

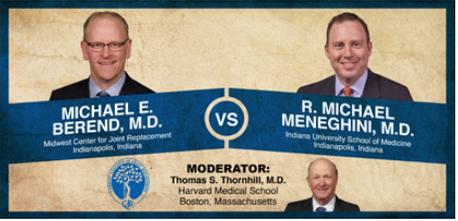
Orthopedics This Week

WEEK IN REVIEW

4 Corporate Ortho's 1st Half Sales Report >> For the first half of 2017, we estimate the number of orthopedic procedures globally increased 3-4%. The fastest growing sector was extremities. The slowest was spine. Pricing pressures remain a key drag on sales growth. Orthopedics is in a transition, here is a mid-course report.

8 Mega Ortho Lawsuit Is About Blankets >> One of the fastest-growing new class action lawsuits is about a warming blanket used in knee and hip replacement surgeries. Over 1,300 plaintiffs have joined the lawsuit. What's going on? The plaintiffs are alleging that that cuddling up in the operating room might lead to surgical site infections. Here's what's going on.

11 Berend v. Meneghini: Liposomal Bupivacaine Injectables: Game Changers in Pain Management >> The #1 game changer in large joint arthroplasty has been the shift from inpatient surgery to better pain control and outpatient surgery. Liposomal bupivacaine is the poster child of this shift, but is it worth the extra \$300? Michael Berend and Michael Meneghini debate this question in an absolutely stellar review of the latest data.



16 Spine Surgery Not Driving Opioid Use; Managing Weekend TKA Patients; Remove Hip Fractures From Bundle! >> Spine surgeons aren't the problem when it comes to opioids, says a new study. Have TKA later in the week, have more issues! New research says, "Remove hip fracture patients from bundled payments."



BREAKING NEWS

- 19 **Histogenics** Moves Onto Phase 3 Clinical Trial for NeoCart

- 19 New **Spinal Cord Injury** Repair Company Launched

- 23 \$4.5 Million Verdict for **Lost Sex Life**

- 21 FDA Clears **Osseus' Cervical Implant**

- 22 FDA Clears **Novel German ALIF, PLIF and TLIF Implants**

- 24 **Highest Radiation?** Trauma and Deformity Surgeons!

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Over the past 30 days, the value of public orthopedic companies has declined at roughly twice the pace of the overall stock market—(2.87%) versus (1.4%) S&P 500. On a Price/Earnings basis, orthopedic stocks are cheaper at 22.77x than S&P 500 stocks at 24.19x. But on a price to sales ratio basis, investors still pay a premium for ortho—\$4.60 per \$1 of ortho sales versus \$2.07 for each \$1 of S&P 500 sales. Finally investors think that ortho companies will be able to grow earnings at a 13.98% rate over the next five years while the S&P 500 is being pegged at 4.58%.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Smith & Nephew	19.53%	0.83%	In addition to Navio and investments in Trice Medical, SNN also made a key investment in wireless patient monitoring (LEAF) and a handheld point of care imaging for displaying bacterial concentration in wounds.
2	2	Exactech	9.05	(2.76)	In 2015 Exactech's management set in motion a strategic plan which resulted in the divestiture of spine and biologics and accelerated extremities product development. Result: stronger sales growth in 2016, 2017 and beyond.
3	5	Medtronic	21.05	(2.62)	This week Medtronic Spine reports results for the July quarter. Management has been making steady progress and for the April quarter, outpaced spine industry growth rates. Most analysts expect another good report.
4	6	Stryker	22.38	(1.32)	Minnesota's own Mary K. Brainerd—a fellow St. Thomas MBA grad—joins Stryker's board of directors. Formerly President of HealthPartners, she gives SYK yet another strategic advantage.
5	4	Orthofix	8.01	4.44	Top performer in the Power Rankings. Wall Street may finally be realizing how strong the management team is—not only in terms of sales and earnings—but also managing expectations.
6	3	ConMed	8.92	(4.87)	Low single digit revenue growth rates and an operating profit margin of about 9% of sales—those are the two principal reasons CNMD's valuation is the 3rd lowest in orthopedics.
7	7	Zimmer Biomet	22.28	(15.02)	Oversold. After dropping another 15% in the last month, this equity is below even the bargain basement. For a company earning 22 cents on every sales dollar, this is too cheap.
8	8	Johnson & Johnson	29.09	(1.91)	JNJ remains the bellwether medical equity. With Obamacare limping along on, essentially, a month to month basis the investors collective opinion of healthcare in the U.S. is illustrated in JNJ's performance.
9	9	Integra LifeSciences	11.60	(9.94)	Integra will close its massive strategic purchase of Codman Neurosurgery in the 4th quarter. Integration, of course, will be THE issue. Management is confident of day one readiness. Fingers crossed.
10	10	Globus Medical	26.72	(7.04)	Globus Medical is probably the most interesting company in orthopedics. Marches to its own strategic beat while also delivering world class execution.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Lattice Biologics	LBL.V	\$0.10	\$10	31.11%
2	MicroPort Scientific	853	\$0.96	\$1,394	16.50%
3	Alphatec Holdings	ATEC	\$1.92	\$26	13.85%
4	Aurora Spine	ASG.V	\$0.13	\$4	12.37%
5	MiMedx Group	MDXG	\$16.52	\$1,858	9.69%
6	Orthofix	OFIX	\$48.00	\$872	4.44%
7	Wright Med Grp N.V	WMGI	\$28.72	\$3,010	4.13%
8	Smith & Nephew	SNN	\$35.40	\$15,489	0.83%
9	Stryker	SYK	\$144.29	\$53,974	-1.32%
10	TiGenix	TIG.BR	\$1.05	\$272	-1.45%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Pacira	PCRX	\$35.80	\$1,444	-26.94%
2	NuVasive	NUVA	\$64.06	\$3,254	-20.43%
3	RTI Biologics Inc	RTIX	\$4.65	\$277	-19.13%
4	Zimmer Biomet	ZBH	\$111.38	\$22,521	-15.02%
5	Xtant Medical Hldgs	XTNT	\$0.65	\$12	-14.95%
6	Integra LifeSciences	IART	\$50.22	\$3,921	-9.94%
7	Amedica Corp	AMDA	\$0.35	\$13	-7.97%
8	Globus Medical	GMED	\$30.11	\$2,899	-7.04%
9	K2M Group Hldgs	KTWO	\$23.45	\$1,015	-5.29%
10	Conmed	CNMD	\$48.60	\$1,357	-4.87%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Zimmer Biomet	ZBH	\$111.38	\$22,521	19.04
2	Smith & Nephew	SNN	\$35.40	\$15,489	19.76
3	Johnson & Johnson	JNJ	\$132.63	\$355,979	20.63
4	Globus Medical	GMED	\$30.11	\$2,899	20.90
5	Medtronic	MDT	\$83.41	\$113,356	23.77

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MiMedx Group	MDXG	\$16.52	\$1,858	98.92
2	MicroPort Scientific	853	\$0.96	\$1,394	98.56
3	NuVasive	NUVA	\$64.06	\$3,254	75.97
4	Orthofix	OFIX	\$48.00	\$872	68.76
5	TiGenix	TIG.BR	\$1.05	\$272	47.31

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	\$19.05	\$637	1.54
2	Globus Medical	GMED	\$30.11	\$2,899	1.98
3	Zimmer Biomet	ZBH	\$111.38	\$22,521	2.26
4	Stryker	SYK	\$144.29	\$53,974	2.49
5	Exactech	EXAC	\$29.95	\$430	2.80

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	\$48.00	\$872	10.34
2	Conmed	CNMD	\$48.60	\$1,357	6.95
3	MiMedx Group	MDXG	\$16.52	\$1,858	6.59
4	MicroPort Scientific	853	\$0.96	\$1,394	6.57
5	NuVasive	NUVA	\$64.06	\$3,254	5.21

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Xtant Medical Hldgs	XTNT	\$0.65	\$12	0.13
2	Alphatec Holdings	ATEC	\$1.92	\$26	0.22
3	Aurora Spine	ASG.V	\$0.13	\$4	0.45
4	Amedica Corp	AMDA	\$0.35	\$13	0.64
5	RTI Biologics Inc	RTIX	\$4.65	\$277	1.01

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Nevro Corp	NVRO	\$84.01	\$2,474	10.82
2	TiGenix	TIG.BR	\$1.05	\$272	10.15
3	MiMedx Group	MDXG	\$16.52	\$1,858	7.58
4	Pacira	PCRX	\$35.80	\$1,444	5.23
5	Globus Medical	GMED	\$30.11	\$2,899	5.14

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

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Corporate Ortho's 1st Half Sales Report

BY ROBIN YOUNG

Patient demand for orthopedic products and services remains an extraordinarily powerful and enduring engine of revenue growth for suppliers and providers alike.

For the first half of 2017, these arthritic and injured patients fueled a 4.95% rise in recon surgeries as compared to the same period in 2016.

That rate of growth was above the average rate of 4.4% recorded over the past 6.25 years. (See graph below.)

Arthritis is the primary underlying physiological reason for recon surgery and 52 million people worldwide have been diagnosed with arthritis.

For many reasons, but primarily aging, the number of patients diagnosed with arthritis will increase by another 50% between now and 2040.

The recon procedure growth rates we have recorded for the past 25 quarters (average 4.4%) are likely to remain at these levels for decades.

Beyond recon, these same factors, principally aging, are fueling rising demand for extremity and spine procedures.

Global extremity procedure growth rates for the first half of this year came in at between 7-10%. Extremity procedures, fueled by reverse shoulder sur-

geries, are the fastest growing sector of orthopedics.

Spine and trauma procedure growth rates were under 2% for the first half of 2017—a continuation of the patterns we saw in 2016.

Pricing and Other Headwinds

The orthopedic industry is in transition toward higher rates of cost efficiency and product (patient outcome) quality. Other industries have been through similar disruptions. The auto industry, for example, moved from cars like the best-selling 1968 Pontiac Grand Prix with a 3.8 liter, V8 gas engine (16 miles per gallon) to one of this year's top seller, the 2017 Toyota Camry with a 2.5 liter, hybrid engine (51 miles per gallon), remote sensors, cameras and internet connectivity.



