

# Orthopedics • This Week

## WEEK IN REVIEW

**4 Aetna, Humana, Anthem and United's Urge to Merge** >> Remember the Golden Rule? Whoever has the gold, rules. Get ready. BIG changes are in the works at Aetna, Humana, Anthem and UnitedHealthcare. With tens of billions of dollars sloshing around these companies, it seems that bargaining power is shifting in their favor. But large employers have other ideas.

**8 Aesculap Enters Lumbar Disc Maelstrom** >> The FDA just approved Aesculap's artificial lumbar disc. The marketplace for lumbar discs has been brutal. Cervical has fared much better as LDR has shown. Can Aesculap breathe new life into lumbar artificial discs? A couple of top spine surgeons are hopeful, but the opinions are not exactly universally held. Are the payers ready for Act II of lumbar artificial discs?

**12 Three New Studies: CT Scans Uncover Widespread SI Joint Degeneration // Distressed Patients Mean Dissatisfaction With Surgeon // Delay of Primary ACL Reconstruction Linked to More Injury** >> New research from Stanford indicates that surgeons should not over-rely on CT scans when diagnosing lower back pain. Listen up: Patients who report being distressed are less likely to be satisfied with their surgeons! And a new study pinpoints exactly where delaying a primary ACL reconstruction can affect patients.



**15 Two Aarons Square Off Over Cementless Fixation: Hofmann v. Rosenberg** >> "Twenty-five years of implant retrieval has shown that we definitely have a solid attachment with cementless devices," argues Aaron Hofmann. Aaron Rosenberg counters, "The literature and registries clearly show that it sometimes is just silly not to cement (patients with osteopenia, patients with significant bone defects, the elderly)."



## BREAKING NEWS

- 18 Found! Regulatory "Blueprint" for Chondrocytes**
- .....
- Predicting Which RA Patients Won't Respond to Biologic Drugs
- .....
- New K2M Deformity System Cuts Surgical Steps in Half
- .....
- Clearasil for Shoulder Surgery?
- .....
- Gold Knee Implant, Literally
- .....
- CMS to Offer Data to Entrepreneurs and Innovators

For all news that is ortho, read on.

# Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**THIS WEEK:** Last week CMS proposed to mandate bundled payments for total joint surgery. They're calling it Comprehensive Care for Joint Replacement (CCJR). They are proposing a five year test in 75 cities. It would also allow for gainsharing. This is a major development. Bundling has been around for a while and suppliers are prepared to serve that market. But now CMS wants to mandate it. Huge. It would cover 35% of the U.S. population initially.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	22.78%	0.37%	It's earnings season and Wall Street expected SYK to grow sales 1.9% and earnings 8.3%. Modest sales growth, but rising margins.
2	3	ConMed	10.41	4.45	Two more medical device heavy weights join CNMD's board. Obviously Wall Street likes it; the stock keeps rising.
3	4	Integra LifeSciences	13.74	1.74	Last four quarters, IART has beat Wall Street's estimates. Can they do it again in the June quarter? We wouldn't bet against it.
4	7	Johnson & Johnson	28.44	0.66	Greek existential crisis, China's stock market meltdown and new CMS rules. We see nervous investors gravitating to JNJ.
5	9	Smith & Nephew	20.19	1.57	Recommendation upgrade from Wall Street firm Berenberg to "Buy." Most analysts expect SNN to grow sales over 6% for June quarter.
6	2	Zimmer Biomet	30.35	(6.03)	ZBH is now in integration mode and will be for at least a year. Most analysts expect zero sales growth for the June quarter.
7	6	RTI Biologics	7.50	(1.95)	RTIX is the 6th least expensive equity in orthopedics. And over the last four quarters, it has beat estimates every time. Can they do it this quarter?
8	8	Medtronic	27.92	(2.35)	Launches CD Horizon Solera for MIS, transforaminal lumbar interbody fusion. Gives surgeons new flexibility in terms of approach.
9	5	Globus Medical	30.87	(1.97)	Most analysts expect very little earnings growth for the June quarter, but continued double-digit sales growth.
10	10	NuVasive	9.30	(4.73)	Rounding out the top ten is NUVA—with the highest valuation. Analysts are expecting a big earnings quarter for June.



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## 2015 SPINE TECHNOLOGY AWARDS

**SUBMISSIONS DEADLINE: AUGUST 14, 2015**

# Robin Young's Orthopedic Universe

## TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	\$11.61	\$1,261	14.27%
2	ConMed	CNMD	\$58.49	\$1,614	4.45%
3	Integra LifeSciences	IART	\$63.06	\$2,077	1.74%
4	Smith & Nephew	SNN	\$34.89	\$15,604	1.57%
5	CryoLife	CRY	\$11.30	\$320	1.16%
6	Johnson & Johnson	JNJ	\$99.53	\$276,001	0.66%
7	Stryker	SYK	\$96.37	\$36,467	0.37%
8	TiGenix	TIG.BR	\$0.82	\$132	-0.06%
9	Orthofix	OFIX	\$33.22	\$623	-1.04%
10	RTI Biologics Inc	RTIX	\$6.55	\$376	-1.95%

## WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Aurora Spine	ASG	\$0.47	\$9	-33.40%
2	Bacterin Intl Holdings	BONE	\$3.05	\$22	-20.78%
3	MicroPort Scientific	853	\$0.43	\$617	-16.82%
4	LDR Holding Corp/	LDRH	\$41.19	\$1,095	-8.14%
5	Zimmer Biomet	ZBH	\$106.81	\$21,712	-6.03%
6	NuVasive	NUVA	\$46.77	\$2,262	-4.73%
7	Wright Medical	WMGI	\$26.37	\$1,355	-4.70%
8	K2M Group Holdings	KTWO	\$23.26	\$939	-4.24%
9	Alphatec Holdings	ATEC	\$1.40	\$140	-4.11%
10	Tornier N.V.	TRNX	\$25.56	\$1,252	-3.91%

## LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	\$99.53	\$276,001	16.78
2	Exactech	EXAC	\$20.72	\$290	17.86
3	Zimmer Biomet	ZBH	\$106.81	\$21,712	18.36
4	Globus Medical	GMED	\$25.39	\$2,410	18.79
5	Stryker	SYK	\$96.37	\$36,467	22.02

## HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MiMedx Group	MDXG	\$11.61	\$1,261	116.10
2	NuVasive	NUVA	\$46.77	\$2,262	96.47
3	CryoLife	CRY	\$11.30	\$320	60.15
4	RTI Biologics Inc	RTIX	\$6.55	\$376	42.87
5	ConMed	CNMD	\$58.49	\$1,614	31.61

## LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	\$25.39	\$2,410	1.54
2	Zimmer Biomet	ZBH	\$106.81	\$21,712	1.84
3	CryoLife	CRY	\$11.30	\$320	2.01
4	Exactech	EXAC	\$20.72	\$290	2.01
5	ConMed	CNMD	\$58.49	\$1,614	2.22

## HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MiMedx Group	MDXG	\$11.61	\$1,261	7.74
2	NuVasive	NUVA	\$46.77	\$2,262	6.31
3	Smith & Nephew	SNN	\$34.89	\$15,604	4.87
4	Medtronic	MDT	\$74.37	\$105,334	3.36
5	Johnson & Johnson	JNJ	\$99.53	\$276,001	3.10

## LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	\$3.05	\$22	0.60
2	Alphatec Holdings	ATEC	\$1.40	\$140	0.68
3	Exactech	EXAC	\$20.72	\$290	1.18
4	RTI Biologics Inc	RTIX	\$6.55	\$376	1.39
5	Orthofix	OFIX	\$33.22	\$623	1.59

## HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$0.82	\$132	15.80
2	MiMedx Group	MDXG	\$11.61	\$1,261	9.05
3	LDR Holding Corp/	LDRH	\$41.19	\$1,095	7.33
4	Medtronic	MDT	\$74.37	\$105,334	5.20
5	Globus Medical	GMED	\$25.39	\$2,410	4.90

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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# Aetna, Humana, Anthem and United's Urge to Merge

BY ROBIN YOUNG

The big insurance news this week was Aetna Inc.'s \$35 billion bid to acquire Humana Inc. There are only a handful of major private health insurance carriers in the United States and #3 wants to buy #4.

It's the largest deal *ever* in the insurance industry.

It would create the #2 health insurer after Anthem—at least in terms of membership. In dollar terms, it would be #2 behind UnitedHealthcare.

With the flood of cash coming into payers courtesy of Obamacare and a more robust employment economy, apparently the urge to merge is irresistible.

A week before the Aetna/Humana deal was announced, the *Wall Street Journal* reported that Anthem was considering a \$45 billion takeover of Cigna. And United was kicking around the buyout of Aetna. And Centene Corporation actually announced a \$6.3 billion bid to buy Health Net, Inc.

Where are insurers finding all this money? We know health insurance is profitable, but this is ridiculous.

## How Profitable are the Health Insurance Payers?

Based on their financial filings with the Securities and Exchange Commission (SEC), here is how profitable the top five payers are. (See *first table on page 5*.)

In 2014, the top five payers booked nearly \$6 billion in profits on \$71 billion in revenues. To put that in per-



Photo creation by RRY Publications, LLC

spective, that is more than \$1 million per employee. In terms of profits, that's more than \$88,000 per employee.

And the most profitable of them all is Anthem. The *least* profitable on this list, Humana, is being gobbled up by Aetna.

## By Contrast, How Profitable Are the Hospitals?

According to their SEC filings, hospitals are less than half as profitable as health insurers. Here is how the top four hospital networks stack up. (See *second table on page 5*.)

On a per-employee basis, the largest and presumably most efficient hospital networks in America earn about \$28,000 (before interest, depreciation or taxes). By contrast payers earn nearly \$90,000

(\$88,088) per employee or 307% more than the healthcare providers.

