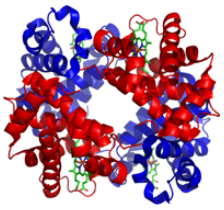
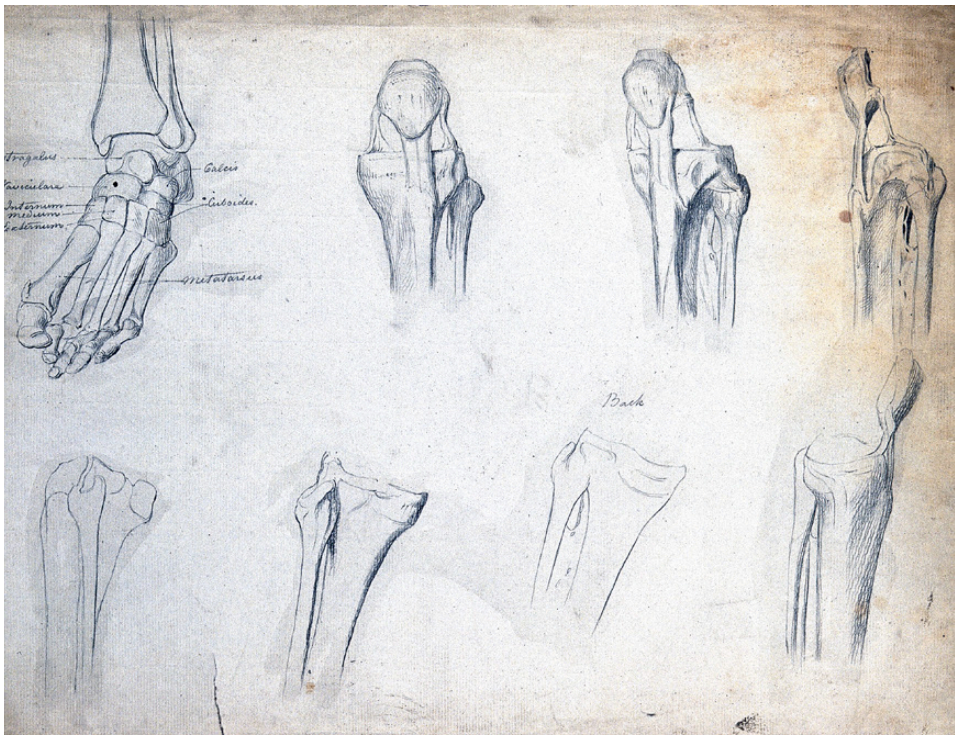
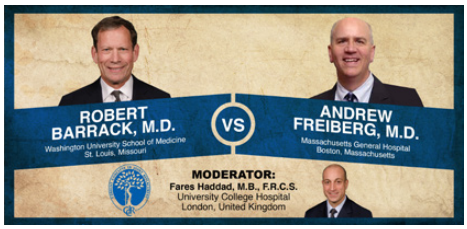
VOLUME 10, ISSUE 36 | NOVEMBER 11, 2014

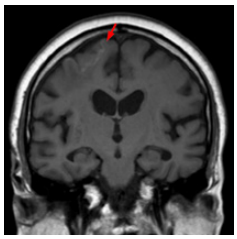
Orthopedics This Week

WEEK IN REVIEW









BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Unemployment hits a six-year low and the major stock indices hit record highs after rising for the third week in a row. Should be a good Christmas this year for all equities. For orthopedic companies, the wind is clearly at their back as demand continues to rise and the number of insured patients grows and grows. Most analysts are updating their models for 2015 and 2016.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	3	Stryker	11.52%	3.70%	Second least expensive equity in orthopedics as measured by P/E, PSR and PEG.
2	1	ConMed	10.51	5.24	Analysts are still forecasting as if the old management was in charge—namely down sales and flat earnings.
3	4	Zimmer	29.12	4.49	New name (Zimmer Biomet) and new senior management team announced. Now comes integration.
4	5	NuVasive	8.01	15.94	Five of the 10 top ortho performers this past month are spine companies. Leader of the group, NUVA, has the best valuation.
5	7	Globus Medical	29.68	8.70	Trading at roughly 5.5x sales, GMED is the most expensive of the companies in the Power Rankings. Doesn't faze buyers.
6	6	Medtronic	28.84	3.61	If any equity should respond to rumors of medical device tax repeal it is MDT. Unless it is Covidien before then.
7	10	Smith & Nephew	19.92	0.53	Analysts are really quite bullish on SNN's sales and earnings this quarter. Consensus is 8.70% sales gain and 22% earnings jump.
8	2	MicroPort	16.53	(3.31)	Sellers re-emerged this past week on no news. Hard to get much visibility on sales and earnings.
9	8	Integra LifeSciences	12.57	(6.31)	Cheapest stock in all orthopedics. And investors are still looking for a reason to buy this Blue Light Special.
10	9	Symmetry Medical	6.55	(5.98)	Weak sales but decently strong earnings. Most buyers staying on the sidelines until things settle down.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc	BAXS	$0.22	$11	83.45%
2	MiMedx Group	MDXG	$10.24	$1,083	43.42%
3	K2M Group Holdings	853	$17.00	$631	21.69%
4	NuVasive	NUVA	$41.75	$1,964	15.94%
5	Globus Medical	GMED	$21.48	$2,542	8.70%
6	LDR Holding Corp.	LDRH	$34.25	$892	7.98%
7	Tornier N.V.	TRNX	$25.50	$1,247	6.52%
8	Bacterin Intl Holdings	BONE	$4.07	$27	5.99%
9	RTI Biologics Inc	RTIX	$5.09	$290	5.82%
10	ConMed	CNMD	$41.77	$1,150	5.24%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Alphatec Holdings	ATEC	$1.39	$136	-13.13%
2	Exactech	EXAC	$21.42	$296	-11.19%
3	Wright Medical	WMGI	$27.95	$1,427	-9.72%
4	TiGenix	TIG.BR	$0.63	$102	-8.90%
5	CryoLife	CRY	$10.06	$281	-7.11%
6	Aurora Spine	ASG	$1.25	$20	-6.68%
7	Orthofix	OFIX	$29.01	$535	-6.39%
8	Integra LifeSciences	IART	$47.05	$1,543	-6.31%
9	Symmetry Medical	SMA	$9.27	$348	-5.98%
10	MicroPort Scientific	853	$0.48	$686	-3.31%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$68.10	$66,937	17.50
2	Johnson & Johnson	JNJ	$108.20	$302,864	18.02
3	Exactech	EXAC	$21.42	$296	18.79
4	Zimmer Holdings	ZMH	$108.19	$18,322	18.88
5	Stryker	SYK	$87.47	$33,092	20.41

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MiMedx Group	MDXG	$10.24	$1,083	1021.04
2	RTI Biologics Inc	RTIX	$5.09	$290	304.35
3	Orthofix	OFIX	$29.01	$535	185.33
4	Symmetry Medical	SMA	$9.27	$348	113.29
5	NuVasive	NUVA	$41.75	$1,964	107.77

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	$10.06	$281	1.15
2	Exactech	EXAC	$21.42	$296	1.25
3	Globus Medical	GMED	$21.48	$2,542	1.74
4	ConMed	CNMD	$41.77	$1,150	1.79
5	Integra LifeSciences	IART	$47.05	$1,543	1.98

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MiMedx Group	MDXG	$10.24	$1,083	68.07
2	RTI Biologics Inc	RTIX	$5.09	$290	20.29
3	Orthofix	OFIX	$29.01	$535	10.07
4	Symmetry Medical	SMA	$9.27	$348	9.44
5	NuVasive	NUVA	$41.75	$1,964	9.43

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Baxano Surgical Inc	BAXS	$0.22	$11	0.54
2	Alphatec Holdings	ATEC	$1.39	$136	0.66
3	Bacterin Intl Holdings	BONE	$4.07	$27	0.80
4	Symmetry Medical	SMA	$9.27	$348	0.87
5	RTI Biologics Inc	RTIX	$5.09	$290	1.15

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.63	$102	17.81
2	MiMedx Group	MDXG	$10.24	$1,083	11.20
3	LDR Holding Corp.	LDRH	$34.25	$892	8.00
4	Globus Medical	GMED	$21.48	$2,542	5.52
5	Wright Medical	WMGI	$27.95	$1,427	5.05

