

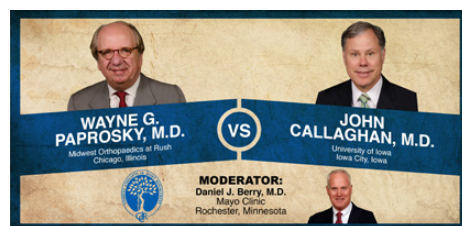
# Orthopedics • This Week

## WEEK IN REVIEW

**4 Stryker's OtisMed Guilty of Fraud >>** OtisMed Corporation and its former CEO Charlie Chi pled guilty on December 8, 2014 to illegally marketing the OtisKnee device. The company did so in direct violation of an FDA warning not to market the product. Why did they do it? A slew of federal documents tell the story. Read it here.

**7 Orthopedic Residents Trained Differently Than Neuro Residents in Spine? What? // Slick New Spine Cage From Israel Goes in "Like a Ship in a Bottle"! // Kathleen Weber, M.D. to Head MLB Physician Group >>** Why is there such lack of consistency between orthopedic residents and neuro? Alan Daniels, M.D. tackles the subject. New Israeli cage goes in "like a ship in a bottle." Very slick! Major League Baseball picks Rush University's Kathleen Weber, M.D. to head its physician group.

**10 Paprosky, Callaghan Debate Constraint Versus Big Heads >>** "Cup position is critical," says Wayne Paprosky. "And if the abductors are deficient then I'm not sure there is an advantage to constrained liners." "Really?" says John Callaghan; "There are good results with large heads in revision surgery. And if you need something very large you can go to the dual mobility rather than jumping straight to a constrained liner."



## BREAKING NEWS

**13 Lima Corporate** Installs Its 100,000th Hip Stem

**Stryker Buys London Healthcare Company**

**MiMedx Investigated, Sues Organogenesis**

**Efficacy of Athlete Stem Cell Treatments Questioned**

**\$1.8 Million NIH Grant Targets Implant Longevity**

**Hammertoe Correction System Gets FDA Clearance**

**For all news that is ortho, read on.**

# Orthopedic Power Rankings

## Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**THIS WEEK:** Virtually the entire orthopedics industry will be in San Francisco this week. Hopefully, the only earthquakes will be metaphorical in nature. Why are they there? JP Morgan conference—at 33 years old it is both the oldest and most popular healthcare meeting of the year. In short, it's a mob scene. But deals get started or killed there. This year? Eyes are on Stryker and Smith & Nephew.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Integra LifeSciences	12.57%	9.86%	Investors like IART's new strategic initiatives. At these valuations, hard not to envision upside.
2	2	Stryker	11.52	2.12	Investors are certain that a SNN deal is in the works. Who knows for sure. What is certain is that SYK is getting cheaper.
3	8	Exactech	10.44	2.11	Could EXAC be next up in the M&A merry go round? Very attractive, well-run company. Good fit? Speculators are buying.
4	7	NuVasive	8.01	8.57	RBC just upgraded NUVA and Bloomberg thinks they are ripe for expansion. All we know is investors adding NUVA to their portfolios.
5	6	Zimmer	29.12	6.01	So while SYK and SNN are dancing, Zimmer and Biomet just go about the business of merging.
6	3	ConMed	10.51	2.42	ConMed's value has increased nicely since new management took charge. Now investors are wondering—what are CNMD's new programs to build value?
7	4	Smith & Nephew	19.92	9.70	Getting just a tad expensive with all of this merger talk. The higher SNN's stock goes, the more difficult a reasonable deal for SYK becomes.
8	5	Medtronic	28.84	1.60	Medtronic's shareholders approved their merger into Covidien. What does it mean for spine and Memphis? Well, there is at least one former Danek-ian at COV.
9	9	Globus Medical	29.68	2.24	Pre-announced fourth quarter results and soundly beat Wall Street's estimates. GMED is THE most expensive stock on the Power Rankings.
10	10	Johnson & Johnson	28.44	(1.22)	The problem with JNJ is that it is so-o big. For example, 1% sales growth = \$700 million in new sales—even if global currencies go against you.

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# Robin Young's Orthopedic Universe

## TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	K2M Group Holdings	KTWO	\$22.36	\$830	14.37%
2	LDR Holding Corp.	LDRH	\$34.81	\$907	10.40%
3	Integra LifeSciences	853	\$54.02	\$1,771	9.86%
4	Smith & Nephew	SNN	\$36.40	\$16,270	9.70%
5	NuVasive	NUVA	\$49.94	\$2,349	8.57%
6	CryoLife	CRY	\$11.37	\$318	8.49%
7	Alphatec Holdings	ATEC	\$1.40	\$139	7.69%
8	Zimmer Holdings	ZMH	\$118.21	\$20,019	6.01%
9	Aurora Spine	ASG	\$1.23	\$19	4.65%
10	Bacterin Intl Holdings	BONE	\$2.88	\$19	2.85%

## WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	\$9.27	\$991	-16.94%
2	MicroPort Scientific	853	\$0.42	\$592	-11.77%
3	RTI Biologics Inc.	RTIX	\$5.07	\$288	-6.11%
4	Orthofix	OFIX	\$28.51	\$526	-5.72%
5	Wright Medical	WMGI	\$26.80	\$1,369	-5.20%
6	Tornier N.V.	TRNX	\$25.60	\$1,252	-2.99%
7	Johnson & Johnson	JNJ	\$104.94	\$293,739	-1.22%
8	TiGenix	TIG.BR	\$0.65	\$104	-0.09%
9	Medtronic	MDT	\$74.40	\$73,233	1.60%
10	Exactech	EXAC	\$22.76	\$314	2.11%

## LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	\$104.94	\$293,739	17.56
2	Medtronic	MDT	\$74.40	\$73,233	18.63
3	Globus Medical	GMED	\$24.24	\$2,375	19.93
4	Exactech	EXAC	\$22.76	\$314	19.96
5	Zimmer Holdings	ZMH	\$118.21	\$20,019	20.38

## HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MiMedx Group	MDXG	\$9.27	\$991	924.32
2	RTI Biologics Inc.	RTIX	\$5.07	\$288	424.52
3	Orthofix	OFIX	\$28.51	\$526	182.14
4	NuVasive	NUVA	\$49.94	\$2,349	128.91
5	CryoLife	CRY	\$11.37	\$318	38.93

## LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	\$11.37	\$318	1.30
2	Exactech	EXAC	\$22.76	\$314	1.33
3	Globus Medical	GMED	\$24.24	\$2,375	1.47
4	ConMed	CNMD	\$45.22	\$1,245	1.94
5	Integra LifeSciences	IART	\$54.02	\$1,771	2.13

## HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MiMedx Group	MDXG	\$9.27	\$991	61.62
2	RTI Biologics Inc.	RTIX	\$5.07	\$288	28.30
3	NuVasive	NUVA	\$49.94	\$2,349	11.28
4	Orthofix	OFIX	\$28.51	\$526	9.90
5	Smith & Nephew	SNN	\$36.40	\$16,270	3.48

## LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	\$2.88	\$19	0.56
2	Alphatec Holdings	ATEC	\$1.40	\$139	0.68
3	RTI Biologics Inc.	RTIX	\$5.07	\$288	1.14
4	Exactech	EXAC	\$22.76	\$314	1.27
5	Orthofix	OFIX	\$28.51	\$526	1.32

## HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$0.65	\$104	18.28
2	MiMedx Group	MDXG	\$9.27	\$991	10.26
3	LDR Holding Corp.	LDRH	\$34.81	\$907	8.13
4	K2M Group Holdings	KTWO	\$22.36	\$830	5.27
5	Globus Medical	GMED	\$24.24	\$2,375	5.15

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

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# Stryker's OtisMed Guilty of Fraud

BY WALTER EISNER

Charlie Chi and his board of directors at OtisMed Corporation were riding the razor's edge in September 2009 with their cutting guide device, the OtisKnee.

