

# Orthopedics • This Week

## WEEK IN REVIEW

**4 AAOS 2014: Capture the Bundle >>** The 2014 AAOS Annual Meeting looked to the future. Healthcare reform anxiety is still around. But, says AAOS's new leadership, great opportunities lie ahead in a time of disruption. In the exhibit hall, the ortho bazaar is back. And the smartest guys in the room are encouraging their colleagues to "Capture the Bundle."

**8 Virtual Reality Coming to Grand Rounds // Same-Day Bilateral Knee Replacements Safe // Major New Study Finds Off-Label THA, TKA on the Rise! >>** Could Virtual Reality come to Grand Rounds? A new program is laying the groundwork for just such a future. HSS's new study finds that RA patients do as well as OA patients with same same-day bilateral knee replacement. A major new Cleveland Clinic study finds that off-label THA and TKA is on the rise.

**11 Blunt Observations From the AAOS Exhibit Hall >>** Kevin Stone, M.D., shares his honest and candid observations of some of the products, papers and new technologies that came from the podiums and filled the exhibit hall of the recently completed AAOS annual meeting. Make sure you're sitting down and have an adult beverage at hand.



**AAOS**  
AMERICAN ACADEMY OF  
ORTHOPAEDIC SURGEONS

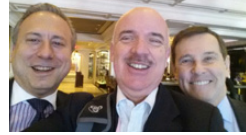
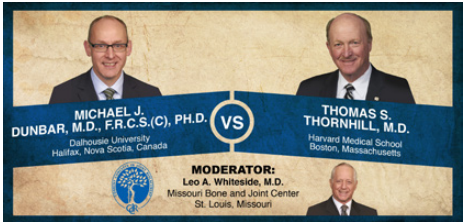
**ANNUAL MEETING HIGHLIGHTS**



# AAOS 2014

## Annual Meeting

**15 All Poly Tibia: Dunbar Debates Thornhill >>** "We shouldn't be afraid of the all polyethylene construct. There's been good evidence since 1984 that it's a safe construct," says Michael Dunbar. Tom Thornhill counters, "Cost is increasingly going to be an issue...and this is going to be a zero sum game. In my practice I use a modular tibial component that is cemented."



## BREAKING NEWS

- 19 Liquid Water Discovered on Surface of Minnesota**
- .....
- CONMED Rolls Out Hall Powered Instruments**
- .....
- Orthofix Restates Revenues**
- .....
- Same-Day Surgery OK for OA Knees**
- .....
- 7 Million Americans With Artificial Knees, Hips**
- .....
- The Passing of a Legend: Frank Jobe, M.D.**

**For all news that is ortho, read on.**

# Orthopedic Power Rankings

## Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**THIS WEEK:** Wall Street's bulls are looking for reasons to extend last year's surprising gains. Most recently citing the NY Fed's white paper that stocks are cheap. But institutional investors aren't buying. They want to lock in gains. Defense is the tone of the market right now. But defensive to what? Ortho stocks, reflecting the general mood, are slipping back—with three notable exceptions (JNJ, MDT and GMED).

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	15.71%	(0.73%)	Zack's raises Stryker to a BUY on the basis of rising earnings estimates and a 5.6% sales growth rate.
2	2	Zimmer	27.31	(1.73)	2014 is the year of the knee and ZMH is riding that wave like Kelly Slater hanging 10 at Waikiki.
3	4	Johnson & Johnson	26.58	6.95	Even Kobe Bryant is talking about dividend investing. When the market gets nervous, buyers want JNJ-style 3% yield dividends.
4	5	Medtronic	28.84	4.50	All the news is non-spine. Core-valve, Renal Denervation. Diagnostics. Where's spine? What's new at the #1 spinal implant supplier?
5	3	Integra LifeSciences	11.77	(0.83)	IART never has a shortage of announcements. But... cheapest ortho stock and sales expected to rise 8.50% this quarter. Anyone noticing?
6	8	NuVasive	6.30	0.54	There are two basic watchwords with NUVA—innovation and customer responsiveness. And Q4's report was better than expected.
7	7	Globus Medical	28.29	6.83	Valuation is not a big deal for GMED buyers. At 35x earnings, this equity is among the most expensive in orthopedics.
8	6	Smith & Nephew	20.25	(3.25)	The ArthroCare acquisition could ultimately prove to be one of SNN's smartest moves. Integration will be the key.
9	9	CONMED	10.37	(9.19)	The market is telling the story here. Down 9% in the last month, most institutions think the VOCE Capital run is over.
10	10	Symmetry Medical	6.50	(7.13)	The issue with SMA is basically no sales growth and operating margins that are about 6% of sales.

# Robin Young's Orthopedic Universe

## TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	\$0.87	\$48	50.00%
2	Orthofix	OFIX	\$30.29	\$551	35.16%
3	Johnson & Johnson	JNJ	\$97.44	\$275,592	6.95%
4	Tornier N.V.	TRNX	\$20.57	\$998	6.91%
5	Globus Medical	GMED	\$25.80	\$2,411	6.83%
6	Medtronic	MDT	\$60.41	\$60,459	4.50%
7	Alphatec Holdings	ATEC	\$1.50	\$146	3.45%
8	RTI Biologics Inc	RTIX	\$3.90	\$220	2.90%
9	NuVasive	NUVA	\$37.36	\$1,738	0.54%
10	ArthroCare	ARTC	\$48.23	\$1,658	-0.06%

## WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc	BAXS	\$1.02	\$48	-31.54%
2	MiMedx Group	MDXG	\$5.80	\$612	-17.85%
3	CONMED	CNMD	\$42.49	\$1,156	-9.19%
4	TiGenix	TIG.BR	\$1.11	\$179	-8.45%
5	Aurora Spine	ASG	\$3.51	\$55	-7.94%
6	Symmetry Medical	SMA	\$9.63	\$361	-7.31%
7	Wright Medical	WMGI	\$30.51	\$1,512	-5.92%
8	Exactech	EXAC	\$22.09	\$301	-4.41%
9	CryoLife	CRY	\$9.63	\$269	-3.41%
10	Smith & Nephew	SNN	\$76.81	\$13,731	-3.25%

## LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	CryoLife	CRY	\$9.63	\$269	15.93
2	Zimmer Holdings	ZMH	\$93.71	\$15,796	16.31
3	Medtronic	MDT	\$60.41	\$60,459	16.38
4	Johnson & Johnson	JNJ	\$97.44	\$275,592	17.79
5	Exactech	EXAC	\$22.09	\$301	18.39

## HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	\$37.36	\$1,738	100.27
2	Symmetry Medical	SMA	\$9.63	\$361	72.52
3	ArthroCare	ARTC	\$48.23	\$1,658	31.86
4	Integra LifeSciences	IART	\$45.20	\$1,465	28.49
5	Globus Medical	GMED	\$25.80	\$2,411	24.84

## LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Exactech	EXAC	\$22.09	\$301	1.02
2	Globus Medical	GMED	\$25.80	\$2,411	1.62
3	Zimmer Holdings	ZMH	\$93.71	\$15,796	1.69
4	CONMED	CNMD	\$42.49	\$1,156	1.80
5	Stryker	SYK	\$80.54	\$30,460	2.19

## HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	\$37.36	\$1,738	9.66
2	Symmetry Medical	SMA	\$9.63	\$361	6.04
3	CryoLife	CRY	\$9.63	\$269	3.98
4	Integra LifeSciences	IART	\$45.20	\$1,465	3.35
5	Johnson & Johnson	JNJ	\$97.44	\$275,592	3.01

## LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	\$1.50	\$146	0.72
2	Symmetry Medical	SMA	\$9.63	\$361	0.90
3	RTI Biologics Inc	RTIX	\$3.90	\$220	1.11
4	Exactech	EXAC	\$22.09	\$301	1.27
5	Orthofix	OFIX	\$30.29	\$551	1.38

## HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$1.11	\$179	41.56
2	MiMedx Group	MDXG	\$5.80	\$612	10.35
3	Wright Medical	WMGI	\$30.51	\$1,512	6.24
4	Globus Medical	GMED	\$25.80	\$2,411	5.55
5	ArthroCare	ARTC	\$48.23	\$1,658	4.39

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

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# AAOS 2014: Capture the Bundle

BY WALTER EISNER

The Annual Meeting of the American Academy of Orthopaedic Surgeons (AAOS) is always a tale of two cities. For the 2014 meeting in New Orleans one might say it was the best of times and even better times.

The Surgeon City is made up of surgeons, research, scientific and procedure debates and the politics of reimbursement, regulations and practice models. The other, the Corporate City, is made up of engineers, sales people, tools, instruments and implant devices.