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

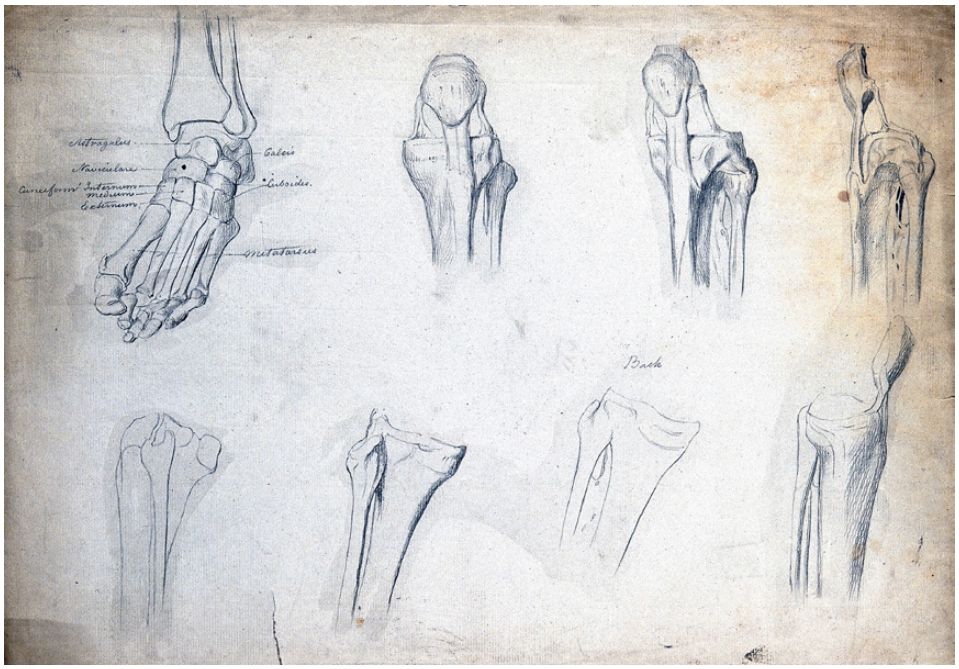
Ortho's Fastest Growing Sector is Extremities

BY ROBIN YOUNG

Surveys come. Surveys go. But this one from RBC Capital Markets stood out for the unalloyed optimism expressed by surgeons in one specific corner of the orthopedics market—Extremities.

Imagine a medical products sector with no pricing pressure, growing surgery backlogs, high single-digit procedure growth rates and rising levels of implant and instrument innovation. Is such a place still available in U.S. healthcare? According to RBC's October 28, 2014 survey of 50 U.S. foot/ankle surgeons, the extremities market has evolved into just such a place.

Here just a few quotes from the survey.



Wikimedia Commons and the Wellcome Trust

Pricing

"Approximately two-thirds of U.S. surgeons said that they have seen no signs of increasing pure implant pricing pressure in forefoot, midfoot and hindfoot implants and in ankle fusion procedures at their hospital/practice over the past 12 months, which makes foot/ankle one of the few orthopedic markets with little to no pricing pressure"

And it gets better.

"Overall surgeons said that pure implant pricing increases for forefoot, midfoot and hindfoot implants were approximately 1-2% in 2014 and surgeons expect similar 1-3% y/y [year-over-year] increases in 2015 depending on the type of procedure. Additionally, we believe that mix benefits from continued penetration of higher-priced implants (i.e., hammertoe implants and total ankles) are adding to the overall U.S. foot/ankle market growth. This gives us confidence that the U.S. foot/ankle market can continue growing 10%+ y/y in 2015."

Growing Backlogs

"Surgeons expect their foot/ankle backlog to continue growing and anticipate that their backlog 6 and 12 months from now will be 4.3 weeks and 4.4 weeks, respectively. For 2015, U.S. surgeons point to expectations for high-single-digit y/y volume growth in the U.S. foot/ankle market."

Innovation

"Surgeons expect total ankle penetration to increase by approximately 4-5 points annually over the next two years, reaching about 39% penetration by 2016. Said a different way, about 90-95% of U.S. surgeons say that penetration of total ankles will either stay the same or increase in their practice over the next one and two years.

"Stryker/Small Bone Innovations' [SBi} S.T.A.R. total ankle was ranked as the highest quality total ankle replacement system, followed by Wright Medical's [WMGI] INBONE and INFINITY listed as the #2 and #3 highest ranking total ankles. U.S. surgeons appear to be comfortable with the S.T.A.R. total ankle.

"WMGI is in the process of launching its much anticipated INFINITY total ankle, which management claims is: 1) more bone conserving; 2) easier to implant; and 3) more durable long-term relative to other total ankles on the market."

The Survey

The Royal Bank of Canada is the largest bank in Canada serving 18 million customers worldwide. It also runs one of the most respected research groups on Wall Street. For an inside look at how respected RBC Capital Markets is on Wall Street, read Michael Lewis's amazing book *Flash Boys* about the rise of high-frequency trading in the U.S. equity markets. There was plenty of bad behavior by many big name Wall Street firms documented in *Flash Boys*—except by RBC. It was, in fact an RBC employee who uncovered much of the shenanigans surrounding high frequency trading.

RBC is also, incidentally, the largest company in Canada.

The surgeon extremity survey was organized by Glenn Novarro, Managing Director at RBC Capital Markets and one of the more senior healthcare analysts on Wall Street. Formerly of Bank of America and Credit Suisse, Novarro is known for his thorough analysis and nearly 80% accuracy rating.

The three authors of the report were Glenn Novarro, Brandon Henry CFA (Associate Analyst) and Julia Kufman (Associate).

The RBC Extremity surgeon survey was inaugurated in 2010 and has steadily documented the rising level of surgeon optimism in this market. To a large extent, that optimism has occurred under the radar but has come from two easily recognized factors: innovation and a comparatively favorable reimbursement environment.

Today's Extremity Market

According to Deaton Consulting the U.S. extremity implant market, which grew about 10% y/y in 2013, is a 152.8 thousand procedure market. *(See table 1 on page 6.)*

Shoulder implants represent the largest portion by far of the extremity implant market. It is also, by far, its fastest grower posting up a whopping 16% change between 2012 and 2013.

But the foot/ankle market, riding the success of SBi's S.T.A.R ankle and with a handful of new total ankle and hammertoe products streaming into the market, is starting to accelerate.

Twelve companies supply approximately 98% of all foot/ankle implants and instruments. Those companies and their respective market shares—as estimated by RBC—are: *(See table 2 of page 6.)*

The merger of Wright with Tornier will mean that five companies (Arthrex, DePuy/Synthes, Smith & Nephew,

Extremity Procedures Market			
Procedures in 000s	**2012**	**2013**	**Annual Change**
Shoulders	81.2	93.9	16%
Digit	45.4	45.9	1%
Elbow	6.3	6.5	3%
Ankle	4.3	4.6	7%
Wrist	1.9	1.9	0%
All Extremities	139.1	152.8	10%

Table 1: Courtesy of Deaton Consulting and RBC Capital Markets

Market Share in Foot/Ankle Procedure Market		
Manufacturer	**2014 Expected**	**Next 12 Months**
Acumed	4.2%	3.8%
Arthrex	13.0%	13.3%
Biomet	3.1%	2.9%
DePuy/Synthes	23.4%	22.7%
Exactech	0.8%	0.8%
Integra LifeSciences	3.8%	3.9%
Orthofix	3.5%	3.9%
Smith & Nephew	13.0%	12.3%
Stryker / Small Bone Innov	12.3%	13.8%
Tornier / Orthohelix	3.0%	3.3%
Wright Medical	12.9%	11.6%
Zimmer / Normed	5.0%	5.4%
Others	1.9%	2.4%
TOTAL Foot /Ankle	100%	100%

Table 2: Courtesy of RBC Capital Markets Extremity Surgeon Survey

Stryker/SBi and Wright Medical) will have approximately 78% of the foot/ankle market.

RBC's survey of active foot/ankle surgeons reports that three companies, Arthrex, DePuy/Synthes and Stryker/SBi have increased their market shares the most over the last 12 months.

Said Novarro of the results: "We were a bit surprised to see JNJ/Synthes once again at the top of this list although the acquisition of Synthes by JNJ has increased the company's presence in the foot/ankle part of the trauma space. Separately, we were not surprised to see SYK/SBi toward the top of this list. Recall that SYK began to build a dedicated foot/ankle sales force over two years ago to call on podiatrists post the completion of the privately held Memometal in early July 2011. This investment has obviously been paying off for the company as SYK's foot/ankle business has been growing about 30%+ y/y. Additionally in late June 2014, SYK announced that it was acquiring Small Bone Innovations, a leader in the total ankle space with its S.T.A.R. total ankle."

And, not surprisingly, the surgeons also selected the same companies (Arthrex, DePuy/Synthes, SYK/SBi along with Wright Medical) as the companies with the best products and training programs for physicians. Isn't it always the case? The best training combined with top products equals growing market share.

Again, to quote directly from Novarro's survey: "Interestingly, the top three manufacturers that have increased their foot/ankle presence most in hospitals over the past 12 months were also listed as the top manufacturers that have the best product/procedure training for foot and ankle procedures. More specifically, about 20% of U.S. surgeons listed SYK/SBi as the manufacturer with the best product/procedure training, followed by DePuy/Synthes at about 18% and Arthrex at about 16%. Wright Medical was #4 on the list as about 14% of surgeons said that WMGI provides the best product/procedure training for foot/ankle procedures."

The Rise of Total Ankle

Give the V-Bros (Tony, Mark and John) credit. After their amazing success pioneering motion preservation in spine, they turned their attention to ankle replacement. As before, the brothers accurately spotted the opportunity very early on and then went through the grueling effort to raise the capital, design the implants and instruments and then run the regulatory and reimbursement gauntlet. As in spine motion preservation where the V-Bros implant (Pro-Disc) is the unquestioned market leader, in foot/ankle the S.T.A.R. ankle is market leader and is inspiring an entirely new generation of innovative ankle replacement products.

