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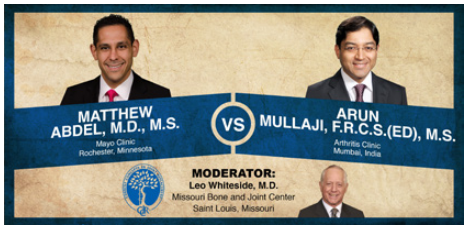
Orthopedics This Week

WEEK IN REVIEW



BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Russian consumer products company Oasis is buying Pabst Brewing company (makers of Colt 45 Malt Liquor). That's one way to get capital out of Russia. Speaking of hangovers, the Alibaba party pushed the Dow to a record high on last week—just 10 days before October—traditionally the worst month on the investor calendar. We would not be surprised to see investors sit on their capital now until Q3 earnings season kicks in.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	11.52%	1.16%	Second least expensive ortho equity and poised, say analysts, to post 16% earnings growth in Q3.
2	2	Zimmer	29.12	4.19	ZMH had a good run this past month. Looking ahead to 2015, it'll all be about integrating Biomet.
3	6	Medtronic	28.84	3.23	Buyers finding their way to MDT. Maybe they're reflecting on management's comment that spine will grow in 2015.
4	5	Globus Medical	29.68	5.07	Odd. Stock is strong (which makes sense), but consensus opinion is that Q3 earnings will be...down?
5	4	NuVasive	8.01	2.39	Looking ahead to 2015, NUVA appears to be on track to hit three quarters of a billion dollars in sales—$750 million!
6	3	Integra LifeSciences	12.57	2.07	Hey! A deal! IART buys MDT's MicroFrance, ENT and laparoscopy lines. Market didn't seem to notice. Still cheapest ortho equity.
7	9	Symmetry Medical	6.55	5.44	Federal Trade Commission smiled on SMA's divestiture deal. So investors smiled on SMA.
8	7	Exactech	10.26	0.97	For a $250 million (sales) ortho company, EXAC is still a comparative bargain. Sales this year expected to rise about 6%.
9	8	Conmed	10.51	0.62	Voce Capital declared victory and went home. OK. Now. Can CNMD deliver sales and earnings growth? Consistently.
10	10	Johnson & Johnson	26.58	4.63	Expensive conglomeration of disparate medical and pharmaceutical companies. Dividend yield now down to 2.50%.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Tornier N.V.	TRNX	$24.20	$1,184	13.46%
2	LDR Holding Corp.	LDRH	$29.75	$773	11.93%
3	Alphatec Holdings	ATEC	$1.70	$167	10.39%
4	RTI Biologics Inc	RTIX	$5.12	$291	8.47%
5	Wright Medical	WMGI	$31.57	$1,592	8.23%
6	MiMedx Group	MDXG	$7.29	$771	5.50%
7	Symmetry Medical	SMA	$9.69	$364	5.44%
8	Globus Medical	GMED	$19.67	$1,856	5.07%
9	Johnson & Johnson	JNJ	$107.99	$304,563	4.63%
10	Zimmer Holdings	ZMH	$103.99	$17,566	4.19%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc	BAXS	$0.29	$14	-19.61%
2	MicroPort Scientific	853	$0.50	$714	-18.28%
3	Aurora Spine	ASG	$1.76	$28	-11.27%
4	Orthofix	OFIX	$31.29	$577	-6.54%
5	CryoLife	CRY	$10.21	$285	-2.48%
6	Smith & Nephew	SNN	$87.37	$15,604	0.43%
7	K2M Group Holdings	KTWO	$14.14	$525	0.43%
8	ConMed	CNMD	$37.61	$1,028	0.62%
9	Exactech	EXAC	$23.83	$328	0.97%
10	Stryker	SYK	$82.84	$31,362	1.16%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Globus Medical	GMED	$19.67	$1,856	16.69
2	Medtronic	MDT	$66.22	$64,864	17.02
3	Johnson & Johnson	JNJ	$107.99	$304,563	18.51
4	Zimmer Holdings	ZMH	$103.99	$17,566	18.65
5	Stryker	SYK	$82.84	$31,362	19.80

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$31.29	$577	261.03
2	NuVasive	NUVA	$36.78	$1,728	71.24
3	Symmetry Medical	SMA	$9.69	$364	49.70
4	CryoLife	CRY	$10.21	$285	30.67
5	Smith & Nephew	SNN	$87.37	$15,604	29.84

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	$10.21	$285	1.02
2	Exactech	EXAC	$23.83	$328	1.10
3	Globus Medical	GMED	$19.67	$1,856	1.25
4	ConMed	CNMD	$37.61	$1,028	1.64
5	Zimmer Holdings	ZMH	$103.99	$17,566	2.18

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$31.29	$577	14.19
2	NuVasive	NUVA	$36.78	$1,728	5.82
3	Symmetry Medical	SMA	$9.69	$364	4.14
4	Smith & Nephew	SNN	$87.37	$15,604	2.95
5	Johnson & Johnson	JNJ	$107.99	$304,563	2.61

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Baxano Surgical Inc	BAXS	$0.29	$14	0.70
2	Alphatec Holdings	ATEC	$1.70	$167	0.81
3	Symmetry Medical	SMA	$9.69	$364	0.91
4	Bacterin Intl Holdings	BONE	$5.01	$33	0.98
5	RTI Biologics Inc	RTIX	$5.12	$291	1.20

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.73	$118	20.58
2	MiMedx Group	MDXG	$7.29	$771	9.73
3	LDR Holding Corp.	LDRH	$29.75	$773	6.92
4	Wright Medical	WMGI	$31.57	$1,592	5.92
5	Johnson & Johnson	JNJ	$107.99	$304,563	4.14

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

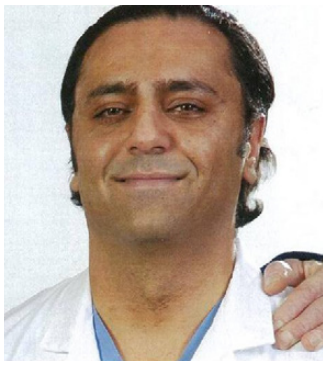
First PODs Prosecuted

BY WALTER EISNER

In the summer of 2011, the principals of Reliance Medical Systems, LLC were secretly recorded making a pitch to potential surgeon-investors for one of 14 physician-owned distributors (PODs) they set up to sell their spinal implants.

Those recordings, a whistleblower lawsuit filed by two physicians and Medicare records are the foundation for a Department of Justice False Claims Act charge against the PODs. The 81-page lawsuit was filed in federal court on September 8, 2014.

The government claims that Reliance's owners, Adam Pike, Bret Barry and John Hoffman, their subsidiary PODs, Apex Medical Technologies, Inc. and Kronos Spinal Technologies, LLC, as well as Aria Sabit, M.D., a participating POD neurosurgeon, made false claims for Medicare reimbursements because those claims were tainted by illegal kick-backs and some of the surgeries were either excessive or unnecessary.



Aria Sabit, M.D./Facebook.com

It's always the accountants!

The secretly recorded conversation allegedly provides evidence that Reliance sought to hide physician ownership and illegally circumvent the Anti-Kickback Statute (AKS).

Photo creation by RRY Publications LLC

The allegations of medically unnecessary or excessive surgeries were made in a separate whistleblower lawsuit filed by Cary Savitch, M.D. and Gary Proffett, M.D., against Sabit, Moustapha Abou-Samra, M.D., and Community Memorial Health System in Ventura, California, where Sabit's surgeries took place.

Reliance Medical

During that secretly recorded meeting on July 26, 2011, Pike and his partner Berry allegedly described the purpose of Reliance's PODs as: "It is about the money. We make lots of money… [We] started this coming out of MBA School together. We were aware of Stark and Anti-Kickback and we knew those existed and we devised a plan around those."

According to the federal complaint, they made a boatload of money. Between 2007 and 2012, the government says Berry and Pike paid themselves $36 million. Hoffman allegedly got about $7 million.

Reliance's attorney, Patric Hooper of Hooper Lundy, disputes that figure, telling the *Wall Street Journal* that his clients earned "much less."

The alleged "tainted kickbacks," went to Aria Sabit, M.D., Sean Xie, M.D., Gowriharan Thaiyananthan, M.D., and Ali Mesiwala, M.D. In all, the government says 35 physicians were involved.

The POD Wars

This isn't the first time Reliance has tangled with the Justice Department. In summer of 2013, the company went to federal court to argue that a Special Fraud Alert from the Office of Inspector General (OIG) declaring PODs "inherently suspect," violated their First Amendment rights to freely discuss legal business with physicians. The federal judge threw out

their complaint, telling them to chill out until they were actually harmed.

POD proponents cite evidence that hospitals save money by purchasing their implants.

Congress and the Justice Department have been waging a campaign against PODs saying that the financial conflicts inherent in physician ownership of a business that earns revenue from devices implanted by the owners treads on the Stark Act and may result in higher implant utilization.

Spine companies, including Medtronic, Inc., NuVasive, Inc. and Globus Medical, Inc. have noted that POD sales have cut into their sales. Some Wall Street analysts have speculated that PODs have captured almost 20% of all spine implant sales.

In this lawsuit, the government has taken the first legal action against PODs.

Sailing Outside the "Safe-Harbor"

The government claims Reliance's PODs didn't satisfy safe-harbor requirements.

