VOLUME 10, ISSUE 13 | APRIL 29, 2014

Orthopedics This Week

WEEK IN REVIEW

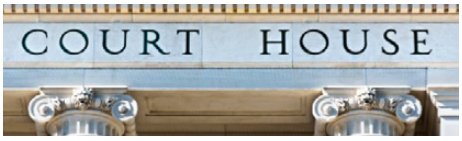
5 Zimmer Agrees to Buy Biomet for $13.35 Billion >> In a stunning move, cross-town rivals Zimmer and Biomet have agreed to combine in a transaction which is valued at just over $13 billion. Here's what it will mean.

7 Remember Artificial Disc Replacement? >> Could cervical disc replacements be the most clinically and economically successful implant that no one pays attention to? After nearly a decade of clinical experience, the data is proving to be even more supportive of cervical total disc arthroplasty (C-TDA). Dom Coric, M.D. and Jack Zigler, M.D. presented fascinating, long-term C-TDA data at Castellvi's Duck Key meeting. Here it is.

11 HSS: Sculco Stepping Down, Albert Stepping Up >> They are entering a new era at Hospital for Special Surgery (HSS) in New York. For 11 years, it has been the vision and drive of Thomas Sculco, M.D. that has led this outstanding facility to new heights. Now, says Dr. Sculco, it is time for a change. Enter Todd Albert, M.D. of the Rothman Institute.

13 Hip Rehab Inferior to Knee Rehab? New Study Says "Yes" // Case Log Chaos Means Under-Employment? Oh-oh // New App: Reduce Fracture on Your Phone and Get Scored! >> Former head of The Knee Society and AAHKS says hip rehab could be better. New study: under-coding may translate into under-employment. New app gives doctors the 'virtual' ability to treat a fracture and get scored for doing so.

16 In Search of a CerviCore "Smoking Gun" >> Nine patients implanted with Stryker's CerviCore implant say the metal-on-metal device poisoned them, that the company misled the public about failure rates and then illegally used OP-1 on them. Their lawsuit contains no "smoking gun," but they clearly want a chance to depose company executives. See what we found.



BREAKING NEWS

20 Androstenedione Chops Joint Replacement Risk

Zimmer Takes Knee Market Share in First Quarter

Stryker Slogs Through First Quarter

DePuy Synthes Finds Stability in First Quarter

12,000 Patent Rehab Study Results Announced

Podiatrist **Going to Jail**

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Zimmer's impending purchase of Biomet will create a hip/knee powerhouse—on paper. The combined market shares in hips would be 35%. In knees 42%. But as we saw when DePuy (JNJ) acquired Synthes, integration can be a slog. Market share is all local. Which reps get which accounts? Calibrating territories will require the wisdom of Solomon. Orthopedic consolidation continues with the news that ConMed is likely for sale. Who will buy this $1.2 billion (market cap) supplier of surgical instruments? Anyone taking odds?

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Zimmer	27.31%	8.59%	Zimmer's purchase of Biomet shows the strategic chops at Big Blue are second to no one. ZMH will likely dominate Recon for the foreseeable future.
2	2	Johnson & Johnson	26.58	2.82	The news from Q1's report is that DePuy's integration of Synthes is nearly done and the early disruption appears to be over.
3	NR	ConMed	10.19	5.59	A very attractive orthopedic franchise, the official word that buyers are welcome should trigger a bidding contest.
4	4	Medtronic	28.84	(1.82)	This week ISSAS spine meeting opens up in Miami. The tone will be very different from the toxic environment that was NASS.
5	7	Smith & Nephew	20.25	1.37	DePuy buys Synthes. Stryker buys MAKO. Zimmer buys Biomet. Did SNN lose the invite to the party? The band is just warming up.
6	3	Stryker	15.71	(3.61)	With ZMH buying its cross-town Warsaw rival, SYK has a chance to pick up a few share points, we'd expect. It will be interesting to watch this play out.
7	6	Alphatec Spine	(5.21)	(14.47)	Wall Street analysts are starting to pick up the new, upbeat vibe from ATEC. Saw an "overweight" from a leading analyst this morning.
8	5	Orthofix	6.75	20.57	New board members. New interim CFO. We are watching the re-making of OFIX. Won't see it in the numbers yet, but the trend is clear.
9	8	Integra LifeSciences	11.77	(1.35)	Still the least expensive equity in orthopedics by the usual measures (PE, PSR and PEG).
10	9	NuVasive	6.30	(9.64)	Lukianov and team taking a prudent and cautious stance to the year. Buyers moving to the sidelines. But this top performer tends to beat expectations.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Orthofix	OFIX	$32.00	$582	20.57%
2	Zimmer Holdings	ZMH	$100.54	$16,950	8.59%
3	ConMed	CNMD	$45.37	$1,230	5.59%
4	RTI Biologics Inc	RTIX	$4.04	$228	3.32%
5	Johnson & Johnson	JNJ	$99.79	$282,240	2.82%
6	CryoLife	CRY	$9.48	$266	2.49%
7	Smith & Nephew	SNN	$76.90	$13,750	1.37%
8	Aurora Spine	ASG	$4.18	$65	0.97%
9	ArthroCare	ARTC	$48.53	$1,670	0.73%
10	Exactech	EXAC	$23.01	$314	0.70%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$0.70	$112	-16.67%
2	Bacterin Intl Holdings	BONE	$0.70	$38	-15.66%
3	Alphatec Holdings	ATEC	$1.36	$133	-14.47%
4	Tornier N.V.	TRNX	$17.68	$858	-12.61%
5	Wright Medical	WMGI	$27.49	$1,370	-11.15%
6	Globus Medical	GMED	$23.03	$2,150	-10.18%
7	Symmetry Medical	SMA	$8.51	$319	-9.66%
8	NuVasive	NUVA	$33.64	$1,570	-9.64%
9	Baxano Surgical Inc	BAXS	$0.93	$44	-6.06%
10	Stryker	SYK	$76.72	$29,080	-3.61%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$58.21	$58,260	15.78
2	CryoLife	CRY	$9.48	$266	15.80
3	Zimmer Holdings	ZMH	$100.54	$16,950	17.22
4	Johnson & Johnson	JNJ	$99.79	$282,240	17.69
5	Stryker	SYK	$76.72	$29,080	18.53

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$33.64	$1,570	93.44
2	Symmetry Medical	SMA	$8.51	$319	65.46
3	ArthroCare	ARTC	$48.53	$1,670	32.14
4	Integra LifeSciences	IART	$44.65	$1,450	28.08
5	ConMed	CNMD	$45.37	$1,230	25.49

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Exactech	EXAC	$23.01	$314	1.05
2	Globus Medical	GMED	$23.03	$2,150	1.47
3	Zimmer Holdings	ZMH	$100.54	$16,950	1.88
4	ConMed	CNMD	$45.37	$1,230	1.96
5	Stryker	SYK	$76.72	$29,080	2.12

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$33.64	$1,570	9.00
2	Symmetry Medical	SMA	$8.51	$319	5.46
3	CryoLife	CRY	$9.48	$266	3.95
4	Integra LifeSciences	IART	$44.65	$1,450	3.30
5	Smith & Nephew	SNN	$76.90	$13,750	2.88

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.36	$133	0.65
2	Symmetry Medical	SMA	$8.51	$319	0.80
3	RTI Biologics Inc	RTIX	$4.04	$228	1.04
4	Bacterin Intl Holdings	BONE	$0.70	$38	1.16
5	Exactech	EXAC	$23.01	$314	1.30

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.70	$112	19.64
2	MiMedx Group	MDXG	$5.73	$605	9.01
3	Globus Medical	GMED	$23.03	$2,150	4.95
4	Wright Medical	WMGI	$27.49	$1,370	4.47
5	ArthroCare	ARTC	$48.53	$1,670	4.42

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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Zimmer Agrees to Buy Biomet for $13.35 Billion

BY ROBIN YOUNG

In a stunning move, cross-town rivals Zimmer Holdings, Inc. and Biomet, Inc. have agreed to combine in a transaction which is valued at just over $13 billion and will affect the work lives of more than 14,000 employees and create a company with combined annual revenues of about $8 billion.

This transaction further consolidates the orthopedic industry as it puts together the #2 player (Zimmer) with the #4 player (Biomet) and reduces the number of major, diversified orthopedic implant and instrument companies from 5 to 4.

The last time Biomet was "acquired" occurred seven years ago in 2007 and the price tag was $11.4 billion.

The purchase will be paid in a combination of stock and cash. The deal is expected to close in the first quarter of 2015 and when the dust settles, Biomet shareholders will own about 16% of the combined companies.

The initial reaction from Wall Street's analysts is positive.

Photo creation by RRY Publications/Logos courtesy of Zimmer and Biomet

Reasons for the Acquisition

In a conference call with Wall Street's analysts this morning, Zimmer's CEO David Dvorak said that there were four basic strategic growth reasons for the deal:

1. The combined companies will be more competitive with DePuy (JNJ), Stryker Corporation, Smith & Nephew and the other emerging suppliers of orthopedic implants. Indeed, on a combined basis the new company will have about 42% and 35% share of the worldwide knee and hip market, respectively.
2. It will improve the diversified portfolio of products for Zimmer. For example, the transaction doubles Zimmer's spine and dental product revenues.
3. It expands the innovation platform. Combined, annual R&D spending jumps to $360 million.
4. And Zimmer points to emerging markets where, in certain instances, Biomet had a sales and distribution presence and Zimmer did not.

From Biomet's perspective, the company had filed to "go public" and was, in effect, already marketing itself to prospective buyers. It turned out there was one big buyer sitting just down the road named Zimmer. And, frankly, these two Warsaw, Indiana-based firms are deeply rooted in a common culture, a common geography, a shared value set so that their combination may well feel to employees and other stakeholders as if it was somehow pre-ordained.

Early Surgeon Reaction

To a certain extent, this merger won't change the day-to-day work of orthopedic physicians. But an increasingly consolidated industry does raise some concerns as well as opportunities as these top surgeons related to *OTW* this morning upon hearing the news.