The Scandinavian Total Ankle Replacement (S.T.A.R) is the only PMA

approved mobile bearing total ankle on the U.S. market. It has been on the market for five years. It has near universal reimbursement and U.S. surgeons are comfortable, generally, with it. In the RBC survey, surgeons characterized the S.T.A.R. as being easy to use with well-engineered instrumentation.

But competition has heated up—all to the benefit of both patients and physicians. Wright Medical's Inbone and the new INFINITY total ankle's received top marks in the RBC survey.

Novarro is forecasting that the U.S. total ankle market will grow at a 20%+ compound annual rate over the next five years arriving to an annual $325 million to $350 million revenue rate by 2018.

Here Comes Hammertoe

Finally, RBC's survey documented that heavy marketing of new hammertoe implants is quickly making this small corner of orthopedics a hot area. Fundamentally, the innovation here is to use an implant instead of a K-Wire. Said Novarro: "U.S. surgeons have increased their hammertoe implant penetration from about 19% in 2012 to 28% currently. Additionally, about 85-90% of U.S. surgeons say that their hammertoe implant penetration will either stay the same or increase over the next one or two years."

About 1.2 million patients present annually for hammertoe and roughly half (600,000) receive treatment. It's a small market. Novarro estimates it at about $75 million to $95 million in annual sales. However, if $500 hammertoe implants catch on as replacements for K-Wires, then the market could blossom into a $300 million segment. The big players are Arthrosurface, Biomedical Enterprises, Integra LifeSciences, Orthopro, Tornier, Wright Medical and Stryker.

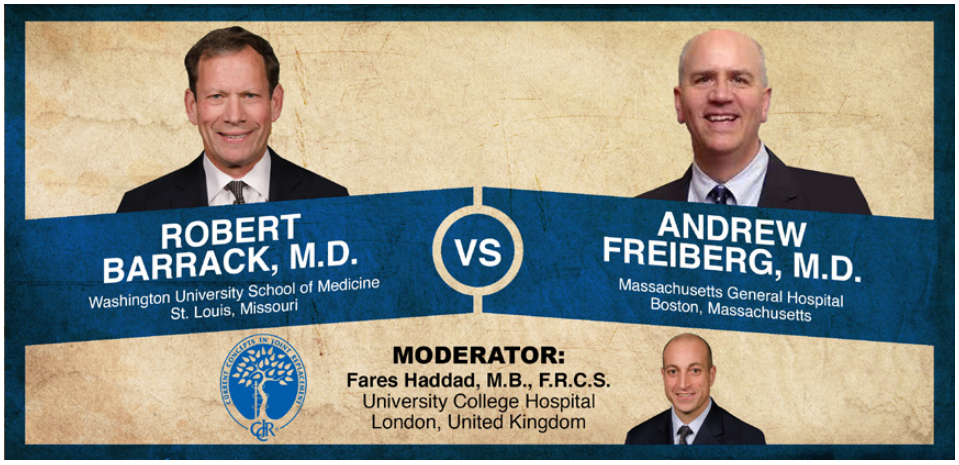
Thanks

Many thanks to the team at RBC for allowing us to cherry pick their outstanding surgeon survey. For more information, please contact the RBC team at glenn.novarro@rbc.com. ♦

Barrack v. Freiberg Over Patella Resurfacing

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

This week's Orthopaedic Crossfire® debate was part of a landmark event, the first Brazilian CCJR meeting. The event, which took place in September 2014, was held in Iguassu Falls. The topic was, "Patella Resurfacing: Rarely, if Ever, Necessary" For the proposition is Robert Barrack, M.D. of Washington University School of Medicine in St. Louis. Against the proposition is Andrew Freiberg, M.D. of Massachusetts General Hospital. Moderating is Fares Haddad, M.B., F.R.C.S. of the University College Hospital in London, United Kingdom.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Barrack: "If patella resurfacing is not done by an expert hand then you find over resection, under resection, an oblique resection, or a disruption in the blood supply. There are a lot of negative sequelae of resurfacing, and these are very underreported. The question is, 'How often do these occur?'"

"Merrill Ritter's group always resurfaces the patella. They report 4.2% failures in less than three years and very few were revised (*CORR* 2001). But this was an average of only 5 years so what's going to happen to these at 10 years? We looked at the question of which presents more clinical problems after knee replacement, resurfacing the patella or not resurfacing the patella. St. Louis is a city where about 50% of the patellas are resurfaced and half are not. We maintained records over a four-year period on all patients sent to us who were complaining of anterior knee pain after a total knee replacement [TKR]. During that timeframe we had 47 cases, of which three-fourths had actually been resurfaced. So in a city where half the patellas are resurfaced and half are not, three-fourths of patients were coming in complaining of anterior knee pain with a resurfaced patella."

"Of those treated surgically, the rate of reoperations was about the same as those treated non-surgically, but there were 4x as many resurfaced patellas that were re-operated on. We saw a lot of early loosening and patella revision; fragmented patellas were also common...loose component that you remove and hope that you maintain continuity of the extensor mechanism. We also saw avascular necrosis [AVN] of the patella; there is no treatment for this. We also saw a lot of late stress fractures. And lateral facet pain was very common when you get oblique resurfacing on an unbalanced patella. Oblique resurfacing was the second most common phenomenon we saw. In one operative case the patella was thick enough that we got some symptom relief."

"We found a 3x higher incidence of problems from resurfacing the patella. The severities of the complications were substantially higher and treatment options were more limited. If you look at our randomized clinical trial, by 10 years the resurfaced patellas had declined more than the unresurfaced. The most compelling study is a randomized trial from Oxford that included 1,700 knees. They found no difference in any score. In a meta-analysis (He et al., *The Knee*, 2011) the reoperation rate was lower for resurfacing, but reoperation isn't reliable because subsequent resurfacing is undertaken because it's perceived as an easy bailout."

"The advantages to not resurfacing the patella are that it's faster, cheaper, there are lower risks of major complications, and you have more options if symptoms do persist. The fact is that a small percentage of patients in each group will be symptomatic. But which retains more options and which has more complications? So the major determinant of a clinical result in the presence of anterior knee pain after total knee is a surgical technique and component design…not whether or not the patella is resurfaced. I do occasionally resurface the patella if it's deformed and not tracking. But for the vast majority it's simply not necessary and counterproductive."

Dr. Freiberg: "Robert, now I know why so many people limp in St. Louis. I believe that patella resurfacing should be done in virtually all patients. The reason is because I don't want to re-operate on my patients. Robert told you that patients do well whether their patella is resurfaced or not. And although Robert showed a lot of cases of patella failure, those were in older designs and older techniques. I think with current designs and techniques patella resurfacing can be done easily, quickly, and predictably."

"The initial failure rate of patella resurfacing in the 1980s was quite high. The issues were: thin poly, metal backing, and not understanding how to do the technique. It represented a large portion of knee revisions. If we look at the literature, at our experience, and our practices today, less than 3% of revision total knees are for failed patellas."

"Patella femoral complications are less frequent due to improvements in prosthetic design and surgical technique. Resurfacing patients have less pain, the procedure is easy, it's not that expensive, adds only about 5-10 minutes to the procedure, and result in lower revision rates. Looking at the unresurfaced groups, about the only thing you can find in the literature is perhaps a decrease in patella fracture at 15 years."

"A meta analysis of 18 Level 1 randomized clinical trials representing 7,000 knee replacements found that the reoperation rate was higher in the unresurfaced patella group, as was anterior knee pain (Pavlou et al., *JBJS*, 2011). A forest plot shows that patella resurfacing reduces the incidence of reoperation; the risk of revision was reduced by 50% using patella resurfacing. Five trials favored resurfacing; only one trial favored no resurfacing. In seven trials there was no difference. While the forest plot was not statistically significant, there is a trend favoring resurfacing with respect to anterior knee pain."

"Midterm data from the Australian registry (with almost 135,000 knees), shows revision for any reason was reduced 25% by patella resurfacing. Revision for patella pain was 17% in the unresurfaced group versus 1% in the resurfaced group. For patella-only revisions, 29% for unresurfaced versus 6% in the resurfaced group. Long term registry data from Norway (representing about 11,000 knees) shows that the risk of revision was reduced by 16% in the resurfacing group. Regarding knee pain, patella resurfacing patients had a remarkably lower revision rate."

"I resurface the patella because I don't want my patients to be in pain after

TKR. I only want to operate on my patients once."

Moderator Haddad: "Robert?"

Dr. Barrack: "I'd say that the registry data is difficult to interpret, and in most of the countries that you reviewed the patella is not resurfaced in a high percentage of cases. We selectively choose registries…you quote registries like Sweden where they cement all their total hips. We don't cement any of our total hips. The problem with registry data is that it's pooled. Clearly, there are a number of designs that are not designed for an unresurfaced patella. There are even symmetric designs that don't have 'lefts' and 'rights.'"

"So if you only include designs that are reasonable for a unresurfaced patella, there are several designs in the registries that perform better, have lower revision rates. If you use a component that's designed for an unresurfaced patella rather than pooling all of the data then it's really not relevant…and you will conclude that you can easily perform a total knee without patella resurfacing and get equal or better results."