Stryker Corporation was dangling a reported \$100 million offer to buy OtisMed, but the FDA was denying OtisMed's request for clearance to sell the device in the U.S. The deal and the future of the company balanced on that razor's edge.

The decisions Chi and the company made at that moment ended up with a December 8, 2014 federal criminal and civil agreement costing Stryker \$80 million, Chi his reputation and the product a 20 year ban from federal payment programs.

## Introduction of the OtisKnee

According to the federal agreement document, here is how it all happened.

Charlie Chi, Ph.D. and others founded the OtisMed in California in 2005 with market introduction of the OtisKnee cutting guide device in 2006. By 2009, the company had grown to over 50



Charlie Chi, Ph.D.  
 pharmacompliancemonitor.com



Image created by RRY Publications, LLC / Source: OtisMed Corporation

employees. Between May 2006 and September 2009, the company sold more than 18,000 devices, generating revenue of approximately \$27.1 million.

Approximately 75% of the devices were sold in conjunction with sales of Stryker's Triathlon Total Knee Replacement System, with representatives of both companies marketing the product. The devices were also sold in conjunction with Biomet Orthopedics, LLC's Vanguard Complete Knee System.

OtisMed had configured its software for use with the Triathlon and Vanguard systems, but not with other knees.

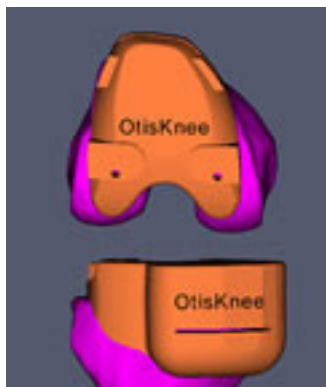
The company claimed that when surgeons used the device, "[the patient] would receive a knee replacement tailor made for [their] own normal (non-diseased) anatomy, and no one else's." The company also claimed that surgeries using the device were accomplished "with less intra-operative decision-

making required from the surgeon... the custom fit technology is all that is needed to ensure proper alignment. In addition, less bone cut and all ligaments are spared, preserving the feel of a more 'natural' feeling knee based on the patient's normal knee function." The company also claimed that surgeries performed with the device were safer than those performed using traditional instruments and resulted in less post-operative pain for patients.

## No FDA Clearance

There was just one problem. None of those claims were evaluated or cleared by the FDA before using them in advertisements and promotional material.

On October 2, 2008, two years after selling the first product, OtisMed finally submitted a pre-market notification to the FDA seeking clearance to market the device. According to the federal settlement documents, the company



OtisKnee Cutting Guides  
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falsely represented to physicians and other potential purchasers that the product was exempt from such pre-market requirements.

### FDA: “Not Substantially Equivalent”

Eleven months later, on September 2, 2009, the FDA sent the company a NSE (not substantial equivalent) Letter and denied its clearance request. The FDA said the company had failed to demonstrate the OtisKnee was as safe and effective as other legally marketed devices.

The FDA noted several deficiencies in OtisMed’s data. For instance, insufficient preoperative information regarding patients included in the data, which was “important to identify whether or not there are certain Triathlon patients who would be contraindicated for the OtisKnee or at high risk for poor results,” and that the missing data regarding follow-up was sufficient “to raise concerns about the failure rate of the Stryker Triathlon when implanted with the OtisKnee Orthopedic Cutting Guides, if some of these missing patients have experienced revisions or failures.”

The agency also said the company did not provide information about “whether and how frequently surgeons judged the cutting angles prescribed by the

OtisKnee to be flawed such that the surgeons found it necessary to forgo using the OtisKnee guides during the surgical procedure.”

### FDA Warning

Because the FDA classified the device into the Class III (Premarket Approval) category, the agency warned the company that “any commercial distribution prior to approval would be a violation of the Act.”

### Illegal Shipments

But on September 9, one week after the denial, the company shipped approximately 218 OtisKnee guides from California to surgeons throughout the U.S.

Between the time of the FDA denial letter and the shipments, Chi and the company received advice from legal and regulatory counsel confirming that, based on the FDA NSE letter, it would be unlawful to continue distributing the device. On September 4, 2009, after a conference call regarding the NSE Letter, the company’s board unanimously decided to stop further shipments of the devices.

Following that meeting, Chi and others at the company, became concerned of the consequences of the FDA letter. Chi feared that suddenly stopping the shipment of the devices would have a negative impact on the brand, image, reputation, and value of the company its devices.

The concern was great because the company was set to be acquired by Stryker Corporation for as much as \$100 million (including potential milestone payments) on the condition that FDA cleared OtisMed’s 510(k) submission for the device prior to closing of the acquisition.

So Chi developed a communications plan to reach out to surgeon and hospital customers to tell them that the OtisKnee device would not be available until FDA granted clearance. The plan was to notify surgeon and hospital customers on September 14, 2009.

But Chi was concerned that causing surgeons who had patients scheduled for surgeries within weeks of the NSE Letter to make last minute changes would exacerbate the negative impact of the NSE Letter on the company’s reputation and value.

### Planning the Crime

According to the settlement documents, on the afternoon of September 9, 2009, Chi and his board had another conference call. During that call the board discussed the outside counsel’s advice. An hour after that call Chi went into the office of the corporation’s Director of Strategic Financial Planning and Analysis (employee #1) and directed the director to work with the company’s Director of Operations (employee #2) to organize a mass shipment of all OtisKnee devices which had been manufactured but had not yet been shipped due to the hold on shipping placed following the receipt of the NSE Letter.

### Circumventing the FDA

Chi suggested that the employees could hide the shipments from the FDA by taking the package to an off-site shipping location instead of having them picked up by Federal Express at OtisMed’s facility or utilizing Chi’s personal Federal Express shipping account. He also suggested hand-writing the Federal Express airbills and backdating the shipment dates to September 4, 2009 or utilizing a temporary employee, rather than regular employees, to hand-write the airbills.

When Chi left the employee's office, he stated "this conversation did not happen."

He then sent the employee a Blackberry message that stated: "We are shipping everything out tomorrow. One shot."

On September 10, the Director of Operations met with Chi and informed him that he or she objected to shipping the devices given the NSE Letter. Chi ordered the employee to carry out the directive. The company then shipped out approximately 218 devices on that day.

### Blowing the Whistle

The employees decided not to follow Chi's advice on avoiding detection suggested by Chi and on October 2, 2009, Richard Adrian, (not identified in the settlement documents) filed a qui tam action in U.S. District Court in New Jersey (*U.S. ex rel. Adrian v. OtisMed Corp. et al.*)

### Admission of Guilt

Charlie Chi admits that he and the company intentionally distributing the device even after their application for marketing clearance had been rejected by the FDA. Chi and the company, now part of Stryker Corp., also agreed to pay more than \$80 million to resolve related criminal and civil liability.

Chi and the company also admitted to violating the False Claims Act. Because the company needed data for the creation of OtisKnee, it directed health care providers to submit claims to Medicare, TRICARE, Federal Employees Health Benefits, and Medicaid programs, for MRIs that were not reimbursable because they were not performed for diagnostic use.

Chi and the company pled guilty to two different judges to distributing,

with the intent to defraud and mislead, adulterated medical devices into interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

### Penalties

The judges fined OtisMed \$34.4 million and ordered \$5.16 million in criminal forfeiture on December 8, 2014. In a separate civil settlement, OtisMed agreed to pay \$40 million plus interest to resolve its civil liability.

OtisMed agreed to be excluded from Medicare, Medicaid and all other Federal health care programs for 20 years.

