

Orthopedics This Week

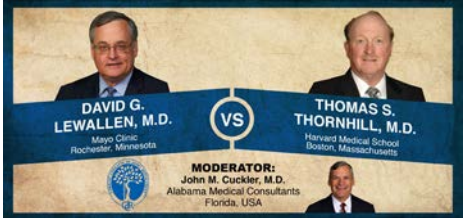
WEEK IN REVIEW

4 What Surgeons Really Think >> Physicians are at the front lines of healthcare change. How are they doing? Not so good, in fact. Deloitte released the results of its annual survey of 20,472 physicians. By and large, U.S. docs are pessimistic about their future and the outlook for healthcare. But there were some bright spots. Here is a summary.

8 The Broken Orthopedic Narrative >> A woman's search for the model number of her failing knee replacement device opened a window into how health care journalists inform patients and the public about orthopedics. Are journalists well informed? Are the data and rules clear? We looked into the window.



12 Lewallen, Thornhill Debate the All-Poly Tibia >> David Lewallen says, "All polyethylene tibias are an underappreciated workhorse for total knee arthroplasty." "Hold up," says Tom Thornhill. "Backside wear is the issue here. And the existing all-poly tibia results are generally [implanted] in low demand patients."



BREAKING NEWS

- 16 Zimmer Buys Small Bones Company**

- Blue Belt's Knee Implant Cleared by FDA**

- 41 Surgical Gloves per Knee Surgery? Really?**

- DiscoCare "Conspirators" Plead Guilty and Not Guilty**

- Medicare Solvency Extended Two Years**

- Technology Holding Back Dumping Fee-for-Service**



For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Lower-than-expected healthcare costs? Last Friday, the *Washington Post* published an analysis that said the National Debt is getting solved—by factors unrelated to the budget battles. The analysis said both a stronger economy and LOWER-THAN-EXPECTED private healthcare costs were the two major reasons! With physician pay down again and patient insurance denials skyrocketing, is anyone really surprised?

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Medtronic	28.65%	6.70%	The pendulum has turned at MDT. News is good these days. And the Yale study is part of it. MDT is interesting.
2	2	Zimmer	29.49	0.69	Buys innovative supplier of foot, ankle, wrist, recon and trauma products. NORMED Medizin Technik! Two buys in two months.
3	3	Stryker	23.68	1.05	SYK's revenue growth is slightly (0.8%) better than the ortho average. But cash flow is above ortho average. How will shareholder's benefit?
4	4	Globus Medical	29.00	2.43	GMED is quite different from most every other ortho company. In many ways, it innovates and operates like a Silicon Valley firm.
5	6	Wright Medical Group	6.84	5.29	Upgraded by Summer Street Research from Neutral to BUY. Now we wait for the June quarter report.
6	8	Integra LifeSciences	12.44	2.58	The Bears and the Bulls are both pulling hard on IART right now. Who will win? Eventually, the bulls. IART's pipeline is the reason.
7	5	NuVasive	7.53	(2.56)	Most analysts are expecting down earnings for the June quarter. But a rebound in the second half of 2013.
8	7	Orthofix	19.68	(12.31)	This is a transition year. Stock is near a 52-week low. New management team hard at work but effect won't be visible for another six months.
9	9	Alphatec	(4.29)	(1.55)	ATEC's technology day received generally good reviews. All in all, it positions ATEC as a technology firm.
10	10	Johnson & Johnson	25.58	(0.64)	The big issue at JNJ is that Pharma appears to be driving growth—not devices. Time for more M&A?

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MAKO Surgical	MAKO	\$12.11	\$568	12.03%
2	Baxano Surgical Inc	BAXS	\$2.18	\$60	11.79%
3	MiMedx Group	MDXG	\$7.14	\$685	8.18%
4	Medtronic	MDT	\$52.08	\$52,914	6.70%
5	Wright Medical	WMGI	\$25.27	\$1,180	5.29%
6	Integra LifeSciences	IART	\$36.17	\$1,015	2.58%
7	Globus Medical	GMED	\$15.99	\$1,472	2.43%
8	RTI Biologics Inc	RTIX	\$4.39	\$247	1.86%
9	Exactech	EXAC	\$18.61	\$250	1.31%
10	Stryker	SYK	\$67.15	\$25,324	1.05%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	\$0.55	\$24	-37.51%
2	Orthofix	OFIX	\$28.06	\$546	-12.31%
3	Symmetry Medical	SMA	\$9.24	\$344	-10.72%
4	Tornier N.V.	TRNX	\$15.69	\$728	-10.55%
5	TiGenix	TIG.BR	\$0.95	\$95	-8.51%
6	NuVasive	NUVA	\$21.68	\$959	-2.56%
7	Alphatec Holdings	ATEC	\$1.91	\$185	-1.55%
8	ArthroCare	ARTC	\$33.71	\$951	-1.40%
9	Johnson & Johnson	JNJ	\$84.91	\$238,503	-0.64%
10	Smith & Nephew	SNN	\$58.95	\$10,659	-0.39%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	\$28.06	\$546	10.92
2	Zimmer Holdings	ZMH	\$78.73	\$13,255	12.67
3	Globus Medical	GMED	\$15.99	\$1,472	14.01
4	Medtronic	MDT	\$52.08	\$52,914	14.04
5	Smith & Nephew	SNN	\$58.95	\$10,659	14.62

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	\$25.27	\$1,180	109.87
2	NuVasive	NUVA	\$21.68	\$959	57.05
3	Symmetry Medical	SMA	\$9.24	\$344	31.86
4	RTI Biologics Inc	RTIX	\$4.39	\$247	25.82
5	ArthroCare	ARTC	\$33.71	\$951	21.89

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	\$15.99	\$1,472	0.93
2	Exactech	EXAC	\$18.61	\$250	1.33
3	Conmed	CNMD	\$32.38	\$909	1.34
4	Zimmer Holdings	ZMH	\$78.73	\$13,255	1.36
5	Integra LifeSciences	IART	\$36.17	\$1,015	1.49

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	\$25.27	\$1,180	10.30
2	NuVasive	NUVA	\$21.68	\$959	4.88
3	CryoLife	CRY	\$6.29	\$173	4.37
4	Johnson & Johnson	JNJ	\$84.91	\$238,503	2.74
5	Symmetry Medical	SMA	\$9.24	\$344	2.66

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	\$0.55	\$24	0.71
2	Symmetry Medical	SMA	\$9.24	\$344	0.84
3	Alphatec Holdings	ATEC	\$1.91	\$185	0.94
4	Exactech	EXAC	\$18.61	\$250	1.11
5	Orthofix	OFIX	\$28.06	\$546	1.18

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	\$7.14	\$685	25.32
2	TiGenix	TIG.BR	\$0.95	\$95	23.38
3	MAKO Surgical	MAKO	\$12.11	\$568	5.53
4	Baxano Surgical Inc	BAXS	\$2.18	\$60	4.09
5	Globus Medical	GMED	\$15.99	\$1,472	3.81

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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What Surgeons Really Think

BY ROBIN YOUNG

Every year the Deloitte Center for Health Solutions, which is the health services research arm of business consulting firm, Deloitte LLP, surveys more than 20,000 U.S. physicians about their attitudes and opinions.

Since this survey was last conducted in 2011, the Supreme Court affirmed the Affordable Care Act (ACA) which put into place sweeping changes including new restrictions on health insurance companies and prospective expansion of health insurance coverage for 33 million Americans.

How have opinions changed since the last survey? We have the answers.

By and large, most U.S. physicians are increasingly pessimistic about the future of their profession and about the many changes they see in the market and U.S. healthcare generally.

Here are a dozen of the key conclusions from this year's physician survey.

