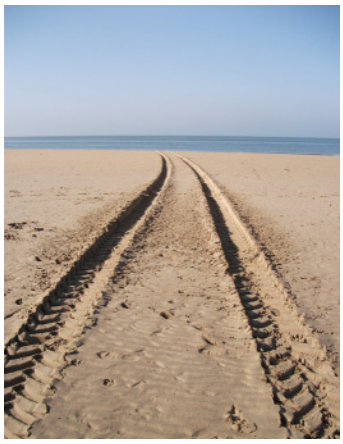
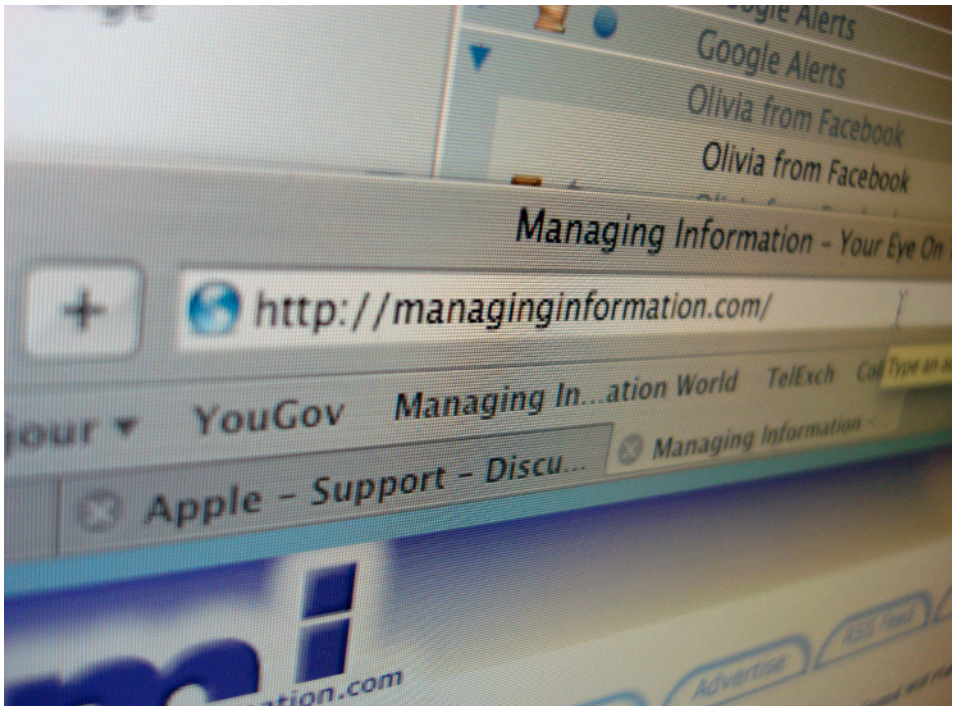
VOLUME 6, ISSUE 39 | DECEMBER 14, 2010

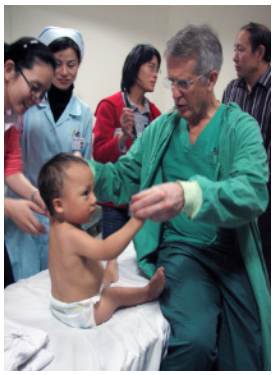
Orthopedics This Week

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: The two best performing orthopedic stocks over the last 30 days are a robotics company and a biologics company. While the lowest valuations are for Orthofix, Medtronic and Zimmer. We think that means that young technology-based companies are finding buyers while large diversified suppliers remain out of favor.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	13.51%	(0.53%)	On average, OFIX has beaten the Street by 15% per quarter for more than one year. Remains the least expensive equity in ortho.
2	2	Medtronic	32.59	1.24	With a 33% operating profit margin and $3.5 billion in cash, MDT is really interesting at these prices.
3	4	Integra LifeSciences	15.37	11.66	Very nice run this past month. Remember, in Q3, Stu and team crushed the Street's estimates.
4	6	Alphatec	1.59	11.65	Top performer in the Power Rankings this past month. New CFO, string of new product introductions helps a lot.
5	5	Exactech	10.79	7.44	EXAC settles with DOJ, pays $3 million. The cloud has lifted.
6	7	Zimmer	27.69	2.75	Good news for ZMH out of Japan—premium pricing for Trabecular metal hip cup.
7	9	Smith & Nephew	22.83	7.52	More buyers than sellers for SNN. The data from the Registries really shows how strong SNN's franchise is.
8	8	Stryker	24.71	1.69	Usually there aren't sales or earnings surprises for SYK. Outlook is for 6% sales growth.
9	NR	Wright Medical	6.36	5.04	WMGI now 7th lowest equity in orthopedics due to low sales growth expectations. We think it is oversold. On the Power Rankings.
10	10	NuVasive	6.51	(9.11)	NUVA being painted with all of spine's troubles. Even so, NUVA will fight for surgeons and the science.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TiGenix	TIG.BR	$2.91	$90	49.3%
2	Mako Surgical	MAKO	$13.89	$473	23.5%
3	Integra LifeSciences	IART	$48.08	$1,360	11.7%
4	Alphatec Holdings	ATEC	$2.30	$204	11.7%
5	CONMED	CNMD	$25.02	$704	8.9%
6	RTI Biologics Inc	RTIX	$2.70	$148	7.6%
7	Smith & Nephew	SNN	$51.76	$9,180	7.5%
8	Exactech	EXAC	$19.07	$246	7.4%
9	Wright Medical	WMGI	$15.01	$588	5.0%
10	Synthes	SYST.VX	$123.54	$14,662	4.0%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TranS1	TSON	$1.79	$37	-12.7%
2	CryoLife	CRY	$5.50	$155	-9.5%
3	NuVasive	NUVA	$22.55	$889	-9.1%
4	Orthovita	VITA	$1.99	$153	-7.4%
5	Bacterin Intl Holdings	BIHI.OB	$6.61	$237	-2.8%
6	Johnson & Johnson	JNJ	$61.91	170,020	-2.4%
7	*Average*			*$11,801*	*-0.5%*
8	Orthofix	OFIX	$28.00	$496	-0.5%
9	Medtronic	MDT	$35.94	$38,820	1.2%
10	Stryker	SYK	$53.00	$21,050	1.7%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Medtronic	MDT	$35.94	$38,820	10.73
2	Zimmer Holdings	ZMH	$53.11	$10,490	12.64
3	Kensey Nash	KNSY	$28.45	$242	12.66
4	Johnson & Johnson	JNJ	$61.91	$170,020	13.12
5	Wright Medical	WMGI	$15.01	$588	13.21

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$51.76	$9,180	71.28
2	RTI Biologics Inc	RTIX	$2.70	$148	35.31
3	Synthes	SYST.VX	$123.54	$14,662	34.53
4	Symmetry Medical	SMA	$9.20	$331	24.03
5	CONMED	CNMD	$25.02	$704	19.98

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Orthofix	OFIX	$28.00	$496	0.59
2	NuVasive	NUVA	$22.55	$889	0.59
3	Medtronic	MDT	$35.94	$38,820	1.13
4	Zimmer Holdings	ZMH	$53.11	$10,490	1.24
5	Smith & Nephew	SNN	$51.76	$9,180	1.27

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Kensey Nash	KNSY	$28.45	$242	3.57
2	CONMED	CNMD	$25.02	$704	2.37
3	CryoLife	CRY	$5.50	$155	2.33
4	Johnson & Johnson	JNJ	$61.91	170,020	2.19
5	ArthroCare	ARTC	$31.11	$841	2.09

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Orthofix	OFIX	$28.00	$496	0.88
2	RTI Biologics Inc	RTIX	$2.70	$148	0.91
3	Symmetry Medical	SMA	$9.20	$331	0.95
4	CONMED	CNMD	$25.02	$704	0.97
5	Wright Medical	WMGI	$15.01	$588	1.12

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$2.91	$90	321.16
2	Bacterin Intl Holdings	BIHI.OB	$6.61	$237	19.26
3	Mako Surgical	MAKO	$13.89	$473	12.23
4	Synthes	SYST.VX	$123.54	$14,662	8.13
5	Kensey Nash	KNSY	$28.45	$242	3.05

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Dr. Slosar's Blast Email

By Robin Young

Morguefile

Two weeks ago, 38 (and counting) emails piled into my inbox from an impressive list of U.S. spine surgeons. Throughout the day, emails streamed in as one surgeon after another banged out their reactions to one, single, particular email.

Dr. Paul J. Slosar's email.

Dr. Paul J. Slosar

Dr. Slosar hit the send button on Monday November 29th. "I'd asked my wife to read it before I sent it out. I didn't want to send out a long and rambling email. But I started thinking about what to say while I was sitting at a faculty conference a couple weeks ago. I'd gotten wind of a new Blue Cross Blue Shield policy on spine fusion reimbursement. Frankly, it made me acutely depressed and angry. "

On Tuesday four guys responded. On Wednesday the responses doubled. On Thursday all hell broke loose. The reaction to Slosar's email showed that he had tapped into a well of frustration among spine surgeons. Each surgeon post triggered another one, then another one. By mid-day on Thursday, the online dialogue had grabbed the attention of probably a hundred practicing surgeons, a handful of surgery department heads as well as the presidents and boards of the North American Spine Society (NASS) and the ISASS (formerly SAS) and the CEO of one billion dollar spinal implant manufacturer.

The source of this spontaneous group reaction was a proposed spine fusion reimbursement policy from Blue Cross Blue Shield of North Carolina. For some reason the BCBSNC note—more than other recent news, and there has been other policy and reimbursement setbacks for spine surgeons lately—plucked a nerve.

Slosar's two page "Call to Action" opened with these words: "I apologize for the length of this communication…. but (I am writing this because of) my emotional concerns for the health and well-being of my patients as well as my love for my profession."

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Dr. Slosar, 48 years old, conducted his residency at Loyola University in Chicago, has degrees from the University of Illinois/Rush Medical College and is a spine surgeon at SpineCare Medical Group in Daly City, California.

"Dr. Slosar", I asked, "What was it about this specific Blue Cross Blue Shield policy statement that prompted you to write your note?"

"Where I practice, in Northern California, it is progressively more difficult to get approval for spine fusion surgery. When we ask why we received a rejection letter, we often hear something about the Milliman guidelines which no one seems to have a copy of. We're getting rejection letters for cases and plans of treatment that we've been doing every day for years. Bread and butter stuff. Spine surgeons who treat low back pain have been singled out unfairly."