Stryker agreed to conduct a review and audit regarding whether other marketed devices have the appropriate FDA approvals and share the results of that audit with the government. Stryker also agreed to annual certifications

from the president of Stryker's orthopedics group and from Stryker's board of directors regarding the effectiveness of the compliance program.

Chi faces a statutory maximum sentence of one year in prison and a \$100,000 fine, or twice the gain or loss from the offense, for each of the three counts of introducing adulterated medical devices in interstate commerce.

### "Betrayed Trust"

"It is vital that products like the Otis-Knee are subjected to the appropriate level of scrutiny," U.S. Attorney Paul J. Fishman said. "Patients seeking medical care are vulnerable; they are often afraid, and in pain. They should be able to trust their doctors. And they should be entitled to trust that the devices their doctors are using are safe, effective, tested, and approved. OtisMed and Charlie Chi betrayed that trust." ♦

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# Orthopedic Residents Trained Differently Than Neuro Residents in Spine? What? // Slick New Spine Cage From Israel Goes in “Like a Ship in a Bottle”! // Kathleen Weber, M.D. to Head MLB Physician Group

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

## **C**onfusion in the Ranks: Variability in Spine Training Amongst Orthopedic and Neurosurgery Residents

Alan Daniels, M.D., an orthopedic surgeon at Brown University, isn't comfortable with the variability that currently exists in residency training for spine surgeons. He tells OTW, “As opposed to, say, otolaryngologists or urologists, who have only one training pathway, spine surgery specialists have two. There are both orthopedic surgery residency and the neurosurgical residency pathways, each with their own strengths and weaknesses for training spine surgeons. Orthopedic trainees who specialize in spine surgery follow residency with a dedicated spine fellowship, whereas neurosurgery trainees often go directly to performing spine surgeries after residency. What makes this situation problematic is that some residency programs provide inadequate spine training. There is so much variability in the training for spine surgeons, and a lack of standards outlining adequate training for spine surgeons. This leads to a situation where some surgeons may be inadequately trained, and patients and other medical professionals become confused about the capabilities and areas of expertise of surgeons who perform spinal surgery in their communities.”

“To study spine surgeon training, my colleagues and I performed a study in which we assessed the Accreditation Council for Graduate Medical Education (ACGME) case logs of graduating



Andrew Huth/Photo creation by RRY Publications LLC

orthopedic and neurosurgery residents from 2009 to 2012. We went into this knowing that orthopedic residents generally perform fewer spinal procedures than neurosurgery residents, however, we desired to explore the trends in spine training between and within each specialty. The average number of reported spine surgery procedures performed during orthopedic residency was 160; for neurosurgery surgery it was 375 procedures. It was not only the number of cases which differed between the specialties, but also the *types* of cases performed. We found a significant difference in the average number of spinal deformity procedures between graduating orthopedic surgery residents (9.5) and graduating neurosurgery residents (2.0). Also, we found that orthopedic residents do a higher proportion of instrumentation and fusion procedures

compared to neurosurgery residents, who participated in proportionally more decompression procedures.”

“We also found a tremendous variability in spine exposure *within* the specialty. We examined the bottom 10% and the top 10% of graduates for spinal instrumentation or arthrodesis procedures, i.e., those who did the fewest and the most procedures. We found a 13-fold difference for orthopedic surgery residents and an 8.3-fold difference for neurosurgery residents. This is concerning because the neurosurgery trainees in the bottom 10% are still going out and doing spine surgery independently, and with no additional training. In orthopedics, these trainees are likely poorly prepared for fellowship, and may or may not be adequately trained following spine fellowship.”

“One of the overarching issues is the ACGME accreditation for spine fellowships is currently voluntary and uncommon amongst spine fellowships. It is debatable whether ACGME accreditation improves fellowship training in any way; however, it is clear that there is little oversight of spine fellowships in both orthopedic and neurosurgery spine fellowships. This is problematic due to the fact that there is clearly variability in residency training for spine surgeons, and thus if this same variability exists among spine fellowships, some spine trainees may be inadequately trained to perform independent spine surgery at the conclusion of training. It is clear that we should monitor this problem closely, and we may wish to consider spine surgeon specialty certification. One important way to improve spine surgeon training would be to create a 3rd training pathway consisting of categorical spine surgery residency train-

ing which would decrease variability in training and allow for a focused and deliberate spine training experience. Although this is extremely controversial, spine surgery has clearly grown into a complex and complete medical and surgical field in recent years, and carefully considering the future of spine surgeon training is overdue.”

**“Like a Ship in a Bottle”...New Cage a Success at TBI** A new spine cage provides a minimally invasive option—and it’s done through a tube. John Peloza, M.D. of the Texas Back Institute (TBI) has performed the first surgery in the U.S. using the FLXfit, one of the world’s first 3D expandable interbody cages. Dr. Peloza tells *OTW*, “The problem with traditional methods is that it puts the implant into a rectangular disc space; if you don’t create lordosis you are creating a segmental flatback, a problem because this distorts the mechanics of

the spine. Our deformity colleagues have understood this for a long time. The surgeons who did degenerative spine work never appreciated this as much; then we found out about adjacent level disease and we always attributed that to a lack of motion in fusion. We didn’t like it, but we accepted it as a reasonable sequelae to the surgery.”

“With the advent of the anterior approach we became able to put in a large graft or implant and put it in with a trapezoidal shape (creating lordosis in the front). The problem with posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF) is that they don’t create enough surface area for the graft, leaving you with nonunions and a lack of lordosis. This goes in like a ship in a bottle, i.e., the implant is built outside the body. You put the implant in through a tube then open it up. This expands the

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surface area and the front part of the implant and creates lordosis.”

“If you’re going to have something that expands then you need to put a

mechanical device in that you can control from the outside. This fits the bill, and it opens up in two dimensions. The design was a challenge, in particular creating something that didn’t take up too much space for the graft. This patient was 63 and had undergone two previous laminectomies. I performed the surgery through an 18mm tube with the aid of an O-arm (thus avoiding fluoroscopy). During decompression I could refer to the anatomy on the computer; and sometimes scarring is helpful because with an O-arm you know where you are. There was hardly any blood loss and while it takes nearly as long as an open surgery, there is less trauma to the tissue so the patient recovers faster, experiences less blood loss and has less pain than those who undergo open surgery.”

**Kathleen Weber, M.D. Voted Head of MLB Physician Group**

The 60 voting members of Major League Baseball (MLB) Team Physician Association wanted the best and they found her. Kathleen Weber, M.D., an assistant professor of medicine and orthopedics at Rush University Medical Center in Chicago, has recently been named head of the MLB physicians group. Dr. Weber, already a member of the organization as a team physician for the Chicago White Sox and an active member of the MLB research committee, will assume the MLB Team Physicians Association presidency in 2016.

Dr. Weber, a member of Midwest Orthopaedics at Rush is board-certified in sports medicine and in internal medicine. She told OTW, “It is a thrill and an honor to have been selected for this position. In

2015 I will be attending medical advisory board meetings in New York and will be working towards organizing and holding the MLB Winter Meeting Team Physician Association/Professional Baseball Athletic Trainers Society Combined Academic Meeting that occurs each year in December. My leadership position and role on the Major League Baseball Medical Advisory Board will be devoted to the health and safety of Major League Players and baseball at all levels. I will assume the role of president in 2016.”

She notes, “In this role I plan to continue the strong leadership and accountability established from prior presidents and continue to build upon the communication between the trainers, strength coaches, physicians, and all levels of the organization. It is important to me that I accurately represent all of the physicians involved in caring for professional baseball players.”