Moderator Haddad: "Andy, if we split your data into patella friendly and non-patella friendly total knees, do you have a feel for that?"

Dr. Freiberg: "It's difficult to look at a design…"

Dr. Barrack: "It's not difficult at all because the registries stratify by design, and there are a number of designs that perform as well or better with an unresurfaced patella…so just use one of those components and you'll do fine."

Dr. Freiberg: "You'll have to let me finish my sentence, Robert. I think we can look at the type and design of the actual implant, but I think the characteristics that make an implant patella friendly are a complex thing to talk about. My point with the registry data is that for reoperation it is as clear as it's going to get. You can look at pain and function, but reoperation—which is higher in the unresurfaced group—pushes us toward doing patella resurfacing."

Dr. Barrack: "That's not a logical conclusion from the registry data because if you have a procedure that is perceived as a possibility, clearly the reoperation rate is higher. And a high percentage of the reoperations are because there's a perception that you can do something else. When you resurface a patella you really can't do anything else. Reoperation is not a reasonable endpoint for that reason. The other problem is that when you resurface a patella and you have fragmentation, AVN, or you just remove the component that's much less likely to be captured by the registry. So

you must be more specific about quoting registry data."

Moderator Haddad: "The tough one is the patient with anterior knee pain after a TKR where the patella is not resurfaced. Who should go on to have an operation and who shouldn't?"

Dr. Barrack: "It's more frequent for us to have patients referred with anterior knee pain with a resurfaced patella. The problem is that once you have a resurfaced patella then you have fewer options. If you're going to resurface the patella in 100 patients to avoid the two or three that may have some problem, you're exposing a lot of patients to an unnecessary procedure. For the handful that do have a problem, you have many options as to where you place the component."

Dr. Freiberg: "The results of patients who have patella resurfacing are inferior if they had not had it done the first time. Also, the legal issues around not resurfacing are particularly difficult in TKR. Do you do partial knee replacement, Robert?"

Dr. Barrack: "No, I do a TKR without patella resurfacing. It's fairly standard in our community and our patients do as well or better than they do in Boston."

Question from audience: "You really need skills to resurface the patella because it's a third procedure. You're doing the femur, the tibia, and then this third procedure."

Dr. Barrack: "Insightful point. The problem is that it's the highest volume procedure in the U.S. and this occurs at the very end of a case and it's done quickly. We see more complications from that part of the procedure than any other."

Dr. Freiberg: "I'd suggest that a capable knee surgeon could make one extra flat cut."

Moderator Haddad: "Thank you, gentlemen." ♦

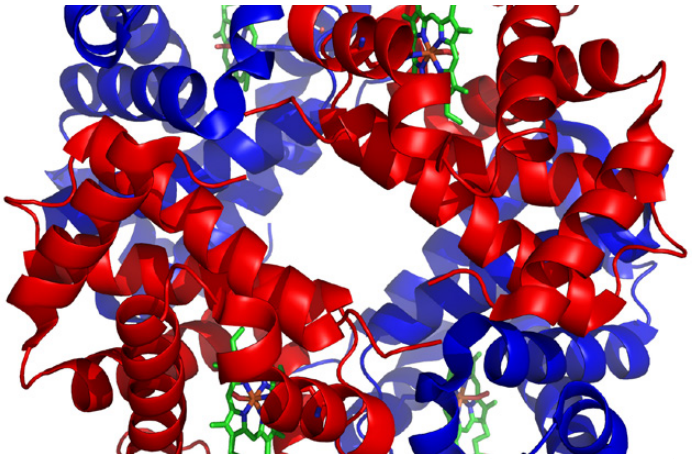
Please visit www.CCJR.com to register for the 2014 CCJR Winter Meeting, December 10 – 13 in Orlando, Florida.

Metal/Plastic Generated Metal Ions Culprit in Unexplained Post-Op Pain // Pre-op Hemoglobin Guards Against Infection?! // Tibial Tunnel CAN be Done Safely in Anterior Fashion

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

Unexplained Pain May Be Elevated Serum Metal Levels From Metal/Plastic!! Question: What presents like a failed metal/metal implant, but is actually metal/plastic? Craig Della Valle, M.D., wanted to know. Dr. Della Valle, an orthopedic surgeon at Midwest Orthopaedics at Rush and associate professor at Rush University Medical Center in Chicago, tells *OTW,* "My colleagues and I began to see a spate of patients with pain that we couldn't explain. As we evaluated them we figured out that the problem was a corrosion reaction between the modular head and stem. We figured that our colleagues around the country must be getting these cases as well…and that most of them probably didn't know what they were seeing."

"These patients present like cases of failed metal/metal, but they have a metal/plastic construct. A couple of years ago we reported on ten cases and then recommended that these patients be treated with a ceramic femoral head and a titanium taper sleeve adapter; we thought that removing the cobalt from the metal head would solve the problem. We have now treated 31 patients using this protocol, namely, changing them from a cobalt chromium head to a ceramic head with a titanium taper sleeve adapter. We had two recurrences and both were early in our experience where we used a new cobalt chrome head instead of ceramic one. The balance of the patients have shown not only that they are doing well clinically, but that they have reductions in their serum metal levels to <1 part per billion, which is what we expect for a well functioning metal on poly bearing."



Wikimedia commons and Richard Wheeler

Those at Rush arguably have the most experience with such cases. Thus, says Dr. Della Valle, "You should look for patients who present with postoperative pain where you have ruled out infection and loosening and you are unsure of the diagnosis. In general, we recommend getting the serum metal levels checked. Most surgeons who see someone with a metal/plastic construct are not going to think that it would make sense to get serum metal levels but that's exactly what you need to do. When it comes to interpretation, things get tricky. Guidelines from the Medicines and Healthcare Products Regulatory Agency in England indicate that serum metal levels should be less than 7 parts per billion—and that number is stuck in everyone's minds from metal on metal bearings."

"Our work shows that in metal/poly bearings it should be below 1 part per billion…above that is abnormal. If a patient has metal/poly serum with a cobalt level of 2 a surgeon may think, 'Well, it's only 2.' In fact, that is highly abnormal! The third piece of the puzzle is that cobalt will be elevated over chromium. If the cobalt level is 7 and the chromium 0.2 then what you are seeing is probably a corrosion reaction. I would say that without even seeing the patient. We recommend getting a metal artifact reduction sequence MRI to confirm the diagnosis. You may find that the MRI shows an adverse local tissue reaction similar to what you would expect from a metal on metal bearing that has failed."

Pre-operative Hemoglobin Protects Against Infection in TJA Accuracy is everything in research. To that end, researchers from The Rothman Institute set out to determine risk factors for surgical site infection after total

joint arthroplasty (TJA) using the most reliable data source possible: National Healthcare Safety Network (NHSN) surveillance program of the Centers for Disease Control and Prevention (CDC). Mohammad Reza Rasouli, M.D., a former research fellow at Rothman who is now a surgery intern at Mercy Health System, tells *OTW*, "While surgical site infection is rare after TJA, it is particularly devastating. We set out to identify patient related risk factors for surgical site infection following primary and revision TJA. We used our database, as well as data reported from our institute through the CDC's NHSN surveillance program."

"The CDC data is considered to be more reliable because infections can be captured through multiple paths in addition to infection surveillance staff. For example, even if someone is admitted to another hospital for surgical site infection a year later than the index TJA that gets captured. This is much more than a retrospective chart review."

"We reviewed more than 6,100 hip and knee surgeries from 2010-2012(either primary or revision cases). We found that the rate of infection was low at 1.3% (80 cases), which is similar to other studies. The highest rate of surgical site infection was in revision total knee arthroplasty, followed by revision total hip arthroplasty. Based on suggestion of the biostatistician we worked with, only few variables that were most likely to affect the rate of infection (age, gender, type of surgery (revision or primary), comorbidities, and preoperative hemoglobin level) were selected. A higher Charlson Comorbidity Index was predictive of surgical site infection, as was the male sex.

In the one year that we followed cases we found that the higher the number of comorbidities the higher the rate of infection. The most interesting finding was that a higher pre-operative hemoglobin level was protective against infection. This is promising, because it is a modifiable risk factor."

Tibial Tunnel Placement: A Bit More Clarity In ACL (anterior cruciate ligament) reconstruction, should you place the tibial tunnel posteriorly or anteriorly? If anteriorly, how far? Who knows? Mark D. Miller, M.D., the S. Ward Casscells Professor of Orthopaedic Surgery at the University of Virginia, is working on some answers. He tells *OTW*, "While a lot of research has focused on femoral tunnel placement, not much has been published on tibial tunnel placement in anterior cruciate ligament reconstructions. In fact, one recent multi-center study suggested that tibial tunnel placement is acceptable anywhere between 30% and 55% of the way across the tibia. Last week

we completed a cadaveric study looking at impingement with anterior tibial tunnel placement. In the old (trans-tibial) technique for ACL reconstruction, we drilled the femoral tunnel through the tibial tunnel; this usually resulted in more vertical femoral tunnel placement. The problem was that this also often led to roof impingement, especially with anterior tibial tunnels. We decided to look at independent femoral tunnel drilling to see if it also leads to this problem."