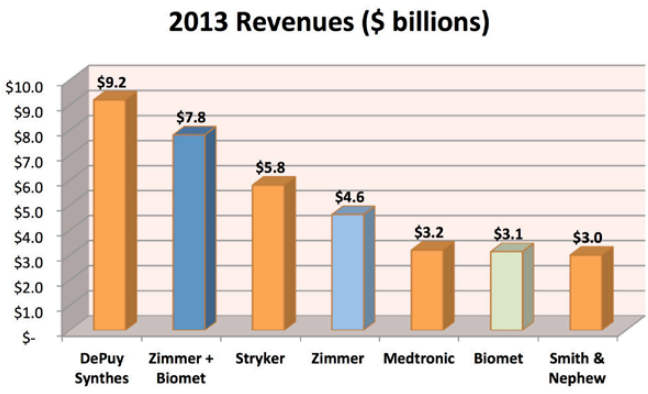
From Javad Parvizi, M.D., FRCS, vice chairman and director of clinical research at the Rothman Institute at Thomas Jefferson University:"The Zimmer-Biomet merger is an interesting development that might provide new opportunities for some orthopedic surgeons that have been working with each of these companies. With such an infrastructure, there could be a real benefit in terms of education and research. The disadvantage—as with any merger—is that it could take away competition between the companies that is clearly useful for developments and progress. Lack of competition may lead to complacency and may deprive others from working with each company individually."

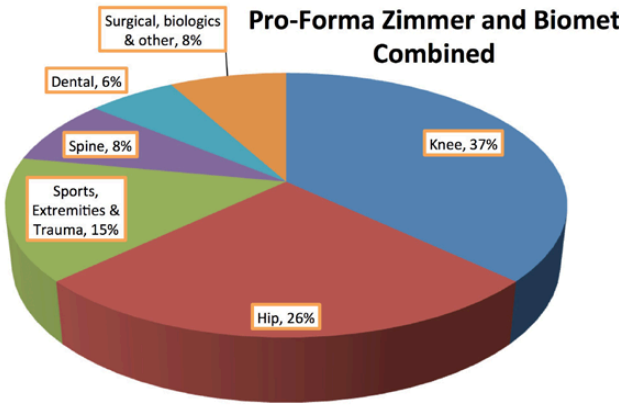
From Tom Errico, M.D., chief division spine surgery, departments of orthopedic surgery and nNeurosurgery at New York University; "Zimmer was very interested in expanding its spine offerings and looked at a lot of companies. This is a huge leap for them and puts them squarely in the game in a positive way."

What Now?

Over the next 8-10 months the lawyers, bankers and management teams at both companies will be combining the two companies. The whole mash up, Dvorak expects, will be done in the first quarter of 2015. In its first year, Zimmer's accountant think that there will be about $150 million of savings from "synergies."

Here are some data points from Zimmer's conference call April 24. ♦





RRY Publications LLC and Zimmer Holdings, Inc.

Remember Artificial Disc Replacement?

BY ROBIN YOUNG

Artificial Disc Replacement /Courtesy of the companies whose implant images are used.

Charité is gone. Several more including CerviCore, Discover and NeoDisc never made it to market.

But the Bryan, Prestige ST, ProDisc, Secure-C, PCM and Mobi-C did.

Kineflex C is close.

It has been nearly 10 years since the first total spine disc arthroplasty (TDA) was implanted in a patient in the U.S. Some discs have left the market. More failed to get through the FDA or Centers for Medicare and Medicaid Services (CMS) or corporate budget gauntlets.

An impressive number—whether still commercially available or not—live on in the patients who received them.

Like ghosts from Christmas past, these implants walk into physician's offices at regular intervals and present themselves for review.

Who's still standing and what's on the Horizon?

With Charité exiting the market two years ago, ProDisc (JNJ/Synthes) is the only lumbar TDA available in the U.S. Six cervical TDA's, however, have FDA approval and are for sale.

In fact, the pace of approvals seems to have accelerated in the last couple of years. Secure-C, PCM and Mobi-C were approved by the FDA in 2012. Then last year, the FDA granted LDR Spine a 2-level indication for its Mobi-C.

National coverage for these TDA's has been spotty but Aetna, UnitedHealthcare and Cigna have now announced national TDA coverage.

With luck, CMS may approve a new CPT code for 2-level disc arthroplasty in 2015.

Two discs—Prestige LP and Kineflex-C—have completed their investigational device exemptions (IDE) studies and are awaiting FDA action. Both are metal on metal cervical disc replacements.

Finally, as we noted above, two TDAs (CerviCore and Discover) were moth balled despite completing IDE studies (like ghosts of Christmas past…).

And there are at least a couple more TDA's sticking their toes into U.S. spine markets (Activ-C and M6-C).

The Data

At Castellvi's Duck Key meeting in early April, Jack Zigler, M.D. (Texas Back

Institute (TBI), Plano, Texas) and Dom Couric, M.D. (Chief, Department of Neurosurgery, Carolinas Medical Center, Charlotte, North Carolina) updated data on the multi-year performance of several of these discs—even the ones which are no longer commercially available.

As a group, they are holding up well. Patients with TDA's are less likely to need re-operations and report greater neurological success than their fusion counterparts.

As for adjacent level disease…also better outcomes than fusion patients, but there is new and better thinking about what adjacent level disease is and what its incidence rates are.

There is now seven-year data on the ProDisc-C and the Prestige-ST. There is five-year data available for the ProDisc-C. And there is two-year data for the Bryan, Prestige-ST, ProDisc-C, Secure C, PCM and Mobi-C.

The results, importantly, are consistent across the studies and each version of a cervical TDA.

Re-operation rates (data from Jack Zigler, M.D.) were 8.3% for the disc replacement (DR) patients versus 21.2% for the anterior cervical fusion (ACF) patients.

Here's the table from Dr. Zigler's presentation at Duck Key →

Cervical Disc vs. Fusion

Texas Back Institute has been one of the most prolific clinical study sites for cervical total disc replacements. All told, TBI physicians enrolled 136 patients in 1 of 6 prospective, randomized FDA IDE total cervical disc replacement trials. Of that group, 84 patients received a cervical disc replacement and 52 received an anterior cervical fusion.

The longest follow up at TBI, which may well be the longest TDA follow up of any clinic or hospital in the U.S., is eight years.

Picking one of the studies (ProDisc-C) at seven years, here is what the data looks like (Delamarter et al.) ↓

Outcome Data	Cervical Artificial Disc Replacement	Anterior Cervical Disc Fusion
Total Re-operations	5.8%	17.0%
Index Level %	4.9% (5/103)	7.5%
Adjacent Level	4.9% (5/103)	11.3%

Source: Delamarter et al.

Interestingly, the longer term TDA data has NOT shown a "tail-up" of Visual Analog Scale (VAS) or Oswestry Disability Index (ODI) scores. A "tail-up" refers to patient satisfaction peaking and then deteriorating as the years go by. For example, the neck disability index scores for ACDF (fusion) patients declined slightly from the 24 months to 84 months period. At 24 months fusion patients reported 60% improvement. At 84 months fusion patients worsened slightly and reported 56% improvement. By contract the C-TDA patients reported 60% improvement at 24 months and then rose slightly to 64% at 84 months. No "tail-up" in other words for the TDA patients.

The Meta-Analysis

The amount of FDA sanctioned clinical studies of cervical artificial discs is impressive. As Dom Couric, M.D. explained in his Duck Key talk, six discs completed their IDE studies and are (or were) available for implantation in the U.S.—the Bryan, the Prestige ST and the ProDisc-C and recently, the Secure-C, the PCM and the Mobi-C 1 and 2 level. One disc is close to completing its study and that is the Kineflex C.

In 2012 the *Journal of Neurosurgery: Spine* published a meta-analysis of

Reason for Re-operation	Total Disc Replacement (TDR)	Anterior Cervical Fusion (ACF)
Decompression Index level	1.2%	0.0%
TDR removal +ACF due to spondylosis	1.2%	0.0%
Adjacent segment *	4.8%	13.5%
SCS Pain Control	1.2%	0.0%
Pseudo #	NA	7.7%

Source: Jack Zigler, M.D.
**Significantly less in TDR group ($p<0.05$)*
 # Trend for lower rate at Adjacent Segment in TDR group; $0.05<p<0.07$

three U.S. FDA IDE cervical arthroplasty trials. The authors (Updadhyaya, Jau-Ching, Trost, Haid, Traynelis, Tay, Coric and Mummaneni) reviewed two-year follow up data from the Prestige ST, Bryan and ProDisc-C trials covering 621 TDR patients vs. 592 ACF patients. Fully 94% of the TDR patients and 87% of the ACF patients completed the two-year follow up.

Ninety-five percent of the ACF patients had a successful fusion.

Here is what the researchers found:

- There was no significant difference between the two groups with respect to ODI, SF-36 or pain scores.
- BUT, patients who'd received the TDR had significantly lower re-operation rates, greater neurological success and a lower adjacent level re-operation rate

These conclusions were consistent across all the studies and mirrored the TBI experience with their six different IDE studies.

Cervical Disc Replacement 12% Cheaper Than Fusion, on Average

Here are the TBI numbers. Fusion advocates; read 'em and weep.

On the day of surgery, CDA (cervical disc arthroplasty) is about 10% cheaper—$20,722 for a cervical disc replacement vs. $22,379 for a cervical fusion. But then the savings mount up during patient follow up.

The savings are even more impressive when looking at cost/month. By the third year, CDA patients cost the system about $761.75 per month while the fusion patients were almost 30% more expensive at $982.35 per month.

Adjacent Level Disease – Misunderstood and Overstated

One of the reasons for artificial disc replacements over fusion is the possibility of degenerative disc disease developing in an adjacent disc level. As the data from multiple IDE studies has shown, TDA does appear to reduce the incidence of adjacent level degeneration.

But…

Have physicians been mis-understanding and overstating the issue of adjacent level disease? Dr. Coric tackled this very interesting question at the Duck Key meeting. The answer is actually "Yes!"

Adjacent level disease is defined as radiographic evidence of disc deterioration above or below the operative level. Clinically this would manifest itself as symptomatic changes which can credibly be attributed to the adjacent levels.

How prevalent is this problem? Probably the most common answer to that question is that 2.9% of the fusion patients will return annually for a re-operation due to some symptomatic disc degeneration at the level adjacent to the operative level.

And probably the most commonly cited paper to support that 2.9% number is Hilibrand's landmark study of adjacent level disease.

But Hilibrand never showed a 2.9% rate. In fact, the number is closer to 0.72%. Dr. Coric did the math. Number of fusion procedures over 10 years in Hilibrand's study = 409 (374 patients). Number of patients who returned for re-operation at the adjacent level = 27. Twenty-seven patients out of 374 patients = 7.2% over 10 years.