“The relevant issues that are discussed at the meetings include not only orthopedic issues that are common to baseball players but other medical conditions that our athletes may encounter. We need to be aware of medical conditions that may affect our athletes such as the recent report of mumps in a professional athlete group. We have many international players that may present with infectious exposure not seen in the U.S. such as a mosquito-borne illness. We also want to continue to work on injury prevention and delve more deeply into the nutrition side of things to ensure that the athletes are primed to deliver their best performances.”

Dr. Weber also serves as the head primary care sports medicine physician for the Chicago Bulls and is the head team physician for the DePaul University Blue Demons, Chicago Force Women’s Football and Malcolm X College. ♦

**MATERIAL DUE: JANUARY 13, 2015**

The advertisement features a central image of a rocket launching from a cloud, with a journal cover titled 'Orthopedics' and 'TAKING BACK MEDICAL DECISION MAKING AND CONTROL' floating above it. The background is a dark blue space with stars and a view of Earth from space.

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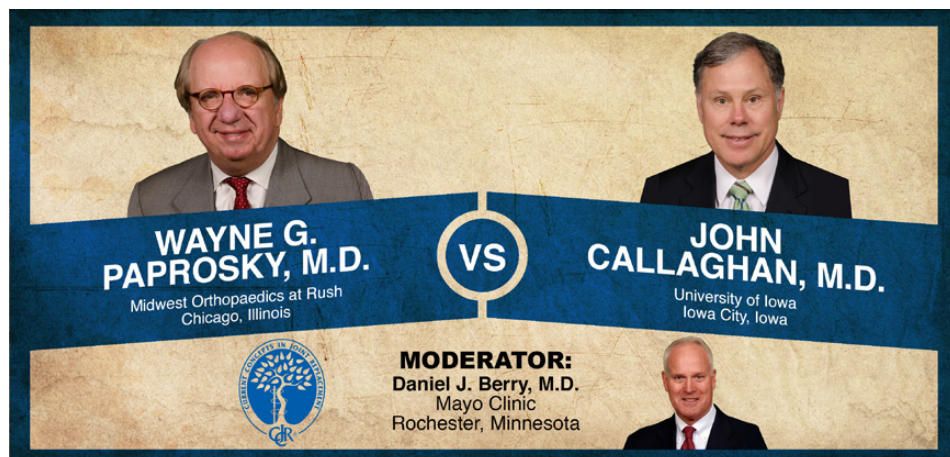
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## Paprosky, Callaghan Debate Constraint Versus Big Heads

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



Current Concepts in Joint Replacement/RRY Photo Creation

“Cup position is critical,” says Wayne Paprosky. “And if the abductors are deficient then I’m not sure there is an advantage to constrained liners.” “Really?” says John Callaghan; “There are good results with large heads in revision surgery. And if you need something very large you can go to the dual mobility rather than jumping straight to a constrained liner.”

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. This week’s Orthopaedic Crossfire® debate is “Use of Constrained Liners in Revision THA: More Problems Than They Solve.” For the proposition is Wayne G. Paprosky, M.D. from Midwest Orthopaedics at Rush in Chicago. Against the proposition is John Callaghan, M.D. of the University of Iowa. Moderating is Daniel J. Berry, M.D. of the Mayo Clinic.

**Dr. Paprosky:** “One of the main reasons for re-revisions is dislocation. People think about instability, revision, constrained liners and it became almost an

automatic reaction. But contemporary studies show increased risk of failure and they require open reduction; they are also associated with decreased range of motion (ROM). If you’re retaining the cup make sure that it’s in the right position...use a CT scan if you have to. And you must evaluate whether the abductors are intact.”

“We can do big heads because we have highly crosslinked polyethylene (XCLP). Head size has long been known to influence the risk of dislocation; big heads and impingement are more for primaries. In these revisions, it’s the jump distance that makes the difference...but jump distance is still dependent on cup position. You lose this advantage if the cup isn’t in the correct position. If the cup is not in the right position get the biggest head you can.”

“What if you can’t get a big head? The tripolar construct, as we have shown at our institution, is a very good method. You should find the biggest poly before you go to the dual mobility; you can get a lot of mileage out of a 48mm poly.

Then you can put a tripolar construct into it and you don’t have to jump right to this dual mobility concept.”

“Several studies show that we have good results using the large head in revision surgery. However, if you’re stuck and you need something bigger (the 48mm is still not stable) then you can go to the dual mobility for this indication rather than jumping straight to a constrained liner. I cement this construct into a highly porous shell.”

“What about constrained liners? John Callaghan has shown a high success rate with one failure at the cement-liner interface. But constrained liners are not all created equal, and there are studies showing a high degree of dislocation. Most of the cases I deal with that are unstable are Type 3B sockets and there is a higher rate of loosening in these cases. You increase the stress at the bone-implant interface, but you don’t need a constrained liner. Go with a big head and if it does dislocate later, once the ingrowth occurs, you can always go to a constrained liner. Many studies show loosening for these very difficult problems.”

“We did a direct comparison between the dual mobility (43) and constrained liners (36) in high risk patients. We had 10 constrained failures, 3 dual mobility failures to redislocation. Two were because of cementation of a smooth surface into a shell.”

“Constrained liners can solve some difficult situations, especially with the deficient abductors. But you have to weigh that against the potential for cup loosening. In conclusion, insta-

bility in revision—like primaries—is multifactorial. And we believe the large dual mobilities are better, especially in patients with severe bone loss. I believe the advantage is uncertain in abductor deficiency...and no matter what you do you must have the cup in the correct position.”

**Dr. Callaghan:** “In revision surgery the dislocation rate is up to 20%; in revisions for dislocations—even in Wayne’s own practice—they’ve only been able to get to 85% success.”

“There is no question that with increasing stability you only use what you need. But what’s available is not always working. Large heads seemed like a good idea, but wear simulators reveal some concerns. But the issue is the high failure rate that we’re starting to see now that is related to trunionosis with larger heads. And is the big head really enough anyway?”


“Lachiewicz has a study with older patients in a primary setting where he didn’t decrease his dislocation rate. Beaulé had 9% recurrent dislocations with larger heads. And the real data that Wayne mentioned is that if you have an absent abductor then the large heads don’t work. Ries showed 33% dislocations using large heads in those situations. And as Wayne said you should really check the abductors. Often we see metal-metal with no trochanter and we get in there and it seems that all you can do is use a constrained liner.”

“Why have they gotten a bad rap? There are different kinds of constrained liners. Some capture between the head and polyethylene—those are bad. But the tripolar ones that capture in the distant site have been effective. Lombardi showed a high failure rate early-on with those captured at the head in the poly. The long-term failure rates when you get to the constrained liner where there

is an inner bearing and an outer bearing constrained at the outer liner are much better. Our data show that most of the motion occurs at inner bearing, so it doesn’t go to the capturing ring.”

“Over 10 years we have looked critically at the distant capturing mechanism; we had 93% success. But we wouldn’t use this in a 45 year old patient. We did have a bit of acetabular and femoral loosening, but these are complex cases; we didn’t see much osteolysis. We had failures, but they were somewhat technique related and they go back to Wayne’s point. If you cement a liner into a shell you can’t cement it in a proud fashion or it will come out. If you malposition it then the patient may dislocate.”


“In spine fusion patients we’ve seen a higher rate of recurrence in those cases recently. In the U.S. a lot more people are getting these big spine fusions. And




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this is Wayne's biggest point: you put this on a big construct and you are at some risk of it ripping out."

"I use dual mobility, but this was a bit alarming—Mathias Bostrom recently gave me this data: a 10% re-revision rate at two years at Hospital for Special Surgery and a 13% re-revision rate if treating for dislocation. So dual mobility cannot take care of everything. We still use this liberally in older patients, but I'm concerned about the spine pathology issue."

