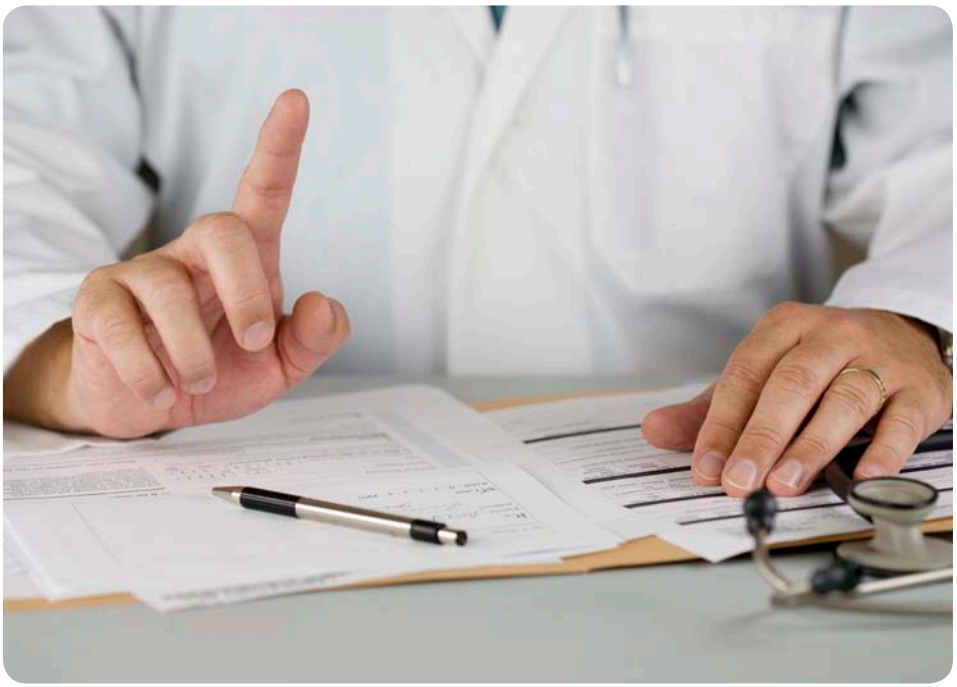
VOLUME 5, ISSUE 37 | DECEMBER 1, 2009

Orthopedics This Week

week in review

05 NuVasive's XLIF Reviewed ♦ Cigna is about to review its previous coverage decision that said NuVasive's XLIF was "unproven." Their review is being watched to see if other carriers will follow suit and whether or not another effort will be made to create a new CPT code for the procedure.

08 In Vogue…the Shoulder ♦ Drs. Ken Yamaguchi, Louis Bigliani, and Evan Flatow weigh in on the latest happenings in the world of shoulder. Percutaneous pinning, new options for rotator cuff tears, and shoulder replacement are all in the mix.



12 Arthrocare Has Sales! Who Knew? ♦ For 576 days, ArthroCare was a company without reported sales, expenses or earnings. The silence ended November 18, 2009. How did ArthroCare's stock perform without reported sales or earnings or a main stream trading venue like NASDAQ? Improbably, the share prices rose 354% or $420 million in total market value.

the picture of success

24 Dr. Christopher Born ♦ He started out as an orthopedic cast technician and is now Chief of Orthopedic Trauma at Brown University. And Dr. Christopher Born is who "they" call when there is a mass casualty event.

breaking news

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ZirMed and **HST*pathways:*** Efficiency Aces

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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
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 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	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

(2004-2008 U.S. Procedure, Sales, Charging and Demographic Data as derived from Medicare AND Private Payer datasets)

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Orthopedics This Week

VOLUME 5, ISSUE 37 | DECEMBER 1, 2009

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Looking back at the third quarter sales reports, we see strong evidence that orthopedic demand is settling into its customary high single-digit growth rate with two sectors; extremities and spine, kicking up slightly to double-digit growth rates. As we said last week, sector rotation coming our way right now.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	2	Zimmer	28.10%	7.77%	Buyers want to own Zimmer again and continue to bid this stock higher.
2	1	Smith & Nephew	22.42	8.82	#1 last week but a resurging and higher operating margin for ZMH bumped SNN out of the top spot.
3	5	Medtronic	31.09	18.23	Consensus is that MDT's sales will soon return to historic growth rates. The Elephant can't dance that well, but valuation is too low.
4	4	Integra LifeSciences	15.37	5.61	Stu is a bit overdue for a purchase. Six/year is IART's pace. Otherwise, Wall Street is looking for a ho-hum 5% growth rate in 4Q.
5	3	Stryker	23.50	3.69	To buy device recycler Ascent for $525 million. SYK is all about lower costs for customer.
6	NR	Wright Medical	6.61	8.42	We're tardy in putting WMGI back on Power Rankings. Starts at #6. Super 3Q report. Hanging ten on the extremities' wave.
7	8	Johnson & Johnson	26.94	5.61	In the last 30 days JNJ has had a break out. Best case, the stock will test $70—15% above today's price.
8	7	Exactech	12.61	3.32	It's just hard to find institutional buyers for micro-cap medical device companies with highly diversified products and markets.
9	6	Orthofix	10.33	(6.59)	Back to being the Rodney Dangerfield of ortho. Not deserved. Strong financial management plus innovation.
10	9	CONMED	6.92	(6.68)	Surprised Warren Buffett hasn't discovered CNMD. Anyway, demand is showing signs of recovery. Next 12 months should be good.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Medtronic	MDT	$42.99	$47,580	18.2%
2	ArthroCare	ARTC	$21.88	$587	16.1%
3	RTI Biologics Inc	RTIX	$4.09	$223	14.9%
4	TiGenix	TIG.BR	$6.39	$157	10.8%
5	Smith & Nephew	SNN	$48.51	$8,570	8.8%
6	Wright Medical	WMGI	$18.15	$701	8.4%
7	Zimmer Holdings	ZMH	$58.52	$12,460	7.8%
8	Synthes	SYST.VX	$132.81	$15,761	6.7%
9	Integra LifeSciences	IART	$32.95	$938	5.6%
10	Johnson & Johnson	JNJ	$62.89	$173,520	5.6%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Osteotech	OSTE	$2.66	$48	-40.2%
2	Regen Biologics	RGBO.OB	$0.50	$5	-23.8%
3	CryoLife	CRY	$5.92	$169	-17.0%
4	TranS1	TSON	$3.44	$71	-16.3%
5	NuVasive	NUVA	$34.79	$1,330	-11.0%
6	Orthovita	VITA	$3.51	$269	-10.7%
7	Alphatec Holdings	ATEC	$4.29	$225	-10.6%
8	Capstone Therapeutics	CAPS	$0.65	$27	-8.3%
9	CONMED	CNMD	$21.24	$618	-6.7%
10	Orthofix	OFIX	$29.92	$513	-6.6%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Symmetry Medical	SMA	$7.99	$286	8.89
2	ArthroCare	ARTC	$21.88	$587	12.94
3	Johnson & Johnson	JNJ	$62.89	173,520	13.61
4	Kensey Nash	KNSY	$23.86	$265	13.82
5	***Average***			***$10,957***	***14.35***

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	I Flow Corp	IFLO	$12.64	$309	292.33
2	NuVasive	NUVA	$34.79	$1,330	176.96
3	RTI Biologics Inc	RTIX	$4.09	$223	50.10
4	Synthes	SYST.VX	$132.81	$15,761	41.30
5	CONMED	CNMD	$21.24	$618	22.04

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	ArthroCare	ARTC	$21.88	$587	0.52
2	CryoLife	CRY	$5.92	$169	0.82
3	Orthofix	OFIX	$29.92	$513	0.84
4	Symmetry Medical	SMA	$7.99	$286	1.06
5	Exactech	EXAC	$15.54	$199	1.10

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$34.79	$1,330	3.31
2	RTI Biologics Inc	RTIX	$4.09	$223	2.14
3	Johnson & Johnson	JNJ	$62.89	173,520	1.85
4	Zimmer Holdings	ZMH	$58.52	$12,460	1.81
5	***Average***			***$10,957***	***1.69***

Lowest Price to Sales Ratio (TTM)

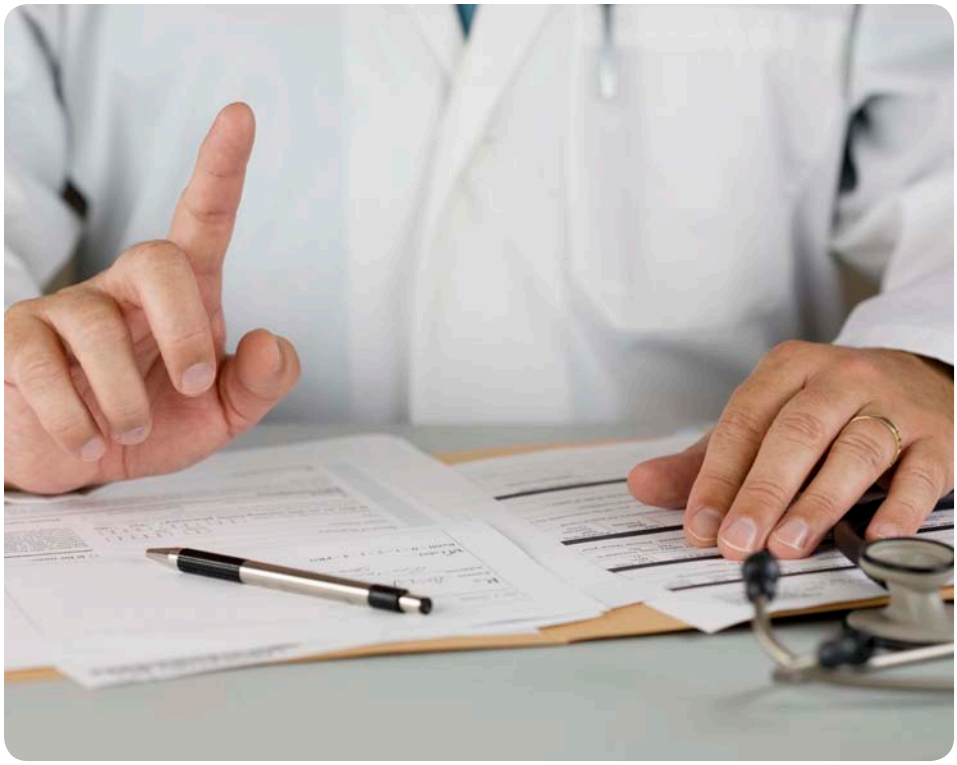
	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$2.66	$48	0.51
2	Symmetry Medical	SMA	$7.99	$286	0.76
3	CONMED	CNMD	$21.24	$618	0.94
4	Orthofix	OFIX	$29.92	$513	1.00
5	Exactech	EXAC	$15.54	$199	1.25

