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Orthopedics This Week

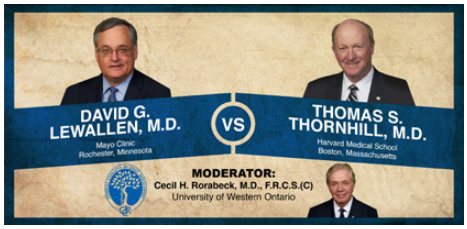
WEEK IN REVIEW

4 Humana Accuses Medtronic of Infuse Racketeering >> In a puzzling legal move Humana Inc. filed suit against Medtronic, Inc. and is trying to invoke the organized crime inspired RICO statute. Humana accuses Medtronic of conspiring with secretly paid surgeon agents to cook peer-review literature and then promote the off-label use of Infuse. Their evidence? *The Spine Journal*, the U.S. Senate and Yale's YODA study.

8 Generic Devices – It's About Distribution >> Given the incremental nature of orthopedic design improvements and the FDA's low tolerance for risk, the value of generics lies in distribution, not in manufacturing. As reimbursement models change, squeezing out cost in distribution is rewarded. That's the opinion of one generic device maker. Read the argument here.

11 Encouraging Data From New 5,000-Patient Anterior Hip Study // Study Confirms: Hinged External Fixation Trumps External Bracing // New Study Nails Reop Rates for Shoulder Arthroplasty >> Five thousand patients is a serious study and this one covers complication rates for anterior hip surgery. Results may surprise! First-of-its-kind study shows that hinged external beats out external bracing. And new research from Mayo Clinic has found that short-term reoperation after shoulder arthroplasty is uncommon.

14 All-Poly Tibia: Cheaper, Better? >> "Saying that modular metal backed tibial trays are somehow the 'gold standard' for modern TKA just isn't true," says David Lewallen. "Wait," says Tom Thornhill. "Most all-poly tibia results are in low demand patients. And, backside wear is now substantially better than it was during the period of time that David showed us."



BREAKING NEWS

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For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: One month ago buyers for orthopedic equities seemed few and far between. Then Zimmer decided to buy Biomet and Smith & Nephew was thrown into play. With that news, the tide of institutional investment sentiment turned, raising the vast majority (78%) of all public orthopedic boats. On average, over the last 30 days, orthopedic equity valuations have risen 4%.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Zimmer	27.31%	7.17%	Standing astride large joint orthopedics, Big Blue is dominating the strategic dialogue, for now.
2	3	Stryker	15.71	7.73	SYK may well match ZMH's move with its own scale play (SNN). But SYK also played the innovation card with MAKO.
3	4	Exactech	10.15	14.59	Big jump this past month as buyers are falling back in lust with large joint recon. Could be a short-term fling.
4	2	Smith & Nephew	20.25	17.03	Medtronic not buying, but Stryker very well might. Closes the ArthroCare deal just in time to negotiate its own sale.
5	9	Symmetry Medical	6.55	11.99	SMA, the largest contract manufacturer of orthopedic implants, has also been rising with Wall Street's shift to ortho.
6	6	Orthofix	6.75	10.17	Call it OFIX's rehab tour. As still new, but battle hardened, CEO Mason meets with investors; he'll set the stage for 2015 and beyond.
7	8	Integra LifeSciences	11.77	5.15	At $1.5 billion market cap and $50 million in annual cash flow, IART, the neuro leader, could well be a factor in consolidating spine.
8	5	Medtronic	28.84	5.31	MDT and SNN? Really? Connecting those dots would be like Judi Dench dating David Letterman. Just isn't right.
9	7	ConMed	10.19	(2.51)	Sale process struggling? That rumor swept the trading floors of several brokers last week.
10	10	Johnson & Johnson	26.58	2.25	Synthes is fully integrated but now DePuy's competitors are going through spasms of consolidation and integration. A positive for DePuy.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	$6.00	$635	17.88%
2	Smith & Nephew	SNN	$91.25	$16,296	17.03%
3	Tornier N.V.	TRNX	$22.40	$1,088	15.64%
4	Exactech	EXAC	$24.58	$336	14.59%
5	Symmetry Medical	SMA	$8.97	$336	11.99%
6	Alphatec Holdings	ATEC	$1.42	$139	11.81%
7	Orthofix	OFIX	$33.03	$609	10.17%
8	Bacterin Intl Holdings	BONE	$0.78	$43	9.09%
9	Stryker	SYK	$85.56	$32,435	7.73%
10	Zimmer Holdings	ZMH	$107.20	$17,990	7.17%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc	BAXS	$0.61	$30	-27.12%
2	Aurora Spine	ASG	$2.96	$46	-17.09%
3	RTI Biologics Inc	RTIX	$4.26	$241	-7.19%
4	ConMed	CNMD	$45.46	$1,237	-2.51%
5	TiGenix	TIG.BR	$0.67	$107	-1.48%
6	Globus Medical	GMED	$24.13	$2,255	0.92%
7	NuVasive	NUVA	$33.96	$1,582	1.77%
8	Johnson & Johnson	JNJ	$103.18	$291,907	2.25%
9	CryoLife	CRY	$9.13	$256	2.82%
10	Wright Medical	WMGI	$30.33	$1,514	4.30%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$62.47	$62,521	16.57
2	Johnson & Johnson	JNJ	$103.18	$291,907	18.30
3	Zimmer Holdings	ZMH	$107.20	$17,990	18.36
4	Exactech	EXAC	$24.58	$336	20.23
5	Stryker	SYK	$85.56	$32,435	20.68

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$33.03	$609	275.55
2	NuVasive	NUVA	$33.96	$1,582	109.56
3	Symmetry Medical	SMA	$8.97	$336	80.80
4	Smith & Nephew	SNN	$91.25	$16,296	28.94
5	CryoLife	CRY	$9.13	$256	27.55

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Exactech	EXAC	$24.58	$336	1.12
2	Globus Medical	GMED	$24.13	$2,255	1.54
3	ConMed	CNMD	$45.46	$1,237	1.98
4	Zimmer Holdings	ZMH	$107.20	$17,990	2.18
5	Stryker	SYK	$85.56	$32,435	2.28

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$33.03	$609	14.98
2	NuVasive	NUVA	$33.96	$1,582	9.80
3	CryoLife	CRY	$9.13	$256	6.89
4	Symmetry Medical	SMA	$8.97	$336	6.73
5	Integra LifeSciences	IART	$46.72	$1,522	2.81

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.42	$139	0.68
2	Symmetry Medical	SMA	$8.97	$336	0.84
3	RTI Biologics Inc	RTIX	$4.26	$241	1.10
4	Bacterin Intl Holdings	BONE	$0.78	$43	1.29
5	Exactech	EXAC	$24.58	$336	1.39

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.67	$107	18.68
2	MiMedx Group	MDXG	$6.00	$635	9.46
3	Wright Medical	WMGI	$30.33	$1,514	5.89
4	Globus Medical	GMED	$24.13	$2,255	5.19
5	Johnson & Johnson	JNJ	$103.18	$291,907	4.06

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

Humana Accuses Medtronic of Infuse Racketeering

BY WALTER EISNER

RICO Act and logos courtesy of Humana and Medtronic

Humana Inc. is accusing Medtronic, Inc. of racketeering under the federal RICO (Racketeer Influenced and Corrupt Organizations Act) statute. RICO was originally put on the books to fight organized crime.

In a federal lawsuit filed in Tennessee on May 30, 2014, the insurer cited *The Spine Journal*, Eugene Carragee, M.D., a U.S. Senate report, and Yale University's YODA Infuse Study as evidence of Medtronic's racketeering "enterprise."

Humana charges that Medtronic paid at least $210 million to key opinion leader (KOL) surgeons to minimize the dangers and exaggerate the effectiveness of the product in peer-review literature. Had Humana know this, it would not have paid for millions of dollars of procedures.

Carragee, the Senate and YODA

We have written extensively on the flawed *Spine Journal* conclusions and called for the resignation of their Editor-in-Chief Eugene Carragee, M.D. The flawed journal conclusions were then used in a U.S. Senate report to call for greater transparency and disclosure by device companies for payments to physicians.

To settle the matter, Medtronic turned over all its clinical data to Yale University to sort out the conflicting opinions about the product, the company's handling of the data and charges of research bias by authors of Infuse studies. The Yale study found some bias on the part of researchers with financial ties to Medtronic, but that, in essence, the data from the Medtronic sponsored clinical trials was sound.

Rare Legal Maneuver

There is nothing new in Humana's lawsuit that hasn't been alleged in previous shareholder and patient lawsuits. Medtronic recently settled a number of patient lawsuits. What is different is that a payer now wants its money back and is accusing the device maker of racketeering.

Legal experts quoted in a recent *Wall Street Journal* article said it isn't uncommon for insurance companies or other third-party payers to sue under the RICO statute to recoup damages related to alleged fraud, but most such claims have been made against pharmaceutical companies. In 2010, a federal jury found that Pfizer Inc. violated the RICO statute by promoting its epilepsy drug


Case 2:14-cv-02405-JTF-cgc

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

CASE NO. _____

HUMANA INC.

Plaintiff,

v.

MEDTRONIC SOFAMOR DANEK USA, INC. and MEDTRONIC, INC.

Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

PARTIES

1. Plaintiff, Humana Inc., is a Delaware corporation with its principal place of

Humana vs. Medtronic-Infuse Lawsuit

Neurontin for unapproved uses, leading health insurer Kaiser Foundation Health Plan Inc. and its affiliates to suffer damages by paying for off-label uses of Neurontin. The jury ordered Pfizer to pay Kaiser damages of about $142 million.

