VOLUME 7, ISSUE 15 | MAY 10, 2011

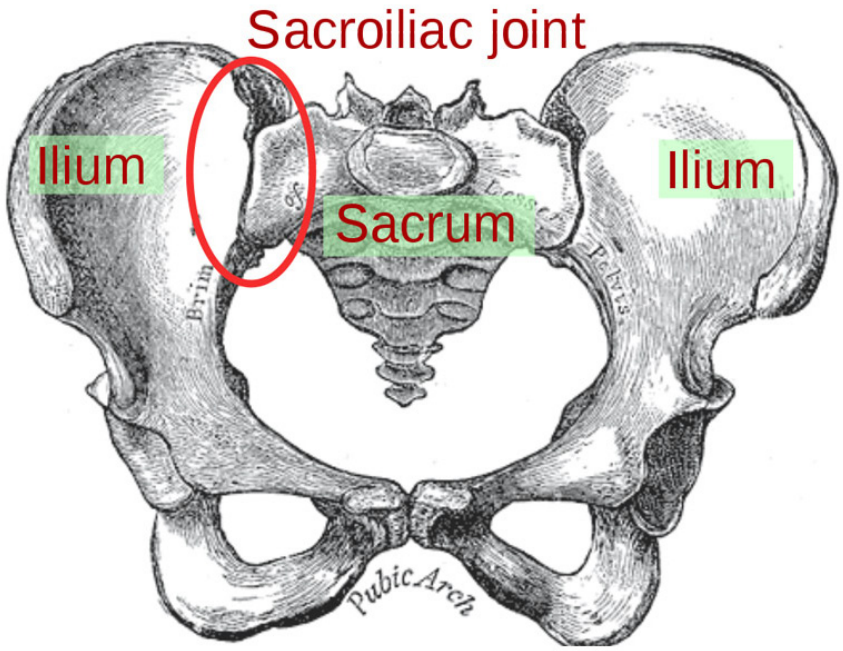
Orthopedics This Week

week in review

4 **An Overlooked Spine Market?** ◆ Spine's innovation rate may no longer be the juggernaut it once was. Independent auditing/actuarial firms (looking at you Milliman) may be trying to re-draw the boundaries of spine care. But none of that seems to be affecting a small San Jose company which could be the next Kyphon. Read about SiBone.

8 **The Risks of PODs** ◆ The *Wall Street Journal*'s claim that a California physician-owned distributorship (POD) paid surgeons to use products, has claimed its first victim—Omega Solutions. Two law firm giants on opposite sides of the POD argument weigh in with their arguments. Read it here

12 **Battlefield Orthopedics: One Unit, 15 Months** ◆ How many soldiers are at risk for injury? Lieutenant Colonel Philip Belmont, Jr., M.D. and his colleagues undertook the first prospective, longitudinal analysis of a large combat-deployed unit in which musculoskeletal combat casualty care incidence rates could be accurately calculated.



picture of success

27 **Dr. George Bagby, Part I** ◆ Dr. George Bagby, inventor of the Self Compression Bone Plate, was declared legally blind at the age of 15. Now 88, he continues to invent, travel to help others around the globe, and work with his prosthetics foundation.

breaking news

16 **NuVasive:** Sunny 1Q in San Diego

Orthofix "Takes Medicine" in First Quarter

Dvorak's Sweet Music in 1Q11

Ascension Orthopedics Hits 40,000 Milestone

93-Year-Old Gets Knees

Zirconium or Chromium: A Toss-Up

Smith & Nephew "Mutineers" Fight Back

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: On paper, the Synthes/JNJ merger ranks as one of the great strategic moves of all time. In orthopedics, it is on par with Danek + Sofamor in the sense that it establishes the market leader for decades to come. For landing the prettiest gal at the dance, JNJ vaults to #1 this week.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	2	Johnson & Johnson	26.33%	9.40%	DePuy will hold the #1 or #2 position in every major orthopedic market. That plus 3.40% dividend yield earns JNJ #1 spot.
2	1	Orthofix	14.49	10.97	OFIX still the best value in all of ortho. Huge write-offs in Q1, clears the deck for the rest of the year's reports.
3	3	NuVasive	6.69	21.57	Outperforms Wall Street's forecasts, ups guidance for 2011. Strong MIS plus direct sales is the key at NUVA.
4	7	Zimmer	27.38	11.2	Beat Wall Street's estimates AGAIN. Stock breaking out technically as new buyers step in.
5	6	Integra LifeSciences	15.18	7.25	With adjustments, IART comes in in-line for Q1. Best news was 71 basis point rise in profit margin.
6	5	Alphatec	1.11	(3.87)	Great Q1 sales growth combined with disciplined spending means that ATEC is holding its own.
7	10	Stryker	25.61	(0.95)	46% sales growth in Neuro and Spine pushed overall sales up a respectable 12%. Up 3 spots this week.
8	9	Smith & Nephew	23.22	(2.15)	Revenues for Q1 up 6% which beat consensus estimates. What's the secret? Strong OUS sales.
9	4	Symmetry	8.08	(2.87)	Missed the EPS number by a penny, but posted 13% sales growth. Hopefully the margin pressure is only a one-quarter glitch.
10	8	Medtronic	31.23	8.21	Could MDT find a strategic fit that is comparable to Synthes/JNJ? The answer is "yes.". But someone has to step up.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Synthes	SYST.VX	$172.08	$20,426	25.4%
2	NuVasive	NUVA	$32.24	$1,280	21.6%
3	Orthovita	VITA	$2.49	$191	16.9%
4	Tornier N.V.	TRNX	$21.90	$4,110	13.9%
5	Bacterin Intl Holdings	BONE	$4.00	$151	11.7%
6	Zimmer Holdings	ZMH	$67.50	$13,000	11.2%
7	Orthofix	OFIX	$36.62	$660	11.0%
8	*TranS1*	*TSON*	*$4.63*	*$97*	*9.5%*
9	Johnson & Johnson	JNJ	$65.27	178,530	9.4%
10	*Average*			*$12,635*	*8.8%*

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	CryoLife	CRY	$5.39	$151	-8.6%
2	Kensey Nash	KNSY	$24.01	$205	-6.9%
3	RTI Biologics Inc	RTIX	$2.71	$149	-5.2%
4	ArthroCare	ARTC	$32.31	$882	-5.0%
5	Mako Surgical	MAKO	$24.98	$1,020	-3.9%
6	Alphatec Holdings	ATEC	$2.98	$264	-3.9%
7	Symmetry Medical	SMA	$9.49	$345	-2.9%
8	Smith & Nephew	SNN	$56.43	$10,070	-2.2%
9	Exactech	EXAC	$17.53	$229	-2.1%
10	Stryker	SYK	$59.69	$23,280	-0.9%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Kensey Nash	KNSY	$24.01	$205	11.53
2	Medtronic	MDT	$42.69	$45,650	12.56
3	Wright Medical	WMGI	$15.63	$594	13.52
4	CryoLife	CRY	$5.39	$151	13.80
5	Johnson & Johnson	JNJ	$65.27	$178,530	13.87

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Orthovita	VITA	$2.49	$191	107.83
2	Smith & Nephew	SNN	$56.43	$10,070	77.71
3	RTI Biologics Inc	RTIX	$2.71	$149	22.63
4	Synthes	SYST.VX	$172.08	$20,426	22.50
5	ArthroCare	ARTC	$32.31	$882	21.46

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Orthofix	OFIX	$36.62	$660	0.69
2	Exactech	EXAC	$17.53	$229	1.07
3	NuVasive	NUVA	$32.24	$1,280	1.39
4	Zimmer Holdings	ZMH	$67.50	$13,000	1.43
5	Symmetry Medical	SMA	$9.49	$345	1.45

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Kensey Nash	KNSY	$24.01	$205	7.23
2	CryoLife	CRY	$5.39	$151	2.92
3	ConMed	CNMD	$28.29	$801	2.35
4	Johnson & Johnson	JNJ	$65.27	$178,530	2.29
5	Alphatec Holdings	ATEC	$2.98	$264	2.20

Lowest Price to Sales Ratio (TTM)

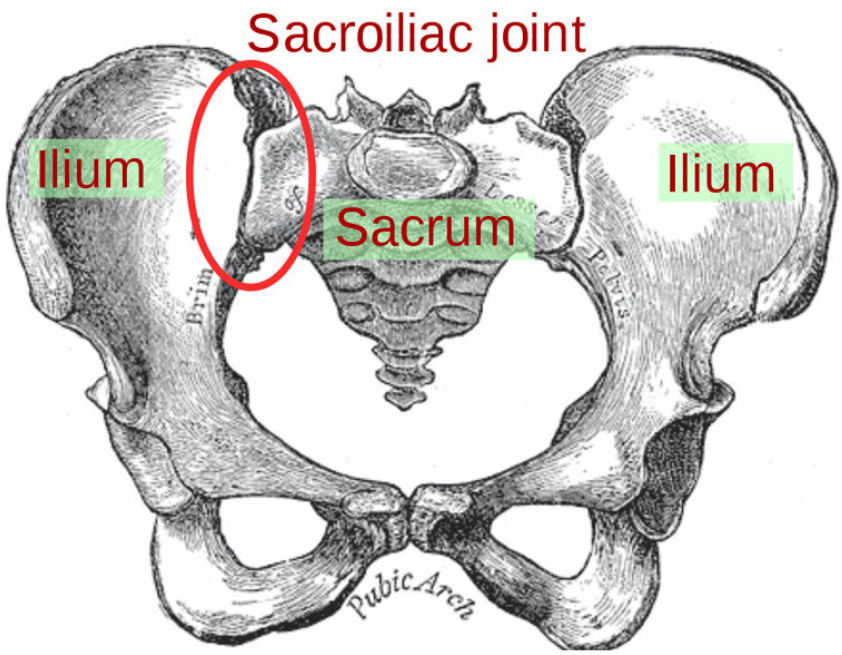
	Company	Symbol	Price	Mkt Cap	PSR
1	RTI Biologics Inc	RTIX	$2.71	$149	0.89
2	Symmetry Medical	SMA	$9.49	$345	0.93
3	Orthofix	OFIX	$36.62	$660	1.08
4	ConMed	CNMD	$28.29	$801	1.09
5	Wright Medical	WMGI	$15.63	$594	1.12

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Mako Surgical	MAKO	$24.98	$1,020	22.17
2	TiGenix	TIG.BR	$1.84	$57	17.86
3	Bacterin Intl Holdings	BONE	$4.00	$151	9.72
4	Synthes	SYST.VX	$172.08	$20,426	5.54
5	TranS1	TSON	$4.63	$97	3.68

An Overlooked Spine Market?