Treating patients is a whole lot more expensive and labor intensive than paying for patients. Compare Hospital Corporation of America (HCA), which manages 162 hospitals, to Cigna Corporation which manages none. Both companies reported about the same level of sales—\$38 billion for HCA and \$36 billion for Cigna. But HCA needed 169,000 employees to gin that up while Cigna only needed 37,000 employees. In effect, one Cigna employee made as much for their company as four HCA employees.

## Executive Pay

As it turns out, insurance executives are paid, on average, more than their counterparts at the hospitals. Which actual-

**LARGEST HEALTH INSURANCE PAYERS IN UNITED STATES**

<b>\$ in Billions - Except/ Employee Amounts</b>	<b>Market Value</b>	<b>Employees</b>	<b>Revenues</b>	<b>EBITDA*</b>	<b>Revenue/ Employee</b>	<b>EBIDTA*/ Employee</b>
Centers for Medicare and Medicaid Services						
Blue Cross and Blue Shield Association						
United Health Care	\$115.95	170,000	\$134.52	\$11.93	\$791,294	\$70,176
Aetna	\$43.83	48,800	\$59.10	\$4.95	\$1,211,066	\$101,434
Anthem	\$43.16	51,500	\$75.07	\$6.02	\$1,457,670	\$116,893
Cigna	\$41.51	37,200	\$35.88	\$3.89	\$964,516	\$104,570
Humana	\$28.08	57,000	\$50.62	\$2.70	\$888,070	\$47,368
<b>AVERAGE:</b>	<b>\$54.51</b>	<b>72,900</b>	<b>\$71.04</b>	<b>\$5.90</b>	<b>\$1,062,523</b>	<b>\$88,088</b>

(EBITDA stands for Earnings Before Interest Taxes Depreciation and Amortization. Basically EBITDA represents profit from operations before all the other, non-operating expenses are removed.)

Source: RRY Publications LLC and Security Exchange Commission

**LARGEST HOSPITAL NETWORKS IN UNITED STATES**

<b>\$ in Billions - Except/ Employee Amounts</b>	<b>Market Value</b>	<b>Employees</b>	<b>Revenues</b>	<b>EBITDA</b>	<b>Revenue/ Employee</b>	<b>EBIDTA/ Employee</b>
Veterans Administration						
HCA	\$37.05	169,000	\$37.76	\$7.69	\$223,432	\$45,503
Tenet	\$5.90	83,160	\$17.12	\$2.09	\$205,868	\$25,132
Community Health	\$7.39	103,000	\$19.37	\$2.90	\$188,058	\$28,155
LifePoint	\$3.87	38,000	\$4.74	\$0.61	\$124,737	\$15,939
<b>AVERAGE:</b>	<b>\$13.55</b>	<b>98,290</b>	<b>\$19.75</b>	<b>\$3.32</b>	<b>\$185,524</b>	<b>\$28,683</b>

<b>Insurers vs Hospitals</b>	<b>402%</b>	<b>74%</b>	<b>360%</b>	<b>178%</b>	<b>573%</b>	<b>307%</b>
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Source: RRY Publications LLC and Security Exchange Commission

ly isn't saying all that much. Executives in both groups are making millions in compensation each year.

Here is what the top executives pulled down at the insurers as compared to their counterparts at these large hospital chains. (See table 3 on page 7.)

On average, insurance executive compensation amounted to about 0.25% of the EBITDA of those companies

while hospital executive compensation amounted to about 0.23% of EBITDA.

**Rate Hikes Coming?**

Is the sky blue?

According to the most recent filings with state insurance commissioners, insurance companies are asking for rate hikes in 2016 that could be as high as 20-40% for certain types of

policies but will likely average around 5-6%.

Insurance company profits, in other words, are heading even higher.

U.S. Senate Majority Leader Mitch McConnell, of Kentucky, commenting on the proposed purchase of Humana (based in his home state) and Aetna, said: "This morning's announcement, as I predicted during the debate five years

ago, is the inevitable result of Obamacare's push toward consolidation as doctors, hospitals, and insurers merge in response to an ever-growing government."

Liberal economist, Robert Reich, kind of agreed saying: "The Supreme Court's recent blessing of Obamacare has precipitated a rush among the nation's biggest health insurers to consolidate into two or three behemoths. The big health insurers have money to make these acquisitions because their Medicare businesses have been growing and Obamacare is bringing in hundreds of thousands of new customers."

In effect, by gobbling up other payers, these insurance giants are buying customers and therefore hundreds of thousands of monthly payments. In fact,

the insurers look at each member as an annuity stream. Taken together, these new Obamacare, Medicare or Medicaid members add up to a Mississippi River of cash flow.

Deep, wide and flowing inexorably into the ever larger insurance company coffers.

### Bargaining Power and the Golden Rule

Aetna said the combined company is projected to have over 33 million medical members, based on memberships as of March 31. Operating revenue is expected to be about \$115 billion this year, with approximately 56% from government-sponsored programs including Medicare and Medicaid. One of Humana's most attractive attributes

is its comparatively high percentage of Medicare enrollees.

Combined, they would have market share of 88% in Kansas, 80% in West Virginia, 58% in Iowa and 51% in Missouri.

Aetna and Humana are also in the same nine states with Medicare Advantage products.

Most analysts agree the triggering event for this mega-merger was the Supreme Court's ruling in favor of continued subsidies for Obamacare. Subsidized health insurance for lower-income Americans essentially guarantees huge new markets for insurers.

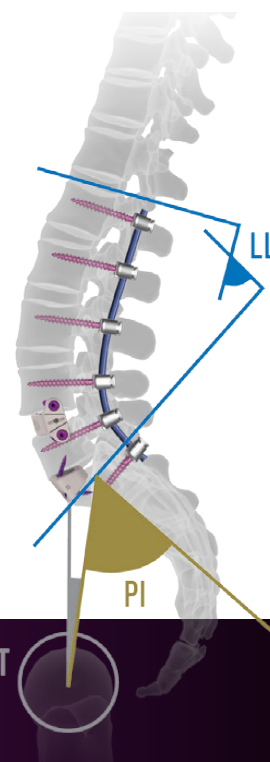
But not everyone is happy with this news. Insurance industry consultant

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EXECUTIVE COMPENSATION— INSURERS V. HOSPITAL CHAINS					
\$ in Millions: Includes Non-Cash Compensation	CEO	CFO	COO	SVP	SVP
Humana	\$6.38	\$1.26	\$34.12	\$1.66	\$1.67
Aetna	\$3.06	\$1.78	\$1.47	\$2.17	\$1.48
Anthem	\$3.53	\$8.41	\$1.50	\$2.54	\$1.84
Cigna	\$10.24	\$1.83	\$2.54	\$1.98	\$5.09
UnitedHealth Care	\$50.93	\$4.64		\$1.57	\$2.33
<b>AVERAGE</b>	<b>\$14.83</b>	<b>\$3.58</b>	<b>\$9.91</b>	<b>\$1.99</b>	<b>\$2.48</b>
HCA	\$5.27	\$1.52	\$29.39	\$10.12	\$5.43
Tenet	\$6.91	\$1.79	\$2.05	\$1.10	\$2.09
Community Health	\$12.68	\$3.18	\$3.25	\$1.87	\$2.29
LifePoint	\$5.92	\$5.15	\$1.92	\$1.41	\$2.18
<b>AVERAGE:</b>	<b>\$7.70</b>	<b>\$2.91</b>	<b>\$9.15</b>	<b>\$3.62</b>	<b>\$3.00</b>

Source: RRY Publications LLC and Security Exchange Commission

Robert Laszewski was quoted in news reports saying: “I think there’ll be huge opposition from the provider industry.”

And potentially at the state level too.

With, for example, an 88% market share in Kansas, that state would have very little bargaining power with a combined Aetna/Humana. The United States is a patchwork of state insurance regulations, insurance commissioners and legislative bodies.

As insurers consolidate (imagine if Anthem bought Aetna/Humana) the economic and political bargaining power with the states, the hospital chains and certainly the large, consolidated orthopedic companies like Synthes/DePuy, Zimmer/Biomet or Stryker can only grow.

Which brings us back to the golden rule.

### Employers Cutting Out the Insurance Middleman

If Wal-Mart were a country, it would be the 25th largest in the world. In terms of revenues, it is 4 times larger than UnitedHealthcare. It is 36% larger than all five of the largest healthcare insurers combined. In terms of employees, it is 13 times larger than the largest healthcare insurer—UnitedHealthcare. With 2.2 million employees, Wal-Mart has bargaining power.

And they’ve decided to start using it.

A couple years ago Wal-Mart, in collaboration with Home Depot, put in place a program that offered a hip or knee replacement surgery, plus transportation for the employee and one other person to and from the hospital, plus hotel rooms and food at no charge if they used one of

three designated hospitals for their surgery.

No Aetna, Anthem, Humana or United required.

Last year, Boeing and some of the hospitals in the Seattle/Puget Sound area teamed up to provide health-care services—also without the benefit of an health insurer in the middle. The mechanism Boeing used to make this happen is the new system of accountable care organizations, or ACOs.

Under this new program, Boeing negotiated its own healthcare service contracts with ACOs in the Puget Sound-area. Their employees started using these providers in 2015. The three ACOs were set up by University of Washington Hospitals, Providence Health and Swedish Heath Services.

When interviewed by the Seattle newspaper about this arrangement, Dr. Elliott Fisher, Director of the Dartmouth Institute for Health Policy and Clinical Practice said: “The advantage for Boeing will be that they can take the middle man out of the equation between the patients and the health system. It may be able to reduce cost, in part because of the simplification of not having the insurance mechanism in the middle.”

The gold, in other words, is with the employers and the largest ones—like Wal-Mart or Boeing—are starting to wake up to that fact.

