

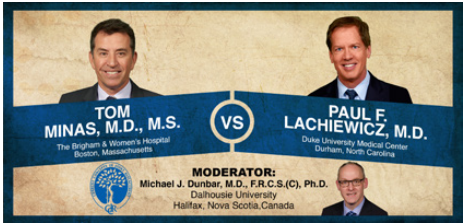
Orthopedics This Week

WEEK IN REVIEW

4 We Rate All 20 Presidential Candidates on Healthcare >> Fifteen Republicans and five Democrats. Each one wants to be President. And each one “knows” how to manage or un-manage healthcare in the United States. Think you know how each candidate stands on healthcare? Think again. There are some surprises.

9 Top Trauma Doc – Clifford B. Jones, M.D. – Joining CORE Institute // Remarkable Sound Wave Treatment Succeeds for Osteoid Osteoma // FORCE-TJR Obtains Certification as a QCDR >> Two osteoid osteoma patients were successfully treated with a remarkable new magnetic resonance-guided high-intensity ultrasound. Famed traumatologist Clifford B. Jones, M.D. joins The CORE Institute. And FORCE-TJR becomes certified as a Qualified Clinical Data Registry.

12 Minas, Lachiewicz Debate Patient Specific TKA >> “Patient specific TKA—especially in large patients or very small patients—gives a precise fit. It’s easy for the OR staff, the jigs are accurate, and you get excellent intraoperative stability,” argues Tom Minas. Paul Lachiewicz counters, “Ask yourself three questions: Does it provide better outcomes and decreased revisions for patients? Is it less expensive? Is it easier for the surgeon? For patient specific instrumentation the answer is ‘NO’ to all three.”



BREAKING NEWS

15 Weigao Orthopaedic Device to Utilize Invibio’s PEEK-OPTIMA

100th FLXfit Expandable Cage Implanted

Major Depression, Anti-Depressants Linked With Lower BMD

Feds Issue Fraud Alert Over Doc Medical Directorships

Medtronic Shareholders Drop Infuse Lawsuit

Exercise Cuts Mortality 40%—New 6,000 Patient Study

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: The market for equities is increasingly bifurcated into stocks which rise or fall over news like the Greek Debt crisis or soft oil prices and stocks which rise or fall over sales and earnings growth surprises. In other words, it's a small cap, stock picker's market. All the large, diversified ortho equities like SYK, ZMH, DePuy (JNJ) or Medtronic spine fall into the first category.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Stryker	22.78%	2.78%	Stryker became the least expensive equity in orthopedics this week based on its composite P/E, Price-to-Sales and P/E-to-Growth ratios.
2	1	Integra LifeSciences	13.74	4.77	Integra's equity has been rising steadily for more than a year and remains comparatively cheap. SeaSpine spin off done.
3	3	ConMed	10.41	4.85	Buyers returned to CNMD last week despite lukewarm sales and earnings outlook for the June quarter. Upside surprise in the works?
4	5	Globus Medical	30.82	5.24	Hires Grant Thornton as new auditor. Most analysts think GMED will report 10-12% jump in sales for June quarter. And earn 30 cents on each sales dollar.
5	4	NuVasive	9.30	10.89	Buyers flocking to NUVA these days. Valuation on a trajectory to reach NUVA's former heights.
6	6	RTI Biologics	7.50	4.62	New analyst coverage combined with a solid financial report for Q1 has investors adding RTI to their small cap growth portfolios.
7	8	Medtronic	27.92	0.43	Medtronic, along with JNJ, are the poster children for medical stocks which are buffeted by global currency, debt or commodity volatility.
8	9	Zimmer	30.35	(0.04)	Is this the week Zimmer and Biomet consummate their long, long courtship and merger?
9	10	Johnson & Johnson	28.44	(2.11)	From mid-2012 to November 2014, JNJ was on a tear rising from the mid-\$60s to over \$100 per share. Now it is treading water.
10	7	Smith & Nephew	20.19	(2.90)	Syncera is SNN's most interesting and innovative initiative in years. Can it affect sales and earnings growth in 2015? That's a long shot.

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SUBMISSIONS DEADLINE: AUGUST 14, 2015

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	LDR Holding Corp.	LDRH	\$44.44	\$1,181	16.55%
2	NuVasive	NUVA	\$49.99	\$2,417	10.89%
3	CryoLife	CRY	\$11.11	\$315	9.78%
4	Wright Medical	WMGI	\$27.65	\$1,421	9.07%
5	Alphatec Holdings	ATEC	\$1.45	\$145	9.02%
6	TiGenix	TIG.BR	\$0.85	\$136	8.58%
7	MiMedx Group	MDXG	\$10.15	\$1,103	7.29%
8	Tornier N.V.	TRNX	\$26.72	\$1,309	6.88%
9	Orthofix	OFIX	\$33.97	\$637	6.69%
10	Globus Medical	GMED	\$25.92	\$2,460	5.24%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Aurora Spine	ASG	\$0.66	\$13	-7.25%
2	Bacterin Intl Holdings	BONE	\$3.80	\$27	-3.06%
3	Smith & Nephew	SNN	\$34.13	\$15,262	-2.90%
4	Johnson & Johnson	JNJ	\$98.35	\$272,729	-2.11%
5	Zimmer Holdings	ZMH	\$112.20	\$19,119	-0.04%
6	Medtronic	MDT	\$75.52	\$107,363	0.43%
7	Exactech	EXAC	\$21.19	\$296	0.52%
8	K2M Group Holdings	KTWO	\$24.70	\$979	1.52%
9	MicroPort Scientific	853	\$0.53	\$751	2.75%
10	Stryker	SYK	\$95.67	\$36,202	2.78%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	\$98.35	\$272,729	16.58
2	Exactech	EXAC	\$21.19	\$296	18.27
3	Globus Medical	GMED	\$25.92	\$2,460	19.18
4	Zimmer Holdings	ZMH	\$112.20	\$19,119	19.29
5	Stryker	SYK	\$95.67	\$36,202	21.86

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	\$49.99	\$2,417	103.11
2	MiMedx Group	MDXG	\$10.15	\$1,103	101.50
3	CryoLife	CRY	\$11.11	\$315	59.14
4	RTI Biologics Inc	RTIX	\$6.57	\$377	43.00
5	Smith & Nephew	SNN	\$34.13	\$15,262	30.46

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	\$25.92	\$2,460	1.57
2	CryoLife	CRY	\$11.11	\$315	1.97
3	Exactech	EXAC	\$21.19	\$296	2.05
4	Con < ed	CNMD	\$56.22	\$1,552	2.13
5	Stryker	SYK	\$95.67	\$36,202	2.56

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MiMedx Group	MDXG	\$10.15	\$1,103	6.77
2	NuVasive	NUVA	\$49.99	\$2,417	6.75
3	Smith & Nephew	SNN	\$34.13	\$15,262	4.76
4	Zimmer Holdings	ZMH	\$112.20	\$19,119	3.75
5	Medtronic	MDT	\$75.52	\$107,363	3.40

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	\$1.45	\$145	0.70
2	Bacterin Intl Holdings	BONE	\$3.80	\$27	0.75
3	Exactech	EXAC	\$21.19	\$296	1.20
4	RTI Biologics Inc	RTIX	\$6.57	\$377	1.40
5	Orthofix	OFIX	\$33.97	\$637	1.63

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$0.85	\$136	16.25
2	LDR Holding Corp.	LDRH	\$44.44	\$1,181	8.83
3	MiMedx Group	MDXG	\$10.15	\$1,103	7.91
4	K2M Group Holdings	KTWO	\$24.70	\$979	6.21
5	Medtronic	MDT	\$75.52	\$107,363	5.30

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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We Rate All 20 Presidential Candidates on Healthcare

BY ROBIN YOUNG



Wikimedia Commons and Paul Farley

We rate all 20 candidates so you don't have to.

Fifteen Republicans and five Democrats. Each one wants to be President. And each one “knows” how to manage or un-manage healthcare in the United States.

With the passage of the Affordable Care Act and the hundreds of legislative and legal attempts to undo that passage, healthcare in America—its costs, its availability, its ability to heal or hurt the body politic—continues to be a very popular political football.

As presidential candidate and Texas Republican Senator Ted Cruz said just after the 2014 mid-term elections:

“A lot of folks in the press said what a disaster it was to stand up

and fight on ObamaCare. That it was going to cost Republicans the majority. It was going to cost seats. Let me point out, we just had an historic election where we won. We've got the biggest majority in the House since the 1920s. And the number one issue that candidates campaigned on was ObamaCare. Not only did the disaster that a lot of folks predicted not happen, it was the biggest victory we've had in a long time.”

