VOLUME 9, ISSUE 35 | NOVEMBER 5, 2013

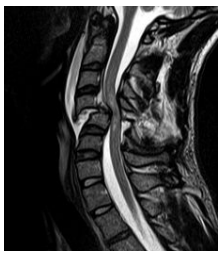
Orthopedics This Week

WEEK IN REVIEW

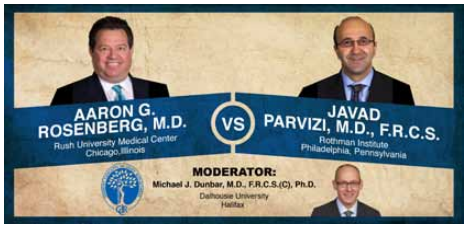
4 Fired Sales Rep Fires Back at Stryker >> Christopher Ridgeway was one Stryker's top salesman. When Stryker fired him he went to work for Biomet. Stryker sued them both, saying Ridgeway violated a non-compete agreement. Then Biomet fired Ridgeway. Ridgeway says Stryker fabricated the non-compete agreement, that there never was an NCA. Here's the rest of this crazy story.

8 Cameron v. Gehrke Over Hinges >> "There is a role for hinges, but not for these current designs. There are no non-rotating fixed axis hinges!" states Hugh Cameron. Thorsten Gehrke counters, "There are clear indications for a hinge knee, such as with extreme valgus deformities. Other primary indications include bone loss with major instability and extra-articular deformity."

11 Definitive Study (69,000 Patients) Last Word on Cement for VCF Care?//RA Patients Twice as Likely to Develop Heart Disease//Spine Fellowships a Hoppin' >> A massive study has found surgical care for spine fractures using cement works better than non-operative care. Researchers from Mayo Clinic have found that RA patients are twice as likely to develop heart disease!



15 Aaron Rosenberg Takes on Jay Parvizi Over Tourniquets >> "No tourniquet! Get the bleeders as they come up," argues Aaron Rosenberg. Jay Parvizi counters, "With a tourniquet you get a bloodless field and better visualization. You can try to cauterize the vessels as they come up, but I don't think you can cauterize bleeding from bone."



BREAKING NEWS

19 Huge Study (n=26,610) Nails *Exercise Statistics*

Australia Identifies **Best and Worst** Performing **Joint Replacements**

Joint Replacement Improves Earnings and **Sex Life**

Chinese Expand **Orthopedic Implant** Capabilities

NuVasive's Big 3rd Quarter Beat

Joint Arthroplasty Readmissions Top 5%

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: NuVasive and Globus, the Young Turks of spine, slam dunked the third quarter with powerful sales growth and rising profit margins. Their reports came fast on the heels of Stryker's and Zimmer's also unexpectedly strong large joint recon report. NuVasive first announced that Q3 sales popped 14% over prior year levels (Wall Street was looking for something closer to 9%), then Globus Medical joined the party reporting a 13% jump. It's a tailwind in ortho these days. Enjoy the ride.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	9	NuVasive	6.30%	27.43%	Tough decision this week. NUVA or GMED? NUVA tops in expected earnings change and added more new sales in Q3. Gets the top spot.
2	8	Globus Medical	28.53	10.03	BUT...GMED is tops in P/E to growth, meaning it's a bargain. AND 5th most attractive P/E ratio.
3	1	Stryker	15.22	9.29	Bounced out of the top spot by the other Young Turks in spine. SYK's now getting ready to digest robotics. In valuation terms, 6th most attractive equity.
4	2	Exactech	10.00	13.92	Solid 25% increase in earnings on top of an 8% rise in sales. Well above Street expectations. No wonder this stock has been so strong.
5	3	Zimmer	27.31	5.87	Earnings season done for ZMH which means back to real business. Viewline System interesting addition to MIS spine line.
6	4	Conmed	9.78	7.60	Yes, earnings disappointed. But margins were ok and management increased its cash dividend by 33%.
7	5	Medtronic	28.84	6.99	While NUVA and GMED's numbers are the headline, MDT continues to transform into a player attacking the market creatively and aggressively.
8	6	Integra LifeSciences	11.77	10.31	Management guided down to the lower end of sales expectations for 2013 and is still cleaning the underbrush out. Uninspiring quarter.
9	7	Smith & Nephew	20.78	3.72	Hips and knees seem to be taking a back seat to wound care. Management's quarterly call signaled it—particularly with Healthpoint's 55% sales jump. No, not THAT Healthpoint.
10	10	Johnson & Johnson	26.73	6.97	Still a defensive stock. And until the DePuy Synthes merger starts to show some synergies, JNJ will remain so.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	CryoLife	CRY	$9.46	$261	34.95%
2	NuVasive	NUVA	$31.22	$1,393	27.43%
3	MiMedx Group	MDXG	$5.46	$526	22.42%
4	Exactech	EXAC	$22.67	$307	13.92%
5	TiGenix	TIG.BR	$0.36	$46	11.77%
6	Integra LifeSciences	IART	$45.26	$1,272	10.31%
7	Globus Medical	GMED	$18.98	$1,762	10.03%
8	Stryker	SYK	$74.03	$28,014	9.29%
9	Tornier N.V.	TRNX	$21.23	$1,014	8.87%
10	Conmed	CNMD	$36.26	$1,001	7.60%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	RTI Biologics Inc	RTIX	$2.84	$160	-26.04%
2	Bacterin Intl Holdings	BONE	$0.60	$31	-20.28%
3	Baxano Surgical Inc	BAXS	$1.18	$53	-14.49%
4	Alphatec Holdings	ATEC	$1.86	$181	-5.10%
5	Orthofix	OFIX	$20.34	$396	-2.68%
6	Wright Medical	WMGI	$26.42	$1,243	-2.11%
7	Symmetry Medical	SMA	$8.08	$301	-0.49%
8	MAKO Surgical	MAKO	$29.83	$1,535	0.95%
9	Smith & Nephew	SNN	$64.41	$11,552	3.72%
10	ArthroCare	ARTC	$36.67	$1,041	4.47%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$20.34	$396	8.17
2	Medtronic	MDT	$57.26	$57,115	15.56
3	Zimmer Holdings	ZMH	$87.89	$14,902	15.72
4	Smith & Nephew	SNN	$64.41	$11,552	15.85
5	Globus Medical	GMED	$18.98	$1,762	16.93

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$31.22	$1,393	82.16
2	RTI Biologics Inc	RTIX	$2.84	$160	76.55
3	Symmetry Medical	SMA	$8.08	$301	44.40
4	Integra LifeSciences	IART	$45.26	$1,272	28.88
5	CryoLife	CRY	$9.46	$261	24.13

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$18.98	$1,762	1.13
2	Orthofix	OFIX	$20.34	$396	1.17
3	Conmed	CNMD	$36.26	$1,001	1.42
4	Exactech	EXAC	$22.67	$307	1.52
5	Zimmer Holdings	ZMH	$87.89	$14,902	1.70

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$31.22	$1,393	6.59
2	CryoLife	CRY	$9.46	$261	6.03
3	RTI Biologics Inc	RTIX	$2.84	$160	5.10
4	Symmetry Medical	SMA	$8.08	$301	3.70
5	Johnson & Johnson	JNJ	$93.37	$263,124	2.71

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$8.08	$301	0.73
2	Orthofix	OFIX	$20.34	$396	0.86
3	RTI Biologics Inc	RTIX	$2.84	$160	0.90
4	Bacterin Intl Holdings	BONE	$0.60	$31	0.90
5	Alphatec Holdings	ATEC	$1.86	$181	0.92

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	$5.46	$526	19.45
2	MAKO Surgical	MAKO	$29.83	$1,535	14.94
3	TiGenix	TIG.BR	$0.36	$46	11.27
4	Globus Medical	GMED	$18.98	$1,762	4.57
5	Johnson & Johnson	JNJ	$93.37	$263,124	3.91

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

Fired Sales Rep Fires Back at Stryker

BY WALTER EISNER

Christopher Ridgeway is a 35-year-old married father of two. He's been fired as a device salesman by both Stryker Corporation and Biomet, Inc.—in just the last 60 days.

Twelve years ago Ridgeway went to work for Stryker as a salesman in New Orleans. For the last seven years, he says in court documents, he generated more sales for Stryker than any other salesman.

Fired and Fired

On September 10, 2013, Stryker fired him for malfeasance. Ridgeway immediately went to work for Biomet, Inc., who he says, recruited him. After Stryker filed a lawsuit against Biomet for torturous interference, Biomet fired him for violating a purported non-compete agreement "NCA" with Stryker.

After firing Ridgeway, Stryker filed an emergency motion in federal court in Michigan seeking an injunction to keep Ridgeway from competing with them in the marketplace, based on the NCA.

Missing Agreement

There was just one little problem. Where was the NCA? Was there proof of the existence of an NCA?

When Stryker went to the federal judge they swore they were submitting a "true and correct copy" of the agreement. But Ridgeway says Stryker fabricated the document by simply attaching his signature page from another man's agreement and then, "slapped it" on the Complaint.

clipartpal.com

Ridgeway alleges that, "Apparently, Stryker lacked the actual agreement" but was "desperate to keep him from going to work for Biomet. "

To prove there was an NCA, Stryker submitted a Declaration from Stryker employee Sarah Krupinski that this was indeed a true copy. Krupinski swore that she had "personal knowledge" of the agreement. But, according to Ridgeway and her own admission, she didn't begin working for Stryker until March 4, 2002, the year following the alleged 2001 agreement.

"Stryker never had anyone sign the alleged agreement," stated Ridgeway, "despite there being an express signature line [for Jonathan Bagrosky, Manager, Human Resources] for this."

"Cut and Paste Job"

But the copy submitted to the Court had an even bigger problem, argues Ridgeway. "The alleged agreement is plainly and visibly not the actual agreement."

