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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: The 23 orthopedic companies we track lost 6.14% of their market value since mid-August. Clearly orthopedic equities weren't spared as concerns over a Chinese led global slowdown washed through the equity markets. A 6% pull back, however, may be viewed as a healthy correction within a longer term bull orthopedic market. Demand continues to rise and millions more patients are now insured. At these lower prices, companies like those on our Power Rankings look even more attractive.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	22.78%	(3.37%)	Nothing but good news. Beat estimates. MAKO, its signature acquisition, is performing very well. And the underlying fundamentals are still improving.
2	5	Smith & Nephew	20.19	(2.32)	Smith & Nephew's own unique orthopedic + wound care portfolio and its low PEG (P/E ratio to Growth rate) attracted buyers.
3	3	Orthofix	2.35	(4.65)	Wall Street's earnings estimates for OFIX up 10% in the last month. Investors are slow to pick up on it. Sounds like an opportunity.
4	4	Johnson & Johnson	28.44	(5.86)	JNJ did decline nearly 6% this past month, but its dividend payout rate and 56 years of increases, makes it the #1 haven in the storm.
5	6	Zimmer Biomet	30.35	(3.36)	Some Wall Street analysts wonder if Zimmer/Biomet merger synergies will counter currency woes. That assumes no integration issues with the merger.
6	9	Integra LifeSciences	13.74	4.24	Integra bought Tornier's Salto Talaris and Salto XT ankle-replacement and Futura toe-replacement products. Market responded accordingly.
7	8	RTI Biologics	7.50	(6.08)	Top execs get Executive Transition Agreements. Is RTI an acquisition candidate? At these prices, it would be a bargain.
8	2	Xtant	(16.41)	(9.31)	Profit taking by investors who only have a cursory knowledge of Xtant. It will take a couple or three quarters to attract the GARP buyers. But they will come.
9	7	Medtronic	27.92	(9.68)	Investors treating MDT like a proxy for global investing. Not the market leader in spine. Begs the question. How would MDT spine trade if it were spun off?
10	10	Globus Medical	30.87	(10.38)	GMED is setting the stage for expansion into the broader musculoskeletal implant markets with its reorganization and board upgrade.

Robin Young's Orthopedic Universe

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$1.32	$221	65.87%
2	MiMedx Group	MDXG	$10.12	$1,102	8.12%
3	Integra LifeSciences	IART	$64.10	$2,337	4.24%
4	K2M Group Holdings	KTWO	$21.08	$871	3.08%
5	Exactech	EXAC	$18.44	$259	2.79%
6	NuVasive	NUVA	$54.05	$2,645	2.58%
7	Tornier N.V.	TRNX	$23.76	$1,171	-0.38%
8	Wright Medical	WMGI	$24.55	$1,262	-1.09%
9	MicroPort Scientific	853	$0.39	$561	-1.54%
10	Smith & Nephew	SNN	$36.15	$16,172	-2.32%

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Alphatec Holdings	ATEC	$0.40	$40	-41.03%
2	Aurora Spine	ASG	$0.24	$5	-12.99%
3	LDR Holding Corp.	LDRH	$37.68	$1,092	-11.11%
4	Globus Medical	GMED	$23.46	$2,230	-10.83%
5	Medtronic	MDT	$69.90	$98,812	-9.68%
6	Bacterin Intl Holdings	BONE	$3.80	$45	-9.31%
7	CryoLife	CRY	$9.64	$286	-8.02%
8	ConMed	CNMD	$51.49	$1,426	-7.38%
9	RTI Biologics Inc	RTIX	$6.18	$356	-6.08%
10	Johnson & Johnson	JNJ	$92.93	$257,333	-5.86%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$92.93	$257,333	15.78
2	Exactech	EXAC	$18.44	$259	16.46
3	Globus Medical	GMED	$23.46	$2,230	18.06
4	Zimmer Biomet	ZBH	$100.20	$20,377	18.22
5	Stryker	SYK	$99.65	$37,524	22.14

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$54.05	$2,645	86.31
2	CryoLife	CRY	$9.64	$286	80.60
3	MiMedx Group	MDXG	$10.12	$1,102	67.47
4	RTI Biologics Inc	RTIX	$6.18	$356	35.76
5	Smith & Nephew	SNN	$36.15	$16,172	32.28

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$23.46	$2,230	1.48
2	Zimmer Biomet	ZBH	$100.20	$20,377	1.63
3	Exactech	EXAC	$18.44	$259	1.85
4	ConMed	CNMD	$51.49	$1,426	2.05
5	Smith & Nephew	SNN	$36.15	$16,172	2.10

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$54.05	$2,645	5.81
2	MiMedx Group	MDXG	$10.12	$1,102	4.50
3	Medtronic	MDT	$69.90	$98,812	3.41
4	Johnson & Johnson	JNJ	$92.93	$257,333	3.26
5	CryoLife	CRY	$9.64	$286	2.69

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$0.40	$40	0.19
2	Exactech	EXAC	$18.44	$259	1.04
3	Bacterin Intl Holdings	BONE	$3.80	$45	1.26
4	RTI Biologics Inc	RTIX	$6.18	$356	1.35
5	MicroPort Scientific	853	$0.39	$561	1.58

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.32	$221	35.21
2	MiMedx Group	MDXG	$10.12	$1,102	9.32
3	LDR Holding Corp.	LDRH	$37.68	$1,092	7.31
4	Medtronic	MDT	$69.90	$98,812	4.88
5	Globus Medical	GMED	$23.46	$2,230	4.70

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

AMA Raises Anti-Trust Objections to Anthem-Cigna and Aetna-Humana Mergers

BY ROBIN YOUNG

This week (September 8, 2015) the American Medical Association (AMA) slammed the proposed mergers of Anthem-Cigna and Aetna-Humana calling them, among other things, anti-competitive and in violation of the federal anti-trust regulations.

These conclusions came as a part of a newly released 2015 edition of AMA's *Competition in Health Insurance: A Comprehensive Study of U.S. Markets*, which offered an analysis of health insurance competition for 388 metropolitan areas, as well as all 50 states and the District of Columbia. The study was based on 2013 data which had been gathered from commercial enrollment in fully and self-insured plans and includes participation in consumer-driven health plans.

According to the AMA study:

- A significant absence of health insurer competition exists in 7 out of 10 metropolitan areas studied. Using the federal anti-trust guidelines to assess the degree of competition in a given market, these markets are rated "highly concentrated."
- In nearly 2 out of 5 metropolitan areas studied, a single health insurer had at least 50% share of the commercial health insurance market.
- Fourteen states had a single health insurer with at least 50% share of the commercial health insurance market.
- Forty-six states had 2 health insurers with at least 50% share of the commercial health insurance market. The 10 states with the least competitive commercial health insurance markets were: Alabama, Alaska, Delaware, Hawaii, Illinois, Michigan, North Dakota, Louisiana, Nebraska, and South Carolina. The 10 states that experienced that biggest drop in health insurer competitive levels were: Idaho, Illinois, Iowa, Louisiana, Missouri, Montana, New Jersey, Ohio, Texas and West Virginia.

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Effects of Mega Mergers

It is important to remember that the data in the AMA study is from 2013.

With Anthem potentially merging with Cigna and Aetna potentially merging with Humana, the levels of insurer concentration will increase significantly.

According to the AMA, the two prospective mergers would diminish competition in up to 154 metropolitan areas in 23 states.

Said AMA President Steven J. Stack, M.D., "A lack of competition in health insurer markets is not in the best interests of patients or physicians. If a health insurer merger is likely to erode competition, employers and patients may be charged higher than competitive premiums, and physicians may be pressured to accept unfair terms that undermine their role as patient advocates and their ability to provide high-quality care. Given these factors, AMA is urging federal and state regulators to carefully review the proposed mergers and use enforcement tools to preserve competition."

Anthem-Cigna Merger

Specifically, said the AMA, the Anthem-Cigna merger would further concentrate insurer market power in 85 metropolitan areas in 13 states. The states affected the most were California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, New York, Ohio and Virginia.

Combined, Anthem-Cigna would be the second largest health care provider (before an Aetna-Humana combina-

Anthem-Cigna	
Revenues (billions $)	$94.98
Employees	86,000
EBITDA (billions $)	$9.91

Aetna-Humana	
Revenues (billions $)	$109.72
Employees	105,800
EBITDA (billions $)	$7.65

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tion—which would push Anthem-Cigna to #3) after United Healthcare. The following table illustrates the size of the combined companies based on 2014 data.

