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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: This market is too high to buy but too solid to sell. Billions of dollars on the sidelines, as a result. Interestingly, Christine Lagarde, IMF managing director urged Fed Chairperson Janet Yellen to delay any interest rate increases. When was the last time a European banker urged an American banker to loosen up? It's a good sign. U.S. economy is growing 2.5-3.0% annually and pulling up the rest of the world.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Integra LifeSciences	13.74%	6.75%	Cash flow is the lifeblood of every business. At IART it is growing 35% YOY. Still least expensive ortho equity.
2	4	Stryker	22.78	2.85	SYK is tied with IART as the lowest valued equity in orthopedics. Operating margins are among the highest in orthopedics.
3	2	ConMed	10.41	5.77	There's a fair amount of operating leverage at CNMD. Investors are hoping management uses it to power up earnings.
4	3	NuVasive	9.30	6.54	NUVA is the most expensive equity on the Power Rankings, but investors still talking about last quarter's upside surprise.
5	5	Globus Medical	30.82	4.12	Earnings could grow faster at GMED, but management is investing in products and markets. In other words, the long term.
6	7	RTI Biologics	7.50	8.33	Raised both sales and earnings estimates for this year. Investors are coming back to RTI—after a seven-year hiatus.
7	6	Smith & Nephew	20.19	0.23	The logistics story at Syncera, SNN's ground breaking sub, is a work in progress. But very intriguing.
8	8	Medtronic	27.92	1.53	Announced Divergence all in one interbody cage at AANS. Nice addition to MDT's extensive spine product line.
9	9	Zimmer	30.35	2.86	Biggest remaining issue is: which Warsaw, Indiana, restaurant will host the closing dinner. Warsaw, right?
10	10	Johnson & Johnson	28.44	(0.58)	Last quarter's sales report for Synthes/DePuy was disappointing. The 7.1% dividend increase helps. But...

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	LDR Holding Corp.	LDRH	$43.94	$1,168	26.77%
2	K2M Group Holdings	KTWO	$24.74	$981	16.26%
3	Wright Medical	WMGI	$27.39	$1,408	9.69%
4	RTI Biologics Inc	RTIX	$6.63	$380	8.33%
5	Alphatec Holdings	ATEC	$1.40	$140	6.87%
6	Tornier N.V.	TRNX	$26.52	$1,299	6.76%
7	Integra LifeSciences	IART	$68.98	$2,272	6.75%
8	NuVasive	NUVA	$49.01	$2,370	6.54%
9	Orthofix	OFIX	$33.89	$636	5.97%
10	MiMedx Group	MDXG	$10.13	$1,100	5.85%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Aurora Spine	ASG	$0.00	$14	-100.00%
2	Bacterin Intl Holdings	BONE	$4.00	$28	-3.61%
3	Johnson & Johnson	JNJ	$98.59	$273,395	-0.58%
4	Smith & Nephew	SNN	$34.17	$15,280	0.23%
5	TiGenix	TIG.BR	$0.80	$129	0.49%
6	Medtronic	MDT	$75.46	$107,278	1.53%
7	Exactech	EXAC	$21.36	$299	2.79%
8	Stryker	SYK	$95.20	$36,025	2.85%
9	Zimmer Holdings	ZMH	$113.25	$19,298	2.86%
10	Globus Medical	GMED	$26.04	$2,471	4.12%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$98.59	$273,395	16.62
2	Exactech	EXAC	$21.36	$299	18.41
3	Globus Medical	GMED	$26.04	$2,471	19.27
4	Zimmer Holdings	ZMH	$113.25	$19,298	19.47
5	Stryker	SYK	$95.20	$36,025	21.76

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MiMedx Group	MDXG	$10.13	$1,100	101.30
2	NuVasive	NUVA	$49.01	$2,370	101.09
3	CryoLife	CRY	$10.79	$306	57.44
4	RTI Biologics Inc	RTIX	$6.63	$380	43.39
5	Smith & Nephew	SNN	$34.17	$15,280	30.50

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$26.04	$2,471	1.58
2	CryoLife	CRY	$10.79	$306	1.91
3	Exactech	EXAC	$21.36	$299	2.07
4	ConMed	CNMD	$56.08	$1,548	2.13
5	Stryker	SYK	$95.20	$36,025	2.54

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MiMedx Group	MDXG	$10.13	$1,100	6.75
2	NuVasive	NUVA	$49.01	$2,370	6.62
3	Smith & Nephew	SNN	$34.17	$15,280	4.77
4	Zimmer Holdings	ZMH	$113.25	$19,298	3.78
5	Medtronic	MDT	$75.46	$107,278	3.37

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.40	$140	0.68
2	Bacterin Intl Holdings	BONE	$4.00	$28	0.79
3	Exactech	EXAC	$21.36	$299	1.21
4	RTI Biologics Inc	RTIX	$6.63	$380	1.41
5	Orthofix	OFIX	$33.89	$636	1.62

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.80	$129	15.39
2	LDR Holding Corp.	LDRH	$43.94	$1,168	8.74
3	MiMedx Group	MDXG	$10.13	$1,100	7.89
4	K2M Group Holdings	KTWO	$24.74	$981	6.23
5	Medtronic	MDT	$75.46	$107,278	5.29

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

So Merge, Already

BY ROBIN YOUNG

Zimmer announced last week (May 28, 2015) that its planned merger with Biomet will not close before mid-June—a month later than the revised date of the end of May, which itself was a revised date from the original estimate of Q1 2015.

It has been a year and a month since the board of directors of both companies approved and announced the deal (April 24, 2014). It's even been seven full months since the new Zimmer/Biomet management teams were announced.

To put those time frames in perspective, the JNJ purchase of Synthes, which represented a larger combination than Zimmer / Biomet, took a year and two months from announcement to closing. Stryker, however, closed its MAKO deal in 2.5 months and Smith & Nephew closed its purchase of ArthroCare in four months.

So if the Zimmer Biomet deal closes in mid-June, it will have taken almost exactly as long as the JNJ/Synthes did to close but six times longer than the Stryker/MAKO deal and four times longer than the Smith & Nephew/ArthroCare deal.

Employees, vendors, shareholders and surgeon customers might be forgiven if they are thinking—So Merge, Already.

Why Is This Taking So Long?

Originally both companies expected that, even with the anti-trust workthroughs, this deal would close in the first quarter of 2015. Now everyone is working hard to wrap it up before the third quarter of 2015.

Wikimedia commons and Heather Katsoulis

Blame it on the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the European Union Merger Regulations. After all, when the deal was announced, holders of approximately 95% of Biomet's outstanding common stock had agreed to the deal.

Especially the European Union (EU) Commission.

The EU Commission assesses all mergers and acquisitions which sell product in the European Union. If sales are above a certain threshold amount, then they get actively involved. The Commission's goal is to prevent concentrations of sales which could significantly impede competition in Europe.

The last time the EU Commission took a hard look at an orthopedic deal it was the Synthes/DePuy deal and that took one year to earn approval.

Zimmer filed its first notification with the Commission in June 2014—about 60 days after announcing the merger. It was an incomplete notification. Zimmer sent a revised notification in July. But it wasn't until the end of August that the Commission formally accepted Zimmer's notification.

From its investigation, the commission spotted potential anti-competition problems for three products and a group of EU markets:

1. Partial (unicondylar) knee implants in Austria, Belgium (including sales in Luxembourg), the Czech Repub-

lic, Denmark, Finland, France, Germany, Greece, Italy, The Netherlands, Poland, Portugal, Slovenia, Spain, Sweden and the UK
2. Elbow implants in Austria, Belgium (including sales in Luxembourg), the Czech Republic, Denmark, France, Germany, Italy, Norway, Portugal, Spain, Sweden and the UK and
3. Total knee implants in Denmark (primary and revision) and Sweden (primary).

So Zimmer went to work to find buyers for its Zimmer Unicondylar Knee ("ZUK"), the Biomet Discovery Elbow ("Discovery"), both across the European Economic Area (EEA), and the Biomet Vanguard Complete Knee System for primary and revision implants ("Vanguard Knee") in Denmark and Sweden.

Zimmer also agreed to give the purchaser of the Vanguard knee in Denmark and Sweden an EEA-wide, non-exclusive license to the rights and know-how that are currently used and are needed for the manufacturing, marketing and sale of an exact copy of the Vanguard Knee.

The Commission also wanted assurances that the buyers would be competitive against Zimmer / Biomet. So in the divestitures, Zimmer agreed to include instrumentation, any improvements and pipeline projects, intellectual property rights and know-how; all licenses, permits and authorizations, CE marks, customer contracts, leases, commitments, orders and records; key personnel, technical assistance and training.

