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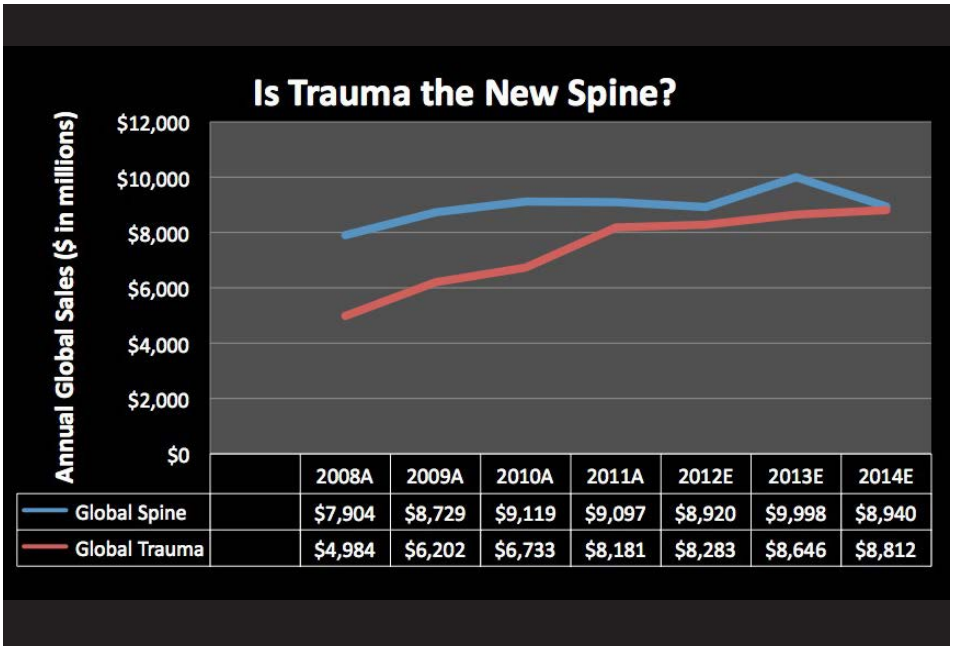
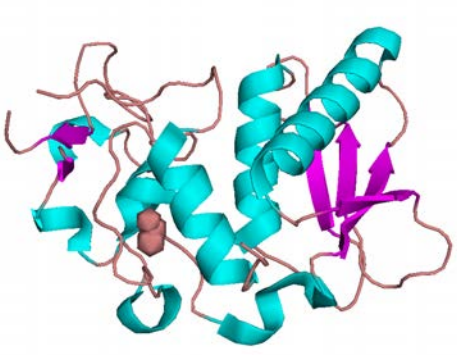
Orthopedics This Week

week in review



	2008A	2009A	2010A	2011A	2012E	2013E	2014E
Global Spine	$7,904	$8,729	$9,119	$9,097	$8,920	$9,998	$8,940
Global Trauma	$4,984	$6,202	$6,733	$8,181	$8,283	$8,646	$8,812



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: The only Fiscal Cliff consensus is that Medicare's budget will be cut. Valuations for orthopedic company equities, which are at historically low levels (ZMH, SYK and others are at about 13x earnings), continue to reflect an industry which has low single-digit revenue growth and margin pressures. New markets and innovation are the basic ingredients of a recipe for higher valuations.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Zimmer	26.37%	2.74%	Zimmer was the big trauma market share gainer in Q3. Still #1 on the Power Rankings.
2	3	Johnson & Johnson	25.58	(1.54)	Despite all the angst from merging Synthes into DePuy, trauma market share rose in Q3. Up one spot.
3	7	Symmetry Medical	5.63	6.44	SMA's numbers starting to reflect international expansion. First Italy, now new distribution in Mexico. SMA is clearly evolving and growing.
4	NR	Exactech	8.64	1.74	With 25% extremity growth and 16% hip implant growth, it's impossible to keep EXAC off the Power Rankings.
5	5	ArthroCare	18.04	11.34	Huge increase in earnings for the third quarter. ARTC reported nearly $14 million versus $4 million last year.
6	9	Conmed	10.39	(0.21)	Two days after presenting at the Piper conference, Zacks upgrades CNMD. To "neutral." Still, right direction.
7	2	Stryker	23.68	2.97	The thing is: SYK has room to grow. New markets and innovative products beckon. Market is waiting for a move.
8	6	NuVasive	7.08	0.63	Very solid investor event in New York which reminded investors that Lukianov and company are stellar managers.
9	4	Medtronic	28.65	1.27	We do firmly believe that MDT will soon stabilize market share in spine. Really, we do. Really.
10	8	Wright Medical	3.58	3.94	How will WMGI make BioMimetics worth 4x the purchase price? That's the question and the promise.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	$3.40	$295	15.65%
2	ArthroCare	ARTC	$33.49	$934	11.34%
3	RTI Biologics Inc	RTIX	$4.47	$250	10.10%
4	Symmetry Medical	SMA	$9.75	$359	6.44%
5	TranS1	TSON	$2.88	$79	4.35%
6	Wright Medical	WMGI	$21.12	$838	3.94%
7	Stryker	SYK	$54.16	$20,592	2.97%
8	Zimmer Holdings	ZMH	$65.97	$11,446	2.74%
9	Exactech	EXAC	$16.99	$226	1.74%
10	Integra LifeSciences	IART	$38.76	$1,048	1.33%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Globus Medical	GMED	$13.31	$1,213	-22.44%
2	Bacterin Intl Holdings	BONE	$1.24	$53	-10.14%
3	MAKO Surgical	MAKO	$13.80	$634	-8.91%
4	Orthofix	OFIX	$37.25	$720	-6.08%
5	Tornier N.V.	TRNX	$16.22	$677	-5.15%
6	CryoLife	CRY	$5.94	$163	-4.04%
7	Johnson & Johnson	JNJ	$69.73	$193,240	-1.54%
8	Alphatec Holdings	ATEC	$1.71	$155	-0.58%
9	Smith & Nephew	SNN	$52.77	$9,525	-0.38%
10	Conmed	CNMD	$27.63	$787	-0.21%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$37.25	$720	12.38
2	Medtronic	MDT	$42.11	$42,958	12.39
3	Zimmer Holdings	ZMH	$65.97	$11,446	12.74
4	Johnson & Johnson	JNJ	$69.73	$193,240	13.49
5	Stryker	SYK	$54.16	$20,592	13.68

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$21.12	$838	66.00
2	NuVasive	NUVA	$14.52	$632	51.86
3	Symmetry Medical	SMA	$9.75	$359	42.39
4	RTI Biologics Inc	RTIX	$4.47	$250	21.29
5	CryoLife	CRY	$5.94	$163	21.21

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$37.25	$720	0.88
2	Conmed	CNMD	$27.63	$787	1.28
3	Zimmer Holdings	ZMH	$65.97	$11,446	1.37
4	Globus Medical	GMED	$13.31	$1,213	1.40
5	Exactech	EXAC	$16.99	$226	1.43

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$21.12	$838	6.52
2	NuVasive	NUVA	$14.52	$632	5.59
3	CryoLife	CRY	$5.94	$163	5.30
4	Symmetry Medical	SMA	$9.75	$359	3.53
5	Smith & Nephew	SNN	$52.77	$9,525	3.05

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.71	$155	0.79
2	Symmetry Medical	SMA	$9.75	$359	1.00
3	Conmed	CNMD	$27.63	$787	1.09
4	Exactech	EXAC	$16.99	$226	1.10
5	NuVasive	NUVA	$14.52	$632	1.17

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.07	$98	85.27
2	MiMedx Group	MDXG	$3.40	$295	38.00
3	MAKO Surgical	MAKO	$13.80	$634	7.50
4	TranS1	TSON	$2.88	$79	4.10
5	Globus Medical	GMED	$13.31	$1,213	3.66

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

Is Trauma the New Spine?

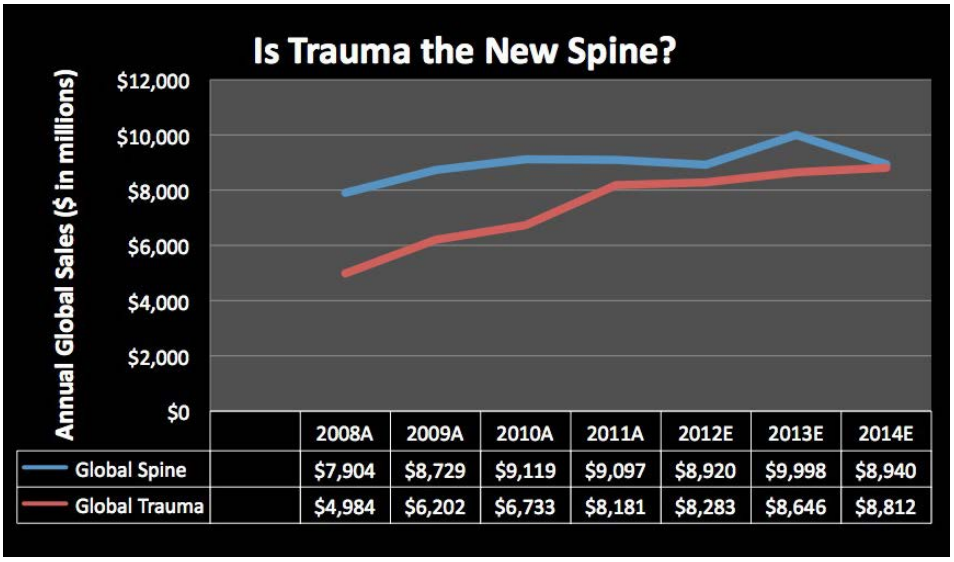
By Robin Young

Fifteen years ago, more hip replacement implants and instruments were sold than any other category of orthopedic product. Ten years ago, knee implants became #1. Eight years ago spinal implants and instruments overtook knee implants and today, sales of products to treat chronic back pain resulting from either degenerative disc disease or such forms of instability and pain as idiopathic deformity are the largest single sector in orthopedics.

For 2012, spinal implant sales will likely reach $8.9 billion. Large joint reconstruction (both hip and knee) will generate about $14 billion in sales in 2012. And sales of trauma products will clock in at about $8.3 billion.

