VOLUME 9, ISSUE 39 | DECEMBER 10, 2013

Orthopedics This Week

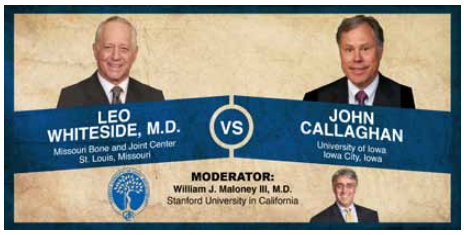
WEEK IN REVIEW

4 Medicare Cuts Hip and Knee Payments >> Medicare is going to inflict some real pain on knee and hip surgeons in 2014 by lowering payments by 10% and 4%. The agency says reimbursements for those procedures have been "misvalued." With sequestration and a 24% SGR cut scheduled in January, are surgeons finally going to stop fixing grandma and grandpa's hips and knees?

8 Flatow, Galatz Square Off Over Reverse Shoulder >> "A reverse is an excellent option for elderly patients, those with poor bone, and patients with compromised rehab," states Evan Flatow. Leesa Galatz argues, "Hemiarthroplasty still has a role: the outcomes are equivalent and complications are much lower, among other things."

12 Notochordal Cells Key to Treating Back Pain // PRP Effective in Three Diseases! // Surgery Improves X-Games Snowboarders Win Rate Three-fold >> The Director of Spine Research at the Mount Sinai is finding new therapeutics for discogenic back pain. Northwestern University researchers have concluded that there are three distinct diseases that could benefit from PRP. And a new study has found that snowboarders earned nearly three times the number of medals after ACL surgery.

16 Whiteside, Callaghan Debate Life-Time Guaranteeing Cementless TKA >> "If I can do an osteointegrated total knee and I can choose the one I want and I do the operation myself then I will guarantee it for a lifetime,' says Leo Whiteside. John Callaghan: "Lifetime guarantees are dangerous in ALL aspects of life. Look at Vegas…marriage capital of the world…50% of those don't work out. Death and taxes are the only guarantees."



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: There are no free lunches and this extended rising market will someday turn. But not this week. Interestingly, emerging market equities seem to have caught U.S. equity market fever—capital liquidity courtesy of the Fed. Fed funds are finding their way into emerging markets. Global optimism is rising, cost of capital is slipping—all of which keeps this bull market running a little longer.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	4	Integra LifeSciences	11.77%	9.98%	That public offering of stock keeps paying dividends to IART. Broader exposure has attracted new buyers.
2	2	Orthofix	16.25	(2.37)	Will OFIX be delisted? Probably not. Eventually OFIX will file its 10Q. Its stock is way oversold and it is the least expensive ortho equity of all.
3	1	Exactech	10.00	3.98	Short time at the top of the Power Rankings. EXAC is up 35.50% so far this year. Some profit taking possible.
4	6	Globus Medical	28.53	3.84	Double digit sales growth and the excellent possibility that GMED will beat third quarter. Up two spots.
5	8	Symmetry Medical	6.50	20.13	Hottest stock on the Power Rankings this week. Who's buying and why?
6	10	Conmed	10.37	6.97	CNMD has a couple of hidden assets—one of which is its core competency in MIS instrumentation. Trend is CNMD's friend.
7	3	NuVasive	6.30	3.25	Profit taking last week and unless there is a new catalyst between now and January 1, this is the trading range.
8	7	Stryker	15.22	1.10	Good business at a fair price. Sure, but also a highly strategic business which, if acquisitions pan out, makes SYK even more undervalued.
9	5	Zimmer	27.31	2.93	Only one company has a lower valuation than ZMH—and that's the company being threatened with delisting. Very cheap.
10	9	Medtronic	28.84	1.17	Nice new study from MDT shows cervical disc replacement superior to fusion after seven years. All good news. Is Medicare paying attention?

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	$6.98	$683	21.60%
2	Symmetry Medical	SMA	$9.43	$351	20.13%
3	CryoLife	CRY	$10.70	$295	14.81%
4	TiGenix	TIG.BR	$0.66	$83	13.03%
5	Wright Medical	WMGI	$30.33	$1,429	12.88%
6	Tornier N.V.	TRNX	$17.53	$850	11.73%
7	Integra LifeSciences	IART	$46.63	$1,498	9.98%
8	RTI Biologics Inc	RTIX	$3.10	$175	8.39%
9	Smith & Nephew	SNN	$70.03	$12,513	7.69%
10	ArthroCare	ARTC	$38.08	$1,081	7.03%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	$0.44	$23	-31.91%
2	Baxano Surgical Inc	BAXS	$1.01	$46	-15.83%
3	Orthofix	OFIX	$20.62	$401	-2.37%
4	MAKO Surgical	MAKO	$29.97	$1,543	0.81%
5	Stryker	SYK	$74.52	$28,200	1.10%
6	Medtronic	MDT	$58.14	$58,044	1.17%
7	Johnson & Johnson	JNJ	$94.44	$266,457	1.50%
8	Alphatec Holdings	ATEC	$1.89	$184	1.61%
9	Zimmer Holdings	ZMH	$92.02	$15,734	2.93%
10	NuVasive	NUVA	$32.71	$1,459	3.25%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$20.62	$401	8.28
2	Medtronic	MDT	$58.14	$58,044	15.64
3	Zimmer Holdings	ZMH	$92.02	$15,734	16.46
4	Smith & Nephew	SNN	$70.03	$12,513	17.16
5	Globus Medical	GMED	$19.48	$1,816	17.38

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$30.33	$1,429	131.87
2	NuVasive	NUVA	$32.71	$1,459	86.08
3	Symmetry Medical	SMA	$9.43	$351	47.53
4	Integra LifeSciences	IART	$46.63	$1,498	29.76
5	CryoLife	CRY	$10.70	$295	27.63

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$19.48	$1,816	1.16
2	Orthofix	OFIX	$20.62	$401	1.18
3	Conmed	CNMD	$39.88	$1,101	1.56
4	Exactech	EXAC	$24.04	$325	1.61
5	Zimmer Holdings	ZMH	$92.02	$15,734	1.73

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$30.33	$1,429	8.79
2	NuVasive	NUVA	$32.71	$1,459	7.00
3	CryoLife	CRY	$10.70	$295	6.91
4	Integra LifeSciences	IART	$46.63	$1,498	3.98
5	Symmetry Medical	SMA	$9.43	$351	3.96

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	$0.44	$23	0.70
2	Symmetry Medical	SMA	$9.43	$351	0.86
3	Orthofix	OFIX	$20.62	$401	0.87
4	Alphatec Holdings	ATEC	$1.89	$184	0.94
5	RTI Biologics Inc	RTIX	$3.10	$175	0.98

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	$6.98	$683	25.25
2	TiGenix	TIG.BR	$0.66	$83	20.33
3	MAKO Surgical	MAKO	$29.97	$1,543	15.02
4	Globus Medical	GMED	$19.48	$1,816	4.71
5	Johnson & Johnson	JNJ	$94.44	$266,457	3.96

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

Medicare Cuts Hip and Knee Payments

BY WALTER EISNER

Surgeons will see their payments from Medicare for knee and hip procedures drop by 10% and 4%, respectively, in 2014. It's been a tough year for physicians, as Medicare payments to providers were cut by 2%—$11 billion—in mandatory federal spending cuts under the sequester that started March 1, 2013.

Will this latest hit in addition to the threat of a 24% SGR (sustainable growth rate) cut in January finally drive surgeons from accepting new Medicare patients?

More on that later.

For months, industry and Wall Street analysts warned of significant Medicare cuts based on the American Medical Association's (AMA) secret recommendations to the agency. On the day before Thanksgiving, CMS (Centers for Medicare and Medicaid Services) dropped this turkey on surgeons with a 1,369-page final rule for Medicare's physician fee schedule.

"Misvalued" Codes

In its news release, CMS noted that it has been engaged in a vigorous effort to review potentially "misvalued" codes, including services for hip and knee replacements. In 2012, CMS asked the Relative Value Update Committee (RUC) of the AMA, which manages the CPT (current procedural terminology) coding set used by Medicare and private insurers for medical services/procedures, to review hip (CPT 27130) and knee (CPT 27447) replacement payment rates.

Andrew Huth and RRY Publications LLC

Jefferies analyst Raj Denhoy reported that the RUC committee suggested that the work RVU component for hips be cut by 10% and knees by 16%. CMS revised these down to 5% for hips and 11% for knees. The final payment rates, which are a factor of the work RVU and other inputs, were then cut by 4% and 10%.

For hips, payment in 2014 will go to $1,393.78 from $1,454.48; for knees the rates are reduced to $1,393.06 from $1,552.81. These rates assume that congress enacts its annual "doc fix" and that the rates are not subject to the 24% SGR reduction.

The Dropouts

Denhoy says the cuts could force some surgeons to abandon treating Medicare patients. "We don't believe the cuts will have any immediate or significant impact on procedure volumes; it simply isn't clear how most surgeons can stop treating Medicare patients as they represent over half of all large joint candidates," wrote Denhoy.

