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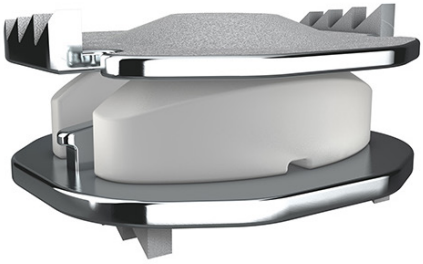
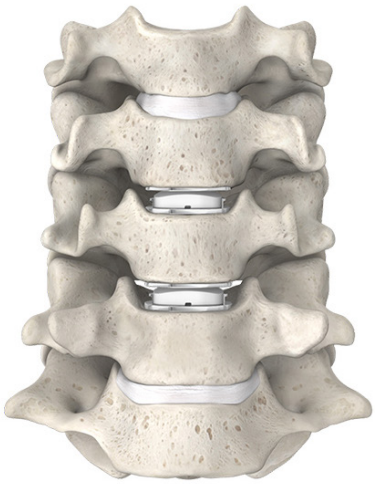
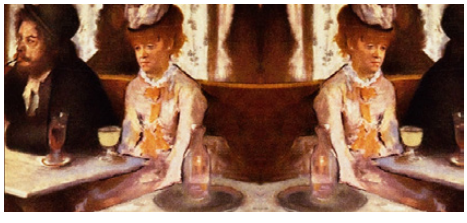
Orthopedics This Week

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: Let's get real. The stock market isn't patients coming in the door. It's not orders for implants or instruments. It's not patients walking, literally, out the clinic door. Stock prices are bobble-head dolls for stat geeks. Orthopedics, by contrast, is stable, rising and routinely profitable. So, channel your inner Warren Buffet and check out the bargains.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Integra LifeSciences	13.74%	2.15%	This week is JP Morgan's annual Healthcare conference in SF. IART will likely add to its fan base this week.
2	3	Zimmer Biomet	31.22	1.58	Positive comments from some of the top analysts brought new buyers into ZBH. It's about rising margins as integration nears completion.
3	2	Stryker	22.94	(5.42)	Major institutional investors appear to be lumping SYK in with MDT and JNJ and selling as a kind of bet on the overall market.
4	6	Smith & Nephew	19.66	1.97	Lot of movement in 2015, but no progress. SNN rose just 1% for all of the year. But 2016, if earnings show any decent growth, could be different.
5	7	NuVasive	13.35	3.79	Ellipse is a great addition. Price was high, but worth it. Adds transformative technology for pediatric scoliosis to NUVA.
6	4	ConMed	11.10	(1.87)	SurgiQuest deal is done. Now comes the hard work. JP Morgan is opportunity to expand on SurgiQuest integration.
7	8	Globus Medical	30.19	(4.10)	Analysts are raising their outlook for GMED's earnings. Globus is becoming more than a spine company. Or an earnings machine.
8	5	Medtronic	27.92	(4.73)	How irrational can Wall Street be? Selling either MDT or JNJ off because oil prices are down or China is cratering is Exhibit A.
9	10	Exactech	10.26	7.76	Which public orthopedic company benefits the most from shelving the device tax? It could well be Exactech—and investors appear to agree.
10	9	Johnson & Johnson	26.73	(4.36)	JNJ, with a ridiculously attractive 3.00% dividend yield, sells off along with the broader Dow Jones average.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Alphatec Holdings	ATEC	$0.31	$31	31.36%
2	MicroPort Scientific	853	$0.49	$700	29.37%
3	TiGenix	TIG.BR	$1.20	$212	17.17%
4	Exactech	EXAC	$18.33	$258	7.44%
5	NuVasive	NUVA	$52.53	$2,579	5.04%
6	Integra LifeSciences	IART	$65.67	$2,429	2.24%
7	Zimmer Biomet	ZBH	$101.55	$20,694	1.77%
8	Smith & Nephew	SNN	$33.59	$15,057	1.70%
9	Aurora Spine	ASG	$0.16	$3	1.33%
10	MiMedx Group	MDXG	$8.55	$932	0.71%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	K2M Group Hldgs	KTWO	$18.31	$755	-9.36%
2	LDR Holding Corp	LDRH	$23.46	$681	-8.00%
3	Xtant Medical Hldgs	XTNT	$2.80	$33	-6.67%
4	RTI Biologics Inc	RTIX	$3.59	$207	-6.51%
5	SeaSpine Hldgs Corp	SPNE	$15.10	$168	-5.68%
6	CryoLife	CRY	$9.86	$281	-5.19%
7	Wright Med Grp N.V	WMGI	$21.72	$2,230	-4.74%
8	Stryker	SYK	$87.89	$33,005	-4.41%
9	Medtronic	MDT	$73.78	$103,746	-4.40%
10	Johnson & Johnson	JNJ	$98.16	$271,603	-3.91%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Exactech	EXAC	$18.33	$258	16.47
2	Johnson & Johnson	JNJ	$98.16	$271,603	17.11
3	RTI Biologics Inc	RTIX	$3.59	$207	18.17
4	Stryker	SYK	$87.89	$33,005	19.08
5	Globus Medical	GMED	$25.47	$2,425	19.65

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	CryoLife	CRY	$9.86	$281	64.70
2	NuVasive	NUVA	$52.53	$2,579	60.30
3	MiMedx Group	MDXG	$8.55	$932	47.50
4	Smith & Nephew	SNN	$33.59	$15,057	30.05
5	Integra LifeSciences	IART	$65.67	$2,429	28.87

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	RTI Biologics Inc	RTIX	$3.59	$207	1.21
2	Globus Medical	GMED	$25.47	$2,425	1.53
3	Exactech	EXAC	$18.33	$258	1.85
4	Smith & Nephew	SNN	$33.59	$15,057	1.95
5	Zimmer Biomet	ZBH	$101.55	$20,694	1.99

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$52.53	$2,579	3.81
2	Medtronic	MDT	$73.78	$103,746	3.69
3	Johnson & Johnson	JNJ	$98.16	$271,603	3.19
4	MiMedx Group	MDXG	$8.55	$932	3.17
5	Integra LifeSciences	IART	$65.67	$2,429	2.55

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$0.31	$31	0.15
2	Xtant Medical Hldgs	XTNT	$2.80	$33	0.72
3	RTI Biologics Inc	RTIX	$3.59	$207	0.79
4	Exactech	EXAC	$18.33	$258	1.04
5	SeaSpine Hldgs Corp	SPNE	$15.10	$168	1.21

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.20	$212	33.78
2	MiMedx Group	MDXG	$8.55	$932	7.88
3	Wright Med Grp N.V	WMGI	$21.72	$2,230	6.46
4	Medtronic	MDT	$73.78	$103,746	5.12
5	Globus Medical	GMED	$25.47	$2,425	5.11

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

Mobi-C's 5-Year Data

BY ROBIN YOUNG

In October 2015, Austin-based LDR Spine released five-year follow-up data for its flagship cervical disc arthroplasty implant, Mobi-C. LDR released 5-year data for BOTH single and double levels. (Both studies were prospective, randomized 2:1, multi-center, two arm, unmasked, concurrently controlled, non-inferiority clinical studies.)

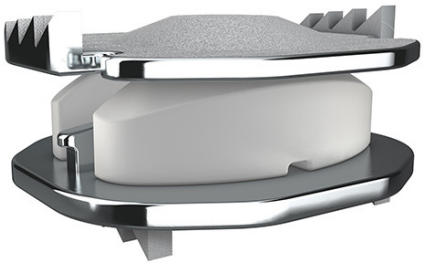
Also released in 2015 were a dozen additional disc arthroplasty studies including a 5-year follow-up for the NuVasive, Inc. PCM cervical disc, 7-year follow-up for the Depuy Synthes ProDisc-C and, just for the record, an 11-year follow up data for the Charité III lumbar disc replacement.

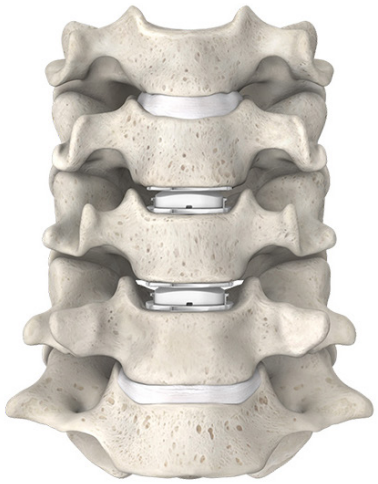
And to make the point that the most recent data is standing on the shoulders of several dozen other investigators, 2016 marks the 10-year anniversary of Fred Geisler's review of the original design and clinical testing of the first true disc arthroplasty implant—the Charité. In 2006 Geisler reviewed 10 years of Charité clinical data—which had been implanted in about 15,000 patients by then.

So as of 2016, clinicians, regulators and payers have 20 years of disc arthroplasty data including multiple FDA approved, prospective, randomized, blinded clinical studies and data on tens of thousands of patients from Europe.

10 Years Ago

Charité was approved by the FDA in October 2004. Worldwide, at the time of approval, the Charité had been implanted in more than 10,000 patients.





Mobi-C/Courtesy of LDR Spine

Fred Geisler, M.D., Ph.D, in his 2006 commentary and review wrote:

"The early experience with the CHARITÉ prosthesis is mixed largely due to limited sizing, rudimentary instrumentation and underdeveloped patient indications. The challenges of the early experience were a necessary step in refining the indications and techniques for lumbar disc replacement in preparation for the FDA Investigational Device Exemption (IDE) study.

In 2006, there was already data from European disc arthroplasty patients with 10-year follow up. Lemaire et al. described clinical and radiographic results in 10 patients with a minimum 10-year follow-up period after disc replacement. They reported excellent or good clinical outcomes in 90% of patients, with a mean range of motion in flexion/extension of 10.3 degrees.

The return to work rate was 92%.

There was a 2% incidence of adjacent-level disease requiring reoperation, and a 5% incidence of posterior revision with no anterior revision procedures."

What Have We Learned so Far?

Twenty years of research is illuminating. Reading the early studies and then walking with the investigators through the years shows how science builds incrementally. You can't exaggerate the importance of iterative studies.

Each one brings an element of 'truth.'

In the early days, the excitement around motion preservation was exhilarating and you can read it in those early commentaries.

Then the analysis of the revisions emerged.

Then the critics began looking at methodologies of the early studies.

Then the core assumptions behind motion preservation were tested—is adjacent level disease real, for example.

At each level, more 'truth' emerged and built on everything that came before.

Today, disc arthroplasty—revised and improved—stands on solid ground. Companies have improved the instrumentation dramatically. Patient selection is much more accurate and, most importantly, the implants themselves and the surgical procedures are vastly better.

Those important advancements have found voice in the North American Spine Society (NASS) clinical guidance statements and the International Society for the Advancement of Spine Surgery (ISASS) policy statements which were issued in 2015. Both societies articulated support for the use of disc arthroplasty to treat patients with degenerative disc disease.

