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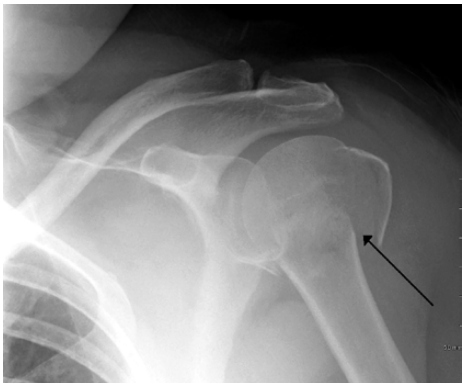
Orthopedics This Week

WEEK IN REVIEW

4 China Wants "Made in China" Orthopedics >> Recent actions by Chinese officials to promote China-made orthopedic devices, raise regulatory hurdles for outsiders, propose a ban on brand names, resort to anti-trust bullying and allegedly promote cyber-attacks on U.S. companies smacks of protectionism if not an all-out trade war. Who are the combatants? Is there a trade war?

8 Which Tommy John Techniques Are Best? (trick question) // Surprising Study: 3D Imaging Only Slightly Better than 2D // Study: RSA Safe, But More Expensive in Morbidly Obese Patients >> Jim Bradley, M.D. details first ever head-to-head trial of two types of Tommy Johns. New study says 3D CT may not make data interpretation more consistent as far as proximal humerus fractures. Vital new research shows that morbidly obese patients can safely undergo reverse shoulder arthroplasty, but their treatment is more expensive.



11 Seitz, Crosby Debate Glenoid Retroversion and Asymmetric Reaming >> "Using augmented implants has not worked in the past. With this arthritic patient I would ream the high side," says Bill Seitz. "No, no," exclaims Lynn Crosby, "Augment it. He has posterior subluxation and 22 degrees of retroversion!"

15 Jones, MacDonald Debate Tourniquetless TKA >> "OK, so you have a bloodless field using a tourniquet in TKA," says Dickey Jones. "But there are many downsides, such as nerve damage and a delay in the recovery of muscle function." Hold on says Steven MacDonald, There is no clinical evidence of nerve damage or delays in muscle function recovery when employing a tourniquet."

BREAKING NEWS

18 Titan Spine Claims First **Warranty Offer** of Devices

Invibio Labs Accredited in the UK

AAOS: New Criteria, App for **Pediatric Elbow Fractures**

Zimmer Attacks Plaintiffs' Attorneys in **NexGen Cases**

Smith & Nephew Settles "Country of Origin" **Whistleblower Case**

Slowing Medicare Spending Fuels **"Doc Fix"** Speculation

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: A Chinese vacuum cleaner called Alibaba is coming into the capital markets this week to suck up billions of dollars of loose capital. New rules for medical device companies in China—no brand names or OUC (outside China) manufactured products (see Walter's article this week – sobering). Ràng rén jīngyà! ("Yikes!")

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	11.52%	3.36%	SNN CFO: we are a "'net buyer' of high growth strategic assets rather than a company 'for sale'." Did SNN 'Heisman' SYK?
2	2	Zimmer	29.12	7.43	Zimmer + Biomet. The deal is in the home stretch.
3	3	Integra LifeSciences	12.57	1.80	Cheapest equity in OTW universe due, almost exclusively, to Wall Street's earnings forecast. Overly ambitious?
4	5	NuVasive	8.01	3.00	One year ago NUVA shocked Wall Street by beating Q3 estimates by 65%. This year? Will outperform expectations again.
5	9	Globus Medical	29.68	5.22	Finally! Wall Street is focusing on GMED earnings power—which should push up GMED's PE and PEG ratios.
6	4	Medtronic	28.84	2.71	Lowest PE ratio in all of orthopedics—$1 earned at MDT is less valuable than, for example, $1 from Orthofix. Crazy.
7	6	Exactech	10.26	1.17	Valuation for EXAC has always been low. Trading is thin. If Q3 sales are strong, bargain hunters should jump in.
8	NR	Conmed	10.51	6.31	Is the soap opera at CNMD over? CEO is gone. Corporate governance changed. Four directors retired. And stock's up.
9	7	Symmetry Medical	6.55	(3.18)	Market cap is $343 million. Cash coming in from OEM deal is $450 million. SMA is worth 76 cents on the dollar in cash??
10	8	Johnson & Johnson	26.58	2.79	Institutions feel warm and fuzzy with JNJ in their portfolios. But at these prices it's barely in the top ten in terms of valuation.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Tornier N.V.	TRNX	$24.77	$1,211	13.42%
2	Wright Medical	WMGI	$32.47	$1,638	9.84%
3	RTI Biologics Inc	RTIX	$5.24	$298	9.39%
4	LDR Holding Corp.	LDRH	$27.34	$710	8.88%
5	Alphatec Holdings	ATEC	$1.68	$165	7.69%
6	Zimmer Holdings	ZMH	$104.94	$17,726	7.43%
7	ConMed	CNMD	$39.78	$1,088	6.31%
8	Globus Medical	GMED	$19.95	$1,883	5.22%
9	MiMedx Group	MDXG	$7.22	$763	3.88%
10	Stryker	SYK	$83.46	$31,597	3.36%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc	BAXS	$0.33	$16	-16.97%
2	MicroPort Scientific	853	$0.52	$734	-14.53%
3	Aurora Spine	ASG	$1.69	$26	-10.93%
4	CryoLife	CRY	$9.86	$275	-6.01%
5	Orthofix	OFIX	$32.47	$599	-3.88%
6	K2M Group Holdings	KTWO	$14.11	$524	-3.42%
7	TiGenix	TIG.BR	$0.72	$116	-3.32%
8	Symmetry Medical	SMA	$9.14	$343	-3.18%
9	Exactech	EXAC	$24.28	$334	1.17%
10	Smith & Nephew	SNN	$87.72	$15,667	1.29%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$65.19	$63,855	16.75
2	Globus Medical	GMED	$19.95	$1,883	16.93
3	Johnson & Johnson	JNJ	$104.58	$294,946	17.92
4	Zimmer Holdings	ZMH	$104.94	$17,726	18.82
5	Stryker	SYK	$83.46	$31,597	19.97

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$32.47	$599	270.88
2	MicroPort Scientific	853	$0.52	$734	94.87
3	NuVasive	NUVA	$37.40	$1,757	71.51
4	Symmetry Medical	SMA	$9.14	$343	46.88
5	Smith & Nephew	SNN	$87.72	$15,667	29.96

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	$9.86	$275	0.99
2	Exactech	EXAC	$24.28	$334	1.12
3	Globus Medical	GMED	$19.95	$1,883	1.26
4	ConMed	CNMD	$39.78	$1,088	1.74
5	Zimmer Holdings	ZMH	$104.94	$17,726	2.20

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$32.47	$599	14.72
2	MicroPort Scientific	853	$0.52	$734	6.32
3	NuVasive	NUVA	$37.40	$1,757	5.85
4	Symmetry Medical	SMA	$9.14	$343	3.91
5	Smith & Nephew	SNN	$87.72	$15,667	2.97

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Baxano Surgical Inc	BAXS	$0.33	$16	0.80
2	Alphatec Holdings	ATEC	$1.68	$165	0.80
3	Symmetry Medical	SMA	$9.14	$343	0.85
4	Bacterin Intl Holdings	BONE	$5.04	$34	0.99
5	RTI Biologics Inc	RTIX	$5.24	$298	1.23

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.72	$116	20.26
2	MiMedx Group	MDXG	$7.22	$763	9.63
3	MicroPort Scientific	853	$0.52	$734	6.41
4	LDR Holding Corp.	LDRH	$27.34	$710	6.36
5	Wright Medical	WMGI	$32.47	$1,638	6.09

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

China Wants "Made in China" Orthopedics

BY WALTER EISNER

When it comes to medical devices, is China turning inward?

American companies dominate the world market for medical devices—with some notable exceptions—London based Smith & Nephew, plc and Shanghai based MicroPort Scientific Corporation, for example. But the global gold standard medical device brands are Johnson & Johnson, Medtronic, Inc., Stryker Corporation and Zimmer Holdings, Inc., to name just a handful.

