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Orthopedics This Week

WEEK IN REVIEW

BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: In terms of stock prices, these past 30 days may well have been the best single month run in years. Overall, the average public orthopedic equity rose 5.87% in the last 30 days. Among the top gainers was Alphatec Spine – who reported outstanding profitability and profit growth. Why? Demand for orthopedic products is rising at an increasing rate.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Integra LifeSciences	12.57%	5.99%	Beat the Street's profit forecasts for Q4 and is STILL the cheapest equity in orthopedics.
2	3	Stryker	23.01	2.16	With AAOS on the horizon, and the macro factors for ortho as positive as they are, SYK equity looks so underpriced.
3	8	Exactech	10.44	6.04	EXAC missed the sales forecast but beat on earnings. Profit margin rose. And buyers stepped in making EXAC a top performer.
4	NR	Alphatec	0.33	11.54	2014 EBITDA was 15% of revenues and up 22% from the prior year. At just $145 million in market cap, way underpriced.
5	2	ConMed	10.51	8.82	2014 earnings were flat and revenues were down. Yes, 2014 is a transition year, but this lowers expectations for 2015.
6	4	Zimmer	29.12	5.14	One thing is clear, the next 12 months are all about digesting Biomet. These things take time.
7	5	Orthofix	7.46	5.95	The last time OFIX released quarterly P&L was the March, 2014 quarter. Presumably, OFIX will soon issue quarterly financials.
8	7	Medtronic	28.84	5.69	Quietly and with minimal fanfare, MDT's spine business is finding it's legs. Could MDT spine's market share be stabilizing?
9	6	MicroPort Scientific	16.53	4.15	AAOS could be MicroPort's opportunity to put its stamp on the orthopedic industry and define its position.
10	10	Smith & Nephew	19.92	3.28	In terms of valuation, SNN is in premium pricing territory – all based on takeover rumors.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	$10.35	$1,107	23.66%
2	Bacterin Intl Holdings	BONE	$3.59	$24	21.69%
3	RTI Biologics Inc	RTIX	$5.32	$303	15.40%
4	LDR Holding Corp.	LDRH	$39.09	$1,035	15.11%
5	Alphatec Holdings	ATEC	$1.45	$145	11.54%
6	Conmed	CNMD	$51.30	$1,414	8.82%
7	TiGenix	TIG.BR	$0.87	$139	7.63%
8	Exactech	EXAC	$23.35	$322	6.04%
9	Integra LifeSciences	IART	$60.01	$1,967	5.99%
10	Orthofix	OFIX	$32.43	$598	5.95%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	CryoLife	CRY	$10.48	$296	-8.95%
2	NuVasive	NUVA	$45.75	$2,203	-1.55%
3	Globus Medical	GMED	$24.28	$2,299	-1.10%
4	Wright Medical	WMGI	$24.63	$1,265	-0.73%
5	Tornier N.V.	TRNX	$24.44	$1,197	-0.49%
6	Aurora Spine	ASG	$1.14	$21	-0.46%
7	Johnson & Johnson	JNJ	$102.51	$285,028	1.01%
8	Stryker	SYK	$94.75	$35,887	2.16%
9	Smith & Nephew	SNN	$36.85	$16,501	3.28%
10	MicroPort Scientific	853	$0.45	$638	4.15%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$102.51	$285,028	17.17
2	Globus Medical	GMED	$24.28	$2,299	18.59
3	Medtronic	MDT	$77.59	$110,571	19.30
4	Exactech	EXAC	$23.35	$322	19.96
5	Zimmer Holdings	ZMH	$120.39	$20,455	20.63

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$32.43	$598	207.18
2	MiMedx Group	MDXG	$10.35	$1,107	207.00
3	NuVasive	NUVA	$45.75	$2,203	103.05
4	RTI Biologics Inc	RTIX	$5.32	$303	83.50
5	CryoLife	CRY	$10.48	$296	48.53

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Exactech	EXAC	$23.35	$322	1.33
2	Globus Medical	GMED	$24.28	$2,299	1.40
3	Conmed	CNMD	$51.30	$1,414	1.56
4	CryoLife	CRY	$10.48	$296	1.62
5	Integra LifeSciences	IART	$60.01	$1,967	2.35

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MiMedx Group	MDXG	$10.35	$1,107	13.80
2	Orthofix	OFIX	$32.43	$598	11.26
3	NuVasive	NUVA	$45.75	$2,203	9.02
4	RTI Biologics Inc	RTIX	$5.32	$303	5.57
5	Smith & Nephew	SNN	$36.85	$16,501	4.84

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	$3.59	$24	0.69
2	Alphatec Holdings	ATEC	$1.45	$145	0.70
3	RTI Biologics Inc	RTIX	$5.32	$303	1.15
4	Exactech	EXAC	$23.35	$322	1.30
5	Orthofix	OFIX	$32.43	$598	1.50

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.87	$139	24.37
2	MiMedx Group	MDXG	$10.35	$1,107	9.36
3	LDR Holding Corp.	LDRH	$39.09	$1,035	7.74
4	Medtronic	MDT	$77.59	$110,571	6.31
5	K2M Group Holdings	KTWO	$20.49	$809	5.13

PSR: Aggregate current market capitalization divided by aggregate sales and the calculation excluded the companies for which sales figures are not available.

"From Kabul With Love" – Dr. Sabit's Misadventures

BY WALTER EISNER

Spine surgeon Aria Sabit, M.D., is sitting in a Michigan jail awaiting trial on federal healthcare fraud charges and trying to procure U.S. citizenship in an unlawful manner. He's sitting in jail because prosecutors convinced a federal magistrate that Sabit would flee the country in a scheme worthy of an Ian Fleming novel.

The federal government says Aria surrendered his medical license in California, effective in 2014, and moved to Michigan, where he was licensed to practice medicine in March 2011. There he opened the Southfield-based Michigan Brain & Spine Physicians Group and began performing spine surgeries.

Or so he claimed. According to a federal indictment, Sabit performed lumbar fusion surgery on a number of patients, but didn't actually install any hardware. Then he allegedly committed the worst sin—billing Medicare for work that wasn't done.

The U.S. Department of Justice (DOJ) charged him with false claims. After a detention hearing on December 4, 2014, the magistrate ordered Sabit held in jail. Prosecutors told the judge they fear he is a flight risk and would try to return to his native Afghanistan to start a hospital and drill for oil. They said he is a member of a politically prominent family.

Aria Sabit, M.D./youtube.com

Image created by RRY Publications, LLC / Source: Kabul Airport/Wikipedia.org

After his detention, a federal grand jury indicted him on eighteen counts of fraud and one count of "unlawful procurement of naturalization" in a 20-page indictment. That happened on December 9, 2014.

Beginning in approximately 2011, and continuing through November 2014, Sabit, according to the indictment, convinced patients to undergo spinal fusion surgeries, "which were either medically unnecessary or never rendered and then billed public and private insurance programs for the fraudulent services."

According to the government's case against him, Sabit allegedly dictated surgical notes that he had performed various spine surgeries, which included laminectomies, discectomies or other procedures, with instrumentation—but which he never actually conducted.

The government is claiming that Sabit's operative reports and treatment records allegedly contained false statements about the diagnosis for the patient, the procedure performed, and the instrumentation used in the procedure. Sabit would also order spinal injections and simultaneously schedule the patient for surgery, "thus not waiting a sufficient amount of time to lapse to ascertain if the non-invasive treatment was successful."

Sabit claimed he used Zimmer Holdings, Inc.'s Transfacet Screw System. But post-operative x-ray and MRI examinations by other spine surgeons revealed

that no medical device had been placed in or around the patient's spine.

"Subsequently, after continuing pain, all patients received second opinions from other doctors stating that no such spinal fusion had been performed and there was no evidence of any screw, or any medical device in the spinal column of the patient," Special Agent Peter Hayes of the FBI wrote in a court filing.

In all, Sabit billed almost $33 million and was paid more than $1.8 million, according to the criminal complaint. He performed surgery on almost everyone who walked through his office, an unnamed employee told an FBI agent.

"He had swagger off the charts," said Tonocca Scott, one of his former patients said of the 40 year-old Sabit in a published interview. "His hair was pulled back. He could have been a guy in a James Bond movie. Why would I go to anybody else?"

Sabit in California—PODS, Lawsuits and Kickback Charges

This isn't the first time the Justice Department had dealings with Sabit or the first time *OTW* has reported on his activities.

Between 2009 and 2010, Sabit was the subject of more than 2 dozen medical malpractice lawsuits in California. Special Agent Hayes testified at Sabit's detention hearing in Michigan that Sabit performed over 200 spinal fusion surgeries in California from June 2009 to December 2010 and that the DOJ had filed a Civil Complaint against him in September 2014.

Hayes also said that DOJ presently has an ongoing criminal investigation of Sabit in California.

Anti-POD Poster Child

During Sabit's detention hearing prosecutors also told the judge that the DOJ's California investigation of Sabit was focused on his participation in a physician-owned-distributorship (POD), which owned a particular device—an Apex pedicle screw made by Reliance Medical.