ISASS wrote:

> "Based on a thorough review of the best available evidence-based scientific literature the International Society for the Advancement of Spine Surgery concludes that lumbar TDR [total disc replacement] is not new, experimental, or investigational. It is a well-tested technology which should predictably lead to better outcomes and less complications than fusion surgery, as well as a protective effect on adjacent levels.
>
> There is sufficient evidence-based scientific evidence to support the safety and efficacy of single level lumbar TDR for patients meeting well established selection criteria. ISASS would support patient authorization guidelines that mirror the selection criteria from the IDE studies, as long as the device is implanted by a trained experienced spine surgeon.
>
> There are now several long-term prospective and retrospective studies available on lumbar TDR which provide objective evidence regarding their safety and effectiveness. Data from prospective randomized clinical trials have reported consistently low rates of re-operations, and extremely low levels of particulate wear debris complications. A list of relevant research is available below.
>
> Based on sound analysis of the scientific literature, the International Society for the Advancement of Spine Surgery recommends universal coverage for single level lumbar TDR in patients meeting the established selection criteria."

Then NASS wrote:

> "Cervical artificial disc replacement (CADR, also known as cervical total disc replacement and cervical arthroplasty) may be indicated for the following diagnoses with qualifying criteria, when appropriate:
>
> 1. Radiculopathy related to nerve root compression from one or

two-level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-4 to C6-7 with or without neck pain that has been refractory to medical or non-operative management.
2. Myelopathy or myeloradiculopathy related to central spinal stenosis from one or two level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-4 to C6-7 with or without neck pain."

The Mobi-C Two-Level Study 5-Year Results

This is a prospective, randomized, FDA supervised IDE study which is designed for a 7-year follow-up. At the 2-year and 5-year marks, Mobi-C demonstrated fewer subsequent surgeries, lower rates of adverse events, lower rates of adjacent level degeneration, and higher NDI (neck disability index) success rates compared to anterior cervical discectomy fusion (ACDF). In fact, at the five year mark, the NDI success score actually improved for those patients who received a two-level Mobi-C At 60 months of follow-up, Mobi-C is statistically superior in terms of overall study success for two-level use.

Here are the results:

Two-level patients at two years

- NDI Improvement:
  - Randomized Mobi-C (n=225): 78.2% (169/216)
  - Randomized ACDF (n=105): 61.8% (55/89)
- No Failure due to Subsequent Surgery:
  - Randomized Mobi-C (n=225): 96.9% (218/225)
  - Randomized ACDF (n=105): 88.6% (93/105)
- No Major Complications
  - Randomized Mobi-C (n=225): 87.6% (197/225)
  - Randomized ACDF (n=105): 72.4% (76/105)
- Overall Success
  - Randomized **Mobi-C (n=225): 69.7%** (154/221)
  - Randomized **ACDF (n=105): 37.4%** (37/99)

Two-level patients at five years

- NDI Improvement:
  - Randomized Mobi-C (n=225): 82.0% (159/194)
  - Randomized ACDF (n=105): 56.6% (43/76)
- No Failure due to Subsequent Surgery:
  - Randomized Mobi-C (n=225): 96.0% (216/225)
  - Randomized ACDF (n=105): 83.8% (88/105)
- No Major Complications
  - Randomized Mobi-C (n=225): 83.1% (187/225)
  - Randomized ACDF (n=105): 78.1% (82/105)
- Overall Success
  - Randomized **Mobi-C (n=225): 62.8%** (120/191)
  - Randomized **ACDF (n=105): 34.1%** (30/88)

The PCM Cervical Disc 5-Year Results

This is a prospective, randomized, FDA supervised IDE study which is designed for a 7-year follow-up.

Here are the results:

At the 5-year follow-up mark, all patient reported outcomes—neck and arm pain visual analogue scale score, neck disability index and general health (36-item short form health survey physical and mental component scores: physical component summary, mental component summary)—were significantly improved from baselines in both groups, and mean scores were significantly better in the PCM group for neck disability index, neck pain, general health and patient satisfaction.

- 2 to 7-year device related adverse events
  - Randomized PCM: 0.5% (1/214)
  - Randomized ACDF: 1.1% (2/190)
- Secondary Surgical Procedures
  - Randomized PCM: 3.3% (7/211)
  - Randomized ACDF: 7.6% (14/290)
- Adjacent-level degeneration as measured radiographically
  - Randomized PCM: 33.1%
  - Randomized ACDF: 50.9%

The author's conclusion: The long term results show good clinical outcomes after ACDF and PCM arthroplasty. PCM patients showed greater improvement in neck disability index and neck pain scores with a lower rate of radiographically adjacent-level degeneration and a trend toward fewer secondary procedures. These data support PCM arthroplasty to be a viable and sustainable alternative to ACDF.

The ProDisc-C 7-Year Results

At seven years, the overall follow-up rate was 92% (152 of 165). There were no significant differences in demographic factors, follow-up rate, or patient-reported outcomes between groups.

Both procedures were effective in reducing neck and arm pain and improving and maintaining function and health-related quality of life.

Neurologic status was improved or maintained in 88% and 89% of the patients in the ProDisc-C and ACDF groups, respectively.

After seven years of follow-up, 30 secondary surgical procedures had been performed in 19 (18%) of 106 patients in the ACDF group compared with seven secondary surgical procedures in

7 (7%) of 103 patients in the ProDisc-C group (p = 0.0099).

There were no significant differences in the rates of any device-related adverse events between the groups.

Said the study authors: "Total disc arthroplasty with ProDisc-C is a safe and effective surgical treatment of single-level symptomatic cervical degenerative disc disease. Clinical outcomes after total disc arthroplasty with ProDisc-C were similar to those after ACDF. Patients treated with ProDisc-C had a lower probability of subsequent surgery, suggesting that total disc arthroplasty provides durable results and has the potential to slow the rate of adjacent-level disease."

Final Thoughts

The Mobi-C 5-year data is impressive. As is the PCM 5-year and the Pro-Disc 7-year and, yes, the Charité 11-year data (see table at the end of this article).

Investigators who've been working with disc arthroplasty patients for all these years have told us that disc arthroplasty patients go home sooner, go back to work in greater numbers and report a better quality of life than their spine fusion counterparts.

Two decades and hundreds of clinical studies work including several level 1 clinical trials, steady improvement in instruments, implants and patient selection and published support from two major spine surgeon societies begs two questions:

1. Why do major health insurance carriers in the U.S. continue to describe disc arthroplasty as an experimental treatment and therefore refuse to provide reimbursement for disc arthroplasty even in patients who meet strict selection criteria?
2. Why are payers denying an effective and well documented treatment for millions of Americans with chronic and debilitating lumbar or cervical degenerative disc disease?

(See table below and on page 8.)

Selection of NEW Disc Arthroplasty Studies Published in 2015

	Clinical Study	Years of Follow-Up	# of Patients	Type of Study	Conclusions	Journal	Publication Date	Authors
1	Disc Arthroplasty: Mobi-C vs anterior discectomy and fusion	4-years	330	Prospective, randomized, multi-center	Four-year results from this study continue to support TDR as a safe, effective, and statistically superior alternative to ACDF for the treatment of degenerative disc disease at 2 contiguous cervical levels	Journal of Neurosurgery	January 2015	Reginald Davis Pierce Nunley Kee Kim Michael Hisey Robert Jackson Hyun Bae Gregory Hoffman Steven Gaede Guy Danielson Charles Gordon Marcus Stone
2	Disc Arthroplasty: Cervical Total Disc	4-Years	164 one-level TDR 225 two-level TDR Total: 389	Prospective, randomized, multi-center, FDA IDE study	A 4-year post hoc comparison of 1- and 2-level TDR patients concurrently enrolled in a 24-center, Food and Drug Administration Investigation Device Exemption clinical trial indicated no statistical differences between groups in clinical outcomes, overall complication rates, and subsequent surgery rates.	SPINE	June 2015	Hyun Bae Kee Kim Pierce Dalton Robert Jackson Michael Hisey Reginald Davis Gregory Hoffman Steven Gaede Guy Danielson Daniel Peterson John Stokes Ali Araghi
3	Disc Arthroplasty: Long Term Outcomes PCM Cervical Disc Arthroplasty	5-years and 7-years	293 at 5 years: 110 at 7 years	Prospective, randomized, controlled, multi-center, FDA IDE study	The long-term results show good clinical outcomes after ACDF and PCM arthroplasty. PCM patients showed greater improvement in neck disability index and neck pain scores with a lower rate of radiographical adjacent-level degeneration and a trend toward fewer secondary surgical procedures. These data support PCM arthroplasty to be a viable and sustainable alternative to ACDF.	SPINE	May 2015	Frank Phillips Fred Geisler Kye Gilder Chistopher Reah Kelli Howell Paul McAfee
4	Disc Arhtroplasty: Discover Artifical Disc vs. ACDF	2-year	153	Randomized, controlled multi-center study	Both groups improved significantly after surgery. NDI changed from 63.1 to 39.8 in an intention-to-treat analysis. No statistically significant difference between the ADR and the ACDF groups could be demonstrated with NDI values of 39.1 and 40.1, respectively.	The Spine Journal	June 2015	Martin Skeppholm Lars Lindgren Thomas Henriques Ludek Vavruch Hakan Lofgren Claes Olerud

5	Disc Arthroplasty: ProDisc-C Total Disc Repalcement vs. AFDF	7-years	209	Prospective, randomized, controlled, multi-center, FDA IDE study	Total disc arthroplasty with ProDisc-C is a safe and effective surgical treatment of single-level symptomatic cervical degenerative disc disease. Clinical outcomes after total disc arthroplasty with ProDisc-C were similar to those after ACDF. Patients treated with ProDisc-C had a lower probability of subsequent surgery, suggesting that total disc arthroplasty provides durable results and has the potential to slow the rate of adjacent-level disease.	The Journal of Bone & Joint Surgery	November 2015	MIchael Janssen Jack Zigler Jeffrey Spivak Rick Delamarter Bruce Darden, Branko Kopjar
6	Disc Arthroplasty: ProDisc-L Disc Replacement	4-years	108	Retrospective review, single site	The procedure led to a statistically significant improvement in the functional scores. The motion of the upper disc segment was 9° (0°–19°) in flexion/extension and 5.5° (2°–12°) in lateral bending. It was 6.2° (0°–14°) and 1.9° (0°–7°) at the lower disc segment. The range of motion was similar in L3/L4 and L4/L5, but was less in L5/S1. Lack of mobility was not correlated with alterations in the functional outcome. The complication rate was 18%.	Orthopaedics & Traumatology: Surgery & Research	February 2015	S. Trincat G. Edgard-Rosa G. Geneste T. Marnay
7	Disc Arthroplasty: XL TDR Lumbar Disc Replacement	3-years	64	Prospective, randomized, controlled, multi-center, FDA IDE study	The results following XL TDR show good clinical and radiographic outcomes out to 3 years postoperative, with clinically significant improvements in pain, function, and general health, few complications, and high patient satisfaction.	European Spine Journal	March 2015	Antoine Tohmeh William Smith
8	Disc Arthroplasty: Costs of Cervical Disc Replacement vs ACDF	na	6,635 ACDF patients, 327 CDA patients	Retrospective matched cohort analysis	Patients who underwent CDA for single-level degenerative disease had lower readmission rates, lower reoperation rates and reduced index and total costs than those treated with acdf. CDA was effective in reducing the monthly cost of care compared with ACDF.	SPINE	April 2015	Kris Radcliff Jack Zigler Jeff Zigler
9	Disc Arthroplasty: Cervical Total Disc Replacement Is Superior to ACDF	na	4,516	Meta-analysis of 19 randomized controlled clinical trials	Cervical total disc replacement presented favorable functional outcomes, fewer adverse events, and fewer secondary surgical procedures. The efficacy and safety of cervical total disc replacement are superior to those of fusion. Longer-term, multicenter studies are required for a better evaluation of the long-term efficacy and safety of the two procedures.	PLOS One	March 2015	Zhang Liang Tao Zhou Li Li Chen
10	Disc Arthroplasty: Comparison of TDR With Lumbar Fusion	2-year	363	Meta-analysis of 6 randomized controlled clinical trials	The present meta-analysis of RCTs reveals that in a long-term follow-up (2 years) TDR shows significant superiority for the treatment of lumbar DDD compared with fusion. However, due to the number of eligible studies in this meta-analysis which are still not enough, more high quality RCTs with long-term follow-up (at least 2 years) are further needed to confirm the clinical benefits with the use of tDR in treatment of lumbar DDD>	Journal of the College of Physicians and Surgeons Pakistan	2015	Nie Chen, Wang Zeng
11	Disc Arthroplasty: An 11-year follow-up of the Charité III lumbar disc replacement	11-year	32	Retrospective analysis, single site	Twenty-eight patients (87.5%) had a successful outcome, as defined by the FDA. Reoperation was performed in 2 patients for adjacent segment degeneration and pedicle fracture. Both VAS and ODI scores showed significant improvement compared to baseline.	European Spine Journal	April 2015	Hai, Lu, Kong, Wang, Zang, Kang, Meng, Wang
12	Disc Arthroplasty: Retrospective study on Effectiveness of Activ L Total Disc	28 months	30	Retrospective case series with radiographic follow-up	At the final follow-up, the success rate was 86.7%. Visual analogue scale score for low back pain and leg pain, and Oswestry Disability Index scores significantly improved after surgery.	SPINE	April 2015	Lu, Kong Hai, Wang Zang, Kang Meng, Wang