"In our clinic I practice state-of-the-art spine surgery using standard indications for lumbar fusions. We get the best results we can for our patients and they are good to excellent with 75-80% of our patients reporting that they are significantly improved and satisfied with their results after fusion surgery. We've had elite athletes who are now pain free. Recently I operated on a law enforcement officer who can now return to duty again. I could go on and on."

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"When I heard about and then read this BCBS policy statement it just hit me. I can't do the job that I have trained my whole life to do. It sucked the wind right out of me. How many patients will have to live lives of debilitating pain because of this proposed policy? I don't think my patients realize what draconian restrictions are being placed on standard-of-care treatments by the insurance companies."

The Proposed Blue Cross Blue Shield Spine Fusion Policy

On September 28, 2010, BCBSNC issued a policy statement regarding coverage for lumbar spinal fusion which BCBSNC said would take effect in January 1, 2011. The relevant section is excerpted in the adjacent text box.

(From the 9/28/10 policy statement from Blue Cross Blue Shield of North Carolina): **When Lumbar Spine Fusion Surgery is covered:** BCBSNC will provide coverage for Lumbar Spinal Fusion procedures for any one of the following conditions:

1. Spinal Fracture with instability or neural compression
2. Spinal repair surgery for dislocation, abscess or tumor
3. Spinal Tuberculosis
4. Spinal Stenosis with ALL of the following:
    a. Associated spondylolisthesis demonstrated on plain x-rays; and
    b. Any one of the following:
        i. Neurogenic claudication or radicular pain that results in significant functional impairment in a patient who has failed at least 3 months of conservative care and has documentation of central/lateral recess/or foraminal stenosis on MRI or other imaging. or
        ii. Severe or rapidly progressive symptoms of neurogenic claudication or cauda equina syndrome.
5. Severe, progressive idiopathic scoliosis (i.e., lumbar or thoracolumbar) with Cobb angle > 40 degrees.
6. Severe degenerative scoliosis with any one of the following:
    a. Documented progression of deformity with persistent axial (non-radiating) pain and impairment or loss of function unresponsive to at least 3 months of conservative therapy. or
    b. Persistent and significant neurogenic symptoms (claudication or radicular pain) with impairment or loss of function, unresponsive to at least 3 months of conservative care.
7. Spondylolisthesis, isthmic (type II), with documented progression of slippage, and with persistent back pain (with or without neurogenic symptoms), with impairment or loss of function, unresponsive to at least 6 months of conservative nonsurgical care.
8. Recurrent, same level, disk herniation, at least 6 months after previous disk surgery, with recurrent neurogenic symptoms (radicular pain or claudication), with impairment or loss of function, unresponsive to at least 3 months of conservative nonsurgical care, and with neural structure compression documented by appropriate imaging, and in a patient who had experienced significant interval relief of prior symptoms.
9. Adjacent Segment Degeneration, at least 6 months after previous fusion, with recurrent neurogenic symptoms (radicular pain or claudication), with impairment or loss of function, unresponsive to at least 3 months of conservative nonsurgical care, and with neural structure compression documented by appropriate imaging, and in a patient who had experienced significant interval relief of prior symptoms.
10. Pseudarthrosis, documented radiographically, no less than 6 months after initial fusion, with persistent axial back pain, with or without neurogenic symptoms, with impairment or loss of function, in a patient who had experienced significant interval relief of prior symptoms.

Please Note: This policy addresses specifically the circumstances under which arthrodesis (fusion) surgery of the lumbar spine is considered medically necessary. It does not address decompression surgery

When Lumbar Spine Fusion Surgery is not covered: BCBSNC will not provide coverage for lumbar spine arthrodesis (fusion) surgery when it is considered not medically necessary.

1. Lumbar spine arthrodesis (fusion) surgery is considered not medically unless one of the above conditions is met.
2. Lumbar spinal fusion is also considered not medically necessary if the sole indication is any one or more of the following conditions:
    - Disk Herniation
    - Degenerative Disk Disease
    - Initial Discectomy/laminectomy for neural structure decompression
    - Facet Syndrome

Several elements of the BCBSNC statement caught the attention of spine surgeons. Here are the top four.

1. **Lumbar spine fusion surgery for degenerative disc disease (DDD) only is not covered**—DDD is the most common diagnosis for lumbar fusion surgery. A significant number of patients report debilitating pain as a result of disc degeneration. Prior to the advent of low profile, internal fixation devices, minimally invasive surgical procedures, biologic adjuncts to fusion or advanced nerve monitoring and surgical positioning systems, the predominate indication for lumbar fusion surgery was spinal deformity or extreme instability (spondylolisthesis, trauma or tumor). The BCBSNC policy by disallowing DDD is being perceived as an attack on a "bread and butter" treatment alternative for spine surgeons and would push the practice of spine surgery back to an earlier era.
2. **Reimbursement is allowed for adjacent DDD but not for primary DDD**—It's hard to understand this distinction. Natural degenerative processes of all aspects of the human musculoskeletal system are well documented in the literature and, to be perfectly plain about it, in the daily practice of medicine. In the case of a perhaps "more noble" degenerative process (osteoarthritis of the hip or knee) there is NO debate regarding reimbursement. But adjacent level disc degeneration instead of primary disc degeneration? Seriously?
3. **The threshold curvature for scoliosis reimbursement is >40o**—According to a small sample of spine surgeons we interviewed, the most recent and best scientific studies indicate that threshold curvature is closer to 30o but that, at any rate, the lumbar fusion surgery decision for scoliosis is multi-factorial and new diagnostic techniques (like ScoliScore) can improve outcomes by employing this multi-factorial approach to patient selection and treatment.
4. **Lack of peer review science and the appearance of bias in the BCBSNC guidelines**—Thousands of peer review journal articles are already available which provide the statistical foundation for improving patient outcomes with surgery when conservative care has demonstrably failed. Instead of looking at those outcome studies, BCBSNC cited articles by long-time fusion critics Deyo and Weinstein to support their guidelines.

ISASS or NASS?

The public forum that flashed into existence from Slosar's email included comments from and about two of the spine surgeon societies—North American Spine Society and the International Society for the Advancement of Spine Surgery (formerly SAS). ISASS Executive Director Kristy Radcliffe reminded Slosar's audience that ISASS had sent an email alert regarding the BCBSNC policy before Slosar's email and was in the process of rallying other societies. Current ISASS President Tom Errico. M.D., who sent out a blast email alert to ISASS members of the BCBSNC pending policy statement said: "I believe that our society, in responding to the North Carolina situation and others like it, needs to take a strong stand at this time."

NASS Executive Director Eric Muehlbauer watched all of the email traffic on Thursday and then early on Friday weighed in saying: "The most respected organizations are the ones who are strong enough to make reasonable statements, acknowledge weaknesses in arguments and highlight areas where further action and discussion are needed. NASS has been at this a long time. Insurers often come to us for our opinion and we are very judicious about our responses."

Regardless, the most significant aspect of last week's spine surgeon email wave is that it occurred spontaneously. In that golden moment the spine surgeon community said very clearly that they are deeply worried and that their core interests are beyond any particular society or company but rather, as Dr. Slosar said, for "…for the health and well being of my patients, as well as my love for my profession." ◆

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Spine Fusion's Line in the Sand

By Walter Eisner

The flash spine-doc mob has had its virtual and symbolic storming of the castle of Blue Cross/Blue Shield in North Carolina (BC/BS).

Now, the establishment of spine care professionals, including: NASS (North American Spine Society); ISASS (International Society for the Advancement of Spine Surgery, formerly knows as SAS); AANS (American Association of Neurological Surgeons), CNS (Congress of Neurological Surgeons); SRS (Scoliosis Research Society); and perhaps AAOS (American Academy of Orthopaedic Surgeons), will step in to make a quiet, thoughtful and evidence-based case to BC/BS.

The societies will attempt to convince their medical peers at the insurance company that the insurer's proposed policy of coverage for fusion related to degenerative disc disease (DDD) is too broad and unreasonable and will throw the baby out with the bathwater.

Morguefile

Response Pending

Or as Chris Bono, M.D., one of the lead authors of a letter under development by the spine societies told us, "In trying to stop unnecessary or questionable fusions, the policy will throw out appropriate fusions."

A quick review.

On September 28, 2010, BC/BS issued a policy statement regarding changes in coverage for lumbar spinal fusion that are scheduled to take effect on January 1, 2011. Among other things, the proposed policy stated that lumbar spine fusion surgery for DDD only will no longer be covered. What really seemed to burn some spine surgeons was that the insurer targeted DDD and stated that it was an insufficient diagnosis for lumbar fusion.

The letter under development by Bono and Joseph Cheng, M.D. of AANS is currently being reviewed by the various societies' policy committees. When completed and negotiated between the societies, a joint letter will be sent to BC/BS. We were told by participants that the goal is to get the letter to the insurer the week of December 13.

Then the politics of influencing an insurance company begins. The politics of who best represents the interests of spine surgeons will also continue.

As former U.S. Speaker of the House Tip O'Neill famously said, "All politics

Tom Errico, M.D.,

is local." Insurance companies are regulated by state governments and political pressure from surgeons in New York, Chicago and San Francisco doesn't carry a lot of water.

Line in the Sand

Tom Errico, M.D., president of ISASS told us as much. Errico also said he has been trying to reach out to spine surgeons in North Carolina and isn't sure that the local docs are sufficiently engaged to pressure BC/BS.

Errico told us that spine surgeons need to "draw a line in the sand" in North Carolina. But before drawing the line, he said surgeons need to get their heads out of the sand. He sees North Carolina as a stalking horse for all other insurance carriers across the country looking for ways to cut their expenses.

Insurance carriers have a financial self interest at stake. "Where's Senator Charles Grassley in this issue?" asked University of Minnesota spine surgeon David Polly, M.D.

Surgeons aren't looking for a blank check. Not all fusion surgery performed today delivers consistent and reliable outcomes. Many of the emails from Paul Slosar's "email flash" a couple of weeks ago acknowledged that surgeons and the broader spine community need to do a better job of patient selection and outcome tracking for lumbar fusion surgery.

Collaboration and Calm Urged

One North Carolina surgeon with his head clearly out of the sand is Charles Branch, M.D., a former president of NASS, who is actively involved in responding to BC/BS. Branch is a neu-

Charles Branch, M.D.