By Robin Young



Mikael Haggstrom/Wikimedia Commons

Spine's innovation rate may no longer be the juggernaut it once was. Independent auditing/actuarial firms (looking at you Milliman) may be trying to re-draw the boundaries of spine care. But none of that seems to be affecting a small company located just off the Junipero Serra Freeway at Winchester Blvd. in San Jose, California. The three-year-old firm appears to have uncovered an overlooked corner of the spinal implant market which, in size, maybe as large as 20% of all spine surgeries! Perhaps even as large as the market for vertebral compression fracture treatment.

SI-BONE and the SI Joint

The new company, SI-BONE, Inc. is being directed by a few experienced medical device hands and one veteran of the Silicon Valley electronics world. Jeffrey Dunn, formerly of INBONE, Active Decisions and before that Velogic (an internet performance company) is president and CEO. None other than Mr. Kyphon himself, Mark Reiley, M.D., is SI-BONE's founder. In the supporting cast are Garret Mauldin, from INBONE, Jeffrey Polack, from Matrix Medica and St. Jude Medical and Kevin Shaw from St. Francis Medical and Medtronic.

Dr. Reiley, aka: "Kyphon1" (as he calls himself in his emails), invented SI-BONE's iFuse implant system to treat sacroiliac pain (see image to the right).

Sacroiliac pain? Isn't that somewhere south of L5? The sacroiliac joint (SI) is a joint complete with synovial fluid and strong ligaments. It's below L5 but above the remaining vestige of the human tail—er coccyx. And there are two of them. Two sacroiliac joints—left and right. Both are weight bearing and together they function to support the spine although, as time progresses they may not necessarily match—which is to say that as we age the characteristics of the sacroiliac joint change.

Because of effects of walking, jumping, skiing, skate boarding, horizontal tangoing, etc., the SI joint's surfaces evolve from flat or planar early in life to distinct angular orientations (losing their planar or flat topography).

SI-Bone's iFuse Implant System

The SI joints can also develop an elevated ridge along the ilial surface and a depression along the sacral surface. The ridge and corresponding depression, along with the very strong ligaments, increase the sacroiliac joints' stability and makes dislocations very rare.

Like most lower extremity joints, one of the SI joints' functions is shock absorption (depending on the amount of available motion at the sacroiliac joint) for the spine, along with the job of torque conversion allowing the transverse rotations that take place in the lower extremity to be transmitted up the spine.

The SI joint, like all lower extremity joints, provides a "self-locking" mechanism (where the joint occupies or attains its most congruent position, also called the close pack position) that helps with stability during the push-off phase of walking. The joint locks (or rather becomes close packed) on one side as weight is transferred from one leg to the other, and through the pelvis the body weight is transmitted from the sacrum to the hip bone.

Like all joints, the SI is subject to degenerative processes and can become inflamed. When it does, the patient will report, typically, unilateral low back pain. Or buttock or thigh pain.

Prevalence of SI Abnormalities

What is the prevalence of sacroiliac joint inflammation?

Drs. O'Shea, Boyle, Salonen, Ammendolia, Peterson, Hsu and Inman tackled that precise question and published their answers March 30, 2010 in the *American College of Rheumatology's Journal of Arthritis Care and Research*.

The investigators studied 315 patients (173 men, 142 women). One hundred patients (31.7%) had signs of SI joint abnormalities; 75 (23.8%) had signs of joint degeneration; and 25 (7.9%) had signs of joint inflammation. The investigators found that the incidence of degenerative SI disease was predominantly found in women (68%), whereas SI joint inflammation was found by the investigators predominantly in men (63%).

In women, the investigators found that there was no correlation between degenerative SI joint abnormalities and degenerative changes in the lum-

bar spine. Of the clinical descriptors evaluated, none were associated with the radiographic findings with the exception of buttock pain, which was associated with inflammatory sacroiliitis. Interestingly enough, the researchers found that neither being overweight nor pregnancy history was associated with degenerative changes in the SI joint.

According to the National Institute of Neurological Disorders and Stroke (a division of NIH), "Americans spend at least $50 billion each year on low back pain." Low back pain is the most common cause of job-related disability and a leading contributor to missed work. Several leading orthopedic publications over the last few years have stated that **anywhere from 15-25% of all low back pain is SI joint in origin.**

According to a study by Bernard and Kirkaldy-Willis, over 22% of individuals who presented with lower back pain actually had sacroiliac (SI) joint pain. A wealth of published clinical literature indicates that SI joint pain frequently mimics discogenic or radicular low back pain, resulting in many patients receiving lumbar fusion instead of SI joint fixation/fusion.

A Unique Company

Frankly, this is the first time we at *OTW* have found a company that was specifically targeting SI joint pain and the diagnostics and implants to treat it.

Said CEO Jeffrey Dunn: "Treating SI joint degeneration and pain is an underserved need that could represent millions of patients. Even surgeons are not generally aware of either the diagnosis or treatment for SI disease. I was having dinner with a surgeon early in the development of this company and he said to me 'Jeff, I don't know what the hell you're talking about. I don't look below L5 and if I looked there I wouldn't know how to diagnose it and if I found it I wouldn't know what to do with it!'"

Continued Dunn, "So we are squarely focused on education. This company's only about two things—education and clinical. "

SI-BONE, Inc. was founded in April 2008 as a spin out when Wright Medical bought Reiley's INBONE Technologies. INBONE, with the ENDO-FUSE Intra-Osseos Fusion System, was founded by Mark Reiley, the inventor of kyphoplasty and the vertebral fracture treatment.

Using the ENDO-FUSE titanium technology (which has been used in more than 1,000 patients), Dr. Reiley and the SI-BONE team developed kind of intramedullary implant to treat SI joint pain and instability. The implant is positioned in the space via a 1.5 inch incision and is significantly less invasive than the traditional sacroiliac (SI) joint fixation/fusion surgery.

Since founding in 2008 SI-BONE has grown rapidly. Said Dunn; "At this stage I can only say that we're having a hell of lot fun. The team is very energized. We have about 50 people. A year ago we had five. Where do we want to take the company? Everyone in the company wants to work at this for a while. We're helping patients. I mean it's spectacular."

Education and Patient Selection

But Dunn has no illusions about the difficulty of the task. "The key here is just

like Kyphon. It's education. Our sales force comes from such firms as Kyphon, NuVasive, Trans1 or St. Francis. They understand how hard the work is. That you have to do the early work. The education work. The diagnostic work. This isn't about the surgery…this is a Mark Reiley invention [and] I can tell you that it works…it's about can we educate 100,000 medical professionals?"

And patient selection.

"I really think one of the biggest problems in spine is diagnosis," said Dunn. "With our approach when you do that injection into the SI joint, the diagnosis is pretty conclusive. That gives me confidence that our surgeons, if trained well, will start with the best patient selection.

This company is all about education. We start with the anatomy, then we go to diagnosis, we show how to do an injection, we show them how to do the provocative test. At the end of the day, patient satisfaction from spine surgery can't be at 60%. Surgeons have to select the right patients and then we'll all be happy—the patient, the hospital, the insurance company and the surgeon."

SI-BONE is just three years old. But the enthusiasm (see related video) at this young company is palpable. We've got our eye on SI-BONE and we fully expect to be hearing and reporting big things as the years unfold. ◆

Watch Interview with Jeff Dunn: **http://ryortho.com/spine.php?article=571_An-Overlooked-Spine-Market**

The Risks of PODs

By Walter Eisner

In an April 13 story, *The Wall Street Journal* (WSJ) claimed that Omega Solutions, a California-based physician-owned distributorship (POD), "sometimes pays surgeons to use its products." We took the *Journal* to task for citing poor evidence in accusing a company of committing a felony in our own story on April 15.

On April 27, *OTW* received a "Letter to the Editor" (reprinted below) from attorneys at the Hogan Lovells law firm. The firm represents device manufacturers and issued a widely published White Paper in 2009, arguing that physician-owned distributorships ran afoul of federal kickback statutes and potentially clouded a physician's ability to choose the best implant for his or her patient.

Publisher: Calvert Litho Co./Wikimedia Commons

Omega Shuts Warehouse, Inventory in Limbo

Michael S Richter/Morguefile

On May 5, *OTW* learned from the CEO of Omega that the company has shut its doors. According to the CEO, device companies that had been selling implants to the Omega POD, notified the company that due to the publicity generated by the *WSJ* article, they would no longer be selling product to the POD. The CEO told us that he's looking at a warehouse full of implants that he and his physician partners will not be able to sell. He says they followed the letter of the law and now their significant investment is in danger of being lost.

Hogan Lovell: PODs Run Afoul of Kickback Statutes

Below is the Hogan Lovell letter to *OTW*, [slightly edited for brevity]. Following the Lovell letter, we share 19 legal requirements for a POD sent to us by the CEO of Omega and prepared by the law firm of Hooper, Lundy and Bookman. Hooper represents PODs and wrote the legal paper cited by many PODs as the opinion they relied on to structure their business.

Dear Editor:

We read with interest Walter Eisner's April 15 response to the Wall Street Journal's April 13 article on…physician-owned medical device distributorships.

As described, the POD relationship with…(any participating hospitals and implant manufacturers) on its face implicates the federal health care programs antikickback law.

This law prohibits payment for the referral of business reimbursable by Medicare and other federal health care

programs. The law has long been interpreted to be violated if even "one purpose" (as opposed to a sole or primary purpose) of a payment arrangement is to induce the purchase of products or referrals for patient services reimbursable under a federal health care program.

Where this improper intent was present, courts have found unlawful remuneration in the giving of an opportunity to earn a profit, and in earning a return on an investment.