Source: RRY Publications, LLC and public documents

NuVasive Buys Ellipse for $380 Million

BY ROBIN YOUNG

Ellipse Technologies, Inc., one of the leading young spine technology companies, has agreed to be bought by NuVasive, Inc. for $380 million which includes about $30 million in milestone payments.

Ellipse, whose MAGEC technology was the highest scoring new spine technology award winner in 2011, was founded in 2005 and had recorded sales of approximately $40 million in 2015, which was 54% higher than the $26 million posted in 2014.

Ellipse's products are marketed and sold in the U.S. and 29 other countries. Revenues outside of the U.S. represented approximately 37% of revenues for 2015. For 2016, Ellipse's management expects that revenues can reach approximately $60 million on a pro forma basis.

MAGEC

Invented by Scott Pool, Arvin Chang and Blair Walker and engineered by the three inventors and Peter Tran, MAGEC revolutionized the treatment of early onset scoliosis in children.

Before MAGEC, children with significant spinal deformity caused by early onset scoliosis were treated with "growing rods" which were implanted and then surgically lengthened approximately every six months in order to match the child's growth and to maintain proper spine alignment.

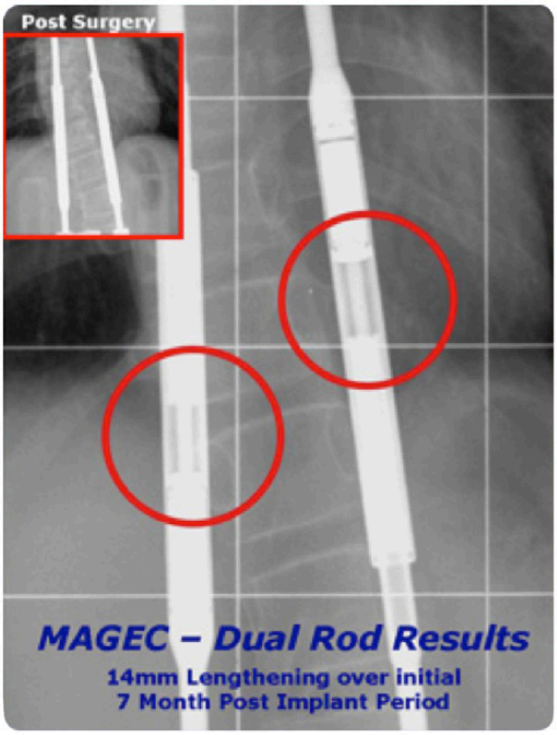
Children had to endure multiple surgeries which, of course, created serious risk of complications to say nothing of the trauma, pain and cost. Some children underwent as many as 15 surgeries over the course of their treatment.

MAGEC changed that. With MAGEC, the child whose spine is being corrected lies awake on an examining table, not a surgical table, for rod lengthening. The device that activates the self-lengthening rod, the ERC, is placed on the child's back, and within a few minutes, the MAGEC rod stretches out gently.

If the child ever feels discomfort, the doctor can shorten the MAGEC rod until the discomfort disappears. The doctor can confirm specific distraction length with X-ray images.

Using MAGEC is easy, comfortable and fast. Because of MAGEC, spine surgeons were able to distract the rods much more often, for example every month, and thereby curve correct in synch with how the specific child grows.

The MAGEC system is comprised of a titanium alloy rod which the surgeon implants (like any other rod) in pediatric scoliosis patients to correct spinal curvature. The rod itself has two ends that are attached by the surgeon to the vertebrae with either hooks or pedicle screws. The inventors built into the MAGEC rod a cylindrical, radially poled internal magnet which drives a lead screw that moves the two ends apart when the internal magnet is non-invasively rotated by use of the MAGEC External Remote Controller. The MAGEC rod may be lengthened or shortened. A magnetic retaining plate embedded in the outer housing of the MAGEC rod assures the surgeon that the desired distraction length will stay in place even during severe patient movement.

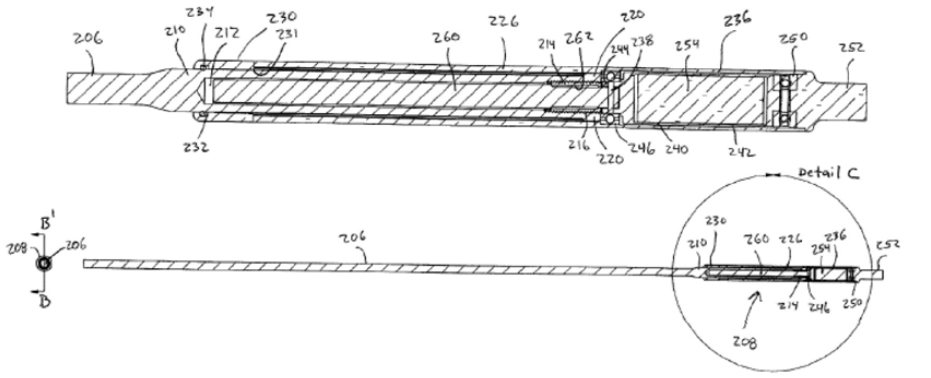


Courtesy of Ellipse Technologies, Inc.

Top Scoring OTW Spine Technology Award Winner

In 2011 Ellipse submitted MAGEC to the august panel of leading spine surgeons for consideration as the leading new spine technology for that year. These top surgeons gave MAGEC the highest number of points that year.

The "Best New Spine Technology Award" is sponsored by *Orthopedics This Week* and all submissions are



Courtesy of Ellipse Technologies, Inc.

judged according to the following criteria:

1. Be creative and innovative.
2. Have long-term significance to the problem of treating the diseases of the spine. Does this technology have staying power?
3. Solve a clinical problem. To what extent does this technology solve a current clinical problem or problem that is inadequately solved today?
4. Does it have the potential to improve standard of care?
5. Is it cost effective?
6. I would use it?

And when these top surgeons assigned a point value to each of these questions, Ellipse's MAGEC was the top vote getter of 2011.

Adds a $1.2 Billion Market to NuVasive's Portfolio

Ellipse is about to become part of NuVasive. In NuVasive's hands, MAGEC's potential to reduce the number of surgeries, reduce complications and improve outcomes for young patients with early onset scoliosis is very large. According to Ellipse's management, the global addressable market opportunity for Ellipse's currently commercialized products was approximately $1.2 billion as of the end of 2014 based on data from Life Science Intelligence, Inc. In addition, Ellipse's product candidates that leverage the MAGEC technology platform addressed a significant global opportunity of more than 690,000 annual procedures based on this data.

NuVasive Chairman and Chief Executive Officer Gregory T. Lucier had this to say about the purchase:

> "Ellipse's revolutionary technology, which has been enthusiastically received by surgeons, has the potential to become the standard of care for spine and orthopedic patients. It is in NuVasive's sweet-spot of game-changing innovation, bolstering our leadership in spine and providing new growth opportunities in the U.S. and around the world. NuVasive remains committed to adult deformity through our Integrated Global Alignment (iGA™) platform, and the acquisition of Ellipse will aggressively insert NuVasive into early onset and idiopathic scoliosis, an important and attractive part of the spinal deformity market for NuVasive where we have tremendous opportunities for accelerated growth. Additionally, this investment expands NuVasive's footprint into new niche markets with highly differentiated technology that—when coupled with our market-making expertise—will be strategically applied in other spine and orthopedic applications, including degenerative spine disease, trauma and knee osteoarthritis. Ellipse's robust product pipeline also enhances internal development and licensing opportunities for NuVasive, including areas where we look to assemble with our iGA™ and neuromonitoring expertise. We are very excited to welcome Ellipse's talented team to NuVasive and look forward to realizing the many operational and financial benefits this transaction creates."

Edmund J. Roschak, president and chief executive officer of Ellipse Technologies, said, "Ellipse has made enormous strides since our founding ten years ago. Joining forces with NuVasive not only validates the promise of our technology, but provides us with the scale and resources necessary to realize our full potential, to the benefit of our surgeon customers and their patients, faster than we could achieve on our own. Additionally, NuVasive's longstanding commitment to developing market-leading, less invasive technological solutions represents a tremendous cultural fit. Innovation, a passion for excellence and improved clinical outcomes have all been hallmarks of Ellipse, and ones that I know will continue as part of NuVasive. We look forward to joining with NuVasive to continue to help improve patient lives."

Wall Street's Reaction

Joanne Wuensch with BMO Capital Markets wrote: "True to its word, the "new" NuVasive management team put its cash to work and announced the acquisition of Ellipse Technologies, a private Aliso Viejo, CA company focused on complex skeletal deformity For NUVA, 1) it accelerates revenue growth; 2) expands its geographic footprint (~37% of Ellipse's revenue was

generated outside the U.S. in 2015); and 3) broadens its product portfolio, building on its efforts in adult deformity with its Integrated Global Alignment (iGA), moving down the spectrum into early onset and idiopathic adolescent scoliosis, and expanding into niche orthopaedic markets (e.g., trauma and knee osteoarthritis). While an expensive acquisition, it does make strategic sense. Further, as we have written, NuVasive is 'growing up' transitioning to a spine solutions company from a spine product company."

Craig Bijou of Wells Fargo wrote: "We view the deal as slightly expensive at about 6.3x next twelve month sales, however, NUVA expects the deal to be accretive to its top-line growth and EPS starting in 2016. Ellipse markets two magnetically adjustable implant systems for spinal deformity (MAGEC) and leg lengthening (PRECICE) which generated about $40MM (+54%) in sales in 2015. Surgeon feedback on both MAGEC and PRECICE has been extremely positive. We believe the Ellipse deal will enhance NUVA's growing presence in the $2B spinal deformity market and provide the company with a growth opportunity in the orthopedic limb lengthening market."