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rosurgeon at the Wake Forest University School of Medicine

Branch told us that before ranting at BC/BS, spine surgeons need to work collaboratively and thoughtfully to convince the carrier that the proposed policy changes are unreasonable given the evidence.

Branch said that some of the insurer's proposed changes are reasonable, but that key elements are missing. As an example he noted that someone with a severe collapsed disc would not get coverage.

Dr. Bono offered us another example of a hypothetical patient who would be denied reasonable and necessary care under the proposed policy.

The Patient

Louise is a teacher. She is 42 years old and has been teaching for 20 years.

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NuVasive's CEO and Chairman Alexis Lukianov

In 2007 she began to experience back pain. After seeing her chiropractor and then her primary care physician without getting rid of the pain, she took a medical leave and stopped working. She suffers from low back pain and some left leg pain attributable to a dysplastic spondylolisthesis.

"Under the current BC/BS policy Louise would have been referred to a spine surgeon who would have OFFERED HER AN L5-S1 FUSION WITH OR WITHOUT A DECOMPRESSION [Bono's emphasis]. Statistically, her chances of success in eliminating or reducing the pain so that she could go back to work would have been 75%," said Bono.

Under the proposed policy, Louise would not qualify for reimbursement because she didn't present with an isthmic spondylolisthesis.

"Louise is the patient we want to help," said Bono.

Now is not the time to ratchet up the rhetoric, said Branch. The societies will make their case to the carrier that revisions to the proposed policy are needed to make it reasonable. How the carrier responds to the evidence submitted by the societies will determine what spine surgeons will do next.

Industry, Physicians and Politics

One industry leader, NuVasive's CEO and Chairman Alexis Lukianov got involved quickly in joining the fray to draw a line in the Tar Heel sand.

Lukianov confirmed to OTW that he pledged $100,000 to ISASS in the Slosar email stream to aid the society in advocacy efforts in North Carolina as well as providing leadership for patient advocacy in Washington, D.C.

We had to ask, "NASS went to bat for you on XLIF. Why $100,000 to SAS and not NASS?"

In an email reply, Lukianov wrote, "SAS stepped up almost immediately and is working to drive positive outcomes. My intent is to help them use whatever means available to work thru North Carolina so there is not a domino effect

on January 1, 2011. I am also availing NuVasive's resources both financially, as well as organizationally and functionally, in the way of our expertise."

Lukianov added that there have been "concerning" emails from the reimbursement and advocacy docs at NASS implying they are not in favor of supporting DDD as an indication. "Certainly everyone agrees that back pain without failed and prolonged physical therapy is unlikely to need fusion. There are however very clear DDD indications that can be defended for fusion. A straight out exclusion is not reasonable. That is one reason [for ISASS support].

"Secondly," said Lukianov, "surgeons are frustrated that NASS is not actively representing surgeons. NASS was once 100% surgeons and is now 60-70% surgeons. SAS is 100% surgeons. NASS has not responded to the BC/BS crisis. When they do we will consider how to support them."

NASS Successes

Dr. Branch bristles at comments that NASS has not been responsive to surgeons. He cited a successful NASS-led response to a Washington State worker's comp policy proposal a couple of years ago that would have limited coverage. He also noted how NASS succeeded in keeping Medicare coverage for fusion intact with evidence presented at a MEDCAC meeting a few years ago.

NASS was also successful in working with a national insurance carrier earlier this year to properly code XLIF procedures and continue providing coverage for the lateral access fusion procedure.

On the Ground

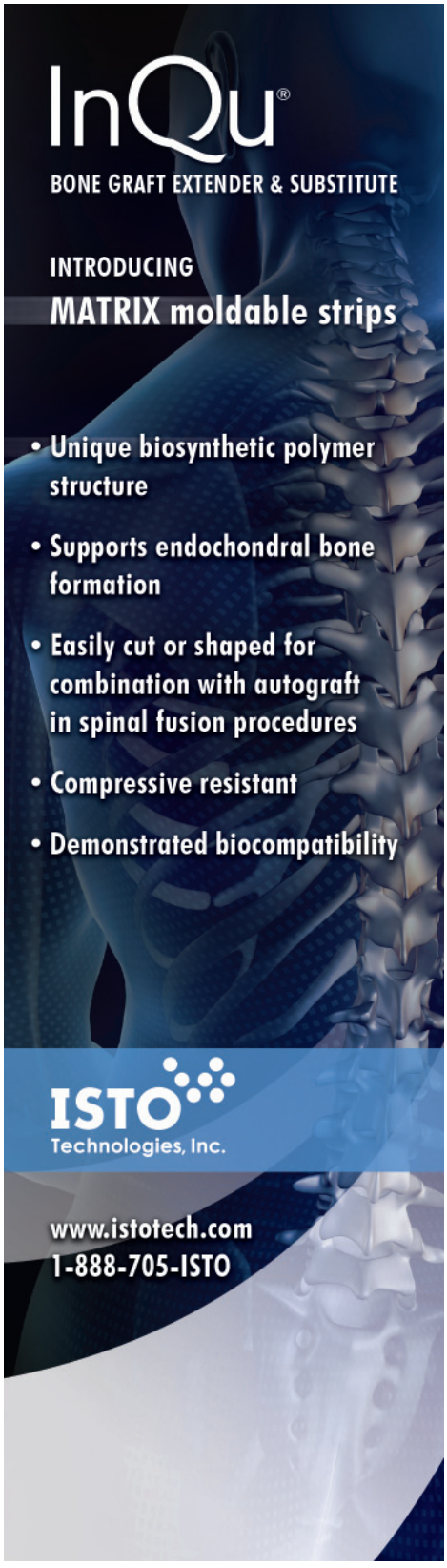
If BC/BS stonewalls and doesn't modify their proposed policy, then local politics in North Carolina take over. Surgeons from outside the state will have very little standing in influencing a local political battle. BC/BS is a giant corporate presence in North Carolina and is regulated by an elected insurance commissioner. It will take our hypothetical Louise to contact the insurance commissioner and her legislator.

There is a Health Care Review Program in North Carolina where, Louise, the insurance policyholder, can request a review of a coverage denial. If Louise is still not satisfied after that, she can request an external review by an independent reviewer. The insurance company is then obligated to follow the findings of that review.

If that fails, then the line in the sand moves to the state's legislature where unions, employers, citizens with back pain and their surgeons can find a sympathetic committee chair to call public hearings.

The decision by BC/BS to be the first state insurance carrier to propose an "unreasonable" policy change for fusion surgery has incited the most spirited surgeon reaction we've seen in some time. We think Dr. Errico can rest assured that his colleagues have pulled their heads out of the sand and are drawing the line.

In the meantime, the debate over who will be the surgeons' (and patients') most effective advocate continues. ◆



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Knees: Just the Facts, Doc

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

If asked, most orthopedic surgeons would say that while they are not scientists, they are grounded in—and have faith in—the sciences. But there is little that is scientific, says our knee expert, about how most knee specialists respond to patient queries.

Dr. Donald Shelbourne, founder of the Shelbourne Knee Center in Indianapolis, has performed more than 6,000 anterior cruciate ligament (ACL) reconstructions…and he has data on every single one of them. He doesn't "think" he knows something…he can prove it. Dr. Shelbourne: "If a patient asks the average orthopedist, 'What are your outcomes for this procedure?' I can almost guarantee that the doctor will say, 'pretty good.' If the patients says, 'Well, how many complications have you had?' the surgeon will most likely respond, 'Not many.' As physicians, we should be able to be much more precise about our work."

Tinker Gray, Research Director at the Shelbourne Knee Center, has been along for the nearly 30-year ride of data collection and analysis. She states, "Dr. Shelbourne planned to collect data from the outset of his practice in 1982. Sports medicine was just starting out, and when I came here in 1984 we established a more systematic way of following up with patients, i.e., we graduated from using old computer cards. We started out asking rather basic questions and then as Dr. Shelbourne found that he needed additional information, we added more and more data points."

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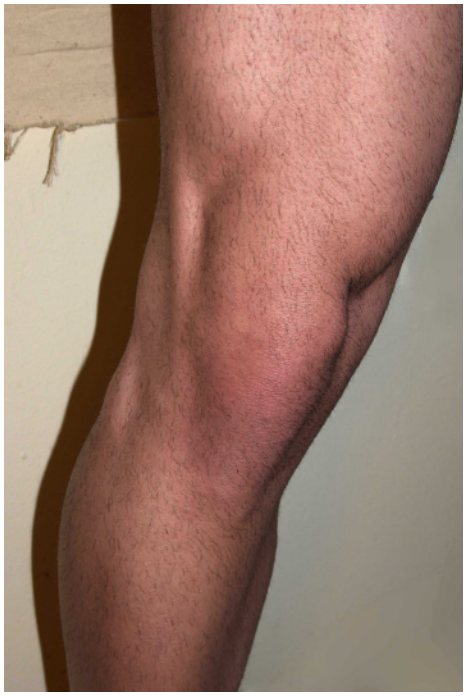

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Ahead of his time, all those years ago a younger Dr. Shelbourne had the radical idea that he wanted to know how good of a job he was doing. "I wanted to have a concrete sense of my effectiveness, where I was faltering and why, and what I needed to change. Even back then I could see that the utility of being able to definitely state, for example, 'XYZ is the best treatment for this type of meniscus tear' would be fantastic. That way, patients and colleagues would know that I am not giving my opinion, I am stating facts."

Although Dr. Shelbourne's work is scientific, it turns out that sometimes, it "just" involves a bit of horse sense. "Years ago I began thinking about the

"If a patient asks the average orthopedist, 'What are your outcomes for this procedure?' I can almost guarantee that the doctor will say, 'pretty good.' If the patients says, 'Well, how many complications have you had?' the surgeon will most likely respond, 'Not many.' As physicians, we should be able to be much more precise about our work."

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typical way that we approached rehabilitation after ACL surgery, namely, putting the patient on a restrictive program with crutches and braces. I did a compliance study because I suspected that our rehab directives were unrealistic. It turned out that the patients who did not listen to me fared better than those who did. The medical student collecting the data told me that almost all patients were not following my mandate that they sleep in the brace (although they were telling me that they were). In the end, we found that those people who did what they felt comfortable doing—and followed their common sense—had a better medical outcome. When I presented the study there was a lot of hubbub, with people saying, 'I don't agree with you,' to which I replied, 'This is not my opinion…these are the data speaking. These are the facts.'"

