VOLUME 6, ISSUE 10 | MARCH 30, 2010

Orthopedics This Week

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Spine Procedure U.S. Market Reports	Code
Spine Fusion	
Anterior cervical fusion	81.02
Posterior cervical fusion	81.03
Anterior dorsal and dorsolumbar fusion	81.04
Posterior dorsal and dorsolumbar fusion	81.05
Anterior lumbar fusion	81.06
Lateral lumbar fusion	81.07
Posterior lumbar fusion	81.08
Spine Refusion	
Posterior lumbar refusion	81.38
Other Spine Procedure	
Discectomy	80.51
Decompression	03.09

Large Joint Reconstruction	Code
Total Hip Replacement	81.51
Total Knee Replacement	81.54
Revision of Hip Replacement	81.53
Revsion 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 Market Reports	Code
Ankle Fusion	81.11
Triple Arthrodesis	81.12
Subtalar Fusion	81.13
Total Shoulder Replacement	81.80
Partial Shoulder Replacement	81.81
Rotator Cuff Repair	81.63
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/ Fixation	79.37

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Orthopedics This Week

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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Are we ready for a deluge of new patients? Probably not, but hospitals are starting to gear up to accommodate up to 10 to 30 million newly insured patients. Who benefits? Hospital equipment suppliers like CONMED and Stryker. Who loses? Already overworked healthcare professionals.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	11.00%	6.34%	Get ready for a huge EPS gain this quarter. Analysts are expecting $0.81vs. $0.17 for the March quarter. Still only 1x sales
2	3	Integra LifeSciences	15.37	7.74	IART has delivered better-than-expected sales and earnings results for each of the last four quarters.
3	4	Johnson & Johnson	27.10	2.19	Medical device tax cut in half, delayed until 2013 and is now a 2.9% sales tax. Uptick in unit volumes starts in 2010, however.
4	2	Exactech	12.61	(2.06)	Consensus of Wall Street's analysts is 9.5% sales growth in March quarter but down earnings.
5	6	Medtronic	31.37	2.51	MDT should be one of the beneficiaries of higher patient volumes coming from the new healthcare bill.
6	7	Stryker	24.71	7.08	Of all the device companies, SYK is the most diversified—implants plus durable hospital goods.
7	5	Alphatec	(0.44)	24.56	Analysts are forecasting nearly 50% sales growth for 2010 and a profitable year.
8	NR	CONMED	7.73	11.93	New surgical shavers, saws, and other power tools—just what hospitals need to accommodate the coming flood of patients.
9	10	Symmetry	11.48	7.79	Numbers look particularly ugly for this quarter—sales down 25%. But the tone for basic ortho is improving, so SMA should rise as well.
10	9	Zimmer	27.71	(0.03)	Most analysts expect ZMH to post a modest 5% sales growth rate this year. Probably overly conservative.

Orthopedics This Week

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Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGBO.PK	$0.45	$4	200.0%
2	Alphatec Holdings	ATEC	$6.39	$346	24.6%
3	ArthroCare	ARTC	$30.33	$815	14.2%
4	RTI Biologics Inc	RTIX	$4.25	$231	13.3%
5	CONMED	CNMD	$24.49	$714	11.9%
6	NuVasive	NUVA	$44.27	$1,720	10.7%
7	Orthovita	VITA	$4.23	$323	10.2%
8	Symmetry Medical	SMA	$9.27	$332	7.8%
9	Integra LifeSciences	IART	$42.88	$1,230	7.7%
10	Stryker	SYK	$56.71	$22,570	7.1%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TiGenix	TIG.BR	$3.73	$115	-21.0%
2	Capstone Therapeutics	CAPS	$0.94	$38	-9.6%
3	CryoLife	CRY	$6.48	$185	-8.1%
4	Smith & Nephew	SNN	$50.34	$8,920	-2.2%
5	Exactech	EXAC	$18.99	$244	-2.1%
6	Zimmer Holdings	ZMH	$57.31	11,620	0.0%
7	Johnson & Johnson	JNJ	$64.38	77,170	2.2%
8	Medtronic	MDT	$44.49	$49,010	2.5%
9	*Average*			*$11,691*	*2.6%*
10	Wright Medical	WMGI	$17.35	$673	3.0%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Kensey Nash	KNSY	$23.37	$256	13.26
2	Medtronic	MDT	$44.49	$49,010	13.72
3	Johnson & Johnson	JNJ	$64.38	$177,170	13.91
4	Zimmer Holdings	ZMH	$57.31	$11,620	14.24
5	*Average*			*$11,691*	*14.34*

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$50.34	$8,920	76.81
2	RTI Biologics Inc	RTIX	$4.25	$231	48.10
3	NuVasive	NUVA	$44.27	$1,720	42.55
4	ArthroCare	ARTC	$30.33	$815	27.99
5	CONMED	CNMD	$24.49	$714	24.62

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CryoLife	CRY	$6.48	$185	0.69
2	NuVasive	NUVA	$44.27	$1,720	0.82
3	Integra LifeSciences	IART	$42.88	$1,230	1.04
4	Smith & Nephew	SNN	$50.34	$8,920	1.06
5	Alphatec Holdings	ATEC	$6.39	$346	1.19

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CONMED	CNMD	$24.49	$714	9.96
2	Orthovita	VITA	$4.23	$323	7.10
3	Johnson & Johnson	JNJ	$64.38	177,170	1.91
4	*Average*			*$11,691*	*1.72*
5	Symmetry Medical	SMA	$9.27	$332	1.67

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$4.09	$74	0.76
2	Symmetry Medical	SMA	$9.27	$332	0.92
3	CONMED	CNMD	$24.49	$714	1.04
4	Orthofix	OFIX	$36.25	$635	1.15
5	Exactech	EXAC	$18.99	$244	1.35

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$3.73	$115	111.58
2	Mako Surgical	MAKO	$13.78	$463	13.35
3	NuVasive	NUVA	$44.27	$1,720	4.80
4	Synthes	SYST.VX	$122.39	$14,524	4.28
5	Orthovita	VITA	$4.23	$323	3.51

Orthopedics This Week

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FDA v ReGen, Act II

By Walter Eisner

Make no mistake about it. The March 23rd FDA Orthopedic and Rehabilitation Devices Advisory Panel meeting to conduct an unprecedented "do-over" of ReGen Biologic's Collagen Scaffold's FDA clearance was about political theater, not science.

Wikimedia Commons

Not one shred of new scientific evidence was uncovered since the device was cleared by the FDA last year. Jeffrey Shuren, M.D., head of FDA's medical device division, told *OTW* after the meeting that this hearing was held simply to review the FDA's previous decision because the integrity of the FDA's review process had been called into question.

Jeffrey Shuren, M.D., J.D.,/Director of CDRH

But first, let's get the science out of the way.

Favorable Safety Profile

For the second time, in spite of the agency's assertion that the company didn't provided adequate data to show that the knee device was safe; the Panel told the FDA otherwise.

The Panel's opinion, summarized by its chairman and shoulder surgeon John Kelly IV, M.D., was that, "the ReGen device overall has a favorable safety profile. However the Panel has some concerns that the company's

John Kelly, IV, M.D. / pennmedicine.org

study does not fully fulfill the scientific method."

But even Panel member Brent Blumenstein, Ph.D., who has become the Panel's designated slayer of inadequately designed clinical trials, seemed as satisfied as he could be for a 510(k) device. After blowing apart the company's study for not meeting level-one scientific evidence, he commended the company for its study and said, as case history, the study was valuable and the data was "probably better than the predicates."

That was high praise from the Panel member who sank Stryker's OP-1 PMA application with his now famous, "Abuse of the Alpha" critique.

Filler and Scaffold

FDA staff desperately tried to get Panel members to say the device "reinforced and repaired" a soft tissue injury. The Panel members however, refused to pigeonhole what the device does into those terms. Panel member Stuart Goodman, M.D., Ph.D. and orthopedic surgeon, said the evidence clearly showed that the device "fills the space and creates a scaffold", where, Panel member Hollis Potter, M.D., and radiologist added, "no doubt growth of tissue will occur."

The only rough spot for the company came during a "so what?" exchange.

Simply put, for what purpose are you subjecting a patient to the risk of surgery? What is the corresponding benefit? After a partial meniscectomy, a void remains. What's the benefit of filling the void with the body's own cells?

Ultimately, said company presenters, they believed filling the void will prevent the onset of arthritis. But proving that would take decades.

The company was saved by a Panel member who pointed out that the company didn't need to prove that. It only needed to prove that the device worked at least as well as predicate devices.

In the end, Chairman Kelly told *OTW* that the Panel agreed that the device was reasonably safe but the hard scientific evidence to declare it effective was missing. He declined to offer an opinion on whether or not the FDA should confirm their previous clearance.

FDA's Summary

How did the FDA summarize the meeting?

Twenty-four hours after the meeting, the agency issued a statement that contained, in part, the following conclusions of the Panel's findings:

- There was insufficient evidence that the device, at time zero, reinforces and repairs soft tissue injuries.
- The tissues that ultimately grow in place of the device, as it degrades, may serve to partially reinforce and repair in the long term, but not fully and that the definition of repair and replace should be further defined.
- The device is a scaffold that fills a void that reconstructs the removed tissue.
- The anatomic design and comparisons to other products is generally considered safe, but the Panel had concerns about the overall effectiveness.
- Due to the low number of device failures, the device can be viewed as reasonably safe, but the device's effectiveness would need to be analyzed further.