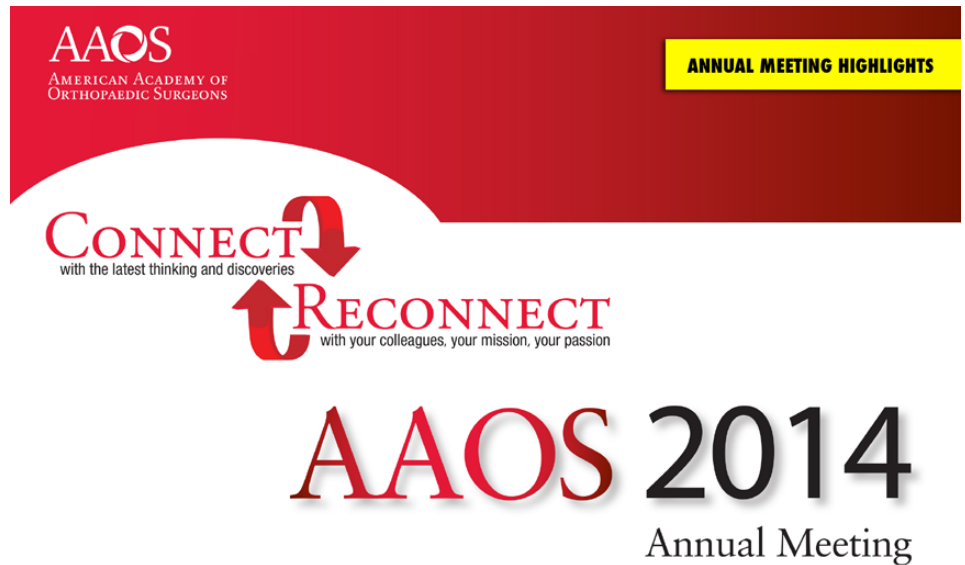
The Corporate City is dominated at its core by the Big Sisters of Orthopedics (Zimmer Holdings, Inc., Stryker Corporation, DePuySynthes, Biomet, Inc. and Smith & Nephew PLC). These in turn are surrounded by the hopefuls who want to be acquired or grow into one of the big sisters. It's all very clean, very tidy and tightly regulated and monitored.

## Business Is Back

One of the healthiest signs at AAOS could be found at the edges of the Corporate City where a growing number of the small newbies and ankle-biters with their barkers, deals and bazaar barter atmosphere were hawking their goods.

Business is back. "Two years ago we couldn't even talk to the docs about new technologies because they were too stressed out over business. This year, they're coming to the booth to ask about new technologies," one of the corporate sales reps told us.

Business was so good; we (this writer) even saw cash exchange hands in the Bazaar neighborhood of the Corporate



aaos.org

City. While English was still the language of choice, more foreign languages than ever were overheard as we walked the hall. Some of the smaller booths began to resemble a Middle East Bazaar with Chinese and Indian peddlers and pitchmen touting their tools and instruments to surgeons from all over the world.

One obviously hastily assembled booth consisting of a card table, tablecloth and a sign was displaying surgical tools. A surgeon from Latin America was digging into his wallet for a few hundred dollar bills and slipped it to the young Chinese woman behind the table. She was trying to figure out what to do with the cash, going to the back of the booth to open her suitcase. She then handed it over to her young male colleague, who stuffed it into his front pocket. Yup, business was back.

## "Capture the Bundle"

Gone was the preoccupation with healthcare reform, Department of Jus-

stice, FDA foot-dragging and anxiety over the decline of physician private practices. In its place was talk of registries, clinical guidelines for payers and physicians finding ways to "Capture the Bundle."

Hospitals are bringing private practice surgeons inside as paid employees, while insurers are buying large health-care systems. The new Medicare and private insurer payment models are quickly switching from paying for volume to "bundling" lump sums together to be shared between physicians, hospitals and other providers.

Richard Rothman, M.D. encouraged his colleagues to stop fighting the last war and focus on ways to seize opportunities opening up under health care reform. "Capture the bundle," he said, by getting more physicians under one healthcare roof, like his academic physician-owned and controlled Rothman Institute in Philadelphia. "Size matters," he said. "We're healers, not business

people, but we have to organize to utilize leverage with payers.”

### Azar Rallies Troops

Incoming Academy President Fred Azar, M.D., was on the same page with Rothman by telling members that the Affordable Care Act (ACA) is now the law of the land and new and younger Academy members are showing the way on how to utilize new technologies to get better, faster and smarter.

Azar is a well-recognized authority in sports medicine and the team physician for the Grizzlies, the National Basketball Association franchise in Memphis. He was recognized as the NBA's Team Physician of the Year after his 13th season with the Grizzlies.

Make no mistake; surgeons were still stressed out over insurance companies, hospitals, politicians, regulators and



Frederick M. Azar, M.D.  
 Source: American Academy of Orthopaedic Surgeons

getting paid for their services. But Azar rallied the troops.

### The Opportunity of Paradigm Shifts

He focused on the significant changes in the world that shape how orthopedic

surgeons practice, and on the implications of those changes.

“Even though they may not rank with say, the move from wired to wireless, the changes affecting orthopedics today genuinely qualify as paradigm shifts—or, in other words, marked, transformative changes,” said Azar

He cited the move from arthrotomy to arthroscopy as a paradigm shift for surgeons as well as the transition from medical record charts to electronic health records.

“What I think is different now, and very encouraging, is that we are riding the wave of change by embracing constant innovation, instead of feeling endlessly buffeted by the unexpected. I like to think of the Academy's approach to managing change as ‘building a bigger box.’”



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When it comes to the paradigm shift in practice management, he said the ACA has brought about a whole new list of unfunded mandates and acronyms.

While many of the greatest cost drivers, he said, are only marginally controllable, the revenue side is even more challenging as surgeons try to make informed business decisions and craft long-term strategies in the face of anticipated payment reform. He notes that many surgeons have been prompted by all this volatility to seek a hospital employment model.

“Does anyone doubt THAT amounts to a paradigm shift in a profession where independence is a part of our DNA? We realize that just as politics are local, so is healthcare delivery. Thus, we recognize that the best way for you to practice in your community differs from orthopedic surgeons elsewhere.”

**Inspiring the Patient Lobby**

Azar said another paradigm shift exists in the area of communications.

Since orthopedic costs constitute the largest portion of Medicare spending, orthopedic surgeons have frequently been seen as part of the healthcare “cost problem.” He pointed to the Academy’s “A Nation in Motion” campaign to raise awareness of what orthopedic services do and to highlight the value provided to musculoskeletal health in America.



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This year the Academy plans to roll out the “Second Firsts” campaign to allow patients to give their accounts of how orthopedic surgery gave them another chance at getting back their quality of life.

“Can you imagine the potential, profound effect an informed army of our patients could have on decision-makers? We have a value proposition to offer to our patients and our ultimate goal should be to capitalize on it by making orthopedics a household name.”

### Policy Agenda

Another paradigm shift, said Azar, has been the rise of regulatory advocacy.

The proposed Sustainable Growth Rate (SGR) fix is an excellent model of the Academy serving as an authoritative resource to members of Congress, he said.

The Academy’s top advocacy items include:

- SGR (Sustainable Growth Rate) reform
- IPAB (Independent Payment Advisory Board) repeal
- Bundled payments and value-based purchasing
- National and local coverage decisions
- Medicare audits
- In-office ancillary services exemption
- Medical liability reform
- Anti-trust reform

### The ACA and Hammurabi Code

But, said Azar, the greatest paradigm shift today relates to the ACA, which

includes pathways for both healthcare payment reform and delivery reform. The enactment of the ACA “is driving historic change in healthcare access, quality and cost.”

“And it was not a Trojan Horse. It is what we thought it would be—an unprecedented intrusion into our practices that threatens patient access to our expertise.”

But, he said, things could be worse if history is any guide.

“In the 18th century BC, the Hammurabi Code mandated that a surgeon be paid 10 shekels of silver every time he performed a procedure with his bronze lancet. However this code also mandated that if the patient died, the surgeon’s hands should be cut off.”

Since then, he said we have created a model of compensation based on services, not results. “But history seems to be repeating itself with proposed payment reform.”

Azar said we appear to be reverting back to the Hammurabi approach as payers are in fact metaphorically trying to cut off surgeons’ hands, even when the outcome may not reflect their efforts.

### Value and Quality

“Value and quality are the buzzwords of the times, and the value equation promotes high quality, low cost services. We all know that these terms are euphemisms for lower reimbursements, but they also represent potential gains in efficiency by managing resources.”

Payers are demanding evidence of that economic value, he said and the Acad-

emy has been investing heavily in quality initiatives which must be done by surgeons.

Azar said 2014 will be especially challenging due to the confluence of the ACA, Meaningful Use Phase Two and the start of ICD-10. He said, “Unbelievably, the number of diagnosis codes will increase by at least five-fold!”

He believes practice revenue will fall due to lost productivity, delayed reimbursement and higher claims denials. A recent AMA (American Medical Association) study estimates the cost of managing the ICD-10 transition will range from \$225,000 for a small practice to \$8 million for a large practice.

“For the government, it will be all about more data collection. For us, it will not be what you do, but what you document.”

He believes that orthopedic surgery offers the greatest social and economic value in all of medicine, and it is paramount that patients have access to orthopedic care, regardless of the disruptive shifts in healthcare.

### The Best of Times Ahead

As 30,000 surgeons and industry executives headed home from the AAOS meeting and the hawkers and barkers packed up the Bazaar, the analysts opined their optimism for the year ahead. For Dr. Azar and his colleagues, they’ll be looking to capture that bundle, turn loose their patients on policymakers and harness the best technologies to get better, faster and more efficient and convincing payers of that value proposition. ♦

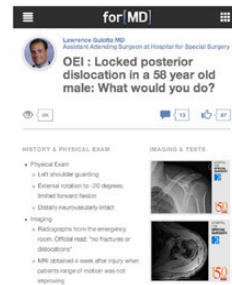
# Virtual Reality Coming to Grand Rounds // Same-Day Bilateral Knee Replacements Safe // Major New Study Finds Off-Label THA, TKA on the Rise!