In short, everything but the kitchen sink.

From Biomet's perspective, to do this deal, the Commission was asking them to sell the Vanguard Knee, which is a major contributor to Biomet's market share in Europe.

On March 30, 2015 the Europeans blessed this union.

Then came the U.S. FTC. Those regulators had their own set of requirements which, surprisingly to some Wall Street analysts, did not include any shoulder implant assets.

Then on May 28, two months after the EU approval, Zimmer announced that it had found buyers for the Zimmer Unicompartmental High-Flex Knee System assets, Biomet Discovery Elbow System assets, and Biomet Cobalt bone cement assets.

Are all the regulator's done? Nope. The FTC staff is still working.

But to be safe, the new estimate time to closing is mid-June.

What Will a Zimmer/Biomet Combination Look Like?

We already know who the 13 new senior executives will be. The line-up is:

- Adam R. Johnson will be Group President for Spine, Microfixation, Bone Healing and Dental. He comes from Biomet.
- David A. Nolan will be Group President for Sports Medicine, Extremities, Trauma, Biologics and Surgical. He comes from Zimmer, but has also worked at Biomet.
- Daniel E. Williamson will be Group President for Knee, Hip and Bone Cement. He comes from Biomet.
- Stuart G. Kleopfer will be President, Americas. He comes from Biomet.
- Katarzyna Mazur-Hofsaess, M.D., Ph.D. will be President, Europe, the Middle East and Africa. He comes from Zimmer.
- Sang Yi will be President Asia Pacific. He comes from Zimmer.
- Robin T. Barney will be Senior Vice President, Global Operations and Logistics. He comes from Biomet.
- Audrey M. Beckman will be Senior Vice President, Strategic Quality Initiatives. She comes from Zimmer.
- William P. Fisher will be Senior Vice President, Global Human Resources. He comes from Zimmer.
- Daniel P. Florin will be Senior Vice President and Chief Financial Officer. He comes from Biomet.
- Emmanuel O. Nyakako will be Senior Vice President, Global Quality, Clinical and Regulatory Affairs. He comes from Zimmer.
- Chad F. Phipps will be Senior Vice President, General Counsel and Secretary. He comes from Zimmer.

(Score: Biomet 6, Zimmer 7).

And we have a pretty good idea of what the financials and market share stats will look like.

Combined, Zimmer/Biomet will be the #2 orthopedic company in the $45 billion musculoskeletal market, behind Johnson & Johnson (DePuy/Synthes). But the real story will be in specific markets:

- **Knees:** Pre-merger Zimmer had a 27% market share and Biomet had a 13% market share. Com-

bined, accounting for divestitures and some integration distractions, market share will likely come in around 40%. JNJ will be a distant #2 at 23%. The new Zimmer/Biomet will dominate in knees.

- **Hips:** Pre-merger Zimmer had a 24% market share and Biomet had an 11% market share. Combined, again accounting for divestitures and some integration distractions, market share will likely come in around 35%. Again, JNJ will be a distant #2 at 25%.
- **Non-Recon:** Pre-merger about 30% of Zimmer's sales came from non-large joint recon products. By contrast, nearly half of Biomet's sales are non-large joint recon. These markets include sports medicine, trauma, extremities, spine, biologics, bone healing, dental and micro-fixation. In this group there will be some nice synergies and likely pleasant surprises—after the first year or two of integration.

Financially, the new company is expected by Wall Street's analysts to be able to post up revenues in the $8.0 billion – $8.4 billion range and earn about $1.5 billion – $1.7 billion.

Zimmer is paying $13.35 billion, not counting legal and other expenses (which probably push the real purchase price much higher). To give that purchase price some context, it is 3.9x sales, which is less than the current average 4.11x PSR (price-to-sales ratio) for orthopedic companies and also less than Zimmer's PSR, which is 4.18x.

In terms of a price to earnings, the $13.35 billion Zimmer is paying is about 14x operating income. The average orthopedic equity is currently trading at about 22x earnings (net earnings, not operating income) and Zimmer is trading at about 17x earnings.

Patience Will Be Rewarded

Although the specific business plans from a year ago may need dusting off and updating, this merger is happening. As we write these words it would appear that June 2015—mid or late—will be the final weeks of an independent Biomet.

To the great relief, we suspect, on the part of both companies' employees, vendors, physician customers and shareholders.

To merge these two longtime rivals and great corporate cultures has been an absolutely monumental task. When it is done, when the mountain is scaled, there will be a sense of near euphoria. And it will be hard earned and well deserved.

It's a fact. Progress is more perspiration than inspiration.

But as they stand at the pinnacle, having doggedly made it up despite fierce regulatory winds and adverse conditions generally, and they gaze at the inspiring view from such lofty heights, they will see yet another mountain ahead of them. An even higher peak.

No, not Everest. The name of this mountain is "Integration."

Now the fun begins. ♦

One Overseas Spine Meeting Beckons Above Them All

BY ROBIN YOUNG

John Rich, writing in *Time*, said this of Kuala Lumpur: "Kuala Lumpur is Asia's green capital, where monkeys scamper close to skyscrapers and the occasional boa constrictor slithers across six-lane traffic. Centered around a colonial inheritance of ordered landscaping and dominated by palm-lined freeways, K.L. offers room to breathe and to contemplate."

For spine surgeons who are more than ready to break away from their demanding practices, breathe and with some of the top deformity surgeons of the U.S. and Asia, contemplate and learn—the IMAST meeting in Kuala Lumpur is a must go.

From July 8 to July 11, in the capital of Malaysia, the Scoliosis Research Society (SRS) is holding its International Meeting of Advance Spine Techniques (IMAST).

Always a terrific meeting, holding it in Kuala Lumpur makes this year's IMAST even more memorable, exotic and professionally fulfilling.

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IMAST Program Highlights

After an evening of banana leaf dining (we're talking all-you-can-slurp heapings of rice, dal and curried whatever on fans of banana leaf in place of plates) spend two and a half days immersed in 190 clinical papers, four spirited debates on technique and surgical issues, talking shop with the top Asian and U.S. surgeons and honing skills at seven hands-on workshops.

Here is a selection of some of the highlights from this year's program:

- **Nine Debates:**
  1. Which Approach Is Superior for Treating Adult Degenerative Scoliosis?
     - Juan Uribe M.D. champions the MIS approach
     - Steven Glassman, M.D. counters with the open approach
  2. What Is the Best Way to Achieve Lumbar Lordosis?
     - Larry Lemke, M.D. goes posterior while
     - Munish Gupta, M.D. says anterior/lateral is best
  3. SI Joint Arthritis Is a Common Entity Requiring Surgical Intervention
     - David Polly, M.D. says "yes" while
     - Todd Albert, M.D. says "no"
  4. Transpoas Versus MIS TLIF: Which Is the Best Technique for Degenerative Spondylolisthesis?
     - John Ferguson, FRACS argues in favor of transpoas while
     - Matthew Scott Young, MBBS, FRACS counters with MIS TLIF

5. Sagital Plane Assessment: Which Is Better, the French or American Perspective?
    - Pierre Roussouly, M.D. says the French perspective rules, but
    - Frank Schwab, M.D. respectfully disagrees
6. What Is the Preferred Approach for Multilevel Cervical Disc Herniation?
    - Matthew Scott Young, MBBS, FRACS argues in favor of arthroplasty
    - Chung Chek Wong, M.G. counters with anterior discectomy and fusion while
    - Morio Matsumoto, M.D. presents the case for laminoplasty
7. Surgery or Bracing for Thoracolumbar Fractures?
    - Ki-Tack Kim, Ph.D. gives the case for bracing and
    - Mark Weidenbaum, M.D. argues in favor of surgery
8. Thoracolumbar Fractures Without Neurological Deficits Are Best Treated With MIS Techniques
    - Chung Chek Wong, M.D. agrees and makes the case while
    - Ronald Lehman, M.D. disagrees and explains why
9. Is BMP Needed for Adult Spinal Deformity Surgery?
    - Shay Bess, M.D. says "yes" but
    - Sig Breven, M.D., says "no"

- **My Worst Complications:** Strategies to prevent/manage complications associated with:
    1. Adult Deformity
    2. Cervical Trauma
    3. Tumor
- **Malaysian Spine Society** ICL – Tuberculosis of the Spine
- **Asia Pacific Spine Society** ICL – Anterior Spinal Surgery Revisited, Correction of Severe Deformity—Tips and Tricks

Award Winning Clinical Papers

There are six award winning papers this year and they are:

1. Implant Materials Generate Different Peri-Implant Inflammatory Factors: PEEK Promotes Fibrosis and Micro-Textured Titanium Promotes Osteogenic Factors: *Rene Olivares-Navarrete, DDS, Ph.D.; Sharon L. Hyzy, MS; Paul J. Slosar,*

M.D.; Barbara D. Boyan, Ph.D.; Zvi Schwartz, Ph.D..