For sure, the next year or two will bring BIG changes to our industry. By 2017, there may only be two or three health insurers in the United States—but, ironically, they may be insuring fewer and fewer employees. ♦

# Aesculap Enters Lumbar Disc Maelstrom

BY WALTER EISNER

**L**umbar replacement discs have become the crazy old uncle at spine family gatherings.

But that didn't stop Aesculap Implant Systems, LLC from submitting another PMA (pre-market approval) application to the FDA for its activL Artificial Disc for the treatment of one-level lumbar degenerative disc disease.

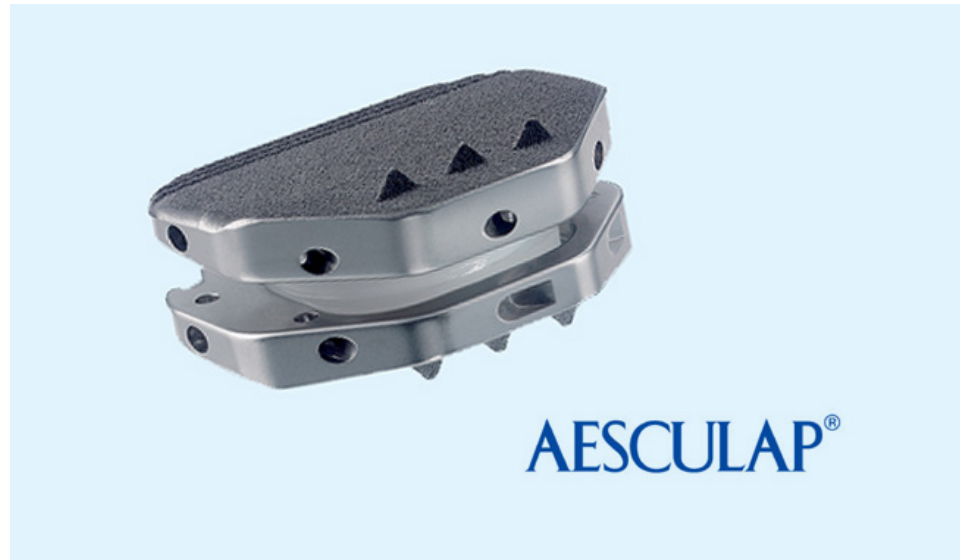
On June 15, 2015, the company announced that the FDA had approved it!

The disc, according to the company, features cobalt chromium endplates which affix to the patient's vertebrae with bone-sparing spikes for initial stabilization. "It is the first lumbar artificial disc with a mobile ultra high molecular weight polyethylene core that supports both controlled translational and rotational movement similar to the movement of the healthy lumbar spine. It offers the widest range of footprints and heights, including an 8.5 mm design, which is the lowest height construct available on the market."

## Lumbar Disc Saga

Lumbar discs weren't always looked at like the crazy uncle. After approving DePuy Spine's Charité disc in October 2004, the FDA followed up two years later by approving Synthes Spine's ProDisc. But payers never warmed up to the devices and when Charité left the market a couple of years ago, ProDisc was left all by itself.

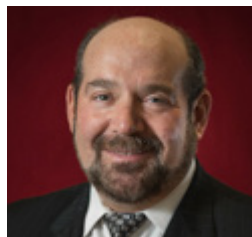
While lumbar discs faltered, the pace of approvals for cervical discs seemed to have accelerated in the last three



*activL Artificial Disc/Aesculap Implant System, LLC*

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 cervical discs has been spotty but Aetna, UnitedHealthcare and Cigna have now announced national coverage.



*Jack E. Zigler, M.D., F.A.C.S.*

Jack Zigler, M.D., Texas Back Institute's medical director, says lumbar arthroplasty has been the "neglected sister" in disc replacement technology.

## Rise of the Cervical Disc

Zigler told us that cervical total disc replacement gained broader acceptance

for a variety of reasons. "Foremost is that it is indicated for reconstruction following a decompression for nerve root or spinal cord compromise. Neurologic pathologies, appropriately diagnosed, that fail to respond to reasonable conservative care have traditionally been treated by surgery, usually by ACDF [anterior cervical discectomy and fusion]. Cervical arthroplasty, once it overcame its safety and early efficacy hurdles, has allowed the seven FDA-approved devices to be approved and reimbursed by the majority of U.S. insurers."

"Not so the case with lumbar arthroplasty," said Zigler.

He says the diagnosis of low-back pain has long been considered a "black box" by insurance companies "frustrated by a wide and ill-defined panoply of surgical indications, and by a mixed bag of results, often including extensive and expensive revision surgeries, leaving patients

with failed back surgery chronic pain syndromes.”

Despite the fact that the FDA studies did a “terrific job” of defining a specific patient population for whom one and two level lumbar arthroplasty (or fusion) would produce reproducibly good results among a broad swath of clinics and surgeons, “acceptance of lumbar arthroplasty as a reasonable surgical option has lagged far beyond that of its cervical cousin,” continued Zigler.

Insurance approval for lumbar arthroplasty has failed to gain traction, “despite long term data showing maintenance of dramatically improved outcomes at five years in both fusion and arthroplasty groups (although better in the ADR [artificial disc replacement] patients), and statistically significantly reduced adjacent level radiographic

degenerative changes above the ADR’s than above the fusions.”

In fact, says Zigler, it lost traction when Aetna, which covered lumbar arthroplasty as soon as the Charité disc was approved, “completely and unscientifically reversed its position after seven years of coverage, now deeming lumbar arthroplasty to be ‘investigational and experimental’ and currently refusing to cover it.”

“This is the maelstrom into which Aesculap enters and adds its level 1 database to that of the ProDisc-L,” added Zigler.

**activL Artificial Disc**

Aesculap says the activL demonstrated non-inferiority in overall trial success compared to conventional total disc

replacement designs (Charité and ProDisc-L) in the Investigational Device Exemption (IDE) trial. In the analysis of primary outcomes from the IDE trial, the disc was non-inferior to the control devices tested but also had a greater overall success rate (p < 0.0001). During their own respective IDE trials, the conventional discs were compared to fusion surgery.

**Indications**

According to the approval order, the device “is indicated for reconstruction of the disc at one level (L4-L5 or L5-S1) following single-level discectomy in skeletally mature patients with symptomatic degenerative disc disease (DDD) with no more than grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physi-

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cal examination, and radiographic studies. The activL artificial disc is implanted using an anterior retroperitoneal approach. Patients receiving the activL artificial disc should have failed at least six months of nonoperative treatment prior to implantation of the device. “

Zigler says “The activL is a somewhat less-semi-constrained disc than the ProDisc, allowing some translational movement of its UHMPE [ultra-high-molecular-weight polyethylene] core on its lower Co-Cr-Mb endplate. It uses a ball-and-socket articulation between the UHMPE and the upper metal endplate. Both metal endplates will be seated in bone with spikes instead of keels, and it offers a slightly lower profile in its smallest size than does ProDisc.”

According to Zigler, patients have done well on extended follow-ups at the TBI clinical site as well as at others.

**Zigler: “Reinvigorated Interest”**

“As a clinician deeply immersed in this technology since its inception, routinely seeing my own patients with 10+ year follow-up continuing to do well, without the problems of my long-term fusion patients, I welcome the entry of Aesculap to the lumbar arthroplasty marketplace. It is a good device with proven safety and efficacy, and it should help reinvigorate patient and surgeon interest in the technology.”

Unlike cervical arthroplasty, where every spine surgeon is familiar and comfortable with the surgical approach, Zigler points out that lumbar arthroplasty is done through an anterior retroperitoneal approach, and the majority of spine surgeons pair with an access surgeon (general or vascular), and “need to be very familiar with anterior lumbar spine surgery. Extensive experience

with ALIF surgery, developing good techniques working in the retroperitoneum and around the great vessels, ureter, and bowel, is highly recommended before surgeons should even consider lumbar arthroplasty training. Preparing and mobilizing the disc space requires a different mental and physical skill set than does fusion surgery.”

Rolando Garcia, M.D. of Aventura Medical Center in Florida, says the activL IDE Trial outcomes “add to the extensive body of evidence supporting the use of lumbar total disc replacement in risk stratified patients.” Garcia was an activL IDE Trial lead investigator who earlier this year co-authored the International Society for the Advancement of Spine Surgery’s position statement on lumbar total disc replacement. “Lumbar Total Disc Replacement is a well-tested technology which should predictably lead to better outcomes and



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less complications than fusion surgery. I am excited to be able to offer the activL technology to my patients.”

The company will be offering a formal training program to surgeons who want to be certified in implantation of the disc. “This demonstrates their commitment to proper patient selection and to good surgical technique, the two essential elements towards good outcome results. With the introduction of this first new lumbar disc replacement to the U.S. market in ten years, we are hoping that lumbar arthroplasty may become more available to patients who are appropriate candidates, and who do not want to have a fusion,” added Zigler.

### McAfee’s Doubts

Paul McAfee, M.D., told OTW that he didn’t think this study or approval “will have ANY impact on the care of patients with degenerative lumbar disc disease.”



Paul McAfee, M.D.

First, he says the individual patient differences (motivation, degree of underlying facet disease, disability, and employment factors) “are more important than the differences in type of lumbar disc prosthesis (fixed or mobile bearing, sizing, biomechanical factors, and biomaterials).” In other words, he says the variation in the patient’s indi-



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cations and selection criteria are more important determinants of long term outcome than the selection or brand of lumbar disc prosthesis.

Second, MacAfee notes this was a non-inferiority study. “The prior IDE FDA trials look great but the insurers and private payers are not approving the surgery.”

Third, he says the complications of failed anterior surgery when “Joe Average” surgeon attempts to reproduce the outcomes of the FDA trials have been substantial. “The repeat dissections anteriorly at L4-L5 are so difficult and specialized that primary lumbar disc replacement is not a viable option at the present time.”

Fourth, according to McAfee, the imaging needs to be MRI compatible, such

as PEEK-on-PEEK, especially for disk replacements in the cervical spine.