After the meeting Dr. Shuren said the agency will issue a decision within weeks.

He told *OTW* that the options available to the agency were to confirm its previous decision, confirm and order special controls, or move to

reclassify the device to a level one device.

If the FDA, after being given the same answer from two advisory panels made up of many different members, does not confirm its previous clearance of the device, a safe product will be kept from doctors and patients and the medical device industry's fears about an unpredictable and fair clearance process will be realized.

Political Theater

This brings us back to political theater, the real purpose of the meeting.

The panel meeting room at the Washington, DC Hilton looked like a wedding with guests of the bride and groom sitting on opposite sides.

The FDA side was filled to the brim with "a lot", as one former FDA manager noted to *OTW,* of agency staffers. They were young, brightly clothed with full heads of hair. They sat dutifully behind their senior managers prepared to make the case against the device.

On the other side of the aisle sat six or seven gray and bald heads from the company. Behind them, empty seats.

Industry Concerns

Before Chairman Kelly could call on the first presenter for the day, the industry representative on the Panel, Robert E. Durgin, a senior vice president and attorney from Biomet offered a prepared statement.

Durgin stated, "The issue of greatest concern to industry as a whole, is the regulatory process—both the process leading to a 510(k) clearance and, in this instance, the regulatory process following that clearance. Now that ReGen Biologics has been granted a clearance, it is absolutely essential that it be afforded due process as the Agency re-evaluates the data submitted in support of that clearance."

He asked the FDA to state what the Agency intended to do with any recommendations that the Panel may make today and what process will be used as the Agency considers those recommendations.

Chairman Kelly was clearly prepared for Mr. Durgin's question and informed Panel members that the purpose of this meeting was to consider scientific evidence and not regulatory procedures.

Stifle Innovation

Four hours later during a public comment period, Susan Krasny, Ph.D., of Stryker Spine and President of OSMA (Orthopedic Surgical Manufacturers Association), echoed Mr. Durgin's concern.

Dr. Krasny told the Panel:

> "When a device undergoes the rigorous 510(k) process…and is cleared…manufacturers of those devices should be assured that those decisions are sound and that the device will not be re-evaluated unless there is evidence of problems associated with the use of the product. A re-evaluation…is not appropriate for procedural objections related to the review process.
>
> A lesser standard could subject any 510(k) decision to re-evaluation at any time, a result that would create uncertainty…and potentially stifle innovation by manufacturers.
>
> "Finally, we are unaware of any legal or regulatory authority for reversing a 510(k) decision without any new evidence regarding the product. **To overturn a carefully considered 510(k) decision without such new evidence would be detrimental to the 510(k) process and would surely lead both the public and companies to lose confidence in the 510(k) process.**"

Dr. Kelly admonished the speaker for introducing a "political" agenda into the proceedings and again noted that the Panel was here for scientific purposes only.

FDA Discomfort and Uncertainty

Apparently, industry was not the only one concerned with the FDA's authority to review a previously cleared device. So were FDA lawyers.

Alicia Mundy of the *Wall Street Journal* reported the day before the Panel meeting that she had reviewed a leaked FDA document which, "underscored concerns among some regulators over potential limits to the agency's authority to revoke an approval, and over the kinds of safety and efficacy issues the FDA could present to the advisory committee."

"If we cannot take the device off the market, does it help to have a Panel decision one way or the other?" asked one FDA scientist during the January 8 meeting attended by the head of the

device division, agency attorneys and scientists, reported Mundy.

Mundy wrote that some agency official said, "Uncertainty over the FDA's ability to re-open approved cases could result in more intense agency scrutiny of medical-device applications, so as to avoid another controversy like the Menaflex approval."

While the reason for the meeting was political, Chairman Kelly probably did the company a favor by squelching any talk of the regulatory process and continually herding Panel members back into a discussion of the science. In fact, Dr. Kelly bent over backwards to assure that the FDA presented its strongest case against the device, once even inviting the FDA to "take liberties" to contribute to the discussion. No one will be able to question the integrity of the handling of the meeting.

The Next Time

So where does this leave industry?

We asked Dr. Shuren if he will be responding to Panel member Durgin's question. He did not answer the question directly, but tried to assured us that this redo of the ReGen device was an isolated and unique situation.

While the FDA's assurances sounded comforting, it is clear that no rules, procedures or predictable regulatory pathway exists that will guide how and when the FDA decides to do another "do over" of a cleared device.

Why Baxter Paid $330 Million for ApaTech

By Robin Young

Danek merges with Sofamor. Sulzer buys Spine-Tech. Synthes buys ProDisc. Certain transactions have the power to change an industry's trajectory or focus.

When Memphis-based Danek merged with Sofamor in 1993 it signaled the start of a period of innovation, growth and wealth creation in spine care. When Sulzer Medica purchased Spine-Tech in 1998 it marked the start of an explosion of innovation and creativity in the intervertebral body space. When Synthes bought Spine Solutions (ProDisc) in 1993 it signaled both the beginning of a rush to create motion preservation implants as well as the beginning of the end of Spine as a "winner's game".

Wikimedia Commons

Looking back in five or ten years Baxter's purchase of ApaTech for $330 million will be seen, we believe, as the seminal event that launched the biologics era in orthopedic surgery.

Biologics at a Crossroads

For a couple of decades now, all ortho CEOs and most surgeons would agree that biologics are the most exciting market basket of technologies on an ever lengthening horizon. No one would disagree that "biologics" (however they defined that term) had, on paper, the potential to be disruptive. Some biologic products in niche markets actually delivered on that promise—InFuse in spine surgery, for example. But, more often than not, the promise failed to materialize. Cartilage repair, for example, has left many start-up

companies and technologies gasping for capital and legitimacy.

The business of processing allograft tissues has become a solid business with 1.2 million annual procedures generating nearly $2 billion in revenues. But the allograft industry is plagued with for-profits with no vision and non-profits with great vision but no access to the capital markets. Probably the most exciting new allograft product currently on the market is allograft stem cells in bone matrix and it is two non-profits (MTF and AlloSource) that are the suppliers and innovators.

Biologic products are at a crossroads. We are, I'm convinced, in the process of moving from structural biologic products to trophic biologic products. Trophic means biologically active. Living cells. Proteins.

Baxter is (quietly) building the biologics platform of the future. ApaTech was the missing plank.

Cartmell and ApaTech

Veteran pharmaceutical executive Simon Cartmell is ApaTech's CEO. Seventeen years at Glaxo Wellcome and a couple years with private equity, led Cartmell to ApaTech. When he arrived, ApaTech was, in his words, a "single issue company" looking for a leader. Cartmell's experience was in global supply chain management with a particular emphasis on integrating R&D with marketing.

Integrating R&D with marketing requires a lot of translating. Cartmell, by his own admission, is in corporate-speak terms multilingual.

Cartmell isn't the first pharma CEO to get biologics. Paul Thomas spotted a diamond in the rough (very rough for those who recall LifeCell in the early 1990s) at LifeCell and eventually sold it to KCI for $1.7 billion in 2008.

When Cartmell took a look at ApaTech in 2003, he liked it so much, that he quit his day job with the money jockeys at 4D Biomedical (a venture firm) and gave ApaTech the leadership it needed. There were eight people at the company when he joined in 2003.

In Cartmell's view the nascent biologics industry needed something more than just another synthetic, structural implant. It needed a biologically active, higher value-added (in terms of patient outcomes) biologic material that gave distributors a better, in Carnell's terms, "quantum of profit margin."

Actifuse

ApaTech's Actifuse product, in Cartmell's view, fit the bill. Silicon-based materials like Actifuse (which is a bioactive glass) have a well demonstrated ability to grow bone. Larry Hench and his colleagues at the University of Florida first documented

this interesting phenomenon in the 1960s. Their work formed the basis, then, of further research at London's Imperial College. The underlying mechanism of action is that when the glass is immersed inside the body it triggers an ion exchange with the surrounding tissues. Long story short, this ion exchange helps to form a porous, gel-like surface layer which has an amorphous calcium phosphate component whereby mineralization gradually creates a form of ceramic called hydroxyapatite.

With InFuse teaching two generations of surgeons about using biologics to improve bone growth and setting a most attractive price reference point, the foundation was in place.

Stryker Partnership

Stryker was ApaTech's first U.S. distribution partner. Stryker, in Cartmell's view, was a very high caliber partner with a particular tactical approach to the market that fit with Cartmell's style. In the U.S., ApaTech and Stryker developed a hybrid distribution model where territory salesmen were supported by ApaTech's biologic products experts. That, combined with a generous and flexible compensation program for Stryker's sales people drove the numbers.

Under Cartmell, ApaTech ***never*** missed its sales or earnings forecast. "We were very disciplined with our cash, never missed a number and, as a result, built significant confidence with our investors," said Cartmell. In 2008, the company raised $45 million in new capital—much of it from existing investors—and bought out some of the older shareholders at a $70 million valuation. That capital allowed ApaTech to build new manufacturing facilities and increase its investment in people from 44 people in late 2008 to 160 people at the time of the Baxter acquisition.