Source: Wikimedia Commons and Beatrice95Perez



Can orthopedics similarly execute a three-fold improvement in cost efficiency—while also incorporating new procedures, technologies and treatment paradigms?

As the following chart makes clear, orthopedic suppliers are dealing with steady pressure to find more efficiencies. (See graph to the right.)

One major venture capital firm described the situation as follows in a recent report to its investors:

“The future of addressing the large numbers of patients with increasing disease severity will require the semi-automation of skilled labor (nurses, doctors, and technicians) in healthcare. We will see this where technology will be used to help physicians choose between therapies based on the specific attributes of a patient, as well as



in diagnostics like imaging where machine learning can be used to ‘pre-read’ or provide ‘clinical decision support’ to radiologists.”

New technologies, therefore, need to be able to drive greater efficiencies as well as improved patient outcomes.

Hip Implant Sales

As the following chart illustrates, the initial Obamacare bump in procedure volumes occurred between Q2 2013 and Q2 2015. Thereafter growth rates settled into a 1-2% year-over-year rate—which is less than the average



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4.4% procedure growth rate. The difference reflects the impact of pricing pressure. If Obamacare morphs into Trumpcare, 15-20 million people will likely lose healthcare insurance. In that case, this chart will, we think, return to negative territory—as it was for all of 2011. (See graph the right.)

The fastest growing sector in hip replacement is anterior hip approach. Fueled by articles in *The New York Times*, *The Wall Street Journal* and *The Washington Post*, the anterior approach is being increasingly demanded by patients who believe it will help them to recover from surgery faster and with less pain. Various top studies show, however, that the anterior hip learning curve is long and difficult—raising the risk of complications during the first 20-40 cases—and essentially no outcome difference between anterior and posterior patients in the long term.

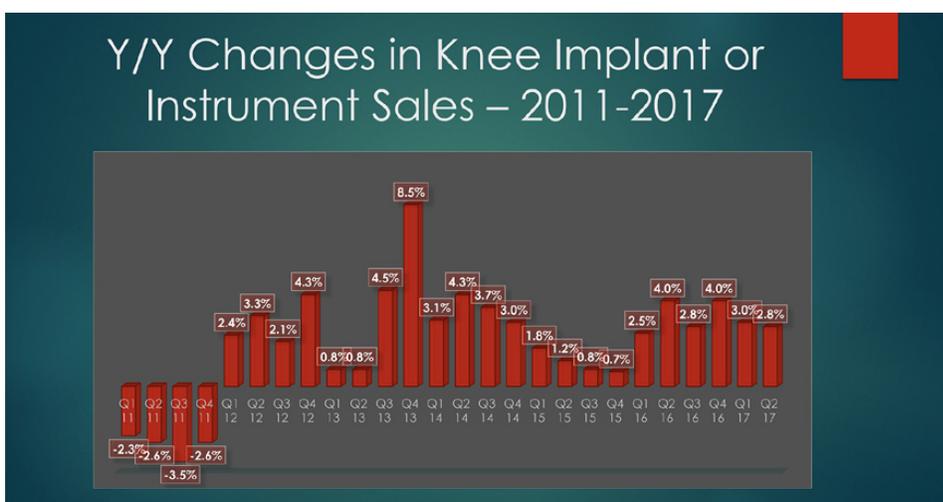
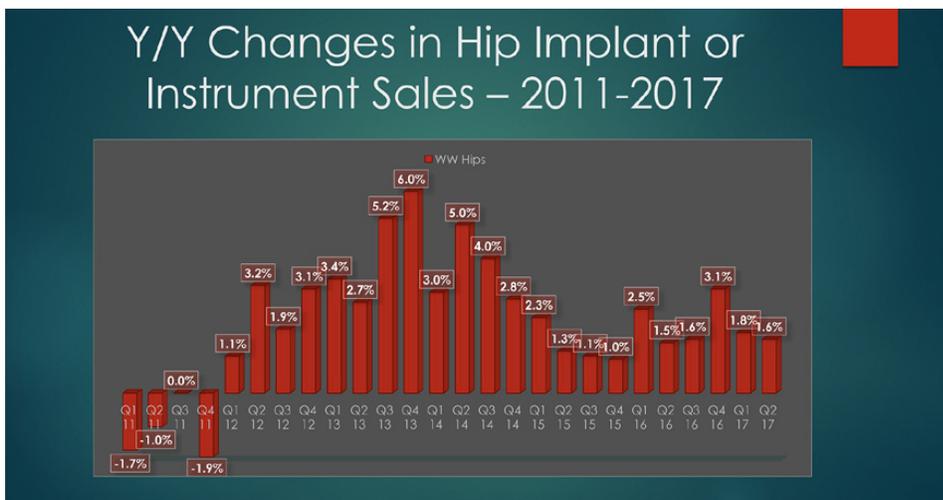
The market for hip implants and instruments remains dominated by four companies: DePuy, Zimmer Biomet, Stryker and Smith & Nephew.

Knee Implant Sales

Sales of knee implants and instruments grew by 2.9% in the first half of 2017, which was about twice as fast as hip implants.

The growth patterns for knees between 2011 and 2017 display many of the same influencers as hips—namely an Obamacare bump, then a return to more average growth rates and, more recently, steady as she goes at between 2.5-4.0%.

Losing health insurance is the single biggest risk to these growth rates in the future. If some version of Trumpcare is signed into law, then these growth rates will reverse. (See graph on the right.)



Robotics is the single biggest factor raising knee arthroplasty efficiency. Quoting again from the venture capital community annual reports:

“Doctors won’t become robots in 2017, but they will augment their capabilities with artificial intelligence and machine learning approaches to diagnose and surgically treat patients and improve efficiency.”

Key players are Stryker’s Mako and Smith and Nephew’s Navio.

Spinal Implant and Instrument Sales

Spinal implant sales for the first half of 2017 likely came in around 0.5%.

Medtronic Spine had not reported as of the date of this article, but given its report for the three months ended April, 30, 2017 (spine sales rose 2.8% on a year-over-year basis – inclusive of BMP), we expect that Medtronic Spine will increase the global spine growth rate of 0.1% to a number closer to 0.5-1.0%.

No orthopedic sector has been hit with as severe headwinds as spine.

For example, payers including Centers for Medicare and Medicaid Services (CMS), continue to give short shrift to excellent clinical outcome and cost efficiency data regarding motion pres-

ervation devices. The near continuous battle with payers over the correct and necessary treatment of severe back pain has introduced cost inefficiencies which have had a long term effect on companies, providers and the capital markets. (See graph below.)

Corporate Mergers and Acquisitions

Over the past five years, the 6 largest suppliers of orthopedic products and services have made 38 acquisitions. The largest were DePuy's purchase of Synthes, Zimmer's purchase of Biomet and LDR Spine, Stryker's pur-

chase of MAKO and, finally, Smith & Nephew's purchase of ArthroCare and Blue Belt.

One purchase that was widely forecast by Wall Street traders that did NOT happen was Stryker's rumored interest in buying Smith & Nephew.

Other acquisitions which did not occur were the mega insurance mergers. Under Obamacare, those mergers seemed pre-ordained. No longer, especially in the face of strong opposition from the Department of Justice and the American Medical Association.

Although orthopedics is a highly concentrated industry, there is likely to be continued purchases of small technology companies by the larger, cash rich diversified suppliers.

So, no change in the pace of M&A activity in orthopedics.

Outlook

For the remainder of 2017 and continuing for the next couple years, we expect to see the following.

- More standardization of basic implants and instruments
- Increased focus on smarter devices and AI driven logistical services—robotic assist devices, for example
- New forms of outpatient instrumentation and treatment protocols
- Continued cost containment strategies from reimbursers

In other words, keep an eye on the Toyota Camry. ♦

Source for all graphs: RRY Publications and Robin Young Consulting

Y/Y Changes in Spine Implant or Instrument Sales – 2011-2017





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Mega Ortho Lawsuit Is About Blankets

BY JESSICA MEHTA

At last count, more than 1,300 lawsuits have been filed against the 3M Company for their very popular Bair Hugger warming blanket—most commonly used for post-operative hip and knee patients.

A key development, the December 11, 2015, transfer of 14 federal lawsuits against 3M Bair Hugger to Judge Joan N. Ericksen's U.S. District Court room, District of Minnesota and its designation as a multidistrict litigation (MDL) set in motion a series of events that have transformed this obscure case into one of the biggest medical device lawsuit involving ortho patients ever.

Forced Air Warming Blanket and Infections

The plaintiffs are alleging that the company's "forced air warming blanket," commonly prescribed after hip and knee replacements, is connected to post-operative joint infections. The December 11 Order from the U.S. Judicial Panel on Multidistrict Litigation allowed all new 3M Bair Hugger cases filed in federal courts to be eligible for transfer to the MDL. An MDL ensures a single judge will address the lawsuits, which reduces duplicative discovery. That speeds the case up.

Bernstein Liebhard LLP, based in New York, is representing the plaintiffs. Partner Sandy A. Liebhard stated in 2015 that "numerous patients ... allegedly developed painful and debilitating deep joint infections due to this device. This litigation has the potential to be large."

The forced air warming blanket is used after some surgical procedures to help



Source: Pixabay/Dieter Robbins, <https://pixabay.com/en/bed-sleep-rest-girl-white-tired-945881/>

regulate body temperature. However, plaintiffs in the case—all of whom had knee or hip replacements—claim the device has a design defect that can allow the surgical site to be exposed to bacteria and contaminants in the operating room. Additionally, plaintiffs claim that 3M Company and its subsidiary, Arizant Healthcare Inc., were aware of the dangers "since at least 2009." The Bair Hugger warming blanket system was developed by Arizant Healthcare, which 3M acquired in 2006.

