VOLUME 5, ISSUE 29 | SEPTEMBER 22, 2009

Orthopedics This Week

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(2004-08 U.S. Procedure, Sales, Charging and Demographic Data as derived from Medicare AND Private Payer datasets)

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Spine Procedure	Code
Anterior cervical fusion	81.02
Posterior cervical fusion	81.03
Anterior dorsal fusion	81.04
Posterior dorsal fusion	81.05
Anterior lumbar fusion	81.06
Lateral lumbar fusion	81.07
Posterior lumbar fusion	81.08
Posterior lumbar refusion	81.38
Discectomy	80.51
Spinal Decompression	3.09

Large Joint Reconstruction	Code
Total Hip Replacement	81.51
Total Knee Replacement	81.54
Revision of Hip Replacement	81.53
Revision of Knee Replacement	81.55
Excision of Semilunar Cartilage	80.6
Cruciate Ligament Repair	81.45
Synovectomy of the Knee	80.76
Removal of Implanted Device Tibia/Fibula	78.67
Hemiarthroplasty	81.52
Hip Resurfacing	00.85

Extremity Implant Market Reports	Code
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Triple Arthrodesis	81.12
Subtalar Fusion	81.13
Total Shoulder Replacement	81.80
Partial Shoulder Replacement	81.81
Rotator Cuff Repair	83.63
Total Ankle Replacement	81.56
Open Reduction of Fracture Radius & Ulna w/ Internal Fixation	79.32
Open Reduction of Fracture Humerus w/ Internal Fixation	79.31
Open Reduction of Fracture Tarsals & Metatarsals w/ Internal Fixation	79.37

Orthopedics This Week

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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Big jump this week for Smith & Nephew—up five spots in the Power Rankings on the strength of a string of new product announcements. Stryker and Zimmer hang on to the #1 and #2 positions. All-in-all, last 30 days were one of the most consistently strong periods in a long while for orthopedic equities.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Stryker	23.28%	12.53%	Just a couple years ago SYK was consistently the most expensive major ortho stock. No longer. Now 7th cheapest ortho stock.
2	2	Zimmer	29.31	13.88	Nice run this past month. Still trading at one-half its all-time high. Buyers are returning to the large ortho companies.
3	8	Smith & Nephew	20.95	16.62	Something of a lagging indicator, SNN outperformed ZMH this month. Several new products announced.
4	3	Orthofix	7.65	10.53	Among the leaders in a rebounding spine market is…Orthofix. Overall spine market growth picking up—now over 11% YOY.
5	7	Alphatec	(8.51)	20.60	Steadily, almost inexorably, ATEC is finding its way into portfolios all over Wall Street.
6	6	Integra LifeSciences	12.32	4.32	In all the water cooler talk about buying bankrupt IST, one often-missed point is that IART manages and buys well.
7	4	Medtronic	31.37	2.46	Can the elephant dance? At all? Anything? Down four spots.
8	5	ArthroCare	16.87	15.66	The buying is slowing. The market is beginning to perceive ARTC as a fair price.
9	10	CONMED	8.28	18.82	Someone believes that the hospital buying will be recovering in the coming year. New buying in the stock.
10	9	Symmetry	10.80	5.52	Whenever things get quiet at SMA, something is usually cooking—and it's usually pretty good.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	I Flow Corp	IFLO	$10.40	$254	39.0%
2	Mako Surgical	MAKO	$8.88	$223	22.5%
3	Capstone Therapeutics	CAPS	$0.85	$35	21.4%
4	Alphatec Holdings	ATEC	$5.21	$273	20.6%
5	CONMED	CNMD	$20.58	$599	18.8%
6	Stryker	SYK	$47.16	$18,750	18.6%
7	CryoLife	CRY	$8.35	$237	17.3%
8	Smith & Nephew	SNN	$45.74	$8,080	16.6%
9	ArthroCare	ARTC	$19.20	$511	15.7%
10	Synthes	SYST.VX	$125.90	$14,941	14.1%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TranS1	TSON	$5.00	$103	-13.8%
2	Orthovita	VITA	$4.28	$327	-8.7%
3	Regen Biologics	RGBO.OB	$1.70	$17	-5.6%
4	Osteotech	OSTE	$4.61	$83	-4.0%
5	RTI Biologics Inc	RTIX	$4.66	$253	0.0%
6	Kensey Nash	KNSY	$28.56	$318	0.9%
7	Johnson & Johnson	JNJ	$60.78	167,500	2.5%
8	Medtronic	MDT	$37.46	$41,460	2.5%
9	NuVasive	NUVA	$41.15	$1,550	2.8%
10	Exactech	EXAC	$15.59	$199	3.7%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Symmetry Medical	SMA	$11.09	$397	10.11
2	ArthroCare	ARTC	$19.20	$511	11.28
3	Medtronic	MDT	$37.46	$41,460	12.46
4	Zimmer Holdings	ZMH	$51.12	$10,960	12.47
5	Johnson & Johnson	JNJ	$60.78	$167,500	13.47

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	I Flow Corp	IFLO	$10.40	$254	99.82
2	RTI Biologics Inc	RTIX	$4.66	$253	80.42
3	Smith & Nephew	SNN	$45.74	$8,080	80.00
4	NuVasive	NUVA	$41.15	$1,550	39.64
5	Synthes	SYST.VX	$125.90	$14,941	39.15

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	ArthroCare	ARTC	$19.20	$511	0.45
2	Orthofix	OFIX	$29.61	$508	0.91
3	Symmetry Medical	SMA	$11.09	$397	0.98
4	CryoLife	CRY	$8.35	$237	1.00
5	Exactech	EXAC	$15.59	$199	1.08

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$41.15	$1,550	4.30
2	RTI Biologics Inc	RTIX	$4.66	$253	2.25
3	CONMED	CNMD	$20.58	$599	1.83
4	Johnson & Johnson	JNJ	$60.78	167,500	1.65
5	Wright Medical	WMGI	$17.86	$690	1.59

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$4.61	$83	0.86
2	CONMED	CNMD	$20.58	$599	0.87
3	Orthofix	OFIX	$29.61	$508	0.93
4	Symmetry Medical	SMA	$11.09	$397	0.96
5	Exactech	EXAC	$15.59	$199	1.21

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$6.73	$166	231.23
2	Regen Biologics	RGBO.OB	$1.70	$17	11.01
3	Mako Surgical	MAKO	$8.88	$223	10.84
4	Synthes	SYST.VX	$125.90	$14,941	9.13
5	NuVasive	NUVA	$41.15	$1,550	4.89

5 Orthopedics This Week
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Is This Tax Good for Business?

By Robin Young

There is a plan working its way through the Senate that proposes to tax device manufacturers $4 billion to pay for increased insurance coverage in America. AdvaMed and the large manufacturers are against it.

We ran the numbers. Not so fast, AdvaMed. To us, Senator Baucus (D-Montana), the Chairman of the Senate Finance Committee, is proposing a government-funded program to increase the demand for all medical devices. Orthopedic companies sold about $30 billion in devices last year. The top 10 device companies sold about $100 million of products in 2008 (see attached table); add in the other couple hundred public medical device companies, and the medical device industry probably sells about $200 billion – $300 billion of products annually.

So this $4 billion tax sounds like a 2% tax.

There are 35 million to 40 million uninsured people in the United States (we saw numbers as high as 47 million, but if you exclude non-citizens the number drops). If Sen. Baucus' plan is half way successful and 15 million new, insured patients come into the healthcare system, orthopedic companies will sell 8% more implants. That's $2.4 billion of incremental revenue, about $1.8 billion in incremental gross profits and, very likely, $1.2 billion in incremental operating profit. If that costs these companies, say, 2% in new taxes, what's the problem?

Last year, on average, the top six orthopedic companies earned 26% on every sale—at

Table 1:Top 10 Medical Device Companies

	Annual Sales ($ in millions)
JNJ	$22,000
Medtronic	$14,800
Baxter	$12,230
Covidien	$10,250
Boston Scientific	$8,060
Becton Dickinson	$7,160
Stryker	$6,610
St. Jude Medical	$4,530
Zimmer	$3,990
Smith & Nephew	$3,680
Synthes	$3,272
Total	$96,582

Source: RRY Publications, LLC

the operating income line (that's after paying for making the products, all R&D, selling, marketing, and administrative costs. The only things missing are taxes and interest expense).

So, let's break this down. The tax is, let's say, 2%. On $30 billion in industry sales (last year's numbers), that's a tax of about $600 million annually. Nothing to sneeze at, for sure.

That tax is supposed to be used to pay for new insurance programs for under or uninsured people. What if it insures 15 million people who are not currently insured? How many will become customers for orthopedic companies?

Here's a quick way to calculate that. There are 177 million insured people in the United States (source: U.S. Census Bureau). Let's assume virtually all orthopedic patients are in that number. If the number of newly

insured people is 15 million, then that is an 8.5% increase. So, 8.5% more orthopedic patients. If our industry is serving 4 million patients annually, then we'd be adding 300,000 new patients with this 2% tax.

But, really, this isn't a 2% tax. It's a flat dollar amount based on market share. Our theoretical $600 million tax would be 2% based on last year's sales, but with 300,000 new patients and almost $2 billion in new revenues, that tax would fall to 1.9% and continue to decline as a percentage of revenues as more insured patients come into the system.

Would orthopedic companies pay 2% of revenues in exchange for 4x that in incremental revenue? Why not? Isn't that what marketing is supposed to do? What percentage of sales is that marketing and sales budget? Which major orthopedic CEO wouldn't invest 2% in the form of marketing and sales expenses to get an 8% bump in sales?

