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Orthopedics This Week

WEEK IN REVIEW

BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Fed chairman put the imprimatur of the U.S. Central bank on the fact of a Chinese economic slowdown. And the international reaction was to resume their widespread sell-off of equities. Counterintuitively, had the Fed raised interest rates, the assumption would have been that the global economy was strong enough to absorb the hike. But the global economy is teetering on the edge of a wider slowdown. And the Fed seemed to acknowledge that.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	22.78%	(5.08%)	SYK's group president–International out the door as CEO Lobo restructures. Emerging markets 8% of SYK sales, below peers at 11%.
2	2	Smith & Nephew	20.19	(2.83)	Consensus of analysts is that earnings growth will accelerate sharply next year.
3	6	Integra LifeSciences	13.74	3.88	Institutional investors delighted by the way this management team has put IART back on the growth path.
4	3	Orthofix	2.35	(6.45	Although institutional investors haven't really jumped on board, Zacks just reiterated that earnings expected to grow 20% this year.
5	4	Johnson & Johnson	28.44	(5.96)	JNJ is the darling of funds that channel Ben Graham. Don't know who that is? Google BG and Warren Buffet, together.
6	8	Xtant Medical	(16.41)	1.03	Third lowest Price-to-Sales in all of ortho. With two new FDA clearances and full line spinal implants, next few quarters should be interesting.
7	5	Zimmer Biomet	30.35	(6.54)	ZBH is the 2nd least expensive equity in orthopedics courtesy of an extremely low future P/E and PEG. But investors want to see how integration is going.
8	7	RTI Biologics	7.50	(9.90)	RTIX is a volatile equity. Always has been. Still sales expected to rise 8%, earnings nearly 100% off a down year last year.
9	9	Medtronic	27.92	(9.22)	The North American Spine Society meeting just a few weeks away. MDT's principled stands at past NASS meetings stand as some of the best moments ever.
10	NR	Exactech	10.26	4.08	Nice jump for EXAC as investors finally get their heads around EXAC's computer assisted knee surgery system.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$1.25	$211	58.94%
2	SeaSpine Holdings	SPNE	$18.42	$205	19.07%
3	MiMedx Group	MDXG	$11.07	$1,206	18.90%
4	K2M Group Holdings	KTWO	$22.87	$945	4.43%
5	Exactech	EXAC	$19.40	$273	4.08%
6	Integra LifeSciences	IART	$64.23	$2,342	3.88%
7	NuVasive	NUVA	$54.92	$2,688	2.58%
8	MicroPort Scientific	853	$0.40	$572	2.34%
9	Tornier N.V.	TRNX	$24.18	$1,191	1.77%
10	Wright Medical	WMGI	$24.97	$1,284	1.34%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Aurora Spine	ASG	$0.20	$4	-20.75%
2	Alphatec Holdings	ATEC	$0.50	$50	-18.03%
3	RTI Biologics Inc	RTIX	$6.19	$357	-9.90%
4	CryoLife	CRY	$9.51	$282	-9.51%
5	Medtronic	MDT	$70.33	$99,420	-9.22%
6	ConMed	CNMD	$51.64	$1,430	-9.05%
7	Globus Medical	GMED	$24.69	$2,347	-7.98%
8	Zimmer Biomet	ZBH	$99.20	$20,174	-6.54%
9	Orthofix	OFIX	$35.95	$678	-6.45%
10	Johnson & Johnson	JNJ	$93.39	$258,607	-5.96%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$93.39	$258,607	15.86
2	Exactech	EXAC	$19.40	$273	17.32
3	Zimmer Biomet	ZBH	$99.20	$20,174	18.04
4	Globus Medical	GMED	$24.69	$2,347	19.00
5	Stryker	SYK	$99.22	$37,362	22.04

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$54.92	$2,688	87.70
2	CryoLife	CRY	$9.51	$282	79.52
3	MiMedx Group	MDXG	$11.07	$1,206	73.80
4	RTI Biologics Inc	RTIX	$6.19	$357	35.82
5	Smith & Nephew	SNN	$35.65	$15,949	31.83

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$24.69	$2,347	1.55
2	Zimmer Biomet	ZBH	$99.20	$20,174	1.61
3	Exactech	EXAC	$19.40	$273	1.95
4	ConMed	CNMD	$51.64	$1,430	2.06
5	Smith & Nephew	SNN	$35.65	$15,949	2.07

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$54.92	$2,688	5.91
2	MiMedx Group	MDXG	$11.07	$1,206	4.92
3	Medtronic	MDT	$70.33	$99,420	3.43
4	Johnson & Johnson	JNJ	$93.39	$258,607	3.28
5	Integra LifeSciences	IART	$64.23	$2,342	2.65

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$0.50	$50	0.24
2	Exactech	EXAC	$19.40	$273	1.10
3	Xtant Medical	BONE	$3.64	$43	1.21
4	RTI Biologics Inc	RTIX	$6.19	$357	1.36
5	SeaSpine Holdings	SPNE	$18.42	$205	1.48

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.25	$211	33.58
2	MiMedx Group	MDXG	$11.07	$1,206	10.20
3	LDR Holding Corp.	LDRH	$41.42	$1,201	8.04
4	Globus Medical	GMED	$24.69	$2,347	4.95
5	Medtronic	MDT	$70.33	$99,420	4.91

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

Medtronic Spine's Plan

BY WALTER EISNER

Rob Carson has a tough job.

Since April 2015, he's been in charge of Medtronic plc's spine's marketing and strategy and, along with business president Doug King and other company leaders, has to figure out how to guide the 800 lb. gorilla of spine through a whole new healthcare economic environment and back to taking market share.

Medtronic and DePuy Synthes have been losing market share bit by bit to smaller competitors over the past few years. But in the emerging post fee-for-service era of Big Data, health system consolidation and need for scale, Medtronic is playing a whole new game.

Over the last couple of months, Carson has been sharing with *OTW* the company's plan to win in this new era. He has the tools. Armed with the biggest intellectual property toolbox in the industry (including Michelson patents) and a scale of access to customers worldwide, the spine market leader is ready to engage this new environment.

The job of the company, says Carson, is to "improve spinal care—through procedure advancements, economic innovations, and global patient access—using all the expertise and resources available to the company. To do these three things, we have to do the basics very well—but also try things outside of the traditional."

Rob Carson, VP Medtronic Spine

Courtesy of Medtronic plc

Four Key Strategies

Central to that vision is alignment. Economic alignment with stakeholder interests and technically alignment with a focus on sagittal alignment of the spine for better surgical outcomes. The company calls this effort the Sagittal Alignment Global Initiative (SAGI).

Carson outlined four key strategies which build on Medtronic spine's strengths:

First, invest in core technologies and cadence. The company needs regular cycles of product releases. Since most are 510(k) in nature, speed matters. As an example he cited the launch of the overhauled anterior cervical fixation interbody device in a $900 million market.

Second, procedure innovation. The company is always searching for new and different ways to access, fixate and stabilize the spine. For example, Carson cited the MIDLF procedure, which rejuvenated the minimally invasive spine surgery (MIS) portfolio. He is very excited about the OLIF procedures program as a new way of access to the mid- and lower lumbar/lumbosacral discs. With OLIF 25 (for the L1/2 to L4/5 levels), the company encourages "thinking outside the muscle"—and staying away from nerves running through the psoas. Meanwhile, with OLIF51the company plans to accelerate and expand the market (the applicability of lateral surgery).

Further out, Carson said Medtronic is the lone company to invest in fusionless pediatric scoliosis.

In biologics, he cited Infuse's product superiority and expectations of future BMP2 fusion innovations. He said the company has been having a "good" dialog with the FDA. "We've built the market's leading portfolio of solutions, one including not only BioGrafts, but also (increasingly) BioSurgicals and BioLogistics offerings. The BioGraft platform is unique, in that its offerings span the range of patients' osteogenic capacity needs."

Third, surgical synergy through Medtronic's Restorative Therapies Group (RTG). By collaborating across RTG businesses, Medtronic can augment procedures with information, power and energy. Through this collaboration, Carson says the company can "enable greater accuracy (with far less surgeon and OR staff radiation exposure), automation and spinal alignment." He notes that the company has recently introduced E4, its latest nerve integrity monitoring system.

Finally, stakeholder alignment. Carson sees a world of value-based decisions for populations with at-risk payment models. "It's a world one can't fully predict, but to which we plan to contribute innovations."

He sees opportunities for products and processes for surgery tools to help surgeons and hospitals streamline their costs. He notes, while the company is aware of the changing role of the sales rep in the OR, as instituted by Smith & Nephew, Medtronic's stakeholder alignment strategies, "will not involve changes in the role of the sales rep."

Scale Matters

The spine business is important to Medtronic. The division provides a big chunk of the parent company's U.S. free cash flow, and, says Carson, "Spinal helps provide a scale, at the enterprise level as we seek to become a better partner in the healthcare landscape around the world."

To large healthcare systems and government in the U.S., scale matters. "We want to bring quality across the board with great breadth and spinal is obviously a big piece of that in both the neuro and orthopedics world."