According to the safe-harbor rules, investment opportunities, among other requirements, cannot be related to expected volume of referrals and no more than 40% of the entity's gross revenue in the past year may come from referrals or business generated from the investor.

In addition, the amount of return for the investment must be directly proportional to the amount of the capital investment.

Exclusive Revenue

The government claims that revenues for the PODs came exclusively from the sale of spinal implants to the hospitals at which the four surgeons performed surgeries. Reliance, through Apex and Kronos charged hospitals as much as $7,500 for each cage and as much as $2,400 for each pedicle screw and $2,400 for each plate and $522 for rods and $1,875 for a crosslink.

The four surgeons mentioned earlier allegedly earned a total of $5.9 million for very small, if any investments in the PODs. And therein lays the problem. By not having any or sufficient capital at risk, the company and investors fell outside the safe harbor provision that allows investments.

Berry, Pike and Hoffman formed Kronos in February 2007. In June of that year they allegedly offered Mesiwala and David Lundin, M.D., an "opportunity" to invest in the company. The two physicians initially shared 40% ownership through Mesiwala's company called SoCal Medical Surgical (SMS).

The government says the doctors paid nothing for their shares.

From August 2007 to September 2008, SMS was paid $769,800. Lundin got $110,000 of that amount and Mesiwala got the rest. Lundin gave up his shares in September 2008, and Mesiwala became the sole physician investor in the POD, owning 25% and generating more than 90% of Kronos' revenues. (A "Safe-Harbor" violation.)

In late 2009, Thaiyananthan was offered ownership. On January 15, 2010, Kronos paid him $79,000. A week later, he invested $100,000 for a 20% interest in Kronos.

Another week later, on January 31, 2010, Kronos paid him an additional $69,400. He invested $100,000 and was paid $148,400 in the same month.

Hidden Ownership

One of the government's main claims is that Reliance and the surgeons did everything they could to hide their financial relationships from patients and hospitals.

In August 2013, following a *Wall Street Journal* article about Sabit and Reliance, Pike and Berry replied with a letter to the editor.

They wrote that Reliance physicians did not hide their interests from patients. "Patients were regularly informed about our physicians' business relationships."

But according to the government, the secret recordings tell a different story.

Pike was recorded saying that he and Berry founded Reliance to "get around" the AKS.

The government says "getting around" the AKS meant structuring the operation in a way to hide the financial relationships with its physician-investors. Their attorneys even advised them in 2006 and 2007 to notify patients that their physicians had a financial interest in Reliance's distributorships.

According to the complaint, Berry explained that the principals did not want anyone to know who its physician-investors were and allegedly said; "Our job is to let everybody outside...of our group think that you're just using this product...We don't want anyone to know that you are an owner."

Pike added that if they sign up after the evaluation period, "the hospital doesn't need to know that. The community doesn't need to know that...No one knows but our own circle."

False Certifications

So, says the government, Reliance made a series of false statements to hospitals that inquired about Reliance's financial relationships with its particular physicians.

In September 2012, Laurann Turner, Reliance's VP of operations, allegedly wrote to a California hospital that had inquired about financial interests, that Mesiwala, "is not a distributor for Kronos Spinal Technologies, nor has he received any payments or remunerations from Kronos as a consultant or investor."

At the time she wrote the letter, Kronos, according to the government, had already paid Mesiwala more than $3 million.

The same thing happened in November 2011 and May 2012 when Reliance allegedly certified to Detroit Medical Center that no "physicians licensed to practice medicine...own all or part of [Apex]." At the time of certification, Sabit, who was now on the hospital's surgical staff, owned 20% of Apex.

Sabit Denies Ownership

When asked about his ties to Apex by his boss, Moustapha Abou-Samra, M.D. and by hospital staff, Sabit allegedly denied any financial interest. He also did not disclose his ties to his patients.

On November 12, 2012, as part of a federal investigation, Sabit testified that he never had been paid any compensation by a medical device manufacturer and that he didn't know of any device company in Bountiful, Utah, the headquarters of Reliance.

By January 2014, Sabit gave sworn testimony in a government investigation and invoked the Fifth Amendment.

"Using Your Own Stuff"

The government further claims that Reliance fully expected its investor-surgeons to use their products.

Reliance did not allow physicians to invest unless hospitals in which they performed surgeries agreed to buy Reliance devices.

Berry and Hoffman allegedly stated that Reliance does not offer investment opportunities to physicians who will not order a high volume of Reliance implants. Hoffman was recorded stating that Mesiwala was not invited because "he's not busy at all."

Pike was recorded telling a potential investor how much they make a month and this "comes from very dedicated employees...and it's our intent not to ever sign someone up unless they are

that dedicated…so that's one of our criteria. "

Hoffman said certain physicians were not invited because they would not be "loyal" to Reliance.

They allegedly told investors that they mandate an evaluation period to "better understand your volume and your commitment to it and then when all agreed and the signing date comes, then it's we know what we got."

On July 20, 2011 Mesiwala was recorded telling a potential investor that "the expectation is that you will be using your own stuff."

The government says before becoming an Apex investor, Sabit had never used Reliance implants. After investing, Sabit used Reliance implants in over 90% of his surgeries at the hospital. He also increased his volume to 130 fusions over the next eight months, an increase of over 100%.

Sabit declined to comment to the *Wall Street Journal* on September 16, 2014, and his lawyer didn't respond to inquiries. Hooper, Reliance's attorney told the *Journal* that his clients "did absolutely nothing wrong" and added: "We are going to defend this thing aggressively."

Sabit reportedly surrendered his medical license in California last month under a settlement with the state's medical board, after the board alleged that he committed gross acts of negligence while treating five patients. He's still practicing in Michigan.

Steinman and Lukianov Comment

John Steinmann, M.D. a leading POD proponent told *OTW* that Reliance's founders are not physicians, but former industry businessmen, who induced allegedly ethically challenged physicians to participate in their scheme.

He added that he and his colleagues have worked to establish ethical POD guidelines that would have prevented this kind of activity.

Alex Lukianov, head of NuVasive, told us, "We applaud the lawsuit by the DOJ against PODs and believe that this first of its kind direct legal enforcement action by the DOJ into this important topic is positive news for our industry."

He added that he thought this case is unlikely to resolve anytime soon, "But surgeons associated with PODs will take notice as the potential for personal liability is now more real. Although this enforcement action should have an impact on the prevalence of PODs in the market, we don't expect them to disappear overnight." ◆

Spike in Tommy John Surgeries "Alarming" // Orthopedics Tops of All Specialties for Volunteerism // ABOS Executive Director Details Question Formation, Security Issues

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

Spike in Tommy Johns Due to "Pitch Younger, Pitch Faster, Pitch More Often" The culprit in the recent upsurge in Tommy John surgeries just may be things that happened years ago, says new research. Neal S. ElAttrache, M.D. is a sports medicine specialist with the Kerlan-Jobe Orthopaedic Clinic in Los Angeles, California. Dr. ElAttrache, the team physician for the LA Dodgers, tells *OTW*, "The number of UCL (ulnar collateral ligament) injuries—and thus Tommy John surgeries—at the professional level has been alarming. We are seeing more primary UCL tears and now also seeing re-tears in players that have undergone previous Tommy John surgery. Some players are having surgery in their teens and early twenties and then experiencing a re-tear several years later, while some re-tear within 18 months of their return to play. As it stands now, just under 1 in 3 pitchers in the professional leagues will have had a Tommy John operation, BUT almost 25% of those who have a Tommy John will not make it all the way back to their previous level of performance."

Wikimedia Commons and Flickr/Json

"From the data trends we are seeing, it appears that this increase is linked to several things, including the number of innings pitched prior to entering professional baseball, year-round participation and early specialization as a pitcher, and high velocity pitching. When a teen is throwing a ball over 90 mph and doing it year-round, he has a much higher chance of ending up in our office. It may be a sudden tear that brings him in, but it's usually due to a series of incompletely healed micro-tears that may or may not be symptomatic, but gradually compromise the elbow until it fails."

"Kerlan-Jobe and ASMI [American Sports Medicine Institute] have conducted independent studies on this topic and are now working together with professional players on this issue. One of the benefits of doing this at the professional level is that it shines a spotlight on the problem. We can say to kids, 'By early specialization and overuse with year-round participation, you are increasing your chances of injury and hurting your chances of progressing in the big leagues. We have studied this and these practices down-grade you.' Some parents and coaches think it's a good idea to play year-round and specialize as a pitcher at age 11, but in fact if they do that before 15/16, they are most likely eliminating the chance that their child will become an elite-level player."

True Story: How Board Certification Exam Questions Are Created When the stakes are high, such as they are with board certification, there is no gambling involved…everything is planned out to the last question. Shep Hurwitz, M.D., the executive director of the American Board of Orthopaedic Surgery, told *OTW*, "The process involved in pulling together the 300+ questions for the board certification and recertification

exams each year is enormous. The 40 question writers, some of whom rotate out each year, are given assignments by the chair of the computer-based exam committee. Afterwards, all of the questions are gathered by the National Board of Medical Examiners (NBME), who do their best to put the content into a similar format and language. Answers are always listed from least to most, so that if it is a surgical procedure question then the choices will go from least invasive to joint replacement…that is done to make all of the questions look the same."