Source: [Fox News Sunday 2014 interview of 2016 presidential hopefuls, Nov 23, 2014](#)

Yup, healthcare policy is “in”. Should we be afraid? Very afraid?

Pontificating Is the Winning Healthcare Strategy

With, count 'em, 20 candidates criss-crossing Iowa and New Hampshire (and another baker's dozen in the wings) there is no shortage of circular and obfuscating healthcare pronouncements. Separating the contenders from the pretenders was no easy task. Credit for compiling each candidate's utterances—which occasionally coalesce into a specific policy or set of policies—goes to www.ontheissues.org.

So, here's how the candidates stack up on the “ObamaCare is a Disaster” continuum: (See table on page 5)

Based on comments collected by *On The Issues* (www.ontheissues.org), which advertises “Every Political Leader on Every Issue,” Ted Cruz and Scott Walker are the most anti-ObamaCare candidates running for President. Nearly 77% and 71%, respectively, of all Cruz and Walker's healthcare utterances being attacks on ObamaCare.

After those two, the discussion broadens out to include all manner of other healthcare care topics. Most surprising, perhaps, is Mike Huckabee.

While Huckabee had more healthcare comments than any of his Republican colleagues, none concerned ObamaCare. That's right. Zero. Huckabee was more interested in talking about subsidizing extraordinary medical expenses, banning smoking from workplaces, portable medical records, changing the culture of healthcare, simplifying healthcare or using prevention and weight loss as tactics to lower healthcare costs.

ObamaCare Is a Disaster

Rank	Candidate	# of "Disaster" Comments ¹⁻² Percentage = Total # of Healthcare Comments	Representative Quote
1	Ted Cruz	10 / 13 76.9%	Throw my body in front of a train to stop ObamaCare. (Apr 2012)
2	Scott Walker	5 / 7 71.4%	To best benefit economy, replace ObamaCare. (Jan 2014)
3	Rand Paul	5 / 11 45.5%	ObamaCare is still unconstitutional, despite the Supreme Court. (Aug 2012)
4	Rick Perry	10 / 29 34.5%	ObamaCare is an abomination for this country. (Dec 2011)
5	Marco Rubio	4 / 12 33.3%	Defund, repeal, & replace federal care with free market. (Jul 2010)
6	Donald Trump	1 / 3 33.3%	Kill ObamaCare before it becomes a trillion-ton weight. (Dec 2011)
7	Jeb Bush	4 / 17 23.5%	ObamaCare is flawed to its core, and doesn't work. (May 2014)
8	Ben Carson	2 / 9 22.2%	ObamaCare robs you of your ability to control your own life. (May 2014)
9	Bobby Jindal	2 / 10 20.0%	Market-based alternatives to top-down ObamaCare. (Nov 2010)
10	Carly Fiorina	1 / 5 20.0%	Repeal ObamaCare; it's vast legislative overreach. (Nov 2014)
11	Rick Santorum	3 / 24 12.5%	I believe ObamaCare will rob America of its soul."(Jan 2012)
12	Mike Huckabee	0 / 35 0%	Healthcare reform requires cultural change over a generation. (Nov 2008)
13	Hillary Clinton	0 / 90 0%	Non-employer system better; but don't turn back ObamaCare. (Mar 2014)
14	Martin O'Malley	0 / 8 0%	ObamaCare will get past the scare tactics and will work. (Feb 2014)
15	Bernie Sanders	0 / 28 0%	Make health care a right, not a privilege. (Nov 1999)
16	Lincoln Chafee	No comments compiled	
17	Mark Everson	No comments compiled	
18	Lindsey Graham	No comments compiled	
19	George Pataki	No comments compiled	
20	Jim Webb	No comments compiled	

Note 1: First number denotes number of "Disaster" comments; second number denotes number of total comments

Note 2: Red denotes predominately anti-government healthcare, blue denotes predominately neutral

Source: RRY Publications LLC

Interesting guy that Huck.

And here is how the candidates line up on the “Socialized Medicine’ is not an oxymoron” continuum: (See table on page 7)

Martin O’Malley hasn’t seen a healthcare problem that government can’t solve. He even out-socializes declared Socialist, Bernie Sanders. More than 87% of O’Malley’s comments are pro-government healthcare while Bernie devoted a mere 35% to his commentary to promoting government’s role in healthcare.

As these tables illustrate, some candidates have staked out simple positions at the far corners of the political spectrum. But a handful are clearly grabbing space in the middle.

One candidate, Donald Trump, appears to be occupying both extremes—while

studiously avoiding the middle. One day he wants to kill ObamaCare. Later he wants universal health insurance coverage.

Based on their comments, the candidates in the middle include Hillary Clinton, Jeb Bush and a couple or more of the current or former governors like Huckabee, Jindal or Perry as well as putative Republican front runner Senator Rubio.

As these tables illustrate, there are Republicans and Democrats who don’t immediately default to one liners and appear comfortable talking about the nuances of the healthcare system as a system.

Rick Perry, for example, talks about the problems of rural healthcare. Hillary Clinton talks about drug costs. Mike Huckabee talks about life style changes

and the role of prevention in healthcare. Marco Rubio talks about prescription drug policy for senior citizens.

Gallup Poll: “Voters Warming to Obamacare”

What do voters want? After all, these candidates must appeal to voters—first of their own party then of all political persuasions.

ObamaCare has been the law of the land for two years now and, according to a recent Gallup Poll, Americans are more positive about federal government doing healthcare insurance now than they were at any time since 2001.

According to Gallup, 43% say they are satisfied with the government’s work in healthcare, up 14 percentage points from 2013. Still, most of the people polled by Gallup (56%)



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Socialized Medicine Is Not an Oxymoron

Rank	Candidate	# of "Disaster" Comments ¹⁻² Percentage = Total # of Healthcare Comments	Representative Quote
1	Martin O'Malley	7 / 8 87.5%	Supports government-run healthcare. (Aug 2010)
2	Bernie Sanders	10 / 28 35.7%	MEDS Plan: Cover senior Rx under Medicare. (Jan 2001)
3	Donald Trump	1 / 3 33.3%	We must have universal health care. (Jul 2000)
4	Ben Carson	2 / 9 22.2%	Government responsibility for catastrophic coverage. (Jan 2012)
5	Rick Perry	6 / 29 20.6%	More federal funding for rural health services. (Aug 2001)
6	Hillary Clinton	17 / 90 18.9%	Universal health care is a core Democratic principle. (Jan 2008)
7	Jeb Bush	3 / 17 17.65	Leave research funding to feds, not state. (Jun 2001)
8	Marco Rubio	2 / 12 16.7%	Expand prescription benefits to low-income seniors. (Jun 2012)
9	Bobby Jindal	1 / 10 10.0%	Establish a national childhood cancer database. (Mar 2007)
10	Mike Huckabee	3 / 35 8.6%	Give Americans Congress' healthcare, or give Congress ours. (Aug 2007)
11	Rick Santorum	1 / 24 4.2%	Voted YES on funding GOP version of Medicare prescription drug benefit. (Apr 2001)
12	Ted Cruz	0 / 13 0%	Defund, repeal, & replace federal care with free market. (Jul 2010)
13	Carly Fiorina	0 / 5 0%	Repeal any federal health care takeover. (Jul 2010)
14	Scott Walker	0 / 7 0%	Didn't accept additional Medicaid money from ObamaCare. (Dec 2013)
15	Rand Paul	0 / 11 0%	Voted NO on the Ryan Budget: Medicare choice, tax and spending cuts. (May 2011)
16	Lincoln Chafee	No comments compiled	
17	Mark Everson	No comments compiled	
18	Lindsey Graham	No comments compiled	
19	George Pataki	No comments compiled	
20	Jim Webb	No comments compiled	

Note 1: First number denotes number of "Disaster" comments; second number denotes number of total comments

Note 2: Red denotes predominately anti-government healthcare, blue denotes predominately neutral

Source: RRY Publications LLC

remain unsatisfied with government run healthcare.

Gallup has been polling Americans about their attitudes toward government healthcare work for 14 years (since 2001). The first time they asked the question, 27% were satisfied with government healthcare work. In the Gallup survey conducted between April 29 and May 2 this year (2015), 43% said they were satisfied.