He concludes that the sponsors of this study “will be lucky to get their money out of it. No reimbursement means no volume. Regardless of the peer-reviewed outcomes and statistical results the payers have not been compelled to reimburse lumbar disc replacement, even with superior long term results with anterior lumbar interbody fusion as a comparative control group.”

### Waiting for the Payers

Whether or not Aesculap’s contribution to the scientific literature and the successful regulatory effort to bring another lumbar spine disc to market are in vain is too soon to know.

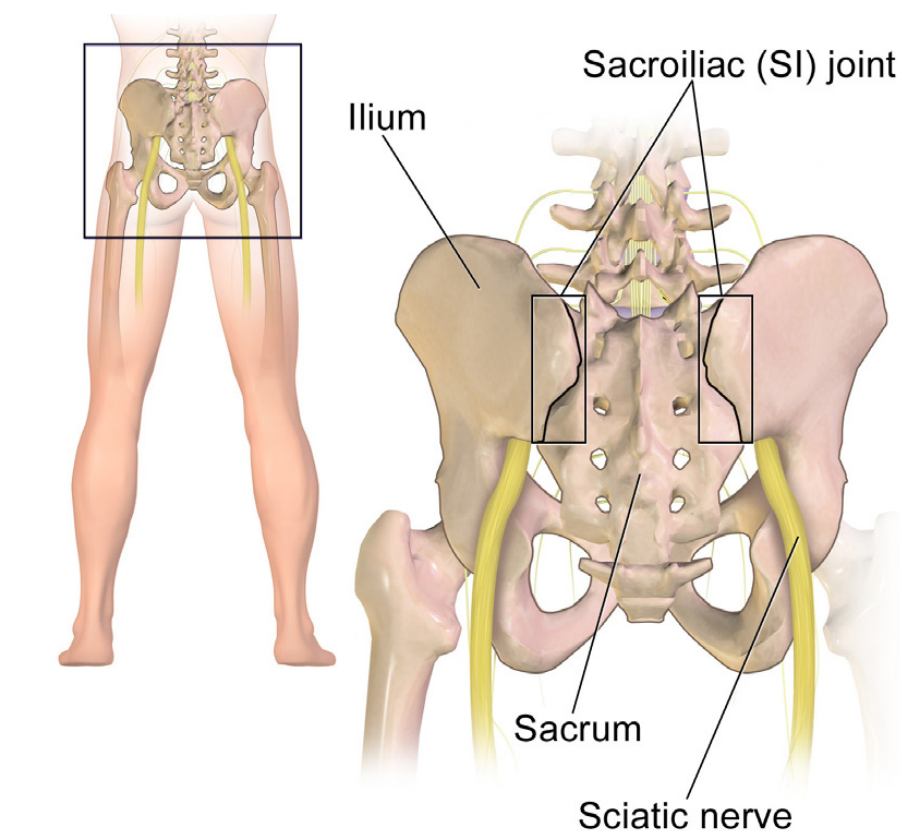
As usual, the payers will decide. ♦

# Three New Studies: CT Scans Uncover Widespread SI Joint Degeneration // Distressed Patients Mean Dissatisfaction With Surgeon // Delay of Primary ACL Reconstruction Linked to More Injury

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

**C**T Scans Uncover Widespread but Asymptomatic SI Joint Degeneration Sometimes you must return to the basics in order to go forward. Such was the thinking behind new research on sacroiliac (SI) joint degeneration from Stanford University and Bellevue Bone and Joint Physicians in Washington. Jonathan-James Eno, M.D., an orthopedic resident at Stanford, told OTW, “For our study, which was just published in *The Journal of Bone and Joint Surgery*, the goal was to establish a baseline prevalence of sacroiliac joint degeneration in the asymptomatic population. We undertook this topic because the prevalence of low back pain continues to be a huge burden on society, and the potential for the SI joint as a source of low back pain has led to a renewed interest in surgical or procedural intervention, including injections and fusions. Arthrodesis has made a comeback recently, in part, because of the introduction of more minimally invasive approaches.”

“Surgeons have traditionally relied heavily on radiographic findings of SI joint degeneration to implicate it as a source of pain. We wanted to evaluate how many asymptomatic patients had radiographic evidence of underlying SI joint pathology. A high prevalence of degenerative changes in the asymptomatic population would suggest that these changes are not necessarily indicative of a source of low back pain in each patient.”



**Sacroiliac Joint**

*Sacroiliac Joint/Source: Wikimedia Commons and Bruce Blausen*

“We reviewed 500 consecutive pelvic computed tomography (CT) scans of patients who had no history of pain in the lower back or pelvic girdle. We excluded individuals who were skeletally immature, had a history of spinal instrumentation, a history of low back, pelvic, or hip pain, a history neurological disease, and those who had undergone prior surgery; we were

left with 373 CT scans (746 sacroiliac joints).”

“The average age of patients was 57, and we had roughly 1:1 male to female ratio. Each CT was reviewed by the senior author and an orthopedic trauma fellow, then it was classified using our proposed novel classification system. The classification system ranges

from 0 (no degenerative changes) to 3 (complete ankylosis of the SI joint). We found that the overall prevalence of SI joint degeneration in at least one joint was 65%; there was significant SI joint degeneration (type 2/3) in almost 31% of the SI joints in our cohort.”

“The message is simply to be cautious when correlating radiographic findings with clinical symptoms. It may be tempting to attribute lower back or pelvic girdle pain to SI joint degeneration seen on a CT, but further investigation to confirm the source of pain may be warranted. Our study should not necessarily discourage our colleagues from operating on the SI joint; it should, as is the case with all of medicine, reinforce the need to correlate clinical presentation, radiographic findings, and confirmatory studies to ultimately determine the correct diagnosis and guide proper treatment.”

**Distressed Patients=Lower Satisfaction Scores**

Orthopedic surgeons are not psychologists. And yet, says data from a study recently published in *The Journal of Bone and Joint Surgery*, you might want to brush up on your listening skills. Amir Abtahi, M.D., chief orthopedic resident at the University of Utah, tells *OTW*, “At first glance the concept of patient satisfaction doesn’t seem like it would be overly complicated, but there has been some research that has shown that multiple factors are involved. My colleagues and I wanted to dig deeper in order to find out what factors are influencing this increasingly important quality metric. We decided to explore the influence of distress on patient satisfaction, and we used the Distress and Risk Assessment Method (DRAM) questionnaire, a tool which has been validated in spine patients.”

“We looked at outpatient clinical encounters at a single academic spine surgery center between February 2011 and January 2013. We had 103 patients in the study, all of whom completed both a patient satisfaction survey and a Distress and Risk Assessment Method (DRAM) questionnaire.

We know that distressed patients have poorer outcomes from orthopedic surgical interventions. What we were looking to determine was, ‘How does distress affect satisfaction with the patient’s provider?’”

“Of the 103 patients, 56 showed no evidence of distress, 22 were ‘at risk,’ 13 were ‘distressed depressive,’ and 12 were ‘distressed somatic.’ We found that distressed patients, in particular distressed somatic patients reported significantly lower patient satisfaction scores. (The mean overall patient satis-

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faction scores were 90.2 in the normal group, 94.7 in the at-risk group, 87.5 in the distressed-depressive group, and 75.7 in the distressed-somatic group. The mean score for the patients' satisfaction with their provider was 94.2 in the normal group, 94.2 in the at-risk group, 90.6 in the distressed-depressive group, and 74.9 in the distressed-somatic group.)”

“We know from a number of previous studies that distressed patients have worse orthopedic outcomes compared to non-distressed patients. This study draws attention to the fact that distressed patients may be more likely to perceive other aspects of their care in a more negative light—including their satisfaction with care. Given that doctors are being assessed on the basis of quality, perhaps we should be adjusting for distress and other patient factors when evaluating physician scores. This is already somewhat of an established concept for inpatient satisfaction surveys. Finally, this study highlights the importance of communication between patient and provider. We are beginning to understand the effect that distress has on various aspects on patient care. If a patient seems to be distressed, it is worth spending a little extra time with them—doing your best to communicate clearly and make sure that they feel heard.”

**Delaying ACL Reconstruction Can Cause Trouble in the Trochlea, Elsewhere** If you delay a primary anterior cruciate ligament (ACL) reconstruction,

will there be more secondary injuries at the time of surgery? And what kind of injuries will those be? Marc Tompkins, M.D., assistant professor of orthopedic surgery at the University of Minnesota, has answered some of those questions for his colleagues. Dr. Tompkins tells OTW, “There has long been a debate about the timing of ACL surgery. In the U.S. we have a high volume of these injuries; while most of our patients undergo surgery in the early post-injury phase, some wait until the symptoms are really bothering them or delay the surgery for other reasons. Having a primary ACL injury doesn't necessarily mean that you have to do surgery right away or at all. I discuss this with my patients, reviewing what kind of activities they want to do. Many of them decide to get to the OR sooner rather than later, but the decision to proceed is theirs.”

“My colleagues and I set out to see if patients whose ACL reconstruction was delayed were more likely to have a secondary intra-articular injury when compared with those who underwent reconstruction immediately following the injury. Our team also hoped to determine if patients who were more active (preinjury) or older were more likely to have a secondary injury when compared with those who were less active and younger.”

“Previous studies have found that there is a link between time of surgery and future injury. We attempted to take the previous information a step further and asked, ‘What about specific areas of the

knee like the patellofemoral compartment?’ It sees more stress when you don't have the anterior/post resistance of the ACL. You also lose rotational functioning of the ACL, so there may be an injury related to shearing in the medial or lateral compartments.”

Dr. Tompkins' work, a retrospective review on 1,434 patients who underwent primary ACLR at one institution between 2009 and 2013, was published recently in the *American Journal of Sports Medicine*. “When we looked at our data, we did find an association between time to surgery and increased incidence of injury in the trochlea, lateral femoral condyle, medial tibial plateau, and medial meniscus. Looking at it by pre-injury activity level together with time to surgery, the less active patients were most at risk for medial meniscal and trochlear injury, while the more active patients were most at risk for medial tibial plateau injury.”