William Plovanic of Cannacord Genuity wrote: "We believe the acquisition fits into NuVasive's portfolio of innovative spinal procedure solutions while also leveraging NuVasive's large sales distribution. Additionally Ellipse's international presence adds to NuVasive's growing focus on international revenue growth. Lastly, we note the added benefit of minimal CAPX and a solid gross margin, which will provide strong FCF for NuVasive on the incremental revenues. Net, net we view the acquisition positively given 1) it brings a novel technology to the NuVasive bag; 2) it is accretive quickly; and 3) it should provide solid FCF almost immediately."

The transaction is expected to close by the end of February 2016, subject to customary closing conditions and regulatory approvals. NuVasive expects to fund the acquisition with existing cash on hand.

After the closing of the transaction, NuVasive plans to maintain a Design Center of Excellence in Aliso Viejo, California, where Ellipse is headquartered. Mr. Roschak will join NuVasive as a member of the NuVasive executive leadership team reporting directly to Mr. Lucier.

Goldman, Sachs & Co. served as exclusive financial advisor to NuVasive and DLA Piper served as its legal counsel. Piper Jaffray is exclusive financial advisor to Ellipse and Latham & Watkins is its legal counsel. ♦

Top Orthopedic Stories of 2015

BY WALTER EISNER

Readers of *Orthopedics This Week* have spoken with their mouse clicks and Google Analytics has identified the top read stories and topics chosen by our readers in 2015.

The consolidation of orthopedics, new technologies, sales rep anxiety, surgeon musical chairs, corruption, passing of an industry giant and finding pain relief for patients are what our readers cared most about.

In descending order here are the top read stories and topics in *OTW* for 2015.

10. Stryker Gets Exclusive Rights to Osiris Bone Allograft

The march towards biologics in orthopedics continued with Osiris Therapeutics, Inc. and Stryker Corporation entering into an exclusive partnership at the end of 2014 for the commercialization and development of Osiris' bone matrix tissue form.

The agreement gave Stryker exclusive rights to BIO⁴. BIO⁴ is "a structural extracellular matrix, osteogenic and angiogenic growth factors, endogenous mesenchymal stem cells and osteoblasts. It possesses osteoconductive, osteoinductive, osteogenic and angiogenic properties that are required for bone repair and regeneration."

Osiris will be responsible for manufacturing, continued research and product improvements while Stryker will be responsible for the commercialization and marketing of the product.

Photo creation by RRY Publications, LLC

Read it here: https://ryortho.com/breaking/stryker-get-exclusive-rights-to-osiris-bone-allograft/

9. Major Study Update, Stem Cells Ease Back Pain

Reducing back pain continues to grab reader attention as a 2013 story reporting Mesoblast releasing the latest in a string of studies examining the ability of a certain type of stem cell to treat back pain demonstrated.

In one of the studies, (*Journal of Neurosurgery: Spine May 2012; Vol. 16; No. 5; Pages 479-488*), researchers injected allogeneic mesenchymal precursor cells (MPCs) into damaged intervertebral discs in what is, essentially, a one-hour outpatient procedure.

The data showed that a single low-dose injection of MPC significantly reduced low back pain in the treated patients and did so at a statistically significant way as compared to the control group, which received hyaluronic acid injections.

Read it here: https://ryortho.com/breaking/major-study-update-stem-cells-ease-back-pain/

8. Orthopedic Residents Trained Differently Than Neuro Residents in Spine

Alan Daniels, M.D., an orthopedic surgeon at Brown University told *OTW,* that unlike other specialties which have one training pathway, spine surgery specialists have two. One is orthopedic surgery residency and the other is neurosurgical residency.

This is a problem, says Daniels, because some residency programs provide inadequate spine training. "There is so much variability in the training for spine surgeons, and a lack of standards outlining adequate training for spine surgeons. This leads to a situation where some surgeons may be inadequately trained, and patients and other medical professionals become confused about the capabilities and areas of expertise of surgeons who perform spinal surgery in their communities."

For instance, in Daniels' training experience, the average number of spine surgery procedures performed during orthopedic residency was 160; for neurosurgery surgery it was 375 procedures. It was not only the number of cases which differed between the specialties, but also the *types* of cases performed. Daniels also found a significant difference in the average number of spinal deformity procedures between graduating orthopedic surgery residents (9.5) and graduating neurosurgery residents (2.0). He also found that orthopedic residents do a higher proportion of instrumentation and fusion procedures compared to neurosurgery residents, who participated in proportionally more decompression procedures."

Read it here: https://ryortho.com/2015/01/orthopedic-residents-trained-differently-than-neuro-residents-in-spine-

7. More Cases Emerge From FBI's California Spinal Cap Investigation

Like watching a car wreck, readers never tired of watching corruption unfold.

A series of stories coming out of a California FBI investigation, called "Spinal Cap," chronicled the guilty pleas of a corrupt hospital owner and marketing consultants who bribed spine surgeons and other providers to funnel patients to his hospital.

By taking advantage of an antiquated California worker's comp law which paid 100% of the hospital's documented costs, Michael Drobot's hospital, Pacific Hospital of Long Beach, bilked the state and private payers for more than $600 million.

Drobot and others also formed shell companies to make unapproved pedicle screws and provide pharmaceutical management. By 2009, a pedicle screw that could be purchased for between $300 and $500 wholesale would end up on a hospital bill at approximately $12,500. Profits soared.

When the California Legislature moved to close the spigot, Drobot allegedly bribed a committee chairman to keep the law on the books. The law was changed anyway and the, now former, state senator is under indictment.

On June 2014, 15 doctors, pharmacists and other medical professionals in Southern California were charged in a $25 million workers' compensation scheme that prosecutors said was linked to the death of a baby.

One of the pharma professionals charged was, you guessed it, Michael Drobot, the managing partner of Industrial Pharmacy Management.

By the end of 2015, more indictments and guilty pleas were coming from spine surgeons who participated in the scheme. Prosecutors say there's more to come in 2016.

Read it here: https://ryortho.com/2014/07/more-cases-emerge-from-fbis-california-spinal-cap-investigation/

6. Dane Miller, Ph.D., Passes Away

It was with a heavy heart that we reported in early 2015 the passing of Dane A. Miller, Ph.D., founder and CEO of Biomet, Inc. He was 69 years old. Dane cofounded Biomet in 1977 and is one of this industry's founding fathers.

Biomet's CEO Jeff Binder reminded us that: "Dane thought of himself as an 'environmental engineer,' and he fostered an ownership culture where team members were empowered to make decisions, take reasonable risks and actively respond to the needs of our customers and their patients. Dane was one of industry's first leaders to use the phrase 'team member' to describe his company's employees. He once told me that the best description of Biomet's culture was that of a 'can-do family.'"

Where Dane Miller ended and Biomet began has always been hard to see. Customers who needed to call him could reach him at home. He also, famously, answered his own phone in the office.

He ate in the Biomet cafeteria where he stood in line, getting a tray and sitting with a new group of employees every week. On business trips, Dane visited hospitals, scrubbed up, put on the surgical gown and watched surgeries. With a doctorate in biomedical engineering, Dane was at home with surgeons, his employees, his products, and his company.

In an era of industry consolidation, Dane helped engineer a deal that would keep Biomet a hometown company, with the merger with Warsaw, Indiana, crosstown rival and his former employer, Zimmer Holdings, Inc.

The passing of Dane Miller reminded us that Warsaw spawned DePuy, which begat Zimmer, which begat Miller and finally reunited Zimmer and Miller.

Read it here: https://ryortho.com/2015/02/dane-miller-ph-d-passes-away-2/

5. Riew, Lenke and Lehman Leaving Wash U Academic Institution

Not since the famous departure of Masters and Johnson and their sex study

from Washington University in St. Louis, did the exit of surgeon scientists from the institution garner as much attention as the departure to New York of Larry Lenke, M.D., Dan Riew, M.D. and Ron Lehman, M.D.

The trio left Wash U to establish a one-of-a-kind spine hospital at the New York Presbyterian Hospital at Columbia University College of Physicians and Surgeons.

Dr. Riew told *OTW* that William Levine, M.D., the Frank E. Stinchfield Professor and recently appointed Chairman of Orthopedic Surgery, had the vision and was willing to make a solid commitment to developing the top spine program in the United States—and was willing to dedicate unprecedented resources and funding to build the program.

Read it here: https://ryortho.com/2015/03/riew-lenke-and-lehman-leaving-wash-u-academic-institutions-re-

4. Smith & Nephew Goes Rep-Less With Some Hips and Knees

Nothing gave sales reps more anxiety than the move by hip and knee makers to sell some of their products with a "no-frill" option that excluded logistical support or an onsite technician.

Smith & Nephew, plc announced that it expected to cut some orthopedic implant prices in half for the target market of 5% to 10% of U.S. hospitals with its Syncera program, which replaced the technician with an iPad app.

When Wright Medical Group, Inc. offered a similar program in 2013, Bank of America analyst Bob Hopkins called it the "Death of the Device Salesman."

There are roughly 6,000 hospitals in the U.S. where about 10% of the U.S. hip and knee procedure market is institutionally driven. That was up from about 5% only two or three years ago and an expected 15% to 20% in the next couple of years.

Read it here: https://ryortho.com/breaking/smith-nephew-goes-rep-less-with-some-hips-and-knees/

3. Orsinger Out at DePuy Synthes, J&J Reorganizes Device Business

When Johnson & Johnson acquired Synthes, Inc. for 21.3 billion in 2011, it made Synthes CEO Michel Orsinger the face of the combined medical device business. By some accounts, including public admissions from company leaders, the integration of the two companies with different cultures and distribution logistics, did not go smoothly.

Then Orsinger was arrested on April 5, 2015, for allegedly assaulting a female family member outside a Sunday morning church service at St. Thomas Monastery in Radnor, Pennsylvania.

According to police reports, the family member saw Orsinger sending text messages during the church service. She asked to speak with him outside the church and allegedly took his cell phone from his hands and ran off. Orsinger pursued her and when he caught her puller her hair and then tackled her after she broke free.

By early May, J&J announced the company was creating a single Medical Devices Group by integrating its surgery and orthopedics business under the leadership of Gary Pruden, then head of J&J's surgery business.

A company spokesperson told *OTW* the two events were completely unrelated and had no comment on the situation involving Orsinger. "It's a personal matter as far as we are concerned," said the spokesperson.

Read it here: https://ryortho.com/2015/05/orsinger-charged-with-assault/

2. The Best Spine Technologies

Innovation still matters to our readers. Each year, *OTW* opens the doors for spine technology companies to compete for the *OTW Best New Spine Technology Award.*

This annual award rewards inventors, engineering teams, surgeons and their companies who've created the most innovative, enduring and practical products in the past year to treat back pain. To win the award, a new technology must meet the following criteria:

1. Be creative and innovative.
2. Have long-term significance to the problem of treating the diseases of the spine. Does this technology have staying power?
3. Solve a clinical problem. To what extent does this technology solve a current clinical problem or problem that is inadequately solved today?
4. Does it have the potential to improve standard of care?
5. Is it cost effective?
6. I would use it?