According to the plaintiffs, the companies never changed the design or release any warnings and "aggressively marketed" the blankets as safe for orthopedic surgeries. "No reasonable and competent physician" would use the blanket if they were aware of the risks, the plaintiffs claim.

200 Million Surgeries Since 1987

Since the 2015 formation of the MDL, more plaintiffs have stepped forward claiming they developed debilitating infections from hip and knee replacements due to the popular air warming blanket. The 3M Bair Hugger warming blankets are used in over 80% of all knee and hip replacements. *The Minneapolis Star Tribune* reported that between 1987 and 2015, the device was used in over 200 million surgeries. Currently, about 50,000 units are in use around the country. The blankets have generated \$31 billion in revenue since it was introduced by Arizant in 1986, according to *Drug Safety News*. The apparatus includes a flexible hose connected to a disposable blanket to deliver a regular stream or warm air to the patient.

However, plaintiffs claim that the blanket interrupts laminar air flow in operating rooms. This allegedly allows contamination from the operating floor to be transported to the warming area, potentially infiltrating the otherwise sterile surgical site. Sepsis and Methicillin-resistant *Staphylococcus aureus* (MRSA) are two of the most common infections named in the lawsuits. Such infections may result in more surgeries and/or permanent disability according to the claims.

Bundle Up

On January 13, 2016, the first Pretrial Order was issued. In less than one month, the 14 initial cases transferred to the MDL had grown to 82. Discovery was stayed for all pending cases, and an Initial Status Conference was scheduled for February 2016. On March 24, 2016, another Pretrial Order was issued, which suggested

the first bellwether trials could start in November 2017. According to the Order, parties had to draft a plan for bellwether case selection by October 17, 2016. Bellwethers are where verdicts might offer insight into how a jury may decide the case. Bellwether selections were ordered to be submitted by March 1, 2017 so case-specific discovery could start on March 2, 2017. Discovery would be completed by July 1, 2017 for the first bellwether trial scheduled for November 6, 2017.

By April 2016, 217 lawsuits were pending in the MDL. By April 15, 2016, the MDL was one of the fastest-growing in the country according to *Reuters*. Three new Pretrial Orders were issued on April 29, 2016, which included a Protective Order. This order describes how confidential data would be handled during discovery. Another order approved direct filing of the lawsuits within the District of Minnesota,

while the other detailed process service through e-mail for summons and complaints of plaintiffs.

On May 24, 2016, the federal court managing the MDL approved the Master Long and Short Form Complaints. This allowed all plaintiffs, from May 24 onwards, to file their claims directly with the District of Minnesota via Short Form Complaints (which are faster and easier to complete). Also on May 24, 2016, a Pretrial Order was issued which created a Common Benefit Fee and Expense Fund. This Fund guaranteed that services and expenses incurred by attorneys for the plaintiffs would be equally shared and distributed.

Closing in on 1,500 Cases

By September 15, 2016, there were 693 lawsuits pending in the MDL. From August 15 to September 15, 2016, 147 new claims joined the MDL. Liebhard

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stated, “We are not at all surprised to see the Bair Hugger litigation growing at this rate ... we have received numerous inquiries from individuals concerned that the forced air warmer system may have contributed to post-op deep joint infection following hip or knee implant surgery.”

On September 28, 2016, the federal court created new protocols for the Plaintiff Fact Sheets and Service. It dictated that all plaintiffs must electronically file a Plaintiff Fact Sheet with signed medical authorization for the defendant’s attorneys. Plaintiffs with pending lawsuits in the MDL had 90 days to comply. Any plaintiffs who join in the future would also have 90 days to file the Plaintiff Fact Sheet and medical authorization.

By October 17, 2016 809 cases were pending in the MDL. Since September 15, 2016, there were 116 new filings. An Order was issued in the U.S. District Court of Minnesota November 16, 2016, in which 150 pending lawsuits were randomly chosen as potential bellwether cases. To be eligible, lawsuits had to be pending in the MDL since at least December 19, 2016. Of the 150 randomly selected, both plaintiffs and defendants got to choose 16. Both parties were required to reveal their selections to the District of Minnesota by January 20, 2017. The

first bellwether trial was scheduled for November 6, 2017.

Case-specific discovery was scheduled for January 21 – March 1, 2017. Prior to case discovery, the parties had to agree on eight total lawsuits from the potential cases by February 10, 2017. Afterward, the Court would select a maximum of eight for the Final Bellwether Trial Pool.

The 2017 Proceedings

Both parties met the January 5, 2017 deadline, each choosing 16 cases. However, there was one overlapping case, making the grand total 31 possible bellwether cases. As of January 15, 2017, 1,105 cases were included in the MDL. There were 166 new lawsuits filed or transferred from December 15, 2016 to January 15, 2017. By March 15, 2017, that number had grown to 1,343.

In May 2017, the federal court chose eight lawsuits of the 31 for bellwether trials. However, two of those cases were nixed by the parties. The federal court has also bumped the beginning of the bellwether trials from November 2017 to February 26, 2018. As of June 2017, 1,988 lawsuits were pending within the MDL. On June 15, 2017, the six cases were officially scheduled via an Amended Order. They include the surnames Kamke, Nugier, Wlaker,

Knueson, Skaar and Gareis (all versus 3M Co.).

Going to Bat for the Blanket

3M has remained largely quiet in regards to the lawsuit—until this past June 1—when it released a research compendium providing a literature review, years of review articles, and letters to the editor and case studies which attest to the safety and efficacy of Bair Hugger. Many of the clinical articles were from peer review journals from databases like Medline, Elsevier Biobase, Embase, and Chemical Abstracts. With a welcome message by Medical Director Michelle Hulse-Stevens, the packet calls Bair Hugger the “gold standard” in patient warming.

Bair Hugger products have been reviewed in more published research than any other similar product, according to 3M. With over 50,000 patients being treated with the warming blanket every day, 3M’s Bair Hugger is well known and trusted in hospitals and clinics around the world.

While the MDL is pending and the bellwether trials have yet to begin, many eyes are on one of the biggest medical device MDLs in history.

No doubt about it. This MDL is just starting to warm up. ♦

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Berend v. Meneghini: Liposomal Bupivacaine Injectables: Game Changers in Pain Management

BY OTW STAFF

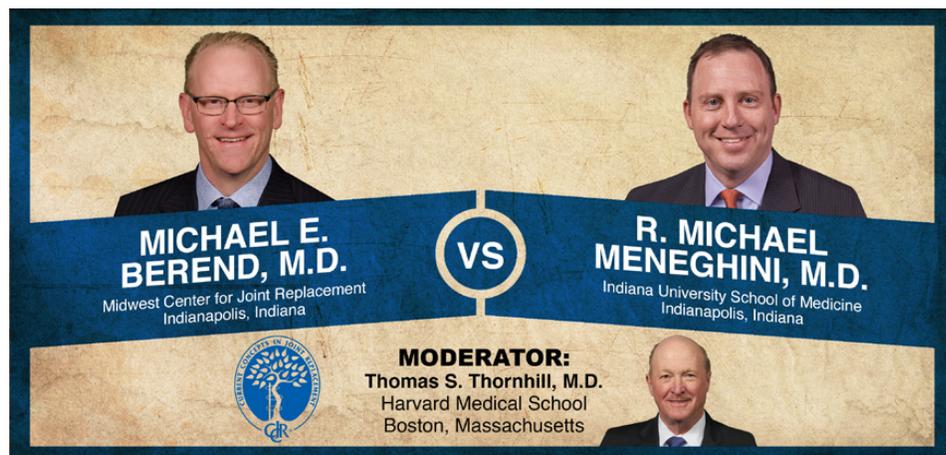
This week's Orthopaedic Crossfire® debate was part of the 17th Annual Current Concepts in Joint Replacement® (CCJR), Spring meeting. This week's topic is "Liposomal Bupivacaine Injectables: Game Changers in Pain Management." For the proposition Michael E. Berend, M.D., Midwest Center for Joint Replacement, Indianapolis, Indiana. Opposing is R. Michael Meneghini, M.D., Indiana University School of Medicine, Indianapolis, Indiana. Moderating is Thomas S. Thornhill, M.D., Harvard Medical School, Boston, Massachusetts.

Dr. Berend: I'd like to share with you our experience with a new type of pharmacologic technology and I think it has made a big difference in our practice.

The definition of a game changer is an event or an idea or a procedure that effects a significant shift in the current manner of doing or thinking about something. Liposomal bupivacaine is part of a series of events that's really changed our practice from inpatient surgery to better pain control and outpatient surgery.

Liposomal bupivacaine was a game changer for us. It's basically Marcaine held in a fatty membrane. Those fatty membranes are grouped together, injected into the pericapsular tissues and then with body heat and pH, the membranes erode and release the medication—sort of a time release capsule for local anesthesia.

We've experienced a lot of other game changing things in arthroplasty: the comprehensive joint replacement proj-



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ect, or bundled payment care, which will certainly pressure us into reducing costs and other system changes. This has forced us to reexamine the entire care pathway for joint replacement and I think liposomal bupivacaine plays a role in that algorithm.

Our current protocol focuses on preemptive pain control with preoperative medications of Celebrex and Neurontin and acetaminophen. We've eliminated narcotic spinals in favor of short-acting local anesthesia spinals. We use an adductor canal block administered under ultrasound which conserves the quadriceps function. We use a general anesthesia with a laryngeal mask for rapid induction. Tranexamic acid has now eliminated the need for post-operative laboratory monitoring. We use a pericapsular injectable cocktail—some with liposomal bupivacaine at the hospital some with a different recipe at our ASC [ambulatory surgery center], and a whole host of medications aimed at pain control and nausea control.

Zero percent of our patients went home the same day in 2010, now it's over 50% in 2016. And there's obviously significant cost savings associated with this type of procedure.

Mike has done a good job to question the superiority of this type of medication. In a retrospective study, an inpatient study I would highlight, with a length of stay of two days, comparing to narcotic spinals, really no difference between liposomal bupivacaine and a standard pericapsular injection.

