

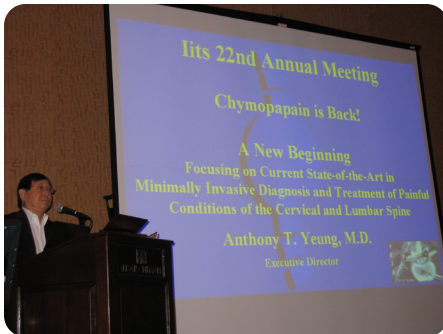
Orthopedics • This Week

Intradiscal Society at Crossroads

By Walter Eisner

When we last met with the endoscopic band of brothers of the International Intradiscal Therapy Society (IITS) in Albi, France, we wondered if the group's tools and strategies to treat spine disease would or should ever become mainstream.

At the IITS' most recent meeting in Phoenix from May 18 through May 23, we observed a Society at a crossroads about its future and place in the mainstream of spinal surgery



Anthony Yeung, M.D., Opening Session IITS09

Society Executive Director and former President Tony Yeung, M.D., delivered on his promise to provide a forum for scientific discourse, and allow for collegial presentations of ideas and debates. Given the level of debate we witnessed at the meeting, as well as the enthusiastic participation of spine surgeons and pain specialists during two days of live surgery and cadaver demonstration workshops at the Yeung family's (with son Christopher Yeung, M.D.)



Workshop at DISC

Desert Institute for Spine Care (DISC), it was clear that attendees walked away with practical ideas for their practices.

This meeting confirmed our appreciation for small, provocative and intimate gatherings where scientists/physicians can duke out concepts without the restrictions that often come with meetings of the larger societies. In a word, it was fun.

Between the meetings in Albi and Phoenix, the group co-sponsored the

first World Congress of Minimally Invasive Surgery and Spinal Techniques (WCMISSST) in Hawaii under the leadership of South Korea's Sang-Ho Lee, M.D., Ph.D. During the Society's business meeting in Phoenix, the group voted to have the next joint meeting of the World Congress and the IITS in Las Vegas in 2010. Tony Yeung will serve as president of that Congress.

In a healthy sign for the Society, members from Europe and Asia

pushed for holding future meetings on their home turf.

But back to the “mainstream” question.

“Surgeons, especially those in leadership roles at the major spine societies, often have academic appointments,” Yeung told OTW. “What they see, which is typically patients with complex spine problems, is far different from what a community surgeon who deals with patients in pain typically sees.” In their teaching, they [surgeons with academic appointments] have either consciously or unconsciously served to be an obstacle rather than a facilitator. That is why I believe IITS is needed, and why we can never be as effective being the stepchild of a major spine organization, even if, on the surface, we are accepted by organized medicine.”

A Healthy Debate: Rauschnig vs. Yuan

Nothing demonstrated that tension more than a staged point/counterpoint discussion between guest speaker Wolfgang Rauschnig, M.D., Ph.D., of Sweden’s University of Uppsala (invited by Society President Eric Gozlan, M.D.) and famed spine surgeon Hansen Yuan, M.D.

Yuan presented a historic review of what is and is not known about nucleus replacement in the disc. He described the treatment algorithm of the progressive invasiveness from conservative care to discectomy, disc herniations, total disc replacement, and fusion. He argued that in the future disc regeneration and nucleus replacement will provide clinical benefits to patients and address their pain.

Rauschnig, one of the world’s leading researchers of the anatomy of the disc with a vast collection of slide samples of discs from cadavers, argued that perhaps we should do less at an earlier stage to prevent the progression of the [disease] process.

In a debate that continued after their presentations on the podium, Rauschnig told OTW, “We do not really understand how this pathology

is progressing. Until a few years ago, fusion was all we knew. Now all of a sudden it’s motion preservation and people are adopting all types of stabilizing and motion preservation technologies.”

Rauschnig added, “I am not a spinal surgeon. In my big collection of slides I have pathologies including post-surgical cases, most of which have been completely silent, asymptomatic and benign. So it is not the pathology, but the pain generators in the lumbar spine pertaining to low-back pain and radicular pain syndromes. Yes, you can say this can hurt because of ‘this,’ but it needs clinical diagnostic means.”

Yuan said he agreed with what Rauschnig showed, but in the case Rauschnig used on the podium, he would not put in a nucleus because it was gone too far. “When it’s too far

gone, the weight bearing is no longer borne by the central disc, but by the rim,” added Yuan.

Yuan continued, “I’m talking about the fact that when the patient has discogenic back pain and total incapacity, those patients are not going in to ‘too-early’ surgery. They are totally disabled. Today you do fusion and we know that’s not a good thing. Today we should look at things that



Rauschnig and Yuan, “Mano-a-Mano.”

are less invasive. Nucleus replacement that is done percutaneously and is minimally invasive is very forgiving.”

“Nucleus replacement is less invasive compared to [replacing] a total disc,” emphasized Yuan. “For that [fusion] patient, I would do a nucleus replacement, if it is a correct one. Where I disagree [with Rauschnig] is that the patient is too far gone for any tissue engineering, gene therapy or regeneration, period.”

Finding Pain

Finding the pain was a recurring theme of the meeting, or as Yeung described it, “bridging the gap between pain management and surgery.”

David Bradford, M.D., Professor and Chairman of the Department of Orthopaedic Surgery at the University of California, San Francisco, discussed

developments in imaging chemical signatures of back pain.

Bradford noted that the recently reported result of a 10-year prospective study by Eugene A. Carragee, M.D., of Stanford University, suggesting that discography can result in accelerated disc degeneration and herniations, is “the first nail in the coffin of discography.”