Ridgeway claims that Stryker simply detached an NCA of another man by whiting out or using Liquid Paper and obliterating the other man's name. "Stryker then took a copy of the document, attached it to a facsimile signature of [Ridgeway's], and presented the altered copy to the Court."

"This is nothing more than a cut and paste job. Because the signature page is genuine, Ridgeway has attempted to obtain a copy of whatever agreement was actually signed, but Stryker has

HOWMEDICA LEIBINGER INC.
D/B/A STRYKER LEIBINGER

EMPLOYEE NON-COMPETE AGREEMENT

This Agreement is made this ___ day of ___ 20__ between Howmedica Leibinger , Inc., d/b/a Stryker Leibinger, a subsidiary of Stryker Corporation ("Company") and _____ ("Employee").

By executing this Agreement, Employee recognizes and agrees that Employee is or will be employed in a position with Company in which Employee will be trained to perform work which involves the sale of highly specialized products to a valuable customer base. Employee will be [illegible] territory comprised of Company's valuable customers. Employee

Ridgeway legal filing

failed to produce this," states Ridgeway's response.

In an attachment, Ridgeway's lawyer notes the Court can "visibly see the broken line under the blank space for a date that was caused by the white out." The Court can also "readily see the visible hole punches for a three ring binder on the alleged non-compete agreement that was taken from another's man agreement."

"These hole punches are circled, so that an easy and clear comparison can be made with the facsimile signature page of Christopher Ridgeway that does not bear any of the three ring hole punches, nor any text of any agreement."

"Stryker has failed to prove that a contract exits that forbids Ridgeway from competing with Stryker. Therefore, the demand for a preliminary injunction should be denied."

Stryker Withdraws Injunction Motion

But before a scheduled hearing on October 30, 2013 to hear the arguments over whether an injunction should be issued, Stryker withdrew their motion. Stryker said the danger of losing business to Biomet through Ridgeway went away because Biomet fired him.

Ridgeway and his lawyer say it was because they had exposed Stryker's fabrication of the non-existent NCA.

On October 23, 2013, Judge Robert Bell granted Stryker's motion and cancelled the October 30, 2013 hearing based on "changed circumstances (Ridgeway's firing by Biomet) and the need to conduct more fulsome discovery."

Judge Bell: "Significant Concerns"

The judge noted that Ridgeway opposed the motion to withdraw because he wanted the opportunity to clear his name and "to reveal to the Court Stryker's deceptive conduct in fabricating a non-compete agreement. Defendant Ridgeway has raised significant concerns about the manner in which Plaintiffs have prosecuted this case." The judge said those concerns can be addressed to the Court by other methods or procedures.

So this is where it stands today. Ridgeway, once a top sales salesman has now been fired twice within two months with no ongoing legal venue to clear his name.

Biomet's Courting

Ridgeway says this all began when Biomet asked him to come to work for them. They asked him if he had an NCA. Based on "repeated" Stryker assurances, he said no. He had no memory of ever signing such a document 12 years ago at age 23.

He said he would never have pursued the Biomet opportunity if he was aware of an NCA when he traveled to Biomet headquarters in Florida to discuss the Biomet offer. By September 10, 2013, he was "almost" convinced that he wanted to leave Stryker and go to work for Biomet. But nothing was signed and no final decision was made.

Terminated

Stryker struck first and terminated all email access on the 10th of September.

He also got a call from his boss, Hunter Cameron to meet with Sarah Krupinski and him at their Marriott hotel room in New Orleans where he was informed of his termination, and he was presented with a termination letter.

The letter warned him of all his obligations under a confidentiality agreement. "Glaringly, no mention was made of a non-compete agreement, nor did the Stryker representatives advise him that he had a non-compete agreement and that he should not go to work for Biomet," states Ridgeway.

RidgewayVents to Scannell

Ridgeway then emailed Tim Scannell, Stryker's Group President, MedSurg & Neurotechnology, on September 22, 2013, thanking him for the good years with Stryker, and confirming that he had not been flipping business to Biomet.

In his email to Scannell, Ridgeway had unflattering things to say about his manager, Hunter Cameron.

"As you are aware employees leave managers not companies! Working for Hunter Cameron was the tuffest [sic] challenge of my career... The only thing I ever got from Hunter was you would take a substantial pay cut to excel your career and basically there was nothing he could [do] for me. When Biomet called me and offered me an opportunity as an agent principal for multiple states and many divisions, I listened because I felt as if Hunter gave me no other options."

Stryker Non-Compete Agreements

Ridgeway argues that even if an agreement existed, Stryker wouldn't be able to enforce it after "repeatedly" telling him that no such agreement existed. Stryker's director of sales until 2011, Robert McKay, signed a Declaration to the Court on October 15, 2013, saying that it was discussed at company leadership and management meetings in the presence of human resources managers that Ridgeway did not have an NCA.

In fact, said McKay, he himself didn't have such agreement until he became manager.

Ridgeway claims he was eventually offered stock options to sign an NCA, but declined.

The Rest of the Charges

In concluding his case, Ridgeway says, "Stryker embellished this perfectly legal conduct into a concocted story about secret code words like 'pancake', which was nothing more than an innocent reference to an earlier joke made by Border over a breakfast at a restaurant regarding a pancake." Similar claims that Ridgeway called his work for Stryker a "dog and pony show" are "untrue and are in stark contrast to the substantial revenues generated by Ridgeway as a top salesman."

Concerning Stryker's complaints that Ridgeway was not permitted to engage in other business activities, Ridgeway says Stryker failed to produce an actual agreement that prohibited him from doing so. Even under the alleged agreement filed by Stryker, "it clearly states that the restrictions 'do not prevent' [underlined] other business activities that are not in competition with Stryker…His other business pursuits clearly did not diminish his performance as Stryker's top salesman for seven years."

As for Stryker's alleged losses, Ridgeway says Stryker's "exaggerated" claim of $3 million in losses is "without any merit whatsoever." He said he never made a single sale for Biomet before getting fired and Stryker immediately replaced him with existing sales personnel.

"Reprehensible Litigation Tactics"

The case got nastier on October 19, 2013 when Ridgeway's attorney petitioned the Court to bar Stryker from communicating directly with his client.

While spending a relaxing Friday evening with his wife and two children, said the petition, Ridgeway "had his home life brutally disrupted by yet further aggressive litigation tactics by Stryker. The unethical bullying conduct of Stryker has now reached a new low." Stryker's Attorney, Michael Wexler, sent an email to Ridgeway that "egregiously denigrated and criticized" Ridgeways attorney, Wade Webster. Ridgeway asked the Court to prevent "these reprehensible litigation tactics."

The "hardball, unethical litigation tactic unleashed by Stryker is consistent with its aggressive approach (1) in representing to the Court that a non-compete agreement of another man (who name was obliterated by white-out and then was attached to a faxed signature page of Ridgeway) was the actual and genuine non-compete agreement signed by Ridgeway, and (2) by its demand for, and insistence that the Court provide, an emergency hearing on a preliminary injunction, only then to seek to withdraw the demand after Ridgeway uncovered the manipulation by Stryker of the alleged employee non-compete agreement."

Christopher Ridgeway didn't get his day in court on October 30. But the judge said there were other avenues open Ridgeway, so we don't think we've heard the last of this case.

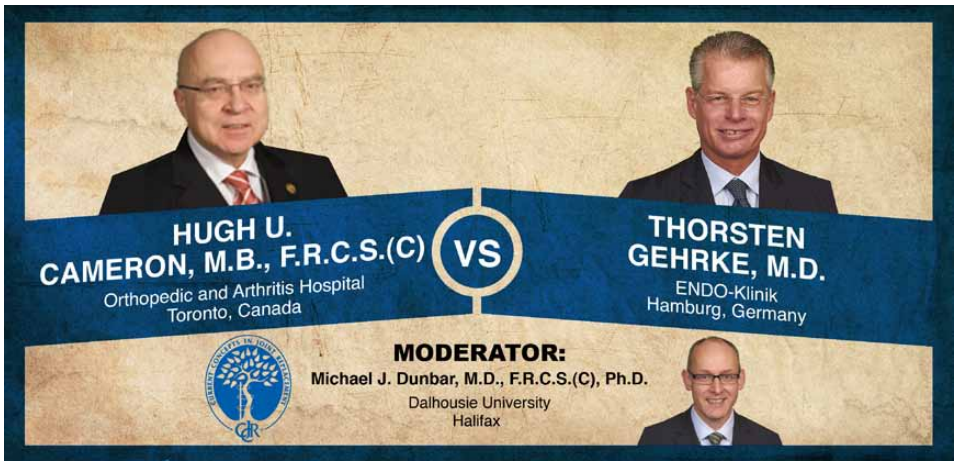
We asked Biomet if they'd hire him back if the NCA turns out to be fabricated. They, like Stryker, politely told us they don't comment on ongoing litigation. ♦

Cameron v. Gehrke Over Hinges

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

"There is a role for hinges, but not for these current designs. There are no non-rotating fixed axis hinges!" states Hugh Cameron. Thorsten Gehrke counters, "There are clear indications for a hinge knee, such as with extreme valgus deformities. Other primary indications include bone loss with major instability and extra-articular deformity."

This week's Orthopaedic Crossfire® debate is "The Role of Hinges: No Role At All." For the proposition is Hugh U. Cameron, M.B., F.R.C.S.(C) of the Orthopedic and Arthritis Hospital in Toronto; against the proposition is Thorsten Gehrke, M.D., from ENDO-Klinik in Hamburg, Germany. Moderating is Michael J. Dunbar, M.D., F.R.C.S.(C), Ph.D. from Dalhousie University in Halifax.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Cameron: "When total knee was in its infancy there were no stems except on hinged implants. The early hinges had a high failure rate. The stems were too short, the trochlear grooves were either poor or non-existent, and hinge mechanisms were often poor and lacked strength."

"I did hinged knees when I could do nothing else. I used the Guepar 2 from France, and my follow up is now over 25 years. I never had a single case of loosening. The problem was that at 20 years the plastic was damaged and worn out—and the spindle was damaged and there were no replacement spindles."