Doctors around the world who want the best implants and instruments rely on "Made in the USA" brands.

China would like to change all that. They are very serious.

Earlier this year the Chinese government issued a "Buy China" directive, implemented a new regulatory device approval scheme that toughens entry for outsiders, indulged in what some call anti-trust bullying, proposed a ban on brand names of orthopedic devices and allegedly, sponsored cyber-attacks on U.S. device makers and health systems to gather market and technology information.

The actions, taken together, make a powerful case that the gloves have come off in competition for China's 300-plus million middle class orthopedic device consumers.

New Device Regulations

New rules by the China Food and Drug Administration (CFDA) which revise the country's core medical device regulations, the Medical Device Supervision and Administration Regulation (MDR), go into effect on October 1, 2014. The new wave of regulations replaces decades-old rules that are no longer keeping pace with market growth.

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One of the most prominent changes is the increase in potential fines for illegally manufacturing or selling medical equipment. The fines, which were originally capped at 5 times the value of the goods, could reach up to 20 times the goods' value. Violating the rules could bring a five-year ban from applying for operating licenses.

The new rules will operate on a tiered scale of severity, based on the exposure of risk to patients. There will also be reinforcements made to the monitoring and recall systems.

"In recent years, we've seen some issues of illegal behavior, and the legal foundation for striking back has not been clear enough. To resolve the problem, we needed a complete revision of the existing legislation," said government officials in a document published on the State Council's website.

"The heightened scrutiny of the health care sector, which is expected to continue in the coming months, will make the China market more complex," said Xiaoqing Lu Boynton, director of the international strategy company Albright Stonebridge, in a recent *Morning Post* article. "It is important for foreign companies to focus on their compliance efforts to minimize risks."

In addition, Katherine Wang, an attorney with Ropes & Gray LLP, located in Shanghai, told us that China CFDA's newly created fast track approval mechanism for innovation devices is reportedly in favor of domestic products.

Wang says she sees increasing tension between the foreign business com-

Katherine Wang/Ropes & Gray LLP

munity and the Chinese stakeholders. "However, I won't necessarily call it a trade war. The government's existing reimbursement and tendering policies may create market access hurdles for foreign companies, but the intrinsic hurdle is the vast price difference between imported and domestic devices."

The new rules are separate from China's medical device Good Manufacturing Practices and its proposed medical device Good Supply Practices, which are both the subject of ongoing rule-makings.

"Buy China" Strategy

In mid-August, the country's health ministry in Beijing said in a statement posted on its website that it intends to promote wider use of local products to, "effectively control unreasonable increases in the cost of medical care and reduce the burden on patients."

With annual growth rates of around 20% expected over the next few years, protectionism concerns are being raised by global companies. Device makers from the U.S., Europe and Japan now dominate around three-quarters of China's medical device market, according to published reports. That amounted to $34.51 billion last year, according to figures from the Hong Kong Trade and Development Council (HKTDC).

These compete with local companies such as Mindray Medical International Ltd and China Resources Wandong Medical Equipment Co Ltd.

"We want to strongly advocate health ministry organizations to use domestically-made medical devices, especially pushing top level class III hospitals to use domestically-made products," said Li Bin, the head of China's National Health and Family Planning Commission in published reports.

Miao Wei, the head of China's Ministry of Industry and Information Technology (MIIT), reportedly said that China needed to raise the level and quality of its homegrown medical devices and cre-

ate incentives for medical institutions to use locally-made products.

Hospitals are the biggest distribution channel for medical devices, accounting for almost 80% of the market, according to HKTDC figures. There were around 13,400 public hospitals in China last year, and a further 11,300 private hospitals, according to a June report from Deutsche Bank.

Shanghai-based Kinetic Medical—which sells percutaneous kyphoplasty (PKP) devices to treat spinal compression fractures—is one of the upstarts trying to compete with foreign companies. Co-founder and Chairman Jay Qin, who formerly worked with Medtronic, recently told *Forbes* that they can offer their devices at much lower prices to local distributors.

"Some multinationals are still trying direct sales in China, which is an impossible approach," Qin said in the interview with *Forbes*. "Kinetic hires distributors to establish connections with hospitals long before the product is launched." The company sells to 600 Chinese hospitals in all mainland provinces aside from Tibet through a network of 200 distributors.

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"While the government acts as the primary payer and hospitals are predominantly state-owned, these highly priced imported products will inevitably face tremendous challenges on market access. Having said that, the government is also loosening its involvement in healthcare services. The growth opportunity for imported medical devices may very likely lie in the private sector," added Wang.

"Dynamite Panda" Cyber Attacks

Medtronic recently disclosed that in 2013, hackers tapped into its computer systems that stored patient records. The company said it believed that hackers from Asia carried out the attempt and that it also affected two other large, unnamed medical device manufacturers.

The San Francisco Chronicle reported earlier this year that China hackers were behind the attack and that Boston Scientific and St. Jude Medical were the other two companies that were targeted.

In July, Community Health Systems, Inc. confirmed that they were hacked in April and June 2014. The company said it believes the attacker was an "Advanced Persistent Threat" group originating from China who used highly sophisticated malware and technology to attack company systems.

Federal authorities told the company that the intruder has typically sought valuable intellectual property, such as medical device and equipment development data. However, in this instance the data transferred was non-medical patient identification data related to the company's physician practice operations and affected approximately 4.5 million individuals.

Reuters reported that security experts said the hacking group, "APT 18" or as some have called them, "Dynamite Panda," may have ties to the Chinese government. The cyber security firm, CrowdStrike, Inc. which has also been monitoring "APT 18" for about four years, said that, based on the targets they have chosen, it believes the hackers are either backed by Beijing or work directly for the government.

In May, a U.S. grand jury indicted five Chinese military officers on charges they hacked into American companies for sensitive manufacturing secrets. China has denied the charges.

Anti-Trust Bullying

The U.S.-China Business Council (USCBC) said in early September that companies facing antitrust investigations in China have been pressured to admit guilt, appear without legal counsel and make statements without being informed of the grounds for investigations.

Last year, we reported that companies have been warned by aggressive regulators not to use external lawyers during investigations.

The Chinese government rejects complaints about its three antitrust regulators and says investigations by the National Development and Reform Commission (NDRC), the Ministry of Commerce, and the State Administration for Industry and Commerce (SAIC) are conducted according to law.

"Some of the NDRC monopoly investigations involve overseas multination-

als, but that does not mean that we are targeting them," Xu Kunlin, head of the anti-monopoly bureau under the NDRC, was quoted as saying.

Ban the Brand

A draft rule issued by the China Food and Drug Administration would prohibit the use of personal, company or brand names to label medical devices marketed in that country. The proposed rule would instead mandate that such products be given generic names in the Chinese language.

In effect, replacing Western script with Chinese language symbols.

A medical device industry spokesperson told us that many global medical device regulators, including the FDA, require the use of generic device naming in certain situations. For example, the FDA's UDI database requires companies to enter Global Medical Device Naming (GMDN) nomenclature and/or codes.

He said the use of generic names helps with data exchange between manufacturers, regulators and healthcare authorities; exchange of post-market vigilance information; supporting inventory control in hospitals and purchasing and supply chain management.

"We understand that the CFDA draft regulations would outline guidelines on the use of generic device naming in similar circumstances, and that they would not preclude the use of trade names on the product label, advertising or IFU," added the spokesperson.

U.S. and Device Industry Response

In an April letter to U.S. Secretary of State John Kerry and Treasury Secretary Jacob Lew, the U.S. Chamber of Commerce urged Washington to get tough with Beijing on its use of competition policy, which it said had been seized upon by China to advance its industrial agenda and nurture domestic companies. The issue was raised at high-level strategic talks between the countries in July.

U.S. orthopedic device companies have been busy getting ahead of the potential problem of protectionism by partnering, acquiring or merging with Chinese companies.

Medtronic acquired China Kanghui in 2012, which was the most competitive orthopedic device maker in China.

In September 2011, MicroPort entered into the market by purchasing Suzhou Best and acquired Wright Medical Technology, Inc.'s OrthoRecon business for $290 million in January 2014.

Stryker also got into the game by acquiring Trauson, China's largest trauma products maker, in January 2013.