Aetna-Humana Merger

According to the AMA, a merger of Aetna (currently the 2nd largest private health insurer) and Humana (#5) would further erode insurer competitiveness in 58 metropolitan areas in 14 states including Arizona, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Mississippi, Ohio, Texas, Virginia, Utah and Wisconsin.

The following table illustrates the size of the combined companies based on 2014 data.

AMA Versus Big Insurance

This is a clash of the titans.

Anthem, Aetna, Humana and Cigna are mammoth. So, however, is the AMA.

In terms of Washington, D.C. influence, AMA may be the top dog. It is, in fact, the second biggest spender on lobbying in Washington, D.C. behind the American Chamber of Commerce. Between 1998 and 2011, the AMA spent $264 million on lobbyists.

The American Medical Association (AMA) was founded in 1847 and is the largest association of physicians and medical students in the United States.

The AMA is also the source of the CPT coding system which pays most physicians for their work.

The issues it fights for on behalf of its members are legendary. Most recently it has lobbied intensively for:

- The Patient Protection and Affordable Care Act as a step toward providing coverage to all Americans.
- Raising Medicare payments to physicians, arguing that increases will protect seniors' access to health care. Since the enactment of Medicare, the AMA stated that it "continues to oppose attempts to cut Medicare funding or shift increased costs to beneficiaries at the expense of the quality or accessibility of care" and

"strongly supports subsidization of prescription drugs for Medicare patients based on means testing."

- Changing medical malpractice law to limit damage awards, which, it contends, makes it difficult for patients to find appropriate medical care. In many states, high-risk specialists have moved to other states with such limits. For example, in 2004, not a single neurosurgeon remained in the entire southern half of Illinois. The main legislative emphasis in multiple states has been to effect caps on the amount that patients can receive for pain and suffering. These costs for pain and suffering are only those that exceed the actual costs of health care and lost income.
- Opposing medical clinics in supermarkets and drugstores. The AMA identified at least two problems with in-store clinics—potential conflict of interest, and potential jeopardized quality of care.

So AMA is, in effect, taking the battle against health insurance mergers to their favorite battlefield, Washington, D.C.

Anti-Trust

Aetna responded to the AMA's allegation of anti-trust issues with this statement:

> "The AMA report focuses on competition in the commercial marketplace, which would not meaningfully change following an Aetna/Humana combination given Humana's very small commercial business. Humana's focus is on Medicare, a highly competitive segment where consumers can choose from an average of 18 private Medicare Advantage plans, in addition to traditional fee-for-service Medicare, which remains the choice of more than two-thirds (68%) of beneficiaries."

The American Hospital Association (AHA) disagrees.

The AHA, which mentioned specifically the Medicare aspects of the Aetna-Humana merger in their September 2, 2015 press release, said that the merger of Aetna and Humana would reduce competition under the privately run portion of the Medicare program—Medicare Advantage.

Specifically, the AHA, which represents some 5,000 hospitals, warned that putting Aetna and Humana together would give Aetna (the surviving company) too much power to raise prices and end choices for senior citizens who buy Medicare Advantage plans.

Enrollment in Medicare Advantage has increased significantly in recent years. Between 2010 and 2014 enrollment was up 42%. With baby boomers entering the Medicare rolls, that growth is not going to slow down.

Said Melinda Hatton, senior vice president and general counsel at the AHA, in a letter to Assistant U.S. Attorney General William Baer in the Justice Department's antitrust division and U.S. Secretary of Health and Human Services Sylvia Burwell: "The deal will not just eliminate current competition between Humana and Aetna, it will eliminate future competition between them. Humana is the second largest insurer of Medicare Advantage lives in the country. Aetna is the fourth largest."

Aetna, however, countered these fears by promising in its merger announcement to "drive better value and higher-quality health care by reducing administrative costs, leveraging best-in-breed practices from the two companies—including Humana's chronic-care capabilities that measurably improve health outcomes for larger populations—and enabling the company to better compete with more cost effective products."

Umm. Ok.

What makes this even more interesting from an anti-trust standpoint is that in 2008, the Department of Justice ordered Medicare Advantage divestitures in Las Vegas as part of the UnitedHealth Group's purchase of Sierra Health Services. Then, in 2012, the Department of Justice (DOJ) ordered Medicare Advantage divestitures in 51 counties as part of Humana's acquisition of Arcadian Management Services, Inc.

That raises a very interesting problem. Said the AHA in its letter to the DOJ: "The scope of the likely competitive harm here is so broad and so deep that the amount of divestitures required to preserve and grow competition may not be feasible from a practical standpoint."

Time to Go To the Mattresses?

Both the AMA and the AHA are slamming these insurance mega mergers. Clearly, combining four very large health insurers raises profound economic and public health concerns particularly when the analysis moves to specific metropolitan areas or states. Wasn't health care reform about greater efficiency, lower costs and better quality care? If one part of the health care system—the payers—become monopolistic and largely immune to price or product competition then, it would follow, all of reform is at risk.

The alarms have been raised and both doctor and hospital associations are going to the mattresses. ♦

Peer-Review Research Fails Reproducibility Test

BY ROBIN YOUNG

On August 28, 2015 the journal *Science* published the result of a massive reproducibility study in which researchers attempted to replicate 100 experimental and correlational studies which had previously been published in three peer-reviewed psychology journals.

The results were not good. After re-running the previously peer-reviewed and published studies the researchers found that only 36% of replications had significant results while 97% of the original, peer-reviewed published studies reported significant results.

The researchers used high-powered designs and original materials when available to test the reproducibility of these studies. And they found that the average (mean) effect size of the replication effects (M_r = 0.197, SD = 0.257) had dropped by almost exactly 50% from the mean effect of the original studies (M_r = 0.403, SD = 0.188).

This is a shocking result. Even more stunning, the lead author of the reproducibility study had submitted one of his own studies for testing and it failed.

How trust worthy are peer review studies?

The implications of this outcome are not insignificant.

Each year orthopedic peer review journals publish thousands of studies which, we ALL assume are used to guide patient treatment. Given this new information, should all peer review studies be treated with even more skepticism than they are currently afforded until they pass a reproducibility test? You can be sure this will not go unnoticed by payers.

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Here are the reproducibility study results in graphic form. This is sobering data. *(See graph on page 9.)*

The pace of clinical study publishing has been rising for decades. Not only is the funding from industry driving clinical study growth but ever more clinical research flows out of Asia, for example, and it is exponentially increasing the number of peer review studies in print.

This reproducibility study puts all this published research in a new light (the difference between 97% and 36% is huge) and begs many questions. Including why not encourage more reproducibility studies?

Blame the "Impact Factor"

Peer review journals are measured by something known as the "impact factor".

Pity the poor researcher who doesn't adapt their work to the "impact factor." They are not published and probably served you a Starbucks Frappuccino this morning.

The Impact Factor measures the average number of citations to recent articles published in a journal. It's frequently used as a proxy for the relative importance of a journal within its field, with journals with higher impact factors deemed to be more important than those with lower ones.

Here are the impact factors for the top 20 orthopedic journals. *(See table on page 9.)*

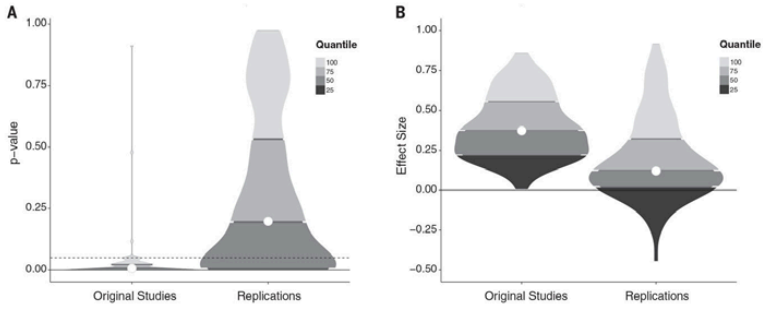
To maximize their journal's impact factor, journal editors understand that they need to publish innovative research. In fact there are many self-help articles for academicians to help them improve their "impact" in the peer-review publishing world. Here are four common suggestions:

- Think of a sexy title. "Academics who wish to improve the citation rate of their journal articles should ensure that title names are informative and memorable." – *Maximizing the Impacts of Your Research*, LSE Public Policy Group
- Be a networking machine. "Improving professional communication, such as through multi-author blogs, will help academics disseminate their research more broadly." – LSE Public Policy Group
- Issue a press release and perhaps even call *The New York Times*. (Source: *The Spine Journal*)
- Finally, add to the "dynamic knowledge inventory, a constantly developing stock of knowledge". – LSE Public Policy Group

Rank	Abbreviated Journal Title	Impact Factor
1	J BONE JOINT SURG AM	5.28
2	AM J SPORT MED	4.362
3	OSTEOARTHR CARTILAGE	4.165
4	J PHYSIOTHER	3.708
5	J BONE JOINT SURG BR	3.309
6	ARTHROSCOPY	3.206
7	KNEE SURG SPORT TR A	3.053
8	J ORTHOP SPORT PHYS	3.011
9	J ORTHOP RES	2.986
10	ACTA ORTHOP	2.771
11	CLIN ORTHOP RELAT R	2.765
12	GAIT POSTURE	2.752
13	J ARTHROPLASTY	2.666
14	J AM ACAD ORTHOP SUR	2.527
15	PHYS THER	2.526
16	SPINE J	2.426
17	SPINE	2.297
18	J SHOULDER ELB SURG	2.289
19	CLIN J SPORT MED	2.268
20	J SPINAL DISORD TECH	2.202

Source: Impactfactorsweekly.com

Fig. 1 Density plots of original and replication P values and effect sizes.