"The questions are then returned to the original writer for editing, who is asked to provide a sentence or two about why the correct answer is the correct answer. They must also support their 'argument' with relevant articles from the literature. Once a year all of the writers come together to review each other's questions. For example, someone writing questions for hand may be partnered with a person writing questions for trauma—it's a great reality check. If a question seems too esoteric to someone who is not in that specialty then it's likely that the question will be put in a different pool (i.e., perhaps used for a subspecialty exam). Sometimes, however, questions are so poor that they cannot be salvaged and must be eliminated."

"The NBME works from a blueprint/formula: 30% of questions must be on adult reconstruction issues, 35% on basic science, 17% on pediatrics, 15% trauma, and a small percentage should be on rehabilitation. Then the ABOS works with the NBME to decide exactly which questions make the cut. Some years it is more than 320 questions and some years it's less. But we always allow for the fact that a few questions will be thrown out at the end of process."

"Roughly 15-25% out of the questions are reused; each year we compare performance on previous exams to performance on the current exam ('equating'). By doing this we can see if the test scores are drifting in a certain direction. We can assess whether the test takers are getting smarter or less smart…or whether the exam is getting harder or easier. If 100% of respondents get a question right then it is too easy and vice versa. Also, the highest 20% performers on the entire exam should get the highest number of correct answers on each question; the lowest 20% should have the lowest number correct. If there is no difference between the top and bottom they we will suspect that the question isn't telling us what we want to know

(i.e., it is not discriminating between good and poor students)."

"Each year about a few months before the exam, the Board meets to review the entire test one last time. This final reality check occasionally catches something of importance. Last year, the board found that a question regarding a child with a painful joint included an X-ray that was clearly an elderly person with arthritis."

"Finally, we do take security very seriously. While we have never had a breach, the radiology examiners did. Those who cheated were leaving the exam having memorized a few questions…then they immediately went to a website where they entered the information. We are ramping up security to prevent this and other types of issues. After all the intensely difficult work that surgeons must go through, this process must be fair for all."

Orthopedics Is the MOST Active Volunteer Specialty With Health Volunteers Overseas (HVO) the focus is on teaching orthopedic surgeons to fish… well, not exactly, but you get the idea. Nancy Kelly, executive director of HVO, tells *OTW,* "Orthopedics remains the most active area of all of our programs. We are operating16 projects around the world, and sending more than 500 people abroad annually; approximately 110 of those are for our orthopedic program. Our overarching goal is to build local capacity through education and training. We do not set out to do direct service, although naturally that occurs during the course of teaching."

"In Ghana our project is located at the Accident and Emergency center and is directed by Peter Trafton, M.D. We have roughly 13 trauma and orthopedic residents in the program, with the majority rotating on other services. Additionally there are six general surgical residents and seven house officers (two-year rotating interns) at one time. Medical students rotate through in one month blocks (14 fourth year and 14 sixth year students at a time). The orthopedic residency training program at Komfo Anokye Teaching Hospital (KATH) currently has accreditation from the Ghana College of Surgeons and is now seeking accreditation from the West African College of Surgeons. An evaluation is scheduled for November; the goal is to have a single unified approval for the residents from both colleges. Volunteers remain engaged in the work post-trip, sending articles to their colleagues in Ghana, suggesting approaches, etc. All of this means that these programs are very attractive to those in Ghana who want to pursue training."

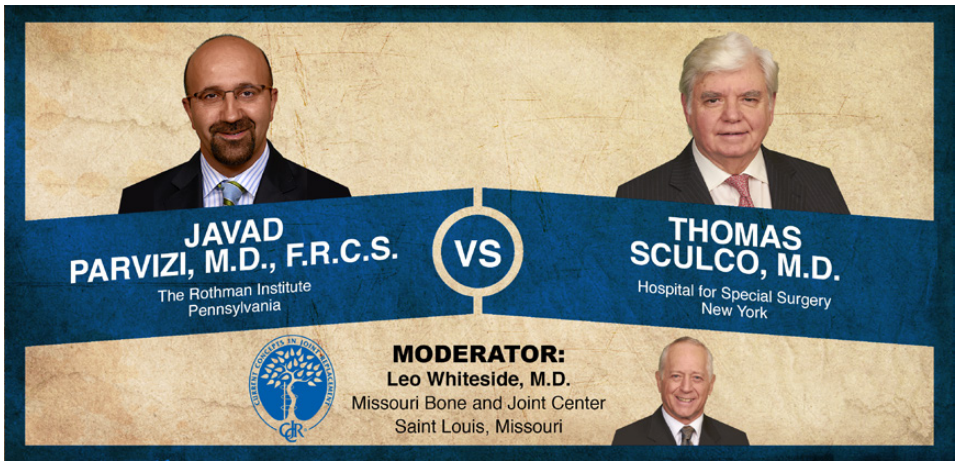
"One of our new projects is in Myanmar, an interesting country that has been popular with our volunteers. We have approximately 12 full-time junior and senior orthopedic surgeons who provide most of the surgical care at two hospitals; the residency program lasts two-three years. After completing the residency, these physicians are considered to be orthopedic surgeons and are sent to work in the rural, more isolated areas in the countryside."

"My vision is that our work should change over time. Yes, we need to be present for a long time because change takes time, especially with so many constraints. Going forward we will perhaps elevate the kinds of training, for example by providing education that involves more technology. We could undertake distance education in combinations with volunteerism, something that could result in more of an emphasis on the subspecialties. Three years from now I would like the training to be more sophisticated and I would like to see more of the local faculty taking over responsibilities." ♦

Parvizi, Sculco Debate Simultaneous Bilateral TKA

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

This week's Orthopaedic Crossfire® debate is "Simultaneous Bilateral TKA: Double Trouble." For the proposition is Javad Parvizi, M.D., F.R.C.S. of The Rothman Institute. Against the proposition is Thomas Sculco, M.D. of the Hospital for Special Surgery (HSS). Moderating is Leo Whiteside, M.D. of the Missouri Bone and Joint Center.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Parvizi: "If white hair is a sign of wisdom, decadence, and intellect then my friend Dr. Sculco will qualify. So we're talking about simultaneous, bilateral knee surgery performed under one anesthesia and one hospital admission. There are few Level 1 studies on this—everything we have is probably Level 3 and beyond."

"We performed a meta analysis at our institution involving 151 papers and over 27 patients. When we looked at complications and mortality, we found that those undergoing simultaneous bilateral TKA [total knee arthroplasty] had a higher rate of cardiac complications than those who had either a staged or single TKA. In addition, deep vein thrombosis was lower in bilateral TKA, but pulmonary embolus was higher in patients undergoing bilateral simultaneous TKA. The same was true for other complications, including urinary and gastrointestinal issues. Interestingly, every paper published showed a higher mortality rate in patients undergoing simultaneous bilateral TKA compared to single. This is notable because most of these patients are supposed to be healthier."

"In another meta analysis published about six years later we showed similar findings, with overall mortality being higher; 30 day mortality in particular was much higher. Neurological complications were also higher in patients undergoing simultaneous bilateral TKA. But if none of this convinces Dr. Sculco, a paper from his own institution should help."

"A publication from his anesthesia department looked at the National Inpatient Sample Survey from 1998-2007. This included over 200 patients undergoing elective bilateral TKA. The incidence of complications overall was 9.5%...eight fold higher than with single TKA."

"His other argument will be that simultaneous bilateral TKA is cheaper and perhaps more cost effective. But because of the increase in these complications, the savings that the hospitals may experience will be offset by treating these patients later (including hospitalization). Also, these patients have longer OR time, so regional anesthesia may not be appropriate; this may predispose them to a higher incidence of complications. Blood transfusion and blood loss in these patients is much higher, leading to a higher requirement for transfusion-related complications—including infection related to immunological problems. We know that development of a bilateral knee prosthetic joint infection is extremely challenging; these patients have between 20-30% mortality within the first five years."

"So, should you be doing bilateral TKA simultaneously in anyone? Yes, but only in a select group of patients…and perhaps only at select institutions. The publication from HSS identified the following as risk factors for complications following simultaneous bilateral TKA: advanced age (65-74), male gender, comorbidities (for example, congestive heart failure increased the odds ratio by 5.5), and pulmonary hypertension. The same paper argued that patients should be admitted to at least a Level 2 care unit with more detailed observation than a routine orthopedic ward… and some of these may require Level 3 full ICU support in the postoperative period."

"So in conclusion, higher complications and mortality have been observed in

patients who undergo bilateral simultaneous TKA. Hence, if you're going to do this then it should be reserved for a select group of patients."

Dr. Sculco: "I'm speaking in favor of simultaneous bilateral TKA. Overwhelmingly, patients want to have both knees done at once because there is less recovery time, one operation, symmetrical recovery…and we believe it is less costly."

"If you have a patient with a flexion contracture of any significance it is especially important that you try to do both at once. If you do the first knee and get it out straight, then it will go on to take on the deformity of the second knee, and you'll lose the correction you got with the first procedure. There are some disadvantages, including increased risk. The short term recovery can be slower, and reimbursement—both to the hospital and physician—is less."

"In a paper that included 501 of my patients who underwent simultaneous bilateral TKA there were no deaths, no strokes, and no myocardial infarctions. However, there was increased morbidity, particularly in patients over 75 and those that had increased preoperative comorbidity."