"This is the same problem we all face in joint replacement surgery: the company stops making the implant. Perhaps they could make a one-off, but I hear that the FDA might prevent that. However, the FDA has just lost another major legal case, perhaps this is possible."

"Regarding spindle wear, we need a mechanism where the whole hinge bearing can be disassembled from the stems, dumped and a new one can be attached to the retained stems. Taking out a fully bowed, completely cemented stem is not easy."

"Currently, hinges are seldom used. We now have good tibial stems; femoral stems are not so good, but are getting better. Trochlear grooves and hinge mechanisms are adequate. But in North America, they all rotate. There are no non-rotating fixed axis hinges. There is a role for hinges, but not for these current designs. All of these designs allow free rotation. There are some cases and some revisions in which a hinged knee must not rotate."

"The current indications for fixed axis hinges are, first of all, an absence of collateral ligaments, especially the medial. A high central post knee will work for awhile, but eventually the post will break. You need a flexion gap of >3cm with a normal extension gap. If the patient gets good flexion the femoral component will jump the post. The current hinges can handle these conditions, but it's the third one, which is what we see more commonly. That is the multiply revised knee with bone loss, severe scarring, lateral patellar dislocation, and significant tibial torsion. The cause of such a situation is unrecognized tibial torsion; a rotating hinge does not solve this problem."

"In tibial torsion, when the patella faces the front, the foot points laterally like Charlie Chaplin. When the foot faces the front the patella faces inwards (winking patella). Many of the patients see sports medicine doctors early in life; their history is usually the same. They are nearly all women who are athletic, they get a minor knee injury and quads atrophy. They lose control of their knees, have knee pain…and nobody can find anything wrong."

"Her patella may have been a bit unstable. In order to hold it in place the tibial tubercle is transferred very medially. She

has multiple operations, none of which work; she ends up with an unsuccessful knee replacement at an early age. The knee hurts, is stiff, and feels unstable. If the doctor only examines the knee then it's a good knee. But when the foot faces laterally, the patella tends to track on the lateral ledge of the trochlea and may be painful. Because she walks with her foot turned out she chronically strains the medial collateral ligament, and her foot eventually collapses due to a tibialis posterior tendon rupture. She ends up with multiple knee revisions, each going up in level of constraint—none of which help much. By this time there are stems in the tibia so it's impossible to do a tibial derotation osteotomy."

"The ligaments and scarred soft tissues have a memory…and they want to go back where they were. If a rotating bearing is used, when the patient wants flexion she will externally rotate the tibia, which she's always done, and the patella will sublux laterally. The final result is that she will have patellar pain and the sensation of instability—in spite of the fact that she has hinge. She will be unable to use the knee as the lead leg on stairs, on patellar loading."

"I wish that one of the North American manufacturers would simply drill a couple of holes in the lateral side of the tibial component so that we could slide in a couple of metal pins to block the plastic from rotating externally."

Dr. Gehrke: "Until a couple of years ago most U.S. orthopedic surgeons were saying, 'I never did a constrained knee in my life' or 'I can solve any problem with a PS or CCK design.' I was asking myself, 'Who operates on extreme cases without using a hinge?' [showing a doctor rotating a leg to the SIDE]… May I ask the audience, 'Who would use anything but a hinged knee in this case?' [audience claps] So there IS a role for hinges."

"There are primary indications for using a hinged knee, such as with very stiff, extreme valgus deformities—I especially lean toward a pure hinge. Other primary indications include bone loss with major instability, extra-articular deformities, or posttraumatic cases. Even very old patients with severe osteoporosis are safe for a hinged knee."

"A 2004 paper from the British *JBJS* showed good or excellent results in 91% of knees; 15 year survival was 96.1%. In our own series of 238 consecutive cases, after 13 years we had a survival rate of 90% and only one aseptic loosening."

"As for revisions, the challenges include instability, severe bone loss, and wear problems. The surgeon would need a high grade of stability and a long distance for anchoring. Instability is one of the most common causes of failure; in some indications it's impossible to use a PS or a CCK design and then use hinges. Or if there is very severe bone loss and there's no other way, then use a hinged knee. At my institution we are doing a lot of infections, and due to radical debridement, most of the stabilizing structures are gone…thus we have to use a hinged knee."

"In 2010 Fares Haddad published a paper where he compared three implant types: posterior stabilized, condylar constrained knee, and rotating hinge. He found that the rotating hinge group had the highest satisfaction rate (88%) and the highest 10 year survivorship (90.6%). Our indications are close to those of Adolph Lombardi. He proposed the use of hinges if everything is gone or at least the medial collateral ligament is gone then we must use a hinged knee."

Moderator Dunbar: "Hugh, if you had access to fixed hinged knees you'd be using them more?"

Dr. Cameron: "No. I use maybe two hinges a year. Before good stems came about we had to use hinges because they were the only ones with stems. But now the stems for the TC3 type knees are pretty good. "

Moderator Dunbar: "One of the subtleties that's emerging here is the difference between a rotating platform hinge and a fixed hinge. When are you using a fixed hinge?"

Dr. Gehrke: "If I have a huge valgus deformity (more than 35 degrees) then I use fixed hinges because otherwise we always have problems with the patella."

Moderator Dunbar: "Do you assess the patient's gait and does that factor into your algorithm?"

Dr. Gehrke: "I would say so."

Moderator Dunbar: "Hugh, do you think the patient's gait—the four dimensional analysis—should be brought into the equation of whether or not we use a hinge?"

Dr. Cameron: "Oh I did mathematics a long time ago. I couldn't work out things like that."

Moderator Dunbar: "Alright, do you think there's a tradeoff to using a fixed hinge in that the knee is a complex joint? Are there tips and tricks in that situation?"

Dr. Gehrke: "You are looking to see the best position of the tibial component. Normally it's right over the tibial tubercle."

Moderator Dunbar: "But I think the point is more subtle. Long term, we're prescribing that this thing moves in this plane, but there may be some rotational components as you flex."

Dr. Cameron: "We're not really talking about using hinges in normal knees—these are totally destroyed knees. So you're not recreating normal anatomy…that doesn't exist."

Moderator Dunbar: "Yes, but it doesn't have to be normal to still have deforming forces. I'm talking about rotational forces at the tibial interface. That force/rotation must go somewhere. Do you cement all your stems and is it because of that?"

Dr. Gehrke: "Yes, we fully cement all our stems. The original hinged knee was a fixed hinge knee (developed at the ENDO-Klinik). Due to the problems of rotational shears and periprosthetic fractures, they developed the rotating hinge knee. Those knees are not normal, and the patient's expectations are not really high after a knee implant. But surprisingly they are working very well."

Moderator Dunbar: "What about metaphyseal fixation versus cementation?"

Dr. Cameron: "With a hinge I would cement—maybe not fully. Their strongest hinge has a stem which is quite good and so you can get away with metaphyseal cementing with that stem."

Moderator Dunbar: "What do you make of Haddad's paper showing that the hinge has a higher satisfaction rate than the other constructs?"

Dr. Cameron: "I always thought that. But we're dealing with completely destroyed knees, which is why you do a hinge in the first place."

Moderator Dunbar: "Your take?"

Dr. Gehrke: "I cannot argue better for hinges. They never have stability problems, and patellar tracking isn't an issue if you've implanted in the right position."

Moderator Dunbar: "So that last paper…it was rotating hinge knees in that case…would you have the same satisfaction rates in a fixed hinged knee?"

Dr. Gehrke: "I don't know. In 90% of cases we use rotating hinged knees; only in 10% of cases do we use a fixed hinge knee. I don't know."

Moderator Dunbar: "And there would be a selection bias there because these are harder cases."

Dr. Gehrke: "Yes."

Moderator Dunbar: "Thank you both." ♦

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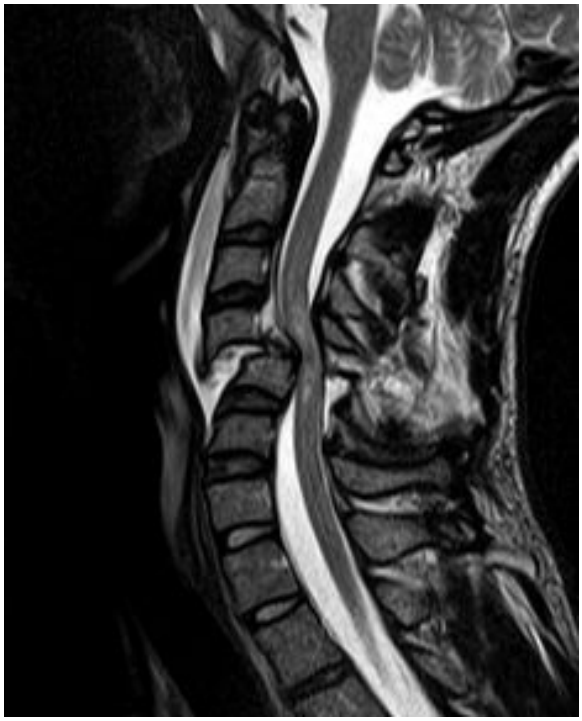
Definitive Study (69,000 Patients) Last Word on Cement for VCF Care?//RA Patients Twice as Likely to Develop Heart Disease//Spine Fellowships a Hoppin'

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

Definitive Study (69,000 Patients) Last Word on Cement for VCF Care? Johns Hopkins researchers, using data from 69,000 Medicare patients, have found that people with spine compression fractures who undergo operations to strengthen back bones with cement survive longer and have shorter overall hospital stays than those who rely on bed rest, pain control and physical therapy. Richard Skolasky, Jr., Sc.D. is Associate Professor of Orthopaedic Surgery at the Spine Outcomes Research Center of Johns Hopkins University. He tells *OTW*:

> "There has been conflicting information in the literature on the effectiveness of vertebral augmentation over nonsurgical care. Cohort studies have shown that vertebral augmentation improved outcomes over non-operative care in terms of pain and functional limitation. More recently, two randomized controlled trials (RCTs) looking at vertebral augmentation versus a sham intervention found that in the short term there is no benefit to vertebral augmentation in terms of pain relief and mobility. There are two camps now. The first camp endorses the results of the RCTs, stating that because the treatment decision depends on the patient and provider, sicker and older patients may not be offered surgery. This treatment bias would lead to worse results among those treated non-operatively. The opposing camp says, 'the RCT studies have only followed patients to six months. Because augmentation restores strength and the anatomic integrity to the vertebrae, you will see longer lasting benefits requiring longer follow-up.'