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Why Weren't These Studies Reproducible?

The studies in this reproducibility test were psychology studies and therefore, to a great extent, dependent on subjective measures. There were, therefore, many potentially confounding variables. Of course, the same can be said for orthopedic studies which rely on such subjective measures as the Visual Analog Scale or the Western Ontario & McMaster pain score.

But there are other reasons.

- Both the original study and the confirming study may be wrong. There may be an unknown variable acting independently of the measured variable.
- The original study result may NOT have been a false positive. The confirming study results may have been a false negative. There may well have been unanticipated factors in the sample, setting or procedure in the confirming study which altered the observed effect magnitudes.
- Publication and reporting bias. The replication studies were not affected by either of these biases but the original studies—especially the low powered ones—were. The replication studies significantly reduced these biases because of replication preregistration and pre-analysis.

And if a sad, clueless researcher decides to submit a paper which merely confirms another person's research? Then that poor sap is not impactful, not relevant.

Except that they are. Actually, they are critically relevant.

Blame the "Impact Factor." Reproducibility studies don't impact the impact factor.

It's Biology, Stupid

With apologies to James Carville and his catch-phrase "It's the economy, stupid," these studies are about biology, which is complex. And the smart researchers aren't looking for correlational data, they're looking for causational data. They are seeking to unlock the underlying mechanisms of pain or healing or degeneration. It's biology, stupid.

So, as the authors of the reproducibility study said in their concluding comments:

> "The observed variation in replication and original results may reduce certainty about the statistical inferences from the original studies but also provides an opportunity for theoretical innovation to explain differing outcomes, and then new research to test those hypothesized explanations. The correlational evidence, for example, suggests that procedures that are more challenging to execute may result in less reproducible results, and that more surprising original effects may be less reproducible than less surprising original effects."

Another way of thinking about this is to remember all of the important "failures" which led to advancing the knowledge of biology. When the outcomes are unexpected, dig into the failure and sometimes reveal an even more valuable insight. Here are two famous examples of failures which opened the door to major biologic advances.

- **Penicillin.** Wrong petri dish. Penicillin was discovered by Alexander Fleming in 1928 after a fortuitous accident (so Dr. Fleming would relate in later years) where he'd mistakenly left a petri dish open and it was contaminated by mold—except for one portion of the dish which seemed to be killing bacteria. Dr. Fleming was a famously poor communicator and orator so his discovery was ignored. He could not even recruit a chemist to help him extract and stabilize the new compound. He continued to persevere—even publishing a widely dismissed paper entitled "A Medium for the Isolation of Pfeiffer's Bacillus." Had other researchers paid closer attention, penicillin for medicinal would likely have sparked great interest and sped its development by almost a decade.
- **Heart Pacemaker.** Wrong part. In 1956 a medical engineer in Buffalo, New York, Wilson Greatbatch. was trying to build an oscillator to record heart sounds at the University of Buffalo when he reached into a box and pulled out a resistor of

the wrong size and plugged it into the circuit. When he installed it, it began to give off a rhythmic electrical impulse and he recognized the rhythmic *lub-dub* as the sound of the human heart. The beat, according to his 2001 obituary in *The New York Times*, reminded him of chats he had had with other scientists about whether an electrical stimulation could make up for a breakdown in the heart's natural beats. Before then, pacemakers were hulking machines the size of TVs. He spent two years refining his device and was awarded a patent for the world's first implantable pacemaker. His first pacemaker was implanted in a 77-year-old patient who lived 18 months with the device. Now, more than half a million of the devices are implanted every year.

Reproducibility Matters But So Does Failure

Reproducibility is one of the defining features of science. But so is failure and the bridge between the two is scientific inquiry and the embrace of the unexpected result. True scientists are curious and comfortable with complexity.

In medicine today there is a powerful trend to using correlational studies and mega-data to make medical decisions. Within that context, the fact that most of these studies did not reproduce well is problematic. But that's not the right conclusion.

Within the context of scientific inquiry these results provide, instead, the valuable opportunity to dig deeper. Perhaps also, these results can push peer review journals and their editors to publish or even encourage confirmatory studies.

Impact factor be damned. ♦

Wright Medical Reaps FDA Approval for Augment

BY WALTER EISNER

Wright Medical Group, Inc. announced on September 1, 2015 that the company has finally achieved FDA PMA (premarket application) Approval for its BioMimetic subsidiary's Augment Bone Graft as an alternative to autograft for ankle and/or hindfoot fusion indications.

It wasn't an easy process after Wright paid $380 million for BioMimetic in 2013.

First, there was a very contentious FDA orthopedic panel meeting and vote in 2011 and then an 18-page "not approvable" letter from the FDA in 2013 which said the company would have to perform a new clinical study. Finally in 2014, after filing an appeal with the agency's Dispute Resolution Panel, the company and FDA's Office of Device Evaluation (ODE) reached an agreement whereby the agency would accept an amendment to the company's PMA application.

After the amended PMA was submitted, the agency finally approved Augment.

Bob Palmisano, Wright Medical president and CEO

Augment Bone Graft/Wright Medical Group, Inc.

Augment is the first new recombinant protein technology for orthopedics to be approved by the agency in ten years and is only the third PMA approved orthopedic device in 2015. The other PMA approvals this year were for Vertiflex Inc.'s Superion Inter Spinous Spacer and Aesculap Implant System's activLArtificial Disc.

Robert Palmisano, Wright's president and CEO, said the approval "underscores the significant effort and perseverance from our clinical trial investigators and Wright's clinical, regulatory and legal teams to bring the product to market."

The approval of Augment "marks a capstone achievement that demonstrates the strength of our science and provides a breakthrough therapeutic option as an alternative to autograft in ankle and hindfoot fusion procedures."

The company will begin commercial sale and distribution of graft in the U.S. and believes this product, as well as its PDGF (platelet-derived growth factor) technology platform, "will be important drivers of the long-term growth of our business for years to come," continued Palmisano.

Christopher DiGiovanni, M.D., the lead investigator for the product's pivotal trial and chief of the Foot and Ankle Service in the Department of Orthopaedic Surgery at Massachusetts General Hospital, Harvard Medical School, said the FDA Approval, "provides a valuable new therapeutic healing option as an alternative to autograft in ankle and/or hindfoot fusion procedures, which is especially important since the outcomes of these interventions can at times be complicated by delayed union or non-union."

Augment

Augment is a blend of calcium phosphate (beta-TCP), bovine collagen and human platelet derived growth factor.

Augment's beta tri-calcium phosphate is the scaffold upon which bone is expected to grow after surgery. The human platelet derived growth factor (rhPDGF-BB) is the signaling protein that triggers new bone growth in the ankle. The conclusion of Wright's clinical study was that the matrix plus the biologic accelerated fracture healing and enhanced joint fusion with no evidence of ectopic bone formation (a plus over Medtronic's Infuse) and no evidence of toxicity.

Augment's PDGF is created using recombinant DNA technology which is more than two decades old and has been used by spine surgeons and other physicians in hundreds of thousands of patients globally.

PDGF is a naturally occurring protein and one of the primary growth factors released when platelets activate and degranulate in response to injury. PDGF is responsible for triggering a number of cellular events critical to bone growth and healing.

"As an FDA-approved alternative to autograft in ankle and/or hindfoot fusion procedures, Augment offers a clear patient benefit by avoiding secondary surgical sites for the harvest of autograft tissue, which can result in prolonged harvest site pain in some patients," stated the company announcement.