In December 2010, Zimmer Holdings acquired Beijing Montagne Medical Device Co., one of the largest orthopedic implant manufacturers in China.

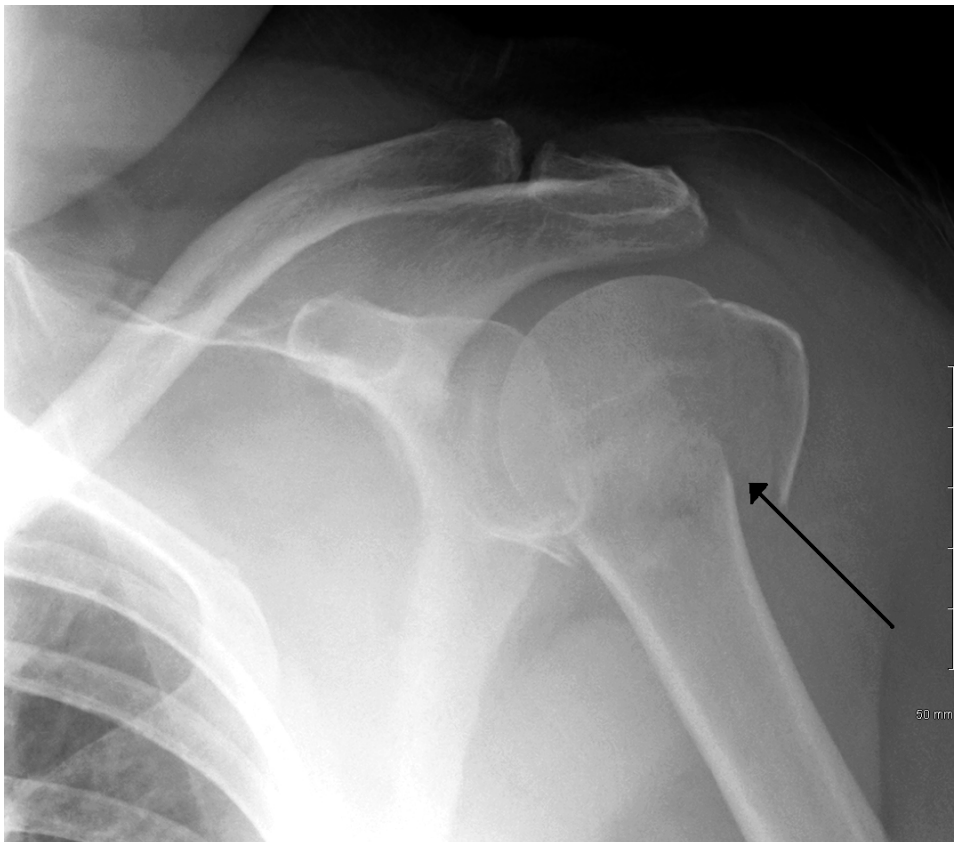
Which orthopedic devices go into Chinese patients will probably not cause much concern to the shareholders of the publicly traded, and for now, U.S.-based orthopedic companies. The concern lies with the workers in Warsaw, Kalamazoo, Memphis and other U.S. cities where most of the world's orthopedic devices have been manufactured.

The Dynamite Panda has taken off the gloves. What will Uncle Sam do? ♦

Which Tommy John Techniques Are Best? (trick question) // Surprising Study: 3D Imaging Only Slightly Better than 2D // Study: RSA Safe, But More Expensive in Morbidly Obese Patients

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

Which Tommy John Surgery Is Best? Answer: Neither! It's a first-in-the-literature…Jim Bradley, M.D., M.S., a sports medicine specialist with Burke & Bradley Orthopedics at the University of Pittsburgh Medical Center and lead physician for the Pittsburgh Steelers, has conducted a head-to-head trial of two types of Tommy John procedures. Dr. Bradley tells *OTW*, "We conducted a prospective randomized clinical trial comparing a modified Jobe technique (as taught to me by Frank Jobe), to the docking technique that was developed by David Altchek. We had an equal number of baseball players in each group—88% docking procedure and 84% of those who had the modified Jobe returned to play at the same level. All baseball players had complete tears of their UCL [ulnar collateral ligament] and no prior surgeries on the ipsilateral shoulder or elbow."



A fracture of the proximal humerus. / Source: Wikimedia Commons and James Heilman, M.D.

"This study, which was conducted with high school and college baseball players, is the first one in the literature to prospectively compare the modified Jobe versus a docking technique by one surgeon, one institution, and one rehab protocol. While the majority of players did well, there was a 12-16% failure rate, which is consistent with the literature. Most lay people think that when someone undergoes a Tommy John procedure they come back better and stronger, something which has been proven untrue by multiple studies. When treating a patient with a partial ulnar collateral ligament tear I often hear, 'Why don't you just fix the arm so that it will be stronger?' Well, it's because it won't necessarily be stronger!"

"It should be noted that there are different scales used to measure an athletes' ability to return to play. There is the Conway scale, the Andrews-Timmerman score, the Kerlan-Jobe Orthopaedic Clinic score, and the American Shoulder and Elbow Surgeons score. For this study we used the Conway score because it is very specific to overhead athletes."

"At present we are building up our numbers. I do approximately 30 such surgeries annually, so it takes a while to attain higher numbers. Our goal is to have 30 enrollees in each group."

Moving From 2D to 3D Imaging Only Marginally Useful Does using a three dimensional CT scan mean that surgeons will rank high on inter-observer and intra-observer reliability? Not likely, says a new study. Marschall B. Berkes, M.D., attending surgeon at Landstuhl Regional Medical Cen-

ter tells *OTW*, "Given the increased use of 3D CT scans to evaluate proximal humerus fractures, my mentors, colleagues and I wanted to see if 3D reconstructions would have an impact on classifying proximal humerus fractures with regards to increasing agreement between surgeons or improving a surgeon's reproducibility, compared to conventional multiplanar 2D CT or X-ray. We also wanted to know if clinical experience had an impact, since at our institutions we have a broad range of physicians (from junior residents all the way up to very experienced trauma trained orthopaedic surgeons) interpreting these images."

"Each fracture was classified according to the AO/OTA (Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association) and Neer classifications. Two trauma surgeons, one shoulder surgeon, two senior orthopaedic residents, and two junior orthopaedic residents were charged with reviewing the radiographs and two and three-dimensional computed tomography scans of forty proximal humerus fractures."

"We found that 3D CT essentially only showed improved inter-observer and intra-observer agreement with regard to classification and treatment of proximal humerus fractures amongst junior residents. I was a little surprised by this. No such effect was seen in those with more clinical experience. I suppose that this may be a function of lack of experience with translating 2D pictures into a three dimensional problem, and the 3D reconstruction may help to compensate for that lack of experience by having a computer translate that two dimensional data directly."

"The biggest challenge was the scale of the project. We had many individuals reviewing hundreds of cases multiple times in order to get the data we needed to make this a valid and useful investigation."

"All that we can conclude from this study is that 3D CT didn't dramatically improve intra-observer reproducibility or inter-observer agreement with regards to the Neer and AO/OTA classification, or treatment recommen-

dation of proximal humerus fractures (except perhaps among those with less experience). "

"This is probably more a function of the nature of the fracture classifications themselves. It is not always black and white—what one may consider a three part fracture, another surgeon would call a four part fracture. And that probably won't change if you looked a plain X-ray, a 2D or 3D CT scan, an MRI, etc. Thus, I would caution readers to remember what this study is, or perhaps more importantly, what it is NOT saying."

"The conclusion is not that 3D CT is not clinically useful. Instead, the core message is that 3D CT does not necessarily make data interpretation (i.e., proximal humerus fracture classification or treatment recommendation) more consistent, from a statistical standpoint. In the end, when an orthopaedic surgeon is taking care of a patient, he or she needs to use the best diagnostic tools in his or her hands to provide the best possible care for that patient, and that is still an individual process that is difficult to apply and analyze on a broad scale."