The 9,539 physicians who opted out of Medicare last year is a small proportion of the 685,000 physicians who participated in Medicare last year. But that was nearly triple from three years earlier, according to the CMS, which has never released annual opt-out figures before.

Where are the dropouts coming from?

Joe Baker, president of the Medicare Rights Center, reportedly said his patient-advocacy group has had an increase in calls from seniors who can't find doctors willing to treat them—mainly from affluent urban and sub-

urban areas where many patients can pay out of pocket if their doctor doesn't accept Medicare. "In most places, doctors can't pick and choose because Medicare is the biggest game in town, or the only game in town," he said.

Surgeon Medicare Options

Surgeons have three Medicare options.

First, those who participate bill Medicare directly and must agree to accept its reimbursement rates for all covered services.

Second, the so-called nonparticipating physicians still file Medicare reimbursement claims but can charge as much as 10% over Medicare's rates for some services, and they must bill patients for the difference.

Third, those who drop out can charge patients whatever they want, but they must forgo filing Medicare claims for two years, and their Medicare-eligible patients must pay out of pocket to see them.

Implant Pricing Risk

The big risk isn't from the dropouts, says Denhoy, but is likely the longer term impact physician rate cuts could have on pricing for orthopedic implants. "Cuts in reimbursement could prompt more clinicians to become employees of hospitals. As incentives between clinicians and hospitals become better aligned, increased price pressure could occur."

He adds that cuts to physician rates can have implications on bundled payment arrangements, which also could lead to more focus on implant pricing.

In terms of potential exposure for the device companies, Denhoy says U.S. hips and knees account for 18% of total sales for Stryker Corporation, while for Zimmer Holdings, Inc., the exposure is a much higher 37%.

Slicing the Pie

The 2014 payment rates increase payments for many medical specialties with some of the greatest increases going to providers of mental health services

Gunnar Anderson, M.D., Ph.D

including psychiatry, clinical psychologists and clinical social workers.

Gunnar Anderson, M.D., Ph.D, president of ISASS (International Society for

the Advancement of Spine Surgery), told *OTW*, "For those who followed the healthcare debate in recent years the CMS physician payment rates for 2014 offers no surprises. While the total payment remains fairly constant, the pie is sliced in favor of the primary care physicians and this year also in favor of mental health services."

Anderson said PQRI (Physician Quality Reporting Initiative) and payment adjustments based on quality are other cornerstones of the new healthcare model. "The population benefits of these efforts are yet to be determined. Some PQRI efforts are unlikely to have major health benefits."

"For the musculoskeletal surgeon the rates are lower as usual. This will likely drive additional surgeons to no longer see Medicare patients."

Collaborating in Their Own Execution

At the request of CMS, AAOS (American Academy of Orthopaedic Surgeons) and AAHKS (American Association of Hip and Knee Surgeons) collaborated with the agency by surveying their members about the procedures. The results, according to an article in the December issue of *AAOS Now*, reflected current trends to reduce hospital length of stay and to accelerate rehabilitation. Procedure times also differed from previous estimates.

Every year, CMS makes changes to the RVUs for procedures, including orthopedic procedures, within the fee schedule. This year, the following four high-volume lower extremity orthopedic procedures were reviewed and the RVUs either revised or left at their current value:

- 27130—Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty [THA]), with or without autograft or allograft. The work RVU has been changed from 21.79 to 20.72, a decrease of 5%.
- 27236—Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement. The work RVU remains the same at 17.60.
- 27446—Arthroplasty, knee, condyle and plateau; medial OR lateral compartment. The work RVU has been changed from 16.38 to 17.48, an increase of 6.7%.
- 27447—Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty [TKA]). The work RVU has been changed from 23.25 to 20.72, a decrease of 11%.

Although the AAOS and AAHKS survey results indicated a difference in procedure time, the Academy pointed out that this was a function of the survey methodology, not a change in the actual work involved in performing the surgery.

No Good Deed Goes Unpunished

Joshua Jacobs, M.D., president of AAOS said, "Although we are disappointed with the devaluation of procedures that


Joshua Jacobs, M.D., President of AAOS

we know provide tremendous value to the individual patient and to society and that CMS did not use the values recommended by AAOS and AAHKS, we are pleased that CMS responded to our extensive regulatory and legislative advocacy efforts to alter the RUC's recommendation of far deeper cuts."

Leaders of the Academy are particularly concerned that CMS did not publish the new values in the July 2013 Physician Fee Schedule Proposed Rule, but waited until publication of the Final Rule to release the values.

"AAOS and AAHKS believe that CMS has an obligation, as a public agency, to solicit and consider stakeholder and public feedback prior to implementing major policy changes such as these. However, CMS choose to ignore requests by AAOS and AAHKS to publish the values earlier, which would have allowed for public comment and input," stated the article in *AAOS Now*.

Lobbying Congress

The societies are continuing to push to get the proposed payments changed by telling lawmakers that if cuts to reimbursement rates continue, many surgeons will just stop fixing Medicare patients.

"Patients now face the potential of having less access to these highly valuable and successful surgeries. Implementation of the CMS values will be a significant setback for the collective health of Medicare beneficiaries. In addition, they might have unintended consequences for society, based on recent studies showing the cost-effectiveness of TKA. (See "*What Is the Societal Value of TKA*?" AAOS Now, September 2013.), "continued the AAOS statement.

The societies are urging their members and patients to take the open comment period to provide written comments to CMS between now and December 31, 2013. AAOS members are also urged to contact their congressional representatives and urge them to force CMS to accept the AAOS and AAHKS recommended values.

The Academy said it will submit extensive comments to CMS on this final rule.

Is this the straw that will break the camel's back and cause more physicians to join their 9,500 colleagues who have already voted with their feet and dropped out of Medicare, or will they continue to try and make it up on volume? The answer may be that it depends on who the surgeon works for.

Tell us what you think. Email walter@ryortho.com and we'll share the results. ♦

Flatow, Galatz Square Off Over Reverse Shoulder

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

"A reverse is an excellent option for elderly patients, those with poor bone, and patients with compromised rehab," states Evan Flatow. Leesa Galatz argues, "Hemiarthroplasty still has a role: the outcomes are equivalent and complications are much lower, among other things."

Current Concepts in Joint Replacement/RRY Photo Creation

This week's Orthopaedic Crossfire® debate is "This Fracture Should Be Treated With a Reverse Shoulder." It involves a 69-year-old woman in good health until she fell on some ice and sustained a fracture to her right, dominant shoulder. She had no other injuries and her neurovascular status was intact throughout the limb. She has a sedentary lifestyle, but does do some gardening and takes care of her grandchildren. For the proposition is Evan L. Flatow, M.D. of the Mount Sinai School of Medicine in New York; against the proposition is Leesa M. Galatz, M.D. from Washington University School of Medicine in St. Louis. Moderating is Thomas S. Thornhill, M.D. from Harvard Medical School in Boston.

Dr. Flatow: "There looks to be a head split, comminution, soft bone and osteoporosis; perhaps there is some callous. This would be a challenging case for internal fixation, especially if it's not a day or two old. There are fewer fracture indications for hemiarthroplasty because we have better percutaneous fixation options, and better internal fixation options. In addition, there's an awareness that avascular necrosis (AVN) is not always a disaster."

"These fracture tools can be useful, although in this case where there is a crack through the head, comminution, soft bone, and an elderly patient, and perhaps a few weeks of early healing, I don't think these would do very well."

"Many stems have been made specifically for fractures. These stems don't often do well…unless you happen to be one of the designers. These are episodic and depend on tuberosity healing, good rehab, and the ability to do this complex operation well."

"The study with the best data comes from Dan Mole's randomized, prospective study of complex proximal humerus fractures; 19 were treated with reverses and 19 were treated with hemis. Tuberosity fixation was with graft in the hemi and without graft in the reverse, so perhaps a technical advantage for the hemi. The results showed that the reverse had better average elevation (115 degrees) versus the hemi (96 degrees). The hemi had better external rotation (15 degrees) versus the reverse (11 degrees); hemi beat reverse for internal rotation as well (L3 versus sacrum). Remember, the reverse has built-in internal impingement in all directions, so you do have more of a check on rotation."

"With a hemi you either get miraculous results and then a lot of terrible results…but you don't have many people at the average. They may report an average of 100 degrees, but no one has that...they are either 40 or 160. With the reverse, however, there was a much more normal distribution and a more predictable outcome."

"Tuberosity healing is not automatically unnecessary in a reverse. In fact, if the tuberosity heals you do better than if it doesn't. But even if it doesn't heal you don't get down into these dismal 30/40 degrees of elevation."

"A system that allows convertibility between a hemi and a reverse—as most do—is very useful. So in summary, reverse is an excellent option for elderly patients, those with poor bone, and patients with compromised rehab."