But, as Mizuho Securities analyst Michael Matson illustrated in his Monthly Med Tech Review dated November 29, 2012, spinal implant sales growth rates have been declining and it is almost certain that 2012's reported sales will be less than 2011.

But sales of products for trauma use, according to Matson, will likely reach $8.3 billion this year, up 4% from 2011.



Mizuho Securities

Trauma

In the third quarter every sector seemed to slow down—except trauma. Hip sales growth, which started this year at a year-over-year growth rate of 2%, slowed to 1% in the second quarter then flat lined in the third quarter ending September 30. Spine, which grew ever so slightly in the first quarter, fell 2% in year-over-year terms in the third quarter. Knees, which slowed to a 2% growth rate, seem to be poised to ease down to a 1% growth rate in the current Q4.

Only trauma is growing steadily. In fact, trauma's growth rate is double that of knees—the only other sector in Matson's analysis that grew in the third quarter. Throughout 2012, sales of implants and instruments for trauma surgeons have grown at a very consistent 4% year-over-year rate.

Why?

According to Matson the market for trauma products has very different forces affecting it than spine or knees or hips. Trauma is all about acute inju-

Constant Currency Growth	2008A	2009A	2010A	2011A	1Q12A	2Q12A	3Q12A	4Q12E	2012E	2013E	2014E
Knees	9%	4%	3%	(1%)	3%	2%	2%	1%	2%	2%	2%
Hips	7%	3%	2%	2%	2%	1%	0%	1%	1%	1%	2%
Spine	13%	12%	4%	(2%)	(1%)	1%	(1%)	(2%)	(1%)	(1%)	1%
Trauma	11%	6%	9%	5%	4%	4%	4%	4%	4%	4%	4%

Source: Mizuho Securities

ry—not a chronic disease like osteoarthritis or degenerative disc disease. "I think there are a few differences between the trauma market and the recon and spine markets," said Matson. "First, most trauma procedures are not elective meaning that it is less cyclical. That said, trauma is not immune to economic growth, however, because there is still a correlation between economic activity and accidents. Second, pricing pressure seems less severe in trauma probably because the implants consume a smaller portion of procedural reimbursement than recon or spine implants. And third, the market is more concentrated and possibly less competitive than the recon and ortho markets because of JNJ-Synthes' dominance."

Indeed, DePuy (aka: JNJ-Synthes) holds a 49.5% market share. Closest to DePuy in terms of market share is Stryker at 18.6%. Most interestingly, despite the rumors and headlines that the merger of Synthes into DePuy caused several Synthes reps and distributors to jump ship, DePuy's market share rose in the third quarter. Indeed, of the five companies that hold in the aggregate 85% trauma market share, only two recorded rising market shares—DePuy and Zimmer!

Spine

There was a moment in time when innovation drove product sales in spine. For the physicians who chose to work with these chronically debilitated patients, innovation was their cat nip. It was, to borrow a phrase from the late great Dr. Charlie Ellis, a winner's game. Then everything seemed to change. From an annual growth rate of 13% in 2008 sales of spinal implants will likely slip by a percent or two this year.

Matson, for example, expects that spine product sales will likely decelerate more rapidly in the fourth quarter of this year. "Yes, my current estimate is for -2% constant currency growth in the global spine market in 4Q12." Said Matson: "The market forecast is generated from my individual company forecasts so this is to some degree dictated by guidance from the companies themselves. I suspect that it could prove conservative and growth could be higher but we will have to wait and see."

So which companies seem to be prospering the most in this market? According to Matson, Globus Medical, NuVasive, Biomet and Stryker are taking share this year.

Trauma Market Share

Company Name	3Q11A	3Q12A	% Change
DePuy	49.3%	49.5%	0.1%
Stryker	18.9	18.6	(0.3)
Smith & Nephew	7.4	7.2	(0.1)
Biomet	4.9	4.9	(0.0)
Zimmer	4.5	4.8	0.3

Source: Mizuho Securities

Spine Market Share			
Company Name	**3Q11A**	**3Q12A**	**% Change**
Medtronic	36.4%	35.0%	(1.4%)
DePuy	24.0	23.6	(0.4)
Stryker	7.8	7.8	0.1
NuVasive	6.2	6.6	0.5
Globus Medical	3.6	4.2	0.7
Zimmer	2.4	2.2	(0.2)
Alphatec	2.1	2.1	0.0
Biomet	1.7	1.9	0.2
Orthofix	1.6	1.6	0.0

Source: Mizuho Securities

Point in fact: spinal implant innovation is not gone. It is, we think, a nearly impossible human activity to suppress. Biomet, as we noted in our annual spine technology issue, introduced an entire line of highly innovative metal and biologic products this year. An independent panel of surgeons awarded Biomet an unprecedented three awards in 2012 for its innovative spine products.

Medtronic, likewise, has invested heavily in innovation and is starting to bring some of these products to market. Unlike its competitors, the Memphis based firm is still working through several legacy products which are on the downside of their life cycle.

The key, as we see it, is for spine products to reposition themselves for a market which is de-emphasizing surgical procedures while seeking improved outcomes for these chronically debilitated patients. In other words, fewer readmissions. Fewer complications. More consistent results.

Knees

Only two companies gained market share in the knee market and they were Stryker and DePuy.

Picking up even half a percent in market share in a well established market like knees is no easy feat. How did Stryker do it? In Matson's opinion, the key was Stryker's Triathlon knee system but more specifically the single-radius design.

"Based on our current estimates, I expect Stryker to gain about 0.3% share in global knees (0.5% in the U.S., 0.1% outside the U.S.) in 2012 over 2011 which is more than any of its competitors." Continued Matson: "I think this is due to ongoing success of the Triathlon knee combined with Stryker's renewed marketing focus on Triathlon's single-radius design. Stryker ran a significant direct-to-consumer campaign this year branding Triathlon as the Get Around Knee and this probably helped it gain share in the U.S."

Hips

DePuy, fresh from acquiring Synthes, is not only the largest supplier of hip implants in the world, but also gained the most market share this past quarter.

Knee Market Share			
Company Name	**3Q11A**	**3Q12A**	**% Change**
Zimmer	25.4%	25.1%	(0.3%)
Stryker	19.0	19.5	0.5
DePuy	17.6	17.8	0.2
Biomet	13.2	13.2	0.0
Smith & Nephew	12.3	11.9	(0.4)
Wright Medical	1.7	1.6	(0.1)

Source: Mizuho Securities

Hip Market Share			
Company Name	**3Q11A**	**3Q12A**	**% Change**
DePuy	24.4%	25.1	0.7%
Zimmer	21.2	21.3	0.2
Stryker	20.1	19.9	(0.2)
Smith & Nephew	10.9	10.3	(0.6)
Biomet	10.3	10.5	0.2
Wright Medical	2.6	2.3	(0.3)

Source: Mizuho Securities

Six companies hold 89% market share. What will be very interesting to observe over the course of the next decade is how China begins to influence these shares. It is certainly worth noting that Medtronic is now producing hip and knee implants in China—the home of the second largest economy, the largest orthopedic surgeon society and a rapidly aging and osteoarthritic population.

China's government has embarked on a massive hospital modernization program aimed to provide more services to more of its aging population. By 2020, China's purchases of hip and knee implants will be second only to the U.S.

Recon

Here again DePuy, despite all of the merger related disruptions from acquiring Synthes does not appear to have lost a step and actually gained the most market share of any company in recon. Smith and Nephew, as was the case in knees and hips, lost the most market share of any company in orthopedics. In recon, SNN lost about half a percentage point in market share. In knees SNN lost 0.4% market share, again the most of any company. Finally, in hips SNN lost 0.6% market share—yet again the most of any company.

What is going on with Smith & Nephew?

2013 and 2014

Matson's outlook for orthopedics is conservative. Spine sales, he thinks, will continue to decline in 2013 and then rise a single percent in 2014. Hips, he's forecasting, will rise 1% next year and 2% in 2014. Knees, he thinks, will rise at a steady 2% average annual rate into 2014.

Recom Market Share			
Company Name	**3Q11A**	**3Q12A**	**% Change**
Zimmer	22.2%	22.2	0.0%
DePuy	20.5	20.9	0.4
Stryker	19.7	19.8	0.1
Biomet	13.0	13.1	0.1
Smith & Nephew	11.1	10.6	(0.5)
Wright Medical	3.0	2.9	(0.1)

Source: Mizuho Securities

But trauma, says Matson, will be the fastest growing major sector with a sustained average annual growth rate of 4%—double either knees or hips.

Bottom line, for those companies in the trauma market, the unique and quirky aspects of this market are a haven in this era of outcome based medicine.

In closing, if those of us in orthopedics think that a 1% or 2% sales growth dip is hard. It could easily be worse. It could be cardiovascular. They really have it rough. ♦

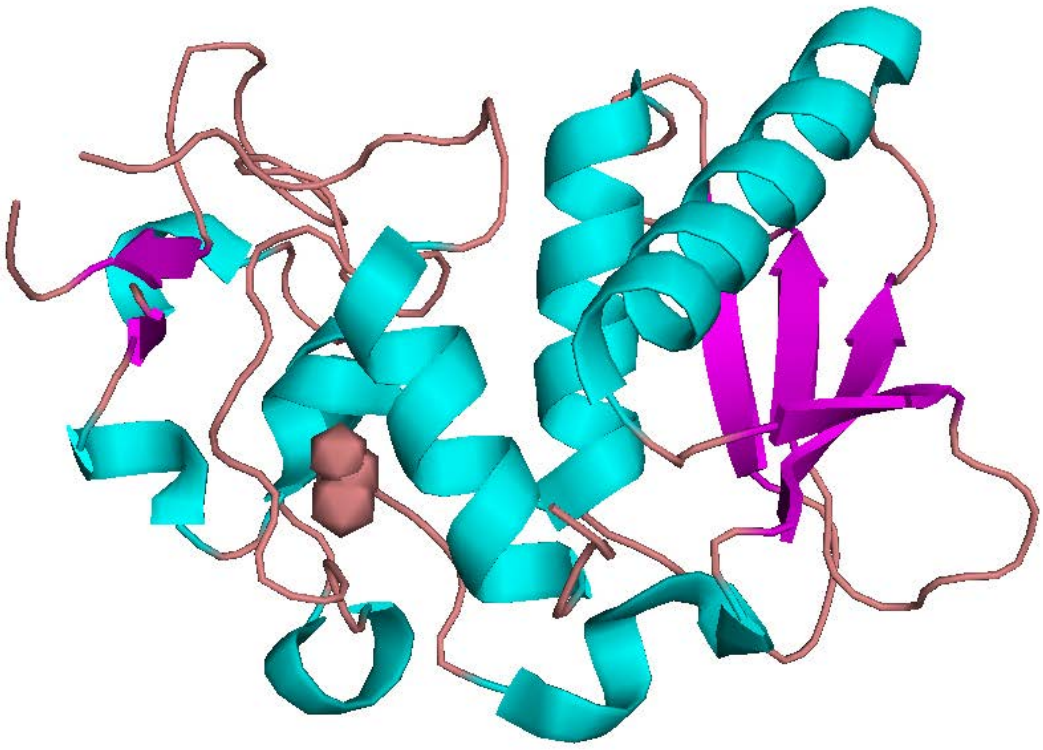
BMP Issue Not Going Away…Registries on the Rise…Poorer Patient, Better Outcomes?