RSA in Morbidly Obese Safe, But More Expensive With obesity not going away any time soon, it is important to get a handle on what consequences this will have on the healthcare system. Mark Frankle, M.D., a shoulder specialist at the Florida Orthopaedic Institute and researcher with the Foundation for Orthopaedic Research and Education (FORE), decided to investigate. He tells *OTW*, "My colleagues and I had a sense that our morbidly obese patients have fared well overall when it comes to primary reverse shoulder arthroplasty, but we wanted to verify this. We studied 21 patients from our joint registry who met the World Health Organization definition for obese, namely, a body mass index (BMI) of more than 40. We also had a control group of 36 patients with a BMI of less than 30. We powered the study such that there were three control patients matched to each obese patient (matched for age and sex)."

"We found that morbidly obese patients had similar improvements in functional outcomes (as measured by the American Shoulder and Elbow Surgeons score) as compared with nonobese patients. They also had similar improvements in functional improvements in shoulder motion. On the downside, they had more total comorbidities than nonobese patients and they were in the OR 13 minutes longer. This extension in surgical time, coupled with the fact that morbidly obese patients had a sixfold higher rate of discharge to rehabilitation facilities rather than to home, means that treating these patients is very costly. In fact, hospital costs were $2,974 higher for those who were morbidly obese."

"The cost of care and value issues are only getting more important. And my colleagues who are considering bundled payment arrangements may not understand when negotiating what resources they will need in order to effectively treat such a medical comorbidity. It is evident that morbidly obese patients cost more to manage, meaning that the value of care is reduced. When we are trying to determine how to provide care and we need to do it in a context of limited resources then we have a real conundrum. How do we make effective, ethical decisions?"

"This work also sheds light on an immense problem we have with clinical studies in the healthcare system—loss to follow-up. Some institutions manage to contend with it better than others, but I'm not sure how they do this. And it has not been addressed in all the discussion of healthcare reform. I'm open to hearing from my colleagues on this topic."

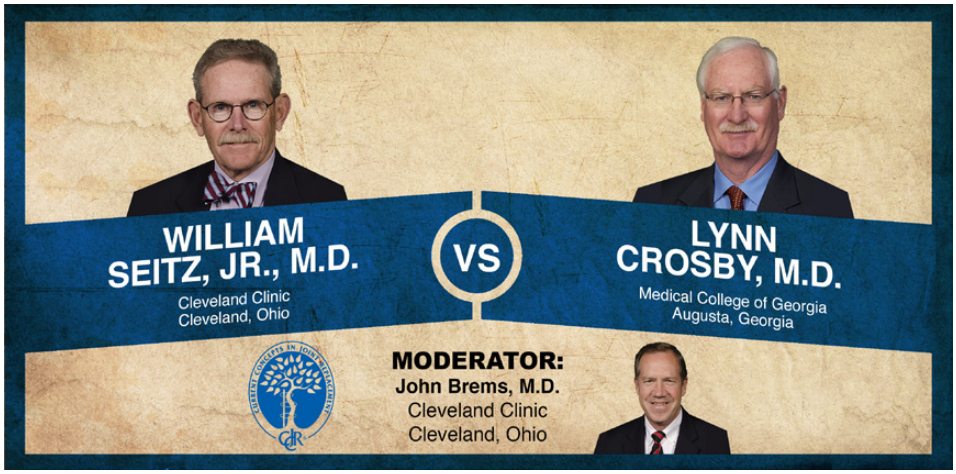
For those wishing to contact Dr. Frankle, he may be reached at: mfrankle@floridaortho.com. ◆

Seitz, Crosby Debate Glenoid Retroversion and Asymmetric Reaming

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

"Using augmented implants has not worked in the past. With this arthritic patient I would ream the high side," says Bill Seitz. "No, no," exclaims Lynn Crosby, "Augment it. He has posterior subluxation and 22 degrees of retroversion!"

This week's Orthopaedic Crossfire® debate is "Severe Glenoid Retroversion is Best Treated With Asymmetric Reaming." For the proposition is William Seitz, Jr., M.D. of the Cleveland Clinic. Against the proposition is Lynn Crosby, M.D. of the Medical College of Georgia. Moderating is John Brems, M.D. of the Cleveland Clinic.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Brems: "This case involves a 58-year-old accountant who is left hand dominant and a recreational tennis player. He has a history of arthritis in his left dominant shoulder and has exhausted all nonoperative modalities. He has a minimum of 20 degrees of posterior glenoid erosion with significant bony loss."

Dr. Seitz: "This is probably between a B2 and a C classification of glenoid posterior erosion. But there isn't a lot of subluxation of the humeral head. Osteoarthritis in the shoulder brings with it a significant percentage of posterior wear. In order to get our implant in we need to have enough vault. So our options are to ream the high side, graft the low side, or augment the implant on the low side with some form of augmented implant."

"The version we see in the glenoid neck can be variable and may represent the patient's normal anatomy based on the varying sizes and shapes of their chest and spine. It's a moving target. Should we even correct to complete neutrality when there are these other factors which affect the position of the scapula vis-à-vis the horizon? It may require maintaining some degree of persistence in retroversion to a smaller degree. Bryce (*Journal of Shoulder and Elbow Surgery*, 2010) showed that when there is posterior wear with subluxation posteriorly then it's very important to ream and to balance the soft tissues."

"From other studies we know that if we try to correct completely, we will not be able to get an implant in. Joseph Iannotti (*Journal of Shoulder and Elbow Surgery*, 2011) and Douglas Nowak (*Journal of Shoulder and Elbow Surgery*, 2009) have demonstrated that trying to completely correct any degree of retroversion greater than 15 degrees brings with it a high rate of inability to insert the implant without violating the cortex."

"Joe Iannotti and Jason Scalise worked on the vault model and did 3D reconstructions of the shoulder to try to use a neutralized glenoid and get it as close to centered as possible, while still allowing some degree of posterior retroversion. The technique for reaming the high side isn't difficult; if it's less than 15 degrees then we can nearly always plane this down to neutral."

"Using augmented implants has not worked in the past. Joe Iannotti developed a technique to try to have an augmented posterior implant. The early results were promising, but Joe has seen a failure of these implants over time. Instead, we map out the defect, planing the high side down to some degree so that we can add a bone graft. Once it's secured with screws we can treat it like a normal glenoid and plane it down neutrally."

"So my approach to this case would be to ream the high side; if it were at 20 degrees I would add some posterior bone graft. Since this patient didn't have any degree of subluxation we wouldn't go overboard, but would do an adequate release in order to keep the

shoulder stable throughout a full arc of motion."

Dr. Crosby: "Normal version in men is a slight retroversion—about 1.5 degrees; in women it's not quite 1 degree. Posterior wear comes from a contracture of the anterior musculature, causing posterior humeral head subluxation. The results in a posterior load concentrating on the glenoid reduce the contact area, causing glenoid wear medialization and posterior instability."

"Excessive posterior wear may appear clinically as a severely retroverted glenoid or as a bi-concave glenoid, as indicated in Walch's classic article (*Journal of Arthroplasty,* 1999) on his B1/B2 type glenoids. CT scan has been determined superior to plain X-ray in measuring version. You must find the cut on the CT scan that gives you the medial aspect of the scapula and the face of the glenoid on the same cut. You draw a line from the medial side of the scapula through the center, drop a line from anterior to posterior and this gives you the retroversion."

"As for reaming the high side, the literature recommends limits to how much eccentric reaming is possible. Farron and Gillespie say 10 degrees; Clavet and Nowak say up to 18 degrees is the recommended correction before you perforate."

"With eccentric reaming, insufficient bone stock develops and you have to implant downsize so you're putting a smaller glenoid on the surface. You can have perforation if you ream too much; implant loosening from the loss of subchondral support is significant. You start with a normal size glenoid and what you may end up with is a small glenoid face that you may not even be able to put a surface on."

"The Columbia group taught us that the volume removed increases quadradically with reaming depth. A 2012 article from the *Journal of Bone and Joint Surgery* by the French group had five year follow up. They cemented keeled glenoids and had a 32% loosening rate."

"Posterior augmented glenoids decrease the amount of reaming and save bone; they eliminate the need for bone graft, rebalance the joint, direct the forces down the glenoid neck, and change the shear forces to compression forces. Eccentric reaming medializes the joint, and this causes imbalance of the muscle tensioning. If you augment it you can rebalance your muscle tension and sig-

nificantly increase your range of motion and balance."