"Everybody was placing the tibial tunnel posteriorly in order to avoid roof impingement, but it may not be the best place because studies (although limited) suggest that anterior placement is both biomechanically and clinically superior. It turns out that with this independent femoral drilling you get less roof impingement…so you CAN put it more anteriorly."

Dr. Steve Howell looked at two dimensional models and he advocated the use of hyper-extension radiographs to determine whether the tibial tunnel impinged on the roof of the femur. We utilized 3D models and drilled more anteriorly and then passed a Goretex graft into the tunnels so we could look for impingement on 3D CT scans. We compared trans-tibial and independent tunnel drilling. The 3D model verified that there was less impingement with independent tunnel drilling, and that we can now safely drill tunnels more anteriorly."

"The next phase will be a clinical study to be carried out at the University of Virginia and the University of Kentucky where we will randomize patients into anterior versus posterior tibial tunnel placement. We will drill two tibial guide pins before drilling the tibial tunnel—one will be less than 35% of the way across the tibial plateau and the other will be greater 35% of the way across. After guide pin drilling, we will open a randomized envelope and determine which pin to drill over for the tibial tunnel. We will attempt to get at least 100 subjects in each group."

"There are some who advocate for more posterior tibial tunnel placement…but there are several biomechanical studies and one nonrandomized clinical study that found that anterior tibial tunnel placement is superior. Our overarching goal is to provide better guidelines for surgeons. We may end up at a point where the best approach is to use intraoperative fluoroscopy to verify tunnel placement before drilling." ♦

COMPANY

RTI Rebuts British Tabloid Charges of Illegal Human Parts Trading

It's been a tough few weeks for RTI Surgical, Inc.

First, in October the FDA challenged the company over the definition of "minimal manipulation" and then the British-based tabloid the *Mail on Sunday* published a story on Sunday, November 2, 2014 that alleged that RTI was linked to "the illegal trade in human remains in Eastern Europe."

"Inaccurate and Misleading"

The company quickly issued a rebuttal on November 3 saying the article was "inaccurate and misleading."

The article said the research done by the Royal British Legion Centre for Blast Injury Studies (CBIS) at the Imperial College in London relies on anatomical material from RTI.

On October 30, 2014, RTI said it advised the reporters of the article that it does work from time to time with scientists and researchers at Imperial College, but the company does not send tissue to the Royal British Legion Blast Injuries Centre. "The research mentioned in the *Mail on Sunday* article is actually related to tissues of xenograft origin, not human—therefore the assertion that Imperial College is sourcing 'body parts' and 'human tendons' from RTI for this study is inaccurate."

"RTI does not supply to anyone, nor has the company ever supplied, anatomic material for research such as may

Wikipedia and Mail on Sunday/Associated Newspapers

be sourced by the CBIS. To include the company in the story about sourcing human anatomical material for the CBIS at all is completely inappropriate."

In what is reminiscent of the "Have you stopped beating your wife?" question, the company was forced to say that is has "never participated in illegal trade of human remains."

The company is a leading global surgical implant company providing surgeons with safe biologic, metal and synthetic implants. RTI is accredited in the U.S. by the American Association of Tissue Banks and is a member of AdvaMed.

The *Mail on Sunday* article also said that RTI was "sourcing tissue from morgues in Ukraine where documents relating to the deceased were forged."

That statement, according to the company, is inaccurate. "Much of the reporting that the *Mail on Sunday* journalists was referencing was from highly sensational and misleading articles from 2012. One of the main sources of those articles has recently been adjudicated to be a misleading representation and therefore unlawful by the German courts. Additionally, allegations that resulted from previous sensational media stories were investigated and monitored by the relevant authorities, including the Ukraine government, the German Health Authorities and the U.S. FDA. None of these allegations ever proved to be accurate."

"RTI is very proud of the work we do, and we hold ourselves to a higher standard for our donor families, our surgeons and their patients. We take these misrepresentations of our company very seriously. We have requested a retraction from the *Mail on Sunday*, and we are exploring all legal options open to us. This sort of reporting is not only unfair to our company, but also to the surgeons and patients who receive our implants as well as the donor families who have generously given the gift of tissue donation to help others," concluded the company statement.

Royal British Legion Deplores Accusations

The Royal British Legion issued its own statement saying it:

> "deplores the *Mail on Sunday*'s cynical attempt to discredit our funding of vital scientific research aimed at improving outcomes for British Armed Forces personnel attacked by explosive devices. The research conducted at The Royal British Legion Centre for Blast Injury Studies at Imperial College London will create world-leading breakthroughs in the prevention, mitigation and responses to explosive injuries.
>
> By necessity, a small portion of this research involves human tissues which are ethically, responsibly, and consensually sourced from legitimate suppliers.
>
> For the *Mail on Sunday* to term this as a 'macabre trade in human legs and feet' is sensational, false, and deeply offensive. We condemn its report and believe that the British

public will support this necessary and life-altering research."

The *Mail on Sunday*

The *Mail on Sunday* is a British conservative newspaper, published in a tabloid format. First published in 1982 by Lord Rothermere, it became Britain's biggest-selling Sunday newspaper following the closing of News of the World in July 2011. — *WE*

Sports Medicine Firms Merge

Breg, Inc. of Carlsbad, California and United Orthopedic Group, Inc. (UOG) of Plano, Texas, have merged. The merger creates what the two firms define as a "leading U.S. provider of sports medicine, rehabilitative orthopedic products and services." The president of Breg, Brad Lee, will be president of the newly combined company.

Breg provides sports medicine products and services, pioneering in cold therapy and innovative bracing. United Orthopedic Group's manufacturing subsidiaries produce non-invasive orthotic rehabilitation products worldwide. The merged firm will offer what its leaders describe as one of the industry's most comprehensive suites of products and services to support orthopedic providers who work at preventing and rehabilitating orthopedic injuries.

The new company's combined product portfolio will feature four major product brands of orthopedic braces, cold therapy devices and deep vein thrombosis (DVT) prophylaxis products called Breg, Bledsoe Brace Systems, Hope Orthopedics and Cothera. Customers will have access to an expanded menu of services to support the operations of their orthopedic practices with the addition of Viscent LLC, a UOG company specializing in billing.

"This merger brings together two leaders who are highly regarded for their patient-centric product design and commitment to serving customers from every angle," said Lee. "As one company, Breg and UOG offer a unique portfolio of innovative, world-class quality products and services that meet most every need of orthopedic providers and their patients. Together we have the opportunity to shape new frontiers in orthopedic care."

In the October 15 press release, the leaders of the two companies note that their "merger comes as demand for rehabilitative products is growing, driven by the aging U.S. population, increasing prevalence of chronic physical ailments and the health care industry's focus on containing costs through non-surgical treatments. With nearly 60 years of combined experience in developing and manufacturing bracing and cold therapy products, the leaders of the two companies plan to leverage their research and development capabilities to develop new devices in collaboration with orthopedic providers."

"I am very pleased to have completed this merger with Breg," said Gary Henley, chief executive officer, UOG. "The combination of our design expertise and operational capabilities puts the company in a much stronger position to support customers with achieving their goals for improving patient outcomes and enhancing the overall patient experience."

Henley will be part of the executive steering committee that will lead the integration of Breg and UOG. Together, the merged company will employ approximately 1,000 people and operate in 47 countries. UOG will operate as a wholly-owned subsidiary of Breg and the combined company will be headquartered in Carlsbad, California. — *BY*

Logos courtesy of United Orthopedic Group, Inc. and Breg, Inc.

New Zimmer Biomet to be Headed by Dvorak and the 12 Disciples

Logos courtesy of Zimmer and Biomet

Meet the new Zimmer Biomet and its leaders.

Zimmer Holdings, Inc. is feeling so confident of regulatory approval of its merger with Biomet, Inc. that the company announced what the combined company will be called after the merger is completed.

On October 30, 2014, the company also announced the future executive leadership team and organizational structure to be led by current Zimmer President and CEO Dave Dvorak. A new brand will be rolled out after the merger. There was no mention of current Biomet CEO Jeff Binder.

Dvorak and the Twelve Chiefs

The executive leadership team of the new Zimmer Biomet will comprise 12 executives reporting directly to Dvorak, and will be organized around three business units, three geographic regions and six functional areas.

Biomet gets five of the positions, including: Spine, Hips/Knees, Americas, Global Logistics and CFO.

Business Units and Leadership

- **Adam R. Johnson**, Group President, with responsibility for the Spine, Microfixation, Bone Healing and Dental businesses. Johnson has served in leadership roles at **Biomet** for 12 years. Johnson currently leads Biomet's Spine, Microfixation and Bone Healing Division.
- **David A. Nolan**, Group President, with responsibility for the Sports Medicine, Extremities, Trauma, Biologics and Surgical businesses. Nolan has more than 20 years of experience in commercial leadership roles at Biomet and Zimmer. Nolan currently leads **Zimmer's** Advanced Solutions portfolio.
- **Daniel E. Williamson**, Group President, with responsibility for

the Knee, Hip and Bone Cement businesses. Williamson has served in senior leadership roles at Biomet for 24 years. Williamson currently leads **Biomet's** Reconstructive Division.