Jeffrey Gibbs, an attorney at Hyman, Phelps & McNamara, told the *Journal* it was "very unusual" to see a suit by a major insurer against a device maker, and even rarer for RICO to serve as the legal grounding. "The dollars at stake here are likely what helped shape this litigation," he said.

Humana claims that not only did Medtronic pay for academic and peer reviewed literature that falsely represented Infuse as safe and effective for uses not approved by the FDA, but also helped hospitals and physicians obtain payments from Humana through, "false statements and fraudulent omissions and concealment to obtain insurance payouts where Infuse and/or BMP was used. Humana would not have paid for such claims had it known the true facts regarding the uses of Infuse and/or BMP or the risks and efficacy of such uses," claims the suit.

Medtronic: Case Is "Baseless"

"The claims in this case are baseless," said Medtronic in a statement submitted to *OTW*:

> "The potential risks and benefits of INFUSE® Bone Graft have been described in the product labeling since 2002, and all payers had access to that information. Medtronic stands behind INFUSE® Bone Graft and will continue to vigorously defend the product and our actions in court.
>
> Medtronic vigorously disagrees with any suggestion that the company improperly influenced peer-reviewed published manuscripts. Medtronic does not compensate physicians for the use or endorsement of our products, and disagrees with any suggestion to the contrary.
>
> Physicians are compensated for their intellectual property rights and contributions through royalty payments, and for legitimate and documented consulting services provided to the company. Royalty and consulting agreements help medical device companies develop life-saving technologies and are a commonplace and appropriate practice in the medical device industry."

Flawed "True Facts"

The source of the "true facts," referred to in the suit, is the June 2012 issue of *The Spine Journal* which charged that

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researchers not only downplayed the dangers of Infuse, but failed to report any adverse events with the product. *The Spine Journal* further alleged that the researchers did this because of hidden payments from Medtronic.

The Spine Journal/Photo creation by RRY Publications

In direct contrast to *The Spine Journal*'s flawed review of early Infuse studies, *OTW* was able to document reports of adverse events by researchers in those early studies. Furthermore, *OTW* double checked *The Spine Journal*'s allegations of financial influence and determined that many of Medtronic's payments occurred years after the publications of the early studies or were for intellectual property unrelated to Infuse, or were paid by their academic institutions to conduct the research.

Off-Label Promotion

In addition to the alleged manipulation of clinical data and undisclosed payments to the surgeons, Humana says Medtronic promoted Infuse off-label from approved FDA applications.

At the January 10, 2002 FDA orthopedic panel meeting considering approval of Infuse, Humana says Thomas Zdeblick, M.D., Hallett Matthews, M.D. and Scott Boden, M.D. presented testimony for the company and assured the panel that only the use of Infuse for the single level lumbar anterior approach would prevent leakage of the BMP product into the neural elements of the spine.

Surgeon "Coaching"

The suit also alleges that according to internal Medtronic documents made available to the U.S. Senate, company officials coached the surgeons on their testimony in front of the panel. Human also alleges that the company ghostwrote some of the scientific articles.

Anyone who has ever attended an FDA orthopedic panel meeting knows this is true. All the clinical evidence gathered for the panel meeting is proprietary company information and cannot be disclosed without their permission. FDA convened panels always ask questions during the meeting. The company and their surgeon consultants then huddle together in a private room to provide the panel with answers. Presumably company officials and the consultants are talking to each other before, during and after the meeting.

"Deceptive Marketing"

The suit alleges that Medtronic then engaged in a "sophisticated and deeply deceptive" marketing strategy to expand the uses beyond the approved FDA label. Medtronic did this because the market for the approved uses was very small.

Medtronic spent "hundreds of millions of dollars" to encourage surgeons to use and insurers to pay for off-label uses. However, claims Humana, "the reliable scientific evidence demonstrates that [Medtronic's] claims regarding [Infuse] are false."

(The Yale study has something to say about that at the conclusion of this story.)

Humana further alleges that Medtronic was "wildly successful," listing Infuse sales of approximately $900 million for 2011 alone. The vast majority of those sales were for off-label uses. The success was, in part, due to a reimbursement strategy with insurance carriers using the paid KOL, who were paid $210 million in the form of "disguised royalties."

"Conspiracy"

Humana claims Medtronic and their KOLs "knew and conspired to keep secret that the KOLs were simply highly paid salesmen of Defendants' products, and were not, as they appeared, objective scientists and investigators giving opinions regarding the safety and efficacy of [Infuse]."

Again, Humana points back to the North American Spine Society's (NASS) *Spine Journal*.

"As Doctors Michael Heggeness and Charles Mick (former NASS presidents) observed, there is no way that a surgeon making the decision on what procedure and/or medical device to use for their patients, would use a procedure and/or medical device where the manufacturer of the device had paid the lead authors of the studies amounts ranging from $1.7 million to $64 million..." states Humana's suit.

Scientific Evidence

But back to the scientific evidence.

Humana says Yale's YODA study "confirmed Infuse and BMP did not perform" as represented by Medtronic.

However, in the words of the YODA investigators:

"…using either autograft or rhBMP-2 [Infuse] to enhance fusion rates in patients having anterior lumbar interbody fusion or posterolateral fusion seems clinically reasonable. In some procedures, such as anterior lumbar interbody fusion, graft harvest is a separate procedure and avoiding a second incision and associated graft site pain may be well worth the exceedingly small increased risk for cancer.

Although there is some potential for bias associated with patient-reported outcomes, in general, we consider the body of evidence for comparative effectiveness to be strong."

Finally, the YODA authors addressed Dr. Carragee's comment in *The Spine Journal* that "the risk of adverse events is 10 to 50 times higher than reported in trial publications."

"Our review differs from [Carragee] in that we had access to more extensive and detailed data than did Carragee and colleagues and that after reviewing all of the data, the difference between the adverse events reported in the trial publications and actual adverse events was minimal," wrote the authors.

The Medtronic statement added, "Medtronic strongly believes that the safety profile reported to the FDA and detailed in product labeling support the continued safe use of INFUSE® Bone Graft for approved indications. The Company has reported potential adverse events to the FDA, and those risks have been reflected on the product's label from the time of the FDA's approval,"

YODA Conclusions

The Yale YODA study concluded that we're back where we were before *The Spine Journal*'s assault on Infuse. Infuse works in certain patients and certain indications and not in others. And it is comparable to ICBG (the gold standard) in its ability to stimulate bone growth. Further the YODA authors determined that retrograde ejaculation is a non-issue, the cancer risk is exceedingly small; the clearest case of where not to use Infuse is anterior cervical fusion; and, early Infuse research was biased.

Humana is demanding a jury trial to determine exact damages. ◆

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Generic Devices – It's About Distribution

BY STEPHEN LICHTENTHAL

Generic orthopedic devices can replace 80% of implants sold by conventional vendors, says Stephen Lichtenthal, vice president of business development for The Orthopaedic Implant Company.

Designs and improvements in technology have plateaued in orthopedics. This mature market is ready for the final cycle of economics, says Lichtenthal.

He argues that removing the "omnipresent" sales rep from the operating room, combined with low R&D costs creates the opportunity to generate cost savings for hospitals. It's not about manufacturing, says Lichtenthal, but about the logistics of distribution and managing inventory.

Because the devices are less differentiated from each other, hospitals can go back to managing their own inventory. Conventional manufacturers disagree of course, but no one doubts distribution models are changing in response to new reimbursement models like bundling.

Lichtenthal makes his case. Let us know what you think.

Walter Eisner – Senior Writer, Orthopedics This Week

Photograph by Andrew Huth for RRY Publications LLC

The idea of generic orthopedic medical devices pertains more to a supply chain model rather than copying designs of existing devices.

Furthermore, truly generic implants (defined as being an identical copy of an existing implant) and proprietary, high-value implants provide similar discounts through the modified supply chain model. The term "generic" in the context of orthopedic implants has come to mean change in the philosophy of implant management and the augmentation of the supply chain model currently in place.

"Omnipresent" Sales Rep

Almost entirely exclusive to orthopedic implants, the sales rep has become omnipresent in our hospital systems' supply chains and logistics across the country. This includes reordering materials, re-stocking implant and instrument trays, managing inventory, regularly attending cases in the OR, bringing used sets to the sterilization department and getting them ready for the next case.

Depending on the facility, the entire management for these devices can be out-sourced to the sales rep.

Rep-less Sales and Low R&D

Referred to as "Direct-to-Facility," "Rep-replacement," or "Rep-less," a change in today's distribution model removes

Lichtenthal has a Master's degree in international relations from Seton Hall University and a Bachelor's degree in communications from SUNY Oneonta. Prior to joining The Orthopaedic Implant Company, he worked in various sales and management positions for Standards and Poors, Bloomberg and Pivot, Inc. and start-up companies.

local sales representation from the supply chain.

Removing local sales representation in conjunction with low R&D [research and development] costs creates the savings generic implants generate.

Twenty years ago, a sales rep might have attended a few cases when their company released something truly innovative. Today, they attend the OR religiously, assisting with the painfully mundane, struck with fear that if they are not present, another vendor will swoop in.

Furthermore, proprietary design does not necessarily mean higher cost. R&D only makes up 4.5% to 5% of spend for any vendor in this space. Conventional vendors have already recouped R&D cost several times over on a given implant's design that is, in some cases, decades old. This also speaks to how commoditized these implants are and raises the question as to why they carry hefty price tags.

Designs and improvements in technology have plateaued in orthopedics. This mature market is ready for the final cycle of economics in which value is the end game, thus making generics an exciting and timely opportunity for facilities and doctors poised to take advantage of a leaner supply chain.