After buying into the POD, Hayes said Sabit began to use the Apex in 90% of his surgeries, and earned over $400,000. He added that Sabit had been subject to civil kickback charges in September 2014 based on California kickback allegations and that Federal California criminal kickback charges are likely coming.

A Flight Risk: From Dubai to Kabul to London

Accusations of unnecessary surgeries and false claims are not uncommon. But here is where Sabit is different and the story turns into an international thriller.

The government labeled Sabit a flight risk, noting that he was questioned in September in Atlanta while trying to fly to Dubai. There he allegedly told a customs officer that he owned a company involved in mining in Afghanistan. In his luggage, officers found a ruby and a 3.6-carat emerald, according to the complaint.

Dubai Informant

Special Agent Hayes testified that the FBI had information from an informant who was employed in Dubai, but had first met Sabit in Michigan in late 2013. The informant told the FBI that Sabit had asked him to help obtain a medical license in Dubai because he was considering practicing medicine there or in the United Arab Emirates.

The informant also told Hayes that Sabit went to Afghanistan in December 2013 to set up a hospital in Kabul. When the FBI searched Sabit's house they found plans dated October 2014, for Aria International Community Hospital in Kabul. They also found emails dated around the same time indicating he had invested $300,000 to $400,000 into the hospital with a profit hope of $30 million.

London's Newcastle Upon Tyne

Hayes testified that Sabit traveled to London in November 2013, and based upon papers seized in the home search, was in the process of applying for a position at a London area hospital: "Newcastle Upon Tyne", application dated November 11, 2013.

The application stated that Sabit was applying for the position of consultant spinal surgeon; "I am moving to the U.K., as most of my family resides in the U.K." Hayes testified, and Sabit's wife's subsequent testimony confirmed, that none of Sabit's family resides in the U.K.

Afghan Blue Bloods and Oil

The informant, according to Hayes, traveled to Afghanistan to meet Sabit and his relatives, and government officials—Sabit's father, who was the former Attorney General of Afghanistan; his uncle, the Speaker of the House, the Minister of Mines; Abdullah Abdullah, an individual then running for President of Afghanistan, who lost the final election, but who is now the Chief Executive Officer of Afghanistan.

The informant had an axe to grind. He claims that he had been "stiffed" out of money on a deal by Sabit.

Sabit, according to Hayes, incorporated the American Mineral and Oil Compa-

ny in August 2014, to extract natural resources in Afghanistan. Emails from Sabit to his business partner regarding their proposed venture, said that Sabit had secured the rights to survey and extract the 2 billion barrels of oil available for drilling in northern Afghanistan.

A Sabit August 4, 2014 email states:

> "Through connections and talks with the Government, including the President and incoming Prime Minister, I am able to secure these and any other mineral rights for our companies, and ideally partner with an American company."
>
> "The rights to the grounds and all mineral content are secured. I met with the Minister of Mining and Petroleum, as well as the President of the country. My first cousin is the Minister of Finance. My other cousin is the head of the Central Bank. My uncle is the Speaker of the Lower House. My father is a very influential politician. My point is that we have very significant pull in the Government."

Sabit's Defense

Sabit's wife, an RN, testified that she was willing to surrender her and her daughters' passports and offer the house as security. She also said that Sabit and his father are now estranged.

Dr. Khusraw Sabit is Sabit's younger brother, who lives in Montreal, Canada. He testified on December 8, 2014 that Afghanistan is not safe for Sabit because their father, who has not been speaking to Sabit, also has made many enemies and was kidnaped and released for ransom in 2011-2012.

The Money Flow

Hayes showed the court a flow chart showing some of Sabit's money movement of over $2 million from Michigan Brain and Spine into a joint account that he had with his wife at PNC Bank, and then over $1.7 million was transferred out to six accounts: two held by his wife, and two each held in the name of each of his then-two children, 8 and 6 years-old respectively.

A home search of Sabit's house revealed a proposed complaint for divorce, seeking sole custody of the children. The home search also showed that Sabit had been living in the basement.

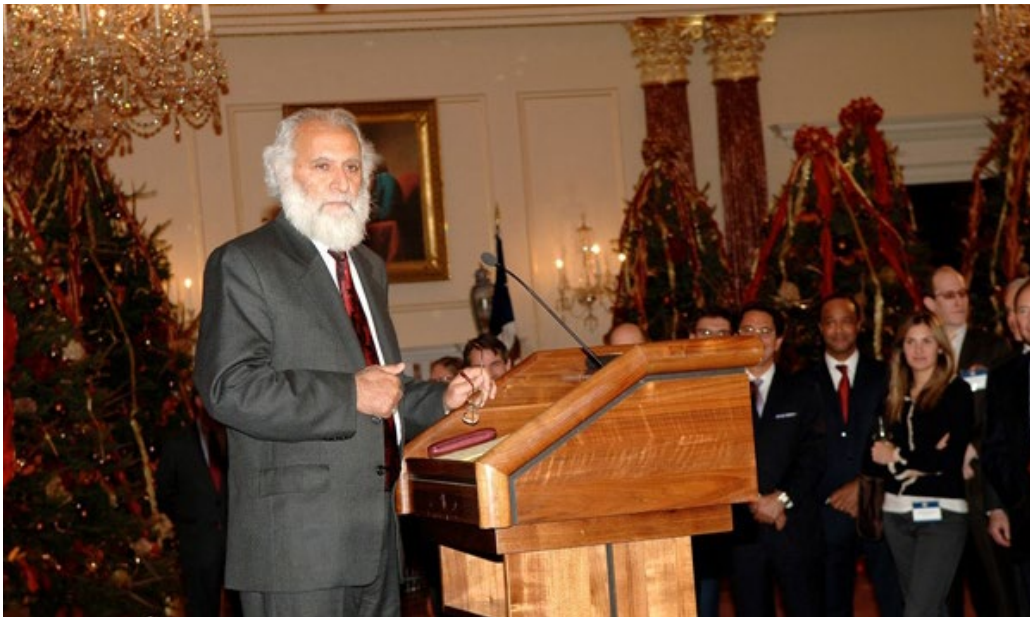
Hayes further testified that the informant said that Sabit had explained that the only reason he was still in the U.S. was because he had young children here, but that if he did leave, the U.S. "would never get him back."

Sabit's "Suspect" Character

After listening to the evidence, the detention hearing judge found that Sabit's character is "suspect given his past conduct of leaving his medical license behind in California and not including that history in his curriculum vita in applying for future medical positions, and his transfer of a significant amount of funds to his wife and children as the investigations unfolded."

The judge noted that prosecutors offered proof that Sabit "has transferred significant sums of money to two of his young children (allegedly around $1,000,000 each), that he claimed to have spent $300,000 on the Kabul hospital project already, that the government has already frozen $750,000 in one of his bank accounts, and that it has not been able to identify accounts into which other transfers may have been made."

The judge ruled that Sabit would remain imprisoned until his trial. ♦



Abdul Jabar Sabit/Wikipedia.org

No DBM. No Allograft. No Bone Void Fill. Better Fusion? Really?

BY ROBIN YOUNG

No DBM? No Allograft? No Bone Void Fill of any kind? Talk about flying without a parachute, or driving without a seat belt.

But that is precisely the conclusion that came from a short press release issued earlier this year by Salt Lake City-based Amedica Corporation. The data was from a prospective randomized study of silicon-nitride interbody spacers.

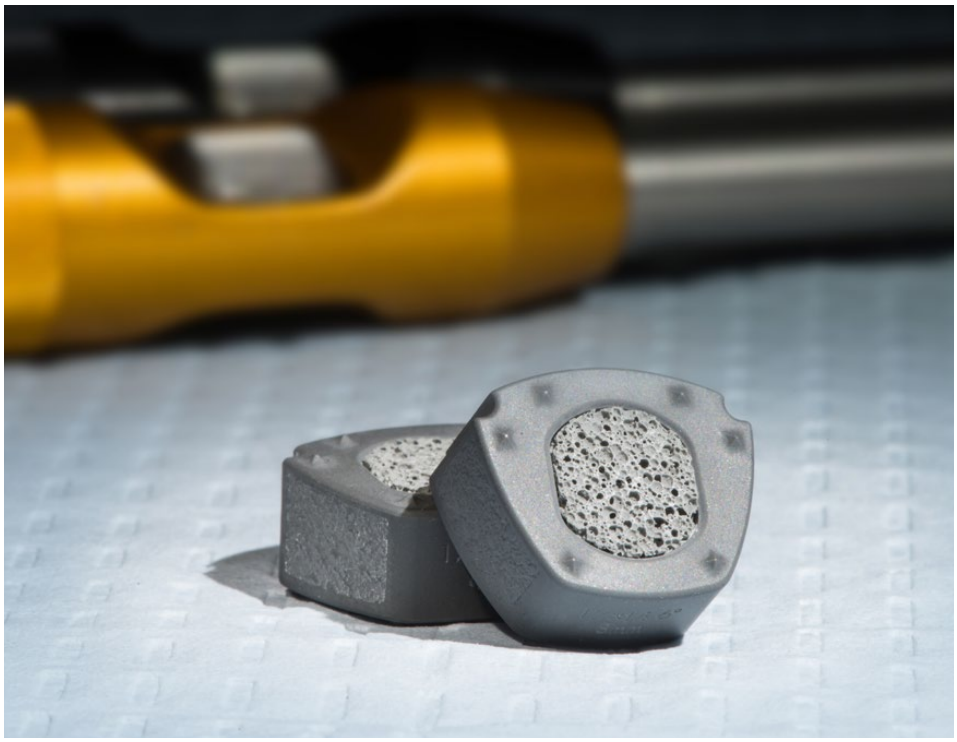
The magic, apparently, comes from silicon-nitride. The study, called CASCADE, showed that composite interbody spacers using two different formulations of silicon nitride ceramic, i.e., a solid phase cortical portion surrounding a structured cancellous ceramic core, had equivalent fusion results to a PEEK spacer with autogenous bone graft.