Geographic Regions and Leadership

- **Stuart G. Kleopfer,** President, Americas. The Americas region will be comprised of the United States, Canada and Latin America. Kleopfer has held the U.S. executive leadership position at Biomet for four years and has been with **Biomet** for 26 years.
- **Katarzyna Mazur-Hofsaess, M.D., Ph.D.,** President, EMEA. The EMEA region will be comprised of Europe, the Middle East and Africa. Mazur-Hofsaess has held an EMEA senior leadership position with **Zimmer** for four years.
- **Sang Yi,** President, Asia Pacific. The Asia Pacific region will be comprised of China, Japan, India, Australia, New Zealand, Korea and Southeast Asia. Yi has held an Asia Pacific senior leadership position with **Zimmer** for two years. Stephen H.L. Ooi, Zimmer President, Asia Pacific, will retire from his current position at the close of the transaction. Ooi will serve in an advisory role following the close.

Functional Areas and Leadership

- **Robin T. Barney**, Senior Vice President, Global Operations and Logistics. Barney has held the Global Operations and Logistics executive leadership position at **Biomet** for seven years.
- **Audrey M. Beckman**, Senior Vice President, Strategic Quality Initiatives. Beckman has served in senior leadership roles at **Zimmer** for 18 years and has been with the company for 28 years.
- **William P. Fisher,** Senior Vice President, Global Human Resources. Fisher has held the Global Human Resources executive leadership position at **Zimmer** for five years.
- **Daniel P. Florin**, Senior Vice President, Chief Financial Officer. Florin has served as the Chief Financial Officer at **Biomet** for seven years. James T. Crines, Zimmer Chief Financial Officer, will retire from his current position at the close of the transaction. Crines will serve in an advisory role following the close.
- **Emmanuel O. Nyakako,** Senior Vice President, Global Quality, Clinical and Regulatory Affairs. Nyakako has held the Global Quality, Clinical and Regulatory Affairs executive leadership position at **Zimmer** for two years.
- **Chad F. Phipps**, Senior Vice President, General Counsel and Secretary. Phipps has held the General Counsel position at **Zimmer** for seven years.

"These announcements mark important milestones that will help advance the effective integration of our two companies upon closing," said Dvorak. "Zimmer and Biomet each have extraordinary talent across all levels, and we are confident that we have put in place a team and organizational structure to drive the combined company into this new chapter. In addition, becoming Zimmer Biomet brings together two well-respected and recognizable names in the industry that share a commitment to new innovations that enhance patient outcomes and improve quality of life."

Dane A. Miller, Ph.D., who co-founded Biomet in 1977, worked for Zimmer before breaking off to become a competitor. Zimmer was founded in Warsaw, Indiana in 1927.

Welcome back, Dr. Miller. — *WE*

Stryker Settles Metal Hip Lawsuits

Stryker Corporation and lawyers representing patients suing the company over its metal-on-metal Rejuvenate Modular-Neck and ABG II Modular-Neck hip implants have settled the claims for approximately $1.4 to $2.3 billion.

Stryker voluntarily conducted a worldwide recall of the products in July 2012.

According to a November 3, 2014 company announcement, Stryker has recorded charges totaling $1.425 billion, representing the low end of the range of probable loss to resolve the lawsuits. "The ultimate cost to entirely resolve these matters will depend on many factors that are difficult to predict and may be materially different than the amounts accrued to date. Further charges to earnings may need to be recorded in the future as additional information related to patient enrollment in the Settlement Program becomes available. It is expected that a majority of the payments under the Settlement Agreement will be made by the end of 2015."

Photo creation by RRY Publications LLC

Payments per Case

The company did not provide an estimate of how many people may have been affected or how many may be compensated. It also did not offer a representation of how much individuals stand to receive. A statement from the lawyers for one plaintiff said that Stryker will provide a base payment of $300,000 to patients who received the implant and underwent revision surgery to remove and replace the devices.

In a June report, MT Services LLC reported that some cases involving revisions of the hips could be worth more than $500,000.

Settlement Program

Eligible U.S. patients are those who had surgery to replace their Stryker hip stems prior to November 3, 2014. According to Stryker, patients eligible for compensation should talk with their attorneys, if they have one, or contact the Settlement Program claims administrator at www.strykermodularhipsettlement.com or 1-855-382-6404. Patients do not need an attorney to participate in the Settlement Program.

Bill Huffnagle, president of Stryker's Reconstructive Division said following the company's voluntary recall and patient support program for recall related care, this settlement provides patients "compensation in a fair, timely and efficient manner."

Metal-on-Metal Saga

Johnson & Johnson's DePuy Synthes division announced a $2.5 billion agreement last November to resolve 8,000 lawsuits over its all-metal ASR implant. A federal jury sided with the company last month in a bellwether lawsuit over its Pinnacle hip metal-on-metal implant.

Barry Meier of the *New York Times* reported on November 3 that all-metal implants once accounted for about one of every three devices used in the estimated 250,000 hip replacement procedures that are performed annually in the U.S. Device companies stopped marketing the devices after evidence emerged several years ago that the metal components could rub together, creating tiny particles of metallic debris that could severely damage a patient's tissue and muscle. Surgeons stopped using the devices in most cases.

Stryker Impact

Bank of America analyst Bob Hopkins said Stryker currently has $4.7 billion in cash and is repatriating $2 billion in cash in 2015. Hopkins says this settlement payout could limit Stryker's strategic flexibility, but Stryker could still find a way to make a larger transaction work if the "strategic rational and return profile were right."

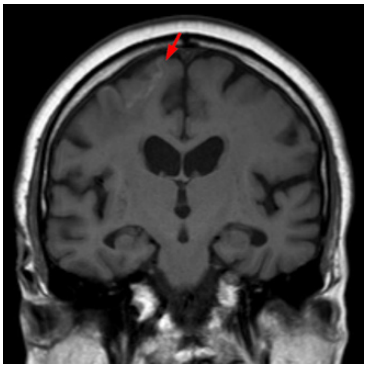
A mediation process in New Jersey where the multicounty and federal multidistrict lawsuits were filed is credited with getting the parties to agree to the settlement. — *WE*

LARGE JOINTS

Arthritis Drugs Causing Strokes, Death?

Researchers in Denmark have found that individuals taking COX-2 inhibitors were 19% more likely to die after stroke than those who did not take these drugs. For this study, published online November 5, 2014 in *Neurology,* researchers studied newer generation COX-2 inhibitors, older generation COX-2 inhibitors, and non-selective nonsteroidal anti-inflammatory drugs (NSAIDS) such as ibuprofen.

"While newer versions of these COX-2 inhibitors drugs have been pulled off shelves, older ones are still frequently prescribed," said study author Morten Schmidt, M.D., of Aarhus University Hospital in Aarhus, Denmark, in the November 4, 2014 news release. "Our study provides further important evidence solidifying the risks of certain arthritic pain relievers and death from stroke."



Wikimedia Commons and Hellerhoff

According to the news release, "The researchers looked at 100,243 people hospitalized for a first stroke in Denmark between 2004 and 2012 and deaths within one month after the stroke. Researchers looked at whether participants were current, former, or non-users of these drugs within two months of the stroke. If they were current users, researchers noted whether people were new users who had just started taking the drug for the first time or were long-term users."

Participants currently using "COX-2 inhibitors were 19% more likely to die after stroke than people who did not take the drugs (10.4% versus 8.7%). New users of the older COX-2 drugs were 42% more likely to die from stroke than those who were not taking the drugs. Those taking etodolac were 53% more likely to die from stroke."

There was no relationship found between the non-selective NSAIDs and increased stroke death. The team also found no connection between chronic use of any of the drugs and stroke mortality.

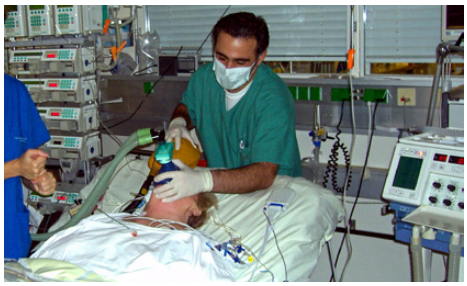
"Our study supports stepping up efforts to make sure people with a higher risk of stroke are not prescribed these medications when other options are available," said Schmidt. — *EH*

Better Outcomes When Anesthesiologists Coordinate TKA Care

Knee replacement patients go home from the hospital sooner, are more satisfied and spend less for their treatment when a physician anesthesiologist coordinates their care. That is the result of a study by researchers at Kaiser Permanente, the nation's largest Health Maintenance Organization.

The researchers collected outcomes data after they had put into practice a system called a "perioperative surgical home (PSH). This consisted of a physician-led system of care that guides the patients through the entire surgical experience.

The study included 546 patients who had knee replacement surgery within one year prior to the implementation



Wikimedia Commons and Mr. Arifnajafov

of the PSH and 518 who had the procedure within one year after the PSH was in place. The national average for length of stay after knee replacement is four days. Forty percent of patients spend time at a skilled nursing facility after leaving the hospital.