1. The performance of the U.S. health care system is suboptimal, but the Affordable Care Act (ACA) is a good start to addressing issues of access and cost.

Physicians are highly critical of the performance of the U.S. health care system. Only 31% give a favorable grade of "A or B"—which is down from 35% in 2011.

Defensive medicine is still a problem, but a declining one. In this year's survey 71% said that defensive medicine was a



Source: Wikimedia Commons and Paul Clarke

major influence on overall health care system costs. In 2011 that percentage was a whopping 91%.

Less than half of all physicians (44%) think that the ACA is a good start. But the percentage of physicians who believe that the ACA is step in the wrong direction declined (38% in this survey and 44% in 2011).

Seven in 10 physicians are satisfied with practicing medicine. But, primary care providers (59% satisfied) are the least satisfied when compared with their specialist colleagues (63% of surgical specialists, 67% of non-surgical specialists).

Younger physicians were more satisfied than older ones (aged 25-39, 80%) and less experienced physicians were more

satisfied than their more experienced colleagues (10 years or less, 73%).

Four in 10 physicians rank patient relationships as the most important element of job satisfaction followed by protecting and promoting the health of individuals (3 in 10) and intellectual stimulation (2 in 10).

Interestingly enough solo physicians are happier (61%) than those who practice with between 2 and 9 colleagues (36%) or 10+ physicians (31%).

2. Compensation is falling and clinical autonomy is evaporating.

Half (51%) of all physicians think that physician incomes will fall dramatically in the next one to three years. Significantly more solo physicians (68%)

believe that their incomes will fall than those in practices of 2 to 9 physicians (51%) or 10+ physicians (44%).

Nearly half (49%) of all physicians think that capitation will replace FFS (fee for service) payments in the next one to three years.

About a fourth (26%) of all physicians believe that the sustainable growth rate (SGR) mechanism will be repealed in the next one to three years.

Six in 10 physicians say that it is likely that many of their colleagues will retire earlier than planned in the next one to three years.

Four in 10 physicians report that their take-home pay decreased from 2011 to 2012. Over half of the physicians surveyed reported having a decrease of 10%. Among those physicians whose

take home pay decreased by any amount in 2012, 4 in 10 believe that it was a result of the ACA. In 2011, the last time this survey was conducted, about half (48%) of all physicians believed that their income would decrease in 2012 as a result of the ACA.

Physicians identify the trade-offs between larger (e.g., large medical groups, health systems, hospitals, and health insurance plans) versus solo practices: Larger practices are perceived to be better placed to secure superior third-party payer contracts and offer the greatest financial success potential, whereas solo practices are perceived to offer greater clinical autonomy and, therefore, personal satisfaction.

Nine in 10 physicians report that their greatest concerns about financial viability is under an episode-based (bundled) payment structure. Physicians are wor-

ried that they will not receive adequate payment for their services and that they will be penalized for factors out of their control.

Surgical specialists are significantly more concerned about inadequate payments than primary care physicians (90% versus 79%).

3. For physicians, the key to job satisfaction is patient relationships.

The greatest single element of job dissatisfaction among physicians is less time for each patient. Among primary care physicians the percentage identifying that element was 26% and among non-surgical specialists it was 21%

Surgical specialists mentioned long hours and long work weeks as being a key element of job dissatisfaction (20%).

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And rounding out the top three causes of job dissatisfaction is dealing with Medicare/Medicaid/government regulations – 22%.

4. Medical liability (malpractice) reform is a major concern to physicians.

Few (1 in 10) physicians believe that liability (tort) reform will pass in Congress in the next one to three years.

More physicians who are younger (aged 25-39, 16% and aged 40-49, 15%) versus older (aged 50, 59% and aged 60 and up, 11%) believe that such reform will pass. Among those significantly more likely to believe reform will occur are physicians who work in an Accountable Care Organization (ACO) (19%) versus those who do not (9%).

5. Health insurance exchanges (HIXs) are unlikely to be ready for enrollment by the 2013 deadline.

Only 2 in 10 physicians believe that health insurance exchanges (HIXs) will be implemented by the 2013 deadline for receiving enrollment applications or that HIXs will force insurance companies out of business in the next one to three years.

6. Physicians are likely to increasingly compete with mid-level professionals in primary care.

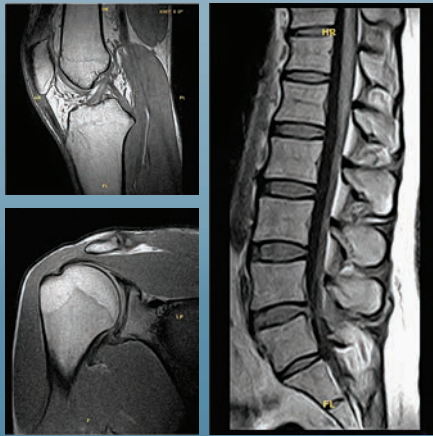
A large majority (8 in 10) of physicians believe that mid-level professionals will play a bigger role in direct primary care delivery and that insurers will aggressively negotiate to preserve mar-

gins. Not surprisingly, 6 in 10 say that many physicians will retire earlier than planned.

7. Medicaid and Medicare reimbursements may be problematic, prompting many physicians to limit or close their practices to these enrollees.

Most (9 in 10) physicians believe that Medicaid reimbursements will not increase to match Medicare rates for primary care services in the next one to three years. If Medicare lowered payments or switched to vouchers, physicians would react. What would they do? A quarter of physicians would place new or additional limits on the acceptance of Medicare patients if there were potential payment changes to the Medicare program, such as lower payments or a switch to vouchers.

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8. Physician-hospital integration expected to increase.

Although most physicians have not consolidated or considered it, 31% of the surveyed physicians report having done so in the past one to two years.

The primary reason physicians consolidated in the past one to two years was in order to gain or retain income security (29%) or leverage negotiation power with payers (21%). About two-thirds of all physicians believe that physicians and hospitals will become more integrated in the next one to three years.

9. Clinical decision-support information technologies that reduce unnecessary services and increase clinician adherence to evidence-based practices are of interest to physicians.

Nearly half of all physicians believe that when operating under a bundled payment structure the most important evidence needed when purchasing medical technology beyond safety and efficacy is the potential reduction in instances of needed care.

Seven in 10 physicians believe that physician-led, peer review of new medical technologies (covering both efficacy and value) followed by use of evidence-based guidelines (six in 10 physicians) are the leading best practices in the selection and purchase of medical technologies.

10. Electronic Health Record (EHR) adoption by physicians expected to increase.

Two-thirds of physicians say they use EHRs that meet meaningful use stage

one requirements. Three in five physicians (fairly uniform among physicians by medical specialty) are satisfied with their EHR system. The majority of physicians report numerous benefits to using an EHR system including:

- Faster and more accurate billing for services (74%)
- Time saving through e-prescribing (67%)
- Communication improvement and care coordination capabilities due to interoperability (67%)

Seven in 10 (72%) of all physicians believe that in the next one to three years the majority (80% or more) of physicians will adopt EHRs.

11. Connectivity with consumers (patients) using online or mobile technologies and personal health records expected to become increasingly important to physicians.

One-third of all physicians report that they can communicate with their patients using email or texts. Just over a fourth (26%) say that consumers can be directed to trusted health care web sites. Just under a fourth of the surveyed docs (24%) say that their patients can schedule visits or access test results through a web site and 19% say that their patients can request prescription refills through a web site.

12. Incentives to address consumers' unhealthy lifestyles can help.

The vast majority of physicians (71%) believe that if consumer incentives were widely introduced, financial ones (e.g., direct payments, reduced insurance premiums or reduced co-pays) might work best with consumers in an

attempt to motivate them to engage in healthy behaviors.