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

**Virtual Reality Coming to Grand Rounds?** Let's say you are a fellow in hand surgery at, say, University of the Hand. Wouldn't it be informative to know how an established thought leader from, say, Duke Orthopaedics would treat a specific case? Now that is possible through the Orthopaedic Education Initiative (OEI) on forMD.com. Greg Chang, MHA, was formerly associate director at Duke Orthopaedics and is currently cofounder and CEO of forMD. He tells *OTW*, "The idea for the Orthopaedic Education Initiative began when I was at Duke, and grew from discussions with and leadership from several orthopedic surgeons, including Jay Parvizi from the Rothman Institute and Scott Levin at the University of Pennsylvania. The objective is to allow individuals to connect to one another by subspecialty to share knowledge and learn from experts and colleagues. Our program, forMD.com, allows residents, fellows, faculty, and alumnae of residency programs to collaborate and learn from one another so as to accelerate the evolution of knowledge in the field."

"At present we have 17 academic orthopedic groups that have volunteered to lead these discussions on a rotating basis and four programs have already done so: Duke, Rothman Institute, Hospital for Special Surgery, and Tulane University. More than 40 organizations have signed up thus far; the best news is that a full 20% of all U.S. orthopedic surgeons are already participating."

"There are other orthopedic learning/connection sites on the internet, but



**Frank Petrigliano MD**  
Assistant Professor at UCLA Department of Orthopaedic Surgery

That's a small defect. I would go with an open reduction through the rotator interval and if grossly unstable LT transfer, but probably not necessary. Gunslinger in ER for 4-6 weeks.



**Daryl Osbahr MD**  
Chief of Sports Medicine at Orlando Health Orthopedic Institute

Larry, great case to discuss! I agree with many of the previous comments. I would treat based upon the following order, especially in this over 50 year old patient:  
1. Closed reduction - if stable, leave alone.  
2. If unstable, reduction or fill defect (i.e., open reduction, subscap transfer, or remplissage)  
3. If reduction or fill not possible, then consider allograft, osteotomy, or resurfacing/replacement.

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our differentiating factor is that we allow orthopedic surgeons to connect through natural affinity groups they already belong to. The process is as follows: Each time an institution leads a discussion they select a topic that is considered, i.e., something that hasn't been completely settled in the field and share it with the appropriate subspecialty, society, and/or residency alumni group. A deidentified case is reviewed, along with the appropriate imaging, etc. In the initial phase of the discussion, each surgeon provides treatment options, followed by feedback from the community. Then after a week or two of discussion the faculty member who is leading the discussion follows up with his or her input as to how they would treat them."

For those concerned about site privacy issues, Chang notes, "This is an invitation-only site and the information held at the same level of security that you would find in any web-based EMR or HIPAA compliant platform. Additionally, we sign a contract with each institution verifying that we will not share their information with third parties to ensure the purity of the community and the privacy of all discussions."

"This is a terrific opportunity to provide and access thought leadership on a larger scale, something that usually only happens at large medical conferences or visiting professorships. On a macro scale the goal is to connect the international orthopedic community to share best practices."

## Same-Day Bilateral Knee Replacements Safe for Select Patients

A recent study has found that patients with inflammatory arthritis who underwent same-day bilateral knee replacements had the same outcomes as patients with osteoarthritis (OA). Mark Figgie, M.D. is a hip and knee surgeon at Hospital for Special Surgery in New York. He told *OTW*, "Since inflammatory arthritis is a systemic disease, patients have historically had poorer outcomes, including higher complication rates. We wanted to see if our results with laterals in carefully selected patients were comparable to patients with OA; I was pleasantly surprised at results showing that the outcomes were no different in patients with OA. I expected those with inflammatory arthritis to have higher complication rates, more prolonged hospital stays, and more transfers to a rehab facility."

“The inflammatory patients are in many ways in better shape when they come to us. What we see with OA is patients who are sicker and more obese; in inflammatory arthritis, because the disease is treated more aggressively, then they are often in better condition. However, those with inflammatory arthritis tend to have more severe contractures and joint deformity. If both knees have bad contractures, you should do both knees the same day because if one knee is straight and the other is contracted then the patient won’t rehab properly. This study shows that orthopedic surgeons can take on these patients with difficult deformities and get good results.”

“In a separate study we looked at how patients fare if you do both knees during the same hospital stay, but not on the same day. Patients whose surgeries were five days apart didn’t do as well because you do the first knee and by the time you do the second knee their coagula-

tion factors are out of whack because they are responding to the stress of first surgery. In these cases there was a higher rate of phlebitis, wound problems and ileus. Our recommendation is that if they are not healthy enough to undergo both surgeries the same day then you should stage the operations a couple of months apart.”

“It’s primarily the higher volume joint replacement centers that are doing bilaterals for inflammatory arthritis because you need a coordinated team of cardiologists, rheumatologists, anesthesiologists, etc. Such teamwork is critical to ensuring that the patients are well screened and optimized for surgery.”

**Massive Study: Off-Label THA, TKA on the Rise** Most total hip arthroplasty (THA) and total knee arthroplasty (TKA) patients are becoming off-label, says a 10-year study from the Cleveland Clinic. Wael Barsoum, M.D. is

vice chair of the Department of Orthopaedic Surgery and Chairman of Surgical Operations at that facility. He told OTW, “We are seeing a massive new national epidemiological trend towards off-label THA and TKA. Our cross-sectional study, which involved a weighted sample of 7,769,863 patients, found that the national prevalence of off-label THA and TKA was at least 30.4% and 37.0%, respectively. Based on this study, we can predict that by 2040, most total joint reconstruction of the hip and knee will be off-label (THA, 86.1%; TKA, 91.5%).”

“We also wanted to find out if the labeling makes sense and if patients are doing well. Amazingly, the joint replacement devices that were approved in the 1970s by the FDA still serve as today’s predicate device. So if you want to use the 510(k) process for approval of new implants you are stuck with the same labeling. We wondered if this labeling

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is really based on science. We know that indications for joint surgery have expanded and that patients are living longer and are heavier, so it makes sense that more and more will be off-label. We wanted to know if these patients used more resources and if we are doing them a disservice.”

“The study did show that it is minimally more expensive to care for most types of off-label patients (part of this is the prolonged hospital stay). Also, we found that off-label patients had a slightly greater likelihood for a perioperative complication. Patients with neurological or mental disorders had the worst outcomes of the off-label subgroups that we analyzed. This work makes us cognizant that as more and more joint replacements are off-label, we must expect that some of these patients will stay in the hospital longer and that their care may be more complicated. As we move toward more accountable care medicine we need to think more

of how doctors, systems, and insurers can stratify patients from a risk perspective...this data helps us do that. It doesn't make sense to pay the same amount for someone who is healthy versus someone who is very sick.”

**Michael J. Greller, M.D. Awarded Most Compassionate Doctor Award**

Michael J. Greller, M.D. has been awarded with Vitals 2013 Most Compassionate Doctor Award.

Dr. Greller practices at Advanced Orthopedics and Sports Medicine Institute (AOSMI) in Freehold, New Jersey.

The distinction of Most Compassionate Doctor recognizes physician excellence and is given only to those receiving exceptional reviews by their patients. Only three percent of practicing physicians are selected, making this achievement a testament to Dr. Greller's style, manner, and successful patient care. Moreover, Dr. Greller received this same

honor in 2012, making him a winner in two consecutive years.

Dr. Greller is a board-certified, fellowship-trained sports medicine orthopedic surgeon. He earned his medical degree from Albert Einstein College of Medicine, New York and completed his residency in orthopedic surgery at the Hospital for Joint Diseases Orthopedic Institute—New York University Medical Center. Dr. Greller also completed a fellowship in sports medicine at Temple University, and spent an extra year specializing in minimally invasive arthroscopic procedures of the shoulder, hip, knee, and ankle. Dr. Greller was one of the first New Jersey surgeons to use minimally invasive computer-assisted hip and knee replacements. He is managing partner and president of AOSMI, and secretary/treasurer of the medical staff at CentraState Medical Center. He is on staff at CentraState Medical Center, Robert Wood Johnson University Hospital, and Raritan Bay Medical Center. ♦

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## Blunt Observations From the AAOS Exhibit Hall

BY WALTER EISNER AND KEVIN STONE, M.D.

**C**autious: This article has forthrightness and candor. It should only be read by seated and calm readers.

The recent annual meeting of the American Academy of Orthopaedic Surgeons (AAOS) in New Orleans brought surgeons back to device company booths to talk about new technologies which, in turn, led to papers and science and...a fair amount of BS.



Kevin Stone, M.D./TED.com

TED speaker and one of the most innovative and knowledgeable sports medicine physicians in the world, Kevin Stone, M.D., of the Stone Clinic in San Francisco, graciously agreed to give *OTW* his honest and candid observations of the products, papers and new technologies that filled the exhibit halls and were presented from podiums at AAOS's annual meeting.

Dr. Stone is one of the most demanding physicians we know and he really cast a discerning eye on the products, research and companies he encountered at AAOS.

His comments are interesting and insightful. And straight to the point. — *Walter Eisner, Senior Writer*



Logo courtesy of AAOS.org/Photo creation by RRY Publications LLC

### Biologics: Science Ahead of Performance

One thing that Dr. Stone noticed right away was the tremendous interest among the companies in biologic products and instruments that can put biologic treatments into the hands of physicians (scaffolds, PRP, bone marrow harvests for stem cells). But, he noticed, most major orthopedic suppliers have overlapping offerings. And, furthermore, the papers which these firms trotted out were, frankly, weak.

“Unfortunately while the intuitive understanding of biology says these should work, the papers presented dem-

onstrated that the science is far ahead of the clinical performance. PRP (platelet-rich plasma) in particular seems to be a mixed bag of multiple growth factors with no consistency either between the products or even from the same patient at different times of the day. With this dramatic difference from what the regulatory bodies are used to seeing, one only wonders how the field will remain wide open and how the payers will deal with this variability in treatments and outcomes.”