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$6.39	$157	219.61
2	Mako Surgical	MAKO	$8.91	$296	11.38
3	Synthes	SYST.VX	$132.81	$15,761	9.63
4	NuVasive	NUVA	$34.79	$1,330	3.93
5	Kensey Nash	KNSY	$23.86	$265	3.28

NuVasive's XLIF Reviewed

By Walter Eisner



Cigna is about to review its previous coverage policy for XLIF (extreme lateral interbody fusion) on December 15. It labeled the procedure as "investigational or unproven" in 2007.

That item was included on Thursday, November 23, in a research report written by Potomac Research Group Senior Analyst David Blaszczak. The report was entitled, "Coverage for NuVasive's XLIF Appears to be Going in the Wrong Direction."

His report said recent coverage policies from Ætna, United Healthcare and Cigna were "possibly highlighting a negative trend" for NuVasive's XLIF procedure.

XLIF Unproven/Investigational?

The Potomac report also noted that United Healthcare had deemed the XLIF procedure as an "unproven technology" this past July and that just last month, Ætna revised their clinical policy to state that the procedure is "investigational."

NuVasive's XLIF

The markets reacted immediately and by the time NuVasive's stock stopped dropping two trading days later, the company's market cap had dropped by over $300 million dollars.

But even more important then the company's stock price, were the questions of whether or not there would be another move to create a new CPT code for an extreme lateral

interbody fusion procedure and whether or not providers had been billing properly for the procedure.

Company Conference Call

NuVasive announced on November 25 that it will host a conference call on this issue on Monday, November 30, at 5:30 p.m. ET. The conference call will include comments from management followed by a short question and answer session. The dial-in number is 877-407-4018. A live webcast of the conference call will be available online from the investor relations page of the company's corporate website at www.nuvasive.com.

Insurers and CMS: Medically Necessary

NuVasive's lateral approach to the interbody space, XLIF, is a registered trade name and insurance companies have no nomenclature that identifies a lateral approach for payment. There is no CPT code for something called XLIF. Based on recommendations from the AMA (American Medical Association) and NASS (North American Spine Society), the lateral approach is identified as an ALIF (anterior lumbar interbody fusion) under physician CPT code 22558. Where exactly a patient's front is distinguished from their side has never been determined by code.

Blaszczak wrote that the majority of carriers are covering XLIF or consider it medically necessary. "There is no policy in Medicare at this time so all XLIF procedures are currently covered. However, recent changes among Ætna, United, and Cigna may draw interest to local Medicare medical directors."

"CMS [Centers for Medicare and Medicaid Services] has shown interest in possibly making coverage changes to spinal fusion in the past," stated Blaszczak, a former staffer at the agency. "There was an advisory panel meeting at CMS several years ago on spinal fusion but CMS has backed off developing a national coverage decision (NCD). There are no coverage policies at CMS on the local level that address XLIF; therefore all XLIF procedures will be covered in Medicare.

Based on questions regarding possible coverage decisions last year, CMS seems to be focused more on bone morphogenetic proteins (BMP) and kyphoplasty/vertebroplasty.

Wall Street Analysts: No Near-Term Impact

In response to the Potomac report, Wells Fargo analyst Mike Matson wrote on November 20 that the three insurance carriers cite a lack of published studies comparing the safety, efficacy and learning curve of XLIF to standard approaches.

"Our checks indicate that it's unlikely that an insurer would be able to tell the difference between a true ALIF and an XLIF based on a hospital claim submission. However, insurers periodically audit hospital claims and might request a refund if hospital records revealed that ALIF procedures were actually XLIFs."

At that point Matson believes hospitals might attempt to bill the patient. However, he thinks hospitals would be unlikely to recover the full amount. Such an ordeal could cause a hospital to stop doing XLIFs but would likely take some time to play out. As a result, Matson doesn't expect a near-term impact on NuVasive.

Matson believes that if this proves to be a significant issue, NuVasive could work with the insurers to highlight existing data on XLIF and attempt to convince them to cover the procedure. If necessary, he says NuVasive could fund additional studies to support the XLIF (e.g., a head-to-head trial of XLIF vs. ALIF).

Joanne Wuensch, an analyst with BMO Capital wrote on November 23 that this was not a coding but a reimbursement issue since NASS had already backed the codes for reimbursement filing. Wuensch wrote that work-arounds can be dangerous and payers may eventually take legal action. She cautioned that some physicians may back away from XLIF procedures until there is clarity on the coverage side.

Good Outcomes

But that being said she noted this situation "is diametrically opposite the locus of the problem: because of the patient outcomes, physicians are increasing the use of the procedures and more companies are trying to increase their presence by providing tools for lateral access."

NuVasive's largest competitors have announced their own lateral access instrumentation plans and it is unlikely they would have made such investments if they believed reimbursement would be a problem.

XLIF Déjà Vu

This is not the first time this issue has been raised.

This past March, Raj Denhoy, then an analyst with Thomas Weisel Partners, wrote that questions about reimbursement for the XLIF procedure had lingered.

Denhoy noted that surgeons were reimbursed, on average, about $1,500 per procedure under existing ALIF codes. There are additional payment for implanting devices and additional levels performed. If a vascular surgeon is used, as is often the case in ALIF but rare in XLIF, the payment increases by 25%, but it must be split with each surgeon typically receiving half. "The guidelines are very explicit in how surgeons should bill for the procedures and if clinicians are coding aggressively, they are doing so at their own risk," warned Denhoy.

XLIF takes about 30% to 50% less time than ALIF, according to Denhoy, and it is much more profitable for surgeons to perform XLIF. "Where this could be a concern," continued Denhoy, "is if there was a move to change the codes so that XLIF received its own payment level that better reflected the less time it takes to do the procedure."

NuVasive has not advocated for a change in the codes.

There has been lots of speculation about where this will all end up for NuVasive. The Cigna meeting on December 15 may render all such speculation moot.

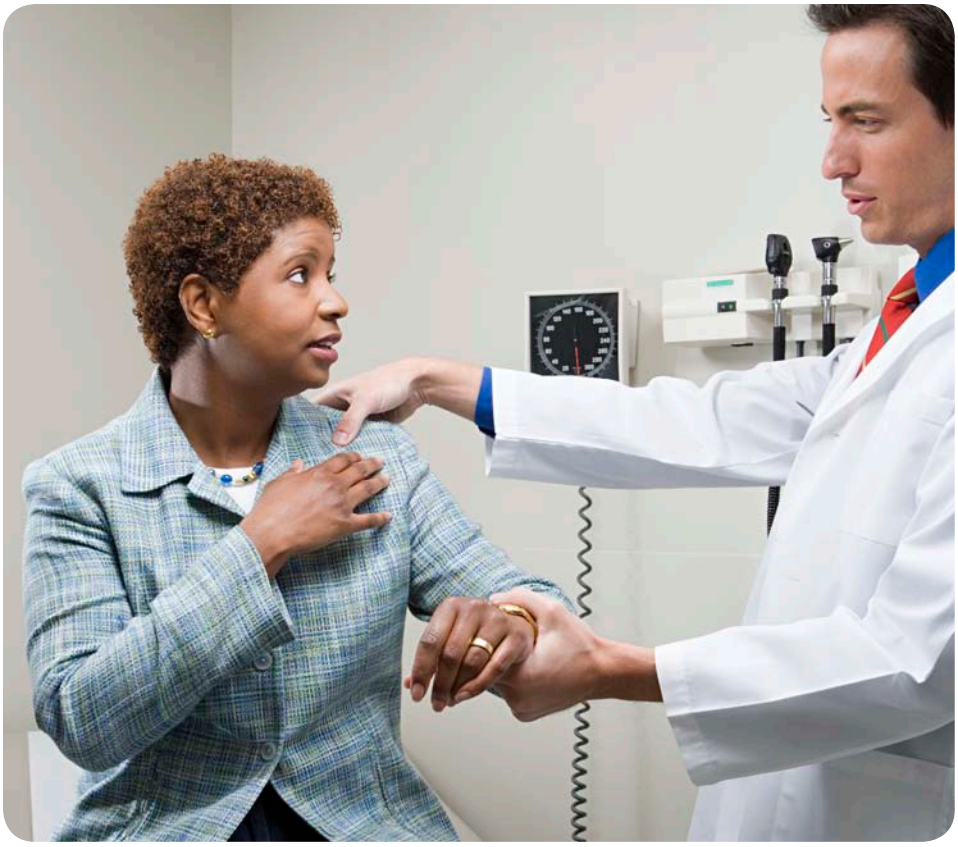
XLIF has lots of data showing that the procedure results in less blood loss to patients, less operating time, fewer complications, and fewer refusions. If a new CPT code were to be created, insurers could potentially lower reimbursements. This would be a perversion of the "value" philosophy recently articulate by NASS' new president, Ray Baker, M.D., in *OTW*.