**Moderator Berry:** "Would you agree that with the advent of large diameter heads and dual mobility implants that the use of and indications for constrained implants have gone down?"

**Dr. Callaghan:** "It should go down, but I'm not sure if it has."

**Moderator Berry:** "Wayne?"

**Dr. Paprosky:** "I've seen a decline."

**Moderator Berry:** "What are the indications for constrained implants?"

**Dr. Paprosky:** "My main indication is when I go in to do a poly liner exchange on a female with a well fixed component and a small diameter cup. Or, revision for trunionosis or something along those lines. Or I just have to go to a skirted ball and I don't have stability... that's when I go to a constrained liner."

**Moderator Berry:** "So Wayne, you'd use it in situations where the abductor is deficient or when you just can't rees-

tablish sufficient stability in surgery to feel comfortable that anything else will work?"

**Dr. Paprosky:** "Yes, and most of the time these cups are small and I can't even get to a 36mm head."

**Moderator Berry:** "John?"

**Dr. Callaghan:** "Same indications except in elderly patients I'm a bit more liberal. And if I've gotten into a revision situation with my acetabular construct and I know that the screws are the way I want them and I'm not concerned about ripping out the shell, then I'll use them in older patients."

**Moderator Berry:** "Both of you have said that you're worried about using constraint if you have a fresh cup in—particularly in a revision—and you have a tenuous situation in terms of bone fixation. And you both say that you're more liberal about constraint if you've already got a bone ingrown cup or a cup with a lot of fixation. Do you like to emphasize that, John?"

**Dr. Callaghan:** "Yes, and I give Wayne great credit for bringing that up."

**Dr. Paprosky:** "The big issue is when the abductors are not there. You are going to destroy some constructs if you liberally put a constrained liner in, especially a type three socket."

**Moderator Berry:** "All constrained implants will eventually impinge intra-articularly, so what do you do in surgery to minimize that?"

**Dr. Callaghan:** "I use a posterolateral approach with extended osteotomy; I want to protect the backside more. I still use an extended lip and I'm more concerned about impingement up the front than I am about anterior instability. We put our cups in a bit more vertical now with tantalum and such and then we can realign the liner...but you must ensure that you do that realignment a bit more horizontal than that verticality."

**Moderator Berry:** "If you cheat to have a cup that's flat and anteverted then you'll increase the risk of posterior impingement."

**Dr. Callaghan:** "I don't think you can totally do it with a constrained cup. I take patients through a ROM, but that Stryker liner only gives you about 80-90 degrees of motion."

**Dr. Paprosky:** "These things—because of abductor deficiency, trunionosis, and metal issues—they are flopping into external rotation. The failures that I've been seeing—the posterior aspect of the acetabulum, the ring are destroyed and there's more metallosis from the rings. And this is a huge problem because there's no way to control multidirectional instability."

**Moderator Berry:** "Thank you, gentlemen." ♦

Please visit [www.CCJR.com](http://www.CCJR.com) to register for the 2015 CCJR Spring Meeting, May 17 - 20 in Las Vegas, Nevada.



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COMPANY

## Stryker Buys London Healthcare Company

Stryker Corporation announced on January 5, 2011 that it was acquiring a London-based healthcare company.

No, it wasn't Smith & Nephew and it's not London, England. The acquisition is London, Ontario-based CHG Hospital Beds, Inc. The company designs and makes low-height hospital beds and related accessories.

With over 35 years of experience, the company sells in markets across Canada, the U.S. and the United Kingdom. It was an all-cash transaction and no dollar amount was announced.

According to a Stryker press release, CHG's beds "allow a patient's feet to sit flat on the floor while he/she is sitting at the edge of the bed. The low-height

design helps reduce the risk of patient falls that are related to entering and exiting hospital beds. Among CHG's innovative offerings is the recently launched Spirit One bed which is an expandable low-height bariatric bed for the acute care segment."

CHG's website says the company "revolutionized" the healthcare industry through the development of the first low hospital bed in 1996, and the first acute care low bed in 2003. The company holds eight low hospital bed patents.

Stryker Group President Tim Scannell said the acquisition, "aligns with Stryker's commitment to offering products that enhance the quality of care for both patients and healthcare professionals; in this case, aiding in the prevention of patient related injuries resulting from a fall from a hospital bed."

The transaction is expected to be neutral to Stryker's 2015 earnings per share excluding acquisition, integration-related and intangible amortization charges and accretive thereafter. — WE

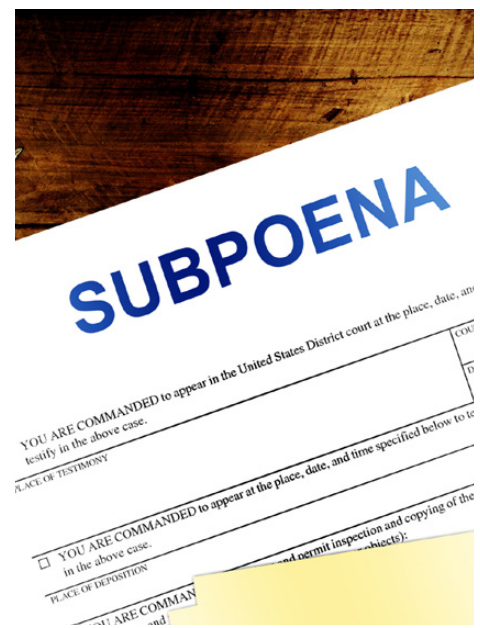


CHG Hospital Beds/CHG Hospital Beds, Inc.

LEGAL

## MiMedx Investigated, Sues Organogenesis

On New Year's Eve, MiMedx Group, Inc. announced that the feds are conducting a civil investigation of the company's sales and marketing practices. In an unrelated matter, the company also announced it was suing a competitor, Organogenesis, Inc. for "tortious interference."



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MiMedx develops, processes and markets regenerative biomaterial products and bioimplants processed from human amniotic membrane.

Company Chairman and CEO Parker H. Petit issued the following statement announcing the receipt of a federal subpoena:

"I can assure you that the corporate officers at MiMedx are not aware of anything that would stimulate this investi-

gation. We have continually maintained and improved a robust compliance program. We have been very focused on the thoroughness of our compliance policies and our staff adhering to those policies. For instance, MiMedx employees participate in a thorough training program regarding our policies and the standards that have been established and enforced to assure their understanding and adherence to our compliance programs. Employees may convey anonymously and directly to senior management and our Board of Directors any form of concern, complaint or inquiry related to our compliance programs or other issues. With the significant growth we are experiencing, this has been and continues to be an initiative in which we devote considerable time, attention and resources.”

### Advanced BioHealing Fallout?

Petit referenced another federal investigation into the sales and marketing practices of Advanced BioHealing (ABH), the original manufacturer of Dermagraft. “We anticipated that the ABH investigation could lead to a review of other industry participants, particularly in view of the fact that several industry participants, including MiMedx and some of our competitors, have hired former ABH employees. We screen all of our applicants very carefully. With respect to former ABH applicants, we sought additional input from some former ABH corporate management who joined MiMedx and who were familiar with the suspected violations and the individuals involved. Approximately 18 months ago, we had confirmation of a violation of our compliance policies, and within 24 hours, that individual was terminated.”

Petit says he expects this investigation will “confirm that our policies and pro-

cedures are working as intended. If any issues are uncovered, we will certainly address them promptly and take steps to ensure future compliance.”

### Settlement Likely

Needham & Company analyst Mike Matson, urged investors to take the long view. Matson said 21 med tech companies have received subpoenas from the feds since 2003. He noted that 16 were settled with 14 requiring fines, 11 required corporate integrity agreements and 6 ended in deferred prosecution agreements. The average length of time from subpoena to settlement was 3.8 years and the average fine was \$38 million. Some investigations took over six years and some fines were as low as \$6 million.