Dr. Galatz: "Factors to consider when approaching any patient with a fracture

are age, comorbidity, osteopenia, how many parts to the fracture, what is the displacement, is it a high/low energy injury, and whether there is joint incongruity."

"Over the past several years we have seen an evolution of treatment concepts. Locking plates have offered interesting options; percutaneous pinning—which isn't always applicable—is applicable to certain fracture types…and hemiarthroplasty shouldn't be ignored."

"Indications for fixation include minimal metaphyseal comminution, two-part surgical neck fractures, selected three-part fractures, and valgus impacted four-part fractures. Remember that not all four-parts are created equal. Also, patients do better with their own bone. So in my opinion if a fracture can be fixed it should be fixed."

"Regarding AVN, in a valgus-impacted fracture there is about an 11% risk of AVN, compared to a situation where there is a lot of lateral displacement (high risk of AVN). I think fixation should be considered in every case because outcome is far and away better if patients are better with their own bone and if they heal anatomically. Age and activity level are relative. Advanced age and osteopenia are not contraindications to fixation."

"If a fracture is not amenable to fixation then you can do a humeral head replacement. This could be with older patients, those with a high risk of failure of ORIF, and patients with articular incongruity. In older people you want to minimize the likelihood of a second procedure. This must be done correctly. You have to restore soft tissue anatomy, restore bony anatomy, and with fracture specific stems."

"Failure of tuberosity healing is our main indication for converting to a reverse after a fracture. But here is why hemiarthroplasty still has a role: the outcomes are equivalent, reverse implants are more expensive, complications are much lower, and the reoperation rate is not demonstrated to be higher with a hemiarthroplasty. In looking at a risk value analysis we see that superior outcomes with a reverse are not estab-

lished. There are mostly Level 4 studies and few contain both groups. There is poor reporting of results as well. In the literature you find that there are not huge differences in active forward elevation between a hemi and a reverse."

"One of our fellows did a review of all of this literature and found these differences in the ASES scores: 65-80 for hemi, 47-67 for reverse; the constant score was 44-68 for both groups. The reverse is also significantly more expensive ($12-15K versus $7-8K). But here is what's really important. A 2007 study by Bufquin found a 4X higher chance of a complication with a reverse. Possible complications are: neurologic injuries, pain syndrome, dislocations, acromial fractures, periprosthetic fractures, and deltoid dehiscence. These complications are unique to a reverse—dislocation, acromial fractures, and deltoid injury—we don't hear about these after hemiarthroplasty. Importantly, there is a very high incidence of neurolotic injury after a reverse."

"Complications such as dislocation, loosening, scapular notching, and tuberosity migration are significant. So overall, the results of a hemi and a reverse are similar if tuberosity healing occurs. And it is true that the hemi often results in these disparate groups and a reverse may find this middle ground. But be aware of this complication rate…a good hemi is not necessarily a bad operation."

"So always consider your bone preserving options because with an anatomic reduction and stable fixation, if that person heals, they will have a superior result to any arthroplasty. Hemi and ORIF have lower complication rates and reverse has introduced new complications not previously seen in the fracture setting. Valgus impacted fractures are very amenable to fixation in all age groups. Age and osteopenia are not contraindications to fixation."

Moderator Thornhill: "What about nonoperative therapy?"

Dr. Galatz: "Age and activity level are important considerations. In this fracture with the superior migration of the tuberosities relative to the head I'm not sure this person would have a good result. She is also a lower-demand per-

son, but she does enjoy gardening so I think we could do better. There is a report of nonoperative treatment of valgus impacted fractures in the British *Bone and Joint Journal* that showed reasonable results, but we need to consider head position. When there is a lot of inferior luxation those patients often don't do well…then you're dealing with a malunion or a nonunion."

Dr. Flatow: "I agree with Leesa. I think the difference in the shoulder is because there's so much scapula-thoracic motion—remember you can fuse the shoulder and still be functional—but if there's not a lot of pain a bad result after a fracture is often livable. So conservative treatment is an option, and they can often have good function with what we would consider displacement. But in patients who want great motion and great function you have a somewhat higher standard."

Moderator Thornhill: "Leesa, are you going to go in with the idea of trying to fix this, and will you do any other studies—like a CT? What will be the thing that makes you abandon that and go to a hemi? Then, what would make you abandon that and go to a reverse?"

Dr. Galatz: "I usually get a trauma series of X-rays, and if I have good films then I don't necessarily need a CT. However, if this was my only X-ray, I would get a CT scan. I might try and reduce this. The one thing I look at to determine whether or not I can get this stable is metaphyseal comminution. Her medial metaphysis looked fairly good. What is concerning is the joint incongruity. I always try reduction; I have fluoroscopy in the room with every arthroplasty because I think that not only with fixation, but if you do a hemi it's helpful to have fluoro there to ensure the tuberosities are reduced correctly. So I probably would put something under the head and try to gently lift it up; if I can't get it in a few minutes then I would consider arthroplasty."

Moderator Thornhill: "Evan, would you try to fix this or go right to a reverse?"

Dr. Flatow: "I'd have to see more films. I agree that in general fixation is always better if it is possible. In some cases like the valgus impacted four-part they are candidates for pinning (which seems to work better in older patients because you keep all the soft tissue). What's troubling is that it looks like there is some early healing and a bit of head incongruity…and those are harder. So I'd have that discussion with the patient, and I may go in ready to fix it…or I may go in ready to do an arthroplasty."

Moderator Thornhill: "What about the subscapularis if you do a reverse?"

Dr. Flatow: "I always try to get some repair."

Moderator Thornhill: "How are you going to get enough length in your reverse to get the construct tight enough so that you're not going to have a dislocation?"

Dr. Flatow: "Most of us do a mixture of deltopectoral and superior approaches, and for fractures the superior approach can be useful because if the tuberosities are pulled apart you're looking right down on the glenoid. There is a much lower rate of instability after a superior approach because you leave everything inferiorly."

Moderator Thornhill: "Leesa, who should fix this?"

Dr. Galatz: "I'm on the shoulder service, so of course it should be fixed by the shoulder service. There are very talented trauma surgeons, but sometimes in the trauma setting you can do some things to make conversion to an arthroplasty more difficult."

Moderator Thornhill: "Thank you." ♦

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Notochordal Cells Key to Treating Back Pain // PRP Effective in Three Diseases! // Surgery Improves X-Games Snowboarders Win Rate Three-fold

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

New Translational Work on DD and Notochordal Cells While others have done work on back pain and notochordal cells, James Iatridis, Ph.D., is pushing the basic science envelope into the translational arena. Dr. Iatridis, Professor and Director of Spine Research at the Mount Sinai School of Medicine in New York, tells *OTW*, "Notochordal cells, which are present in the youngest intervertebral discs, produce several factors that may be usable as an injectable therapeutic. Everyone loses these cells as they age, and it is believed that this loss contributes to degenerating discs [DD] and back pain that so many people suffer from. We have an ongoing series of studies looking at how these notochordal cells might be harnessed to help us define and derive therapeutics."

Photo Creation by RRY Publications LLC/Wikimedia Commons and Jkitteridge

"In our first paper, a systematic review that was just published in the *Global Spine Journal*, we describe several targets for therapeutic interventions and candidates that may be useful for treatments. We describe the importance of distinguishing between the structure modifiers that cause matrix breakdown and symptom modifiers that result in painful conditions. Age related changes to the spine involve matrix breakdown, but disc degeneration (DD), which causes a patient to see their doctor is because of pain…which involves neurovascular growth into intervertebral discs. Much of the existing research on DD and therapeutics address matrix breakdown by focusing on promoting matrix regrowth and repair. We think it is also important to address symptom modification—including inhibition of neurovascular ingrowth. We found that the literature suggests some candidates for this work. These include sonic hedgehog, semaphorin 3A, noggin, and other proteins that are highly abundant in notochordal cells."

"Our next paper, which is just out in *Arthritis Research and Therapy*, involves a novel culture system where we can induce controlled 'maturation' of these notochordal cells to track their loss and to identify proteins useful for disc repair. Following that, we will determine mechanisms for loss of notochordal cells and also use an animal model to screen the efficacy of these treatments for discogenic back pain."

PRP a "Go" for Tennis Elbow, Knee Osteoarthritis, ACL Reconstructions? New clarity regarding platelet-rich plasma (PRP)…Wellington K. Hsu, M.D. is the Clifford C. Raisbeck Distinguished Professor of Orthopaedic Surgery and Director of Research in the Department of Orthopaedic Surgery at Northwestern University Feinberg School of Medicine in Chicago. Dr. Hsu and colleagues have just published a review article of over 60 studies in the *Journal of the American Academy of Orthopaedic Surgeons* examining the

use of PRP in orthopedics. Dr. Hsu tells *OTW*, "Right now we have many opinions on whether PRP should be used for certain orthopedic applications, but this is one of the first studies to provide actual evidence-based guidelines for each of the proposed conditions. We concluded that there are three distinct diseases that could benefit from PRP based on this evidence: tennis elbow, knee OA [osteoarthritis], and ACL [anterior cruciate ligment] reconstructions. Regarding tennis elbow and ACL reconstructions, we found that the bone to tendon healing interface in this biologic environment seems to accommodate the delivery of PRP. In these areas, the PRP is confined and can be localized. As for OA of the knee, it is yet unclear why PRP works well here. There are theories about the anti-inflammatory effects from the growth factor or cell population, but we cannot say for sure."