To clarify things, we examined three categories of fracture care: non-operative, vertebroplasty and kyphoplasty. We looked at differences in survival at six months, one year, two years and three years after surgery. In addition, we examined complications, length of hospital stay, charges assessed by the discharging hospital and/or the health care provider delivering services, 30-day readmission rates and the need for repeat procedures.



Cervical Spine MRI of patient with SCI: C4 fracture and dislocation, spinal cord compression/Wikimedia Commons

Our data set was large enough to allow for adjustment for age and presence of comorbid conditions. We chose 2006 as the index year and identified patients diagnosed with vertebral compression fractures [VCF]. We excluded those who had previous spinal surgeries. We found that patients treated with vertebroplasty had a higher two-year survival rate (67%) compared to non-operative care (61%); for kyphoplasty two-year survival was 75%. Those undergoing kyphoplasty had higher charges and shorter hospital stays and were less likely to develop pneumonia compared to those who had non-operative treatment. The upshot is yes, surgical care is initially more expensive, but may actually be cost effective in the long run.

Our study relied on administrative data, thus, we know there are certain limitations to the interpretation of our results. The Medicare population may not be representative of the larger U.S. population, especially in terms of racial and ethnic composition. The literature shows that racial and ethnic minorities may use healthcare differently than white patients. There remains the concern that sicker patients may be getting

placed in non-operative groups. While we attempted to adjust for that statistically you never know if you have adequately adjusted for everything. What is needed are prospective studies with adequate demographic and clinical matching of patients."

RA Patients Twice as Likely to Develop Heart Disease Those with rheumatoid arthritis (RA) have enough to contend with...including the prospect of developing cardiovascular disease. In fact, says a new study from Mayo Clinic, if there is a high disease burden on the joints in the first year of RA, there is already a very strong predictor of future cardiovascular disease. Eric Matteson is chair of Rheumatology at Mayo Clinic in Rochester, Minnesota. He tells *OTW*,

"My colleagues and I set out to learn why people with RA are at an increased risk for heart disease. We know that inflammation can affect the blood vessels of the heart muscle, something that is likely a major contributor to an increased risk these patients have for heart disease. It's interesting to note that RA adds even more risk to the already known risks of smoking and cholesterol.

We looked at the disease severity of RA and found that those with the worst RA are twice as likely to develop heart disease. We wanted to know what was happening at the molecular level, and we found that people with RA and heart disease have higher levels of certain biomarkers that are associated with cytomegalovirus stimulation. This may lead to an alteration in the immune system and that may be related to why people get heart disease and how it develops.

This work is an indication that we need to pay more attention to the possibility of heart disease in people with RA. Orthopedic surgeons should be aware of the relationship with heart disease and when evaluating these patients for surgery should take this into account. It may involve a preoperative close look at whether the person has heart disease, i.e., stress testing, an echocardiogram, and assessment of carotid blood vessels. At Mayo we have created a cardiology-rheumatology clinic where patients can be evaluated by a cardiologist—even when they may not have traditional risk factors for heart disease."

Roberto Civitelli, M.D. Elected President of ASBMR Roberto Civitelli, M.D., has been elected president of the American Society for Bone and Mineral Research (ASBMR). Dr. Civitelli is

the Sydney M. & Stella H. Schoenberg Professor of Medicine at Washington University in St. Louis. In addition to his research, Civitelli serves as chief of the Division of Bone and Mineral Diseases and director of the Metabolic Skeletal Disorders Training Program at the School of Medicine. He also treats patients at Barnes-Jewish Hospital. Dr. Civitelli's research focuses on cell communication and signaling in bone and their roles in metabolic bone diseases, especially osteoporosis.

Civitelli earned his undergraduate and graduate degrees in medicine from the Siena University School of Medicine in Siena, Italy. He came to Washington University in 1985 as a fellow in endocrinology and metabolism. In 1989, he joined the faculty as an assistant professor of medicine, becoming an associate professor in 1995 and a professor in 2000, with joint appointments in orthopedic surgery and cell biology and physiology.

Dr. Civitelli is editor emeritus of *Calcified Tissue International* and also has served on the editorial boards of *The Journal of Clinical Endocrinology and Metabolism*, the *Journal of Bone and Mineral Research* and *The Journal of Laboratory and Clinical Medicine*.

Dr. Civitelli has received the Fuller Albright Young Investigator Award from the American Society for Bone and Mineral Research, and Washington University has recognized him with the Outstanding Faculty Mentor Award.

Spine Fellowship Match Reaches Milestone Edward Dohring, M.D. is an orthopedic surgeon with the Spine Institute of Arizona, and is the spine surgery fellowship director at that facility. Dr. Dohring, who is chairman of the North American Spine Society (NASS) Resident and Fellowship Education Committee, says that spine fellowship programs are in better shape than ever. He tells *OTW*:

> "We have recently learned that we have hit a new high as far as applications to the spine fellowship match—both on the part of residents and spine programs. This is likely due to the fact that the application process has been reorganized. At one point, before a formal matching process was instituted, residents were told, 'We will offer you a spot now but you must give us an answer within 24 hours.' Programs were anxious because there are many more fellowship program spots in spine than there are American graduate candidates. However, this process was not fair to residents.

NASS, the Cervical Spine Research Society, and the Scoliosis Research Society decided to put teeth behind the match. They determined that if a program offers a position before the match date, then for two years program representatives would not be allowed to present papers and not allowed to participate as faculty at their meetings. Nor could individuals from these programs serve in officer positions for those organizations. Programs came to realize that 'cheating' on the match backfires in the form of peer disapproval. And residents realized that they don't have to accept a position in haste, because the chances were high that they would get into one of their favorite programs (93% get one of their top three choices). Now everyone is on the same page, and we are turning our focus to the quality of fellowship education. We now see that many programs are not matching unless they offer a higher quality program. Residents are asking, 'OK, do they just want someone to do rounds and take call, or is this a program that is mostly focused on training me thoroughly.'

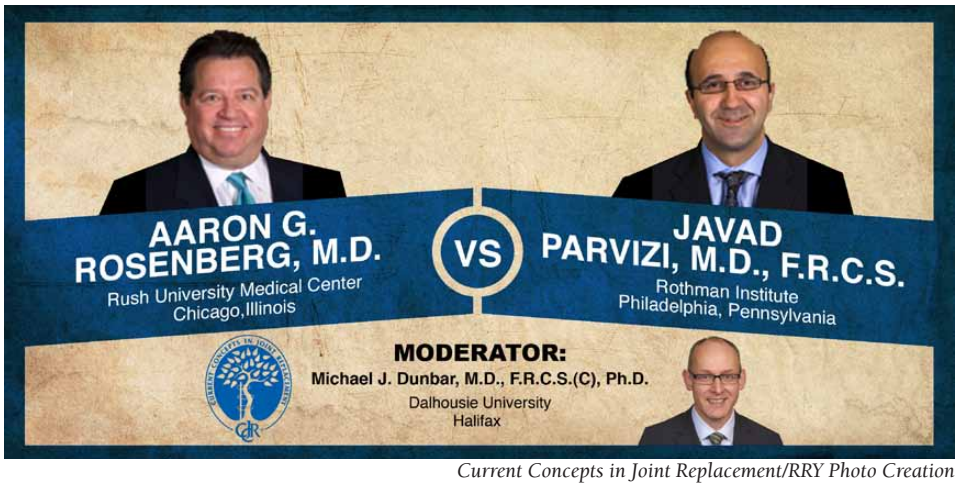
These advances are especially important because spine fellows have a slightly higher failure rate on the American Board of Orthopaedic Surgery part two exam. This has put the onus on fellowship programs to ensure that graduating fellows have a strong conceptual as well as technical foundation in spine. Indeed, the American Council for Graduate Medical Education (ACGME) is creating, with help from NASS members, educational "milestones" for spine fellowships and their fellows: for example, one milestone might be that fellows should be able to understand the indications for, and competently perform, a laminectomy within three months of the start of their fellowship. These milestones will be incorporated into the ACGME certification process, and if programs and their fellows ignore the milestones then they will receive a warning of sorts, or eventually risk losing their accreditation." ♦

Aaron Rosenberg Takes on Jay Parvizi Over Tourniquets

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

"No tourniquet! Get the bleeders as they come up," argues Aaron Rosenberg. Jay Parvizi counters, "With a tourniquet you get a bloodless field and better visualization. You can try to cauterize the vessels as they come up, but I don't think you can cauterize bleeding from bone."

This week's Orthopaedic Crossfire® debate is "The Tourniquet-less TKA [total knee arthroplasty]: Let It Bleed." For the proposition is Aaron G. Rosenberg, M.D. of Rush University Medical Center in Chicago; against the proposition is Javad Parvizi, M.D., F.R.C.S. from the Rothman Institute in Philadelphia. Moderating is Michael J. Dunbar, M.D., F.R.C.S.(C), Ph.D. from Dalhousie University in Halifax.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Rosenberg: "I was talking to Seth the other day when he said, 'Hey Aaron, do you want to debate Jay Parvizi?' You can imagine my response…$%##&*%. But, we are here to talk about improving results in total knee arthroplasty. Going without the tourniquet—or reducing tourniquet time—is one of the ways that we can improve our recovery curve."