We asked Carson how, specifically, how the company will be able to increase its "Cadence" of new product introductions.

Carson noted the Solera Voyager, OLIF procedures, ZEVO and Divergence on the cervical side, Elevate as well and anatomic PTC (pure titanium coating). [All of these are now

in, at minimum, the limited market release phase.]

Benefits of Incremental Innovation

"We recognize incremental innovation is still really important. It's the foundation in spine and broader orthopedics. I think sometimes we use incremental innovation as a damning term. There is a place for incremental improvement or said another way, optimizing the implants and delivery system that are out there and PTC devices, of which there are currently three, are examples of that.

They span the cervical to lumbar spine—but are really just the start of this first strategy. This year we'll bring additional anterior and posterior interbody technologies to market—and going forward new options in trauma and complex spine. There will be a planned stream.

Solera Voyager is an example that really ties in to both the core tech improvements and cadence and also surgical synergy.

We've moved beyond the place where compatibility (with navigation and power) is really an option (i.e., we've reached a point at which we expect to enter the market with fully integrated systems—NAV, NIM and/or power-enabled out of the gates).

So, out of the box we're creating both navigation and power use systems compatibility. So it's an incremental innovation of its own that helps to optimize a minimally invasive TLIF, but it also furthers our surgical synergy strategy.

Navigation has progressed to a point where there is a lot of clinical value, due to its accuracy, but also economic value, due to reduced likelihood of revisions and associated costs."

One of the main hurdles to surgical synergy adoption and even to minimally invasive procedures historically, says Carson, is a perceived and sometimes real learning curve such that if you're not invested personally in climbing that learning curve, you're going to suffer greater inefficiency and time in the OR.

"We're really worked on optimizing the work flows for navigated procedures

such that they are very efficient with OR time, which is costly.

So I think that that's the improvements in workflow in the economic environment we're in where one is increasingly incentivized not to bring a patient back to the O.R. or not to rehospitalize."

Sales Reorganization

He told us that the company has taken a big step in integrating the sales leadership across spine, neuro and surgical technologies. It has reorganized commercial teams at the regional management level by creating a single group of regional vice presidents (RVPs) who divide the country.

"Those RVPs are no longer business specific, they span all of the Restorative Therapy Group businesses." And they bring scale. Carson says part of the mix will be spine, neuro (including pain therapies), (dbs) and also surgical tech (including navigation) neurovascular, which was part of the Covidien acquisition, and Kanghui (Medtronic's ortho and spine platform in China) are additional key businesses in RTG.

RVPs will have responsibility across business lines. Their view is not about maximizing the returns for any one business, as done historically, but instead maximizing the size of the "whole pie."

In Praise of the Bundle

The goal is to help the company's healthcare customers treat spine patients only once and keep them from returning to the operating room. New payment systems, like bundled payments, come with heavy financial risks for providers who miscalculate the costs of care for their patients. CMS (Centers for Medicare and Medicaid Services) has mandated that a significant portion hip and knee replacement procedures be reimbursed under bundled payments. While spine has not yet been included, company Chairman and CEO, Omar Ishrak has praised that payment approach and believes Medtronic would do well under that system.

Omar Ishrak, Ph.D./Courtesy of Medtronic plc

And that's where the four strategies come in.

The ability to access all of the company's restorative therapies helps drive the surgical synergy strategy. It also recognizes the element of stakeholder alignment.

"We're recognizing the evolving need and structures of health systems, so the more our 'go to market' approach and our interface with hospital clinical and administrative leadership reflects 'one voice,' it's is better for everyone," said Carson.

This is particularly noteworthy in large integrated health systems where surgeons are no longer the only voice in making purchasing decisions. "Without question, surgeons play a leading role in a multi-stakeholder decision-making process—but it is a partnership."

Carson says it's a mixed landscape with some health systems and hospitals, including ACOs (accountable care organizations), where the extent of alignments among stakeholders now includes payers along with the administration and surgeons.

"The trends are clearly for increased alignment and partnerships. This [strategy for value-based healthcare] is one more thing we can do to be a better partner."

Wrapping Strategies Together

Carson says wrapping each of the four strategies into a cohesive whole aligns the surgeon's, the hospital's and the payer's incentives.

"Think of an integrated health system as the best example.

In that setting what one is going to want, regardless of where you sit in the stakeholder spectrum, is to intervene once and only once. You want an enduring outcome. And sagittal alignment is absolutely part of that enduring outcome, there's data that shows that."

If you create the right amount of lumbar lordosis in your L 4-5 spondy patient then the chances that that patient is not going to have a revision in five years are lower.

While the plan is young, the behemoth is starting to stir. Medtronic's spine sales of $763 million for the quarter ending August 31, 2015, kept up with the general growth of global spine sales.

Rob Carson and Medtronic have the tools and scale to change the way spine care is created and delivered to patients in this new healthcare environment.

But as he said, "it's unpredictable." ♦

Venture $$ Wave Breaking Towards Wearables

BY ROBIN YOUNG

In retrospect Randy Theken was right. Theken is the inventor of the eDISC, the first artificial lumbar spinal disc with embedded microelectronics.

Theken's disc sensors collected patient motion and load data and then transmitted it via a handheld PDA communicator to surgeons who used it to assess patient performance.

Today we would call Theken's eDISC a biosensing, wearable technology. Theken developed his eDISC about a decade ago and it never did catch on.

In retrospect, if the size of the venture dollars flowing into digital data from all sources including biosensing, wearable technologies is any clue, he was on the right track. He was inventing an entirely new medical device category.

Wikimedia Commons and Mats Stafseng Einarsen

$3 Billion Invested in 2015

And that's not counting the $2.7 billion paid for TriZetto.

The list of the top ten digital health care data tech companies is at the end of this article.

But, suffice it to say, biosensing data collection, integration and analytics is the latest bright shiny object grabbing the attention of big time venture capital.

According to Rock Health, the first venture fund dedicated to funding and researching the digital health market, digital health startups have raised more than $3 billion in 2015 which includes more than $700 million in funding in the third quarter alone. That's a 100% increase year-over-year. The funding is going into firms which build digital medical devices, software for analytics and big data, tools for health care management, and administration tools for payers and providers.

Juniper Research is the most often quoted market research report on this emerging medical device category (*Smart Health & Fitness Wearables: Device Strategies, Trends & Forecasts 2014-2019*) and they are saying that biosensing wearables could "dominate the [health] market until at least 2018."

Despite the underwhelming launch of the Apple Watch (which had its own biosensing abilities) Apple is pouring dollars into this area and its core digital health partnership is with Epic and Mayo Clinic around the comprehensive concept of the HealthKit.

The HealthKit is a FREE software interface with purports to connect everything patient and practice related including patient records, invoices, diary, bookings, finances, financial reports and Medicare claims. https://www.healthkit.com/

In effect, the bet on HealthKit is an attempt to put all this data—whether derived from wearable devices or other sources—into a comprehensive database which moves wearable data beyond counting steps to something extraordinarily powerful.

Enter the FDA.

The FDA's Take

So long as wearables don't make claims about treating specific diseases or conditions or inherent risks to consumer

safety, then, say the experts, the FDA won't consider biosensing wearables to be medical devices.

But the line is getting fuzzy.

If a biosensing wearable is marketed as a way to treat obesity (which is considered by the FDA to be a medical condition) then it could come under FDA medical device oversight. Increasingly the power of biosensing wearables, particularly when they integrate with the patient's other medical data, can play an essential role in managing, diagnosing and potentially treating patient's conditions.

Consider the power of a wearable which monitors blood pressure and alerts the wearer to change behavior when blood pressure hits certain pre-defined levels.

Here is a copy of the FDA's draft guidance document for wearables: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM429674.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

The FDA wrote that wearables which make the following general wellness claims are not subject to FDA oversight:

- Weight management
- Physical fitness
- Relaxation or stress management
- Mental acuity
- Self-esteem
- Sleep management
- Sexual function

Examples of claims which would NOT be exempt from FDA oversight include:

- A claim that a product will treat or diagnose obesity
- A claim that a product will treat an eating disorder, such as anorexia
- A claim that a product helps treat anxiety
- A claim that a computer game will diagnose or treat autism
- A claim that a product will treat muscle atrophy or erectile dysfunction
- A claim to restore a structure or function impaired due to a disease, e.g., a claim that a prosthetic device enables amputees to play basketball

Really, These New Systems Will Affect Patient Outcomes

Look at the infrastructure being created. There's no question but that it will be used explicitly to manage and direct and affect patient outcomes—for a long list of diagnosis.

Apple has its iOS 8 app called Health which along with the HealthKit cloud

API creates the basis for integrating data from multiple apps and monitoring devices.

In addition to Apple and Google, here are the other companies making bets in the medical data integration market:

Acer, Appirio, Basis, Cambridge Consultants, Clothing+, Cutecircuit, Fitbit, GOQii, Hexoskin, Humana, Jawbone, Microsoft, MyFitnessPal, Nike, Owlet, Polar, Proteus Digital Health, Qardio, Qualcomm, Ralph Lauren, Razer, RunKeeper, Samsung, TAG Heuer, Timex, Withings, Xiaomi.