As we have noted here before, insurance companies are in the risk management, not healthcare business and this may represent another example of insurers transferring risk to the hospital, patient and manufacturer.

Everyone should take a deep breath until December 15.

In Vogue…the Shoulder

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



Despite having to wait while spine and other specialties took the spotlight, the shoulder doesn't have a chip on its, well, shoulder. It is quite mature… and maturing.

An Exciting Time for Shoulder Specialists

Dr. Ken Yamaguchi, the Sam and Marilyn Fox Distinguished Professor of Orthopaedic Surgery at Washington University School of Medicine in St. Louis, Missouri, notes, "Shoulder fellowships are one of the fastest growing fellowships around. It's actually shocking how competitive it is to get a spot these days. But we need only look at the facts, one of which is that shoulder ranks just behind lower back pain as the top reason why patients seek out a doctor for musculoskeletal care. As shoulder problems are generally degenerative, and individuals over 70 are the fastest growing segment of the population, the volume should increase even further in the future. Additionally, patients are more sophisticated consumers now and tend to seek out shoulder specialists."

The President of the American Shoulder and Elbow Surgeons, Dr. Evan Flatow, is also encouraged by the momentum in shoulder training. Dr. Flatow, the Chair of Orthopaedics at The Mount Sinai Medical Center in Manhattan, states, "Training is much more structured than in the past, with an established committee of fellowship directors who organize the application and match procedure to ensure that it is friendly to applicants. There has been significant attention paid to the issue of scheduling, i.e., programs are working together to ensure that interviews are not all held on the same day. That way, applicants can see all of the programs they are interested in before the offers are made."

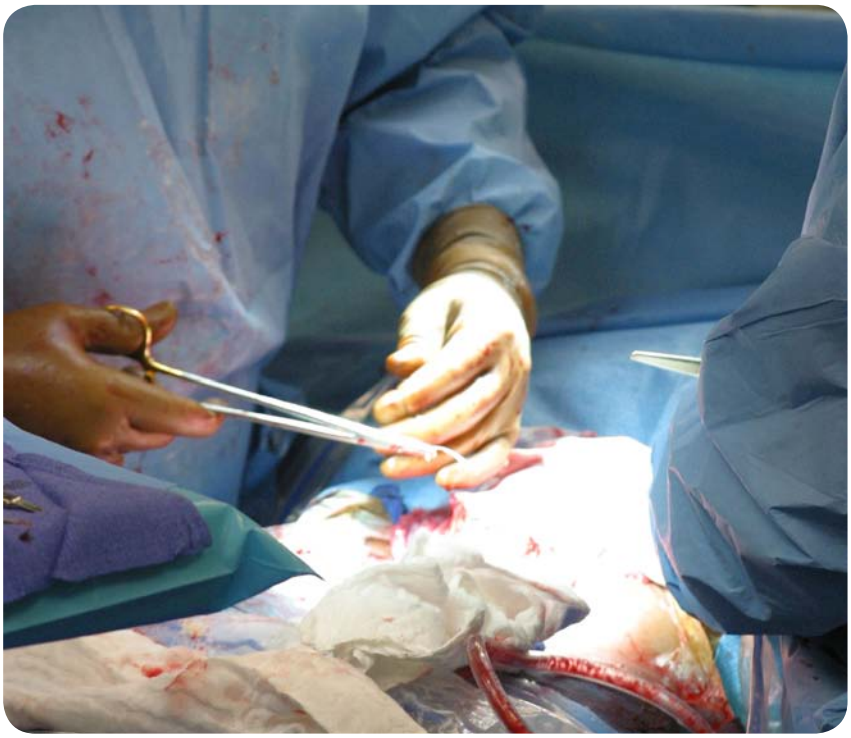
Dr. Louis Bigliani, the Frank E. Stinchfield Professor and Chairman of Orthopedic Surgery at Columbia University and past President of the American Orthopaedic Association, has helped to take the shoulder global. "We have seen shoulder surgery evolve into a worldwide subspecialty in the

last few years, in particular due to the efforts of the International Congress of Shoulder and Elbow Surgery (ICSES). In 2007 we had a superb meeting in Brazil, with over 1,000 shoulder and elbow surgeons in attendance; next year we will travel to Edinburgh, Scotland, for our 11th meeting. These events, along with the new shoulder training program in Asia, have helped to facilitate the transfer of scientific information and knowledge to fellow surgeons around the world."

Shoulder Innovations and Research

Whether in the ORs of the American West or those at the tip of South America, today's shoulder surgeons are learning a profusion of new techniques. Dr. Yamaguchi: "There have been significant innovations in all four areas of shoulder surgery, namely, trauma, reconstruction, rotator cuff surgery and joint replacement. Take percutaneous pinning of fractures, for example. While these injuries used to involve large, debilitating surgeries, the broken bone can now be reconstructed through a tiny incision. And because the shoulder is built for motion, it is important to limit the surgical trauma and minimize scar tissue. The only controversial issue with regard to percutaneous pinning is how bad of a fracture you can use it with. Some people say that a severely compromised bone may need more than several little pins. The fact is that percutaneous pinning is not easy, and we need better training, along with simpler instrumentation."

Dr. Flatow adds, "Fifteen years ago most fractures were treated with joint replacement if the proximal humerus was shattered. Now, many of the shoulders that used to need replacement or plates and screws can be managed with percutaneous MI fixation in which we manipulate the fragments with pins and joysticks. There is a significant learning curve, however, which results in resistance by some orthopedists. And unlike elective surgery, fractures come in the door marked 'trauma,' which makes everything more difficult because the cases appear at random. But if learned properly, it is a very successful operation."

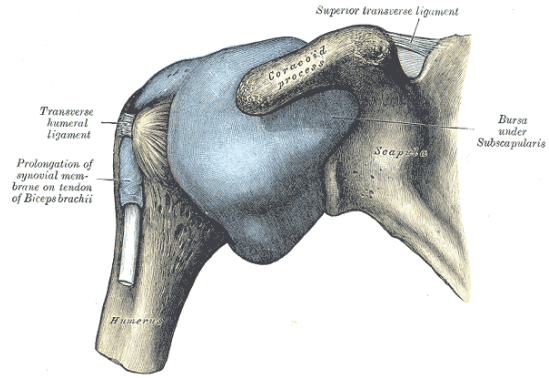


Dr. Flatow continues, "Two years ago my partner, Dr. Brad Parsons, along with Dr. Gerry Williams of the Rothman Institute, and Dr. Leesa Galatz, Dr Yamaguchi's partner, presented the results of a multicenter study at AAOS. We pooled our cases and results with percutaneous fixation and found excellent results and

minimal morbidity. In the days of plates and screws, if you had to operate again, there was a concern about avascular necrosis. We found that the initial surgery was less invasive and that if there were complications they were not serious. Now we are looking at the longer term results and are anticipating a low complication rate, good muscle strength, and healthy range of motion."

As for the part of the shoulder that is "in charge of" stability and strength—the rotator cuff—it has many new options. Dr. Yamaguchi explains, "Rotator cuff tears are one of the most common ailments in all of medicine. Our data show that half of people over 70 experience rotator cuff tears. One treatment for this condition that has exploded is arthroplasty; surgeons can now do a reverse ball and socket prosthesis in which they cut off the humeral head and put in a prosthetic socket. This procedure has allowed us to take care of extreme rotator cuff problems, and has been an absolute game changer.

Dr. Yamaguchi elaborates, "It was developed years ago by Dr. Grammont in France and has been used in Europe for 15 years, and was approved in the U.S. about five years ago. I have had the privilege of being on a design team at Zimmer and working through the development process for one of their rotator cuff products."



Gray's Anatomy Capsule of shoulder-joint (distended). Anterior aspect/commons.wikimedia

Dr. Bigliani adds, "In severe osteoarthritis of the shoulder, posterior glenoid (socket) bone loss poses a challenge to properly placing a glenoid prosthesis. We have been using a computer simulation to evaluate the extent of bone loss and deformity. We are also trying to determine how to evaluate the proper positioning and placement of the glenoid prosthesis such that stress is reduced across the implant. We obtain data from CT scans of the shoulder, put it into a computer and do virtual surgery. By putting the glenoid in different places and looking at the best position, we can determine deformity patterns and be better prepared for the OR."

Dr. Flatow: "Many of the courses that my colleagues and I teach focus on how to select the right patient. We typically recommend the surgery only for older patients because if you put the implant in a younger person, it might wear out, break or loosen. While there may be appropriate times to perform the surgery on a younger patient—perhaps someone who is very active and seeking a higher level of functioning—that person should thoroughly understand the risks involved."

And where would any joint be without arthroscopy? Dr. Yamaguchi says, "As recently as five years ago there were many surgeons doing large, open surgeries for rotator cuff repair. As arthroscopy has become more popular, however, most shoulder surgeons are comfortable with the approach. And now that the instrumentation has been refined, it is easier for those surgeons who have less experience with the procedure. The major issue now is that there are times that the patient doesn't heal because of biological issues such as age. In the not so distant future, however, we can probably provide medications or growth factors to repair the site and enhance the ability of the rotator cuff to repair."

Elaborating on the repair issue, Dr. Flatow states, "There is some controversy surrounding the findings that many of these repairs don't heal. We are one of the labs doing research into predicting the factors that control healing and are seeking ways to improve both the technical steps and the possibilities of newer biologic treatments. One of the projects in our lab, for example, involves turning stem

cells into tendon cells. This is early scientific work by our colleague, Dr. Herb Sun, but we are trying to figure out many ways to grow and develop natural tendons biologically."