"Rice has the only real clinical article on augments (14 patients). The conclusion was that there was no benefit. They only corrected five degrees, and the correction was on the articular side. So the fixation is knocked down the neck of the glenoid. They had radiographic loosening in only one case, and no mechanical failures (this was the early augment trial by Rice from Mayo Clinic – *CORR* 2008). More recently, 8 and 16 augments have become available; the correction is on the nonarticular side and the joint is rebalanced because of the placement of the peg augments."

"So far my group has 40 shoulders with an average age of 62 and an eight month follow-up. The results have been fairly predictable…all the scores have increased…the Constant is up almost 30 points from the beginning. The range of motion (ROM) has increased by 33 degrees of forward flexion and 25 degrees of active external rotation. There have been no reoperations to date and no repeat posterior subluxations."

"So in this patient presented here today who has posterior subluxation and 22 degrees of retroversion I say 'no' to reaming the high side. Augment it instead!"

Moderator Brems: "Bill, do you ream over a guide pin or do it free hand?"

Dr. Seitz: "These days I ream over a guide pin. The CT scan is helpful in replicating the anatomy. Today we can get 3D printed replicas of the native bone to use as a trial. Joe Iannotti has developed patient specific techniques with a jig that fits over the glenoid based on that 3D printing and guides the guidewire exactly to the center of the glenoid. And you don't want to take this down to subchondral bone."

Moderator Brems: "Lynn, you talked about using a CT scan, yet in the last several years we've seen reports that even the best interpretive CT scan isn't as good as a 3D CT interpretation."

Dr. Crosby: "Correct. The literature is clear on that. It's the positioning of the scapula…it moves a bit, so 3D corrects that."

Moderator Brems: "If you use bone graft, which one?"

Dr. Crosby: "I'd use the humeral head if I was going to bone graft."

Moderator Brems: "Do you use the augmented glenoid or do you prefer bone graft to plastic augmentation?"

Dr. Crosby: "Now that we have augment available we use it."

Moderator Brems: "In reconstructing with either of your techniques how effective is it to getting the soft tissue back? It's been stiffened, shorted…is it necessary to reestablish anatomic cuff tension as opposed to getting good soft tissue balance?

Dr. Seitz: "When you have trials in you should test and see where you need to do posterior plication anterior releases, etc…it's that soft tissue balancing that makes a difference. But we don't need to correct to neutral to restore what is 'normal.' Take a patient with kyphotic spine. There is a reason why they have posterior wear…it's because of the position of the scapula."

Moderator Brems: "What degree of retroversion will you accept postoperatively?"

Dr. Crosby: "Five degrees."

Moderator Brems: "Where is the sweet spot between reaming and not having to use bone graft or the riskier techniques posteriorly where you end up with a smaller glenoid and less bone versus an anatomic glenoid and more retroversion?"

Dr. Crosby: "The problem is that these people are contracted anteriorly and can't get their arm back to neutral. You have to balance the soft tissue and you're going to try to do that without removing much bone. The more medially you get, then your humeral component also goes medially and you may affect your deltoid power also."

Moderator Brems: "Bill, if you end up perforating how do you address that?"

Dr. Seitz: "There are now poly glenoids which have a trabecular type button on the back which can be implanted and you get bone ingrowth through there. If you do perforate and you're going to cement you must be careful to keep that posterior defect covered when you cement. Otherwise, it will leak out and it won't pressurize."

Moderator Brems: "If you perforate would you cut a peg off?"

Dr. Crosby: "I'll take SURGICEL and stuff it into the perforation and put bone grafts on top of that."

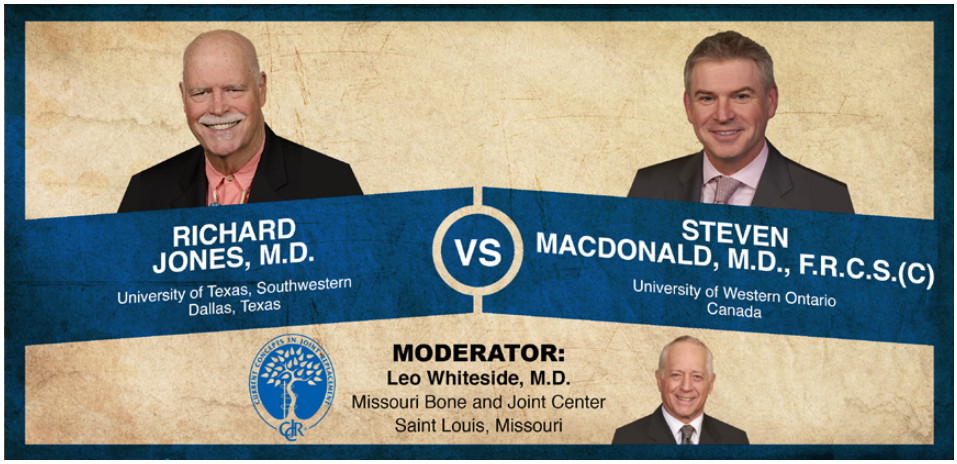
Moderator Brems: "Thank you both." ♦

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

Jones, MacDonald Debate Tourniquetless TKA

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

"OK, so you have a bloodless field using a tourniquet in TKA," says Dickey Jones. "But there are many downsides, such as nerve damage and a delay in the recovery of muscle function." Steven MacDonald counters, "There is no clinical evidence of nerve damage or delays in muscle function recovery. And several studies show decreased *overall* blood loss."



Current Concepts in Joint Replacement/RRY Photo Creation

This week's Orthopaedic Crossfire® debate is "Tourniquetless TKA: Let It Bleed." For the proposition is Richard Jones, M.D. of University of Texas, Southwestern. Against the proposition is Steven MacDonald, M.D., F.R.C.S.(C) of University of Western Ontario. Moderating is Leo Whiteside, M.D. of the Missouri Bone and Joint Center.

Dr. Jones: "What's the benefit of doing a total knee arthroplasty (TKA) with a tourniquet? You have a bloodless field…and there MAY be a better bone cement implant interface for fixation. The downside is nerve damage: direct (secondary to pressure); indirect (secondary to hypoxia). And there is a delay in recovery of muscle function."

"There are vascular issues, such as altered hemodynamics with limb exsanguination. There is a 20% increase in circulatory volume when putting the Esmarch on for the tourniquet. And there is reactive hyperaemia when you release the tourniquet as well as a 10% increase in limb size that increases soft tissue tension and secondary pain."

"There is a higher risk of vascular injury, particularly in artherosclerotic or calcified arteries. There is increased risk of DVT [deep vein thrombosis] with trauma to the vessel walls; also, increased levels of thrombin/antithrombin complexes, which leads to 5.3x more risk for large venus emboli propagation when you do transesophogeal echocardiograms."

"We've also observed increases in wound healing disturbances and a higher propensity for wound leakage. In our early experience, we had high risk patients who had previous DVT or pulmonary embolus, multiple scarring and compromised cardiovascular structure. But for the last 15 years we have used no tourniquet on any primary or revision total knee."

"A survey by the American Association of Hip and Knee Surgeons (AAHKS) found that 37% always use a tourniquet, 58% always use a tourniquet except if there is a vascular concern; only 5% of the entire AAHKS population use a tourniquet and then put it up during cementation."

"Our operative protocol: regional anesthesia because it helps control blood pressure and reduce bleeding. The incision and approach is made with the knee in 90 degrees of flexion. When you're there, you can do meticulous hemostasis…all vessels are readily seen and coagulated. We inject 0.25% ropivacaine with epinephrine periarticularly; posterior tissues are coagulated, and we do saline jet lavage. Then we deliver filtered carbon dioxide under pressure that dries and prepares the cement beds. We finish it up with three grams of tranexamic acid and 100ccs of saline topically administered after the cement sets. We do routine closure and a bulky, compressive Robert Jones-type knee dressing."

"We found no real differences in blood loss. We thought that they had less postop pain, but we didn't do Visual Analog Scales on these patients. They probably had a faster straight leg raise and perhaps better knee flexion, but I have no statistical evidence. There were definitely fewer wound healing disturbances. The cement penetration was equivalent."

Dr. MacDonald: "I have performed total knees without tourniquets on a

select few patients, i.e., the vasculopaths with no distal pulses and those in the cadaver lab. There are few randomized clinical trials to guide us, and there is no registry data, and there are many opinion pieces. So why use a tourniquet?"

