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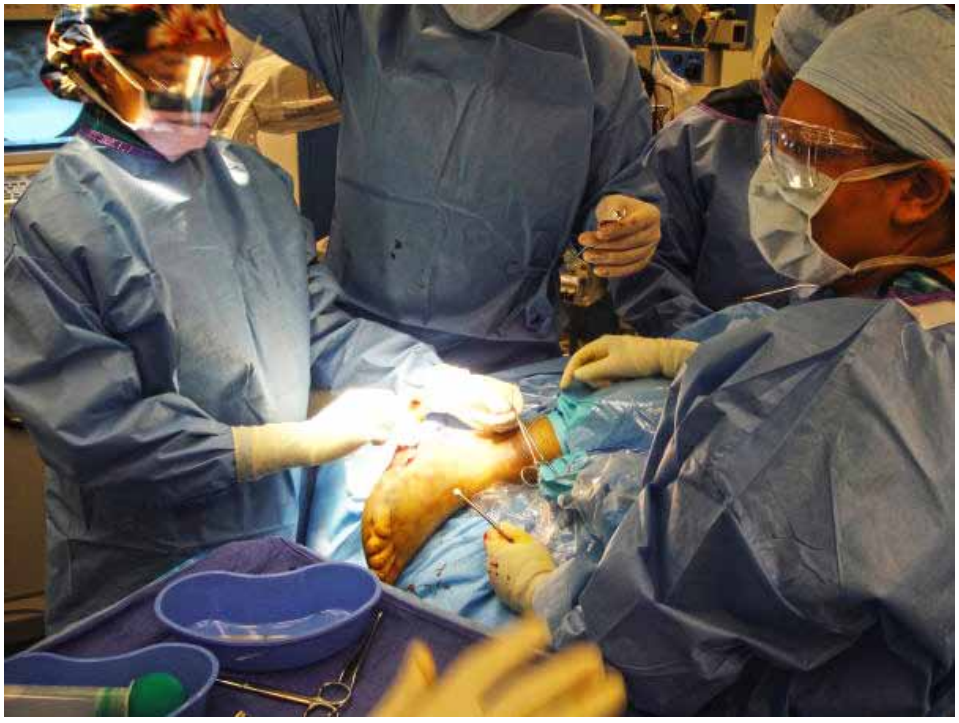
Orthopedics This Week

WEEK IN REVIEW

The Washington Post



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: By its tone, the market seems to be in a momentum phase. Final chapter in a bull market? Momentum buyers choose companies with near-term sales or earnings momentum which, in turn, drives money into high beta stocks, more volatile companies. Stable but slower growth companies, like SYK, ZMH or JNJ, get less attention. When might this bull market break? Possibly mid Q1 2014. Then safe havens like...SYK, ZMH or JNJ get their due.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	NuVasive	6.30%	30.00%	Uniformly enthusiastic responses from analysts after NUVA's NYC meeting. RW Baird raised price target.
2	4	Exactech	10.00	12.03	Net income up 25%, U.S. sales up 11%. Management has beaten estimates 3 of the last 4 quarters.
3	2	Globus Medical	28.53	7.91	Added $52 million to cash balances in the third quarter. Yet earnings were $20 million. Very impressive.
4	3	Stryker	15.22	3.76	Wall Street is still talking about SYK's very smart strategic move into robotics with MAKO. Talking, not buying.
5	7	Medtronic	28.84	5.53	This week MDT reports and most analysts think hardware sales will be flat to slightly up with Infuse down 8% and Kyphon off 11%.
6	5	Zimmer	27.31	3.27	What's ZMH's strategic direction in this rapidly shifting healthcare market? SYK buys MAKO. JNJ buys Synthes. ZMH?
7	8	Integra LifeSciences	11.77	3.44	IART buys Confluent Surgical from Covidien and adds another important biomaterial to the product line.
8	10	Johnson & Johnson	26.73	3.60	JNJ has increased its dividend for 51 consecutive years and is delivering 2.80% dividend yield currently.
9	9	Smith & Nephew	20.78	4.09	SNN gets no respect. Why? Because SYK and ZMH grow faster in hips and knees than SNN. SNN's growth is coming from wound care.
10	NR	Orthofix	16.25	6.99	The sellers have finally washed out. OFIX has the lowest composite valuation in entire Ortho Universe.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$0.70	$89	85.32%
2	NuVasive	NUVA	$32.89	$1,468	30.00%
3	CryoLife	CRY	$10.01	$276	26.71%
4	MiMedx Group	MDXG	$5.55	$543	18.09%
5	Exactech	EXAC	$23.47	$318	12.03%
6	Globus Medical	GMED	$18.55	$1,729	7.91%
7	Orthofix	OFIX	$21.28	$414	6.99%
8	Medtronic	MDT	$58.55	$58,402	5.53%
9	Smith & Nephew	SNN	$65.40	$11,709	4.09%
10	Stryker	SYK	$74.21	$28,082	3.76%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	$0.45	$23	-31.81%
2	Tornier N.V.	TRNX	$17.16	$832	-19.17%
3	Baxano Surgical Inc	BAXS	$1.10	$50	-19.12%
4	RTI Biologics Inc	RTIX	$2.98	$168	-16.53%
5	ArthroCare	ARTC	$34.49	$979	-6.53%
6	Symmetry Medical	SMA	$8.12	$302	-5.03%
7	Alphatec Holdings	ATEC	$1.87	$182	-4.10%
8	MAKO Surgical	MAKO	$29.91	$1,540	0.57%
9	Conmed	CNMD	$36.94	$1,020	2.21%
10	Wright Medical	WMGI	$28.25	$1,331	3.03%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$21.28	$414	8.55
2	Medtronic	MDT	$58.55	$58,402	15.91
3	Smith & Nephew	SNN	$65.40	$11,709	16.06
4	Zimmer Holdings	ZMH	$90.59	$15,489	16.20
5	Globus Medical	GMED	$18.55	$1,729	16.54

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$32.89	$1,468	86.55
2	RTI Biologics Inc	RTIX	$2.98	$168	80.32
3	Symmetry Medical	SMA	$8.12	$302	40.93
4	Integra LifeSciences	IART	$45.09	$1,449	28.77
5	CryoLife	CRY	$10.01	$276	25.54

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$18.55	$1,729	1.10
2	Orthofix	OFIX	$21.28	$414	1.22
3	Conmed	CNMD	$36.94	$1,020	1.45
4	Exactech	EXAC	$23.47	$318	1.57
5	ArthroCare	ARTC	$34.49	$979	1.64

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$32.89	$1,468	7.04
2	CryoLife	CRY	$10.01	$276	6.38
3	RTI Biologics Inc	RTIX	$2.98	$168	5.35
4	Integra LifeSciences	IART	$45.09	$1,449	3.85
5	Symmetry Medical	SMA	$8.12	$302	3.41

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	$0.45	$23	0.71
2	Symmetry Medical	SMA	$8.12	$302	0.74
3	Orthofix	OFIX	$21.28	$414	0.90
4	Alphatec Holdings	ATEC	$1.87	$182	0.93
5	RTI Biologics Inc	RTIX	$2.98	$168	0.94

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.70	$89	21.68
2	MiMedx Group	MDXG	$5.55	$543	20.07
3	MAKO Surgical	MAKO	$29.91	$1,540	14.99
4	Globus Medical	GMED	$18.55	$1,729	4.48
5	Johnson & Johnson	JNJ	$94.39	$266,316	3.96

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

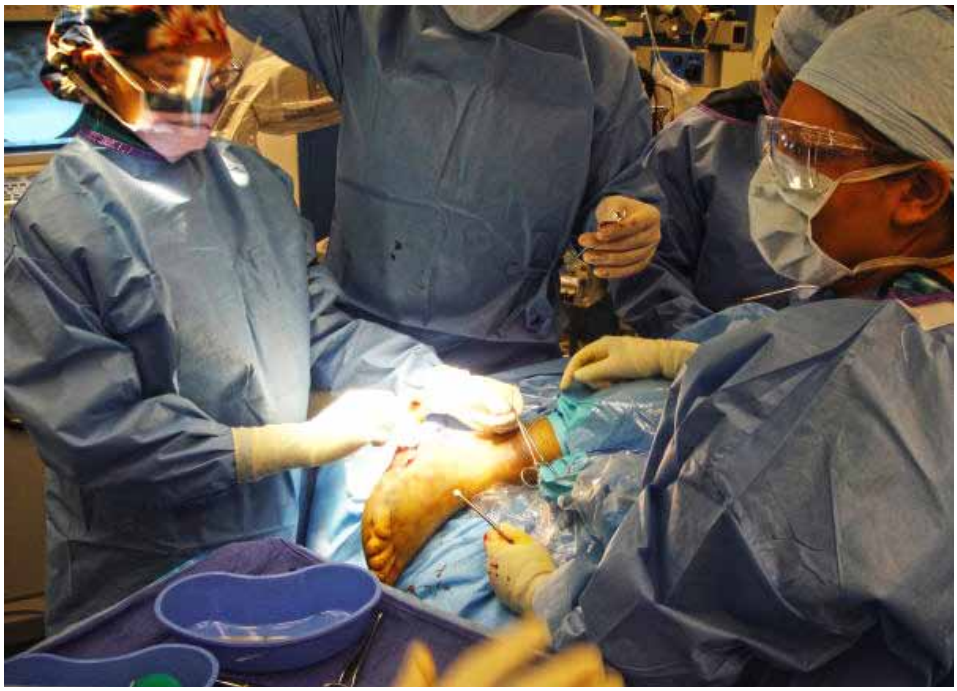
The 26 Top Foot & Ankle Surgeons in North America: 2013

BY OTW STAFF

If an orthopedic surgeon has suffered a calcaneous fracture or a needs an ankle replacement, to whom do they turn? We asked! Leaders in the foot and ankle realm let us know their thoughts on the top North American orthopedic surgeons in their subspecialty.

*Here is that list. We don't have "the market" on lists…this isn't the be-all and end-all list—but it is **a** list of who are arguably the finest foot and ankle physicians, teachers, investigators or administrators in the country. This information was obtained via a telephone survey of thought leaders in the field. The information in quotes is what we heard about these surgeons.*

In alphabetical order, here are the top 26 foot and ankle surgeons in North America.