In 2015, 39 new products were submitted and four judges, Frank Phillips, M.D., Steven Garfin, M.D., Stephen Hochschuler, M.D. and James Schwender, M.D., selected nine winners. Biologics and Imaging technologies impressed the judges the most.

The winners were; 7D Surgical, Aspen Medical Products, Benvenue Medical, Inc, Cytonics Corporation, Invuity, Inc., LifeNet Health, LinkSPINE, Spine Wave, Inc. and Titan Spine LLC.

Read it here: https://ryortho.com/2015/10/the-nine-best-new-spine-technologies-for-2015/

1. Employees of Zimmer Biomet, What to Expect

By far, the biggest story of the year for *OTW* readers was the $14 billion merger of Zimmer Holdings, Inc. and Biomet Inc.

A series of stories chronicled the behind the scenes maneuvering and negotiations between Zimmer's CEO Dave Dvorak and Biomet's CEO Jeff Binder, the tortuous regulatory pathway through the Federal Trade Commission, European and Japanese regulators and the business implications of the creation of this new orthopedic "Superpower."

But the single story that attracted our readers most was a guest feature story written by Dru De Angelis, titled, "*Employees of Zimmer Biomet, What to Expect.*"

Over 25,000 employees at both companies wondered about their jobs and careers. As a former Zimmer sales executive turned human resources expert, De Angelis said that, "Merger and Acquisition 101 teaches that the top brass must convey the message that 'everyone is going to be fine! Don't run away.' But as we all know, cuts will come. The issue is how will you maneuver in the new corporate mash-up?"

De Angelis' message was that cuts will come, political players will win and employees must follow the power and build alliances.

Lastly, said De Angelis, "If you are one of the unfortunate ones who get laid off, don't take it personally and don't let it drag you down. There IS life after Zimmer/Biomet. Keep your chin up and strive toward finding a great place for you to contribute to the ongoing success of a new team. Leverage your talent and experience in a fresh environment. Godspeed!"

Read it here: https://ryortho.com/2014/05/employees-of-zimmer-biomet-what-to-expect/

So another year of laying down the first draft of orthopedic history has passed and as usual, our readers keep reminding us of what is important. 2015 is dead. Long live 2016. ♦

Alcohol Abuse Kicks Infection Risk up 15X // Cognitive Behavioral Therapy Powerful Pain Treatment // Whoa Surgeon…Don't Forget to Treat the Pathology

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

Alcohol Abuse Kicks Infection Risk up 15X Wael Barsoum, M.D., president of Cleveland Clinic, Florida, is wading into an area where few orthopedic surgeons tread. Recognizing that treating certain patients means going beyond the normal scope of duty, Dr. Barsoum embarked on a project to assess how the misuse of alcohol affects outcomes after hip and knee arthroplasty. He told *OTW,* "We really know very little about how patients who drink to excess fare after these surgeries. The issue is not that physicians don't understand the importance of the problem, but it is difficult to accurately assess a person's history in terms of alcohol consumption in a preoperative office visit, and important information which would help the surgeon in this regard may be missing from his/her medical record. Not much work has been done in this area; of the two papers we found, one involved 60 patients and another involved 185 patients. This study was able to access information on 8.3 million patients who underwent THA or TKA, making it landmark research."

"We utilized records from the National Hospital Discharge Survey and divided patients into two groups: those who misused alcohol (50,861) and those who did not (8,321,371). The tradeoff with these databases is large numbers of patient records at the expense of granular detail. In this case, we used ICD-9 codes to identify patients who were coded as having alcohol dependence or alcohol abuse, which are fairly difficult to define and undoubtedly underreported."

Absinthe-drinkers by Edgar Degas/Wikimedia Commons

"If a patient tells you that he or she consumes one to two alcoholic drinks per day, it is typically safe to assume that they actually drink more than that. There have been times when I asked a patient, 'Do you drink alcohol?' and the person has said, 'Yes, but not much.' Upon digging a little deeper, however, it turns out that they're drinking a case of beer a day. It's like the times I have asked someone, 'Are you diabetic?' and he or she replies, 'no.' 'So why do you take insulin?' I ask. 'Oh, it's for my sugar.' It comes down to their understanding of what is considered normal in terms of alcohol consumption."

"In our study, we found vast differences in discharge status, comorbidities and perioperative complications. Those who misused alcohol were nine times more likely to leave against medical advice and had longer hospital stays. And orthopedic surgeons should be prepared for the fact that these patients are much more likely to have complications. Those who misused alcohol had a higher rate of total complications than those who did not (33% versus 22%). And 'misusers' had significantly higher rates of all complications except urinary tract infection, pulmonary embolism, and deep vein thrombosis. Also critical is that patients who misused alcohol had a 15x higher risk of infection. We need to keep a closer eye on the incisions, and even bring these patients back one week postoperatively to check them out."

"Finally, alcohol misusers were 23% more likely to have a blood transfusion. To address this, we should be giving patients something to minimize the risk of blood transfusion (a less aggressive anticoagulant, give them a topical hemosealant, etc.)."

So what to do with those who drink more than average? "Anecdotally, these patients tend to start getting frustrated early in their hospitalization; some facilities deal with this by letting patients drink alcohol in the hospital. The other option is to do something preoperatively to minimize the drinking, perhaps giving the patient a benzodiazepine such as Librium. The other option is to ignore it, although clearly our research shows that this is not the best option for the patient in terms of his/her surgical outcome."

"If a patient at our facility is not interested in reducing their alcohol intake before surgery, then we allow them to have alcohol while in the hospital. While at first glance it sounds like an odd solution, honestly, it is safer because the alternative—benzodiazepines—are not something familiar to most patients. We always link the issue of providing alcohol with a very honest conversation about why we are taking this route, as well as the risks involved."

"It may be that higher risk patients should be sent to a higher acuity environment. But know that ignoring the problem will only create more issues. You need to have a strategy regarding alcohol misuse."

Cognitive Behavioral Therapy Powerful Acute Pain Treatment When psychiatrists at Harvard Medical School set out to study the relationship between depression and physical pain in patients recovering from musculoskeletal trauma, they were pleasantly surprised. The team, led by Ana-Maria Vranceanu, Ph.D., also included David Ring, M.D., Ph.D., chief of the Hand and Upper Extremity Service at Massachusetts General Hospital.

The team set out to estimate the prevalence of clinical depression and post-traumatic stress disorder (PTSD) at two points in time following the occurrence of a musculoskeletal trauma. They also

wanted to study the relationship of these psychological variables to at Time 1 (1-2 months) to musculoskeletal disability and pain intensity at Time 1 and Time 2 (5-8 months).

Regarding clinical depression, 35 of the 152 patients met the criteria at Time 1, and 29 of the 136 patients at Time 2. As for PTSD, 43 of the 152 patients met the criteria at Time 1 and 25 of the 136 patients at Time 2.

Catastrophic thinking (as measured with use of the Pain Catastrophizing Scale) at Time 1 was the sole significant predictor of pain at rest, pain during activity, and disability (as measured with use of the Short Musculoskeletal Function Assessment Questionnaire—SMFA) at Time 2.

Bottom line: The researchers found that catastrophic thinking is strongly associated with pain intensity and disability in patients recovering from musculoskeletal trauma.

Asked what led to this work, Dr. Vranceanu told *OTW*, "During my clinical internship in behavioral medicine I was introduced to Dr. David Ring, who was interested in the psychosocial aspects of orthopedic pain. At that point I started becoming involved in clinical work with patients with hand and arm pain within the orthopedic practice, as part of a multidisciplinary team. At the same time, David and I started a research program of psychosocial factors in hand and arm pain, that since then has exploded to patients with orthopedic trauma as well as general orthopedic pain."

"I was pleasantly surprised as to how powerful evidence based skills interventions like Cognitive Behavioral Therapy (CBT) are for patients with acute pain. We know that although CBT works for chronic pain, effect sizes are relatively small and engagement in treatment is limited. With patients with acute pain, treatment can be as short as two sessions, and average four sessions, thus much more cost effective. I was and continue to be amazed by the wonderful work on psychosocial factors done by Dr. David Ring, as well as his keen knowledge and passion for this line of work."

"Psychosocial treatments delivered early on in patients at risk for chronic pain work, prevent transition to chronic pain, and are cost effective. Using a biopsychosocial framework that accounts for the mind body interaction, combined with empathy and a shared decision making can greatly increase patient outcomes as well as patient satisfaction."

Whoa Surgeon…Don't Forget to Treat the Pathology "Focus on function and pathology," says Keith

Baldwin, M.D. An attending surgeon at the Children's Hospital of Philadelphia (CHOP), Dr. Baldwin is an expert on neuromuscular conditions and director of orthopedic trauma at CHOP. He tells *OTW*, "My training and experience as a physical therapist have given me a window into the ways the physicians and physical therapists can collaborate for the benefit of their patients. While orthopedic rehabilitation is not a true discipline, it is central to what every orthopedist does. This is only going to be more true as we move forward with the use of quality metrics outcome measures and readmission assessments when it comes to payment decisions."

"A clear, personalized rehabilitation program goes a long way toward reducing the risk of postoperative complications and improving outcome. Whether you are a joint surgeon or a spine surgeon or anything else, you must think about all you do in terms of this question, 'How does what I am doing help people live their lives 3-4 months after surgery, and how does it improve their function?' Reflect on whether your procedure is a step in the rehab process… or is it the thing that will cause the person to need rehab? As a research director at CHOP and heavily involved at the University of Pennsylvania, I try to get joint and sports surgeons to think about the disease they are treating as opposed to the joint they are treating. Joint surgery is only one thing that can be used to treat, say, osteoarthritis. But typically, orthopedic surgeons are not focused on the pathology; they are action-oriented people, and are focused on what they can *do* to correct the problem, rather than the problem itself."

"When we were opening an outcomes center at 'Penn' I emphasized that we shouldn't be collecting surgical outcomes, but rather outcomes of disease at various severity. For example, we shouldn't be only looking at rotator cuff patients who had shoulder scopes, but that we should collect data on everyone and see which patients had single row with such-and-such technique, who had physical therapy, etc. Obama and the federal government are not interested in whether your shoulder scope worked…they are interested in how all people with rotator cuff tears do. Insert any pathology for that statement and you will get some idea of the issue. For a certain severity of problem, we must show for example that surgery as a portion of the entire treatment is a useful tool in the treatment of that pathology over the natural history or conservative treatment. Ideally, we are trying to understand the whole pathology rather than just being a technician." ♦

COMPANY

K2M's Third Titanium Lateral Interbody System Cleared by FDA

K2M Group Holdings, Inc. has received FDA 510(k) clearance to market Cascadia, its third lateral interbody system featuring the company's Lamellar Titanium Technology. The company also received FDA 510(k) clearance and a CE Mark for the Cascadia AN and TL interbody systems in 2015.

Lamellar Titanium Technology

Lamellar titanium technology is the company's proprietary technology that uses 3D printing with the goal of allowing for bony integration throughout an implant. In addition to U.S. regulatory clearance, K2M also received a CE Mark for the system.

According to a January 8, 2015 company announcement, the technology uses "an advanced 3D printing method to create structures that were once considered impractical with traditional manufacturing techniques. Starting with a titanium powder, the implants are grown through the selective application of a high-energy laser beam, allowing for the incorporation of both a porosity and surface roughness that pre-clinical data have associated with bone growth activity."