Hospital Managed Inventory: Back to the Future

When "going direct," the hospital has come full circle, returning to a time when they managed their own inventory, case in and case out. The manufacturer receives orders from the hospital, not the sales rep, and sends it out. Upon receipt, a hospital employee re-stocks and accounts for inventory. In doing so, savings realistically equate to 40% to 60% when compared to rep-dependent vendors' pricing. Crucial to successful implementation of generic orthopedic implants is managing inventory.

Starting in the late 90s, hospitals grew tired of buying sets and corresponding inventory because doctors were continuously being sold on the latest and greatest from the industry, requiring the purchase of sets and inventory over and over again. A line was drawn and the policy of "consignment only" was largely adopted.

Sadly, this has painted hospitals further into the corner that has helped pricing stay falsely high. Without paying for sets up front, the cost of replenishing implant trays, in part, has gone up dra-

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matically. If a restaurant with 60 tables keeps ketchup at each table, they are not re-ordering one at a time as needed. The restaurant keeps several cases in the back because the pricing is better when buying in bulk, and operationally, a table is sure to be missing ketchup if they relied on the sales guy to bring the bottle "just in time".

More impressive than the percentage points are the actual dollars saved. Generic implants are seeing adoption in all major areas of orthopedics—trauma (hardware for internal fracture fixation), total joint reconstruction, spinal correction/fusion and sports medicine. The savings range from a few hundred dollars a case to several thousand dollars a case.

Bundling Drives Value

Incentivizing the surgeon to find better value is the lynchpin to driving prices down.

While in their infancy, true bundled payment programs are proving to be fruitful for provider, facility and most importantly, patients, in the pursuit of better value. These bundled payment programs reimburse facility and surgeon with one, predetermined payment. The result is that physician and facility are aligned and driven to find the best value for the best delivery of care.

A separate reimbursement for facility and surgeon is a large impediment to lower healthcare costs. The movement is considered to be one where healthcare migrates from "fee-for-service" to "pay-for-performance." Under fee-for-service, incentives are all volume driven and do not reward value. Pay-for-performance awards best practices and highest value. Admittedly, the transition is a glacial process with programs still being tested and data proving validity are distant. So why are doctors adopting the use of generic implants if their reimbursement is not increasing? More appropriately, which doctors are championing this effort?

The incentives are not in their reimbursement per se, but rather the quality of medicine they practice. Large, academic hospitals are proving to be the most progressive in moving to generic devices.

While methodologies vary, large, academic hospitals provide service-line reinvestment when doctors create better value. Whether it's for research, expanding the fellowship program, or adding supporting clinical staff, all of these things add up to doctors being able to practice better medicine and further its science.

Rewarding the Adapters

Another crucial attribute these hospitals share is that case volume has forced hospital staff to manage many of the screw and plate sets for fracture fixation without a sales rep. So, they have been paying premium prices for their implants without getting the premium service touted by company representation.

Ironically, a lack of case volume has led many facilities situated in sparsely populated regions to manage their own hardware as well. For sales reps with wide territories that include rural areas, they spend as little time as possible in these facilities. The volume just doesn't justify their driving hours each way to cover a case. Just like academic facilities, small rural hospitals handling any kind of orthopedic trauma are doing things on their own because they have to.

Both of these types of facilities have evolved to be self-sustaining out of necessity and now their logistical competency can be rewarded.

Spine and Total Joint Reps Add Value

Realistically, generics can comfortably replace 80% of implants sold by conventional vendors. More accurately, 20% of cases see a real value-add in having the sales rep attend cases in the OR. Minimally invasive spine surgeries and total joint revision cases are examples of this. With multiple trays of instrumentation and complex techniques, a sales rep can help support a case by being able to provide guidance should something not go according to plan during the case.

Evolving and Adapting

The evolution of the orthopedic implant industry over the last 30 years is a remarkable one. U.S. healthcare's "fee-for-service" has allowed price increases across the board to run rampant. Implant designs are decades old. Differentiation among the crowded field of vendors is minimal in the most exaggerated comparisons. Yet, the price of implants has gone up an average of 8% a year. It is a new world. The spotlight is on savings in healthcare and today's supply chain in orthopedics sorely lacks the fundamental approach to being part of the solution we need to save our country's healthcare system.

Just like generic pharmaceuticals, generic implants can bring billions in savings annually and are the next logical step in our urgent pursuit of value and accountability in healthcare. ◆

Encouraging Data From New 5,000-Patient Anterior Hip Study // Study Confirms: Hinged External Fixation Trumps External Bracing // New Study Nails Reop Rates for Shoulder Arthroplasty

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

Photo creation by RRY Publications LLC/Wikimedia Commons

5,000 Patient Anterior Hip Study Results Announced Over 5,000 patients and three high volume orthopedic centers may just convince some surgeons to take a chance on anterior approach hip replacement. Steven Barnett, M.D. of the Hoag Orthopedic Institute in Irvine, California, tells *OTW,* "Despite adoption of anterior hip surgery, there has not been a great deal of clinical research in this area as compared to other approaches. We set out to look at patients from the day of surgery until 90 days postop and examine the safety of this approach. Our retrospective chart review included 5,000 patients from three centers: The Hoag Orthopedic Institute (along with Dr. Robert Gorab and Dr. Jay Patel), St. John's Health Center (where we worked with Joel Matta, M.D.), and The Anderson Orthopaedic Clinic (where we worked with William Hamilton, M.D.)."

"We found an overall complication rate of 3.28%, which is equal to if not lower than that of other approaches. If you break that number down, the rate of medical complications was 1.36%; and surgical complication rate was 1.9% (hematomas, infection, deep vein thrombosis/pulmonary embolism, intraoperative fractures, dislocations). The dislocation rate for the entire cohort was 0.23%. These are short term results, so we can't comment on functional comparisons of patients down the road. We can say, however, that using an anterior approach to hip replacement is safe and has a reasonable complication rate."

"Our goal now is to continue to track these patients out to five to ten years in order to determine how they are faring functionally. I'm pleased to be able to say to my naturally cautious colleagues, that if they are considering this approach, they can move forward. My own patients who are five years postop are doing as well if not better than those

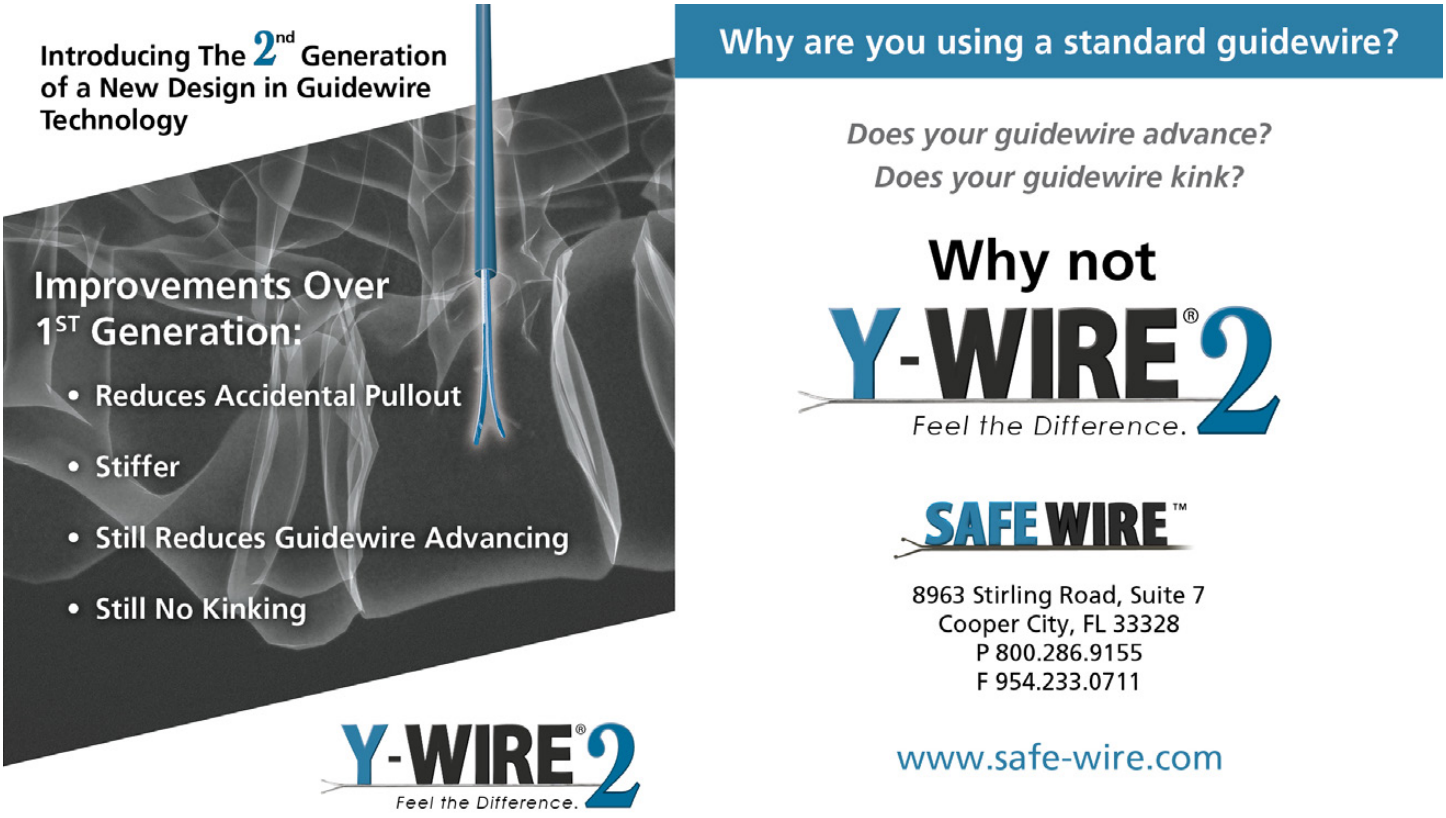
on whom I used a posterior approach. At this point in my career, I do 100% of my total hip patients with an anterior approach."

