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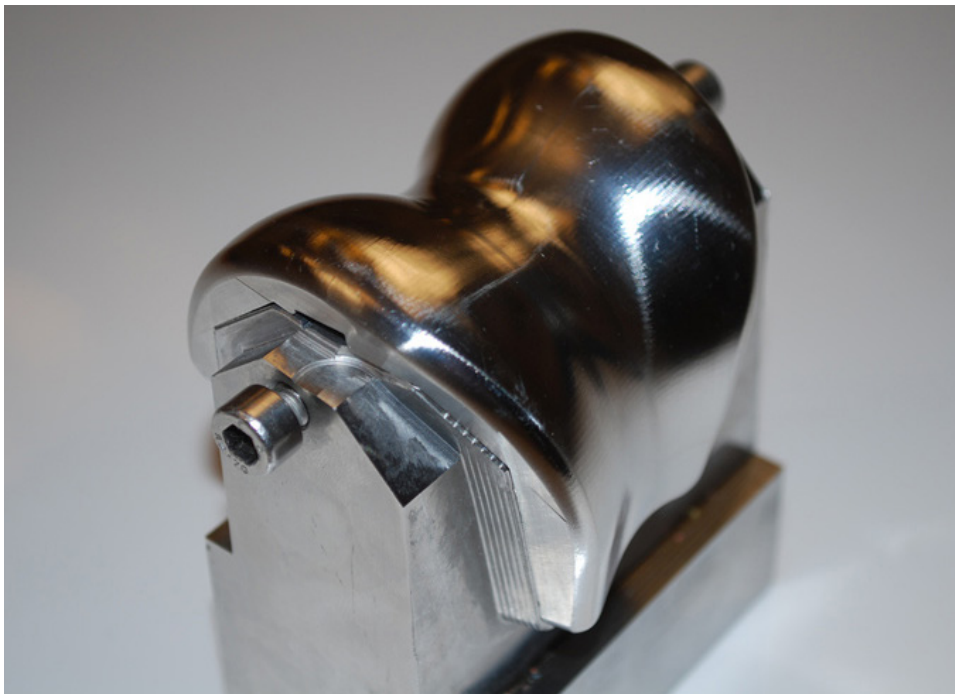
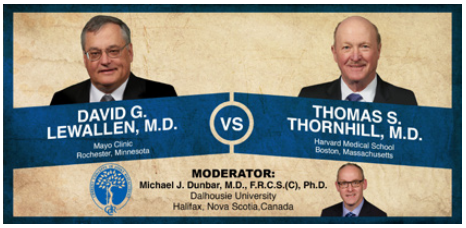
Orthopedics This Week

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: Health care companies in the S&P 500, which include everything from health insurers to medical device manufacturers to biotechnology companies, are up 26% in the past year. That's the hottest of all S&P sectors. Can it continue? Maybe not. Ortho companies are trading at an average future P/E is 17.6x. Average PSR is 4.01 and average PEG is 3.34x. And revenues are only growing at low single digits.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	22.78%	0.10%	Not only the lowest valuation in ortho, but also a great cash flow story with a 23% operating margin.
2	2	Integra LifeSciences	13.74	(1.24)	Second lowest valuation in ortho. Re-organizing for higher rates of growth and profitability. SeaSpine spin off nearly done.
3	3	ConMed	10.41	4.13	Value of ConMed is up 34% in the last year as investors bet on new management unlocking hidden value.
4	6	RTI Biologics	7.50	4.82	Over the last four quarter RTI has consistently outperformed analysts' expectations. Analysts forecasting 8.30% sales growth this year.
5	4	Globus Medical	30.82	0.19	Analysts increased their earnings outlook slightly for 2015, from $1.02 to $1.04. Sales still expected to grow about 9%.
6	5	NuVasive	9.30	2.77	The most expensive, in valuation terms, equity on the Power Rankings. But new management brings with it new possibilities.
7	8	Zimmer	30.35	(1.47)	One of Wall Street's savviest investors, Eric Mindich, has bought a huge stake in ZMH. Interesting timing.
8	7	Medtronic	27.92	(2.64)	Medtronic is officially an Irish company. In celebration, it raised the dividend 25% and announced a $6 billion stock buyback.
9	10	Smith & Nephew	20.19	(3.35)	Arthrex just paid SNN $99 million as part of a patent infringement settlement. That's a lot of suture anchors.
10	9	Johnson & Johnson	28.44	(3.61)	It is so interesting to see how JNJ zigs while other ortho equities zag. JNJ's stock clearly marches to different set of bongo drums.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Orthofix	OFIX	$34.42	$646	5.49%
2	MiMedx Group	MDXG	$11.02	$1,197	5.40%
3	RTI Biologics Inc	RTIX	$6.74	$387	4.82%
4	ConMed	CNMD	$58.43	$1,613	4.13%
5	LDR Holding Corp	LDRH	$43.12	$1,146	3.70%
6	TiGenix	TIG.BR	$0.82	$132	3.19%
7	NuVasive	NUVA	$49.66	$2,401	2.77%
8	Tornier N.V.	TRNX	$26.36	$1,292	2.61%
9	Wright Medical	WMGI	$26.90	$1,383	2.28%
10	CryoLife	CRY	$11.20	$317	1.73%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Aurora Spine	ASG	$0.57	$11	-20.03%
2	Alphatec Holdings	ATEC	$1.31	$131	-9.03%
3	MicroPort Scientific	853	$0.51	$725	-6.39%
4	Bacterin Intl Holdings	BONE	$3.40	$24	-5.29%
5	Johnson & Johnson	JNJ	$99.86	$276,916	-3.61%
6	Smith & Nephew	SNN	$34.37	$15,370	-3.35%
7	Medtronic	MDT	$76.71	$109,055	-2.64%
8	Exactech	EXAC	$20.99	$294	-1.78%
9	Zimmer Holdings	ZMH	$112.66	$19,198	-1.47%
10	Integra LifeSciences	IART	$67.58	$2,226	-1.24%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$99.86	$276,916	16.84
2	Exactech	EXAC	$20.99	$294	18.09
3	Globus Medical	GMED	$25.78	$2,447	19.08
4	Zimmer Holdings	ZMH	$112.66	$19,198	19.37
5	Stryker	SYK	$96.88	$36,660	22.14

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MiMedx Group	MDXG	$11.02	$1,197	110.20
2	NuVasive	NUVA	$49.66	$2,401	102.43
3	CryoLife	CRY	$11.20	$317	59.62
4	RTI Biologics Inc	RTIX	$6.74	$387	44.11
5	ConMed	CNMD	$58.43	$1,613	31.58

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$25.78	$2,447	1.56
2	CryoLife	CRY	$11.20	$317	1.99
3	Exactech	EXAC	$20.99	$294	2.03
4	ConMed	CNMD	$58.43	$1,613	2.22
5	Stryker	SYK	$96.88	$36,660	2.51

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MiMedx Group	MDXG	$11.02	$1,197	7.35
2	NuVasive	NUVA	$49.66	$2,401	6.70
3	Smith & Nephew	SNN	$34.37	$15,370	4.79
4	Zimmer Holdings	ZMH	$112.66	$19,198	3.76
5	Medtronic	MDT	$76.71	$109,055	3.46

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.31	$131	0.63
2	Bacterin Intl Holdings	BONE	$3.40	$24	0.67
3	Exactech	EXAC	$20.99	$294	1.19
4	RTI Biologics Inc	RTIX	$6.74	$387	1.43
5	Orthofix	OFIX	$34.42	$646	1.65

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.82	$132	15.80
2	MiMedx Group	MDXG	$11.02	$1,197	8.59
3	LDR Holding Corp	LDRH	$43.12	$1,146	8.57
4	K2M Group Holdings	KTWO	$25.10	$995	6.32
5	Medtronic	MDT	$76.71	$109,055	5.38

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

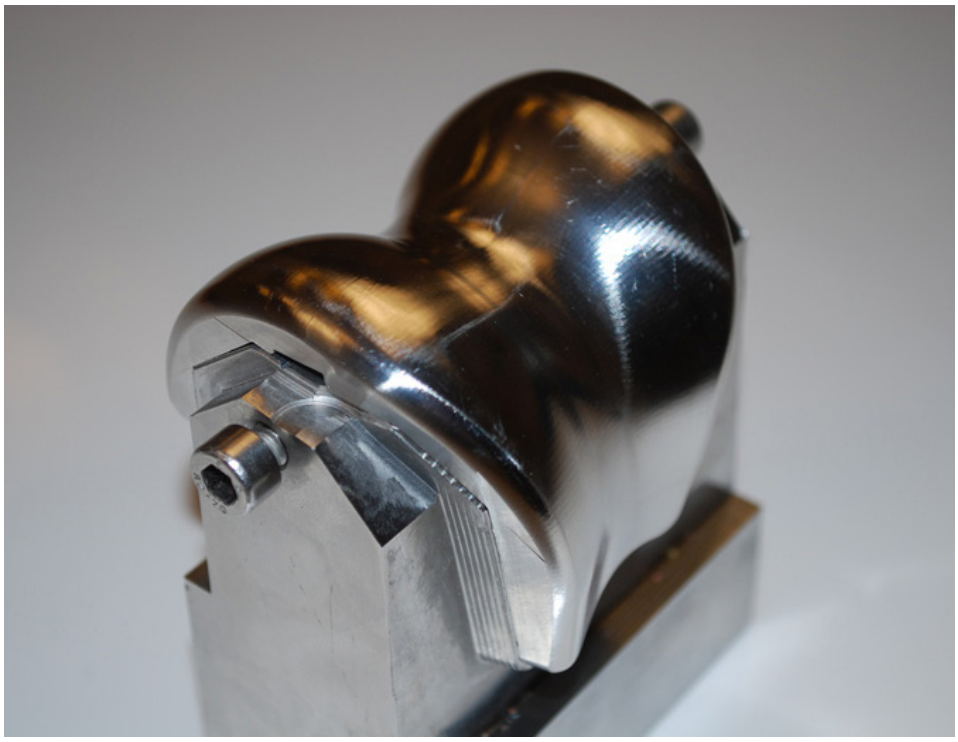
Did BCBS Cause a 500% Leap in Total Knee Surgery Rates?