Said Gallup: “Americans’ higher satisfaction with the government’s work in healthcare is reflected across the three major partisan groups. A solid 65% of Democrats this year are content with the government’s role in healthcare, contrasted with 39% of

independents and 15% of Republicans. While Republican satisfaction is by far the lowest, it is up modestly from 7% two years ago. Satisfaction among Democrats and independents rose 12 and 13 percentage points, respectively.”

Will Positions Change?

If Americans are increasingly comfortable with ObamaCare, will positions evolve?

It is noteworthy that the Supreme Court is getting ready to rule on a key provision of ObamaCare. How will these candidates respond if the Court rules, in effect, to defund health insurance to millions of Americans?

While it is likely that the candidates at either extreme—O’Malley or Sanders for the Democrats, Cruz, Walker or Santorum for the Republicans—will wallow in their intransigence, the others will likely evolve—probably toward the middle. Where most voters are.

And part of the enjoyment of this political season is to watch, as the debates happen, how the candidates wiggle and squirm under the heat and pressure of the Presidential campaign pressure cooker.

Assuming, of course that a stage exists which is large enough to hold all the Republican candidates. ♦

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Top Trauma Doc – Clifford B. Jones, M.D. – Joining CORE Institute // Remarkable Sound Wave Treatment Succeeds for Osteoid Osteoma // FORCE-TJR Obtains Certification as a QCDR

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

Clifford B. Jones, M.D. Joining CORE Institute Dr. Clifford Jones, a world renowned orthopedic trauma surgeon, is joining The CORE Institute. Dr. Jones' work has been widely recognized, from winning an Achievement Award from the American Academy of Orthopedic Surgeons to being named a Top U.S. Orthopedic Trauma Surgeon in 2012 in *Orthopedics This Week*.

“Dr. Jones has earned a national reputation as a leading traumatologist and we couldn't be more excited that he chose to join our talented team at The CORE Institute,” said Dr. Jason Scalise, vice chairman at The CORE Institute, in the June 4, 2015 news release. “While many orthopedic physicians know Dr. Jones for his research that has been recognized in several highly regarded medical journals or for the hundreds of lectures he has given, his patients know him for his personalized treatment plans to help each patient receive the best possible outcomes. It is with great excitement that we welcome him to the CORE team.”

Dr. Jones told *OTW*, “My first steps in this new role will be to specifically create an enhanced, well-functioning orthopedic trauma program at The CORE Institute in collaboration with Banner Healthcare concerning orthopedic trauma cases, education, treatment and prevention and improve upon the orthopedic trauma system for the state of Arizona. This will involve orthopedic trauma surgery but will also include a



Clifford B. Jones, M.D.

comprehensive, complete and consistent bone health program which will hopefully improve primary fracture healing and secondary or subsequent fracture prevention in both young and old patients.”

First in U.S.: Osteoid Osteoma Treated With MR Ultrasound Method Two cancer patients are much healthier today thanks to sound wave energy. Doctors from the Sheikh Zayed Institute for Pediatric Surgical Innovation at Children's National Health System are the first in the United States to treat osteoid osteoma using an experimental magnetic resonance-guided high-intensity focused ultrasound (MR-HIFU) method.

According to the May 27, 2015 news release, the MR-HIFU method makes use of “focused sound wave energy to heat and destroy the targeted tumor under MRI guidance. This precise and controlled method does not require a scalpel or needle, greatly reducing the risk of complications like infections and bone fractures. It is also a faster treatment option, with expected total procedure time of an hour or less. In the U.S., MR-HIFU is used to treat uterine fibroids and painful bone metastases from several types of cancer in adults, but it has not been used in children.”

Asked what has prevented this kind of surgery from being more widely used, Karun Sharma, M.D., Ph.D., director

of Interventional Radiology at Children's National and principal investigator for the osteoid osteoma trial, told OTW, "MR-HIFU is a relatively new technology that is not yet widely available. It is currently used in adults for painful bone metastases and uterine fibroids. It is also being investigated and developed for many other diseases, including cancer and epilepsy. This is a very promising non-invasive treatment option but more clinical trials are still needed before it becomes more widely used."

"Both participants were evaluated by our multidisciplinary team and found to be suitable for MR-HIFU ablation. Our team includes members from interventional radiology, oncology, surgery, and orthopedics as well as biomedical engineers specializing in MR-HIFU. In both cases, the osteoid osteoma lesions were accessible to the MR-HIFU beam

and far enough from critical structures like nerves to be safely treated."

"Patients who are unable to have an MRI are not appropriate for this treatment option. For example, patients who have a prosthesis, pacemaker or another non-MRI compatible device. Also, the location and size of the tumor are important considerations. For example, patients who have very large tumors or tumors which are very close to large nerves may not be appropriate for this treatment at this time."

Looking forward, Dr. Sharma noted, "As part of our current research study using MR-HIFU to ablate osteoid osteoma, we will follow the participants for one year after their treatment. Other projects our team in the Sheikh Zayed Institute for Pediatric Surgical Innovation at Children's National are working on include exploring the use of MR-

HIFU as a noninvasive technique for ablating growth plates and malignant solid tumors. We have an open clinical trial for children and young adults with refractory soft tissue tumors, which is being performed in collaboration with Dr. Bradford Wood's team at the NIH [National Institutes of Health]. We are also exploring the use of MR-HIFU to enhance delivery of local chemotherapy to tumors."

FORCE-TJR Certified as Qualified Clinical Data Registry Since 2010 the details of 30,000 total joint patients have been tracked by FORCE-TJR (Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement). Now, FORCE-TJR has been certified as a Qualified Clinical Data Registry (QCDR).

As part of this certification, says the June 4, 2015 news release, FORCE-

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TJR has developed **new** measures that are not related to The Physician Quality Reporting System (PQRS). These include:

- Pain and functional status assessment for hip and knee replacements
- Improvement in pain and function after hip and knee replacements
- Mental health assessment for patients who undergo hip and knee replacements
- Assessment and improvement on patients with osteoarthritis in the hip or knee

“The new QCDR designation allows FORCE-TJR to define new quality measures, including patient-reported outcomes, and to submit these data to CMS on behalf of our members—without any additional data collection. The data serve both their internal quality moni-

toring and meet the CMS mandate,” said Patricia Franklin, M.D., FORCE-TJR’s registry director.

David Ayers, M.D., co-lead of FORCE-TJR and chair of the Department of Orthopedics and Physical Rehabilitation at UMass Medical School, told OTW, “Our biggest opportunity is that we are transitioning away from a federally funded grant program which was funded by the Agency for Healthcare Research and Quality (AHRQ) for the first four years, and AHRQ defined the number of hospitals and surgeons who were able to participate in first cohort. We are transitioning to a public/private partnership that allows FORCE-TJR to accept an unlimited number of new members, and as a result, we are expanding rapidly.”

“Our other challenge is that 40% of surgeons and physicians are not partic-

ipating in the PQRS program. Because the healthcare system is transitioning from a volume-based reimbursement system to a value-based reimbursement system, clinicians are becoming frustrated that they cannot build their own infrastructure needed to collect data. They often don’t realize a program such as FORCE can facilitate collecting what they need to participate in the PQRS program, and can also collect information needed for bundled payment programs, and to explicitly show the value of the care that they provide their patients. Surgeons and physicians need to know that by joining FORCE-TJR, our method will make the entire process exceedingly easy because we collect information for them.”

“FORCE-TJR is expanding more rapidly than ever because more and more surgeons are recognizing the benefits of our program and want to join.” ♦

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Minas, Lachiewicz Debate Patient Specific TKA

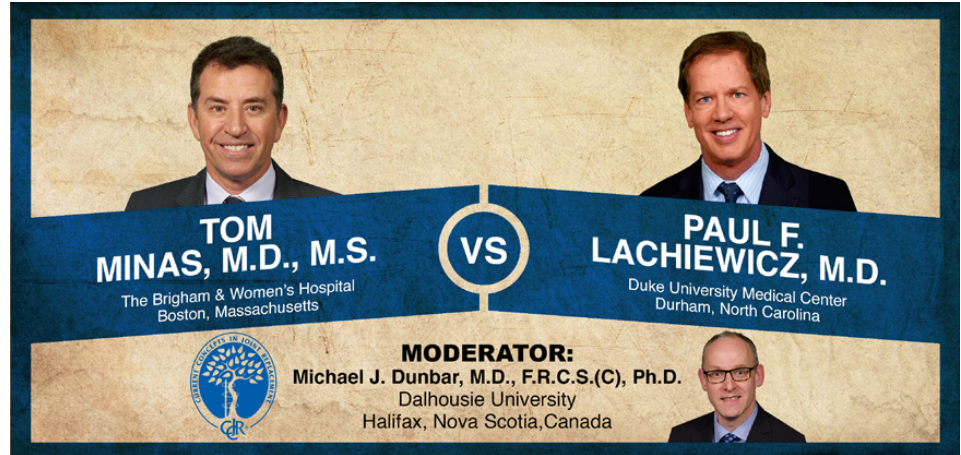
BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

“Patient specific TKA—especially in large patients or very small patients—gives a precise fit. It’s easy for the OR staff, the jigs are accurate, and you get excellent intraoperative stability,” argues Tom Minas. Paul Lachiewicz counters, “Ask yourself three questions: Does it provide better outcomes and decreased revisions for patients? Is it less expensive? Is it easier for the surgeon? For patient specific instrumentation the answer is ‘NO’ to all three.”

