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Orthopedics This Week

week in review

picture of success

breaking news

For all news that is Ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Really excellent buying interest just prior to second quarter earnings reports. Despite an overall market malaise, investors are paying attention to orthopedic stocks and anticipating decent reports from folks like OFIX, EXAC, WMGI and KNSY.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	13.5i1%	14.54%	OFIX is a gift. By three valuation measures the least expensive ortho stock. By track record, the most likely to beat expectations.
2	4	Kensey Nash	38.72	13.36	You like cash? KNSY's got cash. You like cash flow? KNSY's got cash flow. You like cheap? 13x P/E!
3	2	Johnson & Johnson	27.1	4.07	JNJ trades on another planet from the ortho crowd but it still forms an important plank in any ortho platform.
4	5	Exactech	12.72	9.33	There is a fundamental inconsistency in analyst forecast for EXAC. Zero earnings growth on 11% sales growth? That's a stretch.
5	3	Symmetry	11.48	8.09	Last quarter institutional holders sold 29% of their holdings. Stock is up 8%. Who is buying? And why?
6	7	Wright Medical	5.61	6.39	Upgraded by RBC to outperform just prior to second quarter report. Analysts looking for 8% sales growth.
7	6	Smith & Nephew	22.83	1.28	SNN is the $4 billion orthopedic company that gets no coverage. Only three analysts. Stryker, by contrast, has 25. Go figure.
8	10	Stryker	24.71	6.18	Speaking of the mob that covers SYK, in true herd style they're predicting 9% sales growth. Sounds about right.
9	8	Zimmer	27.69	5.64	Twenty-two analysts cover ZMH. They're expectations are low—only 5% sales growth. It's tough being the industry's boy scout.
10	9	Integra LifeSciences	15.37	(1.38)	The market was trained to view IART as a deal stock. With 25% earnings forecast, maybe IART is an operating company?

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Synthes	SYST.VX	$122.91	$14,587	18.0%
2	Orthofix	OFIX	$32.84	$578	14.5%
3	Kensey Nash	KNSY	$23.51	$229	13.4%
4	Exactech	EXAC	$18.05	$232	9.3%
5	Symmetry Medical	SMA	$10.82	$389	8.1%
6	Wright Medical	WMGI	$17.49	$679	6.4%
7	Stryker	SYK	$52.38	$20,780	6.2%
8	Zimmer Holdings	ZMH	$56.22	$11,400	5.6%
9	*Average*			*$11,234*	*4.1%*
10	Johnson & Johnson	JNJ	$60.54	$166,970	4.1%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Orthovita	VITA	$2.12	$163	(17.83%)
2	TranS1	TSON	$2.58	$53	(14.85%)
3	TiGenix	TIG.BR	$2.15	$66	(9.44%)
4	RTI Biologics Inc	RTIX	$2.93	$160	(8.15%)
5	CONMED	CNMD	$17.93	$523	(7.58%)
6	Capstone Therapeutics	CAPS	$0.68	$28	(4.23%)
7	NuVasive	NUVA	$35.31	$1,380	(3.71%)
8	ArthroCare	ARTC	$29.15	$786	(2.83%)
9	Mako Surgical	MAKO	$12.26	$414	(2.31%)
10	Osteotech	OSTE	$3.03	$55	(1.94%)

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Medtronic	MDT	$37.23	$40,320	11.23
2	Kensey Nash	KNSY	$23.51	$229	12.76
3	Johnson & Johnson	JNJ	$60.54	$166,970	12.97
4	*Average*			*$11,234*	*13.05*
5	Zimmer Holdings	ZMH	$56.22	$11,400	13.55

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$45.95	$8,170	64.88
2	RTI Biologics Inc	RTIX	$2.93	$160	48.72
3	NuVasive	NUVA	$35.31	$1,380	31.93
4	Symmetry Medical	SMA	$10.82	$389	21.59
5	Orthofix	OFIX	$32.84	$578	18.00

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CryoLife	CRY	$5.66	$162	0.67
2	Orthofix	OFIX	$32.84	$578	0.74
3	NuVasive	NUVA	$35.31	$1,380	0.80
4	Alphatec Holdings	ATEC	$4.59	$401	0.83
5	Exactech	EXAC	$18.05	$232	0.95

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CONMED	CNMD	$17.93	$523	7.00
2	Symmetry Medical	SMA	$10.82	$389	2.04
3	Johnson & Johnson	JNJ	$60.54	$166,970	1.99
4	*Average*			*$11,234*	*1.72*
5	RTI Biologics Inc	RTIX	$2.93	$160	1.52

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$3.03	$55	0.56
2	CONMED	CNMD	$17.93	$523	0.74
3	RTI Biologics Inc	RTIX	$2.93	$160	0.98
4	Orthofix	OFIX	$32.84	$578	1.06
5	Symmetry Medical	SMA	$10.82	$389	1.07

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$2.15	$66	64.39
2	Mako Surgical	MAKO	$12.26	$414	10.71
3	Synthes	SYST.VX	$122.91	$14,587	4.30
4	NuVasive	NUVA	$35.31	$1,380	3.43
5	Stryker	SYK	$52.38	$20,780	3.01

Orthopedics on the Edge

By Jacqueline Rupp

U.S. Soldiers in Sadr City/Wikimedia Commons

In medicine, necessity certainly does springboard invention. For the U.S. Armed Forces, regenerative medicine is probably a necessity no one wished they'd have to tackle. But the need is of course there. We've all seen the images of U.S. soldiers returning home with battle scars that have no hope of healing. Lost limbs and improvised explosion device injuries (accounting for a startling 75% of injuries according to the *Journal of Orthopaedic Trauma*) are now common place in military hospitals. Today we're able to keep wounded soldiers on the battlefield alive, but they are returned home severely disabled. Two years ago the government decided to do more than just search for better artificial limbs or technologically-advanced prosthetics. Instead the Armed Forces made the bold step to dive head first into the futuristic world of regenerative medicine.

And so the Armed Forces Institute of Regenerative Medicine (AFIRM) was born.

It almost makes for the perfect sci-fi movie: combine top secret military maneuverings with experimental medicine and visions of lab-grown limbs get conjured up. Except there is very little secrecy or military status quo to this project. This project is ambitious not just because it's about stem cells and growing new body parts. It's also unique in its scope and collaborative spirit. This is after all the first time in the country's history where every branch of the military has come together and aligned themselves with top-tier medical researchers.

A Web of Research

The Department of Defense describes AFIRM as a "multi-institutional, interdisciplinary network working to develop advanced treatment options for severely wounded servicemen and women." Receiving funds from the U.S. Army Medical Research and Materiel Command along with other branches of the service including the VA and matched funding from public and private donors, the Institute is divided into two distinct consortia, with each working in conjunction with the U.S. Army Institute for Surgical Research (USAISR) out of Fort Sam Houston, Texas.

The Rutgers and the Cleveland Clinic consortium:

- Rutgers, The State University of New Jersey
- Cleveland Clinic
- Carnegie Mellon University
- Case Western Reserve University
- Dartmouth Hitchcock Medical Center
- Massachusetts General Hospital/Harvard Medical School
- Massachusetts Institute of Technology
- Mayo Clinic
- Northwestern University
- Stony Brook University
- University of Cincinnati
- University of Medicine and Dentistry of New Jersey
- University of Pennsylvania
- University of Virginia
- Vanderbilt University

The Wake Forest University and The McGowan Institute for Regenerative Medicine at the University of Pittsburgh consortium:

- Wake Forest University
- McGowan Institute for Regenerative Medicine, University of Pittsburgh
- Allegheny Singer Research Institute
- California Institute of Technology
- Carnegie Mellon University
- Georgia Institute of Technology
- Oregon Medical Laser Center
- Rice University
- Stanford University
- Tufts University
- University of California, Santa Barbara
- University of Wisconsin
- Vanderbilt University

AFIRM Press Conference/ Wikimedia Commons

Each consortium received $42.5 million to divvy up over five years (so three more years to go!) but additional public and private sources meant that nearly triple that amount could be counted on for spending, with the lead groups handling distribution.

But enough about budgets, let's get to the research!

The main goal of this Institute is to streamline research and turn bold aspirations into actual outcomes. From their respective regenerative projects.

An interesting offshoot of these academic and defense collaborations is the role the medical device market has played. Ever a willing participant in innovation, commercial partners are clamoring to join this exclusive club with the benefit of future civilian applications dancing in their heads.

Like medical innovations of the past, today's battlefield injuries are spurring medical researchers on, challenging them with polytraumatic blast injuries that generally involve massive soft tissue loss, infection and damaged blood vessels. But there's also no denying that any regenerative advancements for wounded warriors will have beneficial results for the rest of us too.