By Elizabeth Hofheinz, M.P.H., M.Ed.

BMP Issue Not Going Away A certain spine surgeon has been thinking a lot lately about the BMP controversy. He tells *OTW*, "It's a real mess… the average orthopedic surgeon is at a loss as to whom to believe and whether or not BMP is safe. The surgeons who have been the principal investigators in the BMP studies—and who reported that even higher levels were safe—had significant conflicts of interest. True, there is no concrete evidence that the lower dose of BMP (4mg)—which is FDA approved—is associated with cancer. But when the dose was ramped up to 40 mg there did appear to be some association between BMP and cancer. A big issue is that the data was there but the original investigators who reported the results failed to include the data related to the cancer association. I still think that BMP is reasonably safe at a lower dose; but I would be very cautious about using it on a patient with a history of cancer. If someone has had a lump removed from a breast and the spine surgeon wants to use BMP…not a good idea."

"The worst is that now we are stuck because you may get a better fusion with the higher dose. But then it's like taking 20 aspirins instead of 3. Medtronic has contracted a new group of independent researchers from Yale to review and reanalyze the cancer data. I don't think they will find anything dramatically different, but they might say that they don't have enough data. And the question is, 'Who will fund the study that would yield more answers?'"

Lower Income, Higher Satisfaction Rate? A recent study by researchers from Mayo Clinic and the University of Alabama has found that patients earning $35,000 a year or less report better outcomes after knee replacement surgery than people who earn more. Study co-author Jasvinder Singh, M.D. of the University of Alabama at Bir-



Crystal Structure of Bone Morphogenetic Protein 1 Protease Domain/Wikimedia Commons and Pymol

mingham told *OTW*, "These patients were also less likely to report moderate to severe pain, which was quite surprising. In other health care settings, lower-income individuals are disadvantaged for health outcomes. There are several possible reasons, although we did not test them in the current study. We believe that a better outcome in patients with lower income may be due to expectations about a more positive outcome and not much gap between expectations and actual outcome of total knee arthroplasty, which have both been shown to impact total knee arthroplasty outcomes. Total knee arthroplasty is a surgery done mostly for an aging population, with many being Medicare eligible. Another reason may be that the negative effect of socioeconomic disparity on health care access and health outcomes leads to a lesser impact once patients are Medicare-eligible and have uniform health care access (which accounts for >2/3rd of all patients undergoing arthroplasty). This study highlights that total knee arthroplasty has good results regardless of income status."

As for how they will proceed with future research, Dr. Singh told *OTW*, "Future research needs to assess the reasons why outcomes were better in those in low-income group. Studies should assess whether this is related to differences in patient expectations, patient goals and/or medical and psychological comorbidity."

AAOS Wins CLIO Award…Again! For the fourth time, the American Academy of Orthopaedic Surgeons (AAOS) has been honored with a CLIO Healthcare Award. The Academy accepted the Bronze CLIO along with its co-recipient, the Pediatric Orthopaedic Society of North America, for their television public service advertisement "Sedentary." "Sedentary" is a TV spot that uses humor to address childhood obesity; the creators of the advertisement depicted things children could do without physically moving. The CLIO was accepted at a recent award ceremony in New York City by the renowned Sandy Gordon, director of Public Relations for AAOS, and representatives from advertising agency August, Lang, & Husak.

Training Orthopedists, Saving Nations Andrew Pollak, M.D. is chief of the Division of Orthopaedic Traumatology and associate director of Trauma at the R Adams Cowley Shock Trauma Center. He tells *OTW* about novel research that could vastly alter the future of many nations. "My colleagues and I have done a cost effectiveness analysis of surgical trauma care as it applies to developing nations. We built our concept based on the population being treated in Haitian emergency rooms and clinics. Fundamentally, it is an assessment of value as compared to other medical interventions that are frequently put in place in the developing world—such as immunizations. We have shown that despite the major cost associated with the startup of a surgical education program, the long-term costs are in fact less than that of other common interventions, including an antiretroviral therapy program."

"When you look at the lifelong surgical skills that this type of a program will transmit to individuals, you find that the long-term value of such intervention is astounding. We do require that surgeons-in-training commit to the two-year program, and we teach these physicians approaches that apply specifically to the needs of the local population. This means that fracture care is the major component, not arthroscopy or total hips. This also cuts down on the possibility of 'brain drain.' We believe these individuals will be highly likely to remain in their respective countries and help strengthen them."

"We are now working with the U.S. government to further this effort. The issue is that it's not in the portfolio of the U.S. Agency for International Development or of the Centers for Disease Control and Prevention [CDC]. However, we have designed a program using similar principles…an educational program that matches the priorities that the CDC has already defined for Haiti, namely, emergency maternal obstetric care (EMOC). We essentially said, 'We will show you that we can teach EMOC effectively in a developing world environment.' Once we do that we will go back and point

to our effectiveness…and say, 'OK, now we want to do the same thing for trauma and orthopedics.' Stay tuned."

Registries on the Rise Alexander Vaccaro, M.D., Ph.D. is a spine surgeon with the Rothman Institute in Philadelphia. He is also vice chairman of the Department of Orthopaedics at Thomas Jefferson University. As if he's not busy enough, Dr. Vaccaro is facilitating the coordination of the existing American spine registries. He tells *OTW*, "At present, there are several popular spine registries in the U.S. The North American Spine Society (NASS) has recently formulated one, the neurosurgeons have one, and then the one that supports the Association for Collaborative Spine Research (ACSR), PhDx. I have the responsibility, along with the Board of ACSR, of coordinating the efforts of our registry with those of others, and finding a coherent way to make the registries 'crosstalk' to one another so that we capture useful data."

"What a lot of people don't understand is that having a registry isn't just saying, 'OK, let's put all our data in a computer.' For a registry to be effective, it *must* be well thought out beforehand. There are different categories of questions: Does the treatment that we render have any positive effect on outcomes? What are the complications of our interventions? What about the effectiveness of X and Y implants? The first thing to consider is the design of the data fields. We must determine what basic information is important to capture so that we obtain basic demographics. Here's the tricky part: it must be universally accepted—including by insurers and the government."

"The typical orthopedist and neurosurgeon are normally too busy to sit and type in a lot of information about their daily patients outside of routine clinic responsibilities, so for this to work what we record has to be very simple. We've determined that the most efficient way is to examine electronic medical records (EMR) and ensure that the data fields we establish for the registry emulate these somewhat to make future data transfer efficient (i.e., sex, age, treatment rendered, etc.). Then you must ask, 'What outcome measures should be used?' Keep in mind that if you ask too many questions the average doctor is not going to use it. We are striving to make data fields similar to what is normally captured in office hours, focusing on basic questions useful for future research. We may use the Oswestry Disability Index, Visual Analog Scale, and abbreviated versions of the SF-36 form; imaging data is also important for more advanced registries and hopefully these will be able to be efficiently imported from the EMR. When the individual becomes an established patient, they may be sent an email with questions, then after treatment they are sent 'ticklers' via email to motivate them to respond as far as how they are faring. If the person does not respond an administrative person takes note of that and will follow up."

"Someone has to pay for all of this. Although the ACSR has a three-year grant for our registry, I'm pushing to obtain federal assistance…imagine, for example, if you got a tax break for participating in this? We will need some type of outside funding because for a practice with around 12 physicians you're looking at possibly $10,000 to 15,000 a year for basic support services. At the recent NASS meeting I argued that we see so many nonsensical treatments in spine—and that the government is pushing for comparative effectiveness research—so having a coordinated registry effort should make complete sense."

"If we can get grants then we can demonstrate to the government that XYZ modality is or is not effective. For example, there are two recent studies—one from our group—showing that if you got an epidural injection you tended not to do as well if you eventually have surgery for spinal stenosis. That is the kind of information that can be gleaned from a registry so that insurers or the government can look into that further and design studies to ask specific questions raised by registry data. We should pay attention to such things…especially because a considerable amount of money is spent in this country on nonoperative and surgical care…and determining what has value should be a priority to all." ♦

Vicious Lawsuit Erupts Over Payer Bullying in Colorado

By Walter Eisner

On August 30, 2012, representatives of Colorado's largest hospitals and insurers met in secret to conspire to drive competing physician-owned ambulatory surgical centers (ASCs) out of business.

That's the claim made by four Colorado physician-owners of ASCs in a lawsuit filed on November 16, 2012 in a Denver U.S. District Court against HCA Inc., owner of HealthOne; Centura Health, a hospital operator co-sponsored by Catholic Health Initiatives and Adventist Health System; Kaiser Health Plan of Colorado and CASCA. The physicians say the defendants violated the Sherman Anti-Trust Act.

HCA's HealthOne, in addition to being largest hospital chain in the U.S., owns 110 surgery centers in 20 states, 14 in Colorado. Centura owns 11 centers in the state.

Wikimedia Commons/Morguefile/RRY Publications LLC

Driving Physicians Out of the ASC Business

The physicians are alleging that HealthOne and Centura Health asked CIGNA, United, Anthem, Aetna, Humana, and Kaiser to join them in a boycott of the physician-owned surgery centers.