Knee Dislocations: How to Have Fewer Failed Ligament Reconstructions In what is purported to be the first prospective randomized study on knee dislocation in the literature, James Stannard, M.D. has determined that hinged external fixation used along with reconstruction following knee dislocation was associated with fewer failed ligament reconstructions than external bracing. Dr. Stannard, chairman of the Department of Orthopaedic Surgery at the University of Missouri and medical director of the Missouri Orthopaedic Institute, tells *OTW*, "Knee dislocations were previously thought to be uncommon, but in fact as we look at trauma patients it is evident that they are more common than we thought. When someone tears a ligament such as the ACL [anterior cruciate ligament] you can reconstruct it and use early aggressive motion to allow the knee to function. This works because the knee has four groups of ligaments; when you have three intact and one torn you don't need anything other than a brace. But if you dislocate the knee and three of the four ligaments are torn, if you use aggressive motion then you risk loosening and the failure rate is higher."

"This was a Level I study involving my results with the hinge and without; we found a remarkable improvement amongst those who had the Compass Hinge. Also, there was a statistically significant lower revision rate amongst those treated with this hinge. You could say this device is like the world's best knee brace. It has pins that go into the bone and hold it where it belongs; there is no motion in the saggital plane, no rotation or side to side motion, and no ligament loosening."

"The most important issue is to determine precisely when to use it. It could be useful in situations where all four of the ligament groups are torn and there is a lot of capsule damage and instability. It could also be helpful if there are associated secondary injuries such as a tibial plateau fracture. This device, which is a powerful tool to obtain motion while maintaining stability, should be used in the most severe cases. It is expensive, with a price tag of roughly $8,000 - $10,000. But if it saves a revision surgery, then that would be worth the cost."

"Our study confirms that hinged external fixation used along with recon-



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struction following knee dislocation has a place in our array of treatment options. We do need more studies to figure out exactly when to use it; ideally we can do additional prospective randomized comparisons to determine the indications. While I don't have anything planned at the moment, we are building up our database of knee dislocations and could potentially partner with other institutions in order to achieve the necessary numbers for such a study."

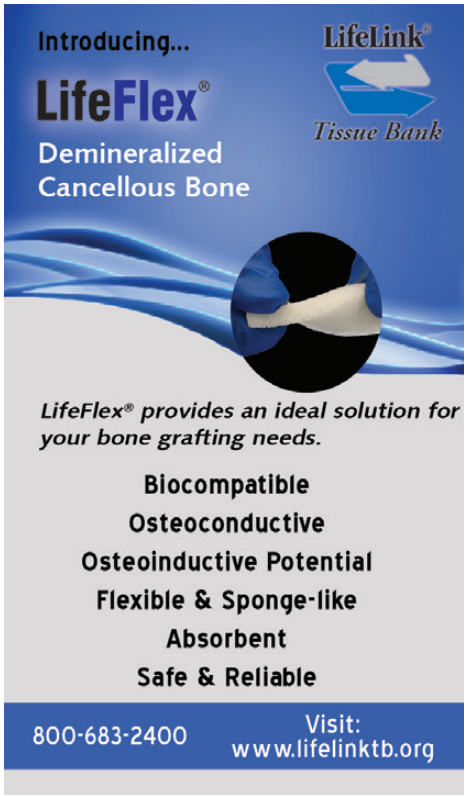
Dr. Stannard notes that the funding for this study came from an unrestricted grant from Smith & Nephew, and that they had no editorial influence.

New Study Nails Reop Rates for Shoulder Arthroplasty A group from Mayo Clinic has decided to fill in some blanks in the shoulder arthroplasty literature. Philipp Streubel, M.D., an orthopedic surgeon with Mayo Clinic, Minnesota, tells *OTW*, "Some of my colleagues and I felt there was a dearth of information in the literature regarding reoperation rates in shoulder arthroplasty, which has a potential of being a major cost driver for this procedure. While there a half a million hip and knee arthroplasties done each year compared to 50,000 shoulder arthoplasties, the latter surgeries are increasing at a higher rate than the former. This is an indication of broader indications and of the fact that patients are staying healthy and active into their later years."

"We conducted a retrospective cohort study of 30- and 90-day reoperation rates after shoulder arthroplasty. We reviewed charts from the Mayo Clinic joint registry from January 2000 to December 2010 identifying 2,823 shoulder replacements. Of those, 45 patients (1.6%) had a reoperation during the first 90 days and 22 (0.8%) during the first 30 days after surgery. We found that patients after revision arthroplasties had a significantly higher risk of being readmitted. We found that the two most important causes of reoperation were infection and instability of the shoulder. One-fifth of patients required at least two reoperations. Reoperation led to either prolongation of the initial hospital stay or a readmission in the vast majority of cases."

"This is the first study to examine reoperation rates after shoulder arthroplasty. It does thereby establish an important benchmark for this metric which may prove useful as new policies for reimbursement are developed. For example, The Affordable Care Act plans on penalizing institutions that have patients with a readmission rate that is higher than expected. The information provided by this study will help in setting such expectations and provide policymakers with a usable metric."

"It should however be kept in mind that this information comes from a high volume joint replacement institution. Several studies have shown that higher volume surgeons at higher volume institutions have fewer complications and lower costs. Our findings may therefore not be generalizable to the general orthopaedic community. This should be recognized at the moment of establishing definitive reference benchmarks."



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David Kim, M.D. Joining OrthoNeuro OrthoNeuro announced today that David Kim, M.D. will join their multi-specialty physician group on July 14th, 2014. Dr. Kim is a fellowship-trained orthopedic spine surgeon who specializes in minimally invasive approaches to the neck and low back. Dr. Kim worked in private practice specializing in spine surgery for over 14 years. He was most recently employed by OhioHealth Orthopedic Surgeons. Dr. Kim has privileges at Dublin Methodist Hospital and is the director of spine surgery at Doctors Hospital.

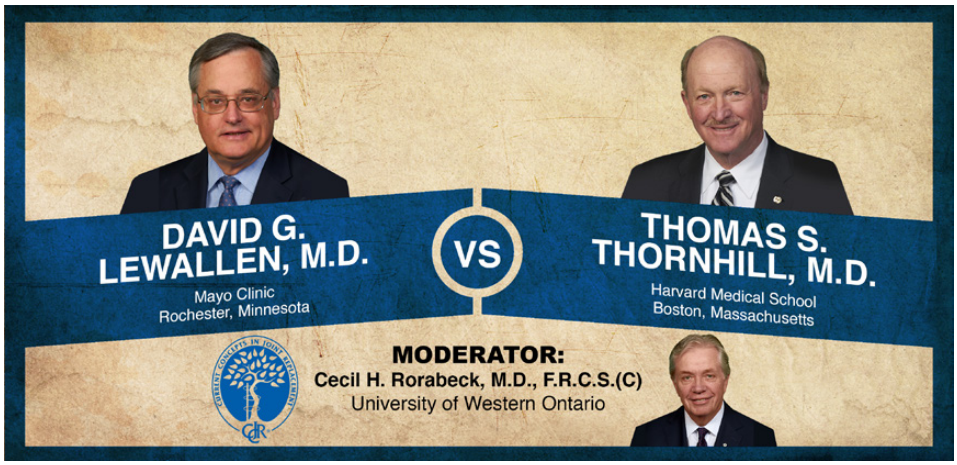
Dr. Kim graduated from Yale University cum laude with a Bachelor Degree in Biology. He attended Medical School at the University of Rochester School of Medicine in Rochester, New York. Dr. Kim was awarded a research grant at the National Institutes of Health in Bethesda, Maryland for MRI and metabolism. He completed his orthopedic residency at Hahnemann University in Philadelphia, and then a spine surgery fellowship at Southern Illinois University in Springfield, Illinois. ♦

All-Poly Tibia: Cheaper, Better?

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

"Saying that modular metal backed tibial trays are somehow the 'gold standard' for modern TKA just isn't true," says David Lewallen. "Wait," says Tom Thornhill. "Most all-poly tibia results are in low demand patients. And, backside wear is now substantially better than it was during the period of time that David showed us."

This week's Orthopaedic Crossfire® debate is "The All-Poly Tibia: Cheaper and Better." For the proposition is David G. Lewallen, M.D. at Mayo Clinic in Rochester, Minnesota; against the proposition is Thomas S. Thornhill, M.D. from Harvard Medical School. Moderating is Cecil H. Rorabeck, M.D., F.R.C.S.(C) from the University of Western Ontario.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Lewallen: "There are no ideas more dangerous than the things we think we know for sure, and then a few years later realize these things weren't so valid. Saying that modular metal backed tibial trays are somehow the 'gold standard' for modern TKA [total knee arthroplasty] just isn't true. The biggest challenge in revision surgery this past decade has been related to particulate debris, and it's not a coincidence that this exploded at the same time the industry converted to modular designs that allowed for backside wear, metal debris, and small particulates from those third body particles."

"I'm not saying that backside wear is the only issue, but I think it was one of the issues that was a driver for the early osteolytic cases. And it's not like we didn't see poly wear years ago. But we didn't see the kind of lysis around well fixed implants that has become so familiar to us…that we accept without question."

"Modularity has been proposed as a great advantage because then we can change the liner. But if you examine the literature you see that it's usually a bad idea. Why? Because many times the things that led to early poly wear were not corrected with a simple poly exchange (malrotation, flexion-extension gap problems). This is in contrast to the occasional late poly change in a patient at 12-15 years. In those very few cases it may provide some small advantage. But abrasion on the top of titanium trays is a problem, and you see it in more than one design. It means extrusion of the inserts…painful."