Edward Anthony Rankin, M.D., Chief of Orthopaedic Surgery at Providence Hospital in Washington, DC, and former Chief of Orthopaedics at Walson Army Hospital and President of the

AAOS (American Academy of Orthopaedic Surgeons), says AFIRM is an impressive example of collaboration and funding. "AFIRM is really spectacular and the fact that defense sectors are working with civilian institutes is really promising. I don't think we have seen any type of collaboration on the scale before." Rankin also looks to the future applicability of this research. "Many major medical advances have come from war. If you look at how our trauma centers are set up, that comes directly from lessons we learned during the Vietnam War. This research in time will undoubtedly become beneficial to the civilian population. But it might not have become a reality if it had not been for this need."

The Rutgers/Cleveland Clinic Consortium (RCCC)

Led by Rutgers's Professor Joachim Kohn, Director of the New Jersey Center for Biomaterials and George Muschler, M.D., orthopedic surgeon at the Cleveland Clinic, RCCC has a host of exciting research projects going on. Here are just a few of the highlights:

The RCCC Limb Salvage and Regeneration Program

- Optimizing Cell Sources for Repair of Bone Defects: The Cleveland Clinic is working to develop tools that will allow for the harvesting, collecting, processing and concentrating of key osteogenic connective tissue progenitors (CTP-Os) for bone repair. This includes a machine that can be used in the OR that will deliver rapid concentration and selection of stem cells.

- Molecular Surface Design (MSD) for Controlled Cell- and Tissue-Scaffold Interactions: How do you get cells to play nice with implanted material? The goal here is to create a molecular surface design method that cells and tissues won't be able to resist. The bioactive material could then be attached to bone scaffolds. The beauty of this project is that it can work hand-in-hand with other AFIRM projects that focus on developing advanced scaffolds.


Hand Transplant/Wake Forest Pittsburgh Consortium

In addition to these Limb Salvage projects, the RCCC is also working on nerve regeneration (Optimizing Nerve Conduit Scaffolds for the Repair of Segmental Nerve Defects, Optimizing Cell Sources and Local Drug Delivery to Enhance the Repair of Segmental Nerve Defects), facial reconstruction (maybe you heard about the nation's first full facial transplant?) and burn/scaring projects.

The Wake Forest Pittsburgh Consortium

Similarly, the Wake Forest Pittsburgh Consortium is focused on individual projects within the five areas of AFIRM focus, led by Anthony Atala,

M.D., of the Wake Forest Institute for Regenerative Medicine and Rocky S. Tuan, Ph.D., Director of the Center for Cellular and Molecular Engineering at the University of Pittsburgh. Here's what they've got going on:

- Recruiting Cells for Regeneration: The inspiration for this project came from the humble salamander, which can re-grow limbs as needed. The team is hoping to figure out a mechanism for bringing a large number of stem cells to the site of an injury where re-growth is needed. But the team also has to figure out how to tell the cells what's needed to be grown—a finger, a toe, an arm?

- Hand Transplantation: Although hand transplants are currently available, one major drawback to the procedure is the course of disruptive anti-rejection drugs that a patient is required to take for a lifetime. This research team is working to reduce this burden by using bone marrow cells with novel proteins to allow for better acceptance of the transplant.

- Oxygen Generating Biomaterials: When blood supply is road blocked because of injury, tissue is deprived of oxygen which limits healing. But if there was an injectable form of oxygen-producing biomaterial, this could not only nourish the tissue but help foster viable blood vessel networks.

- Identifying Genes Involved in Limb Regeneration: Taking a nod from the promise of extracellular matrix research, this project is working to identifying the genes that play a role in regeneration.

Ironically, regenerative medicine itself is getting renewed life from this project. After an initial surge in interest at the turn of the millennium, interest seemed to flounder when the realities of research showed that progress would not be an overnight sure-thing. AFIRM is proving that is takes a strong commitment and serious funding to allow scientists to explore these ambitious possibilities. But the collaborative spirit of divergent groups working together is also pretty darn inspiring in itself.◆

Biologics Trumps Bionics

By Robin Young

Why replace arthritic knees with metal and plastic components when you can simply transplant a fresh and healthy replacement cartilage? Or, perhaps, more to the point, can meniscal allograft transplants work as well as traditional total knee arthroplasty (TKA) over the long term? A new study published last week in the UK version of JBJS (Journal of Bone and Joint Surgery) is the longest and largest prospective study of meniscal allograft transplantation and articular cartilage repair in patients with significant chondral damage in history. Finally, we may have an answer to these two very interesting questions.

Before this study, the literature described patients with minimal chondral damage and follow up was typically under 24 months with one exception—Verdonk et al. described 100 meniscal allograft transplants with a mean follow-up of 7.2 years.

Every year, approximately 608,000 total knee replacement operations are performed in the United States. But nearly four times that number of patients see physicians for meniscal derangement, articular cartilage disorders or cartilage tears of the knee. In 2009, according to PearlDiver estimates, there were fully 2.5 million cartilage repair interventions of one kind or another.

Along the way to TKA are a range of therapies that attempt to slow down the chronic deterioration of the knee joint. Hyaluronan acid (HA) knee injections, for example, are performed approximately 850,000 times each year. This study clearly shows the potential of meniscal transplants and pulls back a curtain on a future where biologic repair might actually trump bionic repair.

Kevin R. Stone, M.D./Inc. Magazine

The study followed patients for as long as 12 years (which is the longest such follow-up for meniscal transplants). The average length of six years follows as the second longest timeframe, with reported outcomes at specific time intervals along the way. For sure, such a long road map has necessary detours and road bumps (like subsequent knee interventions) but it is still a road map. And, with 115 patients in the study, a well populated map at that! Here's the link: (http://stonere-

search.org/pdf/Stone.MeniscusSurvival.JBJSBr.2010.pdf). And here, like a Sanborn's travel guide, is our summary of this study's high and low lights along the road to biologic knee repair.

Authors Stone, Adelson, Walgenbach, Pelsis and Turek (from The Stone Clinic in San Francisco) started with patients who suffered long-term problems. Of the 119 transplants, 118 were associated with chronic injuries, defined as a period of three or more months from the time of injury to surgery. The mean time from the injury to surgery for the patients in this study was 14 years, although one rugged individual had waited nearly 40 years for this treatment.

This was a tough crowd. These patients had been in pain for, on average, 14 years. They'd had, on average two prior surgeries. And they were class IV and III Outerbridge.

Most of the patients had had other interventions before this transplant. On average, these patients had 2.1 procedures (0 to 9) performed on the affected knee prior to meniscal allograft transplantation. Post-operatively, a little under half of the patients had further surgeries but none had a total knee replacement.

Finally, the surgeries were, in fact, a bundle of procedures. On average, the study's authors performed five procedures in addition to implanting an allograft meniscus. What were the other procedures?

- Articular cartilage paste grafting (n = 67)
- Microfracture (n = 69)
- Medial opening tibial osteotomy (n = 15)
- Anterior cruciate ligament reconstruction with a bone-patellar tendon-bone allograft (n=10)
- Middle-third patellar tendon autograft (n=6)
- Tendon Achilles allograft (n=1)

For the record, there was no significant difference in the average number of concomitant procedures between those cases that failed (5.3, SD 1.6) and those that did not (4.9, SD 1.7) (p = 0.333).

The implants were all donated cadaveric meniscal tissue. Most were fresh-frozen (n=94) or cryopreserved (n=24) but one was irradiated.

These patients had seriously bum knees. One of the most commonly used measures of knee deterioration is the Outerbridge visual classification system. The five grades of the Outerbridge system are:

1. Grade 0 - normal
2. Grade I - cartilage with softening and swelling
3. Grade II - a partial-thickness defect with fissures on the surface that do not reach subchondral bone or exceed 1.5 cm in diameter
4. Grade III - fissuring to the level of subchondral bone in an area with a diameter more than 1.5 cm
5. Grade IV - exposed subchondral bone

A big old 82% (97 knees) of these patients were Outerbridge grade IV—the worst level—and the remaining patients in the study (n=22) had Outerbridge grade III injuries. This was a tough crowd. These patients had been in pain for, on average, 14 years. They'd had, on average, two prior surgeries and they were class IV and III Outerbridge. Ok, let the games begin.

How did the meniscus transplants perform?

Specifically, patients reported statistically significant improvements in pain and activity levels as compared to baseline levels and those improvements, with a single exception, stayed in place for up to ten years post-operatively. The single exception was in the Tegner score where, for the seventh year, the reported pain relief and activity level declined from the fifth year but then rebounded in the tenth year. But that was the only case. Every other measurement showed strong and consistent gains.