It is difficult to argue that the one-purpose test is not violated by the POD business model. Plainly, at least one purpose of a hospital's agreement to purchase products through a POD is that it provides the physician owners with a direct financial return for each hospital referral, a return that could not be achieved (and a referral that could not be secured) if the hospital bought direct from the manufacturer or from a distributor without physician owners.

Likewise, manufacturers agree to sell through a POD because they believe that this direct financial return will lead the owner physicians to order their products in lieu of products that that do not generate profits for the doctors performing the procedures.

There is no business risk to anyone involved, since the owner physicians control both product choice and patient referral. The direct financial return that results from both of those discretionary decisions protects the hospital, the suppliers, and the doctors from any business risk. [our emphasis]

Federal agencies charged with enforcing the health care "fraud and abuse" laws apparently share the concern that a business model whose profits are generated primarily by physician referrals creates the risk of abuse that run afoul of those laws.

The HHS Office of Inspector General (OIG) has said that it has "serious kickback concerns when companies link investment opportunities to the ability to generate business and offer returns on investment that are disproportionate to business risk." It believes that POD arrangements "should be closely scrutinized under the fraud and abuse laws because they raise the type of risks that [those statutes] were designed to address."

The OIG also has affirmed that "the fact that a substantial portion of a venture's gross revenues is derived from participant-driven referrals is a potential indicatorof a problematic joint venture." And the OIG has reminded industry on many occasions that "increased costs to the Medicare and Medicaid programs and harm to beneficiaries" are not necessary in order for an arrangement to violate the law.

The Centers for Medicare and Medicaid Services (CMS) has echoed this concern, stating its belief that POD arrangements "may serve little purpose other than providing physicians the opportunity to earn economic benefits in exchange for nothing more than ordering medical devices" from their POD. "When physicians profit from the referrals they make to hospitals through physician-owned implant and medical device companies ('POCs'), we are concerned about possible program or patient abuse."

So why do PODs continue to proliferate?

***In part, the arrangements are so beguilingly free of business risk and full of profit potential that it is difficult for physicians to resist their allure in the absence of visible enforcement proceedings.** Add to this that federal enforcers appear to be biding their time, waiting for just the right case, and the short-term opportunities may appear to outweigh the long-term negatives. But as hospitals who lived through the government's enforcement campaigns against billing for medical residents will recall, it is little help when faced with such proceedings to plead that "we thought it was ok at the time because nobody tried to stop us."*

Responsible implant manufacturers, hospitals, and physicians should pay close attention lest they become poster children for a new wave of enforcement.

Sincerely,
Thomas N. Bulleit
Sara Kraner

Hooper, Lundy: The Indirect Compensation Exception

The Hooper, Lundy and Bookman website offers the following February 2011 *Health Law Perspectives* titled, "Regulatory and Structural Considerations for Physician-Owned Medical Device Companies," by Eugene Ngai and Charles Oppenheim.

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HEALTH CARE LAWYERS

"The physician-owned device company arrangement is likely to create an indirect compensation arrangement between the physician-investor and each hospital to which that physician-investor refers Medicare patients for hospital services.

However, a properly structured physician-owned device company may rely on the indirect compensation arrangements exception. This exception is met if the agreement between the physician-owned device company and the hospital provides for the medical devices to be sold at fair market value, and at a price that does not vary during the term of the agreement based on referrals or other business generated by the referring physician-investor. In addition, the agreement must be set out in writing and signed by the parties, and must not violate the federal anti-kickback statute."

http://health-law.com/health-law-perspectives/february-2011/#3

POD Legal Requirements

The following "Legal Requirements for Medical Distributorship," prepared by Hooper Lundy was shared with *OTW* by the CEO of Omega:

1. *The company will hire and employ its own personnel.*
2. *The company will purchase products directly from manufacturers/distributors under its own contracts.*
3. *The company will sell products directly to its own customers such as hospitals or surgery centers under its own contracts.*
4. *The company will manage its own inventory.*
5. *The company will have its own distinct office and warehouse space for operation of its own business.*
6. *Products will be shipped to the company by the manufacturer/distributor and will be separately warehoused by the company before resale to hospitals or surgery centers.*
7. *The company will hold any and all licenses or governmental approvals necessary for operation of its business.*
8. *The investment price offered to physicians will not be based on the projected referrals from the physicians, nor will the amount being offered to physicians reflect the anticipated referrals generated from the physicians procedures.*
9. *No physician's investment interest will be subject to repurchased for failure to use the company's devices in their surgeries.*
10. *The investing physicians will not be pressured in any way to utlize the company's devices in their surgeries.*
11. *The investing physicians will not exert pressure on the hospitals or surgery centers to purchase the devices from the company.*
12. *The company will be adequately capitalized for its operations through the initial capital contributions of its members and that the*

physician investments will not be nominal. The members' capital contributions will not come from the manufacturers/distributors that sell devices to the company, nor will the managers or its affiliates loan funds to the physician investor for their capital contributions.

13. *The use of the devices will at all times be medically necessary.*
14. *The company will not bill patients or payors (including Medicare and Medi-Cal) for the devices.*
15. *The company will have written agreements with the manufacturers/distributors for purchase of the devices.*
16. *The company will have written agreements with the purchasers, hospitals or surgery centers, for the sale of the devices.*
17. *The purchasers, hospitals or surgery centers will be charged a fixed price based on negotiations, which will not increase with the use of more devices.*
18. *The company will generally have a fixed list of prices that will be generally available to all purchasers, hospitals or surgery centers.*
19. *However, the company may be willing to accept lower pricing if the purchaser dictates lower fixed pricing. The payments by the purchasers will not be higher than fair market value for the devices.*

The CEO of Omega told *OTW* that he and the physician owners followed all these rules and risked a significant amount of capital. That risk is now in danger of becoming a loss. The sooner the government acts to advise physicians, manufacturers and distributors about the legality of PODs, the better. There are too many implants in warehouses in limbo. ◆

Battlefield Orthopedics: One Unit, 15 Months

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

Thankfully, most Americans don't live in a world of armored Humvees and improvised explosive devices (IEDs). But those who do…those who wake up in a compound or tent every morning in Iraq and Afghanistan and head out to do battle deserve the finest musculoskeletal care that the United States can provide. Lieutenant Colonel Philip Belmont, Jr., M.D. is one of the dedicated military orthopedists who is trying to ensure that this happens. Dr. Belmont: "We have a solemn covenant, not only to conserve the fighting strength of the U.S. military, but also to provide the best possible musculoskeletal surgical care to our soldiers."

And to know how to improve, one must get a lay of the land. To this end, Dr. Belmont and his colleagues undertook the first prospective, longitudinal analysis of a large combat-deployed unit in which musculoskeletal combat casualty care incidence rates could be accurately calculated.

Describing the origins of this work Dr. Belmont states, "The most significant impetus for our study was the fact that more than half of all injured soldiers in Iraq and Afghanistan reported extremity wounds. While there is now widespread use of body armor and vehicular armor, as well as a highly integrated trauma system, we are still seeing massive extremity injuries due to the enemy's use of deadly IEDs. My colleagues and I decided to study one unit from beginning to end so that we could examine the full spectrum of injuries with a known denominator…this enabled us to determine the incidence of each type of injury as well as the mechanisms of injury. We studied this group of soldiers for 15 months, and hopefully captured information that sheds light on the impact of the evolving nature of conflict on U.S. troops."

U.S. Military staff/Wikimedia Commons

"While there is now widespread use of body armor and vehicular armor, as well as a highly integrated trauma system, we are still seeing massive extremity injuries due to the enemy's use of deadly IEDs. My colleagues and I decided to study one unit from beginning to end so that we could examine the full spectrum of injuries with a known denominator…this enabled us to determine the incidence of each type of injury as well as the mechanisms of injury."

Spc. Henry/Wikimedia Commons

Creating the Data Base

True surgeon-researchers, Dr. Belmont and his team knew that they needed a full understanding of the nuances of the data collection and analysis—no small task given that there were 4,122 soldiers deployed with the brigade combat team. He states, "We created a casualty database, used electronic medical records, and utilized an existing combat casualty roster of the unit. The military's Joint Theater Trauma Registry (JTTR), a prospective database, was also helpful as it contains information on each injured soldier who goes to a hospital or is treated by a surgical team. There have been more than 40,000 trauma cases entered within the JTTR database and data collection now occurs over a period of days instead of months. The JTTR has been used to assess the epidemiology of combat injuries and musculoskeletal combat injuries to the extremities as well as to evaluate the effectiveness of treatment modalities on combat casualty outcomes. By using all of these resources we were able to capture nearly 100% of musculoskeletal combat injuries."

But how exactly is musculoskeletal combat casualty

defined? "Musculoskeletal combat casualty definitions can significantly affect casualty analysis results," indicates Dr. Belmont. "The inclusion of soldiers killed in action, those returned to duty, and those with non battle injuries in any cohort analyzed will affect the distribution of musculoskeletal wounds and mechanism of injury. Similarly, inclusion of only the primary or dominant wound, without taking into account secondary wounds, can also lead to altered data. As a result, the reporting of musculoskeletal combat wounds from previous wars may be biased toward more severe injuries, with less severe wounds being overlooked. In contrast, the data presented here includes all musculoskeletal combat wounds sustained by soldiers wounded in action."

With an eye toward improving on past attempts to capture this data, Dr. Belmont states, "Previous studies of musculoskeletal combat casualties were compiled from hospitals or surgical treatment facilities and generally excluded soldiers evaluated and treated in an ambulatory setting. The result is that you have an underestimation of the magnitude and nature of orthopedic combat casualties."

Primary Findings

So what are the details on that unfortunate news? "Our primary findings were twofold. First, we can see how the enemy has changed, i.e., their increasing reliance on explosive devices and the fact that these devices are especially deadly. In our study, we found that 36.4% of all soldiers who sustained musculoskeletal combat injuries were lost from the theater of operations… something that is attributable to the effectiveness of the enemy weaponry and tactics. The good news, however, is that our military medical system has not only become more advanced, but it is better integrated and can thus provide level one trauma care within an hour of an injury—the standard goal now. When a soldier gets injured, the first combat lifesaver is their buddy or the medic. This person will perform first aid, may apply a field tourniquet, and will give the soldier pain medication. At that point they call in for an evacuation (usually by helicopter)."