Anticipated Sales

The company has guided analysts to expect sales in the U.S. to ramp up gradually during the first six months after launch of the product while hospital value analysis committees review Augment and physicians get educated about its use. Augment's sales, say analysts, are likely to be in the range of $10 million to $12 million in the first seven to eight months post-approval. Sales will begin in the next several weeks once the company builds inventory and begins to fill up its U.S. distribution network.

FDA Drama

Augment is now ready for the market, but the drama of the FDA road to approval will not soon be forgotten by regulatory staffs at device companies.

Orthopedic panel member Brent Blumenstein, Ph.D., a statistical consultant said Augment's trial had "no meaning." Agency staff had also suggested a risk

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for "potential" cancer formation in patients receiving Augment based on a Black Box warning for a Johnson & Johnson product called Regranex. Augment contains the same PDGF molecule as Regranex. Regranex is FDA approved for use as a foot ulcer treatment.

Right before the panel was about to vote, Sam Lynch, D.M.D., D.M.Sc., founder of BioMimetic made an unscheduled and impassionate presentation to the panel.

"Please," he pleaded, "judge our product by our clinical evidence, not some other product." Lynch told the panelists that the company's recombinant human platelet-derived growth factor (rh-PDGF) had been in clinical use for over five years, in 250,000 patients as a dental product (sold under the brand name GEM 21S). Furthermore, Lynch pointed out, 600 patients in the U.S., Canada and Europe had already been treated with Augment and not one significant adverse event was ever reported.

The final vote was 12-6 in favor of approving Augment as a safe treatment for ankle surgery.

The panel members spoke publicly about their votes. Panelists and clinicians Glenn Johnson, M.D., and Sam Nasser, M.D., Ph.D., both said they were swayed by Lynch's summation and were openly critical of the FDA for not presenting the safety record of the company's dental product. When the panel was discussing adverse reaction definitions, Nassar said he thought the agency came in to the meeting with an agenda. Mark Malkerson, the agency's representative on the panel, gamely told the panel that the agency would endeavor to do better in the future.

The panel went on to vote 10-8 that Augment for ankle fusion surgery was effective and, finally, voted 10-8 that this PDGF biologic product when used by surgeons in hindfoot and ankle surgery, delivered benefits that outweighed the risks.

But the panel recommendation wasn't enough for the chastised agency staff which issued the 18-page "not approvable" letter saying the company would have to perform a new clinical study. That's when Wright Medical's regulatory staff went to work and worked the appeals process and final approval.

Biggest Pure Play Extremity Supplier

Wright Medical's FDA victory comes as the company is finalizing a merger with another extremities company, Tornier. Shareholders approved the merger on June 18, 2015. With the merger, the new Wright Medical will be the largest pure play supplier of extremity implants and instruments with sales of $650 million and a double digit sales growth future to, most analysts expect $825-$875 million by 2016.

Extremities is the place to be in orthopedics these days with comparatively less pricing pressure than other orthopedic sectors, a growing backlog of surgeries, high single-digit procedure growth rates and rising levels of implant and instrument innovation.

According to an October 28, 2014 RBC (Royal Bank of Canada) Capital Markets survey, approximately two-thirds of U.S. surgeons said that they have "seen no signs of increasing pure implant pricing pressure in forefoot, midfoot and hindfoot implants and in ankle fusion procedures at their hospital/practice over the past 12 months, which makes foot/ankle one of the few orthopedic markets with little to no pricing pressure."

Additionally, continued the survey, RBC believes that "mix benefits from continued penetration of higher-priced implants (i.e., hammertoe implants and total ankles) are adding to the overall U.S. foot/ankle market growth. This gives us confidence that the U.S. foot/ankle market can continue growing 10%+ y/y in 2015."

In addition to Augment, Wright is in the process of launching its Infinity total ankle, which management claims is more bone conserving, easier to implant and more durable long-term relative to other total ankles on the market.

Foot and Ankles' Fab Five

The merger of Wright with Tornier will mean that five companies (Arthrex,

DePuy Synthes, Smith & Nephew, Stryker/SBi and Wright Medical) will have approximately 78% of the foot/ankle market. According to the RBC survey, surgeons also selected the same companies as the companies with the best products and training programs for physicians. About 20% of U.S. surgeons listed SYK/SBi as the manufacturer with the best product/procedure training, followed by DePuy Synthes at about 18% and Arthrex at about 16%, with Wright Medical was #4 on the list at about 14%.

Wall Street Expectations

While the company expects U.S. sales of Augment over the next seven to eight months to be in the range of $10 million to $12 million in an ankle and/or hindfoot fusion procedures market of approximately $300 million, Needham & Company analyst Mike Matson said pricing could limit adoption.

"On one hand, Augment has strong clinical evidence from its pivotal trial to support its use which should help it navigate hospital value committees. On the other hand, we think that Augment is an expensive product with a cost of $2,500-$3,000 per procedure (which places it above stem cell bone graft products but below Infuse). Given the price, we think that Augment ends up mostly being limited to higher risk patients including smokers, diabetics, revisions, and/or post-traumatics. As a result, we think a more realistic long-term annual sales target is $100 million (which should still provide a multi-year growth benefit)."

Matson also notes a possible upside, and risk.

There is potential for Augment to be used off-label in other extremities procedures and even other orthopedics procedures such as in spine and trauma. Given Medtronic plc's issues with Infuse (the last biologic approved by the FDA), it remains to be seen how tightly the company polices Augment use. "We think that it's in Wright Medical's interest to try to do what it can to prevent off-label use," added Matson.

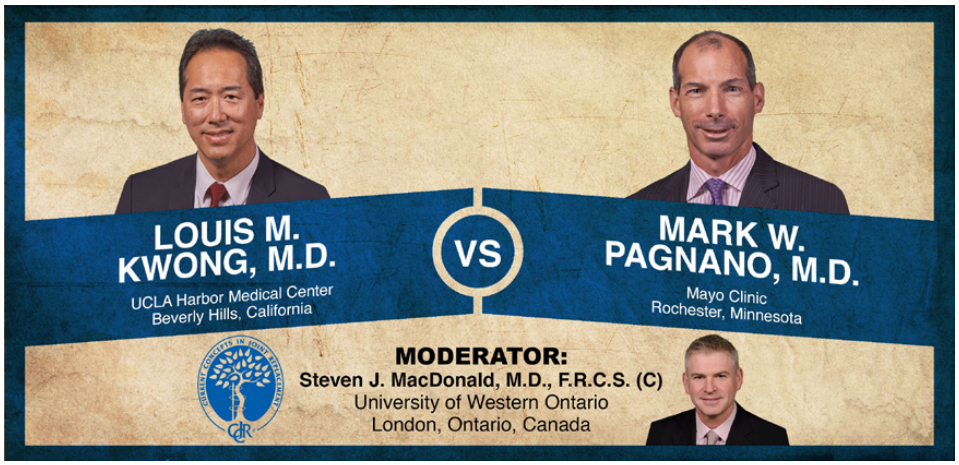
Given the long and torturous regulatory road and the company's painful Justice Department deferred prosecution agreement experience a couple of years ago, Matson is probably right.

Wright Medical's got a good thing going as it is. ♦

Kwong vs Pagnano — The Cementless TKA: Lifetime Guarantee on Parts & Labor

BY OTW STAFF

This week's Orthopaedic Crossfire® debate was part of the 16th Annual Current Concepts in Joint Replacement® (CCJR) – Spring meeting, which took place in Las Vegas this past May. This week's topic is "The Cementless TKA: Lifetime Guarantee on Parts & Labor." For the proposition is Louis M. Kwong, M.D., of the UCLA Harbor Medical Center, Beverly Hills, CA. Mark W. Pagnano, M.D., Mayo Clinic, Rochester, Minnesota is in opposition. Moderating is Steven J. MacDonald, M.D., F.R.C.S.(C). from the University of Western Ontario.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Kwong: Cementless total knee arthroplasty was first explored over three decades ago. Early failures of cementless total knees were attributed primarily to failure of the tibial and patellar components which were a result of a number of factors such as implant design, material failure, inferior polyethylene, metal-backed patellar components -- all of these factors contributed to osteolysis and early failure.

Despite this, early designs did demonstrate the ability to achieve good to excellent, intermediate to long-term follow-up. In Aaron Hofmann's series at 12 years, 93.4% survival. Leo Whiteside's series at 15-18 years, 98.6% survival, but when no cementless patella was utilized. And Merrill Ritter's series at 10 years, 100% survival of the femoral component, 97.4% survival of the tibial component, but a patellar failure rate of 16.4%, demonstrated that further work was needed in this area.