Probably the biggest risk for orthopedic manufacturers is if the number of insured patients does NOT appreciably increase. That, we think, is the real bottom line here. Both orthopedic manufacturers and President Obama have a common objective—more customers for orthopedic treatment. What is really interesting is that Congress appears to be working hard to create and fund a program which would almost guarantee millions of new patients each year (of which hundreds of thousands would be new orthopedic product customers each year).

In our calculations, if the number of new insured patients does not reach 6.5 million, then the industry loses money. More than 6.5 million new insured patients and the incremental profits are greater than the tax.

Why AdvaMed doesn't like this deal.

AdvaMed's President, Stephen J. Ubl, issued the following statement on September 9 in response to Senator Baucus' draft healthcare reform proposal.

"AdvaMed supports broad-based health care reform that will ensure all Americans have access to quality, affordable health care. From the outset we have worked with congressional leaders and the White House to help achieve this important goal for our nation. However, our industry will vigorously oppose the proposed $40

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billion tax ($4 billion over ten years) on medical devices and diagnostics that is included in the draft reform proposal."

We read a September 8 draft of Baucus' "Framework for Comprehensive Health Care Reform" and we saw $4 billion. Here's the language:

> ***"Medical Device Manufacturers Fee.*** Under this proposal, an annual fee of $4 billion would be imposed on the medical devices manufacturing sector beginning in 2010. The fee would be allocated by market share."

But Mr. Ubl objected to this tax for the following reasons:

1. The tax will fall most heavily on small companies.

2. Device manufacturers will have to share the pain from Medicare cuts as it is.

3. It will stif e innovation. We're not sure why the 2% tax would come out of the R&D budget instead of marketing…but Mr. Ubl is positioning AdvaMed's opposition on that conclusion. Apparently, in order to maintain those 26% profit margins, Mr. Ubl thinks that companies will cut R&D.

Steer, Don't Fight

The U.S. government is creating a government-funded program to significantly increase customers for orthopedic products. Not surprisingly, it is working up a tax on device companies to partially pay for the program. If orthopedic manufacturers decide to fight this, they will appear to be reactionary. If they recognize that a program is coming together which increases demand for their products, then they should endorse it in principle and then work to steer it so that it becomes a win-win for industry, patients and physicians.

Glow-in-the-Dark Doc: Radiation Exposure

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

There are a few orthopedists who might like to enter the OR—or exam room—with a bullhorn. Their colleagues, naturally focused on the patient's damaged anatomy, might not be paying much attention to the invisible danger lurking nearby…radiation.

The Sobering News on Radiation

Dr. Brian D. Giordano, an orthopedic resident at the University of Rochester Medical Center, has researched the effects of radiation on both patients and surgeons. And he's concerned. "Orthopedists are increasingly reliant on radiographic imaging for our diagnostic and therapeutic work, thus putting our patients and ourselves in a vulnerable position. While patients are only occasionally exposed to radiation, surgeons may be exposed on a daily basis. In the last 20 years there has been a focus on making interventional procedures less invasive. While that has its upsides, of course, the downside is that we are now even more heavily reliant on indirect visualization, such as intraoperative fluoroscopy, which can be used to help guide the placement of various implants and facilitate reductions."

Dr. Glenn Rechtine, also an orthopedist at the University of Rochester, is most alarmed about what is emanating from that beloved piece of diagnostic equipment—the CT scanner. "The statistics are sobering—patients are being subjected to 30 times more radiation now than they were 20 years ago. The greatest risk for patients is not from the OR or the C-arm but from a CT scanner. CT scans comprise only 5% of X-ray imaging but almost 50% of total radiation exposure to patients. Most doctors just don't know what they're subjecting their patients to. In fact, 95% of physicians grossly underestimate how much radiation exposure both they and their patients are getting. Only 14% of doctors have undergone any training on radiation."

Exposure 101

Exposure usually begins in medical school. Dr. Rechtine: "Basic training can make a big difference in the level of exposure. For example, setting up a C-arm in a different way can change the amount of radiation exposure 50 fold. If patients are getting 50 times more radiation, then the doctor is too."

Left agog by the nonchalance of some of his colleagues, Dr. Rechtine says, "About four years ago when I started this work, the radiation physicist did a presentation at Rochester on the dangers of radiation. It was disheartening to see a surgeon doing a crossword puzzle during the talk."

Pounding the drum louder, Dr. Rechtine has taken his message to wider audiences. "I have done presentations for the Cervical Spine Research Society, the North American Spine Society, and other entities. One powerful example I give is of a front to back X-ray of a trauma patient in the ER. The technician taped a hemostat to a film cassette and held this seven feet away while he was taking the X-ray, the point at which we traditionally think we're safe from radiation. When the film was developed you could see the hemostat—there was scatter radiation. Yes, it was a small amount but the point is that it's not 0. All you have to do is use the tools available to us—lead aprons, for example—and you can decrease your exposure."

On one occasion Dr. Rechtine got a creative suggestion for combating the cavalier attitude of some of his colleagues. "A couple of years ago I was invited to speak at the University of Kentucky department of orthopedic surgery. When the program director told me that I was on the schedule to talk about radiation safety Friday night, I said, 'No that's the banquet. Families are there.' The program director said, 'Glenn, I have heard your talk and have been pounding on the surgeons to change, but to no avail. It's time to talk to the spouses.'"

The Need for Research

Giving a bit of background on his research, Dr. Giordano notes, "We used a highly sensitive radiation monitor and found a chink in the six foot rule. We stood 20 feet away from a mini C-arm and were still getting 40 times the background radiation dose.

Unfortunately, the dogma with regard to a mini C-arm is that because we use radiation reduction tools you don't have to be as careful."

Dr. Rechtine: "Someone I know actually stands ***inside*** the C-arm with his foot on the pedal…and with no apron. I evaluated the radiation exposure report of 24 attendings at a major university over a period of six months. 'Miraculously,' the total exposure was 0. That was because of the 24 surgeons using the C-arms, only four of them picked up their radiation badges. Even these four didn't wear them in surgery."

"Such complacency carries forth in a lack of awareness of how radiation impacts patients," says Dr. Rechtine. "In general we are too casual about writing prescriptions that exposure our patients to radiation. And most times the patients don't know enough to object. Estimates are that there are 30 times more CT scans being done now as opposed to 20 years ago. It has also been estimated that 2% of all cancers are from the excessive use of CT scans. If, for example, someone is in the hospital, he or she may have an abdominal CT four days in a row to see if something has changed. Or, if a trauma patient gets a CT of the abdomen, something might be picked up that leads to a CT of the spine. So they get a spine CT, which has more radiation than an abdominal CT. It is a tough call to make in some cases."

And it's especially hard if people are muddying the waters. Dr. Giordano: "I recently wrote a letter to the editor at the *Journal of Neurosurgery: Spine* about an article they published on the 'safety' of minimally invasive spine surgery. I pointed out that surgeons doing this procedure get a fair amount of radiation and patients gets huge doses…and yet the title included the word 'safety.' The high doses were essentially passed off as meaningless."

But Dr. Giordano has hopes of making an educational impact with the younger generation. "Residents in particular are at a heightened risk for

exposure because of all the minimally invasive techniques and use of the C-arm fluoroscopy in the OR. Because they are still learning, their skill levels are not as adept, so they repeat the tests. And when they are first learning to work with pedicle screws, they are checking every step of the way with an X-ray."

Europe is often ahead of the U.S., not just on the clock, but in thinking. Dr. Rechtine: "I went to a meeting in Vienna with the International Atomic Energy Agency where we worked on a serious plan to educate doctors on the dangers of radiation exposure. Actually, the EU is on the brink of mandating that every doctor using a C-arm undergo a two day training course. While I would like to see that happen here, I think we're a long way away."

Uncovering the Facts

But Dr. Giordano's research *goes* a long way toward making a case for prevention. "We conducted a series of studies, in the first one using mini C-arms to image anthropomorphic hand specimens (synthetic specimens with the tissue equivalent of human tissue). We positioned 13 radiation dosimeters at different angles and distances relative to our specimen, which we then imaged for a total of 300 seconds. After 155 sequential fluoroscopy images, we found minimum levels of radiation outside the direct path of the radiation. The point of greatest exposure was at the sensor positioned directly in the palm of the phantom limb. Based on our findings, we determined that a surgeon would exceed the annual radiation dose limit after approximately ninety-two minutes of direct beam exposure. If, however, the patient and the OR team remain beyond 15 centimeters from the point of focus on the image intensifier, they should only be exposed to minimal radiation."

He continues, "Our initial imaging scenario offered some reassurance that beyond the direct path of

the X-ray beam the surgical team was being subjected to minimal radiation. However, this did not take into consideration the effect to the patient, or how the radiation dose is effected by suboptimal imaging conditions such as varying the size of the specimen or the distance within the arc of the C-arm. We realized that there was much more we needed to understand about the relationship between radiation exposure and specimen size, position, and tissue density. Namely, we became curious about how much exposure the patient and surgical team were being subject to during in a 'worst case scenario'."

Taking a step-by-step approach, the team then asked, "What would happen if we used a larger specimen?" Dr. Giordano: "Using large and mini C-arms, we imaged a cadaver ankle and foot under three scenarios. The best case scenario meant that the specimen was nearly touching the image intensifier. The worst case scenario involved placing the ankle/foot within two inches of the radiation source, while in the 'middle' scenario the specimen was ten inches from the radiation source and the image intensifier."