Strong Compliance Culture

In addition, said Cartmell, ApaTech was clean. "Right from the beginning, we made sure that we wouldn't fall victim to some of the 'tricks of the trade'. We built a strong compliance culture because we wanted to ensure that our surgeon relationships were appropriate and fully compliant."

By the time Baxter came calling, ApaTech had had seven acquisition offers. By the time Baxter came calling, ApaTech was bringing in $60 million in annual revenues and had doubled in size from 2008. By the time Baxter came calling, ApaTech had one of the strongest biologic product distribution systems in orthopedics with significant and market leading networks in both the U.S. and the EU.

So why Baxter and not Stryker?

A Bellwether Deal

The answer to that question, we believe, is why this transaction is such a bellwether deal for orthopedics.

Consider the following:

1. Baxter has been running stem cell clinical studies longer than ANY orthopedic company has been offering allograft stem cell products

2. Baxter has more expertise in all of the components of blood (like mesenchymal stem cells) than JNJ, Medtronic or any of the orthopedic companies. Baxter is a market leader in treating hemophilia and providing a full range of biologic blood products including immunoglobulin, pharmaceuticals and drug delivery products

3. Baxter has fibrin sealants – ARTISS
4. Baxter has PEG sealants – COSEAL and TISSEEL
5. Baxter has FLOSEAL surgical hemostat and GELFOAM PLUS

In short, Baxter has the science and the surgical biologics technology platform to deliver the full range of biologics to the surgeon today…and will guide the surgeon to a future of trophic biologic products including stem cells.

Baxter speaks surgery from the biologic perspective.

Virtually every orthopedic company speaks surgery from a bio-mechanics perspective.

Last year Baxter reported more than $500 million in surgical biologic sales revenues. Baxter's pipeline, which is heavy with trophic biologic products, could make it the dominant surgical biologics company. In every one of the 26 major surgical arenas Baxter will be a player.

Stryker can't, for example, sell hip retractors to heart surgeons. But Baxter can sell sealants, hemostats, stem cells and delivery systems to orthopedic, cardiovascular, general surgeons—indeed all 26 major areas of medicine. What Baxter is demonstrating is that biologics, as a product platform, drives distribution and sales efficiencies. One product line sold to 26 major surgical sectors is more profitable than one product line sold to only orthopedics or, more narrowly, only for shoulder repair.

ApaTech and Baxter

What will Baxter do with ApaTech?

According to Cartmell, there will be no changes to the distribution system ApaTech built with Stryker in the U.S. and with independent reps in the EU. Baxter, said Cartmell, will build on the foundation he and his team have built at ApaTech. According to Cartmell, Baxter's regenerative business will use Actifuse and the other products in ApaTech's pipeline to create a scaffold for Baxter's products.

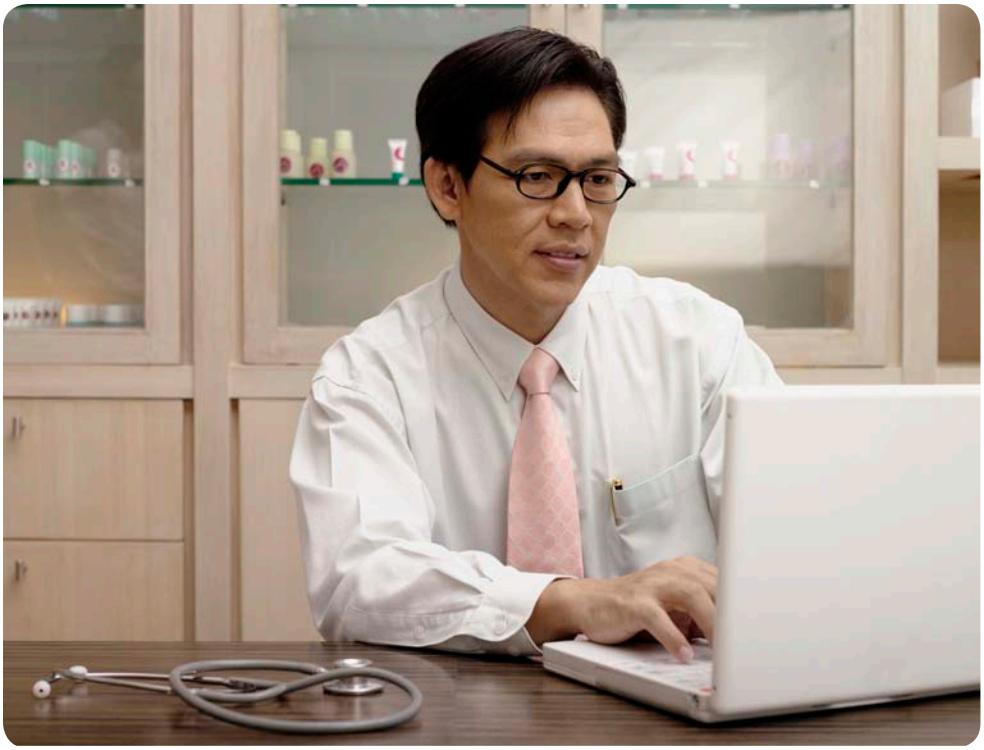
Products that are in Baxter's sales bag now as well as future products (advanced sealants, glues, stem cells, parathyroid hormones and other products) will likely find their way onto the Actifuse scaffold. A more biologically active Actifuse creates a more "trophic" implant.

Why did Baxter pay $330 million for ApaTech? Because Baxter thinks it can double biologics product sales to over $1 billion with ApaTech's bioactive silicon products and do it over a broad range of medical specialties—not just orthopedics.

As Simon Cartmell said in closing, "We didn't need to sell, but the combination of Baxter's pipeline and our products made paying tomorrow's price today supportable."

Here Comes the Spine Registry!

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



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There are those who hear an increasingly louder government drumbeat…and it sounds like "proof, proof, proof." Dr. Rick Guyer, co-founder of Texas Back Institute, explains, "In 2006, during my tenure as President of the North American Spine Society (NASS), I raised the possibility of creating a spine registry. It was becoming clear to me that we should have a way to objectively evaluate both treatment methods and surgeon performance. There was a lot of naysaying at the time, however. Views are shifting now, and people are beginning to see a day in the not too distant future when government will institute just such a program. I am of the opinion that it's better to begin our own registry than wait to be told how exactly to implement one."

Dr. Ray Baker, the current President of NASS, concurs…it's time to get out in front of Uncle Sam. "We have reached out to other societies to develop a collaborative registry and have received commitments from the Scoliosis Research Society, the American Association of Neurological Surgeons, the Congress of Neurological Surgeons, the International Spine Intervention Society, and The International Society for the Advancement of Spine Surgery. All are willing to participate in the development of a registry project."

"Many registries are set up for a specific reason, i.e., to look at one topic. In the end that is not a particularly useful tool. We are planning to include a variety of topics and will do it in such a way that the database is absolutely configurable. It is pointless to ask one subset of questions but then a year from now when a different issue arises you are unable to address it. I don't want us to restrict ourselves by having to present all of the questions at the outset…the field is dynamic and the registry should be as well."

While the surgeons and others at NASS who are working on a Spine Registry want to preempt any government "mandatoryness" coming their way, they don't want to get ahead of themselves. Dr. Guyer says, "The pilot test will include one—probably simple—topic, which remains to be decided. We want to be able to follow patient progress from start to finish, including

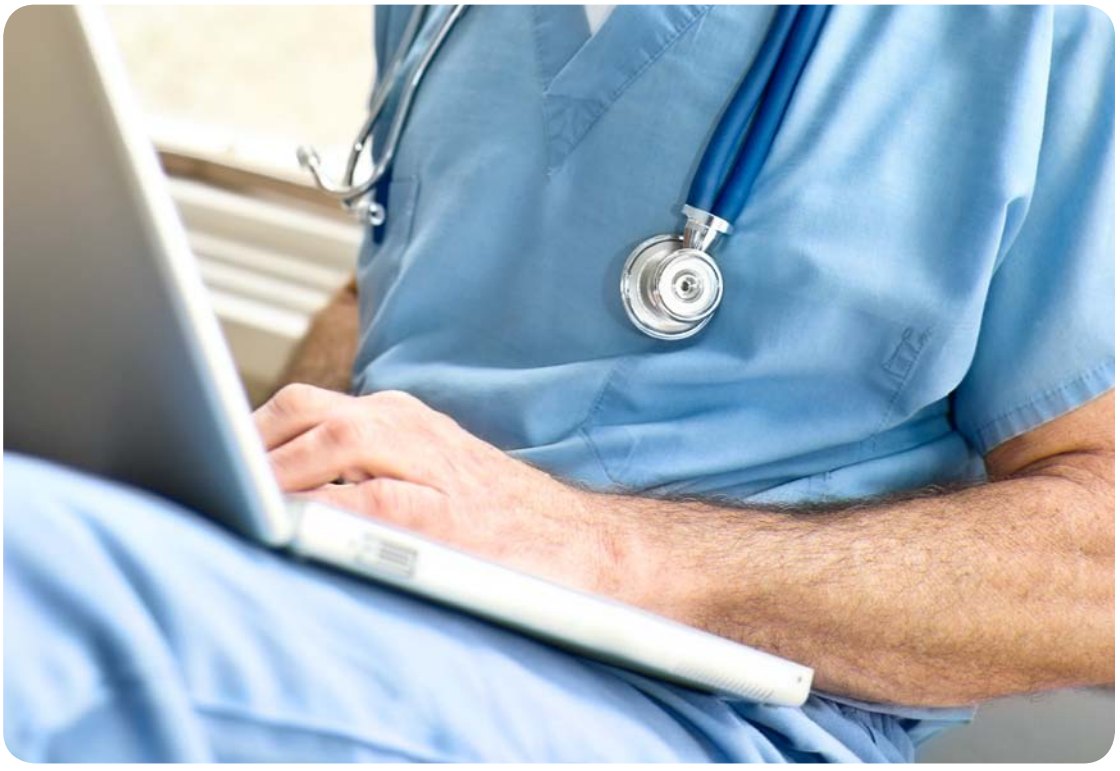
complication rates, etc. While there were some academicians who said that there were too many obstacles, we believe that it's possible to do this on a simple level where methods are validated. We think it's possible to move forward without taking a purist approach, i.e., you begin collecting data in a reliable fashion. Any form of detractor will eventually end up realizing that we are increasingly in a position where we must prove that what we do as surgeons is effective."