BY ROBIN YOUNG

Did total knee surgery utilization rates rocket six-fold in Kansas for newly insured because of Obamacare or was there another reason—one tied to a viscosupplement policy change from Blue Cross Blue Shield of Kansas (BCBS)?

In April 2015 the Society of Actuaries issued a report which documented a nearly six-fold jump in total knee surgery utilization rates for new insurance enrollees in Kansas in the first quarter of 2014.

Analysis of insurance utilization rates by both the Society of Actuaries and the American Academy of Actuaries are the foundation of the underwriting process for all health insurance providers. It is also the source of information about the effects of Obamacare.



Knee Prosthesis/Source: Wikimedia Commons and Jordiferrer

This particular report caught our attention because it focused on new Obamacare enrollees and it showed that total knee surgery utilization rates had increased 500% for new Obamacare enrollees. That's the largest increase of any procedure.

500% Increase in Total Knee Surgery

Authors Rebecca Owen, FSA, MAAA, health research actuary and Daniel Maeng, Ph.D., research investigator, Geisinger Health System, wrote that after their preliminary examination of the use of healthcare services after the advent of the Patient Protection and Affordable Care Act (ACA) that "new enrollees appeared to have used preference-sensitive treatments at a level that exceeded the expectations of differences due to demographics alone, such as those used in actuarial rate calculations."

Furthermore, they wrote, "The average cost of care for these treatments incurred by the new enrollees appears to be much higher than the average cost of care incurred by members with continuous coverage, due to a higher proportion of more expensive treatments."

Like surgery.

By "preference-sensitive" services, Owen and Maeng mean medical procedures that can be delayed by the patient if there is an alternative treatment available or if there aren't good clinical guidelines or, most important, if there's no insurance coverage..

Here are the results of the Owen and Maeng Kansas analysis: *(See table on page 5.)*

Utilization rates for total knee replacement (TKR) rocketed to 6.19x historic rates. The next closest was lower back pain surgery utilization rates which jumped 2.49x.

That is a huge relative increase—almost three times higher than the second most popular procedure.

Service Category	Historic Utilization Rate (# of Procedures per Member Month x 1000)	Utilization Rate for New Enrollees (# of Procedures per Member Month x 1000	Change From Historic Rates
Knee Replacement Surgery	0.03	0.22	6.19x
Lower Back Pain Surgery	0.94	2.35	2.49x
Upper Endoscopy	1.20	2.94	2.44x
MRI/MRA	3.83	7.23	1.88x
CT	2.01	3.49	1.74x
Gallstone	0.25	0.38	1.51x
Knee Arthroscopy	0.40	0.41	1.01x
Dermatology	6.08	5.51	0.90x
TOTAL	**14.75**	**22.53**	**1.53x**

Source: Rebecca Owen, FSA MAAA Health Research Actuary Society of Actuaries Daniel Maeng, Ph.D. Research Investigator Geisinger Health System

(It is noteworthy that of the eight procedures analyzed, three were orthopedic.)

In fact, concluded the authors, in the first quarter of 2014, new enrollees were 50% more likely to opt for this market basket of preference-sensitive procedures than new enrollees in 2013.

50% more likely!

No Wonder Health Insurance Premiums Are Rising

Reports like this from either the Society of Actuaries or the American Academy of Actuaries form the basis for insurance company health policy rates. If Obamacare is going to result in a sharp increase in surgery utilization, then premiums will rise to pay for it.

But the data is preliminary. As the authors cautioned readers, a single quarter's results do not a trend make. "Actuaries who use these results as a reference point for work with their own populations should keep these differences in mind, and should be careful not to stretch the utility of these results too far. It appears that there is pent-up demand for some kinds of services—particularly preference-sensitive services—and it will be interesting to see if this tapers off over the year."

Health insurance rates are rising. All payers were required to tell regulators if they plan to raise rates by 10% or more before a June 1 deadline, under the ACA. Some of the proposed rate hikes are well in excess of 10%. On average, said Caroline Pearson, vice president for health reform at the consulting firm Avalere Health, on National Public Radio, the insurance hikes for 2016 will likely be around 6%—which are higher than average.

Until this year, health insurers have had to guess at Obamacare enrollment and healthcare service utilization rates. Initially, the rates were low. This was, after all, the Affordable Care Act.

With preliminary 2014 data coming in (e.g., The Society of Actuaries report), insurers are beginning to create expense models and adjust their rates accordingly.

And that report said that utilization rates for total knee replacement jumped by a factor of 6.19x (about 500%).

Kansas Blue Cross Stopped Reimbursing for Viscosupplementation in 2014

Not mentioned and likely not known to the authors of the Society of Actuaries report is that Blue Cross Blue Shield of Kansas City eliminated coverage for viscosupplementation in late 2013 and Blue Cross Blue Shield of Kansas eliminated coverage in May 2014.

What role does viscosupplementation play in determining rates of total knee replacement?

According to data submitted at the 2015 OARSI (Osteoarthritis Research Society International (**OARSI**) World Congress) it plays a powerful role in delaying TKA.

According to this data, viscosupplementation injections delay total knee replacement surgery by as much as two years. Patients who do not receive a viscosupplement injection, on average, went on to have a TKA within 114 days of an OA (osteoarthritis) diagnosis.

The study was conducted by researchers from UCLA, Louisiana State University and Seikagaku Corp. It was sponsored

by two viscosupplement companies—Bioventus and Seikagaku Corporation.

The researchers looked at data for 182,022 patients who'd been diagnosed with OA. From the date of the diagnosis, patients who received a hyaluronic acid (HA) viscosupplement injection in their knee were able to more than double the time to total knee replacement surgery.

Patient who did not receive an HA injection, had a total knee replacement within 114 days, on average. Patient who DID receive an HA injection were able to delay their knee replacement to 386 days after OA diagnosis. The more HA injections the patients had, the longer the delay. Patients, for example, with three courses of HA injections were able to delay, on average, the total knee replacement 875 days.

The researchers were Roy Altman M.D., at UCLA, Sooyeol Lim MSc., Seikagaku Corp., Grant Steen Ph.D., with Bioventus and Vinod Dasa M.D. at Louisiana State University.

Perfect Storm for TKA?

The number of health insurers who are canceling reimbursement for HA injections is rising and it is coming at a time when insurance coverage for musculoskeletal treatment has expanded dramatically. In the past 24 months payers in Florida, Oregon and Massachusetts have stopped paying for HA injections.

Total knee replacement, like many other musculoskeletal procedures, can be delayed if there are alternative treatments available—like viscosupplementation. But if viscosupplementation is no longer reimbursable, then, according to the OARSI study, total knee replacement rates will likely increase.

TKA, of course, is reimbursable. At significantly higher rates than viscosupplementation.

More insured. Fewer options for patients with OA of the knee.

Is this the perfect storm for TKA?

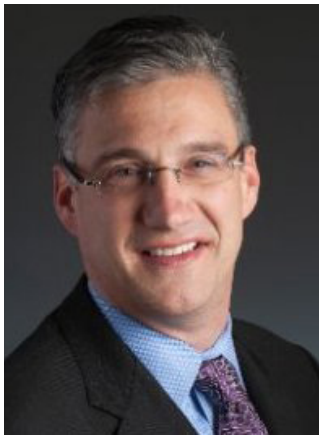
To read the Society of Actuaries report for yourself go to this link: https://www.soa.org/Research/Research-Projects/Health/2015-pent-up-demand-health.aspx ♦

SeaSpine Goes Public

BY ROBIN YOUNG

We caught up this week with new SeaSpine CEO Keith Valentine somewhere between Minneapolis and Chicago as he and CFO John Bostjancic were on their 7th presentation to institutional investors that day. It was the middle of the afternoon and the two long-time orthopedic and spine industry execs were literally in transit.