2. Morbidity and Mortality of Complex Spine Surgery: A Prospective Cohort Study in 679 Patients Validating the SAVES System in a European Population: *Sven Karstensen, PSc; Tanvir Bari; Martin Gehrchen, M.D., Ph.D.: John Street, M.D., Ph.D.; Benny Dahl, M.D., Ph.D., DMSci*
3. A New Genetic Locus Increases Risk of Idiopathic Scoliosis in Females: *Carol Wise, Ph.D.; Swarkar Sharma, Ph.D.; Douglas Londono, Ph.D.; Walter Eckalbar; Xiaochong Gao; Ikuyo Kou; Atsushi Takahashi; Morio Matsumoto, M.D.; John Herring, M.D.; Shiro Ikegawa, M.D., Ph.D.; Nadav Ahituv; and Derek Gordon, Ph.D.*
4. Prediction of Outcomes in AIS: Results from BrAIST: *Lori Dolan Ph.D.; Stuart Weinstein M.D.*
5. When Does Growth Stop? Results of a Longitudinal Study Comparing Menarche and Skeletal Maturation of the Pelvis, Hand and Elbow to Growth Completion: *James Sanders, M.D.; Debbie Dang, M.D., Ph.D.; Xing Qiu, Ph.D.; Mariano Menendez, M.D., P; Christopher Cook, M.D.; Sarah Hans, M.D.; Daniel Cooperman, M.D.*
6. Magnitude, Location and Factors Related to Regional and Global CorrectionLoss in Long Adult Deformity Contructs Report of 183 Patients with Two-Year Follow Up: *Christopher Ames, M.D.; Virginia Lafage, Ph.D.; Justin Scheer, BS; Michael Kelly, M.D.; Richard Hostin, M.D.; Robert Hart, M.D.; Eric Klineberg, M.D.;Themistocles Protopsalitis, M.D.; Vedat Deviren, M.D.; Daniel Sciubba, M.D.; Shay Bess, M.D.; Christopher Shaffrey, M.D.; Frank Schwab, M.D.; Justin Smith, M.D., Ph.D.; International Spine Study Group*

Faculty

And holding this whole meeting together is an outstanding faculty representing the top clinicians, professors, researchers and scientists from Malaysia, Asia, Australia and North America. And, of course, one of the highlights of a meeting like IMAST is the proximity to these top surgeons. While the podium presentations are good, it's the conversations afterwards that matter the most.

And then, of course, there is Kuala Lumpur.

4 Things to See and Do in Kuala Lumpur

Kuala Lumpur is one of Asia's top destinations for eating and shopping. The city has become a cultural melting pot with some of the world's cheapest 5-star hotels, great shopping at every price range and amazing food.

Here are four things to see and do in Kuala Lumpur:

1. **Shop at the Bukit Bintang:** If the Champs-Elysees merged with Times Square and added a splash of Las Vegas, you'd come close to Bukit Bintang. This is one of the world's best shopping and people watching experiences.
2. **Banana-Leaf Dining:** Quoting from travel writer John Rich: banana-leaf dining is "instantly satisfying on many levels—social, culinary, tactile." This is Tamil culture at its best and Trip Advisor says that the Sri Nirwna Maju Restaurant has the best banana leaf dining in all of Kuala Lumpur. Here's a photo.
3. **Batu Caves:** About 18 miles outside of K.L., the Batu Caves are 400 million year old limestone caves that house one of the most popular Hindu shrines outside of India. Wild life includes monkeys and the shrines are incredible, this is one of the great places to visit in Asia.
4. **Little India:** Quoting John Rich again: "Grotty steam-table joints alternate with groceries peddling papaya-tomato soap, while spices waft along with tabla rhythms and the range of stacked embroidered textiles outdoes any tropical sunset. It's a cozy, safe enclave too: Madras without the madness."

For more information and to get your reservations in place go here:

And enjoy a great, memorable and professionally rewarding meeting. ♦

Bukit Bintang/Wikimedia Commons


Banana-Leaf Diring/TirpAdvsor


Batu Caves/Wikimedia Commons

B.A.S.E. Jumping Orthopedic Surgeon! // *JBJS* Associate Editor Talks Levels of Evidence // Hoag Orthopedic Institute Pulls in 5 Star Rating From CMS

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

B.A.S.E.-Jumping Orthopedic Surgeon! Omer Mei-Dan, M.D. knows how to get out of trouble in the OR…and at 15,000 feet. One of the world's few B.A.S.E. (Building, Antenna, Span, Earth) jumpers, Dr. Mei-Dan, an associate professor of orthopedics at the University of Colorado, can peer deep inside the experiences of his patient-athletes.

When asked how an orthopedic surgeon got to be a B.A.S.E. jumper, he quickly pointed out that it was the other way around. "I was always an extreme athlete, and B.A.S.E. jumping was just one of the adventure sports that I was undertaking in my younger years. When I was still living in Israel, my extreme activities landed me on television with a sponsorship by Red Bull. I came to see that medicine, and specifically orthopedic surgery, would be the best fit for my interests. I wanted to be amongst people like myself—people who were interested in using their bodies in calculated, smart, fun, and advanced ways."

Perhaps his most publicized jump was in 2000 from the Eiffel Tower. "It's something in life that you never get to repeat; the man who did his dive shortly after my jump perished in the attempt. I practiced for that jump for an entire year. It was particularly complicated because you have to fly through the balcony on the first floor…and there's not much margin for error. If you deploy too early you're going to hit part of the structure. It all came off perfectly.

Barak Naggan

The execution was 100% accurate, we purchased tickets so that we couldn't be accused of trespassing, and, most importantly, we ensured that no one was below me when I jumped."

Asked if B.A.S.E. jumping has made him a better doctor, Dr. Mei-Dan replied, "It is important that I understand my patients' sports enough such that I understand the biomechanics, associated equipment, and techniques. If I operate on a rock climber and that person wants to get back to climbing, then I can help them with a safe rehab protocol that results in a quicker return to climbing. I help these patients navigate their passions in educated ways. It is easier when you treat soccer or basketball players because most health care providers know what they do. It's not the same with people who do extreme sports; most people don't know what that person faces as they are hauling themselves up a mountain, or free diving, or ice climbing."

"Take a rock climber who is on crutches…someone who is accustomed to climbing twice a day. There are mental

implications here, and my being able to speak their professional language and share common experiences helps establish an especially strong rapport."

"From a clinical perspective, the fact that as an extreme sports athlete you have to think quickly and react fast and accurately, sometimes 'out of the box', as your life depends on it. That usually translates to my work as a physician. You're working—fast—off the XYZ algorithm and then, in case of need, bifurcating quickly off that algorithm."

"When descending during a jump, you decide on the visual parts that you want to mark. There is no time to look at a stopwatch, and no time to take your eyes off what is around you. You can count, but it's not very accurate when you're in a free fall."

Asked about any other particularly exciting jumps, Dr. Mei-Dan notes, "I jumped into a hole in the deepest vertical cave in the world (in Mexico). I first rappelled down about 1,500 feet to the bottom to check out the landing area. It was like a cone, starting at about 50 feet in diameter, but opening to an area the size of football field at the bottom. When I jumped I had to intentionally delay opening my chute so that I was as far as possible from the surrounding walls when I did open it."

So will we see this orthopedic surgeon flying off the Leaning Tower of Pisa any time soon? "No," says Dr. Mei-Dan, "It's too low…not so interesting."

"What I enjoy most is the nature… climbing a mountain and then jumping off. I'm taking a hard look at the Norwegian fjords for my family summer vacation."

Refining Levels of Evidence When he's not in surgery, Robert Marx, M.D., an attending orthopedic surgeon at the Hospital for Special Surgery (HSS) in New York City and professor of orthopedic surgery at Weill Cornell Medical College, is busy ensuring that orthopedic research is of the highest quality possible. Dr. Marx is associate editor for Evidence-Based Orthopaedics and deputy editor for Sports Medicine and

at *The Journal for Bone and Joint Surgery* (*JBJS*). He tells *OTW*, "Prior to assigning levels of evidence at *JBJS*, for 10 years, I assigned levels of evidence for research papers appearing in *Clinical Orthopaedics and Related Research*. It is clear to me—and it has been validated in the literature—that the quality of orthopedic evidence has consistently improved over the last two decades. We are heading in the right direction."