Matson said he thinks it’s unlikely that the investigation will cause the company’s revenue growth to slow, though it may drive higher legal expenses.

### Organogenesis Lawsuit

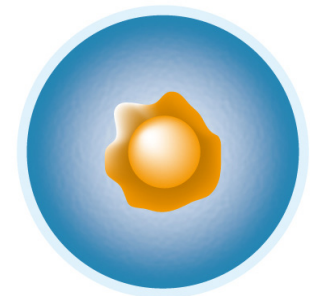
In the separate New Year’s Eve announcement, MiMedx said it filed the “tortious interference” lawsuit against Organogenesis after it discovered through a Freedom of Information Act request that Organogenesis allegedly provided misinformation about MiMedx’s products to the Veteran’s Administration (VA). The alleged misinformation caused the VA to remove MiMedx’s allograft from their supply schedule. The company says the VA ultimately determined that the action to remove their allografts was not warranted and issued an apology to the company.

Organogenesis is the maker of Apligraf and Dermagraft, products which compete with MiMedx allografts. — WE

## BIOLOGICS

### California Stem Cell Agency Launches CIRM 2.0

The California Stem Cell Agency, created to accelerate stem cell treatments to patients with unmet medical needs, is announcing the launch of CIRM (California Institute for Regenerative Medicine) 2.0.



Wikimedia Commons and Database Center for Life Science (DBCLS)

“Our mission is to accelerate the development of stem cell therapies for patients with unmet medical needs. Today, in officially launching the first three programs under CIRM 2.0, we have boldly reaffirmed our commitment to continuously seek new and innovative ways to better serve that mission,” said C. Randal Mills, Ph.D., the president and CEO of CIRM, California’s stem cell agency, in the December 31, 2014 news release.

According to the news release, CIRM 2.0 is a “radical overhaul of the way the Agency does business.” The process will be faster, and the agency will be an active investor. “Each project will be partnered with a project-specific Clinical Advisory Panel (CAP) to help advise and guide it forward. Importantly, every panel will include at least one patient advisor with first-hand

experience of the specific condition, who will provide input, recommendations and the appropriate sense of urgency that can only come from the unique perspective of someone living with the disease.”

Asked what orthopedic researchers would be particularly interested to know, Dr. Mills told *OTW*, “First, we have reduced the time from application to funding from 22 months to just 120 days, making it one of the more efficient sources of capital available. Second, the program is not just limited to cell therapies. Small molecule and biologics that have an effect on endogenous stem cells as the primary mechanism of action are also eligible. Lastly, the program is open to applicants from outside of the state of California. We want to attract exceptional technologies into California, so obviously the best deal we will offer is to those who are located here or are moving into the state. But if you are located outside of the state, we will partner with you on those activities that can be accomplished within California.”

Looking toward the next year at CIRM, Dr. Mills added, “This first phase of CIRM 2.0 targets clinical stage programs. We are investing \$50 million in these projects during the first six months of 2015 alone. In 2015 we also intend expanding the program to include earlier stage projects in the discovery and translational stages. With close to \$1 billion in reserve we have the resources we need to make these programs effective and successful. Our mission at CIRM is to accelerate the development of successful therapies for patients with unmet medical needs. CIRM 2.0 will help us do that and we want everyone with a promising stem cell therapy to know that we are open for business.” — *EH*

## Efficacy of Athlete Stem Cell Treatments Questioned

*MIT Technology Review* writer Antonio Regalado wrote: “The NFL Has A Problem With Stem Cell Treatments.” The problem he was referring to in his article is the fact that professional athletes are getting injections of stem cells to hasten their recovery from injuries and researchers have yet to come up with evidence that the treatment really works.

Beginning about eight years ago, doctors began extracting small amounts of a player’s fat or bone marrow, which contains stem cells, and injecting it back into the site of injury. The idea was to encourage tissue regeneration. Regalado noted that NFL quarterback Peyton Manning is reported to have had a stem cell treatment to his neck in 2011.

Many doctors are in agreement that there is only thin medical evidence to support the use of stem cell treatment. But physicians who are administering the treatment respond saying the treatments often have good results and should be given a chance.

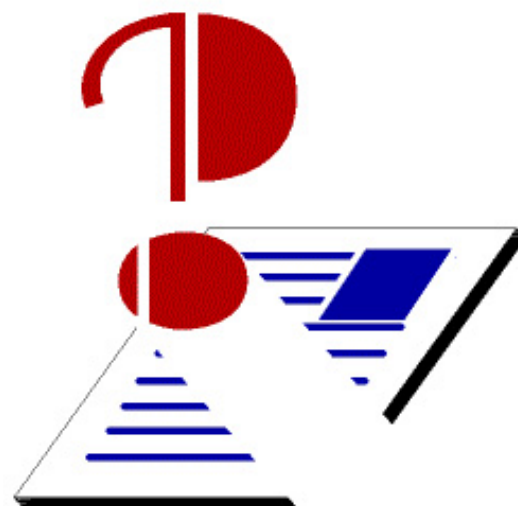
Regalado quoted Rice University researchers Kirstin Matthews and Maude Cuchiara, as saying that “the NFL should create an independent panel and fund research on whether stem cell treatments actually work, similar to what it did after facing questions around concussions and brain injury.”

“I think they should be more proactive. They should get ahead of this one,” said Matthews.

Freddie Fu, M.D., an orthopedic surgeon who is chairman of sports medicine at the University of Pittsburgh Medical Center and doctor for the school’s sports teams, told Regalado, “Any of these injections have a placebo effect. We don’t know what we are putting in. We don’t really know exactly what it does, biologically.”

Placebo effect or not, the treatments are becoming routine. Kenneth Mautner, director of primary care sports medicine at Emory University and team physician for its athletics department, told Regalado that he performs about two to four bone marrow injections a week. “I’ll be the first one to tell you it’s a new procedure,” he says. “The evidence from human studies is really weak at this point.”

Chicago area physician Mitchell Sheinkop, M.D. estimates that he has injected stem cells from bone marrow into the hips of about 400 patients in the past two years. The demand is there.



Wikimedia Commons and Baumst

Regalado reports that Shane Shapiro, M.D., an assistant professor of orthopedic surgery at the Mayo Clinic in Florida, is carrying out a test on 25 older adults who have arthritic knees. Shapiro is obtaining bone marrow from each subject, spinning it in a centrifuge to concentrate the stem cells and injecting them into the arthritic knees. Each participant is injected with stem cells in only one knee. The other knee gets a shot of salt water. Those saltwater treated knees are the controls. Shapiro does not expect to learn the results of his test for a year.

In the meantime the stem cells injections go on, fueled by hope and occasional dramatic results. Bone marrow stem cell treatments offered by doctors in the U.S. are not regulated by the U.S. Food and Drug Administration. — *BY*

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**LARGE JOINTS**

**\$1.8 Million NIH Grant Targets Implant Longevity**

Artificial hip and knee joints are wearing out too soon—often after 10 to 15 years of use—and researchers at the Voland College of Engineering and architecture at Washington State University (WSU) are determined to do something about it.

Susmita Bose, Ph.D., professor in the School of Mechanical and Materi-



National Institutes of Health

Courtesy of NIH

als Engineering and her colleagues, have received a five-year, \$1.8 million National Institutes of Health grant to improve the way bone implants integrate into the body.

Every year in the U.S. about one million titanium joint replacements are installed using acrylic bone cement. These materials, according to Bose, are foreign to the human body, do not bond strongly with the tissues surrounding them and usually fail after a decade or more. For younger patients, this presents a problem as they then have to go on to have revision surgery.