After that meeting, which was held at the offices of the Colorado Ambulatory Surgery Center Association (CASCA), physician owners of the Kissing Camels, Cherry Creek, Arapahoe and Hamden surgical centers claim that a number of health insurers took actions "designed to further their agreement to attempt to marginalize or put out of business" the physicians. And that those actions were a result of that meeting and the agreements reached with HealthOne, Centura, and CASCA.

Terminating Practices

For instance, one insurance company terminated from its networks a number of physicians and practices affiliated with the four (Kissing Camels, Cherry Creek, Arapahoe and Hamden) ASCs. "These terminations were designed to deter referrals of patients and surgeries to these facilities," states the lawsuit.

That same insurance company has allegedly threatened many other physicians and practices with termination if they continue to treat patients at the four physician facilities and has threatened primary care physicians with termination if they continue to refer patients to surgeons who perform surgery at those facilities.

"In fact, that insurance company went one step further and threatened to terminate primary care physicians who referred patients to specialists who ultimately performed surgeries and procedures at the Plaintiffs' facilities," continued the allegations.

The day after the "secret meeting" at CASCA, that company allegedly sent a letter to Metro Denver Pain Management purporting to terminate that practice "for cause" for "continued use of SurgCenter on Dry Creek [Arapahoe]."

The lawsuit continues that another health insurance company present at the meeting has threatened practices affiliated with the physicians with termination from their provider networks on the basis of their treatment of patients at those facilities.

On September 6, 2012, that insurer sent letters to providers that performed surgeries and other procedures at SurgCenter facilities including Colorado Hand Center and Interwest Rehabilitation, purporting to terminate those practices from its provider network for "inappropriate referrals."

After the meeting Kaiser notified Kissing Camels that it no longer intended to finalize its previously negotiated participation agreement with the physicians.

In addition Kaiser has refused to authorize the treatment of its members at Kissing Camels Surgery Center on an out-of-network basis, even when surgery is urgently needed.

A Centura administrator named Brent Ashby allegedly said it was his goal to put Kissing Camel out of business.

Anticompetitive Restraint of Trade

As a result of HealthOne's and Centura's "anticompetitive restraint on trade," the physicians say patients who sought treatment at Kissing Camels have been required by their health insurers to seek treatment at ambulatory centers owned by the hospitals.

Hospitals Accuse Physician ASCs

The real culprits, according to the hospitals and insurers reported in a *Denver Post* story on November 21, are the physicians who own surgery centers. Their attorneys claim the physician ACSs are illegally waiving co-pays and deductibles for patients, then "purposefully" charging insurers out-of-network fees at up to 1000% markups.

Colorado isn't the only place were insurance companies and physician-owned ACSs are fighting it out. According to the *Post,* a California lawsuit claims physician-owned ACSs have cost insurers tens of millions in overpayments.

Aetna alleges fraud, unfair competition and unjust enrichment, "cherry-picking" of patients with the best insurance plans, and promises to doctor-investors of 800% annual returns on their money.

The California suits focus on Bay Area Surgical Management. The doctor-owned surgery centers' method of doing business "shocks the conscience," said an Aetna lawyer.

CASCA Pawn of Hospitals

CASCA sent a letter to Colorado state regulators asking for an investigation of the new centers and their financial arrangements.

The physicians' lawsuit says CASCA is a tool of its biggest hospital members, who are trying to protect their own surgery centers.

Argument for ASCs

Hospitals generally require large amounts of capital expenditures and employ significant staffs, both of which result in costs that are allocated across all procedures performed at the hospitals.

As healthcare costs increased, ASCs developed as an alternative to hospitals and provided comparable procedures at lower costs for patients who do not require hospitalization. While hospital systems have formed surgery centers, those hospital systems have, according to the physicians, an inherent conflict of interest to direct as many patients as possible to the hospitals where the hospitals are paid more for the services in order for the hospitals to cover their significant costs.

In fact, through their relationships with doctors and otherwise, hospitals have the ability to direct many patients to the site where they will receive their procedures.

In a fair and open market, the physicians who own their own ASCs claim that hospital ASCs cannot compete in terms of price or quality with the physician-owned model.

Advantages of the Physician Owned ASC

According to physicians who own their ASC, the treatments performed at their centers are less likely to result in infection than if similar procedures were performed in hospitals.

They also point out that the treatments performed at their centers are almost always less expensive than similar procedures performed at hospitals. Patients can schedule procedures at their centers with more flexibility than if they were scheduling similar procedures at hospitals, where surgeons must compete with longer, less predictable and emergency surgery procedures. Patients find that they have fewer cancelled and/or delayed procedures when they come to the physician-owned center.

And the list goes on. In general, patients find more convenience such as closer parking and shorter wait times when they have procedures at the centers instead of at hospitals such as the Defendants in this action.

Prices are lower. For example, the lawsuit claims Medicare pays $1,332.19 for carpal tunnel surgery when performed in a hospital in Colorado, but pays only $762.31 when that same surgery is performed in a free-standing ASC.

As a further example, Medicare pays $4,246.76 for reconstruction of a wrist joint when that surgery is performed in a hospital, but pays only $2,457.95 when that same surgery is performed in a free-standing ASC.

So, as a result of these factors and others, say these physician owners, hospitals are unable to compete with physician ASCs with respect to surgical procedures that can be performed on an outpatient basis.

"Defendants have experienced an increasing number of patients exercising their rights to make their own healthcare decisions by choosing these lower cost, more efficient, and generally safer facilities. As such, the Defendants have resorted to the concerted activity and anticompetitive practices," alleged in this complaint.

Fighting Over Patients

The physicians and hospitals aren't fighting over the law. They are fighting over patients who don't require hospitalization. They're not even fighting over science, they're fighting over billings.

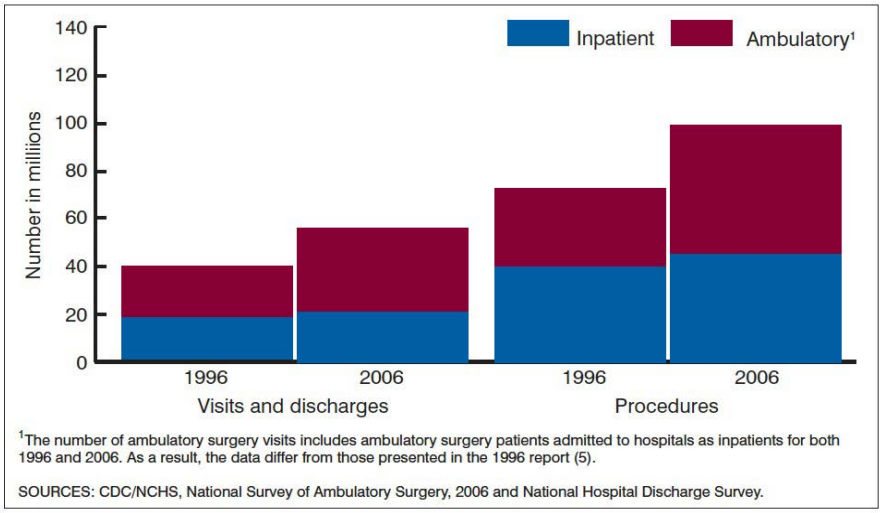
According to the 2006 National Survey of Ambulatory Surgery estimates, 53.3 million surgical and nonsurgical procedures were performed during 34.7 million ambulatory surgery visits in 2006. *(See Graph on page 14)*

Of the 34.7 million visits, 19.9 million occurred in hospitals and 14.9 million occurred in freestanding ambulatory surgery centers.

Freestanding ASCs on the Rise

The rate of visits to freestanding ambulatory surgery centers increased about 300% from 1996 to 2006, whereas the rate of visits to hospital-based surgery centers remained largely unchanged during that time period. *(See Graph on page 14.)*

Average times for surgical visits were higher at hospital-based ambulatory surgery center than for visits to free-standing centers for:



¹The number of ambulatory surgery visits includes ambulatory surgery patients admitted to hospitals as inpatients for both 1996 and 2006. As a result, the data differ from those presented in the 1996 report (5).

SOURCES: CDC/NCHS, National Survey of Ambulatory Surgery, 2006 and National Hospital Discharge Survey.

Figure 1. Ambulatory surgery visits and discharges of hospital inpatients with procedures: United States, 1996 and 2006 (revised)

Survey of Ambulatory Surgery

- the amount of time spent in the operating room (61.7 minutes compared with 43.2 minutes),
- the amount of time spent in surgery (34.2 minutes compared with 25.1 minutes),
- the amount of time spent in the postoperative recovery room (79.0 minutes compared with 53.1 minutes),
- the overall time (146.6 minutes compared with 97.7 minutes).

Most patient visits were related to the digestive system with musculoskeletal related visits coming in second.

Good Business

Considering that over 1 million hospital discharges for just hip and knee replacements took place in 2010, the market opportunity for surgery centers is huge. Kenneth Pettine, M.D. told us that he believed over 40% of those procedures could be performed at surgical centers. "Hospitals are full of sick and dying patients with an epidemic of infections." Infections are practically non-existent at ASCs said Pettine. He plans to open his own center in Colorado in the near future.

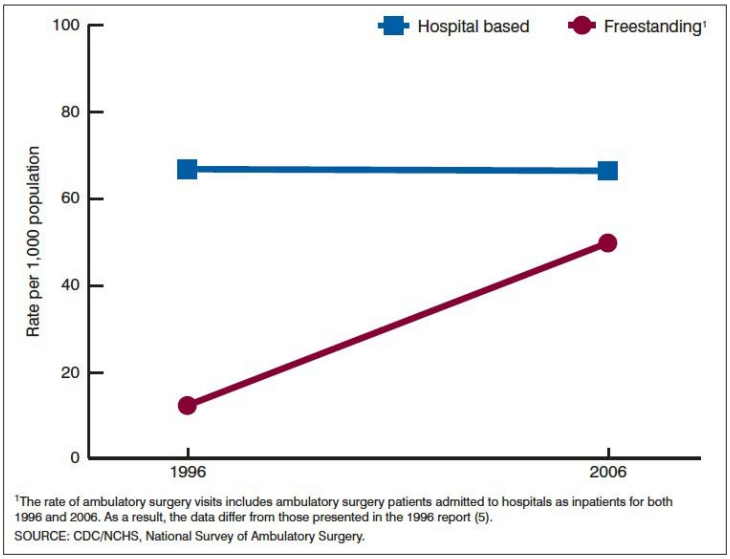
Medicare encouraged the development of ambulatory surgery over concern about rising health care costs. The new health care law does not prohibit their growth as it does for physician-owned hospitals.