Three-Year Post Menallo

Here's the discussion from the paper:

> "Apart from the Tegner index score seven years post-operatively, all patient-reported subjective outcome scores showed a significant improvement at all intervals. Comparison between patient-reported subjective outcome scores over the two to 12 years of follow-up showed no significant changes, indicating

Meniscus Allograft

maintenance of improvement over time. Wilcoxon's rank-sum revealed a non-significant change of median Tegner index from baseline to seven years (p = 0.076). At baseline, the mean Tegner index score was 0.38 (SD 0.22; 0 to 1); the mean Tegner score was 3.2 (SD 2.0; 0 to 9). At seven years, the Tegner index ratio was 0.49 (SD 0.28; 0 to 1). The mean Tegner score was 3.9 (SD 2.3; 0 to 7). It should be noted that the comparison of seven-year scores with baseline is based on a small number of reported scores (n = 21), and that no significant difference is seen when seven-year Tegner index data are compared with the two- (p = 0.159), three- (p= 0.159), five-(p = 0.170) or ten-year (p = 0.842) post-operative intervals, using the Wilcoxon's rank-sum test. In only seven knees (5.8%) was more severe pain described at the most recent follow-up on the isolated WOMAC pain question compared with the baseline value. Median baseline pain score was 1 (mild) among these patients, and all nine reported only one pain level higher at the most recent follow-up."

What should patients and their surgeons expect post-operatively?

Having a meniscal transplant did deliver statistically significant pain relief and activity improvement for the vast majority of patients in this study. But it did not necessarily mean the end of surgery. Forty-seven percent of the patients (n=56) required up to five additional operations. Those operations included:

- Debridement (n=73)
- Chondroplasty (n=39)
- Notchplasty (n=16)
- Microfracture (n=8)
- Removal of osteophytes (n=12)
- Removal of loose bodies (n=11)
- Articular cartilage past grafting (n=7)
- Excision of a Baker's cyst (n=2)
- Anterior cruciate ligament reconstruction (n=1)

Failures and Complications

About 19% of the patients required further operations on the meniscal transplant itself. These operations were 14 medial and 9 lateral partial meniscectomies. In seven of the knees that underwent subsequent partial meniscectomy, the meniscal transplant eventually failed. One patient went on to have a total knee replacement.

The study's authors performed eight revision surgeries (6.7% of the total) with one patient undergoing two revision surgeries. The authors revised six knees during the early post-operative period at a mean of seven months (1.9 to 12.4). It turns out that three of the patients failed to follow their rehabilitation protocol, and one patient felt the allograft tear while turning over in bed two months post-operatively. The authors revised two of the cases more than three years after the primary operation, one at four years, and one at 3.3 years, and then again 2.5 months later. The patient whose knee required two revisions still had an intact meniscus at the end of the study—which was 7.6 years after the patient's primary operation.

Two of the revision cases ultimately failed and one of those elected to have the allograft removed at 1.7 years while another chose to have a knee replacement at 3.9 years. One of the patients who had a revised meniscal transplant died at 4.7 years post-op with an intact meniscus. The remaining five revision cases are considered by the study's authors to be non-failures at a mean of 2.5 years (1.0 to 4.4).

The most common post-operative complications were infections and those occurred in only four knees. Three of these infections were deep, while one was superficial. All of the infection cases were treated by the study's authors arthroscopically with irrigation, debridement and intravenous antibiotics. All infections resolved, but one deeply infected knee ultimately suffered failure of the allograft, which was subsequently removed 12.5 months later.

All in all, this was a kicking good study which was dense with valuable and practical information. Hopefully, surgeons on this side of the pond will take note.◆

Confessions of a Reviewer

By Walter Eisner

At the recent Innovative Techniques in Spine Surgery meeting in Los Cabos, Mexico, spine surgeons on a panel were complaining about insurance companies.

That's not newsworthy.

The speakers at the Drs. Frank Phillips, Todd Albert and Alex Vaccaro meeting were speaking in general terms about insurance company reviewers denying surgeons' requests for spine procedures as a matter of course. The speakers obviously were preaching to the choir, receiving lots of nodding heads from their colleagues in the room.

One lone voice spoke up.

"Not so," said the lone voice belonging to Gaetano Scuderi, M.D.

Morguefile

"I'm a spine surgeon *and* a reviewer for insurance carriers. I can tell you that I routinely approve spine procedures if the surgeon provides the information required to let me see that the procedure is in the best interest of the patient."

The exchange and ensuing conversation between the surgeons was a vivid reminder of why, in spite of frequent complaints that there are too many spine meetings, there is a need for surgeons to meet and share their experiences.

The science of spine care is unsettled. The opportunity for surgeons to learn from Scuderi, their colleague reviewing their requests to get insurance coverage for a procedure for their patients, only moves the science along and benefits individual patients. It just shows that more opportunities for spine surgeons to get together should be encouraged.

New Era of Decision Making

"We are entering a new era," Scuderi told *OTW*. "Peer review and evidence-based medicine are increasingly being factored into the decision making process. Cost containment, while providing value for services, is becoming the norm. For too long we have accepted irrational disbursement of medical care. Recall bias and errors by physicians cause more mishaps and deaths monthly than 9-11. Doctors are fast no longer becoming the captain of the ship—except when he or she gets sued—and even there that argument has worn thin."

"The new era I am talking about refers to the difficulty in getting 'fusions' approved following traditional discectomy or laminectomy. More data has been published showing no significant improvement over conservative care, and fusion is very expensive. Unless someone can show increased work capacity or earlier RTW (return to work), to justify the added cost, this will be increasingly difficult."

Scuderi brings some gravitas to his comments. He's a Clinical Assistant Professor at Stanford University, a Diplomat of the National Board of Medical Examiners, holds four patents, including one on biomarkers and methods for detecting and treating spinal pain. Scuderi has also published 35 arti-

"As a reviewing doctor it is not uncommon for me to know more about the patient than does the treating doctor."

cles that include physician coauthors named Garfin, Vaccaro and Carragee.

He's also been an orthopedic reviewer for 15 years and performs reviews for several local and national companies. They include medical insurance companies, auto insurance and contract review companies.

"Often it is difficult to assess the treating providers' thoughts based upon the file and charts that I receive. Physicians are not adept note takers and often don't use accepted medical language that will prompt simple approval. My goal is to consider what the best care is for the patient. I try to do my best in determining if a patient will derive a clinically significant benefit from a recommended intervention."

"My perspective is that the insurance companies are just trying to obtain the best outcome for intervention. Increasingly they are turning to evidence-based medical outcomes, though there isn't much in the landscape."

Spine Surgery Influence Model

One of the examples on the landscape is the Spine Surgery Influence Model put into effect on March 22, 2010, by UnitedHealthcare in Arizona, California, Colorado, Missouri, Ohio, Texas and Wisconsin, effective March 22, 2010.

The model is intended to improve the quality and consistency of care for patients who are undergoing inpatient spinal procedures through the use of evidence-based guidelines, review of medical records and peer-to-peer discussions of selected cases. The process is not a precertification, preauthorization, or medical necessity determination.

The insurer says the process will be used as an educational program to "promote physician discussion around providing spinal care consistent with nationally developed guidelines." The insurer also says that the application of this model is, "expected to result in a reduction of unnecessary spine surgeries."

The model leverages existing notification requirements and processes to compare the planned procedure to predefined criteria established by North


Gaetano Scuderi, M.D.

American Spine Society Guidelines (NASS) and Milliman CareGuidelines to determine adherence with guidelines for the planned inpatient spine surgery.

Inappropriate Procedures

Cases found to be inconsistent with guidelines will be reviewed by licensed staff using requested medical records. If the secondary review of the case does not demonstrate adherence to the guidelines, a health services medical director will engage the surgeon in a peer-to-peer discussion to better understand the therapeutic decision made for the patient. The surgery will be covered regardless of the outcome of this medical review process.

The request for medical records and/or a peer-to-peer discussion is triggered by the receipt of a notification from a physician for an inpatient spine surgery that is considered "potentially inappropriate," by the NASS and Milliman guidelines. The initial reason the procedure may be considered "potentially inappro-

priate" could be due to limited information contained in the notification. The request for records is to obtain more detailed information as suggested by evidence-based guidelines, and to determine whether a peer-to-peer discussion should occur. While UnitedHealthcare facilitates this discussion, the insurer says the ultimate decision about appropriate treatment is still in the hands of the physician.