Porous tantalum has been an important contributor to the clinical success of modern cementless total knee replacement. It has this reticulated trabecular geometry, which emulates the structure of human cancellous bone. The pores are shaped like a dodecahedron—a 12-sided figure with each side shaped like a pentagon and up to 85% of the material is porous by volume.

The first prosthesis that was developed with the use of this material was a monoblock porous tantalum tibia. This is a single piece design with the polyethylene direct compression molded into the all porous tantalum base with interference fit achieved through the hexagonal pegs and fixation holes which are dimensionally smaller in size. The next prosthesis was a monoblock patellar component. This is not a metal backed component. It is a single piece, direct compression molded with thick polyethylene on the periphery to address the design deficiencies of earlier generation patellae.

Mayo Clinic reported their five year experience with 117 of these cementless tibias and they found no difference in survival compared to a cementless implant. They had a 3.5% overall reoperation rate and no revisions of this monoblock cementless tibia for aseptic loosening.

Our experience at Harbor-UCLA closely reflects that of the Mayo experience. We had 115 patients, average 7 years, up to 11 year follow-up. These were all cementless reconstructions with a monoblock tibia, monoblock patella, and a titanium fiber mesh PS femur. This is a non-selected series, all performed by orthopedic residents. We had 95.7% survival. Five patients did undergo revision. One died secondary to pulmonary embolism. But there was no x-ray evidence of osteolysis or loosening. No revisions for aseptic loosening, with high patient satisfaction.

Now what are some of the advantages of eliminating cement? Eliminating concerns associated with cementing like monomer induced hypotension; thermal necrosis of bone; and possible third-body wear from retained debris. But perhaps the greatest savings, is

the savings in time. We saw an average 18 minute reduction in OR time by eliminating the steps which are important in doing a technically good job in cementing. Time savings due to the shorter operation time—we reduce the time under anesthesia; with potential reductions in infection risk and possible decrease in overall morbidity and mortality.

So in summary, performing cementless total knee is straightforward and relatively easy. The intermediate to long-term clinical performance has been good to excellent. While it is not possible to give you a lifetime guarantee on parts and labor, there are clinical outcomes that demonstrate that cementless fixation should be considered as a reasonable alternative to cemented fixation.

Dr. Pagnano: It's my contention that in 2015 cemented fixation remains the gold-standard for total knee arthroplasty fixation.

I think we all agree that the goals of total knee replacement are to alleviate pain and improve function for our patients. We want to do that in a way that's reliable, reproducible and durable. In most series, cemented fixation gets good initial fixation, which helps contribute to that reliable pain relief and the technique has proved reproducible over decades of use. It's not difficult to understand and put into play the best way to cement a total knee replacement and make it reproducible. If we look at the durability, there's lots of data out there on the durability of cemented total knee constructs, and now there's survivorship out to 15 or more years from multiple centers around the globe.

The Mayo Clinic study that won the Knee Society award in 2006…1,000 cemented cruciate retaining total knee replacements of a single design… the 15 year survivorship free of revision for aseptic loosening was 98.6%. Hard to improve on that.

We then look away from single surgeon or single center series to registry data from the English, the Australian, the Swedish and the New Zealand registries. In every single example, cemented fixation does a little bit or a lot better than non-cemented fixation.

So often you'll hear a case, well maybe cement is okay for the elderly, but we're in a new era where we're introducing total knee replacement to younger and younger patients. There are series from 10 years ago, with 10 and 8 year data, again 94-98%, but more recently there's 30-year data available from New York with 82% survivorship with aseptic loosening as the endpoint.

In conclusion, I think the answer to the durability question is…at 15 to 20 years loosening of cemented total knee replacements is a relatively uncommon problem. In fact, the most common problems in the first 20 years after cemented total knee replacement are infection, instability, stiffness and periprosthetic fracture. Those are problems that are independent of fixation type. Those aren't going to disappear by moving to an uncemented implant. Can uncemented fixation work? It certainly can. There are a number of single surgeon series that have 10 to 20 year data that show good results. But I would make this contention…if you look at any single knee design, it's difficult to show any series in which the uncemented version of that design has outperformed the cemented. So pick your favorite manufacturer, pick your favorite knee implant design and do this head-to-head comparison… the cemented always beats the uncemented.

The further advantages of a cemented knee—it's technically a little more straightforward, the bone cuts that are necessary during the surgery are probably not quite as demanding since the cement acts as a grout and helps to make up for small differences in the bone cuts.

The question of efficiency or speed—that's a plus or a minus. No cement to deal with—probably a small advantage and a small incision surgery. Once fixed, the question is, 'Is it more durable?' Well, I await data to show that is actually the case.

No question that there are some disadvantages. While the Mayo Clinic has had good results with an uncemented tibial component as outlined in the previous talk, others have not replicated that experience. There have been trabecular metal tibias that have failed early, that result in pain and unhappy patients relatively early after surgery. Further the uncemented knee is a little more difficult to work up if it becomes painful.

So in summary, the studies of uncemented implants have not demonstrated better long-term fixation than cement to date. Is cement perfect? Clearly not. Is it better than uncemented to date? I would say yes. So at present,

the cemented total knee is the fixation standard. Uncemented knees need better reliability and simpler reproducible techniques. This may happen in the future, but it hasn't happened yet.

Moderator MacDonald: Are we there in 2015, Louis, are we there? And the reason I'm asking that is certainly…and Mark brought it up…not just in fixation, but in bone preparation. I'm not sure there have been massive advances yet in the bone preparation and being able to get that good interface, so what are your thoughts on today?

Dr. Kwong: I believe that we are on the threshold of the cementless total knee coming of age. But so many factors impact the longevity of the reconstruction—surgical technique, handling of soft tissues, and for the cementless, the preparation of the bony interfaces. All play a role in the clinical outcome for either cement or cementless.

Moderator MacDonald: Mark, what do you think needs to be done to get us there, if we should even go in that direction?

Dr. Pagnano: Fundamentally, I don't think our understanding of what routinely makes an uncemented total knee work has actually improved over the last decade. While we're all fond of looking at new materials, we saw some examples of a trabecular metal component that seems to have a good track record, and yet the same manufacturer introduces a new trabecular metal component and it's been pulled off the market. So we don't quite understand what makes a total knee that's uncemented work perfectly. For 10 years, or longer, we've continued to argue that total knees are going to go the direction of total hips, but I think the forces around a total knee are fundamentally different than those around a total hip.

Moderator MacDonald: At this point in time, we really at this point of time we have achieved 98% survivorship for cemented total knee fixation and I think for cemented total hip. This is a global audience and while in North America we're certainly biased towards resurfacing the patella, one way to do a cementless total knee would be to just leave the patella unresurfaced and you would not have to experiment with a new design for cementless patellae. What are your thoughts on that?

Dr. Kwong: I find that in speaking with a lot of surgeons who do not resurface the patella, it's specifically what you're referring to is they don't want to deal with problems referable to the patellofemoral joint often thought of as the low back or weak area of the knee. Potential problems with failure fixation, whether it's cemented or cementless.

I just want to comment on Mark's statement, which I think is very important to elaborate more on…the recall of a new version of that prosthesis was actually a voluntary recall, a class 2 recall. Same material, same basic design, yet there was a 0.61 complaint rate out of about 7,400 implants, a complaint of radiolucency and some revisions for loosening. So it shows it is not just the material, and not just the mode of fixation, but all these other factors. Subtle changes in design. Surgical technique. Things for which you started off this discussion session with emphasizing how the preparation and things that are in control of the surgeon all have an impact on the outcome.

Moderator MacDonald: Gentlemen, I thank you for a very well balanced debate. I think we had an excellent discussion. ♦

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

COMPANY

Xtant Medical Receives FDA Clearance for Cervical Plate

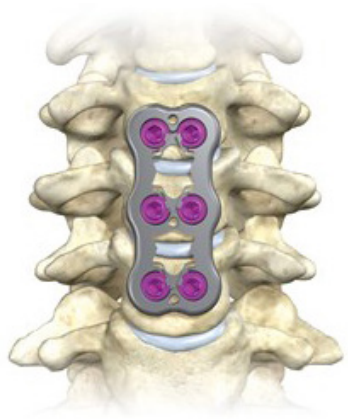
Xtant Medical Holdings, Inc., formerly known as Bacterin and X-Spine, announced on September 9, 2015 that the company's Aranax Cervical Plate has been cleared for the market by the FDA.

The company says the implant is the "latest generation of anterior cervical fixation with an enhanced locking mechanism, low profile features, increased screw angulation and intuitive instrumentation."