"There is no argument that a tourniquet reduces intraoperative blood loss. In a meta-analysis of 15 papers with 1,000 total knees there was significantly greater intraoperative blood loss without a tourniquet. That is intuitive. In this analysis, overall blood loss—intraoperative and postop—was not significantly different whether or not you use a tourniquet."

"Several studies show decreased blood loss overall. In a randomized clinical trial (RCT) with 72 patients the tourniquet group had lower overall blood loss, but had slightly more postoperative pain."

"In another RCT looking at using a tourniquet just for cementing or using it for the entire procedure, they were going to do over 200 cases, but they stopped at 65 because of the higher risk of transfusion if you're only using it for part of the procedure. As Dickey noted, it's a given that we want a dry bone surface for cementing; if you don't have that the theoretical risk is late loosening. I use pulsatile lavage with a tourniquet, but there are different ways to get a dry bone surface. But they all come with a cost in terms of dollars and time. In a series of 3,000 total knees they found a direct correlation between OR time and infection. They concluded that steps to minimize intraoperative delay should be instigated, and that care should be exercised when introducing measures which prolong the duration of joint replacement."

"An excellent paper was published recently that demonstrated—tourniquet versus no tourniquet—about a five to six minute difference in operative time. So be cautious in changing your technique."

"The stated downsides to a tourniquet are either basic science theories, rare, or short term. Vessel wall damage with increased DVT. A recent paper refutes it. All patients underwent an ultrasound and there was no difference between the groups. There is no clini-

cal evidence for an increase in wound healing disturbances or delay in muscle function; nerve damage is rare."

"Don't use a tourniquet if you're concerned about the theoretical risks. Don't use one if you have alternate ways to achieve it that are cost neutral and don't increase OR time. If you're highly evolved, good looking and intelligent—like Dickey—you should use it."

Moderator Whiteside: "We have a question from the audience."

Audience member: "Don't use a tourniquet on a diabetic. I don't use a tourniquet until I cement. Protect the diabetics."

Dr. Jones: "Good point."

Moderator Whiteside: "Dr. Jones, is there any amount of tourniquet trauma that is acceptable? If you have a patient who you know who is going to bleed like hell, do you never use a tourniquet?"

Dr. Jones: "No sir."

Moderator Whiteside: "Steve, is there ever a case in which you decide the patient may be too sensitive to tourniquet pain?"

Dr. MacDonald: "I use one for everyone unless someone is a vasculopath. The ones I find most frustrating are the morbidly obese patients where you put the tourniquet on and inflate it and they still leak out around that."

Dr. Jones: "Even getting a tourniquet around there may take an extra large and then to apply enough pressure to make a difference to give you a bloodless field leads to more problems."

Dr. MacDonald: "We have different thigh diameters like you do. I'll go up to 350 on those patients; if they're still bleeding out around that then it becomes a venous tourniquet so I release it and do the work around it. I will try to put it up for cementing in those cases."

Moderator Whiteside: "So you're ready to take this down and abort the tourniquet altogether."

Dr. Jones: "Steve, is 350 your upper limit?"

Dr. MacDonald: "Yes."

Moderator Whiteside: "Dickey, all the gear you use to achieve hemostasis… how expensive is it?"

Dr. Jones: "The Carbojet system is about $100 per case. What you're buying is the sterile tubing to deliver it. The hardware and the gun are part of the OR system."

Moderator Whiteside: "So the hospital does absorb considerable expense, including the disposable tourniquets. Steve, how do you manage tourniquets in a long, difficult case?"

Dr. MacDonald: "This usually pertains to revisions more so than a primary. I put the tourniquet up at the beginning and I keep an eye on the time. My bottom line is I want the tourniquet up for cementing. For most revision knees, we'll get it up, cement, and then have to release the tourniquet for closure because we're close to the two hour mark. I will often leave it up 10-15 minutes after the two hour mark, but that is my cutoff."

Moderator Whiteside: "Is that at one time or the total for your entire case?"

Dr. MacDonald: "That's one time. If you had a really long revision you could put it back up. It should be down for probably 30 minutes."

Moderator Whiteside: "Thank you, gentlemen." ◆

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COMPANY

Titan Spine Claims First Warranty Offer of Devices

Paul Slosar, M.D., says it's the first time in his experience that a device company in the spine market has offered a warranty for its devices.

One-Time Free Replacement

On September 8, 2014, Mequon, Wisconsin-based Titan Spine, LLC announced it is offering a warranty for its Endoskeleton line of spinal interbody fusion devices. Through the warranty, Titan Spine provides a one-time free replacement of any eligible Titan spinal interbody fusion device if revision surgery is required within the five-year warranty period, as outlined within the terms of the agreement.

Slosar, who is the company's chief medical officer, added that Titan's line of interbody devices has a "unique advantage with its ability to promote specific cellular behavior that supports an advanced environment for bone growth and fusion. This warranty highlights the recognition that our engineered spine implants continue to lead the surface technology space."

Proprietary Surface Technology

Titan's proprietary implant surface technology consists of a unique combination of roughened topographies at the macro, micro, and cellular levels. "This combination of surface topographies is designed to create an optimal host-bone response and actively participate in the fusion process by promoting new bone growth, encouraging natural production of bone morphogenetic proteins (BMP's) and creating the potential for a faster and more robust fusion," stated the company announcement.

"We continue to stand behind our products," said Peter Ullrich, M.D., former surgeon and CEO of Titan Spine. "Over the last few months, we've received positive feedback regarding our warranty from the field and we are proud to offer it as a testament to the knowledge that our products are engineered for optimal success in patients. Ultimately, the warranty demonstrates the significant confidence we have in our products and the science validating our surface technology. On the heels of the recent FDA clearance of our TL lateral system and winning the Whitecloud Award for Best Basic Research from the Scoliosis Research Society (SRS) at IMAST 2014, we look forward to accelerating momentum by providing our physician customers an additional reason to trust that our products will successfully perform in patients."

RRY Publcations LLC

In addition to its Wisconsin facility, the company also has a facility in Laichingen, Germany. — *WE*

Invibio Labs Accredited in the UK

Confidence building…Invibio Biomaterial Solutions is announcing that its laboratories have been accredited to ISO 17025:2005 by UKAS (United Kingdom Accreditation Service). As noted in the September 2, 2014 news release, "this achievement demonstrates that Invibio's Laboratories can consistently produce valid test results for each of the standards for which they have been accredited, averting the need to validate results through third-party laboratories."

Invibio Biomaterial Solutions

This stamp of approval, says the company, "means that test data for the accredited standards generated by Invibio's laboratories are validated as being precise and accurate." Going forward, Invibio's will need to rely less on third-party testing laboratories.

"For years, Invibio's PEEK-OPTIMA polymers have been the preferred

materials of choice for spinal interbody fusion devices" noted Keith Cartwright, Quality & Regulatory Leader, Medical & Regulatory Compliance at Invibio, in the news release. "Accreditation to ISO 17025:2005 reassures them that our polymers and the processes under which they are tested and validated meet the highest international standards. This accreditation underlines our dedication to continually improving our quality assurance procedures in both production and testing."

"This successful accreditation to ISO 17025:2005 not only demonstrates our unremitting pursuit of quality, it also means we can further streamline our material properties testing operations and move new products to market faster," commented Craig Valentine, Regulatory Affairs Director, Medical & Regulatory Compliance at Invibio. "By not having to rely on third-party test laboratories, we will be saving time and speeding time-to-revenue for our customers as well as ourselves."

Keith Cartwright told *OTW*, "Before our lab obtained this accreditation, third party laboratories were used to verify that Invibio PEEK-OPTIMA polymers met test specifications, which could add weeks to the production cycle of PEEK-OPTIMA shapes and components. Now that Invibio is accredited to perform these tests, we eliminate the time and costs associated with sending our products out for external testing, minimizing the time it takes to get these products from the manufacturing line to the supply shelf. Now, some of our customers are evaluating how they might be able to consolidate their supply chain by shifting third-party testing that they were performing independently to Invibio." — *EH*

LEGAL

Zimmer Attacks Plaintiffs' Attorneys in NexGen Cases

Zimmer Holdings, Inc. is fighting back against plaintiffs' attorneys who filed lawsuits on behalf of patients implanted with the company's NexGen knees.