"The next phase of treatment is when the injured soldier goes to a level two or three center. Level two is a forward surgical team, which is normally comprised of 20 people, including one orthopedic surgeon. This team, which focuses on stabilizing life threatening injuries, is with the unit, but is contained away from the fighting. Level three care is at a combat support hospital (usually located in one of the larger military bases). And of course, the military does its best to protect soldiers with body armor, Kevlar helmets, as well as armored vehicles. Think about the difference, say, between the Korean War and how things are today…now, a soldier can sustain direct fire to the head or torso in some cases with little or no injury. That is progress."

Costs and Benefits

And the cost of this progress? "Many more severely injured soldiers are surviving their wounds, in part because the Department of Defense has made it a priority to improve armored tactical vehicles and thereby increase crew protection by initiating the Mine Resistant Ambush Protected (MRAP) vehicle program. Casualty figures suggest that the quick pace of the development of MRAP vehicles with 'V' shaped hulls has helped to reduce U.S. military fatalities from IED attacks. Figures compiled on the website icasualties.org reveal that in 2009, the percentage of U.S. military service members who were killed in IED attacks decreased to 40% compared to 50% in 2008. All of this is great news…but it does mean that the volume of surviving soldiers requiring extensive, often long-term treatment, has increased significantly. In fact, the estimated initial hospitalization and projected disability benefits for soldiers sustaining combat extremity wounds in Iraq and Afghanistan between October 2001 and December 2005 is $1.66 billion dollars."

From the site of battle, all the way to U.S. military facilities such as Walter Reed, there is always a bill that must be paid. And generally speaking, the payment involves a substantial amount of fracture care, soft tissue treatment, and

amputations. Dr. Belmont notes, "Of the 242 soldiers in our study who experienced musculoskeletal injuries, 24% had fractures and 36% had soft tissue wounds; approximately 9% of those injured in this study sustained major amputations. In the future we need to closely examine our outcomes with regard to complex limb salvage, spine treatment, and long bone fractures. Walter Reed and Brooke Army Hospital are leading the way and following patients longitudinally."

Regarding the issue of how to handle the threat of IEDs and other deadly munitions, Dr. Belmont leaves that to the military brass. "I feel that it is not necessarily my place to suggest how to change things but instead I would like to focus on how to best treat the musculoskeletal combat casualties of the all-volunteer force. All military orthopedic surgeons fully understand not only their role in providing optimal treatment to musculoskeletal combat casualties in order to conserve the fighting strength of the military but also the solemn covenant of providing the best possible musculoskeletal surgical care to those brave United States military service members who defend our nation. The all-volunteer force's exceptional performance coupled with the sacrifice of its human treasure upon the battlefields of Iraq and Afghanistan should continually remind us all that service in the defense of the country is a fundamental responsibility of citizenship."

Next Steps

The Combat Musculoskeletal Injury Study has resulted in ground gained for the U.S. military. To make even more progress, states Dr. Belmont, there is no getting around further research. "While our study has allowed us to determine exactly how many soldiers are at risk of injury and enables the calculation of musculoskeletal combat casualty care statistics, only a large, prospective, and scientifically rigorous study of all soldiers wounded in Iraq and Afghanistan can truly characterize musculoskeletal injury patterns in the present conflicts. We hope that this study may serve as an initial benchmark, to which future investigations on this topic can be compared." ◆

company

NuVasive; Sunny 1Q in San Diego

Alex Lukianov was in a very good mood. He even let analysts ask more than the allowed number of questions during the company's first quarter earnings call on May 4.

And why shouldn't the Chairman and CEO of NuVasive, Inc. be happy to answer extra questions? His company just announced that revenue rose 14% during the first quarter and was confident enough about the remainder of 2011 to raise full year guidance by $5 million. The company now expects revenue between $530 million to $540 million for the year.

New Product Launches

The optimism for the remainder of the year was driven by the expected launch of the company's PCM motion preserving device for the cervical spine and Progentix, a synthetic biologic. Lukianov also noted the anticipated launch of the company's MaXcess 4 late this quarter. He said the retractor "is the culmination of our years of XLIF experience. The retractor has been redesigned for strength, precision, fluorovisibility, and seamlessly integrated neuromonitoring, which will make the XLIF procedure even more reproducible and easier to learn."

But this call with analysts wasn't about the company's performance; it was about the state of the spine market. It has become a given by many that NuVasive is a proxy for the spine industry as the largest pure play spine company.

Sunshine/Wikimedia.org

Lukianov: Last Man Standing

The call made clear that Lukianov has seized the mantle of industry leader in working with spine societies to fight the pushback from insurers as private payers have increased the level of scrutiny and the enforcement of criteria necessary to preauthorize lumbar surgery. While Medtronic continues its search for a new leader and uncertainty exists as DePuy and Synthes combine their spine operations, Lukianov seems like the last man standing to take the fight to Milliman and insurers.

Stabilized Payor Landscape

Lukianov noted the reimbursement environment began to deteriorate late in the third quarter of 2010. But now, says the Chairman, the landscape is stabilizing after compressing by 10% tp 20% and he feels confident that NuVasive is "appropriately forecasting" the impact of this new landscape. In fact, Lukianov believes that surgeons are getting better and more efficient in getting payor denials overturned. He expressed confidence that efforts by the spine societies to formulate new surgical guidelines will make sense to insurance companies and will allow the market to resume high single digit growth in the future.

According to Lukianov, minimal disruptive spine procedures will reach $1.8 billion in revenue in 2011 and still only constitutes 20% of the market. He believes that percentage will eventually reach 80%, and NuVasive will continue to outpace the market in grabbing that additional revenue.

DePuy/Synthes Opportunity

Lukianov believes the uncertainty of how the DePuy/Synthes merger will impact those companies' sales staffs gives NuVasive an opportunity to expand its own sales force. He believes many of Synthes' directs sales staff will not want to join the distributorship model of DePuy.

Improved Lumbar Outlook

In conclusion, Lukianov told analysts, "We are pleased to be able to raise revenue guidance today in light of a mar-

ginally improved outlook for our U.S. lumbar business this year. As our focus shifts toward the achievement of our next milestone, the evolution of NuVasive into a $1 billion revenue company, we are laser focused on maintaining the startup mentality that is the very source of NuVasive's success as a prolific new product innovator. With speed as our competitive edge, we expect to continue to sustain industry leading growth."

It's always sunny in San Diego.

—WE (May 6, 2011)

Orthofix "Takes Medicine" in First Quarter

Orthofix International NV reported flat 2011 first quarter revenue of $139.2 million on May 5.

One might call it a quarter of "taking your medicine" as the company announced $46 million in charges related to two government investigations. One was for the anticipated resolution of the company's bone growth stimulation investigation. The other was in connection with a Foreign Corrupt Practices Act investigation of its former Mexican distribution entity.

Agreement "In Principle" With Government

The company reported that it has reached an agreement in principle with the United States Attorney's Office for the District of Massachusetts. The final settlement is subject to the negotiation and execution of definitive agreements with the United States Attorney's Office, the United States Department of Justice, and the Office of Inspector General of the United States Department of Health and Human Services.

"We [still] think that the resolution of the stimulation investigation is a significant positive since we think it will eliminate a major overhang," wrote Mizuho Securities analyst Mike Matson in a investor note on May 6.

Implants and Biologics Shine

Within the company's spine segment, the stimulation business dropped 8%, but implant and biologic sales saw a 14% increase. Orthopedic sales rose 6% and sports medicine sales climbed 5%.

Jefferies analyst Raj Denhoy wrote that stimulation remains a tough market: "Orthofix has achieved about 55% share, making further share gains harder. Also, the use of stimulation in spine has come under increasing insurance scrutiny. Still, the stimulation market remains underpenetrated. We view 3-5% as a sustainable growth rate for the segment, with Orthofix likely to underperform that mark in 2011 but returning to market growth in 2012."

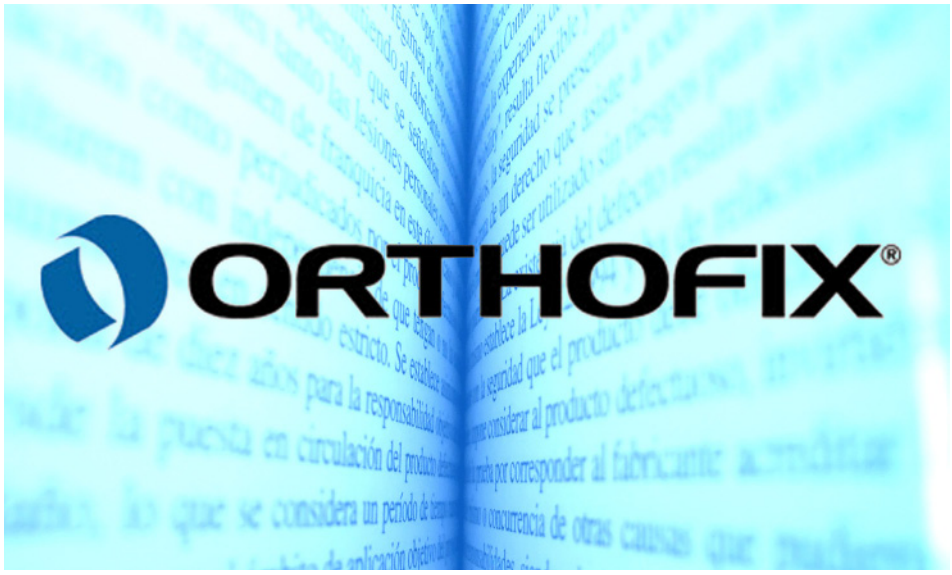
The growth in orthopedics was led by the company's external fixation platform along with the increased use of Trinity Evolution in orthopedic applications. Growth in the company's sports medicine market sector was due to improved performances of the bracing product lines.

The company reiterated its net sales guidance, which is expected to be between $580 million to 590 million for the full year 2011.

—WE (May 6, 2011)

Orthofix 1Q11	Sales $ in million	% Change
Total Reported Sales	$139.2	0.2%
Spine Stim	38.6	down 8.0%
Spine Implants/Biologics	34.0	14.0%
Total Spine	72.6	1.3%
Orthopedic	40.5	6.0%
Sports Medicine	24.7	5.0%

Source: Orthofix International NV.