He noted a genuine concern in a number of papers on the role of hyaluronic acid (HA), with some organizations now refusing to reimburse for it while

others claim it has dramatically delayed the time for joint arthroplasty for many patients. “The role of joint lubrication in cartilage repair versus arthritis is yet to be defined although the science suggests that HA is very beneficial to healing cartilage.”

**Shoulders: Cuff Repair Stuck in the Past Century**

Stone noted that there appeared to be considerable overlap in topics at the Specialty Day meetings of AANA (Arthroscopy Association of North America) and AAOS. He said the hot topic is whether or not the extensive rotator cuff repair techniques using multiple anchors and sutures is any better than a more cost effective single anchor approach. “The success of cuff repair remains a disturbingly low

number with possibly as many as 40% re-tears. The rehabilitation of rotator cuff repairs remains in the 20th Century with many top surgeons afraid to let their patients have active motion or strengthening for months after repair. This is reminiscent of the old days of ACL surgery.”

“SLAP [superior labrum, anterior to posterior] lesions of the shoulder are now being referred to as the plica of the shoulder with many papers demonstrating that very few (5%) of all SLAP tears need any surgical treatment. This is dramatically different from a few years ago when all the rage was new techniques in SLAP repair.”

The biceps tendon, added Stone, remains similar to the meniscus of the knee. “When diseased, the only treat-

ment is destruction of the tendon by removal or anchoring non-anatomically. It is odd that there is almost no science around repairing this structure which so obviously plays a key role in the shoulder.”

**The Knee and Meniscus Replacement: A House Divided**

For knees, Stone said meniscus replacement remains quite divisive.

Papers at the Meniscus Transplant Study Group focused on the importance of repairing the meniscus skirt ligaments in order to restore normal anatomy. He said there were multiple comments on expanding the indications for meniscus replacement, since it appears to provide long-term pain relief and improved function even in arthritic



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knees. He noted a paper by the Rush group demonstrated significant success in a series of 200 patients, though there was a high reoperation rate for scar tissue and other issues.

“A dramatic paper presented at the AAOS confirmed earlier data from Stone et al. that there was no difference in patients who received a meniscus

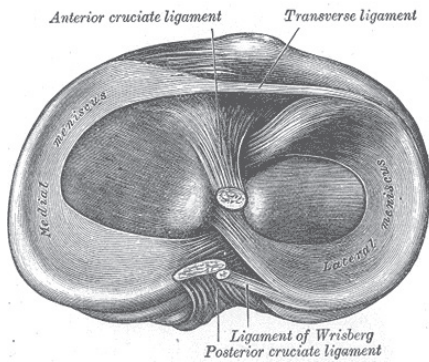
transplant plus an osteotomy versus those who received the transplant alone. Alignment did not affect outcomes. This contrarian data disturbed many of the osteotomy surgeons particularly in Europe but is supported by other studies as well. The contrary argument was presented at the AANA meeting in a panel where the surgeons repeated the dogma that meniscus transplantation was only for the young and healthy knees without mal alignment. The techniques presented were old time open surgery despite the fact that all arthroscopic meniscus transplant techniques have been well published. It is unclear why the anti-meniscus transplantation bias still exists but the contrast is stark in the opinions and data.”

Stone said data on long-term successful outcomes of CMI [collagen

meniscus implant] implantation from Europe continues to be reported, particularly by the Rizzoli group. “Zero complications in over 24 years of clinical use now should convince the FDA that revoking the approval for a device that helps so many people without a downside was a dumb idea. But don’t hold your breath. The CMI may come back as a PRP delivery device to augment meniscus repairs.”

### Put a Nail in the Double Bundle Coffin

Finally, Stone said the double bundle era is coming to a close for many surgeons. “Hyped by the companies that sold many more fixation products and by one of the university groups, the data is simply not convincing enough surgeons that two holes are better than one for anatomic ACL surgery.” The



Knee Anatomy/Wikimedia Commons

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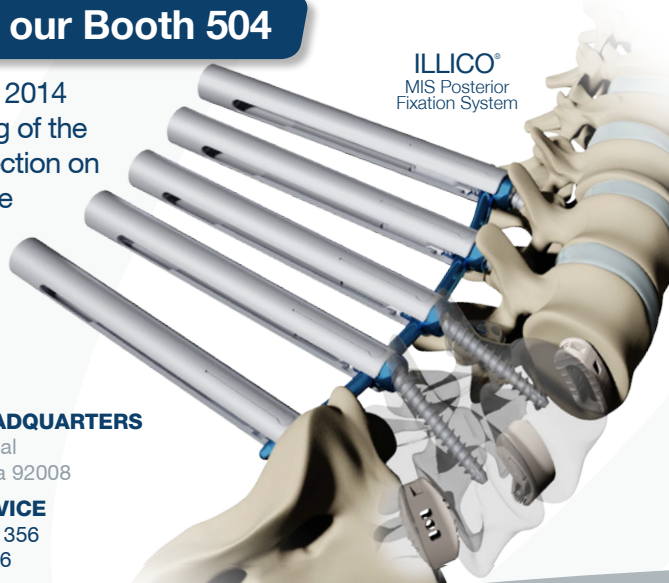
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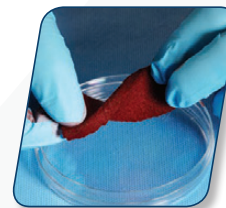
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best contribution from that era, said Stone, was to alert many surgeons of the importance of putting the ACL into the anatomic footprint.

### The End of Hardware

The take away for general orthopedic surgeons and companies, said Stone, is that orthopedics is entering the anabolic era and leaving the age of cortisone and hardware as primary treatments.

“We have come to understand that it is better to stimulate repair by adding growth factors, cells, tissue, and scaffolds to injured areas rather than remove the tissue (meniscus, biceps tendon, damaged cartilage, hip labrum) even if the outcome is not perfect. ‘Better is better than artificially replaced,’ is the mantra of the biologic surgeon. Patients are becoming aware that cortisone represents inhibition of healing and that metal and plastic represent the

last resort. The reports that up to 50% of patients with total knee replacements still have pain are circulating amongst the golfing crowd.

### Safety First, Effectiveness Post-Market

He says that if the FDA approval process is to modernize and understand the gradations of improvement then shifting to safety approvals first with crowd sourced outcome data to follow new products is the way forward. Translated, he says this means, let new products on the market after safety studies and let the efficacy be determined by total post market release data. While not acceptable in the past, the Internet has provided the tools for far more clear data.

### Big Data and Reimbursement

“Most patients have cell phones, email and are registered in some type of

electronic record. The increased use of EMRs makes data collection even easier with integrated outcomes tools. For those not using EMRs, several companies have started to provide tools to organize and streamline the collection of outcome data. For surgeons, there is no longer any excuse to not follow all patients with at least subjective outcome measures filled out electronically. Look for these big data sets as a requirement for approval in the not too distant future.

So if it is better to stimulate repair first, which products to use? Is a partially repaired or restored joint with modest improvement better than a removed joint? Outcome data will decide the answer to these questions. For surgeons and companies alike, outcome data will rule the reimbursement world. ♦

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# All Poly Tibia: Dunbar Debates Thornhill

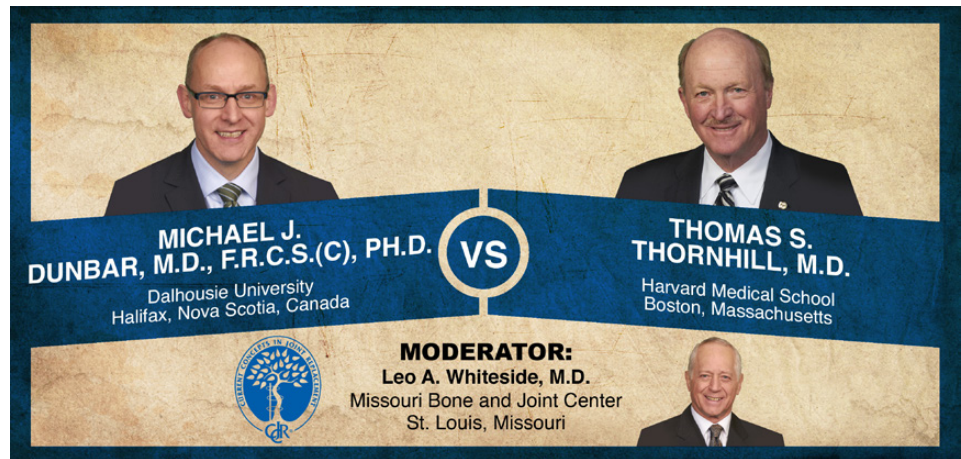
BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

“We shouldn’t be afraid of the all polyethylene construct. There’s been good evidence since 1984 that it’s a safe construct,” says Michael Dunbar. Tom Thornhill counters, “Cost is increasingly going to be an issue... and this is going to be a zero sum game. In my practice I use a modular tibial component that is cemented.”

This week’s Orthopaedic Crossfire® debate is “The All Poly Tibia: Cheaper and Better.” For the proposition is Michael J. Dunbar, M.D., F.R.C.S.(C), Ph.D. from Dalhousie University in Nova Scotia; against the proposition is Thomas S. Thornhill, M.D. from Harvard Medical School in Boston. Moderating is Leo A. Whiteside, M.D. of the Missouri Bone and Joint Center in St. Louis.