In December 2015 Pierce Nunley, M.D., director of the Spine Institute of Louisiana, completed the first surgical case using the Cascadia system. He said the design of the implant offers him, "a greater bone graft volume than my normal Aleutian PEEK implant, while increasing the endplate contact surface area and still allowing me the ability to radiographically evaluate the fusion." The increased endplate contact is accomplished through the implant's hourglass design.

Nunley added that by incorporating the porosity and rough surfaces of the Lamellar technology into the lateral interbodies, an alternative now exists to the traditional PEEK and Titanium cages commonly used in direct lateral fusion procedures.

The company says its technology incorporates titanium with a surface roughness of 3-5 microns and is designed to allow for direct bony ongrowth. The technology also incorporates 500 micron longitudinal channels throughout the implant which, in conjunction with traverse windows, create an interconnected lattice designed to allow for bony integration.

The system includes a full range of implant sizes and is designed to work in conjunction with the company's Ravine lateral access system, offering a full line of instrumentation for the far lateral transpsoas approach.

Eric Major, K2M's president and CEO, said the regulatory milestones, coupled with the successful completion of the first surgical case late last year, "underscore our commitment to expanding our minimally invasive spine portfolio by bringing innovative and differentiated technologies and products to the global spine market." — WE

FDA CLEARED

CASCADIA™ Lateral Interbody System/Courtesy of K2M and photo creation by RRY Publications, LLC.

LEGAL

FDA Seeks Input on Intended 2016 Guidance Documents

Courtesy of the FDA

The FDA intends to publish a number of guidance documents in 2016. The agency also wants to hear from you regarding whether or not previously issued final guidances should be revised or withdrawn.

On December 28, 2015, the agency provided three lists for comment.

"A-List"

The "A-List" contains guidance documents the agency fully intends to publish during the upcoming year.

Draft guidance topics include:

- Medical Device Decision Support Software
- Use of Symbols in Labeling
- 510(k) Modifications
- Software Modifications
- 510(k) Third Party Review Program
- Companion Diagnostics Co-Development
- Use of Real-World Observational Patient Data to Support Decision Making for Medical Devices
- UDI Convenience Kit
- Public Notification of Emerging Postmarket Medical Device Signals

"B-List"

The "B-List" contains guidance documents the agency intends to publish "as resources permit."

Draft guidance topics include:

- Medical Device Interoperability
- Patient Access to Information
- Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies
- Patient Matched Instrumentation for Orthopedics
- Dual 510(k) and Clinical Laboratory Improvement Amendments Act (CLIA) Waiver by Application
- Defining the Unique Device Identifier (UDI)

"C-List"

The "C-List" contains final guidance documents that were issued in 2006, 1996, 1986, and 1976, subject to "focused retrospective review."

Final guidance documents include:

- Panel Report and Recommendations on PMA Approvals #P86-5 (Blue Book Memo)
- Statistical Guidance for Clinical Trials of Non Diagnostic Medical Devices
- Indications for Use Statement
- Medical Device Reporting: An Overview
- Guidance Document For Testing Bone Anchor Devices
- Guidance Document for Testing Biodegradable Polymer Implant Devices
- Continued Access to Investigational Devices During PMA Preparation and Review July 15, 1996 (Blue Book Memo D96-1)
- The Establishment and Operation of Clinical Trial Data Monitoring Committees for Clinical Trial Sponsors

Submitting Comments

The agency's Center for Devices and Radiological Health (CDRH) invites you to submit comments to docket FDA-2012-N-1021. Comments may include draft language on the proposed A-list and B-list topics, suggestions for new or different guidance documents, for which commenters should state the potential guidance topic, reasons the guidance is needed, and proposed policy or information for FDA to consider on the topic, or the relative priority of guidance documents.

The agency says you may also include suggestions that CDRH revise or withdraw a final guidance document that issued previously as part of its retrospective review, for which commenters should address why the guidance document should be revised or withdrawn and, if applicable, how it should be revised.

You can submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Current FDA and CDRH guidance documents can be found on the CDRH Guidance Document Web page. http://www.fda.gov/MedicalDevices/deviceregulationandguidance/guidancedocuments/default.htm. — *WE*

BIOLOGICS

New Synthetic Bone Graft Boosts Bone Regeneration

Researchers from Queen Mary University of London (QMUL) School of Engineering and Materials Science (SEMS) have manipulated the pore structure of a new bone graft to mimic natural bone tissue. The new graft is known as Inductigraft, and was able to guide bone tissue regeneration in as little as four weeks.

The study was co-led by Dr. Karin Hing, reader in Biomedical Materials at QMUL's Institute of Bioengineering. As indicated in the December 17, 2015 news release, "By eight to twelve weeks its performance alone matched that of the new graft mixed with the clinical gold standard, called autograft, which is made up of the patients' own bone containing living cells and growth factors."

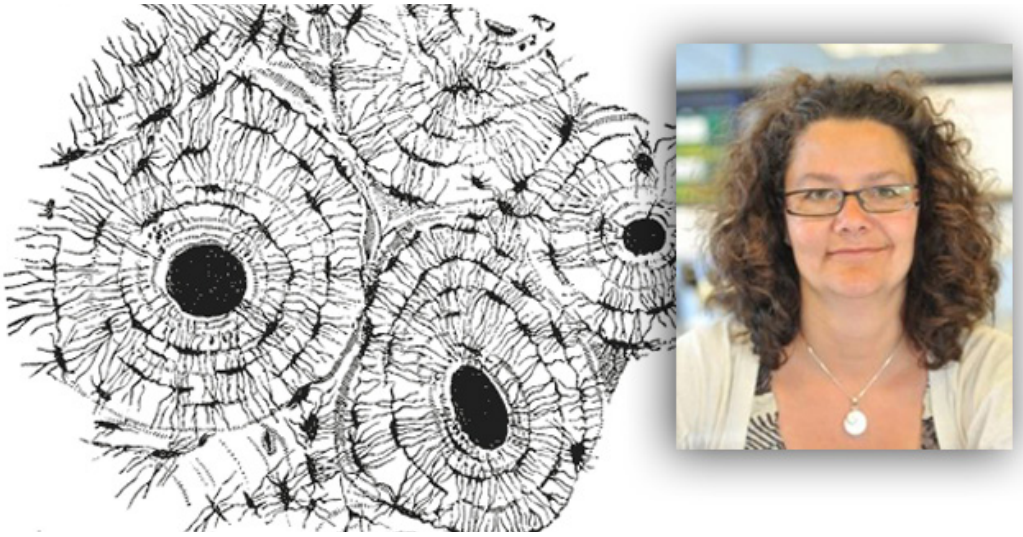
Asked what makes their approach so exciting and unique, Dr. Hing told *OTW*, "The combination of an optimised chemistry and an optimised pore structure. Regarding the former, the graft is made from a silicate-substituted calcium-phosphate, hydroxyapatite, which has a similar crystal structure to natural bone mineral. We believe that one of the key beneficial effects of this chemical modification is to alter the surface chemistry to aid recruitment and enrichment of key proteins to the surface of the graft, such as adhesion proteins and growth factors which in turn aids bone cell attachment, proliferation and development.

"As for the optimised pore structure, the graft has two 'levels' of porosity, macropores (that can be seen by eye) and strut pores (tiny pores within the dense 'struts' of the graft). Both of these levels of porosity are highly interconnected to enable cell and blood vessel penetration into the macroporosity and nutrient (and possibly even cell) transfer across the graft struts. This is similar to the sort of multi-level pore structure found in cancellous bone, where in addition to the 'sponge-like' macropore structure of cancellous bone, the individual trabeculae of bone contain an interconnected network of micro-pores known as lacunae, within which the osteocyte bone cells reside."

"Both these factors combine to produce a synthetic bone graft substitute material that is able to support and guide bone's native regenerative ability to promote bone regeneration at the treatment site."

"Having developed synthetic bone grafts which perform well in pre-clinical trials and clinical practice (products are available for clinical use through Baxter Inc. who acquired the university spin-out company ApaTech Ltd., that we set up to move our research from the bench to the bedside). The next challenge is to understand how a synthetic ceramic based graft is able to guide/promote osteoproductive behaviour. This knowledge could be used to further develop 'smart' synthetic bone grafts and should also be communicated to surgeons so that they can make more educated, confident decisions about the type of bone graft that they want to use in theatre. To this end we are running a number of different research projects looking at how different aspects of the grafts structure and chemistry may affect the biological response."

"That optimised bone graft substitute materials have the potential to support bone regeneration in situ, by adopting the bodies' native bone regenerative capabilities. For some patients this may negate the need for a second operative procedure to harvest autograft, so reducing theatre and patient recovery time and the added risks of donor site infection, morbidity and chronic pain." — *EH*



Dr. Karin Hing/Queen Mary University of London

Knock Down Inflammation With Maple Syrup!

You might want to consider maple syrup in your morning café…a group of researchers from Université Laval in Quebec have found that arthritis and other inflammatory diseases might be helped by a molecule found in maple syrup.

According to the December 22, 2015 news release, "Discovered in 2011, quebecol is the result of chemical reactions during the syrup-making process that transform the naturally occurring polyphenols in maple sap. After successfully synthesizing quebecol and its derivatives, Université Laval researchers under the supervision of Normand Voyer, Ph.D., a chemist with the Faculty of Science and Engineering, evaluated its anti-inflammatory properties."

Wikimedia Commons and Kevstan

Daniel Grenier, Ph.D., of the Faculty of Dentistry then developed an in vitro model for determining the anti-inflammatory potential of natural molecules. "We take blood cells called macrophages and put them with bacterial toxins," explained Professor Grenier. "Macrophages usually react by triggering an inflammatory response. But if the culture medium contains an anti-inflammatory molecule, this response is blocked."

"The most powerful derivative has a simpler structure and is easier to synthesize than quebecol," said Normand Voyer. "This paves the way for a whole new class of anti-inflammatory agents, inspired by quebecol, that could compensate for the low efficacy of certain treatments while reducing the risk of side effects."

The study's coauthors were Sébastien Cardinal, Jabrane Azelmat, Daniel Grenier, and Normand Voyer. The work was published in a recent issue of the journal *Bioorganic & Medicinal Chemistry Letters.*

Dr. Voyer told *OTW*, "The anti-inflammatory activity of maple syrup has been

demonstrated, we were interested in figuring out which compounds from the syrup could be responsible for the activity. We had a polyphenol in hand, quebecol, and we used it as a starting point."

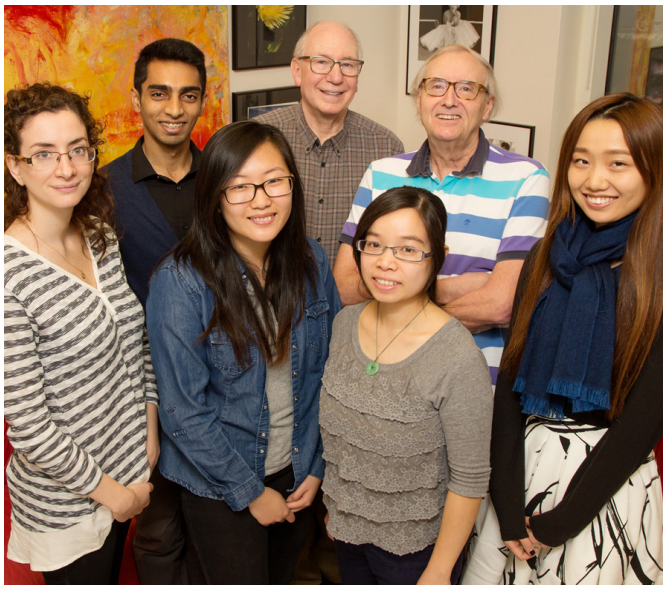
"Interestingly, quebecol is indeed anti-inflammatory in our in vitro model. Polyphenols in general are known to possess some anti-inflammatory activity. However, more interesting is the fact that some derivatives of quebecol have more powerful anti-inflammatory activity."