In the meantime, Dr. Baker wanted to learn the lessons of those who have already waded in the registry waters. He explains, "I flew to Brussels to meet with representatives from the European research entity Spine Tango, but they themselves are struggling with the participation issue. Sweden has no such problem because participation is compulsory. Our plan for the pilot study is to select centers that are dedicated to research and ask those sites to commit to inputting *all* of their cases. This should allow us to work out the kinks in the system, and gain more information to move forward. Spine Tango spent 18 million Swiss francs to develop the database…to avoid initial large expenditures we want to get our toes wet one drop at a time."

As for what not to do, Dr. Guyer says, "Trying to mandate registry participation is useless… we know we won't get anywhere. Also, it is important to collect all of the *appropriate* data. You don't want to go through the data and find that you have a lot of useless information—or that you have a glitch. For example, someone may forget to program in a particular field and then XYZ data can't be retrieved."

But back to the issue of participation. How indeed can doctors be motivated to input data? "It has to be a positive experience," states Dr. Guyer. "Registry data would be helpful for educating patients or for improving the physician's skillset. I envision a process where the doctor finishes surgery and immediately enters the information. Then when the patient returns there is a portal where you and the patient enter outcome measures."

While some surgeons may think they wear a cape, Dr. X across town may be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the real spine superhero. As Dr. Guyer notes, "There are numerous ads these days for treatments that are unproven. I look around Dallas, for example, and see laser treatment being offered as a cure all for all low back problems. With a registry, patients can utilize it like Consumer Reports and can look up Dr. X and see how he compares to his peers. At present, and well, forever, the selection of a physician has been based on personal recommendations and doctor/patient relationships. A registry would provide a more objective evaluation of their doctor, which will in turn improve patient care. Unless physicians have ways of evaluating themselves you may end up in a situation where you think you're doing a great job, but in fact you need improvement."

No resting on our laurels, says Dr. Guyer. And no ignoring the failures. "We need to examine and learn from unsuccessful surgeries and move toward consensus on various clinical issues. Spine could take a lesson in thoroughness from the airline industry—there is a crash and they make improvements based on what they learn during the course of the investigation. We do procedures, attend meetings, and do presentations but we don't course correct. This points to a uniformity of care issue. How can patients maintain confidence in the medical system if there are such varying approaches to treatment? Only recently I had a new patient who said, 'I have been to three doctors, each of whom has suggested a different treatment. One recommended a three level surgery; another wanted to do a one level; the last one didn't think surgery was indicated at all. How am I supposed to know that the one you're recommending is correct?'"

With his eyes set on advocating for patients, physicians, and the field, Dr. Baker is taking his next steps on the registry. "There will soon be a meeting involving the Agency for Healthcare Research and Quality, NIH, the National Committee for Quality Assurance, the National Quality Forum, insurers including Blue Cross Blue Shield, Center for Medicare and Medicaid Services, AARP, employers, and researchers in which we will try to select common outcome tools that could be accepted across agencies and payers. (The meeting was not convened because of the NASS database but happened to be a convenient time.) The collaborating societies have also hired a value consultant, Boston Health Economics, and are going to examine what tools we need in order to incorporate value into the database. (Value is loosely defined as cost divided by quality.) But then there are the outcome measures that are important to patients. For example, let's say you have a patient with cardiac issues and diabetes, and thus would not score well on the standard outcome measures. But, postoperatively he can now perform activities that are important to for his happiness and wellbeing."

"Oh, they want cases?" says Dr. X. "I'll input the five outrageously successful discectomies I did in the last few weeks." As for the post surgical patients in the waiting room, Dr. X doesn't think of those much. Dr. Baker states, "We designed the pilot as a feasibility study because if you don't get 100% participation then the data in the registry becomes useless. For example, you're a spine surgeon in private practice who only inputs one quarter of your cases. Which quarter? Perhaps you will opt to only include your most successful cases."

In the event that all goes well for the pilot study, there is the omnipresent question "who will pay?" When the bill comes, will some conveniently need to visit the restroom? Dr. Baker: "There are three ways to fund this registry. The first possibility is that the government or third-party insurers will compensate doctors to maintain outcome data. The second option is that it will be funded by a combination of sources, including industry, and the data will be compartmentalized to include independent modules. The data can then be used for FDA applications whereby, say, they use the registry for two years and collect data to support the efficacy

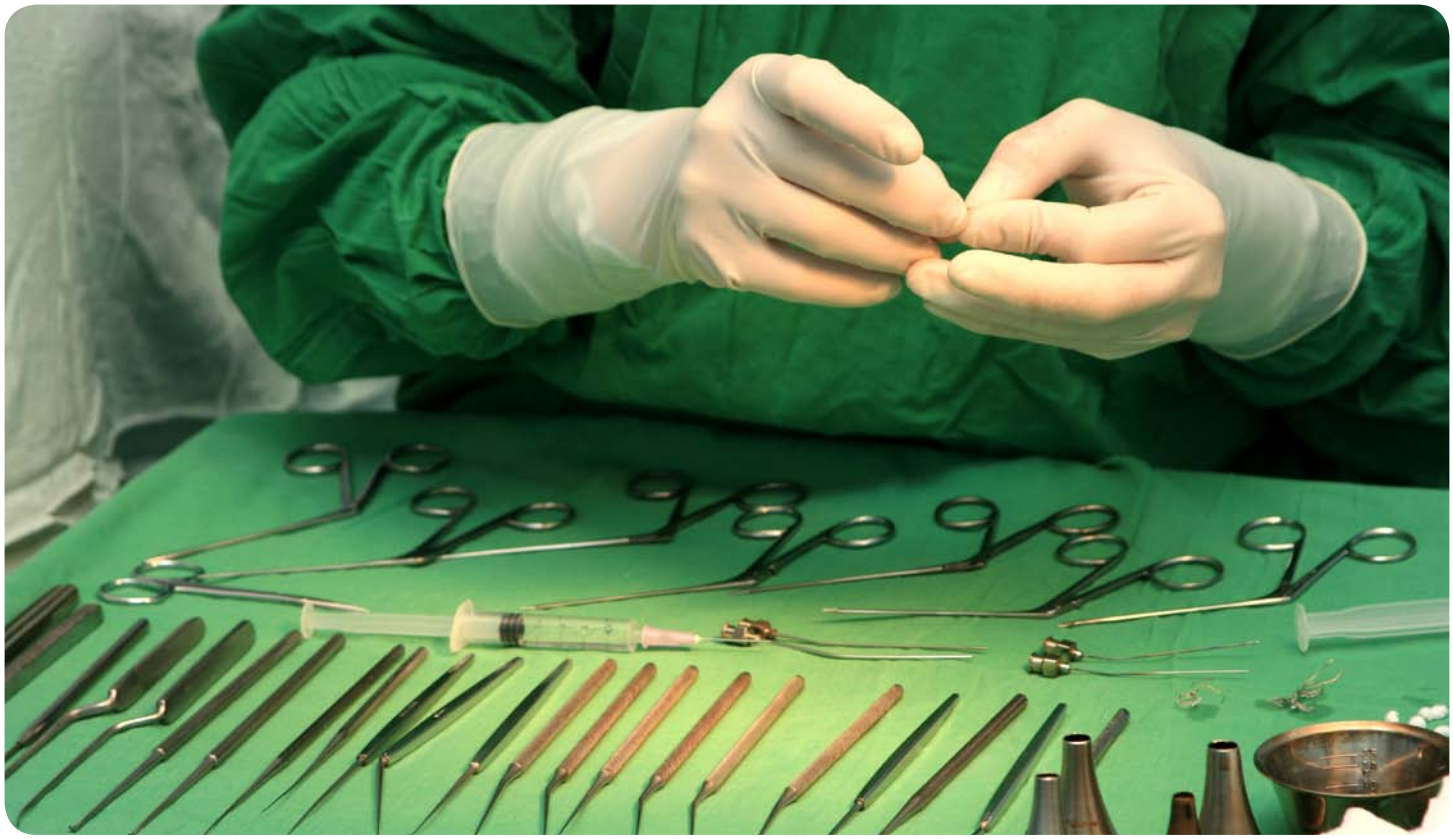
of a certain treatment…definitely less expensive than a company having to put together its own registry on multiple occasions. Lastly, and quite possibly, there is a chance that the government will place the cost burden on physicians."