This week’s Orthopaedic Crossfire® debate was part of the 31st Annual CCJR – Winter meeting, which took place in Orlando this past December. This week’s topic is “Patient Specific TKA: Optimizes Outcomes.” For the proposition is Tom Minas, M.D., M.S. of The Brigham & Women’s Hospital. Paul F. Lachiewicz, M.D. of Duke University Medical Center is in opposition. Moderating is Michael J. Dunbar, M.D., F.R.C.S.(C), Ph.D. from Dalhousie University.

Dr. Minas: “I wonder what has changed since the 1980s. We put in a knee replacement that is ‘symmetric’ in an asymmetric space; we try to get the best anterior-posterior (AP) or medio-lateral (ML) fit. There is also overhang and possibly soft tissue impingement; and we continue to loosen and release some sides and stuff the other side.”

“Despite this, we have excellent survivorship out to 20-25 years, but patient dissatisfaction ranges from 15-40% (looking at all studies the average is 20%). So when we considered developing an anatomical custom knee replacement system we thought about form and function.”



Current Concepts in Joint Replacement/RRY Photo Creation

“The iTotal has a mechanical axis alignment, patient specific fit (ML and AP), restoration of medial and lateral surfaces independently, and restoration of ligaments to the original state. Bone preservation with this implant is about 40% better than the off-the-shelf implants because of the design characteristics of the femur. It is a dual insert design, and because each poly is individually manufactured, it has better poly wear. The medial and lateral joint lines are different, both distally and posteriorly, and that’s what we try to restore. We do this by CT scanning the hip, knee, and ankle, and virtually realigning the patient’s leg to neutral mechanical axis.”

“In our first 13 cadavers we found that regarding the entire postoperative leg alignment, we were within 1.2 degrees of neutral on every one. The kit includes disposable, nylon-printed, individualized jigs, and one reusable tray.”

“You can either do a classic gap balancing technique or a measured resection. We restore the distal-medial and lateral posterodistal joint lines; once the osteo-

phytes are removed, then minimal soft tissue balancing is required.”

“Kinematic studies done in cadavers (Patil, S et al.) looked at rollback and lateral liftoff, rollback with flexion, and lateral liftoff with extension. These Scripps researchers found that in pre- and post-operative cadavers for the custom implant it was virtually the same. With the off-the-shelf implant there was a difference and there was lateral liftoff and anterior paradoxical rollback. When Komistek et al. looked at two different groups of custom manufactured versus off-the-shelf implants (10 of each) they found that the custom implant more normally mimicked natural kinematics...with no liftoff and normal posterior rollback.”

“Regarding individualized jig accuracy, Gary Levengood found that pre- and post-operative alignment was within 0.2 degrees of neutral mechanical axis. This was done intraoperatively with computer navigation before doing cuts (but not adjusting his cuts); all patients obtained extension.”

“In young patients who have good flexion preop you often lose flexion with a total knee replacement. But what I see in these patients is very deep flexion and a healthy-appearing range of motion (ROM)—even after osteotomy surgery.”

“Because I can’t review my own cases, we had one of our attendings (Andreas Gomoll) look at 110 consecutive knees with an average age of 56.1, an average body mass index of 30, and nearly two years of follow-up. We only had two patients fail, one for tibial subsidence and loosening due to obesity and osteoporosis...and the other because of global laxity. As for patient reported results, 87% were ‘good’ or ‘excellent’ while 98% of patients said they were ‘somewhat’ or ‘completely satisfied’ with their results.”

“My experience is that especially in large patients or very small patients the fit is precise, it’s easy for the OR staff, the jigs are accurate, and excellent intraoperative stability with no midflexion laxity.”

Dr. Lachiewicz: “There are five bad ideas in knee replacement: carbon-reinforced poly, the metal-backed patella, low-molecular weight heparin, gender-specific knees, and now, patient-specific (PS) instruments. This is the reinvention of computer-assisted navigation that shifts the work from the intraoperative to the preoperative setting. You have to get an MRI or CT scan, the surgeon has to review and adjust the engineer’s plan for fixed deformity, flexion contracture, and ligament balance.”

“The marketed advantages of patient-specific instruments sound like the

Holy Grail: ‘avoid outliers, provide better outcomes, patient satisfaction, and implant durability, and less stress for the surgeon.’ The disadvantages? The MRI is \$1,000 and the jigs are \$1,500. Then there’s the work that your office staff has to do, your own learning curve, and your prep time (\$500/hour?).”

“A prospective study by Stronach, Peters, et al. (66 knees) found that the guides didn’t fit in 12% of the femurs, the implant size changed in 77% of the femurs and over 50% of the tibias. As for cost-effectiveness, Slover et al published a study in 2012 using a Markov model. They assumed that an MRI costs \$1,000 and the jig manufacturing costs \$1,500. The assumed survival of the conventional instrument was 94.3% at 10 years and 90.1% at 15 years. Because of the increased cost of PS instruments

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of \$4,600 the revision rate is going to have to be reduced by 50% in order for this to be cost effective...and this is just not going to happen.”

“Robert Barrack’s colleague, Ryan Nunley, published a 2012 study of 50 conventional versus 50 PS instruments (the Signature) and 50 other PS instruments (OtisMed). They found that the outliers were similar in all three groups; there were even more valgus outliers with both PS instrument systems. The Nunley study found similar tourniquet times, 12 minutes less in the OR with PS instruments, and a hospital savings of \$25 per case—nothing significant.”

“With Barrack’s 2014 data he found no difference between the custom cutting guide cohort and the standard cohort as far as incremental improvement in clinical outcome, and there was a trend for more improvement with the standard instruments. Also, patient satisfaction and residual symptoms were identical between the two groups.”

“Barrack, Nunley et al recently completed a systematic review of all Level I, II, and III guidelines where they examined alignment, efficiency, and results. The overwhelming consensus was that PS instrumentation does not improve TKA outcomes. In 2009 I published on conventional instruments, and we spent five minutes preoperatively templating your components. Doing that, I got into the high 90s—and even 99%—on the tibial coronal alignment.”

“You should ask yourself three questions: Does it provide better outcomes and decreased revisions for patients? Is it less expensive? Is it easier for the surgeon? For PS instrumentation the answer is overwhelmingly ‘NO’ to all three.”

Moderator Dunbar: “Tom, Paul hit you hard with data!”

Dr. Minas: “My talk was about patient specific implants, not on PS instrumentation. The instrumentation that was designed here was to place these implants accurately. It began with MRI based PS instruments, which didn’t turn out well because everything couldn’t be referenced off the cartilage because it was a ‘guesstimate.’ The calcified tidemark can be as thick as 5mm. CT guidance turned out to be very accurate when we were developing these instruments; with the cadaver knees we were within one degree each time.”

“Regarding the early postop follow-up, because the joint line is restored so accurately, and the sagittal J-curve is the same, we don’t see midflexion laxity in these knees.”

Dr. Lachiewicz: “Tom, your slides said that patients were somewhat satisfied or very satisfied. How many were actually very satisfied? That is our goal with these instruments and implants. Also, it’s never been shown that patient satisfaction is related to the J-curve. Also, I think that your patient population is not like what the rest of us are doing (a BMI of only 30). Patients with high BMI are more dissatisfied with TKA.”

Dr. Minas: “I agree. However, previously my partner and I looked at 400 consecutive off-the-shelf implants that he and I did. The highest patient satisfaction we got was 85%. My highest BMI with these patients was 59, so we did have a big range...but I like the idea that I take so little bone away.”

Moderator Dunbar: “Paul, it’s perhaps a bit narrow for you to say that we’d have to reduce the revision rate by 50% in order to be cost effective.”

Dr. Lachiewicz: “I think eventually the insurers will determine what is viable and what’s not...and Tom didn’t mention the cost of this.”