“When the cartilage and meniscal injury occurred merits further study. We don't know for sure that the injuries didn't occur at the time of the ACL tear, but the fact that there is an association with time to surgery suggests that some of the injuries may have occurred after the ACL tear. It is possible that damage to the cartilage or meniscus can occur just with daily activities when the ACL is not functional. Or, there may have been people in each of the time to surgery groups who went back to playing cutting or pivoting sports between ACL injury and ACL surgery.” ♦



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## Two Aarons Square Off Over Cementless Fixation: Hofmann v. Rosenberg

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

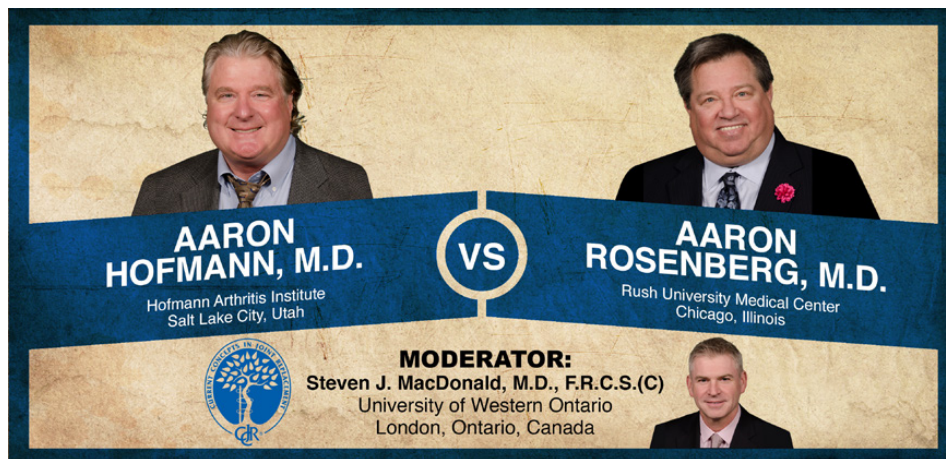
“Twenty-five years of implant retrieval has shown that we definitely have a solid attachment with cementless devices,” argues Aaron Hofmann. Aaron Rosenberg counters, “The literature and registries clearly show that it sometimes is just silly not to cement (patients with osteopenia, patients with significant bone defects, the elderly).”

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 “The Cementless Knee: Lifetime Guarantee on Parts and Labor.” For the proposition is Aaron Hofmann, M.D., of the Hofmann Arthritis Institute in Salt Lake City, Utah. Aaron Rosenberg, 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. Hofmann:** “Let’s talk about an implant that I first implanted in 1985: it was the first asymmetric tibia, has a deep trochlear groove, and has 3D titanium coating. Over one million have been implanted, but it’s less popular now; there were about 6,000 implanted last year.”

“Recently a new patient came to me and it turned out that she needed a poly exchange. She is 55 years old, but she had a cementless knee put in 27 years ago. I think the philosophy of it having to be equal or better than cement holds. The only problem is the cost.”

“I use something called cancellous structured titanium, a 3D porous coating. We learned a lot about this years



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ago while doing implant retrieval. One patient with rheumatoid arthritis had a cobalt-chrome implant on one side and a titanium on the other; the bone seemed to favor the titanium (even in this patient who was on methotrexate and prednisone).”

“We did a study comparing a titanium to a cobalt-chrome plug. You get attachment to both, but you get a deeper, more diffuse attachment if you’re using an implant made from titanium or trabecular metal. I’m still looking for the ideal implant.”

“From a technical standpoint, you have to replicate the normal slope. If you have a kinematic mismatch then the implant is going to be toggling around. And you can’t smoke your way through the bone.”

“The real problem has been on the tibial side. Take a case with a 1/8 slice of the proximal tibia...we know from our experimental work that it’s 78% space and only 24% bone. So this is the

real challenge. How do you get attachment to the proximal bone? We do that by increasing surface contact. We use a bone slurry that we call ‘biologic cement,’ and place it on the cut surfaces of the bone (primarily the tibia). There is science behind this showing that you get 72% initial contact with the implant versus 92% if you use the bone slurry. It’s biologically active, and with a double tetracycline labeling there was a 67% increase in biologic activity. And they can be removed if the porous coating is flush with the implant.”

“In one of our clinical series (Hofmann, Evanich, et al., *Clinical Orthopaedics and Related Research*), well, sometimes when you have a hammer everything looks like a nail. I was doing 89% cementless—way too much. But I was making a point that it can work in the young, the old, and in rheumatoid patients... and we had 98% survival of the metal parts (not the poly).”

“In another paper that shows the young, active patient (Hofmann, Evanich, et

al., *Clinical Orthopaedics and Related Research*), we had 75 patients who had an average age of 42. There was a minimum of nine years' of follow-up. We had 98% survival of the tibia and the femur (that's because there were two infections). This is the patient we should help with a cementless device."

"Twenty-five years of implant retrieval has shown that we definitely have a solid attachment. If we look at past, present, and future, I think that there have been very successful implants that we can learn from. But we are still looking for the perfect implant...but we need something that has a non-porous coated pegs and a stem-able tibial base plate. Give cementless devices a chance!"

**Dr. Rosenberg:** "First of all, the data pretty much shows that cementless fixation, being a biologic phenom-

enon, is subject to some increased variability compared to the mechanical fixation that is obtained with bone cement. An outstanding study by Ritter and Meneghini (*Journal of Arthroplasty*, 2010) included 73 cementless total knees and a minimum 10-year follow-up (with none lost to follow-up). They had 15 failures; 12 were metal-backed patellae and 2 of the tibias loosened at 1 and 2 years. The 20-year survivorship for aseptic loosening of any component was only 75%."

"A study by Park and Kim (*The Journal of Bone and Joint Surgery-British*, 2011) looked at simultaneously cemented and cementless total knees using the same components (one in a cemented fashion and one in an ingrowth fashion). There were 50 patients and multiple high level measurements (radiological results, etc.). Femoral survival was 100% in both at 14 years. Tibial sur-

vival with cement was 100%, whereas it was 98% with cementless."

"Fehring et al. (*Clinical Orthopaedics and Related Research*, 2001) looked at 440 revision total knees; 63% were revised within 5 years of the index arthroplasty (38% because of infection, 27% due to instability, and 8% because of patellofemoral problems, and 7% from wear or osteolysis). However, 13% were from ingrowth failure; only 3% were revised early for cemented implant loosening. They noted that if all arthroplasties in the early failure group were cemented routinely and balanced carefully, the total number of early revisions would have decreased by 40%, and overall failures would have been reduced by 25%."

"A 2003 study by Barrack et al. (*Journal of Arthroplasty*) looked at 82 cementless mobile bearing total knees

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and compared them to consecutive series of 76 cemented knees with the same indications, implant, technique, and follow-up. They found an 8% tibial revision rate for subsidence and failure of ingrowth with the cementless group...versus 0% in the cement group. The cementless group had lower Knee Society Scores and a higher percentage of pain > mild (23% versus 7%)."

"A 2013 study by Meneghini and de Beaubien (*Journal of Arthroplasty*, 2013) looked at the highly-touted tantalum monoblock tibial components; they had 106 consecutive tibias with a posterior stabilized design. There were nine failures at a mean of 18 months, with a medial tibial collapse noted...occurring predominantly in tall, heavy males. The mean height in the failed group was 73 inches versus 66 inches in the well-functioning group. And the mean weight was substantially higher in the failed group than in the well-functioning group (260 lbs. versus 204 lbs.)."

"The Swedish registry shows a higher percentage of uncemented patients that fail at the 100 component-year follow-up (about 40% higher). The UK registry (2011) reported the revision rate at 5 years was about 20% higher. The Australian registry showed that cementless fixation did worse at 100 observation-years; at 10-year follow-up the cumulative percent revision rate was substantially higher."

"As Aaron has mentioned, we can't use this type of fixation in all patients. Let's agree to respect each others' opinions... no matter how wrong yours may be."

**Moderator MacDonald:** "So comment on the registry data on cementless total knees."

**Dr. Hofmann:** "You're not cementing in a cementless device. So if you don't use that surgical technique and do something on the tibia...and the tibia is at risk to increase the surface contact and the biologic activity then you're going to be in that 10-15% loser range. I think it's very technique dependent."

**Moderator MacDonald:** "Obviously, the results and registries reflect some older designs—both cemented and cementless. We're in an era now of enhanced fixation and ingrowth. Is the future brighter for cementless?"

**Dr. Rosenberg:** "I think it is, but the problem is that we're stuck with biology. In some respects I prefer to be a carpenter rather than a biologist...in part because I don't always have the tools that I want. The next era will probably bring us some other biological modifications of the ingrowth surface with protein modifications and other bone-stimulating mechanisms that will help us consistently achieve bone ingrowth."

**Moderator MacDonald:** "What percent of your knees are cementless now?"

**Dr. Hofmann:** "I went from 89% to 8% cementless; it's a cost issue. If the implants cost \$1,000 more per part we know that's crazy because it only costs \$100/\$150 per part to coat them. If the manufacturers were offering something that would equal the cement and the cementing time—less than \$1,000—I bet everyone in this room would jump on the cementless bandwagon."

**Dr. Rosenberg:** "I think we can separate patients into two cohorts: one where it's silly not to cement (patients with osteopenia, patients with significant bone defects, the elderly). Then there are the patients in whom you have greater concerns about the long-term survival

of the implant. I think it's fair to say to the patient, 'This may offer you something that is biologic, and the interface will survive over a longer period of time than cement would.' But we don't have the data to support that."

**Moderator MacDonald:** "Is it sometimes an intraoperative decision? To help the audience, what should they be looking for?"