Last year, there were approximately 220,000 cervical plating procedures performed in the U.S., according to the 2015 iData report. The company says its addressable market for Aranax exceeds $160 million in the U.S.

Indications for the Aranax implant include fusion on one to four contiguous levels of the cervical spine, through an anterior approach (C1-C7 inclusive). The company claims the sterile packaging will reduce facility processing costs for hospitals and improve procedure planning. Aranax project team member, neurosurgeon Brandon Scott, M.D., stated, "The prepackaged sterile implants and streamlined instrumentation are both beneficial and convenient. This translates to a direct cost savings for facilities while maintaining continuity of care for patients."

According to *Spine-Health*, the application of an anterior cervical plant can add considerable stability to the spinal construct. The plates were developed in the 1980s when their use was restricted to long fusions. Surgeons are now also using them for single level procedures and it has become commonplace for surgeons to use a plate as a routine addition to a cervical fusion.



Aranax Cervical Plate/Xtand Medical Holdings, Inc.

The company will make the system available to a limited list of surgeons in the fourth quarter of 2015, with a full launch following in early 2016. — *WE*

K2M's Mono Plate Scores Regulatory Daily Double

K2M, Inc.'s mono cervical plate system has scored a regulatory double with 510(k) clearance from the U.S. FDA and CE Mark in Europe.

The regulatory victories for the company's Pyrenees Mono Cervical Plate System, the company's latest addition to its family of Pyrenees products, allows for the global availability and expansion of the product. The mono plate is the third offering in the Pyrenees family of cervical plates, which also includes a Constrained Cervical Plate System and a Translational Cervical Plate System.

The slim-profile design, according to a September 3, 2015 announcement, "allows for a single point of fixation per level for improved visualization in-situ. The posterior profile of the plate is designed to reduce plate migration in-situ during screw insertion. With screws manufactured from Titanium Alloy and plates manufactured from Commercially Pure Grade II Titanium, the system includes one- and two-level plates."

Mina Foroohar, M.D., a neurosurgeon and president of Northwest Neurosurgery Institute in Arlington Heights, Illinois, said: "Compared to a traditional two hole plate, K2M's monoplate's narrow profile, offers easier use while working under a microscope and provides me with an opportunity to perform less lateral retraction than a wider cervical plate." Douglas Moreland, M.D., a neurosurgeon and clinical assistant professor of neurosurgery at the University at Buffalo in New York, said the plate is, "…very user friendly, as the plate is smaller and requires only one screw per level, which has allowed me to save time during both vertebral body prep for the plate and screw placement."

The company says the plates allow for precise plate contouring because they do not have bend zones. In addition, the plates are designed with lordotic curvature to minimize intraoperative contouring, and all plates can be bent anatomically "without compromising the ability of the screws to lock at any angle." The plates also feature K2M's proprietary tifix locking technology and do not require an additional locking mechanism, as each screw head forms an autogenic lock to the plate upon insertion. — *WE*

Pyrenees Mono Cervical Plate System/K2M, Inc.

Medtronic Spine Sales Rising With Scale

Medtronic plc's spine sales of $763 million for the quarter ending August 31, 2015, kept up with the general growth of global spine sales. But U.S. sales of $518 million lagged behind the market.

Courtesy of Metronic

With an extra selling week, spine sales grew a reported 7%. On a constant currency basis, sales rose 3%. Sequentially, those sales accelerated from a negative 2% growth rate during the immediate past quarter.

Once again, Infuse was the star with sales growing in the low double digits. Core spine was flat globally and declined in the mid single digits in the U.S., and interventional spine declined in the mid single digits globally and high single digits in the U.S., adjusted for the extra week.

Affordable Care Act and Outlook

Omar Ishrak, the company's president and CEO, told analysts on September 3, 2015, that credited for revenue growth was an increase in U.S. surgical procedural volumes driven by an improving economy and the Affordable Care Act.

The company said sales will improve in the upcoming quarters, resulting from recent realignment of the RTG (Restorative Therapies Group) commercial

sales management and upcoming and recent product launches including; Elevate Expandable Cage, Solvera Voyager system, Prestige LP cervical disc, inner-body cage, anterior cervical plate system and the anatomic PTC (pure titanium coating) interbody spacer. Long term, the company is focused on using an "integrated strategy" that takes advantage of its capabilities in capital equipment and surgical tools.

Scale, Scale, Scale

In other words, a broad bag of products.

BMO Capital Market analyst, Joanne Wuensch said while it is clear that a broader bag of products will help in negotiating with hospital purchasing groups, "likely the more politically correct way to communicate the point is that it will provide incremental economic value to its customers, which will be the key to accessing customers. For example, while Medtronic does not have hip or knee products, management did laude CMS's [Centers for Medicare and Medicaid Services] proposed bundled payments for these products, which likely bodes well for paving the way for more value-based health care in the U.S."

Strategy for Growth

Wuensch noted that spine has been a "drag" on the company's overall portfolio for some time. She added that while she and her analysts had anticipated that the company might spin out its spine division, "it seems to be hunkering down, investing, and redirecting, taking a page from the CVG [cardiac and vascular group] playbook to cross-sell and integrate technology opportunities for economic and clinical outcomes."

She pointed to the company's "tangible" changes to the spine group. Those changes include:

1.) Integrating the sales force in the U.S. and in Europe, increasing efficiency in cross-selling
2.) Focusing on the surgical synergy concept, including navigated procedures in spine, driving it more to a standard of care (management estimates that today only 14% of core spine procedures are navigated)
3.) Providing a 'laser focus' on improving innovation in spine and improving product release cadence

In short, Medtronic has a strategic plan to stop being a market share donor and getting back to competing for a bigger piece of the spine pie. — *WE*

BIOLOGICS

FDA Clears Xtant Medical's Bone Putty

Xtant Medical Holdings Inc., a company in Belgrade, Montana, whose subsidiary, Bacterin International, Inc. makes regenerative medicine products has received FDA 510(k) clearance for its OsteoSelect PLUS. The product is a demineralized bone matrix, comprised of OsteoSelect Putty but with the demineralized cortical chips.

Adding cortical chips to OsteoSelect putty eliminates the need to mix bone chips and demineralized bone matrix (DBM) putty intra-operatively, saving time and reducing graft variability.

"We are very pleased with the FDA's decision to approve [sic] OsteoSelect PLUS for marketing and distribution," said Gregory Juda, Bacterin's chief scientific officer. "We developed this next generation bone graft material in response to surgeon demand using design input from surgeon customers.... This is the first 510(k) approval [sic] for Bacterin International since becoming a subsidiary of Xtant Medical."

Xtant Medical Holdings develops, manufactures and markets regenerative medicine products and medical devices for domestic and international markets. — *BY*

Courtesy of Xtant Medical

LARGE JOINTS

Insomnia Worsens Osteoarthritis Pain

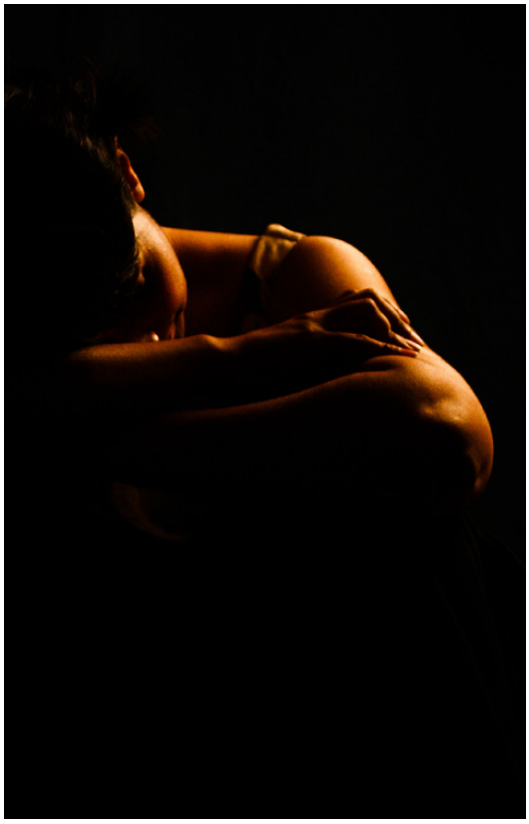
People suffering from osteoarthritis experience more pain in their knees when they also have insomnia, according to a study conducted at Johns Hopkins University School of Medicine. Researchers found that people suffering from both painful knee osteoarthritis and insomnia were more likely to experience a nervous system disorder called "central sensitization," an ailment that causes patients to develop a lower pain threshold.