On July 1, 2015 SeaSpine Holdings Corporation will become the newest member of the public spine company fraternity—symbol, appropriately enough, will be "SPNE." It is being spun out of Integra LifeSciences Holdings Corporation in a tax-free transaction.



Keith Valentine

Honestly, the best part of the SeaSpine presentation is the guys making it.

Considering that sales last year were $138 million, down 5% from 2013, and that SeaSpine lost $24.5 million, this is a corporate fixer upper. But the structural foundation of this company is good and the neighborhood is excellent.

Courtesy of SeaSpine Holdings Corporation

Kirt Stephenson, founder and chairman, couldn't do much better than Keith Valentine and John Bostjancic and the team they're assembling to do the necessary renovations.

The Foundation

The key to SeaSpine is that it is scalable.

A little digging into the SeaSpine numbers reveals some of what Valentine (who could pretty much go anywhere he chose after his career at NuVasive, Inc. and before that Sofamor Danek) found attractive.

Fifty percent of the company's sales are from biologics. Those sales increased in 2014. Spine hardware sales declined and that pulled overall revenues down.

Biologics accounted for $67 million of SeaSpine's 2014 sales which means that, in terms of market share, SeaSpine biologics is punching above its weight. In the bone graft market, SeaSpine holds an 8.6% share. In the demineralized bone market SeaSpine has a 12.3% share.

By contrast, SeaSpine's spine hardware business holds barely a 1% share of the global spinal hardware business.

Right away, Valentine and his team want to leverage that biologic foot print with a couple of new technologies and a pipeline of MIS (minimally invasive surgery), adult deformity and degenerative disc disease (DDD) hardware products.

To put this in perspective, if SeaSpine had the same market share in hardware that they have in biologics, they'd be as large as NuVasive. And in every spine case, biologics and hardware go hand in hand.

SeaSpine also has its own biologics production capabilities—with plenty of excess capacity.

As CFO John Bostjancic pointed out during this presentation, SeaSpine's infrastructure is in place for product and geographic expansion.

So, while SeaSpine may not have a lot of curb appeal, the foundation is solid

and can support Valentine's plans for a much larger company.

The Neighborhood – Spine and Biologics

Every spine surgery depends on a biologic product to create a successful outcome. No corner of the orthopedic industry has come to rely on biologics more than spine and neurosurgery. And the payer attitudes toward spine, while still cool, are much better than they were five or six years ago.

So spine and biologics are an excellent neighborhood to try to rehab a fixer-upper like SeaSpine.

Keith Valentine has been to this rodeo before. Several times. Young Valentine started in the spine business in 1992 at Danek. He's seen and been part of every major procedural, implant and regulatory spinal/biologic cycle over the past 23 some years. He's on a first name basis with every major spine and neurosurgeon. He's helped to build two of the largest and most innovative spinal implant companies ever—Sofamor Danek (Medtronic Spine) and NuVasive.

In the last couple of years SeaSpine has introduced about two new products annually. Valentine told the institutional money managers on the road show that he wants to introduce eight new products in the next six to eight quarters. He's just warming up. This is like stretching exercises for an Olympic sprinter.

For sure, he and Bostjancic want to manage expectations. But both NuVasive and Sofamor Danek were famous for a steady stream of new and strong product introductions. Within a couple of years, SeaSpine will be doing the same thing.

For SeaSpine's distributors, it'll be like drinking from a fire hose.

They should check with their colleagues at NuVasive or Globus Medical, Inc. to see what life is like when there's a new product a month—or more.

But, and here is where Valentine dropped a key clue on the institutional investors on managing a fast growing spine company. None of that product rollout will be remotely possible unless there is a monetary investment in instruments and trays. We're talking a seven, maybe eight figure investment.

The sales reps might be able to sell the new gizmo, but if there's no new instrument tray and training and support for

the surgeon, it's an exercise in futility. And that rep will soon be casting their lot with another of the fast growing young spine companies like K2M, Inc. or LDR Holding Corporation.

Both Valentine and Bostjancic kept repeating a simple mantra on the road show—$47 million; $47 million in cold hard cash; $47 million to build instrument trays and make sure surgeons have the trays where they want them, when they want them and exactly how they want them. For the SeaSpine rep, that's like a warm blankie.

Of course, SeaSpine is not known for its ability to innovate spinal implants, biologic products or instruments. The great innovations of the past five years in spine have come from NuVasive, LDR, K2M, Globus and other fast growing spine firms.

Valentine is pointing SeaSpine at the obvious growth markets for spine—MIS, adult deformity and the bread and butter space, DDD. He highlighted two new products for the fund managers—Accell bone matrix bone void fill and NanoMetalene—but R&D is where he and his team have work to do.

Of course, there are a fair number of very innovative small spine firms who are starving for capital…so perhaps there is a bolt-on or two in SeaSpine's future.

SeaSpine's Background

When Integra acquired SeaSpine in 2011, Integra CEO Stuart Essig said: "SeaSpine is an ideal strategic fit for Integra, as the combination brings together two well-respected innovators in the spinal fusion market. Integra has a track record of successfully executing on and integrating strategic transactions, and we expect to realize the benefits of this combination in both our top line growth and earnings per share over the long-term."

Kirt Stephenson, president of SeaSpine echoed Essig's optimism highlighting specifically: "Integra's broad access to U.S. hospitals and GPO agreements across its selling organizations." To Stephenson, Integra represented a new level of infrastructure and financial resources. As he said at the time, "Integra's strong balance sheet provides stability and growth capital necessary for us to emerge as a leader in a rapidly consolidating market."

Except the spine market didn't consolidate.

When it joined Integra in 2011, SeaSpine was posting up about $50 million in annual sales. Integra paid 1.78x sales. Today, on average, public spine companies are trading for twice that.

Stephenson became Integra's president of U.S. Spine and reported to Brian Larkin, president, Global Spine and Orthobiologics and Head of Strategic Development.

SeaSpine + Theken

Before buying SeaSpine, Integra bought Akron, Ohio-based Theken Spine, LLC (and Theken Disc, LLC and Therics, LLC) three years earlier in 2008. Theken cost $75 million and brought $34 million in incremental sales to Integra. Theken had been growing at a 20% annual rate so Integra paid a bit more for Theken (2.2x sales) than it would later for SeaSpine.

But, unlike SeaSpine, Theken's management did not stay around very long.

At the time, Integra was hoping that Theken would bring several strategic benefits including a whole line of spinal implants, a very innovative portfolio of 3D printed implants and electronics and a base of established spine hardware distributors.

Theken was ten years old in 2008. Its main lines were cervical plates, pedicle screws, spacers, and degenerative/deformity and trauma devices.

Included in the purchase was Therics, a quirky research stage company that essentially 3D printed synthetic bone substitute products.

But the investment in Theken required something. It required, it turned out, SeaSpine and Kirt Stephenson. In short, to be an effective player in the spine market, Integra needed to build scale and upgrade its ability to develop new products and train its distribution network.

On day one SeaSpine doubled Theken's distribution network and put the combined revenue based at a decent $90 to $100 million.

Wall Street's Take

Wall Street believes in Keith Valentine and is trying to assess how much of a fixer upper SeaSpine really is. Our guess is that the smart money will bet on management, but valuation will also reflect the fact that SeaSpine is the 8th public spine company and one that has, to date, been distinctly unable to generate sales growth.

Wall Street invests in two things. Growth and cash flow.

But the pedigree of this team is superb. Investors have made a lot of money in the past betting on SeaSpine board member Stu Essig and new CEO Keith Valentine. We think they'll be delighted for another bite of the apple.

As we said, the best part of the SeaSpine road show was the guys making the presentation.

Finally, one Wall Street analyst who seems to have consistently analyzed Integra and the spin off correctly, senior Wall Street analyst Larry Biegelsen at Wells Fargo, said that spinning off SeaSpine would be accretive to Integra's growth and margins.

As he wrote in 2014 to his clients: "While we would have preferred to see an outright sale of IART's [Integra] spine business, we think the spinoff gives IART the option to separate the business while limiting disruption. We have concerns that a spinoff could be riskier than an outright sale because public company costs will weigh on margins and the spine business would be a relatively small player in the spine market. Given that the spinoff is not expected to be completed for a year, we think it is still possible that IART could attract a potential buyer for the spine business, but we think that scenario is unlikely. Based on our estimates and assumptions, we believe that separating the businesses could accelerate growth at legacy IART by 1-2% and could add 100bps to operating margin."

