, Colorado, USA, there are several ways to find these tears and guidelines on when to fix them. Most patients with a posterior MM tear describe a “pop” associated with a deep squat, pain with deep flexion, joint line pain, or palpable extrusion. On x-ray, it is sometimes possible to see a meniscal ossicle; on magnetic resonance imaging (MRI), a ghost sign, extrusion, and insufficiency fractures may be noted. Dr LaPrade cautioned that since spontaneous osteonecrosis of the knee is often associated with a meniscal root tear, a posterior meniscal root tear should be considered before diagnosing a patient with spontaneous osteonecrosis of the knee, particularly in the presence of significant bone marrow edema.

Surgery is appropriate for type II MM tears with extrusion, bone marrow edema, and lower grade cartilage lesions, as well as LM type II tears with extrusion and torn menisiofemoral ligaments. MM root tears have been successfully repaired with arthroscopic pullout suture surgery [Lee JH et al. *Arthroscopy.* 2009], which is associated with significantly improved clinical and radiologic results compared with meniscectomy ($P < .05$) [Kim SB et al. *Arthroscopy.* 2011]. Dr LaPrade anticipates that new devices, the use of biologics, and improved physical therapy will augment healing.

REPAIR APPROACHES IN MM VS LM ROOT TEARS

There are clear and important differences between MM and LM root tears, noted K. Donald Shelbourne, MD, Shelbourne Knee Center, Indianapolis, Indiana, USA. LM tears are almost always associated with anterior cruciate ligament (ACL) tears and are usually associated with acute injury. Although joint space narrowing (JSN) is not common with LM tears, medial tears almost always occur secondary to JSN that causes extrusion. Patients who had MM tears were 5.8 times more likely to have articular cartilage degeneration [Matheny LM et al. *Knee Surg Sports Traumatol Arthrosc.* 2014].

The data on repair of LM root tears in conjunction with ACL reconstruction tend to support leaving the tear in situ when the menisiofemoral ligaments are intact. One MRI-based study reported no improvement in extrusion in the coronal plane but significant improvement in the sagittal plane 8 months after all-inside repair surgery ($P = .007$) [Ahn JH et al. *Arthroscopy.* 2010]. Another study reported no statistically significant difference in International Knee Documentation Committee subjective scores ($P = .09$) after 10 years between patients with LM root tears left

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in situ compared with patients with no meniscus tears, but these patients did have further JSN indicating some progression of arthritis [Shelbourne KD et al. *Am J Sports Med.* 2011].

Although biomechanical studies have shown that repair of MM root tears can restore joint mechanics [Marzo JM, Gurske-DePerio J. *Am J Sports Med.* 2009; Allaire R et al. *J Bone Joint Surg Am.* 2008], laboratory studies do not accurately reflect “real-world” patients. Patients with an MM tear have JSN on x-ray and extrusion on MRI. Although repair seems appropriate, the meniscus is extruded because of JSN and it is technically difficult to pull it back into a narrowed joint. More importantly, extrusion has been shown to significantly increase after repair ($P < .001$) [Moon HK et al. *Am J Sports Med.* 2012]. Dr Shelbourne approaches MM root tears nonoperatively. He recommends injections to get the patient through the initial painful period then rehabilitation to improve range of motion, leg control, and function.

AAOS CPGs QUESTIONED

Jack M. Bert, MD, Minnesota Bone & Joint Specialists, St Paul, Minnesota, USA, questioned whether some CPGs may interfere with the evolving goal of improved treatment and management of orthopedic conditions. He cited 3 areas where he feels the CPGs have failed by limiting the use of procedures: rotator cuff repair (RCR), arthroscopic debridement of osteoarthritis (OA), and viscosupplementation.

As background, Dr Bert noted that following the publication of several studies between 2002 and 2008 in which debridement was shown to be no better than sham surgery for knee OA [Kirkley A et al. *N Engl J Med.* 2008; Moseley JB et al. *N Engl J Med.* 2002], there was a 39% reduction in the adjusted population-based rate of in knee arthroscopy [Holmes R et al. *Am J Sports Med.* 2013]. Yet, in a review of >273 000 patients that had arthroscopy for knee OA, overall, only 4.1% of patients aged <65 years were converted to total knee arthroplasty (TKA) [Fedorka CJ et al. *J Arthroplasty.* 2014] and in another study, 32.5% of patients with arthropathy had TKA at 9 years from the index arthroscopy indicating that arthroscopy debridement may contribute to a significant delay in TKA ($P < .0001$) [Johanson NA et al. *J Arthroplasty.* 2011].