	CDA Surgery	ACDF Surgery
Initial surgery	$20,722	$22,379
Discharge to 6 weeks	791	1,236
6 weeks – 3 months	1,216	1,497
3 to 6 months	2,147	2,631
6 to 12 months	4,127	4,566
12 to 18 months	3,106	3,914
18 to 24 months	2,862	3,596
24 to 36 months	3,753	4,806
36 to 48 months	1,040	1,526
TOTAL	**$34,979**	**$39,821**

Source: Jack Zigler, M.D.

So, divide 7.2% by ten to get the annual number and it is…0.72%. Which is about 4 times less than 2.9%.

What's the Real Bottom Line?

What's the point of replacing fusion with arthroplasty if we've been overstating the re-op rate due to adjacent level disease?

The Updadhyaya et al. meta-analysis (*Journal of Neurosurgery:Spine*, 2012) looked at 1,213 patients with a minimum of two-year follow-up (cervical total disc replacement: n=621 and for anterior cervical disc fusion: n=592) found that TDR patients had a statistically lower rate of secondary surgery (cTDR 3.1% vs. ACDF 8.2%). The analysis also found a statistically superior rate of success at two-year follow-up.

The McAfee et al. meta-analysis of four FDA approved cervical TDR studies (*Spine Journal*) looked at 1,707 total patients (of which 1,205 had two-year follow-up) and found that TDR patients had a statistically superior rate of clinical success (cTDR 77% vs. ACDF 69%). The study also found that ACDF patients were statistically more likely to have a second surgical procedure.

In the Kineflex C study (Coric et al., *Journal Neurosurgery: Spine*, 2011) the ACDF patients had a statistically significant rate of adjacent level disease. Same results from the ProDisc-C study (Spivak et al., *CSRS, 2012*). Same results from the Mobi-C study (Hisey et al., NASS, 2011).

Bottom line: Whether you want to reduce the risk of adjacent level disease or not, using cervical total disc replacement in the right patients has been shown to reduce the rate of reoperations, deliver higher rates of clinical success and reduce costs as compared to anterior cervical fusion procedures.

Thanks to both Drs. Coric and Zigler for allowing us to use their strong presentations to build this article. ♦

HSS: Sculco Stepping Down, Albert Stepping Up

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

They are entering a new era at Hospital for Special Surgery (HSS) in New York. For 11 years, it has been the vision and drive of Thomas Sculco, M.D. that has led this outstanding facility to new heights. Now, says Dr. Sculco, it is time for a change. Enter Todd Albert, M.D. of the Rothman Institute.

Thomas Sculco, M.D. and Todd Albert, M.D./ Hospital for Special Surgery and The Rothman Institute

Dr. Sculco: "I believe in term limits."

Dr. Sculco, who will be continuing his clinical practice at HSS and will become Surgeon-in-Chief Emeritus, performs 500-600 surgeries per year. He tells *OTW*, "When I accepted this position 11 years ago I had certain goals that I wanted to achieve and I have accomplished most of them. Now it's time to move on; I believe in term limits. I find that if one is in a job too long it can lose some of its vitality. It's good to move aside so that others may assume positions of leadership. At HSS the Surgeon-in-Chief is also Medical Director of the institution and with a busy surgical schedule and a great deal of international travel for teaching and research there is a finite period of time you can serve in this position."

When asked about the accomplishments he cherishes, Dr. Sculco stated, "First of all, in the clinical area there was an access problem. There were many patients who wanted to come to HSS for care but they couldn't access the institution. We needed to physically grow HSS and our faculty. We have doubled the clinical volume to 30,000 operations per year and we have added 40 outstanding orthopedic faculty. Additionally, we now have 35 orthopedic operating rooms, we have created separate ambulatory surgery units for sports medicine and we did the same with hand and foot surgery. In keeping with the original vision of HSS when it was founded 150 years ago, we created a 'pediatric orthopedic hospital' within the walls of HSS to better care for the children who come to us for their treatment."

"I am also proud of our accomplishments on the research side as we now have a vibrant clinician/scientist program where these individuals dedicate 40% of their time to research (we located a generous donor who provided $5 million to make that happen)."

"I have always believed that HSS should be a global leader in musculoskeletal care, therefore I created the International Society of Orthopaedic Centers (http://www.isocweb.org/) so that the largest and best orthopedic centers in the world could interact in a way that promotes optimal care, education and research. We now have 17 members around the globe, including the Rizzoli Orthopedic Institute in Bologna, Italy and Clínica Alemana de Santiago in Chile. We meet every 18 months to discuss many issues related to research funding, academic excellence, and how the field can survive economically in a challenging environment. We believe we should be setting the benchmarks for reduction in infection rates and other complications. At HSS we believe in sharing our clinical pathways to reduce cost but not sacrifice on quality and patients safety."

"I am also proud of our residency and fellowship programs which have grown and provide outstanding orthopedic training to many who come here from throughout the world. I have been blessed to work with an amazing group of faculty and it has been a great privilege and honor to be their chief."

Dr. Albert: "HSS is the Taj Mahal of orthopedics."

Dr. Todd Albert is the Richard H. Rothman Professor and Chairman of Orthopaedics at Jefferson Medical College, and is Past President of The Cervical Spine Research Society. Dr. Albert, who has been at The Rothman Institute for 21 years, says that he is "incredibly excited" to join the "Taj Mahal of orthopedics." He tells *OTW*, "This is going to be an extraordinary opportunity and I'm thrilled that I will be able to work so closely with Dr. Sculco and the incredible staff at HSS. One of my goals is to improve and unify surgery and services so that we can work toward even better population health. My vision is that we will be able to take care of the whole musculoskeletal bundle from start to finish, i.e., deliver and control the bundle of care for any kind of surgery. One way to do that is to create care pathways where everyone agrees what the map looks like...and adheres to it. Also, for a total joint, 50% of the cost of the bundle is *after* the patient leaves the hospital. So we will do our utmost to find a way to get control of that."

Discussing his time at the Rothman Institute, Dr. Albert notes, "When I took over as chair we had a total of 20 physicians. Now we have 107; that is an increase of 500%. So I do understand growth and culture and I think I can help to work toward a unified culture at HSS. In our market we have done very well with the hub and spoke model. HSS is such a good brand, and I think my experience will help to extend that brand into the outlying communities and around the world. And because my mantra is 'teamwork,' I will make every effort to include input from all my colleagues."

Asked how he will know if he is succeeding a year from now, Dr. Albert said, "I'll know things are going well if I can walk down the hall without a Kevlar vest!" ♦

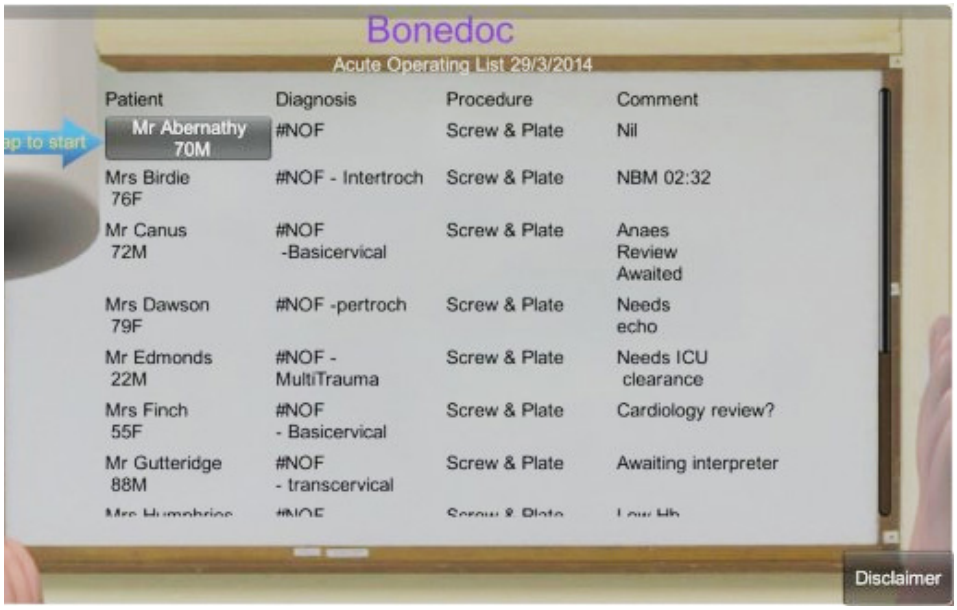
Orthopedics This Week wishes Drs. Sculco and Albert all the best in their new roles.

Hip Rehab Inferior to Knee Rehab? New Study Says "Yes" // Case Log Chaos Means Under-Employment? Oh-oh // New App: Reduce Fracture on Your Phone and Get Scored!

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

Hip Rehab Inferior to Knee Rehab? Doug Dennis M.D. Tackles the Issue Much can be done to improve the rehab experience for knee and hip patients, says Douglas Dennis, M.D., an orthopedic surgeon with Colorado Joint Replacement in Denver. Dr. Dennis, past president of The Knee Society and the American Association of Hip and Knee Surgeons, tells *OTW*, "We have an NIH [National Institutes of Health] grant to conduct a prospective randomized study on accelerated rehab for TKR [total knee replacement]. With traditional TKR rehab the first 4-6 weeks are focused on motion and some strengthening. The results from our pilot study suggest that an accelerated rehab program including more aggressive motor strengthening at an earlier point in time will give the patient better functional results. There are a number of studies suggesting that patient satisfaction after TKR is about 80%. So while these are good operations that lessen pain and improve function, we are still not meeting the needs of knee replacement patients as well as we are meeting the needs of hip replacement patients."

"Total hip surgery is overall a great thing. But when we take age matched patients with normal hips and compare them to those who haven't undergone hip replacement, we find that the functional testing of those who underwent hip replacements was not as good. Hip replacement patients typically receive a list of exercise to do after discharge, so they just essentially go forward without a standardized postop therapy program. This is in contrast to knee replacement where the standard of care is that patients are seen by an outpatient physical therapist for several weeks postop. Do we need a more intensive rehab for total hip patients? If so, what exactly should that involve? For example, we have identified that total hip patients typically have deficits in the quadriceps muscle. When we look at these patient 3-6 months postop the hip musculature is recovering nicely, but quads are holding them back from doing things such as getting out of chairs and going up and down stairs. There is more we can do to help these people."



iMedicalApps.com and Dane Salazar, M.D.