"Let's return to the paper Jay quoted—a large hospital discharge database that included four million TKA. In this population there were 153,000 bilateral knee replacements—not necessarily done simultaneously, but done during the same hospital stay. The mortality was less in the unilateral group compared to the bilateral group. However, remember that these patients are coming back for a second procedure and there is going to be some mortality related to the second operation. So comparing unilaterals and bilaterals isn't always good and may not be totally accurate."

"Interestingly, as you look at these complications as we moved to a more current treatment mode (for example, more current anesthetic management), they all tended to come down. The reduction in the complications is due to many things: improved patient selection, better anesthetic techniques, better perioperative care, and faster surgery."

"Over a 10 year period (1999-2009) at HSS there were 20,000 knee replacements, 3,000 of which were bilateral.

The unilateral populations actually had a higher mortality rate than our bilateral populations…probably due to good patient selection. Even our infection rate was lower in this population. As for hospital charges, a bilateral procedure was $67,000 as opposed to a unilateral times two ($46,652 per), was less even if you factored in the need for rehabilitation."

"We've tried to mitigate the perioperative response from fat emboli and potential acute respiratory distress syndrome. In a randomized trial we published in the *Journal of Bone and Joint Surgery* we used a perioperative steroid to mitigate perioperative complications—in particular, lung complications—after a bilateral procedure. We took 30 patients and gave them three doses of hydrocortisone (one preoperatively, another one eight hours after surgery, and another one eight hours after that). We monitored the inflammatory cytokine IL6 and desmosine, which is a lung enzyme."

"We found that IL6 rises then drops down normally. In the population that received perioperative cortisone there was essentially no change in the elevation of that inflammatory cytokine. Desmosine is a marker that we can use for lung injury. When we looked at the same cohort of patients that received perioperative hydrocortisone, we found a significant reduction in desmosine levels as opposed to those patients in the control population."

"Our clinical findings showed that in the group treated with hydrocortisone there was better range of motion, a reduced need for pain medication, and zero infections. So if you're going to do bilateral knee replacement surgery you should consider using perioperative hydrocortisone to mitigate some of the potential lung injury that can occur from fat emboli (as we have seen in the trauma population)."

Moderator Whiteside: "Jay, when a patient asks to have both knees done at once, what do you say?"

Dr. Parvizi: "If they are sufficiently fit, i.e., no cardiac or pulmonary comorbidities, and if I feel that the risk is justified, then I will offer it to them. But the majority of patients I see don't fall into that category."

Moderator Whiteside: "If they are very eager to go ahead despite significant

morbidity in their history, do you let them make that decision?"

Dr. Parvizi: "I think it's my responsibility as their doctor to make that decision."

Moderator Whiteside: "Tom, what do you do when someone you think is not a good candidate for bilateral simultaneous joint replacement wants it anyway?"

Dr. Sculco: "We have a clearance system. There are many patients who I think are right for a bilateral knee replacement, but they also see an internist and an anesthesiologist. Also, we put a multidisciplinary consensus panel together and we developed a series of guidelines that we adhere to. Adhering to these guidelines has meant that morbidity and mortality is significantly reduced."

Moderator Whiteside: "So you feel that in your hands bilateral TKA has a lower morbidity and mortality rate than if you separated them by three months?"

Dr. Sculco: "If you look at our data—over 3,000 cases—the mortality was less in that population. It was less because these patients are screened and healthier."

Dr. Parvizi: "Leo, that statistic is flawed. You can't just multiply the risk factor by two in these patients. If your chance of getting hit by a car is 10% each time you cross the street it doesn't mean that if you cross the street 10 times that you'll definitely get hit."

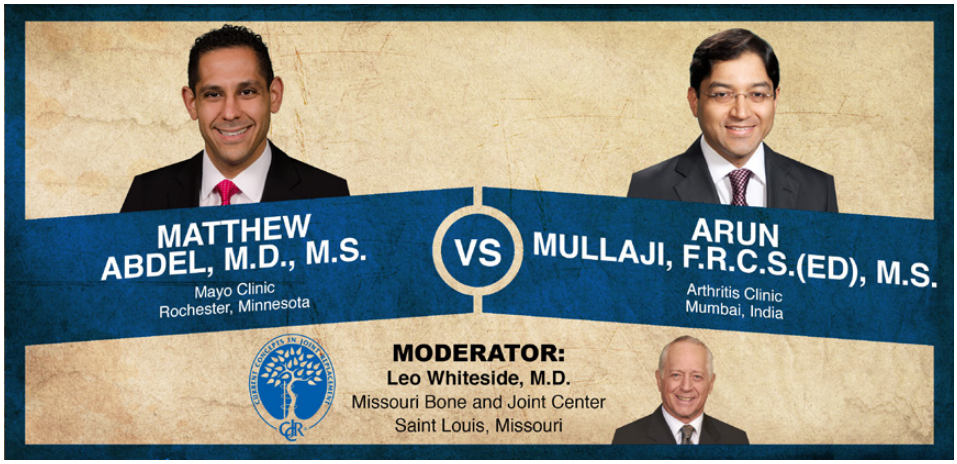
Moderator Whiteside: "Thank you both very much." ♦

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

Abdel v. Mullaji Over the Cementless Knee

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

This week's Orthopaedic Crossfire® debate is "The Cementless Knee: Intermediate Term Guarantee on Parts and Labor." For the proposition is Matthew Abdel, M.D., M.S. of The Mayo Clinic. Against the proposition is Arun Mullaji, F.R.C.S.(Ed), M.S. of the Arthritis Clinic. Moderating is Leo Whiteside, M.D. of the Missouri Bone and Joint Center.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Abdel: "From the literature we can see that there is no question that cemented total knee arthroplasty (TKA) has good long term survivorship (approximately 95% at 15 years). Historical registry data reflects a slightly decreased survivorship for cementless TKA when compared to cemented TKA. However, there is a bias in these studies given that a low proportion of the knees were cementless fixation. There have been past problems with cementless TKA, which include a lack of tibial ingrowth, metal backed patellas, screw track osteolysis, and issues with polyethylene (thin inserts and non conforming articulations)."

"Only 80% of our patients are satisfied with their TKA. I would argue that in 2014 our contemporary TKA patients are significantly different than patients of the past. Now, they are younger, more active, have increasing life expectancy, all mandating modern implant designs and surgical techniques."

"There are multiple benefits of cementless TKA, including diminished operative times, preservation of bone stock, ease of revision surgery, elimination of third body wear, and the potential for improved biologic long term fixation…and thus, survivorship. Multiple long term studies have shown excellent long term survivorship with cementless TKA. A 2012 Cochrane review looking at five prospective randomized trials involving 300 patients with radiostereometric analysis (RSA) show that the risk of aseptic loosening with cementless fixation was half of that with cemented fixation. Knee Society and Hospital for Special Surgery scores were similar between the two groups."

"Another contemporary analysis by Dr. Michael Mont found equal survivorship at 10 and 20 years between cemented and cementless fixation. One of the innovations that has pushed cementless TKA forward has been highly porous metals, including tantalum. Tantalum has a decreased modulus of elasticity, which leads to decreased stress shielding. In addition the increased porosity leads to improved biologic fixation, and thus, stability."

"To test this hypothesis we undertook a prospective randomized clinical trial at Mayo Clinic from 2003-2006 with five knee arthroplasty surgeons. The goal was to assess the durability and reliability of uncemented highly porous metal tibial components in relation to cemented modular tibial components. We randomized 400 patients into three groups, either cemented modular, uncemented monoblock trabecular metal (TM) or cemented monoblock TM. At five years there was equal survivorship between the cemented and uncemented groups. No uncemented highly porous metal component was revised in this series."

"We also examined clinical outcomes and found no statistically significant difference between Knee Society pain and function scores or range of motion (ROM). In summary, at five years uncemented highly porous metal tibial components were as durable and reliable—particularly in that concerning early period where rigid fixation is needed for bony ingrowth with cementless fixation. So it is my contention that cementless TKA has the potential for improved satisfaction and survivorship, preservation of bone stock, decreased operative time, and improved biologic fixation (in the long term) for younger, more active patients. Innovative met-

als have helped, in addition to utilizing surgeons with a high volume practice with cementless fixation."

Dr. Mullaji: "I oppose cementless knees because: most of our patients are elderly, the implant costs far more, the results haven't been superior, it doesn't address most causes of revision, antibiotics and cement reduce sepsis, patellar resurfacing still needs cement, the technique is more demanding, and we don't know what the optimal design is."

"In the most recent Australian registry those under 55 are just a small proportion (8%), and yet it's in these young patients that revision is highest. We have no data showing that cementless leads to fewer revisions in younger patients. An earlier study from Mayo Clinic showing that in a group of patients who had cementless fixation—younger patients—survivorship was far worse."

"Cementless costs almost $600 more per implant, and $150 more if you take into account other factors. For a country that does roughly 50,000 total knees annually, that means a huge savings that may exceed the GDP of several countries."

"The Australian registry shows that the revision rate with cementless is significantly higher than that of cemented—not only in the medium, but in the short term. You've heard about the Cochran Collaboration review. If these show a migration of more than 0.2mm then there is a theoretical risk of loosening. The four papers they looked at showed similar migration or somewhat superior data for cemented."