"*JBJS* works from the level of evidence (LOE) table published by the Centre for Evidence-Based Medicine (CEBM) in the UK. In accordance with their updates, we have made some alternations to our LOE table. We continue to divide studies by type, and the majority of the ranking criteria remain the same. We have, however, flipped the table such that the rows are now columns and the columns are now rows. This change has made the table more intuitive and user friendly; it asks what the research question is and then answers the way a reader would respond."

"We didn't accept everything proposed by the CEBM. For example, they made level one a meta-analysis of randomized controlled trials (RCTs) and level two only RCTs. We didn't think it was appropriate for RCTs to be *only* level two because this kind of study is extremely hard to accomplish in orthopedics. Randomized trials are the highest quality of clinical investigation, and grading them as level two is not an accurate reflection of the level of evidence."

"Looking into the future, we must encourage those in our specialty to conduct the highest quality research possible. In addition, we need to promote high quality research by offering funding to those who are doing it. I have been involved with the International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine, and we have recently developed new a granting process to fund orthopedic research."

As for the most difficult studies to assign a level of evidence, Dr. Marx noted, "Many times it is black and white. When that's not the case, however, the new table makes some allowance for the person assigning the levels to slide one way or other based on the quality of the study, a subtle weakness subtle, or the size of the effect."

"The fact is that you never know what reviewers are going to like. Given that reality, I recommend that my colleagues always submit their manuscripts to the highest quality journal possible. That way, if something is not accepted then it can be resubmitted elsewhere."

Hoag Orthopedic Institute: Only L.A. Hospital Earning 5 stars From CMS At Hoag Orthopedic Institute it's all ortho, all the time…and it's paying off. Hoag Orthopedic Institute (or HOI) is the sole hospital in all of Los Angeles and Orange County to earn the 5-star ranking for patient experience from the Centers for Medicare and Medicaid Services (CMS). Dereesa Reid, CEO of Hoag Orthopedic, tells *OTW*, "We are a real world example of the early writings of Michael Porter and Elizabeth Teisberg, authors of 'Redefining Healthcare.' In constructing our Irvine inpatient facility and our Orange County surgery centers, we built the entire organization around the best ways to provide care to orthopedic patients. We embraced the idea of the value equation because we knew that if we were able to drive quality to the highest level and do it at a low cost then we could meet the demands of today's healthcare environment."

"For example, take fracture care. These are unplanned events that require a specific protocol in addition to our elective cases. Our orthopedic team makes use of best practices in terms of 'time from the Emergency Department to the OR,' etc. It also helps that we have time blocked out on our OR schedule for emergency patients."

"Hoag Orthopedic Institute's success goes back to the original vision of having an organization that is tightly focused on orthopedic care; because of this, we don't have to spend time learning about or handling conditions not related to orthopedics. Our specialty, patient-centric model can be compared to major cancer centers; their outcomes are better because they are focused on providing best practice, efficient care centered around the patient."

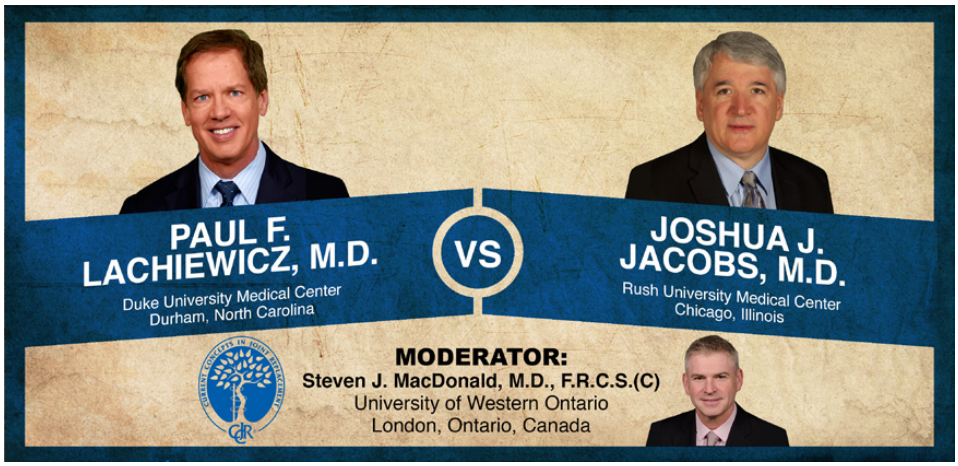
Asked how patient experience is integrated into the clinical care and treatment protocols, Reid noted, "Patients go through preop education, and once they have surgery and arrive on the floor we use technology to facilitate communication including the latest mobile device technology integrated into our clinical systems and EHR. Additionally, we have a novel technology that allows us to interact with patients from the TVs in their rooms. We can program questions into the TV and prompt them, for example, to let us know if the noise too high, if their pain is worsening, etc. And this information is fluid; we change it depending on how our patient satisfaction results are trending. The data is analyzed around the clock, and we can make adjustments very quickly if, say, the lights needs to be dimmed or the room isn't sufficiently clean."

"All of our employees, orthopedic surgeons, and also an outstanding group of anesthesiologists and hospitalists have worked very hard to attain the CMS 5 star rating. They are really top notch." ♦

Lachiewicz, Jacobs Debate CCK in Intraoperative MCL Injury

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

"There is a great track record on constraint for intraoperative MCL injury. The bonuses: no need for sutures or staples, no need for a hinged knee brace, full weight bearing, early ROM, and an excellent long term survival!" argues Paul Lachiewicz. But Josh Jacobs counters, "CCKs in primary TKR are not very conservative…you're resecting a lot of bone. And there are issues of wear and ease of removal."



Current Concepts in Joint Replacement/RRY Photo Creation

This week's Orthopaedic Crossfire® debate was part of the 31st Annual CCJR – Winter meeting, which took place in Orlando this past December. This week's topic is "Intraoperative MCL Injury Requires Constrained Components." For the proposition is Paul F. Lachiewicz, M.D. of Duke University Medical Center. Joshua J. Jacobs, M.D. of Rush University Medical Center is in opposition. Moderating is Steven J. MacDonald, M.D., F.R.C.S.(C) from the University of Western Ontario.

Dr. Lachiewicz: "In the past, people have had a bad taste in their mouths from the so-called constrained prostheses because these did have high rates of complications and loosening. But the modern constrained condylar prosthesis has almost 30 years of a track record."

"It's unusual to have to do this in a primary total knee arthroplasty. It's generally indicated for a fixed valgus deformity, usually in an elderly patient. I'll concentrate today on the incompetent medial collateral ligament (MCL). One example, done by one of my former partners, involved a valgus knee where the MCL was 'slightly weakened' intraoperatively. Five months postoperatively I saw this patient with an embarrassing instability."

"Beware of patients who have a staple or a screw at the medial epicondyle. In one example, a surgeon removed a stone staple from the medial epicondyle. The MCL was thought to be fine, but two weeks postop the knee was unstable. Also, beware of patients with heterotopic bone at the medial joint line. Once that bone comes out to mobilize the knee there is no adequate MCL."

"What happens if there is an 'inadvertent' division of the MCL? This occurs anywhere from less than 1% to almost 3%. If I determine that the MCL is shot, then I will use an intercondylar cutting guide for the femoral component."

"Postop rehab is easy, with routine pain management, no knee immobilizer, no brace, full weight bearing, early range of motion (ROM)…I even use a continuous passive motion machine in the hospital."

"We've published two series on this. The first was with the older version (TCP III, I-B II). We had 44 knees, and a 10-year survival rate of 96%. The main problem with this knee was that the patellofemoral mechanics were not optimal; we had to do a lot of retinacular releases. We had no post breakages—even at 10 years. We did have three revisions."

"In our most recent series (February 1999-present) we used a stem with the tibial component. On the femur I used a .145 mm stem. There were 27 knees with a mean follow-up of five years; we did have two that were an actual disruption of the MCL. We tried to balance all of these knees. I don't routinely go to a CCK (constrained condylar knee); we do routinely use stems. There were no mechanical complications, no loosening, and no post breakage. We did see two patients with stress fractures of the patella."

"Maynard et al. (*Journal of Arthroplasty*, 2014) involved 132 primary CCKs… a lot! This is because their indications were very broad: >5mm of mid-flexion laxity, no aseptic loosening at seven years…but they did have some patellar complications."

"The advantages of CCK for intraoperative MCL injury are that there is no need for sutures or staples, no need for a hinged knee brace, you don't have to manipulate these patients, full weight bearing, early ROM, and an excellent long term survival."