Apple's HealthKit cloud approach probably epitomizes where other companies are heading. The HealthKit service logs data that's been recorded by apps or gathered from mobile sensors and retrieve the content of that health profile. Apple's goal is to make the Health app an entry point to the broader HealthKit service and to also channel in other digital health data apps.

The basis for HealthKit is the Mayo Clinic's patient portal and patient app. From Mayo's perspective, the app is a data repository for wearable digital data and opens up the possibility of a patient and physician dashboard. Wearables which monitor patient blood pressure could alert the physician of abnormal readings in the Health app from which the physician (or, more likely, nurse) could follow-up. Real time.

Just reading the commentary from senior executives at Mayo, it is clear that this is heading into subspecialty use—orthopedics and cardiac are top of the list. Already the discussions are to pull all biosensing data into data aggregators like HealthKit, which not only aggregate the wearable data, but also the electronic medical record, the pharmaceutical record and data from comparable patients and then fully incorporate them into treatment plans.

How can these not affect patient outcomes and why would we not want that?

The Top Ten Digital Health Companies, So Far

Proteus Digital Health: This summer, Proteus Digital Health raised $52 million, bringing its Series G investment round to more than $172 million. Proteus is creating Digital Medicine. Digital Medicine therapy includes drugs that communicate when they've been taken, wearable sensors that capture physiologic response, applications that support patient self-care and physician decision making, and data analytics to serve the needs of doctors and health

systems. Proteus received FDA market clearance in the United States and a CE mark in Europe for its wearable and Ingestible Sensor devices. Headquartered in Redwood City, Calif., Proteus is privately held and funded by leading institutional and corporate investors, including: Novartis, Otsuka, Oracle and Kaiser Permanente.

Teladoc: Teladoc raised a $50.3 million this year. Teladoc is a telephone (call the 1-800 number) medical hotline where patients can confer with a physician. For $35 per visit (plus a one-time fee of $18 and a monthly membership fee ranging from $4.25 for an individual to $7.00 for a family). Teladoc has grown to more than 10 million members in the past decade. According to the company, close to 300,000 people all received medical care in under an hour in 2014. Teladoc is aiming for a share of the 1.2 billion ambulatory visits per year in the U.S.

Chunyu: Chunyu raised a $50 million Series C in August 2014. Chunyu offers an app which allows patients to chat and call real doctors. Asking questions on forums is free with registration, as are 90-second phone calls with physicians. But many of the value added services—longer private consultations by phone, scheduling appointments, and having a private doctor on call—come at a premium. The price depends on the doctor, and the revenue is split between the doctors and Chunyu. *CNN* reported that the app has 30 million users and 40,000 doctors.

TriZetto: Cognizant, an IT consulting company bought TriZetto for $2.7 billion. TriZetto provides practice management/electronic medical records (EMR) systems to hospitals and clinics and is promoting integration software which allows payer systems and clinic systems to communicate and use analytics to monitor, catch and fix issues before they create downstream problems. TriZetto is attempting to more fully integrate all technology platforms including EMR, payer databases and web based, cloud data aggregators. TriZetto is currently working with about 200,000 physicians across the country.

Lift Labs: Lift Labs, which was acquired by Google in 2014, makes Liftware—a spoon which tries to cancel the effects of tremors caused by such neurodegenerative diseases as Parkinson disease. Lift Labs also developed two apps—Lift Pulse and Lift Stride—to measure tremors and to help people with Parkinson's disease prevent shuffling while walking.

PatientKeeper: PatientKeeper was acquired by HCA last year. PatientKeeper software integrates everything a physician needs (clinic notes, medication interactions, lab results, test orders, prescriptions and, soon, data from biosensors) from multiple systems across a hospital, computers and mobile devices into a single dashboard view. About 60,000 physicians are using PatientKeeper.

NantHealth: NantHealth raised $135 million in 2014. NantHealth is trying to combine science and technology into a single integrated clinical platform which can provide actionable health information at the point of care, in the time of need, anywhere, anytime. More generally, NantHealth hopes to provide physicians with actionable, cloud based clinical intelligence at the moment of decision.

Flatiron Health: In 2014 Google led a $130 million Series B investment into Flatiron. Flatiron's OncologyCloud™ integrates electronic medical records for oncology with advanced analytics, a patient portal, and an integrated billing management tool. Earlier this year Flatiron formed a strategic alliance with Guardant Health. Guardant is generating genomic data from its Guardant360™ liquid biopsy platform.

Alignment Healthcare: General Atlantic invested $125 million in Alignment Healthcare. Alignment partners with providers, health plans, and hospitals to create a seamless, fast and continuous end-to-end care program, including clinical care coordination, risk management capabilities, and IT enablement. In short, Alignment integrates disparate data systems. One of Alignment's key partners is Humana.

MedHOK: In January 2014, MedHOK raised $77.5 million. MedHOK offers an integrated care management, quality, and compliance platform that uses web based cloud architecture to help physicians, ACOs, PCMHs, payers, TPAs, PBMs, and other entities to manage and measure care against national quality standards for optimal patient outcomes.

With this kind of money and smarts working in the medical data acquisition, integration and analytics field the future will be nothing like the present. More to come, for sure. ♦

Bess is NYU's New Adult Spinal Deformity Chief // Gajewski Joins OrthoAtlanta // Orchid Acquires Implant Coating Company

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

Shay Bess, M.D. New Chief of Adult Deformity at NYU Shay Bess, M.D., president of the International Spine Study Group Foundation (ISSG), is the new chief of the Adult Spinal Deformity Service for the Division of Spine Surgery in the Department of Orthopaedic Surgery at NYU Langone Medical Center's Hospital for Joint Diseases. Dr. Bess is also serving as Director of Spinal Deformity Research at that facility.

Shay Bess, M.D., NYU Langone Medical Center

Dr. Bess, who was also named associate professor of orthopaedic surgery at NYU School of Medicine, told *OTW*, "Tom Errico and Frank Schwab and Virginie Lafage have done a phenomenal job of creating a high quality clinical and research program that stands out in the crowd. Over the next year our goal is to continue that work by reevaluating why exactly patients report their respective reasons for pain and disability and to begin to identify what individuals want most out of the treatment they receive. More specifically we hope to be able to identify and integrate the patient's individual goals. To date, we just have a general sense of how people are faring, but we must focus more on the individual needs of the patient."

"In order to be able to personalize our evaluations and treatment plans we need to create assessment tools that evaluate both the objective and subjective aspects of the patient. So then rather than just using a standardized questionnaire that administers the same static, fixed questions to every patient, (i.e., each person answers a series of questions and each question has a set number of possible responses) a more effective method to evaluate patients might be to use an interactive algorithm of questions that highlight the individual's experience and needs. In this manner we will be able to more effectively 'tease out what matters most to patients'. So then in a standardized manner we, for example, can differentiate between one patient whose goal is to run a marathon, compared to another patient whose goal is to walk in the shopping mall pain free."

Dr. Bess comes to NYU from Rocky Mountain Hospital for Children/Presbyterian St. Luke's Medical Center in Denver, where he served as Director of the Pediatric Scoliosis Services. He stated, "We also hope to learn and integrate computerized testing that will allow us to look at algorithms and see how patients are responding to treatment and reporting pain. Administratively, this will save time for patients by reducing questionnaire burden, and for research purposes it will result in a questionnaire that generates richer data. Because these adaptive questionnaires can be used as both disease specific and general health metrics we can then use similar data to evaluate outcomes for spine patients, and to also compare to spine patients to patients other pathologies such as osteoarthritis of the hip or the knee. In doing so we can then determine the disease impact of each condition and evaluate how patients respond to treatment, and what is the most cost effective and psychologically helpful treatment. So far, no one else is doing this for spine deformity."

"Fortunately, the ISSG has done a substantial amount of early 'groundwork' in this area. Therefore going forward we hope to be able to utilize the data we obtain and integrate with the intelligence of our talented ISSG members to move this process forward in a thoughtful, thorough and impactful manner."

Dr. Bess attended Columbia University, earned his medical degree from Johns

Hopkins University School of Medicine in Baltimore, and completed his residency at Case Western Reserve University. Dr. Bess did a postdoctoral spine fellowship in pediatric and adult scoliosis and spinal deformity at Washington University in St. Louis.

Timothy Gajewski, M.D. Joins OrthoAtlanta Dr. Timothy Gajewski, a fellowship trained total joint surgeon who received his training at Queen's University in Kingston, Ontario, has joined the team at OrthoAtlanta. Dr. Gajewski is certified by the American Board of Orthopaedic Surgery and is a Fellow of the Royal College of Physicians and Surgeons of Canada.

Dr. Gajewski specializes in reconstructive surgery of the hip and knee, with a special interest in partial knee replacement. Prior to joining OrthoAtlanta, Dr. Gajewski, who has 25 years of orthopedic experience, was at the Cleveland Clinic. As a member of OrthoAtlanta, Dr. Gajewski sees patients in Lawrenceville and Johns Creek. He is on staff at Gwinnett Medical Center.