"Overall," says Dr. Giordano, "Our findings indicate that while there was higher exposure for the large, as opposed to the mini, C-arm, the latter can indeed produce substantial radiation. Additionally, we learned that as the ankle/foot increased in cross-sectional area and tissue density, or was brought nearer to the radiation source, there is a substantial amplification in the patient's level of radiation exposure. In fact, when the large C-arm was used and the ankle specimen was brought from a best-case to a worst-case configuration, there was a tenfold increase in the patient's direct radiation exposure. Repeating this with the mini C-arm, we found that yet again the patient's exposure increased more than tenfold from the best-case to the worst-case scenario."

Dr. Giordano and the team then focused their attentions on quantifying the radiation involved in imaging the cervical spine with a mini C-arm. "Looking at the cervical spine and skull, we found that the scatter radiation to the patient was up to 10 times greater going from a best to worst case scenario. The scatter radiation to the surgeon was more than doubled going from the best to worst case position.

"Then we posed the question of whether imaging a larger specimen or altering the position of the extremity in the arc of the C-arm beam would have an effect on the level of radiation. Theoretically, larger specimens require more radiation to create a higher quality image, but you have more scatter radiation. We added a control—a large C-arm—and found that when the cervical specimen was brought closer to the radiation source, exposure to the patient was markedly amplified. This wasn't the case with surgeon exposure, however, as it did not increase as dramatically. Exposure doses recorded by the peripheral dosimeters varied significantly, something that underscores the influence of the shape of the imaged specimen on reflected scatter."

He continues, "While a larger specimen like the spine produces 10 times more radiation to the patient, there is at least two times more radiation to the surgical team. The reason that both parties are subjected to more radiation is because the cross sectional area of the specimen is much larger. When the C-arm is set to the 'normal' mode, technique factors are automatically adjusted to produce an image of optimal clarity. Therefore, when a larger specimen is placed into the beam, technique factors automatically increase to accommodate the large size of the body area, thus increasing the X-ray dose emitted by the X-ray tube. The traditional argument is that standing on one side or another makes a difference. We found that no matter where you stand there are elevated levels of radiation."

A former Medical Officer in the Navy, Dr. Rechtine gives details on measuring exposure: "The Rem

(Roentgen Equivalent Man) is the unit of radiation exposure. By law, occupational exposures, such as working at a nuclear plant, are limited to five Rem per year. Interestingly, the international standard is two. In 1991 the international standard was changed after investigators revisited Hiroshima and found that the cancer risk from low dose radiation was higher than they had thought. The average level of exposure of those surveyed was three Rem. The policy at our institution is that if you get 1/10 of that you have to meet with the radiation safety expert and explain why the situation warrants that kind of exposure."

Dr. Giordano also wants to lower the definition of a "normal" dose of radiation: "One of the most important things we found when examining the literature on this topic is that many authors look at the best case scenarios and extrapolate forward. The reasoning is, 'Well, the patient and the surgical team are exposed to X, so in a given year a surgeon can do 200 of these procedures before he reaches his limit. This thinking is flawed because the maximum annual occupational radiation level should not be a desirable value we aspire to. Instead, the focus should be, 'How can I change my practice so that I minimize the risk to my patients and myself?'"

In a way, the more you know, the more you should be scared. Delineating how research brings about practical changes, Dr. Rechtine says, "In 1930 the Rem allowance was 500 per year, in 1940, 50 per year, etc.—the real question is what level is safe. We should continue to strive for the concept of ALARA (as low as reasonably achievable)."

The other major issue, says Dr. Jonathan Grauer, Co-Director of the Orthopaedic Spine Service at Yale School of Medicine, is what is clinically relevant. "My colleagues and I are trying to establish what specific X-rays make a clinical difference.

Looking at this issue from an overall resource utilization standpoint, it is clear that certain routine imaging does not significantly impact clinical care. For example, potentially not every postoperative cervical spine series needs an AP image."

But we do need more concrete research on the effects of imaging tests. Dr. Grauer notes, "I went to a radiologist colleague and asked him to produce a relative risk association with imaging and determine how much radiation was being imparted to patients with routine studies. Even though the radiologist said it would be easy, in the end he was unable to give us useful information."

With "niche" practically written in neon, Dr. Grauer and his colleagues moved forward to fill a hole in the literature. "Our overarching aim was to examine the increasingly accepted concept of 'effective dose,' something which takes into account the relative sensitivities of different organs. We began with plain X-rays of the spine, calculated the effective doses, and related them to the amount of radiation associated with a routine chest X-ray. Then our attention turned to CT scans, known to be the worst offenders. We looked not just at the spine, but throughout the musculoskeletal system to find the effective dose of radiation associated with clinical studies."

"Working with a physicist and safety specialist," explains Dr. Grauer, "we found that as you move further from the torso there are dramatically less effective doses of radiation associated with CT scans. For example, in a scan of a distal radius fracture, we found the effective dose of radiation to be less than that of a chest X-ray. Incredibly, a CT scan of the lumbar spine is equivalent to several hundred chest X-rays because of the organs exposed in the process. This work has just been published in the August 2009 edition of the *Journal of Bone and Joint Surgery*."

Final Words of Advice

And if Dr. Grauer had the bullhorn? "Our biggest message is that orthopedists have to understand this concept of effective dose and be aware of what is associated with more and less radiation. We should not be getting films without careful consideration. For example, during my training I noticed that all patients who came in for cervical or lumbar spine problems got a series of four films for the affected region. As we looked at our practice, my partners and I found that flexion and extension films were not routinely clinically mandatory at the time of the initial patient encounter. For the last three years, after we objectively demonstrated this point, we have stayed away from flexion and extension films unless there is a specific clinical question being asked, or for the preoperative patient."

"In the future," says Dr. Grauer, "we will see a more conservative attitude when it comes to ordering imaging studies. And with any luck—and a lot of hard work on the education front—some of this will emanate from the drive to minimize radiation."

Spinal Motion Preservation: Update and Outlook (Part 2 of 3)

By Matt Menze, PearlDiver Spine Analyst

Last week we tackled the concept of motion preservation in the spine. At the start of the new millennium, the concept of motion preservation technology took the spine industry by storm. While clairvoyants preached the end of the world, pundits in the spine industry proclaimed "the end of fusion." Neither prediction came true.

Artificial discs, interspinous process spacers, and dynamic constructs continue to evolve, but to what end? What will become the standard of care?

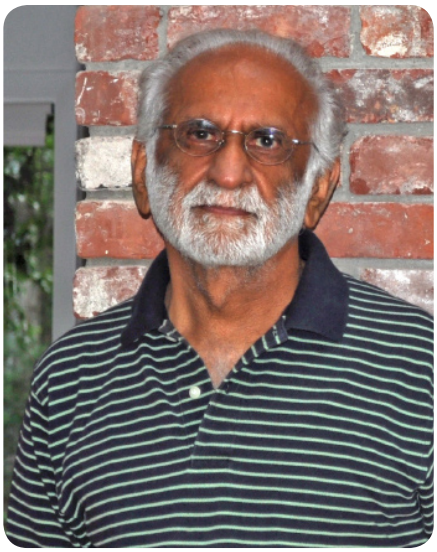
Based on our conversations with leaders in the field, pedicle screw based dynamic stabilization could be the most logical solution for most surgeons and patients who are seeking to preserve motion while still treating spinal instability. There is, in other words, a middle road between disc arthroplasty and spine fusion—a middle road that ultimately may be more consistently successful for patients and their surgeons.

IVP Duplication/ Wikimedia Commons

But one issue continues to emerge as a concern among surgeons with regards to pedicle based motion preserving technologies—pedicle screw loosening.

Pedicle Screws and Motion Preservation

Pedicle screws represent a potential concern when used to anchor a motion preserving device. Certainly, the performance of pedicle screws is well established in rigid fixation. But for motion preserving technologies, long-term data is lacking.



Dr. Manohar Panjabi, Professor Emeritus, Department of Orthopedics and Rehabilitation, Yale University School of Medicine

According to Dr. Manohar Panjabi, Professor Emeritus, Department of Orthopedics and Rehabilitation, Yale University School of Medicine, when surgeons use fixation for fusion, the pedicle screws essentially remain in use for only about six months, and thereafter the screws are not fully loaded. However, when surgeons use pedicle screws with motion preserving devices, those screws are fully loaded throughout the life of the device. How can researchers and device manufacturers ensure that dynamic screws will withstand carrying a full load for a device's entire life-span?

Dr. Vijay Goel, Co-Director at the Engineering Center for Orthopaedic Research Excellence at the University of Toledo notes that pedicle screw testing is more rigorous in dynamic stabilization devices than in rigid fixation devices. Researchers often test pedicle screws in dynamic stabilization

Dr. Vijay Goel, Co-Director at the Engineering Center for Orthopaedic Research Excellence at the University of Toledo

devices for 5 million cycles, but they only test screws in rigid fixation devices for as low as 2.5 million cycles. Dynamic screws are sometimes slightly stronger at the head than rigid screws, which helps the dynamic screws hold greater loads throughout the life of the device.

Dr. Avinash Patwardhan, Director of the Musculoskeletal Biomechanics Laboratory at Edward Hines Jr. VA Hospital and Professor of Orthopaedic Surgery at Loyola University Medical Center, also notes the importance of pedicle screw design in motion preserving technology:

"The biggest problem in dynamic stabilization devices is maintaining good fixation to bone. A very rigid device could loosen or break, as seen in the Dynesys device, because of the high rigidity of the device.

"This was taken into account in the design of Stabilimax NZ. By providing a ball and socket joint at each pedicle screw-device junction, only the compression-tension force

Dr. Avinash Patwardhan, Director of the Musculoskeletal Biomechanics Laboratory at Edward Hines Jr. VA Hospital and Professor of Orthopaedic Surgery at Loyola University Medical Center

in the device is transmitted to the screw without causing any bending moments, which theoretically lowers the incidence of screw breakage. You also don't want a dynamic stabilization device to bear the full load. You want it to share the load with the rest of the spine. If you put 100% of the load on the device, the chances of device failure increase."