"To sort out when exactly PRP will quicken healing we need more level one and level two studies. We have come a long way, however, regarding evidence. As recently as 2011, orthopedic surgeons were frustrated with the fact that patients wanted PRP because some celebrity athlete had used it. The demand for PRP is only increasing, and researchers are responding by looking into evidence to support use in various applications. In the next couple of years we will hopefully see insurance companies taking another look at PRP."

X-Games Snowboarders: Three Times More Medals Post-Surgery

Joshua Harris, M.D.is a member of the Department of Orthopaedic Surgery at Houston Methodist Orthopedics and Sports Medicine and he tells *OTW*: "During my sports medicine fellowship at Rush University Medical Center in Chicago my colleagues and I began evaluating the performance and return to skiing and snowboarding in elite winter athletes competing in the Winter X-games. The stresses placed on the knees in these high-level athletes make them a very unique population to study for several reasons. The confounding variables influence the rate of return and performance upon return. These variables include, but are not limited to, contracts, scholarships, endorsements, bonuses, coaches, agents, family, etc. The multifactorial decision-making process for not only the surgery but also return to sport has prompted the Rush group to focus on determining the optimal ACL program from the diagnosis to the surgical treatment to the post-operative rehabilitation with a safe and reliable return to sport."

"We hypothesized that there would be at least 80% of skiers and snowboarders would be able to successfully return

to the X-games. This hypothesis was confirmed—87% of skiers and 70% of snowboarders were able to return to sport. However, what was surprising was that snowboarders actually competed for an additional 7.3 years following surgery (versus skiers who competed for 2.6 years after surgery). Following surgery, skiers earned a similar number of medals (24) compared to pre-injury (22). However, snowboarders earned nearly three times the number of medals (7 versus 19). The difference in length of competition in the X-games (i.e., years of play) is likely the reason to account for why snowboarders earned more medals (1.9 medals per snowboarder) than skiers (1.6 medals per skier) following surgery."

"Although there is no one specific 'return to sport' test that permits safe return to play without any risk, our group at Rush has also developed and implemented a functional sports assessment that tests and optimizes any potential deficiencies in the entire core and lower extremity muscle kinetic chain. The test identifies any 'weak spots' that can be improved prior to return to sport to help potentially reduce the risk of repeat knee injury. Future work at both Rush and at Houston Methodist is focused on identifying the optimal patient-, knee-, surgical technique-, and rehabilitation-specific characteristics to safely permit return to sport at the highest performance level possible in all types of athletes. In addition, ACL prevention programs are being integrated into athletes' workout routines to help reduce the risk of ACL tear."

Kerlan-Jobe, Santa Monica Group Team Up With Cedars Sinai The Institute for Sports Sciences (ISS), recently established by the Kerlan-Jobe Orthopaedic Clinic and the Santa Monica Orthopaedic and Sports Medicine Group (SMOG), will be partnering with Cedars-Sinai Medical Center to jointly pursue strategies for leadership in orthopedics and sports medicine regionally, nationally and internationally.

Each of the three entities will continue to see patients in their current locations under each of their respective brands. And while ISS will serve as a management company and play the lead role in managing the clinics, surgery centers and imaging centers associated with the Kerlan-Jobe and SMOG groups, plans for ISS also include coordination of research and clinical trials with Cedars-Sinai, including the advanced use of orthobiologics, and activities related to development of new approaches to orthopedic treatments that minimize surgery whenever possible.

The Institute for Sports Sciences was formed by the two groups and Sovereign Healthcare, a private healthcare

management company based in Southern California. Sovereign will remain a management partner with the Institute for Sports Sciences and work closely with the physician leadership and the team from Cedars-Sinai.

Jeremy Hogue, CEO of Sovereign Healthcare and on behalf of the Institute for Sports Sciences, told *OTW*, "ISS has been in the planning phases for a few years and the hours spent by the physician leadership of both groups have been immense. We've evaluated a lot of different opportunities and structures for how we could collaborate. All of us involved see the opportunity to enhance the strengths of the two groups and Cedars-Sinai as well as collaborate on more clinical and research efforts together. There is tremendous synergy, where adding the pieces together makes the whole significantly stronger for all involved."

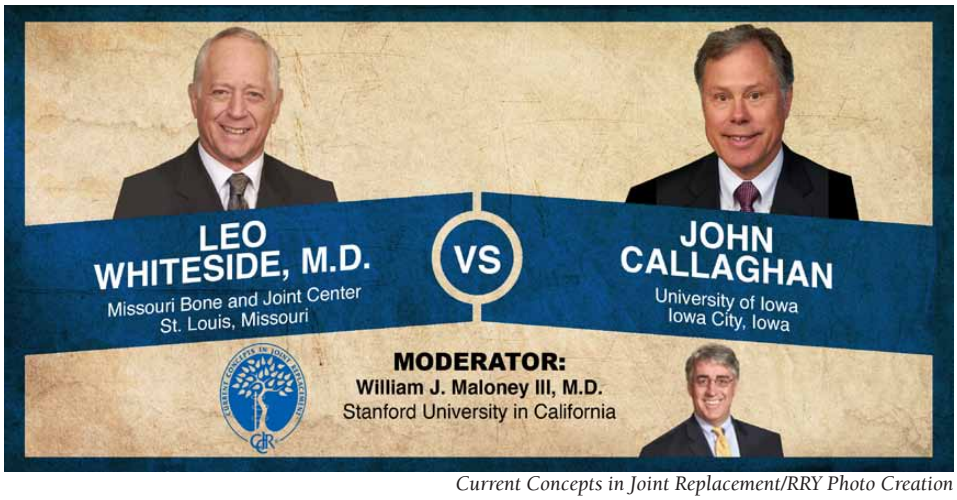
"We are optimistic that within one year we will begin seeing some tangible results of putting this vision into action. First and foremost, our goal is to improve patient care by offering more coordinated care across the full spectrum of orthopedic subspecialties so that we can deliver the most advanced and clinically proven treatments to every patient who walks through our doors. These two groups already do this extremely well, but we will always strive to be better. Beyond that, the two groups and Cedars will be working as true partners on everything from research and education efforts, best practices at the clinics and surgery centers to how we approach payers, employers and other third parties where we can offer a lot of value as providers. And last, I would definitely say that we expect significant physician growth in the two groups as well as potentially a third or fourth group that align with the ISS mission. The announcement we made this week is only the beginning." ♦

Whiteside, Callaghan Debate Life-Time Guaranteeing Cementless TKA

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

"If I can do an osteointegrated total knee and I can choose the one I want and I do the operation myself then I will guarantee it for a lifetime,' says Leo Whiteside. John Callaghan: "Lifetime guarantees are dangerous in ALL aspects of life. Look at Vegas…marriage capital of the world…50% of those don't work out. Death and taxes are the only guarantees."

This week's Orthopaedic Crossfire® debate is "The Cementless TKA: Lifetime Guarantee on Parts and Labor." For the proposition is Leo Whiteside, M.D. of Missouri Bone and Joint Center in St. Louis, Missouri; against the proposition is John Callaghan from the University of Iowa. Moderating is William J. Maloney, III, M.D. from Stanford University in California.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Whiteside: "If I can do an osteointegrated total knee and I can choose the one I want and I do the operation myself then I will guarantee it for a lifetime. But it depends on the design, porous technology, instruments, and technique. We're trying to improve upon the knee that gradually worsens over time—and that's the typical cemented total knee replacement."

"Ranawat's data from 1993 shows that this failure begins at about five years in the more challenging patients. You see the same thing in Dr. Callaghan's data…that after ten years falloff begins to occur. These interfaces are crucial…the bone-cement interfaces are crucial and the cement-metal interface is a big issue. We continue to see reports that have failure at the interface between the metal and the cement. It doesn't always show up on cement, but when you get in you find that the implants are loose in the cement and the cement is broken up underneath those implants."

"Bone ingrowth offers advantages. Early reports were not favorable, primarily due to inadequate design and engineering. Inadequate fixation with little pegs made the PCA (porous coated anatomic) fail at a higher rate. The terrible metal-backed patellar components…gamma radiated poly with flat implants was a bad idea…poorly locked polyethylenes…all coincided with starting cementless technology."

"Porous coating technologies are a big issues. Patch porous coating leads to osteolysis and failure in many cases. But reliable technology has been here since 1980. An alignment system and a tibial finishing system that allows you to fix the implant tightly to bone and have it be stable. You want a reliable stem with peripheral porous coating and peripheral capture…and in situations where you don't have hard bone, it's good to have a stem extender that allows you to make it tight, make it fit, and get it fixed in virtually every case."