I think it allowed us to ask 'Is it worth the cost in our individual environment?'

In our clinical experience of outpatient arthroplasty over the last two years—1,200 hips, knees and partial knees—we saw no readmissions for pain control using this type of medication. It really surprises me in the postoperative care of arthroplasty patients that pain control has largely been solved with a multi-modal program.

Our readmission rate is under 2%. If you take out manipulations, it's under 1%, and that's significantly reduced from what's reported in the literature.

Our average length of stay now for partial knee is just under three hours and for other total joint arthroplasty procedures is under five hours.

And importantly, if you look at patient satisfaction over the last two years running, 98% good to great using this type of program.

So I think multi-modal programs are worth your time, whether you resurface the patella or not. Outpatient joint replacement, I believe to be the future of our craft. Liposomal bupivacaine does play a role. There are obviously advantages and disadvantages, and cost is one consideration.

Dr. Meneghini: Mike and I were in practice early on together and as a young surgeon, many of my senior

partners were very influential on me and Mike was no exception. I have a tremendous respect for Mike as a surgeon, as a partner, and he came up with some memorable quotes. One is 'if you're a farmer and you have really bad knee arthritis, you can put the knee in backwards and they'll still do great'. Turns out that's supported by the data. Robert Barrack would tell you that if the disease is really, really bad that a knee replacement will do very, very well.

Is liposomal bupivacaine a game changer? Let's look and see if it is supported by the data.

We published a somewhat controversial study in 2014 that brought to light some of the issues around this cocktail. We did a retrospective cohort study with two surgeons looking at just traditional periarticular injection versus liposomal bupivacaine and we did 85 knees with traditional and 65 knees with liposomal bupivacaine. Once the spinal wore off,

we found that for the remainder of their hospital stay, the liposomal bupivacaine group had higher pain scores.

When we looked at those patients who rated their pain as mild, the liposomal bupivacaine group (after the first 24 hours) had fewer patients that rated their pain as mild. So we actually did better with the traditional group.

Now let's look at the highest quality research. Let's look at prospective randomized trials because now we have a few of them on liposomal bupivacaine to pull from. A study out of University of Louisville just published—105 knees—looking at liposomal bupivacaine versus a modified Ranawat protocol with a mixture of ropivacaine, epinephrine, ketorolac, and clonidine. No difference in the groups between narcotic usage or range of motion.

Another randomized prospective trial, *Journal of Arthroplasty*, 2015, by Bill Schroer presented at AAHKS on 111 knees.





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[†] Amer. J Sports Med 2011 39: 1238 originally published online February 22, 2011.

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Liposomal bupivacaine against a control group of just plain 0.25% bupivacaine. Again no difference between groups in VAS pain scores and narcotic usage.

One from Jefferson...162 TKAs in a double-blinded prospective randomized control trial...88 patients with liposomal bupivacaine and 74 with a controlled or standard bupivacaine. Again, no difference between groups in VAS pain scores or narcotic consumption.

I think the highlight is the cost. The liposomal bupivacaine, right now, is \$320 and standard bupivacaine is \$5.00. So a dramatic difference. And in the era of bundled payments, couldn't agree with Mike more...bundled payments are going to force us to make decisions. Good decisions.

We were challenged on whether our technique was what the manufacturer recommended and so we added a third arm. We just published a study in the

Journal of Knee Surgery. We added 41 patients using the same protocols across the board, and just used the manufacturer's recommended technique of a ton of injection sites, a very small needle, and still came up with the same conclusions. Again, no difference.

In summary, I do think liposomal bupivacaine does not offer a substantial benefit over traditional periarticular injection. Now if you don't have a lot of pain control, or if you don't have the proper pain protocols in place, or your anesthesiologists are doing dermal nerve blocks, I think it may offer a benefit. But compared to a traditional injection, it comes at a significant greater cost. The real game changers...and Mike alluded to this, I think we agree completely on this...multi-modal pain protocols and patient education expectations have been the real game changers in getting patients out of the hospital with better pain control.

Moderator Thornhill: Mike, let me ask you something. You put in your multi-modal thing of pericapsular injectables. What is that?

Dr. Berend: It's either group A or group B from what Mike presented. So in the hospital we currently use the liposomal bupivacaine mixed with Marcaine. In our outpatient center, for cost, we use the same ropivacaine, clonidine, and ketorolac...a narcotic-free injection. So we use some type of pericapsular injection. What the recipe is, how you're going to balance the cost structure in your own environment...I think that's up to you.

Moderator Thornhill: Correct me if I'm wrong, but my understanding with liposomal bupivacaine, you can use regular bupivacaine, you can't use lidocaine, you can't use ropivacaine, you can't use Toradol, you can't use clonidine, you can't use epinephrine.



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Dr. Berend: I would defer to the manufacturer for what you can add/mix with it. Whether it's on label or off-label. The short answer is you don't want to use anything that will lyse the liposomals too early and cause a rapid release of Marcaine. I think if you're using topical betadine in the wound, you're using some other tranexamic acid, we're worried about anything additional that you are doing.

Moderator Thornhill: I actually asked the manufacturers because I didn't know and I wanted to see and it turns out you're right, you can't add anything else. You can add bupivacaine, but they will not recommend adding medications.

Dr. Berend: In a certain ratio, that is correct.

Moderator Thornhill: Okay, Mike, help me out with this. I use ropivacaine, clonidine, Toradol, epinephrine, QS it with saline. To me it's every bit as

important in where you put it and how you put it in as what you use. Tell us how to put it in.

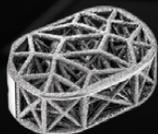
Dr. Meneghini: Couldn't agree more. I think what we've learned the optimal technique for periarticular injection... when we're done with the procedure we inject the periosteum, we inject the synovium, we inject the retinaculum. And we use the same cocktail that you and Mike both alluded to. But we do not inject the posterior capsule... there's some data out of Duke years ago that the posterior capsule may not be as advantageous. A lot of people propose that it is. We just choose to stay away from those structures in the back of the knee; stay safe at the anterior aspect of the knee.

Moderator Thornhill: I actually think putting it in posteriorly maybe the most important thing. What I do is I use... of the 100cc that I use, 20cc on the medial side, and I put 10cc on mesial

side of the lateral side. If it put it out laterally I've had a couple of transient perineal nerve palsies. But I think it gets rid of that posterior pain and hitting the periosteum is key. I don't put anything superficial to the capsule. Where do you inject and how do you inject?

Dr. Berend: I do it exactly the same. I do put it in the posterior capsule, but only on the medial side. I think there are 20 things you've got to consider in the care map of the knee arthroplasty patient. This is one of them. What flavor you use is important. But I think there's cost throughout the entire care map that we're now challenged to consider in terms of bundled care, for an episode of care. Whether you use post-operative therapy or knee immobilizer, those may be much larger cost issues than whether you use an expensive medication. So it may be of significant value for you to shift your hospital to shorter length of stay, which saves \$1,200 a day, which is worth the cost of the medication.

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Moderator Thornhill: But every little thing counts and if you look at Mike's point of the \$300 bucks versus \$6 bucks or something like that, if you say it doesn't really change the length of stay in the studies he showed us, and it isn't any better in pain control, isn't that \$300 bucks just added to "detract" from the bundle?

Dr. Berend: Absolutely and that's why when we're paying the bill at a surgeon-owned center, we don't use it. When it's part of a global cost where you're negotiating with the vendors, hospital relationships, you're worrying about a Foley catheter, and A-line laboratory things—things that you can largely eliminate now—I think it's one of 10 things you're going to consider in the cost of the care of the patient. And it may be worth it in some environments. It may not in others.

Moderator Thornhill: Tell me if I heard you right. Are you saying that in a place like an ambulatory center where you have a real dog in the fight, you don't use it? Whereas in the hospital you do?

Dr. Berend: That's what I'm saying. The hospital and I aren't getting along particularly well right now.

Moderator Thornhill: What do you think if you could prolong the nerve block efficacy? With this or any other type of medication—whether you mix epinephrine, clonidine or anything to potentiate the effect of the local, I think that's where the real value is going to be. If you can do a sensory only block that's extended, I think that's of significant value.

Dr. Meneghini: I fully agree.

Moderator Thornhill: I think we're looking at the data. I appreciate your

Midwestern honesty and your evidence-based medicine. Good job. ♦

Please visit www.CCJR.com to register for the 2017 CCJR Winter Meeting, – December 13 - 16 in Orlando, Florida.

Senior Editor: Jay D. Mabrey, M.D., whose 35 year career in orthopedics included residency at Duke University Medical Center, service in the United States Army Medical Corps, Fellowship at the Hospital for Special Surgery and a long, distinguished career at Baylor University Medical Center where, in addition to his overall leadership at that institution, developed the Joint Wellness Program that helped patients get up after surgery more quickly, developed the first virtual reality surgical simulator for knee arthroscopy and chaired the FDA Orthopaedic Device Panel, is Orthopedics This Week's newest contributing writer and editor.



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Spine Surgery Not Driving Opioid Use; Managing Weekend TKA Patients; Remove Hip Fractures From Bundle!

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



Courtesy of Andrew Huth © and Wikimedia Commons

Spine Surgery Not Driving Long-Term Prescription Opioid Use A light is shining on physicians these days when it comes to the opioid epidemic. One new study excludes spine surgeons from the bulk of the problem, however.

The study, "[Risk Factors for Prolonged Opioid Use Following Spine Surgery and the Association with Surgical Intensity, Among Opioid-Naive Patients](#)," was published in the August 2, 2017 edition of the *Journal of Bone and Joint Surgery*.

Andrew Schoenfeld, M.D. is an orthopedic spine surgeon at Brigham and Women's Hospital in Boston, Massachusetts, and was a co-author on the study. Dr. Schoenfeld told *OTW*, "In light of the opioid crisis, we thought it was important to investigate the extent to which spine surgical interventions were responsible

for initiating a process that culminates in sustained opioid drug use."