In the early 1980s, the Medicare program was expanded to cover care in ambulatory surgery centers, and a prospective payment system based on diagnosis-related groups was adopted for hospital inpatient care that created strong financial incentives for hospitals to shift less complex surgery to outpatient settings.

According to the 2006 survey, ambulatory surgery has been increasing since the early 1980s. Two major reasons for the increase are advances in medical technology and changes in payment arrangements. The medical advances include improvements in anesthesia, which enable patients to regain consciousness more quickly with fewer after effects and better analgesics for relief of pain. In addition, minimally invasive and noninvasive procedures have been developed and are being used with increasing frequency.

Controlling Means of Production

As orthopedic surgeons find themselves increasingly on the receiving end of a paycheck from their hospital employers, opportunities to keep control over their own means of production seem to be shrinking. Four physician-owned surgical centers in Colorado are fighting to keep that opportunity alive. ♦



¹The rate of ambulatory surgery visits includes ambulatory surgery patients admitted to hospitals as inpatients for both 1996 and 2006. As a result, the data differ from those presented in the 1996 report (5).

SOURCE: CDC/NCHS, National Survey of Ambulatory Surgery.

Figure 3. Rates of ambulatory surgery visits by facility type: United States, 1996 and 2006

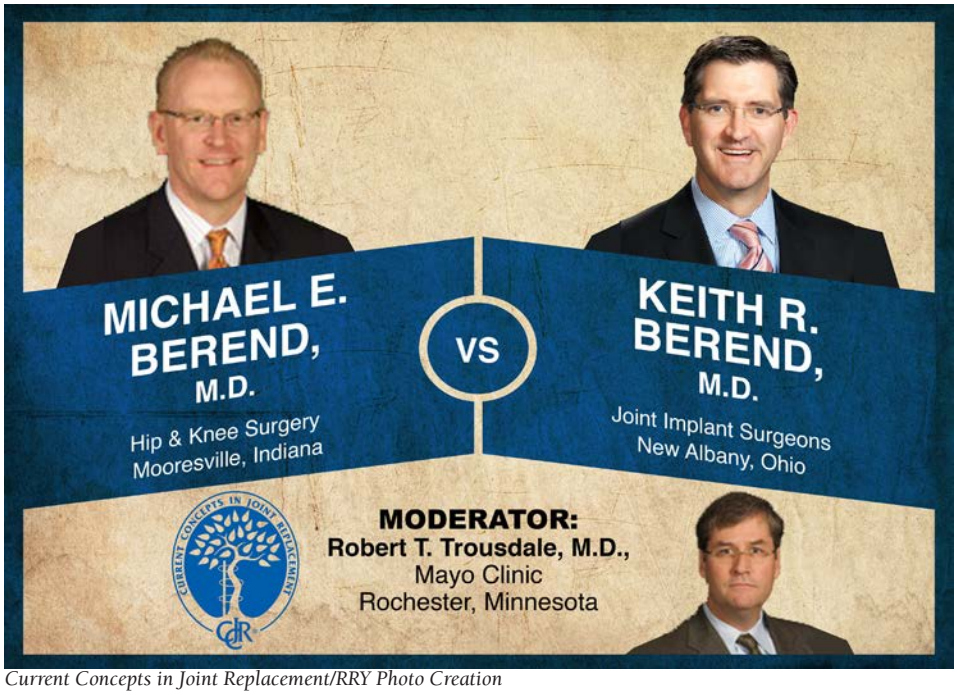
Survey of Ambulatory Surgery

Berend V. Berend: Is MIS a Risk Factor of Early TKA?

By Elizabeth Hofheinz, M.P.H., M.Ed.

"There's not much MIS [minimally invasive surgery] about a TKA [total knee arthroplasty]. Regardless of the incision or the surgical approach, it's the same biologic response, same bone removal, etc.," says Michael Berend. "Alright," says brother Keith Berend, "MIS is a misnomer. It has to do with other factors like patient expectations and perioperative anesthetic. I think MIS should be credited with drawing our attention to all of these various things."

This week's Orthopaedic Crossfire® debate is "MIS: A Risk Factor of Early TKA – Brotherly Love!" For the proposition was Michael E. Berend, M.D. of the Center for Hip & Knee Surgery in Mooresville, Indiana. Against the proposition was Keith R. Berend, M.D. of Joint Implant Surgeons in New Albany, Ohio. Moderating was Robert T. Trousdale, M.D., of Mayo Clinic in Rochester, Minnesota.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Michael Berend: "When you're the older brother, the saying of 'older and wiser' has been a dogma for many years; 'younger and misguided' is my opponent today. I've been feeding Keith information for many years [photo of elder brother bottle-feeding baby brother]. When he was a resident I was early to MIS. I think we've all realized we were doing a bit more than we needed in the '90s. I think that we've trained folks to ask the wrong questions. How big is the incision? We've gone from inches to centimeters. And the recovery to how many weeks. So I think MIS will need to be redefined into 'Must Insist on Seeing.' For both of us 40% of our practice is now partial knee replacement. So I think as Keith has stated previously, the only conservative, minimally-invasive operation is a partial knee replacement."

"There's not much MIS about a TKA. Regardless of the incision or the surgical approach, however you define the surgical approach, it's the same biologic response, same bone removal, same basic implants, same rehab…and I would submit, 'Is it less predictable to do it through a smaller window?' Certainly we've gained a lot of information from anesthesia protocols and preoperative education. And we've emerged with a whole series of closet MIS zealots…and my brother is one of the lead people."

"MIS is a misnomer. In a series from Niki of 147 knees, with all approaches, various enzyme measurements looking for the biological response—they found no difference in muscle injury with MIS versus standard. Another group—from Karpman—prospective and randomized…small series (59 knees), three groups, various definitions of surgical approach. Only at one time point were they improved at two weeks, not one week or six weeks…and all the outcome measures were similar."

"If you look at Kolisek, a prospective randomized study, there was no improvement clinically, no differences in the X-ray, three month outcomes were the same, and there was unfortunately a 10% wound healing problem with MIS."

"In a series from Tashiro, they looked at clinical measurement, X-rays, and OR time. Again, small improvements at the two week mark when the patient still has their staples in. Fortunately there was no coronal malalignment; there was a medial shift in the implant, which may be a problem. And they found an almost 56 minute increase for the total knee replacement. If you take that and add in what Steve MacDonald talked about, that infection rates were higher in TKA in the group that had 33 minute longer operative time."

"If you look at a series of early revisions for malrotation, 81% of their knees were revised in less than two years in this series. So if it's difficult to assess femoral component rotation, this may be a risk factor."

"If you look at all the risk factors together that we know for late tibial loosening and TKR failure—including infection, fracture, poly resin, resection depth, etc.—MIS is added to that. And a number of the factors—infection, time, alignment, ligament balance, femoral component rotation—all would be negatively affected. Tom Fehring has shown that these factors account for early revision in the U.S.: infection (38%), instability (27%), aseptic/wear (23%), patellofemoral (8%)…and all of these are a risk with MIS."

"A series from Barrack first suggested that MIS may need to be added to the risk factor list. It was a multicenter study, 237 revision knees, mainly revised for instability and loosening. The ones with an MIS knee were revised at an average of 14 months, compared to those with a standard knee at 80 months."

"If you look at Dalury and Dennis—30 mini versus 30 standard—13% greater than four degrees of malalignment. Certainly this is unacceptable. We have

shown that if you miss the mark in the obese patient with greater than three degrees, a rather precipitous drop in failure."

"So MIS is not for all patients, not for all surgeons. There is a significant learning curve, perhaps up to 50 cases. Let's take the good and leave the bad. Careful surgery will win the day in the end."

Dr. Keith Berend: "We grew up in the same household and yet Mike is so off base in terms of the way the future has moved forward. As he said, we agree on one thing…partial knee replacement is probably the only truly minimally invasive surgery we can offer our patients. One of the problems with any debate over MIS is that we don't really know what it means. There is no standard outcome measure. And none of the prospective randomized trials address the standardization of perioperative protocols."

"If we look at what has been reported, there's a subvastus, quad sparing, midvastus, a limited medial parapatellar [approach]. The goal is the same: minimize trauma to the suprapatellar pouch and minimize trauma to the extensor mechanism. And there are many articles that look at each of these approaches."

"The reported benefits…Mike showed the studies that showed no benefits, but there's an equal if not greater number that show benefits. Basically, the patients recover faster. The issue is whether this is safe. And I think we all got alarmed by the study from Bob Barrack and Lowry Barnes that was in the *Journal of Arthroplasty* a year ago. My conclusions from that study: they excluded infection in their series, which I think skews the data somewhat; the MIS patients were younger; the time to revision was shorter with MIS; less than 20% of their revision cases, however, were MIS…and those MIS cases were revised more frequently for malposition and instability."

"This isn't a new concept. If we look back, Fehring and Sharkey both have reported pre-MIS era revision rates and again, half the patients or more were revised early. So it's not a new finding that MIS patients are revised early. Almost half of the patients were revised for malalignment and instability, if you exclude infection. The numbers are no different if you look at early revision rate pre-MIS and early revision rate post-MIS. So Mike, wake up and smell

the coffee. It's not an issue of operative technique…it's an issue of what's happening in our community and what's happening in our world."

"If we look from when Insall and others pioneered knee replacement, there were ongoing failures—and greater than 50% of the knees that were going to fail had already failed by the time Barrack and Lowry Barnes published their article. So the early failures have already occurred in the open technique. We won't see early failures in open technique if we're not doing it. Instead, we see the early failures in the MIS technique because MIS is something that's just occurred recently."

"Our data from Adolph Lombardi's series: two years, single surgeon, 1,300 knees…compared with two surgeons, 3,600, and the study group being the minimally invasive group. If we look at knees requiring manipulation, the minimally invasive group was almost half that of the standard group. Early reoperation rate: less than half the early reoperation rate in the MIS group."