No DBM, allograft, synthetic fillers or biologics. Just a spacer.

The CASCADE Study

The CASCADE study, which was a blinded, randomized clinical trial that compared outcomes of spinal fusion surgery between Amedica's composite silicon nitride spacers manufactured with a central core of cancellous structured ceramic (CsC), to PEEK (polyether ether ketone plastic) spacers filled with bone autograft.

The investigators enrolled 104 patients and the fusion scores, which were independently scored, were compiled at 12 months follow-up.



Courtesy of the Amedica Corporation

The study conclusions were: Neck Disability Index scores decreased similarly in both the treated group and the control group and was consistent with clinical improvements reported in the literature. Importantly, the incidence of cervical spine fusion was statistically identical between the treatment group and the control group—**and consistent with figures reported in other studies.**

The lead investigator for the study, Mark P. Arts M.D., Ph.D., Neurosurgeon at the Medical Center Haaglanden, The Hague, Netherlands said of the results; "Surgeons have long known that autograft is the holy grail of bone healing. All osteoinductive and osteoconductive formulations on the market today aspire to show healing rates that are comparable to autograft bone. Hollow-body PEEK spacers used in cervical and lumbar spinal fusion must be filled with osteoconductive materials, such as allograft, bone autograft, or synthetic biologic formulations. The CASCADE study is the first to show that a synthetic material can heal and fuse as well as the patient's own bone. **We have shown that it is no longer necessary to use hollow interbody spacers filled with bone or bone void fillers to achieve optimal fusion results.**" (emphasis added)

Long and Difficult Road

The news comes at a critical time for Amedica. The company, which is pub-

lic, has struggled since its IPO in 2014. Its market capitalization sits at just $11 million. And the company has struggled for visibility in the crowded U.S. interbody fusion segment.

The CASCADE study results, which were announced in January 2015, may well have put Amedica at an inflection point.

Over the years Amedica has raised and spent well over $100 million to, among other things, build a state-of-the-art ceramics manufacturing facility in Salt Lake City. Sales are starting to pick up. But, aside from one intrepid Wall Street analyst (and former orthopedic industry executive), almost no one is paying attention to Amedica's clinical data.

In October 2014 Amedica's board brought in Sonny Bal, M.D., J.D., M.B.A., to take on the CEO and Chairman duties.

Since arriving at the company, Dr. Bal instituted a nearly-40% headcount reduction and sharpening the company's focus to OEM and other partnerships, which can augment its retail spine business and develop a variety of new products targeted at the sports, extremity, and total joint lines. "We are focused on leveraging our unparalleled expertise and depth of science in silicon nitride to develop products that simplify surgery, and address clinical concerns related to the limitations of legacy materials, such as metal and plastic that have been with us since the 1960's. A new generation of patients will demand biomaterials with extreme performance, durability, and biocompatibility. We are ideally positioned to meet that need."

Speaking From the Head and Heart

Dr. Bal is a long-time investor, board member and silicon nitride researcher and a true believer and enthusiast for the technology, so he is speaking from both the head and heart. "Silicon nitride was developed for demanding industrial applications, such as aircraft bearings, internal combustion engine and turbine components, and space technologies. Its biomedical applications are facilitated by the facile nature of the material, "he says. "'As fired' (solid) silicon nitride facilitates bone ongrowth. Polished silicon nitride is ideal for orthopedic bearings and in fact has demonstrated less wear and better toughness than existing ceramic total joint components. Indeed, the space shuttle engines rely on similar bearings to improve their reliability. Porous silicon nitride encourages bone ingrowth

without biologic additives. All formulations show anti-bacterial behavior, and these material properties reflect a 'living', bioactive surface that is complex and interesting from a biologic and engineering standpoint," said Dr. Bal.

Dr. Bal is Professor of Orthopedics at University of Missouri, a well-known and published U.S. implant surgeon, and an attorney focused on medico-legal education; positions he has put on the back burner to guide Amedica in its quest to prove silicon nitride as the optimal material for interbody spacers.

Amedica's DNA is as a biomaterials company. And its silicon nitride spacers are arguably the best, state-of-the-art biomaterial for a variety of orthopedic implants. Enough money has been sunk into the company, they should be.

Spine and Large Joints

The FDA has allowed Amedica to use a labeling claim that its silicon nitride discourages bacterial biofilm adhesion. That was also based on an intriguing series of studies. Those were in vitro and in vivo studies that showed that silicon nitride discourages bacterial biofilm adhesion. Which have clear application for large joint implants.

Amedica sold 50% more silicon nitride in 2014 than in 2013, which off a low base, hasn't impressed Wall Street very much. Amedica expects to have a silicon nitride product for total joints in 2015. And the exact product applications or partnerships are still being worked out.

But Amedica's data regarding silicon nitride interbody spacers is really interesting and may signal the beginning of clear company and product differentiation. Amedica's spacer isn't just a silicon nitride version of the myriad of hollow core PEEK spacers already in the market…it is an integral silicon nitride porous core, which appears to eliminate the need for bone void fillers while demonstrating equivalent fusion outcomes.

This is more than interesting. It's different.

Enter K2M and Spinal Kinetics

So what are other spinal implant companies doing? Also innovating -- albeit in different ways. Most other companies are innovating PEEK spacers by, for example, bonding titanium or other materials to the periphery to overcome its well-documented aversion to bony ongrowth. But adding new materials to PEEK also adds cost, potential failure modes, and still must be filled with expensive (DBM) or very expensive (stem cell DBM or growth factor biomaterials) biologics to facilitate fusion.

Certain key spine companies have started to get involved with Amedica. Spinal Kinetics recently signed an OEM deal with the company and plans to sell silicon nitride implants into the EU. Likewise K2M has signed on and been especially helpful with the CASCADE study investigators. Some of Amedica's composite spacers, which are already available in Europe could come to the U.S. soon. In February Amedica filed its 510(k) for CSC with the CASCADE data.

If a Study Falls in the Forest, Will Anyone Hear It?

The CASCADE study is creative and important. That study showed that a synthetic spacer material could deliver better bony ongrowth than PEEK. Can the company make a case for a simpler, faster and less expensive approach to cervical fusions? If a study is reported will the payers notice?

Sadly, it's an uphill battle. In the fee-for-service, stack-as-many-codes-as-you-can conundrum that is our U.S. healthcare system, the geniuses at the payers might well miss such an interesting development as the CASCADE study.

In the coming pay-for-performance world a study like this could find more takers.

Amedica's CASCADE dilemma reminds us a little bit of another study that demonstrated equivalent fusion rates to the then-gold standard, iliac crest autograft. That study showed that a new, off-the-shelf, procedure-simplifying (albeit expensive) biomaterial delivered equivalent fusion procedures as the old, tedious standard.

Remember Infuse? ♦

Alex Vaccaro Leading Rothman Institute Boldly Into the Future // The Ortho Side of NASCAR // Hoag Orthopedic Institute New Model for Harvard

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

Alex Vaccaro, M.D. and Rothman Institute

Alex Vaccaro Leading Rothman Institute Boldly Into the Future

Alex Vaccaro, M.D., Ph.D., president of The Rothman Institute in Philadelphia, is taking that facility into the future with strong leadership and well conceived expansions. Dr. Vaccaro told *OTW*, "As an organization we continue to look for strategic market/regions regarding growth for the organization. Currently we have 20 offices throughout the Philadelphia and South Jersey region and look to fill in 'market pockets' as well as expansion opportunities in the broader market base such as Central and Northern New Jersey."

The Rothman Institute currently has ownership interest in nine of its office locations and is in the development phase for two further offices. In addition to ownership interest in a number of surgical facilities such as Specialty Hospitals and Ambulatory Surgery Centers, The Rothman institute owns a number of technology companies such as Business Analytics, Outcome Measurements, Telemedicine and Home Physical Therapy Applications.

"We have spent a significant amount on technology over the last seven years as we feel it will be an integral part of our success in the future of health care," said Vaccaro. "Our clinical outcome systems includes patient education and patient satisfaction tools and along with our Business Analytics Systems will allow us to continue to improve the quality of care, be cost effective and be the 'Value Provider' that the market and consumers are demanding in the future.