In the study, the average length of stay in the hospital for the PSH group was 1.9 days, versus 3.2 days before the PSH was instituted. In the PSH group, 94% of patients went home after being released from the hospital and 6% went to a skilled nursing facility. In the pre-PSH group, 80% of patients went home after being released from the hospital and 20% went to a skilled nursing facility.

"The patient rather than the surgery becomes the center, and the physician anesthesiologist proactively manages all aspects of care, before, during and after the surgery," says Chunyuan Qiu, M.D., lead author and physician anesthesiologist, Kaiser Permanente Baldwin Park Medical Center, Baldwin Park, California. "Before the PSH was implemented, there was no quarterback overseeing the entire process, leading to fragmented, disjointed care that caused delays.".

The 30-day readmission rate was low in both groups. In the pre-PHS group doctors readmitted 1.2% to the hospital while .9% of the PSH group were readmitted. Kaiser Permanente officials estimate that the reduced length of stay in the hospital and skilled nursing facility for all patients saved $1.4 million. — *BY*

Obesity Is Big Complication for TKA

Orthopedic surgeon William M. Mihalko, M.D., Ph.D., of Campbell Clinic Orthopaedics in Memphis, Tennessee, lays it on the line. "Obesity," he says, can have a significant impact on a patient's outcome from elective orthopaedic surgery." He co-authored "Obesity, Orthopaedics and Outcomes," a study published in the *Journal of the American Academy of Orthopaedic Surgeons* in which he noted that even though patients with obesity face higher surgical complication rates, orthopedic procedures can help minimize pain and improve bone and joint function.

That is the good news. The bad news is that osteoarthritis is associated with obesity. The need for a total knee arthroplasty (TKA) is estimated to be at least 8.5 times higher among patients with a body mass index (BMI) greater than or equal to 30, compared with patients who have a BMI within the normal range of 18.5 to 24.9. Every pound of body weight places four to six pounds of pressure on each knee joint.

Mihalko reports that obesity is a strong independent risk factor for pain. The disease nearly doubles the risk of chronic pain among the elderly, he writes, and adolescents with obesity are more likely to report musculoskeletal pain, including chronic regional pain, than their normal-weight peers.

In addition to the wear and tear on joints, excess weight also affects injury status, Mihalko maintains. The odds of sustaining musculoskeletal injuries is 15% higher for persons who are overweight and 48% higher for people who are obese, compared to persons of normal weight.

The study authors recommend that patients with morbid obesity, a BMI of 40 or higher, be advised to lose weight before receiving a TKA. Doctors should offer resources for weight loss before surgery; and counsel patients about the possible complications and inferior results that may occur if they do not lose weight.

An orthopedic surgeon in Minnesota, known to the writer, had a patient with a BMI of 50 who needed a new knee joint. He refused to perform the surgery until the patient lost some weight. She was irate with her surgeon but, the doctor reports, she is presently on a weight-loss program. — *BY*

Wikimedia Commons and Danieltilolijr

EXTREMITIES

Prosthesis Gives Amputee Sense of Touch

Stacy Lawrence, writing for *Fierce Medical Devices*, reports on a Swedish truck driver who is the first in the world to receive a prosthesis that has a direct connection to his bone, nerves and muscle. The prosthesis, called an osseointegrated implant system, responds to the truck driver's body impulses by means of neuromuscular electrodes.

Doctors amputated the patient's right arm about ten years ago. Lawrence explained how the prosthesis works.

Wikimedia Commons and Magnus Manske

"The technology requires that a titanium implant be surgically inserted into the bone and fixated to it through bone ossification over time. An abutment is then attached to the implant and the prosthesis is attached to it. Electrodes are surgically implanted in nerves and muscles to control the prosthetic system. These electrodes receive signals that are sent via the osseointegrated implant to the prosthesis. Then the signals are converted into motions."

Max Ortiz Catalan, a research scientist at Sweden's Chalmers University of Technology, said, "Reliable communication between the prosthesis and the body has been the missing link for the clinical implementation of neural control and sensory feedback, and this is now in place." He reports that the patient can now feel his prosthesis, control it and can perceive touch. He can handle delicate activities such as taking eggs from a carton. The researchers believe that this technology may be the missing link for enabling sophisticated neural interfaces to control sophisticated prostheses. — *BY*

TRAUMA

Doc Crusades to Correct Poor Splinting

More than 90% of potential pediatric fractures are splinted improperly in emergency rooms and urgent care centers, according to a study by researchers at the University of Maryland School of Medicine. They are presenting their findings at the American Academy of Pediatrics National Conference in San Diego. Improper splinting can lead to swelling and skin injuries.

The study, which was reported in *Medical Press*, examined 275 children and teenagers who had initially been treated at emergency rooms or urgent care facilities in the state of Maryland. They were all later evaluated by University of Maryland pediatric orthopedic specialists.

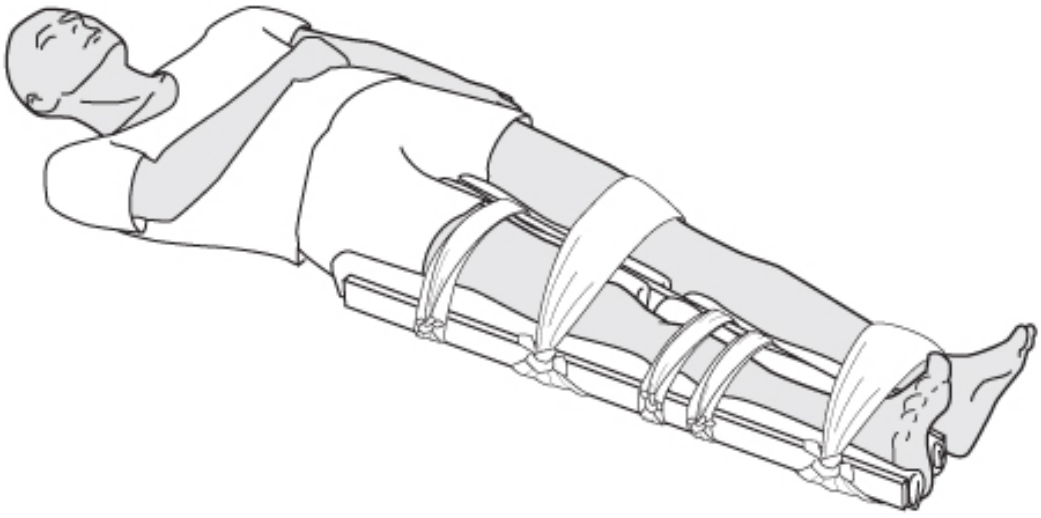
"Splints are effective for immobilization of fractured extremities in children and adolescents when placed appropriately," said the presenting and senior author, Joshua M. Abzug, M.D., assistant professor of orthopedics at the University of Maryland School of Medicine. "Unfortunately, many practitioners in emergency departments and urgent care settings incorrectly applied splints, potentially causing injury," he said.

As reported by *Medical Press*, "the researchers found that the most common reason for improper placement of a splint was putting an elastic bandage directly on the skin, which occurred in 77% of the cases. In 59% of the cases, the joints were not immobilized correctly, and in 52%, the splint was not the appropriate length. Skin and soft-tissue complications were observed in 40% of the patients."

As a result of the findings, Abzug believes that health care professionals need more extensive education and training on proper splinting techniques. He plans to conduct a follow-up study working with providers in emergency departments and urgent care centers on how to correctly apply sprints.

He said that he became aware of the problem when patients came into his office with improperly placed splints. He recalled, "I observed a lot of cases where a splint was placed incorrectly, so instead of just making note of it, I wanted to be more rigorous in coming up with a way to possibly fix the problem." He advises parents to take it seriously when a child complains of pain from a splint. "If there is any question, get in to see an orthopaedist as quickly as possible. Any child complaining of pain away from the point of the fracture or experiencing swelling may have an improperly placed splint," he said.

Abzug is creating educational signs that he hopes will be placed around the emergency departments at community hospitals and in urgent care facilities. The signs will include photos of a correctly placed splint and instructions on how to apply a splint using all up-to-date guidelines. — *BY*



Courtesy of AO Foundation

REIMBURSEMENT

Obamacare Will Survive Republican Congress

"Obamacare," the Affordable Care Act, will not be "repealed or fundamentally changed" by the next U.S. Congress.

That's what Robert Laszewski of *Health Care Policy and Marketplace Review* and one of our favorite insurance and healthcare reform experts says after Republicans took over the U.S. Senate in midterm elections on November 4, 2014. He's admittedly not a fan of Obamacare, but offers statistics and non-partisan insight to explain the insurance implications of the law.

Laszewski penned a commentary on November 5, to offer his views of what will happen to Obamacare now that the Republicans took over the U.S. Senate and increased their majority in the U.S. House of Representatives.

Here is what Laszewski had to say:

Obamacare: Death by a Thousand Votes?

We didn't see a Republican tide on election night.

We saw a Republican tsunami.

A year after Obamacare went into effect and Democrats said people would come to support it voters gave one Republican candidate after another, who made Obamacare a big part of each of their campaigns, one victory after another.