"I agree with Mike: MIS is a misnomer. It has very little to do with the efficient surgery and the size of the incision. It has to do with other factors that we've heard so much about, including preoperative education and perioperative anesthetic. I think MIS should be credited with drawing our attention to all of these various things."

"MIS starts in the office with aligning patient expectations and understanding the rehabilitation protocols. The operative intervention is just a small part of it. MIS is multifactorial. We have to align patients' expectations, educate, have medical optimization, know that the anesthesia team is as important as the surgery team, have pain management throughout the postoperative period, have efficient and safe surgery, and then have physical therapy postoperatively."

Moderator Trousdale: "Keith, the series you did with Adolph…you showed some difference in outcomes between the MIS and the standard group. What other variables did you change in those two series?"

Dr. Keith Berend: "No. That's the important part of this whole MIS series…the surgery is one part of it. We changed each one of those variables."

Moderator Trousdale: "Michael, what are the factors that we've changed in the last two decades that's influenced the outcome the most?"

Dr. Michael Berend: "Probably the anesthetic protocol, pain control, patient education…all those things changed at the same time. Rehabilitation was different, time off the walker was different and all of those factors together lead to clinical improvement. Some of the reoperation rates you observed…the manipulation rates seem excessively high. Early return to operating room rate seems excessively high, even compared to most standard series."

Dr. Keith Berend: "MIS is a package. It's a multidisciplinary system. But MIS surgery really should be credited with bringing that all to the forefront."

Moderator Trousdale: "We've changed the anesthesia, what we tell patients, as well as what we do in the OR, and all of a sudden we say that it's because of what we do in the OR that needs to be addressed. So Keith, what surgically are you doing differently with your so-called MIS technique that you think may affect outcome?"

Dr. Keith Berend: "It's mixed in terms of which exact step in the operation, just as which exact step in the whole program makes the biggest difference. But we don't evert the patella for the entire operation, we don't dislocate the tibia for the entire operation; I think there's a difference in the way we balance the knee now in the end versus big periosteal stripping versus intra-articular correction. A lot of small things that have come about because it's harder to do the operation through a small incision. The instruments have improved, and our choreography in the OR has also improved."

Moderator Trousdale: "Keith, do you tell your patients they're getting an MIS surgery?"

Dr. Keith Berend: "No."

Moderator Trousdale: "Michael?"

Dr. Michael Berend: "No, but we've made the exact same changes they've made. I think the pressure for all of us to make smaller and smaller incisions is huge and negative."

Moderator Trousdale: "What outcome tools should we be measuring, Keith?"

Dr. Keith Berend: "I don't think that we have one outcome tool that is sensitive enough to measure that. The biggest issue with knee outcomes—whether MIS or non or partial versus total—is the ceiling effect for the high performer. All the studies measure different things, and a lot of them are surrogates. They're not 20 year outcomes, they're 'How far did you bend your knee at six weeks?'"

Moderator Trousdale: "Michael?"

Dr. Michael Berend: "We used to talk long term survivorship and now we're saying, 'I can do stairs at a week' or 'I can go back to work at three weeks'… and I think that's the wrong message to be sending to our patients."

Moderator Trousdale: "So what do you tell your patients about recovery before the surgery?"

Dr. Michael Berend: "We tell them two days in the hospital, three to four weeks on a walker, a cane for a month, that it takes a year to get over the operation."

Moderator Trousdale: "When do you have them driving?"

Dr. Michael Berend: "Left knees, whenever they want. Right knees, we negotiate…about four to six weeks."

Moderator Trousdale: "Keith, anything different?"

Dr. Keith Berend: "Really no different, but I think your point, Bob, is that one of the real dangers with the MIS craze is setting the wrong expectations for our patients. We need to not oversell the recovery."

Moderator Trousdale: "Thank you, gentlemen." ♦

Please visit www.CCJR.com to register for the 2012 CCJR Winter Meeting, December 12 - 15 in Orlando, Florida.

"You may now view content from the CCJR Meetings on the CCJR Mobile™ App. Please scan the QR code to download the CCJR Mobile App to your Android or iOS mobile device, or visit www.ccjrmobile.com."

company

NuQu's Promising Phase I Results

ISTO Technologies, Inc.'s NuQu cell-based biological therapy to treat lower back pain had no serious and unexpected safety concerns, showed promising treatment results and could eliminate a number of surgical spine procedures.

That's the conclusion of a scientific paper reporting on Phase I of a clinical trial of the therapy published in the latest *Journal of Neurosurgery*.

The manuscript, entitled, "Prospective study of disc repair with allogeneic chondrocytes," was submitted by Domagoj Coric, M.D., Kenneth Petting, M.D., Andrew Sumac, M.D. and Margaret O. Boltes, R.N.

12 Month Post-Treatment

The authors report 12 month post-treatment results of a single-arm study using MRIs, the Oswestry Disability Index (ODI), the Numerical Rating Scale (NRS), the 36-Item Short Form Health Survey (SF-36) and other measures. The study was designed to evaluate the safety and initial efficacy of NuQu in 15 patients at 2 clinical sites.

Dr. Coric, lead clinical investigator for the project and a practicing neurosurgeon at Carolina Neurosurgery and Spine Associates and chief of neurosurgery at Carolinas Medical Center, both in Charlotte, North Carolina, commented, "Given the limited treatment options available today for patients suffering from chronic low back pain, NuQu potentially represents a unique and innovative technology that could eliminate a number of surgical procedures and improve quality of life for a sizable patient population."

Journal of Neurosurgery

NuQu

NuQu is comprised of tissue-expanded juvenile chondrocytes that are supplied frozen to the physician, and then thawed and combined with a fibrin carrier at the time of use. The chondrocytes are delivered percutaneously under 2D-fluoroscopic guidance. The company anticipates that patients treated with NuQu will demonstrate faster recovery rates than traditional surgical approaches.

Phase II

In October the company announced the initiation of a Phase II clinical trial to further evaluate the efficacy and safety of the therapy. The company expects to commence enrollment in the randomized, double-blinded, placebo-controlled trial in the fourth quarter of 2012 at multiple U.S. clinical sites.

Mitchell Seyedin, Ph.D., president and CEO of the company, said the results from the initial clinical experience with NuQu "support our belief that this technology may represent a breakthrough treatment for degenerative disc disease by promoting regeneration and healing of the disc. We believe that the publication of the 12-month data from our Phase I trial in a peer-reviewed journal validates our commitment to NuQu." He added, "This technology has the potential to be a cost-effective non-surgical solution to disability from chronic low back pain and we believe that the results from our Phase II study, which includes a placebo control, will support this promise."

—WE (November 30, 2012)

DePuySynthes Spine President Replaced

Namal Nawana resigned from his position as worldwide president, DePuySynthes Spine on November 27. Max Reinhardt, current vice president, worldwide marketing, will be named the new president.

Debbie Williams, the company's communications director, confirmed the news to *OTW* in an email on the same day.

Max Reinhardt and Namal Nawana/DePuySynthes Spine

Namal Nawana

Nawana took the DePuy Spine position in March 2011. Since then, DePuy merged with Synthes, Inc. to form DePuySynthes, the largest orthopedic company in the world. Michel Orsinger, head of Synthes took over as head of the combined companies.

Nawana began his career as a research engineer at Royal Adelaide Hospital in 1992 before serving as a product development engineer with Howmedica International. He was with Johnson & Johnson and DePuy for more than 15 years, serving in roles in engineering, marketing, sales and general management in Canada.

In 1997, Nawana joined Johnson & Johnson Orthopaedics as a technical support manager in the UK. He was promoted to sales director, DePuy Orthopaedics and Trauma, France and where he led a team that achieved a sales turnaround. In 2004, Nawana was promoted to general manager for DePuy Canada and later was appointed to lead and build the DePuy business in Australia. When promoted to area vice president of Johnson & Johnson Medical, Australia and New Zealand in 2009, he assumed responsibility for MD&D (Medical Devices and Diagnostics) franchises in Australia and New Zealand, leading a team of over 700.

Williams told *OTW* that Nawana was pursuing opportunities outside of Johnson & Johnson.

DePuySynthes

Including the Synthes business, worldwide spine sales for the company was down 3% on an operational basis with the U.S. down approximately 6% during the last quarter. Outside the U.S., sales grew approximately 1% operationally.

Dominic Caruso, Johnson & Johnson's CFO told analysts on October 16 that since the closing of the deal that united DePuy and Synthes in mid-June, "Our first priority is no disruption to customers. But the updates that we're getting tell us that things are moving along just fine. We're integrating obviously the spine businesses, because they're the two businesses that we had that were similar. So that's where the bulk of the integration is occurring."

"And so far so good. We're going to take this carefully. We're going to be measured in the way we do this so that there's very little disruption if any, and we're confident that's the right way to do it for the long term. The leaders are intact. We're very pleased to have the Synthes leadership team join Johnson & Johnson, and as you all know, Michel Orsinger, the previous CEO of Synthes now leads our entire combined orthopedics business."

Max Reinhardt

Reinhardt began his career with Johnson & Johnson at DePuy Spine in 2002 as director of sales and marketing in the UK. In 2006, he relocated to the U.S. as vice president, U.S. sales for DePuy Spine, then in early 2011, assumed the position of vice president, worldwide marketing for DePuySpine. Earlier this year, he was appointed to lead the combined DePuySynthes Spine Global Marketing organization.

He earned his Higher National Diploma at Sparsholt College of Agriculture in the UK with a degree in fish farming and fisheries management and his Master of Science degree in marketing from the University of Hull, also in the UK. He started his career in sales, marketing and general management roles for medical device companies including Steris and Olympus.

—WE (November 27, 2012)

Symmetry Signs Agreement With Italian Company

Symmetry Medical Inc. has announced that its subsidiary Symmetry Surgical, Inc. (SSi) has completed an exclusive distribution agreement in Italy with Biocommerciale Srl. In this new partnership, Biocommerciale will distribute Symmetry Surgical's portfolio of surgical instruments, which includes leading brands and products formerly part of Codman surgical instruments, SSi and Olsen Medical.