In addition to the technology companies, The Rothman Institute has ownership interest in Velocity Sports Performance Centers in both Cherry Hill, New Jersey and Washington Township. "This allows athletes of all levels as well as the 'weekend warriors' to participate in high performance training and wellness."

"As an organization we are essentially creating a hybrid academic teaching culture with a large clinical practice base. We are following through on our commitments to a profound clinical and operational transformation that involves looking at a whole different level of effectiveness in patient care and population health. This model allows us to continue our culture of academic and teaching and integrate evidenced

based medicine with our clinical practice. We feel this is the future of health care. We feel this culture, along with our outstanding physicians and staff, as well as our technology will help us not only survive, but thrive in the new world of health care."

Orthopedics at 200 Miles Per Hour

Nascar drivers are extremely protected these days in their cars, in part because of a tragic accident 14 years ago with the death of Dale Earnhardt and in part because of the work of a physician assistant from OrthoCarolina. About eight years ago Bill Heisel noticed that help was needed in the motorsports arena. Heisel tells *OTW*, "Those working in the motorsports industry have to contend with the longest season in professional sports—February through November. Few people realize how taxing these jobs are on the body…and the vast majority of injuries occur amongst the pit crews."

Heisel, who works with 19 teams including Joe Gibbs Racing, Stewart-Haas Racing and Hendrick Motorsports, states, "I have been enamored with the seriousness with which NASCAR takes safety. Since the 2001 death of Dale Earnhardt things have greatly improved, with softer walls called Safer Barriers, advances in the car construction and design engineering, and the overall goal of making the driver part of the vehicle rather than passenger. Drivers are essentially cocooned in the cars. There are improved crumple zones in car that allow energy to be dispersed around—rather than through—the driver. There have been major advancements in safety seat design and seat material. Truly, we went from drivers making their own seats to the use of carbon fiber technology that is custom molded to fit the driver perfectly (the way a custom knee brace is made for an NFL player). This has given us an improved ability to strap the driver into the seat with more sophisticated belt technology that keeps him or her from going forward or submarining' (scooting out the bottom of the seat)."

"For the drivers, the biggest medical issue they usually have to contend with is related to being in a 150 degree plus car for four hours (on a 100 degree day). To handle that—as well as the G-forces—drivers have to be at a whole different level of fitness. They are true athletes and train like true athletes with conditioning and weight training exercises. In a hit that occurs at the corners you're talking about more than 70G due to the deceleration forces. If you're taking a 200 mph turn at Daytona and you pull to an immediate stop, then that's when the G-forces get enormous."

"My biggest fear is that the guys on a pit crew will be hit by cars…it happens every season in minor impact events. At every pit stop there is the potential

for long bone trauma as a result of a car skidding in or brakes failing. With a 3,400lb car zooming into the pit area, we always worry that a crewmember might get pinned against the concrete wall in the event of a mechanical parts failure or miscalculation in speed and distance by the driver."

"The days of pit guys working without helmets and fire suits are long gone; now, pit crews train as athletes too. The workouts are heavy lifting and conditioning as well as live pit stops in practice three days a week during the season…and it's fast. A pit stop of 12 seconds or less is considered to be very good; an outstanding pit stop is in the high 9s or 10s for 4 tires and fuel. We see a lot of upper extremity injuries amongst the tire changers. They get tendonitis in elbows and knees, wrist and hand injuries from pulling tires or getting a hand stuck between the sheet metal and inside the tire well. There are injuries from the vibration and torque forces coming off the nitrogen powered air guns. The jackmen injure their shoulders, backs, elbows and more. They get injuries including, tendon ruptures (rotator cuff, biceps, triceps and quad and patella tendon), and herniated lumbar discs because their role is to pick up each side of the car with a lightweight jack in addition to being fast around the car during stops and stepping off a 4 foot high concrete retaining wall. The tire carriers carry tires from the pit wall to the car and then bring the old tires back. They are carrying these 70lb tires with the rims and inner liners…and stepping off a 4 foot high pit wall—so the risk to knees and shoulders is evident."

"I have been a physician assistant for 25 years, and I'm thrilled to have been a part of the evolution of care for this niche in orthopedics. It has been a rewarding experience to have taken sports medicine principles and modified them in order to treat people who participate in motorsports."

Harvard and Hoag Orthopedics Team up to Rethink Healthcare Delivery Hoag Orthopedic Institute (HOI), which only opened in 2010, was recently approached by Harvard due to its rapid, efficient growth and its successful model. Dereesa Reid, CEO of Hoag, tells *OTW*, "In 2006, The CEO and Board Chairman of Hoag Memorial Hospital Presbyterian along with Dr. James Caillouette, Orthopedic Surgeon read the now-famous book by Michael Porter and Elizabeth Teisberg, *Redefining Healthcare*. The board of Hoag embraced the philosophy that we needed new models of care in order to drive value. Hoag Orthopedic Institute a newly formed entity was a startup and we didn't have any metrics. So we created them and collected the appropriate data. From the beginning we had a commitment to driving value in our hospital and two surgery centers. Early on, we began by making our data transparent internally with physicians and employees then in 2013 we began publishing our data in our annual *Hoag Orthopedic Institute Outcomes Book*."

"One of the things that has helped us produce outstanding clinical outcomes is that we are able to empower doctors involving them in leadership positions as well as day to day shared decision making with our clinical teams. We know that traditional hospital service lines have some degree of success, but they cut across legacy chains of command lack clear lines of authority and organizational alignment. When you can step off to the side and only do orthopedics, then that is exceptionally efficient and clinically focused around providing the best care possible for orthopedic patients. When we collect data it is not comingled with data that you would normally find in an acute care hospital. When we show the data to our doctors and staff, it is clear that it's only orthopedic data. This makes it much more likely for people to actually believe the data. When I discussed data with Robert Gorab, M.D., the Chief Medical Officer at HOI, he noted, 'Data drives behavior. We will look at the clinical data and see how people are using supplies and then show this information to the doctors… and that will drive behavior.' And it did. No one wants to be an outlier, so once people know that the data is reliable they adjust their practice patterns move toward best practices."

"One of the projects we are working on with Harvard is the International Consortium for Health Outcomes Measurement, a nonprofit started by Michael Porter. The meetings, which attract 400-500 people from all over

the world, have the agenda of defining international standards for patient reported outcomes. Each year is different medical conditions are studied; now we are participating in the ICHOM osteoarthritis group."

"Last year, we also participate in the Institute for Healthcare Improvement's Joint Replacement Learning Community, led by Harvard's Dr. Robert S. Kaplan and Derek Haas where Harvard professors have the opportunity to teach to laypeople. There were over 32 orthopedic groups spanning the U.S. and several international countries. Our multidisciplinary team consisted of cost accountants, clinical quality nurses, performance improvement experts, etc. It wasn't just an opportunity to learn from the professors, but it was a chance for the orthopedic groups to share best practices."

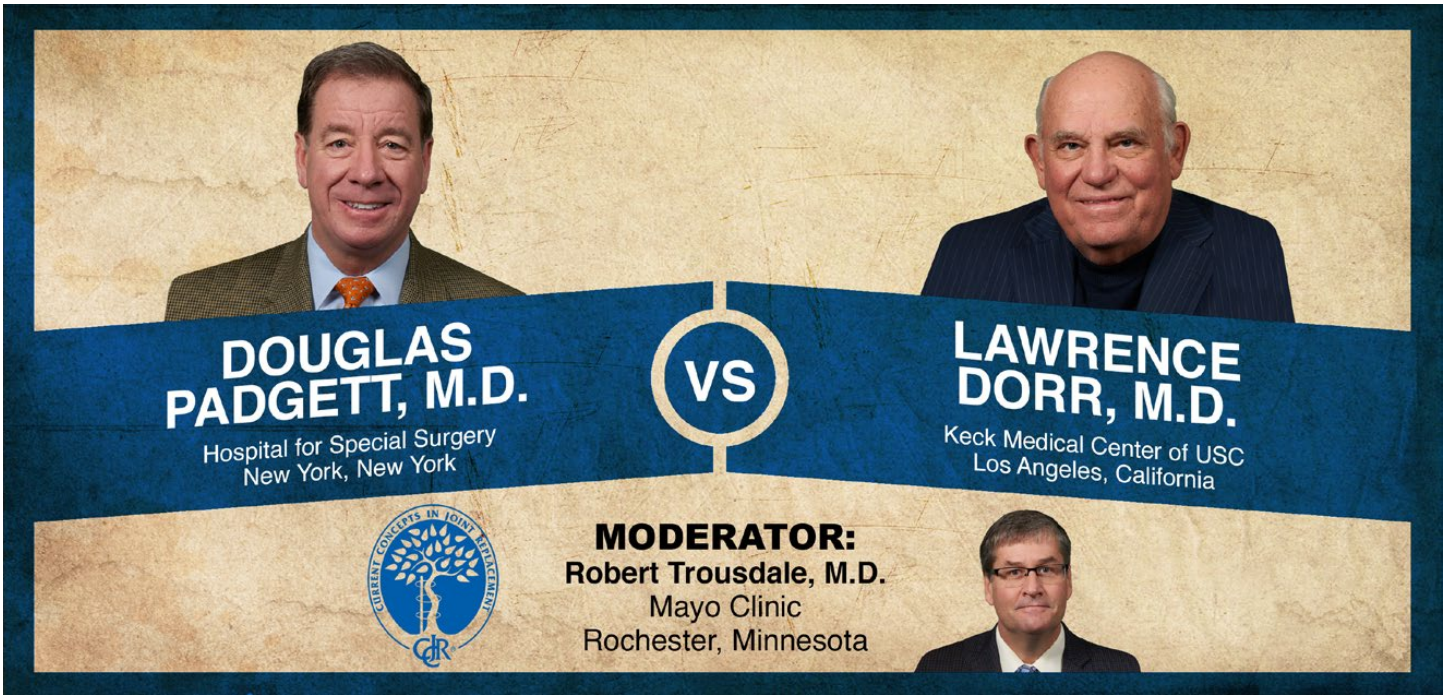
"Afterwards, I was approached by Dr. Robert Kaplan, who said, 'You are doing exceptional work and we want to do a case study.' So he, along with Jonathan Warsh (also from Harvard) travelled to Orange County to visit HOI. They spent hours interviewing leaders, physicians and staff. . It was such an honor to work with Dr. Robert Kaplan, who wrote THE book on balanced scorecards, he was impressed with how we were reporting and making our data actionable throughout our organization."