Dr. Jacobs: "From the article by Galante et al. (*Clinical Orthopaedics and Related Research*, 1991), we know that coronal balance is critical to total knee arthroplasty (TKA). The general consensus is that an injured MCL with coronal imbalance should be addressed."

"We have published on this (Leopold et al. *The Journal of Bone and Joint Surgery,* 2001). We had 16 cruciate retaining (CR) TKA with intraoperative MCL injuries. It involved a primary repair and six weeks in a hinged knee brace; there was no increased constraint. We had excellent results, with a mean Hospital for Special Surgery (HSS) Knee Score of 93 and no instability at a mean of 45 months."

"We took this further, looking at a larger cohort (including varus and valgus knees) and had a longer follow-up. It was a retrospective review of intraoperative MCL injuries during primary TKA from 1991-2009. We either repaired it end to end for mid-substance lacerations or with a suture anchor/screw washer for avulsions. We exposed the ligament, used running, locking, non-absorbable braided sutures for end to end repair of mid-substance lacerations. For avulsions, two sutures were used in a running/locking fashion distal to proximal, then proximal to distal tied over a screw washer or to a suture anchor."

"We placed the sutures into the ligament prior to cementing, and the sutures were tensioned with the knee in mid-flexion with a final polyethylene spacer in place. The patient was placed in an unlocked knee hinged brace for six weeks. During rehab we ordered unrestricted, full weight bearing, along with free ROM in the hinged knee brace. The brace was discontinued at six weeks."

"We looked at HSS Knee Scores, radiographic reviews, subjective complaints of instability, and the physical exam. And of our nearly 4,000 consecutive primary TKAs, there were 48 intraoperative injuries (split between lacerations and avulsions). We lost 3 patients, leaving us with 45 and a mean follow-up of 89 months; 35 were cruciate retaining, 10 were posterior stabilized. They were mostly varus knees."

"There were no subjective complaints of instability in any of these patients. There was no instability on the physical exam in full extension or in 30 degrees of flexion; there was no need for functional bracing. And their HSS Knee Scores increased 46.8 points after repair. Finally, there was no radiographic evidence of instability and ROM was respectable. Four knees did require manipulation under anesthesia, and three knees required revision; there was no hardware migration or breakage."

"The paper by Lotke did have suboptimal results with repair, but our results suggest that primary repair works…whether it's a varus or a valgus knee…whether it's a laceration or avulsion. However, stiffness was a real problem, so it made us wonder whether the brace was really necessary. We can get away with this because of the important role of the posterior cruciate ligament (PCL) in secondary valgus stabilization (as reported by one of the investigators in Leo Whiteside's lab). And after MCL release, valgus laxity was statistically greater in patients that had a PCL sacrifice or a PS prosthesis."

"There are problems with increased constraint, including increased stress at implant interfaces and increased stress and poly wear of the tibial post; it's certainly less conservative. These are all of the reasons we don't use these implants routinely for primary TKA. And, you may be in a situation where you rupture an MCL intraoperatively and semiconstrained implants may not be available."

"To cave a bit to Paul's argument, we still think you should use caution when using a PS because of the important secondary stabilizing effect of the PCL."

Moderator MacDonald: "Paul, what do you do to minimize injury to the MCL in the first place…so that you're not in this situation?"

Dr. Lachiewicz: "In the severe varus knee you must be certain that you're not stripping all the way down. You do a minimal release at the start, put the spacer block in (or trial component). During the cuts you need a retractor, a Hohmann under the MCL…don't cut it. But there is going to be the rare case where it will be disrupted."

Moderator MacDonald: "Josh, same question."

Dr. Jacobs: "Often, you don't realize that it's happened until you're putting in your spacer or trials. I agree…you do a bit of a medial release initially, then make sure that at all times the MCL is protected with a retractor (and that they aren't retracting too forcefully)."

Moderator MacDonald: "So you can either repair it or constrain with polyethylene. Paul, do you ever repair it?"

Dr. Lachiewicz: "I did once, and I put multiple sutures and took it through a stress and the sutures just ripped through. I think the fears that these things are going to loosen have not been borne out. We have 15 year data on people who were 50 when we put them in…they do well."

Moderator MacDonald: "Josh, what do you do?"

Dr. Jacobs: "We have on occasion used a CCK when the MCL was totally irreparable. Back to the other point, though, we don't use these CCKs in primary TKA because they're not very conservative…you're resecting a lot of bone. If you have to go back and remove it for infection it is not easy and you sacrifice even more bone. Furthermore, there is the issue of tibial post wear, which isn't an issue with CR and not as much of an issue with PS. Even though your survivorship is high in terms of aseptic loosening, what about wear and ease of removal? These create issues that are best avoided."

Moderator MacDonald: "So if you're going to use the constraint for MCL rupture do you always need to stem it—even if you have good quality bone?"

Dr. Lachiewicz: "Tom Sculco had a paper with the HSS version of the CCK where the initial results (without a stem on the femur) looked good, but the follow-up has revealed femoral component loosening. I don't usually cement the femoral stem; I put a stubby stem extension, something you can remove without much difficulty if you have an infection."

Moderator MacDonald: "Thank you, gentlemen." ♦

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

COMPANY

Medtech: Green Light to Market ROSA Robot

The surgical robot experts at Medtech are announcing that the company has received official authorization to market its ROSA robot in Australia for minimally invasive surgical procedures on the brain, and also spine surgery.

"This is an important milestone in the company's development and ongoing expansion of our market opportunity. This authorization to market ROSA in Australia and the signing of a distribution agreement with Surgicom is a reflection of our strategy to increase our commercial presence at international level, including the Asia-Pacific region, where we already have strong momentum," commented Bertin Nahum, President, CEO and Founder of Medtech, in the May 18, 2015 news release.

Nahum told *OTW*, "We are very pleased to report that we have seen a notable uptick in the global adoption of ROSA surgical robots. The sale of eight surgical units in the first five months of 2015 now brings the total number of robots in use up to 41 worldwide. We hope the dynamism we are seeing in the U.S. market continues with the FDA clearance of ROSA Spine later this year. In the coming year we aim to drive adoption of both ROSA Brain and ROSA Spine globally, with specific focus in U.S. and Asian markets." — EH

Medtech

LEGAL

Grassley Demands Medicare Advantage Investigation

Senator Charles Grassley is turning his investigative attention to alleged fraud in the Medicare Advantage (MA) program. The program is a kind of private Medicare for about 16 million elderly beneficiaries paid for by Medicare and run by private insurers.

Grassley, a co-father of the Sunshine Act, recently sent letters to CMS (Centers for Medicare and Medicaid Services) and DOJ (Department of Justice) regarding allegations of "Risk Score" fraud by the private MA insurers. Another Senator, Claire McCaskill, sent a similar letter to CMS asking what steps the agency was taking to address alleged Medicare Advantage fraud and abuse.

Medicare.gov
The Official U.S. Government Site for Medicare

Senator Charles Grassley/Source: U.S. Senate and Medicare.gov

"Risk Score" is a formula based on a beneficiary's health that lets CMS figure out what fee to pay private insurers each month per beneficiary. The higher the risk, the higher the payments. There have been recent allegations in False Claims whistleblower lawsuits that insurers like Aetna, Cigna, UnitedHealthCare and others have been fraudulently inflating risk scores.

$70 Billion Improper Payment Estimate

Here's an example provided by our colleagues at *Policy and Medicine*. If a physician documents that a patient is drug or alcohol dependent, the government pays the plan $2,400 extra for the added risk and associated anticipated expense. A recent article from The Center for Public Integrity said that when a home visit "unearths a medical condition, as it often does, health plans may be able to raise a person's risk score and collect thousands of dollars in added

Medicare revenue over a year—even if they don't incur any added expenses caring for that person." The Government Accounting Office has estimated that Medicare made $12 billion in improper payments to private insurers in 2014 for the MA program and nearly $70 billion from 2008 through 2013, based on inflated risk scores.

Fed Cover Up?

But, allegedly, the government already knew this.

Back in March 2015, the *Financial Times* reported that a study commissioned by the federal government in 2009 concluded that MA programs were overcharging. "However," stated the report, "the study was mysteriously never published," until it was unearthed by the Center for Public Integrity through a Freedom of Information Act request.

McCaskill, a Democrat, wrote that, "With fraudulently inflated risk scores potentially costing taxpayers billions of dollars every year and resulting in less money in the Medicare Trust Funds for our seniors, this is an issue that must be investigated further." Grassley, a Republican, wants to know what approach DOJ and CMS are using to fight Medicare Advantage fraud. The DOJ is reportedly investigation the whistleblower's false claims charges.