Seven in 10 (70%) of the surveyed physicians agree that consumer incentives could be very helpful to achieve better treatment compliance, but fewer (55%) physicians agree that incentives are sufficiently powerful to motivate consumers to address lifestyle issues and positively change behavior.

Seven in 10 (69%) of surveyed physicians agree that consumer incentives based upon cost-sharing could be counterproductive, leading consumers to avoid or delay seeking necessary treatment. ♦

In conclusion, this year's Deloitte survey could not be more clear. Physicians, who are the engine that runs the U.S. healthcare system, are increasingly pessimistic about their future and the future of healthcare. With declining incomes and reduced clinical autonomy, who can blame them? So, what does this mean for orthopedic clinicians and the companies who support them? That is the billion dollar question.

To read the full survey; http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/us_chs_2013SurveyofUSPhysicians_031813.pdf

The Broken Orthopedic Narrative

BY WALTER EISNER



Image created by RRY Publications, LLC / Source: Wikimedia Commons and Cpl. Brian Adam Jones

On May 29, 2013, a television news reporter from Los Angeles posted a question on the message board of the Association of Health Care Journalists (AHCJ).

The reporter asked about a caller who had contacted her about the caller's total knee replacement surgery. According to the caller, it had been paid for by Medi-Cal, California's Medicaid program.

According to the reporter, the caller was having serious problems following knee replacement surgery. The caller gave the reporter access to her surgical report which noted the implant came from Zimmer. The report did not, however, indicate a model name or serial number of the Zimmer device.

The incision, placement, cementation and closure were all well documented in great detail, but no device identification. The patient was having a tough time getting information on her own.

So, asked this reporter, who is responsible for providing that information—the hospital or the surgeon?

“Seeing her case, I’m sort of amazed Medi-Cal even covers knee replacements considering all the risk and possibility of future expense,” added the reporter.

Responses began to pour in from experienced health care reporters about the effectiveness of knee replacement sur-

gery, HIPAA (Health Insurance Portability and Accountability Act) rules, inappropriate surgeries, informed consent, patient experience and even the age of the surgeon who performed the surgery.

The Orthopedic Narrative

The exchange between health care reporters provided insight into how the narrative of the current state of orthopedics is explained to the public by reporters. That narrative is informed by assumptions about device effectiveness, privacy rules, payer decisions, perceived human and corporate greed and, even altruism. All these assumptions were nakedly on display as responses to this Los Angeles reporter poured in.

Russian Roulette Odds

One of the first respondents asked why the reporter considered knee replacement a risky surgery.



Wikimedia Commons

“Knee replacement is one of the lower risk surgeries. A knee replacement can mean the difference between mobility and disability, including the ability to work and get off of Medi-Cal. By maintaining mobility one often can prevent or forestall obesity and associated disease such as diabetes, chronic conditions that can be very expensive over the long run,” wrote one journalist.

However, another reporter responded that “apparently, only about half the patients are better off afterwards in terms of clinically significant differences in QOL (quality of life) and 15-20% of people with TKAs [total knee arthroplasty] wind up with severe to extreme persistent pain. (*BMJ Open* <http://bmjopen.bmj.com/content/2/1/e000435.full>).”

”Some patients start with some mobility and wind up without any mobility at all, with pain at rest, worse than they

were before. Isn’t that risky? That’s like Russian roulette odds,” he added.

No Randomized Trials

“The striking thing about [TKA] is that there are 600,000 procedures a year in the U.S, at a cost of \$15,000 per procedure, mostly paid by Medicare, (*JAMA* 308:1227). There is not a single randomized trial of its effectiveness and adverse effects with QOL endpoints like pain and mobility,” he concluded.

He referenced a Danish group which started a prospective randomized trial last year (the MEDIC-study) and they will have results in 10 years. (*BMC Musculoskelet Disord.* 13:67).

Randomized Surgery?

“It would be nice if there was ‘good’ data, came back a response. “But how would you conduct the study? How would

you randomize patients? Is it ethical to conduct surgery before they ‘need’ it? Is it ethical to delay surgery if they ‘need’ it? I know [hospitals] do have a metric they use to decide who gets surgery. My surgeon had to propose it, and a panel reviewed the request prior to surgery.”

Survey Says...

We asked Zimmer, the largest knee maker in the world, about the claim that only half of patients are better off and 10-15% of patients end up with severe to extreme persistent pain


In a written response, the company said the *BMJ* article used MEDLINE and EMBASE databases as data sources and was only a systematic review. “High quality meta-analysis publications use AMED, CINAHL, Embase, Medline, Cochrane library, PEDro that are more recognized to conduct these types of research.”

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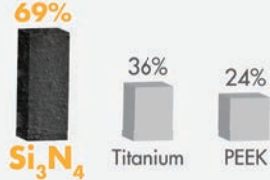


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REFERENCE: 1. Webster TJ, Patel AA, Rahaman MN, Sonny Bal B. Anti-infective and osteointegration properties of silicon nitride, poly(ether ether ketone), and titanium implants [published online ahead of print July 31, 2012]. *Acta Biomater.* <http://dx.doi.org/10.1016/j.actbio.2012.07.038>. Accessed September 12, 2012.

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The study in the article, according to Zimmer, excluded studies that reported mean values of pain outcomes. “There is strong evidence in the literature that in appropriately selected THA [total hip arthroplasty] and TKA patients, significantly higher improvements in QOL are observed (Quintana et al, 2006). Earlier published studies (Rissanen et al 1996) demonstrated major improvements in pain, sleep and physical mobility and reported that on average, **most patients attained a similar QOL as the comparable general population; and only 4.7% of hip and 9.7% of knee patients had a lower HRQOL.**”

Poor Journalism

The reporter citing the *BMJ* article was also critical of his colleagues in the media who, he wrote, “aren’t doing a good job either.” He noted a *New York Times* writer’s glowing stories about the wonderful results of TKA... “They [reporters] go to orthopedics meetings and copy the glowing press releases right into their news stories, without following journalism 101 rules and get-



<http://www.bgsu.edu>

ting an independent expert to comment on it...Patients simply can’t inform themselves by reading the newspapers or searching online.”

Ouch.

HIPAA

The television reporter said she contacted Zimmer but was told that without a serial number there was no information they could provide her and that their database is not searchable by name because of HIPAA.

“I don’t think this is true,” replied the critical reporter. “HIPAA allows medical providers to exchange information for administrative and operational purposes.”

“This is a major tool in the bureaucrat’s toolbox of quick ways to dismiss questions that they don’t want to answer: ‘The law doesn’t let us give out that information.’ That’s an effective response because most reporters don’t understand law so they can’t follow up.”

Device Maker HIPAA Responsibilities

We asked Zimmer about a manufacturer’s HIPAA responsibilities.

The company said device makers are not HIPAA covered entities as they only sell implants to distributors and hospitals. To be considered a covered entity, a health care provider must conduct certain electronic standard transactions defined in HIPAA, all of which relate to the submission and payment of claims for health care goods and services.

“Hospitals and implanting surgeons are HIPAA covered entities. Under HIPAA, they are permitted to disclose a patient’s protected health information to Zim-

mer without patient authorization for treatment purposes and to comply with FDA oversight regulations for manufacturers of medical devices,” said the company in a written response.

“Generally, Zimmer does not receive information about the patient receiving a specific implant—the information is captured in surgery planning schedules by distributors, but is not maintained in any database or registry. The only link Zimmer has to the specific product is the peel-and-stick label on the packaging identifying the serial number of the individual implant. This is kept by the hospital/and or passed along to the patient. With this information, Zimmer can confirm whether a patient had an implant and what kind of implant they have had.”