Orthofix International NV

Dvorak's Sweet Music in 1Q11

Zimmer Holdings/Wikimedia Commons

"There was a lot that was good in Zimmer's 1Q11 results," wrote BMO Capital Market analyst Joanne Wuensch in an April 28 investor note. That must have been sweet music to Zimmer's President and CEO David Dvorak.

Volumes and price appear stable as the company reported a 5% increase in revenue to $1,116 million for the quarter.

Hips, knees and extremities sales were all up in the Recon division, which rose 3.4% to $842 million. Hips jumped 6.8%, knees rose 0.4% and extremities grew by 11.7%. Only spine showed a decline, dropping 5.2%. Trauma also did well, rising 16.1%.

Zimmer 1Q11	Sales $ in million	% Change
Total Reported Sales	**1,116**	**5.0%**
Reconstructive	$842	3.4%
Hips	337	6.8%
Knees	462	0.4%
Extremities	43	11.7%
Trauma	$70	16.1%
Spine	$57	down 5.2%

Source: Zimmer Holdings

Wuensch said that the company appears to be gaining share in hips and knees and new products appear to be gaining traction. Dvorak pointed out a 10% increase in research and development expenditures during the quarter and said he expected that trend to continue. Mizuho Securities analyst Mike Matson wrote that given Zimmer's new products launches and the ongoing metal-on-metal (MoM) hip issues facing competitors, the company can continue to gain market share over the next few quarters.

Dvorak told analysts that MoM hips had dropped from about 25% of the market to around 10%-15%. Zimmer was never big in MoM and now accounts for fewer than 5% of the company's hip sales, added Dvorak. He said the company's Continuum Cup hip device, among other products, was driving their growth.

Reporting after the announcement of the Johnson & Johnson/Synthes "Big Bang," Dvorak was asked by analysts what the merger meant to Zimmer. Dvorak said that scale does matter in orthopedics but the company "lives in musculoskeletal" and critical mass is more important than being #1 or #2 in every segment.

Larry Biegelsen, Wells Fargo's analyst, wrote that trauma, spine and dental are areas where Zimmer would most likely add scale. "Near-term, we think the JNJ/Synthes deal could create some disruptions, especially in spine, that could benefit Zimmer," said Biegelsen.

Dvorak was very bullish about the second half of 2011 as the company expects employment rates to rise giving more Americans health insurance coverage.

"Our first quarter performance demonstrated continued progress toward our goal of consistently achieving growth at or above market rates in all of our geographies and businesses. We will continue to deliver value to our stakeholders through product innovation, operational excellence initiatives and disciplined capital deployment," concluded Dvorak.

After having a target on his back due to declining sales following a significant disruption of physician consulting rela-

tionships during the federal monitoring process, stability and market share growth must, indeed, be sweet music to a guy named Dvorak.

—*WE (May 3, 2011)*

Ascension Orthopedics Hits 40,000 Milestone

Biocompatible can be very compatible with market success…Ascension Orthopedics, Inc., widely known for its pyrocarbon orthopedic implants, is announcing that they have reached an industry milestone with the distribution of more than 40,000 pyrocarbon extremity joint replacements worldwide.

Jerome Klawitter, Ph.D., Founder and Chief Science Officer of Ascension Orthopedics, is a pyrocarbon pioneer. He used the material in the manufacture of mechanical heart valves and small joint implants…and his collaboration with the Mayo Clinic led to the founding of Ascension Orthopedics in 1992. In 2000, the company launched its PyroCarbon MCP Total Joint; since that time, Ascension has been dedicated to successfully using pyrocarbon in both hemi and total joint arthroplasty applications. Currently marketed devices include pyrocarbon implants for the finger, thumb, wrist, elbow, shoulder and foot. Ascension has several other pyrocarbon-based extremity products at various stages of development that are not yet commercially available.

"Our commitment to research with pyrocarbon is based on the material's proven durability, enhanced wear resistance and biocompatibility against native bone and cartilage. The elastic modulus of pyrocarbon is very similar to cortical bone and allows a more effective transfer of load from implant to bone, reducing stress shielding and potential bone resorption. Pyrocarbon's combination of low surface friction and non-adhesive properties may contribute to the preservation of cartilage observed clinically. The body friendly characteristics of pyrocarbon make it an excellent choice for orthopedic applications," stated Klawitter in the May 3 news release.

To get up to your elbows in PyroCarbon implants, you could sign up for one of Ascension's anatomic workshops. These events are led by surgeon faculty in the U.S. and Europe, with the next scheduled workshops planned for Saturday, May 14 in Chicago, Illinois and Friday, June 17 in Guildford, UK.

—*EH (May 3, 2011)*

Ascension Orthopedics, Inc.

legal

Smith & Nephew "Mutineers" Fight Back

Three of the nine alleged Smith & Nephew mutineers accused by the company of planning to steal company secrets and compete with the company, are fighting back.

Walker Claims "Libel"

According to an April 21 article in the *Memphis Daily News*, Bonnie Walker, one of the employees fired by Smith & Nephew, has filed a counterclaim against the company.

The article quotes from her counterclaim: "On or about March 11, (Smith & Nephew) decided, incorrectly, that Ms. Walker had participated in the wrongful acts alleged in its original complaint against Ms. Walker... (Smith & Nephew) thereupon published written statements outside the pleadings in this action in which Smith & Nephew expressly accused Ms. Walker of a crime—to wit, stealing.

"As a result, Smith & Nephew has committed libel per se, for which Ms. Walker is entitled to recover actual, consequential and exemplary damages."

Walker's counterclaim also asserts Smith & Nephew has not paid an unspecified sum of money it owes her "pursuant to her employment contract."

Wald and Deken Claim "Owed Money"

Another of the fired employees, Andrew Wald, has filed a counterclaim asserting that he is owed money. His counterclaim, according to the article, says that the company "converted" funds from his bank account and failed to pay additional money owed to him.

A third former employee, Ashley Deken, filed a counterclaim similar in wording to Wald's. The article states that she also filed an affidavit in which she emphatically denied taking part in any improper scheme.

Wikimedia Commons

"I have not engaged in the conduct in which Smith & Nephew has accused me," Deken said in the affidavit. "I have not misappropriated or disseminated any trade secrets belonging to Smith & Nephew."

The company has accused the nine former employees of conspiring to use company trade secrets regarding Visionaire, a patient matched instrumentation program for knee replacement surgeries, to start their own competing business.

Andrew Burns, Smith & Nephews' spokesman told *OTW* last month that a temporary restraining order was issued against the former employees on March 11 and will stay in effect until a hearing scheduled for July 14.

—WE (April 28, 2011)

extremities

Exactech Launches Shoulder Plate

Very high level "tinkering"… Exactech, Inc. announced today that it is fully launching the Equinoxe Fx Plate after an extensive development process.

Exactech, Inc.

In the April 28 news release, Kenneth Egol, M.D., professor and vice chair at NYU Hospital for Joint Diseases in New York City and chief of the division of Orthopaedic Trauma, said that surgeons are reporting excellent early results through the use of this innovative new plate design. He noted: "The design team of surgeons and Exactech engineers worked diligently to identify clinical shortcomings common to complex shoulder fractures. We then collaborated to design an implant that

addresses those clinical challenges. We're excited about the fracture plate's potential to reduce humeral head collapse following a traumatic injury to the shoulder. It also allows surgeons to deploy bone void filler after the plate is seated, which we have shown to minimize head collapse and thus improve outcomes in clinical practice."

"From a strategic perspective, offering surgeons the ability to call one sales representative to provide the full array of solutions for a clinical challenge is differentiating and adds meaningful value," added Darin Johnson, Exactech's marketing director, extremities.

Dr. Egol told *OTW*, "In the design team's vast clinical experience we noted three major areas of concern for fracture—construct failure:

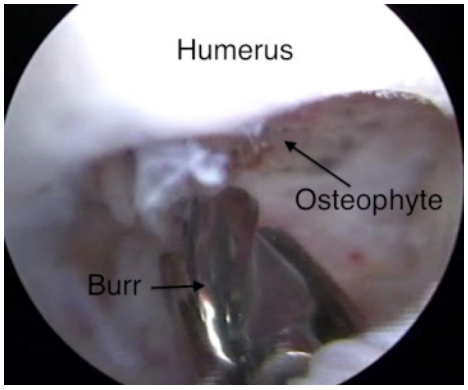
1. Varus displaced fractures subject to shear loads
2. Locking screw penetration of the humeral head
3. Adjunctive rotator cuff fixation to the implant to aid in construct stability."

"We believe we have addressed each issue with simple solutions. We offer the surgeon the ability to utilize a modular blade in lieu of proximal screws. In internal testing we have shown the increased surface area of this type of fixed angle fixation counteracts shear seen at the cortex. Also, we have added a port for 'graft' delivery to the fracture site void. We have clinical data showing the addition of CaPO4 cement helps resist humeral head settling and thus screw penetration. This work has been presented at the Annual meeting of the Orthopaedic Trauma Association in 2010 and at the annual meeting of the AAOS in 2011. This modification to the plate allows this step to be performed at any time during the procedure. Finally, we have improved upon the current designs of 'in-plate' suture holes. This modification enables the surgeon to pass the cuff augmentation sutures after the plate and screw construct has been applied as opposed to prior to plate application. We believe this modification will allow all treating surgeons to utilize this aspect of fixation, even if forgotten until the end of the case."

—EH (May 4, 2011)

Innovation for Shoulder OA

Validation—and liberation—for aching shoulders…The Steadman Philippon Research Institute (SPRI) in Vail, Colorado, has recently validated a new treatment developed by Peter Millett, M.D., M.Sc., to help manage the symptoms associated with osteoarthritis of the shoulder. In the initial study group that has undergone the CAM (Comprehensive Arthroscopic Management) procedure, the vast majority reported a significant improvement in the pain, stiffness and overall weakness related to the disease. The initial data will be reported in *Arthroscopy.*



Steadman Philippon Research Institute

Dr. Peter J. Millett, an orthopedic shoulder surgeon and sports medicine specialist with The Steadman Clinic said in the April 28 news release, "The CAM procedure was developed because we began to see a higher occurrence in younger patients—predominantly athletes—with advanced arthritis of the shoulder. In addition, older patients who wish to remain active were in need of other options in order to delay total joint replacement surgery."