Wikimedia Commons and Ladyde12

Ned Amendola, M.D. is professor and director of the University of Iowa (UI) Sports Medicine Center. Dr. Amendola was named recipient of the Kim and John Callaghan Endowed Chair in Sports Medicine by the UI in June 2009. "He is an outstanding surgeon who treats many injured college athletes. Specifically, he is very good with malalignment problems of the foot and ankle. He is also a talented educator."

John G. Anderson, M.D. is the chairman of the Spectrum Health Department of Orthopaedic Surgery; he practices with Orthopaedic Associates of Michigan. "He has exceptional academic, programmatic, and organizational skills. His commitment to patient care and advancing the art of surgery puts him at the pinnacle of care providers."

Robert B. Anderson, M.D. is an orthopedic surgeon with OrthoCarolina, and is a past president of the American Orthopaedic Foot & Ankle Society (AOFAS). He is also a founding member of the Foot & Ankle Institute at OrthoCarolina. "His breadth of experience is enormous, and he is routinely called upon for complex cases. He is the one so many athletes seek out for treatment."

Judith F. Baumhauer, M.D., M.P.H. is a professor in the department of orthopaedics at the University of Rochester Medical Center. She is a past president of the AOFAS and is currently president of the American Board of Orthopaedic Surgery. "She is involved in clinical trials with the Carticept Medical and the U.S. aspects of rhPDGF. She has the ability to listen and then bring together people with totally disparate ideas… and leave them walking away thinking that XYZ solution was reasonable."

Gregory C. Berlet, M.D. is an orthopedic surgeon at the Orthopedic Foot and Ankle Center in Westerville, Ohio. "He is very widely known, well published, and is a much sought after speaker. He co-designed two different ankle replacement systems, and is extremely sought after for training expertise."

Donald R. Bohay, M.D., F.A.C.S. is an orthopedic surgeon with Orthopaedic Associates of Michigan. He is also clinical professor in the Department of Orthopaedic Surgery at Michigan State University and director of the Grand Rapids Orthopaedic Foot and Ankle Fellowship Program. "He has a great understanding of fusions and how they

affect foot and ankle symptoms. He is an outstanding educator who has contributed to developing nationally recognized successful academic programs."

James W. Brodsky, M.D. is an orthopedic surgeon with Orthopedic Associates of Dallas, and is clinical professor of orthopedic surgery at the University of Texas (UT) Southwestern Medical Center and Texas A&M Health Science College of Medicine. He is also director of the Foot and Ankle Surgery Fellowship Training Program at Baylor University Medical Center and UT Southwestern Medical Center. Dr. Brodsky is a past president of the AOFAS. "He is known for having published high quality articles on gait analysis. He has done great work on the effect of forefoot arthritis on gait and on various interventions and how they affect gait."

Christopher P. Chiodo, M.D. is chief of the Foot and Ankle Surgery Service at Harvard, as well as an instructor at that institution. "He is doing important work on clinical outcomes in multiple arenas. This is insightful work that requires diligence because it takes so much time."

Thomas O. Clanton, M.D. is director for Foot and Ankle Sports Medicine at the Steadman Clinic in Vail, Colorado, and is a past president of the AOFAS. "He has extensive experience working with professional athletes in football, basketball, and skiing. "He is quite a good physician, a good surgeon and just a nice person."

J. Chris Coetzee, M.D., Mb ChB is an orthopedic surgeon with Twin Cities Orthopedics in Minneapolis and clinical associate professor at the University of Minnesota Department of Orthopaedic Surgery. "He is uniquely talented and has a terrific grasp of issues happening in the field."

Timothy R. Daniels, M.D. is associate professor of surgery at the University of Toronto and head of orthopedic surgery at St. Michael's Hospital. He is also Adjunct Scientist in the Keenan Research Centre of the Li Ka Shing Knowledge Institute of St. Michael's Hospital. "He is involved in a cutting edge project on ankle arthritis and rhPDGF. He is a real thought leader and pushes the envelope regarding new surgical techniques and treatment options for foot and ankle fusions and hard-to-treat clinical problems."

Richard D. Ferkel, M.D. is an orthopedic surgeon with the Southern California Orthopedic Institute, and is director of the Sports Medicine Fellowship Program at the same facility. Dr. Ferkel is also a clinical instructor of orthopedic surgery at the University of California Los Angeles. "He is a very good ankle arthroscopist…quite experienced and pioneering. He is the consummate edu-

cator to surgeons, fellows, and residents because he knows how to lead, is well spoken, and is exemplary with regard to patient care."

Mark A. Glazebrook, M.S.C., Ph.D., M.D., FRCS(C) is an assistant professor of surgery in the division of orthopedics at Dalhousie University in Nova Scotia. "He is a tremendous researcher who has great clarity of thought. He has great new ideas and is honest about his work."

Steven L. Haddad, M.D. is Senior Attending Physician at the Illinois Bone & Joint Institute in Chicago, as well as is section head of Foot and Ankle Surgery at NorthShore University Health Systems. Dr. Haddad is the current president of AOFAS. "He is a great inventor, and is very passionate about foot and ankle surgery. He is on the forefront as far as ankle replacement research and is a wonderful product developer."

Kenneth Hunt, M.D. is an assistant professor of orthopedic surgery at the Stanford University Medical Center in California. He practices at Stanford Hospital and Lucile Packard Children's Hospital. "He combines clinical expertise with research acumen like few others. With a keen interest in sports injuries of the foot and ankle and a leadership role in the Orthopaedic Foot and Ankle Outcomes Research (OFAR) network, Ken will undoubtedly help shape the field of foot and ankle surgery as he progresses through his career."

Jeffrey E. Johnson, M.D. is a professor of orthopedic surgery at Washington University School of Medicine in St. Louis. "He has a great ability to manage very complex cases and deformities; his surgical approach involves multiple, well thought out steps. He is a very unassuming guy that everyone likes."

Sheldon S. Lin, M.D. is associate professor at Rutgers New Jersey Medical School in Newark. "His work involves trying to determine whether biologics truly add to fusion rates. He is a true scientist, something that is really needed now that there are so many stem cell products out there."

Thomas H. Lee, M.D. is an orthopedic surgeon at the Orthopedic Foot

and Ankle Center in Westerville, Ohio. "Beyond his excellent clinical work, he has been a tremendous leader in the area of AOFAS membership; he possesses a strong understanding of electronic media. He has really ignited a spark amongst people with regard to international volunteerism."

Jeremy J. McCormick, M.D. is assistant professor of orthopedics at the Washington University School of Medicine in St. Louis. "He is a young guy with an inquisitive mind who is asking all the right questions regarding arthritis of foot and ankle and then designing research around that to improve on conventional wisdom."

William C. McGarvey, M.D. is an associate professor in the department of orthopaedic surgery at The University of Texas Medical School at Houston. He is also program director of the UT Orthopaedic Surgery Residency Program. "He is an outstanding foot and ankle surgeon, and is an expert on trauma and small wire fixator frames."

Murray J. Penner, M.D. is a clinical associate professor at the University of British Columbia in Vancouver. He is also a staff orthopedic surgeon at Cambie Surgery Centre and at St. Paul's Hospital, both in Vancouver. "He is a rising star who is doing a lot of work in total ankle arthroplasty. He is a great researcher who is doing studies on total ankle arthroplasty and looking at the results of the STAR Ankle."

Charles L. Saltzman, M.D. is professor and chair of orthopaedic surgery at the University of Utah in Salt Lake City. He also holds an adjunct Professorship in the Department of Bioengineering. Dr. Saltzman is a past president of the AOFAS. "He is probably the smartest foot and ankle surgeon in America. He is a great thinker and does groundbreaking research on the mechanics of forefoot surgery."

Bruce J. Sangeorzan, M.D. is chief of the Orthopedics Service at Harborview Medical Center in Seattle. He also is professor and vice-chair of the University of Washington's Department of Orthopaedics and Sports Medicine. Dr. Sangeorzan is president-elect of the AOFAS. "He is widely respected and sought after. He is a world expert on reconstructive treatment of patients after severe foot trauma."

Lew C. Schon, M.D. is director of foot and ankle services at MedStar Union Memorial Hospital in Baltimore. He is also founder and director of the Orthobiologic Laboratory at that facility. He is a past president of the AOFAS. "He has a breadth of talents, i.e., anything from complex fusions to fine nerve work. He processes multiple components of complex deformity in various clinical situations."

Keith L. Wapner, M.D. is an orthopedic surgeon with Pennsylvania Orthopaedic Foot and Ankle Surgeons. He is also clinical professor of orthopedic surgery at the University of Pennsylvania. He is a past president of AOFAS. "He is an innovator and has made significant contributions to the technology in orthopedics. He is down-to-earth, humble guy who infuses sanity and calm into both the chaos of the OR and into society meetings."

Alastair S. E. Younger, M.B., Ch.B., M.Sc., Ch.M., F.R.C.S.(C) is an associate professor at the University of British Columbia in Vancouver. "He is widely versed in clinical research on ankle arthritis and deformity and deformity. He is internationally recognized for his clinical expertise." ♦

Looming Medicare Cuts for Hip and Knee Surgeons?

BY WALTER EISNER

Biomet Inc.'s CEO Jeff Binder and Jefferies LLC's analyst Raj Denhoy warn that physician payments for hip and knee replacements could face a "significant" CMS (Centers for Medicare and Medicaid Services) rate cut beginning January 2014.

Binder rang the warning bell on his blog in September and Denhoy issued an investor note in October.

Secret Recommendations

According to Denhoy, CMS requested a review of relative value payment rates of certain procedures including hips (CPT 27130) and knees (CPT 27447) in 2012. The request was made to the American Medical Association's Relative Value Update Committee (RUC). The AMA manages and owns the CPT (current procedural terminology) codes used by Medicare and private insurers for medical services and procedures.

Those recommendations are secret and have been the subject of a lawsuit brought by general practitioners who argue the RUC is weighted heavily for specialty societies and in violation of open meeting laws.

While confidential, Denhoy said he understood the RUC committee completed its work in reassessing the relative value of hip and knee procedures and have made their recommendations to CMS.