Post-Market Surveillance

The company said it cannot share patient information with a reporter without the authorization of a patient. “If a patient reached out to the company via our consumer contact centers, we have staff trained to conduct Product Event Reports (PER) in cases of complaints. The PER process involves identifying the serial number on the peel-and-stick label and using this information to confirm the implant a patient has received, and process any complaint related to its performance. This is an important part of our post-market surveillance process, as we can identify trends in product performance related to complaint rates.”

Hospital Stonewalling

In short, hospitals and physicians are required under HIPAA to give patients access to their health information. “The patient in question should be able to get copies of her medical records directly

from her treating providers,” concluded the Zimmer response.

Another reporter noted that if the hospital can't dig up the serial number they would, “certainly be in violation—they have to record that information. They're clearly not taking her seriously on her own, they already made a major omission by not having included the serial number on the surgical report, and they're stonewalling if they're telling her to get the device info from the device manufacturer...If this were a wealthy patient with private insurance, would she have to ask twice?”

High Pressure Docs, Malpractice and Consent

The same poster that questioned TKA effectiveness also cited a recent article from *JAMA (Journal of the American Medical Association)* that, he says, “describes a high-pressure sales job by an orthopedic surgeon to perform bilat-

eral total knee replacements (among other things) on a 76-year-old woman with multiple sclerosis. The surgery was inappropriate and dangerous for the reasons the author gives. The surgeon recommended—and tried to schedule—surgery without even asking about cardiac history. “

“I've covered medical malpractice conferences. It's malpractice to perform surgery without informing the patient of the risks. “

He said the larger issue is that doctors aren't supposed to tell patients that they need elective surgery. They're supposed to inform the patient of the risks and benefits and let the patient decide, according to the patient's values and preferences.

The Lesson

The story of the poor woman in search of her device information opened a

window into disparate views held by health care journalists about orthopedics as they inform patients, the public and each other. The message to providers and device makers is that even well informed journalists and patients are confused and often misinformed.

The lesson? How journalists write about orthopedics creates a general narrative about manufacturers, surgeons and hospitals. When that narrative does not align with reality and, as is increasingly the case in the U.S., disparages the system, then it can find expression in the form of increased government scrutiny and payer skepticism.

As we learned from the responses to one journalist's question, some writers about orthopedics still do not understand their subject well. ♦

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Lewallen, Thornhill Debate the All-Poly Tibia

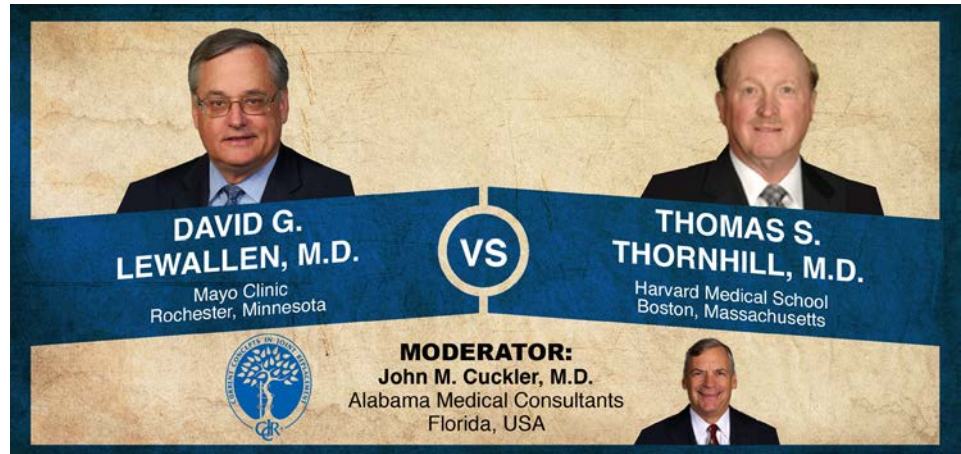
BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

David Lewallen says, “All polyethylene tibias are an underappreciated workhorse for total knee arthroplasty.” “Hold up,” says Tom Thornhill. “Backside wear is the issue here. And the existing all-poly tibia results are generally [implanted] in low demand patients.”

This week’s Orthopaedic Crossfire® debate is “The All Poly Tibia: Cheaper and Better.” For the proposition is David G. Lewallen, M.D. at Mayo Clinic in Rochester, Minnesota; against the proposition is Thomas S. Thornhill, M.D. from Harvard Medical School. Moderating is John M. Cuckler, M.D. from Alabama Medical Consultants in Florida.

Dr. Lewallen: “All polyethylene tibias are an underappreciated workhorse for total knee arthroplasty. There are no ideas more dangerous than the things we think we know for certain. These are all concepts that I’ve learned from mentors, which we’ve subsequently come to learn weren’t so true (‘suction irrigation tubes are good for infected joints,’ ‘bone loss around failed total joints is to due cement disease,’ etc.).”

“Modular tibial trays are the gold standard for modern total knee arthroplasty, but the day will come when we look back on this with some perplexity. The biggest challenges we’ve faced the last decade have been polyethylene wear, osteolysis and bone loss. This kind of particulate driven bone resorption is not something that was seen when I was a resident. This is an advent of more modern designs, particularly the modular tibial tray.”



Current Concepts in Joint Replacement/RRY Photo Creation

“Anything that drives down particle size can produce significant osteolysis. What we thought we knew for sure was that it was all about the topside, but you have cases like the 28-year-old Geomedic with significant poly wear. At the time of revision we are accustomed to seeing delamination, large sheets of poly...but you can’t find a case of significant blow-out lysis with older designs.”

“When you look at insert exchange in the literature it’s usually a bad idea. The results are often poor; there’s often something else wrong that simple poly liner exchange doesn’t solve. And locking mechanisms move at the beginning and then more over time—regardless of design. There is tibial surface abrasion, third party debris—and it’s not just in a single design.”

“There are many reports of locking mechanism backside failure and back surface wear in the literature. If you look at monoblock designs at long term follow-up...very durable results. And yet we put in a modular tray where the results are not as durable.”

“A single surgeon series from Dr. Ranawat with a particular design showed superior results with a monoblock. In a series from Weber they showed several-fold higher problems with revision, radiolucencies, and lysis with modular implants. Our Mayo database contains over 10,000 patients. We looked at all the different tibial designs and compared the metal-backed to all-poly by different manufacturers. Even when we removed the one design we knew was an outlier, the all-poly implants did better—even when corrected for age, gender, and obesity. So it’s hard to make the case that there’s some great advantage to metal backed trays...and in fact I think there’s probably a disadvantage.”

“Cross-linked poly may help, and we may get some help from the effect it has on reducing wear. But what about the material properties? It’s more expensive, and rotating platforms, stress shielding. Time will tell...in the meantime, use a modular tray only if you must, but otherwise use a cemented all-poly tibia.”

Dr. Thornhill: “There are benefits to all-poly tibia: costs less, good long term results, and compression molded polyethylene. Our polyethylene has improved; there is better wear resistance, better mechanical strength, and better oxidative resistance. And there is no backside wear.”

“But all-poly tibia results are generally in low demand patients, and backside wear is less than it has been. The fact is that as you go into the area where you had metal backed components with holes and screw osteolysis and designs that really weren’t made for cementless fixation (and had a lot of osteolysis)—many of those were the modular designs with significant backside wear.” “Some things have improved backside wear in modular components. There is improved metal tibial surface, a ten-

dency to go to polished cobalt chrome, stronger polyethylene (so it has better mechanical stability), and less wear on both the femoral/tibial and the backside. There is reduced micromotion with a better locking mechanism and better interference fit.”

“Modularity facilitates intraoperative and revision options. You can change the congruity from a cruciate retaining to a cruciate substituting, but it does require some other changes. You can change the congruity to an ultra congruent; you can also change tibial thickness and increase conformity in a revision where the tibial tray is fine.”