During the CAM procedure, damaged cartilage and labral tissue is removed and regenerated. Scarred ligaments and capsular tissues are released to restore mobility. The most important aspect of the procedure is the decompression of the axillary nerve; freeing up this nerve alleviates much of the pain associated with osteoarthritis of the shoulder.

Dr. Millett told *OTW*, "We developed the CAM procedure because I was seeing so many young patients with glenohumeral osteoarthritis who wanted to remain active and who did not want to undergo joint replacement. I wanted to develop a joint preservation procedure for these patients. I knew from some of the joint preservation work at our clinic on knees (Dr. Steadman) and hips (Dr. Philippon) that the concepts of alleviating the stiffness and re-shaping the bones could help. I THEN made the critical observation that many of the patients I was seeing were complaining not only of stiffness but also of pain in the back and side of the shoulder. These areas are innervated by the axillary nerve. I hypothesized

(1) that this nerve could be getting compressed or entrapped by the large inferior bone spurs that typically occur in osteoarthritis of the shoulder,

(2) that the nerve compression could be contributing to the symptoms, and

(3) that this might be alleviated by decompressing the nerve arthroscopically (removing the bone spurs and freeing up scar tissue around the nerve).

"We now have anatomic data from several MRI studies and clinical outcome data from another study that support this concept and validate the CAM procedure as a treatment option. Most important, we have many grateful patients, some now up to four or five years out from surgery, who are active and pain free."

—EH (April 29, 2011)

large joints

93-Year-Old Gets Knees

Orthopedic surgeons in India tested the limits of joint replacement surgery in two recent cases. One was bilateral knee replacement surgery on a 93-year-old man and the other was a hip replacement on a woman who, because of severe rheumatoid arthritis, had been unable to sit up for 20 years.

Dr. Raju Vaishva, senior consultant in orthopedics at Apollo Hospital in Delhi, performed the knee surgery on SN Bhatt on April 14. "He came to us in 2010 with a history of osteoarthritis for the past ten years. He had been confined to using a wheel chair as the disease led to progressive knee pain and deformity in both the legs," said Vaishva.

Bhatt, a retired college administrator, said, "I am a living example for the people who think that there is no life after the age of 60. People who are above 60 should stop feeling miserable and think of living a quality life."

Vaishva believes that Bhatt is "the oldest man in the country to have undergone this surgery. Though a surgery at this age is a risky affair if other complications are involved, in Bhatt's case there was none so it became easy to conduct the surgery. He is an active man with no additional aging ailments."

The situation was very different for Pushpalata Sawant, who has been bedridden for 20 years with rheumatoid arthritis. Because the patient did not move appreciably over this period, several joints below her neck, including her knees and hips, fused over time.

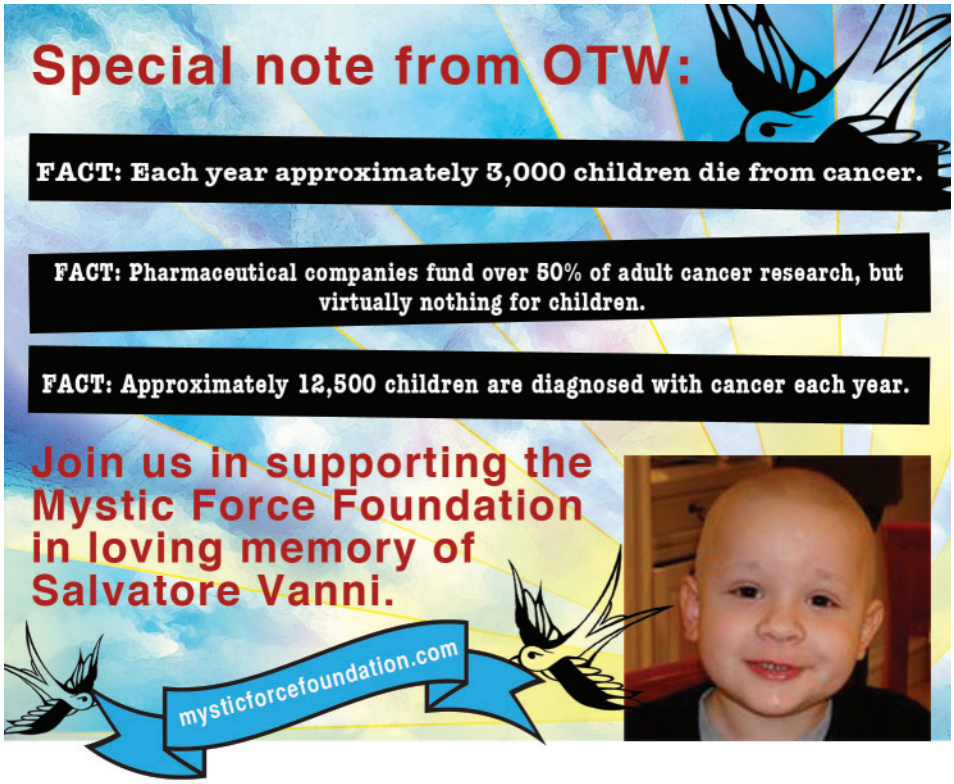
Last week, the 53-year-old Sawant underwent hip replacement surgery. She can now sit up. In another three months, doctors plan to perform knee replacement surgery to enable her to use her knees as well. "The surgery has been performed and she is sitting after

Anton Azbe/Wikimedia Commons

20 years," said Pushpalata's mother. "After the knee operation, she will be able to bend her knee," said doctors.

"Her surgery was delayed because the Sawants could not generate funds for the operations. A lot of donations have come through now," said Dr Shreedhar Archik, a consultant orthopedic surgeon at Lilavati Hospital, Mumbai. Doctors say there is no surgery to rectify the fusion of bones in Sawants' neck and spine.

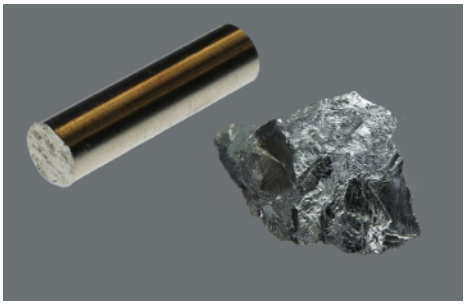
—BY (May 6, 2011)



Courtesy of RRY Publications LLC

Zirconium or Chromium: a Toss-Up

If you are a fan of either oxidized zirconium or a cobalt-chromium for femoral components in total knee arthroplasty hold your applause because, once they are installed in a patient, there appears to be no difference. That is according to a study published in the April 6 issue of *The Journal of Bone & Joint Surgery.*



Zirconium rod/Chromium/Wikimedia Commons

Catherine Hui, M.D., from the North Sydney Orthopaedic and Sports Medicine Centre in Australia, along with her colleagues, compared the performance of oxidized zirconium femoral components with cobalt-chromium. They hoped to learn whether the use of oxidized zirconium components had adverse clinical effects. Previous studies had suggested that oxidized zirconium on ultra-high molecular weight polyethylene had better wear properties than cobalt-chromium on the same polyethylene.

Forty patients (eighty knees) with primary osteoarthritis underwent simultaneous bilateral cruciate-retaining total knee arthroplasty. For each patient, the two knees were randomly assigned to receive either the oxidized zirconium femoral component or the cobalt-chromium component.

The investigators found no significant postoperative differences in the clinical, subjective, and radiographic outcomes between the oxidized zirconium and cobalt-chromium implants at five days; six weeks; and one, two, and five years. Outcome measures included the Western Ontario and McMaster Universities Osteoarthritis Index, Knee Injury and Osteoarthritis Outcome Score, Knee Society Score, and British Orthopaedic Association Patient Satisfaction Scale. Radiographic outcomes include the Knee Society total knee arthroplasty roentgenographic evaluation and scoring system and measurement of radiographic wear. Patients and assessors were blinded to the treatment groups and results. The oxidized zirconium femoral implants showed no adverse events.

A follow-up five years after surgery showed that 44 % of the patients had no preference as to which knees had been implanted. Of those who did, 38 % preferred the cobalt-chromium prosthesis compared with the oxidized zirconium knee.

—BY (May 5, 2011)

trauma

One-Sport Kids at Risk

Young athletes who specialize in one sport have more injuries than those who engage in multiple activities, according to a study by the Loyola University Health System. According to the study, specialization appears to increase the risk of injuries.

The investigators enrolled 154 athletes with an average age of 13 into their study. Eighty five of the participants had come to Loyola for treatment of injuries while 69 were there to get sports physicals.

"Young athletes who were injured tended to have more intense specialized training in one sport," said Dr. Neeru Jayanthi, medical director of primary care sports medicine and senior author of the study. He believes parents and coaches should be cautious about intense specialization in one sport before and during adolescence. Jayanthi presented his findings at the annual meeting of the American Medical Society for Sports Medicine on May 2.

The researchers graded the athletes in the study on a six-point sports-specialization score:

- Trains more than 75% of the time in one sport
- Trains to improve skill or misses time with friends
- Has quit other sports to focus on one sport
- Considers one sport more important than other sports
- Regularly travels out of state
- Trains more than eight months a year, or competes more than six months.

The average sports-specialization score of uninjured athletes was 2.75, while the average score of injured athletes was 3.49.The study found that 60.4% of the injured athletes specialized in sports, while only 31.3% of the uninjured athletes specialized.

Jayanthi said young athletes should be closely monitored for injuries, especially if they spend 11 or more hours a week in a single organized sport or more than 20 hours a week in all sports. Injuries in young athletes include minor conditions such as muscle strains and knee cap pain, overuse injuries such as rotator cuff tendonitis and Osgood-Schlatter disease (painful lump below the kneecap) and severe injuries such

Wikimedia Commons

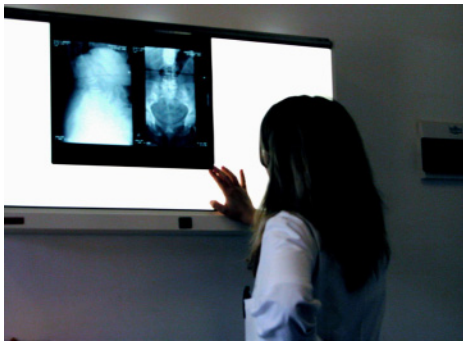
abnormalities in knee cartilage and stress fractures in the spine.