"The literature on backside wear and locking mechanism shows problems. In a study of Dr. Ranawat's cases (Rodriguez, J.A., *CORR*, 2001) of modular monoblock versus all-poly tibial components, there was a big difference at seven years (75% with metal backed modular versus 96% with all poly monoblock). In another series (Weber, A.B., *Journal of Arthroplasty,* 2002) they found a 2.5 times revision rate, higher radiolucencies, and balloon osteolysis was 17 times more common in the modular devices. What are we doing?"

"We reviewed 10,000 patients and 14,524 primary TKAs at our institution and examined implant design issues on the tibia. We found that across designs polyethylene tibias outperformed metal backed modular designs. This was true even after correction for age and gender. Initially it looked like the CRs (cruciate retaining) were better than the PS (posterior stabilized), but when we removed one problem design the other designs showed equivalent performance of CR and PS."

"The etiology of osteolysis is multifactorial…but modular designs are part of the problem. Perhaps crosslinked poly and vitamin E poly may be ways to solve the problem, but there are things we still don't know. The knee is not a hip, and there's a different pattern of abrasion, as well as delamination and pitting. As far as expense, recent redesigns of modular implants are an improvement. And if you choose a chrome/cobalt rotating

platform design, then you have an issue of stress shielding. If you don't do revision surgery you don't care about this; but if you do, this matters."

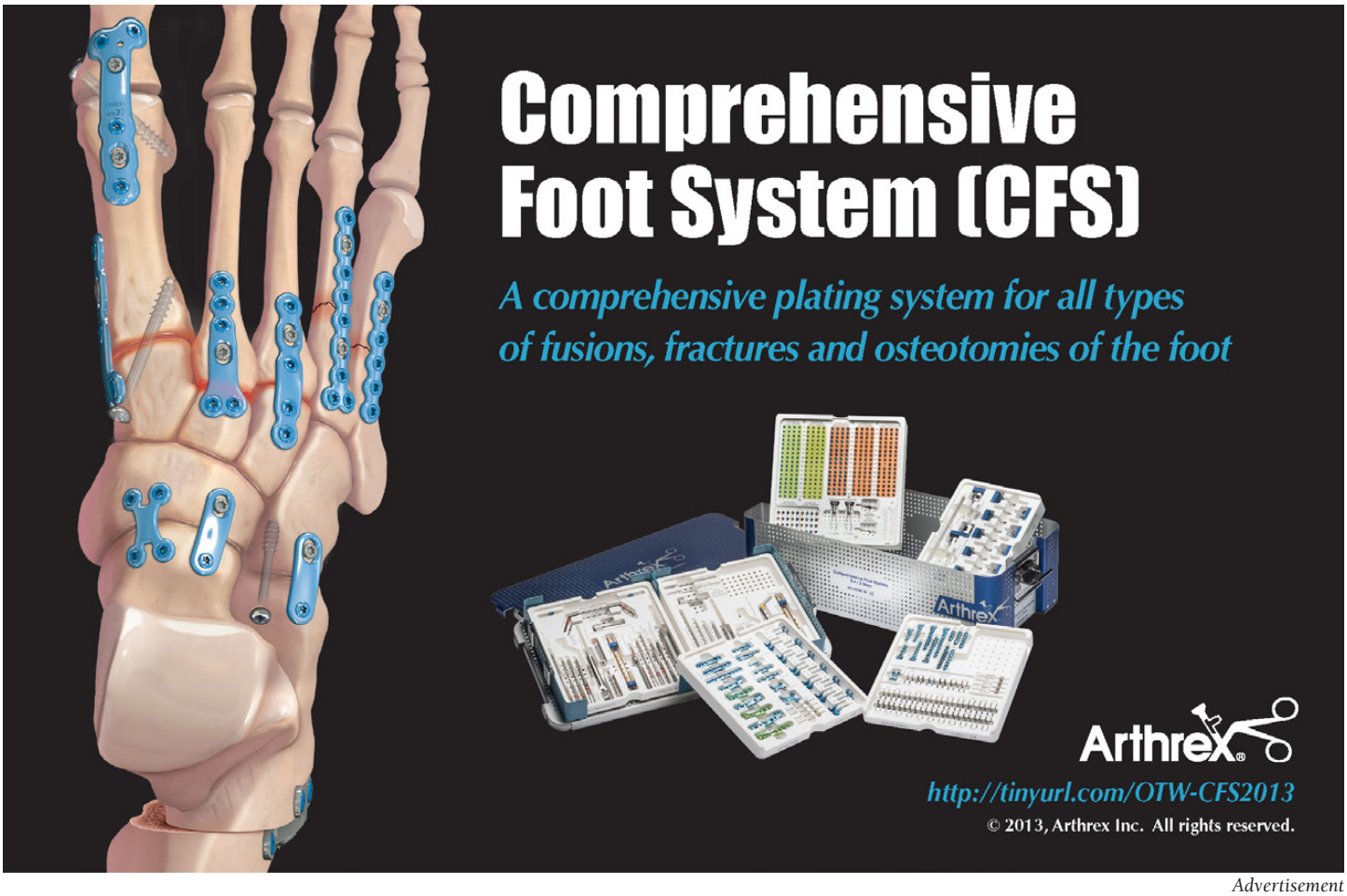
"You should consider the use of cemented all-poly designs for some, if not all, of your patients."

Dr. Thornhill: "I have a two-handed stranglehold on a loser because I think there are many things that David says that are true. In terms of cost, an all-poly tibia is only going to get more important; they also have good long term results. Our polys are now more wear resistant, have better mechanical strength, and they are more oxidatively resistant; they also don't have the problems with backside wear."

"However, most all-poly tibia results are in low demand patients. And, backside wear is now substantially better than it was during the period of time that David showed us. From that time period until now those problems—which were actually issues of poly and locking mechanism—have improved."

"In most cases we no longer use screws and thus avoid the issues of screw osteolysis, fretting, and portals for the bioactive particles to get into the tibial interface and cause loosening. Also, we've improved the metal tibial surface and reduced micromotion by having a better locking mechanism and a better interference fit. When the issues David discussed were occurring, I actually moved away from fixed bearing to where almost 80% of my cases were rotating platforms. I did this because I thought that was the easiest way to get away from backside wear. While I still use some rotating platforms, my percentage has almost flipped back to all fixed bearing."

"There has been a switch from titanium to a cobalt chrome tray. The poly not only has better mechanical properties, but it has a better force fit, a beefed-up bumper mechanism. Now, I agree with what David said about there being problems with this, but it does facilitate some interoperative and revision options…with the caveat that if there are other problems, isolated component exchange is not very good."



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"Now that we have tibial femoral bearing mechanisms with the inserts—CR, PS, ultra-congruent—you can change your congruity within the CR and the PS profile. Sometimes on the PS side you do have to be careful of what femoral component you are using. And I must admit that each time I revise a knee I invariably put a tibial insert in that's about two millimeters thicker just because of the loosening that I've caused by entering."

"Tibial bone loss and weakness are important when we talk about kinematic alignment and allowing varus. There can be a disparity of bone and sclerosis; in such a case, cement creates a uniform proximal tibial mantle. You can do that with an all-poly tibia and with a metal back. In an old article by Walker and Reilly (1979) they discuss the lower bending stresses in a metal-backed tray in that situation. Think for a moment: if you are now tolerating varus then that may come into play more in a kinematic alignment knee. The bending moment in the poly tray may in fact be beneficial."

"As for the clearing of cement, if you use a modular system you can make sure that you've cleared it—particularly if you're using a tibial insert as a trial when the cement is curing. Regarding fixation options, we will get to cementless components, which will hurt the all-poly tibia. So at present I use a modular tibial component and some all-poly components in elderly, low demand patients. But the economics may dictate a change in selected patients."

Moderator Rorabeck: "David, is this an all or nothing thing with you?"

Dr. Lewallen: "Currently, I think probably around 30-40% of my patients get an all-poly tibia. I use modular implants in complex primaries where stems or augments are needed because that is a requirement. I also use a modular design in the very obese patient—it is technically easier than putting in a monoblock. I will use a modular implant with some very young patients, hedging my bet for the second or third decade (for exchange of the insert). I also have access to a monoblock metal-backed implant that I'll use as an alternative to the all-poly sometimes."

Moderator Rorabeck: "Is there any minimum thickness of an all-poly tray that you would recommend?"

Dr. Lewallen: "I haven't avoided using the narrowest of the available implants. They're much thicker than the stated

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size because for labeling purposes…but they're right around 10mm/"

Moderator Rorabeck: "Tom, do you use any all-poly tibias in your practice?"

Dr. Thornhill: "Yes, in the elderly, low demand patient who has reasonable bone."

Moderator Rorabeck: "An elderly person with reasonable deformity and reasonable range of motion?"

Dr. Thornhill: "Yes, and with reasonable tibial bone."

Moderator Rorabeck: "What about reasonable thickness?"

Dr. Thornhill: "The studies say that once you get above 8-10mm of poly it behaves almost like the stiffness of a metal backed tibia, not only for the bending moments but for the Von Mises stresses in the proximal tibial bone."

Moderator Rorabeck: "David, of the 10,000 cases that you were doing, presumably the content the oxidation of the tibial inserts varied?"

Dr. Lewallen: "Yes."

Moderator Rorabeck: "Did that have any impact?"

Dr. Lewallen: "We weren't able to look at that variable because some of the manufacturers actually changed the poly three or four times during the study period—so we weren't sufficiently powered to look at that issue."

Moderator Rorabeck: "So Tom, if you were going to do one today, what kind of poly would you use on an all-poly tibia?"