Biocommerciale has more than 30 years of experience working with hospitals and healthcare professionals in the Italian marketplace, and distributes medical devices and surgical instruments as well as sterile processing and operating room supplies to more than 1,000 hospitals, clinics and medical facilities.

In the November 26, 2012 news release Chris Huntington, chief operating officer of Symmetry Surgical, said, "We are excited to partner with Biocommerciale and expand our growing global presence into Italy, giving medical professionals access to our portfolio of new and innovative surgical instruments. We look forward to driving growth in the Italian market from our existing brands, as well as innovations resulting from our focus on new medical devices and services that benefit surgeons and clinicians—and their patients—worldwide."

Huntington told *OTW*, "As projected in our integration plan for the surgical instruments business we acquired in 2011 from Codman, we are excited about the opportunity to expand our Symmetry Surgical presence in Italy, a key European market. Biocommerciale is a high-quality, respected company in Italy, and is well positioned to drive adoption of Symmetry Surgical's portfolio throughout the country as we transition from our support services with Codman. We look forward to continuing to strengthen our relationship and introduce new products into the Italian market in the future."

—EH (November 27, 2012)

Image created by RRY Publications, LLC

legal

AdvaMed Chief Predicts Device Tax Delay

Stephen Ubl, the president and CEO of the world's largest medical technology association, AdvaMed, told investors at a Wells Fargo luncheon on November 26 that he is hopeful that Congress will, in a bipartisan manner, delay implementation of the device tax as a "bridge to repeal."

Stephen Ubl, President/CEO AdvaMed/AdvaMed

His comments were reported by a Wells Fargo investor note and confirmed to *OTW* by AdvaMed.

The Two-Step "Cliff" Solution

Regarding the so called "fiscal cliff," Ubl said the cliff is likely to be avoided in two stages, with a down payment to pass this year (before holiday break) that sets the broader frame work for a longer term solution to be worked out in 2013. A deal on the device tax could occur as part of the fiscal cliff solution.

The fiscal cliff was created by Congress when Republicans and Democrats agreed on tax hikes and spending cuts in exchange for raising the nations' debt ceiling.

According to Ubl, the potential risks for the medical device industry is more on the customer side (i.e., labs, hospitals) feeling the pressure of rate reduc-

tion, that could have some incremental impact on pricing.

Device Tax Repeal Uphill Battle

While AdvaMed is working to prevent implementation of the device tax, full repeal of the tax remains an uphill battle, Ubl told investors.

AdvaMed was successful in cutting the original device tax proposal in half. Ubl believes there will likely be 12 to15 Democrats in the Senate who will ultimately support addressing the tax. While many of these Democrats may be publically less vocal about repeal of the tax, there is consistent work being done behind the scenes, according to Ubl, because the medical device industry touches so many different constituencies across the country.

Final Tax Rules Expected

If the tax is not delayed or repealed, Ubl predicted that final regulations should be issued with ample time for compliance before the device tax is implemented, and while he believes that a specific rule will come out before the end of the year, he indicated that companies are still obligated to pay the tax even without specific guidance in place.

Predicts Better FDA

Ubl also believes that the FDA, under the new Medical Device User Fee Act (MDUFA) law with more rigorous application review goals, greater emphasis on FDA accountability and increased resources, will substantially improve the agency's review times.

The new user fee law is establishing total review time as the new standard, with the goal of reducing active FDA review times for both premarket approvals (PMAs) from 680 to 320 days and 510(k)s from 138 to 90 days. Ubl noted a decline in FDA Center for Devices and Radiological Health (CDRH) performance in recent years, including increase in total review times and number of review cycles.

Additionally, MDUFA sets out the "no submission left behind" program to ensure that device applications that miss their review deadlines do not further languish at the FDA. Ubl also noted that new CDRH resources, with a focus on hiring of more review staff and better training, should also help to reduce the review backlog.

Further, Obama's re-election which has solidified the Affordable Care Act (ACA) as the law of the land, has created a new paradigm where there will be increased willingness to examine individual components of the law, according to Ubl.

—WE (November 30, 2012)

Supremes Give Obamacare Challenge New Life

The U.S. Supreme Court is giving Jerry Falwell-founded Liberty University in Virginia another bite of the Obamacare apple.

The Court, which had previously shot down Liberty's petition to find the Affordable Care Act (ACA)—Obamacare—unconstitutional, has ordered the Fourth Circuit Court of Appeals to rehear Liberty's challenge.

The appeals court shot down Liberty's challenge to the law last year, finding that the Anti-Injunction Act prevented Liberty from challenging the law until they were actually harmed. The Supreme Court considered the Act during arguments when it declared the ACA constitutional in June.

Abortion, Contraception and Religious Freedom

But on November 26, the Court reversed its previous dismissal of Liberty's original appeal and ordered the Fourth Circuit to review whether or not Congress exceeded its power and violated religious freedoms by enacting insurance requirements for employers and individuals. The Fourth Circuit will also review Liberty's contention that the employer mandate requiring companies with more than 50 employees to provide health insurance that falls within certain price parameters or pay a fine, improperly penalizes employers that do not cover abortion services.

The Obama administration did not oppose the lower court reviewing these unresolved issues not addressed in the Supreme Court ACA decision.

The Contemplation of Justice/Wikimedia Commons and Matt Wade

Law360 reports that religious objections to the ACA have centered heavily on disagreement with a requirement that most employers provide access to contraception under their benefit plans, and rulings have been mixed as courts gauge which employers qualify for religious exceptions.

This month, for example, an Oklahoma federal judge rejected a bid by Hobby Lobby Stores Inc. to stop the enforcement of the ACA's contraception rule, finding that the for-profit Christian-affiliated company does not have free religious exercise rights under the First Amendment.

But last month, a Michigan federal judge preliminarily exempted an outdoor power equipment company called Weingartz Supply Co. from the same rule, finding that religious protections might be violated because the operation was founded as a family business and remains a closely held family corporation.

Michelle Browning Coughlin, a health care attorney at Bingham Greenebaum Doll, told *Law360* that Liberty faces a tough path when it comes to overturning the employer mandate, and that its best hopes might rest with the Religious Freedom Restoration Act of 1993, which generally requires religious exemptions from laws unless compelling public interests outweigh such free-exercise concerns.

The Circuit Court could decide the case as early as this spring. That decision would likely be appealed to the U.S. Supreme Court by the losing side. Then the Supreme Court would have to decide whether to grant the appeal and schedule another round of arguments. That would likely not happen until the Court's next term.

—*WE (November 27, 2012)*

biologics

Europe Leads World in Regenerative Medicine

Regenerative medicine is one of the most promising fields of medical research, offering the prospect of disease reversal. According to a special report in *Science/Business*, Europe currently leads the world in the therapeutic applications of a series of technologies that fall under the heading of regenerative medicines. These range from patches of decellularised pig tissue for use in repairing veins, to patient-specific cell therapies for repairing damaged knee cartilage and human embryonic stem cell-based (hESC) treatments for degenerative eye diseases.

The first European-developed therapy based on hESCs is due to enter the clinic in 2013. The product, developed in collaboration between Pfizer Inc and University College London, is a treatment for age-related macular degeneration, a cause of sight loss and blindness.

In October *Science|Business* convened business leaders, politicians, research funders, patients' representatives and scientists to the British Embassy in Brussels to debate the challenges that exist for Europe to maintain its lead in the field. The goal was to translate publicly funded science into marketed products that could provide significant health benefits and deliver on the commercial potential of regenerative medicine.

Some EU member states and pro-life members of the European Parliament (MEPs) are lobbying for the existing

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restrictive rules on funding embryonic stem cell research to be further tightened in its successor, the proposed €80 billion Horizon 2020 program, which currently is under consideration by the European Parliament.

The EU Research Commissioner Máire Geoghegan-Quinn has made it clear she intends to resist any change, noting that a great deal of time and effort was spent sorting out the existing "triple-lock" agreement. The triple-lock states that any EU-funded embryonic stem cell research must conform with the laws of the country in which it is undertaken; that the research is subject to ethical review; and that EU money cannot be used for the derivation of new human embryonic stem cell lines, or any research involving the destruction of human embryos. The European Council supports retaining the triple-lock agreement.

The European Commission's approach to funding regenerative medicine research in Horizon 2020 is based on the assessment that it is potentially a high value technology that will deliver life-changing treatments. "It is a new paradigm for medicine," said Arnd Hoeveler, Head of the Unit for Advanced Therapies and Systems Medicine, DG Research and Innovation. An analysis by *Science/Business* of the Advanced Therapy Medicinal Products coming before the European Medicines Agency shows they are mostly sponsored by academics, charities and start-ups. Few larger and better-financed companies are involved in the field. "There is a need for public sector support if the promise of the new technology is to be realized," Hoeveler said.

The therapeutic power, the huge unmet medical demand, and the difficulties involved in scaling-up and commercializing regenerative medicines is highlighted by the research of Suchitra Sumitran-Holgersson, Professor of Transplant Biology at Gothenburg University, Sweden.

Sumitran-Holgersson has developed a technique for removing all the cells from a vein taken from a deceased donor and repopulating it with a patient's own endothelial and smooth muscle cells, obtained by differentiating stem cells obtained from the bone marrow of the recipient. In the case of a 10-year-old girl who had an obstruction of the portal vein feeding blood between the intestines and the liver, the graft immediately provided a functional blood supply. And because the donor's cells were replaced with her own, there is no need for the girl to take drugs to suppress her immune system.

When details of the case were published in *The Lancet* in June 2012, it drew thousands of emails and inquiries from around the world, convincing Sumitran-Holgersson there is a widespread need for this type of regenerative medicine. "How can I build the infrastructure and get the therapy out there?" she asked.

It is an unfortunate circumstance that cell therapies involve huge amounts of know-how that cannot readily be copied in a legal document such as a patent. However, intellectual property protection is important to investors, and therefore small companies and the innovative physicians they represent, are unlikely to get funded to start out on the long path to market unless they have patents.