However, a strong recommendation against arthroscopy with lavage or debridement in patients with a primary diagnosis of symptomatic knee OA was issued in the 2013 American Academy of Orthopaedic Surgeons (AAOS) Evidence-Based Guideline on Treatment of Osteoarthritis of the Knee [Jevsevar DS et al. *J Bone Joint*

Surg Am. 2013]. A closer look at the recommendation, however, shows that it does not apply to patients with knee OA and a primary diagnosis of meniscal tear, loose body, or other mechanical derangement. Similar difficulties exist with the CPGs for RCR [Lubowitz JH et al. *Arthroscopy.* 2012].

Dr Bert cautioned that arthroscopic debridement should be performed for the right reasons (ie, mechanical symptoms from a torn meniscus or loose body) and should be coded appropriately for the procedure performed. He furthermore believes that the recommendation against the use of viscosupplementation should be ignored since it was based on the AAOS's misuse of the minimal clinically important difference and improvement metrics.

THE FUTURE: MSC USE IN HUMANS

The use of mesenchymal stem cells (MSCs) to repair large, full-thickness defects of the articular cartilage in animals was successfully performed >20 years ago. Constance R. Chu, MD, Stanford University, Stanford, California, USA, discussed recent studies that are expected to expand this procedure in humans.

In 2007, investigators were able to achieve histologically superior cartilage repair by using an adeno-associated virus vector to deliver transforming growth factor-beta-1 to rats implanted with human bone marrow MSCs [Pagnotto MR et al. *Gene Ther.* 2007].

However, because bone marrow MSCs are not readily available for use, attention has turned to the use of bone marrow concentrate (BMC). In an equine model, the use of BMC in addition to microfracture resulted in healing of acute full-thickness cartilage defects that was structurally superior to that seen with microfracture alone at 8 months (macroscopic scores, $P = .009$; histological scores, $P = .02$) [Fortier LA et al. *J Bone Joint Surg Am.* 2010]. Human studies with MSCs include a prospective case control study that failed to show clinical benefit after 5 years [Wakitani S et al. *J Bone Miner Metab.* 2008] and a 2013 meta-analysis of 11 studies using both MSCs and BMC, which showed limited evidence of benefit using clinical metrics [Pastides P et al. *Osteoarthritis Cartilage.* 2013]. Clinical metrics are less sensitive than structural metrics as noted in another equine study showing improved arthroscopic appearance with no differences in clinical outcome metrics after injection of MSCs 1 month after microfracture [McIlwraith CW et al. *Arthroscopy* 2011]. Many questions related to issues, such as host factors and donor factors, remain regarding how best to employ stem cell therapy clinically. However, based on promising animal studies, Dr Chu is confident this therapy will play a role in the future of orthopedics.



FDA'S REGULATION OF STEM CELLS

Brian J. Cole, MD, MBA, Midwest Orthopaedics at Rush, Chicago, Illinois, USA, believes that overregulation by government, particularly the regulation of stem cells, presents a particular challenge to the development and implementation of emerging technology in the United States. Under the current FDA regulations stem cells are regulated as both a device and a biologic. Five orthopedic trials were withdrawn or canceled in 2013 due mainly to the inability to overcome the regulatory burden relating to study design and patient enrollment. There have been no new regulated products in > 16 years, due mostly to the conflicts between clinical reality and requirements set forth in the FDA Guidance Document.

In the only level 1 MSC study in the United States, adult human MSCs were delivered to the knee of 55 patients following partial medial meniscectomy [Vangsness CT Jr et al. *J Bone Joint Surg Am.* 2014]. Compared with controls, patients with OA who received MSCs experienced a greater reduction in pain along with evidence of meniscus regeneration at 2 years of follow-up ($P \leq .05$).

Human tissue and cellular and tissue-based products are placed into 3 categories: category 1 includes non-human tissue and cellular and tissue-based products; category 2 contains lower risk products (noncombination, minimal manipulated, nonsystemic effect, or autologous products labeled for homologous use only) such as allogeneic cartilage and minimally manipulated articular allografts; category 3 covers higher risk products such as placental cord blood and cultured bone marrow and fat stem cells [FDA. <http://www.fda.gov/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/tissue/ucm427795.htm>. Accessed April 2, 2015]. Each category is subject to specific regulations with regard to regulation and use.

One reason for the lack of studies has been the requirement for randomized controlled trials; however, a meta-analysis published in 2000 noted the lack of outcome differences between randomized clinical trials and well-designed observational studies; and the FDA has just approved an historical control trial using patient-level data on microfracture. Possible solutions to increase the number of trials include treating clinical solutions as an "orphan drug" situation, the use of 2:1 vs 1:1 randomization, the allowance for clinical heterogeneity, the inclusion of phase 1 and 2 data, assessing for noninferiority, and the ability to use registry data.

Dr Cole sees progress with FDA approval of devices coming more quickly and more opportunities for studies on the biologics.



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