Whichever party ends up holding the bill, there is little question that patients will benefit from a registry. "Randomized, controlled trials are meant to evaluate whether a procedure/treatment is effective, but effective and efficacious are legally and technically different. These trials select a specific patient population in order to prove that a given treatment works in a specific population, but these patients are not the ones who walk through our doors. Take the situation with BMP2…it was originally authorized by the FDA for LT cages for standalone fusions, but has been used off label 99% of the time. So determining which of those patients is actually benefitting from it is a challenge. Going from an idealized population to an everyday population is where a registry excels because it involves the average doctor's everyday population."

In crafting the database, Dr. Baker and the NASS team have taken pains to encourage active participation from other important parties. "If you have five different societies doing five registries it's quite likely that they will not communicate. To undertake such an approach is all too expensive with few, if any, benefits. Not only have we at NASS taken every opportunity to include other societies, but we are stepping back from the lead. Foremost in our thoughts is that when groups work together egos and animosity can come into play…we want to avoid that at all costs."

And they also want to ensure that there isn't even a hint of impropriety. Dr. Baker: "There has been absolutely no industry participation in the development or maintenance of the database. Such stringent firewalls are necessary so that it is clear to everyone that there are no conflicts of interest."

So going forward, when the surgical gloves come off, well, just get ready to type.



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company news

Replication Medical Clears Hurdles

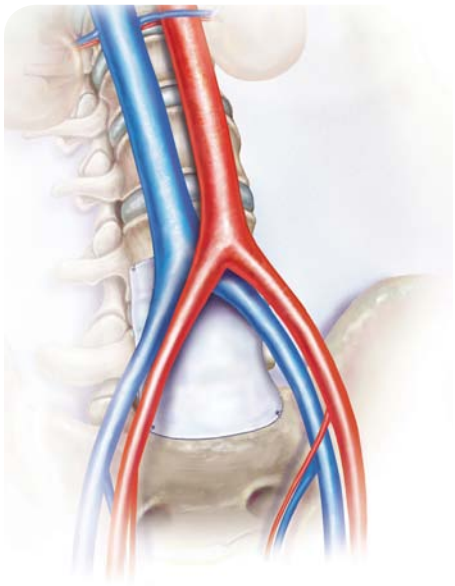
Replication Medical says it has received a CE Mark for its GelFix Posterior Spinal Distraction implant and FDA clearance for it EnGuard Vessel Guard.

The company is developing proprietary, hydrogel-based products for the spinal market and other surgical applications.

The Gelfix device is a one-piece posterior spinal implant made from HPAN, a biocompatible hydrogel which exhibits, according to the company, "mechanical properties including compressive resistance with a dynamic response. The Gelfix distraction implant is used as a spacer between the spinous processes to provide separation and prevent nerve pinching. The product is available in three sizes to fit the typical range of spinal stenosis patients."

The EnGuard Vessel Guard is indicated for use as a cover for the spinal blood vessels following anterior vertebral surgery. The device is inserted between the anterior surface of the spine and the spinal blood vessels at the conclusion of a primary surgery. The vessel guard can be affixed to the surrounding soft tissue, periosteum or directly the vertebra(e) using sutures or staples.

"This product is intended to help the spine surgeon do a better job when revision surgery is necessary by protecting the major blood vessels



EnGuard Vessel Guard/Replication Medical

which are in close proximity to the lumbar spine," said Ann Prewett, the company's President and CEO.

The company's announcement on March 8 noted that the safety and effectiveness of the EnGuard for reducing the incidence and severity and extent of post-operative adhesion formation have not yet been established.

Ann Prewett said, "Our products provide a technologically advanced alternative to the conventional metal and hard plastic implants which have dominated orthopedics and spine to date."

One of the company's surgeon advisors, Carl Lauryssen, M.D., noted, "The key to the procedure is the minimally invasive technique which can be used to implant the device. We insert the implant between the appropriate spinous processes and in 8-10 hours, the implant increases in size and gives us the stability that we need."

James Yue, M.D., Chairman of Replication's Scientific Advisory Board, added, "Prior to the introduction of vessel protection barriers, the surgeon knew that he was in for a long day when performing a revision anterior procedure. Today, this is less likely the case. Given the exciting and promising animal studies and clinical experience observed thus far, the EnGuard Vessel Guard should be considered for most, if not all, anterior procedures."

EnGuard is available in the U.S., while GelFix is not yet approved for sale or distribution in the U.S.

—WE (March 23, 2010)

Amedica Announces Patent and JV

Amedica Corporation has been granted a U.S. Patent for its ceramic-on-ceramic bearings for articulating joints used for total joint replacement and spinal disc applications.

The company uses a proprietary silicon nitride ceramic technology to develop and commercialize implants for the orthopedic market. It has brought to market various spinal implant products, while products under development include reconstructive hip and knee implants

The company says its new advance bearing surfaces covered under this and

company

other pending patents will be used as ultra-low-wear bearing components for motion preserving implants.

The patent holder, Ashok Khandar, Ph.D., Vice Chairman and Chief Science and Technology Officer of the company said, "The combination of high strength and toughness of our silicon nitride ceramics provides us with a unique and versatile surface-bearing technology, which offers surgeons wider design choices and better anatomic fit and function compared to currently available alternate bearing options."

Patent Description

The granted patent number 7,666,229. is described in the patent abstract as the following:

"An implantable articulating bone prosthesis (e.g., hip or joint prosthesis) is provided, which includes a pair of articulation components respectively defining a pair of articulation surfaces movably engageable with each other. Each of the articulation surfaces is formed from a biocompatible ceramic (e.g., doped silicon nitride ceramic) having a flexural strength greater than about 700 Mega-Pascal (MPa) and a toughness greater than about 7 Mega-Pascal root meter ($MPam^{0.5}$)."

This patent news comes on the heels of the company's February announcement of a joint venture agreement with Orthopaedic Synergy, Inc., a holding company for OMNIlife Science and Enztec, global designers, manufacturers and distributors of reconstructive surgery and implants and instruments.

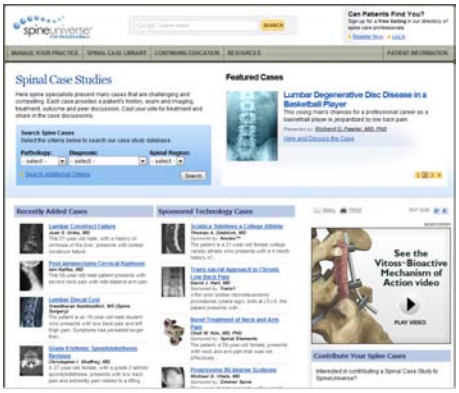
—WE (March 25, 2010)

SpineUniverse Expands Services

Send out the Hubble telescope… SpineUniverse is expanding the galaxy for spine surgeons. SpineUniverse, a Vertical Health web site, has added exciting new services and enhanced others. Their efforts are directed at helping spine surgeons navigate today's challenges, including economic pressures, staying current with advances in the field, understanding updated CME requirements and regulations, attracting new patients, and knowing how to best care for their patients.

Bill Paquin, CEO of Vertical Health, told OTW, "We've seen nearly 17,000 healthcare professional visits to the cases in our library since launch of the new site on January 18th. The search tool is being heavily used by professionals looking for cases by diagnosis, treatment, region and pathology. We're excited about what this means for the value of our case library to both the surgical community and industry as a whole."

company



Vertical Health/www.spineuniverse.com

New services include:

Expanded Community Case Discussion—Now, with the SpineUniverse Spinal Case Study Library, spine surgeons can join the discussion of peer reviewed cases, adding their comments and questions. With 2,500 spine surgeons already active in the Spinal Case Library, the new discussion functions will further enhance the value surgeons receive.

New – Online CME—Responding to regulatory changes that have increased CME requirements for surgeons and limited companies' ability to support surgeons' participation, SpineUniverse has included a new site that provides high-quality CME modules online—www.spineCME.org. At no cost, spine surgeons can click on any of the programs, review the content, pass a brief test, and immediately print their CME Certificate.

Expanded – Practice Promotion to 10 Million Patients Annually—The free-of-charge Find a Specialist tool enables spine practices to promote their services to patients specifically in their zip code, or surrounding zip codes, and/or to patients with specific conditions. Premium Members can take advantage of new features including photos and maps highlighting multiple practice locations. SpineUniverse also launched Group Practice Listings that cater to small and large spine centers by featuring staff members and main practice information.

—EH (March 25, 2010)

legal & regulatory

FDA Absolves Stryker's Hip Facility

Stephen MacMillan must be grinning like a Cheshire Cat.

Stryker announced on March 23 that a 2007 Warning Letter from the FDA related to its manufacturing facility in Mahwah, New Jersey, has been resolved.

The Warning Letter, dated November 28, 2007, was filed after FDA inspectors determined that quality gaps had contributed to faulty Trident hip implants. It was one of two U.S. warning letters the company received from the FDA in 2007 over failures in its quality systems. The other Warning Letter was related to Stryker's Hopkinton, Massachusetts, biologics facility in 2008. Stryker also received a Warning Letter in 2007 related to its Cork, Ireland, manufacturing plant, and that one remains in place.