Officials of the Centers for Disease Control and Prevention estimate that 52.5 million U.S. adults, roughly about a quarter of the population, suffer from arthritis. About one in ten men and one in five women over age 60 have osteoarthritis.

Unrelenting pain is a common complaint among patients with advanced osteoarthritis, and one of the reasons patients have total joint replacement, explains Santa Rosa Orthopaedics surgeon, Michael McDermott, M.D. "Joint replacement surgery is typically recommended to patients who have tried non-surgical treatment but still have joint pain."

Knee osteoarthritis patients who sleep well (do not have insomnia) and are not plagued with constant chronic pain, function better than do those with the double whammy of insomnia and chronic knee pain.

The research revealed that the combination of lack of sleep, and the inability to find relief from constant pain caused by osteoarthritis causes people with knee osteoarthritis to not only suffer more pain, but to also exhibit poorer physical function when compared to knee osteoarthritis patients that do not suffer from insomnia. — *BY*



Wikimedia Commons and Russavia

Bundled Joint Replacement Set for Colorado

The 500,000 member and $45 billion Colorado Public Employees Retirement Association (PERA) is offering retirees in the pre-Medicare program a new hip and knee replacement benefit option called PERA Care Select. For most pre-Medicare retirees enrolled in an Anthem plan, there will be no out-of-pocket cost or co-pays associated with either of these procedures, according to *PR Newswire*, which reported on the development.

More than 10,000 retirees are eligible for the program. The benefit is available at five health care facilities through a partnership with HealthONE facilities that is offering the procedures at a fixed price. The typical total cost of a hip or knee replacement can vary by as much as $40,000 within the state of Colorado.

According to the *PR Newswire* writer, there is no direct correlation between cost and quality. "Most recent studies have found that the association between cost and quality is moderate, and that there is no clear indication if that association is positive or negative." the author wrote.

"We all need to work together to crack the code on cost confusion while delivering high quality, cost-effective health care," said Gregory W. Smith, executive director and CEO of PERA. "The new PERACare Select benefit for hips and knees allows Colorado PERA retirees to become better consumers and advocates of their own health care, which improves the patient experience and saves money for both the patient and the overall health care system."

Courtesy of Colorado PERA

A Mayo Clinic study revealed that more than seven million people in the U.S. are presently living with a hip or knee replacement. Researchers expect this number will increase greatly as the population ages.

Colorado PERA provides retirement and benefits to more than 529,000 individuals. HealthONE is the largest healthcare system in the metro Denver area with more than 10,000 employees. — *BY*

Dental Floss Infects Knee Replacement

Go easy with the dental floss.

A Minnesota woman flossed so energetically, and forcefully that her gums bled and she passed a serious infection to the five year old joint replacement in her knee.

According to Ala Dababneh, M.D., at the Mayo Clinic, where the patient was treated, the woman sought help when her right knee became swollen and painful, and she started experiencing chills. Doctors diagnosed a serious infection in her replaced knee.

Blood tests revealed the infection to be a bacterium called Streptococcus gordonii which is generally found in the mouth. When the patient explained that she often flossed until her gums bled the mystery was solved.

Dababneh suspects that the bacterium probably entered the patient's bloodstream through her injured gums and then traveled to her knee, where it established itself.

To treat the infection, the medical team opened up the woman's knee, flushed out as much of the infection as they could and then prescribed antibiotics. The patient made a complete recovery but will have to continue taking antibiotics. Dababneh explained that because

Wikimedia Commons and MGA73bot2

implants do not have an immune system to keep them safe, they are more vulnerable to infections,

"It's a rare event. I don't want people to worry that just flossing is going to cause them an infection in their prosthetic joint," Dababneh said in an interview in *Live Science*. — *BY*

REIMBURSEMENT

CMS Data Problems Impact 2016 Value Modifiers

If you are a physician who hired a vendor to submit data to the 2014 Physician Quality Reporting System (PQRS) via electronic health records and qualified clinical data registries (QCDR), your data is not going to be used for the 2016 value modifier.

The Centers for Medicare and Medicaid Services (CMS) reported at the end of August that various errors occurred in the system. If you are a physician or practice that reported directly, you're okay.

The agency said the errors resulted in inconsistencies between the electronic health records (HER) and QCDR data so the information cannot be used to calculate quality performance for the 2016 value modifier, nor can PQRS performance information be included on Physician Compare.

The good news is that there is no impact on the physician for the meaningful use EHR incentive programs, because he/she is judged only on whether or not he/she successfully reported rather than on his/her actual performance.

Physician Quality Reporting System/RRY Publications

There will be no need for physicians or group practices to submit a PQRS informal review request.

Value Modifier Problems

But the value modifier is a problem because that involves actual quality scores in addition to simply having reported. Therefore, CMS says it will not be able to accurately calculate the PQRS portion of the Quality Composite Score. Instead, the score will be based solely on the claims-based outcomes measures and Consumer Assessment of Healthcare Providers and Systems Survey, if applicable.

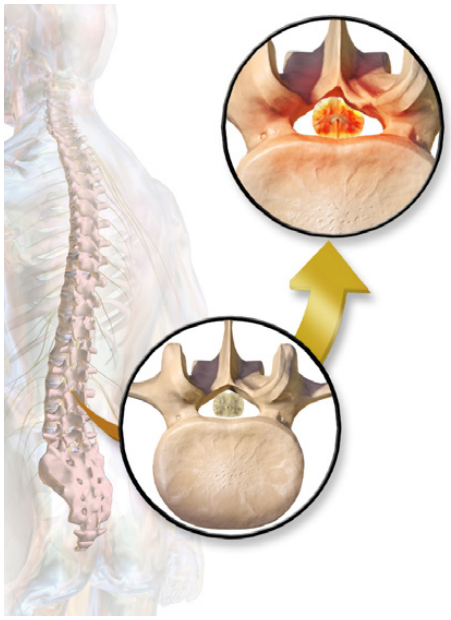
By late 2015, the agency, for the first time, will publicly display a subset of individual 2014 PQRS measures through star ratings on physicians' individual profile pages. Since 2014, CMS has publicly reported PQRS quality information on group practices participating under the group practice reporting option through star ratings.

The American Medical Association (AMA) says because of the intervention of the AMA, CMS will only report information through star ratings on physicians and group practices that were successful with 2014 PQRS. Physicians and group practices will also have the opportunity to review the information before it goes live and flag problematic information. The preview period will last 30 days and is expected to start October 5, 2015. In order to review a preview report, a physician will have to access the report through the PQRS Portal and have an EIDM (Enterprise Identity Management System) account. — *WE*

SPINE

Study: Spinal Stenosis Patients DO Respond Well to Epidural Steroids

Contradicting a previous study published in the *New England Journal Medicine* (*NEJM*), a new study has found that patients with spinal stenosis experienced a good short term benefit after receiving epidural steroid injections (ESI). The findings were published in a letter in the journal Pain Medicine.



Spinal Stenosis / Courtesy of Bruce Blausen and Wikiversity Journal of Medicine

According to the September 4, 2015 news release, researchers from Boston University School of Medicine (BUSM) performed a retrospective case series, using multiple methods of injections and various steroid choices and found specific epidural steroid injections to be very effective.

"The 2014 *NEJM* study on lumbar epidural steroids for spinal stenosis pain allowed for extreme variability in injection method and steroid type,"

explained co-author Anthony K. Savino, M.D., chief resident, BUSM's department of neurology. "We feel that interlaminar (between vertebrae) injection, at the worst stenosis level, with long acting steroid is very helpful for spinal stenosis pain, and our case series supports this. Doing injections the way we propose will help with spinal stenosis pain, making walking easier/better and may help some patients avoid surgery."

Senior author Michael Perloff, M.D., Ph.D., told *OTW,* "Senior pain physicians will tell you (anecdotally) that spinal stenosis epidurals need to be at the worst level and interlaminar (as tranforaminal doesn't 'get in') to have benefit. When we set up the clinical search engine, eight patients met criteria. I felt blinded, as I did not remember the individuals. Surprisingly, when reading the specific post procedure clinic notes most got very good benefit for months and longer."