**Dr. Dunbar:** “The all poly tibia is a cheaper construct. Why? In order to provide a modular component there is a lot more engineering and machining involved. The engineering is quite complex, and this engineering needs to take place both on the tibial base plate side and on the polyethylene. That raises the question, ‘Why do we need to do that?’ Because issues of fixation and modularity—which have large been solved by engineering—but they weren’t trivial and they can still persist. By these I mean backside wear and the movement associated with modularity.”

“The other issue is that by this engineering that’s required you have less poly per unit of volume. So per bone resection when you use a modular tray you get less poly to run on. When you have sub-critical levels of thin poly on metal-backed trays, any third bodies can become critical wear issues.”



Current Concepts in Joint Replacement/RRY Photo Creation

“One of the major claims that is put forward is that the reason we need modularity is that we can go back and do simple revisions. I think that is false. A paper from Mayo looking at the effectiveness of isolated tibial insert exchange in revision TKA [total knee arthroplasty] looked at 56 isolated tibial insert exchanges. I quote: ‘Isolated tibial insert exchange led to a surprisingly high rate of early failure. Tibial insert exchange as an isolated method should therefore be undertaken with caution—even in circumstances for which the modular insert was designed and believed to be of greatest value.’”

“If you think about the reasons we have for failure in TKA, the early failures occur due to infection and instability and the late failures occur for aseptic loosening and polyethylene wear. Neither early nor late reasons for failure can be routinely addressed with an isolated poly exchange. The fact is that all-poly tibial components are not a new concept and there is a lot of data on how they perform—enough to do meta analysis. A 2011 study in *Acta Orthopaedica* by Tao Cheng had a forest plot demonstrating

that there’s no difference between the metal backed and all poly tibias. But, there were significantly more lytic lines in the metal backed group.”

“So what do these lytic lines mean? A 2005 study in *Acta Orthopaedica* by Hans Hyldahl looked at radiostereometric analysis (RSA) data...two groups of 20 patients—all poly versus metal backed. They found significantly more adverse RSA motion with the metal backed tibial component. Why might this be? It turns out that the rigid metal backed tibial component with a high modulus of elasticity can produce liftoff with asymmetrical tibial load. If you have a keeled construct with a metal back and a high modulus and you get any sort of asymmetric load, then that leads to liftoff. Conversely, on the other side you get subsidence...so the component teeter-totters, which isn’t the case with the all polyethylene component.”

“More concerning is that continuous motion, which is a prognosticator of long term failure, is much higher in the metal backed group than it is in the all poly group.”

“Finally, we’re told that modularity of metal backed tibial components is needed to balance the knee at the time of surgery. I’d suggest that surgeons with a ton of experience—like Dr. Thornhill—do not need this modularity.”

**Dr. Thornhill:** “If you use an all poly tibia you have to cement it. Unfortunately I don’t have a big argument. I think much of what Michael says is true. Cost is an issue, there are good long term results, and there is better poly. And you don’t have the problem that Mike pointed out of backside wear.”

“All poly tibias are generally done in low demand patients, backside wear is less than it used to be, and there are some facilitated things with modularity. As for backside wear, we now have an improved metal tibial surface with polished cobalt chrome. We have improved

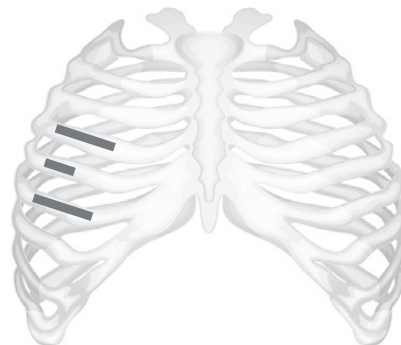
poly which is mechanically stronger with better locking mechanisms. We have reduced micromotion, particularly with a better interference fit. As for motion, with crosslinked poly the micromotion almost approaches that of the preassembled unit.”

“There are some interoperative options that are facilitated by this and I agree that doing an isolated poly exchange is not terribly common. But with most systems now we can change conformity. You can go from CR to PS (cruciate retaining to posterior stabilized) and save the tibia, but you have to think about the femur. They now have these ultra-congruent trays, but in my revisions I rarely save the tibial tray. You can increase tibial thickness, which will help you in conformity if you have global instability. But doing that for flexion instability does not work.”

“With regard to tibial bone loss, I think that oftentimes you will see sclerotic bone on the posteromedial side and then porotic bone once you clear the surface off. In this case I think cement is beneficial because it will give a uniform proximal tibial mantle. Then, if you look at the bending moments in an old article (Walker and Reilly, 1979) we see that you do better with offset loads. And I’d have a little issue with the argument of liftoff of a stiff metal backed component because, Michael, you being from the Maritimes know the function of the keel of a boat with or without a center-board. With cement it shouldn’t lift off unless it bends.”

“As for fixation, if you’re going to use an all poly tibia you must use cement. When you examine the results of cementless tibial fixation things have changed. They now have multiple

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types of metals that do have better scratch fit and are probably friendlier to ingrowth. And they are now modular so you will get the benefit. We talked about having cemented hips and then hybrid hips, and now mostly cementless hips. Michael, I know you still cement the femur in 95% of yours, but I'd suggest that we will change to cementless tibial designs."

"In my practice I use a modular tibial component that is cemented. The economics may dictate the change for selected patients because the low demand patient is probably going to need a low demand knee."

**Moderator Whiteside:** "Mike?"

**Dr. Dunbar:** "You summed it up nicely. I think we're going to be forced to look at the all poly construct because of cost constraints. The concern is that center by center we will just deploy it for all comers. We should become more patient-specific in our approach in identifying those patients who do fine because long term cement will be the weak link on fixation. We're probably going to be moving away from that based on Nakama's recent Cochrane review which showed that long term uncemented implants outperform cemented implants. My point is that we shouldn't be afraid of the all polyethylene construct. There's been good evidence since 1984 and there continues to be evidence that it's a safe construct. We shouldn't apply it to everyone; we also need better tools such as gait analysis, etc., in order to determine who should get these devices."

**Moderator Whiteside:** "Tom?"

**Dr. Thornhill:** "We published an article with a mathematical algorithm showing how to determine how to match

a patient's need with the implant... because cost is going to be an issue. It is going to be a zero sum game. We're now looking at bundled payments, and when the total cost that is available for reimbursement is affected, we may see

a change in the pattern of behavior (giving lower cost implants to people with lower demands)."

**Moderator Whiteside:** "I've heard that for so many years so I maintain some

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skepticism. Mike, you quoted a study suggesting that revision of the poly component in an isolated circumstance doesn't work very well. Do you know of any articles in the literature showing that it has worked well?"

**Dr. Dunbar:** "No."

**Moderator Whiteside:** "Well, having written one of those articles..."

**Dr. Dunbar:** "Right, well we're trying to make a strong point one way or the other, and trying to pull out some educational points."

**Moderator Whiteside:** "I'll send you a copy."

**Dr. Dunbar:** "Sign it, would you?"

**Moderator Whiteside:** "Tom, do you ever do an isolated revision of the poly?"

**Dr. Thornhill:** "Yes, and it tends to be in a PS knee that is well aligned, well rotated, and globally loose."

**Moderator Whiteside:** "Or worn out?"

**Dr. Thornhill:** "Yes, as long as I have something that I can get with better locking mechanisms."

**Dr. Dunbar:** "I think the analogy is that if your car tire wears asymmetrically and you keep replacing the rubber then you're better off realigning the tire at the same time. It's rare to have symmetrical wear, etc."

**Moderator Whiteside:** "What about the young, heavy patient? Do you see an advantage to a man in his early 40s—a laborer—with traumatic arthritis who is going to need a knee replacement, and needs to get back to work?"

**Dr. Dunbar:** "No. I'd suggest that a monoblock, low modulus, advanced porous material that can deform under load would be an advantage in that person."

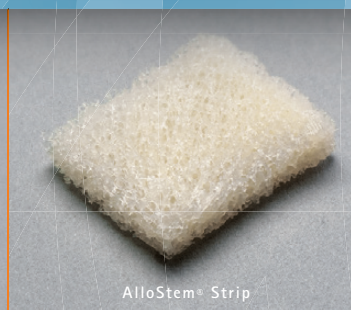
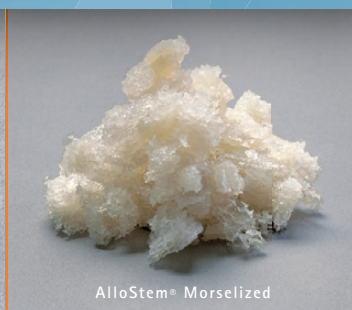
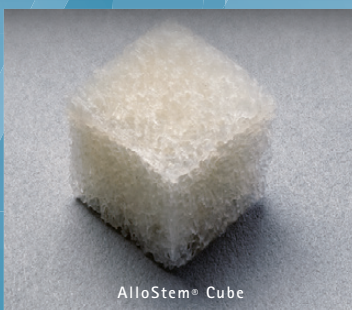
**Moderator Whiteside:** "Tom, same question."

**Dr. Thornhill:** "I'd be using a modular one anyway. But there's one other instance where it happens...extremely rare...but in someone with a well fixed implant I have used an angle bearing insert that could correct some of their malalignment. You can balance the soft tissues. That's another case where I might leave the tibial component and put in an insert."

**Moderator Whiteside:** "Thank you, gentlemen." ♦

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GENERAL INFO

## Liquid Water Discovered on Surface of Minnesota

March 26, 2014

By FOURTHCROWN

FORT LAUDERDALE—In a press conference held Tuesday morning, NASA officials have announced the discovery of liquid water on the surface of the region commonly referred to as Minnesota. The discovery has come as a surprise to the space exploration organization, which has listed the state of Minnesota as “unsuitable for any and all biotic life” since mid-November. Temperature trends extrapolated from four months of hard data had extensively confirmed the scientific community’s well-formed hypothesis that Minnesota temperatures were unlikely to shift above “subarctic status.”