Final Note

We've been covering the spine industry since 1995. Lack of innovation has hurt spine companies and SeaSpine is a text book case of that. Spinning it off, landing Keith Valentine, and making biologics a center piece of the rehabilitation story sounds to us like the right formula for getting up to speed with the other innovative, strong spine growth companies. ◆

Hand Surgeon to Lead AMA? // Leesa Galatz, M.D. New System Chair at Mount Sinai // James Kang, M.D. to Chair Orthopedics at Brigham and Women's

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

Andrew W. Gurman, M.D. and American Medical Association

Andrew W. Gurman, M.D., Orthopedic Surgeon, to Lead AMA A hand surgeon from Pennsylvania has just been tapped to lead the nation's largest physician association—the American Medical Association (AMA)—Dr. Andrew W. Gurman, a former speaker and vice speaker of the Pennsylvania Medical Society House of Delegates and chair of the Pennsylvania Medical Society Political Action Committee, will assume the presidency in June 2016. Dr. Gurman is in private practice in Altoona, Pennsylvania.

A native of New York City, Dr. Gurman grew up in Mount Vernon, New York, and attended Syracuse University. He received his medical degree from the State University of New York Upstate Medical University, Syracuse, in 1980. Dr. Gurman completed a surgical internship and residency in orthopedic surgery at the combined Montefiore Hospital/Albert Einstein program in New York City, and a fellowship in hand surgery at the Hospital for Joint Diseases Orthopaedic Institute, also in New York City.

Asked what role has best prepared him for this new position, Dr. Gurman told *OTW*, "I have already served on the AMA Board of Trustees for eight years as vice speaker and then as speaker. I have also been a member of the AMA executive committee, so the information stream has been the same as that which goes to the presidents. In the capacity of AMA board member and executive committee member, I have become familiar with the strategic plan, the advocacy agenda, and the issues facing physicians, patients, and the AMA. I have had the opportunity to represent the AMA within the federation at state medical society meetings and other venues, and have also been the face of the AMA at events in the larger business community such as rotary clubs."

"The AMA's influence and expertise supports physicians' efforts to put patients first while responding to the multiple challenges of a complex, diverse and evolving health care system. Beyond advocacy, ethics and best practices, I intend to focus my tenure on meeting physicians' needs and advancing the AMA's three strategic areas: improving health outcomes for the 86 million Americans living with pre-diabetes and the 70 million with hypertension; accelerating change in medical education to ensure physicians are prepared to meet the needs of a 21st Century health care system; and enhancing physician satisfaction and practice sustainability."

"I also intend to continue my ongoing work to promote AMA efforts aimed at curbing prescription drug abuse, misuse, overdose and death. We are engaged in advocacy efforts with state and federal policymakers supporting a public health approach to address the problem. That approach includes increased access to treatment and prevention programs and lifesaving overdose prevention medications like naloxone, enhanced education for physi-

cians and patients and modernized and fully funded prescription drug monitoring programs."

Leesa Galatz, M.D.: New Chair at Mount Sinai Leesa Galatz, M.D., Chief of the Shoulder and Elbow Service at Washington University in St. Louis, has been named System Chair of the Department of Orthopaedics at the Icahn School of Medicine at Mount Sinai in New York. She will assume her new role in October 2015.

An accomplished, recognized leader in the research arena, Dr. Galatz is the associate editor for basic science for the *Journal of Shoulder and Elbow Surgery* and is a peer reviewer for other orthopedic publications. She told *OTW*, "I am really pleased to be joining Mount Sinai Orthopedics and I'm excited about the many clinical and research initiatives we have planned. My initial efforts will be focused on strengthening the individual divisions at the different hospitals. We have plans to recruit new physicians and scientists to the department to round out the existing outstanding complement of faculty. I want to create a sense of unity and stability across the system and foster the academic mission of the department."

Asked about her research priorities, Dr. Galatz noted, "One of the new developments will be the Mount Sinai Center for Orthopedic Outcomes Research. We are partnering with the Department of Population Health Science and Policy to initiate a large-scale clinical research program. The size and breadth of the Mount Sinai System in New York will enable us to study clinical outcomes, health care value, and treatment effectiveness over a very large population. This will empower us to make a real impact on clinical care. In addition, we will expand our basic science faculty and provide resources to existing faculty in order to enrich our program of basic and translational research."

James D. Kang, M.D.: New Chair at Brigham and Women's Brigham and Women's Hospital is welcoming a new chair of the Department of Orthopaedic Surgery—Dr. James D. Kang. An acclaimed researcher and surgeon, Dr. Kang has been on the faculty of the University of Pittsburgh ("Pitt") since 1993.

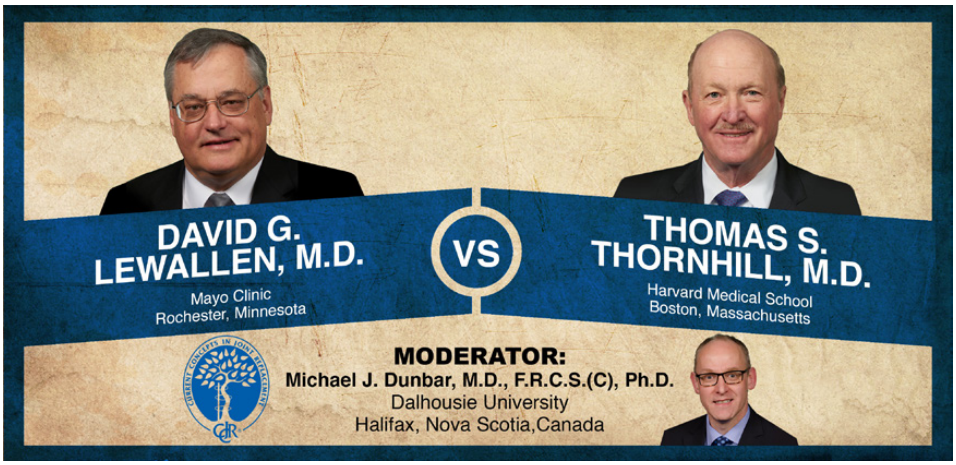
At present, Dr. Kang holds several posts at Pitt: the Executive Vice Chairman for Clinical Services, tenured Professor of Orthopaedic and Neurological Surgery, Professor of Physical Medicine and Rehabilitation, UPMC Endowed Chair in Orthopaedic Spinal Surgery, and Director of Ferguson Laboratory Musculoskeletal Research Center for Spine Research in the Department of Orthopaedic Surgery. Dr. Kang also recently became president of the International Society for the Study of the Lumbar Spine.

Dr. Kang told *OTW*, "My role as Vice Chairman at the University of Pittsburgh as well as my various roles in the University of Pittsburgh and UPMC committees on quality and education has prepared me well for my new role as Chair at the Brigham. Most importantly, I have had great mentors in my career who have shaped my principles in leadership in academics. People like Dr. Freddie Fu, Ed Hanley, Henry Bohlman, James Herndon, to name a few."

"First of all, I will be getting to know the Brigham culture and try to get to know the faculty of the department. I will articulate to them the vision of the department and develop a team approach to achieve these goals. Our goal would be to continue the work begun by my predecessors (Drs. Tom Thornhill and Clem Sledge) and bring the Brigham orthopaedics to a higher level of excellence in basic science and clinical research." ♦

Lewallen, Thornhill Debate All Poly Tibias

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



Current Concepts in Joint Replacement/RRY Photo Creation

"Modular platforms are more expensive, unproven, and you have a rigid implant along with bone stress shielding," argues David Lewallen. But Tom Thornhill counters, "You have fewer options with an all poly tibia, including the fact that you can't go without cement. And if you cemented an all poly tibia you can sometimes miss the fact that there is cement left towards the back."

This week's Orthopaedic Crossfire® debate was part of the 31st Annual CCJR – Winter meeting, which took place in Orlando this past December. This week's topic is "The All Poly Tibia in Patients <60: An Affordable Care Act Alternative." For the proposition is David G. Lewallen, M.D. of Mayo Clinic in Rochester, Minnesota. Thomas S. Thornhill, M.D. of Harvard Medical School is in opposition. Moderating is Michael J. Dunbar, M.D., F.R.C.S. (C), Ph.D. from Dalhousie University.

Dr. Lewallen: "There are no ideas more dangerous in medicine than the things we think we know for sure. For example, that suction irrigation tubes are optimal for the two stage treatment of infected total joints or that bone loss around failed total joints is due to cement disease. And on and on."

"So what about modular, metal backed tibial trays? My biggest challenge has been huge bone loss from a manmade iatrogenic plague related to implant design. It involves particulate poly with cement debris, facilitated by metal particulate, facilitating activation of macrophages and histiocytes and significant bone loss."

"There are many types of poly wear and deformation…and I'm not saying that the only reason they fail is because of modular trays. But it's an important part of the equation and it's been underestimated. We thought that the tibial articular surface was the main focus for problems, but if that was really the problem then where were all of these cases in the early part of my career when we had implants that weren't optimal in design or materials and that had lots of wear?"

"There are isolated cases that have done well, where the poly is worn out at 10-14 years and you change the poly and the patient improves. But these early poly exchanges usually end in disaster."

"The other problem with modular trays is locking mechanism instability on the interface that can lead to debris, backside wear and osteolysis. It's not a single design problem."