"We know that the tourniquet gives us better visualization because it eliminates blood from the field; it also allows for more rapid surgery. There was a recent analysis by Smith and Hing that looked at 16 outcome parameters and 15 studies comparing tourniquet and no tourniquet in a randomized fashion. The no tourniquet patients had greater intraoperative blood loss, but there was no difference for total blood loss, transfusion rate, or any of the other measures assessed. There was, however, a trend for more complications in patients with tourniquets."

"A 2011 meta analysis by Tai, et al. looked at blood loss in several randomized studies. In total measured blood loss there was a slight favoring of the tourniquet, but there was one study with a huge outlier. As for calculated blood loss, it slightly favors no tourniquet; intraoperative blood loss does favor the use of the tourniquet. But postoperative blood loss favors no tourniquet."

"There are other ways of minimizing blood loss during surgery that have become popular since those studies were done. They include the use of transexamic acid, an antifibrinolytic that has been extensively studied, has been shown to be safe, and that dramatically reduces blood loss. I like to use a bipolar sealing technology. If I can see the oozing areas and stop it then that means less blood in the knee postoperatively, as well as a dramatic reduction in the incidence of hemarthroses postoperatively."

"There are several randomized studies that have shown less pain, less swelling, and earlier flexion achieved without the use of a tourniquet. So I believe in no tourniquet…get the bleeders as they come up. As you become more experienced with this your visualization is not inhibited. Your operative time is slightly lengthened, but what you get for that 'price' is a knee that is less swollen the day after surgery, and a significant decrease in the amount of postoperative intraarticular bleeding. And avoiding a tourniquet has shown not only less thigh pain, less overall bleeding, and a trend to fewer complications, but local thrombogenic and fibrinolytic activity is decreased because releasing the tourniquet causes a systemic rise in thromboembolic activity."

"A paper from Sweden was just published in *Acta Orthopaedica* looking at 50 patients, randomized to TKA with or without a tourniquet. They were all cemented total knees and all had the same implants. They performed radiostereometric analysis (RSA) at regular intervals because they wanted to see

if not using the tourniquet influenced cemented fixation. They measured pain, visual analog scores, morphine consumption, overt bleeding, transfusions, total bleeding as measured by hemoglobin dilution, and ROM [range of motion] at two years. They found no difference in the RSA maximal total point motion scores, so the quality of the fixation was identical. The total bleeding at day four only was slightly less in the tourniquet patients, but pain was lower in the non-tourniquet group. The ROM at two years was 11 degrees greater; that is an impressive increase in flexion given a relatively small change in technique."

"To my debate partner, let's agree to compromise, no matter how wrong you may be."

Dr. Parvizi: "Aaron is one of the greatest scholars I know, and quite honestly ever since I knew that I would be debating him I've been taking my anti-anxiolytics. I usually take my formidable opponents out for a drink, feed them some tequila and try to get them arrested so they won't make it to the podium. I tried that with Aaron, but unfortunately he still made his way here."

"So why not use a tourniquet? Expense, vascular injury, potential for embolization, possible rhabdomyolysis, metabolic effects when you release it, and possibly issues with the extensor mechanism alignment. I use a tourniquet because I like a bloodless field. Some of these are revisions, complicated cases, and it provides better visualization. You can try to cauterize the vessels as they come up, but I don't think you can cauterize bleeding from bone."

"Lower blood loss has already been proven, but you should examine all of the studies. Even though there is one outlier every single study shows

that blood loss is either on the line or favors tourniquet. As for intraoperative blood loss, there is a recent meta analysis (Alcelik, 2012) showing extremely good results in terms of blood loss and transfusion. There is shorter operative time when you use a tourniquet and I stress that operative time translates to numerous things during surgery: reduced bio burden, lower surgical site infections, efficiency in the OR."

"Regarding operative time, just about every surgery with the exception of two favors tourniquet. Is there higher VTE [vein thrombosis embolism]? I'm not sure that this has been studied properly. One of the problems is that when we release the tourniquet there's a lot of fat and marrow emboli that make their way to the lung. We have done a study showing that the majority of these emboli that are read by the radiologists as pulmonary emboli are actually fat and marrow emboli that are irrelevant and resolve with time."

"Again, in the 2012 Alcelik study showing that possibly there is a slightly higher incidence of DVT [deep vein thrombosis] or pulmonary embolism. But these studies do not make a distinction between fat and marrow emboli and a true pulmonary embolism. And the more you look for it the more of it you are likely to see. I think it does lead to higher postoperative blood loss. I agree with Aaron in that once you release the tourniquet if you have not done a good cauterization during surgery you are likely to encounter a higher incidence of bleeding postoperatively. But that is for people who just cut through without any respect for the vessels and the capillaries and don't cauterize them during surgery."

"We published a study in 2001, and we have what we call a surgical APGAR score. The more bleeding you see the more stress the patient has to endure in the postoperative period. Transfusion rate has been shown to correlate with higher rates of surgical site infection. In a recent *New England Journal of Medicine* transfusion rate was shown to correlate with increased mortality. For every APGAR score going up you will see an associated decrease in outcome in terms of systemic. So there are more complications with bleeding and that's because of the oxidative stress after surgery."

"So for those of you who say, 'Why use a tourniquet in TKA,' I say, 'Why not?'"

Moderator Dunbar: "Aaron, you don't ever use a tourniquet?"

Dr. Rosenberg: "There are cases where there is a lot of bone bleeding and that is the most difficult to stop. In those cases I put the tourniquet up. I do think that there is a consistent decrease in the amount of post-operative pain, swelling, and fewer hemarthroses. I don't put the tourniquet on in cases where there are previous vascular surgery."

Moderator Dunbar: "Jay, do you use a tourniquet on every case? Who would you not use it on?"

Dr. Parvizi: "Patients who have had previous vascular bypass, particularly in the lower extremity. In those patients I worry about embolizing the vessels. And in some patients applying a tourniquet is extremely difficult; in short people with massive thighs you get a venous type tourniquet and you don't get the proper bleeding control."

Dr. Rosenberg: "Jay and I agree on almost everything that we do, except for some technique-related areas. The

principle is the most important thing. For me, the principle is to minimize the damage I do during the case. I have some partners who put the tourniquet up to very high levels, regardless of the patient's thigh and blood pressure."

Dr. Parvizi: "Great point. Some studies show it should be only 100 mm mercury about the systolic. You don't need to crank it up to 400. Also, if you're not using a tourniquet you can't just go in slashing like a ninja and go all the way to the end of the procedure because that blood loss is extensive. You must control bleeding as you go along."

Moderator Dunbar: "Aaron, are you aware of any papers showing a functional difference in the quadriceps after total knee, with or without a tourniquet."

Dr. Rosenberg: "There are papers showing that there's better quadriceps function without the tourniquet in the first few days postop. But I don't think the first few days are important…not nearly as important as getting the knee in right, getting the balance correct, etc. This is why I think we've backed off on MIS. And, avoidance of the tourniquet does allow me to do one of the important things intraoperatively that I don't get a chance to do, which is to get the bleeders."

Moderator Dunbar: "Jay, do you let the tourniquet down at any point to check for bleeders?"

Dr. Parvizi: "No, unlike Aaron I try not to cut through main vessels. No, we don't let the tourniquet down to check for bleeders—that is dangerous. You don't use a tourniquet, then put it up and cement, and then let it down again…that never made sense to me. During cementation is when fat and marrow embolization happens, and the extent of that embolization is associated with increased oxidative stress."

Moderator Dunbar: "I think the strongest data Aaron presented is the RSA data. Do you think that is a relevant finding?"

Dr. Parvizi: "It's relevant and supports what I have been saying here."

Moderator Dunbar: "The fact that the migration pattern is stable is interesting, but you need to see what the technique was."

Dr. Rosenberg: "Regardless of the fixation issues they did have 11 degrees more flexion in those knees at two years."

Moderator Dunbar: "Thank you both."
♦

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COMPANY

NuVasive's Big 3rd Quarter Beat

NuVasive, Inc., built for speed and growth, continued with double-digit revenue growth in the third quarter. The 14% growth over last year's third quarter to $169.2 million wasn't the heady 20%+ growth rate of years past, but still way over the market which is only growing in the lower single digits.

"NUVA put up a big $10 million beat," wrote Jefferies analyst Raj Denhoy.

Third quarter sales prompted company management to up full 2013 guidance from $655 million to $670 million. Net income was $18.3 million. Cash and equivalents assets came in at $303 million. The company is still, ultimately, shooting for $1 billion in revenue.

In making the sales announcement on October 29, 2013, Alex Lukianov, chairman and CEO, said, "The execution of our market share taking strategy has been outstanding through the first three quarters of 2013, and we are pleased to be increasing full year revenue and non-GAAP operating margin guidance to reflect solid outperformance. We are building on the momentum established at Eurospine and at NASS [North American Spine Society] to close this year well and kick off 2014 with continued strategic execution!"

The company saw accelerating sales growth in lumbar (+12%), cervical (+27%) and biologics (+11%) and international (+31%). Monitoring sales were down 4% as the business is still hampered by reimbursement problems.

Spine Market Improving

During a call with analysts, Lukianov said last quarter's reported results suggest that U.S. spine market growth improved slightly from the flattish rate of growth experienced all of last year and into the first quarter of this year. "We are encouraged by the improvement, but we still believe that the market is stabilizing. As a result, we are wary of calling a quarter or two of improvement in market growth a trend. We expect U.S. market growth will be flattish this year and into 2014."

Fighting Insurer Pushbacks and PODs

He said progress has been made against some of the market dynamics that have been pressuring growth for the last several years. "The publication of the systematic literature review on fusion for degenerative disc disease in the April issue of the journal *Spine* is being used to fight insurer pushback against lumbar spine fusion on a case-by-case basis."

While not directly attributing market share gains to a recent Office of Inspector General POD (physician-owned distributor) alert, Lukianov said the competition from PODs appears to be slowing. He noted the development and implementation of anti-POD policies by several hospital systems. "However, we believe that PODs will likely need to be dismantled on a grand scale to materially impact market growth."