The cuts could be 20% or more says Denhoy. But because of the lack of transparency between CMS and the AMA RUC, details are not available.

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January 2014 Crunch Time

CMS didn't include those potential changes in the 2014 proposed rule for physician payments published in July 2013. However, says Denhoy, changes could be included in the agency's final interim rule expected to be published this November and take effect in January 2014.

As usual, the agency will likely allow for a brief public comment period after publishing the interim rule, but those comments would only be considered for the 2015 rule and not impact any cuts made to the final fee schedule for 2014.

Clinicians Speak Out

Clinical societies like AAHKS (American Association of Hip and Knee Surgeons) and companies like Biomet are mounting limited public policy advocacy efforts ahead of the publication of the 2014 final rule.

Joshua Jacobs, M.D., President of the American Association of Orthopaedic Surgeons (AAOS) said in an October 15, 2013 statement that total hip and knee replacement surgeries are two of the most successful and life-enhancing surgical procedures. They relieve almost all pain for over 90% of patients who have the procedures, which allow patients to return to work and adds tremendous value to their lives. "To reduce Medicare physician payments for these procedures would severely limit beneficiary access to these important surgeries."

AAHKS President Thomas Fehring, M.D., said Medicare should not cut rates for hip and knee replacement surgery without giving doctors and their

patients a full explanation, and without a fair comment opportunity.

"And while those we've spoken to handicap the odds of implementation of these rate cuts at 50/50, the risk around such a large cut is worth noting heading into the publication of the rule this November," wrote Denhoy.

Impact on Surgeons and Industry

What would such cuts mean to orthopedic surgeons and device companies?

Denhoy says Medicare pays for about 55-60% of hip and knee procedures. If significant cuts to physician payments are implemented, the repercussions for the device companies would likely be "more perceptual than actual, at least at the outset."

The bigger issue is if surgeons would be willing to accept those rates and treat Medicare patients. Despite threats to the contrary, Denhoy thinks most clinicians probably would accept those rates.

Patients Held Hostage, Surgeons Flee Medicare

Biomet's Binder disagrees.

In a 2013 September blog titled *"Possible reimbursement cuts for total joint surgeons? Seriously?"* Binder asks, "What can CMS possibly be thinking? How will this improve patient access to quality care?"

The short answer, he says, is that it won't, potentially forcing America's elderly patients to delay needed treatment and endure ongoing disability, while discouraging talented doctors from pursuing the specialty that treats bone and joint disorders—the leading cause of adult disability in the U.S.

He quotes a 2010 a survey of the AAHKS' membership which reported that deep pay cuts will result in surgeons being forced to abandon Medicare:

> "If Medicare were to decrease surgeon reimbursement up to 20%, 49% to 57% of AAHKS surgeons would be unable to provide care for Medicare patients, resulting in an unmet need of 92,650 to 160,818 total joint arthroplasty procedures among AAHKS surgeons alone. Decreases in funding for surgeons and inadequate support for subspecialty training will likely impact access and quality for Americans seeking [total joint replacements]."

Declining Reimbursement Equals Surgeon Shortage

Binder wrote that the 2013 Medicare national payment amount for a primary total knee is $1,552. For a primary total hip, it's $1,454. "Both rates are much less than 1996 rates in unadjusted and inflation-adjusted dollars. Both rates include the surgery and 90 days of physicians' post-operative care."

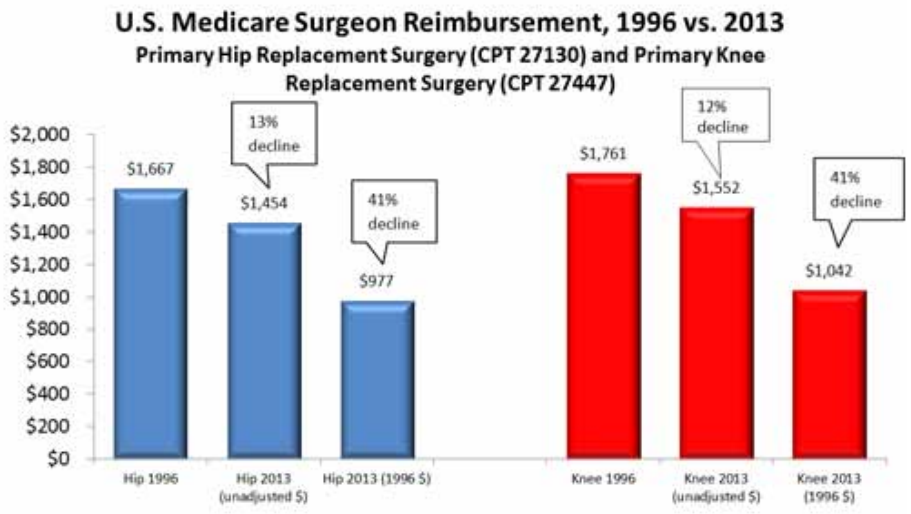
"Ask yourself: if you knew that, over the course of your career, your pay rate would shrink 41%, wouldn't you think about other ways to make a living?"

Medicare pay cuts, wrote Binder, would exacerbate an already-looming shortage of orthopedic surgeons. "Fehring, et al. determined that the number of total joint surgeons will be unable to meet patient demand for joint replacement by the year 2016."

According to Binder, what's driving this potential shortfall in timely treatment is the fact that more joint replacement surgeons are projected to leave the workforce than to begin practice.

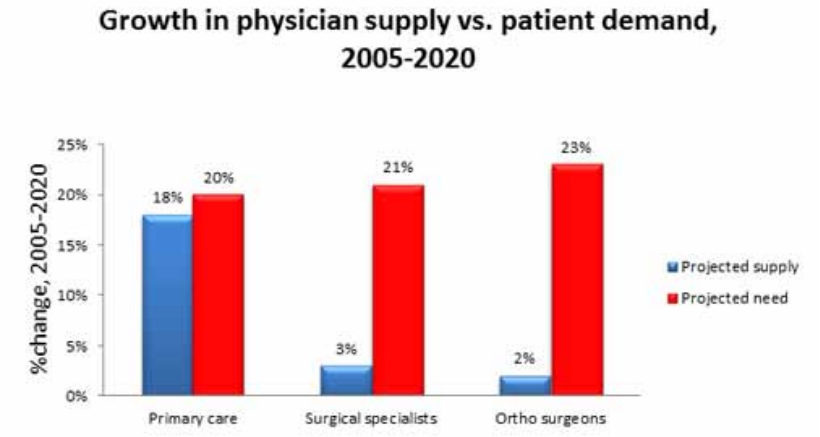
He points out that these projections were made in 2010, *before* the current proposal for cuts in physician reimbursement for primary hip and knee replacement, and before the implementation of Obamacare. "The U.S. Government's own figures also point to a looming threat to patient access."

In a 2008 report on physician workforce, Binder says the government



Source: MCRA, CMS Physician Payment Schedule

projected a huge gap in the growth of orthopedic surgeon supply and patient demand for their services. Further reductions in surgeon reimbursement will only aggravate an already-predicted shortage.



Source: HRSA, 2008

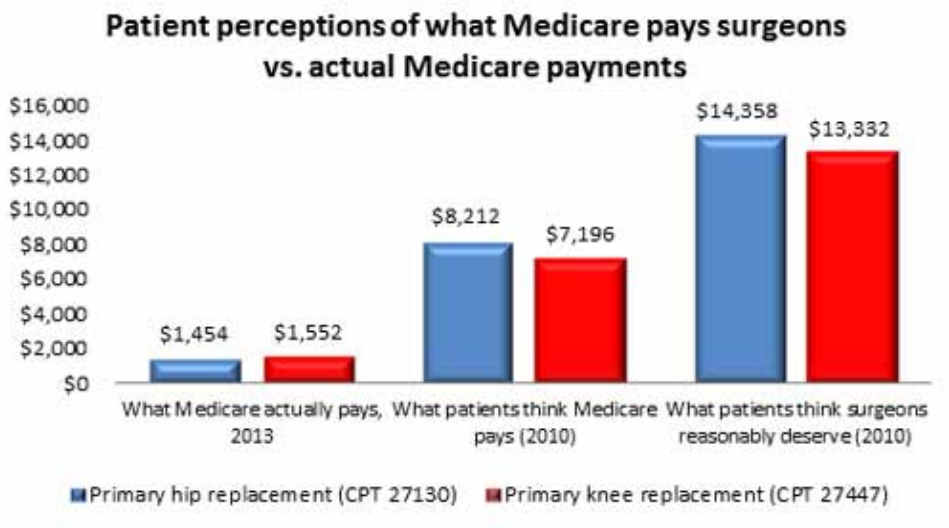
The data reveal that surgical specialties will face the most severe shortfalls. 'Yet current healthcare payment policies focus almost exclusively on creating more primary care physicians, while apparently attempting to reduce patients' timely access to specialists who treat complex conditions," added Binder.

Bad Public Policy

"Besides ignoring the impact of a surgeon shortage on patient access to needed care, policymakers seem to forget their pronouncements about creating a value-based healthcare system. Ironically, the pay cut for surgeons being considered coincides with new research that shows tremendous societal savings from total joint replacement, as compared to non-surgical treatment."

He notes that total knee replacement surgery generates a net economic lifetime benefit of nearly $19,000 per patient, or $12 billion for the year 2009 alone, from increased earnings and reduced costs related to ongoing disability.

While Medicare may think that physicians are overpaid for performing joint replacement surgery, Binder cites evidence that patients think physicians should be paid nearly *ten times* what Medicare actually reimburses. "Patients also estimated that Medicare pays five to six times more than its actual reim-



Source: Foran JR, et al., "Patient Perception of Physician Reimbursement in Elective Total Hip and Knee Arthroplasty," J. Arthroplasty, May, 2012

bursement. When informed of Medicare's actual payment rate, they're appalled."

Binder added that if Medicare follows through with the proposed reductions in physician reimbursement, we may see fewer of these procedures being done, at precisely the time that the need for these procedures is expected to increase dramatically.

Denhoy says that while potential cuts from CMS are to physician rates; it should be taken in the larger context of Medicare looking to lower payments broadly, particularly in orthopedics.

In terms of potential impact on 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 at 37%.