Dr Goel couldn't agree more.

"Unlike posterior instrumentation in fusion systems, posterior dynamic stabilization (PDS) devices are expected to function throughout the life of the patient. This makes both the screw design and the implant design equally critical. A true dynamic stabilization implant (one that has an optimum stiffness profile, permits interpedicular travel, and thus maintains a near normal center of rotation) will impose lesser loads at the bone-screw interface as compared to a fusion system. You can further reduce the loads at this interface by using devices, such as in Stabilimax NZ, which avoid or reduce bending moments."

"While conical screws are favorable mechanicallythey are also the least forgiving surgically. If, for example, the screw height needs to be adjusted during surgery, backing out a conical screw has a detrimental effect on its purchase. Hence, some combination of a cylindrical and conical geometry should be used for a PDS screw in order to maintain the most strength in the region where the screw holds the heaviest load.

"Also, while a stiffer screw is less prone to fracturing, it could also be more prone to loosening, which is definitely a concern for PDS systems. This factor should be kept in mind while designing a PDS screw. HA (hydroxyapatite) coating theoretically seems beneficial for the loosening issue, but we need to see clinical data to validate that theory. Other surface treatments, like the dual shot peening of the Stabilimax second generation pedicle screw, may also help decrease screw loosening. These coatings can improve the surface roughness and fatigue life of the screw without necessarily making the screw stiffer."

According to Dr. Goel, manufacturers and designers employ a wide range of materials in dynamic stabilization devices, but it is important to differentiate the device from the screw. Screws are primarily made of titanium. The devices may be comprised of polymers, titanium, cobalt chromium, carbon fiber, and PEEK (polyaryletheretherketone) which has the advantage of being radiolucent. Another emerging biomaterial that manufacturers could use in dynamic stabilization devices is nitinol. Nitinol is a shape memory alloy made of nickel and titanium originally developed by the U.S. Navy. However, Dr. Goel notes that nitinol is a difficult material for manufacturers to use during fabrication, and there could be issues with fatigue resistance. Still, Dr. Goel expressed his confidence that these issues would eventually be overcome, allowing for nitinol to play a greater role in orthopedic devices in the future.

The Neutral Zone and Pedicle Screw Based Dynamic Stabilization Technology

Dr. Panjabi's research has focused on the elements of motion in the spine and spinal instability as it relates to back pain. In his two-part article entitled "The Stabilizing System of the Spine" published in the *Journal of Spinal Disorders,* he postulates that the spinal stabilizing system consists of three subsystems: the passive subsystem (spinal column), the control subsystem (neural) and the active subsystem (spinal muscles). If any one of these subsystems dysfunctions, then the others may compensate, maintaining normal functionality of the spine. However, injury to one or more of these subsystems can lead to low back pain.

Based on extensive experimental studies conducted by him and his colleagues, Dr. Panjabi has identified what he terms the "neutral zone" in the spine. The neutral zone (NZ) is the initial part of the range of motion within which spinal motion is produced with minimal internal

resistance. It is the micro-motion that the spinal segment inherently exhibits around its neutral posture. Other experimental studies of spinal injuries have shown that the NZ is a more sensitive indicator of spinal instability than the full range of motion. Dr. Panjabi postulated that an increase in NZ could lead to back pain. If one could preferentially stabilize the NZ, then one could reduce the back pain and simultaneously allow spinal motion.

The Stabilimax NZ (Applied Spine Technologies), displayed in Figure 1, is based on Dr. Panjabi's theories regarding the interaction of subspinal systems and the experimental findings concerning the neutral zone. With two uniquely arranged springs, this device can preferentially decrease the neutral zone.


Stabilimax NZ (Applied Spine Technologies)

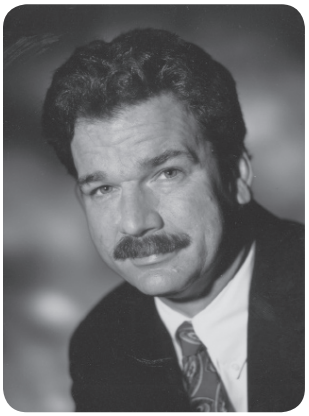
Do PEEK and Tension Band Technologies Allow Enough Motion?

Dr. Patwardhan expresses doubts as to whether pedicle based dynamic stabilization devices incorporating PEEK or tension bands truly allow enough motion. He describes devices based on PEEK as "bogus," and states, "If you just take a PEEK rod it will not stretch enough to allow the motion that is sought after in a true dynamic stabilization device, and it will not allow enough excursion. In the case of a tension band device such as Dynesys, there is an elastic bumper at the end of the band which compresses to allow some excursion, but the Dynesys has very little motion because it doesn't allow adequate pedicle to pedicle travel."

Dr. Patwardhan suggests that the real key is to incorporate a spring into pedicle based dynamic stabilization devices. The spring can be made out of titanium or cobalt chrome, depending on the fatigue characteristics.

Is There a Future for Tension Band Technologies?

Based on our conversations with leaders in the design and theory behind pedicle based dynamic devices,


Dr. Paul McAfee, Chief of Spinal Surgery at Towson Orthopaedic Associates

implants such as the Dynesys that utilize tension bands may not provide the desired degree of motion in technologies of this nature. According to Dr. Paul McAfee, Chief of Spinal Surgery at Towson Orthopaedic Associates, the basic problem with the Dynesis is that it is too stiff to provide the appropriate amount of motion. The other issue is that the PET (polyethylene terephthalate) cord on the Dynesys could stretch out over time and contribute to instability.

However, the industry is not giving up on tension band devices. The Transition posterior dynamic stabilization system marketed by Globus Medical incorporates tension band technology and overcomes several of the drawbacks seen in the Dynesys device. The Transition system has an extra bumper as compared to the Dynesys device which allows for additional motion. Additionally, Dr. McAfee notes that the device allows for a "soft stop" which decreases the chances of screw loosening.

Next Week: We close our three-part series with a discussion of the use of dynamic stabilization as a hybrid device and the resurgence of dynamic stabilization as the future of motion preservation in the spine.

Orthoville to OrthoWorx

By Walter Eisner

Orthoville held a revival meeting on September 11. The tent was the brand new Orthopaedic Capital Center on the campus of beautiful Grace College in Winona Lake, Indiana.

The secular gospel for the 200+ parishioners attending the Indiana University Kelley School of Business Life Sciences Conference was delivered by Indiana native son and Rhodes Scholar, David Johnson, President and CEO of BioCrossroads. The gospel was in the form of a report paid for by the Lily Endowment.

In addition to David Johnson, the conference brought in national industry experts from Washington, the media, and top leaders of local orthopedic companies.

Dr. Blanchard Addressing Attendees, photo courtesy of BioCrossroads

"Lessons From the Orthopaedic Capital of the World"

The 58-page BioCrossroads report, *"Lessons From the Orthopaedics Capital of the World,"* laid out a blueprint for future industry and community growth for Indiana's orthopedics industry and the need for the folks of Warsaw and Kosciusko County to agree on a common vision for their community's future.

Warsaw has been the center of the orthopedics world ever since Revra DePuy figured out that the trees in Kosciusko County had the perfect qualities to make splints for wounded soldiers. Founded in 1895, DePuy begat Zimmer in 1926, followed by the engineer Miller who spawned Biomet in 1977. Eventually Danek, now Medtronic, joined them. Today, the area is home to one of the most concentrated clusters of manufacturing anywhere in America.

Grace College Orthopaedic Capital Center, photo courtesy of BioCrossroads

These giants are supported by dozens of Warsaw-based suppliers and contract manufacturers such as Symmetry Medical. "Collectively," says the BioCrossroads report, "these enterprises earn more than $11 billion in annual revenues, representing better than a 50% market share in the United States, and more than a 33% market share in the world." The report went on to state

that since 2001 the area's orthopedics industry employment base has grown by 39%, adding 2,800 jobs to reach nearly 6,000 jobs today.

Playing in the Local Sandbox

So what's the problem? Why the need for a new plan?

Johnson said while the sector has been tremendously successful, their research makes it clear that "global pressures now confronting the whole economy...have sparked a broadly perceived need for a community and industry engagement strategy focused on education, talent recruitment and retention, workforce and community development to ensure sustainability."

In other words, the people of Warsaw have to figure out a way to better educate their workers, keep the ones they have and make their community a place were top talent wants to live, work and play. When you compete with the lure of Beale Street in Memphis—the "other" orthopedic cluster—the quality of "community" in the Warsaw area becomes a significant factor. In a community where the leading industry players are used to going to the mat for market share, working together will require the sale of a common vision and a degree of collaboration not seen in the past.

The current spotlight on physician consultation practices of the "Big 3" in Warsaw by the U.S. Department of Justice "only intensifies the isolation of these companies from one another," says the report.

Warsaw Mayor Ernest Wiggins told us during a reception that the community

Warsaw Mayor Ernest Wiggins

has to do something to attract and keep employees for their orthopedics businesses. He also quickly pointed out that Warsaw is also the home of the largest printing presses in the world; home to the world's largest manufacturer of projection screens; and home of the famous CoCo Wheats hot breakfast cereal.

Regional Cooperation

The Mayor sees a bigger picture than just his community. Warsaw has been jealously guarding its industrial treasures as other cities have offered alluring incentives for expansion in their communities. "This has to be a regional effort," the Mayor told us.

Warsaw is not very similar to small towns dominated by one industry. In this industry town, there are three major competitors perched on various edges of town. They compete for market share, employees and intellectual property. But ultimately, their employees go to the same churches, their kids attend the same schools and work is cautiously brought up at little league baseball games.