"And regarding what we tell patients about survivorship, we quote old data that's from metal backed, monoblock implants…and then we put in a modular device. If you actually graph the results then the modular implants don't do as well. In his own series, Dr. Ranawat has shown a big difference between all poly and metal backed implants (96% versus 75%). A report by Weber (*Journal of Arthroplasty*, 2002) showed a several-fold increase in revision, lucencies, and osteolysis with modular implants."

"We at Mayo just published a review of tibial component designs that involved 14,524 primary knees. We had 865 revisions, and we found that across all designs, all poly tibias outperformed their metal backed alternatives. Interestingly, the cruciate retaining (CR) knees seemed to do better than the posterior stabilized (PS) knees…until we took out one implant that was over-represented in the series. After that, the difference between the CR and PS knees disappeared."

"The etiology of osteolysis is multifactorial, but modular, titanium baseplates are part of the problem. So why not solve it with crosslinked poly? A knee is not a hip. We have issues with the manner in which wear occurs, and with delamination and pitting. There are also

concerns about the performance of the material in terms of the connection and the post. They are also more expensive."

"Rotating platforms were another design effort to solve this backside issue. But there are tradeoffs with anything we change. These platforms are more expensive, unproven, and you have a rigid implant along with bone stress shielding."

Dr. Thornhill: "We published a study last year using quality adjusted life-years and incremental cost effectiveness ratios. It basically said that if you want to offer a 20% decrease in long term failure at a 50% increased cost you're only going to have an advantage if you use it in young people."

"There are long term results of all-poly tibias, and we do have better poly in terms of wear, mechanical strength, and oxidative resistance. I use moderately crosslinked poly in the knee and then there is no backside wear."

"Chit Ranawat (and others) have results showing that all poly tibias are found in low demand patients. Backside wear is reduced; it clearly was a problem—a poly problem and a component design problem."

"To reduce backside wear we now have an improved metal tibial surface, better poly, and reduced micromotion with a better locking mechanism and better interference fit. And this is in lots of different implant systems. Also, we moved from a titanium to a highly polished cobalt-chrome tray (maintaining the same thickness). We have a wider profile so there is a better force fit; there is an increased locking mechanism because that was the failure leading to significant backside wear and motion."

"Backside wear and motion has decreased by about 90% with modularity. Now, if you just do a poly exchange you're often going to miss the problem you're looking for. But there are intraoperative options. You could go to slightly more constraint or move to a more congruent liner. But if you switch from a CR to a PS then you must change other things in terms of flexion/extension balances. If I'm opening the knee for almost any reason then I generally destabilize the knee a bit and I put in a poly that is somewhat thicker. In an all-poly I don't have that option."

"Tibial bone loss is a problem. In a knee with a sclerotic rim that's been drilled, when you curette everything that's there and prepare to cement, you have a discontinuous mantle. Cement creates a uniform proximal tibial mantle. But if you have an all poly tibia then the high

bending stresses on the poly are mollified by having a metal tray with lower bending stresses."

"When I put in my trial and try to cement it I am very careful to prevent cement in the back; if you use an all-poly tibia you can sometimes miss that. And the last thing is fixation options. I used to debate against uncemented tibias. There is no uncemented option here, however, and we are increasingly moving to uncemented tibias. In an all-poly tibia you must have cement."

"I use a modular tibial component with a newer poly, moderately crosslinked. The economics may dictate this change in selected patients. But I don't think these are the patients—less than 60."

Moderator Dunbar: "David, Tom made a good point about the concept of intraoperative options. How do you feel about losing that option?"

Dr. Lewallen: "You must decide at some point in the procedure in terms of the width of the poly, and with current trials it's easy to do that. Some people are insecure about the notion of not being able to swap out the insert until they put the first stitch in the extensor mechanism, but it's easy to make that decision about five minutes earlier."

Moderator Dunbar: "Do you ever find yourself in a situation where you have a tibial baseplate in and you're trialed with a poly and gone on to a different poly?"

Dr. Lewallen: "If you have trial components then there is slightly more stability to the knee than with cemented components. You can factor that into your decision if you can't decide which poly width to use."

Moderator Dunbar: "Dave made the point that the data we're quoting about metal backed tracks are actually about monoblocks. Tom, how do you feel about that?"

Dr. Thornhill: "The mid 1990s were a dark period because the gamma in air polyethylene decreased the mechanical strength and increased backside wear. The tighter the knee the more balanced it is. Our trials are a bit tighter, partly because of the friction…most of them are delrin and they are somewhat stickier."

Moderator Dunbar: "Dave, the all poly—meaning the lack of an interface between the modularity—or is it about the modulus?"

Dr. Lewallen: "It's hard to separate the two. But, we've now seen enough retrievals of these radial abrasions on the trays, and it's the metal particulate that helps facilitate small particles of polyethylene. It's not the total amount

of wear that is so astronomical in some of these metal backed trays, but the metal particulate allows very small particulate poly to be generated…and hence the huge lesions."

Moderator Dunbar: "So would you prefer an all poly or a monoblock with a low modulus baseplate?"

Dr. Lewallen: "I actually use a monoblock porous ingrowth implant, which you can also cement. It eliminates backside motion, so that's a good option in a young patient if you want to go to a cementless implant."

Moderator Dunbar: "Do you think these prostheses deform under load?"

Dr. Lewallen: "Having some deformation in the proximal tibial isn't a bad thing in order to maintain bone quality. There are data showing better preservation of bone on quantitative computed tomography around such implants."

Dr. Thornhill: "You need to load the bone, and once you get above roughly 10mm of poly you increase the stiffness. But when there is a big disparity between the medial and lateral sides then you're better off with metal backing."

Moderator Dunbar: "So maybe we're oversimplifying it. Dave, when would you not use an all poly?"

Dr. Lewallen: "Some knees have major bone deficiency at the time of primary surgery. If you need a stem or a metal augment then that's when the tradeoff is worth it."

Moderator Dunbar: "Tom, who is the best patient for an all poly?"

Dr. Thornhill: "An elderly, low demand patient."

Moderator Dunbar: "Thank you, gentlemen." ♦

Please visit www.CCJR.com to register for the 2015 CCJR Winter Meeting, December 9 - 12 in Orlando, Florida.

COMPANY

DePuy Synthes and AO Foundation Continue Cooperation

DePuy Synthes and the AO Foundation (Arbeitsgemeinschaft für Osteosynthesefragen) are going to continue Synthes' 55-year history of professional education and new product development cooperation for at least five more years.

On June 18, 2015, the two organizations announced the signing of a five-year cooperation agreement.

Through the agreement, DePuy Synthes will be the "industry partner for the AO Technical Commission (AOTK) for each of its specialty areas: trauma and corrective surgery of the musculoskeletal system, spine, craniomaxillofacial, veterinary products and related instruments and implants."

The announcement notes that the "AO Specialties continually redefine the state-of-the-art in their respective fields, maintaining activities in research, development, clinical investigation and education."

The two organizations will also "collaborate on innovation and certification of new DePuy Synthes Companies products by AOTK that will then be used in AO educational activities. More than 200,000 health care professionals are expected to participate in AO programs globally over the next five years."

AO Foundation History

The AO Foundation is a nonprofit organization founded in Switzerland in 1958 by 13 surgeons as a study group.

Dr. Suthorn Bavonratanavech, President AO Foundation (left), Rolf Jeker, CEO, AO Foundation (middle), Ciro Roemer, Company Group Chairman, International Markets, DePuy Synthes Companies
Image Credit: DePuy Synthes

In 1949, according to the AO website, "a Belgian surgeon, Robert Danis, M.D., published a book entitled *Théorie et Pratique de l'Ostéosynthèse*. This, his second book on fracture fixation, documented his concepts of early functional rehabilitation following rigid fracture fixation." Danis' work "attracted the attention of a young Swiss surgeon Maurice E. Müller." After meeting with Danis in March 1950, Müller gathered a small group of Swiss surgeons, including: Robert Schneider, M.D., Hans Willenegger, M.D. and Martin Allgöwer, M.D. and formed the study group to conduct research in bone healing, "with particular reference to the influence of the mechanical environment of the fracture upon its healing pattern."

The foundation provides "professional education to a global network of surgeons, operating room personnel, and scientists in more than 100 countries." Since the foundation began collaborating with Synthes in 1960, a "substantial investment has been made in research, development and education. In addition, vital training including direct hands-on courses has been provided to more than 450,000 surgeons and 150,000 operating room professionals from 124 countries around the world," according to the press announcement.

Sales of all AO products are done through DePuy Synthes. — *WE*

SpineGuard Completes Financing for "Smart" Screw

SpineGuard, S.A. has finished raising the rest of a $3.1 million equity round of financing to accelerate the market launch of its "smart screw" for spine surgery.