Moderator Dunbar: “But if we’re just focusing on revision rate as the outcome are we missing some of the other ‘lifts’ that we may get?”

Dr. Lachiewicz: “I reject the notion that PS instruments or custom total knees have greatly improved patient satisfaction.”

Moderator Dunbar: “Tom, what about constitutional varus?”

Dr. Minas: “It probably occurs in a quarter to a third of males that I treat. I don’t leave them in constitutional varus; the tibial cuts are at 90 degrees to the axis of the tibia. The only difference is that the joint line is preserved because you can use a thinner poly on the medial side and a thicker on the lateral side.”

Moderator Dunbar: “But if we’re going to be truly patient specific should we eventually deviate from that?”

Dr. Minas: “I like Mark Pagnano’s approach, namely, err 1-2 degrees of varus in constitutional varus.”

Dr. Lachiewicz: “It’s not been proven. If you look at patients who seem to wear their poly sooner, they are left in slightly more varus than those with neutral mechanical alignment. That’s my opinion.”

Moderator Dunbar: “Thank you, gentlemen.” ♦

Please visit www.CCJR.com to register for the 2015 CCJR Winter Meeting, December 9 - 12 in Orlando, Florida.

COMPANY

Weigao Orthopaedic Device to Utilize Invivo's PEEK-OPTIMA

China-based Weigao Orthopaedic Device Co., Ltd. has chosen to work with Invivo Inc. on its spinal stabilization system known as Tulip. The device uses semi-rigid rods made from PEEK-OPTIMA, and is meant for one to three spine level surgeries. Surgeons may choose from either a 6.35mm-diameter round rod or a 6.35x7.2mm-diameter oval rod.

“Throughout the product development and clinical adoption of our

PEEK-OPTIMA semi-rigid rods Invivo was a great help to our company. This includes technical support and testing during the R&D phase,” stated Kui Yang, Vice General Manager of Sales at Weigao Orthopaedic Device, in the May 28, 2015 news release. “Invivo invited, for example, overseas clinical experts to China to exchange experience in PEEK-OPTIMA based semi-rigid rod techniques. In addition, multi-center program discussions assisted in launching the product and promoting its clinical adoption. We appreciate the value of our relationship with Invivo, and we hope to continue our collaboration.”

The news release indicates: “Being non-metallic, PEEK-OPTIMA does not produce metal ions when implanted and offers, in addition, high strength

combined with a modulus very similar to that of human bone. The proven implantable material, with a 15-year history of successful clinical application, has been widely used in the therapeutic treatment of the spine, orthopaedics, arthroscopy and trauma, with PEEK-OPTIMA used in over 5 million implanted devices worldwide.

Asked what this means for Invivo's international expansion, John Devine, Ph.D., Strategic Business Unit Director, Medical commented to *OTW*, “It is extremely important to Invivo that we drive and deliver innovation globally. We are already a global player and emerging markets will be a key part of our future growth, both for Spine, our existing core business, and for our new platforms such as Dental, Trauma or Knee. The collaboration we have with Weigao is a fantastic example of our ability to work together at all stages of the medical device development in terms of development, testing and clinical introduction. It's essential that we form great partnerships like these to meet the need for clinically impactful, cost effective solutions for the Chinese medical device market.”

When asked about their plans one year from now, Dr. Devine added, “We expect our material to deliver benefits in relation to improved load sharing and reduced stress at the bone screw interface for the Tulip device. We very much hope that this success evolves to deliver more innovations for Weigao in their key areas of spine and traumatology.” — *EH*



Weigao Orthopaedic Device Co., Ltd.

100th FLXfit Expandable Cage Implanted

Dom Coric, M.D. of Carolina Neurosurgery and Spine Associates, has successfully implanted the 100th FLXfit 3D expandable cage.

Expanding Orthopedics Inc., the Akiva, Israel-based company that manufactures the device announced FDA clearance of the device last summer. The first surgery using the FLXfit was performed last December by John Pelozza, M.D. at the Texas Back Institute.

Creating Lordosis

Pelozza said the device was an improvement because it covers a large surface area of the disc space and it expands in the front of the disc space, creating lordosis. He said what makes the device unique is that it can “go in through a tube. Therefore, it works with a very minimally invasive approach, allowing for less muscle damage and quicker recovery for the patient.”

Expanding Orthopedics CEO Ofer Bokobza said on June 5, 2015 that the device can be used in open or minimally invasive surgery (MIS) techniques. He was also “extremely excited” by the fast acceptance of the device in the U.S. market, “with a growing number of

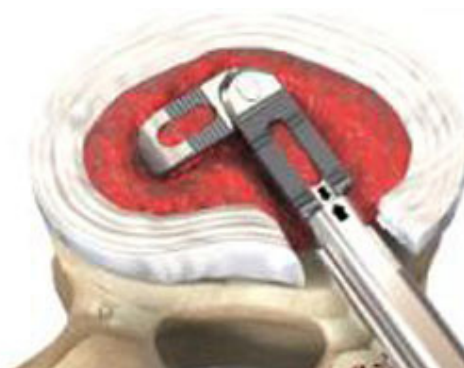
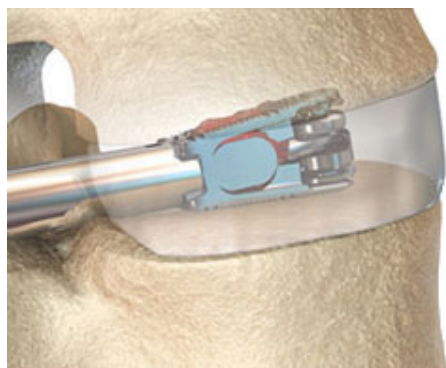
surgeons adopting it as their preferred IBFD (interbody fusion device).

Coric said he has been using expandable cages for many years and has found the FLXfit to be a “great alternative” for his TLIF (transforaminal lumbar interbody fusion) surgeries.

The device offers an “articulated, self-guided design with large, anterior type, footprint coupled with a unique expansion mechanism to restore lordosis angle and tight anatomical fit. In addition, its unique shape and anterior positioning enables ample space for pre- and post-, bone graft packing,” said Coric.

He likes the in-situ lordotic expansion which, he says, allows for restoration of the disc height, segmental lordosis and overall sagittal balance. Coric thinks that devices like the FLXfit “could create a shift in the way surgeons and patients will look at fusion procedures. It’s a dramatic evolution from locking the patient’s anatomy at a given state using static spacers towards reconstructing the patient’s optimal anatomy using devices which combine large footprint support with in-situ lordosis correction.”

To see the device being implanted, click here: <https://www.youtube.com/watch?t=10&v=Kg-f92vK6FA>. — WE



FLXfit 3D Expandable Cage/Expanding Orthopedics Inc.

Foot Drop Orthosis Maker Funds Grants

There’s not much good that can be said about foot drop. It keeps people from staying in motion and can aggravate co-morbidities like diabetes and high blood pressure. But the Kinetic Kids program in San Antonio, Texas, benefits whenever a ToeOFF ankle foot orthosis made by Allard USA is sold.



Photo Courtesy of Kinetic Kids, Inc.

Through a grant from the Rockaway, New Jersey-based Dralla Foundation, the Kinetic Kids program can pay for a weeklong bike camp for children with special needs. The camp helps kids learn to ride a regular bike. The program works as 85% of the kids are successful in riding independently. That makes for healthier kids, and eventually, healthier adults. The program has received three grants from the foundation.

The Dralla Foundation, founded by Peter Allard, is funded by a percentage of proceeds earned by Allard’s company, Allard USA. The company “manufactures a range of orthopedic devices designed to improve physical function and enhance quality of life for individuals with physical challenges.”

Grants Made

According to the foundation, almost \$150,000 in grants have been awarded

since 2011 to fund events and programs that help adults and children with physical challenges. This past year, recipients included:

- Bay Area Outreach & Recreation Program
- Colorado Adaptive Sports Foundation
- Daring Adventures
- Heroes on the Water
- Kinetic Kids, Inc.
- Rehabilitation Institute of Chicago
- Telluride Adaptive Sports Program.

Grant Program Administrator Jennifer Buehler says, “The testimonials we receive from our grant recipients are full of stories of people having fun and doing things they never thought possible. We are excited about the impact we have already made but we want to do more. With a goal to acquire more funds to be able to offer more and larger grants, we have begun to accept donations.”