"An example of one of our protocols was the preoperative screening and screening for MRSA (methicillin-resistant staphylococcus aureus). We were not merely approaching a potential MRSA problem a couple of days before the surgery, but far in advance. Another unusual aspect of Hoag Orthopedic Institute is that our orthopedic surgeons decided to empower their anesthesia colleagues to study and determine the best pain protocol. This was a very unusual, collegial, and productive decision and is just one example of how our orthopedic surgeons engage and empower our anesthesiologists."

"And recently, our spine doctors began evaluating products based the value equation. In other words, analyzing product offerings bases on achieving the best outcomes at the lowest cost then as a group pro-actively reached out to the nurses, saying, 'Here is the product we selected and we want to work with you so that you know exactly how to use it.' I've never that seen that in orthopedics and especially not in spine. I must say that when an administration sees doctors stepping up like that they should recognize them." ♦

Padgett v. Dorr: Constrained Sockets in Revision Hips

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.



Current Concepts in Joint Replacement/RRY Photo Creation

"Constraint should be reserved for cases where there are no other options. These liners can compromise fixation and they don't always work," argues Doug Padgett. "Failure with constrained liners is caused by either poor judgment or poor technique," counters Larry Dorr. "Dual mobility is hot stuff, but it's going up against the tried and true constrained liner."

This week's Orthopaedic Crossfire® debate is "Use of Constrained Sockets in Revision THA: More Problems Than They Solve." For the proposition is Douglas Padgett, M.D. from Hospital for Special Surgery in New York. Lawrence Dorr, M.D. of Keck Medical Center of USC in Los Angeles is in opposition. Moderating is Robert Trousdale, M.D. of the Mayo Clinic.

Dr. Padgett: "Larry, you're wrong. Instability factors are complex; we know that for primary hips, patient, surgeon, and implant factors are all involved. But there are unique issues in revision surgery and the priorities are to fix it and make it stable so that it doesn't pop out. Kevin Bozic has shown us the magnitude of the problem…instability is the number one reason for revision. The results of revision hip, however, in every single series: instability, instability, and instability. Why? What holds a hip in place? Soft tissue constraints. The role of soft tissues in reducing instability in primary hips—mostly observational work from our institution—noted that with enhanced soft tissue repairs dislocation rates decreased."

"As for soft tissues in revision work, the predicate example…simple liner head exchange; at 15 years never had problems with instability. Take out the liner, remove the head, and put it back in without changing component position. What is the number one problem? Instability…suggesting there are soft tissue problems."

"What about alignment? The Lewinnek safe zone is often misquoted. In our work on 7,000 total hips we found that it doesn't exist. Even if it did, can you hit it? The guys at Massachusetts General couldn't. We used the robot and we hit it, but they still dislocated. Why is this? I would like to thank Larry for thinking about spinal-pelvic alignment, pelvic tilt, pelvic obliquity, as well as 3D images."

"So why not go with more constraint? We were early adapters of this technology, and of the treatment in revision. We reported our success, along with John Callaghan from Iowa. Like most things it is subject to the effects of time. Merlot grapes are either going to become a

$2,000 bottle of wine or they are going to become red wine vinegar."

"My concern is that these constrained liners can compromise fixation. And they don't always work. You could have a simple problem like ring breakage…the big ball is out, the small ball is out, or the entire ball is out. What about dual mobility? It has had success in high risk groups, preventing dislocation in the fracture group…and it is increasingly used in revision. But there are problems with dual mobility including intraprosthetic dislocation."

"In revision work we need to focus on fixation. Also, use bigger heads. A randomized controlled trial from Rush and Vancouver clearly demonstrated that larger heads were effective in reducing instability rates. It's also important to repair the soft tissues, reestablishing the capsular, check range of motion, develop a robust capsular flap, reattach through drill holes, and consider prophylactic bracing. That is sketchy… I think it's better to be stiff and stable than flexible and unstable."

"In summary, I think constraint should be used only if there is truly no other option, such as in patients whose muscles are compromised or who have cognitive dysfunction. But constrained liners do cause more problems than they solve."

Dr. Dorr: "We're talking about patients in whom there is a loss of biological constraint of the hip. In a primary hip replacement you have this as well as mechanical constraint. In many revisions you don't have good biological constraint. There is loss of the abductor function and a very weak or absent capsule. And let's further define this patient as being 70 years old."

"With this type of patient you can use a constrained liner if your surgical technique and judgment is good. It's not difficult and every one of you can do it. If you hear of someone having 25% failure with constrained liners then either their judgment or their technique was not good."

"First of all, the liner has to be press fit against the metal edge. You can't worry about the thickness of the cement column. You can't use a small liner inside a big cup, and try to get a 4mm cement column. Also, you need a mechanical interlock for the cement, which just means that you roughen up the plastic and the metal. And it's best if you don't use a hood."

"Failures are caused by altering that technique. You try to tilt the liner to change the version because your component position isn't good…or you use too small (or big) of a liner. So my technical tips are to use a power drill to scratch the implant so that you get the mechanical interlock. Use the cement with more liquid because you've got

to get that to press fit. If you let the cement get doughy then you'll have trouble getting the liner all the way into the cup. And if you have rotational pegs take them off with a carbide bit and leave the pressurization on until the cement is hard outside of the body."

"I don't like a hood because it can increase impingement. We get really good range of motion with this if the components are in good position. And when we cement, we put the ring halfway in because if you get cement into the ring groove then you're not going to be able to get the ring to seat and lock into the plastic afterwards."

"Dual mobility is hot stuff and it's going up against the tried and true constrained liner. So in this match up the constrained liner is going to show everyone exactly what it can do. It can be done in all primaries and revisions, you won't have any dislocations, and it will last forever."

Moderator Trousdale: "So Doug what is your absolute indication for a constrained liner?"

Dr. Padgett: "In the revision setting it would be in those who are muscularly compromised…or perhaps the patient that has global soft tissue deficiency."

Moderator Trousdale: "Larry, what about the position of the native socket in revision hip/instability situations?"

Dr. Dorr: "You can't compensate for bad component position with a constrained liner. Nor can you tilt the liner to try and change the version of the cup. That's going to cause failure…it's going to cause impingement and flip out. The cement isn't that strong. It's got to be press fit against the metal shell."

Moderator Trousdale: "Does fixation of the socket matter? Are you happy to put in a constrained liner into a well positioned socket that's well fixed or can you put a constrained liner in 'fresh' into a complex revision surgery?"

Dr. Dorr: "You can always cement it into a well fixed cup. I've used it for 20 years and only had 3 failures; 2 of them were my own fault. But let's say you've got a bad revision situation with bad acetabular bone and you have compromised fixation of the cup…and then you use the constrained liner. If I had to do it in that situation because I had no medius and no capsule and I needed mechanical constraint, I'd put that patient in a cast postoperatively to let the bone heal and to get some static control."

Moderator Trousdale: "Doug, how would you handle that?"

Dr. Padgett: "The priority there would be fixation. I would lean towards not using a constrained liner, and I would use a big head if there are any soft tissues to repair the capsule. I would probably use a brace. I'd use a cup that can mate with a favorable constraining device such that if the patient becomes unstable later then I'd feel confident that there is a good option."

Moderator Trousdale: "Larry, can you cement a constrained liner into a solid cobalt-chrome monopiece cup that was a metal-metal bearing?"

Dr. Dorr: "Sure. You can scratch it up and get the mechanical interlock."

Moderator Trousdale: "Titanium scratches pretty well, but what are your tricks for scratching cobalt-chrome?"