Tinker Gray adds, "At the time, it was accepted that 10% of patients who underwent ACL surgery had to have surgery later for range of motion problems. When the medical student was calling postop patients he also found that those who did weight bearing exercises earlier than Dr. Shelbourne had advised had better ROM. That gave some insight into that fact that ACL rehab wasn't where it needed to be."

Dr. Shelbourne is inflexible when it comes to creating flexible, healthy knees. He says, "Let's take kneecap dislocations. Our results were not consistently good with these conditions, so we wanted to dig in and see why. I set the bar at what I thought was a normal goal—that both knees would be symmetric. Our treatment objective is to make the patient feel like they have two normal knees (which is what they want). So we found that it makes sense to start by asking, 'What is different about the knee that feels comfortable to them, i.e., the healthy knee?'"

"Our initial results were 75% to 80% (as far as making knee mirror knee), but the patient populations weren't homogenous. People with dislocated kneecaps can have a congenital predisposition for the condition; there could also be a trauma dislocation on top of that. So in our database section on patellar realignment we have seven different types and can subclassify things. Since we have begun this process our success rate on patellar dislocations has gone up to 90%. The problem overall is that surgeons don't have good success rates with operative treatment. Patients present seven different ways, but many surgeons only operate one way."

From her view inside the workings of the Shelbourne data machine, Tinker Gray says, "I have seen over the years that surgeons tend to think, 'Oh, well,

"In the end, we found that those people who did what they felt comfortable doing—and followed their common sense—had a better medical outcome. When I presented the study there was a lot of hubbub, with people saying, 'I don't agree with you,' to which I replied, 'This is not my opinion…these are the data speaking. These are the facts.'"

"Once you start to collect data don't wait a year or two to analyze it. That way you can best detect any problems with coding, sorting, etc., and can rectify them. Remember that as time goes on you will be getting more curious and experienced, and will be asking more questions—meaning that specificity in coding is also critical."

XYZ patient hasn't returned to see me so they must be doing fine.' No, no, no… we have learned…you must find the patients and ask how they are doing."

And how do they manage this gargantuan process? Tinker Gray: "Each year during the anniversary month of someone's surgery a computer program sends a letter and survey to the patient via email. If there is no response, then we send out a paper survey. All of the surveys are validated statistically, and measure pain, stability, everyday functioning, and activity level in terms of sports or work activities. The surveys are very specific, i.e., there is one for older patients with osteoarthritis, another for patients who are heavily involved in sports, etc. People write a lot of comments on our surveys and Dr. Shelbourne reads every one of them. This has been an important lesson: the doctor has to be involved. One might be tempted to hire an outside company or just say, 'My research department is going to handle that,' but taking one of these routes means that your understanding of the results will not be as clear."

Gray, the one who dots the 'I's and crosses the 'T's when it comes to the database, has advice for those surgeons and/or practices embarking on substantial data collection. "Think it through from the beginning as far as the type of factors you want to evaluate. For example, for ACLs there are different types of meniscal tears and varying treatment approaches. It is best to collect this specific information at the time of surgery and record it in a manner that allows you to sort it properly."

And while you may think that you have a simple system, and can wait awhile before undertaking the data analysis, that could lead to a hornet's nest of issues down the line. Gray states, "Once you start to collect data don't wait a year or two to analyze it. That way you can best detect any problems with coding, sorting, etc., and can rectify them. Remember that as time goes on you will be getting more curious and experienced, and will be asking more questions—meaning that specificity in coding is also critical. For example, if there is a lateral meniscus tear you should indicate whether the tear was in the middle third, anterior part, etc. You would also want to code for the way the tear is different from others, as well as the different ways of repairing it. Not going to this level of detail means that you can't answer the question, 'Is ABC type of tear more amenable to repair than XYZ tear and how exactly it should be treated?'"

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"The fact that very few people are collecting this data is rather surprising. It's a bit like playing basketball and taking shots, but not looking to see if they go in. If a 15-year-old kid asks me, 'What will my knee be like in 10 years?' I can't envision telling him, 'I don't know.'"

Among other things, Dr. Shelbourne sees 200 ACL tears and 20 patellar dislocations per year. Such volume naturally creates the opportunity for detailed knowledge. "The average orthopedic surgeon sees 20 ACL tears a year and one or two patellar dislocations. That is just not enough to recognize patterns. But I am surprised to be so alone in the woods. The fact that very few people are collecting this data is rather surprising. It's a bit like playing basketball and taking shots, but not looking to see if they go in. If a 15-year-old kid asks me, 'What will my knee be like in 10 years?' I can't envision telling him, 'I don't know.'"

But most surgeons are not able to provide such information…it just doesn't exist, says Dr. Shelbourne. "A couple of years ago we got a call from a well known knee surgeon who said, 'I am supposed to give a talk on failure after ACL surgery, but I can't find any data. Can you help me out?'"

"Unfortunately, once most orthopedic surgeons walk out of the OR they don't have much interest in postop… they are moving on to the next case. If the patient is truly motivated, however, then he or she is going to want some answers. If the surgeon says, 'Go home and elevate your leg 8 inches' there are patients who will say, 'Why not 12 inches?' If you say, 'Do your rehab exercises two or three times a day' some patients will ask, 'Why not four?' We surgeons are the ones in charge of this whole process and yet so often we can't give specific answers. I actually feel sorry for patients. Orthopedists used to be good at treating musculoskeletal problems—now most of us are only good at operating on musculoskeletal problems."

And the barriers to changing this situation? "Think about it," says Dr. Shelbourne, 'any funding out there is coming from companies to sell you things to use in the OR. They are not exactly motivated to further nonoperative or postoperative treatment. There is more likelihood that laboratory or animal research will be funded because that is usually a relatively quick one or two year study. To follow patients long term, however, is a substantial commitment of resources…not to mention the issues with obtaining IRB approval for even simple follow-up of patients."

But Dr. Donald Shelbourne and Tinker Gray get the job done…and provide data and guidance to anyone seeking to provide the ultimate in data-based knee care for patients. ◆

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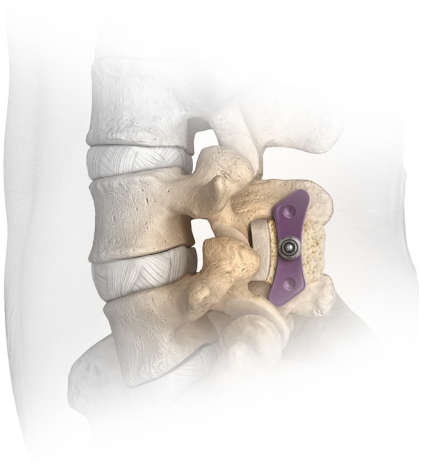

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"Think about it," says Dr. Shelbourne, 'any funding out there is coming from companies to sell you things to use in the OR. They are not exactly motivated to further nonoperative or postoperative treatment.

company

HSS: New Outcomes, Research Center

Bringing together a panoply of research stars under one roof… Hospital for Special Surgery (HSS) announced the creation of the Center for Musculoskeletal Outcomes and Patient Oriented Research to translate information collected from an extensive patient population into studies regarding musculoskeletal disorders.

"Through this new Center, Hospital for Special Surgery will report on the effectiveness of orthopaedic and rheumatology treatments, so physicians, government agencies, medical device and drug companies, health insurance companies and, most importantly, patients have the facts they need to make the best informed health care decisions," said President and CEO Louis A. Shapiro in the news release.

Center researchers, including experts in biostatistics and health policy, will lead the development of an International Consortium of Orthopedic Registries, as a result of an FDA contract.

"The Center will provide the resources and environment within which basic, clinical, translational and health researchers can collaborate in identifying treatments, clinical pathways and quality measures that can lead to significant improvements in musculoskeletal health," said Chief Scientific Officer Steven R. Goldring, M.D., in the news release.

Timothy Wright, Ph.D., Director of the Biomechanics Program at HSS told *OTW*, "The basic 'building blocks' are:

HSS Surgeon Mark Figgie, M.D., and Timothy Wright, Ph.D., director, Biomechanics Program, work together on innovations in custom joints.

developing a framework (or strategic plan) for cooperation among all of the participating national and international registries on the basis of important questions in safety and effectiveness of orthopaedic devices; comparing the data elements that are currently being collected by all of the registries to define the space within which this cooperative effort can operate; and establishing a means for amassing data from multiple registries in a secure, quality manner and performing analyses of the data to answer the questions being asked."

Dr. Wright also commented to *OTW*, "No research projects have been agreed to at this point, since the conference hasn't been held yet. Initial projects may concentrate on utilization of various technologies (e.g., alternate bearing materials in total hip replacement and unicondylar or other partial knee replacements) for which safety and effectiveness can be defined by revision of the implant (one of the few if not the only outcome that most of these registries track). This initiative comes from the FDA, so regulatory bodies like them will be helping to frame the questions."

Art Sedrakyan, M.D., Ph.D., Director of the Comparative Effectiveness Program at HSS told *OTW*, "There would be a series of initiatives before the consortium is established, some of which are: showcasing the best practices in building registries from those who are in a process of planning their registries or at early stages; defining the data elements needed and definitions; and agreeing on strategies to overcome methodological challenges in conducting multinational studies."

—EH (December 8, 2010) ◆

Stryker Cuts Off OP-1

It's over. Stephen MacMillan and Stryker Corporation have washed their hands of OP-1.

Photo manipulation by RRY Publications. Source: morguefile.com and Stryker Corp.

FDA problems, criminal indictments and reimbursement issues finally pushed the company to sell its BMP, OP-1 product to the Japanese Olympus Corporation for $60 million. Senator Chuck Grassley of Iowa even got into the act when he criticized University of Minnesota spine surgeon David Polly, M.D., for not using the product in a clinical test.

Seeing a dejected, but gracious, MacMillan sitting alone in the audience after an unsuccessful FDA panel meeting and not even offering a speaker at the recent MEDCAC meeting to consider if Medicare should pay for BMPs, clearly sent signals that Stryker had lost faith.

The company announced on December 6 that it has a definitive agreement to sell the OP-1 product family, which includes OP-1 Implant, OP-1 Putty, Opgenra and Osigraft, for use in orthopedic bone applications to Olympus.