While young athletes are specializing in all major sports, Jayanthi said the most intense specialization occurs in certain higher skill sports such as tennis, gymnastics and dance.

—BY (May 6, 2011)

Study Supports Bisphosphonate/Fracture Connection

More data, less debate?…Recently, the suspected connection between bisphosphonates and fractures was confirmed as a result of a study led by Per Aspenberg, professor of prthopedics and researcher at Linköping University in Sweden. The national study, which included 12,777 women 55 years or older who had fractures of the femur, has been published in the May edition of the *New England Journal of Medicine*.



Bastet78/Wikimedia Commons

A total of 59 subjects were diagnosed as having fatigue fractures (atypical femoral fractures). Of these patients, 78% had taken bisphosphonates whereas only 5% of the general population had received the same treatment. The relative risk of an "atypical" fracture is increased 50 times with bisphosphonate treatment, but the absolute increase in risk is only 5/10,000-treatment years.

The authors indicate that the connection between the bisphosphonates and the fractures is so strong that they can confirm a causal connection. However, this study also indicates that the risk of fatigue fractures diminishes once a patient ceases to be administered bisphosphonates. Following a one-year cessation from the

medication, the risk of a fracture occurring is reduced by 70%.

"This may indicate that one should use the types of bisphosphonates that are administered seldom, and that the medication should be concluded after some years' treatment," said Professor Aspenberg in the May 5 news release.

He added, "The principal effects of bisphosphonates remain: They significantly reduce the risk of fractures in patients with osteoporosis. So even if a negative connection has been established, this relates to a very small group and minimal overall risk. Bisphosphonates prevent many more fractures than they cause. All forms of medication retain side effects and one needs to be aware of that. It is important to only use medication when needed and it should not be prescribed for healthy people."

"We conducted a similar study in 2008 but on a smaller scale; where we delivered similar results. That study was published in Acta Ortopaedica, which is a lesser-known journal and it did not get attention from the research community."

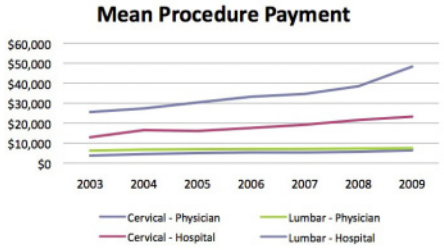
—EH (May 6, 2011)

reimbursement

Hospitals Trump Docs for Fusion Payments

Hospitals have seen a 9.5% annual increase in payments from private payers for lumbar fusion procedures over the last six years. Physicians only saw a 2.6% increase over the same time period.

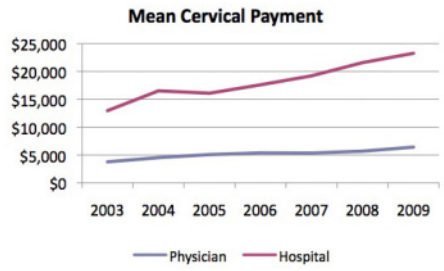
"Wow, I had no idea," said a spine surgeon to Zimmer, Inc.'s Mark Domyahn, MBA, at SAS's 2011 Annual Meeting held the last week of April in Las Vegas.



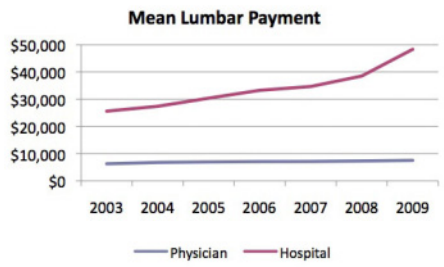
Mean Fusion Procedure Payment. Source: Zimmer, Inc

Domyahn, Zimmer's Director, Global Market Access, Policy & Reimbursement, had just shown the surgeon data that showed hospitals were seeing significantly higher increases in payments for spinal fusion procedures than physicians. The data came from a poster presentation titled: "Trends in Commercial Insurance Payments to Hospitals and Physicians for Spinal Fusion Procedures".

According to Domyahn and his team's analysis, between 2003 and 2009, hospitals saw annual mean fusion procedure payments increase by 7.8%. Physicians only saw a 3.3% increase. For cervical fusion procedures, hospitals saw their annual mean payments rise by 8.7%, while physicians saw only a 7.9% rise. For lumbar fusion procedures the numbers were more pronounced. Hospital saw annual mean payments jump by 9.5%, while physicians saw only a 2.6% annual rise.



Source: Zimmer, Inc.



Source: Zimmer, Inc.

As more hospitals snatch up private practices and physicians become employees or contractors, it is important for physicians to be armed with good data on their value to the hospital. That will be even more important as physicians hook up with hospitals in Accountable Care Organizations.

Domyahn told *OTW* that based on the Zimmer analysis; it appears that hospitals have been more successful in negotiating with commercial payers regarding reimbursement rates compared to physicians. "This may be due in part to the low changes to the Medicare physician fee schedule over the past decade," said Domyahn.

The Zimmer study was a retrospective database audit with data derived from the Thomson Reuters MarketScan Commercial Claims and Encounters Database from January 1, 2003 through December 31, 2009. During this period, 142,245 inpatient admissions for spinal fusion procedures were identified.

According to the poster: "Hospitals looking to maximize revenue are focusing on high growth and highly profitable procedures. Spinal fusions represent one of the fastest growing and most profitable procedures performed in hospitals. This is due in part to the payer mix of spinal fusion procedures, as the majority of these

procedures are commercially insured patients (52.2%). While Medicare physician and hospital payment rates are publicly available and commonly referenced, commercial payments to hospitals and physicians for spinal fusion procedures are not well documented in the literature."

"We want surgeons to have the same picture as hospitals of private payment data," said Domyahn.

—WE (April 29, 2011)

Mean Commercial Insurance Payment — PHYSICIAN ($)									
Description	ICD-9 Proc. Code	YEAR							CAGR
		2003	2004	2005	2006	2007	2008	2009	
Cervical									
Cervical fusion, anterior	81.02	$3,562	$4,246	$4,964	$5,251	$5,158	$5,402	$6,192	8.2%
Cervical fusion, posterior	81.03	$6,295	$7,591	$6,875	$7,187	$7,732	$9,018	$8,984	5.2%
Weighted Average - Cervical		**$3,761**	**$4,520**	**$5,063**	**$5,372**	**$5,334**	**$5,677**	**$6,407**	**7.9%**
Thorocolumbar and Lumbar									
Dorsal and dorsolumbar fusion, anterior technique	81.04	$6,873	$7,048	$7,353	$7,129	$7,274	$7,300	$9,203	4.3%
Dorsal and dorsolumbar fusion, posterior technique	81.05	$6,401	$7,953	$7,836	$8,457	$8,072	$9,172	$10,414	7.2%
Lumbar and lumbosacral fusion, anterior technique	81.06	$5,244	$6,567	$6,747	$6,969	$7,276	$7,248	$7,387	5.0%
Lumbar and lumbosacral fusion, lateral transverse process technique	81.07	$5,377	$5,757	$6,598	$6,253	$5,382	$6,724	$6,646	3.1%
Lumbar and lumbosacral fusion, posterior technique	81.08	$6,236	$6,546	$6,657	$6,906	$6,938	$7,018	$7,299	2.3%
Weighted Average - Lumbar		$6,262	$6,762	$6,950	$7,076	$7,115	$7,286	$7,516	2.6%
Total Spinal Fusion		**$5,596**	**$6,272**	**$6,450**	**$6,624**	**$6,666**	**$6,870**	**$7,041**	**3.3%**

Source: Zimmer Holdings

Mean Commercial Insurance Payment — HOSPITAL ($)									
Description	ICD-9 Proc. Code	YEAR							CAGR
		2003	2004	2005	2006	2007	2008	2009	
Cervical									
Cervical fusion, anterior	81.02	$11,796	$14,867	$15,091	$16,166	$17,456	$19,285	$21,532	9.0%
Cervical fusion, posterior	81.03	$27,734	$35,190	$34,450	$39,322	$43,331	$49,762	$44,192	6.9%
Weighted Average - Cervical		**$12,958**	**$16,531**	**$16,096**	**$17,610**	**$19,224**	**$21,599**	**$23,280**	**8.7%**
Thorocolumbar and Lumbar									
Dorsal and dorsolumbar fusion, anterior technique	81.04	$16,917	$16,687	$18,998	$19,730	$20,661	$23,324	$54,812	18.3%
Dorsal and dorsolumbar fusion, posterior technique	81.05	$35,062	$40,835	$41,356	$58,862	$52,739	$57,964	$82,901	13.1%
Lumbar and lumbosacral fusion, anterior technique	81.06	$30,643	$36,438	$41,102	$43,508	$49,227	$51,733	$55,963	9.0%
Lumbar and lumbosacral fusion, lateral transverse process technique	81.07	$24,056	$24,667	$33,631	$33,090	$33,303	$40,292	$43,684	8.9%
Lumbar and lumbosacral fusion, posterior technique	81.08	$27,926	$29,362	$33,218	$34,822	$36,209	$40,173	$43,299	6.5%
Weighted Average - Lumbar		$25,594	$27,386	$30,377	$33,256	$34,655	$38,504	$48,337	9.5%
Total Spinal Fusion		**$22,233**	**$25,015**	**$26,593**	**$29,104**	**$30,761**	**$34,136**	**$37,604**	**7.8%**

Source: Zimmer Holdings

THE PICTURE OF SUCCESS

Dr. George Bagby, Part I

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

Caption

Declared legally blind at the age of 15, George Bagby could have let this fate write his story. Instead, he put on his new, rose-colored glasses and saw a world of opportunity. Dr. Bagby, inventor of the Self Compression Bone Plate, is now 88 years of age…and he is just now introducing a new technology that could make significant inroads into less expensive care in the developing world.