Dr. Gajewski told *OTW,* "My initial focus since joining OrthoAtlanta has been getting into the community to meet with area physicians, businesses and residents to let them know that I am available to serve them. My priority is to establish trust with each and every patient that I see."

Orchid Orthopedic Acquires Implant Coating Company—Alhenia Alhenia, a European company that supplies coatings to implant manufacturers, has just been acquired by Orchid Orthopedic. Alhenia, based in Switzerland, has experience with coatings on peek and polyethylene, ceramic coatings, cold spray coatings, titanium on metal and ceramic substrates and anti bacterial coatings. For many years Alhenia has machined implants and instruments along with a wide variety of finishing capabilities to complete the entire value stream for orthopedic components.

Mike Miller, CEO of Orchid, told *OTW,* "Adding Alhenia supports our long-term strategy to have full value stream services on three continents: North America, Europe and Asia. We are continuing to look at businesses that will support this strategy and be a good fit to our Orchid culture. The timing is something that cannot always be controlled but when the right opportunity comes it makes sense to execute."

"We are hoping to be able to integrate Alhenia within the Orchid family over the next year. We will know we are successful if Alhenia continues to grow as they have been and we have more full-value stream projects that tie together our multiple sites that include Alhenia." ♦

Patella Resurfacing: *Rarely, if Ever Necessary*

BY OTW STAFF

This week's Orthopaedic Crossfire® debate was part of the 16th Annual Current Concepts in Joint Replacement® (CCJR) – Spring meeting, which took place in Las Vegas this past May. This week's topic is "Patella Resurfacing: Rarely, if Ever Necessary." For the proposition is Robert L. Barrack, M.D., Washington University School of Medicine, St. Louis, Missouri. Wayne G. Paprosky, M.D., Rush University Medical Center, Chicago, Illinois opposes the statement. Moderating is Aaron G. Rosenberg, M.D., Rush University Medical Center, Chicago, Illinois.

Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Barrack: Now legendary American football coach—Woody Hays for the younger people in the audience—said that three things can happen when you pass the ball and two of them are bad. That's why he always ran the ball. In total knees there's a corollary with that. There are about five things that can happen when you resurface a patella and four of them are bad. You can over resect, under resect, resect obliquely, you can disrupt the blood supply and the sequelae of all these are serious problems. But the people who resurface patellas will say, 'Well, it's pretty rare, it doesn't happen very often.' I would take issue with that and I have data that I'll show you as to why I do.

One of our leading centers with high volume joint surgeons (Berend, et al, CORR 2001) looked at their patellas 2, 3, 4 years after surgery and they found a high percentage of them didn't look so good on x-ray—4.2% failures that they classified as either collapsed, fragmentation or lateral subluxation at an average follow-up of only 5.5 years. Now, it makes sense if you look at an x-ray and you see fragmentation or any of these phenomena, that in a 10- to 12-year period you know this is just not a good situation.

So the question is, at a referral center what are the problems that we're seeing? There are 10,000 or 20,000 total knees with unresurfaced patellas and a fewer number with resurfaced patellas. Which ones are causing the problems? Over a course of a year we studied how many patients were coming in with anterior knee pain and were they mostly resurfaced or unresurfaced. We looked at these follow-ups and we had 46 cases. Three-fourths of them actually had been resurfaced. Three times as many problems were occurring with resurfaced patellas.

We saw early loosening, patella revision…this is a problem there's no solution for. Fragmented patella, loose component. What do you do for that? A whole extensor mechanism allograft? Many of these patients can still fully extend their knee. They're a little weak. They're frequently painful. But you just tell them to live with it. Fragmented loose patella. AVN of a patella. If you cut a little too thin, you do a lateral release, they're painful. You get a bone scan, it's very hot. There's no solution to this problem as well. Latent stress fractures. Lateral facet pain is very common. If you leave any overhanging bone and the extensor mechanism is not well balanced, this causes pain.

So there are a lot of advantages to not resurfacing the patella. It's faster, it's less expensive. I can guarantee you as we shift more towards uncemented total knees; people are not going to pay the extra expense because it's just not worth it. Mainly there's a lower risk of major complications and as symptoms develop you have more salvage options. So a small percentage of patients are going to have symptoms in the front of their knee, whether or not you resurface the patella. But which retains more options, which has more serious complications? So the major determinant of the clinical result and the presence of anterior knee pain is a surgical technique and the component design, not whether or not you resurface the patella. So is it really necessary? I occasionally do it for

a deformed mal-tracking patella, severe rheumatoid, but for the vast majority, it's simply not necessary.

Dr. Paprosky: I'm obviously on the other side of this. Robert's in St. Louis and that data's mostly from St. Louis. Patella components don't get loose. Anterior knee pain is markedly reduced with the new designs. If not, don't blame the patella. Why do you think the patella? AVN, I haven't seen one in a long time. Modern patellofemoral articulations have changed. External rotation of the component has been a game changer and it doesn't take long to do it—maybe 60 seconds.

But patella resurfacing really is like food, cars and sports…it depends on where you live. If you live in Sweden; if you live in Chicago where we happen to resurface the patella. They don't resurface the patella in Asia. We resurface in Chicago. I don't use chopsticks to eat and if you work where I work and you drive the kind of car they have in Germany where they selectively resurface, they're going to selectively steal your car in Chicago.

So what are the advantages? When looking at a 2-year study (Schroeder-Boersch H, et al, Arch Orthop Trauma Surg, 1998), 40 randomized patients, within 24 months the advantage of patella resurfacing could be seen according to the Knee Society score. We see superior functional results.

When we looked at expected value decision, the expected value refers to the predicted consequences of a decision, and we found in this particular series from 2008 (Helmy et al., CORR), anterior knee pain with a resurfaced patella was 12% compared with 26% without the patella. Jay Parvizi's series (CORR 2005) looked at a meta-analysis comparing with and without resurfacing the patella, paying particular attention to patient satisfaction. This randomized clinical trial relevant to patellar resurfacing was done over a period of time, looking at 14 articles, and found that secondary resurfacing for anterior knee pain was needed in 8.7% of non-resurfaced patients. When we looked at it, secondary resurfacing is required in this series for 1 out of 10 patients.

When we look at more articles including Robert's from 2001, we find that the summary for incidence of anterior knee pain for resurfaced patella was 13%, non-resurfaced from this series was 24%. Even in Robert's series there was some anterior knee pain. When we look at incidence of revisions and re-operations, it's 3% versus 8% for the non-resurfaced patella. When we look at incidence of revision of the patellar

component, and there's no revision in the non-resurfaced because it wasn't an operation, it's 1%. Incidence of re-operation for mal-tracking is equal. Incidence of patella fracture—okay, a little bit higher in resurfaced patellas—so that is going to occur.

Proper technique and modern total knee designs, which in my opinion is a game changer. I would agree with a lot of what Robert said if this would have been before rotation of the components, the old box-like IB series without rights and lefts—that was a different story. I used to do that. I used to leave many of them unresurfaced, but I've kind of evolved. So I say resurface the patella routinely to reduce incidences of re-operation, with proper technique in measuring and cutting the patella, proper orientation, there is little downfall nowadays. Given all the evidence, why would you want to make a choice? Just go ahead and resurface the patella. Why not finish the job? It's like saying, 'Well, the house is unfinished, but at least it lets more light in, so why finish it.' I will give Robert one concession. The Cardinals are better than the Cubs, but that still doesn't mean we're going to not resurface the patella.

Dr. Barrack: I think there are lies, damn lies, and statistics. When you say patella resurfacing was required in 6%, 8%, 10% of the cases, it was just an easy thing to do so people did it. In fact, if you resurface the patella you have an equal amount of pain but you just tell patients to live with it because there isn't an easy bailout procedure. If you hold the line and resist the easy option of just resurfacing an unresurfaced patella, you're re-operation rate will be much lower and your results will be the same.

As far as anterior knee pain, again these are pooled data. When you showed the PFC Sigma, the AMK, you alluded to old designs and how you didn't resurface the patella in those older designs. Well, you shouldn't quote statistics from those older designs because with the newer techniques and the newer designs with extended grooves and a smoother, more congruent surface, you simply don't need to resurface the patella. And a complication rate in your hands and high volume surgeons' hands may be lower, but in the community that's the last part of the case and it frequently does lead to complications.

Dr. Paprosky: With the older designs I found that you had more incidences of avascular necrosis because we were doing lateral releases and we didn't have rights and lefts. Boxy designs like I alluded to. We didn't know anything

about rotation until 6-7 years ago. As those things have changed and we have better designs, it's much easier to get the operation done. We balance the flexion extension gaps better with a greater variety of sizes, and I'm commenting as a PS surgeon. Because of what has evolved with the components, I think it's much, much easier now to do it…the instruments…you can plane down the patella without doing lateral releases. It's a much easier operation to get right.

Dr. Barrack: A key thing, Wayne, though is the data you were quoting of the increased incidence of anterior knee pain was largely with those older designs. So with the never designs and the newer techniques, you'll find that you really don't need to do it.

