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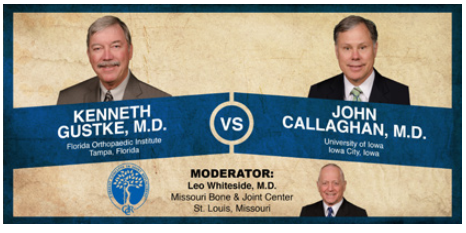
Orthopedics This Week

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: DJIA hit its 31st-record close this past Friday. And now we're in December. The Dow has ended positive in five straight Decembers starting in 2009. December boasts the best average stock market gain for the year 1.43% (July is second with 1.34%). And, finally, December has produced a gain in 84 of 117 years, or roughly 72% of the time (excluding 1914). So, for all orthopedic equity holders, enjoy the holidays!

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	11.52%	7.19%	All the analysts are dusting off their old models of SYK + SNN now that the six-month British imposed no merger period has ended.
2	3	Medtronic	28.84	10.19	European commission cleared Medtronic's $43 billion merger with Covidien. FTC also cleared deal on asset sale clauses.
3	4	NuVasive	8.01	13.96	NUVA seems to have shifted into a new, higher gear. And stock buyers are making sure it is in their portfolios before year end.
4	2	Zimmer	29.12	3.83	Still slogging through the European approval process for the Biomet deal.
5	7	Smith & Nephew	19.92	6.02	Wall Street might be enamored with an SYK and SNN match. But SNN looks like a reluctant bride.
6	5	Globus Medical	29.68	11.20	Brean Capital initiates coverage with a Buy. Ironically, analysts are actually forecasting down earnings for this quarter.
7	6	ConMed	10.51	1.46	2015 will be a pivotal year for CNMD. It will the first full year under this new management.
8	8	MicroPort	16.53	(1.30)	It has been a while since MicroPort reported news that investors could chew on. And it shows in the drifting price.
9	9	Integra LifeSciences	12.57	(0.39)	IART is the least expensive equity in all of orthopedics. With the spin-off of spine, the business may have a sharper focus in 2015.
10	NR	Johnson & Johnson	28.44	2.55	Back on the Power Rankings. On a valuation basis, JNJ is back in the top ten in terms of value.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	K2M Group Holdings	KTWO	$18.91	$702	28.81%
2	MiMedx Group	MDXG	$11.06	$1,183	23.03%
3	RTI Biologics Inc	853	$4.90	$279	15.84%
4	NuVasive	NUVA	$43.93	$2,067	13.96%
5	Aurora Spine	ASG	$1.56	$25	13.24%
6	Globus Medical	GMED	$23.04	$2,257	11.20%
7	Medtronic	MDT	$73.87	$72,711	10.19%
8	Stryker	SYK	$92.91	$35,150	7.19%
9	Smith & Nephew	SNN	$34.71	$15,503	6.02%
10	Exactech	EXAC	$22.18	$306	4.18%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc	BAXSQ	$0.01	$1	-94.77%
2	Bacterin Intl Holdings	BONE	$2.98	$20	-26.78%
3	Alphatec Holdings	ATEC	$1.28	$126	-16.34%
4	Symmetry Medical	SMA	$9.01	$338	-10.53%
5	Wright Medical	WMGI	$29.29	$1,496	-9.37%
6	LDR Holding Corp.	LDRH	$32.63	$850	-5.78%
7	Orthofix	OFIX	$27.92	$515	-4.81%
8	Tornier N.V.	TRNX	$26.69	$1,305	-4.17%
9	TiGenix	TIG.BR	$0.65	$104	-3.46%
10	MicroPort Scientific	853	$0.49	$702	-1.30%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$108.25	$303,004	18.02
2	Medtronic	MDT	$73.87	$72,711	18.92
3	Globus Medical	GMED	$23.04	$2,257	18.95
4	Zimmer Holdings	ZMH	$112.29	$19,017	19.36
5	Exactech	EXAC	$22.18	$306	19.46

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MiMedx Group	MDXG	$11.06	$1,183	1102.80
2	RTI Biologics Inc	RTIX	$4.90	$279	410.28
3	Orthofix	OFIX	$27.92	$515	178.37
4	NuVasive	NUVA	$43.93	$2,067	113.39
5	Symmetry Medical	SMA	$9.01	$338	59.34

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	$10.10	$282	1.15
2	Exactech	EXAC	$22.18	$306	1.30
3	Globus Medical	GMED	$23.04	$2,257	1.39
4	ConMed	CNMD	$42.43	$1,168	1.82
5	Integra LifeSciences	IART	$49.24	$1,614	1.92

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MiMedx Group	MDXG	$11.06	$1,183	73.52
2	RTI Biologics Inc	RTIX	$4.90	$279	27.35
3	NuVasive	NUVA	$43.93	$2,067	9.92
4	Orthofix	OFIX	$27.92	$515	9.69
5	Symmetry Medical	SMA	$9.01	$338	4.95

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Baxano Surgical Inc	BAXSQ	$0.01	$1	0.03
2	Bacterin Intl Holdings	BONE	$2.98	$20	0.58
3	Alphatec Holdings	ATEC	$1.28	$126	0.61
4	Symmetry Medical	SMA	$9.01	$338	0.85
5	RTI Biologics Inc	RTIX	$4.90	$279	1.10

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.65	$104	18.27
2	MiMedx Group	MDXG	$11.06	$1,183	12.24
3	LDR Holding Corp.	LDRH	$32.63	$850	7.62
4	Wright Medical	WMGI	$29.29	$1,496	5.29
5	Globus Medical	GMED	$23.04	$2,257	4.90

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

"Healed" Athletes Crashing and Burning! // ACL/PCL Preserving Knee Set to Surge in Joint Replacement World // Todd Albert's First Five Months at HSS

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

Athletes Who Frighten the Best Surgeons When David Altchek takes a phone call from a despondent coach these days, it just may be because a "healed" player crashed and burned. Dr. Altchek is an attending orthopedic surgeon and is the Medical Director for the New York Mets. He tells *OTW,* "It is really eerie that high level players who have had a full year of recovery after ACL reconstruction of the knee or ulnar collateral ligament (UCL) reconstruction of the elbow are getting reinjured so often. It's unsettling to think that we have done a solid procedure and that the patient has rehabbed well, and then everything falls apart. Postop, these patients pass all the required milestones easily; then, within several months of intense competition, they reinjure their knee or elbow."

Wikimedia Commons and BarenakedKevin/Image created by RRY Publications LLC

Dr. Altchek, clinical professor of Orthopedic Surgery at Weil Cornell Medical College, says, "We are now recruiting patients who have 'failed'—for the knee it is high school, college, and professional athletes. For the elbow it's college level or professional pitchers. We want to see what kind of similarities there are in these patients. We hypothesize that it's something to do with healing, i.e., that the new ligament never really matures to ultimate strength so it can't bear the loads involved. To what extent it is the biology we don't know. In the ACL a clear pattern emerged immediately. If we did a hamstring graft on aggressive pivoting athletes in soccer and lacrosse (particularly females) there was less pain at the time of surgery when compared to patients with patellar tendon grafts. In the former group there was a higher incidence of this immediate re-tearing. A Scandinavian study of 45,000 ACLs confirmed that finding."

"So we're taking data from the past five years (failed surgeries versus those who did well) and comparing it to controls. The two study groups will include athletes from the same sport who had the same graft, same surgeon, and same physical characteristics. We will be getting a prospective MRI of the knee and elbow at three month intervals to examine variability in graft healing and maturity. It's a scientific approach to determining if we are not waiting long enough to put these athletes back in the game. I will say, however, that I do believe we are waiting long enough because it is eerie how they just explode after a full year of recovery."

"One hypothesis is that a subset of these patients injures an associated ligament known as the 'anterolateral ligament' (which is poorly defined). Repairing this ligament causes major trauma to the patient and does not result in a big difference in stability of recovery…so we never fix it. But, it may be that some patients need this repaired; their bodies may need the support of this 'sister' ligament.

Quieter, ACL/PCL Preserving, More Natural Knee! A team of joint preservation superstars have dusted off a concept that was waiting in the wings…

and given it wings. Adolph V. Lombardi, Jr., M.D., F.A.C.S. is president of Joint Implant Surgeons, Inc. in New Albany, Ohio. Dr. Lombardi tells *OTW*, "Along with my colleagues—Keith Berend, Craig Della Valle, Jeff DeClaire, Chris Peters, Professor Thomas Andriacchi, and Jorge Galante—I have developed a new design of a knee that preserves the anterior cruciate ligament (ACL) and the posterior cruciate ligament (PCL). With roughly 120 surgeons across the globe implanting them, the preliminary comments from patients are that the knee feels more normal than a standard knee. For the surgeon, it feels more stable during the procedure."

"While the concept of an ACL/PCL preserving knee is not new, it didn't gain traction because the instrumentation was archaic. The design involved putting in the femur and tibia and doing distraction in flexion and extension…it was cumbersome. The new instrumentation that we have developed is very streamlined; the most challenging part is cutting the tibia and preserving the central island of bone. We have also developed a new way of doing the procedure. The femoral and patella preparation is straightforward; on the tibial side we've been through a couple of iterations in making the jig, how to do the cutting, how to set the rotation of the island and how to set the depth of resection. All of these are critical…and we can finally say that this process is user friendly."

"We have made a point to release this product slowly so as to ensure that surgeons grasp each aspect of the process…and so that we can catch any issues early on. The big difference is that this knee gives the patient added proprioception and enhanced stability. The knee does well on the Lachman's Test and the Anterior/Posterior Drawer Test; patients report that there is less noise than a standard knee and that it has a better range of motion and good stability."

"We are requiring that surgeons do cadaver training because we want to ensure that they are totally comfortable with the technique. We learned that we must be meticulous about the cementing technique because when you do a standard knee you can displace the tibia all the way forward and you have to pressurize the cement. When you

keep the ACL you can only displace it partially forward."

"Looking ahead to the next six months or so, with the purchase of Biomet by Zimmer I predict that we will see an explosion of this technology because they will probably try to adopt it to their Persona line as well. I see this technology as a new element in the continuum of constraint in total knee arthroplasty (TKA). You start with a patient who has one or two compartment disease and do a partial replacement…and depending on the enthusiasm for partial knee arthroplasty, this could represent 15-20% of someone's practice. The next element we'd like to look at are knee replacements for those patients who are active and have intact ACLs, but who have more disease in the lateral compartment. In these cases you can't do a uni so this new knee would be a good fit. The utilization of the knee will depend on the surgeon's 'appetite' for doing partial knee replacement."