No claims payment reductions will take place, even if the procedure is found to be inappropriate during the notification process, or if there is lack of participation in clinical record submission and/or peer-to-peer discussion.

Lessons From the Reviewer

Scuderi says the current treating provider often has no idea of what was done in the past, what did and did not work, what co-morbid conditions the patient may have that would preclude a particular surgery or intervention that might put the patient at risk.

"Sometimes there is a lack of knowledge on what the peer-reviewed research informs on a specific intervention. Physicians need to be aware of current literature and if they are recommending something outside usual parameters, be ready to justify their decision-making process," says Scuderi.

According to Scuderi, surgeons commonly use the PA (physician's assistants) or ARNP (advanced registered nurse practitioners) to do the initial evaluation. The surgeon on the next visit sees the patient personally and for the PMH portion states "See Past History" or "See Medications" without ever having consulted these data.

"As a reviewing doctor it is not uncommon for me to know more about the patient than does the treating doctor," added Scuderi. "When I speak to the treater and inform him/her of co-morbidities, or that what the patient had is uncommon to what the physician recommended previously, the reply many times is 'Oh. I did not know that. Then that changes my opinion about what should be done. Thanks for telling me.'"

Physician's assistants, as well as advanced registered nurse practitioners, commonly see and screen patients, or at the very least write the notes or dictate for the attending physician. Scuderi notes that these individuals are usually not familiar with important phrases in getting a treatment approved.

Confession

But sometimes even a review pro hits a snag.

Recently Scuderi was the subject of a review for a procedure that was subsequently denied. "I probably did a poor job in communicating my intentions and rationale to the physician reviewer and subsequently the intervention was denied. A written appeal thoroughly outlining my justification led to a successful outcome.

"In retrospect, I should have included my thought process into my original surgical recommendation which probably would have obviated the process."

Documentation is very important to reviewers. Scuderi says reviewers are looking to save the treating physician's time and prevent unnecessary delays in patient care. If proper documentation describing the necessity of an epidural injection, for example, describes a positive SLR test and dermatomal pattern consistent with a disc herniation finding on MRI, then it is likely to be approved.

"Contrarily, a disc bulge identified on an imaging study together with a lack of any specific findings and no tension signs and the complaint of primarily low back pain will likely lead to reviewer denial of a proposed epidural injection," Scuderi warned.

As Scuderi said earlier, increasingly, carriers are turning to evidence-based medicine to assist in ultimately determining if a treatment will be allowed.

The Discography Hotbed

A current hotbed, according to Scuderi, is in the area of spinal fusion

surgery, where surgeons are required to document the necessity of stabilization following a procedure.

"With current evidence on discography quite negative, (long-term complications, accelerated degeneration and failure of this diagnostic modality to improve outcomes of fusion), reviewers are increasingly denying this diagnostic! We need the Academy/NASS to step up and coordinate a multicenter study (especially from big volume centers) to show carriers the utility of these interventions. Maybe the answer is in the high volume centers, like they found in cardiac surgery and hip replacement surgery," concluded Scuderi.

Scuderi may have been a lone voice in Los Cabos, but he's worth listening to.◆

Hear Ye, Hear Ye: The AAOS COP

By Elizabeth Hofheinz, M.P.H., M.Ed.

RRY Publications

Dr. Smith: "I can testify to the fact that this patient's right leg is longer than his left leg." Attorney: "And you measured the patient's legs, correct?" Dr. Smith: "Well, no—I estimated it."

This is a situation that might appear on the desk of Dr. Murray Goodman, Chair of the American Academy of Orthopaedic Surgeons (AAOS) Committee on Professionalism (COP). Dr. Goodman describes the origins of the committee: "In 2001 the Florida Orthopaedic Society approached AAOS with the concern that errant expert witness testimony was rampant in their state. The issue was brought before the Board of Councilors and they felt that this was something that should be addressed by the Board of Directors [BOD]. The Board then conducted two surveys of AAOS members and found each time that an overwhelming majority of the membership felt that this was a critical issue."

The Board of Directors decided on a two-pronged approach, says Dr. Goodman. "The first goal was to educate the membership on the ethical principles of expert testimony, i.e., that it should be fair and impartial, etc. The second goal was to create an Expert Witness Affirmation statement that asks members to attest that they will abide by certain principles in testifying. Over 7,000 of our members signed this document, something that has often cropped up during trials. An opposing attorney might ask, 'Are you aware of the AAOS affirmation statement and did you sign it?' and, 'Is your testimony in compliance with that statement?'"

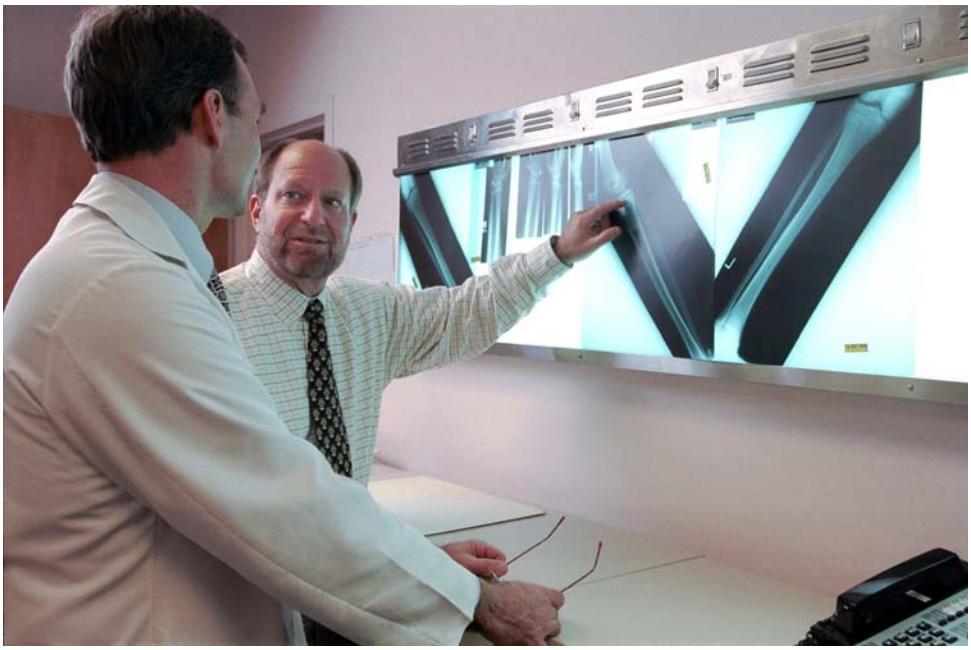
"Why stop at the courtroom?" they thought. Dr. Goodman notes, "It became apparent that there were issues in other arenas, so we began exploring a set of minimal standards for professionalism. Today we have standards covering six topics: Advertising by Orthopedists, Providing Musculoskeletal Services, Professional Relationships, Expert Witness Testimony, Industry Conflicts of Interest, and Research and Academic Responsibilities. As the process evolved, the Board determined that only an AAOS member could file a grievance against any other AAOS Member for a perceived violation of the standards, and that the COP

"We tell surgeons that if they are giving their opinion they should clearly state that it is opinion…and that if it differs from the majority opinion then they should explain why."

would hear both sides of the story; we then would make a recommendation to the Board of Directors. Early on we decided that it was most appropriate to do this in stages…merely because someone files a grievance doesn't mean it should escalate to a board level."

It is important, of course, to sort out the situations that merit attention versus those that resemble playground finger pointing. Dr. Goodman: "Any complaint is first screened by the General Counsel's office to determine if it is valid. For example, the general counsel will examine whether the expert witness testimony was given after the standard of professionalism was enacted, and whether or not there is documentation of what allegedly happened. Only after this step does the issue come before the COP, at which point we review all of the available information provided by both parties. We then decide whether there is sufficient evidence of a violation of a Standard of Professionalism in order to hold a hearing. This is called *prima facie* determination. If we see a potential violation then both parties are notified that there will be a hearing."

"Each side is allowed 30 minutes to make a presentation and 5 minutes to question the other party. Each person may have an attorney present, as well as another physician or witness. Then the COP meets and discusses each of the allegations. If we determine that there was a violation of the Standards of Professionalism, then we decide what, if any, disciplinary action to recommend to the BOD."



American Academy of Physician Assistants.

So how to decide whether the person receives a serious wag of the finger or, for example, a more significant punishment—expulsion from the membership? Dr. Goodman: "One physician was suspended for a year because he testified too narrowly about the standard of postoperative care regarding the timing of beginning formal physical therapy; he failed to review medi-

cal records that he should have known were available and that contained important information which called his testimony into question. Some of his testimony before the committee clearly contradicted his previous sworn testimony. Another physician was disciplined because of his narrow interpretation of the standard of care regarding leg length discrepancy following total hip arthroplasty. Other witnesses were not disciplined when it became apparent that their testimony was accurate and that the Grievant (person submitting the complaint) was actually the one who deviated from the standard of care."