Dr. Dorr: "Just use a carbide bit with an Anspach or a Midas."

Dr. Padgett: "It may be easier to make multiple perforations in it…to actually drill right into the cobalt-chrome cup."

Moderator Trousdale: "We grouped constrained liners all in the same category. Are some better performers than others? Also, please comment on the range of motion patients get with various constrained liners."

Dr. Padgett: "They run the gamut from the less constrained dual mobility options to the more constraining of the tripolar designs. I think the ones that are simply ring-locked may be less predictable in their success. The most success we've had is with the tripolar design."

Moderator Trousdale: "Larry, regarding the cup you showed, how much flexion does that patient get before the neck impinges on the constrained locking ring?"

Dr. Dorr: "If you have a good combined anteversion of your cup and stem—and remember that the cup itself is usually not the problem as far as dislocation. There are papers showing that the combined anteversion causes dislocation. So if your combined anteversion is good, and you cement in a liner without a hood, then the range of motion isn't much different."

Moderator Trousdale: "Thank you, gentlemen." ♦

Please visit www.CCJR.com to register for the 2015 CCJR Spring Meeting, May 17 - 20 in Las Vegas, Nevada.

COMPANY

DePuy Hip Settlements Could Top $4 Billion

There are 1,400 new DePuy ASR metal-on-metal hip patients who are now eligible to participate in the U.S. Settlement Program.

DePuy Orthopaedics, Inc. has agreed to extend the existing U.S. Settlement Program to include eligible ASR hip implant patients in the U.S. who had surgery to replace their ASR hip after August 31, 2013, and on or before January 31, 2015. The existing U.S. Settlement Program was announced in November 2013 and has compensated eligible ASR patients in the U.S. who had surgery to replace their ASR hip as of August 31, 2013.

The agreement between the company and the Court-appointed committee of lawyers representing ASR plaintiffs was announced on February 20, 2015.

Mindy Tinsley, a DePuy spokeswoman said by extending the benefits to an additional group of ASR patients, the company is, "again providing fair compensation to U.S. ASR patients without the delay and uncertainty of protracted litigation. DePuy has been committed to the well-being of ASR patients worldwide, and the company continues to advance innovative treatment options to serve those who need joint replacement surgery."

1,400 New Patients

The new agreement allows the 1,400 new patients who've had ASR hips removed since 2013 to seek about $300,000 each in compensation. They join approximately 8,000 other cases

Wright Schulte LLC

that were part of the original agreement. The existing Settlement Program has now resulted in payments for the vast majority of the more than 7,500 patients who enrolled in the program.

$4 Billion

According to data compiled by *Bloomberg*, the extension, which will cost around $420 million, pushes the total cash compensation payments to about $3 billion and will resolve more than 90% of current patients suits over hip removals. Carl Tobias, a product-liability law professor at the University of Richmond in Virginia told *Bloomberg* that the total cost of the settlements over the ASR implant will exceed $4 billion by the time DePuy resolves all implant cases.

That includes payments DePuy has agreed to pay to cover hip recipients' medical costs and payments to the company's lawyers

Recall

In August 2010, DePuy issued a voluntary recall of the ASR Hip System after receiving new information from the U.K. National Joint Registry as part of the company's ongoing surveillance of post-market data concerning the ASR Hip System, which showed a revision rate that was not in line with data previously reported in that registry. The company says the product continues to perform well in some patients. —*WE*

AAOS Opens New HQ and Learning Center

The American Academy of Orthopaedic Surgeons (AAOS) officially opened its new 180,000-square foot, five-story building on February 21, 2014 in Rosemont, Illinois.

The building will house the Academy's headquarters and more than 25 orthopedic organizations and a state-of-the art Orthopaedic Learning Center (OLC). Along with AAOS, the equity partners for the headquarters are: the Arthroscopy Association of North America (AANA), the American Orthopaedic Society for Sports Medicine (AOSSM), the American Association of Hip & Knee Surgeons (AAHKS), and the Orthopaedic Learning Center (OLC).


AAOS HQ/American Academy of Orthopaedic Surgeons

Frederick Azar, M.D., AAOS's president, said, "This beautiful new building, with its state-of-the-art technology and space for growth, flexibility, and distance learning to enhance patient

care, represents a unified commitment to the future of orthopaedics and orthopaedic education."

The Academy had outgrown its previous headquarters and wanted to expand and upgrade the Learning Center.

The new OLC, according to an Academy press release, is twice the size of the previous facility and offers:

- Distance learning opportunities, including an international reach for web-based courses;
- A BIO Skills Lab with a large format high-definition display system, digital light processing (DLP) projectors and high-definition broadcast cameras;
- A 24-station skills lab that can be divided into two 12-station labs to accommodate multiple courses at the same time;
- An auditorium able to seat up to 180 participants, divisible into three separate rooms, with state-of-the-art technology including a 3-D projector; and,
- A central audio-visual (AV) control room for all OLC technology.

"Today, the Academy unveils the future of orthopaedics," said Karen Hackett, FACHE, CAE, the organization's CEO.

Construction on the new, energy-efficient building began in August 2013 and was completed in approximately 18 months. The Academy will be taking up about two and a half of the five stories. The other orthopedic organizations will take up the rest. Hackett said it was important to the Academy to keep the orthopedic community in close proximity for easier communication. —*WE*

Infuse Sales Climb, Medtronic Holds Steady, Spine Market Grows

Ahhh, the luck of the Irish. Dublin-based Medtronic plc reported on February 17, 2105 that sales of Infuse BMP (bone morphogenetic proteins) have climbed almost double-digits in each of the last two quarters. Luck and the pluck of Omar Ishrak, the company's CEO and chairman.

The company continues to believe that the BMP business has turned a corner and expects BMP revenue year-over-year growth going forward.

On a reported basis, overall spine revenue of $740 million declined by 1%, but rose 2% on a constant currency basis due to a weak dollar.

U.S. Sales Grow

Core spine revenue of $543 million was down 2% (up 1% constant currency) and reported biologic (Infuse) revenue rose 8%. U.S. revenues were $522 million, up 1% over the previous year's quarter. Management said its core spine business differentiate itself through its Surgical Synergy program, which includes imaging, navigation, and powered surgical instruments. On a constant currency basis, interventional spine revenue of $75 million remained flat and BMP revenue of $122 million increased 9%.

The $740 million beat Wall Street expectations by around $20 million. With $1.7 billion in free cash flow during the quarter for all of Medtronic, there's plenty of room for deviation.

Growing Spine Market

RBC Capital Markets analyst Glenn Novarro said that similar to DePuy Synthes, Medtronic's spine business continues to lose share in the worldwide spine market, but those share losses continue to moderate. Needham & Company analyst Mike Matson estimates the com-

Medtronic Spine 3Q15	Sales $ in million	% Change
Total Reported Sales	**$740.0**	**down 1%**
Core Spinal	$543.0	down 2%
Biologics	$122.0	8.00%
Interventional Spine	$75.0	down 3%

Source: Medtronic plc

Medtronic Spine Headquarters / Source: Memphis Business Journal

pany lost 0.5% from the previous year's quarter.

These numbers were good news for all spine as the worldwide spine market's growth improved sequentially for third straight quarter, according to Novarro.

Management estimated that the worldwide and U.S. core spine markets grew low-single-digits on a constant currency basis and it was the third quarter in a row of modest sequential improvement in the spine market. Novarro estimates that the U.S. spine market was up approximately 3.0 to 3.5% in the quarter while international spine market growth was up high-single-digits on a constant currency basis.

Novarro says he believes the underlying health of the worldwide spinal market improved sequentially during the fourth quarter, with better than expected U.S. and international growth. "This better than expected U.S. growth was in line with our takeaways post NASS [North American Spine Society] and our recent U.S. spine surgeon survey."

They must be smilin' in Dublin and doing a jig in Memphis. — *WE*

LEGAL

Spineology Sues Wright Medical Over Reamer Patent

Minnesota's Spineology, Inc. claims Tennessee-based Wright Medical Technology, Inc., "willfully" infringed on one of its patents.

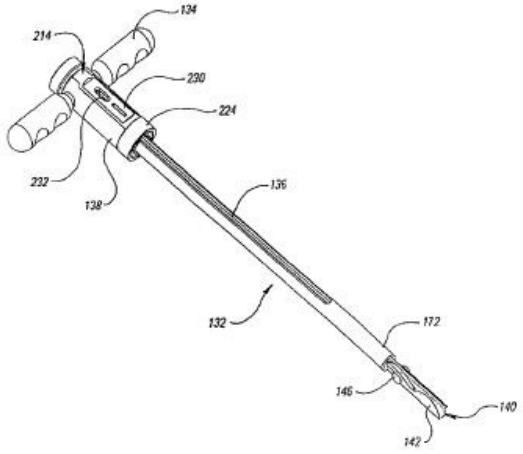
In a lawsuit filed on January 27, 2015 in a Minnesota federal court, Spineology says that in October 2006 it sold Wright Medical 50 of its expandable reamers, "solely for Defendant's use in procedures for core decompression of the femoral head in avascular necrosis. No license to the '757 patent was conveyed to Defendant in that sale."