Todd Albert Shaking Things Up at HSS

Five months in we decided to see how Todd Albert, M.D. is managing the 107 surgeons at Hospital for Special Surgery (HSS). Brought on board in June 2014 as Surgeon-in-Chief and Medical Director, Dr. Albert is doing some restructuring and empowering those around him. He tells *OTW*, "This hospital is flat out amazing, with incredible staff who provide a phenomenal patient experience. That being said, there are always ways to improve any situation. My major initiative has been to strengthen the service chiefs (arthroplasty, spine, sports, etc.) using what I call 'distributive leadership.' I told them, 'You are the CEOs of your corporation. Take charge.' We have 107 surgeons and a total of 4,000 employees; you either leave people to their own devices or you have accountability structures that are like branches of a tree. If the service chiefs all do their jobs and are empowered then we can all start pulling in the same direction."

"The two most challenging services to restructure have been spine and sports medicine. Spine was an issue because there were essentially two services—spine and scoliosis—but they were not really working collaboratively. I made it into one service under the leadership of Frank Camissa, with leaders of research, education and fellowship. It's been important to let the deformity surgeons know that they are included and that we honor the history and accomplishments of their service. There is an increasing need for deformity work and HSS is well known for its exceptional care of these patients."

"The sports medicine service has been challenging because it is one of the most famous services here with a large number of surgeons…26. It contains a significant nonoperative component, which, along with the surgeons, is kept busy taking care of nearly every professional sports team in the New York [area]. We had two co-chiefs on this service for many years, but it was complicated. I named Bryan Kelly as the sole chief of this service. Thus far he is doing a great job with the distributive leadership, and has created subdivisions within sports for shoulder, knee, elbow, and general sports medicine, etc…and each subdivision has its own divisional leadership."

"We will be hiring a new Chief Scientific Officer in the next six months and he or she will be an internationally acclaimed basic scientist who possesses the sensitivity to conduct and oversee translational and clinical research. We perform 30,000 surgeries annually, meaning that we touch so many patients and thus are well positioned to define best practices in orthopedic surgery. My aspiration is that HSS will be THE center for national trials. We already have the bandwidth, but to reach this goal we need a platform at the service level. To this end, I will push for accountability in clinical research and the development of functional registries for each service. We want to provide the tools and give authority to the surgeons to collect baseline data that can be used to run the registries and therefore run large trials. This may require an additional Clinical Research Chief who may be identified and brought on board in concert with or shortly after the new CSO." ♦

Integra Pirouettes in Spine

BY ROBIN YOUNG

Wikimedia Commons and jmabel

When Integra LifeSciences Holding Corporation announced in early November that it was planning to spin off its spinal implant business (the 300 employee, $140 million in revenue SeaSpine, Inc.) we could only reflect on how different spine is from the rest of orthopedics.

The rest of orthopedics appears to be collapsing into a literal handful of companies. Synthes into DePuy. Biomet into Zimmer. MAKO, Small Bone Innovations, Berchtold and Patient Safety Technologies into Stryker. Tornier into Wright Medical.

But spine? New public spine companies seem to be popping up roughly every 18 months or so. Here's a list: *(See table on page 9.)*

In the last decade seven pure play spinal implant companies have tapped the public markets for a total of $893 million and, as a group, are now generating about $1.7 billion in annual revenues. Public investors think this group is worth about $5.9 billion or roughly 3.4x sales.

Now Integra's SeaSpine may join the party (the exact form of the spin-off remains to be determined). Of course, as Baxano (formerly TranS1) is demonstrating, the party can lead to a massive morning after headache. Baxano's market value is now down to about $1 million following its bankruptcy announcement. Since going public as TranS1 in October 2007, investors had pumped more than $123 million into the firm to, obviously, no avail.

Unlike any other sector in orthopedics, spine is not consolidating and, in fact, with these kinds of cash balances and market values, this group has the wherewithal to continue to challenge the much larger and better capitalized integrated orthopedic companies: Stryker, DePuy, Zimmer and Medtronic for market share.

These newly public companies are no longer ankle biters. They're players with access to the capital markets.

And here comes Kirt Stephenson's SeaSpine—quite a bit larger and, presumably better capitalized, than the last time it was independent.

SeaSpine

SeaSpine was founded 12 years ago and in its ninth year was acquired by Integra LifeSciences for $89 million (cash). At the time, 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 and one of the most highly regarded spine industry executives 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."

Company	IPO Date	Net Funds From Stock Sales Since and Including IPO ($ in millions)	Trailing Annual Sales ($ in millions)	Current Market Value ($ in millions)	Cash on the Balance Sheet ($ in millions)
SeaSpine, Inc.	tbd	tbd	$140.0	tbd	tbd
K2M Group Holdings, Inc.	May 2014	$121.9	$177.0	$667.0	$23.0
LDR Holding Corporation	October 2013	$77.5	$134.0	$869.0	$83.0
Aurora Spine, Inc.	September 2013	$3.3	$0.3	$40.0	$1.0
Globus Medical Inc.	August 2012	$30.0	$450.0	$2,130.0	$276.0
Baxano Surgical, Inc. (TranS1, Inc.)	October 2007	$123.0	$20.0	$1.0	$3.0
Alphatec Holdings, Inc.	June 2006	$254.8	$206.0	$134.0	$21.0
NuVasive, Inc.	May 2004	$282.3	$749.0	2,040.0	$300.0

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 (and Theken Disc and Therics) three years earlier in 2008. Theken cost $75 million and brought $34 million in incremental sales to Integra. Theken has 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 need 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 $90-100 million.

SeaSpine's Differentiation

SeaSpine, if it becomes a publically traded company, will be compared to K2M, LDR, Globus, NuVasive and the other innovative, effective young spine companies. How will SeaSpine try to differentiate its product offerings?

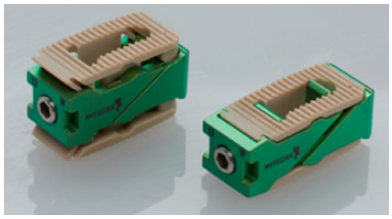
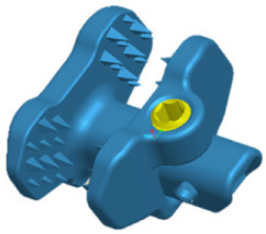
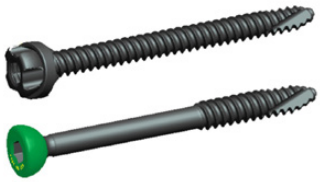
Here's a sampling of their most distinctive implants and what SeaSpine is hoping to convey that is innovative about each one. *(See table on page 10.)*

Wall Street's Take and the Corporate Wardrobe Malfunction

Wall Street's reaction was mixed.

Glenn Novarro from Royal Bank of Canada said: "Spine spin-off does not create much shareholder value in our view." Novarro wrote that Integra's decision to spin off spine would add, at best, ~$3-$5/share to Integra's intrinsic value.

Larry Biegelsen from Wells Fargo, however, said that the spine spinoff would be accretive to Integra's growth and margins. As he wrote 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

Brand Name	Glamour Shot	Why We Should Pay Attention
Hollywood™ NanoMetalene® Interbody Device (IBD)		This is a Titanium NanoMetalene™ -coated PEEK-OPTIMA® TLIF cage. That coating, NanoMetalene™, creates improved surface characteristics for bone while preserving radiolucent imaging properties of PEEK-OPTIMA® and maintaining PEEK-OPTIMA's more anatomical material properties. (PEEK-OPTIMA is a registered trademark of Invibio Limited)
Vu aPOD™-L Lateral Intervertebral Body Fusion Device (IBD) System		Anatomic D-shaped implant with convex endplate surfaces Optional SpinPlate™ for additional fixation
Expandable Intervertebral Body Fusion Device (IBD) System		MIS Intervertebral Body Device allows for smaller access window to disc space and then device can be expanded to size in-vivo. Unique titanium/ PEEK-OPTIMA® design allows for large graft window compared to competition.
Spinous Process Fixation System		This is a posterior plate system expands space between adjacent spinous processes to promote bone fusion and limit spinal extension. The procedure to implant is MIS and it offers anatomic fit and multi-level constructs. Its combination insertion and clamping instrument simplifies technique
Facet Screw System		These are bilateral screws which are placed through the facet joint to stabilize the spine as an aide to fusion. These screws can be implanted using a percutaneous or mini open technique. It's low profile and a locking screwdriver keep screw securely locked to the driver. The roughened surface helps bone ongrowth and it comes with a variable washer for better fit and improved fixation
Daytona™ Deformity System		This deformity system has extended tab screws and a locking cap for rod reduction and correction without the use of additional tower components. The rods are pre-contoured rods in multiple materials and stiffnesses to better match each patient. It also comes with cannulated screw options for use with guide wires and robotic technology.

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".

Finally Piper's Matt Miksic noted that in the most recent quarter Integra's spine revenues were off 11% in the third quarter and missed his estimates. Not a good beginning with analysts. According to Miksic, the sales trajectory for 2014 will be at the lower end of expectations and down, year-over-year by mid-single-digits.

One analyst noted that the spinoff announcement was not a surprise. Indeed, Integra's CFO Glenn Coleman met with the team from Wells Fargo this past August 20 and told them that Integra was considering strategic alternatives for its spine business. "Strategic alternatives" is often the euphemism for sale or spinoff.

We picked up on that and made a short comment in our Power Rankings that Integra was thinking of spinning off spine.

We didn't realize it, but we gotten in the middle of a corporate version of the wardrobe malfunction. Apparently, that comment from Coleman resulted in a bit too much exposure. Too much skin.

We heard from Integra about it and immediately ran an "Errata" saying that we'd read the corporate tea leaves incorrectly. Well…we were correct after all, but we don't regret the "errata." In our view, we engaged in a bit of tactful bit of covering up following Integra's inadvertent wardrobe slip.

Final Note

We understand Wall Street's ambivalence towards this proposed spinoff. But we think this may be exactly the right next step for SeaSpine. From watching corporate wheelings and dealings over the last quarter of a century, we've observed that spin offs usually perform better than analysts expect. So, we're pretty bullish on this deal. In particular we think that Stephenson as Chairman (and a new CEO), SeaSpine should be able to hold its own in the arena with the likes of Lukianov, Paul, Major, Lavigne or King.