"A large scale study (hundreds of patients) would be most useful. Getting physicians to agree on standardization of technique will prove difficult, an obstacle for a multi-center trial. We plan a smaller blinded clinical trial, at one center, with 20-40 patients to hopefully pave the way for a multicenter trial with standardized epidural technique and steroid use for spinal stenosis." — *EH*

Healing Spinal Cord Damage: Another Piece of the Puzzle

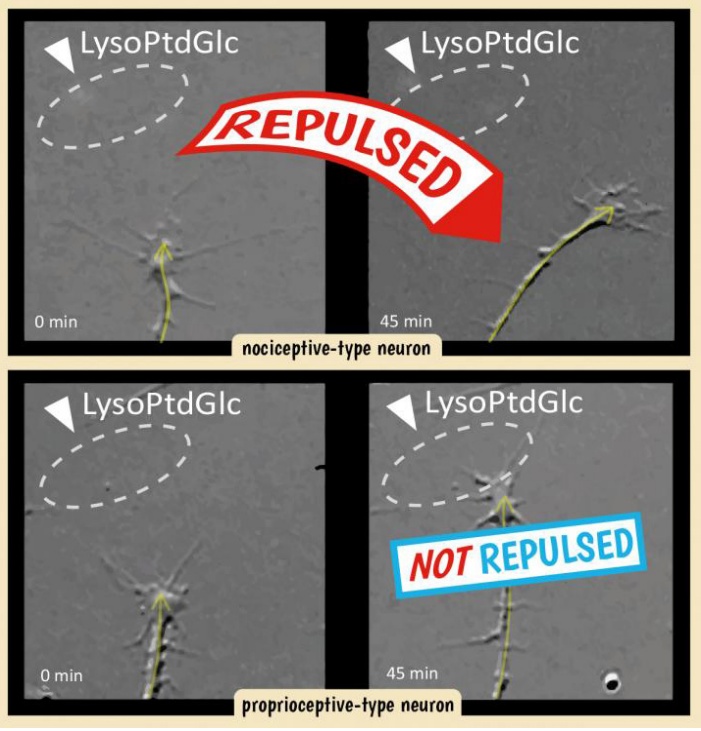
Scientists from the RIKEN Brain Science Institute in Japan have discovered that in addition to proteins, lipids are also necessary for guiding axons. Specifically, a phospholipid released by glial cells controls the positioning of sensory neurons within the spinal cord. "While many proteins are known to direct axon growth and network formation," said Senior Team Leader Hiroyuki Kamiguchi, M.D., Ph.D. in the August 27, 2015 news release, "we discovered that glial cells have the ability to release membrane structural lipids in specific patterns that can then control axon migration and neuron organization. In this case, we found that a lipid called LysoPtdGlc has a major role in separating axons of pain- and position-sensing neurons from each other."

As indicated in the news release, "The researchers found that gradients of LysoPtdGlc repelled axons from the pain-sensing neurons. This function of LysoPtdGlc was confirmed when blocking access to the lipid with an experimental antibody prevented pain-sensing neurons from being repelled…. The researchers then injected the antibody into the spinal cord of chick embryos. Their hypothesis that LysoPtdGlc was responsible for directing axon growth proved correct; the axons of pain-sensing neurons were no longer repelled, and instead migrated into the region on the spinal cord reserved for position-sensitive neurons."

"After determining that LysoPtdGlc's ability to repel pain-sensing axons was controlled through a particular type of protein receptor on axons, the team tested over 100 receptors and found one—GPR55—that responded well to LysoPtdGlc. The team confirmed that this protein is also expressed in the spinal cord, and when they labeled axons in GPR55 knockout mice, they found pain-sensing axons had erroneously entered the upper-medial portion of the spinal cord—similar to when they had blocked LysoPtdGlc function by injecting the antibody into chick spinal cords."

Dr. Kamiguchi told *OTW,* "It was surprising to find that lipids, not proteins, mediate glia-to-neuron communication that regulates axon tract formation in the spinal cord."

Asked what orthopedic surgeons may like to know about this work, he added, "I think there are many unidentified bioactive lipids that could be new drug targets for nervous system disorders including spinal cord injury." — *EH*



RIKEN Brain Science Institute

PEOPLE

In Memoriam: Jesse George Jackson

He was a man known for giving people chances…and second chances.

Jesse George Jackson, one of the earliest orthopedic product distributors in the modern era and the person who was described by one friend as the "Godfather" of orthopedics in the West, has passed away.

Jackson, who died on July 19, 2015 in Flaming Gorge, Utah, was just shy of his 80th birthday.

He is survived by his children LaVon (Kwan), Julie, Brett (Christi), Matt (Jessica), Jessica, Danny, and his family of friends. His many grandchildren and great grandchildren will miss him deeply. He was preceded in death by his parents Jesse and Florence Jackson, his sister Jeanine Fritzsche, and his son Clay Jackson.

A memorial service was held by the pond of Wasatch Lawn Mortuary on July 28, 2015, in Salt Lake City, Utah.

In addition to building the distribution, training and support infrastructure for modern orthopedic products and services in the western states, Jackson also co-invented (with Craig Shelling) a novel cannulated bone screw in 2005 (patent # 7731738).

Longtime friends Rob and Tonya Behrens said of Jesse Jackson:

> "Jesse George Jackson, a past CEO of OrthoPro and at one point, the largest Zimmer distributor in the U.S., was known as the Godfather of Orthopaedics in the West. Jesse personally changed the lives of thousands of young men and women and made them better. I am one of those men. He gave me an opportunity 29 years ago that changed the course of my life. His legacy will never be forgotten."

Dignity Memorial®

> "Jess was one of the most generous people I have known; he also knew the power of the 'Debit.' Jess lived every day to the fullest with passion and regard for others. He lived life on his terms. Those close to Jess will fondly remember all of this about him."

> "To his wives, children and grandchildren, I say thank you for sharing this legend with the orthopaedic community. Know that he had a tremendous influence and was respected by many."

Radd Berrett also called Jesse Jackson a friend. He told *OTW*:

> "My job interview with Jesse was a four day road trip through Idaho, Wyoming, and Montana. We hit every hospital, doctor, and fly fishing spot on the map; and cleaned up at all of them. To this day, over 25 years later, I still live my life with his 'It's not about the destination—there isn't one. It's all a journey' approach to life."

> "There was truly only one Jess Jackson," said Steve Phippen to *OTW*. "Jess was known for giving people chances. He gave me my first opportunity to break into an industry that I've loved from day one. It changed my life and the life of my family for the better. I am forever grateful to Jess Jackson for taking a chance on me."

> "Jess also gave many people a second chance. I saw numerous individuals who were trying to rebuild their lives and Jess, at great personal risk gave them their 'second chance.'"

> "Mentoring was important to Jess, and he glowed brightest when speaking of the next young person he was bringing into the industry and how well they were doing. At a critical decision making point in my career, Jess dropped everything and took four days to drive with me to Seattle from Salt Lake City to consult with another person in the industry. He only did this for my personal benefit; there was no way for Jess to benefit from this trip."

> "Jess was a very encouraging person. When I lacked self-confidence at various stages in my career he was always giving encouragement and building confidence. They say some of the most influential and important people are those that believe in you when you don't believe in yourself."

> "I also want to note that he was a non-judgmental person. Jess circulated with people from every walk of life and background and all were comfortable in his presence. You could be exactly who you are when with Jess Jackson."

> "I could go on for hours about the sacrifices Jess made for me. Many thanks, my dear friend." — *EH*

Charles Bush-Joseph, M.D. Now in Presidential Line for AOSSM

Charles Bush-Joseph, M.D., a sports medicine orthopedic surgeon and managing partner at Midwest Orthopaedics at Rush, has been elected to the presidential line for the American Orthopaedic Society of Sports Medicine (AOSSM). He is serving as vice-president for 2015, president elect for 2016 and president for 2017.

Midwest Orthopaedics at Rush

"I've been a member of the AOSSM for many years and have seen the impact it has made on sports medicine," explained Dr. Bush-Joseph in the August 28, 2015 news release. "I'm honored to be trusted by members to lead the organization over the next two years."

Dr. Bush-Joseph has cared for high school, collegiate and recreational athletes for many years. He is the head team physician for the Chicago White Sox and associate team physician for the Chicago Bulls. Dr. Bush-Joseph was elected president of the Major League Baseball Team Physician Association for 2012.

Dr. Bush-Joseph, a professor at Rush University Medical Center and the Associate Director of the Rush Orthopaedic Sports Medicine Fellowship Program, told *OTW,* "I would envision my role as president would be to advance AOSSM's mission of research and education to the benefit of all athletes. The society will continue to develop injury prevention strategies, advanced training methods, and innovative treatments that encourage all to participate in sports, fitness and competition. Collaboration and knowledge sharing with other international sports medicine societies will raise of the standard of care worldwide."

"The most pressing issue in sports medicine is that we need to encourage our youth to participate in sports and fitness, yet insure player safety at every level. Overuse injuries and concussions continue to dominate our research interests." — *EH*

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