Case Log Chaos Leading to Employment Problems? When Dane Salazar, M.D., a former orthopedic surgery resident at the Loyola University Chicago Stritch School of Medicine, wished two graduating residents good luck several years ago, he got quite a surprise. Dr. Salazar tells *OTW*, "A review by the Residency Review Committee (RRC) revealed that while having identical rotation schedules and similar operative experiences these two graduating residents had widely disparate cases in their ACGME case logs. My colleagues and I were interested enough to conduct a survey of residents, and we found that the coding practices amongst orthopedic surgery residents in the United States were vastly different. The Accred-

itation Council for Graduate Medical Education (ACGME) case log system is supposed to [give] an accurate representation of the operative experience of the orthopedic surgical resident and a summary of their operative training. As we ventured into this study, we found substantial variability in how residents logged cases and what they considered to appropriate and inappropriate to log. Due to a paucity of guidance some residents believed that case logs should mirror the billing codes utilized by the attending surgeon while others felt that unbundling certain CPT codes more accurately reflected the operative experience."

"We proposed seven common hypothetical orthopedic scenarios and asked residents if they would routinely log these cases into their ACGME case log and if so what code(s) they would commonly utilize. We saw substantial variability in both which procedures would have been recorded and what CPT codes would have been used."

"Both under-coding and over-coding are issues that can follow a resident into his or her employment. More and more future employers are asking to review the ACGME case log; and presumably operative volume and accurate reporting are being taken into account during hiring decisions. Additionally from the residency program standpoint, a large variability amongst graduating residents can be a real red flag when residents who are supposed to have roughly the same training experience have vastly different coding logs."

"We were surprised to learn that roughly 10% of respondents stated that training programs were inputting the cases into the log on their behalf. The case log system is based on manual entry and self-reporting by residents. These inaccuracies are likely multifactorial and are hypothesized to occur for several reasons: (1) residents do not keep written logs; (2) residents do not value the importance of logging every case, especially non-operating room procedures; (3) long periods of time often elapse between performing the case and entering the data, which can lead to inaccurate memory recall; (4) residents do not unbundle their cases appropriately or do not utilize appropriate CPT codes; (5) there is variability in interpretation of the ACGME's definition of the term 'procedure' (i.e., does the term 'procedure' include joint injections, closed reductions, casting, or splinting?); and (6) there is no consensus on logging cases depending on a resident's level of involvement in a procedure (i.e., resident surgeon, first assistant, or second assistant)."

"We plan to do a follow on project where we survey residency program directors and chairs; it will be interesting to see if there is variability between these individuals as far as what they expect. This will be a good litmus test on the guidance and direction that residents are receiving. The case logs really should accurately reflect the surgical experience of residents. The project highlighted some important issues in surgical education and I feel was at least in part the impetus for the recent improvements in guidance from the ACGME."

New Virtual Surgical App for Orthopedists How about reducing a fracture on your phone? A new app makes it possible to practice on virtual patients and get scored for your work from a mobile device. Nathan Skelley, M.D. is a third-year orthopedic surgery resident at Washington University in St. Louis School of Medicine, and is a reviewer for the web site iMedicalApps.com. Speaking on this new app by Otago Innovation Limited, Dr. Skelley tells *OTW*, "Bonedoc is a mobile app that simulates the treatment of hip fractures in a game environment. It gives doctors free reign over how to address patient positioning, fracture reduction, incision and implant placement. With Bonedoc, the user is graded on their ability to reduce the fracture and properly place implants. Your actions at one point of the operation will affect how you do at a later point during the operation. The app also makes it possible to share scores, which can create competition (and possibly enhance the learning process) among users."

"The mobile app uses certain finger gestures to simulate surgical techniques. For example, the first task involves using fluoroscopy to position the hip fracture for surgery. During this time the user positions the foot with their finger while using fluoroscopy images. Once the fracture is reduced on AP and lateral views, the doctor then must make the incision. A single line incision is made with one finger swipe and spread apart to make four points to view the fracture. Retractors are not utilized in the app. The drill feature is uniquely simulated and provides for partially drilling and measuring screw depth by sliding the finger on the screen. There is, however, no function for depth gauging screw length, moving fluoroscopy to check screw alignment, or removing screws if unsatisfied with placement."

"After fixation is complete, the app removes the surrounding soft tissues and allows the surgeon to view their fixation construct in isolation with the bone; the doctor can move around freely and zoom in and out to check their work. If they score high enough to pass, they can progress to the next surgery on the operating room list."

"There are a few minor bugs, and limitations to the app. There is only one body region tested in the simulator and limited discussion of anatomy. It would be nice to operate on other simulated joints and fractures. Similarly, without haptic feedback on a mobile device, it is difficult to truly simulate the operating room environment. A major challenge with any surgical simulation program is that if you ask five orthopedic surgeons how to treat XYZ issue you are likely going to get five different responses. This makes designing and scoring a surgical simulation challenging. However, basic surgical simulation is becoming an increasingly important part of training physicians and this app is a great low-cost step in the right direction. It is a serious game that creates a first person surgeon instead of a first person shooter."

"Overall, this is a useful training tool. The 'restart' button is not a privilege that we have in the OR. Apps, like Bonedoc, have great potential to improve the education and training of future orthopedic surgeons."

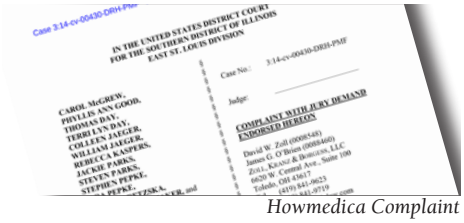
Capt. (Dr.) Nathaniel Nye Wins Sports Medicine Research Competition Capt. (Dr.) Nathaniel Nye, a fellow in the National Capital Consortium Sports Medicine Fellowship at the Uniformed Services University, or USU, of the Health Sciences here, and Fort Belvoir Community Hospital, Virginia, won first place in the research competition at the American Medical Society for Sports Medicine, or AMSSM, annual meeting this month, earning the Best Overall Research Award.

Dr. Nye's project, "Does abdominal circumference of body mass index better predict lower extremity injury risk?" was one of 32 semi-finalists selected for presentation at AMSSM's annual meeting from more than 150 overall submissions. This marks the second consecutive year that the AMSSM's Best Overall Research Award has been won by a USU Air Force physician. ♦

In Search of a CerviCore "Smoking Gun"

BY WALTER EISNER

Carol McGrew and eight other patients implanted with Stryker Corporation's CerviCore cervical disc filed suit against Howmedica, owned by Stryker on April 11, 2014 in an Illinois federal court for alleged damages caused by the disc.


IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS
EAST ST. LOUIS DIVISION

CAROL McGREW,
PHYLLIS ANN GOOD,
THOMAS DAY,
TERRI LYN DAY,
COLLEEN JAEGER,
WILLIAM JAEGER,
REBECCA KASPERS,
JACKIE PARKS,
STEVEN PARKS,
STEPHEN PEPKE,

Case No.: 3:14-cv-00430-DRH-PMF

Judge:

COMPLAINT WITH JURY DEMAND
ENDORSED HEREON

Howmedica Complaint

The Plaintiffs claim the disc was "unreasonably dangerous due to design defects, manufacturing defects and insufficient warnings." Their case rests on similar metal ion poisoning arguments used in the DePuy ASR metal-on-metal hip lawsuits, with an additional claim of improperly using OP-1 during some of the surgeries.

CerviCore Disc

The CerviCore disc was initially developed by SpineCore, Inc. In 2004, Stryker purchased SpineCore for $120 million in cash, plus up to $265 more when CerviCore and another SpineCore product, FlexiCore, gained FDA approval and were launched.

SpineCore was founded in 2001 by Thomas Errico, M.D. and J.P. Errico. In the 2004 Stryker press release announcing the acquisition, the company said after completion of enrollment in a clinical study, a two-year patient follow-up was planned prior to submission of a premarket approval (PMA) application to the FDA. The company said it expected to submit an IDE (investigational device exemption) application to the FDA for the CerviCore before year end and begin a clinical study in 2005 which would lead to submission of a PMA application in 2008.

www.swinglecollins.com

The company recruited the Plaintiffs, along with 391 other people to take part in the study. The patients signed "Consent to Participate in a Research Study" forms.

Dangerous Metals Alleged

According to a description in *Motion Preservation Surgery of the Spine*, published by Elsevier, Inc. in 2008, the device is "composed of two opposing cobalt-chromium-molybdenum bearing surfaces backed with a titanium plasma spray coating to enhance osseous fixation. Two fins on each baseplate, each with three spikes, help achieve initial fixation. An anterior vertebral body stop decreases the chance of posterior placement or migration."

The Plaintiffs allege the company portrayed the disc as a device made entirely of titanium.

However, according to their claims, the company used cobalt, chromium, molybdenum, titanium, and nickel to construct many of the discs implanted in the patients, who were not told of the "dangerous" metals contained in the disc.

One of the patients, Colleen Jaeger's original consent form contains the following description of the CerviCore unit: "The CerviCore Disc is made of two saddleshaped plates and it is implanted in place of the degenerated disc after it

The Cervicore artificial cervical disc/ www.spine-health.com

is removed. It is made entirely of metal (a cobalt/chrome/molybdenum alloy with a titanium coating)."

Drs. Jonathan Stieber, Jeffrey Fischgrund and Jean-Jacques Abitbol co-authored a book chapter entitled "The CerviCore Cervical Intervertebral Disc Replacement," in which they listed one of CerviCore's contraindications as: "Allergy to components of the device, including cobalt, chromium, molybdenum, titanium, or nickel." James Yue, et al., *MOTION PRESERVATION SURGERY OF THE SPINE: ADVANCED TECHNIQUES AND CONTROVERSIES*, p. 238, Saunders, 2008.

In 2011, according to the suit, Stryker took out a full page ad in the program for the April Las Vegas meeting of the SAS International Society for the Advancement of Spine Surgery that, "bragged… CerviCore was '[c]omprised of CoCrMo – biocompatible material with a history of safety and proven durability with low metal ion release and wear rates in orthopedic implants.'"

Jaeger claims she was informed that she was one of the few who would have her metal levels monitored. She says the company "flatly refused to conduct metal ion tests in many patients and flatly refused to provide most with the results of any tests it had conducted." The patients claim to suffer from symptoms consistent with metallosis.

The company's manufacturing processes were "so faulty they increased the metal-on-metal CerviCore device's likelihood of emitting metal ions into the subject's body," says the suit.