'757 Patent

U.S. Patent No. RE42,757 (the '757 patent), is entitled "Expandable Reamer" and was reissued on September 27, 2011.

Spineology claims that Wright Medical's X-REAM percutaneous expandable reamer infringes on their '757 patent. The company also claims the infringement is willful because it sent Wright Medical a cease-and-desist letter in March 2014 and made numerous calls to Wright Medical's lawyers informing them of their alleged infringement and asking for a response.

According to the lawsuit, the only response Spineology received was to be



'757 Patent Expandable Reamer/Knobbemedical.com

told that Wright Technology was considering the patent infringement allegation. Wright Medical made no defense to Spineology's allegations, according to the suit.

"Defendant [Wright Medical] has not informed Spineology of any specific grounds for a belief that the claims of the '757 Patent were not infringed, were invalid, unenforceable; nor did Defendant provide any other specific reason why it would not be liable for infringement...The acts of infringement by Defendant are willful, intentional, and in conscious disregard of Spineology' s rights in the '757 Patent," states the lawsuit.

Relief Sought

Spineology is asking the court for a preliminarily judgment and permanently enjoining and restraining Wright Medical from directly infringing, inducing infringement, and/or contributing to the infringement of the '757 Patent. The company also wants Wright Medical to pay treble damages for willful infringement. The court is asked to determine damages.

Wright Medical had no comment on the lawsuit. —*WE*

Device Industry Lays Out "Innovation Agenda"

AdvaMed, the medical device industry's largest trade group, has unveiled an "Innovation Agenda" which it says will not cost a lot of tax dollars because the recommendations are mostly process reforms.

The set of policy proposals were released on February 10, 2015 and outline a series of regulatory, reimbursement, tax, international trade and R&D reforms which will help "speed patient access to the next generation of life-changing innovations," according to the group.

The initiative includes specific recommendations under five policy pillars:

Improve FDA's Regulatory Processes

- Meet and exceed the groundbreaking 2012 user fee agreement goals for such key objectives as reductions in total review times and more frequent and substantive interactions between FDA and product sponsors.
- Revitalize the "least burdensome standard" for regulatory review through enhanced reviewer training and encouraging the use of valid scientific evidence from such sources as registries, experience in foreign markets, and peer-reviewed journal articles, where appropriate, to support safety or effectiveness determinations.
- Encourage FDA to accept international consensus standards.
- Streamline the CLIA waiver process to accelerate the availability of point-of-care, rapid diagnostic information to physicians and patients.
- Allow the use of central Institutional Review Boards to facilitate the conduct of multicenter clinical trials.
- Reduce the review burden on FDA and companies by allowing companies to self-certify minor changes to devices if their quality system has been certified as capable of evaluating such changes.
- Improve the advisory committee process to reduce delays in product approvals and enhance the fairness and transparency of the process.
- Encourage the development of technologies for rare diseases and pediatric populations.
- Work with FDA to assure that postmarket surveillance is effective and efficient; provides timely, reliable, and actionable data; minimizes unnecessary burdens on providers and industry; and is facilitated by smooth implementation of the Unique Device Identifier program.

Restructure CMS's Coverage and Payment Processes

- Establish automatic Medicare coverage of FDA-approved clinical tri-

Innovation Agenda/AdvaMed

als rather than requiring a duplicative and potentially time-consuming separate Medicare approval process.
- Expand coverage of telehealth services, including remote monitoring, and of disposable, prevention and treatment technologies used in the home.
- Streamline Medicare's process for granting temporary outpatient and physician payment codes to new technologies and prohibit Medicare contractors from arbitrarily denying payment for these technologies.
- Require state Medicaid programs to take patient views into account in making coverage decisions.
- Increase the transparency and fairness of the local coverage determination process.
- Improve the new technology add-on payment program to capture a larger share of important new technologies and set payments more appropriately.
- Establish payment levels more promptly for new technologies used in the inpatient setting, using the best available data.
- Improve the methodology for establishing payment for technologies used in the outpatient setting and for updating payments to ambulatory surgical centers.
- Implement ICD-10 this fiscal year.

Reform the U.S. Tax System and Repeal of the Medical Device Excise Tax

- Repeal the medical device excise tax.
- In the context of comprehensive tax reform, create a level competitive playing field for made-in-America medical technology.
- Enact new tax incentives to invest in start-up companies creating new treatments and diagnostics;
- Lower the overall corporate tax rate.
- Provide incentives comparable to those of other countries for development and manufacturing of technology.
- Conform the treatment of international earnings to that of competitor nations.

Improve Access to International Markets

- Work with the U.S. government to encourage foreign governments to establish regulatory and payment systems for medical technology that are fair, transparent, nondiscriminatory and based on international best practices.
- Enact Trade Promotion Authority to negotiate the Trans-Pacific Partnership and the TransAtlantic Trade and Investment Partnership, and assure that those agreements include provisions that improve market access for medical technology.
- Enforce provisions of existing trade agreements such as the U.S.-Korea Free Trade Agreement to assure fair access for U.S. technology products.

Support the Maintenance and Growth of an R&D Infrastructure

- Provide steady growth in funding for the National Institutes of Health and the National Science Foundation.
- Improve the Small Business Innovation Research and Small Business Technology Transfer programs by raising the amount of funding (in the context of rising NIH and NSF funding), allowing larger individual grants to better recognize the costs actually incurred by start-up companies.
- More effectively tap the vast intellectual resources of our nation's universities and academic health centers by providing federal technical assistance to establish and diffuse technology transfer best practices.
- Streamline Institutional Review Board activities to reduce barriers to initiating collection of clinical data on new treatments, particularly for multicenter trials, without sacrificing protection of human subjects.

Who Will Pay?

Speeding up FDA reviews, increasing CMS coverage and payments, reforming the U.S. tax system, repealing the medical device tax and funding increases will certainly cost some money. Repealing the excise tax alone would cost $26 billion over the 2015-2024 period, according to the Joint Committee on Taxation. But as AdvaMed leaders have told us in the past, it's not their job to tell Congress where to cut funding to pay for policy initiatives which they believe strengthen U.S. medical device manufacturing.

AdvaMed has laid out an agenda. Policymakers will have to make financial choices.

"Advanced medical technology can provide solutions to the challenges facing global health care systems – improving patient access to high quality, efficient care," said AdvaMed Board Chairman Vincent A. Forlenza, chairman, CEO and president, BD. "Our industry is committed to the development of new diagnostics, treatments and cures that improve public health. Policies that promote a sustainable health innovation ecosystem are required in order to put these technologies in the hands of the public." —*WE*

LARGE JOINTS

Wine OK but Hold the Beer

Wine lovers rejoice. Regular wine drinkers are less likely than drinkers of other beverages to develop knee osteoarthritis (OA), according to a British study reported by Nancy Walsh, senior staff writer for *MedPage Today.* But beer drinkers beware. The same benefit does not accrue to you. Rather the odds of getting OA increase.

The study was conducted by Michael Doherty, M.D. of the University of Nottingham, U.K., and his colleagues. They found that when they compared people who drank wine the odds for getting knee OA were 0.55 among those who drank four to six glasses of wine per week and were 0.48 for those who drank seven or more.

For beer drinkers it was a different story. Walsh reported that the odds ratio for knee OA were 1.76 for those who drank 8 to 19 half-pints of beer per week, and 1.93 for those drinking 20 or more half-pints per week.

In reviewing the results the investigators immediately considered the fact that "alcohol itself is not necessarily the factor that influences the risk of knee OA but that other factors contained within wine and beer may exert differential effects on the risk of OA."

Few studies have looked at alcohol consumption as a risk factor for OA. This study included 1,001 individuals with knee OA, 993 with hip OA, and 933 healthy subjects who served as the controls. They found that the subjects with OA were more often obese, had lower socioeconomic status, and more commonly had gout and cardiovascular disease than did the controls.

According to Walsh, the researchers found no link in a model adjusted for multiple factors including age, gender, body mass index, smoking, joint injury, and physical activity. And unlike wine and beer drinkers, they found no association between the drinking of spirits and knee OA. —*BY*

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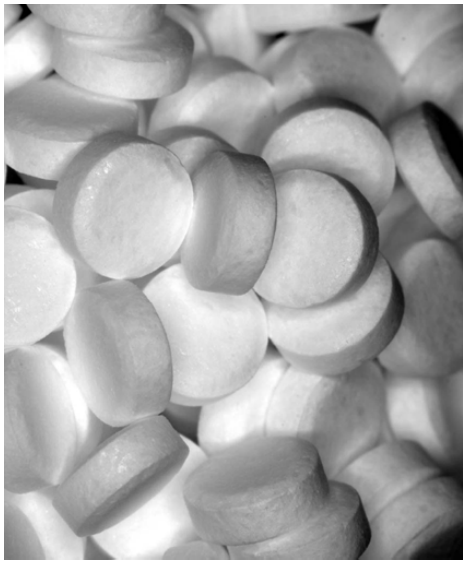
Hormone Replacement Therapy Cuts Hip Revision Rates

Hormone replacement therapy (HRT), taken by a patient after a total knee or hip arthroplasty, was associated with almost a 40% decrease in the rate of revision surgery, according to *Med Page Today* senior staff writer, Nancy Walsh. Walsh reported on a study funded by the National Institute for Health Research and conducted at the Nufield Orthopedic Center, University of Oxford, United Kingdom.