Bose plans to attack the problem by improving the bone-like material that is used as a coating on the titanium-based implants. The researchers will mix ions commonly found in the body—such as magnesium, zinc and calcium—into their coatings and will add tiny amounts of medicine, such as antibiotics or osteoporosis medications, to the coatings.

Bose and research team member Amit Bandyopadhyay, Ph.D., already have received patents on their innovative method of delivering medicine to a patient, which could be used like a time-release drug to fight infection or to build bone strength.

“This work could have a profound effect for younger patients and for those who undergo revision surgeries where bone volume is compromised,” said Bose. “A few extra years for these hip or knee replacements can make a tremendous difference,” said Bandyopadhyay, also of WSU’s School of Mechanical and Materials Engineering.

According to the University press release, Bandyopadhyay and Bose have been leaders for more than a decade in 3D printing of bone materials and improved materials for bone implants. In preliminary studies, they have used nanomaterials to make coatings that are stronger and more biocompatible than those currently available. — *BY*

## Study Shows Less Pain After Joint Replacement Surgery

A survey of 2,626 adults between the ages of 45 to 75 who are living with the pain of osteoarthritis (OA) found that those who had not had joint replacement were in worse shape where their physical, mental, emotional and

spiritual health was concerned than their fellow Americans who had.

The Harris Poll conducted the survey on behalf of DePuy Synthes Companies and found that joint pain is just not an uncomfortable fact of life but that it significantly impacts aspects of health.

More than 9 out of 10 adults (94%) with OA who have had a knee or hip

joint replacement reported that joint pain had been a significant burden in their lives before their joint replacement surgery.

Those who have had a joint replacement, 71%, were more likely to be satisfied with their overall mental health than were those who had not undergone a joint replacement (64%).

The good news, of course, is that severe OA is treatable. To raise awareness of the effects of joint pain on overall health and energy levels, DePuy Synthes Companies has launched an educational campaign called It's More Than Joint Pain. At the campaign's website, *MoreThanJointPain.com*, adults living with joint pain can take an online survey that compares their answers to the national average of adults who have undergone joint replacement surgery. — BY

**IT'S MORE THAN  
JOINT PAIN**  
FIND OUT HOW OSTEOARTHRITIS AFFECTS YOUR LIFE

Courtesy DePuy Synthes

## Lima Corporate Installs Its 100,000th Hip Stem

Lima Corporate, an Italian medical device company located in San Daniele del Friuli, Udine, reports that it has installed 100,000 of its C2 Hip Stems since the product was launched. This puts the company on track to install more than 40,000 implants of

the entire Hip Femoral Prosthesis line by the end of 2014.

Professor Cremonese of the Ospedale di Cittadella, in Padua, Italy, designed the C2 Hip Stem which, according to the company, has since become an integral part of the Lima Corporate Total Hip Arthroplasty solutions. Officials report that the firm is strongly committed to internationalization. Lima Corporate has 14 foreign subsidiaries worldwide

along with production facilities in Italy and the Republic of San Marino.

Professor Cremonese is Director of Orthopaedics and Traumatology at the Veneto Regional Center for the diagnosis and treatment of osteoarthritis of the hip. He has performed more than ten thousand orthopedic surgeries with particular focus on surgery of the shoulder and hip. Professor Cremonese is also a faculty member of the Italian Society of Arthroscopy.

“We expect demand to continue to accelerate next year,” said Luigi Ferrari, Chief Executive Officer of Lima Corporate. “The C2 Hip Stem is implanted in more than 17 Countries worldwide, supported by over 14 years of clinical history and success remaining one of Lima’s most successful stems. The stem is designed to significantly improve the patient’s quality of life”. — BY



Courtesy of Lima Corporate

EXTREMITIES

## Hammertoe Correction System Gets FDA Clearance

Cartiva, Inc. claims to have the first intramedullary hammertoe implant designed to maintain continuous bone-to-bone contact through a unique suture locking system.

And now American patients will have access to the company's ProxiFuse Hammertoes Correction System after the FDA granted the company 510(k) clearance to market the system in the United States.

According to the company's January 7, 2015 announcement, hammertoes are one of the most common deformities of the lesser toes where the second, third or fourth toe cause the toe to bend at the middle joint instead of pointing forward. In the U.S., approximately 600,000 annual surgical implant procedures are performed to treat hammertoes.

The common intervention is to fuse the joint after the ends of the bone are cut and the toes is straightened out. Pins, screws or other implants are used to keep the toe straight while the bone ends heal together. While multiple fixation methods have been used to keep the correction stable, the most common method has traditionally been the use of a pin-like device known as a Kirschner wire, or "K-wire." The company

says K-wires have been associated with complications including broken hardware, loosening, bending, migration and pin tract infection. Furthermore, patient dissatisfaction can be high as the K-wire protrudes from the tip of the toe during the four to six week healing process.

### ProxiFuse System

The ProxiFuse system is specifically developed for fusion surgery and is used for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe and mallet toe. Tiny Nitinol anchors on each side of the joint are secured into the bone, connected by a strong, self-locking suture fiber. Once tightened, the system, according to the company, "is designed to deliver continuous compression across the joint to be fused. A small PEEK body provides rigidity across the fusion site."

According to instructions on the company's website to surgeons, "Using the

graduated bone awl and disposable delivery instrument that are included in the tray, the surgeon inserts the anchors on each side of the PIP (proximal interphalangeal) joint. With the PEEK body to guide and stabilize the implant, the two sides are compressed by pulling the suture. The PEEK body's ability to be repositioned after insertion results in a lower amount of soft tissue release required to realign the middle phalanx compared to other intramedullary devices."

"The proprietary knot system holds the compressed bones together throughout the recovery period, reducing the likelihood of malunion."

Timothy Patrick, president and chief executive officer of Cartiva said, "We believe our system resolves many of the shortcomings of existing products, such as fixation and stability."

Alpharetta, Georgia-based Cartiva was founded in 2011 after spinning out from Carticept Medical, Inc. — WE



ProxiFuse Hammertoe Compression System/Cartiva, Inc.

## Bisphosphonates Cut Endometrial Cancer Risk in Half

New research from the Henry Ford Health System in Detroit is revealing that women who use bisphosphonates could have about half the risk of developing endometrial cancer as women who do not use these medications.

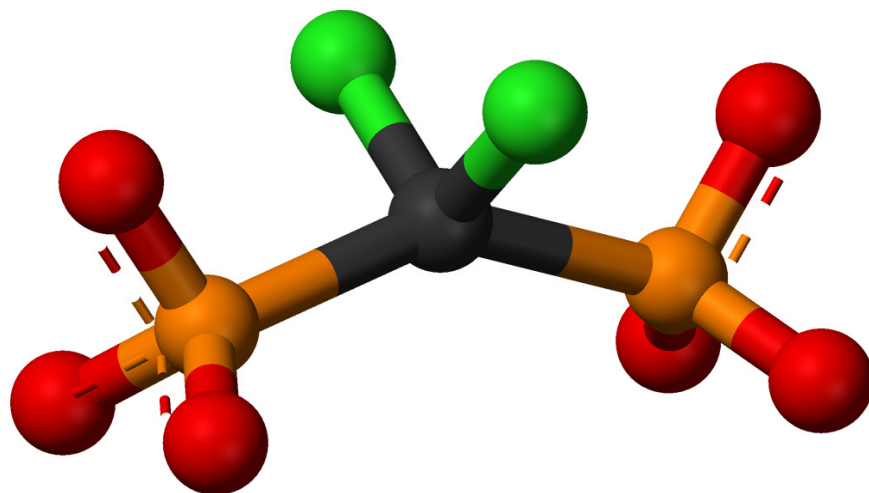
Sharon Hensley Alford, Ph.D. led a team that evaluated information from the National Cancer Institute's PLCO (Prostate, Lung, Colorectal, and Ovarian) Screening Trial. In the analysis, which included 29,254 women, researchers looked at data for only those bisphosphonates that contain nitrogen as these are known to have stronger anticancer activity.