Binder's Summary

Binder summarized it this way:

1. There are too few surgeons to address projected demand for total joint replacement surgery, and the shortages are projected to become even more pronounced in the coming years.
2. Total joint replacement surgery addresses the #1 source of disability in the U.S. and has been shown to actually generate societal savings and contribute to improved general health.
3. Total joint replacement surgeons have endured a 41% reduction in Medicare reimbursement since 1996, in inflation-adjusted dollars.
4. Medicare is now considering a pay cut that will discourage surgeons from providing total joint replacements to Medicare patients, aggravating an already-looming patient access crisis for a highly beneficial and cost-saving procedure.
5. The cuts, if implemented, will stand for at least one year because CMS will not revisit its proposal in 2014.

"If the notion of a pay cut for joint replacement surgeons confuses you, rest assured you are not alone. The potential pay cut policy under consideration is worse than nonsensical; it's potentially damaging to the health of U.S. citizens and will destroy, rather than create, value," concluded Binder.

Finally, wrote Binder, "If CMS is truly interested in delivering high-quality, high-value healthcare, it needs to stop hammering on the surgeons who are creating medical miracles for patients every day and saving society billions of dollars every year in the process. Medicare should be doing everything possible to ensure that every patient who needs joint replacement is able to get it in a timely fashion from a highly-trained orthopedic specialist. What they're considering is precisely the wrong move at the wrong time." ♦

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*Data is available on file.

IMPORTANT SAFETY INFORMATION

HUMANITARIAN DEVICE

OP-1 IMPLANT is authorized by Federal law for use as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments have failed. The effectiveness of this device for this use has not been demonstrated.

OP-1 PUTTY is authorized by Federal law for the repair of symptomatic, posterolateral (intertransverse) lumbar spine pseudoarthrosis in patients for whom autologous bone and/or bone marrow harvest are not feasible or are not expected to promote fusion and who have at least one of the following compromising factors: osteoporosis, diabetes or nicotine use. The effectiveness of OP-1 PUTTY for this use has not been demonstrated.

Brief summary of contraindications and warnings:

- OP-1 IMPLANT/OP-1 PUTTY is contraindicated in patients who (1) are pregnant (2) have or have had a malignancy (3) are skeletally immature (4) are pregnant or want to become pregnant within 2 years of treatment (5) have a known hypersensitivity to the active substance or to collagen (6) have an autoimmune disease or immune suppression (7) have been previously treated with OP-1 IMPLANT or OP-1 PUTTY.
- The use of OP-1 IMPLANT/ OP-1 PUTTY may result in (1) the formation of localized ectopic or heterotopic bone outside of the treatment site (2) development of an immune response against BMP-7 or Type I collagen.
- There are no adequate well controlled studies of OP-1 IMPLANT/OP-1 PUTTY in (1) pregnant women (2) patients with autoimmune disease or immune suppression (3) patients with renal impairment.

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NASS' Empty Response to the Post's Article

BY ROBIN YOUNG

Courtesy of The Washington Post

On October 27, Peter Whoriskey and Dan Keating wrote an article for *The Washington Post* newspaper about spine fusion surgery and used the example of a single patient and a single surgeon to make a case that spine fusion surgery may be over used.

The North American Spine Society (NASS) took exception to Whoriskey/Keating's article and wrote a letter.

The letter, which we reproduce at the end of this article, said that the "issue of unnecessary surgery is of paramount interest to NASS" and a "serious issue" but that it was "inappropriate to roundly condemn the concept of fusion, per se."

Per se.

NASS went on to say that "Spinal fusion is currently undergoing rigorous scrutiny; the indications for spinal fusion are being evaluated and re-evaluated constantly".

All of which is well and good but we could not help but notice that, for some reason, NASS couldn't come up with a single study to cite which would offer support for spine fusion surgery.

In fact, the NASS letter was really a string of opinions and assertions with no supporting data.

Too Much Fusion Surgery?

The *Post* article emphasized the point that there may be too many spine fusion surgeries. The authors quoted Gunnar Andersson, M.D., chairman emeritus of the department of orthopedic surgery at Rush University Medical Center in Chicago as saying the "critics of spine fusion surgery, who believe spinal fusions are being performed too frequently, are "'not wrong.'"

As a general proposition, most surgeons would agree that some of their colleagues over use spinal fusion while other colleagues, conversely, under use spinal fusion. This is, in other words, not a new topic.

When is spine fusion indicated? Would it be for instability, degenerative disc disease, stenosis, burst fractures, all of the above or none of the above? For which patients? Anterior, posterior or lateral access? Biologics? Patient psy-

chology? Many, interrelated factors determine whether spinal fusion surgery is the treatment of choice for any particular patient.

How do physicians answer such questions?

Most spine surgeons, we would argue, augment their training and experience by doing studies, tracking outcomes and presenting, listening, reading and debating at peer meetings like, well, NASS's annual meeting.

NASS' role, it seems to us, is to foster non-partisan study, debate and education for surgeons. Evidence Based Medicine, in other words. And when, for example, spine fusion surgery is challenged, we would expect NASS to respond with evidence.

The *Post's* Story Outline

According to the *Post* story, the incidence of spine fusion surgery has increased dramatically in the last decade. Surgeons, hospitals and suppliers of spine fusion implants have benefited financially during this period. And, said the *Post's* two authors, many of these spine fusion surgeries may have been unnecessary and performed to financially benefit surgeons and hospitals. Furthermore, many spine fusion patients ended up worse off for the surgery. One patient in the story, a 62-year-old former pipefitter, was diagnosed with "lumbar stenosis and degenerative problems." But, wrote the *Post's* authors, "instead of curing him, the surgery has all but crippled him."

SPORT Studies

In fact, hundreds of clinical studies exist at NASS and from a large number of peer-reviewed journals which offer comprehensive data for the efficacy of spine fusion surgery. But NASS' letter didn't go there. In fact, in response to the *Post's* assertion that spine fusion doesn't work consistently, NASS said that a review and scrutiny of spine fusion surgery is currently in process. Perhaps NASS believes that spine fusion is unsettled science?

Certainly the most famous study which explicitly compared surgical intervention to non-surgical treatment of spine disorders is Dartmouth's SPORT (Spine Patient Outcomes Research Trial) study. This study was discussed and reviewed extensively at more than one NASS annual meeting.

The SPORT study was organized by Dartmouth University about ten years ago and was funded in part by The National Institute of Arthritis and Mus-

culoskeletal and Skin Diseases, the Office of Research on Women's Health, the National Institutes of Health, and the National Institute of Occupational Safety and Health, the Centers for Disease Control and Prevention.

As designed by Dartmouth (which has been a critic of the volume of spine surgery since the 1980s) the studies covered 2,500 patients, randomized them to either a surgery arm or a non-operative arm and followed them for five years. Thirteen sites participated.

Here is a summary of the results:

- **Intervertebral disc herniation, published in *JAMA*, November, 2006**
  - o While both groups improved substantially after treatment, the improvement from standard surgery was more rapid. Patients who had surgery also reported better results in physical function and satisfaction one and two years after the operation.
- **Degenerative spondylolisthesis, published in *The New England Journal of Medicine*, May, 2007**
  - o Patients with spinal stenosis accompanied by degenerative spondylolisthesis who were treated surgically showed substantially greater improvement in pain and function through two years follow-up compared to patients treated non-surgically.
- **Spinal stenosis, published in *The New England Journal of Medicine*, February 21, 2008**
  - o Patients with spinal stenosis who were treated surgically showed significantly greater improvement in pain, function and disability

through two years follow-up compared to patients treated non-surgically. Because patients in the randomized cohort "crossed over" either from the non-operative arm to have surgery or from the surgery arm to remain non-operative, the analyses were non-randomized, as-treated comparisons with careful control for potentially confounding baseline factors.

Carragee: "No Complications"

Eugene Carragee, M.D., is still the editor-in-chief of NASS' peer-reviewed journal, *The Spine Journal* (*TSJ*).

The Washington Post authors asked Dr. Carragee to comment on the single patient's case which, in their view, was a case study for debate over when spinal fusion surgeries were necessary. The patient suffered from compression of the spine and degenerative discs.

The *Post* authors wrote that Carragee had "said that a simpler procedure known as a decompression often offers patients, without complications, as much benefit as a fusion and poses fewer risks."

We could not help but chuckle at Carragee's comment that decompression surgery is without complication. If memory serves, he has engaged in a scorched earth campaign against his colleagues who'd mentioned that there were no complications in Infuse studies from a couple decades ago.

Decompression surgery—which has a strong success record and a comparatively low complication rate—does most certainly have a risk of complication, as has been amply documented in the pages of the journal Carragee edits.

Carragee may occasionally be wrong but never in doubt.

NASS's Response Letter

Here is what the NASS Executive Committee had to say about *The Washington Post* article:

"The Executive Committee of the North American Spine Society (NASS) read the October 28, 2013 Washington Post story on spinal fusion ("Spinal fusions serve as case study for debate over when certain surgeries are necessary") with great interest and concern.

The issue of unnecessary surgery is of paramount interest to NASS, from many perspectives, including humanitarian, ethical, scientific and economic. Recognizing that the issue of unnecessary or poorly or marginally-indicated surgery is, indeed, a serious issue, it is nonetheless inappropriate to roundly condemn the concept of fusion, per se.

Fusion of the spine is an invaluable tool in the surgeon's armamentarium to alleviate intractable pain and return patients to healthy, productive lives. As in ALL surgical procedures, the key is the surgical indication for the individual patient. Overuse or underuse are both bad medicine and do the patient a disservice. There is universal support for spinal fusion in cases of instability, fracture, tumor, infection, deformity. Simpler and safer treatments, if available, should always be pursued first. And, before proceeding with surgery, the potential risks and chances of success must be completely understood.

Pain in the lower back is the #1 cause of disability in the United States and worldwide. Neck pain is #4! Together they cause more than 5 million years of disability in the US alone—enough for every person to be disabled by a spine condition for more than six days each year. Patients are demanding access to effective, thoughtful therapies that allow them to remain active and maintain their quality of life.