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The most common reason joint replacements fail after the first year, according to Walsh, is aseptic loosening, resulting from osteolysis in the neighboring bone. The study authors wrote, "The mechanisms underlying loosening are still obscure, but it is widely accepted that periprosthetic bone loss secondary to chronic inflammation and osteoclastic activity is the main pathway. Strategies aimed at reducing periprosthetic osteolysis and the consequent bone loss and migration would seem a logical way to reduce arthroplasty failure and hence the need for revision."

Researchers looked at the rate of revision of 224,733 women following hip or knee joint replacement from 1986 to 2006. Two thousand seven hundred of the women had been HRT users and 8,100 had not. The later group was the control subjects. The mean age was 65 and 56% of the women had had a hip replaced.

The results, according to Walsh: the use of HRT for six months or longer was associated with a failure rate of 2.61 per 1,000 person-years-at-risk which compared with a failure rate of 4.25 per 1,000 for non-HRT users.

The timing of the HRT use also proved to be significant. There appeared to be little or no benefit if it began before the arthroplasty but there was a "strong protective effect" observed when it was taken following the surgery. The subject's adherence to the treatment and the size of the HRT dose also influenced the outcome. Those with high adherence had a decreased hazard ratio of 0.22.

Walsh quoted the study authors who wrote, "Animal studies have suggested that estrogen deficiency exerts a negative influence on bone tissue around knee implants, while HRT minimizes periprosthetic bone loss and improves bone ingrowth around the implant." —*BY*

Florida Joint Replacement Cost Disparities

The recent research conducted by Blue Cross Blue Shield into variations in the cost of hip and knee joint replacement surgery, two of the fastest-growing medical procedures in the United States, continues to reverberate. The study is titled, "*A Study of Cost Variations for Knee and Hip Replacement Surgeries in the U.S.*"

Researchers looked at claims for more than 53,000 procedures in 64 healthcare markets from 2010 to 2013 and found that typical joint replacements cost an average of a little over $30,000. But there were price swings of as much as 313% depending on where patients had their surgeries performed.

In Florida the study reviewed medical markets in Orlando, Jacksonville, Fort Myers-Cape Coral/Punta Gorda, and Tallahassee. According to the report, the medical facilities in the city of Orlando showed the greatest price disparities. It was 88% for knee and 89% for hip replacement surgeries, while the price differentials amounted to only 6% for knee and 2% for hip replacement in Tallahassee.

When comparing Florida markets, researchers found that average costs for knee replacements ranged from a high of $32,600 in Tallahassee to a low of $28,100 in Fort Myers. A hip replacement cost from a high of $30,222 in Jacksonville to a low of $27,500 in Orlando.

"Extreme price variation in healthcare can have obvious financial consequences for individuals and employers," the study's authors wrote. "And from a macroeconomic perspective, it can have serious implications for the sustainability of (the) U.S. healthcare system." — *BY*

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SPINE

Dirty Dancing Actress' Neck Saved by Mobi-C

Actress Jennifer Grey was in so much pain that she wasn't up for much activity…Dirty Dancing or otherwise. After more than 30 years of severe neck pain, Grey underwent surgery and received a two-level artificial disc replacement using Mobi-C technology from LDR Spine. Robert Bray, Jr. M.D., founder of the DISC Sports and Spine Center in Los Angeles, performed the surgery.

Jennifer Grey/Courtesy of thedoctorstv.com

Jennifer Grey had been suffering with neck pain for years, brought on by a tragic car accident. Grey, also known for her season 10 victory on *Dancing With the Stars*, sought out Dr. Bray. According to the DISC website, Dr. Bray indicated, "Jennifer's exam was very abnormal. When I tapped her reflexes, they were very jumpy, which is a sign that

something is pressing against the spinal cord…"

"She was told no. No, she cannot dance. No, she cannot do any type of workout. No, she cannot play any sports." Dr. Bray adds, "Frankly, I told her she probably shouldn't be driving around."

Grey and Dr. Bray recently appeared on an episode of *The Doctors* to explain her journey. She commented in the January 29, 2015 episode, "After four surgeries I said to him [Dr. Bray], 'Can I do *Dancing With the Stars*?' 'Yeah, you can do it,' was his answer. The second to last night I was doing the freestyle and it didn't feel quite right. Turns out, I had ruptured my disc."

And although she won the competition, her condition worsened. "I did not want to go out at night, I did not want to get up to workout in the morning…I was making my daughters lunch and all of the sudden I was just crumpled on the floor crying."

Dr. Bray stated on ***The Doctors***, "It's a new procedure to do multiple levels of disc replacement, especially next to an existing fusion. The very first incision to the last stitch is done under high power magnification. The space is literally stretched back open to recreate height in the disc. The disc replacements devices are tapped into place…"

Joe Ross, executive vice president of Global Marketing for LDR Spine, told *OTW*, "LDR is pleased to see another example of a Mobi-C recipient who has benefitted from cervical disc replacement. Our hope is that Jennifer's appearance on *The Doctors* helps to spread further awareness about the procedure and educate others on their treatment options."

And how is Grey now? "I'm pretty fantastic." — *EH*

PEOPLE

McLeer and Ainsworth Move to ChoiceSpine

ChoiceSpine, LP not only acquired Baxano Surgical Inc.'s Veo Lateral Access & Interbody Fusion System in early February, but the company also acquired Steve Ainsworth, Ph.D. Ainsworth was TranS1's third employee and served as the company's vice president of Research and Development throughout the Baxano acquisition. He will serve ChoiceSpine in the same capacity.

In a February 25, 2015 press release, ChoiceSpine also announced the hiring of Tom McLeer as senior executive vice-president. McLeer will serve as an advisor to ChoiceSpine founders Rick Henson and Marty Altshuler, assisting with strategic planning and business development.

McLeer was most recently senior vice president of U.S. Commercial Operations for Alphatec. He had responsibility for U.S. Sales and Marketing, Research and Development, and Biologics. Before Alphatec, McLeer was chief marketing officer and general manager of spinal operations for Pioneer Surgical.

The company said it had double-digit growth in 2014 with the introduction of two new fusion systems and three line extensions. It anticipates growth of 25% in 2015 due to the launch of four new systems to be introduced over the next few months.

In August and September 2014, ChoiceSpine announced FDA 510(k) clearance for its Lancer Pedicle Screw System and the Thunderbolt Minimally Invasive Pedicle Screw System.

Henson and Altshuler started ChoiceSpine in December 2006 in Knoxville, Tennessee. They acquired Orthotec, then, a $40 million dollar company and now hold the exclusive rights for the U.S. market, several patents and six specific spinal conditions. Orthotec is the company to which Alphatec agreed to pay $49 million over the next seven years to settle a lawsuit filed by Orthotec alleging fraudulent transfers of assets of a company that Alphatec had previously acquired. —*WE*

Top and bottom: Tom McLeer and Steve Ainsworth, Ph.D./Courtesy of ChoiceSpine, LP

David W. Bates, M.D., M.Sc. Leading Innovation at BWH

David W. Bates, M.D., M.Sc. has been named senior vice president and chief innovation officer at Brigham and Women's Hospital (BWH), effective immediately. Dr. Bates, editor of the *Journal of Patient Safety*, will also continue to lead the Division of General Medicine and Primary Care at BWH.

"Innovation is at the core of our academic mission," said Elizabeth G. Nabel, M.D., president of Brigham and Women's Health Care, in the February 6, 2015 news release. "Dr. Bates brings a depth and breadth of experience in this area, and under his leadership, the Brigham will support innovation and collaboration to help solve the important and difficult health care challenges of today and tomorrow."

Dr. Bates, who previously served as the Chief Quality Officer at BWH, "will focus on identifying opportunities to drive transformative change at BWH, with the goal of translating inventions, discoveries and new ideas into services and products that benefit patients and improve the delivery of care. He will also serve as executive sponsor of the Brigham Innovation Hub (iHub), a catalyst of innovation across the hospital."

"Dr. Bates is also a professor of medicine at Harvard Medical School and a professor of Health Policy and Management at the Harvard School of Public Health, where he co-directs the Program in Clinical Effectiveness. He also serves as medical director of Clinical and Quality Analysis for Partners HealthCare. He directs the Center for Patient Safety Research and Practice at BWH and serves as external program lead for research in the World Health Organization's Global Alliance for Patient Safety."

Brigham and Women's Hospital

Dr. Bates told *OTW*, "Through my experience leading a patient safety research center, I have been exposed to and involved in many partnerships that require interaction with my colleagues in industry. These opportunities, along with my experience in commercializing several ideas, make me excited to continue this work of facilitating innovation in a systematic way across the Brigham." — *EH*

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