The transaction also includes the sale of the manufacturing facility in Lebanon, New Hampshire.

The Stryker announcement says the company will redirect a portion of the related R&D spending to other internal projects including its clinical efforts already underway with BMP-7 for potential use in osteoarthritis and research into other non-orthopedic applications. Given the early stage of these clinical efforts and the expected scope of data to be required by FDA, commercialization of BMP-7 is not expected for at least five years.

The company may have washed its hands of OP-1 but retains rights for future development of the protein for soft tissue and osteoarthritis while exiting the core business and manufacturing assets, and significantly reducing its costs related to the program.

—WE (December 7, 2010) ◆

Quality...

Rachel Frank, allograft meniscus recipient and Research Fellow in Orthopedics, Rush University Medical Center. 2009 Hawaii Ironman 70.3 Triathlon Finisher.

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Exactech Joins DPA Club

Exactech has joined the club of hip and knee makers to pay the government to settle charges related to consulting agreements with orthopedic surgeons.

Exactech announced on December 7 that the company will pay about $3 million to the government under a 25-page Deferred Prosecution Agreement (DPA). Under the agreement, the U.S. Attorney in New Jersey, Paul Fishman, will not prosecute the company if obligations during a 12-month period are met. Fishman, Chris Christie's successor, commenced the investigation in December 2007. The government accused the company of conspiracy to violate the Federal Anti-Kickback Statute.

Under the DPA, an independent monitor will review and evaluate the company's compliance with its obligations under the DPA. The U.S. Attorney acknowledged in the agreement that the government does not allege that the company's conduct adversely affected patient health or patient care.

The company also entered into a Civil Settlement Agreement (CSA) with the government.

Pursuant to the CSA, the company will settle civil and administrative claims relating to the matter for a payment of $2,991,889, without any admission by the company. Exactech has also entered into a five-year Corporate Integrity Agreement (CIA) with the Office of the Inspector General of the United States Department of Health and Human Services.

Exactech Chairman and CEO Bill Petty said, "We are pleased to resolve this inquiry, which we feel is in the best interest of our stakeholders. We will continue to practice the highest standards of ethics, which have been and will continue to be hallmarks of our corporate culture."
The company had already set aside approximately $3.5 million in anticipation of a settlement and legal expenses.

The DPA is available on Exactech's Web site: http://www.exac.com/

— *WE (December 8, 2010)* ◆

Morguefile

DePuy ASR Lawsuits Consolidated

If you watch television or read the newspapers, you know that practically every personal injury lawyer in the U.S. has been fishing for potential clients to sue DePuy over its recalled ASR XL Acetabular hip replacement system. The product was recalled in August 2010.

Numerous lawsuits have been filed throughout various jurisdictions throughout the U.S. The recall affects 93,000 people, including 37,000 in the U.S.

Lawsuit Consolidation

Those lawsuits are now being consolidated in the federal court in the Northern District of Ohio by order of the Judicial Panel on Multidistrict Litigation. The panel indicated that at least seven different lawsuits over the recalled systems are currently pending in six different states. Each of the cases being transferred come from different federal court districts, including two from different districts in Alabama, and one from California, Kentucky, Illinois, Mississippi and Utah.

U.S. District Judge David A. Katz in Toledo will supervise evidence-gathering efforts in the cases. "Such consolidation will serve the convenience of the

Photo manipulation by RRY Publications. Source: morguefile / DePuy

parties and witnesses and promote the just and efficient conduct of the litigation," said a panel statement. *Bloomberg News* reports that about 150 federal lawsuits are pending.

A DePuy spokeswoman said that DePuy recalled both the ASR XL Acetabular System, a total hip-replacement product approved by the FDA in August 2005, and the DePuy ASR Hip Resurfacing System, which wasn't used in the U.S.

Shades of Sulzer

Some trial lawyers are comparing this suit to the 2001 Sulzer AG agreement where the company paid $1 billion to settle product liability suites involving defective hip and knee replacements by its former Sulzer Medica unit. They believe this litigation has the makings to be significantly larger because Sulzer was a relatively small company with little to no product liability insurance.

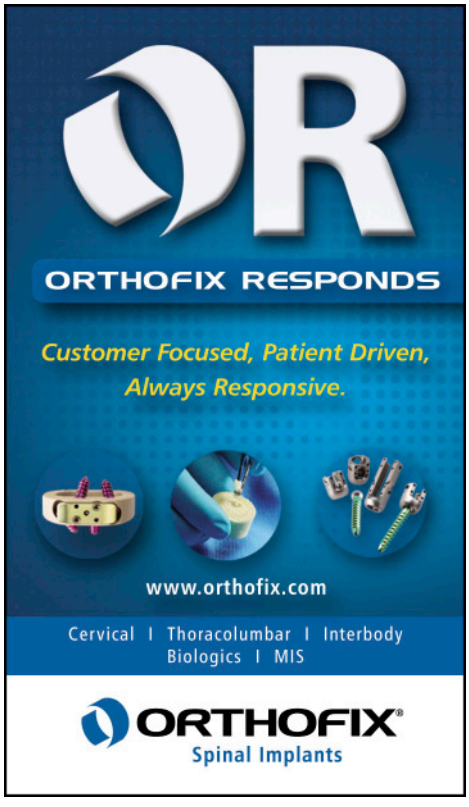
In addition, in the Sulzer litigation there were no allegations of toxic injury from the implants. In this case, there are allegations of toxic exposure to chromium and cobalt, both of which can have serious adverse health effects. Thus, the damages here may include revision surgery to get the metal-on-metal implant out, systemic hypersensitivity to the metal load in the body (requiring use of non-metal replacement devices), bone loss around the implant, metal shavings in the tissues causing necrosis of the tissue, cobalt poisoning, non-malignant tumors, and increased risk of cancer.

"DePuy looks forward to working with Judge Katz and counsel for plaintiffs to address the issues raised by this litigation," said the DePuy spokesperson in an e-mail to *Bloomberg News*. "DePuy remains committed to covering reasonable and customary costs of testing and treatment for patients who need services, including revision surgery if it is necessary, associated with the ASR recall."

While the pretrial management of the cases in a consolidation are often managed similar to how a class action lawsuit would be handled, each claim will still remain an individual lawsuit.

If a settlement agreement is not reached following pretrial proceedings and any bellwether jury trials, each of the consolidated cases would be remanded back to the jurisdiction where they were originally filed for trial.

—*WE (December 7, 2010)* ◆



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biologics

Training Stem Cells to Sit, Stay

Stem cells, while showing promise, can sometimes have a mind of their own. They like to migrate.

How can clinicians deliver stem cells to the proper treatment site and ensure that they will, in effect, sit, stay long enough for a therapeutic effect? Injecting stem cells directly into a heart muscle, for example, can have minimal therapeutic effect if they are washed away by the bloodstream.

A team of intrepid stem cell whisperers from Worcester Polytechnic Institute believe they may have found a clever solution. The team's paper, "Fibrin microthreads support mesenchymal stem cell growth while maintaining differentiation potential ," was published online, ahead of print, on November 29, 2010, by the *Journal of Biomedical Materials Research*.

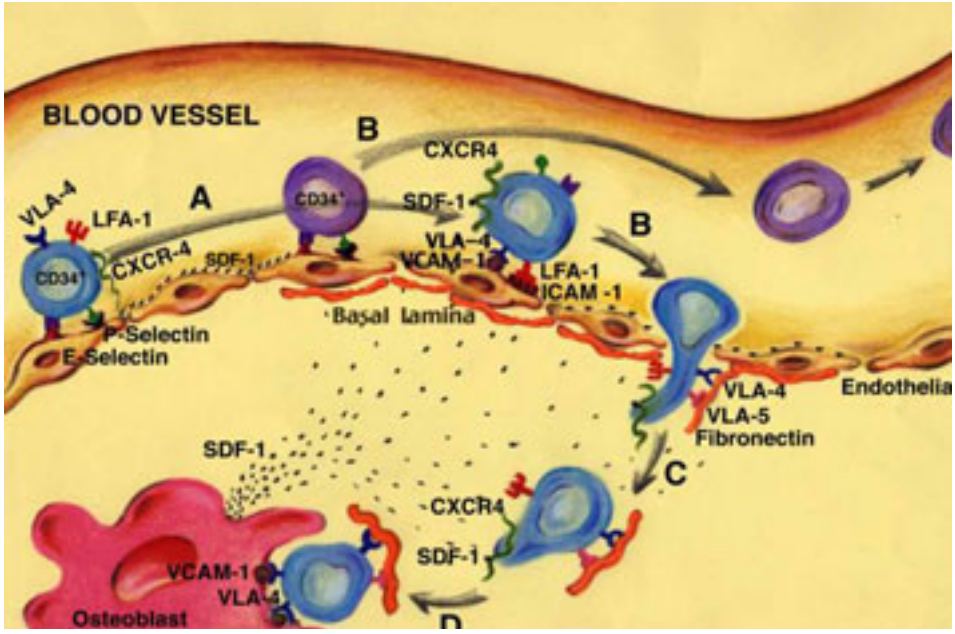
The paper describes a novel technology (fibrin microthreads) that would give a surgeon the power to deliver stem cells to targeted areas of the body and ensure that they will stay in place. As described by the Worcester team, biopolymer fibrin microthreads are bundled by a supplier into biological sutures and then seeded by the surgeon with stem cells. The adult bone-marrow-derived stem cells expand and multiply while attached to the threads were found by the Worcester team to retain their ability to differentiate and grow into other cell types.

The microthreads, which are about the thickness of a human hair, are made of fibrin, a protein that plays a vital role in the healing cascade—as do stem cells. The threads can be engineered to have different tensile strengths and to dissolve at different rates once implanted so they can be fine-turned to a variety of uses.

Once the stem cells are seeded onto the fibrin threads, they attach and bind themselves to the threads. The Worcester researchers cultured the seeded threads for five days after which the cells began to multiply until the two-centimeter-long threads were virtually covered, each with nearly 10,000 human mesenchymal stem cells. Glen Gaudette, Assistant Professor of Biomedical Engineering and lead author of the paper, reported that after the seeding and growing process, the team attached the microthreads to a surgical needle and drew them through a collagen gel made to simulate human tissue. When the threads were drawn through the gel, the vast majority of the stem cells remained alive and attached to threads, suggesting they could be sutured into human tissue.