Stay tuned for sure. ♦

Spinal Cap III: "Screwed in California" Part 2

BY WALTER EISNER

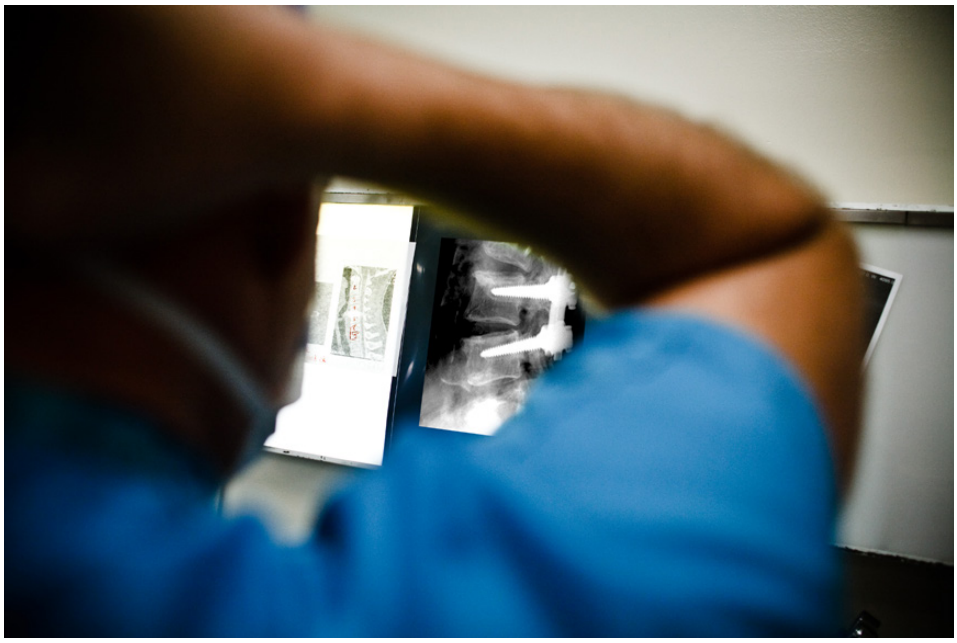
The alarm bells started to ring in South Africa when Richard Walker of Ortho Sol Development (Pty) Ltd, a surgical supply firm, looked at pedicle screws sold by California-based Spinal Solutions LLC and saw what appeared to him to be product tampering and counterfeiting.

The "brighter yellow luster" of a few screws caught his eye, according to a report by the CIR (*Center for Investigative Reporting*) in California on November 3, 2014.

Ortho-Sol had been selling their pedicle screws to Spinal Solutions until the company stopped paying its bills. Walker was able to repossess some of his screws and noticed the tampering.

According to a whistleblower lawsuit filed by former Spinal Solutions and workers comp employees, Walker emailed them that, "Unethical perverse incentive payments made to surgeons for product use and Roger's sudden flamboyant increase in lifestyle from mediocre to upper class property, flashy vehicles, aircraft and yacht purchases," contributed to those alarm bells.

Roger and Mary Williams/The Press Enterprise



Andrew Huth and RRY Publicaitons LLC

"Roger" is Roger Williams, the former owner of Spinal Solutions, in Murrietta, California.

Williams and a slew of alleged accomplices, including self-admitted felons, Michael Drobot and Paul Randall and participating hospitals and surgeons, are accused by the whistleblowers of bilking the California Workers' Comp system out of hundreds of millions of dollars. The whistleblowers allege that the accused illegally inflated device prices through a web of marketing, management and manufacturing companies.

Worst of all, claim the whistleblowers, Williams et al., were so greedy that they hired a machine shop to make cheap counterfeit and non-FDA cleared pedicle screws and paid surgeons illegal kickbacks to implant them in patients.

Act III, Scene 2, Spinal Cap III: "Screwed in California"

Welcome to the last scene of Act III of Spinal Cap III: "Screwed in California."

In the previous scenes the whistleblowers accused the defendants of establishing spinal hardware distributorships and paying unlawful kickbacks to surgeons to use their hospitals and implants. They then sold the hardware to collaborating hospitals at grossly inflated prices.

In this final scene, the whistleblowers accuse the group of defendants of overinflating the price of the "counterfeited" devices to hospitals, which in turn falsely billed the state workers

comp program. A group of surgeons is also accused of knowingly utilizing the counterfeit screws and rods sold to the hospitals, with the hospital's knowledge and collaboration.

In a final twist of the screw, Drobot sues the lawyers accusing him of participating in the alleged counterfeit scheme.

The Discovery

Walker, according to *CIR*, had his fears confirmed when testing showed Spinal Solutions' devices were not using his firm's medical-grade titanium. The uneven threads showed potential for backing out or breaking. He told the whistleblowers that he feared the laser-etched markings intended to make them look authentic could be toxic to patients.

Two years later, an employee of Spinal Solution alerted the FDA of the alleged counterfeiting. The FDA swooped in and issued a Warning Letter to the company in January 2012.

The FDA found that the devices were not made in conformity with the current good manufacturing practice requirements of the Quality System regulation

In April 2013, the company recalled its APLIF system.

The whistleblowers say they are in possession of the counterfeit screws and rods. They also have bills, invoices, agreements, and copies of payments that evidence the kickbacks. They also claim to have obtained detailed admissions from individuals involved in the scheme.

Making of the Screw

Williams allegedly hired William Crowder of Crowder Machine & Tool Shop to make the screws and rods. Williams intended to bill the hospitals and insurance carriers for the counterfeit implants as if they were FDA-approved screws. The whistleblowers claim that Crowder employees confirmed that they made the counterfeit implants for Spinal Solutions and Williams.

The whistleblowers say they met with Crowder, who told them that Williams hired him to make the screws and rods. He told them one of the implants was intended to look like the FDA-cleared pedicle screws manufactured by the "U&I Corporation," a South Korean device company that makes FDA cleared implants. The defendants allegedly put "U&I Corporation" on the counterfeit implants.

"Mic" McGrath, another defendant, provided the whistleblowers with samples of the counterfeit screws. They also met with U&I's chief engineer who had flown to the U.S. for a meeting and upon examining the implants confirmed that the samples were counterfeit.

In an interview with *CIR*, Crowder, now in his late 80s, admitted to making scores of copies of surgical screws for Spinal Solutions. He said the company bargained him down to $65 a screw—less than half of what they usually cost.

CIR showed photos of hardware implanted in a patient who is suing the defendants to engineers at U&I Corporation.

The engineers noted the finishes and lot numbers on some of those screws and connectors did not match their product. "But the dead giveaway was the logo, they said, which lacks the firm's signature forward-leaning font," reported *CIR*.

During an interview with *CIR* at the company's U.S. office in Orange County, California, General Manager Sung Hwang identified three of the patients' four screws as fakes.

"This is obviously not what we did," Hwang told *CIR*. "I feel sorry because (patients) got the surgery with improper devices, so they might suffer from it."

Physicians reportedly ordered the implants for their surgeries at hospitals in California, Nevada, Texas, Wisconsin and Maryland.

Williams: "The Richest Guy on Earth"

Williams is described by *CIR* as a man who "indulged in luxury—private planes, strip club spending sprees, courtside seats at L.A. Lakers games—as the company collapsed into debt. Attorneys looking to serve him with legal documents now say they can't find him."

According to *CIR*, Williams spent 16 years in the orthopedic sales business with his father before he went out on his own. He started Spinal Solutions in 1999 and launched a firm selling knee and hip implants which he turned into an $18 million-a-year business.

Counterfeit U&I Corporation Screw/Adithya Sambamurthy/CIR

By 2008, his planes were shuttling staff and surgical equipment from coast to coast. "He lived like the richest guy on earth. Like a movie star or something," Andreas Leuthold, a pilot who worked for Williams, told *CIR*.

Williams withdrew thousands of dollars from Spinal Solutions' account to patronize strip clubs like the Spearmint Rhino Gentlemen's Club. When creditors later asked why, he said, according to court transcripts, "Because I felt like it."

But he didn't pay his medical device suppliers.

He reportedly began relying on Lenders Funding LLC, a firm that fronted cash at an interest rate of 35%. By 2013, Williams owed about $35,000 per month—solely in interest payments—and imploded in debt.

Quin Ruding, a businessman who helped keep Williams afloat when he started to have cash flow problems in 2012, told *CIR* that Williams made it clear the consulting deals and free flights were tools to keep doctors hooked on his products.

Bob Garrison, another pilot said Williams told him, 'These doctors are greedy. They're so greedy, you can't believe it. All I do…I take advantage of their greed."

Billing of the Screw

California law allows providers to mark up implants by 10% or $250 of "documented paid cost."

The whistleblowers say they are in possession of billing documents that show that distributors created invoices inflating implant costs from 2-10 times the actual purchase price. The hospitals allegedly inflated the invoices further.

As an example, on December 31, 2009 "Mic" McGrath submitted an invoice to Spinal Solutions for his "commission" on the sale of implants for a particular surgery. The invoice reflects the "list price" that Spinal Solutions should have billed to Tri-City Medical Center (a defendant hospital). The total list price was $22,155 ($5,580 for 4 screws, $2,799 for 2 other screws, $850 for two rods, $2,850 for 6 screw caps, $1,495 for "Medium Crosslink," and $8,590 for two ALIF Cages).

However, Spinal Solutions allegedly billed Tri-City for a total of $95,223 for the same hardware.

Tri-City then billed the workers' comp carrier, Berkshire Hathaway a total of $285,645 for the same hardware on precisely the same patient, a $263,490 markup.

In January 2012, Drobot, through International Implants, charged Pacific Hospital $32,456 for implants. A few days later and without yet having paid

for the implants, Pacific billed their carrier $64,930.

Patients and Their Lawyers

There are now 32 suits filed by former patients and lawyers say there may be thousands more patients with counterfeit devices implanted in their bodies.

Among the plaintiffs is a patient who says that when hardware was removed from her body after she developed complications related to lumbar fusion surgery in 2008, the lot numbers on the removed devices didn't match those on the delivery slips. Instead, she says, what was removed were non-FDA-approved knock-offs.

Drobot Countersues

On October 22, 2014, Michael Drobot filed a $50 million defamation suit against attorneys Brian Kabateck and Robert Hutchinson, and the law firms of Kabateck Brown Kellner, Cotchett Pitre & McCarthy and Knox Ricksen.