DePuySynthes Integration Woes

Lukianov was asked about DePuySynthes' acknowledged difficulties with integration of their spine team. Did he think NuVasive benefitted from that?

"I think that there's been an ongoing abundance of qualified salespeople, and they've certainly been coming from the major players in our general direction. Needless to say, there's always some churn. But there's definitely an abundance. I wouldn't say it's entirely changed. I think the entire acquisition has obviously created a fair amount of disruption among the distribution networks. So yes, I think [it's had] an impact."

Jefferies' Denhoy says he sees NuVasive poised for above market growth/share gains on a combination of recent product launches (Bendini System, MAS PLIF, PCM Cervical Disc) and continued penetration of XLIF in Japan.

—WE (November 1, 2013)

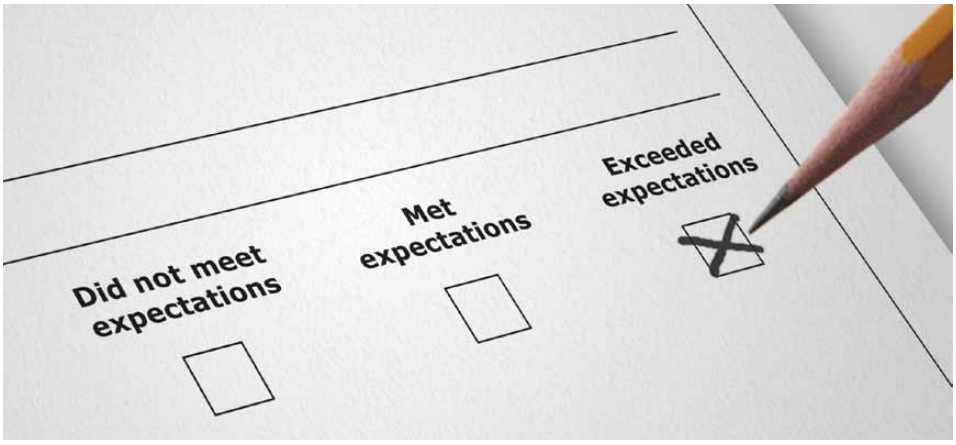


Photo creation by RRY Publications LLC

Amedica and K2M Sign Distribution Agreement

Amedica Corporation, a biomaterial company headquartered in Salt Lake City, Utah, has entered into a distribution agreement with K2M to provide access in Europe to Amedica's Silicon Nitride interbody spinal fusion devices. K2M is the world's largest privately held spinal device company.

Earlier this year, Amedica and K2M conducted a pilot program in select markets in Europe where surgeons integrated Amedica's Silicon Nitride interbody devices into their offerings for patients suffering from a variety of disorders requiring spinal fusion. According to company officials, the pilot program demonstrated a need in these strategic markets for spinal fusion devices devised from a different biomaterial.

"K2M is committed to providing the best and most innovative technologies to meet the needs of patients around the world suffering from spinal disorders and we believe our relationship with Amedica will help us further this goal," said Eric Major, K2M's president and CEO.

"K2M has an outstanding sales and marketing team that has created a global reputation for providing leading edge technology to their customers. Our Silicon Nitride interbody product line will be integrated into K2M's current portfolio of interbody spinal fusion devices," said Eric K. Olson, Amedica president and CEO. "We believe that there is a need in Europe for interbody fusion devices that exceed the capabilities of existing PEEK and Titanium-based devices," he said. "With this distribution channel in place, we believe Silicon Nitride interbody spinal fusion devices will increasingly be the solution that surgeons rely on to deliver optimal patient outcomes in spinal fusion procedures." Amedica is a privately owned company that was founded in 1996.

Courtesy of Amedica

Courtesy of K2M

—BY (November 1, 2013)

Cardinal Health Invests in Intralign

Intralign has announced that Cardinal Health, Inc. has made an investment to contribute to the expansion of intra-operative management solutions for hospitals. A portfolio company of Altaris Capital Partners, LLC and Heritage Group, Intralign offers surgical assistance in combination with analytics and process design services to help providers optimize quality and cost of major joint replacement and other surgeries.

"It's a tremendous privilege for an industry leader like Cardinal Health to support our vision for implementing sustainable change management solutions within hospitals and health systems to improve the cost-effectiveness of healthcare delivery," said Rick

Wikimedia Commons and Milad Mosapoor

Ferreira, Intralign president and CEO, in the October 28, 2013 news release. "Today, Intralign's services focus on the intra-operative space—where more than 40% of the cost of the total episode of care is incurred. We help hospitals and clinicians understand cost drivers and help them gain control of the process."

The value of Intralign lies in the unique combination of in-surgery support and resource management with analytics and service line process optimization. Through its intra-operative clinical support services, Intralign makes high-quality Surgical First Assistants (SFAs) available in the operating room, eliminating the need for hospitals to have SFAs on staff, reducing procedure time, and ensuring efficient use of resources before, during and after surgery. The benefit of intra-operative support is enhanced by Intralign's analytics services, which enable the hospital to utilize internal and external data to gain a comprehensive and action-oriented understanding of resources usage, treatment quality, etc. The company also offers intelligent care design support to help providers enhance the flow of people and activities in the delivery of major joint replacement, so that ideal efficiencies and quality goals are realized.

"It's important to us at Cardinal Health that we support the innovation coming from companies like Intralign in order to give providers actionable information, allowing them to address clinical, business and financial challenges in this new era of healthcare," said Lisa Ashby, president of Medical Devices and Diagnostics at Cardinal Health.

Rick Ferreira told *OTW*, "Intralign is thrilled to welcome Cardinal Health as an investor. Awareness of the need to focus on efficiencies and throughput in the orthopedic space is growing explosively, and our hospital partners are excited about the value we bring, as investments like this help us grow our solutions to combine clinical and operational goals."

—EH (November 1, 2013)

Stryker Settles Foreign Bribery Charges

The Securities and Exchange Commission (SEC) charged Stryker Corporation with making illicit payments of $2.2 million to healthcare providers in Argentina, Greece, Mexico, Poland, and Romania in violation of the Foreign Corrupt Practices Act.

On October 24, 2013, the government announced that Stryker agreed to pay more than $13.2 million to settle the charges. The company did not admit to any wrongdoing.

The SEC investigation found the illicit payments were incorrectly described as legitimate expenses in the company's books and records. Descriptions varied from a charitable donation to consulting and service contracts, travel expenses, and commissions. Stryker made approximately $7.5 million in illicit profits as a result of the improper payments.

"Stryker's misconduct involved hundreds of improper payments over a number of years during which the company's internal controls were fatally flawed," said Andrew M. Calamari, director of the SEC's New York Regional Office. "Companies that allow corruption to occur by failing to implement robust compliance programs will not be allowed to profit from their misconduct."

The SEC's order instituting settled administrative proceedings details improper payments by employees of Stryker's subsidiaries as far back as 2003. They used third parties to make the payments in order to win or keep

ynaija.com/Bribery

lucrative contracts for the sale of Stryker's medical technology products. For example, in January 2006, Stryker's subsidiary in Mexico directed a law firm to pay approximately $46,000 to a Mexican government employee in order to secure the winning bid on a contract. The result was $1.1 million in profits for Stryker. The subsidiary reimbursed the Mexico-based law firm for the bribe and booked the payment as a legitimate legal expense. However, no legal services were actually provided and the law firm simply acted as a funnel to pay the bribe.

According to the SEC's order, Stryker's subsidiary in Greece made a purported "donation" of nearly $200,000 in 2007 to a public university in Greece to fund a laboratory that was a pet project of a public hospital doctor. In exchange for the payment, the doctor agreed to provide business to Stryker.

The SEC's investigation also found that Stryker's subsidiaries bribed foreign officials by paying their expenses for trips that lacked any legitimate business purpose. For example, in exchange for the promise of future business from the director of a public hospital in Poland, Stryker paid travel costs for the director and her husband in May 2004. This included a six-night stay at a New York City hotel, attendance at two Broadway shows, and a five-day trip to Aruba.

The SEC's order requires Stryker to pay disgorgement of $7,502,635, prejudgment interest of $2,280,888, and a penalty of $3.5 million. Without admitting or denying the allegations, Stryker agreed to cease and desist from committing or causing any violations and any future violations.

—*WE (October 31, 2013)*

LARGE JOINTS

Joint Arthroplasty Readmissions Top 5%

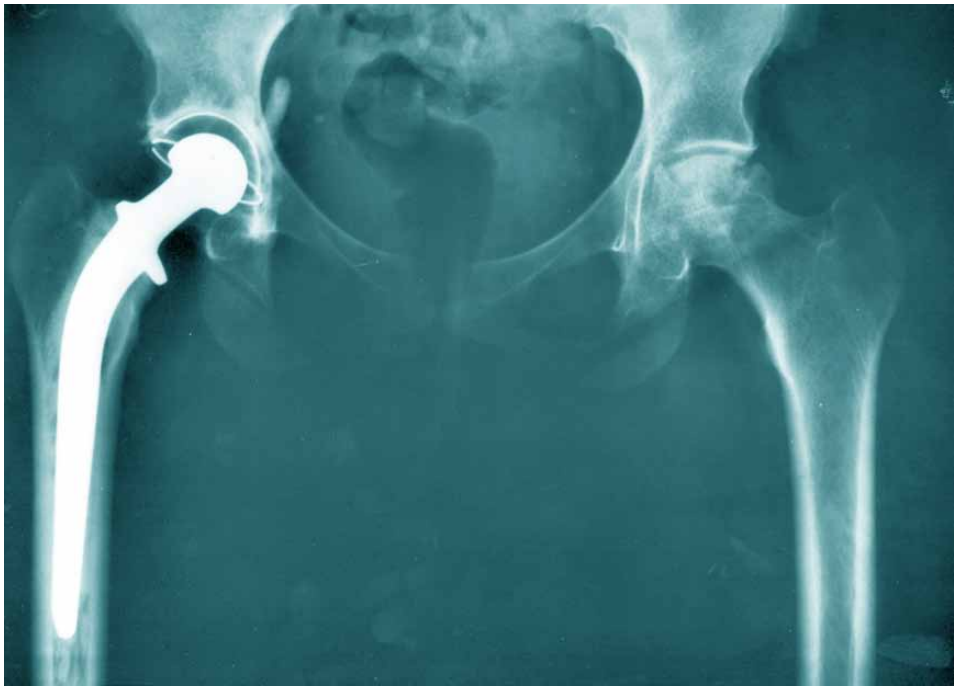
A little more than 5% of patients who undergo total hip and knee arthroplasty return to the hospital within 90 days for an unplanned readmission, according to a study published in October in *The Journal of Bone & Joint Surgery.*

Benjamin Zmistowski, from Thomas Jefferson University Hospital in Philadelphia, conducted the study. He and his colleagues examined the incidence, causes, and risk factors for readmission following total joint arthroplasty. They used data from an institutional arthroplasty database for 10,633 admissions for primary arthroplasty (5,207 knees and 5,426 hips) performed from January 2004 through December 2008. They identified patients requiring an unplanned readmission within 90 days of discharge from the same database.