The companies are known locally for differing cultures. Biomet has had a reputation for casualness, Zimmer is a bit more dressed up, and DePuy is button-down, being owned by Johnson & Johnson from New Jersey.

A visit to this conservative community will not show evidence of remarkable cooperative action that one would expect from such a wealthy town. Big government is not welcomed here, even local big government.

The Mayor's comfort with regional cooperation was highlighted in the report by noting that neighboring communities such as Ft. Wayne, which has housing and business services, and South Bend, which has university, research and medical centers not available in Warsaw, could serve to "extend Warsaw's vitality and sustainability."

Innovation and R&D

That Warsaw is a manufacturing hub is well-known, but it is also a growing

Redefining Metal Bearings

Precision contoured aSphere™ M-Spec heads approximate the shaping that occurs during the in vivo run-in wear phase. This results in an 80% reduction in wear debris and a 77% reduction in metal ions compared to industry-leading Pinnacle® Ultamet® metal bearings.[1]

DePuy aSphere™ M-Spec heads: another meaningful innovation from Pinnacle® Hip Solutions.

PINNACLE® HIP SOLUTIONS

1. Data on file at DePuy Orthopaedics, Inc.

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center of innovation and R&D. The BioCrossroads report mentions that Zimmer has 800 researchers working in Warsaw, and there are currently more than 30 sponsored research partnerships with institutions such as Purdue and Notre Dame down the road. The citizens of Warsaw have also generated patents at six times the national average. Intellectual property matters in this community, and cooperative efforts to foster that local resource received a lot of attention from attendees at the September 11 conference.

For example, orthopedics isn't just about hips, knees, hammers, nails, screws, and plates anymore. The future of orthopedics lies in biological and regenerative treatments. As Zimmer's chief scientist, Cheryl Blanchard, Ph.D., told us recently, "We're in the 'meeting unmet clinical needs' business."

But threats to Warsaw's preeminence are evident. The report cited some local challenges:

- "Significant" shortfalls in the education of orthopedic workers,
- Difficulties in attracting and retaining senior talent,
- Absence of locally accessible industry support services,
- Transportation and infrastructure challenges, and
- An increasing need by smaller orthopedic players for access to innovative research, new technologies and capital.

Collaborative Seedlings

The report said the community has "developed opportunistically" rather then strategically and this may not serve it well as it addresses its future challenges. There was praise for the collaborative planning and investments totaling more than $6 million for shared facilities used for education and technical development purposes at both Grace College and Ivy Tech Community College.

The 56,000-square-foot Orthopaedic Capital Center on Grace College is a center for community events and conventions. It was built in partnership with Biomet, DePuy Orthopaedics, Paragon Medical, Symmetry Medical, and Zimmer.

But the big opportunities were identified in the area of developing intellectual capacity.

The report identified an opportunity to "establish a center of research, testing and education, building on, but also extending beyond, sponsored research partnerships and educational investments the companies in the cluster have already made. Such a center could potentially be college-

and university-led, and provide a platform for engineering, business, and regulatory and other technical support services responsive to widely acknowledged orthopedics sector needs."

This was all music to the ears of Zimmer's Blanchard, one of the key organizers of the project. Blanchard said she has been working on this effort since joining Zimmer. With the presidents of the orthopedics divisions of DePuy and Biomet, David Floyd (a local Grace College graduate) and Jon Serbousek, respectively, joining Dr. Blanchard at the conclusion of the conference to support this effort, the revival meeting may well spur Orthoville into a makeover and we'll have to begin referring to Warsaw not as Orthoville, but as the business "League of OrthoWorx."

OrthoWorx

Now that the revival meeting is over and the blueprint has been delivered, what happens next?

We'll give the final word to the folks from BioCrossroads.

"There is definitely an energy that emerged as a result of the release of the BioCrossroads Orthopedics report and the IU Kelley Conference last week. The research we did seems to have sparked a broadly perceived need for a community and industry engagement strategy focused on education, talent recruitment and retention, workforce and community development to ensure sustainability. And, we've heard from several community and industry leaders who are interested in taking a role in the development of the initiative and getting involved," said Lori LeRoy, BioCrossroads' public relations and marketing manager.

David Johnson and Industry Leaders, photo courtesy of BioCrossroads

LeRoy continued, "We're now in the process of developing a Warsaw-based, regionally focused organizational initiative that can better define and prioritize the challenges and opportunities, and then seek funding to bring the best and most responsive ideas to life.

"During David Johnson's panel that included Cheryl Blanchard, Jon Serbousek, David Floyd, Toby Buck, Brian Emerick (Micropulse CEO), Ron Manahan (Grace College President) and David Finlay (Lake City Bank), we heard positive signs that everyone wanted to be engaged moving forward. Specifically, there seems to be a lot of interest in working on educational opportunities, both K-12 and higher ed, as well as developing some of the other recommendations. They all have a common goal of driving the community and industry forward so that the sector continues to thrive.

The BioCrossroads report concludes that it is important to establish a "credible, highly consultative, participatory, and strongly supported branded community initiative—soon. An organization such as OrthoWorx…is in the best position to translate opportunities into action."

Creating a new vision of a future and rebranding a community that has been one of the most successful little towns in America will not be easy. But as Mayor Wiggins told us, "We have to do it."

Go OrthoWorx!

company news

Integra Spine Buys IST Assets

For $9.25 million in cash, Integra Spine is now the proud owner of most of defunct Innovative Spinal Technologies' (IST) intellectual property (IP) and assets. Integra acquired the assets in an auction process conducted by a bankruptcy trustee after IST filed for Chapter 7 bankruptcy protection this past May.

IST's IP was created by spine surgeons at Texas Back Institute and will now continue to find their way into patients through the efforts of Integra's spine leader, Randy Theken.

Theken said on September 14 that the IST portfolio adds a minimally invasive spinal implant system to their existing portfolio.

"This acquisition gives us innovative products that can be readily available near term, as well as IP that will support a pipeline of new products, particularly in the rapidly growing field of minimally invasive spine surgery."

The collapse of IST has been well documented and the public disagreements between former IST leader Scott Shorer and Texas Back co-founder Stephen Hochschuler, M.D., played out like a dime store melodrama. Questions about how $75 million in venture capital was spent and corporate strategies pursued by company leaders are unanswered and we may still not have heard the end of the collapse of IST. But for now, the drama has moved from collapse to a rising Phoenix.

Dr. Hochschuler told *OTW* on September 16 that he believes that, "this is a smart buy [for Integra] if they can resolve the outstanding IP issues and finish the products."

The product lines acquired in, what some called a fire sale, include the Paramount MIS/Open system for percutaneous lumbar fusion procedures, the Paramount interbody fusion system, and the Cordant anterior cervical plating system, as well as the product development assets related to IST's Axient product line for posterior dynamic stabilization. Integra Spine acquired IST's portfolio of over 100 U.S. and foreign patents and patent applications, its trademarks, and its product inventory, and assumed certain of its patent license agreements.

Theken and Integra Spine expect to launch the Paramount MIS/Open system into a potential $687 million market the first quarter of 2010.

The company expects to launch the Paramount MIS/Open system into, according to a 2009 iData report cited by Integra in its press release, a potential $678 million market the first quarter of 2010.

IST reported that it generated approximately $2.2 million of revenue in 2008.

Acquisitions have been a major growth strategy for Integra. Through product expansion and acquisitions, the company's consolidated revenues increased from $42.9 million in 1999 to $654.6 million in 2008.

Integra management stated in the announcement that they expected the acquisition to be neutral to earnings in 2010 and they would provide further guidance during its third quarter conference call in November.

—WE (September 15, 2009)

legal & regulatory

Synthes Awarded Damages From Medtronic

Synthes scored a $21 million patent victory over Medtronic on August 26 in a Memphis federal court. The patent issue involved Synthes' ProDisc-L and Medtronic's Maverick artificial lumbar discs. Not only did the federal judge issue a permanent injunction against

legal & regulatory

Medtronic, but he also doubled Synthes' actual damages and said that Medtronic's "willful infringement" entitled Synthes to recover its legal fees.

Synthes filed suit against Medtronic in 2007 saying that Medtronic's Maverick was infringing on its '071 patent. A jury found in favor of Synthes in 2008 saying that Medtronic had willfully infringing on Synthes' patent.

On August 19, 2009, the Court denied Medtronic's motion for a new trial. Medtronic is appealing these rulings to the U.S. Court of Appeals.

ProDisc-L is a total disc replacement device used to replace diseased vertebral discs in the lumbar spine. It was approved in 2006 by the FDA. The Maverick is awaiting FDA approval.

The damages were for the period until the end of 2008 and involved U.S. Patent No. 6,936,071.

—WE (September 14, 2009)

FDA User Fees Rise 8.5%

Starting October 1, 2009, the FDA is increasing medical device user fees by an average of 8.5% for fiscal year 2010, according to a notice in the *Federal Register* on August 3.

The standard fee for a premarket application, including a premarket report and efficacy supplement, will now be $217,877, an 8.5% increase over the fiscal year 2009 rate of $200,725.

The fiscal year fees, which take place from October 1 through September 30, 2010, include:

- Panel-track supplement, $163,340
- Real-time supplement, $15,245
- 510(k) premarket notification submission, $4,007
- 30-day notice, $3.485
- 513(g) (21 U.S.C. 360c(g)) request for classification information, $2,940
- Annual fee for periodic reporting on a class III device, $7,623
- Annual establishment registration fee, $2,008

If a business has gross receipts or sales of no more than $100 million for the most recent tax year, it can qualify for reduced small business user fee rates ranging from 25% to 50% of the standard user fee.