“Dealing with tibial bone loss is important because there is significant weakness. There are data from years ago showing that if you get greater than 8mm of polyethylene, some of the

bending moments that occur are not as important. But they are still not good, particularly in situations like in a varus knee where you see a lot of sclerosis on one side and osteopenia on the other side. Once you clear this off you see a significant discrepancy between the medial tibial plateau and the lateral tibial plateau in this varus knee.”

“Cement actually creates a uniform proximal tibial mantle to prevent the bending moments. When you get thick enough polyethylene the moment is decreased, but still not similar to a modular system. As for fixation options, I think we will at some point move to un-cemented designs. The results to date are mixed on these systems. I think the economics may dictate a change in selected patients. But at the present time I’ll stick with modularity because I believe the backside wear problem is less.”

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1. Roche MW, Coon T, Pearle AD, Douchis J. Two year survivorship of robotically guided medial MCK onlay. 25th Annual Congress of ISTA; October 3-6, 2012; Sydney, Australia.
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Moderator Cuckler: “David, your opponent suggests that an all-poly tibia should only be used for low demand patients. Do you agree?”

Dr. Lewallen: “I think it’s reasonable to put an all-poly tibia in patients of all ages. I use a cementless monoblock tibial design in some young, active patients because we are studying those patients and learning whether that will be a more durable solution for them. The argument that was just made about bone ingrowth perhaps being more durable than cement fixation over the long term is an untested premise. We have our first prospective, randomized group out to about five years; we need longer follow-up. I use modular trays occasionally, such as with bone deformity, and in some very obese patients I will use a modular tray because it’s technically much easier to do the operation in those patients than

it is to put in a monoblock posterior stabilized design.”

Moderator Cuckler: “Is severe osteoporosis a contraindication to the all-poly tibia?”

Dr. Lewallen: “No.”

Moderator Cuckler: “Tom, is there any time you can think of when you wished you had an all-poly tibia?”

Dr. Thornhill: “No.”

Dr. Lewallen: “How about when you’re removing a well fixed one, Tom?”

Dr. Thornhill: “I will use some all-poly tibias. I probably shouldn’t admit this, but I think I’m far enough away from home to be able to say this: in spite of all the trials and checking, I occasionally have a situation where I say, ‘I wish

I had an insert that was 2mm thicker.’ That’s when I’m really glad that I have a modular component.”

Moderator Cuckler: “So one of the advantages of modularity is the ability to change either the conformity of the bearing surface or the thickness of the surface at your final trial reduction, correct?”

Dr. Thornhill: “Yes, when I open a knee for other reasons, just the price of opening the knee in most cases, destabilizes it. I put a tibial insert back in that is at least 2mm thicker. And we haven’t mentioned that if you have a primary knee with a bone defect you should use an augment, which is a benefit of a modular system.”

Moderator Cuckler: “How do we balance the cost and the advantage of modularity versus the excellent performance of the all-poly tibia?”



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Dr. Thornhill: “If you can have a single tray that can accept many different thicknesses and configurations the fact is that you will drive the cost down. If you argue purely on the basis of cost then there’s a stronger argument for an all-poly tibia. I think that the functionality that you get with modularity and intraoperative decision making—remembering that technical problems are a major cause of failure—I think modularity wins.”

Moderator Cuckler: “David said that the revision of the failed all-poly tibia is almost always more straightforward than the revision of the modular tibial component. True or false?”

Dr. Thornhill: “True.”

Moderator Cuckler: “So why not use an all-poly?”

Dr. Thornhill: “I don’t go into an operation with the idea that it’s going to fail. The Mayo data is a massive registry of multiple implants, and they go back to the time when we had all the problems...and backside wear was the major culprit.”

Moderator Cuckler: “David, what about the ability to change the stability mechanism of the tibial component?”

Dr. Lewallen: “There is a bit of a learning curve when you go from modular implants to an all-poly or monoblock.

There’s a bit of slop in the knee that goes away once you cement the interfaces. It can be the source of a little more laxity in the knee.”

Moderator Cuckler: “And the difficulty in cleaning the posterior recess of the tibial and femoral components once they are cemented?”

Dr. Lewallen: “Good exposure...it’s a matter of seeing what you are doing.”

Moderator Cuckler: “And adequate exposure is obtained how?”

Dr. Lewallen: “I like to see the entire backside of the tibial component. I don’t like operating through portholes. Particularly for the occasional surgeon it’s important to have excellent visualization to avoid positioning errors and to be able to clean cement out thoroughly.”

Moderator Cuckler: “Tom, I don’t think you’d say that you would get worse exposure than David just because you’re using a modular device.”

Dr. Thornhill: “I think there are two areas of the knee that you really need to see. I was going to argue about clearing cement with a modular system, but it would be somewhat disingenuous of me because I save the posterior cruciate and I put the final insert in when I cement the femur...and I cement all my components at the same time. You need

to be able to see the anterolateral part of the tibia in order to prevent abnormal rotation; and I think you need to see the posterolateral part of the tibia in order to ensure that your components are in right and the cement is cleared.”

Moderator Cuckler: “So whichever way you go, get great exposure. Thank you, gentlemen.” ♦

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COMPANY

Blue Belt's Knee Implant Cleared by FDA

Blue Belt Technologies, Inc., after a bruising marketing squabble with MAKO Surgical Corp., announced on June 4, 2013 that the FDA has granted 510(k) clearance to market its Stride Unicondylar knee implant system.

The company said the implant system will be co-marketed with Blue Belt Technologies' NavioPFS precision orthopedic surgical system which has

been commercially available in the U.S. since December 2012.

Company President and CEO Eric Timko said the company remains "focused and committed to continuing to build out NavioPFS's open architecture for implant selection. Allowing our customers to adopt technology while continuing to maintain their long-term existing relationships with implant manufacturers will allow Blue Belt to reach a wider physician audience."

Jess Lonner, M.D., attending orthopedic surgeon at the Rothman Institute in Philadelphia added, "Stride's optimized aspect ratios, implant design and size offerings will reduce the need for compromise and enhance functional and clinical outcomes. Additionally, its geometry interfaces well with NavioPFS to allow efficient and accurate bone preparation."

The system is available for treatment of both medial and lateral compartment osteoarthritis. The company expects to begin marketing the system immediately.

Blue Belt is developing surgical instruments for use initially in orthopedic procedures and then for other surgical specialties, including neurosurgery, spinal and otolaryngology ("ENT"). The company's NavioPFS system incorporates patented technology to provide control to surgeons via a handheld, computer assisted bone cutting tool.



Stride Implant System/Blue Belt Technologies, Inc. —WE (June 6, 2013)

Zimmer Buys Small Bones Company

Zimmer Holdings, Inc. enlarged the company's footprint in small bones with the acquisition of Tuttlingen, Germany-based Normed Medizin-Technik GmbH.



Normed Medizin-Technik GmbH

A June 4, 2013 Zimmer announcement stated, "The acquisition of Normed will strengthen Zimmer's Extremities and Trauma product portfolios and new product development capabilities in the fast growing foot and ankle and hand and wrist segments." No sum was given of the cost of the acquisition.

Normed was founded in 1988 and is billed as "an innovative global medical company that provides a broad range of plates, screws and specialized instruments for foot and ankle and hand and wrist surgeries." You can view company products on their YouTube site: http://www.youtube.com/user/normedgermany?feature=results_main

Company products include: titanium osteosynthesis systems for foot and upper extremities surgery; the Haensel/Clavicula plate system and pediatric orthopedic devices.

—WE (June 5, 2013)

TranS1 Becomes Baxano Surgical

TranS1 Inc. is now Baxano Surgical, Inc. after the company announced on May 31, 2013 that it completed its acquisition of Baxano, Inc.