Dr. Thornhill: "I would use a moderately crosslinked poly with an antioxidant in it. And I don't think it's like we were discussing with the mouse calvarial model that they're less immunoreactive. I just think that it's oxidatively resistant. I think you can do that with any number of antioxidants, including vitamin E. I'm not sure about the role of that in the hip."

Moderator Rorabeck: "Would it be fair to say that if you were going to do this that you'd be mainly doing CR type knees?"

Dr. Lewallen: "I do PS exclusively. It does raise the point of vitamin E. I think this is attractive when it comes to a post because it maintains a little better strength than the irradiated product. But for surgeons who are under pressure about cost, it's certainly a way to lower your profile."

Moderator Rorabeck: "Thank you both." ♦

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

Advertisement

COMPANY

Polymer Meniscus Earns IDE From FDA

Active Implants, LLC has been granted Investigational Device Exemption (IDE) approval by the FDA to conduct a pivotal clinical trial for its NUsurface Meniscus Implant.

The study is a prospective, randomized, multicenter study to demonstrate superiority of the device compared to the current standard-of-care for patients with persistent knee pain following meniscectomy surgery.

Elliott Hershman, M.D., the company's chief medical advisor, says the device is a "novel, composite polymer implant, which is used to treat knee patients who have pain and disability arising from osteoarthritis caused by a previous meniscectomy, meniscus dysfunction or insufficiency." He added that the device was designed to meet the needs of patients too old for meniscus repair and too young for a knee replacement. The device is implanted by orthopedic surgeons using an arthroscopic approach and a mini-open procedure and is approved in Europe under CE regulations and in Israel.

The company says in a May 29, 2014 press release that it believes the device could be used to treat several hundreds of thousands of patients a year whose earlier meniscectomy treatments have not been successful but are not yet candidates for knee arthroplasty. The potential worldwide market for the device is estimated at more than $2 billion annually.

OUS Studies

According to company Chairman and CEO Henry Klyce, clinical studies outside the U.S. (OUS) have shown that the device results in "significant pain relief and restoration of function" compared to currently available treatments." He said the company hopes to obtain premarket approval by the FDA.

Cross-section of the NUsurface meniscus implant

NUsurface Meniscus Implant/Active Implants, LLC

The company has been working with knee sports medicine surgeons in Belgium, Italy, Israel, The Netherlands, Sweden and Germany for the past three years conducting a prospective controlled, multi-center trial. Peter Verdonk, M.D., Ph.D., an investigator in the trial from Orthopaedic Center Monica Hospitals Antwerp and University of Ghent, Belgium, said, "I am impressed with the results observed to date and believe this technology could represent a new method of treating patients with meniscus problems who are often on a long and painful progression to knee replacement."

$60 Million Raised

Active Implants is a privately-held, multi-national company, headquartered in Memphis, Tennessee, with additional offices in Driebergen, The Netherlands, and Netanya, Israel. The company, founded in 2004, has raised $60 million, according to press releases from their website. — *WE*

Medtronic Squashes Smith & Nephew Takeover Report

Bloomberg reported on June 4, 2014 that Medtronic, Inc. is joining Stryker Corporation in evaluating a purchase of Smith & Nephew plc (S&N). Medtronic management quickly threw cold water on that report at a Wall Street analyst meeting on June 5.

According to "people familiar with the matter," *Bloomberg* reported that a takeover could see Medtronic move its tax domicile overseas and give the company better access to its overseas cash.

Medtronic CEO Omar Ishrak, reported *Bloomberg*, has said he wouldn't rule out a tax-inversion deal.

"Strategically, we do have this current problem that we have a lot of cash outside the U.S.," he said in a May 20 telephone interview. "We encourage some kind of U.S. tax reform that allows us access to that cash in a more reasonable way."

The company is looking to broaden its offerings in its three key areas—heart, muscle and skeleton and diabetes products, Ishrak said. "We intend to fill these areas out and we want to globalize."

According to the people, Medtronic's preparations for a bid are at an early stage and no offer is imminent.

"A More Serious Bidder"

The unidentified sources also told Bloomberg that Medtronic is a more serious bidder than Stryker, which confirmed last week that the company was in the early stages of evaluating a bid. Stryker was responding to a request from British regulatory authorities to state their intentions. That regulatory body has not made a similar request of Medtronic, as of this writing.

Analysts at Barclays Plc wrote that buying S&N would bolster Medtronic's business of making devices for the spine and its orthopedics operations. Medtronic is a more plausible buyer of the UK company than Stryker because Medtronic would have a lower risk of antitrust obstacles, they said.

The transaction, according to people in the Bloomberg article, would probably be structured as a tax inversion, with Medtronic using S&N's corporate shell to move its legal residence to the UK. The gap between the 35% federal tax rate and much lower levies in some European countries is spurring such deals—including Pfizer Inc.'s now shelved effort to acquire AstraZeneca Plc. The UK has a 21% corporate income tax rate.

Medtronic Throws Cold Water on Speculation

After speaking with Medtronic management at the June 5 analyst meeting, Wells Fargo analyst Larry Biegelsen wrote that he does not believe the company will bid on S&N as reported by Bloomberg.

He noted that British regulators had not asked Medtronic to issue a statement, as they did with Stryker. In addition, he said management indicated that deals will be based primarily on strategic fit and not financial reasons like tax inversion.

Medtronic management indicated to Biegelsen that the company sees a better fit for spine with its neuro business than with ortho. The company will only enter a market if it feels it can be a top player. S&N only has about 12% of the hip and knee market.

Logos courtesy of Medtronic, Smith & Nephew and Stryker

The company also indicated to Biegelsen that while it generates the majority of its cash outside the U.S., it believes it can return 50% of cash to shareholders over the next five years without doing a tax inversion. "This suggests to us that the financial rationale for doing a S&N deal is not that compelling for Medtronic."

Bidding War With Stryker?

Biegelsen had previously said that a Medtronic offer could start a bidding war with Stryker.

Before the analyst meeting, Biegelsen wrote that a potential Medtronic acquisition of S&N could make strategic sense. "Medtronic would benefit from market entry into orthopedics (hip and knee implants), advanced wound management, sports medicine (joint repair), trauma, and arthroscopic enabling technologies. S&N has 12% share worldwide in the hip, knee, and reconstructive orthopedic markets. While Medtronic has a large, established spine business (~$3B), orthopedics and wound management represent gaps in their portfolio."

Biegelsen also said that if there is a bid from Medtronic, the acquisition would enable broader product bundling opportunities to help the company better meet the demands of a hospital environment increasingly driven by cost cutting. He would, however, be concerned that S&N's relatively small 12% share in hip and knee implants would put Medtronic at a competitive disadvantage to larger ortho players such as DePuy Synthes and Zimmer Holdings, Inc.

Apparently, so would Medtronic's management. — *WE*

Nextremity: FDA Clearance, CE Mark for Forefoot System

Nextremity Solutions, Inc. has announced that its latest proprietary forefoot surgery system, the MSP Metatarsal Shortening Plate and System, has received FDA clearance and CE Mark certification. The MSP system is positioned for metatarsal shortening osteotomies to correct toe angulation/dislocation and relieve pressure. It provides the company with a product candidate in another key segment of forefoot surgery. The company will prepare for a limited product release in the coming weeks.

In the May 27, 2014 news release, Nextremity President and CEO Rod K. Mayer, remarked, "We are very pleased to obtain key regulatory approvals for MSP so soon after last month's Re+Line launch. Initial surgeon feedback on MSP is that we have achieved an important innovation for forefoot surgery. This is encouraging as we expand our product portfolio."

Lon S. Weiner, M.D., chief of orthopedic trauma at Lenox Hill Hospital in New York, explained, "The MSP plate is designed to provide a greater level of precision and repeatability because the osteotomy guide and metatarsal reduction/control have been engineered into the implant. We enthusiastically await the clinical experience of our surgeon colleagues."

Judith F. Baumhauer, M.D., M.P.H., professor, Department of Orthopaedic Surgery, Foot and Ankle Division, University of Rochester commented, "Based on my cadaver lab experience with MSP, I believe that the plate's control of metatarsal segments will provide for a more stable and precise fixation. It has the makings of a game changer product."

Rod Mayer told *OTW*, "Once again we are excited to take another step forward in advancing techniques that will address unmet clinical needs in forefoot surgery. Based upon initial cadaver labs and feedback from our Surgeon Advisory Board, we are confident that we have developed a game-changing technology that will address the concerns expressed by foot and ankle surgeons with current techniques and their clinical results. We look forward to our national and global launch of this product at the completion of our BETA evaluation, which begins in mid-July 2014." — *EH*

Nextremity Solutions, Inc.

LEGAL

Jury Convicts Former ArthroCare CEO and CFO

Michael Baker and Michael Gluk have been found guilty of fraud by a federal jury in Austin, Texas, for their part in ArthroCare Corp. shareholders losing over $400 million in value in 2008.

Baker was immediately taken into custody, pending sentencing.

Fraud and False Statements

Baker, the former company CEO, and Gluk, the former CFO, were convicted on June 2, 2014, for artificially inflating sales and revenue numbers to meet company sales projections. Specifically, Baker was found guilty of conspiracy to commit wire and securities fraud, wire fraud, securities fraud and false statements. Gluk was found guilty of conspiracy to commit wire and securities fraud, wire fraud and securities fraud.

New Management

Baker resigned in February 2009 after the company announced that the U.S. Securities and Exchange Commission (SEC) and U.S. attorneys were investigating its business practices. Gluk resigned in December 2008. New management entered into a two-year deferred prosecution agreement with the company, and in January 2014, the company said it would pay a $30 million fine to resolve the SEC investigation.