"With the reported increase in risk score gaming, and the monumental cost that the taxpayer will shoulder for such wrongdoing, it is imperative that CMS implement safeguards to reduce risk score fraud, waste and abuse. Moreover, if the reports of abuse are true, CMS should increase its auditing practices," Grassley wrote.

Neither CMS nor the Justice Department has commented on the letters. — *WE*

BIOLOGICS

New HSS Study: Bone Fill in a Septic Condition Praised

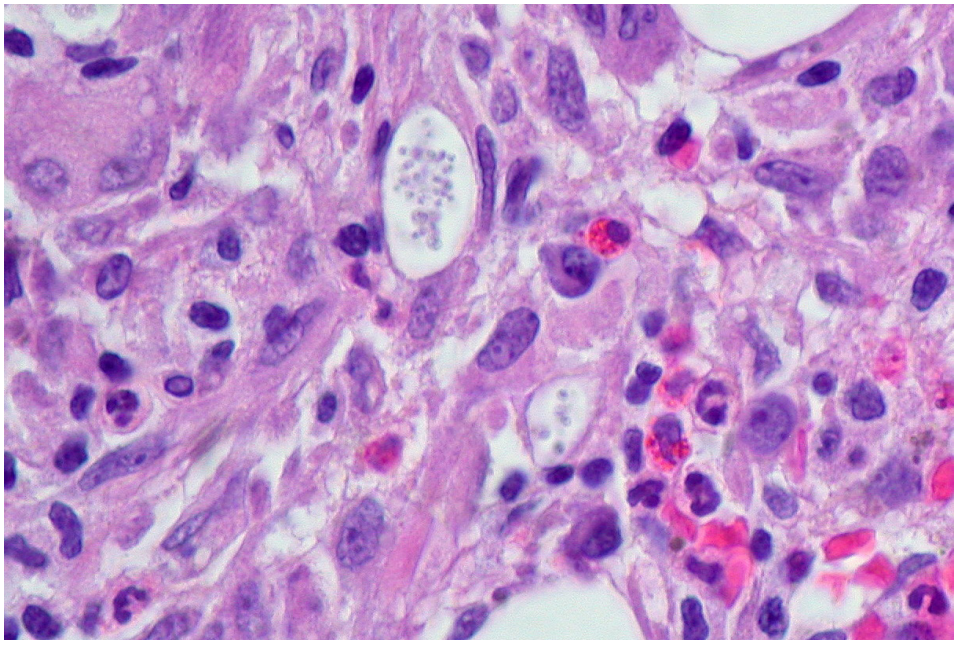
Study results of CERAMENT|G, reported at the 2015 Orthopedic Research Society Annual Meeting, demonstrated that the Swedish product promoted new bone growth and decreased the rate of infection when compared to patients treated without a bone filler.

The manufacturer, headquartered in Lund, Sweden, is Bonesupport AB, a maker of injectable bone substitutes for use in orthopedic, trauma and bone infections.

"Treatment of chronic osteomyelitis often leaves a large critical defect which requires a bone void filler, yet current void fillers are inadequate because of donor site morbidity, expense or their propensity to encourage infection, " said Mathias P.G. Bostrom, M.D., orthopedic surgeon at Hospital for Special Surgery in New York and co-author of the study. "This study showed CERAMENT|G to be effective in decreasing the rate of infection and simultaneously increasing new bone growth, two essential functions for successful management of osteomyelitis."

Bonesupport officials describe Cerement|G as an injectable, bone graft substitute designed to fill bone gaps and voids and to augment hardware and bone fractures during surgical procedures. CERAMENT|G, they claim, has been shown to remodel into healthy native bone within 6 to 12 months.

"This is the first animal study to evaluate CERAMENT|G in a septic condition and we were very pleased with the results," said Bonesupport CEO Lloyd Diamond. Osteomyelitis, or bone infection, is reported to be a $1.7 billion annual cost where prolonged, long-term antibiotic therapy, multiple surgical interventions and the threat of amputation are required to combat the problem. — *BY*



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BioStructures: First Application of Prohesion

BioStructures, LLC has announced the first application of Prohesion, its patented surgical wound technology that is an activated type I collagen wound filler. With Prohesion, type I collagen fragments that have been sheared to a powder format.

BioStructures CEO Russell Cook stated in the June 2, 2015 news release, "We are very pleased to offer another unique and innovative product under the BioStructures umbrella. Utilizing our expertise in collagen, we are able to offer products that not only assist in better patient care, but will benefit the hospital by reducing complications with surgical wounds. Prohesion provides yet another technology platform expanding on our Bioactive, Collagen, Synthetic, DBM and Allograft suite of products."

Asked about an interesting point during the development phase, Cook told *OTW*, "We were able to identify a need of spine surgeons for which a comprehensive solution is not currently available. The need for a solution that was identified was complications associated with surgical wounds. BioStructures' Prohesion allows the surgeon to apply hydrolyzed active collagen fragments to the surgical wound which benefits all phases of wound care including inflammation, proliferation, maturation, infection, granulation and remodeling."

"It is our hope that Prohesion will eventually become the standard of care for hospital facilities in the management of surgical wounds." — *EH*

BioStructures, LLC

LARGE JOINTS

Rates of Joint Replacement Among Veterans Increasing

American servicemen and women are getting new hips ad knees at an increasing rate. Over an 11-year surveillance period, researchers discovered that service members in their 30s and early 40s were having the joint replacement procedure done more often. They were also remaining in the military for a longer period following rehabilitation.

Service members who were 40 years old or older were at greater risk for both hip and knee replacements. During the period of 2009 to 2013, incidence rates also increased in the following age groups 30–34 years (45%); 35–39 years (10.7%); 40–44 years (13.0%); and 45 years and older (3.8%)

In 2014 the rates of knee and hip replacements were identical—1.6 per 10,000 person years. It appears in the report, published by the Armed Services Surveillance Center, that service members may be electing to have joint replacements at earlier ages due to improvements in surgical techniques and the increased durability and longevity of prosthetic joints.

The report documents a total of 3,905 joint replacements among 3,805 active members of the Army, Navy, Air Force, Marine Corps, and Coast Guard Among the cohort of service members who had a joint replaced during 2004–2012, 18.2% had retired; 5.2% had been medically disqualified from service; 6.3%

Wikimedia Commons and Timothy Wilson

had otherwise left service; and 70.3% were still in service one year after their joint replacement.

Of the services, the Army and Coast Guard had the highest overall rates of joint replacement (2.89 and 2.88 per 10,000 person-years,) The Coast Guard had the highest rate of hip replacement (1.54 per 10,000 person-years) and the Army had the highest rate of knee replacement (1.46 per 10,000 person-years).

The Army and Coast Guard had the highest rates of shoulder replacement

The report concluded, "It takes years of training and experience to produce a seasoned NCO or Officer. If joint replacement allows servicemen and women to remain on duty longer and continue being valuable contributors to the military, then it will be a good thing for the U.S. Armed Forces." — *BY*

Knee Replacement Surgery #1 Under Obamacare

Is anyone surprised?

After the Affordable Care Act went into effect a lot of Americans stopped limping. The most "preference-sensitive" procedure undergone by new subscribers to Obamacare was knee replacement surgery, according to a report by the Society of Actuaries.

A preference-sensitive procedure is defined by Dylan Scott, writing for *National Journal*, as one without which a patient can continue for some time. However, their quality of life can be greatly improved for patients who have the surgery.

Wikimedia Commons and Michael Rivera

"These results show how giving health insurance to people who lacked it before can improve their quality of life," said Larry Levitt, vice president of the Kaiser Family Foundation.

According to Scott, the authors of the report studied the newly insured in the state of Kansas, which they found has similar demographics to the United States as a whole. They found that getting more people on insurance has released pent-up demand for preference-sensitive procedures, which might cause rates to increase in the short term. While the actual number of knee replacements was relatively small and therefore not a statistically precise measure—it did offer a sense into where the pent-up demand is within the health care system.

They speculated that once the formerly uninsured get healthy, costs should stabilize. "Just because new enrollees used more services initially doesn't mean that will necessarily be true looking ahead," Levitt said. "This study may give insurance regulators some evidence to push back on insurers that are proposing big rate increases for 2016 based on how much health care enrollees used in 2014." — *BY*

REIMBURSEMENT

CMS Offers More Incentives in Shared Savings Program

CMS (Centers for Medicare & Medicaid Services) just updated rules governing how providers, such as ACOs, (Accountable Care Organizations) can get their share of the Medicare Shared Savings Program.