Terree Bowers, Drobot's lawyer, says the accusations are false and that Drobot and Pacific Hospital "had absolutely nothing to do with allegations concerning the counterfeit screws."

Bowers said the lawsuits are "scare tactics" and that they are "reprehensible."

Frank Pitre, a lawyer for one of the accused law firms reportedly said, "This is a bully who is using lawsuits in an effort to intimidate people. We won't be scared in our effort to expose issues about public safety."

"[Drobot] is an admitted felon," Robert Hutchinson said. "This raises the issue of how can we defame someone when their own actions have tainted them far worse than any comments. He should know it's not going to work."

Hutchinson said the lawsuit is characteristic of a Strategic Lawsuit Against Public Participation, commonly known as SLAPP, used to try and censor, intimidate or silence critics by hampering them with legal costs until they abandon their criticism.

Act IV?

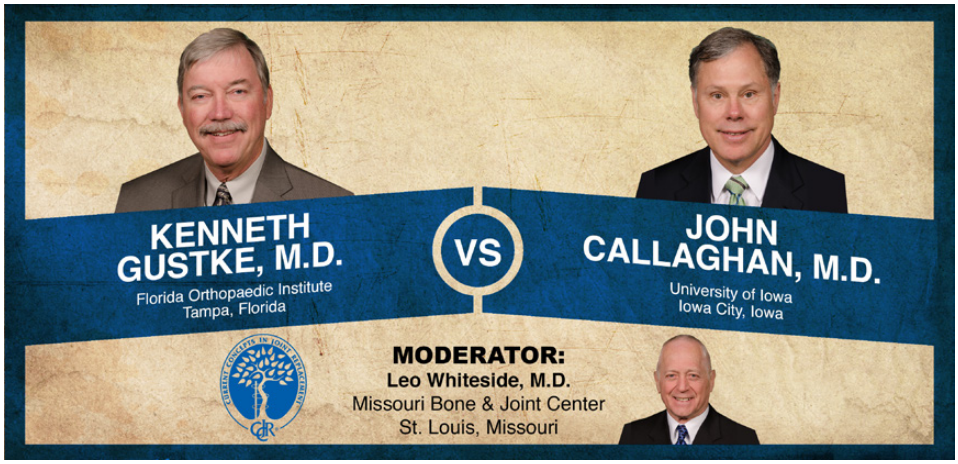
The lawsuits have been filed. The lawyers are looking for Williams and Drobot is waiting to be sentenced. Patients are hoping their pedicle screws don't break and some surgeons are looking over their shoulders.

No doubt, there will be an Act IV to this ongoing drama in California. ♦

Gustke Debates Callaghan: Ultracongruent Liners or Posterior Stabilization

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

This week's Orthopaedic Crossfire® debate was part of a landmark event, the first Brazilian CCJR meeting. The event, which took place in September 2014, was held in Iguassu Falls. The topic was "The Posterior Stabilized Knee: No Post Required." For the proposition is Kenneth Gustke, M.D. of Florida Orthopaedic Institute; against the proposition is John Callaghan, M.D. of the University of Iowa. Moderating is Leo Whiteside, M.D. from Missouri Bone & Joint Center.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Gustke: "There are two popular options: a standard posterior stabilized component with a post and cam. The alternative is an ultracongruent liner. Over 50% of the total knees done in the U.S. are of a posterior stabilized (PS) design. The popularity is justified if you look at the survivorship figures: 97% at 15 years."

"With a PS you get increased knee flexion from forced femoral rollback and you don't have to worry about posterior cruciate ligament (PCL) balance. But complications can occur that are unique to the PS design. Many patients say that they feel clicking. The sound isn't the problem, but the sound comes from impingement between the post and cam."

"A retrieval study found that over 30% of PS designs demonstrated some significant wear. The ultimate outcome of wear is a post fracture; this is due to excessive implant velocity that occurs when the post strikes the femoral cam. Then there is dislocation of the post jumping. Lombardi showed that even though it's a small occurrence it can occur in well balanced knees at around 20 degrees of knee flexion if the post is short."

"More common is patellar clunk syndrome, which occurs because of hypertrophic scarring at the superior pole of the patella from soft tissue impinging on the proximal portion of the intercondylar notch. This is unique to the PS because the intercondylar notch extends more anteriorly to prevent post impingement and hyperextension."

"You're also going to have to remove more bone. Doing this, especially in small femurs—if the box sizes are the same—could be a risk for periprosthetic fracture. There's also a concern that this hard stop that occurs because of the post engagement may increase stress on the tray locking mechanism and cause increased backside wear. A report looking at Insall-Burstein IIs at six years shows 16% osteolysis. The wear issues have motivated many of the manufacturers to pursue mobile bearing type liners with their PS designs."

"So is the rotating platform (RP) the savior of the PS design? Theoretically, you'll have decreased polyethylene wear. But studies have shown that there's really no significant difference in wear when compared to a fixed bearing—although there is some aseptic loosening and osteolysis seen at 10 years. But there's perhaps an increased risk of clunk syndrome. And it creates new problems, such as bearing spinout in 1-5%; soft tissue impingement and crepitation that necessitates reoperation in up to 4% of cases; unexplained hemarthrosis."

"The ultracongruent liner has an increased anterior poly buildup of 10-12.5mm. It has a more conforming surface when the knee is in extension… and it's less conforming in flexion. And it's a dynamic stabilizer rather than a static stabilizer, so there's less stress on the locking mechanism. There's no high velocity impingement on the post…

and it provides resistance to posterior subluxation throughout the entire knee range of motion."

"In a study done in Seth Greenwald's lab they showed that at 90 degrees of flexion PS and ultracongruent liners are fairly similar. But at full extension ultracongruent liners provide better stabilization than a PS. There are some comparison studies in the literature looking at ultracongruents vs PS. Parsley and Argenson showed equal range of motion (ROM), knee scores, and patient satisfaction scores."

"My philosophy is to always try to save the PCL. If it's appropriate rollback I retain the PCL, but if it's too tight I would either increase the slope, do a partial PCL release, or substitute with an ultracongruent liner. On my last follow-up the average Knee Society score was 93; knee flexion was 117 degrees. With one known revision for poly wear (with a new insert only), and one revision for instability."

Dr. Callaghan: "Why should he put in an insert without the post? There's no question that you can get conformity without the post. I found two articles related to that liner, and the one prospective randomized study that Ken alluded to. None of them had long term follow-up. In 2014 Peters from Utah reported on cases from 2003-2008; there was a minimum two year follow-up and the aseptic revision rate was only 0.88. The ROM in that study was 110 degrees."

"You can have mobility without congruity, congruity without mobility, and mobility with congruity. What Ken mentioned was congruity without mobility, which can put high constraint forces on the interface below that on the tibia. The other option is the cruciate retaining (CR) type of design."

"So why an ultracongruent insert? Conforming inserts are beneficial to prevent posterior subluxation of the tibia. Those of you who know the LCS (low contact stress) knee know that it's very ultracongruent. The issue is not with revision…it's a problem with ROM. The average motion in our study was only 105 degrees. It's well understood now that to get motion you have to have rollback. After 90-110 degrees of motion you need rollback…and a post provides that. I don't see how an ultracongruent liner could possibly do that."

"In a fluoroscopic study, Komistek showed that an ultracongruent liner stays in the center of the dish…you never get rollback. With a PFC (press fit condylar) type of design, however, that post gives you rollback and allows you

to flex to 115 or 140 degrees (depending on how you design the prosthesis)."

"CR, PS, RP…they all have very low failure rate in the registries. When you look at meta analyses or follow-ups of multi-institutional studies you see that the PS design has better motion."

"Chit Ranawat's recent work shows a 95% satisfaction rate, so the not having a quiet knee issue that Ken brought up isn't true today. The failures in Chit's group, as with a lot of groups today, are infection and traumatic fractures—not revision for loosening. The ROM in this group was 119 degrees."

"The motion all occurs at the top in a fixed bearing, whereas with a mobile bearing the rotational motion is at the lower bearing surface. Retrieval analyses have demonstrated less cam/post damage with a mobile bearing PS than with a fixed bearing PS. As for clunk, we've shown about a 1.2% prevalence. It's very design specific. If the box is recessed it is better."

"Ultracongruent is good, but good is the enemy of great. A PS gives you that."

Moderator Whiteside: "Ken?"

Dr. Gustke: "There's no question that a PS knee gives you good results. And what you alluded to is that a PS by its design forces the rollback and allows for increased flexion. But my results with flexion are very similar to the results of a PS knee's flexion. And even though there may not be as much rollback that's forced, it's still functional and gives excellent ROM."

"The other thing with an ultracongruent liner is that it's not a total condylar device…it's not congruent throughout the entire knee ROM. So if the soft tissues allow for some posterior glide of the glide of the femur on the tibia then it can allow for it. The reason that the literature isn't full of articles is because this implant hasn't been adopted by a lot of manufacturers because they have PS designs."

Moderator Whiteside: "Ken, have you seen any downsides to the deep dish polyethylene?"

Dr. Gustke: "No, and I use it frequently in revisions. It's my go-to liner for revisions without a posterior cruciate ligament."

Moderator Whiteside: "I've occasionally found cases where the tibia slipped back on the lateral, but not the medial…and the medial side was so prominent that it had to be trimmed."

Dr. Gustke: "The issue with anterior buildup is whether it's going to rub on the patellar tendon or the inferior bone

of the patella. Most designs now allow for a cutout of the mid-portion of the ultracongruent liner anteriorly. If you ever see issues where it may impinge then you just take a beaver blade and trim it off."

Moderator Whiteside: "John, what about the Mayo Clinic study showing a higher failure rate after about 10-15 years in PS knees?"

Dr. Callaghan: "Maybe it's because they didn't get the motion that you get with a CR knee. It wouldn't surprise me to see some studies out to 15 years by good surgeons with a little higher failure rate."

Dr. Gustke: "Part of the issue with that study was that the implant used didn't have a very good locking mechanism. It's that backside wear from the constant velocity of the post hitting the cam, causing a locking mechanism to loosen the poly and generating backside wear. The other issue you have with the post is that you can't highly crosslink it."

Dr. Callaghan: "I think with antioxidant poly that this may not be an issue in the future."

Moderator Whiteside: "I've seen enough studies of mobile bearing poly with under surface wear that it makes me concerned that you have a plastic post wearing and a major underside of the poly wearing…and another post down the center of the tibia. Are we going to have a volumetric wear issue?"