The company asked U.S. Federal District Judge Rebecca Pallmyer in Northern Illinois to sanction three attorneys for plaintiffs in the multi-district litigation overseen by the judge.

According to an August 28, 2014 article on the *MassDevice* website, the company wants Charles Johnson, Sheila Bossier and Karen Beyea-Schroeder to cover the company's costs in preparing to try the cases as part of the bellwether process, according to court documents.

Zimmer had selected three cases—Shoat v. Zimmer, Davis v. Zimmer and Teague v. Zimmer—as potential bellwethers after five of its initial six selections were withdrawn for lack of merit, according to court documents. But after Zimmer began the discovery process for the suits, lawyers for the three plaintiffs said the cases wouldn't stand up after all.

Cases Not Supported by Expert Report

The company alleges that when it's attorneys inquired of plaintiffs' attorneys whether they intended to serve case-specific expert reports, the individual plaintiffs' attorneys responded by email, using the same language, stating that "[a]s the case has progressed it does not appear that it can be supported by a case specific expert report for a personal injury claim."

"Plaintiffs' attorneys abandoned 5 of Zimmer's 6 1st-round case picks for trial after Zimmer had expended significant effort over months investigating them," Zimmer argued. "Now, once again, plaintiffs' attorneys' conduct in Teague, Davis and Shoat is tantamount to dismissal, again frustrating this court's long-stated intent to alternate bellwether trials of both plaintiff and defense picks. Worse, plaintiffs' attorneys never informed Zimmer that they did not intend to pursue these claims."

pixabay

"Instead, plaintiffs' attorneys silently let the July 15, 2014, deadline for their case-specific expert reports pass without serving any reports, leaving Zimmer to piece together in the ensuing days the conclusions (1) that plaintiffs' claims would not be supported by expert testimony and (2) that plaintiffs' attorneys did not intend to take these cases to trial."

Lawyer Attack Deja Vu

This isn't the first time Zimmer has bitten back against attorneys representing patients suing the company over the NexGen knee.

Zimmer filed a lawsuit in the U.S. District Court for the Northern District of Indiana on February 16, 2011 against three personal injury law firms the company says were, "making inaccurate and misleading statements about the Zimmer NexGen Knee System through letter writing, internet and television advertisements and websites that incorporate Zimmer's name and brand."

The lawyers issued retractions.

Note to Plaintiffs' Bar: Zimmer is run by a smart lawyer. Do your homework. — *WE*

Smith & Nephew Settles "Country of Origin" Whistleblower Case

In what is believed to be the first settlement of its kind, Smith & Nephew plc has agreed to pay $11.3 million to settle a whistleblower lawsuit that accused the company of violating the Trade Agreements Act (TAA).

Made in Malaysia

Sam Cox, a former Smith & Nephew information technology manager filed a qui tam suit in 2008, claiming that the company had sold the Department of Veterans Affairs orthopedic devices in 2007 and 2008 that it had bought from Malaysia-based Straits Orthopaedics, Inc. while claiming they were made in the U.S.

The TAA requires government contractors to certify that they will only sell products to the government that originate in the U.S. or a country that has signed a trade agreement with the U.S. The law gives a preference to companies that sell products manufactured in the U.S. or in a country that is a trading partner. In this case, Smith & Nephew violated the TAA by selling products that were manufactured in Malaysia, which is a country that has not executed a trade agreement with the U.S.

Straits Orthopaedics

According to FDA documents, the Straits Orthopaedics manufacturing plant in Penang, Malaysia, is owned by Straits Orthopaedics in Vancouver, Washington.

A November 16, 2012 article on the website *Economic Transformation Programme* (ETP) said Straits Orthopaedics is a medical devices manufacturer and has been in operations for nine years. Its core business is the production, cleaning and packaging of orthopedic devices and accessories such as trauma, reconstructive and wound care products. Over 90% of the company's products are exported, mainly to the U.S.

$11.3 Million Settlement

The settlement was announced on September 4, 2014. Cox will receive $2.3 million, the government $6 million and $3 million will go to the lawyers of the whistleblower law firm of Sanford Heisler.

H. Vincent McKnight, Jr., Co-Chair of Sanford Heisler's whistleblower practice, said, "Today's settlement sends a clear message to those medical device companies that routinely violate the Trade Agreements Act by misrepresenting the 'Country of Origin' of goods sold under contract to U.S. Government agencies." McKnight continued: "This inaugural settlement will create a ripple effect for other medical device companies that choose to turn a blind eye to their obligations under the Trade Agreement Act. The Government has turned its attention to these flagrant violations and is stepping up enforcement."

The government declined to intervene in the case, although Cox's attorneys said the government team was essential in securing the settlement. — *WE*

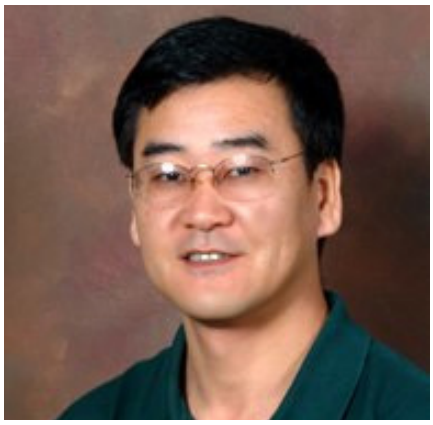
Smith and Nephew, plc

LARGE JOINTS

Protein Protects Against Arthritis-Related Bone Loss

Researchers from Georgia Regents University (GRU) have found that a small protein named GILZ may be protective against bone loss that can accompany arthritis and the medicine meant to treat it. Could the drugs currently in use—which have the side effects of bone loss and diabetes—be supplanted by GILZ?

Working with colleagues, Dr. Xing-Ming Shi, Ph.D., a bone biologist at the Medical College of Georgia (MCG) at GRU, focused on "tumor necrosis factor alpha, a proinflammatory cytokine that helps regulate immune cells and is a major player in arthritis. Tumor necrosis factor alpha primarily works though promoting inflammation, which is great if the target is cancer.



Xing-Ming Shi, Ph.D., Associate Professor, Department of Orthopaedic Surgery, Department of Neuroscience & Regenerative Medicine, Source: Georgia Regents University

However, when tumor necrosis factor alpha becomes dysregulated, it can also cause diseases like arthritis and inflammatory bowel disease."

Per the September 12 MCG press release: "The researchers crossed mice bred to overexpress tumor necrosis factor alpha throughout the body with mice that overexpressed GILZ in just their mesenchymal stem cells. These stem cells produce the osteoblasts, which make bone. They also make fat, and when the cells stop making as much bone, they tend to make more of it. Shi's lab has shown that GILZ can coax mesenchymal stem cells back to making more bone and less fat."

Dr. Shi said, "While the mice that overexpressed only tumor necrosis factor alpha quickly developed arthritis along with significant bone and weight loss, those that also overexpressed GILZ had significantly less bone loss."

"Our previous studies have shown that the GILZ transgenic mouse can make more bone," said Dr. Nianlan Yang, MCG postdoctoral fellow. "We wanted to see if GILZ would still have a bone protective effect in an inflammatory environment similar to arthritis."

As indicated in the news release, "Glucocorticoids and GILZ are both produced naturally in the body. Glucocorticoids are steroid hormones that help regulate the body's use of the fuel glucose and dampen the immune response." — *EH*

OA Clue Found in Alteration of Cell Behavior

A team of researchers from the University of Liverpool has found new information on how cells change their behavior at the onset of osteoarthritis (OA). The researchers, from the University's Institute of Ageing and Chronic Disease, have learned that "changes in the rate at which molecules in joint cartilage (mRNA) are created and destroyed are fundamental to causing this change in behavior."

By upsetting this balance—with more mRNA being destroyed—the cells cease to function as effectively.

Wikimedia Commons and Milorad Dimic, M.D.

Senior lecturer in orthopedic sciences, Dr. Simon Tew said in the September 4, 2014 news release, "Osteoarthritic cartilage cells have a significant number of genes whose mRNA is destroyed more rapidly than those in healthy cells. This affects some genes that we already know are involved in osteoarthritis as well as some that are less well studied."