"This work is very preliminary and far from being ready for the clinic. However, it opens the door to the development of a potential new family of anti-inflammatory agents in the future. Also, the work demonstrated that maple syrup has significant nutritional value compared to other sweeteners. We are still pursuing our investigations." — *EH*

Strategy for Antibiotic Resistance: Repurposing

What to do about antibiotics and drug resistance? University of Illinois chemists and their collaborators have an idea… repurposing! There are drugs already approved to treat things such as parasitic infections and cancers, that—lo and behold—just may work as antibiotics agents against staph infections.

The work, which was led by Eric Oldfield, Ph.D., a chemistry professor at the University of Illinois, was published in the *Proceedings of the National Academy of Sciences.*



(L to R): Lici A. Schurig-Briccio, Noman Baig, Boo Kyung Kim, Robert B. Gennis, Xinxin Feng, Eric Oldfield and Tianhui Zhou / L. Brian Stauffer and University of Illinois Board of Trustees

According to the news release, "The researchers were interested in finding compounds that sabotage the bacteria's energy production line, shutting down cellular processes within the bacterium. These agents, called uncouplers, are already used to treat parasitic infections. Inspired by clofazimine, a leprosy drug that is now being used to treat tuberculosis, the researchers searched among drugs that are either already available or in development to find uncouplers based on their chemical structures." (Liz Ahlberg, December 22, 2015)

Dr. Oldfield told *OTW,* "It is important to understand that we are focusing on new leads having multiple mechanisms of action and that it will be challenging to optimize such compounds. Then again, Sir James Black, winner of the 1988 Nobel Prize in Physiology and Medicine, famously stated that, 'The most fruitful basis for the discovery of a new drug is to start with an old drug.'"

"About a decade ago we discovered that some drugs like amiodarone and dronedarone (heart drugs) acted as uncouplers (as well as sterol biosynthesis inhibitors in parasitic protozoa). More recently we found that the fertility drug clomiphene was also an uncoupler and was also found to kill staph, blocking cell wall biosynthesis (like penicillin). Screening several of these sorts of drugs led us to discover numerous potential leads that work by targeting both enzymes as well as cell energetics."

"It is possible that some of the leads might be developed to treat nosocomial staph infections (post surgery); and there are definitely new drugs needed for osteomyelitis, gunshot wounds etc." — *EH*

LARGE JOINTS

Teasing Out "Microdomains" in Tissues Could Help Meniscus Repair

A team of researchers from the University of Delaware (UD) and the University of Pennsylvania has clarified details on the structure and function of fibro-cartilaginous tissues. Their work could aid in the development of improved strategies to treat injuries such as meniscus tears…as well as new therapies for osteoarthritis and age-related degeneration. Their findings are reported in *Nature Materials.*

In the January 4, 2016 news release, Dawn Elliott, Ph.D., professor and chair of UD's Department of Biomedical Engineering, explained that "fibro-cartilaginous tissues are primarily made up of long, aligned fibers that confer strength and stiffness. It turns out, however, that they also have small non-fibrous regions, known as microdomains, that behave very differently from the fibrous areas."

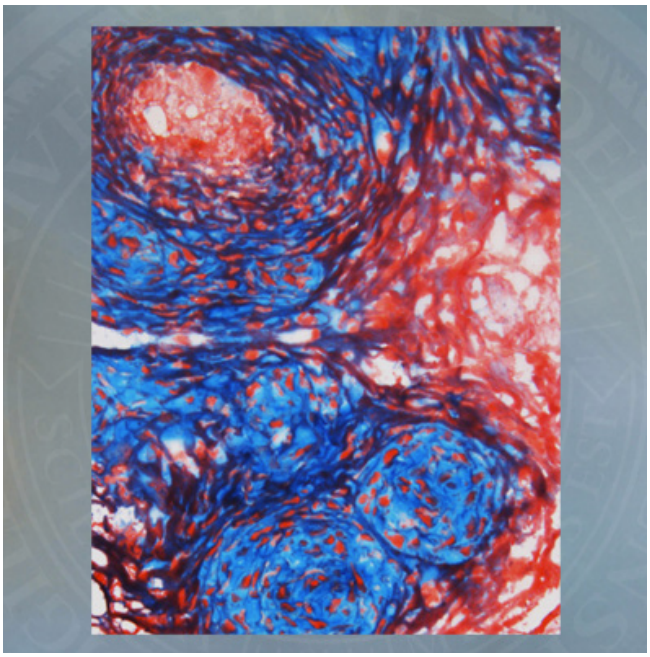
"Dr. Elliott turned to Randall Duncan, professor in UD's Department of Biological Sciences, for help in addressing the issue of cell signaling. With Duncan, the team found that the cells in the microdomains evidenced very high calcium signaling, while calcium signals switched on and off under mechanical loading in the fibrous regions."

"This told us that cells in these two regions behave very differently when the tissue is stretched, which is critical information in the development of therapies to treat disease," said Dr. Elliott.

Then, another researcher was brought in: Robert Mauck, Ph.D., associate professor of orthopedic surgery and bioengineering in the Perelman School of Medicine at the University of Pennsylvania.

As indicated in the news release, "Dr. Mauck and his team created a platform to study microdomain effects under normal and pathological conditions, enabling the researchers to investigate physical structure, mechanical loading and cell signaling under both actual and engineered conditions."

Drs. Elliott and Mauck told *OTW*, "We observed in histological sections that the 'idealized' aligned fiber structure of



Courtesy of University of Delaware

many dense connective tissues is not an accurate description of the actual structure. Instead, we found that there are micro domains of non-fibrous proteoglycan rich proteins throughout these tissues. Based on this observation, we asked ourselves what the function of those micro domains might be, and how they impacted the cells embedded in the tissue that are responsible for remodeling and repair during physiological loading activities."

"We were surprised by how dramatically different the mechanical behavior and cell signaling activities were in these two regions (fibrous and proteoglycan micro domains). We were also surprised to find the pronounced growth of the micro domains with age, disease, and body mass index in humans."

"This work is important given that the meniscus (and intervertebral disc and other fibrocartilages) are loaded and the cells within these tissues respond to load by remodeling or repairing damage. Our findings suggest that the response of the cells in the two regions may alter how effectively they respond to these mechanical loading cues, and this may promote further degeneration. Our engineered constructs that contain these micro domains and effectively mimic the behavior of native tissue will be an important tool for the development of drug and physical therapies to promote tissue repair." — *EH*

TKA Patients With Pain at Midterm More Likely to be Dissatisfied

A new study from the Lexington Clinic in Kentucky has found that patients undergoing total knee arthroplasty (TKA) who report pain 60-120 days postop are more likely to be dissatisfied at mid-term follow-up.

Cale Jacobs, Ph.D. is assistant professor in the department of orthopedic surgery at the University of Kentucky. He told *OTW,* "Approximately 15-20% of TKA patients have been reported to be dissatisfied with their surgery. With the continued increase in the number of TKAs performed annually in the U.S., this equates to more than 100,000 dissatisfied patients each year. However, before we can begin developing interventions to potentially improve satisfaction rates, we had to first investigate the underlying factors associated with dissatisfaction."

"Satisfaction after TKA is undoubtedly multifactorial and has been associated with patient expectations, disease severity, socioeconomic status, depression/anxiety, and race, among others. While multifactorial, the single largest risk factor of dissatisfaction roughly three years after TKA in our work was persistent pain three months after surgery. This finding emphasizes the importance of continuing to improve perioperative pain management, and that a multimodal approach must be maintained even after the patient has been discharged home."

"Knowing that poor mid-term satisfaction potentially hinges on preventing moderate to severe pain persisting longer than three months highlights the need for continued improvements in multimodal perioperative analgesia protocols." — *EH*

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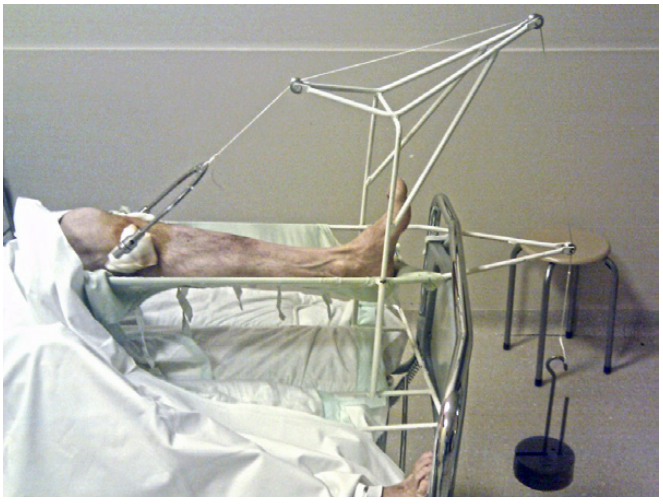
Study Challenges How Bone Fractures Heal

When a study demolishes a century-old belief about how fractured bones heal, it is labeled a "breakthrough."

That is what researchers at Vanderbilt University have achieved in their discovery that fibrin is not essential to bone healing—as everyone once thought. It turns out that it is the breakdown and clearance of fibrin that is essential to the healing process. Tiffany Parnell wrote in *MDNews* that the Vanderbilt study "alters a century-old belief about bone fracture healing."

As Parnell explained, when a bone is broken and normal vasculature is disrupted, the enzyme thrombin converts fibrinogen to fibrin. Fibrin is an insoluble protein that forms a fiber mesh at the site of the injury. Because doctors found fibrin present at every site of a bone fracture they believed, for a hundred years, that the fibrin was forming the scaffold for the bone to heal.

Not so, writes Jonathan Schoenecker, M.D., Ph.D., assistant professor of Orthopaedics, Pharmacology, Pathology and Pediatrics at the Vanderbilt Center for Bone Biology and senior author of the *Journal of Clinical Investigation*-published study.



Leg Splint/Wikimedia Commons and AfroBrazilian

It all began when Schoenecker received a grant to demonstrate the mechanism by which fibrin heals bone fractures. Orthopedic surgeons are concerned about their patients getting deep vein thrombosis. To prevent it they often prescribe anticoagulants. The researchers suspected that anticoagulant use may interfere with fibrin production.

"There's a lot of data that suggests that the use of anticoagulants has a negative effect on healing tissue," Schoenecker said. "Going into this project, the assumption was that the reason why patients were having a hard time healing their fractures or wounds was because we were reducing the amount of fibrin that was laid down. We thought that the template [for healing] wasn't there."