—WE (September 15, 2009)

Physician Thoughts on Reform/Cost-Effectiveness

The thoughts of American physicians in the healthcare debate have been largely voiced by their professional societies. Those societies have been clear in their opposition to a public insurance option for their patients. But what do rank and file physicians think?

Private/Public Mix and 55 for Medicare

A survey of 2,130 U.S. doctors, published in *The New England Journal of Medicine* (NEJM) on September 14, found that 63% of those surveyed favored a mix of a private/public insurance option. The survey also found that 55% of those physicians, regardless of specialty, favored lowering the age of eligibility for Medicare from 65 to 55.

Wary of Cost-Effectiveness

Whether or not we get healthcare reform is a big question mark. What is not in question, however, is the

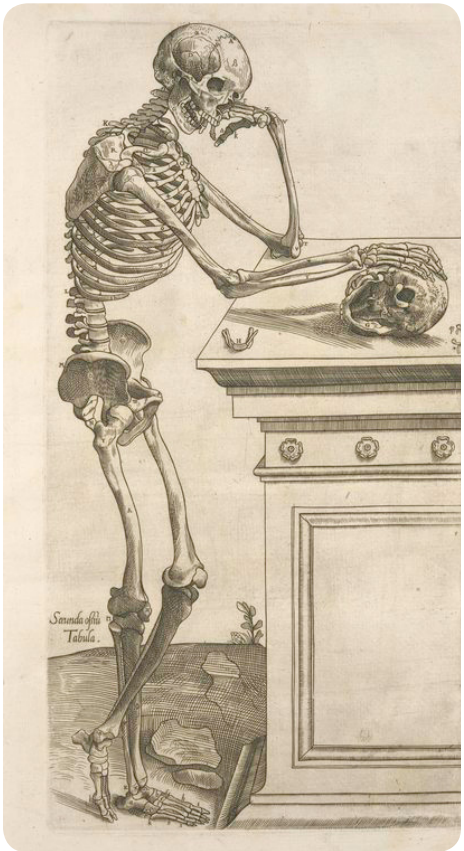
legal & regulatory

$1.1 billion comparative effectiveness appropriation which was part of the February stimulus package.

What caught our attention in the same issue of the *NEJM* was the finding of a second survey of 991 physicians.

That survey, led by Ryan Antiel, M.A., of the Mayo Medical School in Rochester, Minnesota, (10.1056/NEJMp0907876) showed that doctors responding in the survey were split 54% to 45% on whether they supported trying to save money by restricting care to treatments proven to be cost effective.

A majority respondent agreed that "every physician is professionally obligated to care for the uninsured or underinsured (73%), and most were willing to accept limits on reimbursement for expensive drugs and procedures for the sake of expanding access to basic health care (67%)." By contrast, physicians were divided almost equally about cost-effectiveness analysis; just over half (54%) reported having a moral objection to using such data "to determine which treatments will be offered to patients."



Principled Objections and Lack of Incentives

The authors of the *NEJM* article ask why would a majority of U.S. physicians object to using cost-effectiveness analysis in clinical decision making?

They cited both a lack of familiarity and principled objections.

They note the current system reimburses providers primarily on the basis of volume, which favors a greater number of procedures rather than care management. There is little incentive to use evidence-based information such as cost-effectiveness data to guide treatment decisions. CMS has only recently attempted to use evidence to guide determinations about whether services should be provided. Thus, say the authors, a lack of familiarity with such reimbursement practices or fear of change may influence physicians' acceptance of cost-effectiveness data.

But they also say that many physicians may also have more principled grounds for their objections, viewing the use of cost-effectiveness data as implicit rationing or unwelcome intrusion on both their professional autonomy and the physician/patient relationship. They conclude that to gain widespread support from the physician community, advocates of such reform initiatives will need to address such concerns.

Since surgeons and procedural specialists were less willing than other physicians to accept policies that would limit reimbursement for expensive medications and procedures, the authors say reformers can expect opposition to reimbursement reform from such groups unless proposed reforms create incentives that benefit those who currently get paid for providing these goods and services.

To read the full findings of the surveys, click here: http://healthcarereform.nejm.org/.

—WE (September 16, 2009)

biologics

Stem Cells Repair Sheep Nucleus

Last week Mesoblast's Executive Director, Professor Silviu Itescu, presented data that showed quite clearly that a direct injection of mesenchymal stem cells (MSC) into severely damaged sheep intervertebral discs could substantially improve disc health.

2009 Orthopedics This Week Spine technology Awards

Reserve your seats now for the gala banquet!

November 9, 2009 • The Palace Hotel • San Francisco

All of the spine technology submissions have been received, and seats for the Spine Technology Awards and Gala Banquet are going fast.

These awards are the first of their kind and are designed to honor the best spine products, engineering teams and inventors of 2009. Don't miss this unique and important night when 100 attending spine surgeons will vote on entries in eight categories:

- Device Technologies for Cervical Care
- Lumbar Care
- Motion Preservation of the Spine
- Minimally Invasive Care
- Biomaterials
- Diagnostics and Imaging
- Pain Management
- Regenerative Technologies

Each company or individual that submits products for evaluation will be recognized by *Orthopedics This Week* at the podium during the awards ceremony.

The 24 finalists and the first place, second place and third place **awards in each category will be determined by real-time surgeon votes at the November 9 event.** The engineers/inventors for the top three products in each of the eight categories will be invited to the podium to describe their invention. The top three products in each category will receive crystal awards at the ceremony.

Reserve your seats today—the number of spots remaining is extremely limited!

Click here to print a reservation form and obtain more information, or contact Tom Bishow at tom@ryortho.com or Lisa Carpenter at lisa@ryortho.com.

RY Publications

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The study, which was presented at the September 10th OsteoArthritis Research Society International meeting in Montreal, used a single low-dose injection of Mesoblast's allogeneic or "off-the-shelf' adult stem cells. Six months after a single direct intra-discal injection of Mesoblast's cells, discs that were initially severely damaged and degenerated had regenerated and had "become indistinguishable from healthy non-degenerated discs in their histopathology, cartilage content, height, and structure" (quote from Mesoblast).

The control group of severely degenerated discs was either not injected or was injected with hyaluronic acid. The control group had significantly lower disc height ($P<0.01$), disordered disc structure ($P<0.01$), disrupted histopathology ($P<0.01$), and reduced cartilage content ($P<0.05$) at the end of six months.

The results of disc X-rays, magnetic resonance imaging (MRIs), and histopathology were reviewed by three blinded independent experts.

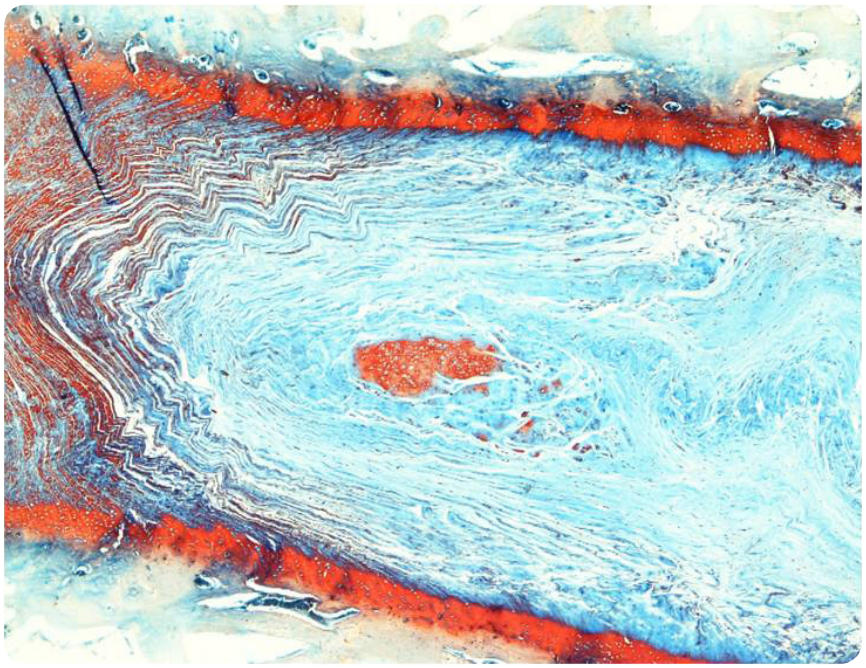
Can stem cells reverse the degenerative disc process? Can allogenic stem cells regrow disc cartilage and sustain a return to normal disc pathology, anatomy and function? Clearly, this small sheep study should trigger renewed interest in moving into human trials as soon as possible.

"These outstanding results indicate that we have been successful in developing a unique biologic disc repair product," Mesoblast's Executive Director, Professor Silviu Itescu, said. "Mesoblast's cells may provide a novel therapeutic approach to reverse disc degeneration and address the number one cause of chronic low back pain," he said.

Chronic low back pain due to degenerative disc disease affects an estimated 4 million people in the United States alone. While short-term benefits may be obtained by bed rest, analgesics, physiotherapy, and steroids, many patients progress to unremitting, severe and debilitating pain due to ongoing progression of disc degeneration. For these patients, the only option is major back surgery involving artificial disc replacement or spinal fusion.

"A simple, non-invasive injection to reverse the degenerative process, and regenerate the disc back to its healthy state, would represent a major product breakthrough into an unmet market segment that is conservatively estimated at more than $US 2 billion per year," Professor Itescu said.

Mesoblast Limited (ASX:MSB) (USOTC:MBLTY) is an Australian biotechnology company committed to the development of novel treatments for orthopedic conditions, including the rapid commercialization of a unique adult stem cell technology aimed at the regeneration and repair of bone and cartilage. Its focus is to progress through clinical trials and international regulatory processes



Histology of stem cell; Source: Mesoblast

biologics

necessary to commercialize the technology in as short a timeframe as possible.