The company produced CerviCore at one of its traditional Stryker Spine plants in Cestas, France, that was used to heat-treating non-articulating products and, according to the suit, was unfamiliar with producing articulating cobalt chromium products.

Rate of Failure Disputed

The Plaintiffs also claim that Stryker misled the public about CerviCore's rate of failure.

For instance, in 2010, they say through four "affiliated" doctors (Drs. Abitbol, Maroon, Edwards and Fischgrund), the company "bragged that at two years, there were fewer device-related surgical interventions in the CerviCore group (2%) than in the Control group (4%)." *2-Year Results from Four IDE Study Sites: CerviCore Intervertebral Disc vs. Fusion, The Spine Journal*, Volume 10, issue 9 Supplement, Pages S139–S140, September, 2010."

However, they argue that the article's sample size was only 49 CerviCore patients and the authors admit they lost track of 18 of the patients, so even one surgical revision would be 3.2% of the population.

Dr. Fischgrund operated on Plaintiff Pepke to correct his CerviCore prior to this article's publication. The suit also claims that long before the article was published, Plaintiff Zaretzka, "had repeatedly reported to her surgeon, Dr. Edwards, that she had unresolved neck pain, hears clicking and grinding noises, suffered from metallosis symptoms and wanted a surgical revision of her device." She says he refused.

Plaintiff Good also claims that long before the article was published, she informed her surgeon, Dr. Fischgrund, the she had unresolved neck pain, suffered from metallosis symptoms and wanted a revision. The surgeon also allegedly refused. Another CerviCore patient, in a separate lawsuit, claims she told Dr. Maroon long before the article that she also had problems.

Thus," claims the suit, "prior to this article's publication, these co-authors knew of at least five surgical interventions caused by the CerviCore device, which is 16% of the responding sample size, not 2%."

Stryker Quality Control Problems

In November 2007, the FDA publicly warned Stryker about quality control problems at its Mahwah, New Jersey, plant. The lawsuit says that the FDA cited the company for taking complaints on failures of one of its hip products, "but not applying lessons learned from that failure to its other products (which would include CerviCore)."

The discs were allegedly manufactured at the French facility and then shipped to Mahwah, New Jersey, for final coating and packaging.

The company's Mahwah facility, "had rampant quality control problems that caused unsafe, unreliable, and contaminant-ridden devices to be released into the market at the very time [Stryker] was manufacturing CerviCore in that facility," states the suit.

OP-1 Use Claimed

Plaintiffs also argue that due to the fact that CerviCore did not have screws, it had to rely on "some" bone growth to hold it in place. To accomplish that bone growth, they say Stryker, "illegally used or promoted the use of its TCP putty (also called Calstrux, Osteogenic Protein-1, or OP-1) in CerviCore patients."

In April 2008, it was widely reported that the FDA warned Stryker Biotech that the company had violated the law by conducting human experiments without a proper IDE.

The FDA, states the lawsuit, discovered Stryker Biotech had illegally entered into contracts with clinical investigators to use OP-1 in combination with some investigational device study. The FDA did not specify which study OP-1 was used with because records remain sealed when a device has not been approved by the FDA. Plaintiffs say the warning, even if it didn't specify CerviCore, "demonstrates Stryker's propensity to conduct studies on human beings without an IDE and to use OP-1 in conjunction with some unapproved study."

Plaintiff Jaeger claims she had to have a revision because, "among other things, she developed a large bone mass growing from the area of her CerviCore." Good claims she was found to have a boney growth at the C5 vertebrae.

"Other Plaintiffs are suffering the ill effects of improper use of OP-1, but, since [Stryker] has consistently resisted providing more testing, providing proper and accurate information, providing proper medical care, and/or removing faulty units, it has concealed the true nature of whether it used OP-1 from Plaintiffs," states the complaint.

Feeling Abandoned

The Plaintiffs say the company became aware of the device's adverse events and its potential for causing metal poisoning during the study period and abandoned the product. They claim Stryker also abandoned them even though the company continued the human study, actively attended Plaintiff's doctors' appointments, and actively denied that the device was faulty.

They claim the company insisted each study participant sign study renewal agreements that contained further waivers in order to continue receiving medi-

cal care. Then, shortly after obtaining each renewal and waiver, the company "abruptly ended its study early and informed Plaintiffs it would no longer provide any care for them."

They say that the company has never provided them with accurate information about what was put in their bodies. Because of this "concealment", they claim they could not have discovered any of this prior to the commencement of this action.

Summary of Allegations

In summary, the nine patients and their spouses allege that the company, knew of multiple dangers with CerviCore, including that it might not implant properly, that its design caused excessive wear, that it was prone to breaking down prematurely, that it was prone to delaminating, that they manufactured it using improper processes, that they manufactured it in a facility prone to contamination, that it was made from cobalt, chromium, molybdenum, titanium, and nickel, and that it was likely to cause metallosis.

They allege "Gross Negligence" because the company knew it operated a human trial outside the bounds of any regulatory approval it obtained; knew they did not have regulatory approval to use OP-1 in conjunction with CerviCore on Plaintiffs or other humans and proceeded nonetheless [and] knew CerviCore presented danger to patients, particularly those with allergies to certain metals but knew the study participants were not being tested for metal allergies."

In a parting shot, the patients say Stryker's conduct was "so despicable and so contemptible that it would be looked down upon and despised by ordinary decent people."

Fishing for a "Smoking Gun"

Plaintiffs want a jury trial, compensatory damages, punitive damages, attorneys' fees and any other relief the court deems proper.

The attorneys for the patients clearly want a chance to depose Stryker executives and go fishing—hoping to find a "smoking gun." So far, plaintiffs have only circumstantial evidence. Stryker has not publicly responded to the allegations. ◆

COMPANY

Zimmer Takes Knee Market Share in First Quarter

In the midst of Zimmer Holdings, Inc.'s announcement of buying up Biomet, Inc., the company also announced first quarter sales results on April 24, 2014.

Net sales of $1.161 billion were up 2% on a reported basis over the previous year's first quarter. Sales rose 3.2% on a constant currency basis. The company expects full-year sales to increase approximately 3.0% to 5.0% on a constant currency basis from 2013 while foreign currency translation will decrease revenues by approximately 0.5% for the full year, resulting in reported revenue growth between 2.5% and 4.5%.

Driven by the hugely successful launch of the Persona Knee, knee sales were up 4%. Hips were flat, extremities rose 9%, trauma dropped 3% and spine continued its slow recovery, climbing 1%. All percentages are on a reported basis.

Zimmer Headquarters/Zimmer Holdings, Inc.

Zimmer 1Q14	Sales ($ in millions)	% Change
Total Reported Sales	**$1,161.0**	**2.0%**
Reconstructive	$872.0	3.0%
Knees	$488.0	4.0%
Hips	$332.0	flat
Trauma	$79.0	down 3%
Extremities	$52.0	9.0%
Spine	$48.0	1.0%

Source: Zimmer Holdings, Inc.

Dave Dvorak, the company's president and CEO said, "Zimmer produced solid results during the first quarter, providing further validation of our long-term growth and stockholder value creation strategies." Needham analyst Mike Matson called the quarter results, "So-So," because the company missed consensus revenue.

As expected, analysts asked Dvorak very few questions about the previous quarter as everyone wanted to know how the merger would impact future sales.

Gaining Market Share in Knees

Matson said the company's recon growth slowed likely due to weather and increased seasonality. On a constant currency basis, Matson said Zimmer's recon growth slowed to 4% from 7% in the fourth quarter of 2013. Constant currency knee growth of 5% and hip growth of 2% slowed from 10% and 3%, respectively, from the last quarter of 2014. He believes that Zimmer held recon share in the quarter with modest share gain in knees offsetting modest share loss in hips.

Matson estimates that based on actual results from Biomet, DePuy Synthes, Stryker Corporation and Zimmer, the recon market grew by 4% (constant currency) in the first quarter. He added that he estimates that global knee growth was 5% and that global hip growth was 3% during the quarter.

—WE (April 25, 2014)

Stryker Slogs Through First Quarter

Stryker Corporation's 2014 first quarter reconstructive sales rose 4.5% to $999 million. On a constant currency basis, sales rose 5.9%. Analysts called the quarter "sluggish" as the company's sales came in slightly below expectation.

ytimg.com and RRY Publications

Stryker 1Q14	Sales $ in million	% Change
Reported Reconstructive Sales	**$999**	**4.5%**
Knees	$348	1.1%
Hips	$318	3.1%
Trauma/ Extremities	$288	8.4%
Spine	$177	0.7%

Source: Stryker Corporation

During a conference call with analysts on April 23, 2014, company management cited the weather as a reason for the sluggish growth. Management expects that delayed procedures will be rescheduled throughout the year.

Knee sales rose only 1.1%, hips climbed 3.1%, and trauma was the bright spot, climbing 8.4%. Spine was relatively flat, rising only 0.7%.

The company's net earnings took a 77% hit in the quarter due to charges for the Rejuvenate, ABG II and Nep-

tune recalls, acquisition and integration related charges.

There was no change to the company's previous guidance which calls for organic sales growth in 2014 to be in the range of 4.5% to 6.0%. If foreign currency exchange rates hold near current levels, the company expects net sales in the second quarter and full year of 2014 to be negatively impacted by less than 1.0%.

Knees Under Pressure

It was not great news for the company's knee sales. Bank of America analyst Bob Hopkins wrote on April 24, 2014 that without the assumed contribution from MAKO Surgical Corporation's knees, the company's knee business would have declined 1% worldwide and 2.6% in the U.S. Management said that integration of MAKO affected knee sales. The company has begun its U.S. clinical trial for a total knee application for MAKO, which it intends to introduce in 2015.

It appears Stryker knee sales are under pressure from Zimmer's Persona knee.

BMO Capital Market analyst Joanne Wuensch said Stryker spine sales decelerated from the mid-single-digit growth of the past three quarters, with implant sales down low-single digits. She added that management said it was "certainly open to looking at acquisitions within spine."

Hip and Knee Market Forecasts

Wuensch forecasts the hip market to be up 2.7% in 2014, versus 3.3% in 2013, and the knee market to be up 3.0% in 2014, versus 3.75% in 2013. Jefferies analyst Raj Denhoy said it is now clear that U.S. recon volumes have normalized over the past few quarters and growth should remain sustainable in the mid-single digits. He cautioned that pricing remains a drag.

Stryker's President and CEO Kevin Lobo said, "The strength of our diversified model was once again demonstrated in the first quarter with solid organic growth of 5%. Our continued investments in internal innovation, coupled with our recent acquisitions, position us well to meet our customers' evolving needs."