"The population under study is representative of the American demographic at greatest risk of developing sustained opioid drug use. The nature of the data allows us to accurately determine prescription opioid drug use before and after the surgical event."

"By six months following discharge, nearly all patients had discontinued opioid use after spine surgery. As only 0.1% of the patients continued opioid use at six months following surgery, these results indicate that spine surgery among opioid-naive patients is not a major driver of long-term prescription opioid use."

"Despite a low risk overall, socioeconomic status and pre-existing mental health disorders may be factors asso-

ciated with sustained opioid use in patients following spine surgery. Additional resources may be devoted to individuals with these characteristics to minimize the potential for post-operative dependence."

"There is of course a great deal of information in the popular media regarding the role that surgical intervention may play in contributing to the opioid epidemic. As we look for constructive ways to respond to this crisis, it does not appear that spine surgery is a major driver of sustained post-operative use among those patients who are not using these types of medications in the period leading up to the surgical procedure."

Needed: Better Management of Weekend TKA Patients What are the facts about weekend hospital stays and adverse outcomes?

This is what a team from Cleveland Clinic and SUNY Downstate Medical Center wanted to determine. Their work, "[Is Day of Surgery Associated With Adverse Clinical and Economic Outcomes Following Primary Total Knee Arthroplasty?](#)" appears in the August 2017 edition of *The Journal of Arthroplasty*.

Michael Mont, M.D., Chairman Orthopaedics at Cleveland Clinic Orthopaedic & Rheumatologic Institute in Ohio and co-author on the study, commented to *OTW*, "In my practice, I noticed that patients who are ready for discharge during the weekend sometimes stay in the hospital until Monday because of the shortage of appropriate staff to complete the discharge process."

"I proceeded to call my colleagues from several orthopaedic centers across the country, who acknowledged that they

are facing a similar problem in their hospitals. Therefore, I decided to analyze a large New York State database to see if this was a global issue in patients who undergo total knee arthroplasty (TKA)."

"The New York Statewide Planning and Research Cooperative System (SPARCS) is a comprehensive healthcare data reporting system established by the New York State Department of Health. This database collects data on all hospital admissions in New York State. One of the limitations of this and many other databases is the lack of long-term follow up. This limitation underscores the need to create and maintain Joint Replacement Registry in the United States."

The authors wrote, "We identified 115,053 patients who underwent primary TKA on a weekday between 2009 and 2013 in New York State."

Dr. Mont told *OTW*, "We found that patients who undergo primary total knee arthroplasty later in the week (Wednesday, Thursday, and Friday), have longer and more expansive hospital course. However, these patients did not have an increased risk of 90-day readmission."

"This report underlines the need to better manage total knee arthroplasty patients during the weekend by providing sufficient staff for discharge processing. This will not only decrease the length of stay and hospital costs, but potentially increase patient's satisfaction."

"Because of the current healthcare shift from pay-for-service to pay-for-value model, all orthopaedic surgeons should strive to improve patient outcomes and satisfaction while attempting to decrease hospital costs. In this



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study, we identified one of the many issues that currently burden the health-care system. I believe we, orthopaedic surgeons, should take an initiative in identifying and rectifying these shortcomings.”

Study: Remove Hip Fractures From Bundle! In order to stop unfairly punishing hospitals, says a new study, the current bundled payment needs to reconsider hip fractures. “[Hip Arthroplasty for Fracture vs Elective Care: One Bundle Does Not Fit All](#),” appears in the August 2017 edition of *The Journal of Arthroplasty*.

Richard S. Yoon, M.D., orthopedic trauma surgeon at the New York University Hospital for Joint Diseases and co-author on the study, commented to OTW, “The

Bundled Payment Initiative set forth by CMS [Centers for Medicare & Medicaid Services] is here and growing. There’s no way out of it other than refining it and maximizing value with cost in any way. We analyzed the fracture subset because we noted outliers that remained consistent through each quarter.”

“A lot of credit goes to the well kept data in the New York SPARCS [State-wide Planning and Research Cooperative System] database—with it we were able to analyze very specific, yet large numbers of data to help answer our questions. Obviously, this still is not as good as level 1 randomized controlled trials, but performed properly, has allowed for very important epidemiological level information that can help mold future health care decisions.”

“Our results indicate that fracture patients shouldn’t be included in the bundle. They are different, largely sicker, patients than those who are scheduled for elective total hip arthroplasty. The risk for complication, readmission, death, ICU [intensive care unit] stay, all went up in the fracture cohort compared to the elective group.”

“We commend CMS for listening and for this past year, removing hip fracture patients from the bundle.”

“This is a great example of orthopaedic surgeons (not only our authors but to those who also performed similar studies) collecting data and collaborating that actually instills change. Let’s continue to do more of the same.” ♦

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1. MacBarb, et al., “Fortifying the Bone-Implant Interface Part II: An In Vivo Evaluation of 3D-Printed and TPS-Coated Triangular Implants,” *Int J Spine Surg*. 2017; 11.

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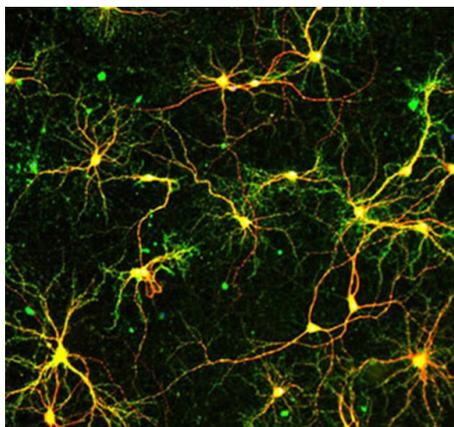
New Spinal Cord Injury Repair Company Launched

Based on an innovative technology from Yale University which has shown promise to grow nerve fibers naturally and restore all facets of nerve function, a new company, ReNetX Bio (formerly known as Axerion Therapeutics), has been launched.

ReNetX Bio is focused on providing physicians with a novel treatment for central nervous system injuries. Its inaugural CEO is Erika Smith, a 25-year veteran investor and entrepreneur who has invested in, managed and successfully exited numerous seed and early-stage investments with funding from Yale and Johnson & Johnson. Most recently, Ms. Smith was director of the Blavatnik Fund for Innovation at Yale University.

The company also announced that it was seeking funding via a Series A financing to pay for its first clinical trial of its lead therapeutic candidate, Nogo Trap, in patients with chronic spinal cord injury.

The company wrote in its July 24, 2017 news release, “ReNetX licensed the rights of the innovative neuro-restorative Nogo Receptor platform technology discovered by Stephen Strittmatter, M.D., Ph.D., at Yale University and founder and scientific advisor to ReNetX. The central nervous system contains major extracellular factors that limit regrowth of neurons. The company has developed a decoy receptor, called Nogo Trap, that binds the growth inhibitors allowing the body to grow nerve fibers naturally and directly targeting



Courtesy of Strittmatter Lab, Yale University

restoration across all facets of growth: axonal regeneration (long distance), axonal sprouting (medium distance) and synaptic plasticity.”

“Spinal cord injury has been a condition so far resistant to treatment by a variety of therapeutic approaches,” said Dr. Strittmatter. “However, based on the research in my laboratory, we believe that we may have an approach that could benefit these patients. Nogo Trap has demonstrated improved neurologic function following central nervous system damage in several animal models. Based on these promising results, we now believe that Nogo Trap should be evaluated in chronic spinal cord injury patients.”

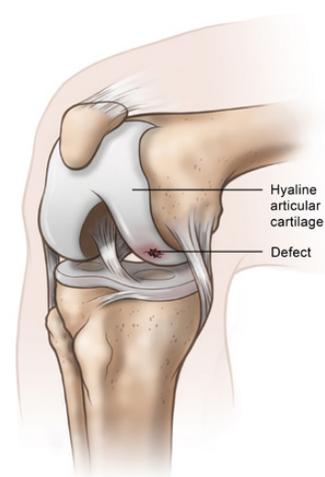
“Spinal cord injury is one of the most significant unmet medical needs with an annual cost of more than \$5 billion per year,” said Smith. “A treatment that could mitigate even only a part of the condition could improve quality of life of these patients. When the funding is in place, we anticipate swift patient recruitment for our chronic spinal cord injury clinical trial. In the long-term, conditions beyond spinal cord injury including glaucoma and stroke.”

Erika Smith told OTW, “When the central nervous system (CNS) is

injured—such as with paralysis in spinal cord injury—the neurons are unable to repair themselves unlike in the peripheral nervous system (PNS). Injury is permanent. The Nogo Trap is a scientific breakthrough in CNS to regrow neurons through the blocking of myelin inhibition factors. In other words—by trapping inhibition factors—the technology harnesses the body’s own ability to heal itself and restore neurons and function.”
— EH

Histogenics Moves Onto Phase 3 Clinical Trial for NeoCart

Histogenics Corporation, a regenerative medicine company headquartered in Waltham, Massachusetts, recently announced the completion of patient enrollment for Phase 3 Clinical Trial for NeoCart in accordance with the Special Protocol Assessment (SPA) agreement with the FDA.



Courtesy of Histogenics Corporation

According to a recent press release, “NeoCart is a tissue-engineered cartilage implant created from a patient’s own cells. The patient’s cells are multiplied in Histogenics’ laboratory and

then infused into a proprietary scaffold to allow them to function like native cartilage.”

Data so far suggests that it can potentially accelerate recovery and reduce pain compared with microfracture, the most common treatment for knee cartilage defects. During microfracture, small holes are made in the bone to heal the cartilage.

The randomized Phase 3 clinical trial will evaluate the safety and efficacy of NeoCart compared to microfracture in 245 patients at over 35 sites in the U.S. and Canada.

The primary endpoint is a dual-threshold responder analysis measuring the improvement in the pain and function of each patient treated with NeoCart compared to those treated with microfracture one year after treatment.