"There may be no disciplinary action or there may be censure, which involves an official letter to the person, as well as publication to the membership of what has transpired. If the person is suspended (which may last up to three years) or expelled from the membership, then his or her name by law must be reported to the National Practitioner Data Bank (this does not happen at the COP stage, but only if the BOD takes the recommended action). We then issue a full report and both parties are notified of the decision and of the fact that either can appeal. If this happens, then the AAOS Judiciary Committee will hear the appeal (but not new evidence). They are looking to verify that due process was afforded to both individuals and that the weight of the evidence supports the recommendations of the COP. After the Judiciary Committee weighs in then the issue goes before the BOD, which decides whether there should be disciplinary action."

So what if after the prima facie stage Dr. A is still insistent that Dr. B acted improperly? "If the COP finds that there was no prima facie evidence then the surgeon making the complaint can post a bond to pay the expenses and force the committee to continue. This has happened on two occasions, both in relation to expert witness testimony. As you can imagine, this can drag on for quite some time. In Massachusetts, for example, a malpractice case takes an average of six years, meaning that the defendant carries this accusation a long time. This person can get bitter and think, 'I went through all this because some expert witness said I did something wrong, but in fact he testified incorrectly.' This raises the point that the COP must adhere to its mission. In a situation such as the one above, the surgeon may say, 'I testified that XYZ was the standard of care and the jury agreed with me.' It is a delicate balancing act because the COP is not in the business of retrying cases."

Surgeons, says Dr. Goodman, must take care not to fall prey to a slippery slope on the witness stand. "Expert witnesses tend to become advocates, so one of the COP's principles is that testimony should be fair and impartial. We tell surgeons that if they are giving their opinion they should clearly state that it is opinion…and that if it differs from the majority opinion then they should explain why. The standard of care may not always be clear, but ***that in*** itself should be made clear. Attorneys often tell surgeons that using terms such as 'always' and 'never' makes for a stronger case, but use of those words can put a witness in jeopardy. It is more prudent to make it clear that in XYZ clinical situation there is more than one acceptable way to deal with a problem."

Dr. Peter Mandell, the original Chair of the Committee on Professionalism, is philosophical. He states, "For the longest time there were no checks and balances on what people were doing on the professional side of things. Everyone was expected to act in a professional manner, but there was no roadmap. There were ethical guidelines, but they had no 'teeth.' The AAOS Ethics Committee had formulated outlines of what doctors should and should not be doing, but on many occasions these outlines were being interpreted differently."

And then there are the egregious transgressions. Dr. Mandell: "On occasion you have a situation where two doctors get into an altercation over a patient in the ER or the OR. In such cases you have to take into consideration whether or not there was a history of fighting or tension between the two. Fortunately, these situations are rare."

As time moves on, says Dr. Mandell, those entering the field today have a different outlook on receiving guidance from various governing bodies. "Those of us who went into medicine around the 1960s and 1970s did so because being a professional meant being in charge…being independent and having the authority to customize the appropriate treatment to each patient. With the new healthcare environment there are numerous entities looking over the shoulders of doctors in every area. While that is a real shift for doctors of my generation, the younger folks don't seem to mind and are in fact pretty accustomed to being told what they can and cannot do."

On the whole, the picture is a positive one, says Dr. Goodman. "Since the program went into effect in April 2005 there have been 80 grievances submitted, 30% of which did not make it beyond the General Counsel's office. We have held 39 hearings and have had 19 official actions by the Board of Directors—14 suspensions and 5 censures. I'm proud that the work of the committee results in more standardized and high level professional behavior on the part of our colleagues. In the end, the patients are the biggest winners. Hopefully this program will educate our members and encourage them to testify in a fair and impartial manner rather than to discipline individuals."◆

company

Medtronic Drill Offers Options

Medtronic has launched an electric drill that gives surgeons the option of using only finger control, foot pedal control, or both.

Midas Rex Legend EHS Stylus Touch/Medtronic

The Midas Rex Legend EHS Stylus Touch high-speed electric drill for spinal, cranial and orthopedic surgical procedures is based on the company's established motor offering high torque and a compact size.

The company says the new drill offers additional features, including:

- Ergonomic positioning and true variable speed adjustment
- Easy-to-use design and quick set-up
- Adjustable speeds from 200 to 75,000 RPM

The drill is powered by Medtronic's Integrated Power Console (IPC) system. With the IPC system's intuitive touch-screen interface, surgeons can use saved custom settings, quickly adjust irrigation via simple remote control, and run multiple Medtronic handpieces. The drill also works with the company's interchangeable Legend tools and attachments.

—WE (July 9, 2010) ◆

Mazor 3D Tool Now in U.S.

Mazor Surgical's 3D imaging tool, the C-InSight, is now available in the U.S. The company says its tool allows better imaging during surgery by transforming existing mobile x-ray cameras (2D C-Arms) into 3D interoperative imaging systems at a lower cost and lower radiation levels than other 3D tools. The Israeli-based company announced on June 28 that the tool's technology enables medical facilities to incorporate 3D imaging capabilities into their existing 2D C-Arms, the standard x-ray device used in operating rooms.

While getting a better view is a positive thing for surgical outcomes, current 3D technologies are expensive and often expose patients and caregivers to high levels of radiation.

Transforms Existing Cameras

According to the company, pairing a C-Arm with their attachment emits approximately one-third less radiation than the average dedicated 3D C-Arm, significantly reducing the patient's and OR staff's exposure to radiation during surgery. The company believes its tool will also reduce the need for post operative CT scans, further reducing radiation and additional cost and time to the patient.

Lower Cost, Lower Radiation

Mazor's CEO Ori Hadomi said the C-InSight is about one-tenth the cost of other available 3D technologies and allows hospitals and outpatient surgical centers to upgrade their existing C-Arms to 3D without straining capital budgets.

"C-InSight was developed with the patient, surgeon and hospital in mind," said Hadomi. "Because surgeons can adjust and correct their surgery during the procedure, there is potential for dramatic improvements in patient outcomes and marked reductions in radiation and health care costs."

"There are over 30,000 C-Arms in the United States and replacing all of them with 3D systems is impractical," added Hadomi. "However, upgrading existing machinery to 3D is an affordable option."

C-Arm/Mazor Surgical

—WE (July 7, 2010) ◆

OrthoWorx Educational Initiative Announced

OrthoWorx of Warsaw, Indiana, announced its first educational initiative in early June.

The Warsaw-based industry and community initiative announced that three local educational partners were collaborating to develop a master's degree in biomedical engineering.

Biomedical Engineering Master's Degree

Trine University of nearby Angola and Grace College and Ivy Tech Community College in the Warsaw area, announced plans to establish a school of professional studies branch campus in Warsaw this fall. The branch will offer a bachelor's degree in engineering. Students will be able to spend their first two years at Ivy Tech and complete their degree at Trine. Further collaboration will allow two years at Ivy Tech, two years at Trine and an additional year at Trine to complete the master's degree in biomedical engineering.

Toby Buck, Chairman and CEO of Paragon Medical and Chair of OrthoWorx's Talent and Workforce Development Committee, told *OTW*: "We were originally engaged with Trine University, which has a strong emphasis on engineering, about how they could extend their reach into the Warsaw-area orthopedic community with programs that would help existing company employees further their educational goals and help attract outside students to the industry.

"The collaboration among Trine, IVY Tech and Grace College was a natural next step because Ivy Tech and Grace College already are physically here and have programs targeted at orthopedic employees and those who want to enter the field."

Toby Buck, OrthoWorx Committee Chair

"Growing Our Own"

"In effect, we'll be 'growing our own' as opposed to looking to the outside to such a degree," added Buck.

In addition to offering these programs to members of the Warsaw community, Buck says he believes students from outside the industry will be attracted to these programs because they will provide specific preparation for careers in orthopedics.

Buck concluded, "We are working with the institutions to make the curricula for these programs as meaningful to the industry as possible. To identify other needs and resources that are common to the industry, OrthoWorx has also commissioned an independent study in the area of workforce development and we are looking forward to those results and other new ideas to advance the community and the orthopedic industry."

In an industry that has thrived on competition, OrthoWorx is striving to find areas of collaboration to benefit the entire community. So far, the efforts are beginning to bear some early fruit.