As indicated in the news release, the researchers compared cells from OA patients to those of healthy patients. The findings show how the cells in joints stop working properly, leading to arthritis and the researchers hope that by understanding this part of the process, new treatments can be developed which address the problem.

Dr. Tew concluded, "We've not discovered the cause of arthritis, but this does shed light on the process of how the disease manifests itself. To develop new drugs to treat one of the leading causes of disability requires the fullest possible understanding of the condition and this discovery is part of that overall picture." — *EH*

EXTREMITIES

AAOS: New Criteria, App for Pediatric Elbow Fractures

Morguefile and anitapeppers/Photo creation by RRY Publications LLC

What to do when a little tyke shows up in the Emergency Room at 7pm with an elbow fracture? Now there is clarity, as the American Academy of Orthopaedic Surgeons (AAOS) has just released new Appropriate Use Criteria (AUC) and a mobile app for the treatment of pediatric supracondylar humerus fractures.

"These are very serious injuries requiring appropriate evaluation and treatment," said James Sanders, M.D., in the September 9, 2014 news release. Dr. Sanders is chair of the AAOS AUC for the Management of Pediatric Supracondylar Humerus Fractures work group. "These criteria will be helpful for clinicians who treat these injuries on an occasional basis."

With these new criteria, surgeons have several algorithms for treating an orthopedic injury or condition. According to the news release, there are even "hypothetical scenarios and possible treatments, ranked for appropriateness based on the latest research and clinical expertise and experience. Optimal treatment may require the surgical placement of a pin to hold the realigned bones, while protecting the surrounding nerves and blood vessels, or nonsurgical treatment with a cast or splint. When not treated correctly, these injuries can result in deformity, limited range of motion and the need for additional surgery."

As noted in the news release, the related app comes with three sections, the first being a list of assumptions/or considerations for treatment:

- "The patient is healthy enough to undergo surgery, if needed.
- A thorough history and physical examination of the patient has been conducted.
- Adequate radiographs (imaging) have been obtained and examined.
- The surgeon who cares for the child can perform the appropriate orthopaedic procedures.
- The surgery will be performed in a timely fashion, in an appropriate location.
- The facility has proper implants, ancillary equipment, and capable support personnel."

"It helps them to ask, 'should we be treating this child, or should the child be transferred to another hospital?'" said Dr. Sanders.

Having agreed that the above assumptions are met, the treating physician is presented with nearly 3,200 possible patient injury scenarios. Then the surgeon selects the correct scenario and proceeds to receive the related treatments ranked for their appropriateness, "helping to ensure optimal care and the best long-term outcome for resuming functional use of the elbow," said Dr. Sanders.

Dr. Sanders told *OTW*, "Developing criteria for the patient who has an associated vascular injury were the most challenging, and we are continuing to develop those criteria."

As for how long it may take surgeons to begin using the criteria, Dr. Sanders noted, "It will probably not be very long for them to be used since most surgeons will find them very logical." — *EH*

REIMBURSEMENT

Slowing Medicare Spending Fuels "Doc Fix" Speculation

Medicare spending will be slower in 2014 than originally projected, says the Congressional Budget Office (CBO) in a mid-year report. The news is reigniting efforts to repeal the sustainable growth rate (SGR) physician payment system.

In an August report titled "An Update To The Budget And Economic Outlook: 2014 to 2024," the CBO reported that net spending for Medicare will increase by only 2% in 2014. That compares to a 15% rise in Medicaid and about 5% for Social Security. Spending on all mandatory programs is projected to rise by 4%.

CBO lowered its projection of spending for Medicare by $9 billion for 2014 and a total of $11 billion for the 2015-2024 period. "Such revisions primarily stem from lower than expected spending for Part A (Hospital Insurance) services and Part D (prescription drugs)," says the CBO report.

Deficit Shrinks $170 Billion

The federal budget deficit has fallen sharply during the past few years, and it is on a path to decline further this year and next year. The deficit will shrink by about $170 billion in 2014.

"Doc Fix" Costs $131 Billion

The CBO report estimates the cost of replacing the SGR formula remains at $131 billion.

At 2.9% of gross domestic product (GDP), the CBO says this year's deficit will be much smaller than those of recent years (which reached almost 10% of GDP in 2009) and slightly below the average of federal deficits over the past 40 years.

ACOs and Bundled Payments

Who gets credit for this $9 billion Medicare windfall?

The *Motley Fool*'s Bruce Japson writes on September 7, 2014 that it appears that Medicare spending is slowing because of partnerships between the government, health plans, and providers of health care to seniors, as well as cost controls woven into the Affordable Care Act.

Placing more risk on doctors and hospitals to perform better through "bundled payments" or from accountable care organizations (ACOs) are generating savings for the Medicare program. Earlier this year, Medicare reported that more than $380 million in savings had been achieved from various such value-based arrangements.

Health insurers that operate Medicare Advantage plans are escalating their contracts with ACOs, which cover more than five million Medicare beneficiaries.

Complication Penalties

One of the biggest cost risks are hospital readmissions and surgical complications. The first year that penalties were levied against hospitals, penalized facilities were ordered to pay more than $220 million, according to the U.S. Department of Health and Human Services. This year, the readmissions criteria under Medicare broadened with total hip and knee replacements being added.

Declining Cost of Wars

While Medicare and Social Security payments are non-discretionary, discretionary spending on other federal programs of $1.17 trillion is down $32 billion (3%) from 2013. The CBO says that decline is almost entirely due to a drop in military spending in Afghanistan and Iraq ($20 billion). Overall military spending will drop by $32 billion.

CBO expects that non-defense discretionary outlays will total $576 billion in 2014. That amount would be about the same as such spending last year and 12% less than its peak in 2010, when outlays were boosted by spending from the American Recovery and Reinvestment Act of 2009. — *WE*

Image created by RRY Publications, LLC.

PEOPLE

Matthew Colman, M.D., Adam B. Yanke, M.D. Join "Rush"

(Left to right): Matthew W. Colman, M.D. and Adam B. Yanke, M.D./Midwest Orthopaedics at Rush

As of August 31, 2014, Matthew W. Colman, M.D. and Adam B. Yanke, M.D. have joined the team of Midwest Orthopaedics at Rush (MOR) in Chicago. Dr. Colman is a graduate of University of Chicago Pritzker School of Medicine, and Adam B. Yanke, M.D. is a graduate of Rush Medical College.

Dr. Colman, who handles patients with sports-related, orthopedic conditions, completed one in Musculoskeletal Oncology at Harvard University and one in Orthopedic and Neurosurgical Spine Surgery at the University of Utah. A graduate of the Orthopedic Surgery residency program at Pittsburgh, Dr. Colman specializes in bone and soft tissue tumors.

Dr. Yanke did his fellowship in Orthopedic Sports Medicine at Rush University Medical Center and holds a special interest in advanced arthroscopy, shoulder replacement (with a special focus on patellofemoral dysfunction) and cartilage restoration.

As indicated in the September 12, 2014 news release, "While in orthopedic training, Dr. Yanke pursued a Ph.D. in the department of biochemistry. During his fellowship, he served as a team physician for Division I collegiate athletics and provided medical coverage to professional sports teams, including: Chicago Bulls, Chicago White Sox and Chicago Riot Rugby. He completed his residency in Orthopedic Surgery at Rush Medical College where he was a Chief Resident Award Recipient. He attended Miami University, Oxford, Ohio, where he majored in engineering physics and zoology with a minor in non-linear mathematics."

Dr. Yanke told *OTW*, "I am very excited to get started at Midwest Orthopaedics at Rush. After training here for nearly 12 years, I'm happy to finally grow roots and start a practice here in Chicago."

Dr. Colman told *OTW*, "My practice combines two disciplines: spine surgery and musculoskeletal oncology, enabling me to provide cutting edge, comprehensive care for patients with spine, tumor or spinal tumor conditions. In addition, I focus on clinical research and education related to these fields. Beginning a practice of this type would not be possible without the incredible work of the support staff and world-class physician partner network at Midwest Orthopaedics at Rush and Rush University Medical Center." — *EH*

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