

# FAI's Hip Damage Not Abated by Arthroscopy

BY DENISE NAPOLI

**A**rthroscopic surgery for femoroacetabular impingement did not eliminate the need for total hip arthroplasty in 10 of

Intraoperatively, all 20 patients were found to have "marked" generalized chondral damage as well as labral lesions. "Grade IV chondral lesions were localized at the impingement zone (ventral-cranial acetabulum) in 14 cases (70%) and at the corresponding femur in 3 cases (15%," wrote the authors. "Microfracturing was performed in these areas in a total of 15 cases (75%)." At the study's end, total hip arthroplasty had already been performed in eight patients, and two patients

were scheduled to undergo the procedure after the study's conclusion. Preoperatively, three of these patients had Tönnis grade I osteoarthritis, two had grade II osteoarthritis, and five had grade III osteoarthritis. A higher preoperative Tönnis grade increased the risk for subsequent THA significantly ( $P = .03$ ).

The remaining nine patients who had not undergone THA and were not planning the surgery did experience significant improvements in range of motion (internal rotation improved from 0.25 degrees preoperatively to 24.5 degrees following arthroscopy,  $P$  less than .001), flexion (from 110.8 to 125.0 degrees;  $P = .005$ ) and pain on the visual analog scale (from 6.0 to 1.8;  $P = .002$ ).

However, the authors said, it is unclear whether the index surgery slowed the degenerative process for the long term or whether a major part of improvement might have been because of the effect of articular debridement or therapy for labral tears rather than the correction of the causative lesion. Dr. Horisberger conceded that the study does have weaknesses. Nevertheless, "If preoperative examinations underestimate the real extent of chondral damage found on arthroscopy, particularly if extended grade IV lesions at the femoral head are seen, THA should be recommended without further joint-preserving treatment attempts," they asserted. ■

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The "discouraging" data indicate that arthroscopic surgery in patients with femoroacetabular impingement (FAI) involving more severe, generalized chondral lesions (grade II or greater on the Outerbridge scale) does not obviate the need for total hip arthroplasty (THA) or even lengthen the interval before the joint replacement procedure is required. "It seems obvious that these patients should not be treated by arthroscopic means," reported Dr. Monika Horisberger and her associates of the University Hospital Basel (Switzerland).

They looked at 150 patients with cam and mixed FAI. Of these, "20 patients showed intraoperative marked chondral lesions of Outerbridge grade II or greater not restricted to the direct impingement zone, and were therefore included in the study," they wrote (*J. Arthro.* 2010 Feb. 11 [doi:10.1016/j.arthro.2009.09.003]).

Preoperatively, according to the Tönnis classification, "[nine] hips had grade I osteoarthritis, [six] had grade II osteoarthritis, and [five] had grade III osteoarthritis." The mean age was 47.3 years (range, 22-65 years) and the mean follow-up was 3.0 years (range, 1.5-4.1 years). Half of the patients were male, and one patient died of causes unrelated to the study.

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# Lack of Effective Therapies May Prompt OA Guideline

BY HEIDI SPLETE

**S**ome osteoarthritis treatments are less effective than previously thought, judging from findings from a review of research conducted since 2006.

The goal of the update of published evidence is to determine whether the current Osteoarthritis Research Society International's (OARSI) recommendations for the treatment of OA, published in 2008, need to be modified. After reviewing this update and collecting feedback, the OARSI Treatment Guidelines Committee will determine whether changes are needed in 2010.

Acetaminophen use and surgical lavage and debridement were among the therapies that may be falling out of favor to treat knee and hip OA, but evidence supporting weight reduction is on the upswing, said Dr. Weiya Zhang, a rheumatologist at the University of Nottingham (England), and colleagues.

The researchers identified 64 systematic reviews, 266 randomized controlled trials, and 21 economic evaluations related to hip and knee OA that were published between January 2006 and January 2009. "Of the 51 modalities of treatment addressed in the OARSI recommendations, 35 have now been systematically reviewed with 16 new or updated systematic reviews in the last 3 years," the researchers wrote (*Osteoarthritis Cartilage* 2010 Feb. [Epub doi:10.1016/j.joca.2010.01.013]). They assessed the best available evidence for effect size (ES) with 95% confidence intervals for improving function and relieving pain and stiffness associated with OA.