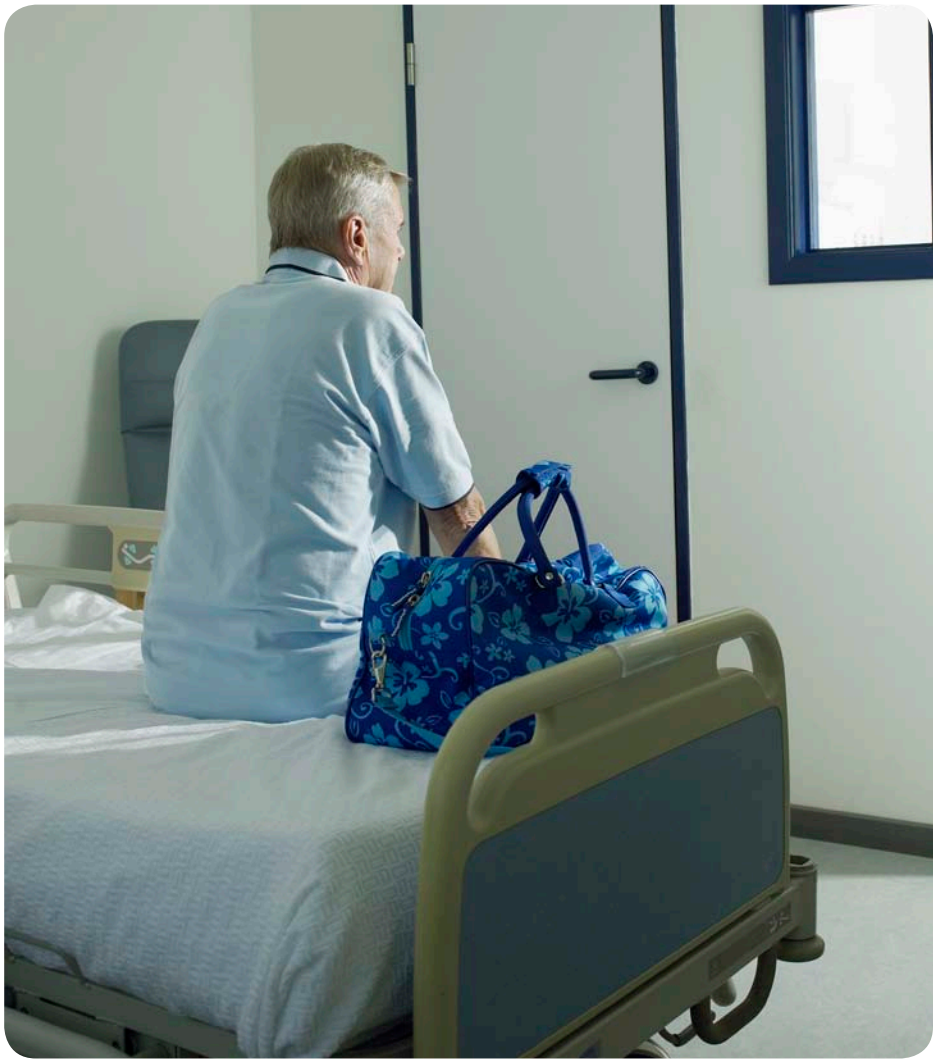
Managing Patient Pain and Anxiety

Whether someone has a host of painful bone spurs, loose bone wandering around the shoulder, or an extreme loss of cartilage, there is help in the form of shoulder replacement. But, whether young or old, patients may be wary of such a serious operation. Dr. Bigliani: "I routinely hear comments from patients along the lines of, 'Hip and knee replacements are routine, but the shoulder is still really hard to do.' I tell them that as long as someone is properly trained in shoulder replacement, the results are consistently good. It is true that the shoulder is a more complicated joint, but much of the success of the procedure depends on postoperative rehabilitation and management."

Regarding the efficiency of many shoulder procedures, the patient can be in—and out—of pain as soon as she can get in and out of the doctor's office. According to Dr. Bigliani, "More and more orthopedic surgeons are converting to doing minimally invasive procedures on an outpatient basis. In my department we are probably doing more outpatient than inpatient surgeries at this point. This includes arthroscopy, rotator cuff repair, calcium removal, elbow arthroscopy, as well as some open procedures."

In the pain relief arena, Dr. Bigliani and his team are going (safely) out on a limb. "One of the exciting things is that orthopedists are increasingly concentrating on pain relief. Here at Columbia we have an excellent orthopedic anesthesiologist—Robin Brown—who has championed interscalene blocks for anesthesia. This procedure, meant solely for shoulder replacement, involves leaving the catheter in the patient's neck for 24 to 48 hours while pain medication is delivered. This way they avoid general anesthesia and have good pain relief and some movement in the hands. Patients typically leave the hospital faster and have a more pleasurable experience while there. These blocks can be tough to learn, however, so they are not very popular."

Picking up on the increasingly popular evidence based medicine thread, Dr. Yamaguchi concludes, "The bottom line is that we need more evidence about what are really the best innovations that will translate to better patient outcomes."



ArthroCare Has Sales! Who Knew?

By Robin Young

Technically, for 576 days, ArthroCare was a company with no current reported sales, expenses or earnings. ArthroCare's silence ended November 18, 2009. The company released its financial statements for the year ended December 30, 2008. Two days later management published the results for the first half of 2009. Six days after that they filed the nine-month numbers for 2009.

South Street, Philadelphia

Technically, companies that sell their stock to the public are supposed to periodically publish their financial results. Technically. So…what happens if they don't? In ArthroCare's case, NASDAQ delisted the stock. ArthroCare's shareholders could still sell (or buy) the shares on a tertiary market known as the "Pink Sheets."

The "Pink Sheets" are like certain sections of University Avenue in St. Paul or South Street in Philadelphia. Rents are cheap. Turnover is high. The clientele keep things interesting. Pink Sheets are also like the $2 window at Pocono Downs but without the benefit of a handicapper's tip sheet. Investors won't find too many $300 million firms among the penny stocks on "Pink Sheet" Avenue.

Stock Performance

Poor ArthroCare. So, how did the company's stock perform without reported sales or earnings or a mainstream trading venue like NASDAQ? Improbably, the share prices rose 354% or $420 million in total market value.

As the following table illustrates, trading on the Pink Sheets with no reported sales and earnings was, in fact, pretty good for ArthroCare's shareholders.

In the 12 months that led up to NASDAQ's delisting, ArthroCare's stock had lost nearly 90% of its value and on the day of delisting the stock had fallen to $4.42 per share. One month after delisting, the stock was up 15.4%. Six months later it was up another 157% to $11.36. This past November 16th, the 300th day since delisting (and still with no reported

ArthroCare Stock Price Performance -- % Change Before and After Delisting								
NASDAQ -- Period Before Delisting				Delisting Jan. 16, 2009	Pink Sheets -- Period After Delisting			
One Year	6 Months	90 Days	30 Days		30 Days	90 Days	180 Days	300 Days
$45.09	(10.8%)	(45.5%)	(67.3%)	$4.42	+15.4%	+104.8%	+157.0%	+353.6%

sales and earnings), ArthroCare's stock was trading 353.6% above its price at delisting—although at $20.05 it was still half the price recorded one year before delisting.

Not shabby—for a delisted stock, with an interim CEO and no current reported sales and earnings.

Enjoyment of Anticipation

But that became history as of November 18th when ArthroCare reported its financial performance for these past many, many, many weeks. How has the stock performed now that there is financial information? It fell about a half a percent (0.55% to be exact).

Perhaps no news was good news.

Perhaps anticipation is 90% of enjoyment.

Perhaps, in the era of transparency—this time of full disclosure and "sunshine laws"—these days when we are told to illuminate every dark corner of human activity, there is a place for mystery. Perhaps, what we imagine and hope for is more compelling than what we have before us. Perhaps, we are all romantics.

I hope so.

Still, eventually CEO Fitzgerald had to open the kimono.

2008 Sales and Earnings

In his last public comment on likely 2008 sales and earnings performance, former CEO Mike Baker said he expected 2008 sales would reach $380 million, up 20% from 2007 levels. Earnings for 2008, he said, would come in somewhere around $1.95 – $2.00 per share.

The actual 2008 sales numbers, as released a couple weeks ago, were $314.2 million, up 12.3% from a restated $279.7 million. Earnings per share for 2008 were actually a loss of $1.31 per share and the EPS for 2007 was reduced to just $0.02 per share from a previously announced $1.50 fully diluted EPS.

2009 Accelerating Sales, Vanished Earnings

In the first nine months of this year, ArthroCare put up pretty decent sales numbers. Overall sales actually rose 0.9% during that period. More good news was that sales rose 7.7% during the July – September time period, which indicates that the rate of sales growth was accelerating.

Even better news is that ArthroCare's Sports Medicine and ENT (ear, nose and throat) product sales rose at nearly double-digit rates and accounted for essentially all the sales growth for the company this year (so far). At this rate, most analysts are forecasting that ArthroCare could end the year with about $320 million in reported sales.

ArthroCare Summarized Statement of Operations for Years Ended December 31,

$ in millions	2008	2007 As Reported	2007 As Restated	2006 As Reported	2006 As Restated	2005 As Reported	2005 As Restated
Statements of Operations							
Product Sales	$299,896	$307,596	$268,495	$253,376	$233,585	$206,533	$198,741
Royalties, fees and other	14,285	11,646	11,221	9,625	10,126	7,801	7,583
Total Sales	**$314,181**	**$319,181**	**$279,716**	**$263,001**	**$243,711**	**$214,334**	**$206,324**
Gross Profit	219,221	234,518	193,335	186,163	172,962	150,128	145,042
Operating Expenses	256,771	181,343	198,022	143,693	139,280	117,069	117,199
Net Income (Loss)	($34,747)	$43,180	$491	$31,675	$27,673	$23,530	$19,084
Basic EPS	$(1.31)	$1.57	$0.02	$1.21	$1.06	$0.97	$0.78
Fully Diluted EPS	$(1.31)	$1.50	$0.02	$1.14	$0.99	$0.89	$0.72

Not bad at all.