"It appears that the cells we grew on the threads behave the same way we would expect mesenchymal stem cells would in vivo," Gaudette said. "So we believe these results are proof-of-principle—that we can now deliver these cells anywhere a surgeon can place a suture."

—BY (December 10, 2010) ◆



Courtesy of the Weizmann Institute of Science, Rehovot, Israel

Device Concentrates Stem Cells

Stem cells, the focus of the emerging field of regenerative medicine, continue to present difficulties in use. While there is evidence that cells within bone marrow are capable of transforming into bone and cartilage tissues, they are most effective when administered to a patient in a concentrated or enriched form. At present there is very little equipment available to enrich stem cell samples.

Concentrator devices on the market are large bulky machines, too large to

Andrew Huth

fit into an operating theater, that work on the principal of a centrifuge. "That is a problem for this type of therapy," explained research fellow James Smith. Ideally, you want to remove a sample of bone marrow aspirate, enrich the stem cells and reimplant them into the patient as part of the same operation, under the same anesthetic. With these large machines you have to take the sample outside the sterile area of the theater to process it. That can take some time."

The present machines are costly. The ideal solution would be a compact device which carries out the enrichment quickly, within the operating theater. "What we need is something small, quick and cheap," said Smith. "And it's a bonus if it's disposable as well so there's no risk of contamination or patient mix-up."

To resolve this problem *Smith & Nephew*, in partnership with the University of Southampton Medical School and Southampton University Hospitals Trust, has developed a device that works using a technology called acoustic wave filtration. It contains a membrane with a closely-controlled porosity which is vibrated with a frequency in the acoustic region. The combination of pore size and vibration frequency, combined with reduced pressure on the opposite side of the membrane to the aspirate injection chamber, allows all of the cells in the sample, except for the stem cells, to pass through, retaining the stem cells on the membrane itself. The device is still in the prototype stage, but Smith & Nephew expects the production model to produce an enriched sample of stem cells from bone marrow in about 15 minutes.

Working with the prototypes, researchers at the Bone and Joint Unit of the hospital found differences in bone marrow. As Smith explained, "When you want to regenerate bone in trauma patients, they are often young and getting bone marrow from them is quite easy—the marrow is thin and easy to process. But when you're looking at revision hip replacements, where you remove a loose hip prosthesis from a femur and you want to regenerate bone around a new one in patients in their 70s, we'd find that the marrow is more viscous and has a lower concentration of stem cells, making it more difficult to process."

The device has promise for three types of surgery—in bone breakage where there is a 10% chance that fractures will fail to heal using traditional setting methods, in spinal fusion in the elderly where one in five cases do not heal properly, and in cases of cartilage focal defect, a condition often seen in athletes where the cartilage of the knee tears.

—BY (December 7, 2010) ◆

Advertisement

large joints

Sodium, Fractures, and Falls

As if there weren't enough risk factors for falls…Now, a Dutch study has found that older adults with even mildly decreased levels of sodium in the blood (hyponatremia) experience increased rates of fractures and falls.

"Screening for a low sodium concentration in the blood, and treating it when present, may be a new strategy to prevent fractures," commented Ewout J. Hoorn, M.D., Ph.D., in the news release. Dr. Hoorn, is with the Erasmus Medical Center, Rotterdam, the Netherlands. He also indicated that hyponatremia does not appear to affect the risk of osteoporosis, as defined by low bone mineral testing, so more research is needed to understand the link between sodium levels and fracture risk.

More than 5,200 Dutch adults over age 55 were included in the study. The 8% of the study participants who had hyponatremia also had a higher rate of diabetes and were more likely to use diuretics than those with normal sodium levels. Patients with hyponatremia had a higher rate of falls during follow-up: 24% versus 16%. However, there was no difference in bone mineral density between groups, so hyponatremia was not related to underlying osteoporosis.

Torsten Henning/ Wikimedia Commons

Nevertheless, the group with low sodium levels had a higher rate of fractures. With adjustment for other risk factors, the risk of vertebral/vertebral compression fractures was 61% higher in the older adults with hyponatremia. The risk of non-spinal fractures was also significantly increased.

"Although the complications of hyponatremia are well-recognized in hospitalized patients, this is one of the first studies to show that mild hyponatremia also has important complications in the general population," added Hoorn.

Dr. Hoorn told *OTW*, "For any physician involved in the prevention and treatment of fractures in the elderly, including orthopedists, the discovery of hyponatremia as a new and independent risk factor for fractures is relevant. If our results are replicated, screening for and treatment of even mild hyponatremia may be a new strategy to prevent fractures."

He also commented to *OTW*, "We believe future studies in this area should focus on the following two aspects. First, with any population-based study, it is important that results are confirmed in another, independent cohort. Second, the finding that hyponatremia is a risk factor for fractures independent of osteoporosis is intriguing. Laboratory studies will be required to unravel how hyponatremia affects bone quality—we propose that the low serum osmolality associated with hyponatremia may inhibit certain sodium channels important for the repair of microdamage to bone."

—EH December 10, 2010 ◆

Robotic Arm Now at NY-Presbyterian

An arm for a knee… the RIO Robotic Arm Interactive Orthopedic System by MAKO Surgical Corp. is now assisting with partial knee replacement surgery for early to mid-stage osteoarthritis at NewYork-Presbyterian Hospital/Columbia University Medical Center. The technology was approved by the FDA in 2005, and to date nearly 5,000 cases have been performed in the U.S.

"Robotic technology is particularly well-suited to partial knee replacement surgery, which requires a high degree of precision. This device is making it possible to treat patients early and with more precision in order to more quickly and effectively eliminate their pain and get their lives back on track," says Dr. William Macaulay, director of the Center for Hip and Knee Replacement at New-York-Presbyterian Hospital/Columbia University Medical Center and the Nas S. Eftekhar Professor of Clinical Orthopaedic Surgery and chief of the Division of Adult Reconstructive Surgery of the Hip and Knee at Columbia University College of Physicians and Surgeons.

According to Dr. Macaulay, the robotic arm provides a pre-surgical plan that details the technique for bone preparation and customized implant positioning using a CT scan of the patient's knee. During the procedure, the system creates a three-dimensional virtual view of the patient's bone surface and correlates the image to the pre-programmed surgical plan. As the surgeon uses the robotic arm, its tactile, acoustic and visual feedback limits the bone preparation to the diseased areas and provides for optimal implant positioning and placement.

MAKO Surgical Corp.

Dr. Macaulay told OTW, "The pre-surgical plan consists of precise positioning and sizing of both the femoral and tibial components. This plan is confirmed and often optimized intra-operatively in dynamic fashion as a result of kinematic testing of the knee as it is taken through its range of motion in the hands of the surgeon as ligamentous balancing is tested in real time. Important aspects (which can be controlled through application of this technology) of the position of the components include: depth of resection (which exactly matches the patient's bone and conserves as much bone as possible); a varus/valgus orientation of the cut which is precisely perpendicular to the long axis of the tibia; perfect rotation of the implants. Additionally, the system allows the surgeon to visualize the implant contact area and correct edge-loading before it occurs."

"Patients report being without pain and are comfortable with the feel of their partially reconstructed knee. The potential advantages are a shorter hospital stay, typically one to three days, as well as a quicker overall recovery," stated Dr. Macaulay in the news release. "In most cases, patients can walk soon after surgery, drive a car within two weeks and return to regular daily activities shortly thereafter."

—EH December 9, 2010 ◆

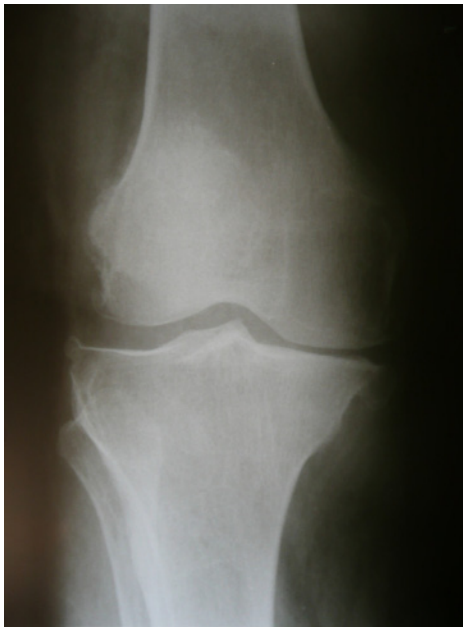
Study: Registry Would Improve Outcomes

More organized data, better outcomes? A new prospective study from Kaiser Permanente has found that having a detailed and standardized national registry of commonly used joint replacement devices would improve patient outcomes and create clinical and financial efficiencies. The study, published in the November issue of the *Journal of Bone and Joint Surgery*, included 80,000 total joint replacement and 5,000 anterior cruciate ligament reconstruction procedures.

Using Kaiser Permanente's national implant registries—the nation's largest registry of implants—the team examined patient demographics, implants and surgical techniques in relationship to outcomes for these procedures. This is the largest community-based research study of outcomes with total knees and hips and ACL reconstruction procedures, and one of few studies conducted with a registry that includes a level of detail to assess outcomes in the United States.

"Our findings demonstrate the critical impact of registries and the important role they play in counseling patients, identifying risk factors, tracking implanted devices during recalls and assessing comparative effectiveness of devices," said study lead author Elizabeth Paxton, director of surgical outcomes and analysis at Kaiser Permanente, in the news release.

Researchers found the three most common reasons for re-operations of ACL reconstruction of the knee were meniscus injury, stiffness, and device removal. The implant registries were also used to track eight recalls and advisories during



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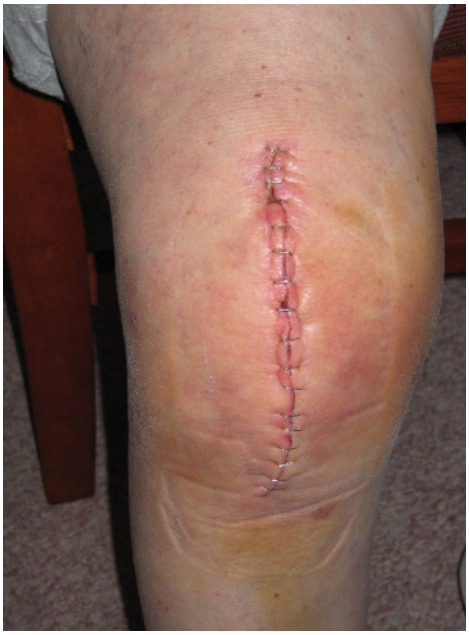

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the study period, which were critical in immediately identifying and following up with patients that were impacted.