Ken Reali, president and CEO of the new Baxano, said the creation of the new company completes a transition to a “high growth medical device company focused on minimally invasive spinal procedures, the fastest area of growth in the spine market. The increased scale of the combined company allows us to offer our surgeon customers a suite of proprietary and differentiated products. Through the continued market penetration of iO-Flex and VEO and the re-launch of AxiaLIF we expect to drive the company into its next phase of growth.”

Upon the closing of the merger the company issued an aggregate of approximately 10.3 million shares of common stock, valued at approximately \$20.1 million based on the May 30, 2013 closing price.

The company’s common stock began trading under the new trading symbol “BAXS” on June 3, 2013 and was trading at around \$2.25.

The company also issued and sold to certain investors approximately 7.5 million shares of the company’s common stock, at a purchase price of \$2.28 per share, resulting in gross proceeds to the Company of \$17.2 million.

Management Changes

Greg Welsh, the former vice president of operations of Baxano, was appointed to the same position of the new com-



Baxano Surgical, Inc. Headquarters

pany effective as of May 31, 2013. Welsh was vice president of operations of Baxano from January 2013 through May 31, 2013. Prior to that, he was the vice president of manufacturing from January 2012 to January 2013, senior director of operations from August 2009 to January 2012, and director of operations from March 2008 to August 2009. Prior to joining, Welsh was director of production at Avantis Medical Systems from 2007 to 2008 and held various senior management positions at Cierra from 2006 to 2007 and Boston Scientific/Target Therapeutics from 1996 to 2006.

Welsh holds a B.S. degree in mechanical engineering from Cal Poly San Luis Obispo and holds a management development program certificate from the School of Business at University of Southern California.

Board Changes

Jeffrey Fischgrund, M.D. resigned as a Class III member of the Board and was reappointed as a Class II member of the Board effective as of May 31, 2013. Michael Carusi and Jonathan Osgood tendered their resignations as mem-

bers of the Board effective as of May 31, 2013; and the Board appointed former Baxano directors Russell C. Hirsch, M.D., Ph.D. and Roderick A. Young to serve as Class III members of the Board effective as of May 31, 2013.

Baxano Surgical, Inc.

The new company describes itself as a “medical device company focused on designing, developing, and marketing products to treat degenerative conditions of the spine affecting the lumbar region. Baxano Surgical currently markets the AxiaLIF family of products for single and two level lumbar fusion, the VEO lateral access and interbody fusion system, and the iO-Flex system, a proprietary minimally invasive set of flexible instruments allowing surgeons to target lumbar spinal stenosis during spinal decompression procedures in all three regions of the spine: central canal, lateral recess, and neural foramen. Baxano Surgical was founded in May 2000 and is headquartered in Raleigh, North Carolina. For more information, visit www.baxanosurgical.com.

—WE (June 3, 2013)

LEGAL

DiscoCare “Conspirators” Plead Guilty and Not Guilty

ArthroCare Corporation’s former senior vice president of strategic business units, John Raffle, has pled not guilty to misleading investors to artificially inflating the company’s stock price.

Federal prosecutors claim that Raffle and David Applegate, another former senior executive at the company, inflated publicly reported revenues through fraudulent sales to DiscoCare between 2006 and 2008. The pair was arrested last August 22.

Applegate Guilty

On May 9, 2013, the Department of Justice (DOJ) announced that Applegate pleaded guilty to two charges of conspiracy to commit securities, mail and wire fraud, and with a false statements violation. Applegate was the senior vice president in charge of ArthroCare’s Spine Division.

DiscoCare Sales

According to court documents, Raffle and Applegate determined the type and amount of product to be shipped to distributors based on the company’s need to meet Wall Street analysts forecasts, rather than distributors’ actual orders. Raffle, Applegate and others then allegedly caused ArthroCare to “park” millions of dollars of medical devices at its distributors at the end of each relevant quarter. ArthroCare would then report these shipments as sales in its quarterly and annual filings at the time of

the shipment, enabling the company to meet or exceed internal and external earnings forecasts.

Between the fourth quarter of 2005 and the fourth quarter of 2007, the government claims ArthroCare reported more than \$37 million in revenue in its financial statements based on purported sales to DiscoCare. However, during the same time period, DiscoCare’s actual net cash payments to ArthroCare for the products were less than \$50,000. Prosecutors allege that, to conceal the fact that DiscoCare owed ArthroCare a substantial amount of money on unused inventory, Raffle and Applegate caused ArthroCare to acquire DiscoCare on December 31, 2007.

Raffle’s Defense

MassDevice reported on May 30, 2013, that Raffle told a Texas federal judge

that he can’t properly prepare for trial unless the court releases the names of his alleged co-conspirators.

“Mr. Raffle is left just weeks away from trial unable to adequately prepare his defense,” according to court documents filed by Raffle’s lawyers. “Without further specificity about the identity of the alleged co-conspirators, Mr. Raffle will be left to guess about the nature of the charges against him.”

Raffle and Applegate could face a maximum prison sentence of five years for the conspiracy charge and 20 years for each count of mail and wire fraud. They also face a maximum sentence of 25 years in prison for each securities fraud count.

—WE (June 6, 2013)



Wikimedia Commons and Toby Hudson

BIOLOGICS

Inventors Stimulate Cartilage With Electromagnetic Stimulation

This is the story of an incubator. The company, Minnesota Medical Physics, occupies one of a row of identical office spaces in a business center located in Edina, Minnesota. CEO Ali Jaafar and Principal Scientist Victor Chornenky, Ph.D., started the company in 2001 to develop “Innovative Solutions to Unmet Medical Needs.” Educated as a physicist, Jaafar is no beginner in business. After a career with Westinghouse, Johnson & Johnson and Becton Dickinson, he left his executive position to found his own company. Chornenky is a physicist whose career includes a university professorship in Moscow, physicist at Harvard and the Smithsonian, and visiting scientist at MIT.

Their approach is to look at a disease state and how it is being treated. If they feel that the existing treatment is adequate, they leave it and go on to another. If not, they look to see if a better treatment can be developed. “We make a comprehensive literature search on the nature of the disease, study and evaluate the newest scientific data on it. Then, based on the data, after long brainstorming, begin to develop new approaches to the treatment. We conceive a product, develop it into an initial prototype, test it, build a clinically suitable prototype and license it to other companies.” Their customers include several major medical device manufacturers.

It was perhaps inevitable that, in their search for better medical solutions to improve the quality of life and treat-



NovoPulse / Courtesy: BioMagnetic Sciences, LLC

ment, they would come upon osteoarthritis and the problem of deteriorating cartilage. Jaafar notes that the standard therapy for osteoarthritis is administration of non-steroidal anti-inflammation drugs (NSAID) and in severe cases, joint replacement surgery. He adds that the NSAID therapy is primarily focused on symptom relief, not on the underlying cause of the disease. The side effects of long-term usage of NSAID, he says, are severe.

In their research the two noted that, over the last decade, investigators have published a number of scientific articles suggesting that pulsed electromagnetic field (PEMF) stimulation, initially developed for treatment of non-union bone fractures, may be effective in the treatment of osteoarthritis.

Jaafar and Chornenky anticipated the potential of PEMF combined with thermal stimulation and embarked on developing an appropriate delivery system. They envisioned that osteoarthritis, a progressive disorder characterized by cartilage degeneration, could be

halted and perhaps even reversed by a combination of appropriately applied thermal stimulation and pulsed electromagnetic stimulation.