Earnings, however, are gone. For the first nine months of the year, the company has lost almost $42 million compared to a loss (restated) of $5.8 million for the same period a year earlier. On an operating basis the nine-month loss was $13.6 million. The cost of accrued dividends and other charges for the Series A 3% Convertible Preferred Stock amounted to $27.3 million and that brought the total loss to more than $40 million.

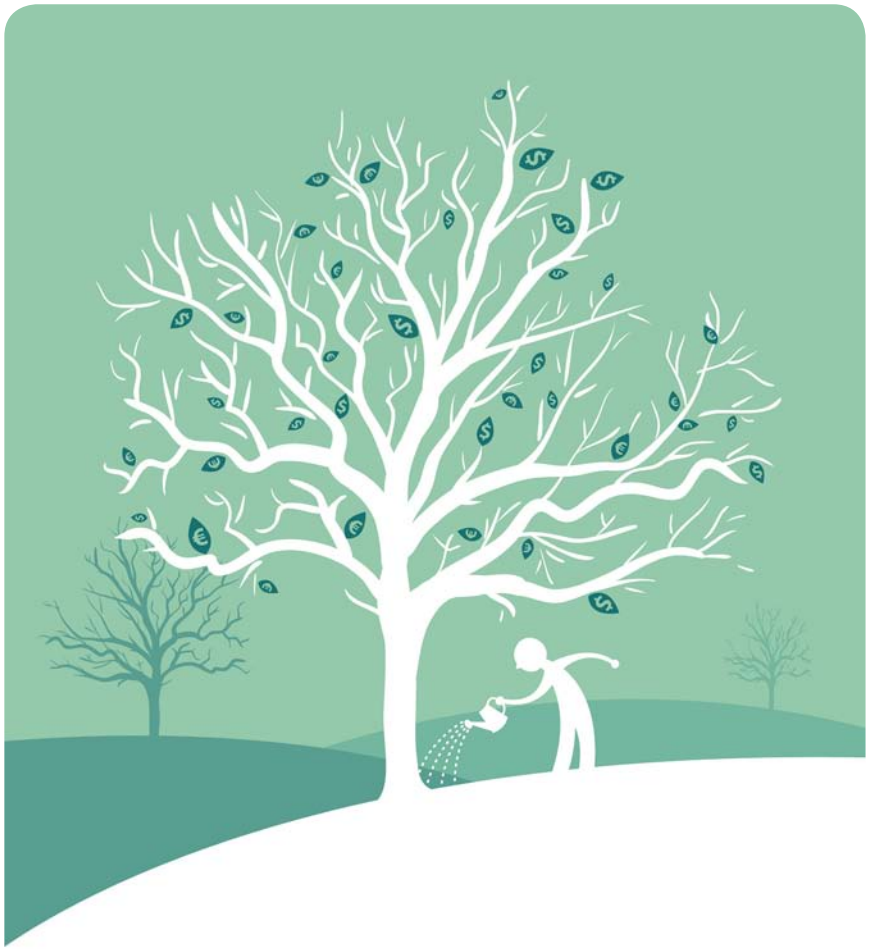
Keys to ArthroCare's Future

There are three keys to ArthroCare's future:

1. **Coblation technology** – this has always been the basis of ArthroCare's business and it remains the company's future. Coblation is a technology that precisely dissolves targeted tissue and limits damage to surrounding healthy tissue. As a platform technology, Coblation significantly improves many existing surgical procedures and sets the stage for many innovative MIS procedures. With Coblation, ArthroCare can sell devices for many markets and surgical indications.

2. **Litigation** – At the front of a long line of litigation is the SEC. The Fort Worth Regional Office of the SEC's Division of Enforcement is conducting a formal investigation into ArthroCare's past accounting practices. Assuming that's eventually settled, management will then confront the U.S. Department of Justice (DOJ). The DOJ is investigating ArthroCare's spine unit's past sales, accounting, and billing procedures, particularly as it relates to its convoluted relationship with DiscoCare. Then there's the grand jury investigation launched by the U.S. Attorney for the Southern District of Florida. Behind the Southern District of Florida is the U.S. Attorney for the Western District of North Carolina who is conducting ***a separate grand jury investigation***. And last but by no means least there are the several private class action lawsuits which have been filed in both federal and state courts. As bad as that may look, in past cases like this (specifically Tyco) once the Feds are settled, the rest seem to fall like dominoes. But, of course, all that remains to be seen.

3. **Merger or Acquisition** – Given all the bad news, one has to ask the question; why is ArthroCare's stock as high as it is? The answer roiling around the blogosphere is acquisition. Ironically enough, in March 2008, as the shorts were pounding ArthroCare's stock with rumors of accounting irregularities, the company hired Goldman Sachs to evaluate its strategic alternatives including sale of the company, recapitalization or whatever. While events ran ahead of Goldman's efforts, the time may well be approaching when some of the prospective strategic or private equity buyers that Goldman surfaced would be interested in revisiting a cleaned up and presumably, SEC/DOJ scrubbed ArthroCare.



The now permanent CEO David Fitzgerald, 75-years-old and veteran of a long and distinguished business career, has been from all accounts an outstanding leader during these extraordinarily difficult months. While we have certainly teased the company over spending 576 days to get the numbers right, given the potential problems that could have resulted from NOT getting them right, the time spent was well worth it. Heck, given how well the stock performed shareholders might be forgiven if they'd counseled more delay.

A Cautionary and Hopeful Tale

Still, the story of ArthroCare is both a cautionary and a hopeful tale. With these corrected and filed financial results, ArthroCare's team and new leadership have demonstrated that both the company and its stakeholders are on the rebound. All of ArthroCare's stakeholders should give Fitz and his team the MVP award for reconstructing a strong future to look forward to.

company news

Symmetry: Build Up in Malaysia

Nothing like the paradise of a Malaysian beach to stir the imagination...and perhaps drive innovation. According to an article in *The Edge Malaysia* ("Symmetry Medical set to invest RM50 million in Penang," Regina William, November 10, 2009), over the next few years Symmetry Medical will triple its employees and double its Penang revenue to $50.In the article,

Penang Hill Funicular Railway/Wikimedia Commons

Brian Moore, the company's President, CEO, and Director, stated, "Symmetry Penang will be the fastest growing facility for Symmetry worldwide. When we started, we only had 35 personnel and we doubled that to 70 recently. We are committed to significantly increasing the headcount here to over 200. We are looking at hiring engineers with medical experience and also personnel to serve this facility's international sales centre."

Regarding the engineers, Chris Huntington, SVP Corporate Development/Director of Asian Operations, told *OTW*, "Engineers at the Malaysian facility are involved in a comprehensive range of Symmetry services, including the manufacturing of cases and instruments, plus the finishing of implants for our Asian customers."

In the article, Moore also was quoted as saying, "Development plans for Symmetry Penang's operations are significant and include and increase in medical-product design and development as well as instrument and implant manufacturing exclusively for Asian markets."

When asked what about Penang makes it attractive, Huntington told *OTW*, "It is strategically positioned to service our Asian customers."

As for using the location as an international sales center, Huntington commented to *OTW*, "The Malaysian operation has progressed very well in the last 12 months and we will accelerate that development in 2010 to increase our marketing presence in Asia."

—EH (November 23, 2009)

This Kryptonite Heals

The FDA has granted clearance to Doctors Research Group to market its bone cement for cranioplasty applications.

The cement named Kryptonite, is, according to the company's announcement on November 16, the first non-toxic, low exotherm cement and bone void filler that offers strong adhesive properties to organic and inorganic materials.

The company said surgeons have been using products containing polymethyl methacrylate (PMMA), brittle, non-adhesive thermoplastic filler that cures in the body at high temperatures, capable of causing necrosis to surrounding tissue. The PMMA products have also presented environmental hazards to medical personal due to the toxic fumes released during mixing and preparation. The company believes that Kryptonite eliminates these hazards.

The product has been for sale for several years in Europe, and more recently in Canada, Latin America and Australia. The material is a self-setting bone cement formed by combining three naturally occurring components to create an adhesive, low exotherm, non-toxic bone repair solution that cures with porous properties and is engineered to mimic natural bone. Another benefit touted by the company is that the material polymerizes in stages, offering

company news

surgeons the option to inject it as a liquid, to secure bone-to-bone adhesion, or to shape it as a moldable putty, to create form-fitting plates which eliminate the need for painful bone grafts that prolong patient recovery times.

Doctors Research Group intends to begin marketing the bone cement immediately. In fact, we saw their prominent display area on the exhibition floor of the recently completed annual NASS meeting in San Francisco.

—WE (November 24, 2009)

GE Healthcare Acquires ONI Medical Assets

ONI Medical Systems sold its line of low-cost MRI scanners to GE Healthcare in October.

The systems include the MSK Extreme 1T and MSK Extreme 1.5T. Both are fully open, dedicated extremity MR modalities that are used in orthopedic and sports medicine offices.

Along with the imaging platforms, GE will also acquire the R&D team at ONI Medical, led by Dr. Peter Roemer, who won a Gold Medal for his research in magnetic resonance this year from the International Society for Magnetic Resonance in Medicine.

Financial terms were not disclosed. ONI Medical has raised more than $31 million in VC funding since 2002 from firms like Ziegler Meditech Equity Partners, Galen Partners and Ivy Capital Partners.