Applications for the public at large also became clear. For example, researchers found an increased rate of ACL reconstructions for specific demographics among men and women, and increased time between injury and surgery associated with an increased rate of additional knee injuries compared to surgery within three months of the original injury.

Elizabeth Paxton told *OTW*, "We hope that other organizations recognize the benefits of registries based on our findings and pursue similar studies to enhance patient safety, quality, and cost-effectiveness. We also hope that our registry and study findings will serve as a model for other national implant registry efforts. Collaboration among existing implant registries and development of regional and national registry efforts may help provide the framework for implant post-market surveillance in the United States."

Paxton also commented to *OTW*, "Kaiser Permanente recognizes the benefit of implant registries for practicing evidence based medicine. We have leveraged our integrated health care system and Electronic Health Record, KP HealthConnect, to develop spine, hip fracture, and shoulder replacement registries. Beyond orthopedics, we have developed ICD, pacemaker, and cardiothoracic registries."

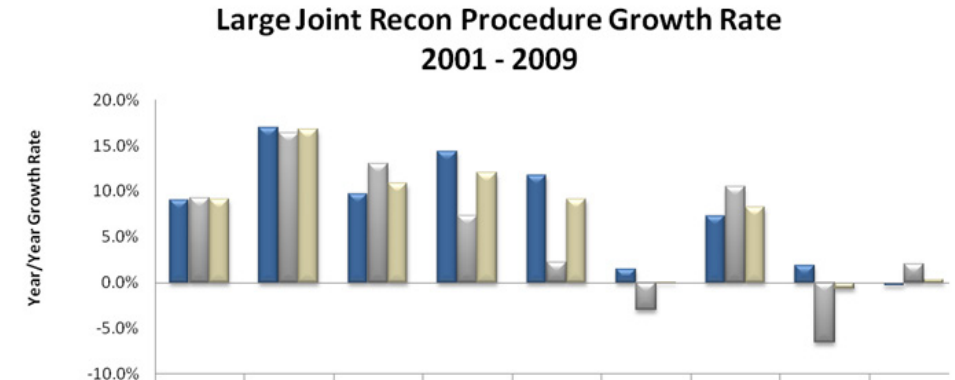
—EH December 8, 2010 ◆

Joint Replacement Procedure Growth

How rapid was joint replacement procedure growth between 2001 and 2008? A new study has put some numbers to the answer to that question and, no surprise, growth was extraordinary. The recently released study by J.A. Singh, M.B. Vessely and W.S. Harmsen of the Mayo Clinic and Olmsted Medical Center, Rochester, Minnesota, found that rates of total hip arthroplasty (THA) and total knee arthroplasty (TKA), which have been increasing steadily since the procedures were introduced and continue to increase in all age groups really grew during the years 2001-2008.

The researchers studied epidemiological data from patients who had arthroplasty between 1969 and 2008. They examined trends in these surgeries according to gender and age and determined the manner in which a patient's underlying diagnosis influenced the decision to undergo arthroplasty.

One very interesting trend uncovered by the investigators was that THA and TKA procedural growth appeared to escalate by 20% and 32%, respectively, between 2001 and 2004 and by 43% and 24%, respectively, between 2005 and 2008. Advanced age, of course, was positively correlated with this significant increase in THA and TKA, although 42% and 38% of the recent THAs and TKAs were performed on individuals younger than 65 years. The need for a THA was unaffected by gender but women were significantly more likely than men to need a TKA.



	2001	2002	2003	2004	2005	2006	2007	2008	2009
Knees	9.0%	16.9%	9.7%	14.4%	11.7%	1.5%	7.3%	1.9%	-0.3%
Hips	9.3%	16.4%	13.0%	7.4%	2.2%	-3.0%	10.5%	-6.5%	2.0%
Large Joint Recon	9.1%	16.7%	10.8%	12.0%	9.2%	0.1%	8.3%	-0.7%	0.4%

Source: PearlDiver Technologies Inc

The authors noted that the high number of TKAs is probably the result of the increasing prevalence of obesity, which has a strong association with knees but a weak association with hips.

—*BY (December 8, 2010)* ◆

reimbursement

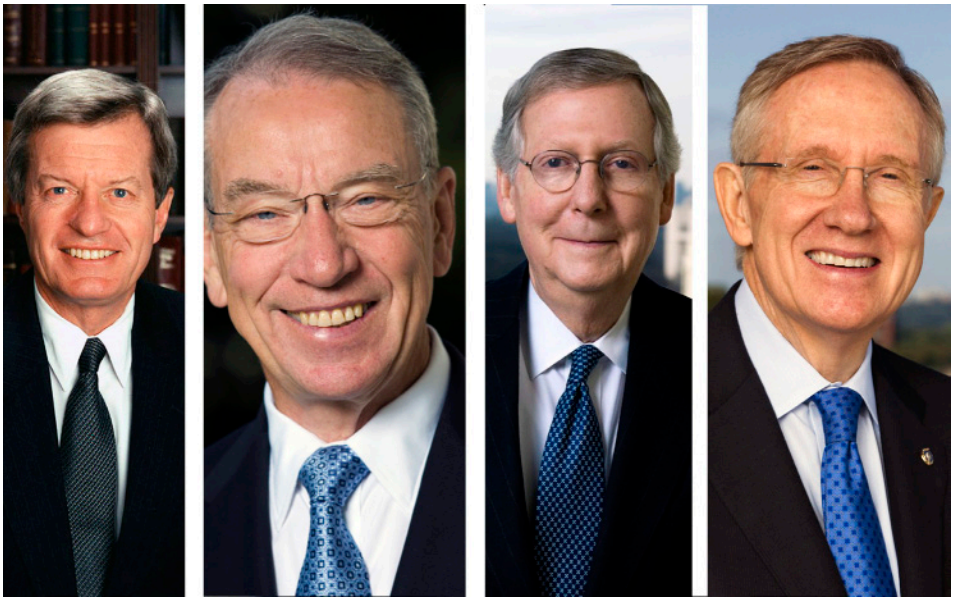
One-Year Doc Fix Agreement Announced

Raj Rao, M.D., Advocacy Chair for the North American Spine Society (NASS) sent out a notice to members on December 7 saying that a deal had been struck in the Senate to extend the current 2.2% Medicare physician reimbursement update for one year.

According to the notice, Senate leaders reached a bipartisan agreement when Democratic and Republican leaders agreed to fund the $19.2 billion package by raising the limits on overpayment of consumer subsidies if they receive too large a subsidy in the health insurance exchanges after 2014.

The new healthcare law requires people to repay up to $200 ($400 per couple) of a subsidy received from the federal government to buy health insurance in state run markets if that person misstates their income or their income changes.

Rao said the agreement will likely include a package of Medicare provisions that were set to expire at the end of the year. A cap on therapy services, funding for claims reprocessing, extending hospital geographic reclassifications, and adding inpatient drugs to the 340B drug discount program could all be included in the package, according to press reports.



Senators Baucus, Grassley, McConnell and Reid/Wikimedia.org

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Senate leaders could bring the package to the floor for a vote as early as December 8 and passage would likely, according to Rao, face little opposition in the House. If signed into law before January 1, the deal would avert a 25% cut in reimbursement rates to physicians.

Bipartisan Effort

Politico.com reported that Majority Leader Harry Reid of Nevada, Minority Leader Mitch McConnell of Kentucky, Finance Committee Chairman Max Baucus of Montana and ranking Republican Chuck Grassley of Iowa announced the deal late December 7.

> **"Working together, we put together a longer-term solution to provide the certainty doctors need and the security patients deserve," Baucus said in a statement.**

Politico's Janet Haberkorn wrote that by passing a one-year time frame fix for the docs, the Democrats eliminated a potential healthcare law repeal vehi-

cle for Republicans in the next session when they have more votes.

If passed by the House and signed into law by the President, this is a big win for docs. In 2010, there were five short-term fixes that physicians say made the Medicare program unstable. Last summer a cut actually took place but was quickly fixed retroactively until December 1.

—WE (December 8, 2010) ◆

spine

First Pedicle Screw System Cleared for AIS

Medtronic has received clearance from the FDA to use one of the company's pedicle screw systems to treat adolescent idiopathic scoliosis (AIS).

According to a company announcement on December 2, AIS is the most common type of scoliosis in children affecting nearly one million kids in the U.S. The company also said this marks the first such clearance by the FDA under the Agency's newly established category for pediatric AIS patients treated with posterior pedicle screw instrumentation.

> **Doug King, General Manager of Medtronic's spine business said, "This is a major milestone for surgeons and their pediatric patients. With this clearance we will now be able to provide training and education to surgeons to treat children diagnosed with AIS."**

The cleared device is the CD Horizon System. The system is a broad platform of fixation technologies, including implants and instruments, designed to provide spinal stabilization and correction in degenerative, deformity, and trauma applications. More than 500,000 individuals worldwide have been treated using the system, including those patients who suffered from such debilitating conditions as spondylolisthesis and spinal fractures.

Limited Intended Use

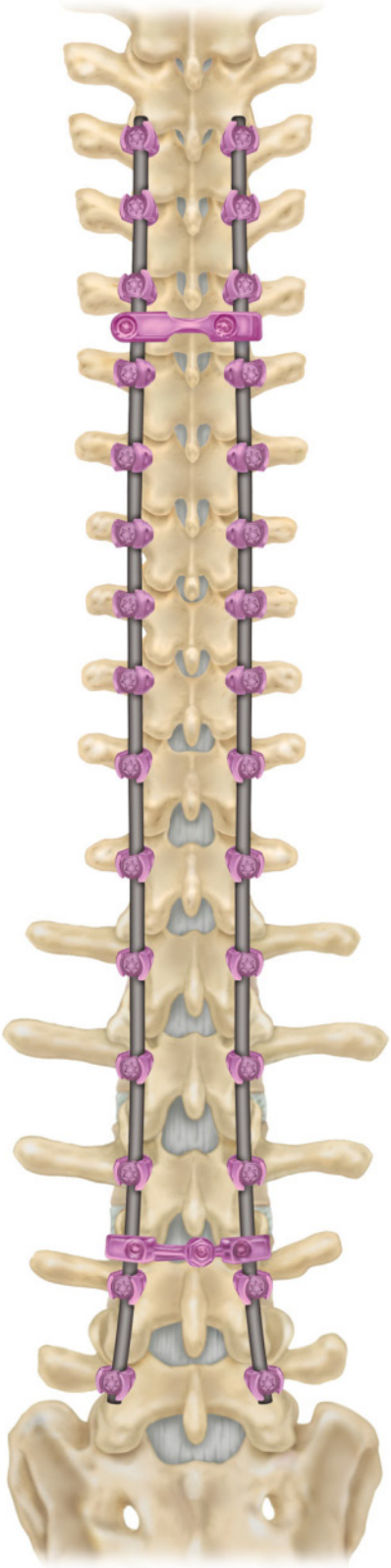
The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

David L. Skaggs, M.D., Professor and Chief of Orthopaedic Surgery at the Children's Hospital in Los Angeles says getting children back to their active lives and potentially reducing the need for additional surgeries are two key advantages of using pedicle screws.