“As we continue to develop our understanding of the incredible conditions in which life can develop, the discovery of liquid water in Minnesota is indeed a watershed moment,” commented Major General Charles F. Bolden, Jr., NASA’s chief administrator. “This planetary region has had all of its aquatic reserves trapped in large ice-masses due to extreme cold for an interminable length of time,” continued Bolden. “The discovery of unfrozen water visible from our high-powered satellites has inspired NASA to redouble our efforts to exhaustively decide if at any point this region could be home to an extremophile-type life form.”

NASA’s announcement has lent a new aura of credibility to the writings of many theorists who insist the Minnesota region plays home to a humanoid race of highly-robust organisms living on a diet consisting of nutrient-dense hot dishes, and whose culture revolves primarily around shitty football teams

and complaining about their climate. These posits, best exemplified in the popular Coen Brothers film, *Fargo*, are still largely dismissed by the scientific community. Maj. Gen. Bolden addressed these unlikely propositions, asking viewers to reflect on “the inconsistencies between ‘intelligent’ Minnesotan life and our current Theory of Evolution. While popular culture may elevate the idea of a large tribe of suspiciously friendly bipods who stoically endure perennial beatings by the Green Bay Packers, this theory has no place in the rational realm of scientific thought.”

Source: The Fourth Crown. Gustavus Adolphus College, St. Peter, Minnesota. amuel Panzer, J.D. Feit, Nate Long, Evan Jones, Max Milnar and Delaney Sweet. The funniest, smartest writing team since the Onion. Better than the Onion. [http://fourthcrown.wordpress.com/news\\_team/](http://fourthcrown.wordpress.com/news_team/)

—RRY (April 1, 2014)



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## CONMED Rolls Out Hall Powered Instruments

CONMED Corporation is hailing the rollout of its Hall 50 Powered Instruments System. The company's newest system upgrade is built upon 50 years of engineering expertise. CONMED says that it "hangs its hat" on the quality of its product, offering its customers dependable power.

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CONMED's Hall 50 handpieces have incorporated an enhanced epoxy potting. CONMED has gone one step further to protecting its handpieces from the damages of moisture intrusion. The company has added a second layer of epoxy between the controller and the electronic circuit board. This added epoxy prevents electronic failure in the event that moisture does seep into the handpiece. Additionally, the company has redesigned the oscillator head such that it incorporates fewer lower-level components. Vibration is reduced, as is noise, and the redesign provides improved resistance to moisture intrusion.

Senior Product Manager Large Bone Power Danielle Whitlock for CONMED tells *OTW*, "We are using a new gasket with this design that is made by Trelleborg Seals, a company that manufactures seals for NASA, Boeing, submarines, and off-shore oil rigs. Also interesting is that we worked with an industrial design firm called FARM, who helped us improve the ergonomics of the handpiece. These things will go a long way towards making this system exceptional."

CONMED Corporation —EH (March 26, 2014)

## Orthofix Restates Revenues

Orthofix International N.V. announced on March 25, 2014 that net sales for 2011 and 2012 were \$42.9 million less than previously reported.



KSL.com

When Brad Mason took over at Orthofix in 2013, the company announced it was reviewing previous revenue reports and would be restating financials in SEC filings. The restatement of revenues was primarily due to illegal sales of the company's spine stimulation devices under previous management. Some of those sales became the target of a Department of Justice False Claims investigation, which concluded with the company settling with the government for \$43 million and some former employees sentenced to jail.

That review process is now completed by the board and the company released a filing on March 25, 2013 with those restatements.

The restatement of the company's previously issued consolidated financial statements resulted in, among others, the following changes:

- Reduction in net sales for the years ended December 31, 2012 and 2011 of \$14.7 million and

\$28.2 million, respectively, and an increase in net sales for the year ended December 31, 2010 of \$1.9 million

- Decrease in net income from continuing operations for the years ended December 31, 2012 and 2011 of \$8.9 million and \$14.5 million, respectively, and an increase in net income from continuing operations for the year ended December 31, 2010 of \$3.2 million
- Decrease in opening retained earnings and total stockholders' equity at January 1, 2010 of \$8.3 million and \$7.6 million, respectively.

“The Audit Committee, with the assistance of independent outside professionals, has conducted a thorough review of these matters,” said Davey Scoon, chairman of the Audit Committee of the company's board of directors. “The Audit Committee has concluded its review and is confident that the company is appropriately addressing the matters, including the internal control over financial reporting weaknesses that led to the restatement.”

### Remediation

The company has also committed to putting systems in place to prevent future sales from coming under the same cloud, including implementing an internal audit program that will take into account the nature of the company's business and the geographies in which the company conducts it. The company is also updating its code of conduct, and all its employees will be required to annually acknowledge their commitment to adhering to its provisions. The company also will inform all new employees and regularly remind all existing employees of the availability of its compliance hotline, through which employees at all levels can anonymous-

ly submit information or express concerns regarding accounting, financial reporting and other irregularities they may have become aware of or observed.

President and CEO Mason said, “The past year has presented us with a unique set of challenges, but we are confident Orthofix is emerging stronger and with a renewed energy to drive our business forward. We are committed to achieving and maintaining a strong control environment, high ethical standards and financial reporting integrity. This commitment has been and will continue to be communicated to every Orthofix employee. It is accompanied by renewed management focus on strategies and processes intended to drive long-term shareholder value.”

Mason is getting the company back to business.

—*WE (March 25, 2014)*

## Executive Changes at NuVasive

NuVasive, Inc., a company focusing on minimally disruptive products and procedures, is announcing major executive leadership changes.

Quentin Blackford has been promoted to the Executive Leadership Committee as Executive Vice President of Finance and Investor Relations. Blackford joined NuVasive in 2009, and with nearly 15 years of financial experience within medical device organizations, his effort and insight will be

invaluable as NuVasive drives toward \$1 billion and beyond in revenues with improved profitability.

The company also announced the resignation of Craig Hunsaker, Senior Vice President of Global Human Resources, which will be effective March 31, 2014. Hunsaker will assist in the transition of his responsibilities to Mike Paolucci, who has been appointed Executive Vice President of Global Human Resources, effective immediately.

Mike Paolucci joins NuVasive from Life Technologies Corporation, a global life sciences company with over \$4 billion in revenue, which was recently acquired by Thermo Fisher Scientific. He brings more than 20 years of broad global human resources experience at the executive and board level that will be instrumental to NuVasive's evolution into a larger, global business. At Life Technologies, Paolucci was responsible for the global compensation and benefit programs that encompassed more than 10,000 employees in nearly 40 countries. He also served as a human resources business partner for various business segments and was responsible for the company's human resources technology systems. Prior to Life Technologies, he served as vice president in various human resources capacities at Hewlett-Packard and EDS Corporation, from 2000 to 2009.



Michael Paolucci (left) and Quentin Blackford (right)

Chairman and CEO Alex Lukianov said, “We are exceptionally grateful to Craig for all of his contributions during his tenure with NuVasive. I am thrilled to welcome both Quentin and Mike to the NuVasive Executive Committee. Their strong propensity for outstanding standards, steadfast focus, and wealth of experience in achieving excellent outcomes will be instrumental to our executive leadership team. I look forward to their contributions and have tremendous confidence in the team we have organized to help us achieve our market share taking strategy.”

Mike Paolucci told *OTW*, “NuVasive has a rich history and culture that has enabled the organization to be the spine industry leader. I see my role as enhancing the current culture through improving the effectiveness of Human Resource programs, policies and processes that will also allow the business and our customers to achieve their goals. This will also allow us to attract the best talent in our industry and continually grow and development our Shareowners—the most important asset we have.”

—EH (March 21, 2014)

## Three Guys in a Bar

First there was Athos, Porthos and Aramis. Then there was Crosby, Stills and Nash. And ten years ago another triad came together—Foster, Viscogliosi and Young. British, Italian and Guatemalan.

It couldn't last. Initially they'd come together under the HealthPoint Banner. But FV&Y ultimately went their separate ways.

At infrequent and intermittent times over the decade the guys would take time from starting companies,

acquiring companies or selling companies to touch base. Years passed between meetings.

Young got older, redder and balder. Viscogliosi got richer, smarter and more influential. Foster got happier, younger and, unfortunately, lamer (sports injury).

Then, in the midst of the celebration that was the 2014 AAOS annual meeting, the three ran into each other in a seedy hotel bar one block off Bourbon Street.

Young and Foster ordered diet cokes. Viscogliosi espresso. FV&Y's conversation took off as if the last ten years had never happened. The three old salts covered all that was new, broken or changing in the orthopedics industry. Could there be any other three individuals who knew as much or had spent so many years analyzing the trends, technologies, companies and people in this industry?

What, they wondered, could they have accomplished if they'd never split up?

Ten years on and old quarrels were gone in the haze of distant memories. Instead

a sense of possibilities unrealized and ideas yet to be developed took hold.

What if....

Yes, JF is active at Healthpoint Capital. Yes, TV is managing partner at VB. Yes, RY runs *OTW*.

But...what if....

The minutes in that old bar turned into, well, one hour. But it seemed like more. Ideas bubbled up, plans took form and by mid-day the three amigos toasted each other and a bold, innovative and ultimately disruptive initiative.

They made an appointment to meet again in New York.

59th and Park. They knew the place.

JF paid the bill.

TV had a second espresso.