NASS is collaborating with Medicare and private insurance carriers to develop evidence-based guidelines for surgical intervention and to define conditions that are best treated without surgery. Spinal fusion is currently undergoing rigorous scrutiny; the indications for spinal fusion are being evaluated and re-evaluated constantly in an effort to develop the optimal indications to serve the best interests of the patient."

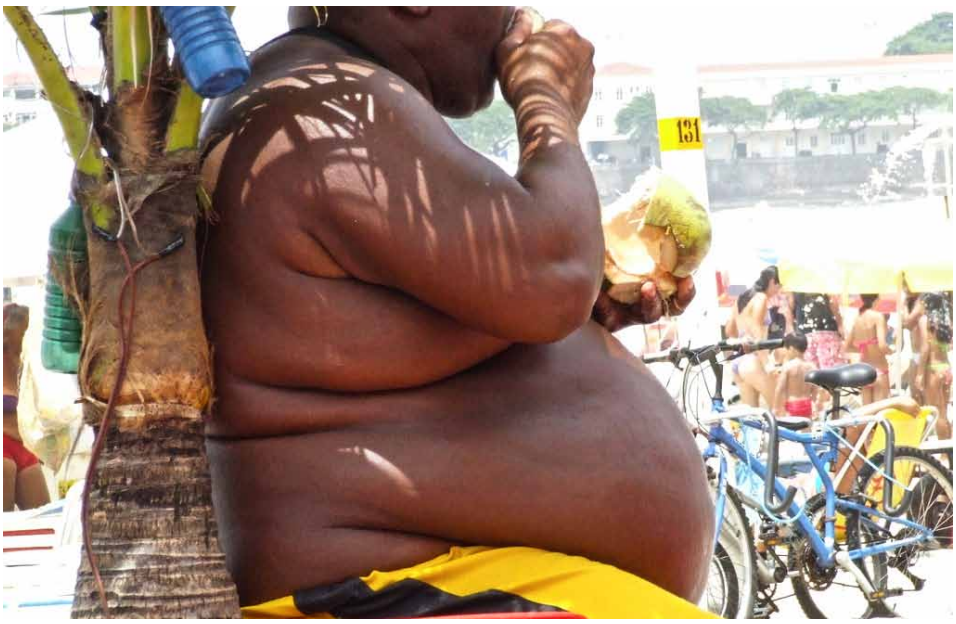
NASS' Role

In many ways the popular press, the insurance carriers, patients and NASS' membership are asking for more evidence-based information with which to navigate the cross currents of healthcare. NASS and the other surgeon societies are natural sources for evidence-based information.

In this instance, unfortunately, NASS appears to have punted a valuable opportunity to educate and inform. It's time NASS figured out its role as a facilitator and disseminator of objective, non-partisan information and education. ♦

1 Minute (60 Seconds) Lowers Back Pain 40% in Obese Patients//More Fractures at Higher Bone Density in Diabetics//Young Patients Unhappy With Reverse TSA Despite Good Outcomes

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



Wikimedia commons and Didier Vidal

Astonishingly Simple Change Lowers Back Pain 40% in Obese Patients A team of researchers—from a study of nearly 7,000 people—has discovered that obese people have an advantage over those of normal size when it comes to exercise. Matthew Smuck, M.D. is a physiatrist in the Department of Orthopaedics at Stanford University Medical Center. He tells *OTW*,

> "Our study found that if you are obese and increase your activity level by only modest amounts, your risk of low back pain is significantly reduced. In fact, improvements in activity are more helpful at reducing back pain risk for obese people than for those of 'normal' weight.
>
> We completed a detailed analysis of people's everyday activity from a 24-hour activity monitor worn for 7 days, focusing on 'bouts' of different levels of activity. A 'bout' is the amount of time someone spends within a certain activity intensity range; we looked at how often each person enters into different ranges and the average amount time spent in those ranges. We found that morbidly obese people spend on average 1.3 minutes in the moderate activity range; we determined that if they increase this average by less than one minute their risk of back pain is reduced by almost 40%.
>
> Interestingly, our work received a comment from a chiropractor, who said, 'Many patients who undergo chiropractic care three times per week for six weeks will be fine.' We have a large population of people with chronic, nonspecific LBP [lower back pain] who are sedentary…and the answer is not to treat them clinically, but to have them get more active. They shouldn't be spending their money—or the taxpayers' money—when they could do just a little more for themselves and reduce their lower back pain. As healthcare providers we want to do something, but sometimes that 'just' means lighting a fire under the patient and requiring them to do it for themselves.
>
> Motivating patients is not always easy. Fortunately, our study showed that even small increases in moderate activity, such as walking or gardening, and reductions in sedentary time can produce big changes in the risk of back pain for overweight and obese patients."

More Fractures at Higher Bone Density in Diabetics A new study from Mayo Clinic endocrinologist Sundeep Khosla, M.D., probed deeper in the bones of diabetic patients than ever before and discovered that these patients have more fracture risk at higher bone densities. Orthopedic surgeons need to watch diabetic patients more closely, says a new Mayo Clinic study. Dr. Khosla is an endocrinologist at that institution. He tells *OTW*,

"There is growing evidence that patients with diabetes have an increased risk of fracture and based on clinical studies it appears that patients with type 2 diabetes fracture at a higher bone density than those without diabetes. This suggests that diabetics' bone is somehow abnormal or that the quality of bone is abnormal. Previous studies have shown that there may be changes in the porosity of bone; our study used a new technology called microindentation to test the idea that the material properties of bone are abnormal in diabetic patients. We found that those with longstanding diabetes did have worse bone material properties as assessed by this technology. The process involved numbing the skin and using a handheld instrument to induce a microcrack in the bone. The depth of the crack was related to bone strength, so the deeper the crack the weaker the bone. In diabetics the probe went in significantly deeper than in non-diabetics.

Also, we looked at average diabetes control in these patients and it turned out that those who had the worst diabetes control over the previous ten years also had the worst bone material strength. So the message to orthopedic surgeons is that just like other complications of diabetes (eyes, feet), bone needs to be considered as another target. These patients should have their bone density evaluated by a DEXA scan…and orthopedic surgeons may want to treat patients with diabetes more aggressively because they fracture at a higher bone density.

We look forward to our next study, which will look at diabetics with fractures versus those without fractures to see if those who fracture have worse bone material strength."

Alarming Rise in MRSA in Pediatric Musculoskeletal Cases A new retrospective case review from the Children's Hospital of Philadelphia (CHOP) indicates that the proportion of pediatric musculoskeletal infections involving methicillin-resistant Staphylococcus aureus (MRSA) compared to methicillin-sensitive S. aureus (MSSA) has increased dramatically over the past decade. This work, which focused on cases at CHOP, was co-authored by Eric Sarkissian, a fourth-year medical student at Drexel University in Philadelphia. Sarkissian told *OTW*,

> "While other studies have shown a rise in MRSA specifically pertaining to the musculoskeletal system—and that these infections are more severe—we wanted to look at what was going on at CHOP because there is reason to believe that MRSA in one area doesn't behave the same as in another area.

We found that the proportion of musculoskeletal cases involving MRSA increased from 12% in 2001-2002 to about 35% in 2009-2010. In addition, we found that MRSA infections were associated with a significantly more complicated hospital stay. The average duration of hospitalization was longer for the MRSA patients (13 vs. 8 days), and more MRSA patients required multiple surgical procedures (38% vs. 15%).

In addition, mean presenting C-reactive protein levels were higher in the MRSA vs. MSSA patients (14.7 mg/L vs. 9.8 mg/L), as were infection-related complications, including deep vein thrombosis, septic emboli, septic shock, recurrent infection, and/or avascular necrosis (24% vs. 6%).

Orthopedic surgeons need to be aware of the serious complications that MRSA musculoskeletal infections can cause in pediatric patients. It is important to use broad spectrum antibiotics early on and to be willing to go to the OR for multiple wash outs.

We may undertake another study to identify predictors of these infections when pediatric patients present. This would be based on their initial lab markers such as elevated temperature, white blood cell count above XYZ amount, etc."

Young Patients and Reverse TSA: Same Outcomes, Worse Satisfaction

The young are restless…A new study, led by Stephanie Muh, M.D., has found that young people aren't always happy campers when it comes to reverse total shoulder arthroplasty (TSA). Dr. Muh, an orthopedic surgeon with Henry Ford Hospital in Detroit, tells *OTW*, "This was a multicenter study involving patients from the Cleveland Shoulder Institute (Reuben Gobezie, M.D.), the Fondren Group (Bradley Edwards, M.D.) and OrthoNeuro in Akron (Robert Nowinski, D.O., F.A.O.A.O.). It is the first study to describe the short term outcomes and satisfaction of young people with reverse TSA. This procedure was originally meant for the elderly with massive irreparable rotator cuff tears, but has become more popular and we are pushing the indications and putting them in younger patients without knowing the clinical outcomes.

The most surprising finding was that the objective outcomes were the same as what we would expect in the elderly (they achieved the same improvement in range of motion and decrease in pain). Subjectively, however, they were less satisfied. This is likely due to their expectations, i.e., the younger population wants zero limitations on their activities. This reinforces the importance of fully educating the patient before proceeding with this surgery.

Another interesting finding was that these young people often had multiple surgeries; some had lots of rotator cuff procedures that failed while others had post trauma surgeries. And, while not clinically significant, we did find that the more surgeries the young patients had, the worse the outcomes and satisfaction. Orthopedic surgeons should impress this on their patients as well and proceed with caution.

The next step is to report on midterm outcomes. We don't know what happens to these young patients after ten years…and we're not sure what the next step will be when their surgeries fail." ♦

COMPANY

$4 Billion Settlement Reported for DePuy Hip Lawsuits

Bloomberg reported on November 12, 2013 that Johnson & Johnson (J&J) has agreed to pay more than $4 billion to settle thousands of ASR (Articular Surface Replacement) metal-on-metal hip lawsuits. That comes to about $350,000 per case.

Previous settlement rumors were in the $2 billion range. The company settled a $2.2 billion case with the feds and pled guilty to a misdemeanor a couple of weeks ago over false marketing of drugs. It's getting to be an expensive Thanksgiving season at J&J. But the settlements may also remove an overhang of suspicion over a company that has long prided itself on a reputation of good corporate citizenship.