ArthroCare was recently acquired by Smith & Nephew for $1.7 billion. The company employs about 1,800 people, including about 280 in the Austin area.

DiscoCare Conspirators

Baker and Gluk were the last company executives under investigation after co-conspirators John Raffle and David Applegate, former senior vice presidents, pleaded guilty to multiple felonies in 2013.

The government claimed that Baker, Gluk and other company officials inflated ArthroCare's revenue by tens of millions of dollars and used sham transactions to manipulate the company's revenue and earnings through end-of-quarter transactions involving a number of distributors, including DiscoCare, which were "based on ArthroCare's need to meet sales forecasts, rather than the distributors' need for products" according to the suit.

The executives "caused ArthroCare to ship millions of dollars worth of ArthroCare's medical devices to its distributors at the end of quarters. ArthroCare would then report these shipments as sales in its quarterly and annual filings at the time of the shipment, enabling the company to meet or exceed internal and external earnings forecasts," according to the suit.

In return for substantial, upfront cash commissions, the distributors agreed to accept the excess inventory in exchange for extended payment terms and the ability to return products.

Baker and Gluk, according to prosecutors, caused ArthroCare to acquire DiscoCare specifically to conceal from investors the nature and financial significance of ArthroCare's relationship with DiscoCare.

$400 Million Shareholder Loss

Between December 2005 and February 2009, ArthroCare's shareholders held more than 25 million shares of ArthroCare stock. On July 21, 2008, after ArthroCare announced it would be restating its previously reported financial results, the price of ArthroCare shares dropped from $40.03 to $23.21 per share.

The drop in ArthroCare's share price caused an immediate loss in shareholder value of more than $400 million.

Baker Will Appeal

Baker's lawyer still believes in his client.

"We obviously disagree strongly with the jury's conclusion but we respect their opinion and very much appreciate their conscientious service," said Rusty Hardin, an attorney for Baker. "We will certainly appeal because we sincerely believe Mike is innocent."

No sentencing date has been set. Both men face up to 25 years in federal prison for each conspiracy charge, 20 years for each count of wire fraud and 25 years for each count of securities fraud. Baker faces an additional 5 years for each count of making false statements. — *WE*

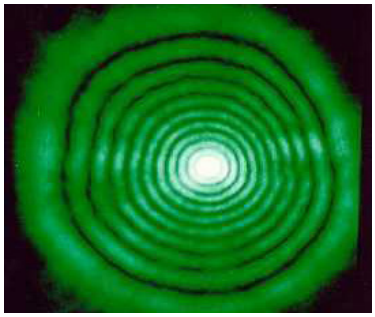
Image created by RRY Publications, LLC

BIOLOGICS

Low-Level Lasers Stimulate Stem Cells

A team of scientists from Harvard University has demonstrated that the application of low-power laser light can trigger stem cells in the body to regenerate tissue. Mark Hawver, writing for *Tech Times*, explained how David J. Mooney, Ph.D., professor of bioengineering, and his team used laser light to trigger human dental stem cells to form dentin. The extraordinary nature of this research is that, if proved successful, this would allow treatment of patients to take place without first removing the stem cells from the body and then replanting them.

The irony here is that medical laser use dates back to the late 1960s. High-power laser light was early found to be destructive to tissue. Only recently have investigators noted the significance of the fact that low-level light therapy results in the stimulation of many body processes. According to Hawver, uncovering how low-level light therapy works at the molecular level helps explain many of the anecdotal observations from previous years and has led to the development of controlled treatment protocols.



Wikimedia Commons and Thepage

Mooney believes this treatment has applications beyond dentistry to wound healing and bone regeneration. Hawver quotes Jonathan Garlick, M.D., director of the Center for Integrated Tissue Engineering at the Tufts University School of Dental Medicine, who called the research "a powerful proof-of-concept, and that the technique, once fully developed and found to be safe, could be widely used."

"I think it's very relevant directly in a variety of different tissues that require stimulation and activation of healing and repair, such as chronic foot ulcers in diabetic patients, bone healing and bone regeneration. I think this has broad applications," Garlick said. — *BY*

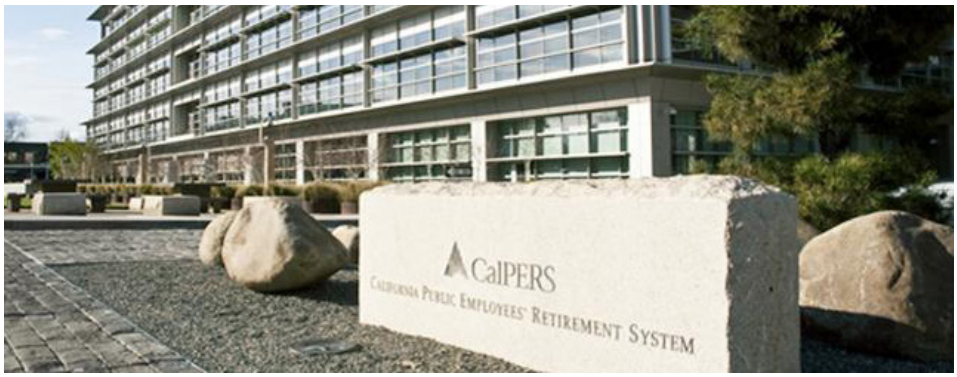
LARGE JOINTS

Reference Pricing a Winner for CalPERS

Three years ago the California Public Employees Retirement System (CalPERS) began what it called "reference pricing." Reference pricing established a standard price for a medication, procedure or service and required its members to pay any charges beyond that price.

CalPERS reports that it has now saved $5.5 million over two years. The savings came about through this initiative that set standard prices for knee and hip replacements and prompted beneficiaries to select higher-value hospitals for the procedures. Details are spelled out in *Health Data Management* reports.

To develop the program, CalPERS asked Anthem Blue Cross to research the average costs for hip and knee replacements among hospitals. Its assignment was to develop a program that would ensure sufficient coverage by hospitals and also meet a certain cost threshold. The program set a maximum of $30,000.



Courtesy of CalPERS

Forty-six medical institutions—including Stanford and University of California, San Francisco, joined the plan. The number of Anthem-CalPERS enrollees who chose a designated high-value hospital for their knee or hip replacement surgeries increased from 50% between 2008 and 2010 to 64% in the first nine months of 2012. The average price for joint replacement procedures fell from more than $42,000 before the initiative to $27,148 in the first nine months of 2012.

The average cost to CalPERS for the procedures fell by 26%. According to the report, the savings resulted from the hospitals lowering their costs, which accounted for 86% of the savings, and the enrollees opting for higher value hospitals. — *BY*

Chocolate Milk Gives Swimmers an Edge

Swimmers—drink those cartons of chocolate milk. Researchers at Indiana University have found that when collegiate, trained swimmers recovered with chocolate milk after an exhaustive swim, they swam faster in time trials later that same day. On average, they shaved off 2.1 seconds per 200 yard swim, and 0.5 seconds per 75 yard sprint, compared to when they recovered with a traditional carbohydrate sports drink or a calorie-free beverage.

"Chocolate milk is an ideal recovery drink. It's a 'real food,' has the right carb to protein ratio athletes need and it's less expensive than many alternatives," said Joel Stager, Ph.D., lead researcher at Indiana University. "From cyclists to runners to soccer players, there's a strong body of research supporting the benefits of recovering with chocolate milk. Now, our research suggests these same benefits extend to swimmers," he said. Competitive swimming is a sport where seconds and even tenths of a second can make a big difference and intense practice routines are the norm. Swimmers must be able to generate a quick recovery from multiple races within a single day.

This study is the first to test the benefits of chocolate milk in swimmers. After completing a debilitating swim the athletes recovered with one of three randomized beverages—reduced fat chocolate milk, commercial carbohydrate sports drink with the same calories as the chocolate milk, or a calorie-free beverage.

Following a five hour recovery period, the swimmers swam three performance test sets. Investigators found that there were significant differences in the aerobic and anaerobic swims, which indicated better recovery after drinking chocolate milk.

Stager says that he first studied chocolate milk because of its unique carb to protein ratio. He says that now more than 20 studies support the benefits of recovering after a hard workout with the high-quality protein and nutrients in chocolate milk. — *BY*

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Yankee Pitcher's Knee Gets Stem Cell Shots

New York Yankees pitcher C.C. Sabathia received a stem cell injection in his right knee to deal with a degenerative condition in the cartilage. James Andrews, M.D., told the Yankees that the repair to the knee would take a minimum of six weeks if it works.

Yankees General Manager Brian Cashman is quoted by writer Del Veddhio as saying, "Our dialogue with Andrews has been good and given the small sample of stem cell procedures, the results are very successful. But he has to be pain free before strengthening, so there is a way to go. Because he is a starter it will take longer. I have no idea how long it will be and if it will be successful. We are hoping it is six weeks to a major league return."

Sabathia is the highest-paid pitcher in Major League Baseball (MLB) history. Currently in his 13th year as a major league pitcher, Sabathia has never had more losses than wins in a season. Sabathia played the first seven and a half seasons of his career with the Cleveland Indians, where he won the 2007 Cy Young Award. He played the second half of the 2008 MLB season with the Milwaukee Brewers, leading them to the Wild Card, their first playoff appearance in 26 years. Sabathia is regarded as one of the most durable pitchers in Major League Baseball, having averaged over 200 innings pitched per season during his career. — *BY*

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George W. Bush Undergoes Partial Knee Replacement Surgery

Former President George W. Bush walked around and up and down a flight of stairs hours after undergoing outpatient knee replacement surgery, according to Bush spokesman Freddy Ford.

The 67-year-old leader had a partial knee replacement surgery at Chicago's Rush University Medical Center on May 24, the Saturday before Memorial Day.