GE Healthcare stated the purchase was in line with the company's "healthymagination initiative" and expands their MRI capabilities. ONI's scanners are specifically designed for extremities so that only the joint being imaged is inside of the scanner. ONI's products also have a small footprint for sitting in limited spaces, allowing clinicians' the same diagnostic capabilities for extremity imaging at a lower cost when compared to a whole body MRI unit.

MSK Extreme 1.0T/ONI Medical Systems

"As one of ONI's original founders and a co-inventor of the MSK Extreme scanners, I am very excited to join the GE team. Our product line is highly synergistic with GE's whole-body MR business. By joining GE Healthcare, we can combine our comprehensive product offerings and expand our global reach, "said Dr. Roemer.

For now, ONI products will continue to be sold under the ONI brand, though in the future they will likely come under the GE Healthcare banner.

—WE (November 25, 2009)

ZirMed and HST*pathways*: Efficiency Aces

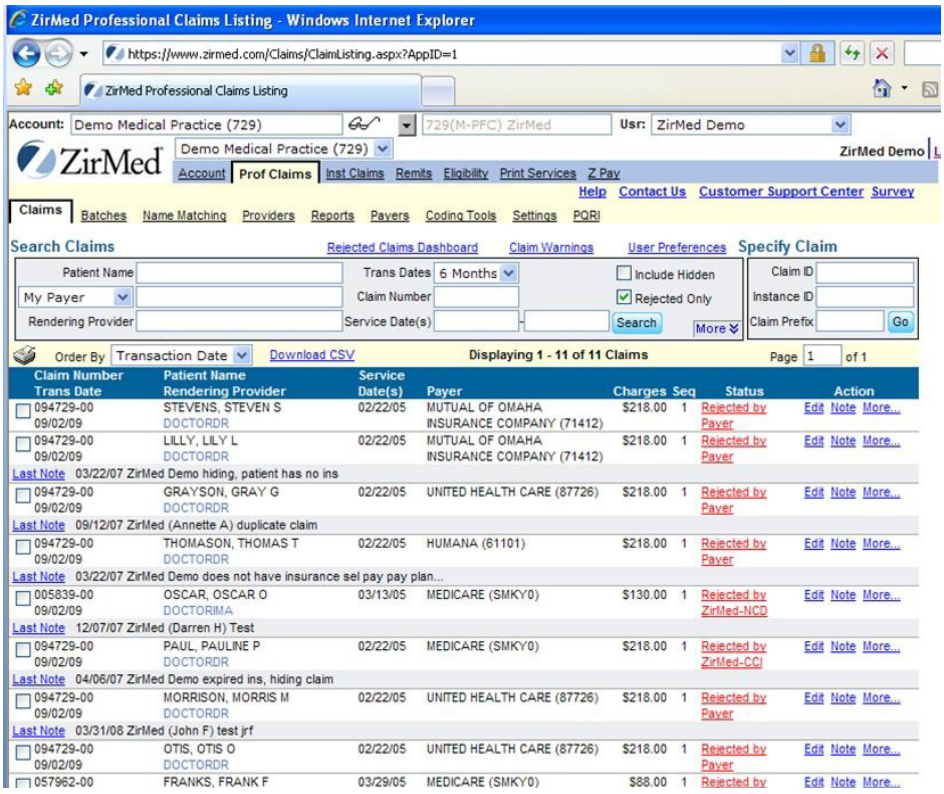
Pacific Surgery Center, a high-volume practice near Seattle with 36 surgeons, might write a love letter to a couple of its vendors. Just over a year ago, these sages began using HST*pathways*, a dedicated Ambulatory Surgery Center (ASC) clinical and financial management software developed by HST, LLC. Concurrently, the clinic also adopted ZirMed's web-based revenue cycle management services.

company news

"We've been fortunate to recruit a number of new physicians to our facility this year," said Fran Gregory, Business Office Manager for Pacific Surgery Center, in the news release. "We've learned that surgeons like working at a place that runs like a well-oiled machine."

"We really value vendors who do what they say they're going to do, and who take responsibility for their products' performance. HST and ZirMed have demonstrated they're willing to do what it takes to help keep our center running at peak efficiency," Gregory added.

According to Pacific Surgery Center, HST*pathways* can smooth out wrinkles in many areas, including scheduling, registration, workflow management, claims, accounts receivable control, statement processing, collections, materials management, clinical logs, case costing, and chart management, among others. The clinic uses ZirMed's professional and institutional claims management as well as its eligibility verification, electronic remittance advice (ERA) and print services. According to Gregory, one of ZirMed's best advantages is its reporting capabilities.



Disclaimer: The names shown are not actual patients and no personal information is being divulged.

"We had looked at other clearinghouse service providers to pair with HST, but HST strongly recommended ZirMed to us. In fact it was almost 'take it or leave it', that's how much HST believes in ZirMed," said Jamie Hilman, Pacific Surgery Center Billing Department, in the news release.

"Every day I do an invoice review, looking for rejections and other red flags. Our billing clerks also place notes in the electronic file so I know where things stand with a particular claim," she stated. "ZirMed tells us automatically what we need to correct in order to expedite payment."

Pacific Surgery Center is giving accolades to ZirMed and HST, who, they say, have drastically improved receivables performance. "Our A/R days run between 22 and 24 on average, where we used to be near 60 days with our previous system," noted Gregory in the news release. "What's more, all eligibility verifications are usually completed electronically within an hour—rarely do we have to call a payer."

"HST*pathways* gives us case costing, which lets us map every consumable item in our clinic to individual patient procedures. Now we can view profitability of our surgical inventories by CPT code. It's a great way to determine if we're spending more on supplies than we need to, or if anything is going to waste," Hilman added.

"Despite the 15% increase in volume this past year, our billing personnel

company news

have been able to keep up without a problem," Gregory reported in the news release. "No bottlenecks anywhere. That's how much smoother things have gone with HST and ZirMed."

Tom Hui, President and CEO of HST*pathways*, told *OTW*, "Most surgery centers recognize that verification of benefits (VOB) is a time consuming and detail-oriented task. If VOB is not performed, it could cause significant financial losses. The combination of HST*pathways* and ZirMed has automated this process. More importantly, HST*pathways* has incorporated an active notification of deficiencies into its work flow automation to assist the staff promptly."

Regarding details on the program's reporting capabilities, Hui commented to *OTW*, "HST*pathways*' payer configuration module facilitates the reliable production of electronic claim files which are sent to ZirMed. Both systems incorporate tracking, monitoring and reporting of claim status to help the surgery center staff to properly 'do' revenue cycle management. HST*pathways* enables the user to view what is not processed or sent and what batches have been sent to ZirMed as part of the normal work flow of the business office."

—EH (November 25, 2009)

legal & regulatory

Ghostwriting on Grassley's Radar

Senator Chuck Grassley wants to know how articles ghostwritten for researchers at ten of American's top medical schools are any different from their students buying their papers from "paper mills"? On November 17 he asked the institutions for their written policies on the subjects.

The Senator says the practice of ghostwriting involves payments from companies to marketing or medical education companies to draft review articles, editorials, and research papers on the device companies' products. These articles are then presented to prominent doctors and scientists at academic institutions to sign on as authors.


"Man With Spirit of Second Wife"/William Hope/ NationalMedia Museum/commons.wikimedia

When the article is then published, the ghostwriters are not identified. Essentially, says the Senator, the companies are using the reputation of prestigious academic institution to promote the sale of the devices.

Ghostwriting as Plagiarism

The Senator notes that some experts consider ghostwriting a form of plagiarism. If students at the universities are caught buying papers from "paper mills," they are punished. Grassley wants to know what happens to researchers at the same universities if they publish studies without acknowledging that they were written by someone else.

legal & regulatory

Specifically, the Senator asks:

1. What is the university's position on medical ghostwriting and/or the use of third-party marketing and/or medical education companies in drafting medical review articles and research papers for faculty?

2. Does the university have any written policies regarding ghostwritten articles? If so, please provide a copy of those policies. Also, please identify the type(s) of information faculty members are required to document and/or report to the university regarding their publication activities.

3. If the university currently does not have written policies on ghostwritten articles, is the university in the process of developing a policy? If not, why not?

4. Since 2004, has the university received and/or investigated any allegations that a faculty member failed to disclose the involvement of a third party that may be paid by a device or drug company in the development and/or drafting of a manuscript? If so, how many allegations did the university receive and what was the outcome of each investigation? Were any actions taken against the faculty member?

5. Please explain the university's position on plagiarism and its policy on students submitting papers purchased from paper mills or plagiarized in other ways.

6. Since 2004, has the university received and/or investigated any allegations that a student failed to disclose the involvement of a third party in the development and/or drafting of a paper? If so, how many allegations did the university receive and what was the outcome of each investigation? Were any actions taken against the student?

The request went to medical schools at Harvard, Johns Hopkins, the University of Pennsylvania, Washington University in St. Louis, University of California-San Francisco, Duke, Stanford, the University of Washington, Yale, and Columbia.

The institutions have until December 8 to respond. Or there will be coal in their stockings. If history is a prologue to the future, we'll soon see some high profile researchers explaining themselves in the media.

—WE (November 23, 2009)

DOJ Recovers $1.6 Billion in 2009

The Department of Justice (DOJ) said it collected $1.6 billion from busts of Medicare and Medicaid fraud rings, off-label marketing, and illegal promotion of drugs and devices during fiscal 2009. It was the second highest annual collection ever.

The bulk of the recovered funds were the result of lawsuits filed by whistleblowers under the False Claims Acts' "qui tam" [on behalf of the king] provision.

Whistleblowers typically collect 15% to 20% of the payout of awarded penalties.