—RRY (September 15, 2009)

geneX, Stem Cells for Non Unions

The graft may be synthetic, but the results are real. The folks at UK-based Biocomposites Ltd. are announcing that pioneering work is being done with regard to cells and healing of non unions. By combining geneX, a synthetic bone graft, with selected and culture expanded mesenchymal stem cells (MSC) to treat fracture non-unions, Professor James B. Richardson of the Robert Jones and Agnes Hunt Orthopaedic Hospital, Oswestry, UK, has been pushing the biologic envelope.

Mesenchymal stem cells

The stem cells are collected in a sample of bone marrow, then purified and cultured expanded; 5 to 10 million stems cells are then combined with geneX and implanted around the fracture site. As indicated by the company, patients who previously faced a life of disability are finding that their injuries are healing and that they can return to an active life.

The work is taking place at Oscell, a National Health Service laboratory in, Oswestry, UK. The Oscell protocol for MSC production includes parameters for patient selection, supervised stem cell harvest, MSC separation, culture and provision to theater staff, together with serum and conditioned medium. All patients are part of a clinical trial with long-term follow up data held independently by the Oswestry Outcome Centre.

According to Biocomposites, geneX has a unique bi-phasic composition manufactured through a proprietary process that confers the product with a reproducible negative surface charge. This property stimulates bone cell activity, accelerating bone formation and fusion by harnessing key proteins and directing cell adhesion and proliferation for rapid osteogenesis. geneX is fully resorbable and is completely replaced by bone. As indicated by the company, geneX overcomes the surgeons reliance on donor tissue presenting both a cost saving and a reduction in the risks associated with its use.

Commenting in the news release, Professor James B. Richardson said "One of the clever things with geneX is the negative surface charge. This demonstrates an improved affinity for the kind of proteins that cells produce to make fractures heal."

He added, "A negative surface charge is the same method that we use in the laboratory to get hold of the cells that are going to form bone. The negative surface charge of the bone graft helps to keep the stem cells at the fracture site. Also the patients' own naturally occurring local cells will be happy to move towards the negative surface. It is only these cells that make bone so logically this is the most important step in getting fractures to heal. Using geneX we are getting some of the best results we have seen."

Professor Richardson told *OTW,* "future plans for research include the completion of our 40 patient study and reporting our findings. The trial design fortunately allowed for the introduction of new bone graft options and since using geneX we have seen some particularly rapid healing."

—EH (September 17, 2009)

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Damage Control Orthopedics

Get them in the OR…but get them out soon. According to a recent review article in the Journal of the *American Academy of Orthopaedic Surgeons* (September 2009), trauma patients with multiple orthopedic injuries who are unstable should be limited to a few hours of surgery when first arriving at the hospital. This principle is known as "damage control."

As indicated in the article, the benefits of such an approach include less blood loss during surgery, fewer

extremities

complications in the intensive care unit, less stimulation to the immune system, higher patient survival rates.

Left Wrist Fracture and Fractured Tibia Fibula; Source: Wikipedia Commons

According to lead author Hans-Christoph Pape, M.D., Chairman of Orthopaedic/Trauma Surgery at the University of Aachen in Aachen, Germany, data shows that too many surgeries and blood loss can weaken the immune system and can lead to a higher likelihood of experiencing complications after surger

"If a patient has just a couple of fractures it is of course useful to operate right away," said Dr. Pape in the news release. "However, if a patient has life-threatening injuries for example, more than three fractures and perhaps a lacerated liver, it is often too dangerous to do all the surgery right away."

Examining data from several trauma registries in Germany, Dr. Pape and his colleagues found that it is often best to use an external fixator to stabilize an orthopedic injury to stop initial pain and bleeding. Then, two or three days later, once the patient is stable, data suggests this period to be a more ideal time to begin other more invasive and time-consuming operations. Dr. Pape and his team compared patient outcomes in about 21,000 trauma patients with the amount of hours each patient had spent in the operating room.

"We found that patients with life-threatening injuries, such as chest contusions or liver lacerations in association to multiple bone fractures, and who have surgery for six or more hours do not always do as well,"

said Dr. Pape in the news release. "If you limit the amount of time in the operating room to less than three hours, patients appear to do better."

In the more severe cases, study authors recommend tapering the amount of surgery, all the while monitoring blood pressure, pulmonary function and immune function to see if patients are stable enough to undergo further surgery.

Dr. Pape told *OTW,* "Usually these patients get clearance from the general trauma surgeon, then get taken care of. However, since the clinical status (i.e., cardiopulmonary situation) can change due to ongoing bleeding from other sources of the body, problems can occur during or after surgery. Since the 1980's, usually orthopaedic surgeons have tried to stabilize all major fractures whenever possible."

"There needs to be close communication between the orthopaedic surgeon, the general surgeon and ICU staff," said Dr. Pape in the news release. "All members of the care team need to re-evaluate the patient throughout the process to see if it is safe to fix the next fracture."

As for why some surgeons might be resistant to utilizing the findings from this study, Dr. Pape told *OTW,* "Some may have issues with billing, some are afraid that patients who first go to the ICU have a higher infection rate because of hospital acquired germs."

—EH (Sept 15, 2009)

Fewer Resident Hours, More Complications

Good intentions gone awry?? According to a new study published in the September 2009 issue of *The Journal of Bone and Joint Surgery* (JBJS), the 2003 reform indicating that residents should be on

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duty no more than 80 hours a week has led to an increase in the rate of perioperative complications for patients treated for hip fractures. Researchers found a variety of complications, with an increasing rate of worse outcomes seen in teaching hospitals.

"The data suggests a statistically significant increase in selected complications after implementation of the duty-hour reforms in teaching hospitals, where residents help deliver care, compared to non-teaching hospitals. This may go against common assumptions regarding outcomes as they relate to the length of resident hours," said study lead author James M. Browne, M.D., in the news release. Dr. Browne is completing an orthopedic fellowship in Rochester, Minnesota. The study was performed at Duke University Medical Center.

Explaining why hip fractures were chosen for study, Dr. Browne told *OTW*, "Hip fractures were studied for a number of reasons. For one, our anecdotal experience was that residents play an integral role in the orthopaedic care of the hip fracture patient. Treatment of a patient with a hip fracture at a teaching hospital often involves several residents working in teams and could be potentially impacted by changes in resident duty-hours. Hip fracture surgery is fairly common and occurs in both teaching and non-teaching hospitals, which allowed us to essentially use non-teaching hospitals as a control group. The morbidity and mortality rate following hip fracture surgery is also higher than many other orthopaedic procedures, which gave us improved statistical power to potentially show a significant difference in outcome."

Dr. Browne and his co-authors at Duke reviewed data from teaching and non-teaching hospitals for 48,430 patients treated for hip fractures in a nationwide inpatient sample database, reviewing two groups: the first from 2001 and 2002 before resident duty-hour reform; and the second in 2004 and 2005 after reform.

The investigators set out to measure changes in the rate of patient death or resulting in-hospital complications since the work hour reform. While no increase in death rates was found, there was an increase in resulting negative outcomes found in teaching hospitals compared to non-teaching hospitals. These outcomes included increases in the rate of pneumonia, hematoma, transfusion, renal complications, and nonroutine

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discharge. Researchers also found an increase in length and cost of stay in teaching hospitals.

"I think it would be premature for a patient to make any medical decisions based on the results of this study. What this data does tell us is that this issue needs to be examined further. Remember, this is limited to hip fracture outcomes tracked during a limited time period and does not take into account any improvements in delivery of care since 2005," said Dr. Browne in the news release.

A recent report from the Institute of Medicine proposes further limitations on resident work hours.

"Surgeons and policy-makers need more data to understand the full impact of these duty hour changes on our patients. As we consider any kind of reform, we must continue to keep the safe delivery of care that results in successful patient outcomes as our number one priority," Dr. Browne added.

Indicating what his next related study would examine, Dr. Browne told *OTW,* "The implementation of duty-hour reform was met with concern and uncertainty. Many teaching programs initially struggled with these limitations but have since implemented systems to effectively deal with duty-hour restrictions. It would be interesting to see if these systems have effectively accommodated the new regulations. We must continue to rigorously study the regulation of work hours and ensure that we have not encountered potentially unintended consequences."

When asked what he would say to residents, Dr. Browne told *OTW,* "Little is known about the impact of work-hour limits on patient outcomes in orthopaedics. Resident performance and healthcare delivery are complex processes, particularly within the intricate system of a teaching hospital. Residents should be aware of vulnerable points in the safe delivery of healthcare. Transfer of responsibility for patient care between residents, increasingly frequent following the implementation of duty-hour limits, is a weak link in many training programs and particularly problematic. Continuity of care is also important and fragmented care should be avoided. Further study is clearly needed to ensure the work-hour regulations have achieved their intended results."

—EH (September 15, 2009)

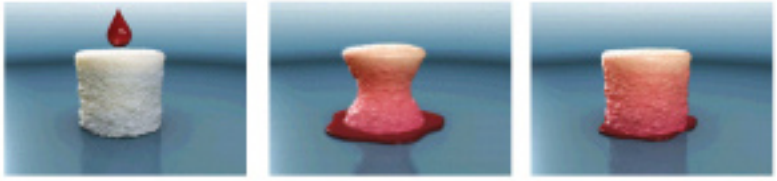
Orthomimetics at Recruitment Milestone

Regeneration for this generation and beyond...UK-based Orthomimetics is announcing the treatment of the tenth patient in a clinical study for Chondromimetic, a dual-layered implant for the repair of damaged cartilage and bone. The single-center study, led by Professor Laszlo Hangody, M.D., Ph.D., D.Sc., Clinical Professor at the Semmelweis Medical School Budapest, Hungary, is evaluating the safety and efficacy of Chondromimetic using multiple outcome variables.