—*WE (April 25, 2014)*

DePuy Synthes Finds Stability in First Quarter

DePuy Synthes Companies orthopedic sales of $2.41 billion improved, on a reported basis, by 1.5% during the first quarter of 2014. On a constant currency basis, sales rose 2.7%.

On a reported basis, trauma was the big performer, rising 6%. Knees were up 3%. Hips rose 1% and spine dropped 1%.

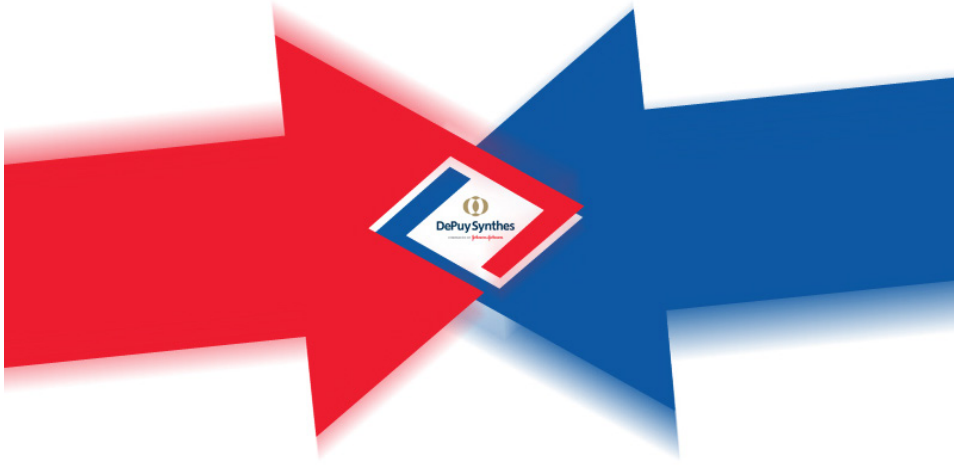
Bumping Knees With Zimmer

Company management told analysts during an April 15, 2014 conference call that knee sales were driven by the Attune Fixed Bearing Knee. The device is now in full commercialization in North America, with launches in 13 European and Asia-Pacific countries under way. The Attune is up against Zimmer Holdings Inc.'s Persona knee, one of the most successful new knees in some time.

Management said hip sales were negatively affected by seasonal volumes, as well as pricing. In the U.S., price for hips was negative 4.1%, offset by modest mix, for a total of negative 3.7%.

DePuySynthes 1Q2014	Sales ($ in millions)	% Change*
Total Reported Sales	**2,421**	**2.7%**
Knees		3.0%
Hips		2.0%
Spine		Flat
Trauma		7.0%

Source: Johnson & Johnson
** Constant Currency*



RRY Publications LLC

Trauma sales included a 10% increase in the U.S. BMO Capital Market analyst, Joanne Wuensch, reported that while it seems that there was some strong market growth, most of the trauma positive recovery was a result of last year's nail recall.

Spine Stabilizing

While spine sales declined, Wuensch noted that the loss was an improvement from a larger decline in the fourth quarter of 2013, "indicating some stability." The company has been clear that Synthes and DePuy integration challenges have contributed to a loss in market share. Perhaps those challenges are fading.

Ortho Market as Expected

Wuensch wrote that there have been several worries regarding the overall health of the device market. "Yes, the 1Q14 did witness softer utilization trends driven by the more difficult winter, and ortho did soften sequentially as expected given seasonality (as well as some influence of the implementation of ObamaCare)." She said management noted that they saw a similar type of year-over-year decline in the rate of utilization, particularly hospital admissions as well as lab procedures, as these have been trending for the least year or so at minor downticks.

Only DePuy Synthes and Biomet, Inc. have reported orthopedic sales for the quarter. "But so far the sequential step down does not seem meaningfully better or worse than expectations (with the exception of hip pricing)," concluded Wuensch.

—*WE (April 17, 2014)*

LEGAL

Podiatrist Going to Jail

The podiatrist from Virginia who pled guilty in January to participating in a Medicare fraud scheme involving bone growth stimulators, is going to jail

Ilene Terrell, D.P.M., was sentenced to five months in prison, five months of home confinement and two years of supervised release on April 17, 2014. She was also ordered to pay a $15,000 fine.

The Lie After the Fact

Specifically, Terrell was sent to jail, not for her part in falsifying patient medical records and prescribing an Orthofix, Inc. bone growth stimulator where the claim would not have met Medicare's guidelines, but for lying about it to a federal grand jury.

Falsified Patient Records

According to the U.S. Attorney's Office in Boston, when Terrell prescribed a stimulator that didn't meet Medicare's guidelines, the Orthofix territory manager, Terrell, and an employee at Terrell's direction often falsified the patient's medical records, making it appear as though the stimulator was not prescribed until three months had elapsed without healing, when in fact that was not true and Medicare should not have paid the claim.

For instance, they deleted references in chart notes that the patient was using the stimulator and was healing, and they created new, fictitious notes at the

Wikimedia Commons

Ilene Terrell, D.P.M.

end of the 90-day period stating that the bone was still broken and that a stimulator would be ordered. Terrell also created fictitious prescriptions and signed Medicare Certificates of Medical Necessity falsely stating that she had ordered the stimulator at the end of the 90-day window, when in fact the patient had received the device months previously. These medical records were altered solely to ensure that Medicare paid Orthofix for bone stimulator claims that did not satisfy the program's payment rules.

Grand Jury Testimony

When Terrell testified before a grand jury in May 2012, she was asked if she was aware that patient records had been manipulated. She said no. When asked about her communications with an Orthofix representative about the government's investigation, she lied about that too. The U.S. Attorney said Terrell discussed the government's investigation at length with the Orthofix representative and instructed him "you and I have not talked." She also threatened him, stating, "If you guys take me out you are never going to live to hear the end of it. If I roll on this, I am serious, heads are going to roll, heads are absolutely gonna roll."

After she learned that her practice administrator of 23 years had provided truthful testimony to the grand jury, she fired the employee.

Bone-Stim Prison Score

Seven other individuals have already been sentenced to short prison terms or home confinement as a result of the government's investigation. One former Orthofix territory manager has agreed to plead guilty to healthcare fraud. Orthofix paid approximately $42 million in criminal fines and civil payments and was sentenced to five years of probation. Current management took over Orthofix after the settlement with the Justice Department.

According to Terrell's web site, "The Foot Doctor of Rappahannock, Ltd.," she is board certified in foot surgery by the American Board of Podiatric Surgery. She provides conservative as well as surgical management of foot and ankle ailments for children, teens, adults and seniors, including diabetic patients.

She has been practicing in the Fredericksburg area since 1986 and has maintained board certification in foot surgery since 1995. Terrell maintains privileges at Mary Washington Hospital and the Fredericksburg Ambulatory Surgery Center. She has served as chairman of the podiatry department at Mary Washington Hospital.

Terrell attended the Pennsylvania College of Podiatric Medicine and the Surgical Residency programs. "She is committed to providing the highest level of care, taking the time to explain your ailment and address your concerns. She believes that ongoing training and product knowledge assists her in her efforts to remain current with new trends in podiatric medicine and surgery," stated the web site.

—*WE (April 22, 2014)*

CE Mark for Aperion Biologic's ACL Reconstruction Device

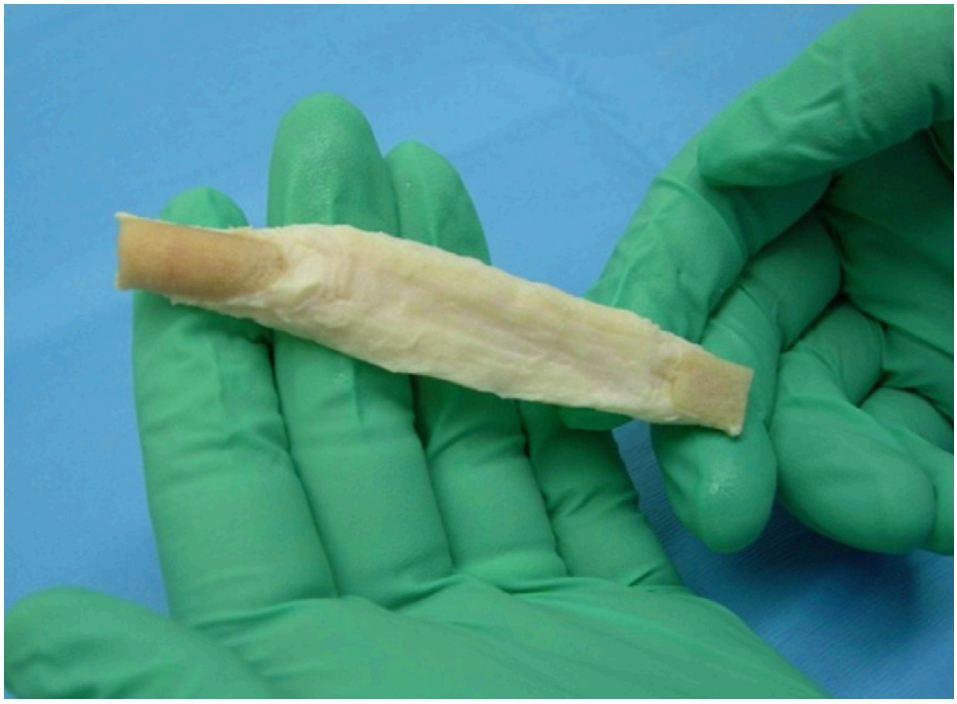
Aperion Biologics, Inc. has been granted CE Mark for the Z-Lig ACL Replacement Device. It is the first engineered biologic device for treatment of revision and multiligament anterior cruciate ligament (ACL) knee reconstruction to be granted a CE Mark or to be approved anywhere in the world.

The approval for the off-the shelf biologic device was announced on April 22, 2014.

The company conducted a prospective, randomized, controlled clinical trial in Europe and South Africa that demonstrated biological acceptance of its bioengineered porcine tendons, re-establishment of knee stability, and remodeling over time into the patient's own human ligament. U.S. clinical evaluation is pending final discussions with the FDA on its approved pivotal clinical study.

Kevin Stone, M.D., company founder, said the international trial and CE Mark approval, "independently confirm the successful results we saw in our U.S. pilot study which now has patients with Z-Lig devices 10 years after implantation. The advantage of an off-the-shelf, biologic device is it avoids the weakening of the patient by taking their own tissue." (Dr. Stone was not a participant in the CE Mark trial.)