Claiming to have the world's first "smart screw" to make surgery "safer," the company said on June 15, 2015 the equity came from two Paceo equity line draws in April and May. In addition to a private placement with institutional investors announced in June, the company issued new shares to investors.

SpineGuard, S.A.

"Despite the cancellation of the public offering announced by the company on June 4 due to adverse market conditions, the company was able to serve most of the subscription demands received. Pursuant to article L. 225-138 of the French Commercial Code, this equity round was reserved for named investors meeting certain criteria as defined in resolution 13 of the shareholders' meeting of May 28, 2014," stated the company.

The company was co-founded in 2009 in France and the U.S. by Pierre Jérôme and Stéphane Bette. The co-founders' goal is to establish its proprietary Dynamic Surgical Guidance (DSG) technology as the global standard of surgical care, initially for safer screw placement in spine surgery and then in other surgeries. The first products using the DSG technology, PediGuard, was co-invented by Maurice Bourlion, Ph.D., Ciaran Bolger,

M.D., Ph.D., and Alain Vanquaethem, Biomedical Engineer.

PediGuard, according to the company, is the world's first and only handheld device capable of alerting surgeons to potential pedicular or vertebral breaches. Over 38,000 surgical procedures have been performed worldwide with the device.

Audio Feedback

The device works by provides audio feedback to the surgeon.

As the probe is inserted past the entry point into the pedicle, according to the company, a high pitch and high cadence feedback might be heard. This is due to the tip being advanced past the blood collected at the entry point.

"A mid-range pitch and medium cadence audio signal can be heard as the probe is being advanced into the pedicle through cancellous bone. A small decrease in cadence and pitch can be discerned as the probe is advanced past the isthmus in the pedicle. The audio signal will return to medium pitch and medium cadence once the tip is in the vertebral body. As the probe is being retracted from the pedicle, a high cadence and high-frequency audio feedback should be expected—this is due to the blood around the tip of the probe."

In 2015 SpineGuard started to expand the applications of DSG into pedicle screws through partnerships with surgical companies in France and the U.S. — *WE*

LEGAL

Zimmer and NexGen Go on Trial in October

The first bellwether trial over Zimmer Holdings Inc.'s NexGen knee implant will start on October 13, 2015.

Courtroom/pixabay.com

Over 1,300 lawsuits have been filed by patients implanted with knee. The device received FDA clearance in 1995 and more than 5 million implant procedures have been performed since then.

Lawsuit Consolidation

In 2011, the U.S. District Panel on Multidistrict Litigation decided to consolidate the lawsuits to decrease the chances of conflicting rulings with judges and duplicative discovery. Consolidation is also more convenient for the parties, witnesses, and court. The lawsuits were consolidated to Judge Rebecca R. Pallmeyer in the Northern District of Illinois.

Allegations surround the company's lack of sufficient product testing, manufacturing and selling of faulty products.

Judge Pallmeyer identified six cases that will serve at the "initial tranche" of bellwether trials against Zimmer. Of these six, three were plaintiffs' picks and the other three were chosen by Zimmer. Plaintiffs in these cases include Ramona Diano, Kathy Batty, Randy Pudwill, Debra Teague, Mertha Shoat, and Ronnie Davis.

Diano is a 72-year-old Philadelphia woman whose implants failed in both knees. According to the plaintiff's steering committee, hers is the most straightforward and comprehensive one, as she belongs to the most common age range and gender for the procedure and her case has the least individual issues, compared with the two other choices.

Her case also includes false marketing allegations, according to the plaintiffs' brief, as advertisements for a gender-specific type of femoral component influenced her decision to choose Zimmer's implant.

Fighting Lawyers

Last September Zimmer filed a motion with Judge Pallmeyer to sanction the lawyers for the patients. Zimmer claimed that attorneys representing plaintiffs Shoat, Davis and Teague had missed a deadline for producing expert reports without providing advance notice that a deadline was going to be missed, or required an extension. Zimmer claimed that such "repeated abandonment of Zimmer case picks has unreasonable and vexatiously multiplied these MDL (multidistrict litigation) proceedings and justifies sanctions."

The patients' lawyers said Zimmer's actions just proved the company was running scared.

Zimmer Celebrates Milestone

At the recent annual meeting of the American Academy of Orthopaedic Surgeons in Las Vegas, the company announced it was "celebrating a key milestone" in 2015 for its NexGen Complete Knee System. "2015 is the 20th year since Zimmer first introduced the NexGen knee system, with its innovative design and component quality, to the market. To date, more than five million implantations of the NexGen knee have taken place worldwide," stated the company.

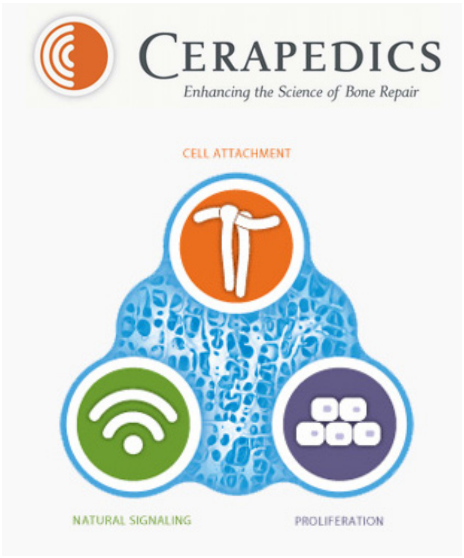
"The NexGen knee has been—and will continue to be—a significant move forward in knee replacement," added Brad Quick, vice president, Knee Marketing for Zimmer.

The case is: *MDL 2272 In Re Zimmer Nexgen Knee Implant Products Liability Litigation.* — *WE*

No FDA Panel Required for Cerapedics PMA Application

The leaders of Cerapedics, Inc. think the FDA is on the verge of approving a Premarket Approval (PMA) application for the company's i-Factor peptide enhanced bone graft.

The company announced on June 16, 2015 that it has been informed that the agency will not need to convene an advisory panel to review the company's application and make a decision about approving the product or issuing a non-approvable letter.



i-Factor Bone Graft/Cerapedics, Inc.

Jeff Marx, Ph.D., the company's president and COO, is happy about the news. He said he was "pleased" about moving forward without a panel meeting. "We appreciate the interactive nature of the FDA review process, which has streamlined our application," said Marx.

Glen Kashuba, the company's CEO, said, "Leading with this excellent clinical profile and what we believe will become the only biologic bone graft approved for cervical fusion, we think that i-FACTOR bone graft will be an important product for patients and clinicians. We are excited to be advancing i-FACTOR bone graft through the regulatory process and are now shifting our focus toward planning for U.S. commercialization." We would like to thank all of our clinical investigators and other contributors. Without their efforts, we would not be in this position today."

Small Peptide

According to the company, i-Factor is the only biologic bone graft that utilizes a unique small peptide (P-15) to stimulate the natural bone healing process. Benefits include "predictable bone formation, and ease-of-use in a wide range of spine, trauma and orthopedic procedures." The technology combines anorganic bone mineral (ABM) and P-15 to act as an attachment factor for specific integrins on osteogenic cells.

Pivotal Trial Comparison

A pivotal clinical trial compared Cerapedics' bone graft to autograft in anterior cervical discectomy and fusion (ACDF) procedures. According to the company, its graft met all four pre-specific primary endpoints (fusion rate, NDI (Neck Disability Index) score, neurological outcomes, and safety success), "demonstrating non-inferiority to autograft with p-values of < 0.0005 for each."

A responder analysis showed statistical significance for superiority in all four primary outcomes, demonstrating 69% success for the bone graft versus 57% for autograft.

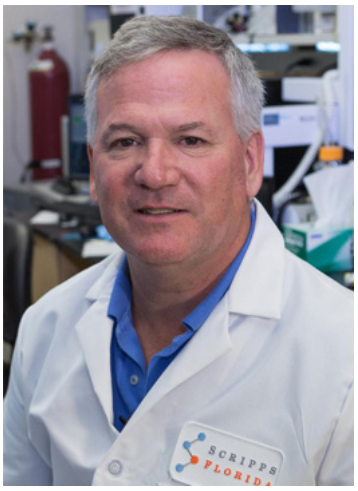
The company also announced that it has filed a response to remaining items from an FDA's review of the graft from a recently completed facility inspection. — *WE*

BIOLOGICS

Study: New Approach to Developing Bone-Forming Cells

A protein known as "PPARγ" just may help develop new bone-forming cells in patients who are losing bone. Researchers from the Florida campus of The Scripps Research Institute (TSRI) have created a novel approach that focused on the protein's impact on stem cells derived from bone marrow. This work has just been published in *Nature Communications.*

According to the June 12, 2015 news release, "The scientists knew that



THE SCRIPPS RESEARCH INSTITUTE®

Patrick Griffin, Ph.D., The Scripps Research Institute

a partial loss of PPARγ in a genetically modified mouse model led to increased bone formation. To see if they could mimic that effect using a drug candidate, the researchers combined a variety of structural biology approaches to rationally design a new compound that could repress the biological activity of PPARγ. The results showed that when human mesenchymal stem cells were treated with the new compound, which they called SR2595 (SR=Scripps Research), there was a statistically significant increase in osteoblast formation, a cell type known to form bone."