J&J's DePuy Orthopaedics recalled 93,000 implants in 2010, including 37,000 in the U.S., after more than 12% failed within five years. That rate is climbing, along with lawsuits by patients blaming the chromium and cobalt devices for pain, metal debris and replacement surgeries.

The company declined to comment on the *Bloomberg* story which cited "three people familiar with the deal," who were unauthorized to speak publicly.

The reported deal will resolve more than 7,500 lawsuits in federal and state courts against DePuy. The agreement, according to *Bloomberg*, doesn't bar patients whose hips fail in the future from seeking compensation from J&J. That means the settlement, which is expected to be announced the week of November 18, is uncapped in terms of its total value because lawyers for patients are still trying to estimate how many of the 12,000 related lawsuits involve patients who had a replacement. Lawyers believe that number may be 7,000 to 8,000 cases.

If the deal is announced, it would be the largest settlement ever involving hip implants. Winterthur, Switzerland-based Sulzer AG paid $1 billion to settle lawsuits in 2001.

J&J has spent about $993 million on medical costs and informing patients and surgeons about the recall, Lorie Gawreluk, a spokeswoman for the company, said earlier this year. The company set aside an undisclosed amount for litigation, which it increased before June 30.

The reported settlement would come after the company lost one lawsuit in a California court, but won a second in Chicago. A third was settled.

—*WE (November 13, 2013)*

Injury Lawyer News/Settlement

FDA Throws FzioMed a Lifeline

Just when you think it's not safe to wade into FDA waters, the agency throws someone a lifeline.

FzioMed, Inc. boss John Krelle announced on November 4, 2013, that FDA Commissioner Margaret Hamburg, M.D. has approved the company's petition for an independent review of its premarket approval application (PMA) for Oxiplex Gel. The agency issued a Not Approvable letter in September 2008.

Wikimedia Commons and MC2 Corbin J. Shea/defenseimagery.mil

Oxiplex Gel

Oxiplex is an absorbable, clear, viscoelastic gel that is applied during lumbar spine surgery. Oxiplex has been approved for sale in the European Union since 2001 and is now approved in 70 countries. It has been used in more than 340,000 surgeries worldwide, said Krelle. The company has been working for 12 years to gain FDA approval to market this device in the U.S.

Medical Device Dispute Resolution Panel

Hamburg's decision means that a special Medical Devices Dispute Resolution Panel (DRP) will be convened. It's the first time we've noted such a panel meeting for a spine or orthopedic device in the past six year. This panel provides advice to the Commissioner on complex or contested scientific issues between the FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, regulatory decisions and actions by the FDA, and Agency guidance and policies. The Panel makes recommendations on issues that are lacking resolution, are highly complex in nature, or result from challenges to Agency decisions or actions. In this case, FzioMed is seeking to have the DRP recommend a reversal of FDA's earlier denial of its PMA for Oxiplex.

A Decade of Persistence

Krelle was obviously happy with the Commissioner. He said the totality of data from the various studies submitted to FDA on Oxiplex, representing approximately 500 patients studied over nearly a decade, combined with extensive clinical success achieved outside the U.S., "demonstrate that Oxiplex can offer increased effectiveness compared to spine surgery alone, while presenting no significant safety risk."

According to the company, no jurisdiction other than the U.S. has ever denied an application for approval of Oxiplex, which has been available outside the U.S. for more than a decade. It is approved in 70 countries including the 28 member states of the European Union, The Russian Federation, Canada, and Mexico, as well as on the continents of Africa, Australia, South America and Asia.

Oxiplex was studied in two U.S. FDA-approved Investigational Device Exemption (IDE) clinical trials, as well as two foreign confirmatory clinical studies in subjects undergoing spine surgery. The company announcement said the IDE pivotal study, which required more than five years to complete, found that subjects having both leg pain and severe preoperative back pain experienced a greater reduction in leg pain when treated with Oxiplex compared to undergoing surgery alone.

"The extensive body of peer-reviewed published literature on Oxiplex, as well as extensive commercial experience outside the U.S. in more than 340,000 surgeries, provides additional evidence of the safety and effectiveness of the device for use in conjunction with spine surgery," continued the company statement.

Potential Jobs Return to San Luis Obispo

The company filed a petition for reconsideration last December. At the time Krelle said that should the FDA reverse its decision, the company would be in

a position to add several hundred well-paying jobs to its U.S. operations. When the FDA first issued the Not Approvable letter, FzioMed was forced to downsize its California operations by 50% and to outsource jobs overseas.

San Luis Obispo, California-based FzioMed is a privately held company founded in 1996 and develops, manufactures and commercializes absorbable surgical biomaterials based on its patented polymer science. The company says its adhesion barriers are used in many surgical applications including spine, orthopedics, hand, tendon, peripheral nerve, gynecology and general surgery. Its spine gel is the number one barrier gel for spine surgery worldwide and is distributed by Medtronic, Inc., DePuySynthes and other independent distributors.

—*WE (November 8, 2013)*

Kiva Coils Beat Medtronic Balloons in VCF Study

An independent evaluation comparing Benvenue Medical, Inc.'s Kiva VCF (vertebral compression fracture) system to balloon kyphoplasty found that Kiva delivered "significant improvements in back pain."

The Pain Physician Journal, the official publication of the American Society of Interventional Pain Physicians, published the results of the peer-reviewed study in the September/October edition of the journal.

The study, titled "Comparison of Balloon Kyphoplasty with the New Kiva VCF System for the Treatment of Vertebral Compression Fractures," was conducted on the basis of matched pairs, with 52 patients suffering from 68 osteoporotic fractures and followed for six months.

Less Pain, Fewer New Fractures and Less Cement

Those treated with balloon kyphoplasty were treated with KyphX-Systems by Medtronic, Inc., the current gold standard of care and most common vertebral augmentation treatment in the U.S. Outcome measurements were Visual Analog Scale (VAS, a measure of pain), Oswestry Disability Index (ODI, a measure of function), cement usage, cement extravasation, height restoration, and new fractures. The study concluded several statistically significant outcomes in favor of Kiva over balloon kyphoplasty:

- Pain improvement was significantly better with Kiva at six months ($p < 0.0001$)
- New fractures following treatment with Kiva were significantly lower, 12%, than after balloon kyphoplasty, 54% ($p < 0.0001$)
- Mean cement used was less than half with Kiva (2.2 – 2.6 mL) vs. balloon kyphoplasty (4.7 – 7.5 mL)

In an October 29, 2013 company press release, Lucia Otten, M.D., of University Hospital in Bonn, Germany, and author of the study said, "Historically, balloon kyphoplasty has offered my osteoporotic VCF patients benefits. We evaluated Kiva as a new treatment option to see if those benefits were improved. Patients in our study treated with Kiva experienced a pronounced improvement in back pain over balloon kyphoplasty. Additionally, patients treated with Kiva demonstrated a lower incidence of newly occurring fractures and we used less than half the cement."

"This study indicates that using Kiva to treat VCFs offers statistically significant advantages over balloon kyphoplasty in addressing pain, as well as in improving

Benvenue Medical, Inc./Kiva VCF Treatment System

longer-term results by reducing future fractures," added Robert Pflugmacher, M.D., professor of surgery at the same hospital.

The company announcement said that although not demonstrated in this study to be a statistically significant difference, cement extravasation was less with Kiva (23%) vs. balloon kyphoplasty (31%). Vertebral height restoration and functional improvement were equivalent in both groups.

Robert Weigle, Benvenue's CEO, said this is the first independent study to show that the Kiva system was better at improving pain and reducing subsequent fractures in patients with VCFs than balloon kyphoplasty. But it's the second to show significant clinical advantages of using Kiva over balloon kyphoplasty.

Kiva System

The Kiva system features a proprietary flexible implant made from PEEK-OPTIMA. The Kiva implant is designed to function as a mechanical support structure and a reservoir to contain and direct the flow of bone cement.

According to the company, the implant is delivered percutaneously in a continuous loop into the vertebral body through a small diameter, single incision. The amount of the implant delivered can be physician-customized during the procedure to adjust to various fracture types. Delivered over a removable guidewire, the implant is designed to provide structural support to the vertebral body and to directionally control and contain bone cement.

—WE (November 7, 2013)

Globus' Solid and Robust Third Quarter

Globus Medical, Inc. added to the positive spine news for the third quarter by reporting $107.2 million in sales, up a whoppin' 13.1% over the previous year.

Analyst Bob Hopkins of Bank of America called it a "robust quarter."

The company beat consensus by $1 million. U.S. sales growth was 13%, while outside the U.S. sales rose 19.1%. According to company management, sales of disruptive technology products increased this quarter to $45 million or by 20.7% from the prior year's quarter. Innovative fusion sales increased to $63 million or by 8.3% from the prior year's quarter.

"We are very pleased with our industry leading top-line growth and profitability this quarter. Our growth this quarter is again attributable to the increased adoption and success of newer, more disruptive products, which are designed to provide better treatment for the patient, and are safer and easier to use for the surgeon," commented David Paul, chairman and CEO. "During the quarter we launched CREO, our next generation pedicle screw platform, one of the most significant projects in our history."

Record Sales Rep Hiring

The company also continued to recruit sales reps at a record pace and launched five new products during the quarter. The company also reiterated its annual revenue guidance of approximately $432 million.

Piper Jaffray's Matt Miksic said that looking ahead to 2014, he believes the company's new product launches in Creo, Kinex and Lattice could help accelerate revenues.

Momentum of the 3 P's

During a conference call with analysts on October 30, 2013, Dave Demski, the company's president and COO said he and his colleagues were continuing to see generally "positive momentums from the three P's: pricing, procedures, and PODs (physician-owned distributors). Consistent with last quarter, pricing pressure remains in the low to middle single digits, somewhat improved from recent years. Payer pushback on procedures seems to have hit bottom. It's not getting any worse, but not improving significantly either."

Goldman Sachs' Aetna Warning

He added that the company has not seen any specific impact from the recent Aetna policy announcement nor does he see this as a material threat in the

Globus Medical, Inc./Corporate Headquarters

long run. A few days later however, Goldman Sachs downgraded the company's stock, saying, "We see the recent Aetna policy change to deny coverage for cervical interbody devices as shaving approximately 0.8%-0.9% off of our prior 2014 revenue estimates alone and the figure could become more meaningful if additional commercial payers follow suit."