—*WE (July 6, 2010)* ◆

large joint

CE Mark for RepRegen

Success…it's elemental. RepRegen, (formerly BioCeramic Therapeutics) has announced the receipt of CE mark approval for StronBone bioactive glass with strontium, the first product that will be commercialized from RepRegen's repair-and-regeneration platform of 'smart' biomaterials for hard tissue, such as bone.

The company's materials, comprised of bioactive ceramics or biomimetic fibrous polymer scaffolds, are designed to support and enhance natural cellular growth and tissue regeneration in vivo. RepRegen boasts the innovation of using strontium, indicating that it boosts performance of bioceramics for bone repair.

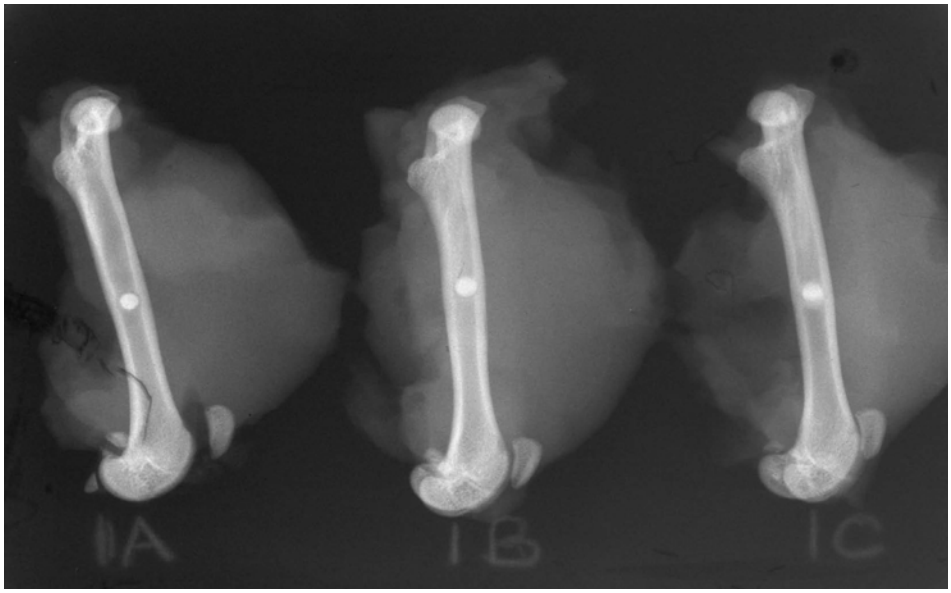
"This European regulatory approval enables us to fast-forward the discussions we are having with several potential strategic partners about our hard tissue platform, in general, and our StronBone product, in particular," said Ian Brown, RepRegen's CEO, in the news release.

"We have previously said that the business opportunities ahead of RepRegen are significant and that some of these opportunities are near-term," added Chairman Dr. Stephen Rietiker. "The company's 'smart' biomaterials related to its hard tissue platform represent great new medical device products for the orthopedic biomaterials market sector that will be well received." Ian Brown told *OTW*, On June 1, 2010, RepRegen announced that three-month data from an in vivo study of its StronBone bioactive glass with strontium demonstrated that it can generate bone quality in and around defects that appears by analytical tests to be significantly superior to a standard bone void filler in the control defect. Specifically, the three-month data demonstrated that the bone in the defect was significantly stiffer—68%—in the StronBone defect than in the control defect; and, the bone in the defect was significantly denser—41%—in the StronBone defect than in the control defect

He also commented to *OTW*, The in vivo and analytical study was conducted at the Institute of Orthopaedics and Musculoskeletal Science at University College London (UCL) by principal investigator Professor Allen Goodship, Professor of Orthopaedic Sciences and Director of the Institute, who will be submitting the data for publication. We believe our platform has the potential to dramatically enhance repair and regeneration of hard tissue, such as bone.

StronBone Bone Graft Substitute is an investigational device in the U.S.

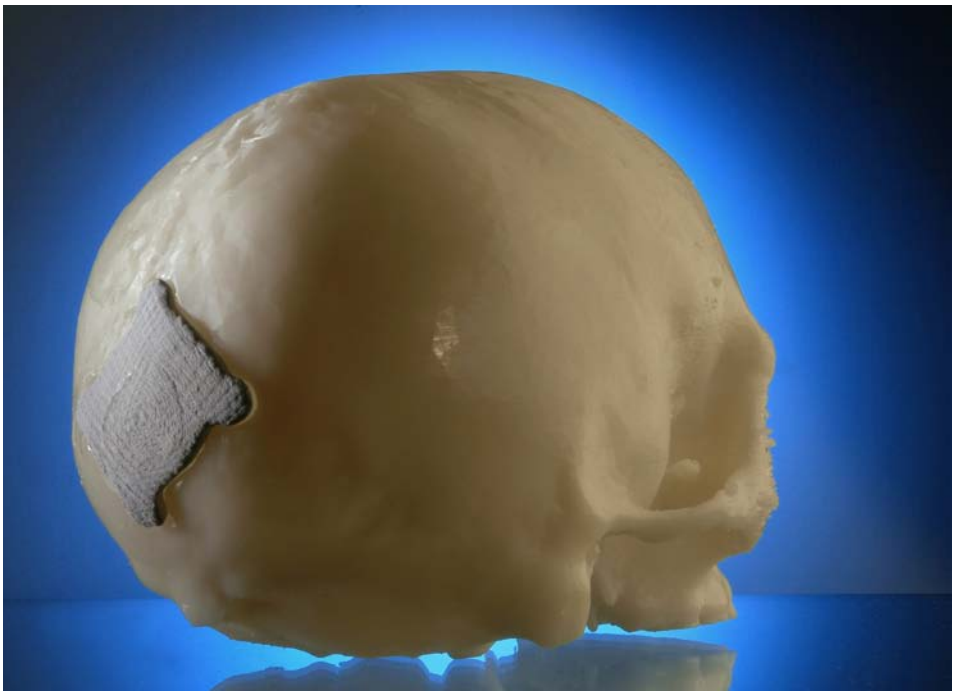
—Elizabeth Hofheinz (July 8, 2010 ◆



Radiographic images of strontium-based bone void filler (see snow-white circles midway in each bone) in three femurs that demonstrate the bone-healing quality of RepRegen's 'smart' biomaterials.

biologics

Lasers and a Custom, Degradable Implant



Fraunhofer-Institut für Lasertechnik

Futuristic facial healing is here… Researchers from Germany have begun using CT imaging to create custom fit, degradable implants (targeted mainly at facial and cranial bones). The new implant, which is porous with precise micro channels occurring at intervals of a few hundred micrometers, helps improve conditions for the healing process.

The structure is a synthetic polylactide (PLA); the stored granules from tricalcium phosphate (TCP) ensure rigidity and stimulate the bone's natural healing process. The body can catabolize both substances as rapidly as the natural bones can regrow, but the material can only be applied in places where it will not be under severe stress. This means that the "Resobone" implants will primarily replace missing facial, maxillary and cranial bones. The manufacturing process, developed at the Fraunhofer Institute for Laser Technology ILT involves Selective Laser Melting (SLM): A razor-thin laser beam melts the pulverized material layer-by-layer to structures that may be as delicate as 80 to 100 micrometers.

The team states that the process is coordinated in such precise sequences that the replacement for a defective zygomatic bone can be produced in just a few hours, while a five-centimeter large section of cranium can be done overnight. Operating room time is also reduced.

Simon Höges, Project Manager at ILT, stated in the news release, "In the past, the surgeon had to cut TCP cubes, or the patient's own previously removed bone material, to size and insert it into the fissure. In addition, the operations are now fewer in number: Physicians no longer take the bone replacement from the patient's own pelvic bone. Similarly, they can dispense with the countless follow-up operations on children to exchange long-term implants that don't grow as the child matures."

Höges told *OTW*, "The interesting and challenging detail on the development of the process is to combine the process of fully melting the material during the laser process to achieve high strength of the produced implants with the use of bioresorbable materials. Following this route it is possible to produce completely bioresorbable implants with interconnecting porous structure and sufficient mechanical strength. The processing of the material following this route is difficult, it has to be insured that the physical properties of the material after processing are almost the same than before."

Höges also commented to *OTW*, "At the moment we are working together with our industrial partner Karl Leibinger Medizintechnik and the University Hospital Aachen to develop a production setup which is able to produce medical implants according to medical standards. Clinical studies will be prepared in this project, animal testing have been performed with positive outcome. Following the clinical studies implants will be available after some years."