And RY wrote the story. To be continued...

—RY (March 19, 2014)



RRY Publications LLC

LEGAL

## Review Times Improving at FDA

The FDA has improved its performance in reviewing device applications since 2010.

Margaret Hamburg, M.D., the agency's commissioner, told Congress on March 13, 2014 that since that date, the agency has achieved:

- 27% decrease in the backlog of lower device applications
- 10% decrease in average total review time
- 43% decrease in higher risk devices backlog
- 32% decrease in average total review time

Hamburg said the agency is at the “cutting edge in terms of review and approval of new products,” compared to the rest of the world. “If you look at drugs approved in recent years, I think about three-quarters of them were approved in the United States first and on devices, apart from the highest risk devices, we are I think at par with comparable other countries in terms of review times. We do ask for more clinical data often on the higher risk devices. But, I think there's some urban mythology about where we stand in comparison to review times and leadership.”

Under the most recent user fee agreement (MDUFA III) with the device industry, the FDA will collect almost \$600 million in fees over five years. The agency plans to hire an additional 200 full-time employees over that time to speed up review times. Hamburg added that since October 1, 2013, the agency has already hired 90 of those employees.



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Janet Trunzo, senior executive vice president, technology and regulatory affairs of AdvaMed, told OTW on March 19, 2014:

“AdvaMed is encouraged by the progress FDA has made in meeting its commitments under the new user fee agreement, but we all recognize there is a long way to go. So far, the agency appears to be meeting its MDUFA III decision goals and commitments for substantive interactions with submission sponsors. Initial data from FDA shows marked improvement in total review times for PMAs [premarket applications] and modest improvement in total review times for 510(k)s compared to the historic highs seen in 2010. We look forward to continuing to work with the agency to ensure accountability under the new user fee agreement and continued progress toward improving the timeliness of reviews.

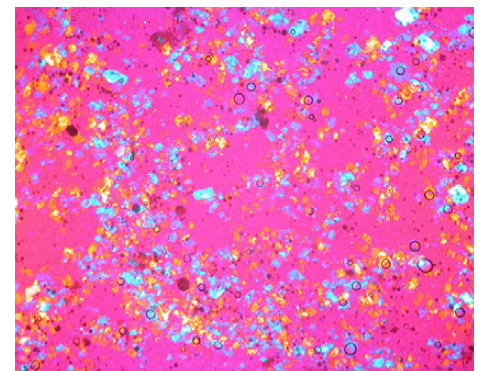
—WE (March 19, 2014)

LARGE JOINTS

## Same-Day Surgery OK for OA Knees

For patients in a hurry, those who want to get their knee replacements over with in as short a time as possible, same-day bilateral knee replacement is a possibility. Does it matter to the surgeon what is ailing those sore knees?

While patients with rheumatoid arthritis (RA) are often sicker than are patients with osteoarthritis (OA), Mark Figgie, M.D., chief of the Surgical Arthritis Service at Hospital for Special Surgery, has found that patients with RA do just as well with same-day bilateral knee replacement as do OA patients, and with no higher complication rate.



Wikimedia Commons and Ed Uthman

According to *American Medical Network*, Figgie and his colleague, Allan E. Inglis, M.D., chair in Surgical Arthritis, analyzed data from 240 RA patients and 3,680 OA patients who had bilateral knee replacement surgeries between 1998 and 2011. There were differences between the two groups. They found that more than 80% of the RA patients were women and that they were more likely to have heart disease, be on medications that suppress the immune system, be obese and were about five years younger than the OA patients.

Despite the fact that the RA group stayed in the hospital longer than did the OA patients (5.8 days instead of 5.4 days) and required more blood transfusions, in the end researchers found no differences in the overall rates of procedure-related, minor and major complications between the two groups.

Despite that encouraging news, Figgie advises that doctors carefully screen their RA patients. Though the bilateral procedure appears to be safe for RA patients who do not have significant heart disease, he notes that, “These are typically more challenging cases, and surgeons will want to coordinate patient care with rheumatologists to avoid flares during the postoperative period.”

—BY (March 27, 2014)

## 7 Million Americans With Artificial Knees, Hips

*Medical Press*, commenting on a study that counted the number of Americans who had received an artificial joint, reports that more than 7 million Americans are presently living with an artificial knee (4.7 million) or hip (2.5 million.) That amounts to 0.8% of the total population. But among adults age 50 and older the rate is 2.3% for hips and 4.6% for knees. For patients 80 years old and older the rate is nearly 10%.

Daniel Berry, M.D., professor of orthopedics at Mayo Clinic and the senior author of the study, said, “This large number highlights how these operations have kept a substantial part of our population mobile despite severe arthritis, something that wouldn’t have been possible before these technolo-

gies were available. These prevalence estimates are within the same ballpark as coronary heart disease, and much higher than heart failure or stroke. To put these numbers in perspective, there are roughly one and a half times as many people living with a hip or knee replacement in the U.S. as people living with heart failure.”

Another finding of the study was that the incidence of total knee replacement (TKR) increased by 120% from 2000 to 2009, 188% for patients ages 45 to 64, and 89% for patients ages 65 to 84. The incidence of total hip replacement (THR) increased 73% from 2000 to 2009, 123% for patients ages 45 to 64 and 54% for ages 65 to 84.

Over the same time period, the number of TKR revisions increased by 133%, and the number of total hip replacement revisions went up by 27%.

*Medical Press* quoted William A. Jiranek, M.D., professor of orthopedics, Virginia Commonwealth University School of Medicine, as saying of the joint replacement patients, “They all need continuing medical attention and some need further surgical attention over the years of having a replacement. As there are no guidelines to define long-term management of these individuals...our prevalence estimates are vital to agencies charged with planning for the provision of health care services.”

An earlier study by a group of health economists found that, by modeling indirect savings of the individual returning to the work force after knee replacement surgery, the lifetime societal net benefit for patients undergoing that surgery averages between \$10,000 and \$30,000.

—BY (March 27, 2014)



RRY Publications LLC and Biloine Young

## TJR Protects Against Cardiovascular Disease

Here is another reason to get that painful hip or knee replaced: it could help your heart. A study, conducted in Canada, has found that total joint replacement (TJR) reduces the risk for cardiac events such as heart attack and stroke by as much as 40%.

It is not hard to figure out why this could be the case. A lack of physical activity is a major risk factor for cardiovascular disease and osteoarthritis, which affects a third of the people over age 65, limits mobility.

Bheeshma Ravi, M.D., an orthopedic surgeon at the University of Toronto Medical Center and the lead author of a study, said, “there is a growing body of evidence that suggests that arthritis is associated with increased mortality secondary to cardiovascular disease, and that this risk is proportional to the degree of disability secondary to arthritis.”

In the study, researchers reviewed the medical data and outcomes of patients, ages 55 and older, who had hip and knee arthritis between 1996 and 1998. The groups were similar in terms of age, sex, body mass index and medical comorbidities. Half of the patients received TJR and half did not.

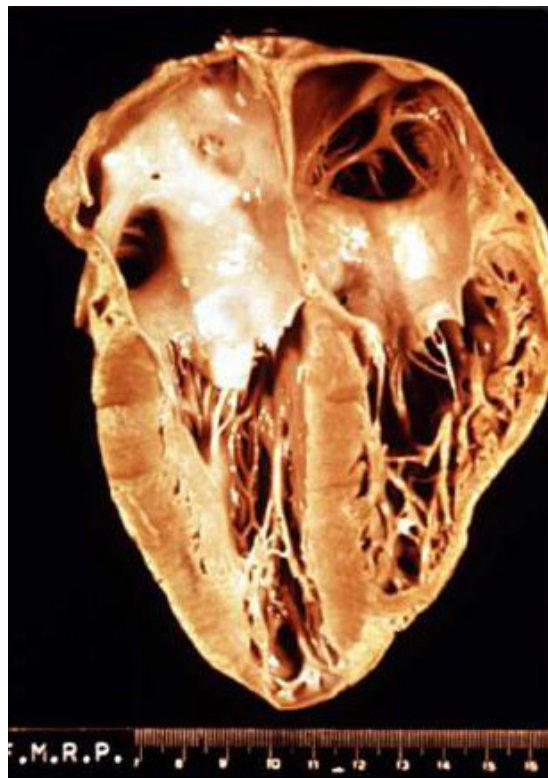
The study found that patients who received a hip or knee replacement were more than 40% less likely to have a serious cardiovascular event, including

a heart attack, stroke, emergent coronary revascularization or death resulting from any of the above.

The study authors concluded that TJR has a cardioprotective benefit in persons with moderate-to-severe arthritis of the hip or knee, possibly due to their increased capability for moderate physical activity. Ravi noted that moderate exercise, such a brisk walk a few times a week, has “direct benefits for hypertension, obesity and diabetes, all of which are risk factors for cardiovascular disease and all of which are highly prevalent in individuals with osteoarthritis.”

The study, “TJA Appears Cardio-protective in Patients with Moderate-severe OA: A Propensity-score Matched Landmark Analysis,” was published in the October 30, 2013 *British Medical Journal*.

—BY (March 20, 2014)



Wikimedia Commons and CDC

## TKR Revisions Rise

It is not news that the number of total knee replacement surgeries are continuing to rise but it is discouraging (and perhaps understandable) that the number of revision total knee replacement (TKR) surgeries are going up as well. Using the Nationwide Inpatient Sample (NIS), researchers looked at the cause of knee replacement failure for 301,718 revision surgeries performed between 2005 and 2010.