Dr. Callaghan: "The problem with the retrievals is that they are the result of failures. If you get anything under a mobile bearing then it may be the worse thing you've ever seen. That's why you go cementless."

Moderator Whiteside: "John, the open box geometry is still up for debate, right?"

Dr. Callaghan: "If you have an open box then you must be a lot more meticulous about getting all of the cement out and preventing excess bone from being in there."

Moderator Whiteside: "Thank you both." ♦

Please visit www.CCJR.com to register for the 2014 CCJR Winter Meeting, December 10 – 13 in Orlando, Florida.

COMPANY

"Imitation, Not Innovation" Urges Harvard Business Review Article

"We don't need no stinkin' innovation, we need more imitation."

That's the message from two healthcare leaders in a November 19, 2014 *Harvard Business Review* article who say providers should focus on existing approaches that actually work and should actively seek out good ideas that have been tried and refined, bring those ideas home, and adapt them for local use.

Roth and Lee: International Institute for Imitation

Anna Roth, CEO of Contra Costa Medical Center (CCRMC) and Thomas H. Lee, M.D., chief medical officer at Press Ganey Associates, somewhat tongue in cheek, propose a new International Institute for Imitation, which would provide easily accessible information for healthcare professionals who want to improve their organizations with the help of proven methods. Roth and Lee want to start an annual prize for the "highest impact implementation" of an idea created by someone else, and encourage embracing imitation for the good of bettering healthcare organizations across the world.

They credit Jon Pryor, the CEO of Minnesota's Hennepin County Medical Center, who they say mused about appointing a Chief Imitation Officer for his organization – "someone whose sole job was to look outside for good ideas to bring home. After all, an idea that has already worked somewhere else is more likely to be effective than one that is completely new and untried."

Roth and Lee offer two examples of effective imitation.

Thedacare's "Visibility Wall"

First, in 2013, a team from (CCRMC) visited the Thedacare Health System. "Inspired by their systems for making organizational performance transparent, Contra Costa took their idea of a 'visibility wall' and created its own. The wall, located in a high-utilization meeting space, exhibits reports of improvement initiatives and their performance, from improving patient wait times and satisfaction to reductions in the rate of sepsis mortality and increases in 'lives saved.' The wall plays a crucial role in sharing goals and improvements underway, and inspires productive conversations about our progress and where we need to do better. It is also helping drive a culture of transparency, where sharing performance data is a way of life."

Utah's On-Line Transparency Program

Second, they offer an example from the University of Utah's Health System that shows how imitation can speed the implementation of an innovation. Utah developed an on-line transparency program with patient comments over four years (2009 to 2013); for the first three years, the comments were only visible to Utah clinicians and staff. "In 2013, Utah made the unedited comments available in full to the public. The result has been improved clinical performance across a range of measures. Piedmont Health System in Georgia heard about this innovation in November 2013, decided to go forward in December 2013, and went live in April 2014. Piedmont skipped the 'internal transparency' phase that Utah had gone through, and cut right to the full transparency phase, because leadership knew that the program worked."

The Treasure of Sierra Madre/Warner Brothers and RRY Publications LLC

Facing Same Challenges

"We know what you're thinking," write the authors. "Health care is

too complex, too specialized, too local to pursue such a systematic emphasis on imitation. To that, we say providers are not as different from each other as they think. In fact, we draw great comfort from seeing how similar health care providers everywhere really are. All providers face the same timeless challenge of relieving our patients' suffering, and we all get great satisfaction when we make a dent in their problems, with efficiency and reliability."

Borrow From Other Industries

The new institute they envision would support taking ideas from other industries as well. For example, they say health care systems have been using the Toyota production system to improve quality and efficiency for decades now. Other examples include adopting methods from the military and aviation safety, such as checklists.

Another example is how Proctor and Gamble has honed its ability to conduct well-organized global searches for new products and solutions, pulling them into their system and then refining them. Roth and Lee urge providers to tap in and partner up with organizations that have expertise in delivering social support services that affect patient health, like access to food, housing and employment.

Be a "Fast Follower"

Finally, they urge providers to leverage the benefits of being a "fast follower." "Let's look to the health systems that are outperforming their peers and imitate them. Let's lower risk and investment in the unknown or unproven. Let's lionize the imitator. It's the faster way to get better." — *WE*

Monovisc Scores J-Code and $5 Million Milestone

The Center for Medicare & Medicaid Services (CMS) has assigned a unique Healthcare Common Procedure Coding System ("HCPCS") code, or J-Code, for Anika Therapeutics, Inc.'s Monovisc product. As a result of getting the J-Code, Anika is receiving a $5 million milestone payment from DePuy Synthes Mitek Sports Medicine, the marketer of the product.

The issuance of the code sets national Medicare reimbursement rates for products. The new J-Code becomes effective on January 1, 2015.

In February 2014, the company announced that the FDA had approved the company's PMA (premarket approval) application for the product.

Monovisc

Monovisc is a single injection supplement to the synovial fluid of an osteoarthritic joint, used to treat pain and improve joint mobility in patients suffering from osteoarthritis (OA) of the knee. The product, according to the company, is the first FDA approved single injection product with hyaluronic acid (HA) from a non-animal source. It is comprised of a sterile, clear, biocompatible, resorbable, viscoelastic fluid composed of partially cross-linked sodium hyaluronate (NaHA) in phosphate buffered saline.

FDA approval of the product, according to the company, was based on data from a randomized, controlled, double-blind multi-center pivotal U.S. clinical study encompassing a total of 369 patients at 31 centers in the U.S. and Canada suffering from OA of the knee.

Patients were randomized to either Monovisc or control (saline injection) and were evaluated for improvement in pain as measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at follow-up assessments out to 26 weeks.

The primary effectiveness analysis compared the proportion of Monovisc patients achieving a greater improvement from baseline in WOMAC pain score versus control through 12 weeks. The safety analysis showed Monovisc had an extremely low rate of adverse events. There were no serious adverse events associated with the product.

Monovisc/Anika Therapeutics, Inc.

The Market

Anika has marketed Monovisc internationally since 2008. The product is currently sold in a variety of territories, including Canada, the UK and several countries in the Middle East, Europe and Asia.

When the FDA approved the product, company President and CEO Charles H. Sherwood, Ph.D. said, "The U.S. market for viscosupplementation therapy is experiencing double digit growth annually. We are moving forward rapidly with Mitek Sports Medicine to capitalize on the strengths of our viscosupplementation portfolio."

Third-quarter total revenue for the company grew 24% to $22.1 million. Sherwood said on October 29, 2014 that Monovisc has been steadily gaining domestic market share since its U.S. commercial launch in the second quarter of 2014. "Monovisc continues to be very well received by the orthopedic physician community and by patients. The improvements we expect as a result of reimbursement and access to formularies for Monovisc should strengthen our U.S. single-injection market position in the quarters ahead." — *WE*

IlluminOss: Conditional FDA Approval for Bone Stabilization System

IlluminOss Medical, Inc. is pleased to report that it has received a conditional "green light" from the FDA to conduct a clinical trial for the treatments of impending and pathologic fractures in the humerus due to metastatic carcinoma.

According to the November 18, 2014 news release, IlluminOss' Photodynamic Bone Stabilization System (PBSS) is the world's first and only system of its kind and offers significant advantages for the treatment of complex fractures. "Benefits observed from the use of the product in patients include smaller incisions, shorter procedure times, and more rapid post-procedure patient mobility with reduced hospital stays and lower complication rates."

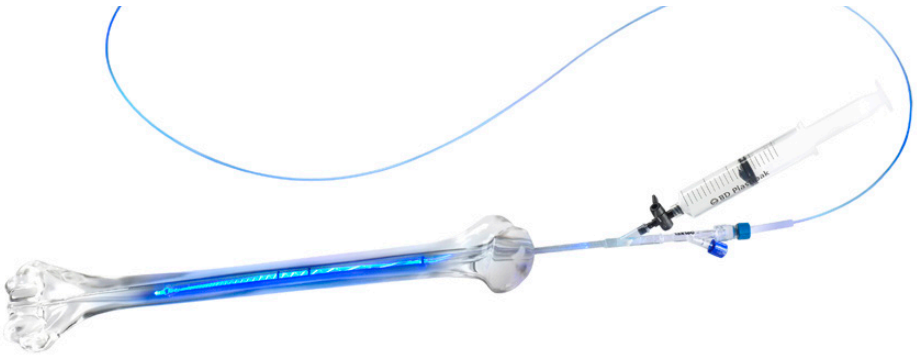
"The minimally invasive procedure incorporates the use of a thin walled PET [pericardial effusion with tamponade] balloon that is infused with a liquid monomer and inserted into the intramedullary canal of the bone conforming to the shape of the patient's specific bone. The device forms as an implant once the surgeon activates the visible light delivered within the PET balloon. Once cured, the implant provides longitudinal strength and rotational stability over the length of the implant."

Dr. Martin Malawer, director of the Orthopedic Surgical Oncology and Professor of Orthopedic Surgery at George Washington University Hospital and Professor (Clinical Scholar) of Orthopedic Surgery at Georgetown University, will lead the first U.S. trial of PBSS.

"From what I have seen to date, IlluminOss' Photodynamic Bone Stabilization System could prove to be a true disruptive technology in the treatment of pathological and non-pathological fractures by orthopedic surgeons," said Dr. Malawer in the November 18, 2014 news release. "This technology will potentially reduce surgery time and morbidity rates, as well as lessen complications and improve patient outcomes."

"We have been exceedingly pleased with the results that surgeons internationally have achieved using our Photodynamic Bone Stabilization System and we are confident that we will see similar benefits for patient outcomes in the U.S. clinical trials," said Robert Rabiner, president and founder of IlluminOss Medical, in the news release. "Obtaining this FDA approval has been the vital first step towards ultimately applying our technology to the treatment of fractures in the U.S. and we look forward to serving this critical market."

Dr. Malawer told *OTW*, "With the first U.S. clinical trial we expect to duplicate the successful findings that have been achieved in Europe where IlluminOss' PBSS has been safely and effectively used in over 500 procedures to date. In my opinion, based on 35 years of experience as an orthopedic oncologist, PBSS will prove to be a truly disruptive technology that will change the surgical method of choice for providing stability for most metastatic tumors, and potentially also for non-metastatic fractures." — *EH*



IlluminOss Medical, Inc.