Stryker Launched Quality Effort

These warning letters spurred the company to spend hundreds of millions of dollars to upgrade its quality systems.

MacMillan, Stryker's Chairman, CEO, and President (whew) said:

> "The resolution of the...Warning Letter is another important step in demonstrating our firm commitment to significantly transforming our quality systems throughout our organization. The investments we have made, and will continue to make, are resulting in solid progress toward our goals."

In addition to committing to spend $200 million over three years to upgrade the company's quality systems, last September Stryker also named Lonny Carpenter to the newly created position of Group President for Global Quality and Operations.

The New Jersey Warning Letter stated that in some instances problems with the device required revision surgeries. According to the letter, "Complaints were also received between January of 2005 through April of 2007 for squeaking noises of hip implants with ceramic bearing components; some of

legal & regulatory

those problems resulted in revision surgeries due to implant failures (fractures, pain, wear particles, and fragments). Furthermore, complaints were received between January of 2005 through June of 2007 concerning improper seating of hip implants in broached bones resulting in bone fractures."

MacMillan has had to spend lots of time with Wall Street analysts on quarterly conference calls explaining the FDA problems. He should look forward to the next quarterly call on April 20.

—WE (March 24, 2010)

Stanford Expands Faculty Marketing Ban

The Stanford University School of Medicine is following the teaching hospitals of Harvard in prohibiting its 660 adjunct faculty from giving paid speeches drafted by medical device and drug makers. In addition to being prohibited from participating in speakers' bureaus, the adjunct facility must now follow the same policies as full-time faculty and are prohibited from accepting industry gifts of any size.

On March 15, Philip Pizzo, M.D, Dean of the school, said that the public doesn't differentiate between adjunct and full-time faculty and either can tarnish the institutions reputation. "Witness the gradual deterioration in how physicians have been perceived," Pizzo told *The New York Times* on March 13.

Stanford University School of Medicine / stanford.edu

> "We have to get back on the high road and avoid the negative interactions in which industry engages physicians in marketing products." He says the institution welcomes interactions with industry that are "positive and collaborative, but thinks the line should not be crossed when the faculty "engages in marketing."

Stanford was among the first academic medical centers in 2006 to implement policies governing their faculty's interaction with industry. In 2008 the institution revised its policy to ban direct commercial support of continuing medical education at the school. The school also bans industry representatives from patient-care areas and prohibits faculty from publishing articles ghostwritten by industry representatives.

No More Private Distinction

David Stevenson, M.D, Senior Associate Dean for Academic Affairs and Vice

legal & regulatory

Dean of the medical school addressed why adjunct faculty where not previously included in the bans. "It did not seem appropriate then to intrude in their private affairs, in that they all have private practices. But we came to realize that they always have the Stanford identity attached to them, even when they are not working on our behalf. Even if they make their best effort not to advertise themselves inappropriately, people unavoidably use those Stanford titles. So we reasoned that if the title were important to them, they should be asked to comply with the same policies to which all other faculty comply."

Pizzo said that some adjunct faculty may choose to leave their adjunct positions, as happened at Harvard. Lawrence DuBuske, M.D., a well-known allergy and asthma specialist, reportedly resigned from his post at the Brigham and Women's Hospital in Boston in January when that institution's new policies went into effect.

—WE (March 25, 2010)

extremities

Higher Education Equals Improved Healing?

In addition to improving your mind, education may also improve your body. In a study presented at the recent American Academy of Orthopedic Surgeons (AAOS) annual meeting (March 9-13), researchers found that patients with higher levels of education experienced better outcomes following a wrist fracture. For each increase in the level of education, patients had a significant increase in their range of motion and a decrease in their reported symptoms over those patients in lower education levels.

The Study

Dr. Nader Paksima, Assistant Professor of Orthopedic Surgery at the NYU Hospital for Joint Diseases, led the research team which followed 387 patients who suffered distal radius fractures. The team categorized education levels into five groups: less than high school, high school graduates, some college, college graduates, and some post-graduate education. After operating on the fractures, doctors followed up with patients at the 3, 6 and 12-month marks. Researchers measured patient recovery by recording X-rays, range of motion, grip strength and by using the DASH questionnaire to measure psychological and functional patient-reported outcomes.

Dr. Paksima adds that, "There have been studies in the past which found other markers of socioeconomic status that indicated improved outcomes, and researchers have looked at education as one of the markers of socioeconomic status." However, many of the previous studies collected retrospective data, and Dr. Paksima's research team felt motivated to return to this topic with a prospective study in order to find more reliable results. "We collected data on an ongoing fashion which typically tends to make the study more accurate," says Dr. Paksima.

Results and Conclusions

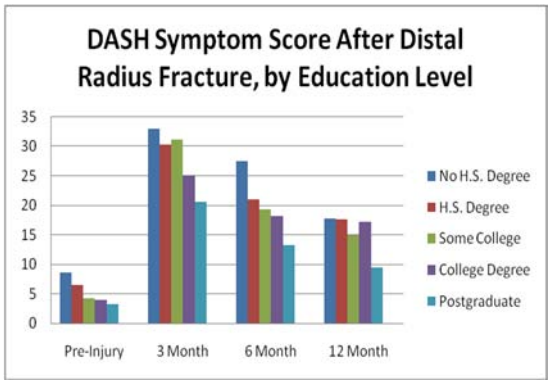
Researchers saw statistically significant differences in outcomes between patients with different levels of education. "For example," says Dr. Paksima, "for each successive level of higher education, patients had a 2 degree increase in their range of motion each time we saw them." Patients with higher levels of education also reported lower DASH symptom scores (meaning better wrist function) as illustrated in the graph.

"When you look at the literature," adds Dr. Paksima, "socioeconomic status has been shown to be a predictor for better outcomes for situations such as heart attacks, cancer recovery, and even emergency CPR."

extremities

Annapolis Graduation / Wikimedia Commons

Theories abound as to the exact connections between socioeconomic status and patient outcomes, and Dr. Paksima has a few ideas of his own. "With something like a wrist fracture, you can just imagine that someone of a higher socioeconomic status would probably have a desk job rather than a working job, they would have better family support, they might be able to attend more therapy sessions, and I think psychologically, especially in terms of education, people can become more engaged in their own care. So instead of feeling victimized by the injury, they can feel empowered to do something about it."



Source: Dr. Pakisma

And how can physicians use this study? Dr. Paksima treats patients with insurance and those without. "Although the treatment they receive is exactly the same," he says, "when you do a study like this, it makes you wonder if you should pay even more attention to those patients who are disadvantaged so that you can make sure they have access to all of the same resources that the other patients would have. You can use this study as something to raise awareness of patients' issues."

—DK (March 22, 2010)

large joints

Kids, Meniscal Repair & ACL Reconstruction

A twist…and then a shout (a shout of joy that is). Researchers from the Mayo Clinic in Rochester, Minnesota, have found that 84% of children 18 and younger had successful clinical outcomes during an eight year follow-up to repair a torn meniscus at the same time as reconstruction of the anterior cruciate ligament (ACL). The success of the meniscus repair, however, depended on whether the tear type was simple, complex or a "displaced bucket-handle."

Providing background, Dr. Aaron Krych, Chief Resident in the Department of Orthopedic Surgery at the Mayo Clinic, told *OTW,* "In 2008, the senior author on this study (Dr. Dahm) published on the results of repair of isolated meniscus tears in the pediatric and adolescent population. We were slightly surprised to find a lower clinical success rate than expected, including 80% for simple tears and 68% for bucket-handle tears, but only 13% for complex tears. In the adult literature, we know that meniscus tears repaired at the time of ACL reconstruction have higher healing rates. Therefore, we wanted

large joints

Antiphon Painter / Matthias Kabel Wikimedia Commons

to undertake the current study and compare the results of meniscus repair in children and adolescents at the time of ACL reconstruction to those performed in isolation (without ACL reconstruction)."

The study, lasting from 1990 to 2005, found that patients had an overall 74% success rate in the repair of their meniscus tear. Patients with simple tears had an 84% successful repair rate. The success rate decreased to 59% for displaced bucket-handle tears and 57% for complex tears. Two years after surgery, these patients had a freedom from failure rate of 90.9%; however, after 8 years, the rate decreased to 76.8%.

When asked about transmitting this information to coaches and trainers, Dr. Krych told *OTW,* "For each patient that undergoes an operation in our Sports Medicine Center, the surgeon works closely with the patient's physical therapist and trainer for a guided rehabilitation program, individualized to each patient. With the new information from this study, we educate those involved with the athlete on a daily basis, and can guide discussions on the likelihood of successful clinical outcome of their meniscal repair."

Regarding his future work, Dr. Krych commented to *OTW,* "From this study, we found that complex tears have a higher clinical success rate when performed at the time of ACL reconstruction compared to when repaired in isolation. This improvement was from 13% to 59% clinical success rate. However, the time period of the study was from 1990-2005, a time when different surgical fixation devices, as well as meniscal enhancement techniques, were being developed. In the future, we would like to see how these improved devices and techniques, along with improved understanding and awareness, may improve the clinical success rate in this patient population."

—EH (March 22, 2010)

Imaging: A Lesson From Hockey

Technology rules! Or does it? According to a recent study, 70% of healthy professional and collegiate hockey players had abnormal hip and pelvis MRIs, despite having no symptoms of injury. These findings might give pause to those surgeons tempted to be

large joints

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overly dependent on imaging for diagnostic purposes.