—EH (July 9, 2010) ◆

legal & regulatory

Virginia vs. Feds Over Reform

The first courtroom hearing over the new health care law took place in U.S. District Judge Henry Hudson's courtroom in Richmond, Virginia, on July 1, 2010. The courtroom is about a mile away from the spot where Patrick Henry gave his, "Give me liberty of give me death" speech in 1775.

The State of Virginia challenged the constitutionality of the federal law's requirement that individuals must purchase health insurance or pay a penalty. Virginia is arguing that the requirement exceeds Congress' constitutional power and collides with a new Virginia statute protecting individuals from being required to buy health insurance.

Spottswood W. Robinson III and Robert R. Merhige, Jr., Federal Courthouse/Government Photo

Standing Questioned

The federal government argued that Virginia had no legal standing to contest the federal legislation and asked the Judge Hudson to dismiss the suit. During the hearing, according to a report by Michael Sluss of the *Roanoke Times*, the federal government argued that Virginia lacks standing to challenge the "minimum coverage" provision because the mandate applies to individuals—and not to the state. The federal lawyer told the judge, "We have a state statute that really does nothing more than declare, 'My citizens don't have to comply with federal law.'"

The federal government defended the individual mandate, calling it a necessary step to control skyrocketing health care costs and force uninsured individuals to pay for medical services they inevitably will receive. "Uninsured individuals are consuming health care services and not paying for them."

Drawing the Line

Judge Hudson questioned whether such a mandate could be extended to require individuals to join health clubs, get physical exams or undergo certain types of medical procedures to improve health and reduce costs. "Where do you draw the line?" the judge asked. Hudson said he would rule on the dismissal motion within 30 days. If he allows the suit to continue, further arguments will be heard in his court in October. The case is likely to go to the U.S. Supreme Court

Twenty other states are challenging the federal health care law in a lawsuit initiated by Florida. Virginia filed a separate lawsuit based on the state's new law. The state law was passed by the General Assembly in February and signed by Governor Bob McDonnell two weeks before President Obama signed the federal health care law.

—WE (July 7, 2010) ◆

Lawsuits Mounting Over DePuy Hip

When DePuy issued an "Urgent Field Safety Notice" on March 8, regarding its ASR Cup and XL head used with DePuy stems in total hip replacements, you knew the lawyers weren't far behind.

The company issued the notice because the Australian National Joint Registry reported a higher-than-expected revision rate for the device.

Sure enough, in early June a Florida woman filed a liability suit against DePuy. Now *MassDevice* reports that three California residents have also filed suit.

The lawyer for the Florida woman told *MassDevice* that his firm had "several more suits in the works."

DePuy discontinued the cup and had phased it out by March of this year

The Accusation

The Californians accuse DePuy of liability for, "manufacturing a defective product, failing to warn patients and doctors of problems with the implant and negligence in designing, manufacturing and selling the product."

Dr. Stephen Graves, the director of the Australian database, told *The New York Times* that the company was too slow in pulling the device from the market. The FDA received about 300 complaints about the ASR cup since 2008, according to *The Times*, with most complainants undergoing revision surgeries to replace the device. According to the story, the device's co-developer, Thomas Schmalzried, M.D., said he and DePuy officials realized that the ASR cup might be more of a challenge to implant properly than competing cups.

Aboutlawsuits.com reported in March that it appeared, "the complications with the DePuy ASR hip may be linked to defects in the design of the hip implant. Orthopedic experts have suggested that the component has a narrow window for proper placement, which could explain the higher-than-expected DePuy ASR hip failure rate when compared with other types of hip replacement implants."

The *MassDevice* story said DePuy, "acceded that the device posed 'a theoretical potential' to 'be more sensitive to component position,' but cited data from other studies and examinations of explanted devices that contradicted that finding." A DePuy spokeswoman said the company does not comment on pending legal matters.

—*WE (July 2, 2010)* ◆

morguefile.com

FDA Panel to Review Amplify BMP

The orthopedics industry is about to try another bite at the apple of getting a BMP (bone morphogenetic protein) through the FDA's Ortho Panel.

The FDA's Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee will meet on July 27, 2010—from 8 a.m. to 6 p.m. at the Holiday Inn, Ballroom, 2 Montgomery Village Ave., Gaithersburg, Maryland—to discuss, make recommendations and vote on a premarket approval application for the Amplify rhBMP-2 Matrix, sponsored by Medtronic, Inc. and filed in 2005. The bone growth material is used for posterolateral fusion treatment of single level lumbar (L2–S1) degenerative disc disease.

Lauren Uzdienski reported on June 28 that an edition of "What's New in Spine Surgery?" published in *JBJS (Journal of Bone of Joint Surgery)* in 2007 describes Amplify as, "having a higher concentration of BMP-2 and featuring a compression-resistant matrix. JBJS also reports some outcomes from the study; among 98 patients in Amplify's pivotal study, which randomized fusion participants to receive Amplify or iliac crest bone graft, the radiographic fusion rate was 88% for the Amplify group and 73% for the iliac crest bone graft group. The authors note that this was 'the first time that a recombinant BMP demonstrated superiority over autogenous bone graft.'"

If approved, Amplify would be the first BMP indicated for use in posterolateral fusions to get through the FDA. The Ortho Panel has already rejected Stryker's OP-1. InFuse, Medtronic's other BMP-2 bone graft substitute, is indicated for use in ALIF procedures in conjunction with a cage, certain tibial fractures and certain CMF procedures,

The Ortho panel also rejected Zimmer's Dynasys system in the past year. Medtronic will be trying to break a string of tough meetings over the last few years for orthopedic products. Most of the rejections have come after attacks from statisticians on the panel that convinced their colleagues that study designs were flawed and inadequate to determine safety and effectiveness of the devices, even when FDA staff found the studies adequate. We'll see if Medtronic has learned how to survive the attack of the statisticians.

—*WE (July 1, 2010)* ◆

reimbursement

2.2% Pay Increase!!!

Happy 4th of July orthopedic surgeons and physicians. You're all getting a 2.2% raise from Medicare until after the fall elections.

Congress finally passed another temporary "Doc Fix" on June 24 and President Obama signed the legislation into law on June 25.

To get Senate approval, the cost of the fix was offset by changes in Medicare billing regulations, antifraud provisions and the tightening of some pension rules. This eliminated objections that the fix would put the federal government deeper into debt.

Medicare had announced on Friday, June 18, that the agency would begin processing physician claims with a 21% cut required by law.

The cuts went into effect on June 1, but Medicare had instructed contractors to hold off on processing claims until the 18th because the agency expected Congress to reverse the cuts. The pay increase is retroactive to June 1.

But wait there's more.

Since there's a pay increase, Medicare thought they might as well troll for more physicians to sign up for the Medicare program.

If you are currently a non-participating physician, you have an opportunity through July 16 to join the Medicare program.

Non-participating physicians/practitioners who would like to become a participating physician/practitioner should download and complete the Medicare Participating Physician or Supplier Agreement (Form CMS-460). You can get the form here: http://www.cms.gov/cmsforms/downloads/cms460.pdf

Any new forms received during this limited enrollment period will be retroactive for claims with dates of service of January 1, 2010, and later. However, the change in participation status will only apply to new claims submitted after your new status as a participating physician/practitioner is processed. Claims previously submitted and processed will not be adjusted for only a change in participation status.

If we get to December without a permanent fix, the payment cut will be 23%, increasing to nearly 30% in January 2011.

You might as well enjoy the "windfall" while it lasts.

—*WE (July 1, 2010)* ◆

people

Figg Jumps Into PearlDiver

Sam Figg, a senior orthopedics industry veteran, is the new director of research of Fort Wayne, Indiana-based PearlDiver Technologies.

Figg spent over 20 years in product planning and management, business development, marketing and research at Zimmer Holdings. Most recently Figg was with the medical device executive recruiting firm Lake City Group.

In this new role, Figg is directing the work of PearlDiver's team of in-house analysts in fulfilling standardized and custom data analysis requests from PearlDiver's list of clients.

Robin Young, PearlDiver's CEO, said, "Adding Sam to our organization makes PearlDiver an even greater asset for our valued customers."

PearlDiver

"PearlDiver is creating a seamless, timely electronic flow of information about charges, costs, medical products, adverse events, complications, co-morbidities and the interaction of these factors on patient outcomes. We're experienced, we're nimble and we're eager to assist medical device makers and others fulfill this country's dream of quality patient care at a reasonable cost. That work starts with solid analysis of all available data, and we're the company that can provide that actionable information. Sam's background fits nicely into our company and PearlDiver is fortunate to now have him on board at our Fort Wayne headquarters," added Young.

Sam Figg, PearlDiver Director of Research/PearlDiver

Figg said he was excited to work with PearlDiver's "bright analysts and an innovative company."