LEGAL

Docs Protest "Putin-Care" in the Streets

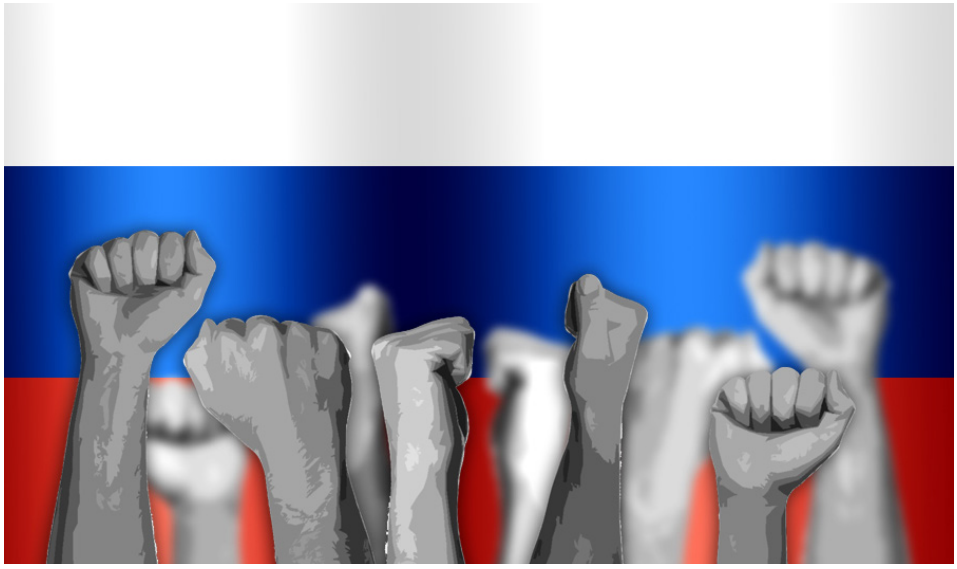


Photo creation by RRY Publications LLC

More than 6,000 doctors and nurses took to Moscow streets on November 23, 2014 to protest the planned closure of at least 28 Moscow hospitals and the firing of up to 10,000 medical staff, as part of a sweeping overhaul that officials say is needed to modernize a decrepit Soviet-era health system.

It is the first mass social protest in Russia in nearly a decade.

And President Obama thinks he's got troubles with his healthcare reform.

"Doctor's Rebellion"

The *AP* reports that the "doctor's rebellion" started in early November when thousands took to the streets to protest the layoffs and hospital closures.

Russian President Vladimir Putin reportedly asked the Moscow government to reconsider the reform as his human rights council hosted a round table discussion with prominent doctors and trade unions that were not consulted when the reform was launched.

One of the protesters, Semyon Galperin, M.D., had spent nearly a decade working at top hospitals and research companies in the U.S. He spent the last ten years in Russia. He was recently given the choice of leaving his Moscow hospital or staying on as a hospital attendant after his job was eliminated as part of the reform.

Galperin works at a hospital that officials say "monopolizes" multiple sclerosis treatment. "Doctors are abusing their position," said an official spokesperson, adding that the city does not need as many neurologists now that Moscow purchased high-tech MRI equipment making it easier to diagnose multiple sclerosis.

Blaming Putin

Moscow officials blame Putin, citing a 2010 Russian law designed to transition from Soviet-era dependency to self-reliance by cutting subsidies to a minimum. "Some of the doctors who are being fired are underqualified. Some of them don't have enough workload," said a Moscow Health Care Department spokeswoman. Putin had vowed to make doctors' salaries twice that of the average employee by 2018. At least for those who still had jobs.

Russian doctors reportedly earn 45,000 rubles ($969) a month, while orderlies earn 26,000 rubles ($560).

Compulsory Health Insurance

But the money to fund hospitals and medical staff is supposed to come out of a fund of compulsory health insurance payments that will see its budget fall by 15% by 2015, the *RBK Daily* wrote. Its budget for health spending in Moscow will fall even more sharply, by 18%.

According to the *AP*, doctors and other state employees are a core of Putin's support base because of heavy subsidies to schools and hospitals.

Apparently, the medical community was not part of the reform discussions and their details only became public in October following a leak in the press. Doctors and hospitals have reportedly not been told why they are being phased out or what is going to happen to their patients.

Putin's presidential human rights council is calling for a halt to the layoffs saying the reform violates a constitutional right to free health care. "The Moscow health department held a number of roundtables with medical professionals, while Moscow Mayor Sergei Sobyanin offered additional severance pay of up to 500,000 rubles ($10,700) per doctor," reported *AP*. — *WE*

Zimmer Gives Europeans More Time for Zimmer/Biomet Deal

The European Commission was supposed to make a decision on the ZimmerBiomet deal by March 11, 2015.

On November 18, 2014, Zimmer Holdings Inc. announced the company had agreed to extend the European deadline by a "limited number of days," and provide the European regulators with additional information.

In October, the Commission opened an "in-depth investigation" into the planned $13.35 billion merger with Biomet, Inc. The Commission said the deal could result in less innovation and higher prices.

Company officials continue to tell analysts that they expect the deal to go through in the first quarter of 2015.

"Deadline extensions are not uncommon in such in-depth investigations. Zimmer has been working closely with the regulatory authorities to facilitate their review of the pending transaction and is encouraged by the substantial progress that has been made to date in connection with the overall regulatory process. Zimmer continues to expect to close the transaction in the first quarter of 2015," stated the November 18 Zimmer announcement.

Unicompartmental Knees and Shoulder Divestitures?

When the Europeans announced their investigation in October, Wells Fargo analyst, Larry Biegelsen said that, according to his consultant, the review is still likely to be resolved through divestitures. The likely areas of divestiture, according to Biegelsen, are unicompartmental knees and shoulders, given the high combined market share.

Biegelsen pointed out that the EU antitrust regulators also launched an in-depth investigation into the Johnson & Johnson/Synthes merger on November 3, 2011, and that deal was cleared on April 19, 2012 after Johnson & Johnson agreed to divest its trauma business to Biomet.

The U.S. government has yet to approve the deal. The Federal Trade Commission (FTC) requested additional information in July. The transaction remains subject to the expiration or termination of the applicable waiting periods under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, approval from the Japan Fair Trade Commission, as well as other customary closing conditions.

BofA Merrill Lynch analyst, Bob Hopkins said back in October that regarding the U.S. timelines, "based on past experience, generally if things go well," a second request may only take three months to turn, but that four to five months is more the norm.

Image created by RRY Publications, LLC / Source: Pixabay and Gerd Altmann

"The possibility remains that the FTC could comment soon, but our conversations with FTC experts suggest FTC and EU regulators will likely coordinate the investigation to the extent permissible in order to reach agreement on any potential conditions placed on the deal. Coordination between the U.S. and EU could potentially push out the FTC ruling into early next year," writes Hopkins.

Both analysts believe the deal is still on track. — *WE*

BIOLOGICS

Tennis Star Treated With Stem Cells

The doctor for international tennis star Rafael Nadal has told The Associated Press that he plans to inject stem cells in the players ailing back next week in Barcelona. Nadal is the 14-time Grand Slam winner who won a record ninth French Open this season.

Nadal's doctor, Angel Ruiz-Cotorro, said that the player's back pain is "typical of tennis players." The doctor said that the stem cell treatment is designed to repair cartilage and is similar to the stem cell treatment Nadal received on his knee last year. Ruiz-Cotorro reported that the cells to be used are Nadal's own, extracted earlier this year, and cultivated "to "produce the necessary quantity" of cells.

"When we have them we will put them in the point of pain," the doctor said, with the goal of "regenerating cartilage, in the mid-term, and producing an anti-inflammatory effect."

According to the press release, several NFL players and baseball players have received stem cell treatment. Nadal's fellow Spaniard Pau Gasol, center of the Chicago Bulls, received stem cell treatment on his knee in 2013. Nadal's record of winning 14 Grand Slam titles ties him with Pete Sampras on the all-time list led by Roger Federer who had 17 victories. — *BY*

Wikimedia Commons and Tabercil

LARGE JOINTS

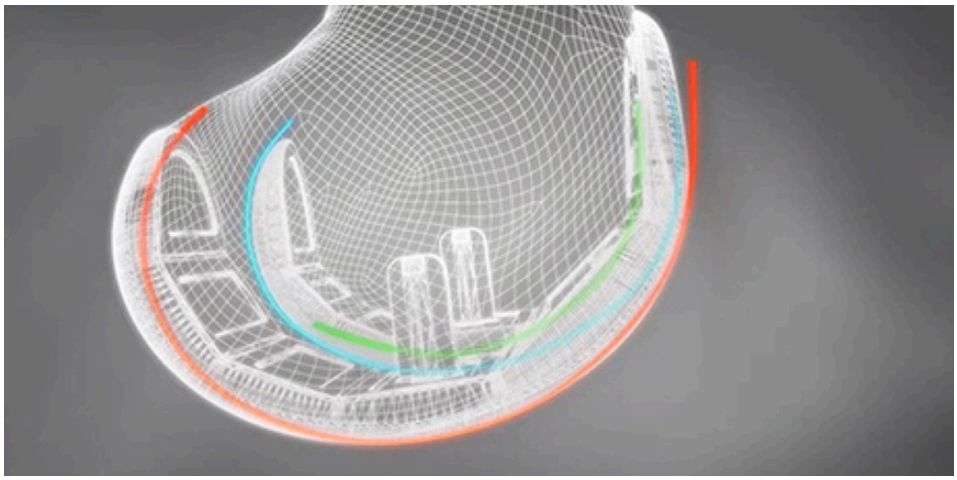
Colorado Surgeon Implants 3-D Printed Knees

A Colorado Springs surgeon, Ronald Royce, M.D., working with Front Range Orthopaedics on Briargate Parkway, is one of the first in the nation to offer 3-D printed knee implants to his patients. As described by Stephanie Earls, writing for *The Gazette*, Royce likens selecting a prosthetic to buying a pair of shoes.

She quoted Royce saying, "You go in and have your foot measured and they say, 'Well, it's between a size 6 and a size 7,' and they bring a shoe out. Sometimes you get a good fit, but sometimes you don't get a good fit and it just feels wrong on your foot."

Royce uses computer mapping software to create a digital model of his patient's knee. 3-D printing makes a precise wax model of the knee and it is this wax model that is used to create the prosthetic. At the same time Royce has a custom jig made that will guide him in positioning the implant during the surgery.