> **"Using pedicle screws in the treatment of adolescent idiopathic scoliosis gives my patients the best chance of correcting their spine and chest deformity, and preventing future surgeries," said Dr. Skaggs.**

King added, "The opportunity to further research and study this patient population will allow us to move forward with our commitment and investment in pediatric innovation. Unlike adults, adolescent spines are still in a period of growth. Medtronic is committed to collaborating with the some of the world's best surgeons to develop and advance technologies to address the unique needs of children."

—WE (December 10, 2010) ◆

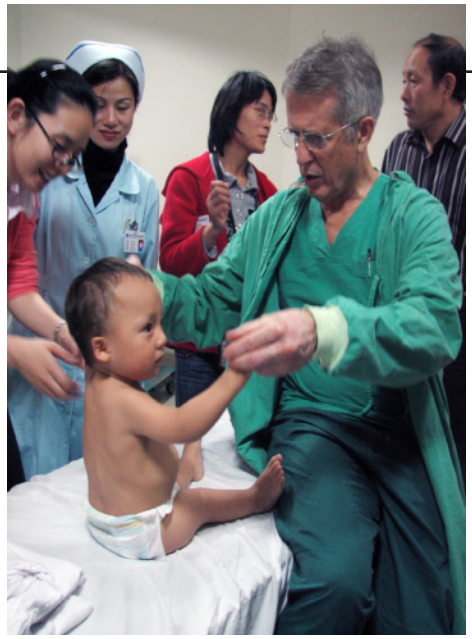


Medtronic

THE PICTURE OF SUCCESS

Dr. David P. Roye, Jr.

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



Dr. David P. Roye, Jr.

He had already given his best for many a patient in Kenya and Romania. But when Dr. David P. Roye, Jr., learned that there were hundreds of orphans in China with little hope of receiving proper orthopedic care, he had to get involved. Dr. Roye, winner of the 2009 Humanitarian Award from the American Academy of Orthopaedic Surgeons (AAOS), is the Executive Medical Director of the Children of China Pediatrics Foundation, an organization that provides orthopedic care to special needs Chinese orphans. Over the years, Dr. Roye has recruited 150 individuals to offer medical and other services to these children.

Born in Oklahoma, Dr. Roye, whose "day job" is as Chief of the Pediatric Orthopedic service at Children's Hospital of New York, is indeed a proud "Okie from Muskogee." Dr. Roye: "I was born in Oklahoma, where the people are extremely genuine. I soon had a chance to experience other locales, however, because my dad was stationed in France during the Korean War. He remained in the service, and we moved a lot, something that was positive because it meant that I had to be open and communicative in order to succeed. I thrived on all of this and developed a real wanderlust."

Regardless of where the young David Roye unpacked his suitcase, his Okie roots were always there. "The openness that I learned early on has truly enhanced my relationships with patients. I love New York, though interpersonal relationships are different here. But, my patients feel that I genuinely focus on them, and they can see that I really care about them. The fact that I traveled and lived in several countries has left me with better insight into what motivates different kinds of people."

Whether talking across cultures or across generations, Dr. Roye draws on his unusual life experiences. "In 1967 I went to Vietnam as an engineer officer. I was a 20-year-old company commander giving orders to people old enough to be my father, meaning that diplomacy and communication skills were essential. I understood for example, that you don't tell the equipment operator what to do without getting on the equipment yourself and having him show you what he does."

Reflecting on his years of training to be a physician, Dr. Roye notes, "My general surgery residency at Roosevelt Hospital was particularly difficult. We were on call every other night, and I wasn't available much for my wife and two young children. I was completely exhausted, so much so that I literally fell asleep and walked into a wall at the hospital. It was also no piece of cake when we packed our four kids up and headed to Toronto for my fellowship. Although being at 'Sick Kids' was clinically rewarding, my wife couldn't work in Canada and we had virtually

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"While I really loved the delivery of clinical care, it was a drip, drip, drip situation. So, I formed a new organization that would expand the delivery of care via policy and management…'International Healthcare Leadership' was born. We tested our curriculum in Beijing this summer and held a symposium where the U.S. Ambassador to China gave the introductory remarks."

no money. I had been offered a job at Columbia University, and was glad to return to the States and begin work in 1981."

Offering some wisdom to future fellows, Dr. Roye says, "Too often people select a fellowship based on the institution's fame. You should also consider the long-term effects of your choice. Ask, 'Is this the best place to develop an academic career? Am I going to learn how to do great research here? Will I develop mentorship skills at this institution?'"

A thoughtful planner *and* an adventurer, Dr. Roye struck out on his own early in life. "I left home when I was 16; I wasn't thrown out, but in fact left with my parents' blessing. We were living in Philadelphia and I wanted to work in Oklahoma and then attend the University of Oklahoma. They bought me a Greyhound bus ticket, and I was officially on my own. I recall the excitement of traveling across the country… I get the same 'charge' even nowadays when I hop on a flight for Beijing."

Two years after starting at Columbia, Dr. Roye dove into his passion—international work. "I began volunteering with Operation Smile, and went to Kenya several times. They were totally under resourced, but had talented young doctors. While the early experience in Romania was rewarding, I was increasingly frustrated by the fact that many surgeons were corrupt and not interested in learning. When my wife and I adopted our sixth child (from Romania), I closed the door on my work there. Following this I was recruited to join a new group which was formed to help Chinese orphans. We have done hundreds of surgeries and lectures, and have established a fellowship program that brings surgeons—and management personnel—to New York each year."

With one hand focused on his current work, and the other daring to reach forward, Dr. Roye took charge. "While I really loved the delivery of clinical care, it was a drip, drip, drip situation. So, I formed a new organization that would expand the delivery of care via policy and management…'International Healthcare Leadership' was born. We tested our curriculum in Beijing this summer and held a symposium where the U.S. Ambassador to China gave the introductory remarks."

"Our immediate goal is to introduce Chinese hospital administrators to evidence-based management. In my lectures I discuss how physician-based leadership in the U.S. has changed to leadership based on professional management teams. In China, management is still largely a top down affair, and is being done primarily by people who don't have management experience."

For those who might want to share their orthopedic talents globally, Dr. Roye advises, "Ensure that the organization has connections with the government and is well established. You don't want to be associated with an entity that is flying below the radar because government officials may put roadblocks up. I also encourage associating oneself with an organization that has continuity. For example, we return to the same hospital for several years and perform staged surgeries. Lastly, you must think of your personal safety. You have a lot to offer and shouldn't jeopardize your talents by working in unsafe or unstable situations."

The parents who greet Dr. Roye when he walks out of the OR in New York would surely agree…they want him to be available for their little ones. When asked about what has made him a success, Dr. Roye says, "The 'simple' ability to talk to people. If parents see that you are approaching the depth of their emotions that they have about their child then they will feel 'heard.' When I have to come out of the OR and tell a parent about a complication like neurological damage or paralysis, I try to do it with as much feeling and respect as possible. Most times, I end up crying with the parents. That vulnerability has been a significant part of my success as a clinician."

And he wants future orthopedists to be equally as empathic and involved. "After a surgery I bring the resident with me to talk to the family. I make sure they know that the family wants to hear the truth…and they want to hear

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that you are sorry this happened—even though it is not your fault."

In addition to his open heart, Dr. Roye also brings a mirror to the job. "I can 'stand outside' of myself and look in and say, 'Such and such is or isn't true.' Also, the ability to see both sides of an argument has slowed me up on a couple of occasions when I could have 'gone for the jugular.' As I built my division, I was careful to do so via consensus. Those who lead with respect for those they are leading—something displayed via consensus building—tend to get farther."

While Dr. Roye could see that was true, and has built an impressive department, he didn't have perfect vision at first. "We now have five pediatric orthopedists, we are nationally known, and are publishing peer-reviewed literature. But at first, as with many young academicians, I was shocked that the administration didn't share my vision. Over time I learned to communicate my vision in an organized, purposeful way. I try to tell ambitious residents and fellows that to get what you want, say, additional faculty, you don't tell the powers that be, 'We need more pediatric orthopedists.' That doesn't work… you have to put some thought into it and be an intelligent salesperson."

To keep his department on track as his field moves ahead, Dr. Roye will likely be doing a lot of selling. And, says Dr. Roye, the growth of pediatric orthopedics lies in, well, "growth". "The wave of the future is in genetics and bone physiology. There is an increasing focus on ways to modulate growth on a molecular basis. Now, there is either too much growth, not enough growth, or asymmetrical growth. One of the things we are considering is, 'What if instead of doing an osteotomy we put a catheter into the distal femoral growth plate?' There is much that will change…I don't expect that anyone a generation from now will be doing scoliosis surgery the way we do now."

Despite his many accomplishments in the professional realm, Dr. Roye says that his "44-year bi-professional marriage" is the pièce de résistance. "My wife is a nurse practitioner and is the Associate Dean of Research at the Hunter-Bellevue School of Nursing; she also has a clinical practice in female adolescent medicine. We have a lot in common, including similar career paths, something that has been important for keeping our marriage solid."

"We have six kids and twelve grandkids, all of whom live close by. We eat Sunday dinners together each week, and had 30 people for last week's meal. My role is to do the majority of shopping and cooking for the meal. In my free time I do triathlons, with my main interest being the biking. I can't maintain a strict training regimen because of my work schedule, but I enjoy the process nonetheless."

Dr. David Roye…stepping back in self-examination and stepping up for kids. ◆

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