The largest recoveries in healthcare came from crackdowns on the pharmaceutical and medical device industries, which accounted for $866.7 million in settlements. The agency said the biggest hauls came from settlements with Aventis Pharmaceuticals, Bayer HealthCare, Eli Lilly & Company, Quest Diagnostics and its subsidiary, Nichols Institute Diagnostics.

This calendar year, the Department reached a settlement with Pfizer in which Pfizer agreed to pay $2.3 billion, the largest healthcare fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising

legal & regulatory

Twenty Dollar Bills/Wikimedia Commons

from illegal promotion of certain pharmaceutical products.

The DOJ said its civil division is especially aggressive in pursuing any allegations of "off-label" marketing, physician kickbacks and marketing the "spread," in which companies highlight the difference between the federal reimbursement rate and providers' lower cost. This is a practice that Boston Scientific, Medtronic, and five other companies were accused of in a lawsuit filed last July.

Reportedly, there are nearly 1,000 civil cases involving healthcare fraud pending with the DOJ, a more than 33% increase in just two past years.

In recent testimony before Congress, the DOJ said that since the False Claims Act was substantially amended in 1986 and through the 2008 fiscal year, the government had recovered over $23 billion on behalf of the various victim federal agencies. Of that amount, $14.3 billion was the result of fraud against federal health care programs—primarily the Medicare program.

—WE (November 25, 2009)

large joints

A Bit Closer to Tx for FOP

A rare, but serious condition is getting attention from a global cadre of scientists. With researchers from the University of Pennsylvania School of Medicine leading the way, those with fibrodysplasia ossificans progressiva (FOP), a genetic disorder in which the body's skeletal muscles and soft connective tissue turns to bone, now have more hope.

The study, appearing in the November issue of the *Journal of Clinical Investigation,* was headed up by Penn scientists Eileen Shore, Ph.D., Professor of Genetics and Orthopedics, and Mary Mullins, Ph.D., Professor of Cell and Developmental Biology. Along with colleagues in Japan and Germany, the researchers demonstrated that the mutation that causes FOP mistakenly sets off a series of biochemical events in soft tissues that kicks off the process of bone development. According to the team, the linchpin of the cellular signaling gone awry is a receptor for a bone morphogenetic protein (BMP). This study gives the first clear glimpse of how FOP might develop at a cellular level in the human body.

"If you think of BMP proteins as the hand that turns on a water faucet, the faucet, or receptor, should stay off if you never turn the handle," Dr. Shore said in the news release. "What our experiments show is that in FOP patients the faucet is leaky, even when it is not actively turned on. The mutation is mildly activating, and so it may take time or the right tissue environment to allow the signal to tip the balance to induce bone formation. This is a very important finding, because it can help explain why the disease progresses as it does." Detailing the conditions of this environment, Dr. Shore told *OTW,* "Very often, episodes of bone formation in FOP are trigged by tissue trauma and injury. A normal process of tissue healing in response to tissue and cell damage includes processes that induce repair through cell differentiation. In FOP, connective

large joints

Characteristic Clinical Features of FOP/Eileen Shore, PhD and Frederick Kaplan, MD, University of Pennsylvania School of Medicine

tissues may have increased sensitivity to these repair processes through activated BMP signaling stimulated by the ACVR1 mutation."

The FOP mutation is a single replacement for a DNA building block in the gene for a receptor protein called ACVR1. In experiments by Qi Shen, a postdoctoral fellow in the Shore-Kaplan lab and Shawn Little, a Ph.D. student in Dr. Mullins' lab, the team found, using both cultured cells and zebrafish, that the specific mutation modifies ACVR1 in such a way that it acts as if it has been signaled by BMP, even when it hasn't. The experiments further show that the mutant ACVR1 receptor alters the usual binding of an ACVR1 partner protein, FKBP1A, which normally keeps the ACVR1 receptor off in the absence of BMP. The result is activation of a cell-signaling cascade that culminates in changes in gene expression, and ultimately, in the formation of new bone.

"FKBP1A is like the safety pin in a hand grenade," said Dr. Kaplan in the news release. "The FOP mutation damages the hand grenade in a very specific way that the safety pin does not work. When triggered by injury, the result is explosive new bone formation."

Dr. Mullins studies BMP signaling in zebrafish, and her long-time interest was a particular gene critical to this process, called *Alk8*. Turns out, *Alk8* is the zebrafish equivalent of human *ACVR1*. Dr. Mullins had already established a zebrafish genetic line that fails to express *Alk8*. When the team inserted the gene for human *ACVR1* into those fish, their normal body plan was restored. But, when they used the FOP mutation instead, the effect was one of overcompensation.

"The FOP form of ACVR1 causes too much BMP expression and we get a hyper-ventralized embryo, too much cell development in the tail region of the fish," Dr. Shore explained in the news release. "So this confirmed our cell culture studies showing the mutant ACVR1 an activating mutation."

When asked about their next steps, Dr. Kaplan told *OTW*, "This seminal study is the first to examine the molecular mechanisms by which the renegade FOP gene leads to explosive new bone formation. Ultimately, the molecular mechanisms will determine the medicines that we develop to treat and cure the disease. FOP is like an atom bomb, and you cannot successfully disarm the bomb if you don't know how the fuse is wired. Using this emerging knowledge to eventually treat FOP is our primary goal. We are extremely grateful for the vital support we have received from many dedicated individuals, families and organizations and we hope that they too are inspired by the progress that is being made. We have come a long way, but still have many challenges ahead."

—EH (November 24, 2009)

FDA OKs Wright's CONSERVE

Calling all youthful pole vaulters, sprinters, and weekend warriors with hip pain…Wright Medical Group, Inc. has a new option for you. The company has announced that the FDA has given the go ahead for Wright to market its original CONSERVE Plus Total Hip Resurfacing System. Those intrigued by this total surface arthroplasty system will find that the bone conservation aspect is a huge plus.

The approval means that Wright may market CONSERVE Plus in the original femoral and acetabular component configuration specified in its premarket approval (PMA) application—and enables the company to initiate efforts to introduce additional enhancements to the system which are currently only available outside of the U.S.

large joints

In Conserve Plus operations, the hip socket is replaced, but the head of the femoral bone is shaped instead of being taken out. A cobalt chrome sleeve is placed on top of the remaining bone.

The approval follows a successful clinical trial involving more than 1,300 patients, including those enrolled under Continued Access protocols, providing patient data of CONSERVE Plus clinical data in postoperative periods of up to

CONSERVE Plus

eight years in length. Wright will commence surgeon training in the first phase of its U.S. introduction. The training is expected to begin immediately upon approval.

"Hip resurfacing represents a valuable alternative to younger, more active patients who desire a hip reconstruction that more anatomically mimics the natural hip," commented Patrick Fisher, in the news release. Fisher, the Senior Director of Marketing for Wright's hip franchise, added, "We have learned that this is an excellent option for patients who meet the criteria for hip resurfacing, and these individuals tend to be very enthusiastic and outspoken about their positive results."

Scott Ellison, Senior Analyst for PearlDiver following the large joint market, commented to *OTW*, "Right now Smith & Nephew really controls the hip resurfacing market, but Wright has always been good at moving into areas that have experienced high growth. In the third quarter their hip revenues grew 6.6% (reported) in comparison to the overall market only grew by 2.1%."

Gary Henley, President & CEO, told *OTW,* "Wright will be conducting numerous hands on training events beginning in the first quarter of 2010. The majority of the hands on training events will take place at the MERI training facility in Memphis, Tennessee. In addition, Wright will be utilizing its state of the art Medical Mobile Laboratory to train surgeons around the country. Our surgeon customers are eager to share the hip resurfacing option with their patients and we are responding with a highly-structured plan."

He added, "With over 1,300 patients involved in the successful clinical trial, the CONSERVE Plus system offers the reassurance of the largest, U.S.-enrolled, multi-center IDE [investigational device exemption] study for a hip resurfacing device. We believe this distinction is important since recent evidence demonstrates that single surgeon results are insufficient for predicting resurfacing's performance in wider use."

—EH (November 27, 2009)

The Picture of Success: Dr. Christopher Born

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

Sometimes when the phone rings, it's a call from home. Other times, it's Homeland Security. Dr. Christopher Born, Chief of Orthopedic Trauma at Brown University, is known for his expertise in handling mass casualty situations.

The Winding Road to Orthopedics

Raised in New York City by a stay-at-home mother and an ophthalmologist father, a young Christopher Born held fast to his parents' educational expectations. "My dad was the son of immigrants and he and his sister both attended college, the first in their family to have done so. Having grown up in the depression, my dad understood the value of hard work and of living within one's means. This made a substantial impression on me…and if you talk to my kids they will tell you there is a tremendous similarity between me and my dad in that respect."

Yet for awhile, he was a bit more focused on merriment. Dr. Born: "When I walked through the doors of the University of North Carolina at Chapel Hill in 1966, I wasn't gracing them with an A student. I was having too good a time to focus on academics—that would come later. In the meantime I had to finish college during summer school, only to be followed by the unnerving prospect of going to Vietnam. As fate would have it, my draft lottery number was 326, meaning that I was not going to be drafted."

So what would he do? At that point there were several options, including geopolitics and sheep. Dr. Born says, "I was a political science major, but I didn't know what to do with it. I ended up taking a year off to travel around the around world by myself, hitchhiking along the way. Part of that time was spent at a sheep station in Australia where I helped care for cattle and sheep on a 16,000 acre farm. In time, however, I knew I would have to come home and face the career music."

"The last few weeks on the farm I had long conversations with myself about the future. I tried to focus myself by thinking of everything that had ever interested or excited me (that I could turn into a work life). I could only come up with two things: art history and biology. The latter won out, and based solely on one course I had taken in high school, I decided to become a physician. I gave in to my interest in various life forms and embryology, despite the fact that I felt I had more of a talent for literature and the arts."