Royce told Earls, "With the old knees, there was no anatomic fit, just sizes. Just measure and hope you'll get a good fit. This is custom. That quality is what makes this knee so exciting." Royce performed six surgeries using the 3-D printed implants in the first week of November, according to Earls. — *BY*



Courtesy of Conformis, Inc.

Zimmer's Periprosthetic Joint Infection Test Available in Europe

The first and only test specifically designed for the diagnosis of periprosthetic joint infection (PJI), is now eligible for sale in several European countries.

On November 19, 2014, Zimmer Holdings, Inc. announced its Synovasure Alpha Defensin test for PJI received Certificate of CE (IVD) Notification and European Authorized Representative (EAR) certificate. According to the company, with both certificates in place, Zimmer, in conjunction with its manufacturing partner CD Diagnostics, is now cleared to launch the test to an initial Tier 1 group of countries, including Germany, Italy, Netherlands, Spain, Switzerland and the UK.

Periprosthetic Joint Infection

According to a June 2010 Guidelines and Evidence Report approved by the Board of Directors of the American Academy of Orthopaedic Surgeons (AAOS), PJI can be caused by "entry of organisms into the wound during surgery, hematogenous spread, recurrence of sepsis in a previously infected joint, or contiguous spread of infection from a local source."

The incidence of PJI after primary hip or knee arthroplasty is over 2% among the Medicare population and is higher after revision arthroplasty than after primary arthroplasty in both joints.

AAOS says PJI requires significant resources to diagnose and treat. Infection is a common cause of revision arthroplasty, with 15% of revision total hip arthroplasties and 25% of revision total knee arthroplasties being due to infection.

Zimmer: "Unparalleled Accuracy"

Matt Monaghan, Zimmer's senior vice president of Global Hips and Reconstructive Research, says the product already delivers "unparalleled accuracy, performance and ease of use in the U.S., and we are very excited to make the same technology available to doctors and patients in Europe. By being able to accurately determine PJI within 10 minutes, the Synovasure PJI Test brings a new level of diagnostics to the European market."

The "Unparalleled Accuracy" of the test, includes:

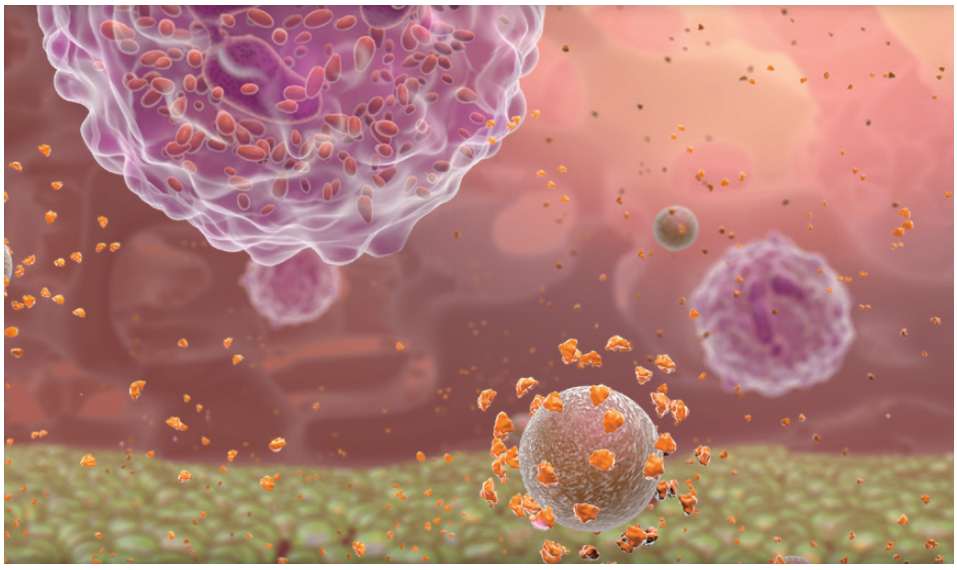
- Achieving 97% sensitivity and 96% specificity by measuring synovial fluid alpha defensing.
- Alpha defensin is an antimicrobial peptide released by neutrophils in response to pathogens.
- Alpha defensin is an ideal biomarker for PJI due to the tremendous separation it achieves between positives and negatives.

Additionally, in performance results backed by data in a 158 patient study, the test maintained its performance in typically challenging situations such as:

- Culture Negative Infection — where 14 of 38 patients with PJI were culture negative and the test correctly identified all 14 as infected.
- Systemic Inflammatory Conditions — test studies included patients with systemic inflammatory disease and its performance was maintained in this population.
- Antibiotic Therapy — where 27% of patients with PJI had been treated with antibiotics prior to aspiration and the Synovasure PJI was not adversely affected in this population.

AAOS Guidelines

The AAOS Guidelines and Evidence Report recommends erythrocyte sedimentation rate and C-reactive protein testing for patients assessed for periprosthetic joint infection. You can read the guidelines here: http://www.aaos.org/research/guidelines/PJIguideline.pdf. — *WE*



Synovasure Alpha Defensin, courtesy of Zimmer Holding, Inc.

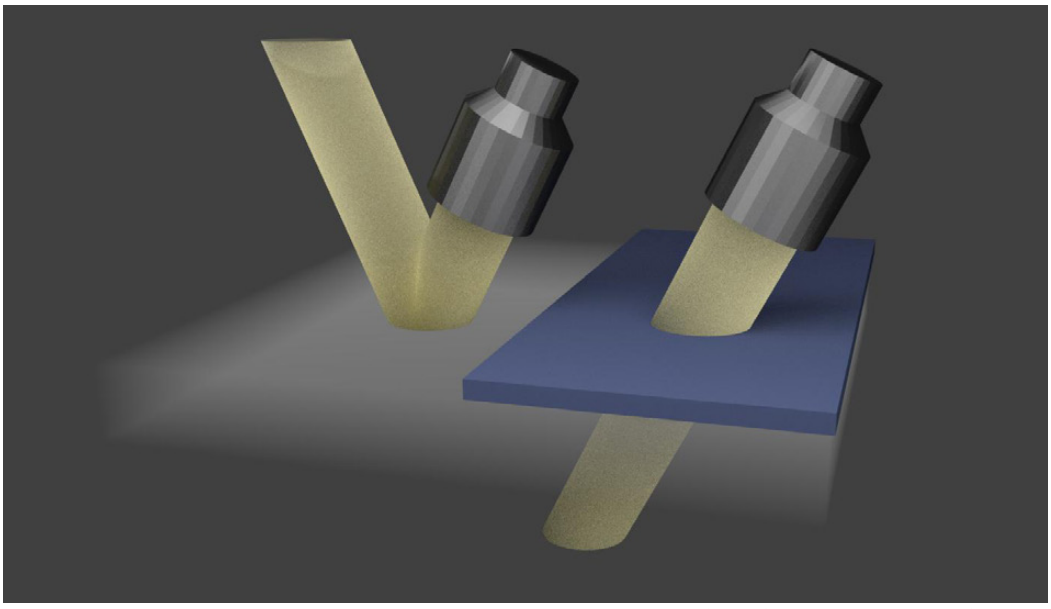
EXTREMITIES

NC State Creates Technique Allowing Ultrasound to Penetrate Bone, Metal

Researchers from North Carolina State University (NC State) have found away around ultrasound's inability to penetrate bone and metal. Using customized structures, the researchers have created "metamaterial structures" that take into account the acoustic properties of the layers that block/distort ultrasound's waves. These blockages are known as "aberrating layers."

"We've designed complementary metamaterials that will make it easier for medical professionals to use ultrasound for diagnostic or therapeutic applications, such as monitoring blood flow in the brain or to treat brain tumors," says Tarry Chen Shen, a Ph.D. student at NC State and lead author of a paper on the work, in the November 20, 2014 news release. "This has been difficult in the past because the skull distorts the ultrasound's acoustic field."

"The metamaterial structure uses a series of membranes and small tubes to achieve the desired acoustic characteristics. The researchers have tested the technique using computer simulations and are in the process of developing and testing a physical prototype."



North Carolina State University and Yun Jing

According to the news release, in simulations, only 28% of ultrasound wave energy makes it past an aberrating layer of bone when the metamaterial structure is not in place. But with the metamaterial structure, the simulation shows that 88% of ultrasound wave energy passes through the aberrating layer.

The scientists indicate that the technique can be used for ultrasound imaging, as well as therapeutically…such as using ultrasound to apply energy to brain tumors in order to burn them. — *EH*

CurveBeam: Eliminating Plain X-rays for Foot, Ankle

One surgeon, one foot, one scan… the pedCAT system just may be eliminating the need to take multiple X-rays. CurveBeam, LLC is announcing that a new software feature automatically generates unlimited standard x-ray views. The company's weight bearing CT imaging system now makes it possible for an orthopedic surgeon to capture standard, three-dimensional volume and multi-planar slices in only one click.