Moderator Rosenberg: It seems to me that in every other joint, metal and plastic resurfacing both sides of the joint has led to generally better results than metal and cartilage or metal and damaged cartilage. Why would the knee cap be different than the hip joint where we pretty well demonstrated that a total hip replacement that is replacing both sides of the articulation seems to yield a higher percentage of good results?

Dr. Barrack: You know the patella is a sesamoid bone. The nerve endings aren't in cartilage; it's a matter of getting the soft tissue balanced because if you're not balanced and you have excessive forces, you get pain from the excessive tension in the soft tissue. But that's going to be the case whether or not you resurface the patella. Having a piece of plastic there is not going to keep you from having pain from that overhanging facet that's putting tension on the tissues. And you have to be careful about the statistics, but certainly if you look at registries, it's very implant-specific. The implant you use in the Swedish registry has a lower revision rate when it's not resurfaced. So using pooled data isn't particularly useful to me because I'm only interested in results with the components I use and I haven't seen a higher incidence of anterior knee pain. Certainly not re-operation.

Moderator Rosenberg: Thank you very much for a lively debate. ♦

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

COMPANY

Blue Belt's Robot Supports ZUK Knee

Blue Belt Technologies, Inc. announced on September 8, 2015, that its Navio robotics-assisted system is now providing commercial support for Smith & Nephew's ZUK unicompartmental (uni) knee.

The ZUK was introduced in 2004 and acquired by Smith & Nephew in June 2015 from Zimmer Holdings, Inc. Zimmer had to divest itself of the knee to gain regulatory approval to acquire Biomet, Inc.

Lauralan Grison, Smith & Nephew's knee reconstruction vice president, said, "This is an excellent time to leverage our partnership with Blue Belt Technologies. Healthcare providers, particularly the fast-growing Ambulatory Surgery Center segment, are seeking affordable, advanced surgical solutions for their orthopaedic care, and introducing this robotics-assisted technology for the ZUK knee further sets us apart in the industry."

Using patented technology, the Navio system works through CT-free navigation and handheld robotics to enable the surgeon to create a surgical plan based on patient anatomy, and, claims the company, brings a high degree of implant placement accuracy. The system's open implant software supports eight different knee systems.

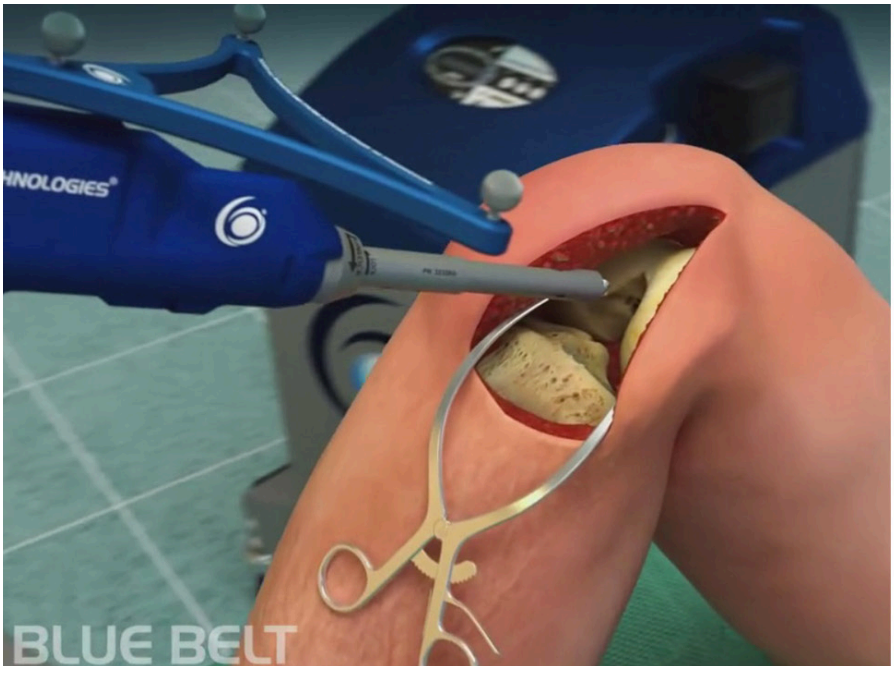
According to the company, the system offers "precise control to surgeons via an intelligent, handheld, computer-assisted, bone-cutting tool [and] provides robotic assistance to the surgeon while performing bone-shaping tasks through minimally invasive incisions." The company's Stride unicondylar knee system provides implant features optimized for use with Navio.

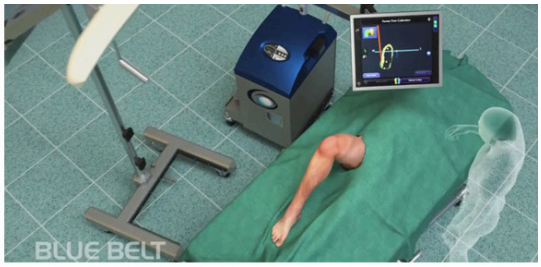
During bone preparation, the robotic-controlled handpiece is tracked in real time in relation to the intended resurfacing plan and is computer controlled to remove only the bone required to place the implant.

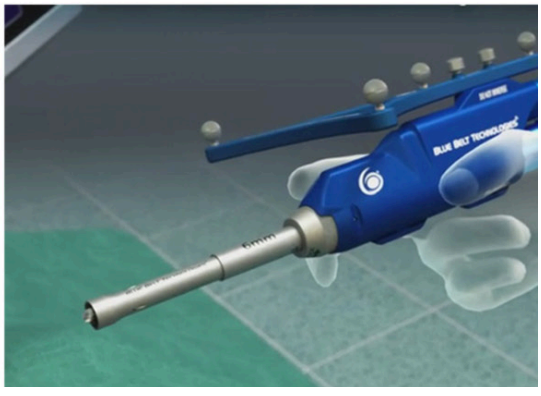
And with no pre-operative CT-scan required, the patient can receive the benefits of robotic guidance without additional time spent on pre-operative procedures. The surgeon simply registers the patient during the procedure using kinematic reconstruction and anatomic landmarks. This information assists the surgeon in planning the implant location and balancing the knee's ligaments.

First U.S. Surgery

In addition to the Smith & Nephew announcement, the company also announced the first U.S. surgery using the Navio system and ZUK implant. The surgery was performed by Michael Miranda, M.D. of the Florida Orthopaedic Institute. "By making partial knee replacements a more accessible option through improved precision, we ensure that the patient receives a surgical procedure that is generally associated with smaller incisions, less scarring, a shorter hospital stay and quicker recovery when compared to the total knee replacement alternative," said Miranda. — *WE*







Courtesy of Blue Belt Technologies

LEGAL

Another Bullet Aimed at FDA's Off-Label Powers

The legal Chinese water torture to the FDA's dying off-label speech power continues. Soon the agency might be afraid to even issue a Warning Letter alleging misbranding.

Photo creation by RRY Publications, LLC and FDA

Sorrell, Caronia and Amerin

First there was *Sorrell v U.S.* in 2011 where the Supreme Court said speech in the "aid of pharmaceutical marketing" is protected free speech under the First Amendment. Then came *Caronia* in 2012 when a federal appeals court said the FDA can't prosecute drug and device manufacturers for making "true" off-label statements. Then this past year, Amerin sued the FDA over the threat of being prosecuted, and the Supreme Court deep-sixed the FDA's argument that the agency wasn't prosecuting speech, but "conduct that is evident of intent."

Pacira and Warning Letter

Now comes *Pacira v FDA* and a labeling case resulting in a Warning Letter.

Pacira, the maker of Exparel, a surgical pain medication, sued the FDA on September 9, 2015.

The drug, EXPAREL, is indicated for "administration into the surgical site to provide postsurgical analgesia" and the indication does not include any limits in the type of surgeries. With the Warning Letter, the FDA was attempted to prevent the company from sharing information about its drug outside of bunionectomies and hemorrhoidectomies, the two types of surgeries that formed the basis of its approval. According to the FDA's guidance on labeling for analgesic drugs, the results of two studies,

one in visceral and the other in non-visceral pain, can be extrapolated to other types of pain.

Back in September 2014, the FDA handed the Pacira a Warning Letter objecting to the company's promotional materials and accusing the company of a criminal violation. The Warning Letter said that the clinical trial section of the label states the drug "has not been demonstrated to be safe and effective in other procedures."

The company acquiesced to the FDA's demands in the Warning Letter while continuing to request a meeting to discuss what it believed to be unlawful restrictions on a broad indication of "administration into the surgical site".

But, according to a law blog written by Michael Walsh and Katherine McGahey, the FDA stonewalled. "Given the threat of criminal sanctions, the company relented and did what the FDA demanded and refrained from disseminating truthful FDA-approved information to physicians. The FDA subsequently issued a 'Close Out Letter' and Pacira continues to refrain from engaging in conduct that the FDA is barred by the First Amendment from prohibiting."