The new evidence for nonpharmacologic therapies included several studies supporting weight reduction. Pooled data from two new systemic reviews showed improvements in pain (ES, 0.20) and physical function (ES, 0.23) after an average weight loss of 6.1 kg (approximately 13 pounds). The ES for pain relief for hip and

knee OA were not significantly changed for acupuncture, education, exercise, and self-management. New research on electromagnetic therapy showed a relatively small improvement in function (ES, 0.33) and no significant effect on pain reduction (ES, 0.16).

The review also yielded some changes in evidence for pharmacologic OA treatments, notably acetaminophen. A review of five new studies of acetaminophen for knee OA showed no significant reductions in effect size for pain relief (pooled

**VITALS** **Major Finding:** Experts will review new evidence to determine whether changes are needed to the OARSI guidelines for the treatment of hip and knee OA.

**Data Source:** An analysis of 65 systematic reviews, 266 randomized, controlled trials, and 21 economic evaluations.

**Disclosures:** Dr. Zhang had no financial conflicts to disclose. Several coauthors have received consulting fees, honoraria, and research support from multiple pharmaceutical and device-manufacturing companies. No potential conflict of interest was identified that would prevent any OARSI Ethics Committee members from participating in the review.

ES, 0.14). Other recent studies showed an increased risk of hospitalization because of perforation, peptic ulceration, and bleeding when acetaminophen doses of more than 3 g/day were used to treat OA (hazard ratio, 1.20). No data from recent studies identified significant changes in the risks and benefits of oral or topical NSAIDs, diacerein, or interarticular corticosteroid injections for treating OA.

For surgical treatments, pooled results showed no benefit for lavage, debridement, or a combination of the two for treating OA, compared with placebo. Effect sizes for pain relief, function improvement, and stiffness reduction were 0.21, 0.11, and 0.05, respectively.

The researchers noted that there is a need for "a continuously updated, comprehensive, and coherent database of well-characterized trials of all modalities of treatment of OA." But they emphasized that treatment guidelines must be based on the best evidence, not simply on updated cumulative evidence. ■

# FDA Rescues High-Concentration Oral Morphine Solution

BY JEFF EVANS

**A** concentrated oral solution of morphine sulfate has been approved by the Food and Drug Administration, rescuing a formulation that had been slated to be taken off the market last year until physician groups spoke up about its clinical utility and lack of equivalent products.

The approval of Roxane Laboratories' product cements the FDA's decision in April 2009 to

reinstate the high-concentration oral solutions of morphine sulfate to the market, but not other unapproved narcotic products for which the agency had deemed that acceptable alternatives were available.

The solution is indicated for moderate to severe, acute, and chronic pain in opioid-tolerant patients (defined as those who are taking the equivalent of 60 mg of morphine per day). It will be available in doses of 100

mg/5 mL and 20 mg/1 mL.

The FDA's decision is a part of the ongoing Unapproved Drugs Initiative that the agency began in 2006. Numerous other previously unapproved drugs, including some opioid formulations, have been approved through the initiative.

"It is a significant step toward ensuring that patients needing this medicine have access to a high-quality product," Dr. Douglas Throckmorton, deputy di-

rector of the FDA's Center for Drug Evaluation and Research, said during the briefing.

Dr. Throckmorton added that actions that "would limit the availability of this medicine could cause unnecessary hardship to these patients and limit the treatment options available to prescribers. As such, we are working with the manufacturer of the approved product, Roxane Laboratories, to make sure that here will be

enough approved drug for all patients. We will also be working with patient organizations and prescribers, so that they are both aware of this approved product.

Roxane met the FDA's standard for establishing the safety and efficacy of the oral solution by referring to the agency's prior findings for similar products. The manufacturer also gave the product a standardized drug label and a medication guide. ■