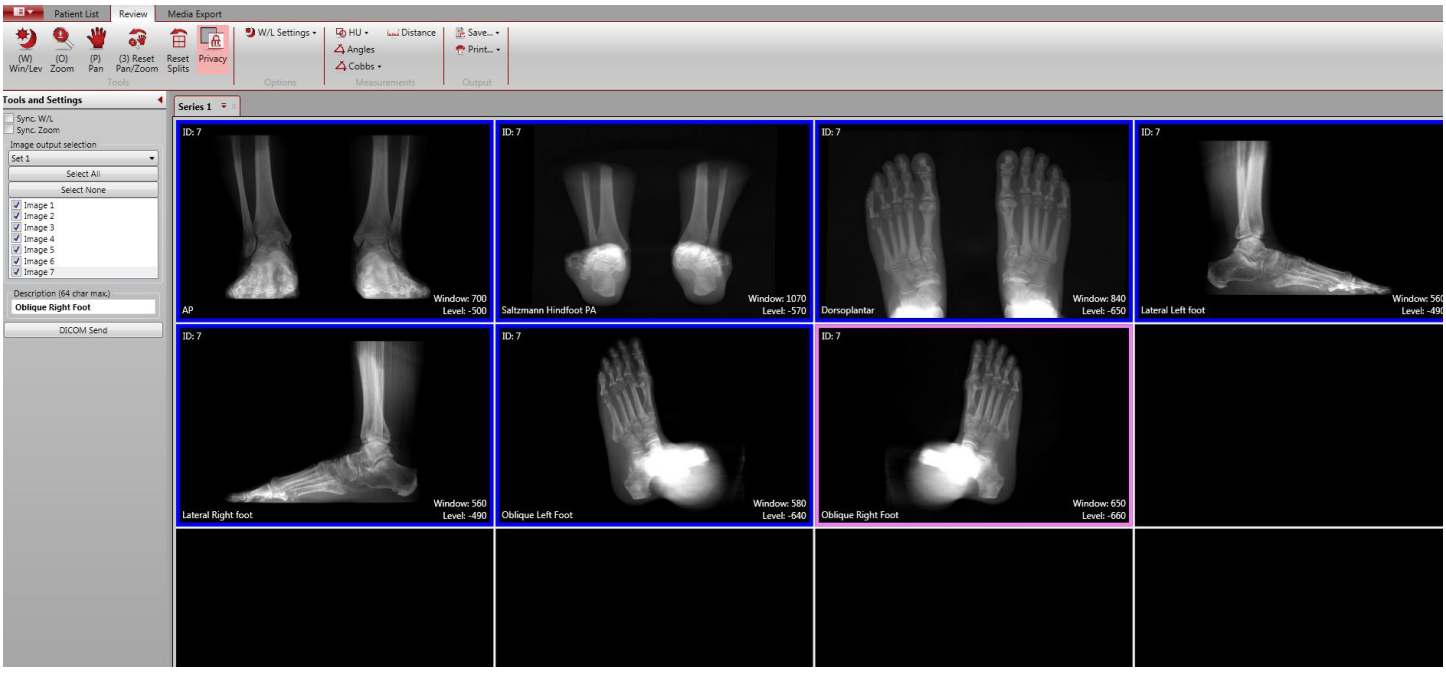
According to the November 12, 2014 news release, because the x-ray views are computed from the pedCAT 3D data, they are anatomically accurate. Plain radiographs are sensitive to the beam angle of the x-ray tube, and could be distorted or magnified. The company indicates that the pedCAT is the first and only cone beam CT imaging system dedicated to the foot and ankle extremity. pedCAT scans are ultra-low dose, according to a study by Dr. John Ludlow published in the *International Journal of Diagnostic Imaging*. One scan exposes the patient to the same radiation as a plain film series of the foot and ankle of about three to seven images. The pedCAT's field of view can capture both entire feet and the bases of the tibia and fibula.

"The software now lets you produce an infinite number of x-ray views from a single pedCAT scan, meaning the patient doesn't have to be repositioned every time you want to capture a different angle,"stated Liz Qualtier, CurveBeam vice president of Customer Care. "A pedCAT scan takes about one minute. There is tremendous potential for workflow efficiencies if a pedCAT is used in place of a traditional x-ray unit."

"Say the physician is looking at a lateral x-ray view and is unsure about whether what he is seeing is a calcaneal fracture, he can quickly switch over to the multiplanar view in CubeVue and scroll through the calcaneus slice by slice for a thorough evaluation," Qualtier said. "And he can accomplish all of this within the patient's initial visit to his office."

CurveBeam President & CEO Arun Singh told *OTW*, "The X-ray feature makes the learning curve for pedCAT technology more accessible to all foot and ankle specialists. The leap from plain radiographs to in-office CT imaging can seem daunting. And perhaps surgeons may have thought the pedCAT is similar to its traditional CT counterpart, and indicated for only the most complex cases. We are confident this new feature will cement that the pedCAT has utility for routine pathologies as well."

OrthoCarolina and the Institute for Foot and Ankle Reconstruction at Mercy are two institutions currently using pedCAT. Singh said that he projects the technology to become commonplace in orthopedic clinics with a devoted foot and ankle section over the next two years. — *EH*



pedCAT, courtesy of CurveBeam, LLC

Big Toe Clinical Trial Nears Completion

All scheduled two-year follow-up patient visits have been completed in Cartiva, Inc's clinical trial that evaluated the safety and effectiveness of the Cartiva Synthetic Cartilage Implant (SCI). Called the MOTION study, it represents the largest prospective randomized clinical study to date for the treatment of osteoarthritis of the first MTP (metatarsophalangeal) joint—the big toe.

"Also known as hallux rigidus, osteoarthritis of the first MTP joint is the most common site of osteoarthritis in the foot, affecting one in 45 Americans over the age of 50, or approximately 2 million people", according to the press release. "The MTP joint, which pushes the foot away from the ground when walking, can become painful and stiff when affected by arthritis. Victims make adjustments to their movements that often have adverse impacts on other joints or lead to a more sedentary lifestyle."

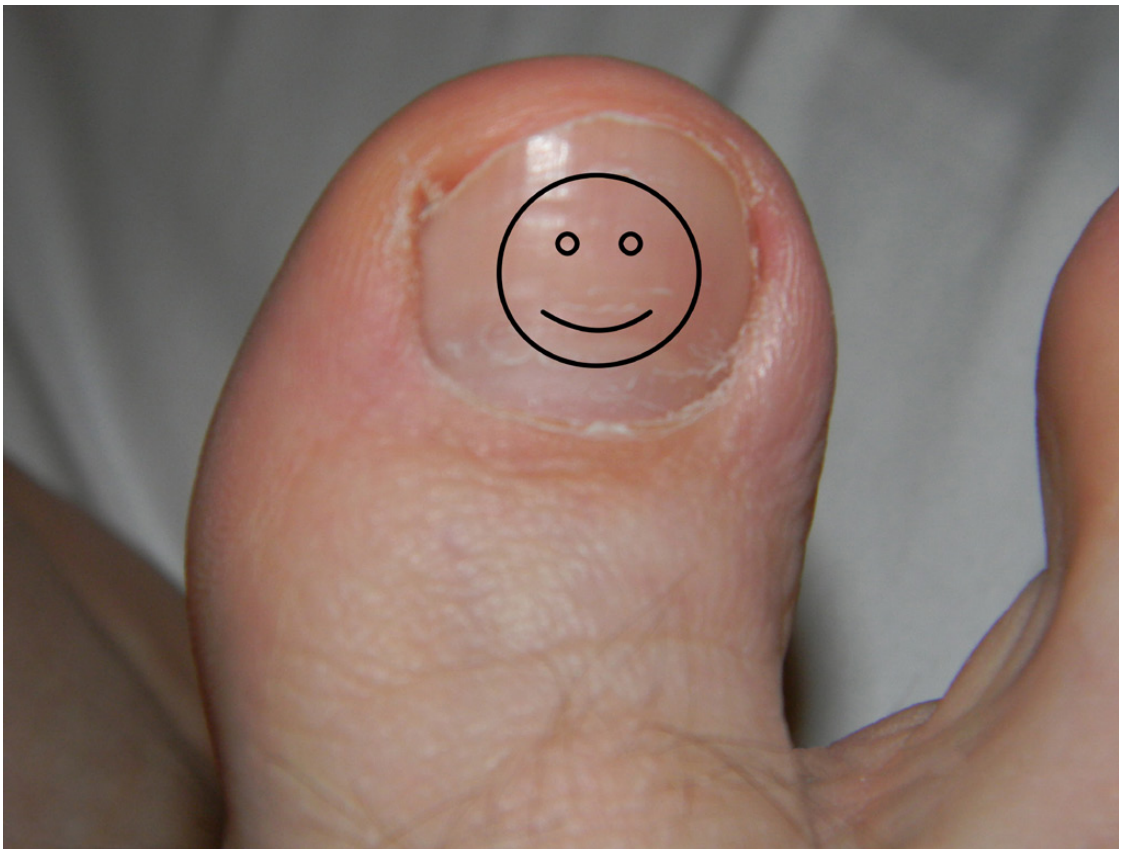
According to Cartiva officials, the current standard of care for osteoarthritis of the first MTP joint is arthrodesis, a procedure involving removal of cartilage, bone resection and fusion of the joint using plates and screws. This, they say, is a permanent correction and usually successful in the elimination of the arthritis pain. The major disadvantage is the resulting restriction of movement of the big toe and the resulting limitations on daily activities and footwear.

The MOTION study, which completed enrollment in June 2012, is a 236 patient study conducted at 12 sites in Canada and the United Kingdom. Researchers followed patients for two years—randomizing patients to receive a Cartiva implant or arthrodesis.

"The completion of the MOTION Study is an important milestone for the company and our technology that puts us one step closer to a potential new alternative for patients with osteoarthritis of the first MTP joint," said Timothy J. Patrick, president and chief executive officer of Cartiva. "We have commenced final data analysis and look forward to presenting the results next year."

"Cartiva SCI has the potential to be a game-changer for those suffering from the debilitating pain of this condition but who wish to maintain motion in their joint," said Judith F. Baumhauer, M.D., Associate Chair of Academic Affairs and Professor, Division of Foot and Ankle Surgery, Department of Orthopaedics at the University of Rochester and Principal Investigator of the MOTION study. "The MOTION study was a very well designed study conducted by leading foot and ankle surgeons in Canada and the United Kingdom, and should provide us a wealth of clinically significant data on this promising technology."

In April 2014, the Food and Drug Administration agreed to a modular review process for Cartiva's premarket approval application for Cartiva SCI. The company has submitted three of the five planned modules, and will submit the final module, including the data from the MOTION study, in the second quarter of 2015. — *BY*



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SPINE

Invuity Throws Light on Minimal Access Surgery

Invuity, Inc., a surgical photonic company based in San Francisco, California, is launching what it calls a "drop in" light to be used in minimal access surgery. Called the Invuity Waveguide XT System, the new product adds to the company's photonics-based portfolio.

According to the company release, Invuity's photonics technology delivers visualization of tissue planes, critical structures and anatomical landmarks. An estimated 30% to 40% of all surgical procedures in the United States are minimal access and the percentage is growing, say company officials. They note that minimal access techniques improve surgical outcomes, minimize risks associated with traditional open surgery, and reduce post-operative recovery and hospitalization time.

The surgeon does have to be able to see what he is doing. Proponents of Invuity's Waveguide XT System report that it can be strategically placed within the incision to direct and shape the illumination deep into the disc space providing startlingly clear visualization without the risk of thermal tissue damage. Warren F. Neely, M.D., Neurosurgery, Christus Santa Rosa Health System in San Antonio, Texas said, "With this innovative drop-in device, surgeons benefit from superior visualization without altering their standard surgical technique or instrumentation."

Company officials say the technology projects thermally cool, brilliant light to volumetrically illuminate deep surgical cavities, providing visualization while virtually eliminating shadows, glare and thermal hazards. — *BY*

Courtesy of Invuity, Inc.

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