—BY (November 26, 2012)

large joints

Ink Jet Printer Creates Cartilage

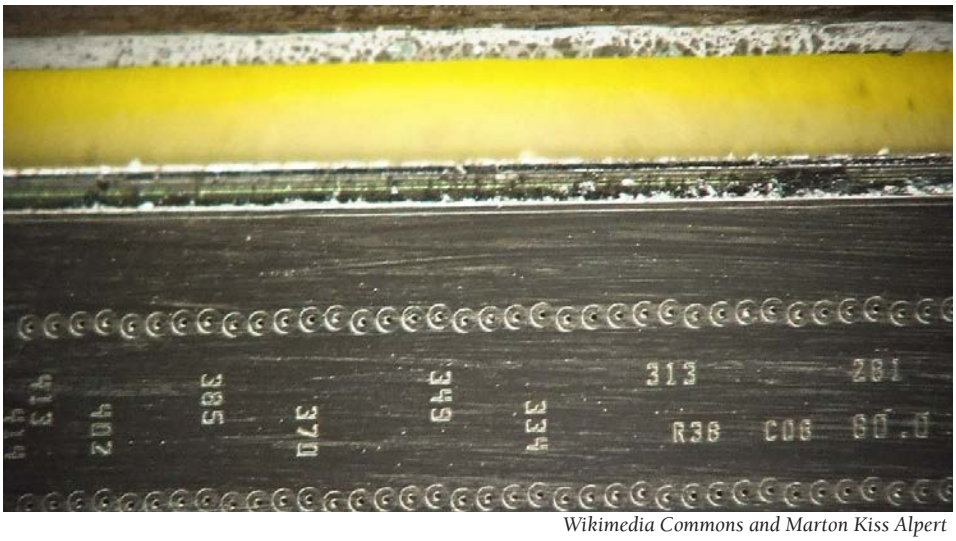
It was only a matter of time before ink jet printers—already modified to produce small parts for machines—would be adapted to create viable tissue. With a goal of creating a framework for cartilage, scientists at Wake Forest University, North Carolina, paired a traditional ink jet printer with an electrospinning machine that can generate fine fibers from a polymer solution. The polymers are porous, a requirement for getting cartilage cells to integrate into the surrounding tissue.

The process, called "bioprinting," is an emerging technique used to fabricate 3D tissue constructs through the precise deposition of cells and hydrogels in a layer-by-layer fashion. In this study researchers alternated the electrospinning of polycaprolactone fibers with inkjet printing of cartilage cells from a rabbit's ear suspended in a fibrin–collagen hydrogel. They were able to fabricate a five-layer tissue construct of 1mm thickness.

The rabbit chondrocytes survived within the printed hybrid construct with more than 80% viability one week after printing. In addition, the cells proliferated and maintained their basic biological properties. The deposition of type II collagen and glycosaminoglycans demonstrated that the fabricated constructs formed cartilage-like tissues both in vitro and in vivo. Researchers tested the cartilage after eight weeks and found that it had developed the structures and properties of real cartilage, thus demonstrating its potential use in humans.

"This is a proof of concept study and illustrates that a combination of materials and fabrication methods generates durable implantable constructs," said James Yoo, a professor at the Wake Forest Institute for Regenerative Medicine, and one of the authors of the study. He and his colleagues believe that their study demonstrates the feasibility of constructing a hybrid inkjet printing system using off-the-shelf components to produce cartilage constructs with improved biological and mechanical properties.

—BY (November 30, 2012)



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Industry Challenges Joint Replacement Pricing

Competition for joint replacements surgery is heating up. According to Chad Terhune, writing in the November 17 *Los Angeles Times*, some U.S. corporations are flying employees in need of hip or knee replacements around the country seeking out the better deals. Stephens Media, a publishing company, is sending its employees in need of surgery to hospitals that offer a low, fixed rate for surgery and also score high on measures of quality of care.

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Terhune reports that the Kroger grocery firm has flown as many as 24 workers to hospitals around the country in search of lowered costs and improved care. He writes that, beginning in January, Wal-Mart Stores will offer employees surgeries at no cost at six selected major hospital systems within the U.S. and will throw in free travel and lodging.

These actions by business reflect the growing frustration of employers with the vastly different price tags hospitals assign to what have become routine operations. The fee-for-service medical model, in which doctors, hospitals, laboratories and pharmacists all send separate bills, is being challenged. "We want to stop paying by the widget in healthcare," Susan Ridgely, a senior

policy analyst at Rand Corp., a nonprofit think tank in Santa Monica, told Terhune

At Kroger, employees may pay 10% out of pocket if they choose one of the company's 19 select hospitals, compared to 25% to 50% out of pocket for other nearby medical centers, Terhune reported. To date, none of the Kroger patients who have traveled for surgery this year have experienced complications or been readmitted to the hospital, Theresa Monti, a company vice president for employee benefits, told Terhune. She said Kroger pays about $30,000 on average for those knee and hip replacement surgeries which is 15% less than what it pays at other hospitals.

—BY (November 26, 2012)

Computer Navigation Not Statistically Different

Computer-navigated total knee replacement (TKR) provides no advantage over the traditional surgical procedure, according to a Korean study reported in the November issue of the *Journal of Bone and Joint Surgery*. The use of computer-assisted navigation has been touted as improving the positioning, sizing and alignment of replacement knee joints, resulting in greater durability of joints and an overall improvement in patient movement.

Researchers in Korea compared the results of 520 patients with osteoarthritis who underwent computer-navigated TKR for one knee and conventional TKR for the other knee. Patients included 452 women (904 knees) and 68 men (136 knees). Patients were assessed before surgery, and then at 3 months and 1 year following surgery, and annually thereafter, for 10 to 12 years (mean assessment duration: 10.8 years). Patients were assessed clinically using the Knee Society rating system and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and radiographically using X-rays or CT scans.

No statistically significant differences were noted between the computer-navigated and traditional procedure scores pertaining to knee function, pain, knee motion and activity, according to the study. In addition, the Knee Society and WOMAC scores were comparable for both procedures.

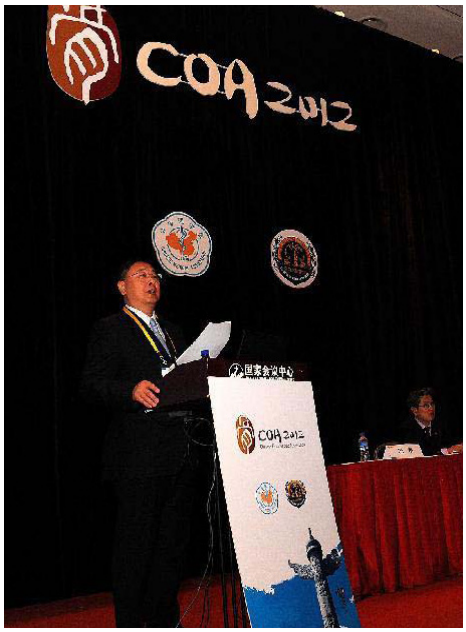
"Our mid-term follow-up data demonstrated no difference in clinical function or alignment and survivorship of the components between the knees that underwent computer-navigated total knee arthroplasty and those that underwent conventional total knee arthroplasty," said Young-Hoo Kim, M.D., The Joint Replacement Center, Ewha Womans University School of Medicine in Seoul, Korea.

—BY (November 30, 2012)

World's Largest Ortho Association Is Chinese

In an effort to pool global resources and improve the skills of surgeons in developing nations, Chinese physicians in

Wikimedia Commons and Robert F. LaPrade



Courtesy of Chinese Orthopedic Association

Beijing have established a world alliance on orthopedics. The World Orthopaedic Alliance (WOA) is a non-profit organization with members from about 70 countries and regions. The organization aims to develop a mechanism to bridge the gap between clinical orthopedic physicians and companies in the industry, according to Wang Yan, who was elected the WOA's founding chairman.

Wang, who is also president of the Chinese Orthopaedic Association (COA), said the WOA will serve as a platform for surgeons and medical equipment companies to cooperate and improve orthopaedics services. He said that the mission of the WOA is to work with government departments, medical equipment companies, doctors and hospitals to create an innovative, comprehensive and cost-effective pattern of thinking that suits local cultures to promote medical education, clinical practice, as well as product research and development.

In China alone, 3% of its more than 1.3 billion people have osteoarthritis and more than 40 million suffer from joint diseases, according to COA statistics. Challenges in orthopedics will become greater in China given its rapidly aging population. It is estimated that the country's population of those above 60 years old will hit 243 million by 2020, accounting for 18% of China's total population.

With a registered membership of more than 30,000 orthopedic physicians, the COA is the largest specialized professional society in both the medical community of China and among orthopedic associations around the world.

—BY (November 26, 2012)

spine

ulrich medical Introduces New Spine Implant

Ulrich medical USA is releasing to the U.S. market its Occipito-Cervico-Thoracic (OCT) System, a low profile, German-engineered spinal implant system designed for the surgical stabilization and fixation of the posterior regions of the spine.

Company officials describe the neon OCT System as including hybrid occipital plate/rods and straight rods, self-drilling and self-tapping screws, cannulated screws, screw-to-rod connectors, spacers, hooks and rod-to-rod crosslinks. The system also utilizes a 4.5mm titanium alloy rod over market-standard 3.0/3.5mm rods. The neon posted screw design allows for what company officials claim to be optimal screw placement and ease of rod attachment at varying angles, heights and directions to better accommodate patient anatomy and pathology.

"We are very excited to bring the robust and versatile neon OCT Spine System to the U.S. market. This is the only complex spine system in its product class with a 4.5mm rod, which provides for very rigid and strong construct options with optimum adaptability to the anatomy, especially in complex trauma and tumor applications," said Erika Laskey, vice president of sales and marketing, ulrich medical USA.

ulrich medical USA, Inc. is a privately held subsidiary of ulrich medical, a medical technology company headquartered in Ulm, Germany. The company is celebrating its 100th year in business.

—BY (November 30, 2012)

Courtesy of Ulrich Medical

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Main Contact Information:
RRY Publications LLC
116 Ivywood Lane • Wayne, PA 19087
TOLL FREE: 1-888-749-2153
Fax: 610-260-6451

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

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

Walter Eisner
Senior Writer
walter@ryortho.com

Biloine W. Young
Writer
bgwy@msn.com

Tom Bishow
Vice President of Sales
tom@ryortho.com

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Production Coordinator
jayme@ryortho.com

Dana Bader
Graphic Designer
dana@ryortho.com