Adam Gridley, president and CEO of Histogenics, told OTW in an interview, “We think it is a very unique endpoint and a pretty high bar to achieve.”

“What makes NeoCart unique is that we are creating full functioning new tissue outside the body. Based on early results, NeoCart provides earlier pain relief and safe and durable results. Patients will be back to function quicker than they would with microfracture.”

He added, “With microfracture there is a lot of variation in response. There is a 30% reoperation rate after 2-3 years and oftentimes osteoarthritis will develop.”

Gridley said that they are on track for top-line year superiority data and potential BLA (Biologics License Application) Filing in third quarter of 2018.

— TR

New Graft Delivery Technology Receives Core Patent

SurGenTec’s Graftgun recently received device and method patent No. 9,668,881 from the United States Patent and Trademark Office for their graft delivery technology that can be used to post-fill implant cages, according to a press release.

The Graftgun not only allows surgeons to use the bone graft of their choice, but it allows the bone graft material to be delivered into bone voids, disc spaces, cages and implants in a minimally invasive way.

“Once the implant has been positioned and the inserter is removed, the device can be connected to post-fill a variety of implants. The Graftgun kit will include a universal loading device which enables

surgeons to load allograft, autograft, or synthetic biologics into the gun’s delivery tube and dispense it to an orthopedic site,” the release said.

“We now have intellectual property that protects our ability to post-fill cages in situ,” said Travis Greenhalgh, CEO of SurGenTec in the release.

“One of the challenges when using expandable or monolithic cages is the ability to post-fill them once inserted into the disc space. The traditional way to post-fill a cage is to use a funnel or an elongated syringe. Most types of bone graft require significant force to extrude the material into the aperture of a cage.”

He added, “Our ratcheting technology provides users the force needed to extrude an array of bone graft materials, while maintaining superior control of the amount of graft that enters the cage and disc space.

A concern with expandable cages is the ability to pack the implant with enough bone graft to provide maximum endplate contact. If there is a void between the bone graft and endplate there may be a higher risk of non-unions. The Graftgun ratcheting technology can help ensure the void is filled.”

SurGenTec is a privately owned medical device company headquartered in Boca Raton, Florida. They hope to release the Graftgun this summer. — TR



Courtesy of SurGenTec

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FDA Clears Osseus' Cervical Implant

On July 3, 2017, the FDA cleared Osseus Corporation's new cervical interbody hybrid composition implant which incorporates rough, porous titanium with the radiolucent and biomechanical properties of PEEK. The newly commercialized implant is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease at one or two contiguous levels within the cervical spine.

Eric Hansen, chief executive officer of Osseus, commented to *OTW*, "During the building days of Osseus Fusion Systems, we had to bootstrap our way up as a self-funded, no venture-capital organization that consists of myself and my partner, Robert Pace, as well as a lean staff of six, three of which are engineers."

"We wanted to compete in the 3D-printed and injection-modeled arena like other large companies, but both processes seemed out of range for

many reasons. I am proud to say that in this very crowded industry, we have developed a product that is extremely unique. As we gathered our surgeon development team of orthopedic and neurosurgeons, our target was to create a robust fusion bed built from titanium to blend with PEEK allowing maximum radiolucent visualization."

"During the design process of Gemini-C, we came up with many iterations and prototypes. We finally ended up with a proprietary way to blend and connect the two materials, avoiding the expensive prices of injection molding. The process and product that we invented will not shed or leach like many of the companies that are working with a post process and spray on method."

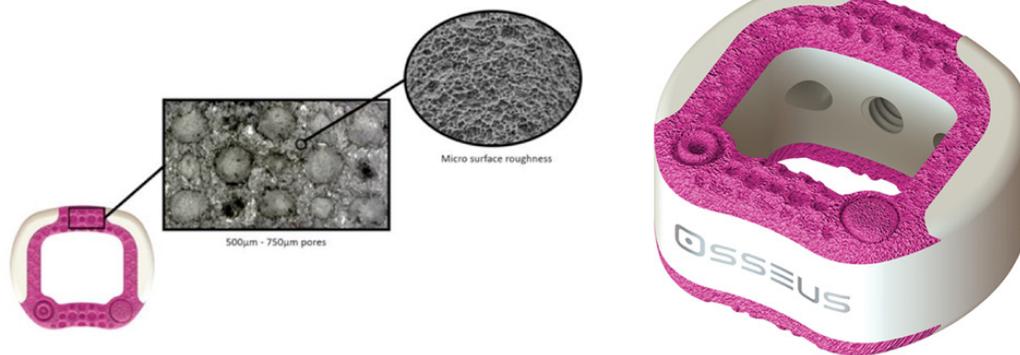
"Since then we have forged our way into the 3D printed arena by hiring young, but sophisticated engineering minds that have experience with two of the top five national spine companies."

"Osseus Fusion Systems is extremely focused on the engineering aspect of the organization. Our core focus is to create a broad product portfolio with new and exciting disruptive technolo-

gies within the spine implant industry. I believe entirely that this industry survives and thrives on small companies like Osseus to accelerate evolution and to create and develop new cutting-edge technologies.

"This industry has always depended on the 'little guys' for ingenuity and speed to market. I learned this with my first company, Surgical Dynamics, and my mentor, Henry Klyce, as we developed the Ray Threaded Fusion Cage. With the next venture, Blackstone Medical, I realized that the larger companies could not follow the path of evolution as quickly as a small, nimble private company could. I've come to find this to be extremely valuable to the industry. Our mission at Osseus is to create a team of inventive, entrepreneurial-spirited surgeons and engineers that can expedite and advance technologies while developing superior quality implants and equally important instruments.

Commenting to *OTW* on the future, Hansen noted, "Osseus will remain private with zero outside investment. Rob and I have managed to get over the hump with our own personal investment of over five million dollars. We are now running at a very sweet 38% EBITA, of which more than 80% of profit goes back into the company that allows us to fast track our product development queue. As we look to the future of this industry, we emulate and receive coaching from private companies like Arthrex and Reinhold Schmieding. We continue to have enormous faith that a privately-owned company can continue to survive and thrive in today's spine market." — *EH*



Gemini-C Cervical Interbody / Courtesy of Osseus Corporation

Stryker Pedicle Screw Cleared by FDA

Stryker Spine's Serrato Pedicle Screw has been cleared by the FDA for sale in the U.S.

On August 16, 2017, the company announced the screw, used in the non-cervical spine, received 510(k) Clearance from the agency.

The company says the screw features enhanced serrated cutting flutes, a "unique" dual-thread pattern with an increased number of leads for rapid insertion, and a patented buttress thread locking mechanism designed to "minimize cross threading and splaying" of the screw head. The screws accommodate a variety of rod diameters and materials to suit the patient's needs—5.5 and 6.0mm diameter rods in commercially pure titanium, titanium alloy, and Vitallium.

Walking the fine line between receiving clearance for something "substantially equivalent" to a previously approved device and something groundbreaking requiring full FDA approval, Brad Paddock, the spine division president, said, "Pedicle screws have been used for decades with very few changes to their design. The design innovations incorporated into Serrato reinforce our commitment to making industry-leading



Xia Spinal System/Courtesy of Stryker Spine

investments focused on providing the advanced spinal products and differentiated technologies that our surgeon customers have come to expect."

The screw is part of the company's Xia 3 Spinal System. The system is an orthopedic spinal system comprised of a variety of shapes and sizes of screws, blockers, and hooks that affix several different types of rods and connectors to vertebrae or the spinal column for purposes of stabilization, or corrective action through the application of force.

The company said the system was developed with the aim to develop better implants and is represented by the patented buttress thread closure mechanism. "What started as a top-loading pedicle screw system for treatment of degenerative spine pathologies has grown to include deformity solutions and a recently introduced trauma/tumor line extension."

"The Xia Spinal System is comprised of implants and instruments for stabilization of the spine during fusion in the thoracic, lumbar and sacral regions, with many features including:

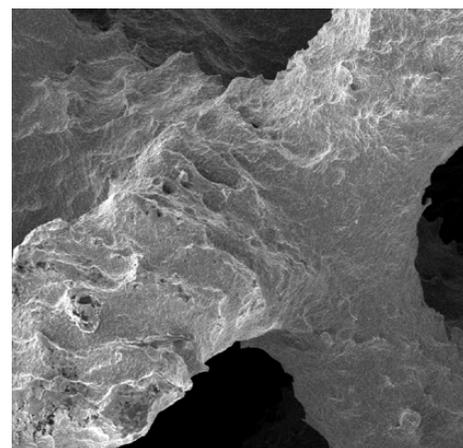
- Reduced profile and implant volume
- Patented buttress thread closure mechanism
- Ergonomically designed instruments
- Available in stainless steel and titanium alloy"

According to the company, the intended use of the system is for use in the non-cervical spine. When used as an anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation system, the system is intended

to provide additional support during fusion using autograft or allograft in skeletally mature patients in the treatment of the following acute and chronic instabilities or deformities: degenerative disc disease, spondylolisthesis, trauma, spinal stenosis, curvatures, tumor, pseudarthrosis, and failed previous fusion. — WE

FDA Clears Novel German ALIF, PLIF and TLIF Implants

Emerging Implant Technologies GmbH (EIT), a medical device manufacturer based in Wurmlingen, Germany, announced that it has received full clearance from the FDA



EIT Cellular Titanium / Courtesy of Emerging Implant Technologies GmbH

to commercialize its spinal interbody product offerings for anterior lumbar interbody fusion (ALIF), transforaminal lumbar interbody fusion (TLIF), posterior lumbar interbody fusion (PLIF) and cervical procedures.

The novel aspect of the company's offerings is its EIT Cellular Titanium structure. As the company wrote in its July 18, 2017 news release, "EIT Cellular

Titanium is a porous titanium structure that has been designed according to scientific insights on ideal pore shape and size to optimize bone ingrowth.”

“Due to the availability of metal 3D printing Selective Laser Melting (SLM) technology and proprietary post-processing methods, it has been possible to create a highly porous, osteo-influential titanium scaffold for osseointegration.”