The lawyers argue that before the regulatory ship sinks entirely, FDA should consider keeping its promise to hold public hearings "and get the reasoned voice of industry, the public, and even the public interest groups to provide guidance on what has become a public health imperative to provide more, not less, truthful scientific and medical information to the medical community and the public concerning approved products."

No date for trial has been set for Pacira. — *WE*

LARGE JOINTS

Heart Attack Risk Soars after Joint Replacements

Have osteoarthritis (OA) and planning joint replacement surgery? Pay attention to your heart. A handful of studies have found that people with osteoarthritis who have joint replacement surgery are at risk for a heart attack in the month following the procedure. The study found that the risk went on over time but patients remained at risk for a blood clot in the legs or lungs for up to three years following the joint replacement surgery.

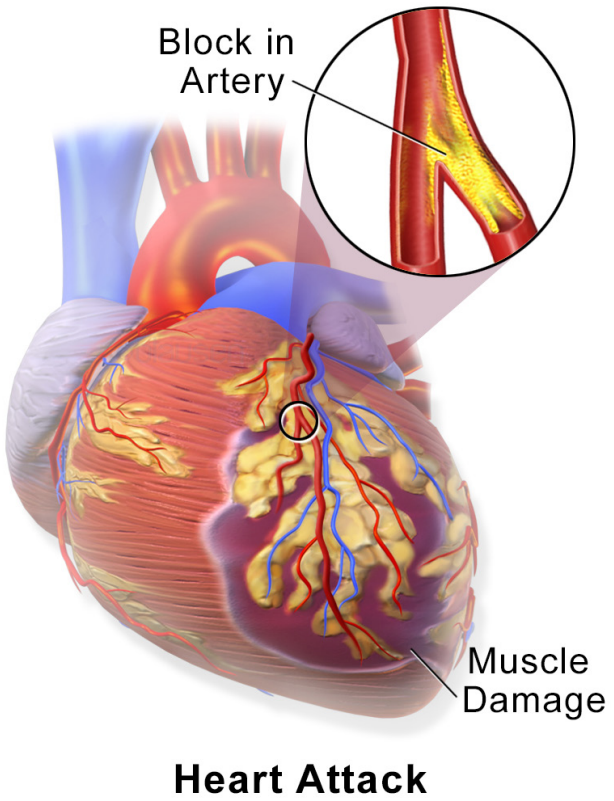
The results of the studies, some of which were conducted in the United Kingdom, were somewhat contradictory. According to Clint Witchalls, writing for *Web MD*, one study found that people with osteoarthritis who had a total knee or hip replacement were at 44% reduced risk of heart attack, stroke or other "cardiovascular event." The study followed the participants for seven years but excluded those who may have experienced a cardiovascular event shortly after having their surgery.

Another study found that people who had total hip or knee replacement surgery had a 25- to 31-fold increased cardiovascular risk during the first weeks after surgery.

In a major study conducted in the United States, according to Witchalls, researchers wanted to find out the short and long-term risks of total joint replacement for people with osteoarthritis. They examined data on 13,849 patients with OA who had the surgery and compared them with 13,849 similar individuals who had OA but did not have total knee replacement surgery.

"They also examined the data on 6,063 people with osteoarthritis who had total hip replacement surgery and compared them with 6,063 similar individuals who did not have total hip replacement surgery", wrote Witchalls.

They learned that people who had total knee replacement surgery were



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almost nine times more likely to have a heart attack in the first month after surgery. The researchers compared this to the experience of people who also had osteoarthritis but did not elect to have the surgery. This became the control group. They also found that people who had total hip replacement surgery were four times more likely to have a heart attack in the month following surgery than were members of the control group.

The risk of heart attack dropped dramatically after one year post surgery. Among the knee replacement patents the risk dropped to the level of the control group. For hip replacement patients, the risk dropped to the same level as the control group within three months. The studies were published in the journal *Arthritis and Rheumatology.* — *BY*

Weight and Age Drive Knee Replacements

What factors are driving the joint replacement business? The annual market for knee implants is roughly $4 billion in the U.S., according to Bloomberg analyst Jason McGorman. John Tozzi, a Bloomberg writer, notes that Americans are getting older and heavier—which means trouble for the knees of the country.

Tozzi writes that the rate of total knee replacements doubled from 2000 to 2010 for Americans over age 45. At the same time the average age of patients increased by more than two years to 66.2. Surgeons performed about 700,000 knee replacement surgeries in 2010 making it the most common patient hospital procedure for people over age 45.

Tozzi points out the two big demographic shifts that help explain the knee replacement boom. One is that people are living longer: He claims that life

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expectancy for 65-year-olds increased by a year-and-a-half from 2000 to 2010.

The fact that more and more Americans are overweight and obese compounds the problem. David Ayers, M.D., chairman of orthopedics and physical rehabilitation at the University of Massachusetts Medical School has analyzed data on 35,000 joint surgery patients. He said that people who have joint replacements before age 60 are more likely to be obese and to have other health problems. "It's not that these are young, healthy, fit people," said Ayers.

Tozzi quotes David Teuscher, M.D., president of the American Academy of Orthopaedic Surgeons, who notes that the force on the knee when going up stairs can be three to five times body weight. "Not everyone who suffers from obesity gets knee pain, but the extra weight can aggravate arthritic knees," he said. — *BY*

Surgeons Perform OK Despite Sleep Disturbance

Do not worry about a surgeon performing surgery following a night of interrupted sleep. He (or she) will do just fine, according to a study conducted of 40,000 patients published in the *New England Journal of Medicine* the researchers, who came from Mount Sinai Hospital in Toronto and from the University of Toronto analyzed health databases of Ontario patients treated between the years 2007 and 2011.

According for writer Susan Hall of *Wall Street Hedge*, patients who underwent surgery in the morning undertaken by a surgeon who had had to wake up in the middle of the night experienced complication or death in 22.2% of the cases. The rate of complication or death in

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normal conditions (when the surgeon had not worked the night before) was of 22.4%.

As Hall wrote, "Sleep deprivation made no difference" The only difference researchers found was when surgeons had to treat two or more patients after midnight. These patients had a 14% greater chance of experiencing complications than did members of the control group. The authors of the study concluded that there is no reason to limit work hours of surgeons because of concerns over patient safety. — *BY*

Study Counts Retained Surgical Items in Patients

What is the numbers and what is the cost to a hospital of retained surgical items (RSIs) during a total joint arthroplasty? And how many of these "never events" take place in a year? A study by Bryce Van Doren, a graduate research assistant at the OrthoCarolina Research Institute, Charlotte, North Carolina, as well as a doctoral student at the College of Health and Human Services, University of North Carolina at Charlotte came up with an answer.

Doren and his associates calculated that the rate of RSIs was one per 6,878 primary total hip arthroplasties and one per 11,961 total knee arthroplasties. The overall rate, according to Rosemary Frei, writing a report for *Pain Management News*, was one per 11,948 procedures. They calculated the cost of a single retained item at $6,412.

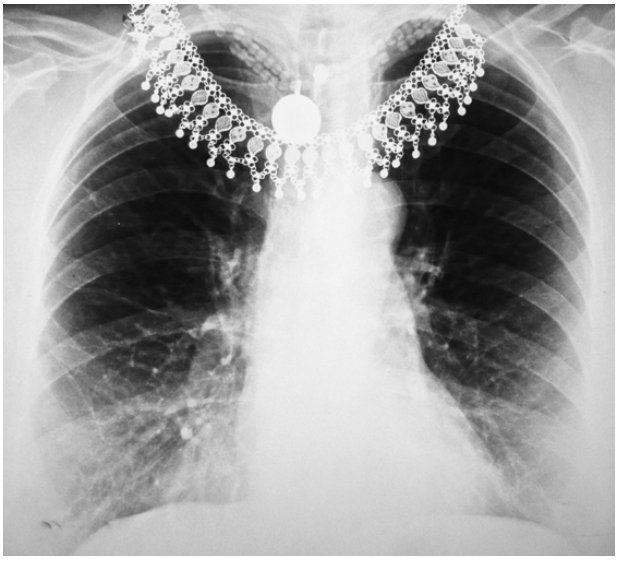
The patients who were unfortunate enough to experience an RSI underwent an average of one additional procedure than did those without an RSI. One doctor expressed surprise that the RSI rate was higher for knee replacements than it was for the hips. "There are not a lot of places for items to get out of sight in a knee," he observed.

The Centers for Medicare & Medicaid Services considers RSIs to be too serious to have a legitimate reason to occur. Therefore the agency does not reimburse hospitals or doctors for any costs associated with the incidents. Writers of the report suggested that this may lead to an under-reporting of the incidence of RSIs.

Frei quoted Robert Cima, M.D., professor of surgery and chair of the Surgical Quality and Safety Committee at Mayo Clinic in Rochester, Minnesota, who said that cost estimates are "particularly difficult to determine" and that the numbers reported are much lower than in his experience handling this issue over the last decade and in published reports.

"In many situations, the bills are written off by the institution, charges are adjusted and any payouts are usually associated with a confidentiality agreement, so the true costs of these events are unknown," Cima said.