Tony Yeung told OTW that it is possible to find and isolate one or more pain generators with the techniques available to surgeons, including discography. “The controversy comes from strong opinions from those who are interested in discography only from a research or academic point of view rather than a clinical position on refining the technique to help the physician decision-maker give the best advice he can give to his patient,” said Yeung.

keratin sulfate in the disc and correlating those findings with pain generation.”

Hansen Yuan was enthusiastic about Bradford’s talk on how to be able to identify lactic acid concentrations: “We keep talking about where the pain is coming from. What Bradford talked about is exciting to me. That’s chemistry and with chemistry we can measure.”

The Return of Chymopapain

Another exciting prospect presented at the meeting was the reintroduction of chymopapain.

Chymopapain was a therapy that soared and crashed during the 1990s. Baxter Laboratories acquired the product in 2001 (marketed as Chymodiactin) but decided to discontinue manufacturing it after some patients reported allergic reactions to the treatment.



Continued
Yeung,
“Some of the controversy with discography may be alleviated by new imaging capabilities (with a 3-tesla MRI) that measure the etiologic sources of pain, [such as] the measurement of lactic acid and chondroitin sulfate /

The product is an enzyme from the papaya fruit used to treat herniated discs. It is injected directly into a bulging disc and works by eating away the inner core of the disc. Some describe it as a “disc tenderizer.” The treatment is called chemonucleolysis and works by breaking down the inner disc, releasing water and shrinking the disc. This takes pressure off the nearby spinal nerve root, the source of the painful symptoms.

Chart Medical

Mike Hurd, the head of Chart Medical, offered attendees an update on his company’s efforts to reintroduce the drug in the U.S. and other parts of the world where it had been widely accepted.



Eric Gozlan, M.D., and Daniel Gastambide, M.D.

The FDA approved Chymodiactin as a pharmaceutical product in 1982. Chart Medical acquired the product in March of this year. Hurd noted that the product was not taken off the market by Baxter in 2001 for reasons related to safety or effectiveness.

According to Hurd, the vast majority of complications occurred in the first two years after the product was released in the U.S. in 1983, and most occurred among the first 10 patients treated by reporting surgeons. Hurd attributed the complications to inexperience with the diagnosis and needle placement by surgeons. In fact, says Hurd, chymopapain injection or chemonucleolysis procedures had fewer adverse reports than lumbar laminectomy for discogenic

radiculopathy procedures in the U.S. in 1980.

In international experience with over 43,000 patients who received the drug, the reported complication rate was 3.7% versus 24.8% for patients who underwent surgical procedures.

Chart Medical is currently in the process of pulling together a Chemical, Manufacturing and Control (CMC) Supplemental filing for the FDA to demonstrate that the product it is producing today is substantially equivalent to the product that was being produced by Baxter before it was discontinued. Hurd estimates the funding requirements necessary for initial commercialization of the product to be between \$5 million and

\$7 million.

Hurd told us that the initial launch of the product will be focused on 20 to 30 centers of excellence. Many of these centers have already agreed to participate in the product reintroduction. Distribution will primarily be direct with select regional distributors in the U.S. International distribution will be determined on a country by country basis.

Challenges of Success

Overall, the IITS meeting had more than 60 presentations which ranged from diagnosing and managing spinal pain, endoscopic approaches, surgical techniques, avoiding complications, evidence-based pain management, and stem cells to many other related minimally invasive subjects.

There were also 29 corporate sponsors and a modest exhibition space.

But the notion of this band of brothers still defining themselves as stepchildren to mainstream spine societies will be a challenge for the young surgeons who will assume leadership of IITS in the future. The presence of a sizeable percentage of surgeons from South Korea and China speaks to the reverence in which American surgeons like Tony Yeung and Hansen Yuan are held. The enthusiasm and clinical skills demonstrated by this new generation may hold the seeds for moving this group into the mainstream.

The presence and participation of SAS (The International Society for the Advancement of Spine Surgery) co-founders Hansen Yuan, M.D., and Stephen Hochschuler, M.D., pull like a magnet on IITS society leaders to move closer to incorporating their subspecialty into a larger organization.

Tony Yeung says that minimally invasive surgery should be a true subspecialty rather than a gimmick to get patients to seek out the MIS surgeons. "What we do will likely become a subspecialty because it is difficult to become good without dedication to the art and technique of true MIS surgery," said Yeung.

He also issued a note of caution.

Yeung said his son and surgical partner, Chris, has expressed some concern over teaching non-surgeons because they may get into trouble quickly as they do not have the skills of experienced surgeons. There is no control over their activities since many own their own outpatient facilities that they can convert into surgical centers. Teaching too many too fast could actually end up hurting the cause of MIS.

Challenges of Succession

During a final session of the meeting, Hansen Yuan echoed those remarks. Yuan said that the positive clinical results of exceptional and experienced surgeons like Yeung now have to

be studied, documented and taught systematically to assure that new surgeons can replicate those results. Stephen Hochschuler said that IITS should step up to define what makes sense and what doesn't make sense from a clinical standpoint.

The IITS being turned over to incoming President Daniel Gastambide, M.D., of France faces the challenge of moving from being revolutionaries to becoming governors. From what we saw, Tony Yeung and the founding band of brothers have succeeded in demonstrating the safety and effectiveness of their craft, and a new generation is ready to step into the mainstream. ♦

Orthopedics This Week is published 40 times a year by RRY Publications LLC, a subsidiary of Robin Young Consulting Group.

100 West Main Street, Suite 350, Lansdale, PA 19446 1-888-352-1952 www.ryortho.com

Reprinted with permission of RRY Publications LLC

© Copyright 2020 RRY Publications LLC