So, how will the Republicans use their convincing result on Obamacare?

Republicans will not have the votes to override any presidential vetoes nor will they have the 60 Senate votes needed for full repeal. But the Republican Senate can now pass lots of anti-Obamacare legislation using budget rules. Remember, the Supreme Court said the individual mandate penalty is a "tax." The health insurance company "3Rs" reinsurance provisions are revenue related. The Obama administration's recently using regulation to take the caps off the reinsurance program is clearly a spending item. The medical device tax could well be a bipartisan target, as would the employer mandate. And, so on.

The even bigger House majority will be happy to go along with the Senate's forcing Democrats to vote on one unpopular piece of Obamacare after another—and then forcing Obama to veto them.

Obamacare will not be repealed or fundamentally changed in the next Congress.

But the Republicans now have the opportunity to prepare the table for 2017—so long as they don't overplay their hand.

What this election result has guaranteed us is that the Obamacare debate is not over.

Odds of Device Tax Repeal

The big issue for device manufacturers still remains the medical device tax

Wells Fargo analyst Larry Biegelsen wrote on Election Day that his Washington, D.C. consultant still believes the likelihood of a full repeal of the device tax is only between 30%-50% with Republicans in control of the Senate. The consultant says the best path forward for the repeal of the device tax would be as a stand-alone bill, or as part of a small package of bills that would win bipartisan support.

The "Offset" Hurdle

"The issue of whether or not repealing the tax needs to be offset [with cuts to other federal spending] is a significant hurdle. It is possible that the medical device industry could face a choice between a compromise that is helpful to only some companies and nothing. The bottom line is we see the likelihood of the device tax being repealed as still lower than 50% even with a Republican-controlled Senate," wrote Biegelsen.

One thing we know for sure about politicians in Washington is that they are rarely predictable about policy. They're only predictable about doing what is necessary to keep their seats and majorities in Congress. — *WE*

Capitol/DoD photo by U.S. Air Force Master Sgt. Cecilio Ricardo

PEOPLE

In Memoriam: Mitch Seyedin, Ph.D.

Mitchell Seyedin, Ph.D., one of the pioneers in regenerative medicine for orthopedics and, most recently, Chief Scientific Officer and Executive Chairman of ISTO Technologies, Inc., passed away on October 8, 2014 after a long battle with pancreatic cancer.

His infectious enthusiasm for the science of regenerative medicine inspired thousands of physicians and orthopedic executives to join him in the great march to regenerative healing and in many ways fueled the development of this entire industry.

Mitch Seyedin's passing leaves a large hole. His colleagues and business partners, all of whom he considered to be his friends, will miss his 1000 watt smile and the pure energy and passion he brought to building a brighter, better future for us all.

Dr. Seyedin is survived by his wife, Sara, and two children, Melissa and Steven.

Dr. Seyedin received an undergraduate degree in chemistry from the University of Wisconsin, River Falls, and a Ph.D. in biological chemistry from the University of South Carolina, Columbia. He was also a Postdoctoral Research Fellow at the University of California, Berkeley.

Mitch Seyedin was an innovator in the truest sense of that word. Prior to leading ISTO, he was co-founder, president and chief executive officer of CBYON, a medical technology company that develops and markets advanced visualization and navigation systems for minimally invasive surgery.

Before that he founded Orquest, Inc., a bone and cartilage tissue engineering company that is now a key part of the DePuy unit of Johnson & Johnson. Dr. Seyedin was president and chief executive officer until 1996, and chairman and chief scientific officer until 1999. Earlier in his career, Dr. Seyedin co-founded Metra Biosystems, Inc., a diagnostic company that went public in 1995 and was acquired by Quidel in 1999.

Mitch rose to national prominence early in his career when he served as director of the Cellular Biochemistry Department at Collagen Corporation, where he was responsible for all aspects of tissue engineering and growth factor research programs and was awarded 11 patents.

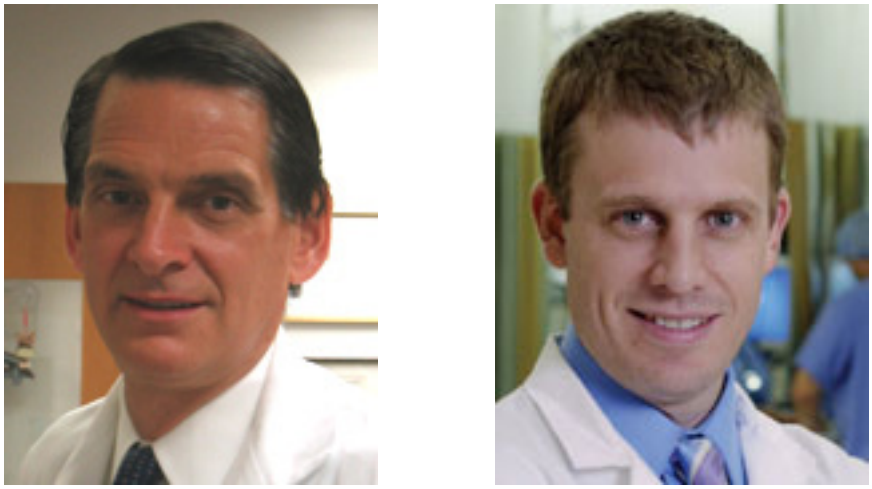
Scott Gill of ISTO Technologies noted, "Mitch was passionate about everything he did and his enthusiasm about work and life was contagious. You could spend five minutes speaking with him about something that he believed in and you would leave the conversation fully convinced that he would make it happen through creativity and determination. He balanced his exceptionally strong scientific mind with a keen sense for business but also a true compassion for the well-being of those that worked for and with him. Anyone that had the pleasure of knowing him or working with him is better off for that experience."

Joseph Lane, M.D. of Hospital for Special Surgery said, "I remember Mitch when he was a recent Ph.D. graduate. He was working at Collagen Corporation and pretty much single handedly developed Collagraft. He was an extraordinary investigator and his skills and determination have been evident throughout his illustrious career. It is an honor and a pleasure to have been friends with Mitch." — *EH*

Donations are requested to be sent to the Mitchell Saeid Seyedin Pancreatic Cancer Fund: http://www.firstgiving.com/fundraiser/mssfund/mssfund?mid=w8Q5AA2&utm_campaign=website&utm_source=email&utm_term=email&utm_medium=email

ISTO Technologies, Inc.

Jonathan Deland, M.D., Scott Ellis, M.D. Receive J. Leonard Goldner Award



Jonathan Deland, M.D. and Scott Ellis, M.D./Hospital for Special Surgery

Jonathan Deland, M.D. and Scott Ellis, M.D., orthopedic foot and ankle surgeons at Hospital for Special Surgery (HSS), were recently honored at the annual meeting of the American Orthopaedic Foot and Ankle Society (AOFAS). Drs. Deland and Ellis received the prestigious J. Leonard Goldner Award, a recognition that highlights the most outstanding research paper presented at the AOFAS annual meeting. According to the October 28, 2014 news release, "The researchers found that the best results after a flatfoot reconstruction were achieved in patients whose foot was not corrected too much with a procedure called 'lateral column lengthening.'"

"In this procedure, a bone graft of various sizes can be placed in the side of the foot to shift the flatfoot. Patient outcomes were measured by the Foot and Ankle Outcome Score, which was validated in a previous HSS study for patients with flatfoot. This information may help guide surgeons at the time of flatfoot surgery, according to Dr. Ellis and Dr. Deland."

Dr. Ellis told *OTW*, "The most interesting aspect for me was that we found that worse outcomes correlated directly with the x-ray parameters of overcorrecting the foot. This recognition means that we can help improve outcomes after the surgery by paying strict attention to how much correction we perform."

Dr. Deland commented to *OTW*, "This study shows how to minimize the chance of a classic problem with correcting a severely collapsed foot, that of lateral overload. The severely collapsed foot is usually from posterior tibial tendon insufficiency, a not uncommon condition. In a severe flatfoot, when a lateral column lengthening (lengthening a bone on the outside of the foot) is necessary, this study shows how to minimize the chance of lateral overload. Lateral overload puts too much weight on the lateral side of the foot and causes lateral discomfort or pain. This has been a significant problem and is not so easy to avoid."

"The meaning of this award for us is that the AOFAS recognizes the importance of our work and, just as significantly, recognizes the value of good research." — *EH*

Orthopedics This Week | RRY Publications LLC

Robin R. Young, CFA
Editor and Publisher
robin@ryortho.com

WRITERS

Elizabeth Hofheinz, M.P.H., M.Ed.
Senior Writer
elizabeth@ryortho.com

Walter Eisner
Senior Writer
walter@ryortho.com

Biloine W. Young
Senior Writer
bgwy@msn.com

Sophie Bodek
Writer
sophiebodek@yahoo.com

ADVERTISING

Tom Bishow
Vice President of Sales
tom@ryortho.com

PRODUCTION

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Email, Web, & Conference Coordinator
jayme@ryortho.com

Dana Bader
Graphic Designer
dana@ryortho.com

116 Ivywood Lane • Wayne, PA 19087
TOLL FREE: 1-888-749-2153
www.ryortho.com