Dralla Foundation

For more information on Dralla’s Grant Program, the organizations supported by the foundation or to help them increase their grants by making a donation, please visit www.dralla.org. You can also connect with Dralla on www.facebook.com/drallafoundation and www.twitter.com/drallafound.

Allard USA

Allard USA is a wholly owned subsidiary of Camp Scandinavia AB, based in Helsingborg, Sweden, a worldwide maker of orthotic devices for over 50 years. Camp Scandinavia was started in 1954 by the Winberg family. Camp International purchased the company in 1982, but then in 1996 Bertil Allard acquired ownership of Camp Scandinavia. Today it is owned by Peter Allard. — WE

LEGAL

Feds Issue Fraud Alert Over Doc Medical Directorships

The federal government continues to warn physicians about getting involved in the business of medicine.

On June 9, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) issued a fraud alert warning physicians about medical directorship arrangements with healthcare companies. This warning follows the OIG’s special fraud alert in 2013 about viewing physician-owned distributorships (PODs) as “inherently suspect” under the anti-kickback statute.

Ensure Fair Market Value

The most recent fraud alert said that physicians who enter into compensation arrangements such as medical directorships “must ensure that those arrangements reflect fair market value for bona fide services the physicians actually provide.”

“Although many compensation arrangements are legitimate, a compensation arrangement may violate the anti-kickback

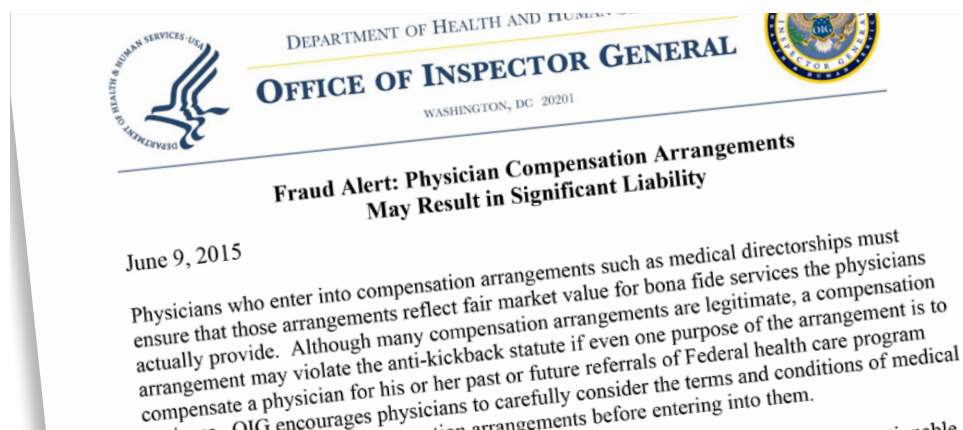
statute if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business. OIG encourages physicians to carefully consider the terms and conditions of medical directorships and other compensation arrangements before entering into them.”

Twelve Recent Settlements

An article in the *National Law Review* on June 11 by attorney Tony Maida observed that while there was nothing particularly new in this warning, the government was publicizing a series of 12 settlements obtained over the last two years under the OIG’s Civil Monetary Penalties Law (CMPL) with individual physicians who had medical director arrangements with Fairmont Diagnostic Center and Open MRI Inc. (Fairmont), an imaging facility in Houston owned and operated by Dr. Jack L. Baker. In 2012, wrote Maida, Baker and Fairmont entered into a \$650,000 False Claims Act settlement concerning allegations that Baker and Fairmont paid illegal compensation to physicians through medical director agreements to induce patient referrals.

Improper Remuneration

The government alleged that the money paid to the physicians con-



Office of Inspector General of the Department of Health and Human Services

stituted “improper remuneration” under the anti-kickback statute for a number of reasons, including that the payments took into account the physicians’ volume or value of referrals and did not reflect fair market value for the services to be performed, and because the physicians did not actually provide the services called for under the agreements.

The government also alleged that some of the physicians had entered into arrangements under which an affiliated healthcare entity paid the salaries of the physicians’ front office staff. Because those payments paid for expenses the physicians would otherwise have had to pay themselves, the OIG alleged that the salaries paid under these arrangements constituted improper remuneration to the physicians.

OIG determined that the physicians were an integral part of the scheme and subject to liability under the Civil Monetary Penalties Law.

Penalties

Baker agreed to be excluded from federal health care programs for six years. After the settlement, OIG pursued “spin-off” CMPL cases against some of the physicians who had the suspect medical director agreements. In total, the OIG collected over \$1.4 million in penalties from 11 physicians and excluded 1 physician for three years. The settlement amounts ranged from \$50,000 to \$195,016.

Avoiding Scrutiny

Maida said physicians should expect to see more OIG scrutiny of their finan-

cial arrangements with the recipients of their referrals. To avoid this scrutiny, he suggests healthcare entities should consider examining their compliance program’s policies and systems regarding review and approval of physician arrangements, including:

- The physician selection process
- The business justification for the arrangement
- An appropriate internal and legal review process
- Making fair market value determinations
- Monitoring physician performance of the services provided for in the arrangement
- Contract management to avoid potential technical Stark Law issues

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Medtronic Shareholders Drop Infuse Lawsuit

Medtronic plc has rid itself of another Infuse lawsuit.

Three shareholder lawsuits filed against former and current directors and officers of Medtronic, Inc. (now Medtronic plc) in Minnesota state court over alleged off-label Infuse promotion, have been dropped by the plaintiffs, with prejudice.

A case dismissed with prejudice is over and done with, once and for all, and can't be brought back to court.

Off-Label Promotion Allegations

The derivative suits were all filed between 2012 and 2014. The suits alleged that, with the knowledge and complicity of officers and directors, the company "designed and executed a scheme to evade the Federal Drug Administration's prohibition against off-label promotion of medical devices in order to increase sales of INFUSE." The suits further alleged that those officers and directors breached their fiduciary duties by causing the company to "conspire with physicians to underreport adverse events in studies involving INFUSE."

According to a Medtronic 8-K SEC filing on June 9, 2015, the plaintiffs in three actions (*Himmel v. Ellis*, *Road Carriers v. Anderson and Cutler v. Ishrak*) voluntarily dismissed their claims. The state court signed three Orders, "effecting full and final dismissal in each case," on May 27 and June 4, 2015.

Allegations "Without Merit"

When the lawsuits were filed, the company set up a Special Litigation Com-



Photo creation by RRY Publications, LLC

mittee (SLC) made up of a retired Minnesota state court judge and a corporate law professor at the University of Minnesota Law School to investigate the claims made in the derivative lawsuits. The committee was given complete authority to analyze the company's legal rights and remedies, and determine whether any rights and remedies should be pursued.

In May 2014, the SLC issued a report which concluded that the claims against the directors and officers of the company "were without merit." The SLC then filed motions to dismiss the suits. Prior to the final hearing of those motions to dismiss and after discovery of internal company documents, the plaintiffs decided to raise the white flag.

Infuse Saga Continues

The company is still involved in numerous lawsuits filed by payers and patients over alleged off-label Infuse promotion. Those cases are bogged down in various federal courts over legal issues involving federal preemption and other procedural issues. After allegations by *The Spine Journal* and Senator Chuck Grassley that improper payments to surgeons tainted clinical studies were largely discredited by the Yale YODA study, Infuse sales have bounced back. — WE

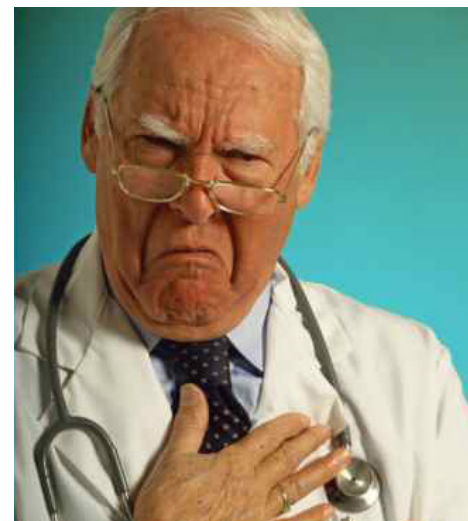
AMA Steps Into Aging Doc Competency Quagmire

When is it time to step away from the operating table and lay down that scalpel? And who should decide?

The American Medical Association (AMA) adopted a plan on June 8, 2015 to create competency guidelines to help decide when it's time for an aging physician to retire. This is new territory for any medical society.

25% of Docs Over 65

There is some urgency to the issue with 240,000 U.S. physicians, or one out of four, older than 65. Physicians have to meet state licensing requirements, but there are no mandates or guidelines to assure competency hasn't been impact-



Policy and Medicine

ed by age. It begs the question: What does age have to do with it if surgical skills are good?