After six years of development of the osteoarthritis device, the two have found research papers that appear to support their original thinking. One paper is a Ph.D. dissertation by Italian Frederica Francesca Masieri who studied the therapeutic implications of pulsed magnetic fields in osteoarthritis pathologies. She concluded that PEMF alone can significantly reduce inflammation in osteoarthritic joints and replace NSAID drug therapy.

The second paper, published by the *Journal of Orthopaedic Research*, reported on multi-year studies carried on by the Department of Orthopedics, Graduate School of Medical Sciences, and Kyoto University. Researchers had found that the effect of mild electrical stimulation (MES) combined with heat stimulation (HS) raised HSP70 protein which plays a crucial role in protecting chondrocytes and stimulating cartilage

matrix metabolism. Jaafar and Chornenky present this as the scientific basis for the device they have spent the last six years developing.

They have received a patent on their first product, called the NovoPulse. It is a wearable framework that positions a pad conducting both heat and electromagnetic stimulation to any location on the spine. The NovoPulse contains several microprocessors, controlling application of the PEMF and heat stimulation. Jaafar explains that, "We take an electrical current and run it through a set of treatment coils for a period of 50-100 microseconds, which creates

the ideal conditions for the electrical field. When the pulse shuts off you have all of this magnetic energy that we capture and convert into heat."

In 2011 Jaafar and Chornenky licensed the technology to a new company, called BioMagnetic Sciences, LLC (BMS). Initially BMS plans to market the invention as a pain management device, but their true long-term goal is a clinical trial to demonstrate that their combination of heat and PEMF stimulation can halt or even reverse the deterioration of cartilage. In the meantime, they have panel tests lined up with physicians overseas in the fall of 2013 and hope to soon have their product on the market.

In a 2012 paper on electromagnetic fields and the human body Chornenky wrote, "The ability of pulsed electromagnetic fields (PEMF) to regrow cartilage suggests the possibility of positive modification of the underlying condition of osteoarthritis, something that today's medicine cannot do. PEMF stimulation could be a new effective treatment of the joints that potentially can slow down and even reverse osteoarthritis."

—BY (June 4, 2013)

Stem Cells Effective Against ALS in Rat Study

ALS (amyotrophic lateral sclerosis) is a horrible disease. Only half of patients are alive three years after their diagnosis. Now, from the University of Wisconsin at Madison, is news that the transplantation of human stem cells improved survival and muscle function in rats used to model ALS.



Wikimedia Commons and Aaron Muller

Masatoshi Suzuki, an assistant professor of comparative biosciences, and his colleagues used adult stem cells from human bone marrow and genetically engineered them to produce growth factors that can support damaged nerve cells. They implanted the cells directly into the muscles of rats that were genetically modified to have symptoms and nerve damage that resembled ALS.

A primer on nerves: motor neurons are often the first to suffer damage in ALS, but it is unclear where the deterioration begins. Many scientists have focused on the end of the neuron where it meets the spinal cord. But Suzuki has observed that the far end, where the nerve touches and activates the muscle, is often damaged early in the disease.

The connection between the neuron and the muscle, called the neuro-muscular junction, is where Suzuki focuses



NovoPulse / Courtesy: BioMagnetic Sciences, LLC

his attention. “This is one of our primary differences,” Suzuki says. “We know that the neuro-muscular junction is a site of early deterioration, and we suspected that it might be the villain in causing the nerve cell to die. It might not be an innocent victim of damage that starts elsewhere.”

Previously, Suzuki found that injecting glial cell line-derived neurotrophic factor (GDNF) at the junction helped the neurons survive. The new study, published in the journal *Molecular Therapy*, expands the research to show a similar effect from a second compound, called vascular endothelial growth factor.

Suzuki found that using stem cells to deliver vascular endothelial growth factor alone improved survival and delayed the onset of disease and the decline in muscle function. That result mirrored his earlier study with GDNF.

But the real advance, Suzuki says, was finding an even better result from using stem cells that create both of these two growth factors. “In terms of disease-free time, overall survival, and sustaining muscle function, we found that delivering the combination was more powerful than either growth factor alone.”

The injected stem cells survived for at least nine weeks, but did not become neurons. Instead, their contribution was to secrete one or both growth factors. “We aim to keep the neurons alive and healthy using the same growth factors that the body creates, and that’s what we have shown here,” Suzuki said, adding, “Because this is a fatal and untreatable disease, we hope this could enter a clinical trial relatively soon.”

—BY (June 4, 2013)

LARGE JOINTS

41 Surgical Gloves per Knee Surgery? Really?

Do surgeons need all those surgical gloves, sterile towels, gowns and drapes to replace one knee joint? Perhaps not, thought three medical students in London, Ontario, who conducted an audit of five knee replacement surgeries performed at the London Health Sciences Centre. As reported by Sharon Kirkey of *Postmedia News*, they found that the average surgical waste per surgery was 13.3 kilograms.

To replace one knee, surgeons used, on average, 64 plastic wrappers, 41 sterile surgical gloves, 29 green sterile towels, 10 vinyl gloves, 5 surgical gowns, 5 surgical drapes, 3 table covers and an assortment of sponges and gauzes. The authors reported that a routine operation “produces more waste than a family of four produces in an entire week.” When extrapolated to the more than 47,000 knee replacements performed in Canada in 2008-2009, the authors

estimated that knee surgeries generated 407,889 kg by weight of landfill waste.

Douglas Naudie, M.D., associate professor in the department of surgery at the Schulich School of Medicine and Dentistry at Western University and consultant orthopedic surgeon at London Health Sciences Centre, is the surgeon the students audited. He was surprised by the amount of waste generated by knee replacement. “I had no idea. I think it kind of opened our eyes a lot.”

Since the audit, Naudie’s hospital has initiated several strategies, including more recycling and ensuring waste is properly separated into “normal” and infectious waste. Kirkey reported on studies showing that up to 85% of non-hazardous solid waste is disposed of as infectious waste requiring “high energy” treatment processes. This includes incineration that is not only harmful to the environment but costs 10 to 20 times more. The London, Ontario, hospital has also reduced by nearly half the number of items that are opened and prepared for surgery but never used.

—BY (June 4, 2013)

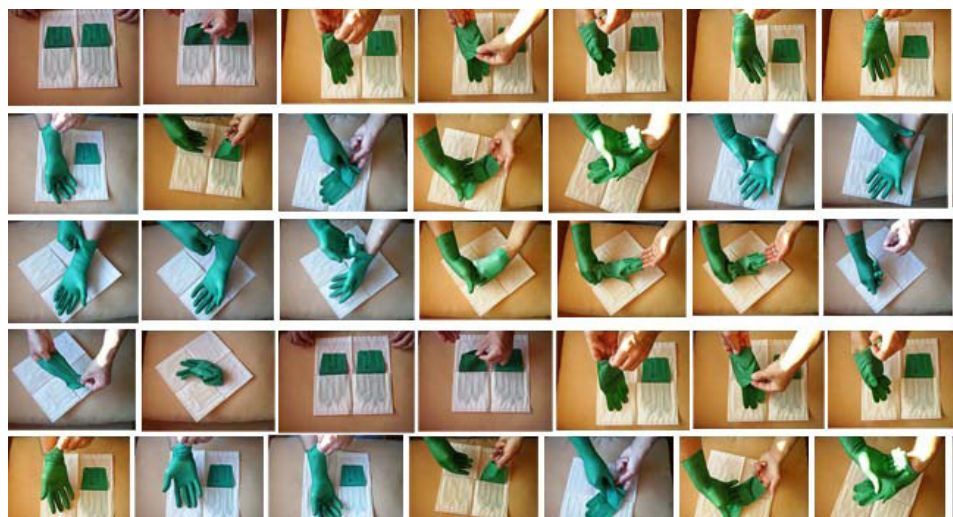


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REIMBURSEMENT

Medicare Solvency Extended Two Years

Medicare's prospects are looking up.