"This study was done to see if abnormal MRI results are found incidentally in active roster hockey players," said Matthew Silvis, M.D., Assistant Professor, Department of Family Medicine and Orthopedics at Hershey Medical Center at Penn State University College of Medicine, in the news release.

As for the history behind this work, Dr. Silvis told *OTW,* "I currently serve as a team physician, along with Dr. Kevin Black (co-investigator), for the Hershey Bears (American Hockey League affiliate of the Washington Capitals). We wanted to determine the prevalence of pelvic and hip MRI findings in professional and collegiate hockey players. Athletic pubalgia (i.e., athlete groin pain) is a common cause of pain and disability in hockey players. This disorder can be debilitating and career threatening. MRI is felt to be superior at diagnosing the underlying problem as it provides contrast resolution and multiplanar capabilities. While we did not exclude symptomatic athletes from the study, the vast majority were asymptomatic and had findings. This information helps us clinically as caution must be taken when interpreting MRI as lesions may be detected that are not temporally correlated with self-reported measures of pain or disability. The bottom line is that imaging does not replace good clinical judgment. You may need to hesitate to avoid reading too much into an MRI."

High-resolution MRIs were taken of the pelvis and hips of 21 professional and 18 collegiate hockey players. Two players reported slight pain (3 on a 10 point scale), with minimal to no disability in relation to their pain. Twenty-one out of the 39 had labral tears; 12 of the 39 had muscle strain injuries of the hips and 2 of 39 had tendinosis (inflammation) of the hips. Overall, 70% of the players had irregular findings on their MRIs—without clinical symptoms.

"This study raises all sorts of questions that should be examined in further studies. For example, will these abnormalities cause problems and symptoms later for these athletes?" said Dr. Silvis in the news release. "But this study shows the limitations of depending too heavily on an MRI. A surgeon may see something in the image, but it isn't causing a problem."

Concerning his future work, Dr. Silvis told *OTW,* "Our results indicate that MRI findings of the hip and pelvis are not uncommon in high performance hockey players and that these findings did not limit play nor were they associated temporally with self reported measures of pain or disability. A prospective study is currently underway to determine if these findings are in fact precursor lesions for future disability."

—EH (March 23, 2010)

STOP Sports Injuries Campaign

According to the American Orthopaedic Society for Sports Medicine (AOSSM), little people involved in sports are having lots of big people problems. Specifically, orthopedists are reporting that the number of youth injuries is climbing to epidemic proportions, and that young athletes are experiencing overuse injuries at a younger age. The high rate of youth sports injuries is fueled by an increase in overuse and trauma injuries and a lack of attention paid to proper injury prevention.

Concerned, the AOSSM and its collaborators have created the STOP Sports Injuries Campaign, which is aimed at helping parents, coaches, healthcare providers and athletes learn more about the prevention, treatment

large joints

Wikimedia Commons

and long-term consequences of overuse and trauma injury.

Overuse injuries not only impact young athletes in the short term, but can lead to long-term consequences. These injuries, which may become apparent during the course of play, can be prevented with proper preventive measures, says AOSSM. These include pre-participation physicals, stretching, cross-training, hydration, and open communication about pain among all participants (coaches, athletes, parents, and healthcare providers).

AOSSM is joined in its efforts by the American Association of Orthopaedic Surgeons; the American Academy of Pediatrics; the American Medical Society for Sports Medicine; the National Athletic Trainers' Association; the National Strength and Conditioning Association; and Safe Kids USA.

The STOP Sports Injuries Campaign will reach out to the youth sports community through a variety of resources, including public service announcements, the STOP Sports Injuries web site (with podcasts, videos, and educational information for all concerned parties), a national media campaign, and injury prevention tip sheets on 12 sports.

Commenting to *OTW* was Paul Saluan, M.D., of Cleveland Clinic. Dr. Saluan, a pediatric orthopedist and sports medicine expert, stated, "Youth injury rates are rising significantly, with an estimated three million injuries a year in children of high school age and younger. This accounts for three billion dollars annually in healthcare costs; add to that the long-term care that will need to be provided for the degenerative joints created from youth sports...that's another three billion dollars. This is a pandemic."

He added, "Young athletes have immature bones that just can't handle the stress that older bones can handle. The fact is that if a kid has a history of injury then he or she is much more likely to experience an injury in the future. All of this adds up to great costs to the child and society. There are a number of studies showing that when a young athlete sustains an injury, he or she is more likely to get involved in alcohol or drug use; their academic performance will likely suffer as well."

—EH (March 23, 2010)

people

Dr. Robert C. Bray Awarded AOSSM Grant

This message was ***not*** delivered by a neuropeptide…more likely by a friendly phone call.

Dr. Robert C. Bray

people

Dr. Robert C. Bray of the University of Calgary has been selected as the winner of the American Orthopaedic Society for Sports Medicine's (AOSSM) $250,000 Ligament and Tendon Repair and Regeneration Grant for his project, "Biological Augmentation of Ligament and Tendon Healing: Role of Neuropeptides."

Along with colleagues Paul Salo (University of Calgary), Per Renstrom and Paul Ackermann (the Karolinska Institute), Dr. Bray will conduct a series of experiments to define the cellular, physiological, mechanical and structural changes in healing chronically injured tendons and ligaments. The team will then assess the impact of blocking the action of a specific inflammatory neuropeptide, or augmenting the action of an anti-inflammatory neuropeptide.

When asked where they are in the process of designing the experiments, Dr. Bray told *OTW,* "We're just at the stage of preliminary testing to determine the correct doses of peptides that will safely promote healing (through reduction of endogenous inflammation and promotion of repair processes) in ligaments, tendons and in joints. This is a significant and crucial step that will be the foundation for the main portion of the project. We're also working on finalizing assays to measure functional outcome in injured ligaments and tendons."

"We are grateful to AOSSM and RTI Biologics for selecting our project and allowing us to continue to study such an important piece of the ligament and tendon repair puzzle," said Dr. Bray in the news release.

This grant is part of a series of three-year AOSSM research initiatives intended to highlight important issues in orthopedic sports medicine and to foster high-level research. The first initiative focused on articular cartilage followed by the current initiative on ligament and tendon repair and regeneration. Following a think tank meeting in January 2009, and a grant workshop in July 2009, the Society solicited formal grant applications from workshop participants. This research initiative is sponsored by RTI Biologics Inc.

"We are proud to provide financial support to AOSSM's research initiatives. The efforts of the AOSSM membership in the field of ligament and tendon repair and regeneration will lead to improved patient care. Continued research in this field is central to both the mission of RTI Biologics and the ongoing scientific leadership of the AOSSM," said Rod Allen, VP of Sports Medicine Distribution, RTI Biologics Inc., in the news release.

As for anything else Dr. Bray would like orthopedists to know about this work, he told *OTW,* "The overall aim of the work is to determine the role of early inflammation induced by peptides after a ligament injury to the ongoing development of osteoarthritis in ligament-injured knees. It's a novel and exciting area of research that could easily lead to a new biological modulation of connective tissue healing."

—EH (March 25, 2010)

Christopher Evans Wins Steindler Award

Most people can't say they're giving hope to 50 million people…but Christopher Evans, Ph.D., can. Dr. Evans, Director of the Center for Advanced Orthopaedic Studies at Beth Israel Deaconess Medical Center (BIDMC) and Maurice Edmond Mueller Professor of Orthopaedic Surgery at Harvard Medical School, was presented with the 2010 Arthur Steindler Award. This honor was bestowed upon him for his work on the world's first clinical trial of gene therapy for arthritis.

The Arthur Steindler Award is made biannually to recognize senior scientists, clinicians and educators who have made significant contributions to the understanding of the musculoskeletal system and musculoskeletal diseases and injuries.


Dr. Christopher Evans

"Arthritis is our nation's most common cause of disability," noted Mark Gebhardt, M.D., Chief of the Department of Orthopaedic Surgery at BIDMC, in the news release. "Nearly

people

50 million Americans are dealing with some form of this extremely painful condition, and that number will only grow larger as our population ages. The innovative research being conducted by Chris Evans holds great promise as a new treatment option for managing this widespread disease."

In 2009 Dr. Evans published the first clinical evidence demonstrating a clinical response to gene therapy in rheumatoid arthritis. He is in the process of developing a further clinical study in the gene therapy of osteoarthritis and has advanced pre-clinical research programs in bone healing and the repair of damage to cartilage.

Commenting on the new gene therapy study, Dr. Evans told *OTW,* "We are in the process of trying to initiate a new gene therapy clinical trial in osteoarthritis. We have been awarded an NIH grant with which to do this, but we have run into major issues with the FDA. I suspect this reflects the 2007 death of a subject in a different arthritis gene therapy trial."

The author of more than 300 papers, Dr. Evans received his doctorate from Swansea University, Wales, UK, which recently bestowed him with an honorary fellowship. He is also the recipient of the Marshall R. Urist Award (for excellence in tissue regeneration) from the Orthopaedic Research Society and is an elected fellow of the Hastings Center, a leading bioethics research institute. Last year, Dr. Evans' laboratory received a National Institutes of Health Challenge Grant of more than $980,000 to develop innovative ways to heal broken bones.