"An article by Bartel and Burstein from 1989 was spot on: a stem with peripheral capture leads to loading of that bone. My clinical results confirm that. When we looked at that type of technology over the past ten years we found—in 256 patients—was one case of loosening. We continued to follow these patients out further to 18 and then 20 years. We found a loosening rate of well under half of 1%. And their pain didn't worsen."

"As for osteointegration the question is how to do it right. Full porous coating is an extremely important part of this design, and an anterior radiolucent line can occur routinely. If you give them an anterior porous coating very seldom do you have trouble. You must have excel-

lent instrumentation that guides the saw and you must be able to redo the tibia if necessary. A stem is a crucial part of tibial fixation. My survivorship results with this in a Profix knee at 12 years were nearly 99%; none were revised for loosening. Aaron Hofmann's study also found no loosening at ten years."

"I now use a thin saw blade—not a big change from 1980—and the same sort of cutting blocks, but just less bone burning. I use a strong implant that is rigidly fixed with a high tech porous coating on the femur and the tibia. As it goes in I'm determining whether I need screws. I remove the initial driver and finish off with a mobile driver that ensures that this thing is going to be seated. For the one out of one hundred that doesn't have good fixation I use screws. I use a secure locking/sealing mechanism that makes sure that the poly doesn't fall apart."

"When I see osteointegration at the tip of the stem I am happy. A ceramic that's made of space age material and fixes well…smoother than metal and much less reactive…and can be put in with a technique that works every time."

Dr. Callaghan: "So why are lifetime guarantees dangerous in ALL aspects of life? I think you can start right here in Vegas…marriage capital of the world, but 50% of those don't work out. Death and taxes are the only guarantees."

"Recently, as part of the knee replacement industry's direct to consumer marketing campaigns there have been suggestions that knee replacements should last a lifetime…or at least 30 years. I've done a lot of wear simulation studies and what happens in the lab is often different from what happens in humans. While some ads contain a lifetime knee warranty, it's important to read the fine print. The 'limited lifetime warranty' contains caveats such as 'for the life of the patient, but one-time free replacement of parts; free replacements of components only.' And they reserve the right to modify or withdraw the warranty at any time without notice. It doesn't sound like a lifetime knee guarantee."

"The real problem with cementless knee replacement is that we already have a problem with patient satisfaction. And for those patients who don't bone ingrow their surfaces… and some of those other designs that Leo said that don't work well with cementless, you don't know what to do with those people."

"I do give Leo credit that the 2012 Australian Joint Registry is showing that cementless fixation is close to that of cemented fixation out to 11 years. Older data has consistently shown cementless fixation to not be as good as cemented. In Aaron Hofmann's paper from 2002 there was 111 month follow-up with no revisions for loosening. In a 2011 paper by Kamath from the *Journal of Arthroplasty* there were 100 knees with tantalum monoblock; all patients were under 55 and there were no fixation failures."

"In Leo's work from 2007 he shows osteointegration, though if you look at most studies about 5-10% don't osteointegrate. So his seven year results are impressive, but seven does not a lifetime make. He has another thing going for him…as we age we decrease our activity level, so maybe these warranties will last a bit longer. There is data showing that we all decrease our activity over time. I would go with a prosthesis with the best long-term track record. For us, those have been with cement. In 2010 we published a study with 119 knees and a minimum of 20 years of follow-up; we had no revisions and one loosening."

"You will have reoperations…even with cement. We had three in that group—one for hematogenous infection and two for periprosthetic fractures. Also, if you're operating on patients who are under age 60 you'll have a lot of them living out to 20 years…so I'm not sure we should be making those types of claims. I think it is unwise to make such guarantees."

Moderator Maloney: "Leo, one minute to rebut?"

Dr. Whiteside: "There's no guarantee that is really a promise. You don't promise a patient it will last a lifetime. But I think that with the right technology you could guarantee a lifetime with that knee. In a small minority you would have to replace them. When my patients ask, 'How long is this knee going to last?' I say, 'I can't promise you how long it's going to last, but you can't wear this out in 20-30 years—unless you start trying to do athletics.'"

Dr. Callaghan: "There is one statement you made that concerns me. I have confidence that a lot of people are going to take their knee replacements to the grave. But the younger patients need to be followed. I think we sometimes give them a false sense of security when we give them those claims."

Moderator Maloney: "Leo, you and others have reported excellent results with different designs. Why aren't we all doing cementless knees?"

Dr. Whiteside: "That's coming. You look at all of the new developments and they are in cementless technology. Cement is 1970s technology."

Moderator Maloney: "John, you quoted a lot of good results with cementless knees…why aren't you doing them?"

Dr. Callaghan: "There's no question with the hip that we know that osteointegration can't work forever. I still have confidence that this could happen with the knee too. I used cementless knees when I started my practice in the 1980s. It wasn't a great design, and as these new designs are coming in people should look at these and try to give those of us who lost confidence with cementless fixation more confidence to return to it in younger patients. One million younger patients will need the operation in 2030 and there aren't a lot of long-term follow-up studies of cement in patients under age 55."

Moderator Maloney: "Leo, one of the problems is that you do a cementless total knee, the patient comes in with pain, and you're worried about osteointegration. You do a cemented one, the patient comes in with pain, and you tell them, 'Go away, it's going to get better.'"

Dr. Whiteside: "No, we'd probably have to operate because it's de-bonded from the cement. Or it's loose and migrating into the lucent lining."

Moderator Maloney: "The tendency with a cementless implant is to eliminate that as a potential early failure mechanism."

Dr. Whiteside: "I don't think it's an early failure mechanism…it goes one step too far so you don't have to take that step later. I don't think that's good practice."

Dr. Callaghan: "That's why I showed you that slide about satisfaction rates. I'm the first to admit that there are people with cemented knees who are not satisfied. But in this country many people are more willing—with a cementless knee that you see bits of radiolucency around—to go in and re-operate on that patient with cement. Now those people don't all get better."

Moderator Maloney: "Leo, perhaps with the bone preparation with cementless designs it's more important. Irrigation…it looks like you're constantly irrigating the bone."

Dr. Whiteside: "You should irrigate and cool and use thinner saw blades... and don't jam your saw blade and make the bone smoke."

Moderator Maloney: "John, in a 40-year-old patient should the goal be a cementless total knee replacement? Do you think it's got a better chance of lasting another 40 years?"

Dr. Callaghan: "We need to take another look at that, especially with the newer polys, the newer surfaces. I think maybe by the time Leo stops operating it might come around."

Moderator Maloney: "He'll never stop operating, so we have plenty of time. Thank you both." ♦

Please visit www.CCJR.com to register for the 2013 CCJR Winter Meeting, December 11–14 in Orlando, Florida.

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COMPANY

Japan Eases Stem Cell Restrictions

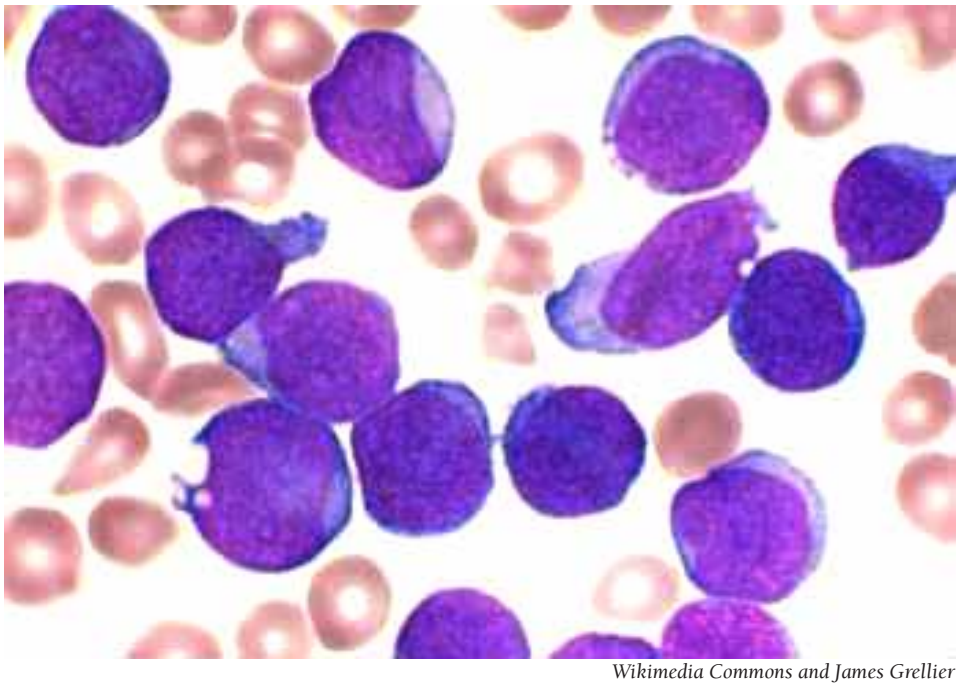
Staff of the Australian biotech firm Mesoblast, claimed by its founder to be the biggest player in this particular biotechnology sector, is excited about this week's legislative change in Japan. The change will allow fast-track approvals of stem cell products. Japan's Diet passed bills to both ensure the safety of regenerative medicine products and enable swift medical treatment using stem cells.