Finally, Demski said the company was pleased with the recent OIG report showing higher utilization and cost associated with PODs. "We see this as yet one more data point in the growing momentum to eliminate this business structure from our industry. While it is impossible to predict the timing, the trend is clearly going in the right direction."

At the conclusion of the call with analysts, Bill Plavonic, Cannacord's analyst, summarized the general theme of the other analysts and said, "Congratulations on a solid quarter."

—*WE (November 5, 2013)*

DJO Global's Match Point Used in Two Cases

DJO Global, Inc. has just announced the first surgical uses of its Match Point System patient-specific shoulder instrumentation in Reverse Shoulder System cases in Sydney, Australia, and in Fort Lauderdale, Florida. The Match Point System is CE Marked and has also received FDA 510(k) clearance.

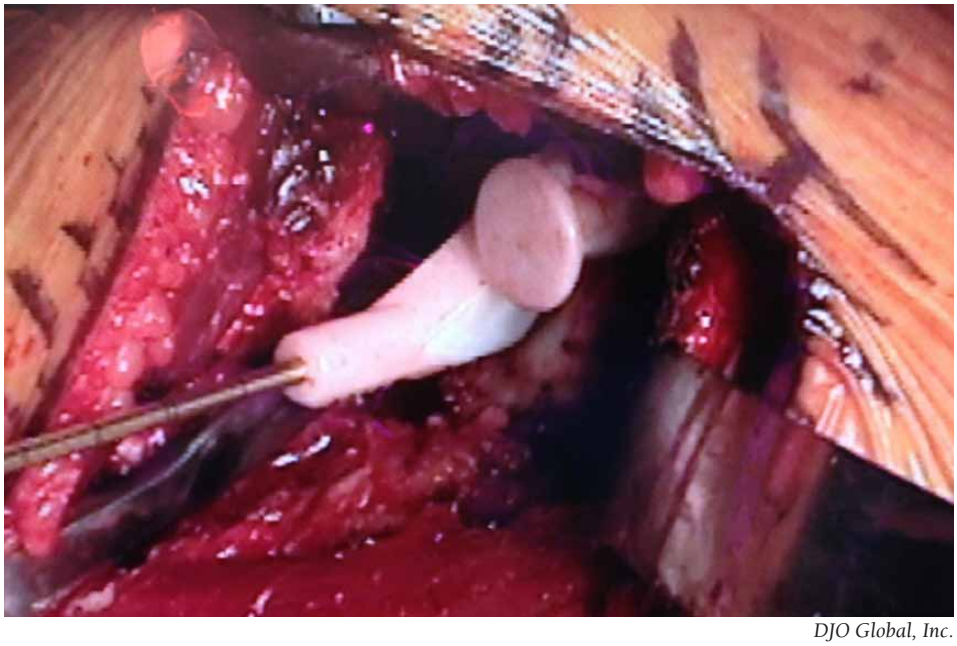
In collaboration with Materialise NV, a company focused on patient-specific instrumentation and innovative software solutions, the Match Point System was developed to provide advanced pre-operative surgical planning and patient-customized drill guides to accommodate a reverse or total shoulder arthroplasty procedure. The Match Point System employs Materialise's proven SurgiCase Connect software to create CT-based pre-operative case plans for surgeons to template and prepare for their reverse shoulder arthroplasty surgeries using the DJO Surgical Reverse or Turon Shoulder Systems. Upon review and plan approval, the surgeon is provided with an ergonomically-designed drill guide that is customized to the patient's unique glenoid anatomy, enabling greater accuracy in implant positioning.

"With the increased patient demand for total and reverse shoulder replacements, surgeons are demanding more in terms of improved instrumentation, planning tools, and techniques for their shoulder cases," said Bryan Monroe, senior vice president and general manager of DJO Surgical, in the October 31, 2013 news release. "The Match Point System is well-suited to address these needs. Our strategic partnership with Materialise has been great; together, we are helping the surgeon to facilitate each patient's return to normal activity."

Dr. Jonathan Levy of Holy Cross Hospital in Fort Lauderdale, Florida, who performed the first Match Point System surgery in the U.S., stated, "I am excited about this technology and its impact on shoulder arthroplasty. It will revolutionize our approach to pre-operative planning and our ability to accurately execute the surgical procedure even in the most challenging of cases."

Bryan Monroe told *OTW*, "The Match Point System streamlines the pre-operative planning process through the use of case management software that also provides enhanced visualization of the patient's unique anatomy. A digitized, 3D scapular model is created, and an algorithm suggests implant positioning for surgeon review. Once the pre-operative plan is approved, a 3D printer creates the patient-specific guide for use in surgery. The surgeon is equipped with a greater sense of preparedness leading up to and during the surgery."

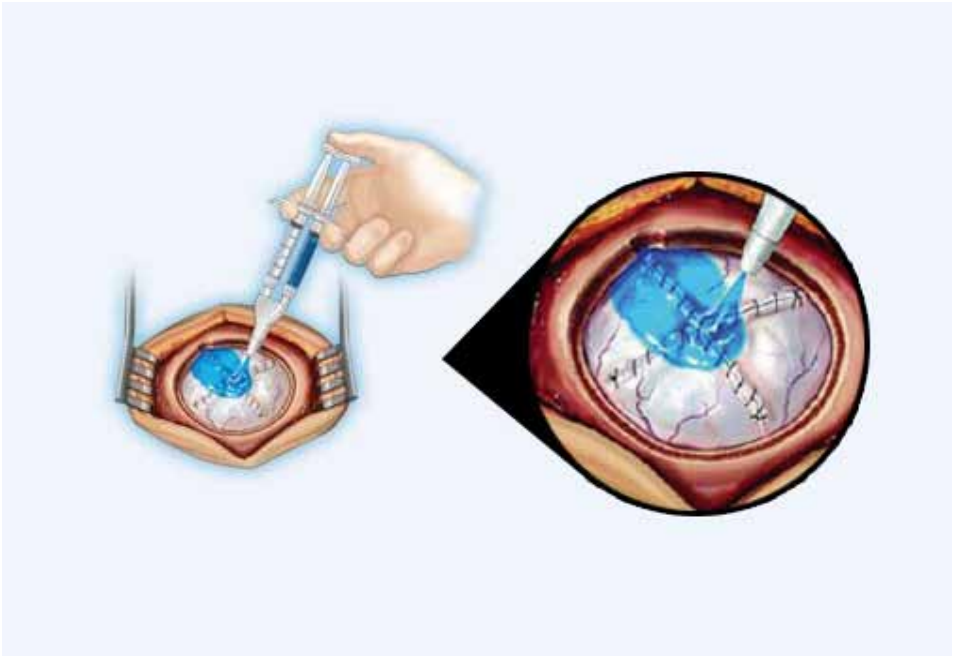
—*EH (November 4, 2013)*



DJO Global, Inc.

Integra LifeSciences Buys Covidien's DuraSeal

Integra LifeSciences Holding Corporation has entered into an agreement with Covidien plc to acquire its Confluent Ssurgical product lines, surgical sealants, adhesion barrier and DuraSeal. Covidien will receive an initial cash payment of $235 million from Integra when the closing takes place, presumably by the end of the first quarter of 2014. In addition, Covidien may receive up to $30 million upon the achievement of certain performance measures.



Courtesy of Covidien plc

Confluent Surgical products include: DuraSeal Exact/Xact, VascuSeal and SprayShield. These products generated approximately $65 million in revenue during 2012 and had gross margins comparable to Integra's regenerative medicine product portfolio. Bryan Hanson, group president, Medical Devices & U.S., Covidien, said, "This transaction allows Covidien to better focus on its global strategic priorities. Based on Integra's presence in neurosurgery and spine surgery combined with a strong portfolio of clinical evidence, we believe these products will thrive under Integra's ownership."

"The addition of the DuraSeal product lines enables our sales force and distributor partners to provide their customers with a best-in-class dural sealant as they seek to support surgeon's efforts to minimize cerebrospinal fluid leaks upon completion of the surgical procedure," said Robert Davis, president of Integra's U.S. Neurosurgery division. "This acquisition perfectly complements our global Neurosurgery growth strategy aimed at providing a broader set of solutions for surgical procedures in the head."

Analysts expect the acquisition to add $57 million to $60 million to Integra's revenue in the first full year of the combination, and to then grow 3% to 5% longer term.

—BY (November 2, 2013)

LEGAL

Stryker/Orthovita Inside Traders Plead Guilty

After Stryker Corporation acquired Orthovita, Inc. in 2011, the feds charged former Stryker marketing executive Mark Foldy with insider trading.

On October 7, 2013, Foldy, along with Mark Cupo, John Lazorchak and Michael Pendolino plead guilty to the charges. On November 13, 2013, two brokers, Lawrence Grum and Michael Castelli each admitted to two counts of conspiracy to commit securities fraud. Grum also plead guilty to four counts of securities fraud and Castelli admitted to five counts of securities fraud, according to the office of New Jersey District Attorney Paul Fishman.

According to a November 14, 2013 *MassDevice* story, Grum and Castelli allegedly acted on tips from Foldy about the impending $316 million deal for Orthovita. The brokers were high school friends of Foldy. The scheme generated $1.7 million in illegal profits and kickbacks.

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Securities and Exchange Commission (SEC) investigators reportedly said the friends conducted the trades under an "elaborate smokescreen," by compiling detailed binders of information on the companies in order to conceal their insider trading as research-motivated decisions.

"This is yet another case where wrongdoers believed they could outsmart investigators by creating an elaborate smokescreen to hide their insider trading," Chief of the SEC Enforcement Division's Market Abuse Unit and Director of the Philadelphia Regional Office Daniel Hawke said in prepared remarks. "Such tactics as using middlemen to pass inside information and compiling research to falsely justify illegal trades will not prevent lawbreakers from getting caught."

Grum and Castelli each face a maximum of 5 years in prison and a fine of $250,000 on the conspiracy counts and a maximum of 20 years in prison and a fine of $5 million on the securities fraud counts. They're expected to be sentenced February 20, 2014.