According to the company, over 600,000 ACL reconstruction surgeries are performed around the globe annually, using either a patient's own tissue (autografts) or cadaver tissue (allografts). "Prior attempts at use of animal tissue or syn-



Z-Lig ACL Replacement Device/Aperion Biologics, Inc.

thetic grafts to meet the high demands of the knee have proven unsuccessful. The Z-Lig provides a revolutionary new option for patients around the world. Aperion's device is designed to provide immediate stability and function to the knee while promoting gradual remodeling into human tissue over time," said the company announcement.

Compatible Animal Tissues

Aperion developed and patented a technique to make animal tissues compatible for human applications. The core platform technology utilizes a proprietary Z-Process, which removes the key antigens from animal tissues, followed by a conversion process that, according to the company, both stabilizes and sterilizes the tissue without affecting its biomechanical or biological properties. This creates functioning scaffolds capable of remodeling into healthy tissue. Aperion's Z-Process is applicable to a variety of tissues used in orthopedic, cardiovascular, plastic, general and other surgical specialties. Currently, the device is not commercially approved for sale in the U.S. or other markets outside of the European Union.

Company Leadership

In addition to Dr. Stone, Aperion's founder, the company is led by their CEO, Daniel Lee. Prior to joining Aperion in 2008, Lee was responsible for the Trurepair business unit at Smith & Nephew Endoscopy. Prior to Smith & Nephew, he was responsible for global marketing activities at Osteo-Biologics, Inc. (OBI) which provided the only off-the-shelf bioabsorbable implant for articular cartilage repair in Europe. OBI was acquired by Smith & Nephew in 2006.

—*WE (April 23, 2014)*

FzioMed Goes to FDA Dispute Resolution Panel in June

FzioMed, Inc. is going to get its day in the FDA's "Court"—the Medical Device Dispute Resolution Panel (MDDRP)—on June 10, 2014.

Medical Device Dispute Resolution Panel

The MDDRP advises the Commissioner of the FDA on complex or contested scientific issues between the FDA and medical device sponsors, applicants, or manufacturers relating to specific products, marketing applications, significant regulatory decisions and actions by the FDA, and Agency guidance and policies. The panel is convened infrequently and makes recommendations on issues that are lacking resolution, in this case it will decide whether to overturn the Center for Devices and Radiological Health (CDRH) denial of the Oxiplex PMA (premarket approval) or uphold the previous decision.

A Decade of Decisions

"For more than a decade, FzioMed has been seeking approval of Oxiplex in the U.S.," said John Krelle, FzioMed's president and CEO. "Over the course of its review, the FDA's Center for Devices and Radiological Health (CDRH) has reviewed data on approximately 500 patients from four peer-reviewed published clinical studies spanning three continents. The totality of data from the various studies submitted to FDA on Oxiplex, combined with extensive clinical success achieved around the world, demonstrate that Oxiplex can offer increased clinical benefit compared to discectomy surgery alone, while presenting no significant safety risk."

Wikimedia Commons and Coldbourne

FzioMed filed their PMA application in August 2007. The agency's orthopedic panel met in July 2008 and voted to recommend against approval. The FDA then issued "not approval" letters in September 2008 and once again in January 2010. In October 2011, the company requested supervisory review by the Office of the Center Director of the not approvable decision. A letter issued on October 9, 2012, by William Maisel, M.D., on behalf of the Office of the Center Director, upheld the not approvable decision.

The company then chose to exercise the option to consider the October 9, 2012 decision letter to be a denial of approval of the PMA and requested an administrative review by filing a petition for reconsideration on November 5, 2012. On November 4, 2013, the company announced that FDA Commissioner Margaret Hamburg, M.D. approved their petition for an independent review of their PMA and a rare special Medical Devices Dispute Resolution Panel meeting.

Shades of Adcon-L

There are echoes of Gliatech's Adcon-L's FDA approval and subsequent recall due to concerns over possible contamination of material from the aluminized paper liner in this case. As of 2012, according to Millennium Research Group, there were no adhesion barriers approved for orthopedic application in the U.S.

Oxiplex

Oxiplex is an absorbable, clear, viscoelastic hydrogel that is applied during lumbar spine surgery. Oxiplex has been approved for sale in the European Union since 2002 and is now approved in 70 countries. It has been used in more than 350,000 surgeries worldwide. The company has been working for 12 years to gain FDA approval to market this device in the U.S.

The company says Oxiplex has been investigated in two U.S studies under an FDA-approved Investigational Device Exemption (IDE), as well as studies in Italy and China, that confirm the results of the U.S. study in subjects undergoing discectomy surgery. "The IDE pivotal study, which required more than five years to complete, found that subjects having both predominant leg pain and severe preoperative back pain, experienced a greater reduction in leg and back pain when treated with Oxiplex compared to undergoing surgery alone," stated the company press release.

In addition, the company statement says patients receiving Oxiplex had fewer reoperations and more patients achieving zero pain scores at study end compared to those receiving discectomy surgery only. "This group of patients has been identified in the literature (including the widely referenced SPORT study as one that often does not experience the magnitude of benefit in reduction of leg pain that is generally experienced following discectomy surgery. Other studies including those from Kleinstueck et al. and el Barzouhi et al., also found higher levels of back pain to be a predictor of a poorer outcome after such surgery resulting in large groups of patients with unsatisfactory outcomes. This is the target group that benefits the most from the adjunctive effect of Oxiplex."

—WE (April 16, 2014)

BIOLOGICS

Androstenedione Chops Joint Replacement Risk

Higher concentrations of sex hormones in women reduced the risk of total knee replacement by about one-third, according to a study conducted by investigators at Monash University and Alfred Hospital in Melbourne, Australia. They found that women who have joint replacements due to osteoarthritis (OA) have different patterns of hormone concentrations when compared to the general population.

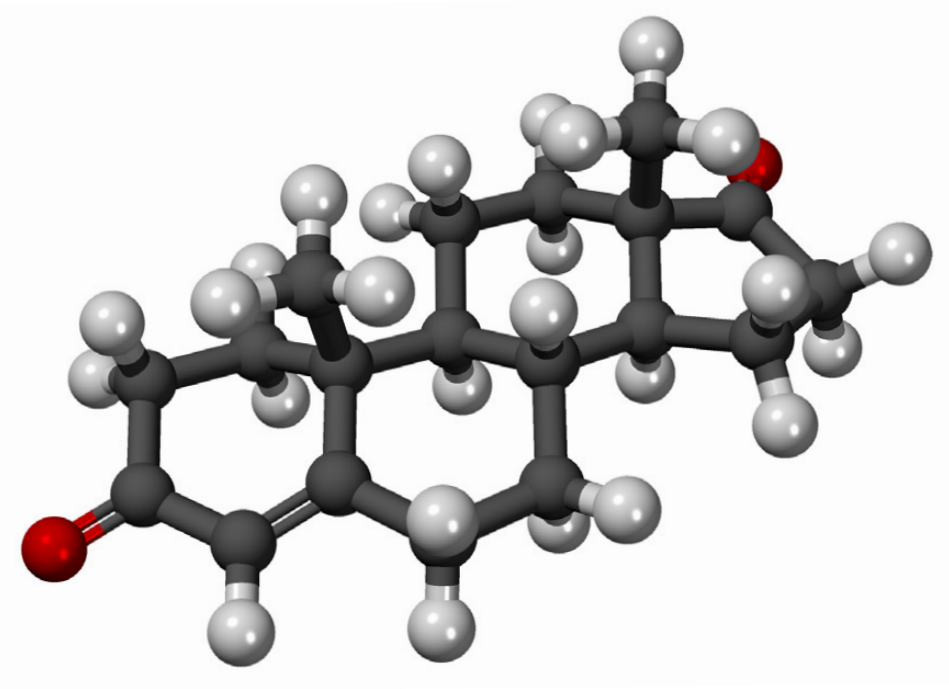
The study group consisted of over 2,600 middle-aged women who had been followed up for 10 years. The finding was consistent with a previous study that showed that women using long-term postmenopausal oestrogen therapy had greater knee cartilage volume than did women who were non-users.

The researchers found that greater androstenedione concentrations cut the risk of total hip replacement by about a third, while greater levels of sex hormone binding globulin was linked to a higher incidence of hip replacement. These associations held even after adjusting for established osteoarthritis risk factors such as age, country of birth and body mass, they said.

The authors of the study believe this to be the first prospective study to explore the relationships between circulating concentrations of endogenous sex steroids and sex hormone binding globulin.

"The findings suggest a role of circulating sex steroids in the pathogenesis of OA and that modifying these steroid concentrations may provide potential strategies for the prevention and treatment of knee and hip OA," they concluded.

—BY (April 21, 2014)



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LARGE JOINTS

12,000 Patient Rehab Study Results Announced

Advanced rehab after knee replacement surgery provides long-term benefits to those who receive it, according to a study conducted by Kenneth Ottenbacher, Ph.D., OTR, director of the Center for Rehabilitation Sciences at the University of Texas Medical Branch in Galveston, Texas.

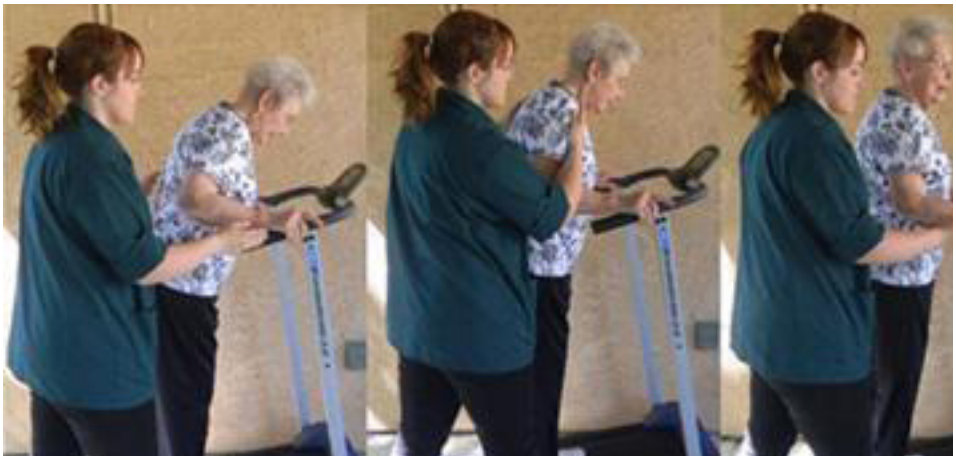
The research team examined data from 12,199 men and women who had knee and hip replacements between 2008 and 2010. All of the research subjects were living independently prior to the surgery and underwent rehab as inpatients. Most of the participants were female. Their average age was 71.