As for what the award means to him, Dr. Evans told *OTW,* "This means a great deal, largely because it is not one of those major awards, such as the Kappa Delta Award, that you apply for. So it means that your research is appreciated without your drawing attention to it! Moreover, the Arthur Steindler Award is given for a sustained body of work generated over a long period, which is nice."

—EH (March 26, 2010)

reimbursement

Docs to Flee Medicare

On March 23 the North American Spine Society (NASS) said that as many as 24% of spine care physicians currently participating in Medicare will drop out of the program if the 21% mandated reimbursement reductions are enacted later this year.

In addition, more than a third of the 340 NASS members responding to a NASS survey over two weeks in March said they would drop out of the program for two years and contract with Medicare patients privately.

The vast majority of physicians remaining in the program would make changes to their practice if the cuts go into effect.

Those changes would include:

- 20.6% would limit the number of Medicare patient appointments
- 14% would reduce time spent with Medicare patients
- 12.9% would stop providing certain services
- 11% would begin referring complex cases

NASS President Ray Baker, M.D., said, "These findings are indicative of the fears resonating among physicians nationwide." He noted that the health care bill passed by Congress did not address the most immediate concerns of physicians.

Raj Rao, M.D., NASS' Advocacy Committee Chairman added that in addition to not addressing a "broken sustainable growth rate payment system," members are also worried about a new Independent Payment Advisory Board and a lack of proven medical liability reforms.

Paolo Veronese, 1585 / Wikimedia Commons

reimbursement

Health Care Reform 2.0

Here's a repackaged idea we offer physician societies to take to Congress. Call it Health Care Reform 2.0.

In return for serving Medicare patients, doctors are given limited protection from lawsuits if they follow physician-approved standards of practice. The money they save in lower private medical liability insurance rates and drop in defensive medicine costs would pay to fix the broken reimbursement system. Patients would still be able to sue the government if they are injured and doctors are held accountable. Everybody's happy...but the lawyers.

—*WE (March 25, 2010)*

The Picture of Success: Dr. Richard Strain

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

Born to missionary parents who roamed the globe, a young Richard Strain thought, "That's nice. Now how about that car?" Dr. Richard Strain, M.D., President of Orthopaedic Associates of South Broward, explains, "As a youngster I didn't understand the value of my parents' work or how accomplished they were. My father was a brain surgeon and my mom was the third woman to graduate from the Yale School of Divinity. Now, of course, I am impressed with their work…when I see the photo of them with Ghandi, I get it."

More concerned with the water temperature of a lake than that of a beaker, Rick Strain was in no hurry to impress anyone academically. He admits, "I was a poor student until 10th grade and truthfully, almost anything could distract me from my studies. Especially fun was the time I spent water skiing—made more wonderful by the fact that I became the state champion one year. It began to dawn on me, however, that if I didn't earn good grades then I would have no future. I did show some affinity for the sciences, and in my 10th grade biology class the teacher said that if we could remove a frog's brain and spinal cord in one piece then we wouldn't have to take the final exam…I was proud to be the only one to accomplish this feat. About the same time my parents were trying to figure out how to motivate me. As I was on my way from being a 'C' student to an 'A' student, my dad said that if I could maintain a 'B' average then he would give me his old car—a Pontiac GTO (which he did)."

Perhaps if Dad Strain had known his son could attain such heights, he would have thrown in a boat. But the need for parental bribery had gone by the wayside. Dr. Strain: "I attended Tulane University for my undergraduate studies where things went so well that I was given the moniker, '4.0 Strain.' Although I majored in engineering, I designed my own curriculum and packed it with a lot of chemistry and physics. For my honors thesis on Xray crystolography I drew upon the distinguished Linus Pauling, who was on sabbatical in our lab after he won the Nobel Prize in chemistry. In fact, I still take Vitamin C because of him."

His confidence (and immune system) boosted, Richard Strain began medical school at Vanderbilt University in 1971. "Unusually, Vanderbilt's medical school was located in the hospital, so that meant we started out with the conviction that the basic sciences

did not have to be divorced from the clinical realm. One particularly impressive mentor was Dr. Jack Davies, an anatomy professor. He said, 'It doesn't matter whether you are a psychiatrist or a surgeon, anatomy isn't going to change. Theories…those are what change.'"

Dr. Rick Strain then headed for Boston. "At Vanderbilt I worked in the lab of Dr. Bill Olsen, who had done his residency at Harvard. In addition to encouraging me to follow in his institutional footsteps, he taught me to be tenacious about my research. So while waiting for the Harvard doors to swing open, I obtained a research grant, developed a basic science animal model and used electron microscopy to examine how nerves are injured by pressure."

Once ensconced in the Harvard milieu, it was a ritual of bagels and Xrays that would launch his days. "In 1975 I began my residency and rotated through a number of different hospitals. While at Massachusetts General we would start our days with Dr. Henry Mankin, an exceptional teacher who met the residents for breakfast every morning. An unknown Xray would go up and we would discuss the differential as Dr. Mankin led us in a round of piercing questions. Also valuable was my rotation with Dr. Richard Scott, the famed total joint surgeon. He insisted on planning out each element of an operation beforehand so that there were no surprises."

But of course there are unintended situations from time to time. And when there were, Dr. Strain was glad to be a witness. "I remained under the tutelage of Dr. Scott and did a tailored mini fellowship (this was a time when no one did fellowships). The words of my father still ring in my ears: 'You learn more watching a good surgeon get out of trouble than at any other time.'"

Heading back to the sunbelt, Dr. Strain then joined a local private practice. "We have a stellar mix of personalities and talents in the group; in fact, no one has ever left the group except in the case of death or retirement. At one point we went to work for a large local hospital, but it turned out to be a major mistake. Physicians tend to put quality of care first and for the most part, those running hospitals don't understand how to deliver quality care. Anything that can be counted they can understand, but the nebulous idea of quality is foreign to them, so you end up with conflicts related to dollars and sense versus quality. I'm not saying they are evil. When you ask a color blind person to dress you they are not being mean when they make you look like a clown. The problem is that other than a few superb institutions, none of the hospital systems in this country are headed by doctors."

But the diplomatic Dr. Strain, now on the AAOS Committee on Professionalism, does understand physicians…and how they should comport themselves. "We discuss doctors who may have violated the Academy's standards of professionalism. For example, we deal with expert witness cases where the doctor has been sued and in his or her role as an expert witness may have violated one of the Academy's standards of professionalism."

On the research front, Dr. Strain looks into a common post-surgical threat—deep vein thrombosis (DVT). "I am the principle investigator in several drug studies and am concerned that so many (40%) joint replacement patients get DVT. There is a new group of oral Xa inhibitors coming out now that have been shown to be effective. These drugs may be what we have been looking for."

And his most memorable moments as an orthopedist? "These are the times when patients show me the strength of the human soul. I recall one child who suffered with osteogenesis imperfecta for years. He had experienced about 35 fractures and had undergone many surgeries…despite this, he always had a positive outlook."

Thrilled with the acumen of those in the field today, Dr. Strain does have a few things that keep him awake at night. "The explosion of subspecialization in orthopedics is dangerous in that surgeons lose the ability to deal with different problems. If someone is a joint guy he just flat out won't see a patient with shoulder bursitis. This fragmentation will have serious clinical consequences in the coming years. It's also lamentable because small towns are wonderful places and you may not be able to live in one because the town needs a generalist."

One medium through which Dr. Strain may be able to effectuate change on the subspecialization—and other—issues, is through his work with residents. "I want my residents to know that although various techniques change, the fundamental principles of the field do not...those are what you ***must*** know. I remember one case I did alongside Dr. John Hall, the Chief of Pediatric Orthopedics at Children's Hospital in Boston. He was cleaning one side of the spine and I was cleaning the other and he looked at me and said, 'Your side isn't clean. Do it right the first time and you don't have to come back and do it again.' I also impress upon my students the importance of thoroughly reading the literature. When our residents start this rotation I give them a CD with all of the papers I want them to read. And in the OR we are continuously quizzing them via the Socratic method. We start with the most junior resident in the room. If he or she doesn't know, then that person asks the next in line, and so forth. Finally, if no one knows, then Helen, our knowledgeable scrub nurse, gives the answer. The residents quickly realize that if they don't read the literature then they will be in my OR for a long time."

Which, of course, would cut into his family time. "My wife Elizabeth and I have one child Britta, our nine year old daughter. One day it just dawned on me that love is spelled 't-i-m-e.' Since she has an extraordinary interest in horses and rides in the local rodeos, we are always there to support her. Our little cowgirl is actually a champion barrel racer. This all began one day when she asked to go to our neighbor's stable and learn how to ride. From that moment on we couldn't get her to leave the stable… she would do whatever was needed… shampoo the horses, clean out the stables…she just loves the world of riding."

Her athleticism hasn't rubbed off on her father, however. "My wife runs a lot, but I don't exercise. My hobby is sort of the opposite of exercise…wine. In 1968 I went into a wine specialty shop in New Orleans and told the owner that I wanted to learn about wine. He gave me two lasting pieces of advice: always consume one bottle next to another, and keep notes. I took my old physics lab book and started writing…I still have that notebook."

Dr. Richard Strain…toasting patients and life.

Orthopedics This Week

VOLUME 6, ISSUE 10 | MARCH 30, 2010

Orthopedics This Week | RRY Publications LLC

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