"Several meta analyses have shown no significant difference in survivorship when utilizing randomized controlled trials (RCT) and when excluding design related failures, fixation techniques don't really matter. A paper from Scandinavia looked at hydroxyapatite (HA) coated tibial components, 14 different trials. Although they were more stable after two years there was no difference in revision rates at two years, as well as at 8-10 years."

"There is a paucity of evidence to support one method of fixation with respect to clinical outcomes. In a RCT which looked at 15 years of a single surgeon using the same implant—a PFC—there was no difference between the groups. Likewise with the Next-Gen—uncemented in one knee and cemented in the other knee in the same patient. At 14 years there were no dif-

ferences. In fact, there have been poorer results with some of the older designs. The Freeman-Samuelson at six years showed a much higher rate of failure of the cementless fixation."

"Cementless fixation doesn't address: the common reasons for failure, infection, pain, instability, or lysis. We know that antibiotics in cement reduce infection (the second most common reason for revision). And we have data to support the use of antibiotic loaded cement as a prophylaxis against infection. Revision for infection is more expensive than for aseptic loosening or mechanical failure."

"We know that patellar resurfacing needs cement, and surgeons who routinely resurface the patella would still require half a pack of cement. It's a demanding technique…to ensure coaptation and to secure initial fixation. If it was really so easy then more surgeons would use it rather than shy away from cementless total knees."

"The European data show that less than 10% of surgeons use cementless total knees, except in Norway and Denmark. In the U.S. less than 10% of surgeons use cementless total knees. We really don't know what the optimum design is…whether there should be a stem, screws, mobile bearing or fixed bearing. We don't know the potential long term hazards of HA and porous coating in the young patient…nor the effect of stress shielding. It's a bad analogy to say that just because cementless works in the hips it will work in the knees."

"So the weight of evidence is against cementless. The results are equivocal and we need larger trials; and we don't have optimum data on design or long term safety."

Moderator Whiteside: "Matt, what techniques must you learn to do cementless TKA?"

Dr. Abdel: "The most important thing is understanding your system. Also, you must have meticulous bone cuts so that you can have appropriate preparation for the cementless components."

Moderator Whiteside: "Arun, in terms of cemented fixation, what does a new user have to know?"

Dr. Mullaji: "Not only is it important to know your device, but you must get accurate cuts, have good alignment and balance. And you have to pressurize the cement. The surfaces on the femur and the tibia are easier than in the total hip"

Moderator Whiteside: "Should there be deep penetration of the cement?"

Dr. Mullaji: "There is data to show that it matters how much cement penetration you get. That is a function of the quality of bone, the quality of preparation, and your actual pressurization technique."

Moderator Whiteside: "Matt, how do you talk to patients about cemented versus uncemented?"

Dr. Abdel: "I am a firm proponent of having an open, honest discussion with the patient. We tell them that there are some designers who are utilizing this, but we don't get into the details of cemented versus uncemented. We share our study data, and say that the concern with cementless fixation is with that early two year period. Our experience is that at five years they have rigid fixation, indicating that they have bony ingrowth that we would expect for the long term. To the issue of cost, the literature shows a shorter operative time with cementless fixation, which decreases the infection. That must be factored in."

Dr. Mullaji: "It's only when you exceed about an hour that infection starts kicking in at a higher rate. There's no data showing an increase in infection in any of these cases."

Moderator Whiteside: "If you're going to base your opinions on prospective randomized controlled studies then you might as well go home because you can't operate. So, what do you think is a bigger disaster: an acute infection post-op with a well cemented total knee or with an uncemented total knee?"

Dr. Mullaji: "It depends on how well cemented it was and how well the cementless fixation incorporated. If you just wait long enough for a cemented infection then it's going to be loose."

Dr. Abdel: "I would argue that it's easier with cementless because—without a stem—you cut right across the pegs. There is a concern about how much third body debris is left with the cement after a deep periprosthetic infection."

Moderator Whiteside: "Matt, where are the pitfalls in development right now?"

Dr. Abdel: "Biomechanically, whether you have a keel or pegs or you use screws, you must have rigid fixation. The system I use has pegs that are slightly undersized when you place them. You need secondary fixation such as hexagonal pegs."

Moderator Whiteside: "Thank you both very much." ♦

COMPANY

Blue Belt's Robot Teams With DePuy Synthes' SIGMA Knee

Stryker Corporation buys MAKO Surgical. Smith & Nephew signs a deal with Blue Belt Technologies, Inc. while Blue Belt and MAKO duke out disagreements in court. Then OMNIlife Science, Inc. announces they've now done 4,000 total knees using their OMNIplasty procedure.

The orthopedic robot wars got even more interesting on September 17, 2014, as DePuy Synthes got into the act and announced an agreement with Blue Belt. It's starting to look like Europe in 1914.

Co-Marketing Agreement

Under the agreement, surgeons will be able to use the SIGMA HP Partial Knee System with Blue Belt's Navio surgical system.

Blue Belt's CEO Eric Timko told us that the commercial co-marketing agreement marks a "significant step towards maximizing the potential for our Navio robotic-assisted partial knee replacement technology. We strongly believe that the open implant platform strategy we have taken is the correct approach in order to allow our surgeons to deliver the best care for their patients while utilizing the implant of their choice. All of our partners deliver strong value to the end user."

Larger Audience

He said providing support for the world's largest provider of orthopedic and neurologic solutions partial knee system provides an increasingly larger audience for Blue Belt.

"These partnerships have the potential to accelerate our company's commercial and clinical traction. As with many of our partners, Blue Belt also sees significant synergies with DePuy Synthes products and efforts. Productive company growth will drive further research into clinical applications for our robotic-assisted surgical tools. We view the basis of our computer control methodologies as being the most versatile available, enabling accurate and precise bone resection for a variety of applications, without being tethered to a robotic-arm based system," added Timko.

The DePuy Synthes announcement said that approximately seven percent of all knee replacement patients worldwide are treated with uni-compartmental knees. The company claims the SIGMA partial knee is the only "truly modular system specifically designed to allow uni-compartmental, bi-compartmental (unicompartmental tibiofemoral with patellofemoral) or staged replacement of the knee joint, meaning surgeons can match the implant specifically to a patient's disease state to retain healthy bone, cartilage and ligaments."

Andrew Ekdahl, head of DePuy Synthes' orthopedic business said combining SIGMA's benefit of enabling surgeons to repair only the parts of the knee that are damaged, with Blue Belt's proprietary technology, enables more precise implant placement and soft-tissue balancing to advance patient care. — *WE*

Logoc courtesy of the comapnies

$1.5 Million to Study Anti-Infection Device

Question: What is portable, inexpensive, and fights infection? The Air Barrier System (ABS), an FDA-cleared device that shields surgical sites from bacteria in the OR. And now, Nimbic Systems, creator of the device, has received a $1.5 million National Institutes of Health (NIH) grant for a pivotal, multi-center clinical trial.

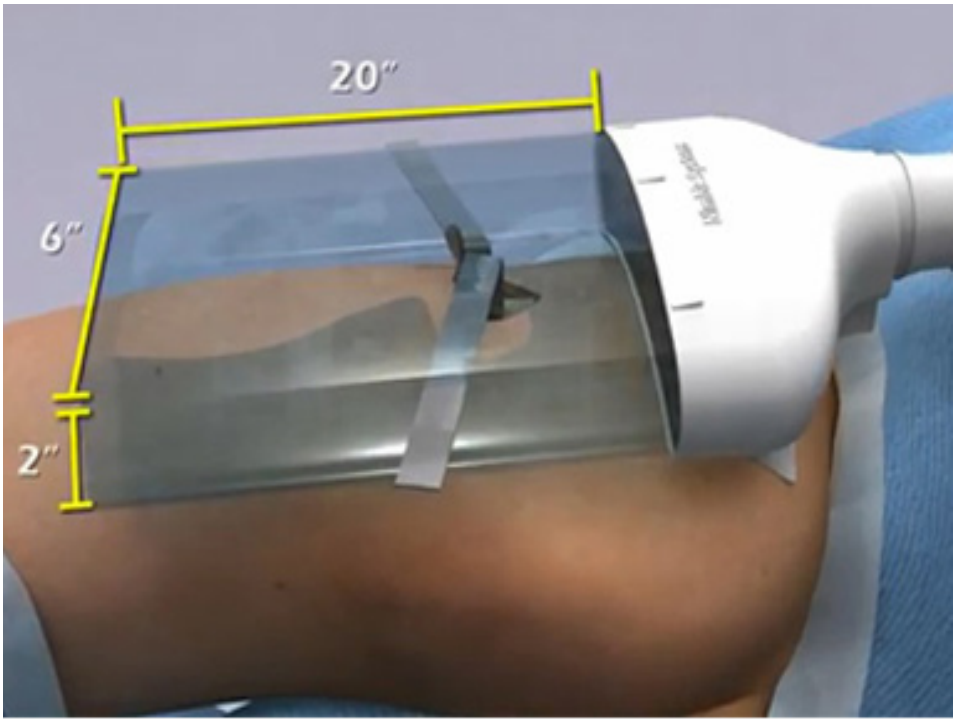
Nimbic Systems

According to the September 15, 2014 news release, the ABS works by "creating a localized clean-air field over the surgery site that prevents airborne microorganisms from entering the incision. Currently, the ABS is cleared for use in hip arthroplasty and posterior spine surgery. In a clinical study funded by an SBIR Phase I grant from National Sciences Foundation and published in the August 2011 issue of *Journal of Arthoplasty*, the ABS reduced the presence of airborne bacteria at incision sites during hip surgery by up to 84%."