The investigators looked at the patient's ability to function when they were admitted for surgery, when they were discharged and three to six months after they left the rehab facility. The measurement included how well individuals could bathe, eat, climb stairs and the condition of their memory. Researchers scored the results on a scale of 1 to 7. The higher numbers indicated higher functioning. The results showed that when participants went into surgery their ability to move around scored an average of 1.6. This improved to 4.2 after their discharge from the hospital and rose to 5.6 in the months following rehab.

"If you can get patients to a certain threshold level, they can do the rest of the rehabilitation on their own," Ottenbacher said. "In a sense, these patients become their own physical therapists."

The study was published in the *Archives of Gerontology and Geriatrics*. It did not deal with the impact of rehab several years following surgery when patients may settle back into patterns established before their joint replacement. Findings presented at the American Academy of Orthopaedic Surgeons annual meeting predicted that first-time knee replacements will rise 673% by 2030 to 3.5 million. Hip replacements will increase 174% in the same time period.

—BY (April 21, 2014)



Wikimedia Commons and KinGal 2013

Bruin Biometrics' Device Shows Promise for Early OA Detection

Bruin Biometrics has reported that its OrthoSonos device is showing promising trends in the detection of early stage osteoarthritis (OA). Initial data show that patients with confirmed severe OA who are scheduled for arthroplasty demonstrate a consistently negative OrthoSonos Health Index (OHI), while patients with healthy joints have a consistently positive OHI. Patients with OA for whom surgery is not yet required reported OHIs trending from healthy to chronic joints.

Bruin Biometrics

Martin Burns, CEO of Bruin Biometrics, told *OTW*, "The study was conducted as an independent UCLA investigator study performed at Harbor-UCLA Medical Center in collaboration with Dr. Louis Kwong as the co-principal investigator. One year from now, Bruin Biometrics anticipates having received approval from both FDA and CE Notified Bodies to market OrthoSonos in European and North American markets."

"Clinical studies being conducted within the coming year are focused on using the OrthoSonos Health Index to discriminate between failing and well-functioning implants with a high degree of confidence, thereby providing vital information for use by clinicians to inform the current day diagnostic dilemmas surrounding joint failure. Implant manufacturers will be deploying OrthoSonos in support of their quality and post market surveillance initiatives. Bruin Biometrics aims to support the U.S. military's efforts to detect early stage osteoarthritis via clinical study enabled deployment of OrthoSonos. Patients will benefit most from early detection of accelerated wear and abnormal tribological patterns. This will offer hope to those millions of patients who do not know whether their joints are functioning well or failing."

—EH (April 17, 2014)

EXTREMITIES

Chickens and Carpel Tunnel Syndrome

Want to experience carpal tunnel syndrome? Go to work for a poultry processing plant. A study by the National Instititue for Occupational Safety and Health (NIOSH) found "an alarming prevalence of carpal tunnel syndrome" among the workers.

Wikimedia Commons and U.S. Department of Agriculture

NIOSH researchers visited a South Carolina plant three times in 2012 and 2013 and found that 42% of the employees who participated in their evaluation had carpal tunnel syndrome. And 41% worked in jobs involving force above the limits recommended for minimising the risk of carpel tunnel syndrome .

Workers in poultry processing plants operate evisceration lines operating at from 90 to 175 birds per minute. NIOSH found that 57% of the participants reported at least one musculoskeletal symptom (not including hand or wrist symptoms) at both baseline and follow-up evaluations. The most common work-related injuries were cuts, punctures and scrapes; repetitive motion; slips, trips and falls; and being caught in or under equipment.

—BY (April 21, 2014)

REIMBURSEMENT

OrthoCarolina and BCBS of North Carolina "Bundle" Up Knees

In early March, Blue Cross and Blue Shield of North Carolina (BCBSNC) established a new bundled payment program for total knee replacement surgery through OrthoCarolina.

Under the agreement with OrthoCarolina, BCBSNC customers will pay a single price for knee replacement surgeries and participate in OrthoCarolina's coordinated care approach. Overall, participating BCBSNC customers are expected to save 10 to 30% on the cost of knee replacement.

"The way insurers have traditionally paid medical professionals is through the 'fee-for-service' model. That model pays medical professionals for each service they provide patients, including tests, appointments and procedures," said Brad Wilson, BCBSNC president and CEO in the March 26 press release. "But bundled payment agreements, like this one, prevent BCBSNC customers from paying unexpected costs. Patients pay one bill, even if they have to come back for another procedure or follow-up visit."

According to studies by the Centers for Medicare and Medicaid Services (CMS), bundled payment agreements provide incentives for doctors and hospitals to work collaboratively to deliver higher quality, evidence-based care to reduce complications and readmissions

One-Time Fixed Price

With this new agreement, BCBSNC customers, including State Health Plan members, between the ages of 19 and 64 will pay a one-time fixed price, rather than receive multiple bills from the surgeon, hospital, physical therapist, anesthesiologist and others. The agreement includes:

- Pre-operative care and appointments for three days before the surgery takes place
- All services associated with the surgery, including post-surgical care, follow-up appointments and physical therapy for up to 90 days after the surgery
- Personalized care coordination from an OrthoCarolina Patient Navigator

OrthoCarolina CEO Dan Murrey said this agreement allows his group to take their commitment to coordinated care a step further. "Our care teams can better communicate with our patients about what they can expect throughout their knee surgery and recovery. We expect to see positive results with the knee replacement episodes and believe it can be expanded to other orthopedic procedures in the future."

OrthoCarolina/BCBSNC and RRY Publications LLC

Better Outcomes, Lower Cost

The BCBSNC press release said that last year approximately 200 of their customers benefited from similar bundled knee payment agreements. On average, their customers saw:

- Cost savings of 10 to 30% for knee replacement surgeries
- Outcomes better than national benchmarks
- A reduction in complications as compared to other total knee replacements performed in North Carolina
- Very high patient satisfaction with the care team

OrthoCarolina is one of the nation's leading independent academic orthopedics practices serving North Carolina and the Southeast since 1922. Its 120 physicians see nearly 1 million patient visits throughout western North Carolina each year.

—*WE (April 16, 2014)*

SPINE

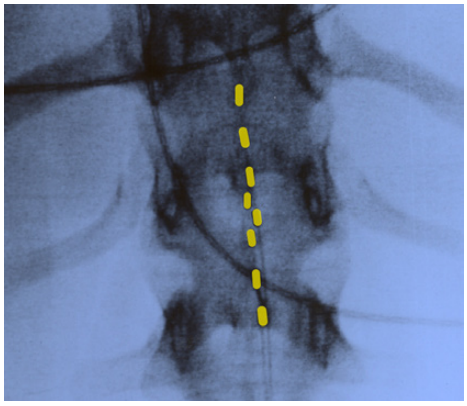
Tiny Study – Big Potential Results

Only four paralyzed patients. There was no control group. None of the four subjects regained their ability to walk. Nevertheless, the study results are remarkable because the subjects, who had complete lower-body paralysis, regained the ability to move their legs and feet voluntarily with electrical stimulation to their spinal cords.

MedPage Today writer John Gever reported on the study which was conducted by the University of Louisville under the direction of Claudia Angeli, Ph.D. and her colleagues. The first subject was 25–year-old Rob Summers who, in 2011, underwent seven months of electrical stimulation to his spine before he could move his lower extremities on his own. Building on their results with Summers, Angeli and her researchers enlisted three new patients who had experienced a spinal cord injury, who had been paralyzed for a least two years and who had no voluntary ability to induce movement in their lower extremities. Contrary to Summers' experience, the three new patients found that they could move their arms, legs, feet and toes within a few days of starting the electrical treatment.

The treatment for all four patients consisted of a 16-electrode device implanted at vertebrae T11 and T12 over segments of the spinal cord L1 to S1, according the Angeli's report which appeared online in the journal *Brain*. They delivered epidural stimulation at varying voltages; with frequencies of 25 or 30 Hz.

In their discussion of the study Angeli and colleagues suggested that the epidural stimulations may have awakened dormant connections: "Anatomical connections may have persisted after the injury that was previously silent because of loss of conduction as a result of disruption of myelin or the ionic channels of the neurons."



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Progress of the patients was uneven. Three of the new patients were moving their legs and feet within 11 days of beginning the stimulation while one patient achieved voluntary control in just 4 days. The subjects needed less and less stimulation as experimentation continued over several months. Eventually, one patient was able to flex his leg without the electrical stimulation. All four of the subjects were male and all had been victims of automobile accidents. One was 33-years old and the others were in their 20's.

—BY (April 18, 2014)

Award Winning Deformity System Implanted in First Patient

Ellipse Technologies, Inc.'s Magnetic Expansion Control Spinal Bracing and Distraction System (MAGEC) received FDA 510(k) clearance in February and now, for the first time since being cleared for commercial sale has been used to treat a young patient with progressive spinal deformity. Patrick J. Cahill, M.D., and Harold van Bosse, M.D. performed the surgery at Shriners Hospitals for Children, Philadelphia.

The MAGEC system, which won the *Orthopedics This Week* Spine Technology Award for 1 of the 10 best new spine technologies in 2011, is for use in skeletally immature patients less than 10 years of age with severe spinal deformities associated with, or at risk of thoracic insufficiency syndrome. According to the manufacturer, the system provides an alternative to traditional growing rods which require repeated lengthening surgeries throughout a child's years of growing. MAGEC's non-invasive lengthening procedure eliminates the need for repeated lengthening surgeries.

"The MAGEC system is a game changer in early onset scoliosis care," said Cahill, regarding the case. "I expect that it will decrease the number of surgeries these young patients have to undergo. The decrease in surgeries will translate into decreased complication rates and cost."

Ellipse Technologies is a privately-held medical device company located in Irvine, California. Company officials report that the MAGEC system has been used by more than 150 surgeons in 24 countries in the surgical treatment of more than 750 children. Pediatric deformity surgeon, Behrooz A. Akbarnia, M.D., performed the first two cases in the United States, prior to the FDA clearance, under the FDA's compassionate use provision in May of 2013.

—BY (April 18, 2014)

Courtesy of Ellipse Technologies, Inc.

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