“This EIT Cellular Titanium structure has been applied in the complete ALIF, TLIF, PLIF and cervical implant line, and clinical case studies and retrieval analysis demonstrate extensive bone ingrowth throughout the total implants in the cervical and lumbar spine in a short time frame.”

“EIT Cellular Titanium Interbody cages target for Smart Spinal Fusion in combining an osteo influential scaffold with designs to address spinal alignment. The implants have been used in over 10,000 cases in over 15 countries including Germany, France, Australia, Korea and the Netherlands. With the milestone of this 510(k) clearance, EIT is moving towards full commercialization effective immediately.”

Guntmar Eisen, co-founder and CEO for EIT, told OTW, “The FDA process went smoothly—we filed the entire portfolio in one application. We will be in all major markets leading the market of 3D printed cages. We will be combining EIT cellular titanium technology with functionality—fully printed functional spinal cages, eliminating the need of combining materials and assembly processes—functional cages based on our IP platform of 3D printed functional spinal implants (MIS, expansion, distraction, sagittal balance correction, coronal plane correction etc....).” — EH

\$4.5 Million Verdict for Lost Sex Life

What is your sex life worth if it has been taken away because of a failed back surgery?

On August 2, 2017, a state jury in Oregon, awarded more than \$4.5 million to a couple after the 30-year-old husband underwent a failed spine surgery which left him with numbness in his genital area, seriously altering his sex life with his wife.

The surgery was performed by neurosurgeon Warren Roberts, M.D., of Tualatin, Oregon.

The *Oregonian* reported that after deliberating for eight days, the jury found that Roberts and his practice, Aspen Spine and Neurosurgery Center, were negligent. The jury awarded Jason Croff \$94,000 in economic losses and \$3.5 million in noneconomic damages for pain and suffering. The jury also awarded his wife, Cassandra, \$1 million for loss of consortium with her husband.

In September 2013, after experiencing back pain, Croff went to see his

primary-care doctor who referred him to Roberts. A month later, Roberts performed surgery with a plan to remove a disc from Croff’s spine. Croff was 27 at the time.

According to the report, Croff claims that Roberts mishandled the surgery, in part by failing to remove the disc and failing to tell him about it. Croff argued that led to his worsening symptoms and causing his permanent trouble to urinate and genital numbness.

Roberts’ lawyers contended that the surgeon did tell Croff that he couldn’t remove his disc and that he would need future surgery. In court papers, Roberts’ attorney argued that Croff couldn’t prove that his medical conditions were Roberts’ fault and that the standard of care had been met.

But the jury disagreed. It was not the only time Roberts has had his professional behavior questioned.

According in a pretrial deposition, Roberts no longer performs neurosurgery and examines patients during house calls after his privileges were revoked at the Legacy Health and Legacy Meridian Park Medical Center in Tualatin.



Gustav Klimt's *The Tree of Life* / Source: Wikimedia Commons and The Yorck Project: 10.000 Meisterwerke der Malerei

In July, Roberts, an African American, filed a \$24 million lawsuit against the medical center, claiming that his privileges at the hospital were revoked as part of a “sham” process, driven in part by racism and the desire of other doctors to remove him as competition.

“No one will even consider him as a neurosurgeon due to the toxic adverse actions reports in the NPDB (National Practitioner Data Bank),” Roberts’ lawsuit states.

Roberts has been practicing medicine since 2001, according to Oregon Medical Board records. He is in his mid-40s.

The *Oregonian* also reported that the Oregon Medical Board issued a notice of proposed disciplinary action against Roberts in 2014 and 2015 for alleged “unprofessional or dishonorable conduct, and gross or repeated acts of negligence.”

Jurors weren’t allowed to hear about those cases after the judge ruled they weren’t relevant to Croff’s lawsuit. — WE

The authors wrote, “Monthly radiation exposure was measured over a 12-month period for 24 orthopaedic residents and 16 orthopaedic attending surgeons. The participants wore a Landauer Luxel dosimeter on the breast pocket of their lead apron. The dosimeters were exchanged every rotation (5 to 7 weeks) for the resident participants and every month for the attending surgeon participants. Radiation exposure was compared by orthopaedic subspecialty, level of training, and type of fluoroscopy used (regular C-arm compared with mini C-arm).”

“Orthopaedic residents participating in this study received monthly mean radiation exposures of 0.2 to 79 mrem/month, lower than the dose limits of 5,000 mrem/year recommended by the United States Nuclear Regulatory Commission (U.S. NRC).

“Senior residents rotating on trauma were exposed to the highest monthly radiation (79 mrem/month [range, 15 to 243 mrem/month]) compared with all other specialty rotations. Similarly, attending orthopaedic surgeons who specialize in trauma or deformity surgery received the highest radiation exposure of their peers, and the mean exposure was 53 mrem/month (range, 0 to 355 mrem/month).”

Moira McCarthy, M.D. is an orthopedic surgeon at HSS, and a co-author on the study. She commented to *OTW*, “I became interested in this topic as a resident. I was using radiation for various uses almost every day. Residents use radiation in the emergency room to reduce fractures several times per night and in the OR [operating room] on a daily basis to ensure appropriate fixation and reduction of fractures.”

“I felt like I was getting radiated a lot and was interested in the overall radiation dose to residents and attendings in different orthopedic specialties. Also, although rare, I was aware of several cases of orthopedic surgeons, females in particular, who developed cancers. As a secondary reason, I wondered whether or not high radiation exposure could be a potential cause.”

“Everyone gets some radiation and some specialties and levels of expertise get more than others. Thinking about this while training definitely had an influence in what field of medicine/surgery/orthopedics I chose to pursue.”

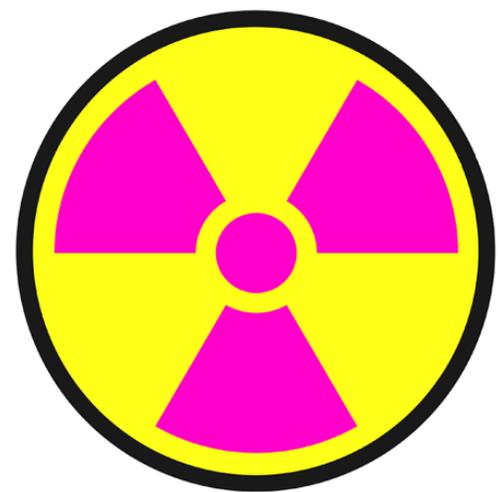
“Everyone should be aware of the risks associated with their chosen job and specialty. Those specialties with higher exposure should take extra precautions to protect themselves with radiation shields for the body, thyroid, and eyes.”

“Radiation is a part of this job. Everyone should protect him or herself appropriately for even the smallest amount of radiation exposure because it is cumulative. Protection from every little bit is potentially helpful in the long run.” — EH

LARGE JOINTS

Highest Radiation? Trauma and Deformity Surgeons!

Trauma and deformity surgeons should be especially careful to gear up against radiation exposure, says new work from Hospital for Special Surgery (HSS) in New York. The research, “Tracking Cumulative Radiation Exposure in Orthopaedic Surgeons and Residents: What Dose Are We Getting?” appears in the August 2, 2017 edition of *The Journal of Bone and Joint Surgery*.



Source: Wikimedia Commons

AJRR: First-Ever Data Summary for Patients

The American Joint Replacement Registry (AJRR) has announced the publication of the 2016 Report to the Public About Hip and Knee Replacements, the first-ever patient summary of the clinical data available in its Annual Report.

“Spearheaded by members of our Public Advisory Board, this report was developed to share what we are learning about hip and knee replacement surgery in the United States,” said Daniel J. Berry, M.D., AJRR Board of Directors Chair, in the July 24, 2017 news release. “We are proud to publish and release this report so patients can better understand how that information is being used to continually improve the quality of their care.”

“AJRR is committed to producing this report every year, in conjunction with the year-end publication of its Annual Report,” writes the organization in its news release. “The report can be accessed on the AJRR website and will be made available to AJRR’s 1,000+ par-

ticipating institutions, as well as industry-leading consumer groups, all of whom are encouraged to share it with the public and their members.”

“The Public Advisory Board is chaired by AJRR Board Member Margaret VanAmmringe, M.H.S. and includes John A. Canning Jr., David G. Mekemson, Timothy M. Mojonier, Richard Seiden, Esq., Diana Stilwell, M.P.H., and staffed by Lori Boukas, M.S.”

Diana Stilwell told OTW, “The key trends we’re seeing are the increase in the number of participating hospitals and the corresponding increase in the number of implants/procedures included in the American Joint Replacement Registry. It’s also interesting to note the decline in hip resurfacing, as well as the increase in the number of ‘linked’ arthroplasties which, over time, will allow clinicians and patients to better understand and manage factors that increase a patient’s chance of needing a repeat joint replacement.”

To access the 2016 Report to the Public About Hip and Knee Replacements, visit www.ajrr.net/publications-data. — EH

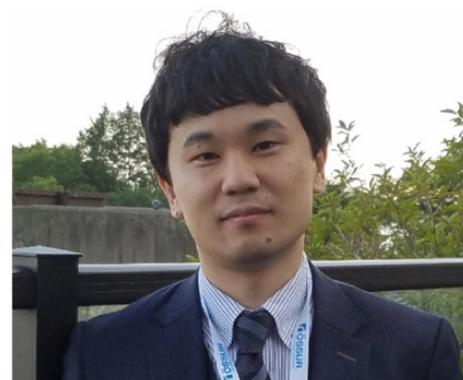
SPORTS MEDICINE

Lateral Ankle Sprain Study Wins Best International Award

This year’s Best International Paper and winner of the T. David Sisk Awards for Research Excellence is a



T. DAVID SISK AWARD FOR RESEARCH EXCELLENCE
2017 RECIPIENT:
BEST INTERNATIONAL PAPER



Lead Investigator Takumi Kobayashi, Ph.D., P.T., Hokkaido, Japan / Source: RRY Publications LLC.

study from Hokkaido, Japan titled: *Intrinsic Risk Factors of Lateral Ankle Sprain: A Systematic Review and Meta-analysis*.