**Dr. Hofmann:** "I make the decision ahead of time. You can look at the X-rays and know that the bone quality is good enough. It's based on the age and activity level of the patient (individuals around 55 years old are great candidates). Otherwise, I'm cementing the majority of my patients."

**Moderator MacDonald:** "Like cemented knees there are going to be some design features that are critical to predictable success. What do you look for in a well designed tray?"

**Dr. Hofmann:** "It should have peripheral pegs of some sort—and a central stem. In patients with soft bone you can add a stem extension."

**Dr. Rosenberg:** "We know the principles that are required for ingrowth, namely, an appropriate mechanical environment and a minimization of micromotion while the ingrowth process occurs. The more rigidly you can initially get component fixation the greater the likelihood that it will withstand the micro stresses that occur during the rehabilitation period."

**Moderator MacDonald:** "Thank you, gentlemen." ♦

Please visit [www.CCJR.com](http://www.CCJR.com) to register for the 2015 CCJR Winter Meeting, December 9 - 12 in Orlando, Florida.

COMPANY

## Flower Orthopedics Receives CE Mark

The single-use bone fixation wizards at Flower Orthopedics are celebrating the acquisition of its CE mark approval. Makers of the FlowerCube, Flower Orthopedics is pleased that the European Union approval covers its entire product line—more than 400 implants.

“Receiving CE marking approval is a significant milestone for Flower Orthopedics. The market response to the FlowerCube concept, to our anatomic implants and to the single-use instruments in the United States has been extremely positive, and we are excited to bring this concept to the European market,” said company President and CEO Oliver Burckhardt in the July 2, 2015 news release. “We are committed to providing our customers in the United States and Europe cost-effective, safe and efficient Ready-for-Surgery treatment solutions that bring true quantifiable value into to the OR.”

The FlowerCube is ready to go once it hits the OR. The implants and instruments are sterile packaged and are single-use. According to the company, “The FlowerCube is delivered ready for use, eliminating set drop off and preoperative on-site sterilization.”

Burckhardt told OTW, “The CE marking approval is an important milestone for Flower Orthopedics, given the growing interest in Europe for our Ready-for-Surgery FlowerCube concept. Mirroring our U.S. experience, medical facilities overseas are looking for standardized bone fixation solutions that are immediately accessible with single-use, sterile implants and instruments that do not require costly and time consuming pre/post surgery processing. While we have been approached by a number of large EU [European Union] distributors over the years, we will take a very deliberate approach to finding the right distribution partners. We are confident that we can build a robust distribution network with strategic-minded partners who embrace our core belief of changing orthopedic bone fixation standards beginning in 2016.” — EH

## World’s Largest Contract Spine Instrument Company Created

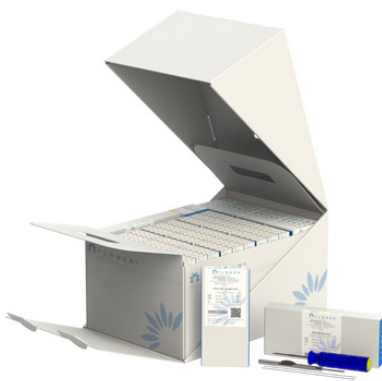
InTech Medical, Inc., a company founded in France in 2000, has acquired Turner Medical, Inc., of Athens, Alabama, making the combined firm the world’s largest provider of surgical instruments to the spine industry and a world leader in orthopedic contract manufacturing.



Courtesy of InTech Medical, Inc.

“InTech Medical is the number one contract-manufacturer in Europe, with a significant U.S. presence. The acquisition of Turner Medical further improves InTech Medical’s manufacturing expertise, expands its U.S. business, its global capacity, and adds the manufacturing of orthopedic implants to its core business.”

“InTech Medical’s demonstrated leadership in contract manufacturing and proprietary orthopedic instrument design is greatly enhanced with the addition of Turner Medical,” said Laurent Pruvost, President of InTech Medical SAS. “What I most value is the unique talent that Turner Medical has developed over the past 35 years. The management’s know-how, combined with that of InTech Medical’s, turns the group into a creative engineering and



Flower Orthopedics

problem solving powerhouse; a serious asset for our clients and a tangible competitive advantage.”

“At Turner Medical, we are all about customer satisfaction and family values,” said company President Bill Turner. “The company was founded by my father John Turner in 1985. We took it from a local machine shop to a nationally-recognized organization with the highest quality standards, latest technologies, and most efficient processes. Merging with In’Tech Medical allows Turner Medical to further develop and provide the services that are most beneficial to our clients, both in the U.S. and internationally.”

According to the press release, In’Tech Medical’s 2015 consolidated sales forecast is \$65 million, to be produced equally between Europe and the United States. The firm has close to 500 employees globally. —BY

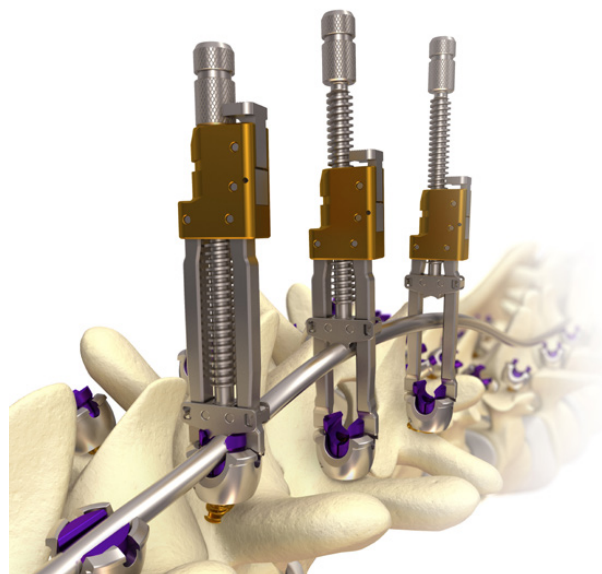
## New K2M Deformity System Cuts Surgical Steps in Half

After receiving FDA 510(k) clearance in January, K2M Group Holdings, Inc. has now launched its next generation pedicle screw system—the MESA 2 Deformity Spinal System.

### Cutting Surgical Steps in Half

A July 2, 2015 announcement by company President and CEO Eric Major states the MESA 2 offers “new capabilities” to the underlying MESA technology and is designed to save time by cutting the number of basic surgical steps in half.

“MESA 2 is the much-anticipated upgrade to our flagship MESA platform. We take great pride in being viewed by the surgeon community as a company that is focused on innovation and differentiation, and we remain committed to developing products that



MESA 2 Deformity Spinal System/K2M Group Holdings, Inc.

will help improve the lives of patients suffering from the most complicated spinal pathologies.”

### System Features

The system “features the next-generation MESA 2 screw, a top-loading, low-profile screw that offers a dual-lead thread pattern for fast insertion.” The MESA technology, according to the company, also features “Zero-Torque” Technology, which gives “surgeons the ability to one-step lock without torsional stress being applied to the spine. Both deformity polyaxial and uniplanar screws are available in this new system.”

The company also says the system features a variety of “easy-to-use reduction and spinal manipulation instruments.” This includes the Quicket, “an updated, quicker version” of the company’s “Cricket rod reduction technology that

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provides quick on/off capabilities, while correcting the spine in all three planes. Additionally, the company says the Over Quicket Final Locker “allows for one-step locking over the Quicket, thus eliminating the need to partial lock.”

The Cricket rod reduction technology received the 2010 *Orthopedics This Week* best new technology award.

To date, nearly 70 surgical cases using MESA 2 have been completed.

Laurel Blakemore, M.D., chief and associate professor of pediatric orthopedics in the department of orthopaedics at the University of Florida, said, “MESA 2 includes enhancements to the original MESA technology and instrumentation. This new system is yet another example of K2M’s pioneering efforts to design innovative solutions for correcting spinal deformities.” —WE

directly at shaking up health care innovation and setting a new standard for data transparency,” said Slavitt. “We expect a stream of new tools for beneficiaries and care providers that improve care and personalize decision-making.”

Starting in September 2015, businesses and product developers will be able to access data through the CMS Virtual Research Data Center (VRDC) which, says the agency, “provides access to granular CMS program data, including Medicare fee-for-service claims data, in an efficient and cost effective manner. Researchers working in the CMS VRDC have direct access to approved privacy-protected data files and are able to conduct their analysis within a secure CMS environment.”

#### Commercial Prohibition Lifted

CMS has historically prohibited researchers from accessing detailed CMS data if they intended to use the data to develop products and make money. “However,” said Niall Brennan, CMS chief data officer and director of the Office of Enterprise and Data Analytics, “as the delivery system transforms from rewarding volume to value, data will play a key role. We hope that this new policy will lead to additional innovation and insights from the CMS data.”

This is the third consecutive year the agency has released hospital-specific data on inpatient and outpatient charges, Medicare payments, and utilization for common Medicare procedures. The agency has also released similar data on physicians and suppliers.

#### September 2015 Kick-Off

However, an article in the *National Law Review* said it “remains unclear” what commercial pur-

poses will be permissible and who CMS considers to be the “innovators and entrepreneurs.” CMS will release additional information about the policy in September 2015, and will begin to accept research requests at that time.

#### Predictive Modeling Tools

Some of the tools or products that innovators and entrepreneurs might develop, according to the agency, “include care management or predictive modeling tools, which could greatly benefit the healthcare system, in the form of healthier people, better quality, or lower cost of care. Even though all data is privacy-protected, researchers also will not be allowed to remove patient-level data from the VRDC. They will only be able to download aggregated, privacy-protected reports and results to their own personal workstation.”

Because technology advancement has allowed the agency to make current data available without higher data costs, researchers will also be allowed to request data on a quarterly basis rather than the annual updates that were available in the past. The agency hopes this change will allow researchers to conduct more rapid analysis of the delivery system. — WE

### LEGAL

## CMS to Offer Data to Entrepreneurs and Innovators

For the first time, ever, CMS (Centers for Medicare and Medicaid Services) is going to let “innovators and entrepreneurs” access detailed CMS data for “commercial purposes” to develop new products.