The new rule creates a new Track 3, which includes, according to the agency, higher rates of shared savings, the prospective assignment of beneficiaries, and the opportunity to use new care coordination tools. There is also a streamlining of data sharing between CMS and ACOs.

There are currently over 400 participating ACOs serving more than 7 million beneficiaries. In the first two years of the program established under Obamacare, the ACO's improved performance in 30 or 33 quality measure and generated over $384 million in savings to Medicare. That's about $300 per participant in the program.

"Accountable Care Organizations have shown early but exciting progress in improving quality of care, while providing more patient-centered care at a lower cost," said CMS Acting Administrator Andy Slavitt. "The ACO rules today strengthen our ability to reward better care and lay the groundwork for more providers to become successful ACOs."

Higher Risk, Higher Rewards

The National Association of ACOs (NAACOS) said CMS is to be commended for adopting some "important improvements to the program, especially for the new high risk Track 3." The most significant change from current rules for Track 1, according to the association, is that the ACOs whose contract is ending this year and achieved certain quality thresholds will be permitted to sign a new three-year agreement and if they were successful in lowering their costs and achieving savings, their new historically based benchmarks will be adjusted upwards to include their savings amount.

"This will partially mitigate the spiraling down of benchmarks for the successful ACOs. We are very pleased CMS has adopted these changes to give the 200+ ACO whose contracts are ending an option to continue in the program. We are also very pleased that CMS will consider for the future, trending and resetting benchmarks based on regional costs. This was one of our strongest recommendations and we still hope it could be implemented in 2017 for all ACOs."

Track 3 will have better savings share, and in 2017, SNF 3-day waiver, Telehealth waivers and self-attestation/ alignment of beneficiaries. NAACOS and other stakeholders strongly recommended these changes.

ACO Association Skeptical

But ACOs weren't totally happy. The association is "very disappointed" that many of their recommendations were not adopted for the majority (400+) of ACOs in the lower one-sided risk Track 1. "While CMS made several other changes in how beneficiaries are assigned to the ACO and data is shared, the remainder of the program policies will not change for at least 2016 and probably 2017."

The association was also disappointed that CMS is not implementing a voluntary beneficiary assignment policy or a two-way risk adjustment methodology for the Track 1 ACOs.

For the program to succeed there must first be a sustainable business model for the one-sided track, noted the NAACOS statement. "Most providers will not migrate to a higher two-sided risk track without a positive experience in a one-

Pixabay and Gerd Altmann

sided risk program. It would appear that CMS is hoping that by building the better business case for the higher risk tracks more ACOs will come."

"I remain skeptical that enough improvements have been made to Track 1 to sustain the growth we have been seeing and am concerned that large numbers of current ACOs are not ready to take on the higher risks of Track 2, 3 or CMMI's Next Generation ACO program", said NAACOS CEO Clif Gaus. NAACOS believes that ACOs continue to be the most promising market-based solution to improving quality and lowering healthcare cost growth and will continue to work with the Administration and the Congress to make further adjustments to the program so that more Medicare beneficiaries and providers are able to participate and benefit from the program's success."

For more information on the Medicare Shared Savings Program, click here: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html. — *WE*

Medicare Releases 2nd Year of Doc Payments Data

On June 1, 2015, the government released the second year of Medicare payments to physicians, hospitals and suppliers. The highest-paid specialists were radiation oncologists, who received an average of $403,512 from Medicare for their services. That was closely followed by dermatologists ($331,108), vascular surgeons ($329,874), and ophthalmologists ($326,621).

Medicare paid all physicians $90 billion in 2013, up 17% from $77 billion in 2012, CMS (Centers for Medicare and Medicaid Services) officials reported on June 1, 2015. The payments went to about 950,000 doctors, nurse practitioners and other individual healthcare providers who participate in the program. That was up from 880,000 providers in 2012.

Photo creation by RRY Publications, LLC

Joint Replacement Top Procedure

Joint replacement was the most common hospital procedure that Medicare paid for in 2013, accounting for nearly 450,000 inpatient admissions and $6.6 billion in payments, or about $13,000 per admission. Total knee replacements led the list. Replacement procedures averaged about 12 per 1,000 Medicare beneficiaries with surgery rates highest in the Midwest and Rocky Mountain states. The average hospital charged around $54,000 in 2013. Medicare, on average, paid around $12,000.

Charges Up, Reimbursements Steady

Overall, the data reportedly showed that hospitals raised their billing prices by 10% between 2011 and 2013, while the amounts paid by Medicare stayed flat.

Physician payments accounted for less than one-fifth of Medicare's 2013 net outlays of $492 billion, which rose from $466 billion in 2012. Payments to hospitals for the top 100 inpatient stays cost Medicare $62 billion in 2013, while the rest went for drugs, privately run Medicare Advantage plans and other program costs.

There was a significant change from how the data was reported last year. This year the government differentiated between what it paid physicians for

their services and what it paid to cover the costs of drugs. Some physicians had complained that they were portrayed as exorbitant billers because the cost of drugs was included in what Medicare paid them.

For example, medical oncologists, who treat cancer patients with chemotherapy and generally coordinate their care, received an average of $181,747. The previous year's data showed them as some of the top Medicare billers, but that largely reflected reimbursements for the cost of drugs—an average $473,926 in 2013. The physician who received the most from Medicare was Anne Greist, M.D., a co-founder of the Indiana Hemophilia & Thrombosis Center. She received $28 million in payments, but nearly all of that—$27.9 million—was for reimbursements for drugs.

The American Medical Association was happy about separating the drug payments from physician reimbursement, saying it "remain[s] concerned that the 2013 data still has significant shortcomings."

"Specifically, the data released today does not provide actionable information on the quality of care that patients and physicians can use to make any meaningful conclusions," stated an AMA press release. "It also does not provide enough context to prevent the types of inaccuracies, misinterpretations, and false assertions that occurred the last time the administration released Medicare Part B claims data."

See for Yourself

To analyze the data yourself, click here: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html — *WE*

SPINE

Benvenue Medical: Kiva Trumps Balloon Kyphoplasty

Benvenue Medical, Inc. has announced that the Kiva VCF (vertebral compression fractures) Treatment System resulted in a substantial cost and resource savings over balloon kyphoplasty (BKP)—the current standard of care. The results were published online in the May/June issue of *Pain Physician*. These savings were documented in the KAST study, the largest randomized, controlled, clinical trial to date versus the standard of care.

"Traditional procedures for treating vertebral compression fractures, such as vertebroplasty and balloon kyphoplasty, have been well documented to be safe, effective and cost efficient," said Wayne J. Olan, M.D. in the May 27, 2015 news release. Dr. Olan is director of Minimally Invasive and Endovascular Neurosurgery at the George Washington University Medical Center and author of the study. "This study shows that the Kiva System is a further improvement in terms of both patient care and cost effectiveness. The more than 30% reduction in adjacent-level fractures shown in the KAST trial with Kiva translates directly to fewer reoperations for the patient and reduced costs for the hospital relative to balloon kyphoplasty."

"In today's healthcare environment, new technology must both improve patient outcomes and add economic value for our facility," said J. Kevin McGraw, M.D., medical director Interventional Radiology at Riverside Methodist Hospital, and a new Kiva user. "This study clearly demonstrates actual cost savings of using Kiva vs. balloon kyphoplasty in the long term. Not only does Kiva provide improved patient outcomes but now we know Kiva is also cost effective."

Asked what hurdles there are to having Kiva accepted over balloon kyphoplasty, Benvenue CEO Robert K. Weigle, told *OTW*, "The VCF category is unique in that there have been no new treatment advances in more than a decade. Kiva is a totally new approach to treating VCFs, so it will take time to increase awareness and educate physicians about the many clinical benefits it offers over other treatments, including BKP. Early adopters and their patients—and even group purchasing organizations like Novation—have recognized the clinical and economic benefits of Kiva. We still have work to do and we're confident that it's only a matter of time before Kiva becomes the new standard of care."

"In multiple published studies comparing Kiva to BKP, Kiva consistently improved patient outcomes in cement extravasation, cement volume and

Benvenue Medical, Inc.

improvement in kyphotic correction (spinal realignment). Kiva has also been shown to reduce the adjacent level fracture rate as compared to balloon kyphoplasty, as well as to significantly reduce the rate of readmissions relative to BKP. The fact that Kiva has been clinically proven to reduce the rate of adjacent level fractures has significant economic benefits—more than $1,000 per patient as demonstrated in the Pain Physician study—not to mention the benefit to patients of not having to endure the pain of a subsequent fracture." — *EH*

Titan Spine: Endoskeleton Looking Good Compared to PEEK

Titan Spine is touting the results of a new study demonstrating a reduced subsidence rate and overall subsidence amount of its Endoskeleton TA device compared to a commercially available PEEK device. The findings emanate from a dynamic mechanical study assessing subsidence rates of spinal implants during continuous cyclic loading.