"Other studies have shown that bisphosphonates may reduce the risk of certain cancers, but we are the first to show that the risk for endometrial cancer may also be reduced," said Dr. Alford in the December 22, 2014

news release. "This study suggests that women who need bone strengthening medications and who have increased risk for endometrial cancer may want to choose the nitrogen form of bisphosphonates because this form may reduce the risk of endometrial cancer."

The news release indicates, "Published early online in *CANCER*, a peer-reviewed journal of the American Cancer Society, the study supports other research that has shown an anti-cancer effect of this type of medication."

Dr. Alford told *OTW*, "I think that this might be most relevant to orthopedic surgeons who are working with patients with low bone density. Although there are potential risks, I am thinking of osteonecrosis of the jaw in particular, to bisphosphonates, my work shows that there are also potential benefits beyond the bone strengthening effects of bisphosphonates. Clinicians consulting with patients about the use of bisphosphonates may want to include the results of this study for the patient's consideration in her decision." — *EH*



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## TRAUMA

## Falls Haunt Lives of Elderly

If one is 65 or older one of the specters that is most personally haunting is the possibility of a fall. One-third of the individuals in that age range do fall with the result that hundreds of thousands suffer from devastating hip fractures each year.



Wikimedia Commons and Adam Jones, Ph.D.

According to research published in the *JAMA Internal Medicine*, and reported on by Hannah Stuart, writing for *MDNews*, more than a third of the elderly living in nursing homes died within six months of fracturing a hip. Nearly half of hip fracture patients in nursing homes die within one year of their break or are rendered incapable of independent locomotion.

Running counter to this trend is the fact that the number of orthopedic procedures performed on patients over the age of 80 has increased. According to

the *Journal of Bone & Joint Surgery*, the rate per 100,000 people over age 80 rose from 181 in 2000 to 257 in 2009 for total hip arthroplasty and from 300 to 477 for total knee arthroplasty over the same time period.

At the same time, according to Stuart, in-hospital mortality rates fell as did rates of complication among patients who had few or no comorbidities.

Stuart wrote that 90% of the elderly patients studied reported a reduction of pain following a knee replacement, 85% of their artificial knees were still functioning after 20 years of use and 60% of the joint replacement patients were women. Ten percent of the patients required revision surgery on their knee replacements after 10 years of use. — *BY*

Dr. Baek with the award for his years of dedication and service. Dr. Baek, a surgeon at Seoul National University Bundang Hospital, is the first Korean to win the AHHA.

“It is glorious, but I only did what I had to do,” Dr. Baek said to *The Korea Times*. “Children should not be scarred by their looks. I would like to return the smiles back to more children in need.”

In 1989, Dr. Baek and his elder brother, Se-Min Baek, M.D., created a small charity to help children in need.

“I and my brother visited public health centers all over the country every weekend to perform operations on children with facial deformities,” Dr. Baek said.

This charity developed into Smile for Children in 1995. Smile for Children performs surgeries on children with craniofacial abnormalities and has since expanded internationally and per-

formed over 3,700 operations. In the past 20 years, over 100 peer-surgeons have travelled to Vietnam, Myanmar, Indonesia, Uzbekistan, and Mongolia to perform surgeries.

In 2014 alone, Dr. Baek travelled to Vietnam, Myanmar, and Indonesia where he supervised over 200 surgeries. Dr. Baek even met with North Korean officials in 2000 in an attempt to help North Korean children.

“It may not be easy, but I believe I can meet North Korean children one day,” he said.

Although the relationship between the two Koreas has since deteriorated, Dr. Baek remains hopeful that he can one day better the lives of North Korean children with facial deformities.

“I feel most rewarded when I see children take their smile back after the operation,” Dr. Baek said. — *SB*

PEOPLE

**Rong-Min Baek, M.D. Wins Prestigious Audrey Hepburn Humanitarian Award**

According to a December 26 article, on November 27, 2014, Rong-Min Baek, M.D. received the Audrey Hepburn Humanitarian Award (AHHA) at the Dongdaemun Design Plaza in Seoul. Dr. Baek, a plastic and reconstructive surgeon, has spent the past 25 years offering his skills and time to help children in Korea and abroad.

The Audrey Hepburn Humanitarian Award recognizes individuals and organizations that have made significant contributions to better the lives of children worldwide. Luca Dotti, Hepburn’s son and the co-chairman of the Audrey Hepburn Children’s Fund, presented



The Audrey Hepburn Children’s Fund co-chairman, Luca Dotti, presents Dr. Rong-Min Baek with the Audrey Hepburn Humanitarian Award./Source: The Korea Times

## Scott Duncan, M.D. New Head of Orthopedics at Boston Medical Center, BUSM

Scott Duncan, M.D., M.P.H., M.B.A. is the new chief of orthopedic surgery at Boston Medical Center (BMC) and chair of the department of orthopedic surgery at Boston University School of Medicine (BUSM). Dr. Duncan's most recent role was system chairman of the department of orthopedic surgery at Ochsner Health System in New Orleans, Louisiana. He served as section head of hand and upper extremity surgery.

"Dr. Duncan is a true leader in his field, and has demonstrated a clear commitment to his patients, his research and to educating tomorrow's physicians," said Kate Walsh, president and CEO of Boston Medical Center, in the January 6, 2015 news release. "He will be

an integral member of the BMC team, and we are confident that his leadership and clinical skills will benefit both our patients and our staff."

As indicated in the news release, Dr. Duncan is an international expert and thought leader in the areas of upper extremity trauma; revision carpal tunnel surgery; small joint arthroplasty; and reconstructive surgery of the wrist, forearm, elbow and shoulder. He frequently presents at medical schools and conferences around the world on topics such as: shoulder arthroscopy, hand trauma, thumb injuries, and utilizing iPads and iPhones in an orthopedic surgery practice. Duncan has served as an international visiting professor of orthopedic surgery, most recently at the Medical College of Peru in Lima.

"Dr. Duncan will be a strong faculty leader," said Karen Antman, M.D., provost of BU Medical Campus and dean of Boston University School of Medicine.

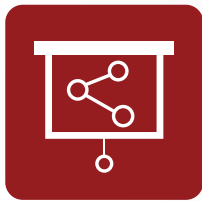
"He is an accomplished surgical investigator with many years of experience in academic administration and research. Orthopaedic surgery will continue to grow and thrive clinically and academically under his guidance."

Dr. Duncan earned his undergraduate degree at Harvard University, then followed that up with his M.D. and M.P.H. at the University of Washington (UW) Schools of Medicine and Public Health. He holds an M.B.A. from the University of Texas, Southwestern Medical Center. He completed his residency in orthopedic surgery at the Campbell Clinic, University of Tennessee, and did a fellowship in hand and upper extremity surgery and microsurgery at the Hospital for Special Surgery at Cornell University Medical College.

Asked about how he will begin this new role, Dr. Duncan told *OTW*, "My first step is to really get to know and understand the people that I will be working with on a personal level. So much of life is really determined by the quality of the relationships, and the bridges that we can build amongst each other, especially when engaging coworkers in an ever changing healthcare environment. The next steps will be working collaboratively with administration, other departments, and my colleagues/partners, to continue to build upon the reputation of this already well respected academic orthopaedic surgery department, medical center, and school of medicine. It is an exciting time to be in healthcare. Both Boston and Massachusetts are leading the way, and I look forward to contributing anyway possible to the benefit of the patients that our institutions serve." — *EH*



Boston Medical Center



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