Mesoblast's Chief Executive and Founder Silviu Itescu told *Inside Business* that the bills enable Japan's government to approve new products conditionally, providing their safety is confirmed in clinical trials, even if their efficacy has not yet been verified. "The Japanese legislature has, just for stem cell products, defined them in a unique category as regenerative medicine," he said. The change means such products might be approved for the Japanese market without having to complete "phase-three" trials.

Mesoblast has begun a partnership with Japanese pharmaceutical company JR Pharmaceuticals for one of its products for graft-versus-host disease which is a major complication after a bone marrow transplant. "We expect that if the Japanese regulators look at that product in a favourable way, that will be the first product launch in Japan in the stem cell space under our arrangement with JCR," Itescu said.

Mesoblast has focused its work using mesenchymal precursor cells (MPC) on inflammatory and immune system diseases, cardiovascular diseases and orthopaedic diseases of the spine where MPCs can be locally administered to potentially repair intervertebral discs or generate new bone.

—BY (December 4, 2013)

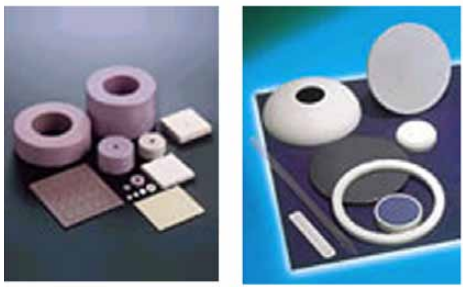


Wikimedia Commons and James Grellier

Amedica Partners With #1 Ceramics Supplier

Amedica Corporation is teaming up with the world's big dog of advanced ceramics. On November 26, 2013, the company announced a deal with Kyocera Industrial Ceramics Corporation whereby Kyocera will use Amedica's Silicon Nitride biomaterial to manufacture medical devices in Vancouver, Washington.

KYOCERA



Kyocera Industrial Ceramics Corporation

Eric Olson, Amedica's president and CEO, said there is an unmet need for advanced biomaterials in orthopedics and spine. "We are seeing an increasing interest for our Silicon Nitride interbody devices and increased interest in this material for use in other applications and want to ensure a consistent supply for surgeons and more importantly, patients."

According to the most recent survey in *Ceramic Industry,* Kyoto, Japan-based Kyocera is the world's number one producer of advanced ceramics. Olson added that with Kyocera's vast experi-

ence in ensuring that market demand is consistently fulfilled for innovative products it is the ideal partner to help broaden availability of Amedica's biomaterial devices.

The deal includes the manufacture of Amedica's spinal interbody devices.

A company press release stated that Silicon Nitride has been shown to help promote bone growth and has anti-infective properties. "Devices made from Silicon Nitride are semi-radiolucent with clearly visible boundaries enabling an exact view of intraoperative placement and postoperative fusion assessment via common imaging modalities. Amedica believes that these are essential characteristics that surgeons seek when choosing the ideal spinal interbody implant for their patients. Amedica has sold over 14,000 of these devices worldwide."

Amedica is also developing products for use in total hip and knee joint replacements.

Kyocera was founded in 1959 as a producer of advance ceramics. The company supplies medical products, solar power generating systems, telecommunications equipment, printers, copiers, electronic components, semiconductor packages and cutting tools. Last year Kyocera reported approximately $13.6 billion in revenue.

The deal with Kyocera comes just a couple of weeks after Amedica announced the company had filed papers with the U.S. Securities and Exchange Commission to raise $35 million in an initial public offering (IPO).

—*WE (December 4, 2013)*

OrthoCarolina Adds Orthopaedic Specialists of the Carolinas

OrthoCarolina has announced the addition of Orthopaedic Specialists of the Carolinas, with providers in Winston-Salem, Clemmons, Kernersville and King, North Carolina. The offices will be the first in the Triad area for OrthoCarolina.

"Patient needs are at the heart of every strategic business decision we make because we recognize that it's important to have top-quality orthopedic care close to home," said Dan Murrey, M.D., CEO of OrthoCarolina, in the December 4, 2013 news release. "It's exciting for us to have Orthopaedic Specialists of the Carolinas on board as we expand our network of locations and patient base. As a team, we will be committed to making sure that people in the Triad region have access to the best personal orthopedic care in locations convenient to them."

Orthopaedic Specialists of the Carolinas currently has 20 physicians, 11 physician assistants and 3 fellows that will become part of the OrthoCarolina team. The OrthoCarolina locations in Winston-Salem, Clemmons, Kernersville and King will treat all types of musculoskeletal conditions and general orthopedics needs as well as subspecialties including sports medicine, shoulder and elbow, arthroscopic surgery, total joint replacement, spine care, hand surgery, foot and ankle and fracture care.

"Collaboration will allow us to bring our patients the latest in progressive technologies, specialties and services," said David Janeway, M.D., president of Orthopaedic Specialists of the Carolinas. "As part of the Piedmont Triad and Northwest North Carolina communities for over 30 years, we will continue to build on that quality and trust as part of OrthoCarolina."

Asked how they will go about integrating this new practice into OrthoCarolina, Dr. Murrey told *OTW*, "We will streamline operations and services, integrating technology and clinical data in order to build an even stronger practice to benefit patients in the region. OrthoCarolina looks forward to joining the existing patient community of Orthopaedic Specialists of the Carolinas as part of the OrthoCarolina family. We are excited to be part of a group that is a leader in the Triad market as we continue to grow our company together."

—*EH (December 5, 2013)*

OrthoCarolina

Fired Rep Sues Stryker

Photo creation by RRY Publications LLC/Morguefile

Christopher Ridgeway, the fired Stryker Corporation sales rep we've written about who accused the company of making up a fake non-compete agreement, is suing his former employer for unfair trade practices, fraud, unjust enrichment and intentional interference with his business relations.

Ridgeway is the owner of Stone Surgical, LLC, which he runs out of his house in Metairie, Louisiana. He formed the company in 2009, while still employed with Stryker, to "engage in the sale of products in the medical field."

Biomet Calls, Stryker Fires

He says Biomet Microfixation, LLC had approached him over the years to enter into a distributor relationship with him to distributed craniomaxillofacial and spinal implants.

The lawsuit alleges that when Stryker learned that he was having serious discussions with Biomet, the company fired him on September 10, 2013.

Ridgeway says Biomet is the "archrival and great competitor" of Stryker in the field of spinal and skull implants. He claims he was Stryker's top salesman for those devices, generating more revenue than any other sales rep in his field.

Uncompleted Biomet Deal

After he was fired, he negotiated a distributorship agreement between himself, as Stone Surgical, LLC and Biomet to distribute skull and spine implants throughout Louisiana. The first deal was signed on September 23, 2013 with no terms for expiration of the contract.

Ridgeway says that Biomet submitted a compensation plan to him whereby Stone Surgical would receive an average of $1.75 million per year for the distribution of the skull implants and a second agreement where Stone Surgical would receive $2 million per year for the sale of spine implants. Both deals consisted of fixed payments plus a commission based on sales.

Stryker Strikes

He says the parties were on the verge of signing the second contract, "When Stryker struck." Stryker filed a lawsuit in Michigan against Ridgeway and Biomet on September 30, 2013, claiming Ridgeway violated, among other things, his non-compete agreement. The company also asked for a temporary restraining order and preliminary injunction to keep Ridgeway from competing with Stryker on Biomet's behalf.

Ridgeway claims Stryker submitted a fake non-compete agreement to the court. He says Stryker frequently tried to get him to sign a non-compete agreement, but he always refused.

Without an enforceable non-compete agreement, Ridgeway says Stryker was "desperate" to stop him and "engaged in an extraordinarily deceptive act to torpedo the new business relationship between Biomet and Stone Surgical" and to "unfairly destroy the prospect" of competing with Stryker.

"Fabricated, Falsified and Fraudulent" Documents

Stryker, according to Ridgway, then served the "fabricated, falsified and fraudulent" document on Biomet, alleging that Ridgeway was in violation of the "invalid and fake non-compete" agreement. Stryker informed Biomet that it was suing Biomet for arranging for Ridgway to sell Biomet devices in competition against Stryker.

"Deceived by this fabricated, fraudulent non-compete agreement," Biomet immediately terminated the agreement with Stone Surgical. Ridgeway says the sole reason Biomet gave him for the termination was that the company believed a non-compete agreement existed between Ridgeway and Stryker and they didn't want to be held liable for damages.

Stryker Amends Complaint

Ridgeway says that after getting caught making up the fake non-compete agree-

ment, Stryker amended their complaint against him and Biomet to delete any reference to the "fabricated" non-compete agreement. Stryker also withdrew their request for a preliminary injunction after Biomet dumped Ridgeway.