Evidence?

As all things medical, what's the evidence that physicians stay too long and harm patients?

The AMA report says that it's typical age-related changes in hearing, vision, memory and motor skills that could potentially affect physicians' competence. But notes the report, there is no evidence that directly links these changes to worse outcomes for patients.

The AMA voted to convene groups to collaborate in developing preliminary assessment guidelines, as recommended in the report. According to an *AP* article, the report says testing should include an evaluation of physical and mental health and a review of doctors' treatment of patients. It doesn't specify who would do the assessing nor how often it would take place.

"Unfortunate outcomes may trigger an evaluation at any age, but perhaps periodic reevaluation after a certain age such as 70, when incidence of declines is known to increase, may be appropri-

ate," the report from the Council on Medical Education says. "Physicians should be allowed to remain in practice as long as patient safety is not endangered." By developing guidelines and standards for monitoring and assessing themselves and their colleagues' competency, physicians "may head off a call for mandatory retirement ages or imposition of guidelines by others," noted the report.

Angry Old Docs

It's a touchy subject for older physicians who bristle at efforts to evaluate their work based on their age.

"I don't myself have any doubts about my competency and I don't need the AMA or anybody else to test me," said William Nyhan, M.D., an 89-year-old pediatrician, genetics researcher, runner and tennis player who works with the University of California, San Diego

and a children's hospital, according to the *AP* story.

"There are a lot of people overlooking my activities" already, he said. "This is a litigious society—if we were making mistakes, we'd be sued."

Current Screening

The Joint Commission requires U.S. hospitals to evaluate physicians' performance on a periodic basis. Most hospitals do these evaluations every nine months for physicians of all ages, said Ana McKee, M.D., the commission's chief medical officer told the *AP*.

The University of Virginia Health System, and Stanford Health Care at Stanford University, require additional scrutiny of older physicians.

Stanford requires a special assessment every two years for physicians over 75.

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The assessment includes a performance evaluation and a comprehensive medical history and physical exam, said Ann Weinacker, M.D., a Stanford quality improvement specialist.

“It is not a pass-fail type of screening. However, if concerns are raised, we require the person to have further evaluation,” she said.

The University of Virginia’s screens physicians starting at age 70 and involves physical and cognitive exams every two years. The university’s credentialing committee chair, Scott Syverud, M.D., told the AP that the vast majority of the physicians score “very well.” Those who don’t “can choose to cut down their practice or even to retire,” Syverud said, although he declined to say if any have been deemed incompetent.

Physician Shortage-Patient Glut

We have seen many warnings that there will not be enough physicians to handle all the new patients covered under Obamacare. With more patients and a looming physician shortage, the AMA and other provider organizations will have to come up with new ways to serve patients.

Stay tuned. — WE

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Major Depression, Anti-Depressants Linked With Lower BMD

Depressed? Cheer up...you’re losing bone, too. According to researchers from the University of Eastern Finland and Deakin University in Australia, recurrent major depressive disorder (MDD) in men is associated with lower bone density. The team also found that



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antidepressants were associated with lower bone mineral density (BMD), but this association was dependent on the person’s weight and site of bone measurement.

While most studies have evaluated the association between depression and lower bone density in women, this study focused on men. According to the June 12, 2015 news release, “The researchers analyzed data from the Geelong Osteoporosis Study, GOS, a large, ongoing, population-based osteoporosis study carried out in the Barwon Health hospital district in

Australia. Between 2006 and 2011, 928 men (aged 24-98 years) completed a comprehensive questionnaire and had BMD assessments at the forearm, spine, total hip and total body. In all, 9% of the study population had had a single MDD episode, and 5% had suffered from recurrent MDD. Furthermore, 7% of the study participants reported the use of antidepressants at the time of assessment. Recurrent MDD was associated with lower BMD at the forearm and total body, while single MDD episodes were associated with higher BMD at the total hip.”

“Antidepressant use was associated with lower BMD only in lower-weight men and varied across the bone sites. For example, the use of antidepressants was associated with reduced bone density in the hip in men weighing less than 110 kilograms [242.5 pounds]. In the forearm, however, the association of anti-depressants with reduced bone density was not observed in men until their body weight was under 75 kilograms [165 pounds].”

This work is part of a Ph.D. project of researcher Päivi Rauma; the findings were published in *Journal of Musculoskeletal and Neuronal Interactions*. — EH

No Hospital Gowns. “Students” not “Patients.” Group Therapy. The Future of Surgery?

The Poplar Bluff Regional Medical Center, Poplar Bluff, Missouri, has changed the way its staff relates to individuals seeking joint replacements. In the first place, they do not call their clients “patients.” Individuals having elective surgery are considered students, not patients. One of the physicians who developed the innovative program, Preston Jones, M.D. says, “We do not see our patients as being sick. Instead, we see our patients as healthy individuals who are coming to the hospital because they have hip or knee pain, and want to live a better life by having joint replacement surgery.”



Wikimedia Commons and Pikiwikiisrael

Students do not wear hospital gowns, but rather are expected to bring their own pajamas and comfortable clothes. Students also follow a daily schedule that begins at 6:30 a.m. the morning after surgery on a unit devoted only to

individuals having joint replacement surgery.

Each morning, students receive a newsletter with their breakfast, letting them know the agenda for the day.



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Two group therapy sessions are held daily—supplemented by individual in-room sessions. Motivational posters are located throughout the halls, and provide a guide for students to measure their success.

Students compete with one another on distance walked each day with progress tracked on a large walking board posted in a common area. Students find the camaraderie and competition to be both challenging and rewarding.

According to the *Daily Journal* of Poplar Bluff, each student chooses a coach—who will be an active participant in their care before, during and after discharge from the hospital. Both student and coach are required to attend a pre-operative class two weeks prior to surgery, where they meet their Bone & Joint Center team. They learn in detail about the procedure, what to expect in the hospital, and how to care for the student after discharge. Coaches learn the program right along with their students, and provide encouragement and support every step of the way.

One person—a Care Coordinator—is named to oversee the student's entire stay, and is their resource before, during and after discharge. All of the staff at the Bone & Joint Center receive special training, and are chosen to work on the unit because of their expertise; positive upbeat nature, and high motivational skills.

“We evaluate each patient on multiple clinical, functional, and patient satisfaction criteria,” explained Ken James, CEO. “These outcomes are then analyzed during monthly performance improvement meetings, and enable Poplar Bluff Regional Medical Center to become an efficient and cohesive team. So, when we say we offer better outcomes, we have the data to prove it.” — BY

World-First in RA Treatment

Australian researchers have developed a novel immunotherapy for treating rheumatoid arthritis (RA). Noted in the June 4, 2015 news release as a “world-first vaccine-style therapeutic approach,” the treatment is said to target the underlying cause of RA.

Professor Ranjeny Thomas leads the team from the University of Queensland's Diamantina Institute. The study is a phase one clinical trial, and is published in *Science Translational Medicine*.

Professor Thomas said in the news release, “We have designed a vaccine-style treatment or ‘immunotherapy’ specifically for individuals carrying high-risk rheumatoid arthritis genes and specific rheumatoid arthritis antibodies, called anti-CCP. This treatment teaches the patient's immune system to ignore a naturally occurring peptide that is incorrectly identified as ‘foreign’, resulting in the production of CCP antibodies and causing inflammation. A personalised immunotherapy was prepared for each patient by taking a sample of their blood and extracting a

particular type of immune cell called dendritic cells.”

“The patient's dendritic cells were then challenged with the ‘foreign’ peptide and an immune system modulator. “The treated dendritic cells were then injected back into the patient.”

Professor Thomas said a single injection of the patient's own immune-modified dendritic cells was found to be safe and to help suppress the immune response in rheumatoid arthritis.

“This in turn was associated with reduced inflammation. At this stage, the technique would not be ideal for widespread treatment or prevention of rheumatoid arthritis because it's costly and time-consuming. However, the promising results of this trial lay the foundations for the development of a more cost-effective, clinically-practical vaccine technology that could deliver similar outcomes for patients.”