Additionally, in April 2015 the company plans to publish the results of its current NIH-sponsored Phase II clinical trial of the ABS. "This Phase II study is a prospective randomized clinical trial that examines the ability of the ABS device to reduce the clinical rate of prostheses-related infection in 300 patients undergoing hip, spine, and certain vascular implant procedures."

Sean Self, president of Nimbic Systems, told *OTW*, "We are fortunate to have formed a partnership with infection prevention thought leaders at Baylor College of Medicine and the University of Texas Medical Branch at Galveston. Multi-center clinical trials require a great amount of communication and leadership in order to obtain valuable data. Our first steps will be to host educational meetings with all of the investigators, nurses, technicians, and other staff to explain the importance of our research and what the essential responsibilities are."

As for where they hope to be six months from now, Self noted, "By April 2015 we expect to have 100 patients enrolled in this multi-center study. The study will enroll 800 patients in total over a two-year period followed by a one-year follow up period to monitor patients for incidences of surgical site infection." — *EH*



Nimbic Systems

LEGAL

NexGen Plaintiffs Lawyers Bite Back at Zimmer

Lawyers representing plaintiffs in the NexGen lawsuits say Zimmer Holdings, Inc.'s claims that they should be sanctioned shows the company is running scared.

RRY Publications LLC

In its motion to sanction the lawyers, Zimmer noted that attorneys representing plaintiffs Mertha Shoat, Ronnie Davis and Debra Teague had missed a July 15 deadline for producing expert reports without providing advance notice that a deadline was going to be missed, or required an extension. Zimmer's motion claims that such "repeated abandonment of Zimmer case picks has unreasonable and vexatiously multiplied these MDL (multidistrict litigation) proceedings and justifies sanctions."

"Regrettable Scare Tactic"

Attorneys for the plaintiffs are having none of it, referring to Zimmer's position as "a regrettable scare tactic."

"Rather than face the music in the bellwether trial process, Zimmer ran scared and selected cases they knew were not

triable," said an attorney representing the plaintiffs. "They were even warned of that by plaintiffs' counsel at the outset. Instead of getting to the truth, Zimmer ran up costs and time at their own peril. Now they're seeking relief for their own contrived crisis. What's really sanctionable is their conduct here."

Gordon Gibb writes on September 12, 2014 on the website, *Lawyersand-Settlements.com*, that with one Zimmer NexGen lawsuit currently underway in federal court in Illinois, both sides are employing various strategies in an effort to further the fortunes of the various antagonists.

A collection of lawsuits alleging Zimmer's NexGen knee replacement failure were consolidated into one multidistrict litigation in August 2011.

We've got ourselves a legal kerfuffle. — *WE*

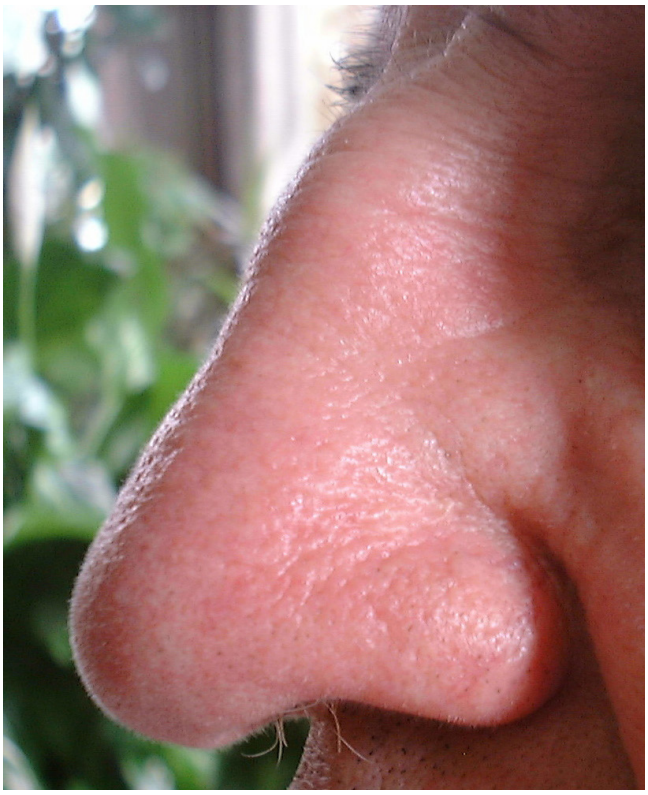
BIOLOGICS

Nasal Cells Grow Cartilage in Knees

Researchers at the University Hospital of Basal, Switzerland, have taken cartilage cells from nasal septums and used them to generate new cartilage for placement in damaged knees. As reported by Joseph Keenan, of *Fierce Medical Devices,* doctors took cells from the nasal septums of seven patients and, after the cultures multiplied, applied them to a scaffold that grew a 30 by 40 millimeter cartilage graft. The graft was used to replace damaged cartilage tissue in the knees of the patients, all of whom were under the age of 55.

The study was published in the journal *Science Translational Medicine*. The researchers noted that the nasal cartilage cell's ability to grow in the knee joint environment was associated with the expression of genes called "HOX genes."

Keenan quoted Professor Ivan Martin, the lead researcher in the study as saying, "The findings from the basic research and the preclinical studies on the properties of nasal cartilage cells and the resulting engineered transplants have opened up the possibility to investigate an innovative clinical treatment of cartilage damage." — *BY*



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LARGE JOINTS

Hospital Guarantees Joint Replacement Surgery

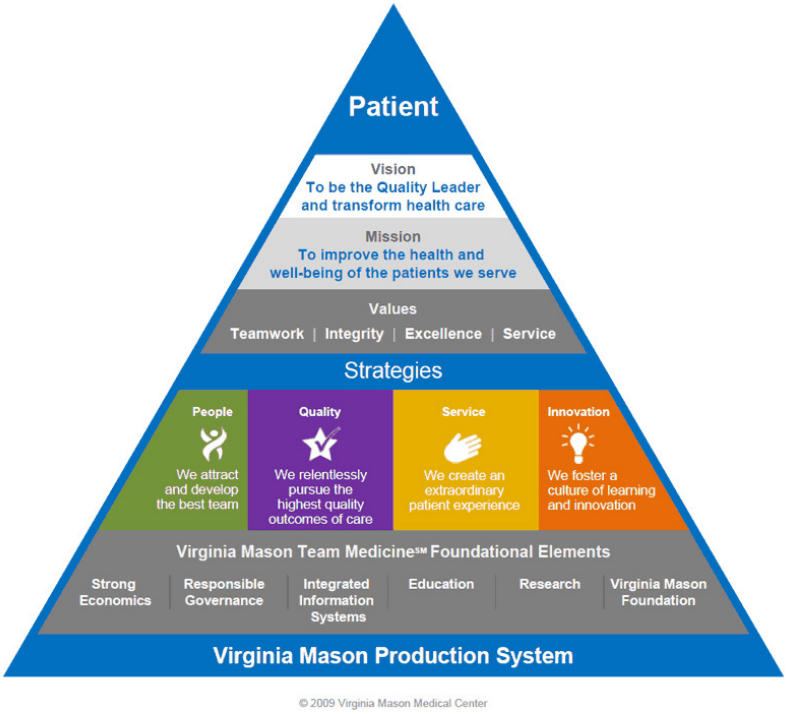
It's guaranteed! Virginia Mason Medical Center of Seattle, Washington, is offering a surgical warranty for hip and knee replacement surgery. According to its news release, the warranty protects patients, insurance providers and employers from incurring additional costs for the treatment of avoidable, surgery-related complications.

The warranty covers the full range of care—diagnosis, surgery and rehabilitation—for an adult patient's hip or knee replacement when all services are delivered by Virginia Mason. The warranty does not cover complications due to failure of the surgically implanted hip or knee device.

Chairman and CEO Gary S. Kaplan, M.D., said, "Health care costs must be tamed. We view our surgical warranty as a significant step in that direction. Offering this assurance speaks to the skill of our surgeons and of their teams, and of our willingness as an organization to stand behind their work." Virginia Mason is the first hospital in its region to offer this protection to patients, their insurers and employers.

According to the National Center for Health Statistics doctors performed more than 719,000 knee replacement surgeries and 332,000 hip replacements in 2010.

"Under the current reimbursement system in our country, hospitals are often paid more for surgery that does not go well than for surgery that is completely successful," Kaplan said. "We find this unacceptable and contrary to the needs of patients, employers and insurers paying the bill. — *BY*



Courtesy of Virginia Mason Medical Center

U.S. Behind in Joint Registry Development

The Brits do it. The Australians do it. So why does the U.S. trail in tracking the performance of medical devices through registries? Organizations such as the Pew Charitable Trust, Blue Cross and Blue Shield and the Science Infrastructure Center run by Weill Cornell Medical College's Medical Device Epidemiology Network are leaning on the Food and Drug Administration to catch up.