Fabricating the non-compete agreement, claims Ridgeway, violates the Louisiana Unfair Trade Practices Act because hospitals, doctors and patients in Louisiana have now been deprived of the choice to select "superior" Biomet products.

Seeking Damages

Ridgeway says he has suffered the loss of revenue he would have received under the agreement with Biomet.

He also says Stryker committed fraud by misrepresenting to Biomet that a non-compete agreement existed between the company and Ridgeway.

Ridgeway claims he is entitled to recover damages against Stryker for unjust enrichment based on Stryker's actions. "Stryker is unjustly enriched by all of the sales of medical devices that it is now able to make that otherwise would have been lost to customers selecting to purchase Biomet devices." In the reverse, Stone Surgical has been "impoverished" by its commissions lost from sales that it would have made by selling Biomet devices.

Stryker's conduct, according to Ridgeway, constituted tortious interference with a contract under the laws of Louisiana and Michigan.

He is asking for jury trial and damages to which he may be entitled. At age 35, he says he has a work life expectancy of another 30 years.

—WE (December 6, 2013)

Aurora's ZIP Passes FDA 510(k) Clearance

The FDA has zipped Aurora Spine Corporation's interspinous fusion system through the 510(k) clearance process.

The company announced on December 3, 2013, that the agency granted clearance for the ZIP Minimally Invasive Interspinous Fusion System. The system was developed as an alternative to pedicle screw systems.

The system has been launched in Europe and already used in 40 surgeries. The company intends to immediately launch the system in the U.S. where there are more than 35 distribution agreements in place.

According to the company announcement, the ZIP features articulating bone anchors, a one-step locking mechanism with no set screw and a large graft space designed for biologic material.

Indications for use in the company's 510(k) filing state that the ZIP is "a posterior, non-pedicle supplemental fixation device, intended for use at single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies0, spondylolisthesis, trauma (i.e,. fracture or dislocation), and/or tumor."

The device is intended for use with bone graft material and is not intended for stand-alone use. The device is available in various sizes to accommodate different patient anatomy.

—WE (December 6, 2013)

Aurora Spine Corporation/ZIP Fusion System

LARGE JOINTS

Volunteer Docs and Companies Provide Free Joint Replacements

Surgeons performed more than one million hip and knee replacements in 2013, but an additional 230 were added to that total between December 2 and December 7. That's when 130 volunteer orthopedic surgeons and 70 participating hospitals provided free joint replacement surgeries to patients who otherwise could not afford them. The physicians and hospitals participated in a program called "Operation Walk USA 2013."

"Helping someone to walk again, and to return to a life without pain, is indeed a cause worth celebrating," said New Albany, Ohio orthopedic surgeon Adolph V. Lombardi, Jr., M.D., president of Operation Walk USA. "Operation Walk USA is now in its third year of providing total hip and knee replacements to underserved patients. This year we have expanded the official dates of Operation Walk to help more patients in need."

The program provides all aspects of treatment: the surgery, hospitalization, and pre- and post-operative care-at no cost to participating patients who may not qualify for government assistance, have insurance or can't afford surgery on their own.

Operation Walk began as an international volunteer medical service organization to provide treatment for patients with arthritis and joint problems in developing countries. More than 6,000 patients have received new knees and hips through the international Operation Walk. The U.S. program began in 2011 and has now installed nearly 300 joints through Operation Walk USA 2011 and 2012.

Device manufacturers Biomet, DePuy, Smith & Nephew, Stryker, Total Joint Orthopedics Inc. and Zimmer are donating the hip and knee implants for Operation Walk 2013. To find a list of participating orthopedic surgeons and cities, visit www.opwalkusa.com, or follow Operation Walk USA 2013 on Facebook.

Courtesy of Operation Walk USA

—BY (December 2, 2013)

Milk Increases Hip Fracture Risk for Males

Drinking more milk as a teenager apparently does not lower the risk of hip fracture as an older adult and instead appears to increase that risk for men. Diane Feskanich, Sc.D., of Brigham and Women's Hospital and Harvard University, Boston, and colleagues have just published this work in *JAMA Pediatrics*.

Morguefile and wax115

Dr. Feskanich and colleagues examined the association between remembered teenage milk consumption and risk of hip fracture at older ages in a study of more than 96,000 men and women with a follow-up of more than 22 years. During the follow-up, 1,226 hip fractures were reported by women and 490 by men.

Study findings indicate that teenage milk consumption (between the ages of 13-18 years) was associated with an increased risk of hip fractures in men, with each additional glass of milk per day as a teenager associated with a 9% higher risk. Teenage milk consumption was not associated with hip fractures in women.

"We did not see an increased risk of hip fracture with teenage milk consumption in women as we did in men. One explanation may be the competing benefit of an increase in bone mass with an adverse effect of greater height. Women are at higher risk for osteoporosis than men, hence the benefit of greater bone mass balanced the increased risk related to height," the authors commented.

Dr. Feskanich told *OTW*, "Our hypothesis was that drinking more milk during teenage years would not be associated with a lower risk of hip fracture in older adults. Our results confirmed this, so it was not surprising. We were surprised, however, to find that boys who drank more milk had an increased risk of hip fracture in later life, which was partly mediated through the greater height attained with higher milk consumption. We will continue to examine milk consumption during adult years and its effect on hip fracture in men and women. Again, we hypothesize that we will not see a significant benefit from drinking more milk."

—EH (December 2, 2013)

REIMBURSEMENT

Winning the Medicare Quality Bonus

Want to earn a bonus and avoid paying a penalty in 2015 under the Physician Quality Reporting System (PQRS)? Then follow these simple government instructions.

If you are paid under the Medicare Physician Fee Schedule (PFS), you will be subject to payment penalties beginning in 2015. The providers and group practices that do not satisfactorily report data on quality measures during the 2013 program year will be subject to a 1.5% payment reduction in their PFS charges.

Individual and Group Practices

Individuals and group practices participating in the PQRS must meet one of the following criteria to avoid getting nicked in 2015.

For individuals who want to earn a 0.5% bonus, you must meet one of the following criteria during the 2013 PQRS program year.

- Meet the requirements outlined in the 2013 PQRS measure specifications found here:
  - (http://www.cms.gov/apps/ama/license.asp?file=/PQRS/downloads/2013_PQRS_MeasuresList_ImplementationGuide_12192012.zip)
- To get the bonus, you must report at least:
  - One valid measure via claims, participating registry, or through a qualified Electronic Health Record (EHR) or
  - One valid measures group via claims or participating registry.
- Elected to participate in the administrative claims-based reporting mechanism October 18, 2013.

Groups in ACOs

Groups in Accountable Care Organizations (ACOs) participating in the Group Practice Reporting Option (GPRO) can avoid the penalty if one of the following criteria is met during the same 2013 PQRS program year:

- Meet the requirements outlined in the 2013 PQRS GPRO Fact Sheet
  - o Report specific ACO/GPRO measure through the Web Interface or
  - o Report at least 3 registry measures (for 80% of the group's eligible patients for each measure) for the GPRO outlined in the 2013 PQRS Measure Specification for Claims/Registry Reporting of Individual Measures.
- Report at least one valid measure through the Web Interface or participating registry
- Elected to participate as a GPRO in the administrative claims-based reporting mechanism by October 18, 2013

Here's where you can view the PQRS Payment Adjustments Tip Sheet: http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2013_PQRS-2015_PaymentAdjustmentTipSheet060313.pdf

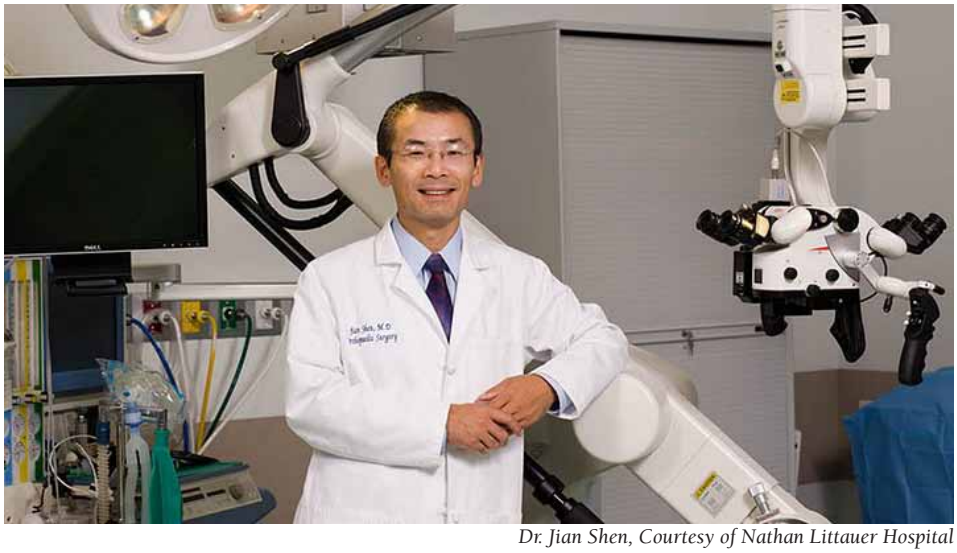
Good Luck!