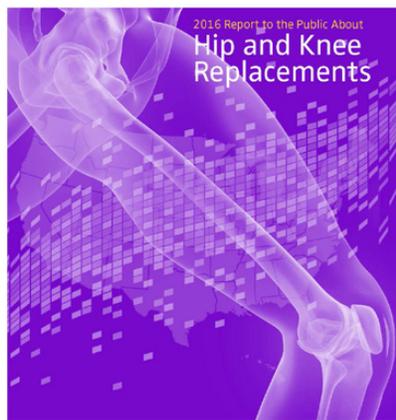
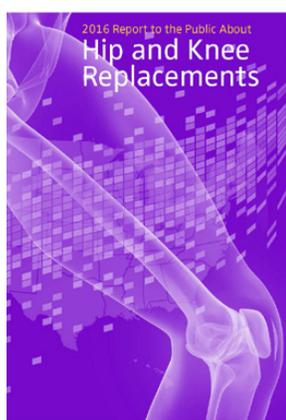
The award was announced at the 2017 annual meeting of the American Orthopaedic Society of Sports Medicine (AOSSM) on July 20 in Toronto, Canada.

Lead investigator Takumi Kobayashi, Ph.D., P.T. received his award at a ceremony at the AOSSM annual meeting. Fellow co-authors, Masahiro Shida, M.S.C., P.T. and Masashi Tanaka, M.S.C., P.T. remained in Japan. All

American Joint Replacement Registry
Improving Orthopaedic Care Through Data

AJRR American Joint Replacement Registry
Improving Orthopaedic Care Through Data

AJRR American Joint Replacement Registry
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Courtesy of American Joint Replacement Registry

three researchers are from the Hokkaido Chitose Institute of Rehabilitation Technology, Hokkaido, Japan.

The T. David Sisk Research Awards were established in 2010 to honor the best papers submitted to *Sports Health* in clinical, laboratory, and international research. The winners receive a \$2,500 cash prize and a plaque.

Dr. Sisk was a strong proponent of *Sports Health: A Multidisciplinary Approach*, and served as the Chairman of the AOSSM Medical Publishing Board of Trustees at the time when the creation of the new journal was proposed. He enthusiastically fostered the journal throughout its initial development and set the journal's course for its current success. Dr. Sisk was a former AOSSM President, Hall of Fame inductee, and active member in the sports medicine community throughout his esteemed career. He died of cancer in July of 2009 but his legacy of teaching and collaboration continues to live on.

What Are the Intrinsic Risk Factors of Lateral Ankle Sprains?

This award winning paper from Japan sought to understand the risk factors for one of the most common injuries in recreational activities and competitive sports. This is not a new question. Many studies have attempted to tease out intrinsic factors that can predict lateral ankle sprains (LAS). But, as the researchers noted in their paper, no consensus has emerged regarding such predictive intrinsic factors.

Dr. Kobayashi and his team used several data sources to set up the study including MEDLINE, CINAHL, ScienceDirect, SPORTDiscus, and Cochrane Register of Clinical Trials. The computerized literature search pulled up 1,133 studies which discussed LAS intrinsic risk factors—notably, written in English.

Finally, the researchers used a modified quality index to assess the quality of the design of the papers and then used a standardized mean difference pool study outcomes.

Here is what the Kobayashi team found.

Body mass index, slow eccentric inversion strength, fast concentric plantar flexion strength, passive inversion joint position sense, and peroneus brevis reaction time were correlated with LAS and, therefore, provide physicians and trainers with, certainly, the raw material for risk factors which could predict LAS. —RY

PEOPLE

99 Year Old Former NYU Professor and Orthopedic Surgeon Dies

Known as a gentleman farmer, Albert Bernard Accettola, M.D., former educator and leading orthopedic surgeon, died at his home in Readington Township, New Jersey on July 18, 2017 at the age of 99.

He is survived by two children, daughter Dr. Judith Hendricks (Keith Hendricks), son, Dr. Albert Accettola Jr. (Iris Accettola), six grandchildren and four great-grandchildren. He was predeceased by his beloved wife Rose Accettola, and son Paul Accettola.

Albert Accettola was born on February 4, 1918 in New York City. He graduated from Wag-

ner College in 1940 and then attended Boston University Medical School, where he graduated in 1944.

Dr. Accettola held positions at Staten Island University Hospital, Bellevue Hospital, Marquette University, and Hunterdon Medical Center, Flemington, New Jersey, where he was a founding doctor of the orthopedic department. He later had a private practice on Staten Island.

Also an educator, Dr. Accettola taught orthopedics as an associate clinical professor at New York University, and was the orthopedic surgeon to all athletic teams at Wagner College from 1949 to 1987. A fencer during his undergraduate years, Wagner College wrote of Dr. Accettola: "Whether with a saber in his hand or a scalpel, Al Accettola has been a gift to Wagner sports."

Dr. Accettola was a member and past president of the Richmond County Medical Society, a past president of the Medical Board of Staten Island Univer-



Albert Bernard Accettola, M.D. / Courtesy of silive.com/news/2017/07/post_1663.html

sity Hospital, and an active member of the New York State Medical Society, serving on numerous committees. According to his obituary, in 1987 Dr. Accettola retired to his 90-acre farm in Flemington, where he remained busy and active with farming, antique restoration and enjoying time with children and grandchildren.

A Mass of Christian Burial was celebrated by the Reverend Jack O’Kane at Saturday, July 29, 2017 at St. Elizabeth Ann Seton Church, 105 Summer Road, Three Bridges. A private cremation was at the Chapel of Ewing Crematory in Ewing Township.

Noel Testa, M.D., clinical professor of orthopaedic surgery at NYU Langone Health, stated, “I knew Dr. Accettola as an attending in the Department of Orthopaedics during my residency. He was a gentleman in the truest sense of the word.”

“Dr. Accettola was a dedicated educator, a talented diagnostician and a skilled orthopaedic surgeon. He was well liked and respected by his peers and his students.”

“He brought quality orthopaedic care to the borough of Staten Island when it was only connected to the rest of New York City by the Staten Island Ferry.” — EH

Justin Irizarry Wins Up & Comer Award

Justin Irizarry, co-founder and chief financial officer of OrthoNOW, has won the *South Florida Business and Wealth Magazine* annual Up & Comer Award in the healthcare category. Irizarry, a graduate of Cornell University who then went on to earn an M.B.A. from Wharton, began his career on

Wall Street as a vice president at Scott-Macon, Ltd.

In OrthoNOW’s July 10, 2017 news release, the company wrote, “OrthoNOW, the nation’s only orthopedic urgent care franchise, is focused on the assessment and treatment of a range of orthopedic and sports injuries, chronic conditions, and preventative protocols—all on a walk-in basis. OrthoNOW recently announced the development of over 40 units coast to coast so far this year and over 100 by year end. OrthoNOW franchisees are comprised of best in class investors, sophisticated business owners and operators, private equity firms, SCAs, orthopedic medical groups, and other forward thinkers committed to disrupting traditional healthcare delivery models. The brand’s strategy is focused on wealth building and portfolio diversification. Irizarry recently received *South Florida Business Journal’s 40 Under 40 Award* for his contributions to the community. He was also selected a finalist for the 2017 CFO Awards by the same publication.”

Irizarry commented to OTW, “I am truly honored and grateful to be honored with this very prestigious award. My journey with OrthoNOW, from its conception to where it is today, has exceeded all of my expectations both personally and professionally. When I began my career as a ‘Wall Street’ executive I never dreamed that I would have the opportunity to be the co-found-

er of a truly revolutionary concept in healthcare. The partnership I have formed with my co-founder, Alejandro Badia, M.D., F.A.C.S., has allowed us to bring our expertise together and conceive a business model that makes both common sense and common cents. The superior outcomes our patients enjoy, and the opportunity to work with all of our amazing OrthoNOW staff, in communities from coast to coast is the reason I get out of bed each and every day.”

“It is very important that the orthopedic community understand that, while time is ticking, OrthoNOW remains a ground level opportunity of merit. Our proven business model allows clinicians to provide superior clinical care while simultaneously creating new revenue streams and future financial security for themselves.” — EH



Justin Irizarry / Courtesy of OrthoNOW



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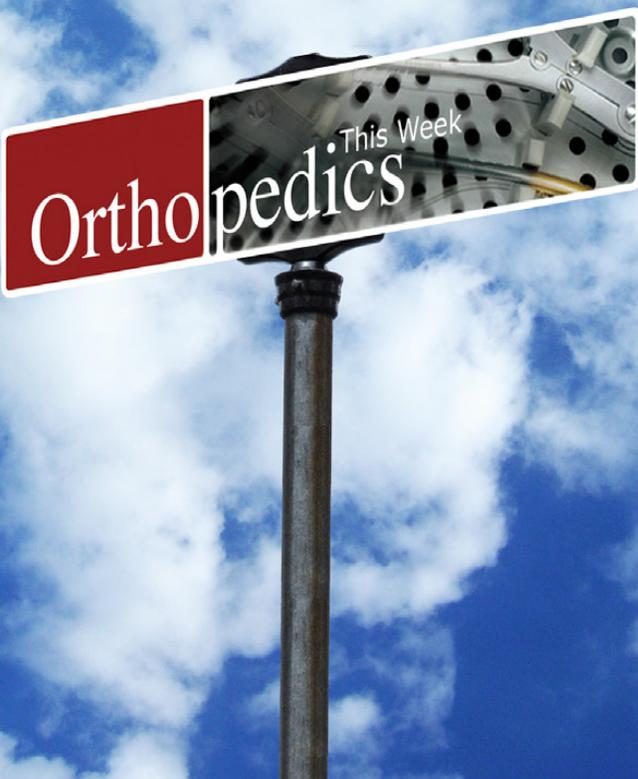
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