Wikimedia Commons and Graham Horn/Photo creation by RRY Publications LLC

Jaimy Lee, writing for *Modern Healthcare*, points out that "device registries gather information about how patients respond after devices are used or implanted." He noted that a carefully kept registry can compare older, less costly devices with newer products. Too often clinical trials involve a small number of patients over a short period of time and so do not provide the needed long term data about how those devices work over the long haul in patients.

Those calling for a federally run registry refer to Johnson & Johnson's recall

in 2010 of metal on metal implants. Clinicians tracking outcomes of the implants in registries in Australia and the United Kingdom were the first to identify the higher failure rates of these hip implants compared with older devices that had been on the market for years. J&J eventually recalled 93,000 hip implants, Lee wrote.

"It's taken us too long to figure out these devices have serious and unexpected safety problems," Josh Rising, M.D. Pew's director of medical devices, told Lee. "There's no reason that we shouldn't be able to identify these problems in the United States."

Lee noted that "many private organizations have developed their own registries to improve clinical and purchasing decision-making." Among those organizations are Kaiser Permanente, the Cleveland Clinic and the Veterans Affairs Department. However the data collected is private, the property of these organizations. Those arguing for the establishment of a federal registry believe the data should be publically available. — *BY*

Torn ACL: Hit the OR or Play it Safe?

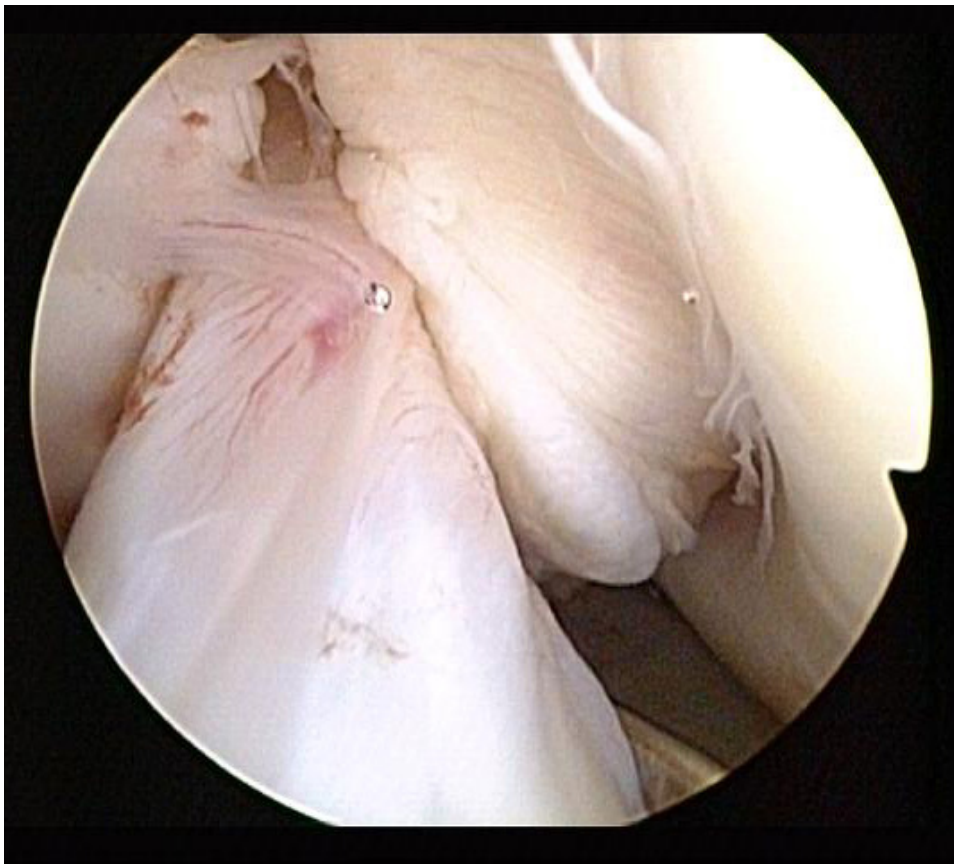
A torn anterior cruciate ligament (ACL)…to operate or not? Knowledge is lacking, say the authors of a recently published article, about the clinical course of nonoperative treatment of an ACL tear. The study, conducted by Grindem et al. from the Norwegian Research Center for Active Rehabilitation in Oslo, Norway, has just been published in *The Journal of Bone and Joint Surgery* (*JBJS*).

This was a cohort study that included 143 patients who were treated operatively and nonoperatively; each participant was measured for isokinetic knee extension and flexion strength and patient-reported knee function were recorded at baseline, six weeks, and two years. The authors found that the 100 patients who chose to undergo surgery were younger and were those who wanted to participate in Level-I sports[1]. Those treated nonoperatively were found to return to level-II[2] sports in the first year much more quickly and in the second year were more likely to return to level-III[3] sports than their surgically treated counterparts.

Regardless if a patient appeared on the OR table or not, the results were roughly the same, say the study's authors. They point to the fact for many patients, neither course of treatment resulted in a full recovery; the authors intend to focus future efforts on improving outcomes for these patients.

Marc Swiontkowski, M.D., Editor-in-Chief of *JBJS*, commented to *OTW*, "Patients consider their future desires in terms of sport related demand on their knee as a major component in their decision making in regards to the option of undergoing ACL reconstruction. The functional demand does relate to the future risk of a meniscal tear and many patients prefer to forego future high pivoting and twisting activities rather than undergo surgery." — *EH*

[1] *handball, soccer, basketball, floorball*
[2] *volleyball, martial arts, gymnastics, ice hockey, tennis/squash, alpine/telemark skiing, snowboarding, dancing/aerobics*
[3] *cross country skiing, running, cycling, swimming, strength training*
Reference: Hefti et al. 1993



Anterior cruciate ligament arthroscopy/Wikimedia Commons and Arthroscopist

OMNIPlasty Tops 4,000 Total Knees

Over 4,000 total knee replacements have been completed in the U.S. using OMNIlife Science, Inc.'s OMNIPlasty technique.

Total Knee Procedure

OMNI's system performs a total knee procedure that uses robotics utilizing the company's OMNI ART software platform. Surgeons can plan and execute a procedure that is specific to each patient using a patented intra-operative 3-D modeling technique that is not dependent on pre-operative CT scans or X-rays.

Jan Koenig, M.D., of Winthrop University Hospital in Long Island, said in a September 15, 2014 company press release that the OMNINAV station "has the look and feel of the future in orthopedic navigation, which is validated by its extreme level of performance and accuracy." Koenig add that "OMNIPlasty offers the only robotically assisted total knee replacement technology on the market, which provides my patients with a custom-tailored solution for their knee arthritis problems."

Which begs the question, how exactly is OMNI's robotic system different from other systems on the market?

Different From Blue Belt and MAKO

George Cipolletti, the president and CEO of OMNI told us that the company's OMNINAV platform is different from the other solutions in several areas.

First, he says it is the only system that performs robotically assisted surgery for total knee replacement, which accounts for 10 times the number of procedures worldwide compared to partial knee replacement (addressed by MAKO/Stryker Corporation and Blue Belt Technologies, Inc.).

"Our hardware platform has a small footprint in the operating room and requires no turnaround between cases, compared to an hour or two for other systems."

Second, he notes that OMNIPlasty uses patented bone morphing technology which is the software that allows a complete 3-D image of the knee to be created intraoperatively without X-rays, while the competitive systems require expensive CAT or MRI scans prior to surgery. "Our OMNINAV system implants world-class knee devices with a proven clinical track record of better than 99% survivorship over eight years for tens of thousands of cases."

No Charge!

Finally, he says "we have a much more cost-effective solution for the hospital, placing OMNINAV stations at no cost to the hospital. The other systems charge from $450,000 to $1,000,000+ per installation."

The OMNI ART software, says the company, is designed for flexibility and customization to any surgeon's particular philosophy, which may result in increased efficiency. Corey Ponder, M.D., from Oklahoma Sports & Orthopedics Institute in Oklahoma City states, "The flexibility we have achieved using OMNI ART software is significant. When changes need to be made during surgery because of unforeseen circumstances, we are able to handle them easily and efficiently. When you combine that time savings with the robotic precision of OMNIPlasty, you have then taken total knee replacement to another level."

Privately held OMNI was founded in 1999 and is located in East Taunton, Massachusetts. — *WE*

OMNINAV/OMNIlife Science, Inc.

Positive Thinking Dulls the Pain

Mental attitudes make a difference—sometimes a big one, according to Esther Yakobov, a doctoral student in clinical psychology at McGill University in Montreal. She found that people who blame others for their suffering and experience life as being unfair to them experience more pain after knee replacement surgery than do those with a different outlook.

Yakobov told Kathryn Doyle, writing for *Reuters Health*, that "Studies conducted with patients who suffer from chronic pain because of an injury demonstrated that individuals who judge their experience as unfair, focus on their losses, and blame others for their painful condition also tend to experience more pain and recover from their injuries slower than individuals who do not."

In the recent study Yakobov studied patients whose disability resulted not from an injury but osteoarthritis. Her subjects were 116 men and women, all of whom had severe osteoarthritis, were between the ages of 50 and 85 and were scheduled for knee replacement surgery in Canada.

Before their surgery they each filled out questionnaires that measured their feelings of perceived injustice. The rated their agreement with statements such as "It all seems so unfair," and "I am suffering because of somebody else's negligence." Another questionnaire measured their pain levels.