In their 2013 report released on May 31, 2013, Medicare trustees projected two additional years to the trust fund's solvency until it runs out of money in 2026. That's a little like saying the Titanic will hit the iceberg a couple of miles closer to Newfoundland.

"Medicare cannot sustain projected long-run programs in full under currently scheduled financing, and legislative changes are necessary to avoid disruptive consequences for beneficiaries and taxpayers," stated the report.

This means Medicare will run out of money as most Baby Boomers hit their mid-70s.

The modest improvement in the outlook for HI (hospital insurance) long-term finances is principally due to:

- Lower projected spending for most HI service categories, especially for skilled nursing facilities to reflect lower-than-expected spending in 2012 and other recent data;
- Lower projected Medicare Advantage program costs that reflect recent data suggesting that certain provisions of the Affordable Care Act will reduce growth in these costs by more than was previously projected;
- Refinement in projection methods that reduces assumed per beneficiary cost growth during the transition period between the



U.S. Social Security Administration

short-range projections and the long-range projections. Partially offsetting these favorable changes to the projections are somewhat lower projected levels of tax income that reflect lower-than-expected tax income in 2012.

Docs Safe

The trustees project that Part B of Supplementary Medical Insurance (SMI), which pays doctors' bills and other outpatient expenses, and Part D of SMI, which provides access to prescription drug coverage, will remain adequately financed into the indefinite future because current law automatically provides financing each year to meet the next year's expected costs.

The trustees also project that total Medicare cost (including both HI and SMI expenditures) will grow from approximately 3.6% of gross domestic product (GDP) in 2012 to 5.6% of GDP by 2035, and will increase gradually thereafter to about 6.5% of GDP by 2087.

"What we're finding is that there's a significant transformation of the private and public sector in terms of how payments are made," Health & Human Services Secretary Kathleen Sebelius said at a news conference.

—WE (June 7, 2013)

Technology Holding Back Dumping Fee-for-Service

Private health insurers want to dump fee-for-service payments systems. The only thing holding them back is the lack of technology in exchanging information with doctors.



Image created by RRY Publications, LLC Source: Morguefile

According to a Porter Research survey reported in the *American Medical News (AMN)* on May 27, 2013, 20% of health plans said at least half their business was "supported" by value-based payment models at the end of 2012. In three years, 45% of plans expect half their business to be supported by value-based payments. In five years, that number is expected to be 59%.

The survey was done on behalf of Availity, a health information network in Jacksonville, Florida, and included 39 insurers.

AMN reported that the survey found that 82% of health plans consider the development of new payment models a "major priority" for their organizations. Health insurers generally are making the biggest effort to convert from fee-for-service to value-based payments in their employer group plans, with 75% saying they were doing so. By comparison, 54% said Medicare plans were a priority for this transition, 46% said Medicaid plans were, and 44% named individual plans. Respondents could choose more than one answer.

Quality Versus Quantity

“The findings mirror other studies and discussions that have taken place in the wake of the Affordable Care Act and other reforms. Payers and others in the health industry view value-based payment models as a way to improve care and control costs by rewarding doctors for quality rather than the number of procedures performed or patients seen. Insurers have implemented pay-for-performance plans and joined doctors and hospitals in accountable care organizations to make the conversion from straight fee for service,” noted the *AMN* article.

Automatic Information Exchanges

Technology was cited by the health plans as essential as they move to value-based payments. Ninety percent of insurers said automating information exchange is critical to the success of moving to such payments.

Less than 50% of insurers currently have real-time automation capabilities between themselves and doctors, and 90% said they use computers and paper for information exchanges.

The study, according to *AMN*, did not detail whether plans believed the lack of technology was because of problems on their end, or a result of many physicians just beginning to adopt electronic health records under the federal meaningful use program, or a combination of the two.

However, 75% of plans said they will automate information exchange with doctors in the next 12 to 18 months so they can begin to implement or expand value-based payment models.

—*WE (June 7, 2013)*

PEOPLE

Dawson Takes Over MAKO Marketing

After a couple of successful intellectual property and marketing fights with competitors, MAKO Surgical Corp. is getting back to business by hiring a new senior vice president of marketing.

On June 3, 2013, the company announced the appointment of Ian Dawson to the position. Dawson is assuming responsibility for the company’s commercial marketing activities formerly overseen by Ivan Delevic. Delevic is transitioning to the position of senior vice president of corporate development. Both men will report to the company’s President and CEO Maurice Ferré, M.D.

According to the company announcement, Dawson has over 25 years of experience in marketing, with the majority of the experience in the medical device field. From June 2008 through May 2013, he served as vice president of North America marketing for Smith & Nephew Advanced Wound Management, a manufacturer and supplier of advanced wound dressings and devices. He was responsible for managing the entire marketing function for North America.

From May 2004 to June 2008, Dawson held various marketing leadership positions with Zimmer, Inc., including senior director of U.S. knee marketing, where he was responsible for directing all marketing programs and activities related to Zimmer’s knee products. From July 2001 to April 2004, he served as the vice president - Product



Ian Dawson/MAKO Surgical Corp.

Group Knee, for Centerpulse Orthopedics Ltd., a manufacturer and supplier of orthopedic implants. Dawson holds a B.S. in Applied Biology from Chelsea College, University of London and a Diploma in Management Studies from Exeter College of Plymouth Polytechnic.

MAKO Surgical Corp. markets its RIO Robotic-Arm Interactive Orthopedic system, joint specific applications for the knee and hip, and proprietary RESTORIS implants for orthopedic procedures called MAKOplasty. The RIO is a surgeon-interactive tactile surgical platform that incorporates a robotic arm and patient-specific visualization technology, which enables “precise, consistently reproducible bone resection for the accurate insertion and alignment of MAKO’s RESTORIS implants.” The MAKOplasty solution incorporates technologies enabled by an intellectual property portfolio including more than 300 U.S. and foreign, owned and licensed, patents and patent applications.

—*WE (June 4, 2013)*



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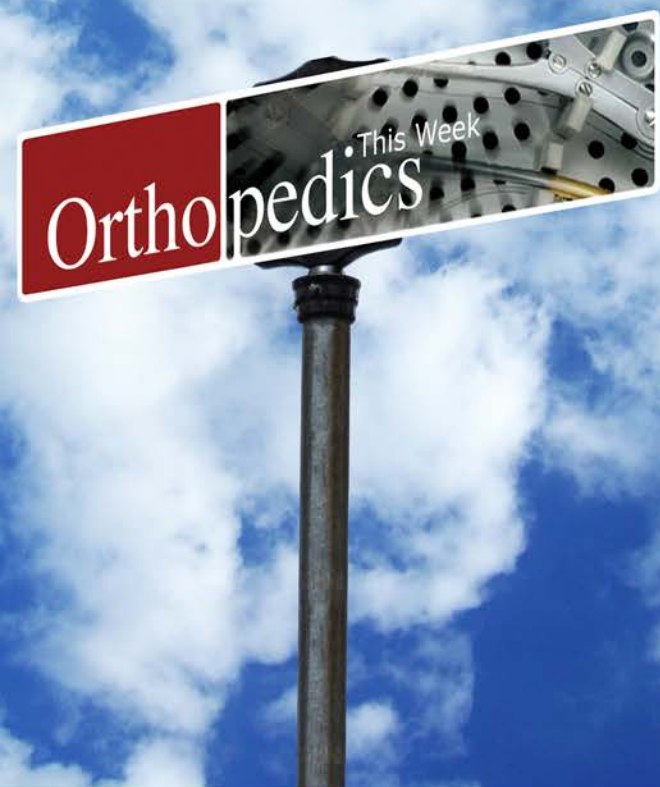
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