Foldy, Lazorchak, Cupo and Pendolino are slated to be sentenced January 20, 2014.

—WE (November 15, 2013)

FDA Panel to Consider Reclassifying Spinal Spheres

The FDA's orthopedic expert panel will meet on December 12, 2013 to make recommendation regarding the classification of spinal sphere devices.


FDA/Advisory Committees

The devices are currently regulated under the heading of "Intervertebral Fusion Device with Bone Graft, Solid-Sphere, Lumbar", Product Code NVR, as unclassified devices and reviewed under the 510(k) premarket notification authority. FDA is seeking committee input on the safety and effectiveness of spinal sphere devices and the regulatory classification for spinal sphere devices.

Since 2005, four manufacturers submitted 510(k) applications to clear their devices. They included Medtronic, Inc.'s Satellite Spinal System, Biomet Spine's Spinal Stabilization Sphere System, Interbody Innovations LLP's Spinal Spheres and PEEK Spinal Spheres and Life Spine's Spinal Sphere System.

These devices are spheres manufactured from metallic (e.g., cobalt chromium molybdenum) or polymeric (e.g., polyetheretherketone) materials. According to the FDA, they are intended to be inserted between the vertebral bodies into the disc space from L3-S1 to help provide stabilization and to help promote intervertebral body fusion.

During the arthrodesis procedure, they are to be used with bone graft for holding bone parts in alignment while they heal. These devices are not intended for use in motion-sparing, non-fusion procedures.

The Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee will meet for two days at the Hilton Washington D.C. North, in Gaithersburg, Maryland. On December 13, the panel will consider reclassifying stair climbing wheelchairs from Class III to Class II.

To read the FDA announcement and participation details, click here:

http://www.fda.gov/AdvisoryCommittees/Calendar/ucm374145.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

—*WE (November 12, 2013)*

BIOLOGICS

Vietnam Testing Knee Stem Cell Treatment

According to *Vietweek,* Vietnam is one of the few countries in the world doing clinical trials to treat knee osteoarthritis (OA) using stem cells taken from a patient's fat tissue. Two of the hospitals conducting the trials say the procedure has proved effective so far.

Bui Hong Thien Khanh, M.D., head of orthopedics at the Ho Chi Minh City (HCMC) Medicine and Pharmacy University Hospital, said that, as of last January, his hospital had performed the trials on 21 patients with OA of the knees. Doctors use a needle to harvest about 100cc of patients' abdominal fat and extract stem cells from the tissues with a centrifuge. They also remove some of the patients' blood and place it in the centrifuge to get platelet-rich plasma. They then put the stem cells and platelet-rich plasma under a low-energy laser before injecting the mixture into the degenerative joints.

Khanh said both the plasma and low-energy laser help activate dormant stem cells, which, after activation, can differentiate into cartilage cells to replace the lost ones, and stimulate the damaged cartilage tissues to regenerate.

Nguyen Van Kinh, Ph.D., an advisor at Bach Mai's Vietnam Gene Therapy Center, said in the most severe cases, it (the stem cell therapy) only helps the cartilage tissues develop and release a fluid to improve the knee joint's lubrication and relieve pain, and cannot return the knee to its original structure. The health ministry has also allowed People's Hospital 115 and Van Hanh General Hospital in HCMC to carry out trials for two years starting in April.

—*BY (November 12, 2013)*

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LARGE JOINTS

Good News for Couch Potatoes—Just Walk

Concerned because you do not get as much exercise as you think you should? Stop worrying. It turns out that

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the movement and activity associated with daily living may be enough. Elin Ekblom-Bak, Ph.D., from the Karolinska University Hospital in Stockholm, and colleagues, conducted a health screening study in which they followed 4,232 men and women, age 60, for an average of 12.5 years. During that time they assessed their subjects' cardiovascular events and mortality.

The researchers found that, regardless of regular exercise, non-exercise physical activity (NEPA) was associated with more preferable waist circumference, high-density lipoprotein cholesterol, and triglycerides in both sexes, and

with lower insulin, glucose, and fibrinogen levels in men, when compared to those with low NEPA.

HealthDay News, which reported the study, noted that for both regularly exercising and non-exercising individuals, metabolic syndrome occurred significantly less frequently in those with higher NEPA levels. A high NEPA level correlated with a significantly lower risk of a first cardiovascular disease event and with significantly lower all-cause mortality. The authors conclude "for future health, promoting everyday NEPA might be as important as recommending regular exercise for older adults." The researchers published their study online in the *British Journal of Sports Medicine*.

—BY (November 3, 2013)

EXTREMITIES

Obesity Bad for TKA, What About TSA?

Obese patients undergo a disproportionately higher number of elective orthopedic surgeries in the U.S. Being fat is linked to higher costs, complications, infections and, in total knee and hip replacement surgeries, revisions. What is its impact on total shoulder arthroplasty (TSA) surgery?

A new study looked at the impact of obesity on both the costs and the outcomes of total shoulder arthroplasty surgery. Lead study author Xinning Li, M.D. said, "Our study found that with short-term follow-up, obesity does not have a detrimental effect on functional outcomes and complication rates in patients after TSA" He added, "In the normal body mass index (BMI) patient group, both the shoulder function and the overall physical function improved after TSA. However, among patients diagnosed with obesity, we found that the shoulder function improved after TSA, but the overall physical function did not improve at final follow-up."

The study involved 76 shoulder arthroplasty patients who the researchers grouped according to their body mass index. They classified one group of 26 patients as "normal," a second group of 25 as "overweight" and a third group of 25 as "obese. They recorded preoperative demographics and complications during and after surgery and also assessed the patients before the surgery and at two years following.

The assessments were done using the American Shoulder and Elbow Surgeons (ASES) questionnaire for pain and function and the Physical Component Summary (PCS) Short Form-36. The study results found that pain diminished comparably in all weight groups at two years post-surgery from a score of 62 to 12 in the normal weight group, 68 to 18 in the overweight group, and 66 to 11 in the obese group.

There was one infection among patients who were overweight that required surgical intervention, and two surgical revisions in the normal weight group. In the normal weight group, the mean ASES scores increased from 38.4 preoperatively to 80.2 at two years post-surgery. The PCS score increased from 38.3 points preoperatively to 53.7 points at two years post-surgery.

In the group with patients who were overweight, ASES scores increased from 37.4 points to 75.2; PCS scores increased from 36.1 points to 39.8. In the group diagnosed with obesity, ASES scores increased from 35.8 to 80 and PCS scores increased from 36.3 to 40.7.

"This data suggests that in the normal BMI patient group who are active, that their overall physical function may have been limited due to shoulder pain," said Li. "Therefore, a total shoulder replacement was able to provide this patient population (normal BMI) with improved shoulder function which resulted in a better physical function. Total shoulder arthroplasty is an excellent procedure for pain relief and functional improvement in patients with shoulder arthritis," he said.

—BY (November 12, 2013)

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Smith & Nephew Launches HEALICOIL REGENESORB in U.S.

Smith & Nephew has just kicked off the U.S. launch of the HEALICOIL REGENESORB Suture Anchor. The company indicates that this new suture anchor is the first device to use the company's proprietary REGENESORB material, an advanced biocomposite that has been shown in pre-clinical studies to be absorbed and replaced by bone within 24 months. The HEALICOIL REGENESORB Suture Anchor was designed primarily for shoulder rotator cuff repair, but is also indicated for use in the knee, elbow, foot and ankle.

"The HEALICOIL REGENESORB Suture Anchor is a perfect marriage of implant design and material," says orthopedic surgeon, Scott Trenhaile, clinical assistant professor of surgery, University of Illinois College of Medicine at Rockford, in the November 7, 2013 news release. "Within this one implant, I get the bone ingrowth and mechanical strengths of the original HEALICOIL, as well as the bioabsorption advantages that come from gradually transferring the stresses to the healing bone as the anchor is steadily absorbed."

All HEALICOIL Suture Anchors use a unique, open-architecture design that eliminates the inner diameter material found in traditional, solid-core anchors. Pre-clinical testing has demonstrated that this design allows for new bone to fill the spaces between the threads and within the central channel by 12-weeks after implantation. In addition, the extended, fully-threaded HEALICOIL REGENESORB anchor design was shown in biomechanical testing to provide more threaded engagement than other biocomposite anchors; delivering greater pullout strength in poor-quality, osteoporotic bone. Additionally, the HEALICOIL inserter engages nearly 100% of the anchor's length, which minimizes stress and provides predictable insertion into hard bone by distributing torque along the entire length of the anchor.

"When we introduced the HEALICOIL PK Suture Anchor, its design set a new standard for innovation in our industry," says Brad Cannon, president, Endoscopy, Trauma and Extremities for Smith & Nephew. "With HEALICOIL REGENESORB, we combined the benefits of that design with an advanced material to raise the standard even higher."

The rotator cuff, which is made up of a group of four muscles whose tendons converge to help stabilize and move the shoulder, is subject to a considerable amount of wear and tear with regular daily activities—especially repetitive overhead motions. Current Smith & Nephew estimates are that over 1 million rotator cuff procedures are performed on an annual basis globally to alleviate persistent pain and help patients regain a full range of motion.

Vivek Munshi, senior market manager at Smith & Nephew, told *OTW*, "Early in the development process, our Advanced Healing Technologies team looked at previous generations of biocomposite materials and recognized an opportunity to improve the bone healing process by incorporating calcium sulfate alongside REGENESORB's other well-studied ingredients, PLGA and β-TCP. This unique formulation of safe and proven materials is what sets the REGENESORB platform apart."

"Of course, designing the right biocomposite material represented only half the challenge. The second challenge was incorporating this material into an existing and well-received implant like the HEALICOIL Suture Anchor. Fundamentally, any suture anchor needs to provide sufficient fixation strength over time and throughout the healing period following the surgical repair. As such, the design and development of the HEALICOIL REGENESORB Suture Anchor was tailored specifically with REGENESORB in mind, all while maintaining the well-accepted open architecture of HEALICOIL PK Suture Anchors. This novel implant design required specialized advanced manufacturing processes in order to strike the optimal balance between mechanical performance and implant absorption rate resulting in the unique and reliable device available today."

—*EH (November 12, 2013)*

Smith & Nephew

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