Schoenecker and his team of researchers from the Schoenecker Lab at Monroe Carell Jr. Children's Hospital at Vanderbilt hoped to determine how much fibrin was necessary to heal a fracture. Their goal was to find the dosage at which anticoagulants are effective at preventing thrombosis but do not deplete fibrin levels to the point that normal wound healing would be disrupted.

According to Parnell, researchers had hypothesized that fibrin was indispensable for fracture repair and that impaired fibrin clearance due to disruption of the fibrinolytic system contributed to healing complications. They tested their theory on three groups of mice and were astounded when the fractures on mice lacking fibrinogen healed normally. "It took six months for us to believe the research," Schoenecker said.

"If anticoagulants do have an effect on fracture healing, it sure isn't because of fibrin," Schoenecker said. "[The study] completely opens up what we can do pharmacologically because we now know that those two things aren't tied together. That's been the fear in orthopedics for a really long time—that the anticoagulant use would drop the amount of fibrin, which makes it so the template isn't there for healing. That's where this work is really a breakthrough." — *BY*

EXTREMITIES

Patient Attends Surgical Run-Through on Cadaver

Sam Barnes, a retired orthopedic surgeon from Tennessee, who broke his ankle several years ago, recently had a complete ankle replacement installed. The night before the surgery he attended a run-through of the procedure on a cadaver with his surgeon James McKinney, M.D., who wanted a test run before operating on his colleague. Besides the surgeon and his patient, company representatives were also on hand for the trial run surgery.

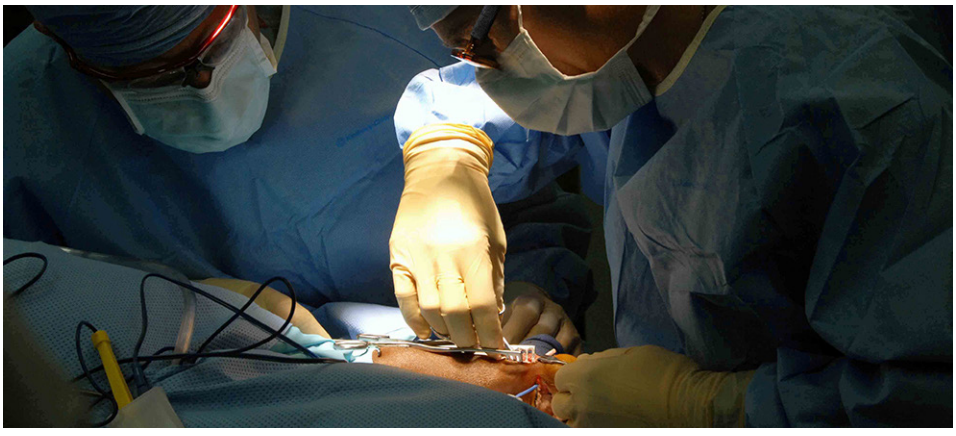
The ankle that was implanted is called the Scandinavian Total Ankle Replacement (STAR). According to *Herald Citizen* of Cookeville, Tennessee, writer Laura Militana, the ankle device is the only three piece mobile bearing non constrained, uncemented total ankle replacement to receive pre-market approval to replace a painful arthritic ankle joint due to post traumatic arthritis or rheumatoid arthritis

Militana wrote that fusion of the ankle had not been a recommended option for Barnes and the successful replacement surgery took about two hours.

According to the Small Bone Innovations' website, the STAR Ankle prosthesis consists of three components:

1. A tibial component with a highly polished flat articulation surface and two cylindrical fixation bars on the proximal side of tibia to anchor the implant in the subchondral bone of the tibia.
2. A talar component, also available in five different sizes for right and left. A ridge running anteroposteriorly in the middle of the gliding surface guides the ultra high molecular weight polyethylene mobile bearing sliding core.
3. The mobile bearing is a sliding core, the flat surface of which articulates with the tibial component while the concave shaped underside articulates with the convex shaped talar component. The anteroposterior articulation is guided by the longitudinal ridge on the talar component and the matching longitudinal groove in the underside of the mobile bearing sliding core.

Barnes told Militana that his pain has declined by 50% and he would recommend the implant, which he estimates can last for 10 years, to anyone who needs an ankle replacement. —*BY*



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Falls Among Elderly Direct Cost: $34 Billion

Approximately 30% of people age 65 or older fall at least once a year, turning falls into a major public health issue. In 2013, the Center for Disease Control and Prevention found that direct medical costs for falls in the U.S. totaled $34 billion. Fall injuries are among the 20 most expensive medical conditions and result in hospital costs averaging $35,000.

Wikimedia Commons and Banksy

EOS imaging, a company pioneering in 2D/3D orthopedic medical imaging, reported the first clinical results from a study designed to determine the correlation between certain sagittal balance measurements and the risk of falling in elderly patients.

The study involved 122 patients at high risk of falling. It was conducted by researchers at the Cochin Hospital in Paris with EOS imaging aimed at improving the screening and prevention of falls. The results of the study showed that specific parameters are significantly associated with the risk of falling and could be used to improve the individual assessment of falling risk.

Professor Christian Roux, Director of the Center for the Evaluation of Bone Diseases at Cochin Hospital in Paris, said: "The prevention of fall and fracture risk in the elderly is a public health priority and screening at-risk patients must be simple and reliable. The preliminary results obtained by the analysis of sagittal balance with EOS are extremely encouraging, especially in light of this need."

EOS imaging CEO Marie Meynadier said, "The analysis of sagittal balance and overall posture are emerging as key elements in the management of diseases related to ageing. The results of this preliminary study show how EOS systems can be used for the first time in prevention and screening. We are pleased to see that our solutions are enabling significant progress in this area."

EOS imaging designs, develops, and markets EOS, a medical imaging system dedicated to osteoarticular pathologies and orthopedics. The company is authorized to market in 48 countries, including the United States. — *BY*

SPINE

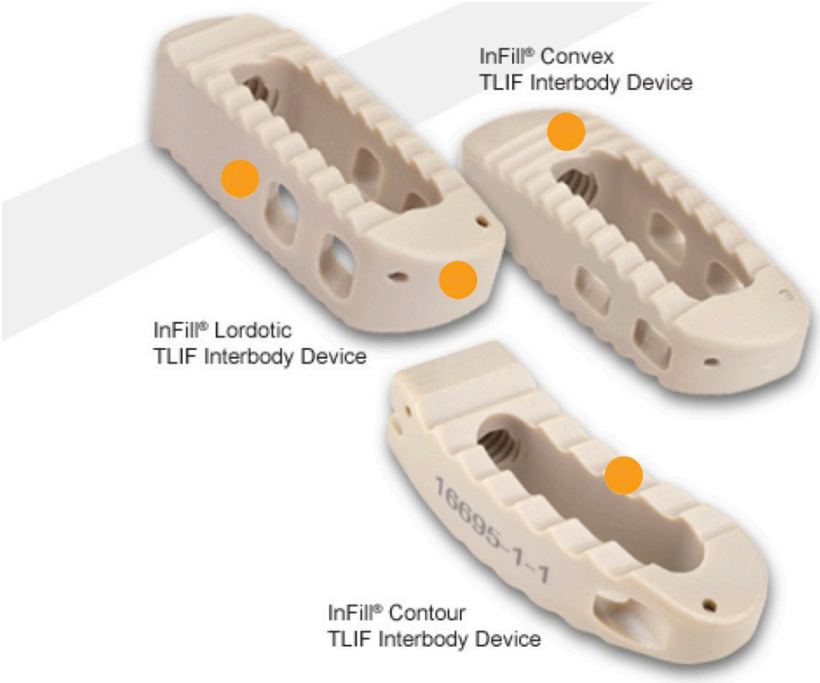
Pinnacle Spine: New Patent for InFill

Pinnacle Spine Group, LLC is announcing the third patent covering the company's InFill fusion technology. The patent, *Intervertebral Implants and Related Tools,* follows on the heels of patents related to spinal implants and methods of post-filling to provide for superior fusion results.

"This new patent significantly broadens our overall intellectual property portfolio and, from a commercial standpoint, meaningfully strengthens our patent position in the area of spinal fusion," said Zach Sowell, President of Pinnacle Spine, in the December 22, 2015 news release. Sowell added that "Pinnacle Spine plans to continue to work with surgeons and partners to improve the company's systems and promote the promising technology behind the InFill family of fusion systems. We believe that maximizing contact between graft and a well-prepared endplate is the best way to promote a robust fusion. The industry clearly agrees, as we are seeing more and more devices and systems adopting in-situ graft delivery. We are proud to be trend setters and look forward to a year of growth in 2016, with many exciting projects already underway."

Sowell told *OTW*, "The biggest challenge was to be sure we adequately protected the novel technology that we have brought to the industry. We are seeing rapid adoption with respect to the technology developed by Pinnacle, which tells us everything we need to know. We believe that by granting the third U.S. patent to Pinnacle, the Patent Office has recognized the unique aspects of the InFill technology. We are currently pursuing additional patent protection related to post-filling and related technologies through a number of U.S. and foreign applications."

"As far as the next six months, we are nearing the finalization of our next generation direct lateral implant, which will continue to optimize fusion when used with our InFill Graft Delivery System. We are about to close a deal with a major player within the spinal fusion industry to expand distribution of our lateral system. We are working with various biologics companies to ensure compatibility with our systems. We are also working to develop a study to examine the increased percentage of graft-to-endplate contact when using the InFill family of fusion systems in conjunction with the InFill Graft Delivery System. We expect an exciting year in 2016!" — *EH*



Courtesy of Pinnacle Spine Group, LLC

PEOPLE

Forbes Recognizes Rock Star Orthopedic Surgeon-To-Be

Forbes magazine has come out with its fifth annual "30 Under 30" list, a montage of leaders in all fields who are—and will continue to—make a major impact on their respective fields. Standing tall on that list is Chris Murawski, a medical student at the University of Pittsburgh. Murawski, who has published 52 articles in peer-reviewed journals, is on track to become an orthopedic surgeon. His areas of interest? Feet, ankles, and knees.

Murawski told *OTW*, "It's an incredibly exciting time in healthcare, and it's an honor to be included among such a distinguished group of individuals. I look forward to collaborating with this group during what is a revolutionary time in medicine, and it's stimulating to envision what may lie ahead."

Chris Murawski

Asked what research he is most proud of, Murawski noted, "Research is a team sport, and any recognition given to one individual is really an acknowledgement of the hard work done by an entire group of dedicated people. Collaborating and witnessing the building blocks that come together for any particular study is rewarding. With that said, I am proud of all of the research that I've been fortunate to play a part in because it has provided opportunities to work on great teams from all over the world, with incredible mentors. Regardless of the project, it's exciting to know the work that has been done may in some way contribute to improving patient care."

"My interest in the lower extremity came from my own ankle injury playing baseball in high school, for which I ultimately required surgery. Although it sounds like a terrible joke, I suppose it's not wrong to say that I 'fell' on this passion."

Asked about his thoughts on medical training, Murawski told *OTW*, "It's crucial to surround yourself with a group of mentors who are supportive, as well always willing to constructively criticize and offer direction. In this regard, Drs. Freddie Fu, MaCalus Hogan, Volker Musahl and Brian Klatt at the University of Pittsburgh and Dr. John Kennedy at Hospital for Special Surgery have all gone, and continue to go, above and beyond in training the next generation of orthopaedic surgeons. I am grateful for them and am keenly aware of the opportunities that they have provided me." — *EH*

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