As reported by the publication *Doctor's Lounge*, the researchers found that in 5.3% of total joint arthroplasties there were 591 unplanned readmissions within 90 days of discharge. Joint-related infection was the most common cause of readmission, followed by stiffness. Independent predictors of readmission within 90 days included black race, male sex, discharge to inpatient rehabilitation, longer hospital stay, unilateral replacement, age, decreased distance between home and the hospital, and total knee replacement.

"It is imperative that measures to limit these complications, through appropriate prophylactic measures and prevention of increased duration of hospital stay and discharge to an inpatient facility, be effectively implemented to limit the physical and psychological impact of readmission on patients and the financial burden to society," the authors wrote.

—*BY (November 1, 2013)*



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Chinese Expand Orthopedic Implant Capabilities

Chinese people's joints wear out too, but replacement implants have, on occasion, been too large. Now a team of 21 experts from France and China's Sichuan Provincial People's Hospital in the southwestern city of Chengdu have co-developed artificial knee joints based on the bone proportion of Chinese people.

Artificial knee joints, domestic or imported, used to be produced according to the skeleton structure of Europeans, said Wang Yue, orthopedic doctor of the hospital. "Westerners are generally larger than Chinese in terms of body size, which is why patients less than 1.4 meters (about 4.6 feet) tall in China cannot find appropriate artificial knees," Wang said.

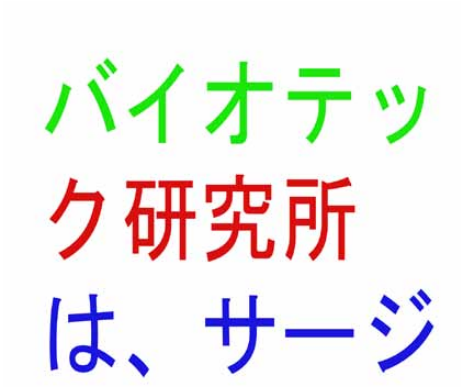

Photo creation by RRY Publications LLC

Former French Prime Minister Jean-Pierre Raffarin said at a press conference that the two countries would further cooperate on the development of artificial joints to meet the growing demand of Chinese people.

—BY (October 30, 2013)

Australia Identifies Best and Worst Performing Joint Replacements

Every year 8,000 Australians have to get back on the operating table because of faulty joint replacements, according to national health reporter Sue Dunlevy, writing for the *Melbourne Herald Sun*. A study by the National Joint Replacement Registry has identified the four devices with the lower record of problems. Even when these four devices are implanted by novice surgeons, the report claims, they have the same risk of requiring revision as when an experienced surgeon implanted them.

This is the first time the registry, which has been tracking the performance of hip and knee replacements since 1999, has reported on the question of how surgeon experience affects the outcome of joint replacement surgery. While it found that surgeons with more than eight years of experience had a lower rate of revision operations, it also found that when surgeons used certain devices their years of experience did not matter.

Dunlevy reported that the two most commonly used hip replacements in Australia—Exeter V40/Trident and Corail/Pinnacle combinations—show no difference in rates of revision regardless of the experience of the surgeon. And with knee replacements there was no difference in the revision rate when comparing surgeon experience for two commonly used LCS/MBT and Nexgen CR Flex/Nexgen combinations.

"We believe this is a very reassuring finding for the public," Australian Orthopaedic Association President Peter Choong, M.D., told Dunlevy. More than 800,000 Australians now have a joint replacement and each year surgeons insert another 90,000 devices at a cost of around $1 billion.

But, according to the registry, hundreds of thousands of patients have been fitted with devices that loosen, get infected, erode and have to be replaced. The registry's annual report identified more than 100 hip and knee replacement devices that have higher than average rates of revision. Of these, it reported eight hip and six knee prostheses for the first time.

The registry's annual report found that hip replacements with a head size of 32mm had the lowest rate of revision, while those with smaller head sizes had the highest rate of revision. Using

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cement to fix hip replacements reduced revision rates in older age groups but cementless fixation worked better in those younger than age 75. Having a device that was constructed from cross linked polyethylene also reduced the rate of revision.

With knee replacements the report found unicompartmental knee replacements had a higher rate of revision than primary total knee replacement. The report also found that using a knee replacement constructed from cross-linked polyethylene may reduce rate revision, the report found. Choong told Dunlevy that the Australian Orthopaedic Association is making this information accessible to patients.

—*BY (October 29, 2013)*

Joint Replacement Improves Earnings and Sex Life

Want to add from $10,000 to $30,000 annually to your lifetime earnings and improve your sex life at the same time? Get a total hip or knee replacement. That is the message of two studies, one published in the *Journal of Bone and Joint Surgery* and the other presented at the annual meeting of the American Academy of Orthopaedic Surgeons (AAOS). The latter study found that the sexual functioning of those who had a total knee replacement (TKR) or hip replacement surgery improved by 90%.

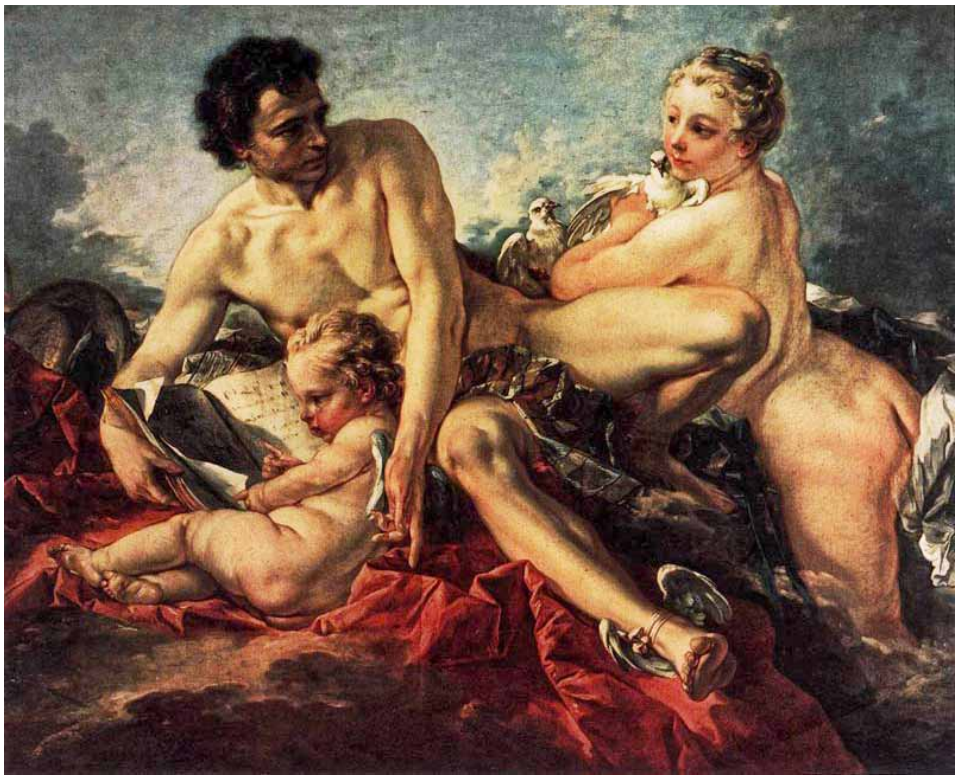
Joel S. Buchalter, M.D., and board-certified orthopedic surgeon, noted to *PR Web* that, "More than 27 million Americans live with osteoarthritis, the most common reason for knee joint replacement surgery. These studies clearly demonstrate that the benefits of this surgery extend much farther than eliminating pain—a top reason for seeking the procedure—and also enhance patients' productivity and quality of life."

The desire to stay active is fueling the growth in joint replacement surgeries nationwide, along with an aging population. TKR surgery is expected to be performed on 3 million patients annually by the year 2030, up from 600,000 in 2009, according to the Agency for Healthcare Research and Quality.

The *Journal of Bone and Joint Surgery* study showed that the societal benefits for knee replacement patients of working age greatly outweigh the combined cost of the surgery and rehabilitation compared to non-surgical treatments for osteoarthritis. More than 90% of those who undergo TKR experience a dramatic reduction of knee pain and significant improvements in the ability to perform common daily activities. Almost half of TKR patients are now under age 65, according to the report in PR Web.

The sexual functioning study presented at the AAOS meeting included 174 men and women with an average age of 58. The study found that 49% had suffered from reduced libido prior to their knee or hip replacement and 53% felt their arthritis had hurt their sexual self-image. After surgery, 81% of those whose sexual activity was previously affected had noticed an improvement in the frequency of sexual activity. "Few people think about the effect knee replacement surgery might have on their sex lives," explains Douglas J. Fauser, M.D., "but this research clearly shows that eliminating their pain can markedly improve their enjoyment."