"These findings demonstrate for the first time a new therapeutic application for drugs targeting PPARγ, which has been the focus of efforts to develop insulin sensitizers to treat type 2 diabetes," said Patrick Griffin, Ph.D., chair of the Department of Molecular Therapeutics and director of the Translational Research Institute at Scripps Florida. "We have already demonstrated SR2595 has suitable properties for testing in mice; the next step is to perform an in-depth analysis of the drug's efficacy in animal models of bone loss, aging, obesity and diabetes."

Dr. Griffin told *OTW*, "We expected our compounds to be neutral on bone or perhaps slightly positive on bone, but the effects are much more pronounced. We see a clear impact on bone turnover and bone density."

"We have a new manuscript under review at a high impact journal that shows the positive effects on bone in obese mice. Because it takes a long time from submission to acceptance the animal work has been completed already—and we are very excited indeed." — *EH*

Cartilage Repairing Stem Cells Identified

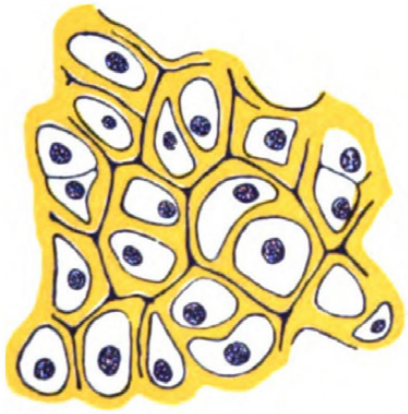
Scientists at the University of York announce, via a paper in *Stem Cell Reports*, that they have identified the individual stem cells that can regenerate tissue, cartilage and bone. The work was carried out working with colleagues at the Erasmus Medical Center in Rotterdam.

Because the stem cells are similar in appearance and are mixed with human bone marrow stromal cells (MSCs) scientists had difficulty distinguishing between them. It was the York researchers who isolated individual MSCs and analyzed their different properties. This allowed the researchers to identify those stem cells which are capable of repairing damaged cartilage or joint tissue, thus opening the way for improved treatment for arthritis.

Paul Genever, M.D., who led the research at York, said: "While stem cell therapy is an exciting new development for the treatment for osteoarthritis, up to now it has been something of a lottery because we did not know the precise properties of each of the cells. This project has helped us to establish which cells are good at regenerating tissue, cartilage and bone, respectively. It will help in the search to develop more targeted therapies for arthritis patients."

Co-Lead author James Fox, M.D., said "Working with colleagues across the Arthritis Research UK Tissue Engineering Centre will help to bring our discovery closer to patient treatment".

The organization Arthritis Research UK funded the research. Director of Research at the charity, Stephen Simpson, M.D., said: "There are eight million people in the UK living with the pain and disability caused by osteoarthritis. We are fighting to find better treatments and one day, a cure. This research is exciting and promising. Identifying specific stem cells that could help the damaged joint to repair itself takes us a step closer to our aim of developing an injectable, safe, stem cell therapy for people with osteoarthritis." — *BY*



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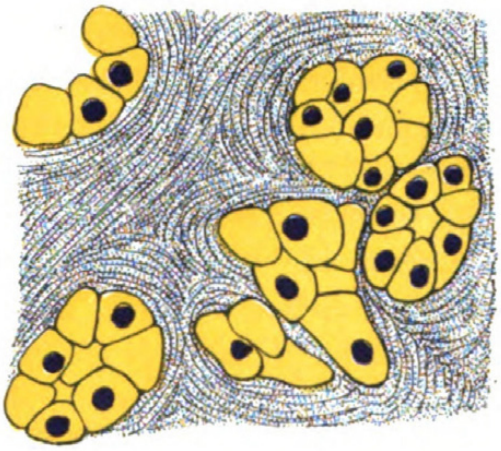

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Wikimedia Commons and Walter Holbrook Gaskell

LARGE JOINTS

Weekend Screen Time=Bad Bones for Teen Boys

Bad to the bone, those electric screens…A new observational study from Norway has found that when boys spend too much time in front of a screen on the weekends it could very well result in poorer bone health. In a collaboration between UiT The Arctic University of Norway, the University Hospital of North Norway and the Norwegian Institute of Public Health, researchers analyzed data from the 961 individuals involved in the Tromsø Fit Futures Study in Norway; the participants were 15-17 year old school students.

According to the June 10, 2015 news release, the team found that boys had about five hours a day of screen time on the weekend; girls had four hours a day on the weekend. It tuned out that 2-4, or more than 6 hours, "in front of a screen were linked to statistically significant reductions of bone mineral density at the femoral neck compared with boys clocking fewer than 2 hours of screen time daily on the weekend. But boys who spent 4 to 6 hours in front of a screen tended to have higher than expected bone mineral density levels. The opposite was true of girls among whom 4-6 hours of weekend screen time daily was associated with higher bone mineral density, even though they took less exercise than those who said they spent less time in front of a screen."

Source: medicmagic.net

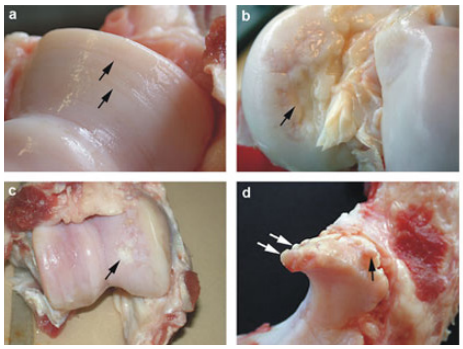
The researchers indicated that the lack of impact of screen time on girls' bone health may be explained by their different body fat distribution.

Anne Winther, a study author and Ph.D. candidate, told *OTW,* "We were surprised at gender difference, so that screen time at weekends was negatively associated with bone mass density levels in boys and positively in girls. This was after adjustments of several confounders known to affect bone, including age, puberty, physical activity levels and weekday screen time."

Winther added, "As results from a cross section study, our findings are relationships only. But these contrasting patterns persisted two years later, and indicate stronger relationships. Screen time during weekends may be a possible indicator of lifestyle factors that may have detrimental effect on bone health. As participation in recreational sports or performing sports at a competitive level seems to exert significant beneficial effect on bone, the best way to promote good bone health in this age group is to encourage such activity. In addition physical activity during adolescence promotes physical activity practice in later life." — *EH*

Cytokine Identified as Factor in Cartilage Damage

New research from the Netherlands indicates that a certain cell signaling protein—cytokine Interleukin-1β (IL-1β)—is critical in the development of blood-induced cartilage damage. Healthy human cartilage samples were cultured for four days in the presence or absence of 50% whole blood. Either IL-1β monoclonal antibody, IL-1 receptor antagonist, or TNF-β monoclonal antibody was added during blood exposure.



Macroscopical joint lesions in sows. a: Cartilage erosion (arrows) on the medial humeral condyle. b: Cartilage ulceration (arrow) on the medial femoral condyle. c: Cartilage repair (arrow) of the medial femoral condyle d: Marginal osteophytes (arrows) on processus anconeus of ulna./Wikimedia Commons and Acta Veterinaria Scandinavica

The June 12, 2015 news release stated, "The researchers found that adding IL-1β monoclonal antibody or IL-1 receptor antagonist resulted in a dose- and time-dependent protection of cartilage from blood-induced damage (early administration after blood-exposure was the most beneficial). In higher concentrations, almost complete normalisation of cartilage was achieved. In contrast, addition of TNF-β monoclonal antibody exhibited no effect on blood-induced cartilage damage."

"As therapeutic agents opposing the activity of IL-1β are readily available, further research is now warranted to investigate whether an IL-1β antago-

nist would be effective in preventing and treating joint damage as a result of bleeding into the joint," said Dr. Simon Mastbergen, principle investigator from the University Medical Centre Utrecht, Netherlands. "Findings also suggest that the quicker treatment is initiated, the less damage to the joint may be sustained."

Dr. Mastbergen told *OTW*, "The next step in investigating the efficacy of blocking IL-1 to prevent/treat joint damage upon bleeding is to perform in vivo studies as the influence of cytokines produced by synovial tissue needs to be integrated as well. In a model of post-traumatic osteoarthritis, opposing IL-1 is shown to prevent cartilage damage. However, in this model also mechanic factors induce damage."

"Before human studies can be performed it is necessary to identify biochemical markers of joint damage to demonstrate turnover of cartilage tissue upon a joint bleed. A first step is made by identifying an increase in CS846 and CTX-II in haemophilia patients upon a joint bleed (Van Vulpen et al., *Osteoarthritis and Cartilage* 2015), but studies in patients with a traumatic joint bleed need to be conducted. Identifying such markers is necessary to have tools to investigate the direct impact of a bleed on the joint as well as the effect of blocking IL-1 after a bleed on cartilage turnover."