Professor Thomas is working on a delivery technology with Dendright Pty Ltd in collaboration Janssen Biotech Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson. — EH



University of Queensland

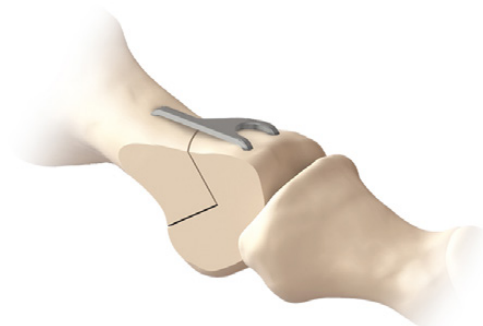
EXTREMITIES

Memory Shape Fixation for Bunion Surgery Launched

BioMedical Enterprises, Inc. (BME), a privately held company in San Antonio, Texas, has launched its Speed Triad Nitinol Bone Fixation Implant—for bunions. Company spokesmen say this is the world's first superelastic shape memory bone fixation system with three legs for stable, six-point fixation. The design, they say, gives surgeons a fast, reproducible way to achieve continuous compressive fixation of osteotomies performed to address bunion deformities.

To treat bunions surgeons typically make a V-shaped cut across the first metatarsal head which allows the head to slide laterally. The traditional fixation

SPEED TRIAD™



Courtesy of BioMedical Enterprises, Inc.

for this procedure is the placement of one or two screws across the osteotomy.

The Speed Triad implant is “made of the shape memory metal Nitinol and is

designed with a bowing bridge and a converging proximal leg that provides compression along the long axis of the bone segments.” Company officials say that, “unlike screws, the Speed Triad has the ability to maintain compression through repetitive loading. The device is available in multiple configurations, for both medial and dorsal placement along the distal first metatarsal. The Speed Triad implant comes ready-to-use on a pre-loaded insertion tool.”

“The Speed Triad implant is challenging the status quo,” stated. Kent Ellington, M.D., attending orthopedic foot and ankle surgeon, OrthoCarolina. “I have been using Speed Triad in patients with mild to moderate hallux valgus for several months. Using the Triad definitely saves me time in the OR, and the clinical results have been consistent, regardless of which placement or configuration of the implant I’ve used. In cases that I’ve used Triad, I’ve been able to expedite the patient’s return to function without complication. Without question, this is an innovation that was long overdue.” — BY

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SPORTS MEDICINE

Exercise Cuts Mortality 40% – New 6,000 Patient Study

A study, published in the May *British Journal of Sports Medicine*, involving 6,000 Norwegian men born from 1923 to 1932 found that exercise late in life allows them to live longer. “Even in the elderly, there is a lot to gain by being moderately active as compared to being sedentary,” said the study’s lead author, Dr. Ingar Holme, professor emeritus at the Norwegian School of Sport Sciences in Oslo.

The study found that increasing physical activity benefited life span as much as did quitting smoking. The men in the study had a check on their health in 1972 and again in 2000. Altogether,



Wikimedia Commons and Gorzaak

they were monitored for about 12 years. Holme reported that 51% of men who were sedentary in their 70s died from any cause compared with one quarter of those who were moderately to vigorously active.

Moderate exercise consisted of exercise sports or heavy gardening for at least four hours a week. Vigorous exercise involved hard training or

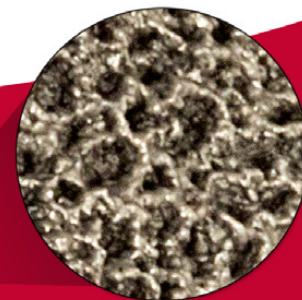
competitive sports several times a week. “Just 30 minutes of moderate activity six days a week was associated with a 40% lower risk of death. More exercise reaped greater benefits, decreasing the odds of death from heart disease or any cause,” the researchers said. Men who were sedentary in their 40s lived five fewer years on average than those who were the most active. — BY



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SPINE

Trial Begins on Novel Spinal Neurostimulator

Mainstay Medical International, a company listed on the Irish and Paris, France Stock Exchanges, has received approval from the United States Food and Drug Administration to begin a clinical trial of ReActiv8 under an Investigational Device Exemption.

ReActiv8 is an implantable neurostimulation system designed to reduce the pain and disability experienced by suffers with chronic low back pain (CLBP). The device is claimed to restore control to the muscles that stabilize the lumbar spine.

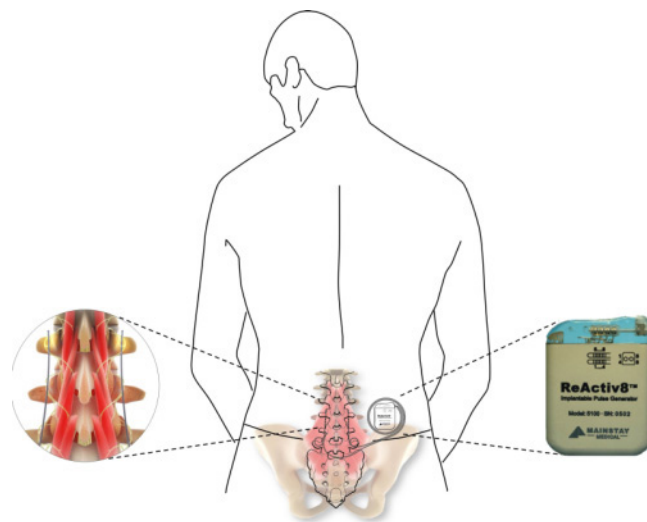
The planned trial will be an international, multi-center, prospective randomized trial designed to evaluate the safety and efficacy of ReActiv8 for the treatment of adults with CLBP. The approval

allows for up to 40 clinical trial sites and for 128 randomized subjects to be implanted with ReActiv8 in the pivotal cohort. Upon successful completion of the trial, and if the results support it, the company plans to submit an application for a Pre-Market Approval, a move which is required to start commercialization in the United States.

The chief investigator for the trial is Christopher Gilligan, M.D., Chief, Division of Pain Medicine at Beth Israel Deaconess Medical Center in Boston and Assistant Professor of Anesthesiology at Harvard Medical School. He also serves as head of the Data Monitoring Committee of the ReActiv8 Trial.

The FDA approval to start a US clinical trial of ReActiv8 is a major step toward out goal

of bringing ReActiv8 to the US market, said Mainstay CEO Medical Peter Crosby. We are impressed with the FDA's responsiveness during the development and review of the trial. It helped us to develop a clinical trial to meet the needs of the company, the FDA and the millions of people who could potentially benefit from ReActiv8." — BY



Courtesy of Mainstay Medical International

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PEOPLE

Bird Elected ApiFix Chairman

Ted Bird, the former president of Orthofix Spine Fixation, as well as vice president stints at DePuy Spine and Medtronic Sofamor Danek, has been elected chairman of the board of Israeli-based ApiFix, Ltd. Bird is currently the chief development officer at the Medical University of South Carolina (MUSC) Institute for Applied Neurosciences.

Bird studied business, economics and political science at the Oakham School in Rutland, England, from 1972 to 1979. He received an Applied Baccalaureate degree from Brown University in 1983, before becoming a sales associate for Dyonics, Inc. His LinkedIn profile says he has, “30 years of international and domestic experience in sales, marketing and executive leadership in the medical device industry. Over 23 years of strong experience, relationships and contacts in the global spinal implants market.”

ApiFix is a commercial-state company with a CE-market minimally invasive treatment system for adolescent idiopathic scoliosis (AIS). The company is preparing to raise its next round of financing to “aggressively” launch the system in Europe, said CEO, Uri Arnin. The system is indicated for patients with a deformity classified as Lenke Type 1 and/or Type 5 and with a Cobb angle from 40 to 60 degrees.

AIS has traditionally been corrected via major open surgery where 10 to 12 vertebrae are instrumented and fused in operations that typically last six hours and cost in excess of \$100,000. The company says its small implant is



Ted Bird/LinkedIn.com

attached to the spine at the apex of the major curve using only two screws. This is a short and “comparatively simple” procedure that takes about one hour. On completion of the procedure, the patient returns home after a short hospitalization period (2-3 days).

According to the company, a clinical study of the system recently published in the peer-reviewed medical journal *Scoliosis* concluded that “there are many drawbacks to the current gold standard of AIS surgery, which are almost nonexistent with the use of ApiFix: considerable blood loss leading to blood transfusions, neurologic deficit includ-

ing spinal cord lesions, late infections, pseudoarthrosis, limitation of spinal motion also affecting non-fused levels, back pain and disc degeneration in the non-fused spinal segments. Almost all of these complications can be avoided by the use of ApiFix.”

“Given that ApiFix is now positioned to fast-forward its substantial commercial opportunity, Ted Bird’s experience and success in the spine industry should prove fruitful as we prepare to raise our next round of financing to aggressively launch The ApiFix System in Europe,” said Arnin. — WE

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