—*BY (October 30, 2013)*



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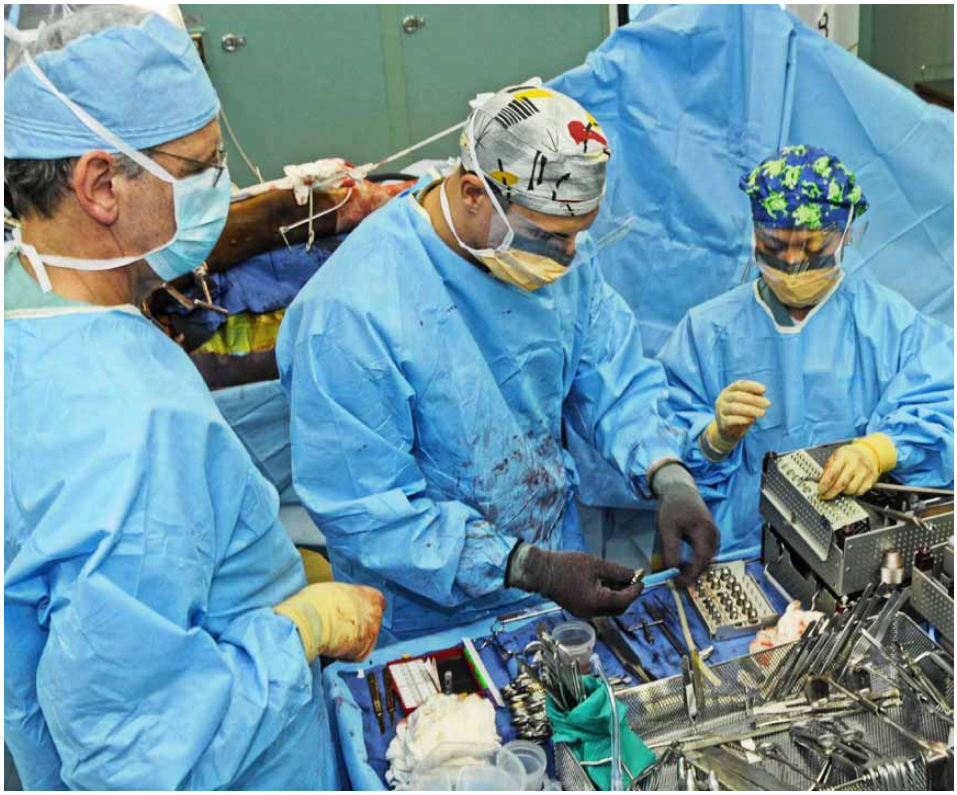
Innovative Hip/Knee Course Coming

Three orthopedic societies have recently announced a unique initiative, the Orthopaedic Resident Training Initiative (ORTI), which will develop, organize and fund three courses in hip and knee arthroplasty for medical residents. The participating societies include American Association of Hip and Knee Surgeons (AAHKS), The Hip Society, and The Knee Society. In addition to the founding societies for this collaboration, The International Congress on Joint Reconstruction (ICJR) will manage the organization and logistics coordination for the courses.

"Residency is a critical part of training our future orthopaedic surgeons, but there is more we can do to ensure they begin practicing with the best hands-on experience," said William P. Barrett, M.D. chair for the AAHKS Committee on Joint Education Ventures, in the October 11, 2013 news release.

The ORTI will engage up to 250 second and third year residents during the spring of 2014 through three inaugural courses taking place in the greater Los Angeles, Atlanta, and Philadelphia areas. Participants will receive cadaveric training in hip and knee replacement procedures and the course curriculum will be developed and delivered by faculty who are members of The Hip Society, The Knee Society, and AAHKS.

"One of the core values of our organization focuses on active collaboration with other groups to help forward the practice of orthopaedics and to ultimately improve patient care," said Vincent D. Pellegrini, Jr., M.D., president of The Hip Society. "This is a great example of how we can work together to improve resident training."



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"The practice of orthopaedics is constantly changing, as new techniques and technologies become available. The ORTI will be another way to get residents trained and ready for improved patient care," said Steven J. MacDonald, M.D., FRCSC, president of The Knee Society.

"ICJR is changing the way training and education is delivered to surgeons," said W. Norman Scott, M.D., FACS, president, International Congress on Joint Reconstruction. "So this organization is uniquely positioned to do the same for the ORTI while seamlessly managing all of the logistics."

The ORTI course curriculum is being developed with the goal of bringing together faculty with diverse, cutting edge experience with the latest advances in hip and knee replacement to educate orthopedic residents through interactive, hands-on sessions. The programs will provide a mix of didactic lectures, expert case study reviews, and hands-on cadaver labs allowing participants to reinforce their learning by working side-by-side with leaders in the field. The selection of the faculty and identification of course talks and workshops are truly a collaborative effort between the participating societies. All are committed to providing the most innovative program for future orthopedic surgeons.

William Barrett, M.D., chairman for the AAHKS Committee on Joint Education Ventures told *OTW*, "We are pleased to offer such an innovative approach to training future orthopaedic surgeons. Providing residents with an opportunity to work with a diverse group of faculty will enhance their training in ways we have not be able to do before."

—*EH (October 29, 2013)*

EXTREMITIES

Yoga Effective in Treating Carpal Tunnel

Experiencing carpal tunnel symptoms? Try yoga. Researchers at the University of Pennsylvania found that yoga proved to be more effective in treating carpal tunnel syndrome than did wrist splints. (Carpal tunnel syndrome is an inflammatory disorder caused by repetitive movements such as typing on a computer. It affects the middle nerve connecting the wrist to the hand.)

The study involved 42 people from the ages of 24 to 77. One group participated in yoga exercises consisting of 11 yoga postures designed to strengthen, stretch and balance each joint of the upper body along with techniques to foster relaxation. The yoga group participated twice a week for eight weeks. The other group received wrist splints to treat their disorder.

Study results, reported by *Telemanagement*, showed that the yoga group had significantly more improvement in grip strength and pain reduction than did those in the wrist splint group. Though the study was a small, preliminary one it was clear in demonstrating that yoga was more effective than splints in treating carpal tunnel syndrome.

—BY (October 30, 2013)

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Biomet Implants First U.S. Stemless Shoulder

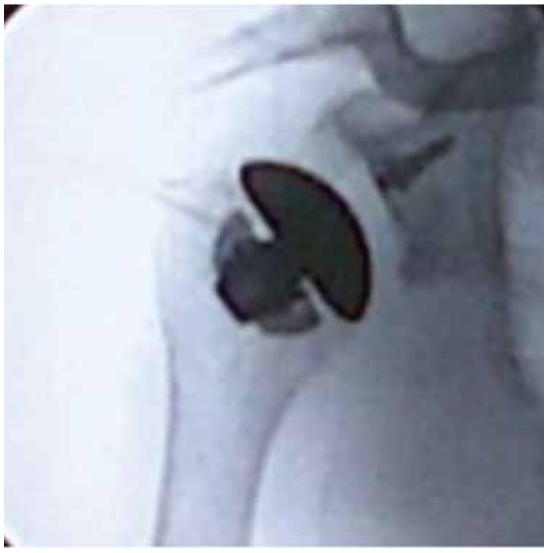
Biomet, Inc.'s new stemless shoulder is moving and grooving in its first U.S. patient. This inaugural implant of the Comprehensive Nano Stemless Shoulder took place in October at the University of Virginia Medical Center in Charlottesville. The surgery was part of an FDA Investigational Device Exemption (IDE) multi-center prospective clinical study and was performed by Stephen Brockmeier, M.D.

"We are excited to be a part of the clinical trial evaluating this potentially significant evolution in shoulder arthroplasty," Brockmeier said. "I was impressed with the initial fixation of the stemless implant and was able to perform the shoulder replacement with minimal bone removal and components aligned with the patient's natural anatomy."

Another participant in the study is Jonathan Levy, M.D., of Holy Cross Hospital in Fort Lauderdale, Florida. He said, "The procedure using the Comprehensive Nano allows me the potential to accurately restore shoulder anatomy without the limitations created by placing a stem within the humerus. The IDE study will allow us to objectively compare the efficacy of stemless and stemmed prostheses."

Biomet developed the Comprehensive Nano shoulder based on the clinical heritage of the Biomet T.E.S.S. stemless shoulder, which has been available in European and international markets since its launch in 2004.

—BY (October 29, 2013)



Courtesy of The Orthopedic Clinic Association (TOCA)

TRAUMA

Huge Study (n=26,610) Nails Exercise Statistics

A study reported in the *British Journal of Sports Medicine* found that certain physical exercise programs either prevent or dramatically reduce the risk of sports injury. Injuries, the study notes, are the downside of exercise, and many sports injuries can be tough to treat. But the study found that certain types of exercise may help people prevent these sports injuries.

Jeppe Bo Lauersen, from the Institute of Sports Medicine at Bispebjerg Hospital in Copenhagen, Denmark, and his colleagues conducted the study. They reviewed 25 previously published studies on sports injuries which included a total of 26,610 study participants with 3,464 injuries. Thirteen of the studies included only adults, 11 included only adolescents, and one study included both. All participants in the studies were injury-free when they were initially enrolled.

Source: Wikimedia Commons

The studies considered one or more of the following different types of physical exercise: strength training, stretching, proprioception (balance exercises) and programs that included more than one type of exercise.

The researchers found that overall physical exercise reduced the risk of sports injuries by 37%. Strength training was found to be the most effective, with a 68% decreased risk of sports injury. Proprioception was associated with a 52% decreased risk of sports injury. Stretching was the least effective method of prevention, with only a 4% decreased risk of sports injury.

The findings on strength training and stretching were similar across studies, even though the studies used different exercise programs. The researchers believe there is a need for further research on the effect of strength training on a wider variety of injuries. They also suggested that future studies should focus on acute and overuse injuries separately.

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