After learning much about single celled organisms, Christopher Born moved on to larger life forms. "In 1972 I began premed studies at Columbia University. I attended school at night and worked in a lab at Sloane Kettering during the day. After a year I decided that I wanted to do something that involved patients, and went to the New York Hospital and asked if there were any jobs available for someone at my level (an orderly, etc.). The administrator initially said, 'no,' but then changed her mind—and my life. 'There is one job as an orthopedic cast technician in the fracture clinic,' she said, 'but you have no experience.' I promptly replied, 'What is orthopedics?'

"She had some faith in me, however, most likely because the only other applicant for the position was a high school graduate, while I was a premed student. I stocked supplies, helped put people in traction, etc. I really enjoyed the materials and learning about the various injuries. It was evident that there was an artistic component to this work. I could also see that it was

necessary to have the ability to assess things in three dimensions."

His next career move almost had him asking, "Se habla ALIF?" Dr. Born explains, "Because of my less than stellar college grades, I didn't get any interviews when I applied to medical schools. I went to Mexico to study Spanish, with my plan being to enter medical school there. While in Mexico I learned that I had gotten an interview, and was subsequently admitted to the Georgetown University School of Medicine. I enjoyed the program, and was heavily focused on getting a surgical residency. In addition to orthopedics, I was considering urology and ENT. My generous father said that he would continue practicing until I made my decision…and that he would give me his practice if I wanted it. In the end, however, I was drawn into orthopedics by the allure of fracture work."

Building an Education and a Career

Entering the orthopedic residency program at the University of Pennsylvania in 1979, Dr. Born soon got to engage in his new passion. "The Chair, Dr. Carl Brighton, had developed an outstanding orthopedic laboratory at a time when such places were uncommon. I worked alongside him in the lab looking at the stresses within bone and what kind of reaction the bone and tissue has—and how that was related to healing."

"Another mentor," continues Dr. Born, "was Dr. Bruce Heppenstall, head of the fracture service, who taught me the importance of being bold, but thoughtful. 'Have a plan and carry it out as quickly as is safely possible,' was his motto. Dr. Richard Rothman also factored heavily into my education, and stressed the value of sticking to your guns when looking at surgical indications. And he was adamant about putting the patient first. He would give an example along the lines of, 'Let's say there is a situation where you want to be a hero. But once you analyze things you can see that proceeding along xyz course of action could elevate the chance of causing harm.'"

He homed in on trauma, but Dr. Born didn't have the widespread options that budding traumatologists have today. "Because of the paucity of trauma fellowships in the US, I made plans to go to Switzerland for a six month AO fellowship. One of my colleagues at Penn, Dr. Bill DeLong, had decided to take a job at Cooper Hospital University Medical Center in Camden, New Jersey, a level one trauma center. After a conversation with Bill, I decided to join him at Cooper, with the understanding that I would do the AO fellowship first. Bill convinced me to go ahead and start at Cooper and said, 'We'll figure this out later.' Whenever I see him these days, I tell him he still owes me six months in Switzerland."

As for Dr. Born, he gave 12 years to Cooper. "From 1984 until 1996 I was the Assistant Division Head of Orthopedic Surgery at Cooper and was an Associate Professor of Orthopedic Surgery at the University of Medicine and Dentistry/Robert Wood Johnson Medical School. It was amazing to work seemingly 24/7 at a level one trauma center, something that was akin to being in a MASH unit. There were only two traumatologists at first, and then we slowly increased to six and brought on residents and fellows. It was a widely respected program, and people talked often of doing a 'Cooper rotation.'"

In 1996 "team DeLong-Born" moved to rejoin the faculty at the University of Pennsylvania. Dr. Born, an Associate Professor of Orthopaedic Surgery who served as the Co-Director of Orthopedic Trauma at Penn, says, "Bill and I were recruited to Penn by Dr. William Schwab, who at one point had been at Cooper with us. Although it was a great learning experience overall, we did have some challenges with regard to getting trauma patients into the OR in a timely fashion. Penn's healthcare system is so vast that there are enormous demands for space… and ours was just one area that needed servicing."

Enthused by the prospect of building a trauma program, Dr. Born—and Dr. DeLong, of course—left for Temple University. "In 2002 Bill and I went to Temple to help build their trauma program. Despite being a level one trauma center, they didn't have orthopedic trauma expertise at the time. It was great to be able to help the Chair, Dr. Joe Thoder, with his academic mission. After two years there I was presented with an opportunity at Brown University, one which was very attractive, in part because my wife and I had a house in the area. My wife had a very successful business in Philadelphia, so she wasn't able to join me full time. We basically settled into a pattern of commuting back and forth between Rhode Island and Philadelphia."

Researching New Technology

On the research front, Dr. Born and his colleagues at Brown have been busy with antibiotics. "My team and I have been studying whether using beads impregnated with antibiotics in wounds that have VAC (vacuum assisted closure) dressings can augment bone healing. The fundamental question at this point is, 'If you put these beads in a wound with a VAC dressing, does the antibiotic still have a high concentration even though there is essentially a vacuum sucking antibiotics out of the wound?' We are wondering if there is a way to modify the time and duration of the VAC cycle to increase local antibiotic tissue concentration. We also have to identify what proper pharmacologic dosage is needed for the VAC dressing combined with antibiotics. It will likely end up being an intermittent schedule, a la VAC on for 20 minutes—VAC off for two or three minutes."

This and other work will ultimately benefit men and women in uniform. Dr. Born: "We have been working with the Veterans Administration and the Center for Restorative and Regenerative Medicine here at Brown to research aspects of managing injuries that are sustained by soldiers. This multidisciplinary group has taken on a lot of initiatives, including neurophysiologic studies. For example, other researchers in the Center have developed a system to place an implant into the motor cortex of the brain that can pick up brain waves. The waves are then interpreted in terms of purpose and can be connected to a computer which can manipulate a robot. This means, for example, that the patient can just think about moving a mouse on a screen and it moves up and down. Simply amazing."

Also important for those in the military, as well as civilians, are advances in prosthetics. "Most prosthetics are passive, such that if you have a below the knee amputation and you walk on it, the feedback you get in terms of where you place your foot in space is limited. The gait cycle takes a lot of energy, not to mention lugging this prosthetic along. Another researcher affiliated with the Center, Dr. John Herr of MIT, has developed a below the knee prosthesis that is active, meaning that it responds to gait and speed. It is in the trial phase now, but thus far people are saying that they have more of a feeling of a normal gait…and that it takes less energy."

With all of the planning, technology, surgical time, and post-op work that goes into implanting a device, wouldn't it be nice, says Dr. Born, if it could actually remain in the patient for a long period of time (and not cause infection)? "Our orthopedic trauma division has submitted a number of grant proposals to the Department of Defense and private foundations to examine the interface between metal and bone, and metal and skin, in order to refine the technology for coating implants. This work should enable us to make antibacterial and antimicrobial coatings and to make coatings that promote bone attachment to the implant. In joint reconstruction they have surfaces with microbeads that are embedded in the cracks and crevices; the body is thus fooled and bone can interdigitate and create a bond. We are looking to do

the same thing with a different technology."

Responding to Disaster

One area where he might not have the latest technology at hand, but where there are other vital challenges, is disaster response. Dr. Born, Chair of the Mass Casualty Response Committee for the Orthopaedic Trauma Association (OTA), explains, "A few years ago it dawned on me that I was unaware of a formal or even an informal system whereby orthopedic surgeons might respond to international disasters. I began trying to increase the awareness and training in this area, with a focus on the fact that responding to disasters has its own unique issues, including, for example, the safety of responders, what kind of disaster has occurred, etc."

"I have come to learn the importance of a seamless command structure, with people who understand how the package is supposed to be put together. So when a disaster happens, there is no question what needs to be done. The first two or three years that we ran this program at the OTA, we had 20-25 attendees. There are an increasing number of competing programs, and this year only five people signed up—so we canceled. We are in the process of rethinking how we structure/approach this next year. There are other educational venues, of course, including the AMA and ACS."

But when Dr. Born gets the call, he knows enough to be ready. "In 2004, I received a phone call at 11:00 one night asking if I would go to Iran. There had been a massive earthquake in the city of Bam, and immediate assistance was needed. I got my cache of equipment that is always at the ready, and linked up with the International Medical Surgical Response Team (IMSuRT), part of FEMA that is based out of Boston. We mustered at Massachusetts General Hospital and flew to Frankfurt, then on to Iran. It was incredible that the city of Bam, which the day before had had 100,000 occupants, had lost 25 to 30,000 people in the earthquake."

"Because of diplomatic issues, the U.S. government couldn't officially send help. However, the Iranian government, working through intermediaries, approached the U.S., and 60 of us private citizens went for two weeks. I found the Iranians to be very welcoming, and was surprised to see how well organized the U.S. team was. All of the equipment worked, and each person knew his or her role. We brought everything we needed and were a self contained unit. After awhile, however, you begin to run out of supplies and get fatigued. Two weeks was our limit."

To any colleagues who might be interested in keeping a "go" bag and mustering in the middle of the night, Dr. Born advises, "The most important thing to keep in mind is that you must be prepared to fly by the seat of your pants. You don't have the equipment you're accustomed to having so you have to 'make do.'"

Whether it's Iran or Philadelphia, his "go" bag is packed. "My wife and I do a lot of traveling back and forth on weekends. She started a master's program in organizational dynamics at Wharton 15 years ago, but had to put it on hold because her business took off. She is now finishing up that program. Our youngest child just graduated from Brown this year and is living in Providence with me, working at the Rhode Island School of Design (RISD) Museum.

Dr. Christopher Born…for when disaster strikes.

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