CMS Acting Administrator Andy Slavitt made the announcement at the recently completed Health Datapalooza meeting.

#### New Tools to Improve Care

“Data is the essential ingredient to building a better, smarter, healthier system. Today’s announcement is aimed



Logo courtesy of CMS

**BIOLOGICS**

## Predicting Which RA Patients Won't Respond to Biologic Drugs

Researchers from the UK have found a way to predict which rheumatoid arthritis (RA) patients will not respond to biologic drugs. The team, from the University of Manchester, was led by Dr. Meghna Jani of the Centre for Musculoskeletal Research.

According to the July 3, 2015 news release, "In order to detect the antibodies and to measure the drug levels in the bloodstream, previously it was thought that the testing to detect the anti-drug antibodies and measure drug levels in the bloodstream, would only be helpful if performed immediately before the next dose of drug was due, when the drug levels are at their lowest in the body. This approach can be difficult to arrange in a clinical setting, as patients take the drugs on different days and at different times."

"There were 311 patients included in the study, who provided blood samples for testing at three, six and 12 months after starting two different types of biologic drugs, adalimumab. The research



Wikimedia Commons and Bernd Bragelmann Braegel Mit freundlicher Genehmigung von Dr. Martin Steinhoff

revealed that a total of 25% of patients on adalimumab developed antibodies, but none were found in the patients using etanercept."

"The researchers also found that higher doses of methotrexate, a drug often given together with the biologic treatment, was associated with lower levels of drug antibodies, suggesting that patients should be encouraged to continue methotrexate at the highest dose they can tolerate, to reduce the risk of developing anti-drug antibodies."

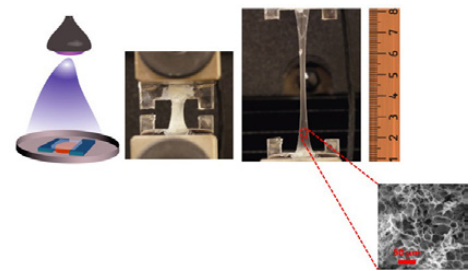
Professor Anne Barton, a consultant rheumatologist at Central Manchester University Hospitals NHS Foundation Trust and Director of the Centre for Musculoskeletal Research at The University of Manchester explained: "The next step will be to explore whether it is cost-effective to use these tests routinely in clinical practice, so that we can adjust treatments in those patients with low drug levels and anti-drug antibodies."

Dr. Jani told *OTW*, "We found even random adalimumab drug levels can provide valuable predictive information as early as three months, on future response to treatment at 12 months. The factors strongly associated with low drug levels were drug antibody formation, a high body mass index and whether or not the patient took the drug as advised (adherence)."

"Our eventual aim as rheumatologists is to get the treatment right the first time in our rheumatoid arthritis patients. If we can use these markers to predict early which patients will fail biologic treatment, we could facilitate a shift to more effective alternative therapy sooner. By doing so, we may prevent long-term joint damage that leads to disability, however this needs to be tested over a longer-term studies in the future." — *EH*

## Protein-Based Gel Advances Wound Healing

Shining a light on healing...Ali Khademhosseini, Ph.D., and Nasim Annabi, Ph.D. of the Biomedical Engineering Division of Brigham and Women's Hospital (BWH) have led a team that has created a new protein-based gel for healing. When you expose the gel to light, say the researchers, it behaves like elastic tissue.



*Brigham and Women's Hospital*

"We are very interested in engineering strong, elastic materials from proteins because so many of the tissues within the human body are elastic. If we want to use biomaterials to regenerate those tissues, we need elasticity and flexibility," said Dr. Annabi, a co-senior author of the study, in the July 2, 2015 news release. "Our hydrogel is very flexible, made from a biocompatible polypeptide and can be activated using light."

As indicated in the news release, "The new material, known as a photocross-linkable elastin-like polypeptide-based (ELP) hydrogel, offers several benefits. This elastic hydrogel is formed by using a light-activated polypeptide. When exposed to light, strong bonds form between the molecules of the gel, providing mechanical stability without the need for any chemical modifiers to be added to the material. The team reports that ELP hydrogel can be digested overtime by naturally-occur-

ring enzymes and does not appear to have toxic effects when tested with living cells in the lab. The team also found that they could control how much the material swelled as well its strength, finding that the ELP hydrogel could withstand more stretching than experienced by arterial tissue in the body. The researchers found that it was possible to combine the gel with silica nanoparticles—microscopic particles previously found to stop bleeding—to develop an even more powerful barrier to promote wound healing.”

“Our hydrogel has many applications: it could be used as a scaffold to grow cells or it can be incorporated with cells in a dish and then injected to stimulate tissue growth,” said Dr. Annabi. “In addition, the material can be used as a sealant, sticking to the tissue at the site of injury and creating a barrier over a wound.”

Dr. Khademhosseini told *OTW*, “For many regenerative engineering applications, it is important to have biomaterials with desired mechanical properties that induce tissue regeneration and healing. These gels offer a potentially useful material particularly for tissues that require vascularization and soft tissue regeneration/mineralization.”

“We aim to move forward by pushing specific medical applications that require tissue regeneration combined with specific mechanical features.”

The BWH team worked with the laboratory of Bradley Olsen, Ph.D. at the Massachusetts Institute of Technology. Also contributing to this work were: Yi-Nan Zhang, Reginald K. Avery, Queralt Vallmajo-Martin, Alexander Assmann, Andrea Vegh and Adnan Memic. — *EH*

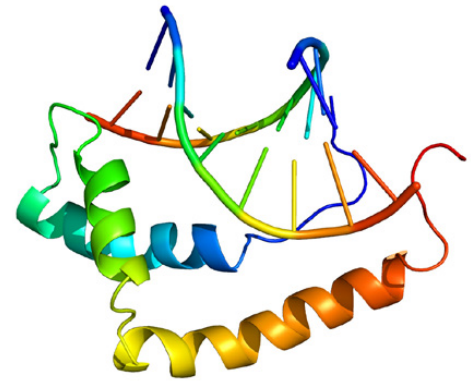
## Found! Regulatory “Blueprint” for Chondrocytes

New research has revealed the role of a protein called Sox9 in regulating cartilage production. University of Southern California (USC) stem cell researcher Xinjun He and University of Tokyo researcher Shinsuke Ohba were two members of the research team.

“Our paper is a blueprint of how the cartilage-producing cell, called a chondrocyte, is made and maintained by Sox9,” said Xinjun He, in the July 2, 2015 news release. He is a postdoctoral research associate in the lab of Andy McMahon, Ph.D., director of the Eli and Edythe Broad Center for Regenerative Medicine and Stem Cell Research at USC.

According to the news release, “The researchers found that Sox9 can bind to the DNA of cells in different ways. In some cases, Sox9 proteins form pairs that bind directly to the DNA in the presence of molecular modifiers. When this particular type of Sox9 binding occurs at multiple sites along the DNA, it turns on the genes that make the cells into chondrocytes. In this type of binding, Sox9 and the DNA don’t fit together perfectly. The researchers hypothesize that the sub-optimal fit could be a way of controlling the amount of proteins that genes make in chondrocytes, and therefore the amount of cartilage, produced by the body.”

“Sox9 is essential to normal skeletal development throughout the body,” said McMahon, one of the corresponding authors on the study. “When people have a Sox9 mutation, they can suffer from a devastating condition of bent bones and respiratory failure called



Wikimedia Commons and Pleiotrope

campomelic dysplasia. Our study advances our knowledge of Sox9’s role in causing this terrible disease—and brings us one step closer to understanding how to potentially treat it.”

Dr. McMahon told *OTW*, “It was most surprising to see the two different modes of Sox9 regulation—direct enhancer mediated and indirect through association with the general transcriptional machinery—and the extensive network of Sox9-bound enhancers around get cartilage genes. These can extend for hundreds of thousands of bases from that target gene.”

Asked about his message to orthopedic surgeons, Dr. McMahon noted, “Given the central role of Sox9 in determining chondrocytes, this data provides a regulatory blueprint for this key cell type. It sets a standard for assessing chondrocytes for repair studies and provides a list of novel targets for better understanding the functioning of cartilage generating cells.”

Regarding related future work, he stated, “I will leave this to the excellent fellows who pioneered these studies in my laboratory, Drs. Ohba and He. There are so many interesting avenues to explore as they embark or continue their independent careers.” — *EH*

LARGE JOINTS

## Gold Knee Implant, Literally

From the press in India comes a report of a 59-year-old woman who received a new knee implant completely coated in several layers of gold.

The patient was Anjali Kore, who was experiencing what she reported as unbearable pain when she tried to walk. Her surgeon, Amit Tyagi, M.D., with the Atlanta hospital at Vasundhara in Ghaziabad briefed her about the gold knee and its advantages. This convinced her to undergo the knee surgery using the gold coated knee implant.

“I was not just briefed about the gold knee by the doctor but also told about the poor quality of various other transplants and the side-effects,” Kore said “So, I got the most effective gold knee implant done. I feel much better and can walk around without support and pain.”



Photo creation by RRY Publications, LLC

“Gold knee is one of the best implants available these days and is the most successful too. It not only increases the life of the implant but also prevents any allergic reactions,” said Tyagi. “Gold knee implants have unmatched hardness. It can withstand corrosive environment stress and strain that all artificial knees are exposed to in the human body.”

The news article indicated that the implant was covered with seven layers of gold. It did not report the company that manufactures the gold implant or its cost.