According to the company, 10 patients are enrolled in phase one of the clinical study with early MRI results looking promising. The second phase of the study will evaluate the new Chondromimetic Instrumentation System for arthroscopic delivery of the implant. The hope is that this new minimally invasive approach will make the surgical procedure quicker and easier and potentially reduce the time that patients must remain in the hospital.

With regard to the instrumentation system, Andrew Lynn, CEO of Orthomimetics, told *OTW,* the Chondromimetic Instrumentation System makes use of the novel shape memory properties of our implant. The ability to compress an implant to fit through a small incision is an important feature for enabling accurate minimally invasive delivery.

Taking the data gathered thus far, Orthomimetics plans to expand its clinical research program to an additional 10 sites in Europe with the aim of recruiting a total of 200 patients who will be collected in a



Shape Memory/Orthomimetics Ltd.

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clinical register to further validate the technique and patient benefits.

Commenting on the clinical trial, Andrew Lynn said in the news release, "We are extremely pleased to report the trial has been conducted to the schedule we set out and that these early outcomes are encouraging. We look forward to building on this progress to establish a set of high-quality clinical data to support the long-term efficacy of Chondromimetic and our commercial efforts."

—EH (September 17, 2009)

The Picture of Success: Dr. Jim A. Youssef

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

From the minarets of Egypt to the mountains of the American West, Dr. Jim Youssef, founder of SpineColorado, has crafted an invigorating life indeed. Born in Minneapolis to parents who immigrated from Egypt, a young Jim Youssef was presented early on with several—*just* several—career options.

Medical Education

"Years ago my dad was working as the tax commissioner for the King of Saudi Arabia, while my mom was the first social worker in that country," says Dr. Youssef. "They met, married, and then proceeded to move around a lot because of his career. Our first stop in the U.S. was Wisconsin, where my sister was born, which was followed by Illinois, then Malibu, California. One day when I was in fourth grade, my mom and I sat down and wrote an essay on what I wanted to do with my life. In the Egyptian culture one is strongly encouraged to become a professor, a physician, or a member of the clergy…not a lot of options, really. But, we had a friend of the family who was a cardiothoracic surgeon, and who did a great job setting my arm when I broke it. I liked him, and respected what he was doing. Medicine—in some form—was going to be it for me."

Before going forward, however, he stepped back in time, in a sense, to one of the world's oldest schools. Dr. Youssef: "In 1985 I undertook a program of study at The University of Oxford in England. I chose Medicine and the Administration of Justice, a track which involved working in the prison system and learning about the profound differences in the American and British legal systems. It's quite reformatory there, unlike most of our prisons in this country. Being able to attend the oldest college in the English-speaking world—complete with 12th century dormitory—and *without* running water, was an absorbing experience. I knew that my future would entail a lot of the hard sciences, so I greatly appreciated the opportunity to study liberal arts for a time. And the structure of learning was very different, including the fact that we attended classes in the professors' living rooms."

Jim Youssef then moved from political science and the formality of England to Mendelian science and the relaxed atmosphere of California. "Throughout my education I had maintained a strong interest in biologics and molecular level science, and in fact was interested in becoming a pediatric immunologist and working with children who had AIDS. That shifted, however, when I got to know someone whose father was an orthopedic surgeon. I was allowed to observe his surgeries and saw that all of his patients turned the corner and got better. I could see that it would be quite an uplifting field."

A youthful Jim Youssef entered the University of California, Irvine School of Medicine, only to be surrounded by his elders. "I was only 23 when I began medical school, whereas my classmates were an average age of 29, were married, and had children. I had a bit of growing up to do because I still thought I could party and do triathlons. The clinical experience was intense because we were at a county hospital and had the opportunity to both see and do a lot of different kinds of cases."

"In my fourth year I went to the University of California, San Francisco, where I did rotations in rheumatology, orthopedics, and pediatrics. During that time I got to know a visiting rheumatology fellow whose father was Chair of orthopedics at Oregon Health Sciences University in Portland. They were expanding their program to include a research post, and I was fortunate enough to

get the position. While there I did genetic and molecular work, met my wife, and got married 10 months later. I was ill-suited for the constant rain in Oregon, however, so I interviewed at Dartmouth's orthopedic residency program, and was accepted in 1992."

The East Coast provided more agreeable weather, new lessons and piqued interests. Dr. Youssef: "In 1992 I left for the East Coast, and found Dartmouth to be a focused learning environment. There were only two residents a year, along with 18 attendings. Dr. Bill Abdu was one of the first people to introduce me to spine, while Dr. James Banta, a profound academician, stirred my interest in spinal deformities. Dr. James Murphy, a hand specialist, taught me the importance of being honest with regard to one's mistakes. It was a very didactic, rigorous environment where we were expected to uphold the traditions of excellence, including wearing a tie—and no scrubs—on grand rounds. I did wear scrubs, however, when I participated in operating on Dr. C. Everett Koop, a Dartmouth alum who had his total knee done at our institution."

The need to be near family then led Dr. Youssef back to the West Coast. "I selected the University of California, Davis for a spine fellowship in part because my father was ill and I wanted to be close to family. At the same time one of my children was diagnosed with a heart defect. When my dad passed away, my fellowship director, Dr. Dan Benson, was extremely supportive. He managed to continue to expect a lot out of me without being off putting."

Advancing His Career and Starting New Initiatives

New opportunities at work also helped distract Dr. Youssef from the stress and worries in his personal life. "The fellows were accorded a significant amount of autonomy and had a large volume of cases, complete with three trauma helicopters. We saw a lot of deformity because we were adjacent to Shriners Hospital. The attending who ran the clinic left Davis, and Dr. Benson asked me to take over his position. This responsibility really elevated my level of practice, and

looking back, I don't think I could have accomplished all that I have without that experience."

However, his next move left some friends and colleagues scratching their heads. "Looking to decompress after my training, I came to Durango, Colorado, thinking that I would leave after a couple of years. While a lot of people I knew thought it was career suicide, I was the first spine surgeon on the western slope of Colorado, and my life here has mushroomed into a prolific practice.

"My partners at the local hospital were very supportive, and I managed to put things into place that are unique in a rural area. I built my practice, SpineColorado, and under that 'umbrella' put all those who care for spine, including orthopedists, neurologists, neuropsychiatrists, physical therapists, and physiatrists. I built an active research department which has six FDA clinical trials underway at present. Also exciting is that I have been able to continue publishing and teaching, things which are rare in a private practice setting in a mountain town."

Convinced that there was room for advancement in the field, in 2008 Dr. Youssef started the nonprofit Resources for Medical Education and Collaboration (RMEC) in order to drive innovation and support medical education. "Under the auspices of the RMEC I helped continue the Emerging Technologies Spine Education Summit Annual Meeting, which was initiated six years ago and now draws approximately 350 attendees. I then put into place other aspects of the RMEC, such as an internship program for premed students and an evidence based registries program."

Dr. Youssef then wondered what a spine surgeon in France, perhaps puzzling over an XLIF procedure, might gain from near instant commentary by a colleague in, say, Detroit. "In 2000 I co-founded Syndicom, Inc., in order to create collaborative consultation environments for surgeons. It was obvious that while consulting on cases via email was possible, it was not a 'live' process and not especially collaborative. Our first effort, SpineConnect, is an online collaborative community involving 1500 spine surgeons in 40 countries who connect and share difficult and unusual cases. It has been so successful that we have now launched ArthrosplastyConnect and TraumaConnect."

Highlighting one of special aspects of working in Durango, Dr. Youssef says, "We have a large population of Native Americans, with the Navajo nation only 20 miles down the road. Most of the people there do not speak English and have enormous health problems. Working with these folks, in addition to coming from immigrant parents and traveling frequently to Egypt, has really opened my eyes to what some people have and what others do not."

Health Care Reform and a Healthy Family

Regarding the future of field, Dr. Youssef notes, "I am concerned about the current rush to create healthcare reform. Healthcare in this country has evolved over two centuries and has resulted in the most sophisticated technologies in the world. The problems are that we have a high rate of medical errors, along with high costs. But managing those issues should not be about taking money away from healthcare providers. We need to put more emphasis on reforming medical liability and put additional responsibility on the medical device companies for being more judicious about the delivery of new technology. There must also be a focused effort on high quality research, in particular as it concerns outcomes and evidence based medicine."

"I am pleased," states Dr. Youssef, "that as a country we have a significant interest in maintaining our health. Those of us who have committed

to the practice of medicine have an obligation to provide the best care we can without becoming mired in the issues of economic loss. Just recently I performed a seven hour intradural disc herniation and never once thought, 'I'm not getting paid for this.' Working in a small town sometimes means you are rewarded with a smile and a hug."

These rewards are also waiting for him at home. "My wife and I have three children, a 14 year old son, a 12 year old daughter, and a 9 year old daughter, all of whom are freestyle skiers. Each weekend during the winter skiing is our life, with everyone piling into the car for the kids' competitions around the state. My wife, Melissa, is very active in our community, and is Vice President of the local school board."

"We recently celebrated the one year anniversary of a stressful, but successful event in our lives. When my wife was 14 years old she underwent a scoliosis fusion. The fusion broke down about a year and a half ago, however, and she required surgery. We went to the medical board and insurance company and got permission for me to perform the surgery, along with my friend Dr. Darrel Brodke. It was the most intense thing I have ever done."

Dr. Jim Youssef…having it all and grateful for it.

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