A partial knee replacement is performed whenever knee osteoarthritis (OA) causes knee pain, loss of range of motion, and decreased functional mobility. The OA only affects one part of the knee joint, typically the medial side, so a partial knee replacement is performed rather than a total knee replacement.

The rehab process after a partial total knee replacement involves improving knee range of motion, restoring strength of the quadriceps, hamstrings, and hips, and controlling pain and swelling around your knee. After the incision has healed, scar tissue massage and mobilization can also be performed to improve mobility of the skin and underlying tissues.

Bush stayed at a nearby hotel after the operation and flew home to Dallas on the following Monday afternoon.

After being diagnosed with runner's knee in 2003, Bush became an avid bicyclist. While president he rode his bicycle at Camp David and at his Texas ranch. Now he leads the Warrior 100K, a ride intended to honor wounded veterans of the wars in Iraq and Afghanistan.

Wife Laura Bush and a secret service detail accompanied the former president on his medical trip to Chicago. — *BY*

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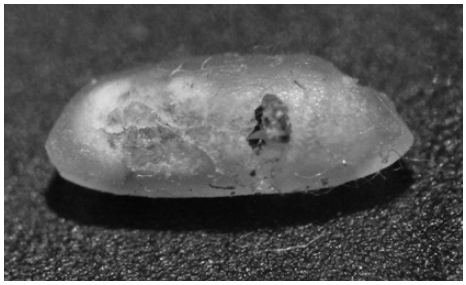
Pacemaker Size of Rice Grain

Ada Poon, Ph.D., an electrical engineer at Stanford University, has invented a way to wirelessly transfer power deep inside the human body. Poon and her team built an electronic device smaller than a grain of rice that acts as a pacemaker. The device can be powered or recharged wirelessly by holding a power source about the size of a credit card above the device, outside the body.



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Reported by Tom Abate for Stanford's School of Electrical Engineering and in the *Proceedings of the National Academy of Sciences,* Poon's discoveries culminate her years of effort to eliminate the bulky batteries and recharging systems that keep medical devices from being more widely used.

"We need to make these devices as small as possible to more easily implant them deep in the body and create new ways to treat illness and alleviate pain," said Poon. According to Abate, Poon's central discovery is an engineering breakthrough that creates a new type of wireless power transfer—using the same power as a cell phone—that can safely penetrate deep inside the body.

Abate explains that the crux of the discovery involves a new way to control electromagnetic waves inside the body.

Before Poon's discovery, there was a clear divide between the two main types of electromagnetic waves, called far-field and near-field waves.

Far-field waves, like those broadcast from radio towers, can travel over long distances. But when they encounter biological tissue, they either reflect off the body harmlessly or get absorbed by the skin as heat. Some current medical devices, like hearing implants, use near-field technology. But they can transfer power only over short distances, limiting their usefulness deep inside the body.

What Poon did was to blend the safety of near-field waves with the reach of far-field waves by taking advantage of a simple fact—waves travel differently when they come into contact with different materials such as air, water or biological tissue. With this principle in mind, Poon designed a power source that generated a special type of near-field wave. She called this new method mid-field wireless transfer.

In the experiment, Poon used her mid-field transfer system to send power directly to tiny medical implants. It is also possible to build tiny batteries into microimplants, and then recharge these batteries wirelessly using the mid-field system. With this method Poon says that she could safely transmit power to tiny implants in organs like the heart or brain—well beyond the range of current near-field systems.

An independent laboratory that tests cell phones found that Poon's system fell well below the danger exposure levels for human safety. She has used it to power a tiny pacemaker in a rabbit and is currently preparing the system for testing in humans. — *BY*

REIMBURSEMENT

96% Medicare Penalty for Readmissions?

Medicare has announced plans to penalize 2,633 hospitals for giving follow-up care to seniors, even if the care was appropriate, according to an online report by *Medical News*. Northwestern Memorial in Chicago, the largest hospital in Illinois, did 1,651 elective hip and knee replacements for Medicare between 2009 and 2012. The hospital faces the possibility of paying 46% of the revenue from those operations as a penalty.

In Philadelphia, Pennsylvania Hospital of the University of Pennsylvania did 1,020 replacements and will pay 57% of that revenue as a penalty. Parkwest Medical Center in Knoxville did 1,079 replacements and will pay a 31% penalty. The Medical Center of the University of California at Davis did 226 replacements and will pay a 27% penalty.

Another example is Froedtert Memorial Lutheran in Milwaukee which did 245 replacements and may pay a 96% penalty. Nationwide, 223 hospitals face penalties which are over a fifth of their revenue from hip and knee replacements.

Hospitals pay these penalties if they readmit more seniors within 30 days after discharge than the national average. The hospitals listed above readmitted 7% to 10% of their patients after hip and knee replacements. The national average is 5%. Medicare released the new rules with data to estimate these penalties on May 15.

According to the *Medical News* writer, hospitals cannot give up this much revenue, and may need a new business model that would reduce their treatment of Medicare patients. The American College of Surgeons warned Medicare last year about "the potential that these hospitals will decrease their care for such patients, thereby creating an access issue." They pointed out that seniors who cannot get hip and knee

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replacements lose the mobility they need to stay healthy.

Medicare charges these penalties one to four years after treatment, even though the readmissions were fully approved by doctors and Medicare at the time of treatment, and were paid for by Medicare.

Doctors Karen Joynt and Ashish Jha of Harvard, writing in the January 23, 2013 issue of the *Journal of the American Medical Association*, found that the penalties fall heaviest on hospitals which serve the neediest patients. They wrote that "large hospitals, teaching hospitals, and safety net hospitals are more likely to receive payment cuts" from readmission penalties. They wrote that readmissions are, "likely related to both case mix (medical complexity) and socioeconomic mix of the patient population." A list of penalties for every hospital, based on Medicare data, is at Globe1234.com. Medicare will take comments on the readmission penalties until June 30. — *BY*

SPINE

SafeWire Receives 510(k) Clearance for Y-Wire 2

SafeWire, LLC, a medical device company focused on the design and development of devices for minimally invasive spine surgery, announced today that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its Y-Wire 2 orthopedic guidewire with additional claims.

The Y-Wire 2 is a patented orthopedic guidewire with a distinctive split tip that is designed to prevent inadvertent advancement of the wire through bone. Upon exiting its delivery mechanism, the Y-Wire 2's distal tips deploy to prevent further advancement.

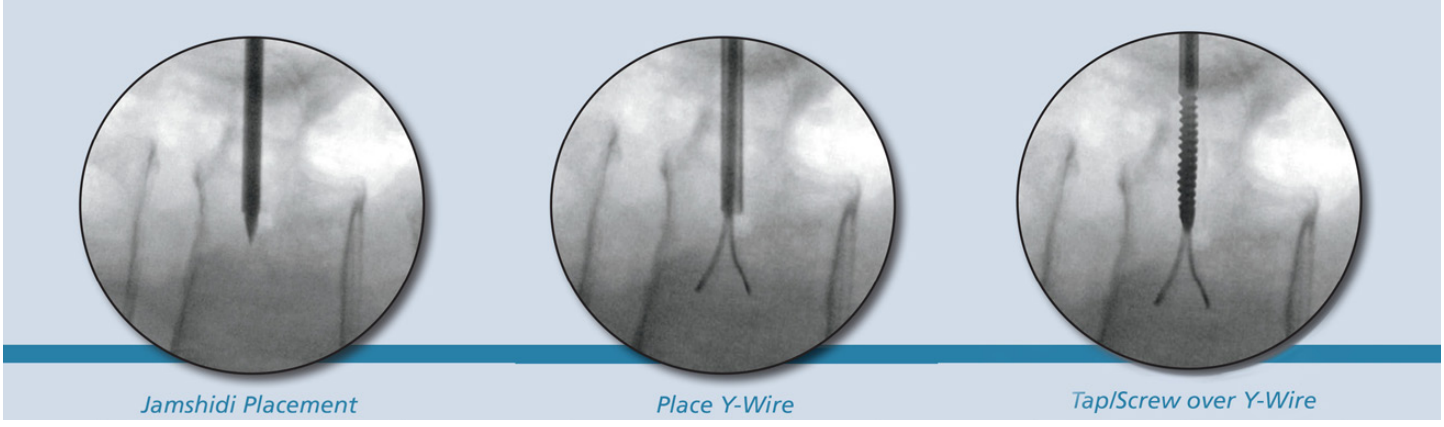
Wyatt Geist, CEO of SafeWire said in the May 30, 2014 news release, "SafeWire is committed to the advancement of minimally invasive instrumentation for spine surgeons and their patients. FDA clearance of the Y-Wire is a significant milestone, and we are excited to provide the surgical community with a guidewire designed to mitigate inadvertent advancement during minimally invasive spinal surgery."

Joseph Zavatsky, M.D., stated, "The Y-Wire 2 provides a solution to an ongoing issue in minimally invasive spine surgery. More importantly, it may also facilitate a return to bicortical fixation in the sacrum. Bicortical fixation in the sacrum has been the standard in open spinal surgery, but its adoption in minimally invasive surgery has been hampered by the issue of guidewire advancement."

The Y-Wire 2 was designed for compatibility with a wide variety of delivery systems such as fluoroscopy, robotics and image guidance making adoption of this innovative technology less disruptive to hospitals with established instrumentation providers.

Asked about the product development phase, Geist told *OTW*, "It was important to be able to differentiate ourselves from all other guidewires."

Asked where he hopes to be in one year with this product, Geist told *OTW*, "It might be best to just say that we will sell over 20,000 Y-Wires in 2014 alone. We will plan for a larger percentage of the market with a deployment of our own cannulation products or potential licensing deals." — *EH*



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