In this study, "Titan's TA ALIF interbody device provided for a 410% reduction in rate of subsidence and a 40% reduction in overall subsidence amount compared to a commercially available ALIF PEEK implant of a similar footprint." All of the company's Endoskeleton devices feature Titan Spine's proprietary technology, consisting of a unique combination of roughened topographies at the macro, micro, and cellular levels. As indicated on the company website, "This unique combination of surface topographies is designed to create an optimal host-bone response and actively participate in the fusion process by promoting the upregulation of osteogenic and angiogenic factors necessary for bone growth, encouraging natural production of bone morphogenetic proteins (BMPs), downregulating inflammatory factors, and creating the potential for a faster and more robust fusion."

Antonio Valdevit, Ph.D., Professor, Department of Chemical Engineering & Materials Sciences at Stevens Institute of Technology, was lead author of the study. Dr. Valdevit told *OTW,* "Most investigations of this type deal with thousands or millions of cycles when dealing with implant/bone or isolated implant fatigue. In this particular case, we applied the techniques to the very early phase of implant/vertebra interactions. In the early phase following surgery, the interactions between implants and the host bone are very different as compared to the long-term effects."

Asked about future research, Dr. Valdevit added, "The research community (in conjunction with clinicians) should arrive at a standardized or, at least, a consensus as to the optimal testing duration and anatomical model for future conduction of these tests that include an animal model so as to reduce the potential for large variations in human anatomical samples. Alternatively one may be able to parameterize anatomical specimen geometry and density with implant performance to arrive at some clinical predictability regarding the dynamic outcomes associated with use of a particular implant under patient-specific conditions. While such an undertaking will require a large number of samples and time, it may provide more relevant clinical data."

"Implant behavioral effects, including subsidence, upon the underlying bone and biological interaction is a dynamic effect and is greatly influenced by both design and material. A study that examines the biological effects under mechanical loading would provide a more physiological and clinical perspective as to implant performance. Such an experiment would consider the dynamic mechanical response in addition to the biological effects of the implant design and material. Conceptually, it would require a bioreactor type of chamber under mechanical loading combined with a stable cellular culture system."

"Subsidence is a dynamic and continuous event and should be evaluated as such. Current standards employ a single compressive force to determine subsidence into a foam representative of bone. Implant performance is a consequence of both design and material which cannot be properly evaluated under a static condition when in reality the environment is dynamic both mechanically and biologically." —*EH*

Titan Spine

PEOPLE

Rising From the Rubble: San Diego Surgeon Helps Those Impacted by Nepal Earthquake

Although the last recorded aftershock struck May 29, Nepal faces a long road to recovery after a record-breaking earthquake rocked the small country on April 25, 2015. The 7.8 magnitude earthquake and subsequent 7.3 magnitude earthquake that shook the region on May 12 resulted in over 8,000 of deaths and tens of thousands of casualties. The Nepalese Army and dozens of international aid organizations have since been dispatched to treat and rescue those affected by this natural disaster. Munish Batra, M.D. and Amber Cheffins Gurung, R.N. are among those who have volunteered to come to Nepal's aid.

Dr. Batra of Rancho Santa Fe, California and Cheffins Gurung of Encinitas, California are members of a medical team that is connected to Doctors Without Borders. This team expects to perform operations on those suffering from traumatic crushing or burn injuries sustained during the devastating earthquakes. These surgeons and nurses will conduct necessary operations in two hospitals, one in the Nepalese capital of Kathmandu and the other in Helambu, a village north of the capital.

Both Dr. Batra and Cheffins Gurung have volunteered on previous humanitarian missions, but the volatile nature of earthquakes presents a potential hazard for the surgical team. Concerned about the dangers another earthquake could cause, one team member canceled after the second earthquake struck in May. Despite the perilous nature of his volunteer expedition, Dr. Batra is still scheduled to depart for Kathmandu on June 5.

"You just hope for the best…I feel like we'll let down literally hundreds of people if we don't show up. I feel like I can't let them down," Dr. Batra said.

Cheffins Gurung, an operating room nurse, is also willing to take risks in order to help those wounded during the earthquake.

"I'm not scared enough not to go," Cheffins Gurung said. "To go and do something good for them, give them some hope there is still good in the world and give them something to live for…it just feels right."

In addition to facing potential danger, Cheffins Gurung has gone above and beyond by being a member of an advance team that had already left for Nepal on May 26. The purpose of this team is to screen patients, obtain supplies, and set up the operating room in preparation for the surgeons. Once Dr. Batra arrives, he expects to perform 25 to 30 operations in a day, for the 8 to 10 days of his stay.

"You get up, have your tea or coffee, and you just keep going until you're too exhausted to operate," Dr. Batra said. "You can do an operation that will make a significant impact on someone within a couple of hours."

Donations to assist these doctors can be made to the GoFundMe page: http://www.gofundme.com/asips. — *SB*

Caption: Photograph of the destruction in Nepal taken from a US Army helicopter
Source: Lance Cpl. Mandaline Hatch

Deyo Wins NuVasive-Sponsored Award

Richard Deyo, M.D., MPH, is the 2015 ISSLS Wiltse Lifetime Achievement Award winner.

ISSLS (International Society for the Study of the Lumbar Spine) awards a yearly winner for "exceptional achievement" in the spinal field. Nominees for the award should be "outstanding individual scientist, clinician or basic science researcher who has made a major contribution to the advancement of knowledge in the field of spinal disorders."

"The main reason why Dr. Deyo got the vote lies in his insistance to emphasize the need to build our practices on evidence. He is appreciated as a moderating voice in a community at times too eager to find indications for surgery. And of course his CV and his work as an educator were paramount in the choice.," Robert Gunzberg, M.D., wrote to *OTW* on behalf of ISSLS.

NuVasive, Inc. is the sponsor of the award which comes with a $15,000 grant.

Dr. Deyo is the Kaiser Permanente Professor of Evidence-Based Family Medicine in the Department of Family Medicine at Oregon Health & Science University (OHSU). He is well known for his published studies which indicate surgeons are performing too many spinal procedures. He is the author of the book, *Hope or Hype: The Obsession with Medical Advances and the High Cost of False Promises.*

The Irony

There is some irony of a critical spine researcher winning a prize sponsored by, arguably, the fastest growing spine company in the last half decade.

Richard Deyo, M.D., MPH/Oregon Health and Science University

We asked NuVasive President and COO Pat Miles about the award. Miles said, "We are proud to be a supporter of ISSLS and appreciative of past winners (i.e., Steve Garfin, M.D.; Ed Hanley, M.D.), however we have no input in to whom the society issues its Lifetime Achievement awards".

"The irony is not lost on me," Dr. Deyo told us on June 2, 2015. "Indeed, I'm a bit surprised by the award, but pleased and honored, needless to say. And I appreciate NuVasive's sponsorship of the award."

Asked about the tremendous rise in spine surgical procedures over the last decade, Deyo said he is the first to acknowledge that modern medicine would be impossible without the medical device and pharmaceutical industries. "I think the increase in spinal fusion surgery in recent years has many factors contributing to it, although I do think that marketing of new devices is one of those factors. In that regard, I long for a higher evidence bar for efficacy and safety of new devices, and stronger post marketing surveillance. I feel that we often know too little about which patients will benefit most from new devices at the time they hit the market."

Areas of Study

According to Dr. Deyo's University web page, his areas of study include "patient involvement in clinical decisions, measurement of patient functional status, and management of common outpatient conditions. His current research includes studies of complications from back surgery in older adults, and of opioid-prescribing patterns for chronic pain. Dr. Deyo is an expert on low back pain and was the principal investigator on the Agency for Health Care Policy and Research Patient Outcomes Research Team on low back pain, and a member of the agency's guideline panel for acute low back problems. He serves on the board of directors of the Informed Medical Decisions Foundation."

He received his medical degree from the Pennsylvania State University School of Medicine and conducted his internship and residency in internal medicine at the University of Texas Health Science Center, San Antonio. He completed his master's of public health at the University of Washington, where he later was appointed professor of medicine and director of the Center for Cost and Outcomes Research.

Unlike some spine surgery critics who pontificate from self-appointed ethical organizations, Dr. Deyo publishes his evidence and submits himself to peer-review and criticism in medical journals. — *WE*

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