Cima added that most orthopedic RSIs are not entire instruments but, instead, are small items such as the tip of a drill or a broken portion of a rod, plate or screw. Trying to remove these items from patients puts them at greater risk for complications than does leaving them in place. — *BY*



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EXTREMITIES

Zimmer Biomet Brings Subchondroplasty to Foot and Ankle

Zimmer Biomet is commercializing subchondroplasty procedures from the knee to the foot and ankle.

The company announced on September 15, 2015 that surgeons have performed more than 10,000 such procedures since 2010, mostly in the knee.

Photo creation by RRY Publications, LLC

The subchondroplasty procedure, according to the company, is a fluoroscopic, minimally invasive outpatient intervention that addresses the defects associated with subchondral bone marrow lesions (BML). Diagnosed using MRI and physical exam, BML are associated with stress fractures or micro-fractures of the bone adjacent to the joint. Left untreated, these defects have been shown to lead to cartilage degeneration, limited function, pain and greater risk for joint deterioration.

Bone Void Filler

Navigation instruments are used in this arthroscopically assisted procedure to inject a specialized bone void filler to

treat the bone defect and begin the healing process, without violating the joint.

Eric Nilssen, M.D. of The Nilssen Orthopedic Ankle & Foot Center at The Andrews Institute, said that prior to subchondroplasty, he had no viable treatment for patients with chronic stress fractures in the foot and ankle. "These injuries show up on MRI, are very painful and often fail to heal with conservative treatment."

Knee Creations, LLC

The company acquired the proprietary technology in 2013 from Knee Creations, LLC, a Viscogliosi Brothers company. Zimmer Biomet now owns 16 patents and 8 trademarks in this area, with numerous others still pending.

According to Zimmer Biomet, the procedure was invented in 2007 by Peter Sharkey, M.D., and Charlie Leinberry, M.D., of the Rothman Institute, Philadelphia, for the treatment of subchondral bone defects associated with chronic BML. Sharkey recognized that, in many of his patients, joint pain associated with knee osteoarthritis was due to BML.

The first surgery took place in 2008 and was performed by Steven Cohen, M.D. Between 2008 and 2012, 69 knee patients were treated at Rothman. All patients were scheduled for total knee replacement but opted for subchondroplasty, instead. Patients were followed for at least 24 months. On average, patients experienced a significant reduction in mean VAS pain scores, and 70% of patients delayed knee replacement for 2+ years.1

Knee Creations then commercialized the technology in 2010. The first surgical usage in the ankle was in 2012 for the treatment of a post-traumatic talar dome lesion. Surgeons, according to the company, have used the subchondroplasty procedure in other joints, as well, including the hip and shoulder. — *WE*

SPORT MEDICINE

Study Compares Barefoot to Shod Running

Six years ago the boom in barefoot running started. Runners debated which was best—running barefooted or shod. Alex Hutchinson reports on a study in the *British Journal of Sports Medicine* that compares the rates of injury of runners running with and without running shoes.

Allison Altman-Singles, M.D., at Penn State and Irene Davis, M.D., of Harvard Medical School, recruited 107 experienced barefoot runners and 94 runners who used ordinary running shoes and followed their injury status for one year. They found that the results were about the same for both groups. Thirty-two percent of the barefoot runners experienced musculoskeletal injuries. That was, for practical purposes the same as the shod group which had 34% injuries.

The big difference was in how far each group ran. The barefoot group covered 24 kilometers a week, while the shod runners ran 41 kilometers per week. The runners wearing shoes were running twice as much as the barefoot runners without experiencing any increase in their injury rate.

Hutchinson quoted Altman-Singles as saying, "Barefoot running attracts a particular demographic. They tend to be older and less competitive, which may be why they choose to run less."

Participants in both groups, according to Hutchinson, had been running for an average of about 10 years. The barefoot runners had been running without shoes for an average of 1.65 years. They did three-quarters of their mileage completely barefoot with the rest in barefoot-mimicking minimalist shoes.

The barefoot runners group reported a total of 57 injuries to their feet. The injuries were cuts, blisters, bruises and stubbed toes. Those who ran in shoes reported only eight types of injuries. — *BY*

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SPINE

SI-BONE: Three New Studies on iFuse

SI-BONE, Inc. is on a publishing roll, with two prospective randomized clinical trials appearing in print, as well as a systematic review of 18 MIS (minimally invasive surgery) SI (sacroiliac) joint fusion studies. The first clinical trial—the INSITE (Investigation of Sacroiliac Fusion Treatment)—was published in *Neurosurgery* and involved 19 institutions. The study, which included 148 patients, examined minimally invasive SI joint fusion as compared to non-surgical management of chronic SI joint dysfunction. At 12 months, clinically important improvements in SI joint pain on the Visual Analog Scale (VAS) were seen in 81.6% of SI joint fusion subjects, but in only 12.5% of those who had nonoperative treatment. Patients in the surgical group experienced sustained pain relief at 12 months; those who crossed over to iFuse treatment did nearly as well as those originally assigned to iFuse surgery.

David Polly, M.D., is professor and chief of spine surgery at the University of Minnesota, and lead author on the INSITE study. Asked about the most interesting portion of the research, he told *OTW*, "A high quality data set that really answers the question. It was also interesting to see that 10% did respond to non-surgical management after having failed it for at least 6 months—now we have to figure out how to identify that subgroup. Hopefully, surgeons will pay attention to the differential diagnosis of low back and buttock pain and not just presume it is spine or the hip."

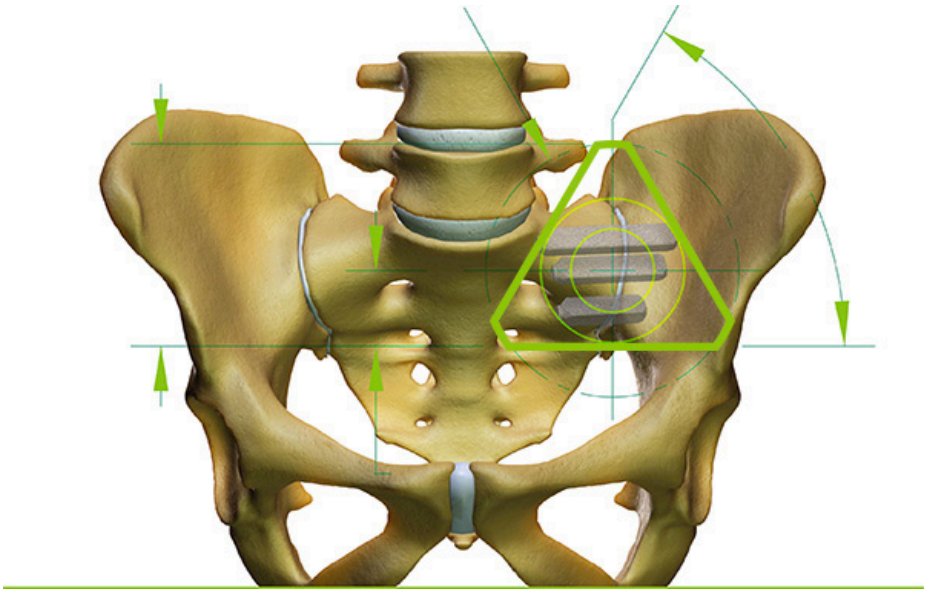
Regarding future work that should be undertaken, Dr. Polly noted, "Figuring out the psychological distress aspect for responders vs. non responders to the surgical treatment."

The second clinical trial—SIFI (Sacroiliac Joint Fusion with iFuse Implant System)—was published in *Global Spine Journal* and involved 26 facilities and 172 participants. The results showed that mean SI joint pain improved from 79.8 at baseline to 30.0 and 30.4 at six and 12 months, respectively. Mean Oswestry Disability Index improved from 55.2 at baseline to 32.5 and 31.4 at six and 12 months, respectively.

The third study, a systematic review and meta-analysis, was published in *International Journal of Spine Surgery*. The researchers reviewed the clinical outcomes of patients who underwent MIS SI joint fusion using a lateral transarticular approach. They found that this approach meant minimal blood loss: 36.9 cc (10-70 cc range), a brief operating time: 59 minutes (27-28 minute range), and a shorter length of stay: 1.7 days (0-7 day range).

Daniel Cher, M.D. is vice president of clinical affairs at SI-BONE, and was involved in all three studies. He told *OTW*, "It was great to see the enthusiasm and excitement from spine surgeons to be able to participate in a surgery vs. non-surgery trial. These types of studies are challenging and very rare these days and of course, the results were really excellent to say the least."

"Hopefully, this research will encourage the use of the iFuse Implant System to perform SI joint fusions in appropriately diagnosed patients with SI joint dysfunction who have failed to respond to non-surgical treatments. Going forward we need long-term follow-up." — *EH*



Courtesy of SI-BONE, Inc.

Patients Choose Pain Relief Over Mobility!

Researchers from the University of Rochester have come across an interesting finding…turns out that patients with back pain prefer pain relief to mobility. The study, just published in the journal *Neurology*, looked at patients who have lumbar spinal stenosis. When asked to choose between treatments that reduced pain or would help them stand or walk, patients overwhelmingly chose pain relief.