All of the participants' knee surgeries were successful and after one year the researchers tested them again. Doyle reported that, "The more a patient agreed before surgery that life seems unfair and others are to blame for their problems, the more pain they reported experiencing one year after surgery. That was true even when age, sex, other health conditions and pre-surgery pain levels were accounted for."

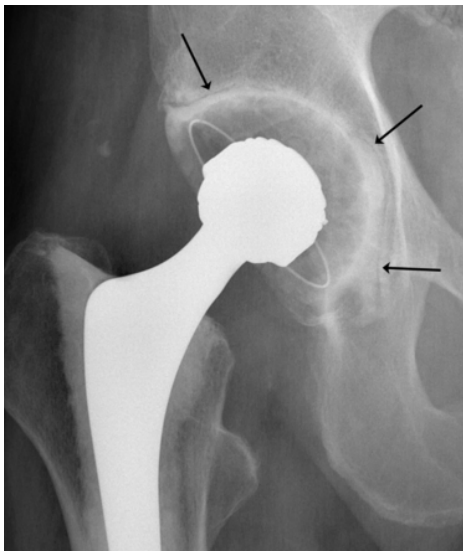
Victoria Brander, M.D., a physical medicine and rehabilitation specialist at Northwestern Orthopaedic Institute in Chicago, commented on the study. "All of these psychological factors point to the fact that patients who perceive themselves as helpless, those who are afraid, those who feel loss of control, have a more difficult time," She noted that the opposite was also true, that people who are self-confident and secure in their own ability to achieve a goal appear to recover more rapidly from knee replacement surgery. — *BY*

Wikimedia Commons

Radiolucency Yields to Computers

A new study by university researchers in the United Kingdom has identified a computerized system that will improve the success of knee revision surgeries and perhaps even help to prevent them.

The underlying problem it addresses is osteoarthritis, the degeneration of joint cartilage and bone—the world's most common musculoskeletal disease. The World Health Organization predicts that by 2020 osteoarthritis will be the world's fourth leading cause of disability, affecting double the number of patients who have cardiac disease.



Courtesy of bone and joint.org.uk

Surgeons in the UK perform about 90,000 knee replacements annually. That figure is expected to rise by more than 600% by 2030, because of an aging population, increased obesity and the fact that patients are getting younger. If a knee replacement lasts 10 to 15 years, a young patient may need one or two revision surgeries during his lifetime. Revision knee replacements can cost up to four times the amount of the original surgery, report the researchers.

Enter the results of the study. Radiolucency is the name of a region surrounding a hip or knee replacement which shows up dark on an X-ray. If it darkens over time that may indicate that the implant is loosening and may need to be removed and replaced. In current clinical practice orthopedic surgeons look at the radiolucency and try to come to a reasonable conclusion.

The good news is that researchers have developed a semi-automated computer program which provides an independent, more reliable radiolucency score than the present subjective surgeons' assessments. The study, published in *Interface*, analyzed six surgeons' assessment of radiolucency in 38 unicompartmental knee replacement radiographs. They then compared the results with assessments made by a semi-automated imaging algorithm.

The results? There was wide variation among the surgeon results with total agreement in fewer than 10% of zones. The automated program had total agreement in 81.6% of zones—demonstrating a far more accurate and reliable means of diagnosing radiolucency.

"Surgeons are given limited guidance on how to define radiolucency and use different assessment criteria which explains the wide and concerning variation found in the surgical assessments in this study," commented Richie Gill, BEng, DPhil, FIPEM, professor of Healthcare Engineering." Using a digital computerized tool that accurately identifies patients with progressive pathological radiolucency would ensure that correct surgical procedures are applied, improving patient outcomes and saving money spent on operations which may not ultimately be successful, "he said.

Senthil Kumar Ganesan, M.D., orthopedic surgeon at the Royal United Hospital in Bath said, "Total knee replacements are on the increase mainly due to the increasing demand from the patients as well as younger patients under the age of 60, undergoing knee replacements. The use of early and accurate diagnostic tools in the diagnosis of early loosening will be of immense help in the knee replacement surgery. This will not only facilitate early treatment it will also help to prevent late complications of neglected loosening." — *BY*

EXTREMITIES

FDA Clears Two Foot Repair Systems

Edge Orthopaedics of Boonton, New Jersey, has received its second U. S. Food and Drug Administration 510(k) clearance for its View Plating System and for its Reduce Fracture Plating System. The View system includes anatomic plates to support multiple indications within the mid-foot while the Reduce Fracture system offers surgeons a wide range of low-profile plate designs to address the most common procedures performed by foot and ankle surgeons. According to the press release, both systems contain titanium alloy and sterile titanium alloy bone screws.

Both plating systems and the compression screws utilize the same instrumentation tray for increased hospital efficiency. Edge COO Anna Kroll said, "By sterile packaging implants and offering one instrumentation tray for multiple product lines, it not only reduces the amount of trays that need to be sterilized and wrapped for a case but it also provides each surgeon the opportunity to change implant needs at a moment's notice. This can be a game changer for operating rooms."

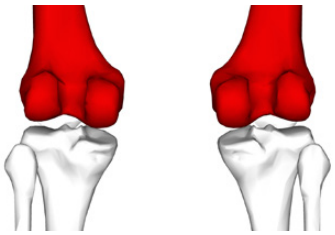
Edge Orthopaedics is a privately held medical device company that develops products for extremity orthopedics. — *BY*

Courtesy of Edge Orthopaedics

SPINE

3-D Implants Tested Worldwide

The Chinese are forging ahead with 3-D printed implants. *Forbes Magazine* and Emily Wasserman, writing for *Fierce Medical Devices,* both report that doctors at Beijing's Peking University replaced a cancerous vertebra in a 12-year-old boy's spinal cord with a 3-D piece that they created from titanium powder. The implant was made with small pores which they believe



Courtesy of www.news.cn

will allow bone tissue to grow into the device. This eliminated the need for cement or screws, explained Liu Zhonguin, the head of the Orthopaedics Department at Peking University.

Not to be left behind, Wassermann noted that in May 2013 doctors at the University of Michigan had created and implanted a 3-D printed tracheal splint in a infant. They created a model of the device by taking a CAT scan of the baby's respiratory track and then printed the implant from bio absorbable plastic.

And in the UK an orthopedic surgeon created a replacement hip from titanium powder using the hospital's 3-D printer and implanted it in an elderly cancer patient. According to a report from Freedonia cited by *Forbes* and Wasserman, the demand for implantable medical devices in the U.S. is expected to increase 7.7% annually to $52 billion in 2015. — *BY*

PEOPLE

Donna A. Saatman, M.D., Jeffrey A. Westerfield, M.D., Joseph M. Zavatsky, M.D. Join FOI

The Florida Orthopaedic Institute (FOI) has announced the addition of three physicians: Drs. Donna A. Saatman, Jeffrey A. Westerfield, and Joseph M. Zavatsky.

According to the September 11, 2014 news release, "Donna A. Saatman, M.D. is fellowship trained in neurosurgery and specializes in the surgical treatment of adult degenerative spinal and peripheral nerve disease. Prior to joining Florida Orthopaedic Institute, Dr. Saatman served as president and chief neurosurgeon in a private practice in Brandon, Florida."

"Jeffrey A. Westerfield, M.D. is board certified in family medicine and is fellowship trained in sports medicine. Dr. Westerfield specializes in musculoskeletal injuries and the acute care and management of concussions for

Donna A. Saatman, M.D., Jeffrey A. Westerfield, M.D., Joseph M. Zavatsky, M.D./Image: Florida Orthopaedic Institute

athletes. Prior to practicing medicine, Dr. Westerfield served in the U.S. Army and U.S. Coast Guard as a Chief Warrant Officer helicopter pilot."

"Joseph M. Zavatsky, M.D. is board certified by the American Academy of Orthopaedic Surgeons, specializes in spine surgery, treats all spinal disorders and patients of all ages. In addition to performing more common degenerative cervical, thoracic and lumbar surgical procedures, Dr. Zavatsky has a special interest in minimally invasive surgery along with adult and pediatric complex spinal deformity and reconstruction."

"Adding new physicians with exceptional experience, training and skills not only increases the services we offer but also enhances the quality of care our patients receive," said Dr. Roy Sanders, president and chief medical officer of Florida Orthopaedic Institute.

Joseph M. Zavatsky, M.D. commented to *OTW*, "My goal is to provide adult and pediatric patients with complex spinal deformities the safest and least invasive options to improve their quality of life and get them back to doing what they enjoy most. I'm supported by a strong team of physicians at Florida Orthopaedic Institute and look forward to working with them to keep the community active."

Jeffrey A. Westerfield, M.D., M.B.A. told *OTW,* "On my first day at work, I had the opportunity to care for athletes' bumps, bruises, concussions and fractures under the Friday Night Lights and the response from parents and coaches was overwhelmingly positive. I believe that being on the sidelines gives me another chance, outside of my normal clinic setting, to provide concussion education and injury prevention to high school athletes."

Donna A. Saatman, M.D. stated, "Alleviating a patient's pain and keeping them active is something I am sincerely passionate about, and I look forward to extending my wealth of knowledge and 10 years of spine experience to patients at Florida Orthopaedic Institute." — *EH*

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