"It is important for orthopedic surgeons to realize the impact of blood on cartilage. The major impact of blood on proteoglycan turnover is a direct result of upregulation of cartilage-degrading enzymes as well as chondrocyte apoptosis and indirect effects by inducing synovial inflammation. As such, minimalizing the amount of blood exposure as well as the duration of blood exposure, either after trauma or major joint surgery, is important." — *EH*

EXTREMITIES

FH Ortho Receives FDA Marketing Approval for CALCAnail

FH Ortho has announced the receipt of approval from FDA to market the CALCAnail System to treat calcaneus fractures and subtalar arthrodesis (rear foot fusion surgery) in the U.S.

CALCAnail System/Courtesy of FH Orthopedics

"The CALCAnail System allows surgeons to employ an innovative reduction technique that reduces surgical trauma and the risk of complications," said Jim Hook, Managing Director of FH Ortho's U.S. operations, in the June 15, 2015 news release. "Surgeons use a through-the-heel approach, with a hollow reamer to tunnel into the calcaneus, making it possible to correct calcaneal tuberosity displacements and obtain good reduction of the joint for intra-articular fractures that are composed of large fragments."

The CALCAnail System involves a "minimally-invasive, closed technique that uses a nail and cannulated screws.... indicated for repair of displaced intra-

articular fractures of the calcaneus, but also subtalar arthrodesis following intra-articular fracture of the calcaneus (subtalar osteoarthritis and malunion) or degeneration of the subtalar joint."

"We are seeing quick action to approve our device applications, which speaks to the quality of the science that supports our submissions, as well as the thoughtful and efficient design that goes into all FH Ortho products," added Hook. "We make a conscious choice to design surgical products that are elegant in their simplicity, and distinguished by their flexibility."

OTW asked Jim Hook: "The word 'thoughtful' seems to be important for your company. Is there a 'backstory' here?"

Hook replied, "'Thoughtful' is a key development philosophy for FH Orthopedics. Our development teams spend many, many hours with the global surgeon community to learn the challenges presented by patients who require both elective and in some cases non elective surgical intervention. Each series of cases provides FH Ortho with invaluable insight that when employed enhances product innovation and outcomes. We strive to bring creative and thoughtful solutions to orthopedic surgeons in the global environment we serve. This is the essence our company DNA. Products within the FH Ortho portfolio are founded in the strong scientific method of observation, thoughtful questioning, solid engineering and eventual commercialization."

"Sales of the CALCAnail are expected to exhibit rapid acceptance in the U.S. Market. The product has a significant clinical utilization in Western medicine and has demonstrable clinical outcomes. U.S. distribution is now being expanded for the planned introduction of an entire range of foot and ankle products. The innovative CALCAnail will be the lead product to be introduced in the U.S. followed by a complete new line of plates, screws, wedges and MIS surgical instruments. Additional products are under active development with notable foot and ankle surgeons in the U.S. and Europe." — *EH*

Austrian Surgeon Adds Feeling to Prosthetic Leg

Professor Hubert Egger, M.D., of the University of Linz in northern Austria and amputee Wolfgang Ragger have made medical history. Together they invented and are demonstrating a leg prosthesis—believed to be the world's first—that provides "feeling" for the amputee.

As Ragger said, "It's like a second lease of life, like being reborn. It feels like I have a foot again. I no longer slip on ice and I can tell whether I walk on gravel, concrete, grass or sand. I can even feel small stones." The 54-year-old former teacher cycles, goes climbing and his limp is barely noticeable, according to Nina Lamparski, the *Medical Xpress* writer who reported the story.

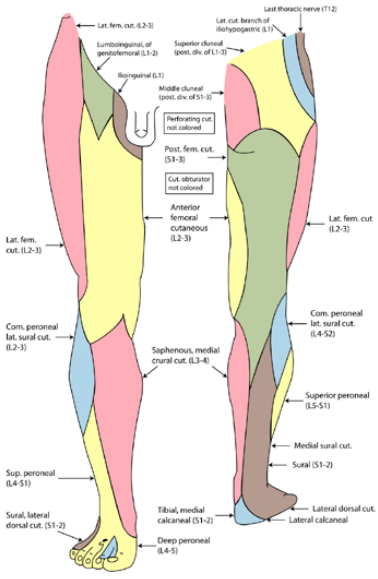
Egger developed the process in two stages. He first rewired the remaining foot nerve endings from Ragger's stump to healthy tissue in his thigh placing the nerve endings close to the skin surface. He then fitted six sensors to the foot sole of a lightweight prosthesis, and linked them to stimulators inside the shaft where the stump sits.

"In a healthy foot, skin receptors carry out this function but they are obviously missing here. However, the information conductors—the nerves—are still present, they're just not being stimulated," Egger said.

"The sensors tell the brain there is a foot and the wearer has the impression that it rolls off the ground when he walks. All things considered, the procedure is a very simple one given the results."

Lamparski writes that this is not the first time the Austrian scientist has caused a stir with his research. In 2010, he presented a mind-controlled prosthetic arm, which the user directed with motor neurons previously connected to the lost limb. Egger explained that for the artificial leg the principle remains the same except that the process works in reverse: Information is passed from the prosthesis to the brain, rather than the other way around.

There was another benefit to the new prosthesis. Ragger became pain free. Within days of undergoing the operation he was no longer experiencing disabling pain. Egger points out that phantom pain occurs because the brain gets increasingly sensitive as it seeks information about the missing limb. The advantage of the "feeling prosthesis," he says, is that the brain once again receives real data and can stop its frantic search. — *BY*



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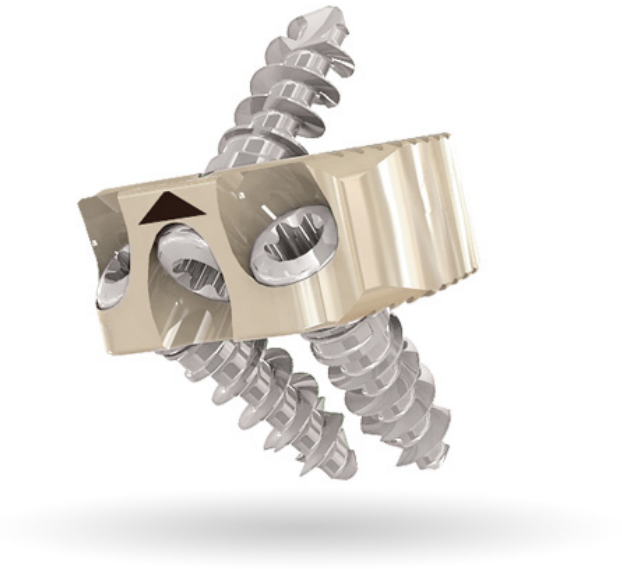
SPINE

Centinel Spine Reaches 20,000 Implantations of STALIF C

Centinel Spine, Inc. has announced that it has hit a milestone of 20,000 of implantations of STALIF C cervical Integrated Interbody devices. The STALIF C device is implanted during cervical fusion procedures to treat degenerative spinal disorders. According to the company, the procedure is attractive to surgeons because it involves a single incision procedure that is minimally invasive and tissue sparing.



Centinel Spine, Inc.

"This is an important milestone for Centinel Spine and our STALIF C product family. It represents our proven success and heritage of healing in anterior column support procedures," said Centinel CEO and President John Viscogliosi in the June 1, 2015 news release. "We are pleased at the continued adoption of our STALIF technology as we strive to meet our vision of becoming the leading anterior column support spine franchise."

The news release indicates, "This design also allows the device to nest fully within the confines of the vertebral body, leaving the anatomy unchanged external to the interbody. The STALIF C three-screw construct features the Anti Back-Out technology, provides compressive fixation at the graft site and is proven to be biomechanically equivalent to a cage and plate."

Viscogliosi told *OTW*, "The milestone of exceeding 20,000 implantations of our STALIF C, Integrated Interbody cervical device is a very exciting milestone for Centinel Spine. It further validates our over 25 years of clinical success in anterior column support and healing, which began with the first lumbar cage the Hartshill Horseshoe."

"Centinel Spine continues to work to define, through clinical success and published biomechanical studies, Integrated Interbody devices STALIF C and STALIF C-Ti (Ti-ACTIVE coated device) as the standard of care in cervical fusion procedures. The STALIF C product family with its recent allogeneic bone graft indication fuel our momentum in achieving this goal."

As for details about the Anti Back-Out technology, Viscogliosi noted, "Anti Back-Out Technology (ABO) is proprietary to Centinel Spine. It provides our surgeon partners and their patients additional security and peace-of-mind from potential screw backout. This feature is a spilt-ring titanium technology that automatically deploys and compresses upon screw insertion. We do not lock or fixate our screw because we believe it may interfere with the bone remodeling process. The ABO feature allows the screw to toggle during the healing process, which should help reduce stress-shielding effect." — *EH*

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