—WE (December 2, 2013)

whatwillmatter.com

SPINE

Trust Wins Star For Rural Hospital



Dr. Jian Shen, Courtesy of Nathan Littauer Hospital

How did a 78 bed rural hospital in an economically depressed region of upstate New York end up with a world-class spinal surgeon? The answer lies in the power of human relationships to influence career decisions, the willingness of a hospital administrator and board to invest in equipment for a surgeon who was a continent away and the skills of a Beijing-born doctor, a former molecular biologist, who was just beginning his career as an orthopedic surgeon.

The story began when two orthopedic surgeons approached Lawrence E. Kelly, president and CEO of the Nathan Littauer Hospital in Gloversville. New York. They wanted to increase the coverage in orthopedics they were providing the hospital. To do that they needed a third partner—a spinal surgeon.

"Great," Kelly replied. He arranged for the hospital to fund the search and cover the recruitment costs and assigned a staff person to handle the paper work. When the search firm told them about Dr. Jian Shen, a 42-year-old former molecular biologist who was finishing up a residency in orthopedics in North Carolina, they all flew down to meet him.

Something significant happened at that face-to-face meeting. The two upstate New York orthopedists and the hospital administrator found they really liked this novice surgeon. They flew him up to Gloversville to take a look at their hospital and the surrounding Adirondacks. He promised to come but he could not begin work for a year because he had agreed to serve a year-long fellowship in San Francisco.

As Kelly explained, "It was a personal connection that we made. We all hit it off. There was trust there." Kelly told Shen, "When you get here our commitment to you is we will do everything that is possible to be done to make sure you are a successful spine surgeon."

Kelly was in constant contact with Shen during Shen's year in San Francisco. Kelly wanted to know what Shen was learning, what equipment he was using there that he would need in Gloversville. As Kelly explained, "We did not wait until he got here to buy a bunch of stuff for him. We bought it before he came, anticipating his arrival."

Looking back on that year Kelly remembers, "We were a small community hospital that was buying all of this equipment for a surgeon who was still 3.000 miles away. The only assurance we had that he would come was his name on a piece of paper. There was a lot of trust involved."

The hospital had also promised Shen that it would have spine patients waiting for him when he arrived. To help fulfill that promise prior to Shen's arrival the hospital put large "Spine Rejoice" billboards on the highway. The local Northeast Public Radio station WAMC featured Shen on a call-in program and WAMC's CEO, local celebrity Alan Chartock, had his bad back successfully treated by Shen. Shen had patients waiting for him from the first week of his arrival.

WMAC's Alan Chartock

Kelly remembers when Shen returned from a medical conference with information about the Mazor Robotic System. He explained to Kelly that, with this system, he could improve the accuracy of his surgery and shorten the recovery time for his patients.

For Kelly, the administrator, "It was a hard one to swallow, but we invested. In a big place it would take me a year to get something like that. Here it took three weeks." Shen, too, noted, "At a major

medical center I would be a nobody. I could say, 'get me a robot' and it might happen in a year. Here I got it in a week." As Kelly put it, "The trustees went out on a limb with my recommendation to invest that way and it has worked out for everyone." Each hospital has invested about $1.75 million in robotic and other specialized equipment for Shen.

What attracted Shen to Gloversville? He said it was very important to him to serve in an under-served area. While the two hospitals where he works are rural, they are on the edge of the capitol area of New York with more than a million population. Shen also credits the hospitals and operative room staffs. "We really get along well," he said. "We have been on the same page from the beginning."

Shen performs the full spectrum of minimally invasive spine surgery thus minimizing damage to soft tissue. Two years and 1,500 patients later he has had no major complications and an infection rate of zero. He says, "Half of my patients leave the hospital from the recovery room, they do not need to be admitted." He has performed several surgical firsts in the region, including the first robot-assisted spine surgery, and two surgical firsts in the United States.

Shen's goal is to create a "minimally invasive spine surgery destination" in upstate New York. Patients are already coming to Shen from New England and from states such as Texas and Florida. The waiting time to see Shen is now weeks long. He is looking for a partner and interested parties can contact him or the hospital by email at spines@nlh.org. "It is getting so busy that I cannot handle it all by myself," he said.

Cheryl McGrattan, vice-president for marketing, communication and community relations for the Gloversville hospital, says the surgery department is now a crowded place with representatives from medical device companies and other surgeons—including some of Shen's own medical school professors—coming to watch him perform surgery. "It is very exciting for us to have this going on," she said.

Shen lives with his wife Wencui and their seven-year-old daughter in Loudonville, New York. He is a graduate of Weill Cornell University Medical College.

—BY (December 4, 2013)

VEXIM: Positive Results for SpineJack

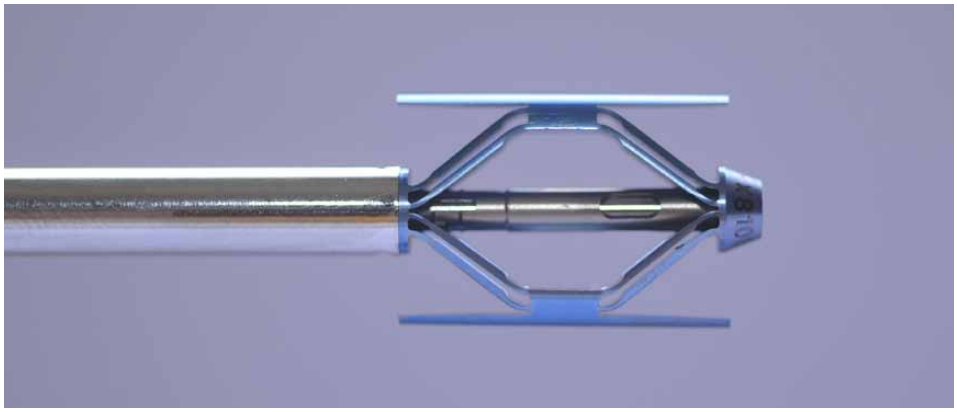
VEXIM, a medical device company specializing in the minimally-invasive treatment of vertebral fractures, has announced that the results of a new comparative biomechanical study carried out by Marburg University's Traumatology Department have been published in *The Spine Journal*.

As in the first biomechanical study published (results disclosed on September 12, 2013), the aim of this new study was to evaluate the anatomic restoration of 24 fractured vertebral bodies with osteoporosis by comparing the SpineJack and balloon kyphoplasty techniques. The results once again demonstrated a significant difference in favor of the SpineJack regarding the restoration of vertebral height that is achieved to reestablish spinal balance.

"The central vertebral height restoration was close to 96% for the groups treated with SpineJack. The clinical implications include better restoration of the sagittal balance of the spine and a reduction of the kyphotic deformity," said Dr. Antonio Krüger in the December 2, 2013 news release. Dr. Krüger is an orthopedic trauma surgeon in trauma and reconstructive surgery at the Philipp's University (Marburg) and is the study's main investigator.

Vincent Gardès, CEO of VEXIM, added, "We are proud of the publication of Dr. Krüger's new study in such a prestigious clinical and scientific review as *The Spine Journal*, and would like to congratulate his team for their in-depth scientific work. The results of our biomechanical studies, combined with those announced recently on two other clinical studies, clearly show the efficiency of the SpineJack and reinforce our confidence in our ability to establish it as a benchmark for the treatment of vertebral compression fractures."

—EH (December 5, 2013)



VEXIM

Denosumab Trumps Zoledronic Acid for Spine BMD

Chicago researchers have found that when comparing denosumab and zoledronic acid for efficacy and tolerability, denosumab had a significantly greater effect on increasing spine bone mineral density…and zoledronic acid caused more flulike symptoms.

The researchers performed a retrospective chart review and survey of 107 patients to compare the efficacy, patient satisfaction, cost and known adverse effects of denosumab versus zoledronic acid, including muscle pain, back pain and flulike symptoms. The denosumab and zoledronic acid groups were statistically similar in all areas but spine bone mineral density (increased 0.060 g/cm2 versus 0.021 g/cm2, respectively) and flulike symptoms (none versus 29% of patients).

Wikimedia Commons and BruceBlaus

"Both groups of patients were satisfied with their treatment despite the discrepancies in the drugs," said Kellen Sheedy, first author and Stritch School of Medicine student, in the December 2, 2013 news release.

"This study helped us quantify the efficacy and adverse effects of these two drugs providing further guidance for physicians who prescribe these treatments," said Pauline Camacho, M.D., study investigator and director of the Osteoporosis & Metabolic Bone Disease Center at Loyola University Health System. "While this was the first head-to-head comparison of these two treatments, larger prospective studies will be needed to confirm these findings."

—EH (December 6, 2013)

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