"Our growing database of fully deidentified and HIPAA-compliant medical records, combined with our technical and analytical capabilities, means we're able to tackle most any request put forth by our clients," said Figg.

With additional offices in Colorado Springs and suburban Philadelphia, PearlDiver began operations in January 2007. Since that time the company's client list has expanded to over 60 companies—primarily medical device manufacturers that now rely on PearlDiver data and analysis to help plan everything from clinical studies to business development efforts. PearlDiver's integrated database contains private, public and patient payer data from across the United States.

—WE (July 9, 2010) ◆

THE PICTURE OF SUCCESS

Dr. Charles Branch, Jr.

By Elizabeth Hofheinz, M.P.H., M.Ed.

Dr. Charles Branch, Jr.

In just three decades, the practice of spine surgery has gone through, first, an explosion of procedural and technical innovation and more recently, the tough review of surgeon industry relationships. Very few surgeons have been so instrumental in all phases of spine surgery development and, indeed, taking the leadership role in designing the future of spine care as Charlie Branch.

But that was an almost unimaginable future when 13-year-old Charles Branch sat in his Canadian living room and saw television images of local French-Canadian violence…images that would affect the trajectory of his life.

Dr. Branch, the Chair of Neurosurgery at Wake Forest University and the former President of the North American Spine Society (NASS), explains, "My dad was a neurosurgeon, and we lived in Montreal in the late '60s, a time when the Quebecois were inciting violence in their efforts to secede. My parents were originally from the U.S., so, concerned about the political environment, they decided to return home. We moved to San Antonio, Texas, where I began the transition from a French/English community to an English/Spanish community."

Enthused by his father's inquisitive mind, it wasn't a big leap for Charles Branch to end up poring over medical textbooks. "I was stimulated by my dad's thoughts on various spine problems and how they might be solved. I first walked through the doors of the University of Texas Southwestern Medical School in 1977. It was a vibrant learning environment, and the teachers and senior residents really enjoyed being doctors. After completing the MD program, I began my neurosurgery residency at Wake Forest University Baptist Medical Center, then known as Bowman Gray. On many occasions I thought, 'Wow, this is an interesting case. How great it will be when I can join my dad in practice and we can share these things.'"

Although enrolled in a clinically oriented training program, Dr. Branch would don a researcher's hat as well. "Bowman Gray was recognized as a classical neuro-spine environment, but when it involved the neck the program was iconoclastic…they treated cervical fractures with wire and acrylic. I had to defend this to my colleagues from other institutions who thought we were loopy. But the results spoke for themselves—the patients did great and the acrylic didn't get infected. In the lumbar region where decompression alone was the norm, my dad was continually questioning this traditional approach. So, in my fourth year I did a rotation in San Antonio and pulled all of my dad's records to see how his failed backs were doing with the PLIF (posterior lumbar interbody fusion). I found that they actually did very well, better than another decompression with solid fusions on the Xrays."

Not willing to ignore the data staring him in the face, Dr. Branch added "advocate" to his list of accomplishments. "In San Antonio I learned the Steffee screw and plate system, something that they weren't doing in North Carolina at the time. Still being questioned by detractors, I said, 'But what about patients who didn't improve after decompression, couldn't some of them benefit from a fusion?' I returned to North Carolina, showed the evidence to my chair, David Kelly, and he ultimately convinced organized neurosurgery to add spinal fusions to the residency training. This dovetailed with the zeitgeist because it was the late '80s, a time when neurosurgeons were feeling threatened because so many fusions were underway and we weren't the ones doing them."

Continuing in maverick mode, Dr. Branch headed to the University of California, San Francisco (USSF). "During fellowship I learned a number of anterior cervical approaches, as well as several treatments for the thoracic discs. I also had the opportunity to work with some world famous brain tumor neurosurgeons. Afterwards, I returned to Wake Forest and started an academic career."

And what of his plans to work with Dad? "Several of my surgeon mentors convinced me that going into business with my dad was a great way to ruin our relationship. I returned to North Carolina and began to use some of the novel brain tumor surgery technology I had learned at UCSF. I also indulged my love of spine, and spent a significant amount of time doing fusions; by the late '90s my major focus was spine. I became 'the PLIF guy.'"

Those tasked with bringing new products to life soon heard of Dr. Branch and his talents. "In 1997 I began working with Medtronic on developing minimally invasive (MI) approaches to lumbar interbody fusion. I'm proud of this work; at the same time, it was a different 'political' environment then, of course. My advice to young surgeons these days with regard to industry is, 'Be creative and be careful.' Industry can facilitate this creativity, but don't get sucked into something that sounds too good to be true. The worst thing that can happen to a young surgeon is to make a poor decision from a relationship perspective that will taint his or her career from the outset."

Detailing his industry work, Dr. Branch says, "In 1998 Sofamor Danek as it was called then, was struggling to get its threaded interbody cage approved by the FDA and their interbody group asked me to help them make modifications. I was concerned that the round threaded cages were too large and that the posterior approaches added the risk of nerve injury. Yet, neurosurgeons were embracing this PLIF technique because it was technically simpler than Cloward's PLIF technique. I advised them to make a posterior impacted device using the stepwise, standardized method of the threaded cage. Ming Liu, an engineer, worked with me to develop a system which gave neurosurgeons a set of tools to use after decompression. One tool allowed them to chisel out the disc space and another let them clean out the soft tissue and put in a cortical bone wedge—*without* stretching the nerves. That is how the Medtronic Sofamor Danek Tangent and Capstone product lines developed."

And because he helped those products along, Dr. Branch was vilified by some parties. He notes, "The most significant challenge was assuming the NASS presidency during a time when the regulatory environment of industry relationships was changing. Here I am, a surgeon who has worked closely with Medtronic on product development… well, I was just the epitome of evil according to some. We at NASS decided to lead the ethics/industry relationship issue; it was challenging to find a middle ground, though, because on the one hand there were people advocating for immediate, strict measures, and others saying, 'No, that is too much too soon.'"

So how did he manage the high wire act? "After some tough, but collegial negotiating, we have arrived at the following positions. First, physician leaders must be very transparent and somewhat separated from industry, despite the fact that the two parties are dependent on one another. Second, the regulatory environment has been putting the brakes on new technology development which we believe will negatively impact healthcare. The government and payors have responded, 'Prove that what you're doing or developing is worth it' and we are addressing this with registry development. Third, we saw the need for a change in mindset such that we can no longer take someone's published literature and say, 'This operation is better than that one,' but not be obligated to show that our personal outcomes with that technology are as good as the published data."

Dr. Branch, who completed his tenure as President of NASS in 2009, says, "*The* 'thing' for the foreseeable future is establishing the value of our work and defending our current practices. It is appropriate that we hold ourselves accountable for reviewing outcomes

and determining what we do well. Traditionally, we have done a lot of 'My TLIF trumps your PLIF' studies, but what we haven't done yet is a 'Dr. A does a better job than Dr. B' comparison. I believe that is the next wave."

And, says Dr. Branch, the future will be based on the size and will of the gorillas. "Healthcare reform involves distinct groups with different interests. The federal government is the biggest gorilla in the room, with the law and funding on its side. The insurance companies are a good sized gorilla themselves. And the professional societies have clout, but also have the substantial challenge of working together (no group wants to let the other group be the leader). If we join forces as a field and can establish group-wide value metrics that we can use to defend the profession against government/payer encroachment then things will improve substantially."

A glimpse of his views on the clinical side of things finds that Dr. Branch is a little old fashioned…with a dash of radical. "There are times when you open up a patient and things aren't what you had hoped for. Maybe the bone quality is poor, for example. In those cases you must be creative and confident that you can fix that person 'on the fly,' and that your solution will be safe and effective. While things such as nerve monitoring and InFuse can be helpful, being able to call on one's experience is invaluable. Younger surgeons don't have that yet, and as we focus more on MI surgery, knowing what you can do with the spine and what you can't is critical. I tell residents that they must learn how to operate open. Why? Because they need to see the relationships between things and know the anatomy so that when they are doing MIS they can know what is under the surface."

The best chance he has of influencing doctors may be on the home front. "My wife and I have five children, three of whom are on the path to become physicians. Our two youngest are still undergraduates and are more artistic like their mother, who is a painter. We live on a large farm and nature preserve and spend a lot of time outdoors. While my medical and administrative work demands much of my life, I am also very involved with mission work. The faith-based group that I work closely with has distributed a good deal of Biblical literature to the former communist countries, areas where the people were starving for this information because they had been so controlled by the government. It is very rewarding to be able to help them."

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