In 2009, in the *Journal of Biomedical Material Research*, authors Zainali, et al. published the results of an animal study where gold coated implants were compared with un-coated implants. The study is available here: <http://www.ncbi.nlm.nih.gov/pubmed/18335533>

The authors wrote in their abstract: “Bio-mechanical push-out tests showed that implants with gold coating had approximately 50% decrease in mechanical strength and stiffness. Histomorphometrical analyses showed gold-coated implants had a decrease in overall total bone-to-implant contact of 35%. Autometallographic analysis revealed few cells loaded with gold close to the gilded implant surface. The findings demonstrate that gilding of implants negatively affects mechanical strength and osseointegration because of a significant effect of the released gold ions on the local inflammatory process around the implant. The possibility that a partial metallic gold coating could prolong the period of satisfactory mechanical strength, however, cannot be excluded.” — BY

EXTREMITIES

## Type 2 Diabetes Risk Factor for Osteoarthritis

Patients who have Type 2 diabetes are more likely to suffer from severe osteoarthritis than are those who are not diabetic. That is the result of a major study reported in *Diabetes Care*. Researchers found that having Type 2 diabetes can double one’s risk of developing severe osteoarthritis to a degree sufficiently advanced to call for joint replacement surgery.



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“The researchers reviewed the medical records of over 900 non-diabetic and diabetic patients for over a period of more than 20 years. The participants were examined every five years and the study outcome was focused on joint replacement surgery.” There were 69 diabetic patients and 858 non-diabetic patients. In the diabetic group there were 13 people, who needed either hip or knee replacement due to severe osteoarthritis and 73 subjects in the non-diabetic group.

In the non-diabetic group only 5.3% eventually needed total joint replacement, while in the diabetic group, it was 17.7%—more than three times greater. The researchers also took into account “risk factors such as body mass index and age, and when they did, they found that those who suffered from Type 2 diabetes were more likely to need joint replacement surgery than those who did not suffer from the condition.”

Georg Schett, M.D. of the University of Erlangen-Nuremberg and chief of rheumatology and director of the Department of Internal Medicine, noted that the study demonstrated that diabetes, body mass index and age were the strong and independent risk factors for joint failure.

He noted that it appears that “high cholesterol and obesity are risk factors for osteoarthritis. People,” he said, “can significantly increase their protection from symptomatic joint disease if they are able to effectively manage their metabolic syndrome.” — BY

## Clearasil for Shoulder Surgery?

What do pimply, embarrassed teenagers have in common with those undergoing shoulder surgery? They can both benefit from the active ingredient in Clearasil, says a new paper to be published in *The Journal of Shoulder and Elbow Surgery*. Researchers from Yale University have found that topical benzoyl peroxide (BPO), with chlorhexidine skin preparation can reduce *P. acnes* on patients’ skin and perhaps lower the risk of postoperative infection.

“The setbacks and costs associated with infection after shoulder surgery

are significant,” said senior author Paul M. Sethi, M.D., Clinical Instructor of Orthopedic Surgery Yale University School of Medicine, in the June 30, 2015 news release. “Our first study identified the patients’ skin as the source of bacteria that may cause infection and highlighted the limitations of current skin surgical preparation. Our team used established dermatologic principles to improve the way we clean the skin. Dermatologists have used BPO to treat *P. acnes* on our face for 50 years. We chose to study this same medicine on the shoulder and the findings are very exciting. Data demonstrates that we can significantly reduce potentially dangerous bacteria after skin treatment with BPO. By reducing these bacteria, we hope to reduce the risk for shoulder infection following surgery.”

Dr. Sethi told *OTW*, “*P. acnes* is one of the most significant pathogens in shoulder surgery; the cost of a single infection after shoulder arthroplasty may be upwards of \$50,000. We have been working to define evidence based methods to reduce the risk of infection

to improve the outcome and value of shoulder surgery.”

“Based on our predicate study, we found that current skin preparations leave residual bacteria on the skin 15% of the time at the beginning of a surgical procedure, and up to 66% of the time by the end of surgery in men. These high rates of residual bacteria, which may be one of the causes of post operative infection, encouraged us to identify enhanced methods of surgical skin preparation.”

As for future research, Dr. Sethi noted, “We plan on a multi-center longitudinal study to determine if this new skin preparation will reduce the actual rate of infection in shoulder arthroplasty across a broad group of patients. This is very exciting as this is a simple, safe and inexpensive way to reduce post operative infection, a potentially devastating problem.”

This research comes out of the Oncology Nursing Society Foundation for Research in Education. — EH



Courtesy of Clearasil and Pixabay

SPORTS MEDICINE

## Those With “Female Athlete Triad” More at Risk for Bone Stress, Fractures

New research from Brigham and Women’s Hospital has found that women who have symptoms known as the “female athlete triad” are more likely to develop bone stress injuries and fractures. The study, published in the *Journal of the American Academy of Orthopaedic Surgeons (JAAOS)*, found that the risk of these injuries increases with each symptom.

“The female athlete triad is a spectrum of symptoms that include low energy availability, menstrual cycle abnormalities, and low bone mineral density. Low energy availability can mean taking in inadequate calories or expending more energy than the body is designed to do. It can result from poor nutrition or eating habits or any type of eating disorder.



Pixabay

der. Any combination of these conditions can lead to premature bone loss in females,” explains lead study author and orthopedic surgeon Elizabeth Matzkin, M.D., in the July 1, 2015 news release.

According to the news release, “The increase is substantial: 15-21% with one symptom; 21-30% with two symptoms; and 29-50% with all three symptoms. The study authors also found that female athletes diagnosed with poor nutrition or low energy availability are two to four times more likely to sustain a sports-related injury. Female athletes who self-reported menstrual cycle abnormalities had a nearly three times greater risk of a bone and joint injury.”

Dr. Matzkin, surgical director of Women’s Musculoskeletal Health at Brigham and Women’s Hospital, told OTW, “There is a significant lack of education regarding the female athlete triad and the potential consequences among health care providers, coaches and athletes. The true prevalence of the female athlete triad is unknown. A full 90% of peak bone mass is accrued by the age of 18 and usually completed by the age of 25. After this, peak bone mass can only be lost or maintained. Thus, it is paramount that our younger athletes maximize their bone density when they can.”

“We are currently working on trying to understand the true prevalence of the female athlete triad. We do know that a relative energy deficiency can result in bone density problems. Any female athlete that presents to the orthopedic surgeon with a stress fracture or stress reaction should be questioned about her nutrition/energy availability for exercise and menstrual cycle. This is important to prevent further bone loss and address any underlying problems contributing to the bone injury in the first place.” — EH

SPINE

## NASS Seeks Low-Back Pain Guideline Feedback

The North American Spine Society (NASS) wants to know what you think about the diagnosis and treatment of low-back pain.



Morguefile

The organization’s Low-Back Pain Guideline Work Group has drafted a list of clinical questions to be addressed in an evidence-based clinical practice guideline. The guideline addresses seven sections, including:

- Diagnosis
- Imaging
- Medical & Psychological Treatment
- Rehabilitation & Exercise
- Interventional Treatment
- Surgical Treatment and
- Cost-Effectiveness

### Questions

Here is an example of the kinds of questions you’ll find from the Diagnosis Work Group:

1. In patients with acute or chronic low-back pain, are there specific history or physical examination findings that would indicate the structure causing pain and, therefore, guide treatment?
  - a. Vertebral body
  - b. Intervertebral disc

- c. Zygapophyseal joint
  - d. Posterior elements
  - e. Sacroiliac joint
  - f. Muscle/tendon
2. In patients with acute or chronic low-back pain, are there history or physical examination findings that would serve as predictors for the recurrence of low-back pain?
  3. In patients with acute low-back pain, are there history or physical examination findings that would predict that an episode will resolve within one month?

To view the draft list of clinical questions, click here: <https://www.spine.org/Portals/0/Documents/ResearchClinical-Care/Guidelines/NASSLBPGuideline-DraftClinicalQuestionProtocol.pdf>

The list is available for public comment until July 14, 2015.

### Feedback Instructions

NASS says reviewers are requested to provide feedback on the proposed questions and suggest any additional questions that may be missing that are important to low-back pain patients and their providers. Comments

should be submitted to [guidelines@spine.org](mailto:guidelines@spine.org).

All submissions will be reviewed and considered for potential inclusion in the clinical question protocol before a systematic literature search and review is conducted. — WE

The screenshot shows the NASS (North American Spine Society) website. The top navigation bar includes links for WHO WE ARE, MEMBERSHIP, EDUCATION, PUBLICATIONS, POLICY & PRACTICE, RESEARCH & CLINICAL CARE (highlighted), and ADVOCACY. A search bar and a 'MY ACCOUNT' link are also visible. Below the navigation bar, a dark banner reads 'Notice of Public Comment Period: Draft Clinical Questions for Low-Back Pain Guideline'. The main content area has a date 'June 16-July 14, 2015' and a paragraph stating: 'The NASS Low-Back Pain Guideline Work Group recently drafted a list of clinical questions to be addressed in an evidence-based clinical practice guideline on the diagnosis and treatment of low-back pain. The guideline on low-back pain will address 7 sections, including: Diagnosis, Imaging, Medical & Psychological Treatment, Rehabilitation & Exercise, Interventional Treatment, Surgical Treatment and Cost-Effectiveness.' Below this, another paragraph states: 'The clinical question list is available for public comment from June 16, 2015 to 11:59PM CST, July 14, 2015. Reviewers are requested to provide feedback on the proposed questions and suggest any additional questions that may be missing that are important to low-back pain patients and their providers. Comments should be submitted to [guidelines@spine.org](mailto:guidelines@spine.org). If applicable, please include your organizational affiliation in the response.' The NASS logo is in the top left corner.

North American Spine Society

The advertisement features a dark blue background with a stylized, colorful, geometric illustration of a human spine. On the left, a yellow box contains the text 'DISCOVER MORE'. On the right, the text '2015 SPINE TECHNOLOGY AWARDS' is written in large, bold, blue letters. Below this, a yellow downward-pointing triangle is positioned above the text 'SUBMISSIONS DEADLINE: AUGUST 14, 2015' and 'AWARDS TO BE PRESENTED: OCTOBER 14-15, 2015'.

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