Wikimedia Commons and Rohnjones

Revision surgeries were more commonly performed on women rather than men (58%) and most of the patients were between the ages of 65 to 74. More than 60% of the patients had comorbidity, something else wrong with them besides sore knees, at the time of their knee replacement surgery.

Infection in the prosthetic knee joint (periprosthetic joint infection) was the most common reason for revision (25% of patients), and mechanical loosening was the cause in 18.5% of the cases. The TKR procedures were more commonly performed in large urban non-teaching hospitals in the Southern and Midwestern regions of the United States.

Elderly and female patients with a moderate number of comorbidities represented the largest proportion of the revision population. The authors suggest that optimizing patient health before surgery and paying meticulous attention to efforts by the surgical team to minimize the risk of periprosthetic joint infection may decrease the number of knee replacement revisions.

—BY (March 20, 2014)

## REIMBURSEMENT

### Poison Pill Scuttles Bipartisan Permanent Doc Fix

Congressional Republicans have thrown a huge monkey wrench into a previously bipartisan effort to fix CMS' much maligned sustainable growth rate (SGR) formula. The bipartisan deal was agreed to in early February.

"It's a sad state of affairs," Thomas Barber, M.D., a lobbyist for the American Academy of Orthopaedic Surgeons, told *Reuters*. "To see something that was supported by both parties get shanghaied into the partisan politics of the day is very frustrating."

Barber was responding to a bill that passed the Republican-controlled U.S. House of Representatives on March 14, 2014 that included a "Poison Pill" provision delaying the implementation of the Affordable Care Act (ACA) for five years. Replacing the SGR will cost \$138 billion. Republicans wanted that money to come out of the ACA. The President has promised to veto any bill with such a provision and Senate leaders have said they would not consider such a bill in their chamber.

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The bill, passed by the House on a 238-181 vote, would repeal the SGR and replace it with a "quality-based rewards" model and provides incentives to physicians participating in alternative payment models.

Physicians will see a 24% cut in Medicare payments on April 1, 2014 unless

a "Doc Fix" is found or another temporary patch is put in place.

"Just last month, both parties worked in a bicameral process to develop good-faith consensus and were historically close to repealing the dysfunctional payment system and improving health-care for America's senior citizens. It



Image created by RRY Publications, LLC / Source: Morguefile and Aidairi

would be a shame for lawmakers to have done all of that hard work only to have it overcome by partisan politics over budgetary issues,” American Medical Association President Ardis Dee Hoven, M.D. said in a statement after the news broke.

The consensus came after several years of collaborative work by the Republican and Democratic leaders of the key congressional committees that oversee the Medicare program. The leaders, from both houses of Congress, also got input and buy-in from physician groups, and from groups representing Medicare patients.

Fred Upton, the Republican chair of the House Energy and Commerce Committee defended the insertion of the delay of the ACA’s implementation by citing a list of other parts of the health law that the Obama Administration has

already delayed. “If the Administration has decided to delay all these things—almost two dozen—why not delay this, too?” he said. “And why not use the savings then, not only to help the physicians...it’s to help the most vulnerable, our seniors.”

“The bill you have on the floor today is not the destination,” said Representative Michael Burgess, M.D., a Republican from Texas. “It is the key that gets you through the door that gets you to the destination,” he reportedly said.

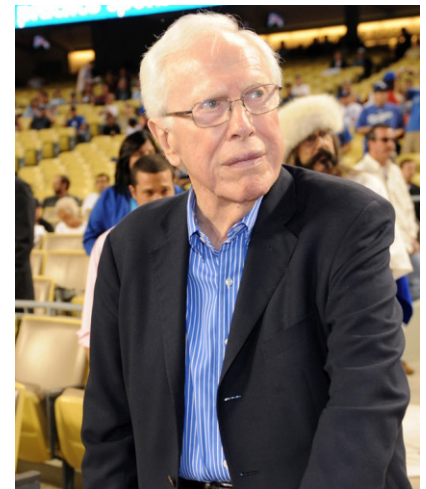
The bipartisan optimism expressed in February has disappeared for now. With mid-term elections on the horizon and the next presidential campaign already underway, kicking the SGR can down the road seems more likely than ever.

—WE (March 18, 2014)

PEOPLE

**The Passing of a Legend: Frank Jobe, M.D.**

On March 6, 2014 the orthopedics world lost a sports medicine pioneer. Frank Jobe, M.D., co-founder of the famed Kerlan-Jobe Orthopaedic Clinic, passed away in Santa Monica, California at the age of 88. Dr. Jobe’s survivors include his wife, Beverly; his sons, Christopher, Meredith, Cameron and Blair; and eight grandchildren.



Frank W. Jobe, M.D., courtesy Kerlan-Jobe Orthopaedic Clinic

James Bradley, M.D., a good friend of Dr. Jobe’s for more than 25 years, told OTW, “Frank Jobe was a humble, serene soul who could flat out operate better than anyone I’ve ever seen. He made even the most difficult cases look like a gentle waltz with those big size 9 hands. One day in 1988 (pre MRIs) I asked Dr. Jobe how he knew that the ulnar collateral ligament in a certain MLB pitcher was incompetent. He said ‘sensitive fingers and thousands of physical exams,’ and just smiled. This man touched the lives of so many surgeons and athletes with a soft encouraging word, kind smile and wink and

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by basically redefining the surgical approaches to the shoulder and elbow in the overhead athlete.”

Frank Jobe was born in 1925 in Greensboro, North Carolina. After graduating from Collegedale Academy, he enlisted in the U.S. Army and went on to serve in World War II as a medical staff sergeant in the 101st Airborne Division. He was captured and held for a short time during the Battle of the Bulge; he went on to earn the Bronze Star Medal, the Combat Medical Badge, and the Glider Badge. Christopher Jobe, M.D., says of his dad’s military experience, “My dad was so impressed with the coolheaded doctors who had to care for patients with bullets flying everywhere. These were the moments that the idea of becoming a surgeon took hold. During the war, dad also volunteered to be a paratrooper because it would mean an extra \$10 per month for him to send home to his mother. He was always a great family man.”

“Dad did discover how to get a decent night’s sleep in the military. He was with our troops on a boat in the turbulent North Atlantic...people were getting sick everywhere. When the rest of the medical corps went to their berths at night dad volunteered to clean up and then he slept on the OR table or a stretcher and actually got some peace.”

Returning to the U.S., Dr. Jobe graduated from La Sierra University in Riverside, California, and obtained a medical degree from Loma Linda University. He was a general practitioner for three years, and then completed a residency in orthopedic surgery and in 1964 joined with Dr. Robert Kerlan as founder of the Southwestern Orthopaedic Medical Group in Los Angeles. It was renamed the Kerlan-Jobe Orthopaedic Clinic in 1985.

“Humble” and “understated” are words that many people use to describe Frank Jobe, including his son, Christopher. He tells *OTW*, “He was a soft spoken, very kind man. He never reacted to anything sensitive immediately...he would walk away and think about things. At one point my daughter was considering becoming a religious study major. The professor told her that the goal of life in Buddhism is to seek happiness and that the most effective way to achieve that was to be kind to others. I told my dad he would make a good Buddhist.”

The Tommy John aspect of Dr. Jobe’s life is widely known. By performing the first reconstruction of the ulna collateral ligament of the elbow, Dr. Jobe saved the career of famed pitcher Tommy John, not to mention countless pitchers after him. Dr. Christopher Jobe tells *OTW*, “He was the most natural orthopedic surgeon I have ever watched. He wasn’t one to start with theory and then come up with solution. He went directly from problem to solution; it was often the rest of us who sought out the theory. Everyone talks about the Tommy John surgery, but I think the greater intellectual feat was the surgery on Orel Hershey. Dad worked out that extra stretch in the front of the shoulder that was responsible for problems in the back of the shoulder. He had a deeply intuitive understanding of biomechanics.”

Neal ElAttrache, M.D. is a sports medicine specialist with the Kerlan-Jobe Orthopaedic Clinic in Los Angeles, California, and is chairman of the Board of that facility. He told *OTW*, “One time we were doing a Tommy John surgery on a baseball player from Japan; there were a number of Japanese surgeons there that day to observe Frank’s technique. Frank Jobe was left handed, but this was not widely known. He sat down at the OR table and said to the interpreter, ‘Tell them I’m going to do

this one for them left handed.’ They thought he was serious; he said, ‘Do you think I should tell them? They do know I’m kidding, right?’

“Frank was the most talented surgeon I have ever seen. When I joined the practice in 1990 he had begun to see that much of what had been done open probably could be done arthroscopically with less invasiveness. So rather than be like his colleagues who stuck with open surgery, Frank embraced arthroscopy and encouraged me to embrace it. For a guy who made his reputation as an open shoulder and elbow surgeon to get up at meetings and say, ‘arthroscopy is better’ was really something.”

Dr. ElAttrache, the surgeon ultimately selected by Frank Jobe to perform his arthroscopic rotator cuff repair, says, “There were big name open surgery legends at these meetings, and Frank was kind enough to protect me when things got rough. At that time the Shoulder and Elbow Society was much smaller; I had just been inducted and my colleagues and I were debating open versus arthroscopic rotator cuff repair. We were having our rear ends hung out to dry when Frank stood up, made the ‘time out’ sign, and announced that he had had both of his shoulders done arthroscopically. That moment completely changed the landscape for surgeons trying new things.”

The supremely talented and kind Frank Jobe will be missed by all whose lives he graced.

*The family asks that in lieu of flowers those wishing to honor Dr. Frank Jobe make a donation to his orthopedic research foundation. The Frank Jobe Foundation//326 S. State Street//Los Angeles, CA//90033.*

—EH (March 21, 2014)

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