"There has long been a debate in the medical community over striking the right balance between pain relief and physical function," said John Markman, M.D., director of the Translational Pain Research Program in the University of Rochester Department of Neurosurgery and lead author of the study, in the September 9, 2015 news release. "While physicians have leaned toward the need to increase mobility, this study shows that patients have a clear preference for pain relief."

Photo creation by RRY Publications, LLC

Included in the survey were patients who had lumbar stenosis with chronic back pain and difficulty standing and walking. The researchers asked patients about their priorities, specifically, whether they prefer a treatment that reduced their pain or one that would allow them to walk further. Of the 269 patients surveyed, a full 79% chose reduced pain over improved mobility.

"Even the patients who could not stand long enough to pick up a letter from their mail box or wash the dishes after dinner chose pain relief," said Dr. Markman.

"This research is an example of the new standards for pain relief that are being created based on input from patients," says the news release. "To a great extent, levels of pain relief have been left to pharmaceutical company scientists and government officials to decide, often with little guidance from patients. There is now a growing demand that new generations of pain medications are not only safe, but meet patient's expectations for pain relief. The most common study populations for these newer drugs are patients with chronic low back pain. Many experts are arguing that new pain relievers, especially those with greater risks like opioids, should not just relieve pain but also improve patients function such as their ability to walk. This new study calls into question those assumptions."

Asked what future research should be undertaken, Dr. Markman told *OTW*, "It is imperative that we develop oral therapies for neurogenic claudication. Validation of an evoked pain methodology such as the one used with a treadmill in this analysis will allow for the study of the underlying mechanism of this pain as well as novel pain relievers." — *EH*

PEOPLE

Karen Licitra and Keith Valentine Join SI-BONE Board

Karen Licitra and Keith Valentine, experienced medical device professionals, are now on the board of directors at SI-BONE. Inc.

Karen Licitra and Keith Valentine, SI-BONE, Inc.

As stated in the September 1, 2015 news release, "Licitra was recently Corporate Vice President at Johnson & Johnson where she led Worldwide Government Affairs & Policy. In this role, she was responsible for Johnson & Johnson's engagements with global government leaders at the multilateral, national and state levels. Her organization also led development of Johnson & Johnson public policy. Previously, Karen was Worldwide Chairman of the Global Medical Solutions Group within Johnson & Johnson's Medical Device and Diagnostics segment. In that role, she was responsible for establishing the strategy and vision for an $8 bil-

lion global portfolio of healthcare companies including Vision Care, Diabetes Care, Ortho Clinical Diagnostics, and Advanced Sterilization Products, as well as the Sedation business unit. She was named to Fortune's 50 Most Powerful Women in Business list in 2012."

"Valentine is currently President and Chief Executive Officer of SeaSpine Holdings Corporation, a medical technology company focused on the design, development and commercialization of surgical solutions for the treatment of patients suffering from spinal disorders. Prior to joining SeaSpine, Mr. Valentine served as President and Chief Operating Officer of NuVasive, Inc. from January 2007 to January 2015 and as President from December 2004 to January 2007, prior to which he served in various senior executive roles in Marketing, Development and Operations after joining NuVasive in 2001. Previously, Mr. Valentine held executive positions at ORATEC that was acquired by Smith & Nephew plc, and spent eight years in various senior roles with Medtronic Sofamor Danek."

Karen Licitra told *OTW,* "I am thrilled to be joining an organization that so highly values clinical evidence and is focused on improving patients' lives. This is an exciting time for SI-BONE and I am honored to be joining the Board as the company moves into its next phase of growth. We are committed to further expanding our clinical and economic evidence supporting the iFuse Implant System to improve payor coverage and thereby expand access for more patients who can benefit from this incredible procedure."

Keith Valentine told *OTW,* "I am pleased to join SI-BONE's Board of Directors, and look forward to working with the Board and management team as they execute on a solid strategy of growth and clinical fulfillment."

"I look forward to collaborating with the team to help expand adoption of the diagnosis and treatment for this common yet often overlooked source of low back pain." — *EH*

James D. Kang, M.D.: New Orthopedic Chair at BWH

Renowned spine surgeon James D. Kang, M.D. has been appointed chair of the Department of Orthopedic Surgery at Brigham and Women's Hospital (BWH). Most recently Dr. Kang was at the University of Pittsburgh Medical Center (UPMC), where he was the executive vice chair for the Department of Orthopedic Surgery, the endowed chair in Orthopedic Spinal Surgery and the director of the Ferguson Laboratory Musculoskeletal Research Center for Spine Research.

James De. Kang, M.D., Brigham and Women's Hospital

"We are thrilled to welcome Dr. Kang, a collaborative leader, to our institution," said Betsy Nabel, M.D., president of Brigham and Women's Health Care, in the September 11, 2015 news release. "He brings a depth of experience in patient care, research and teaching that will enrich our orthopedic services and benefit our patients."

His clinical expertise is in surgical treatment of spinal stenosis stemming from degenerative cervical, thoracic, and lumbar disorders. As indicated in the news release, "His enormous contributions to excellent clinical care and cutting-edge scientific work have been recognized by several leading spine societies, including the International Society for the Study of the Lumbar Spine, where he was just installed as president, the Cervical Spine Research Society and the North American Spine Society."

Dr. Kang earned his M.D. at the University of Oklahoma College of Medicine. He completed his orthopedic surgery residency at the University of Pittsburgh School of Medicine and a spine surgery fellowship at Case Western Reserve University in Cleveland.

Asked about how he will proceed, Dr. Kang told *OTW*, "I will be meeting individually with all the clinical and research faculty to articulate my vision for the department. I will also try to understand each faculty member's aspirations and career goals to allow for synergy with the departmental vision."

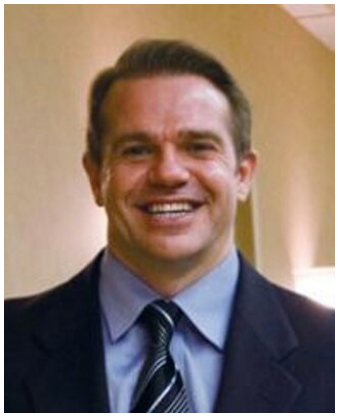
As for his vision of the future, he noted, "I would like to see a strong foundational seed having been established in the basic science and clinical outcomes research arena. Along with growth in the clinical venture in all divisions, I envision a close collaborative atmosphere between the clinicians and the research faculty to carry out state-of-the-art translational research." — *EH*

James Wittig, M.D. Chosen by *Newsweek* for "Top Cancer Doctors 2015"

Dr. James C. Wittig, vice chairman of Orthopedic Surgery, and chief of Orthopedic Oncology and Sarcoma Surgery at Hackensack UMC and director of the Skin and Sarcoma Division at the John Theurer Cancer Center in New Jersey has been named one of the top cancer doctors in the U.S. by *Newsweek*. The September 10, 2015 news release indicates, "In the realm of quantification, Dr. Wittig not only meets the criteria for his accolades wholeheartedly, but surpasses each with his 'undeniable compassion,' his direct doctor-patient relationships and an ongoing commitment to treating musculoskeletal cancers with the most innovative advances."

The "Top Cancer Doctors 2015" is based on peer nominations and physician-led research performed by Castle Connolly Medical LTD.

"The acknowledgement and accolade by *Newsweek* provides patients an opportunity to confirm their decision to seek out Dr. Wittig for specialty care. For many current and past patients, finding Dr. Wittig proved to be a positive



James Wittig, M.D.

beginning of an uncertain journey but one guided by a true leader in his field. The difficulties of orthopedic oncology treatments are lessened by the advances that Dr. Wittig has achieved in his 14+ years handling an array of cases from the straightforward to the most complex ones in nature."

Dr. Wittig's practice is focused on limb-sparing surgery, pediatric and adult bone and soft tissue sarcomas, melanoma, benign musculoskeletal tumors, metastatic cancers, as well as complex hip and knee replacement surgery. He also has special expertise with regard to tumors that affect the shoulder girdle and scapula.

Asked why he believes he was selected, Dr. Wittig told *OTW*, "I think I was selected because I approach each patient as an individual and tailor my treatment according to the needs of each patient and their particular disease. I don't believe in lumping patients into categories. I take a very compassionate and patient centric approach with each patient. While two patients may have the same type of cancer the treatment may vary depending on patient specific variables and needs in order to optimize the outcome."

"I am extremely flattered for being selected for such an honor by my peers. I feel I come to work every day and try my hardest to do the best job I can do. I am incredibly privileged to have so many patients put their lives or their children's lives in my hands. I am reminded every day how precious life is. I have a fantastic career that is extremely rewarding. It comes natural and doesn't feel like work to me."

"My guiding principle of patient care is to always put yourself in your patient's shoes or treat the patient how you would want to be treated or how you would want your mother or father treated. It's always important to be empathetic, patient, compassionate and educate the patient about the disease and proposed treatments. Take your time and explain things in easy terms so patients can understand and know you care about them." — *EH*

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