Along the way he has altered the fate of non-humans in orthopedic need as well. In fact, Dr. Bagby's technology went a long way toward improving the life of Triple Crown Winner Seattle Slew.

From medical school at Temple University, to the life of a country doctor in Minnesota…to the life of a medic in Korea, and then his orthopedic training at Mayo Clinic, Dr. Bagby has held on to some fundamental principles, one of which is, "Do what you say you are going to do."

Indeed, Dr. Bagby doesn't make idle promises. Yes, this is because of ethics…but also because of a longstanding fear of a spanking. Dr. Bagby explains: "At the age of five I snuck into the woods behind our house in Waco, Texas, and decided that I was going to smoke some cedar bark. I ended up being spanked by my parents—with my pants up. Afterwards, my Mom and Dad informed me that if I ever did that again I would have a spanking with my pants down. The message that I took away was: 'If I ever said that I would do something and I didn't then I would be a liar.' Even years later when I went to Korea during the war and became a tobacco smoker, I felt the old fear returning as our troop ship approached the U.S. I was convinced that somehow, my mother would spank me…so I put aside cigarettes forever that day."

Dr. Bagby, who is upset if he tells someone he will arrive at 3pm, but arrives five minutes late, says his devotion to the truth has helped him evaluate patients throughout the years. "There are times when patients, for whatever reason, are not telling the full truth. If I suspected that someone was, say, faking a limp, I would tell them, 'OK, we are done. Put on your clothes and go home.' Then I would look out the window and see that person walking down the street with no limp."

Dr. Bagby was accustomed to being a few steps in front of others. He explains, "While doing my pre-medical training in 1942 I was anxious to get into medical school because I knew it was more appropriate to help the military in the medical field than to be on the front line of the war in Korea. At the time, two years of premed training were

"Somehow, the government thought that I had three *years* of surgical training, as opposed to three months. I ended up at the 171st Evacuation Hospital, where I clearly explained my limitations to Dr. Ed Otis, a well-trained orthopedist. We proceeded, however, and he monitored my surgical work…these were the first inklings that I would become an orthopedic surgeon."

required to enter medical school, but to be competitive, it was better to have three or fours years. As I was about to start my third year of premed training I received a letter of acceptance to Temple Medical School. Coming at such a time of starting my third year of premed training and having been turned down elsewhere for the second year, I thereby misread the letter and assumed that Temple was accepting me for the third year. After rereading it I realized they were accepting me for two years, and that in three days I had to board a train from Minneapolis to Philadelphia to get there in time. This was a watershed moment in my life and I was just ecstatic."

After the hubbub of Philadelphia, Dr. Bagby settled into a solo country practice in Minnesota for four years, then went to Mayo Clinic to refine his talents. "I began my surgical training at Mayo Clinic, but was only there three months when I was called to serve in Korea. Somehow, the government thought that I had three years of surgical training, as opposed to three months. I ended up at the171st Evacuation Hospital, where I clearly explained my limitations to Dr. Ed Otis, a well-trained orthopedist. We proceeded, however, and he monitored my surgical work…these were the first inklings that I would become an orthopedic surgeon."

Brilliance is often disguised as something simple…we just have to see it. When asked about what is behind his success, Dr. Bagby notes, "I am inclined to see little things that others often miss. This is largely because I cannot read quickly, and don't enjoy watching TV, so I find my pleasure in being very aware of my surroundings. The most significant example I have of this is related to my invention of the first compression bone plate (during my time at the Mayo Clinic). One day I noticed that my screen door was sagging, and I accidentally offset a screw and saw that the wood shifted laterally relative to the metal plate. Although this was an accident, I had learned in Korea that compression was very important and came home to Rochester, Minnesota, with the hope of creating some practical compression for a bone plate for fracture fixation. This led me to begin research on dog's femurs and I eventually earned an MS degree in orthopedics at Mayo Clinic. This work resulted in the first Self Compression Bone Plate, a new technology that did not require an added anchor or additional device to create the compression because the screw and plate arrangement became 'Self Compressing.'"

Dr. George Bagby, Inventor of the Self-Compression Bone Plate(1956) and Distraction-Compression Bone Cage (1982).

Dr. Bagby also gives credit to his time in Korea for setting the stage for such an

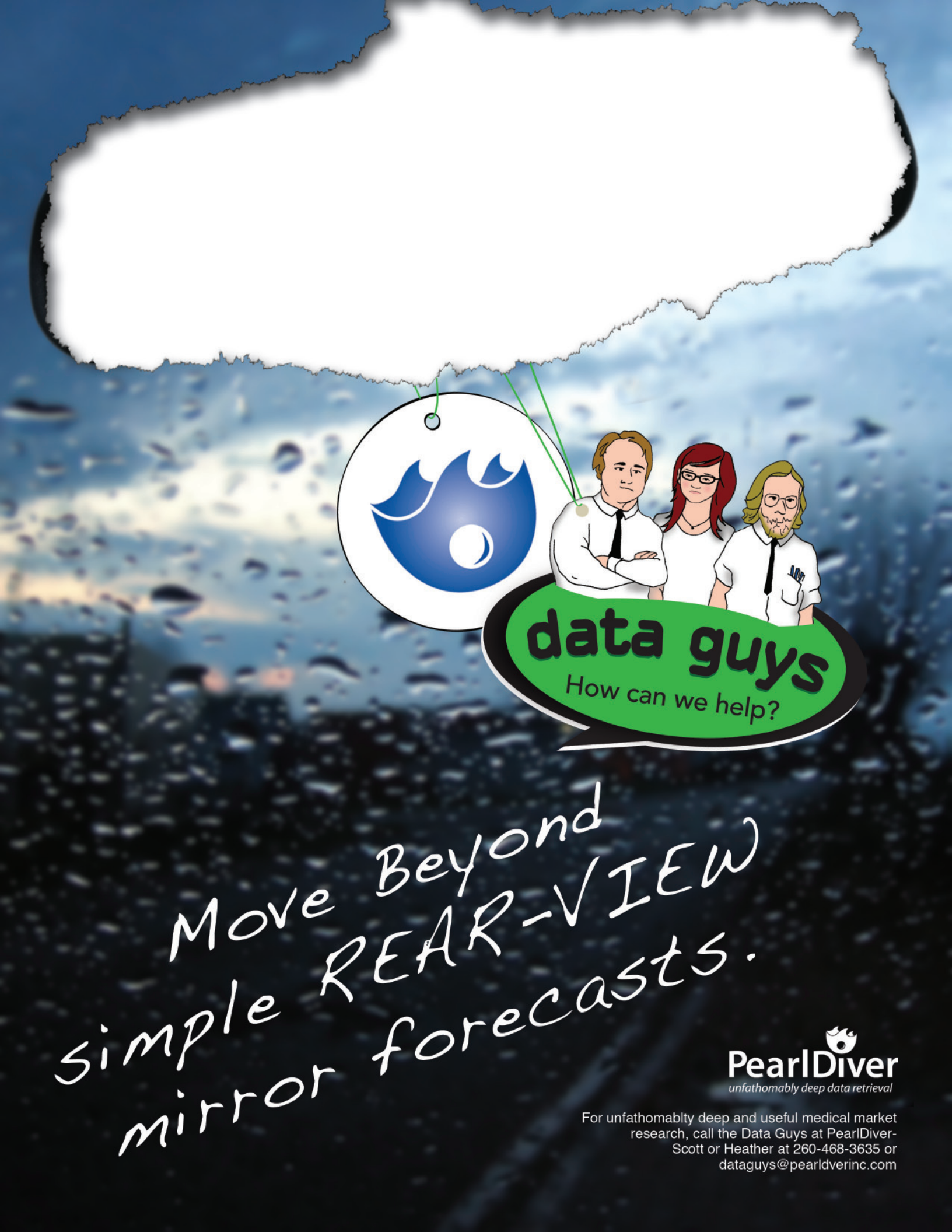
invention. "During the war it was very common for fractures to be treated with traction—for months, even. These were war wounds and so we needed to avoid open reduction and internal fixation. We were fortunate to have a visiting Colonel who specialized in orthopedics; he went from hospital to hospital 'preaching' about how traction pulled the bone apart and slowed healing. I guess I was paying attention when he said that we should be using compression and pushing the bone together."

Detailing the development of his Self Compressing Plate, Dr. Bagby states, "Previous plates meant to encourage compression at the fracture sight were such that the fenestrations in the plate were elongated and the screws were put in loosely. This allowed post operatively the muscles to contract and pushed the bones together. The looseness interfered with the healing process more than the advantage of the compression it created. Other past attempts involved an additional surgery on the plate and screws to create an anchor that was used to push a bone together with the other one. Although the anchor was projecting and had to be removed, it would be removed at the end of surgery before closing the wound. These are just two examples of several implants catering to compression. Worthy of note is that I did not patent it…it was patented by others through the U.S. patent office. In time it was legally considered emasculated and thereby all companies could use it without paying anything to any other than the company that manufactured it. Given that my associates and I in Spokane had treated numerous patients with this technology, and that we published the results in the *American Journal of Orthopedics*, my involvement was obvious."

Whether studying in the medical library or focusing his attention on incoming patients and incoming munitions, Dr. Bagby has had to live with the challenge of limited vision. "Having to be so strongly dependent on corrective eye glasses and having poor reading skills have been real trials for me. Getting through medical texts took me much longer; I learned to rely quite a bit on diagrams and photographs of anatomy. Also, I remember being worried that if I were called into the Army and to the front line it would be frightening enough, but if I lost my glasses in the process I would have less of a chance of getting out of harms way."

Another life trial? Being left fatherless at a young age. "I lost my dad when I was 15, something which deeply affected me because we were very close. I lived with the misconception that he died when he was forty years old. When I hit forty I became rather paranoid that I was going to meet my ultimate fate at this age as well. I worried incessantly until the next year slowly came around. And just when I told myself, 'I'm glad that year is over with,' my family informed me that my father had died at the age of 41! The following year wasn't much fun either."

Next week: Read about Dr. Bagby's work in Bangladesh, his contributions to the veterinary field, and his prosthetics foundation. ◆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