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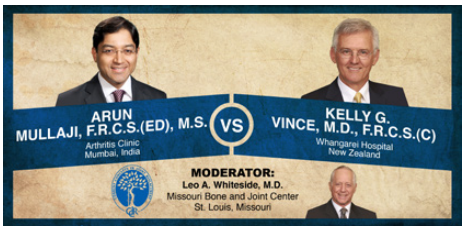
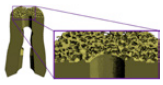
Orthopedics This Week

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: On the eve of the orthopedic industry's annual meeting all parties are gearing up for an eventful week. Wall Street's analysts are affirming that the industry is rebounding and will, no doubt, be looking for confirmation at AAOS. Companies have pre-marketed new products and clinical data. The mood this year is the best since 2007, at least. This week, we're pretty much marking time on the Power Rankings pre-AAOS.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	ConMed	10.37%	12.59%	Annual meeting is May 22 and the two sides are gearing up for the vote. However this turns out the big winner will likely be CNMD's shareholders.
2	2	Stryker	15.71	6.03	Interesting headline late last week: "Stryker Corporation America's fastest growing dividend trading at a 16% discount."
3	4	Zimmer	27.31	6.38	Increases dividend 10%. Should have a banner AAOS. We'll be hanging out at ZMH's booth. We're expecting knees, knees and more knees.
4	3	Smith & Nephew	20.25	8.75	Announces a co-marketing deal with OrthoSensor and will offer with JOURNEY II and LEGION TKA systems.
5	5	Medtronic	28.84	9.46	With the largest market share in spine, MDT is the target for all of these newly public spinal implant companies. In spine, size does have advantages.
6	6	Symmetry Medical	6.50	7.65	With all the costs of closing Cheltenham, most analysts are expecting down earnings this quarter but a nice rebound in Q2.
7	7	Johnson & Johnson	26.58	6.92	As the largest orthopedic company in the world, Synthes/DePuy should be the largest presence at AAOS. But, in this case, size may be a challenge.
8	8	Integra LifeSciences	11.77	8.53	Valuation wise, IART is very inexpensive. And, we note earnings this quarter are expected to hit $0.57 per share from just $0.39 last year.
9	9	NuVasive	6.30	3.20	Wall Street broker raised its target price for NUVA from $42 to $45. NUVA's big meeting is not AAOS, It's AANC/CNS and there NUVA should shine.
10	10	Globus Medical	28.29	9.43	All analysts are enamored with GMED and its management. Which has had the effect of pushing valuation into the ––premium pricing range.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	$0.76	$39	42.11%
2	RTI Biologics Inc	RTIX	$3.90	$220	30.00%
3	Baxano Surgical Inc	BAXS	$1.49	$67	20.16%
4	TiGenix	TIG.BR	$1.25	$200	12.64%
5	Conmed	CNMD	$46.68	$1,270	12.59%
6	Orthofix	OFIX	$22.96	$447	11.40%
7	Medtronic	MDT	$59.91	$59,959	9.46%
8	Globus Medical	GMED	$25.30	$2,359	9.43%
9	Smith & Nephew	SNN	$78.05	$13,953	8.75%
10	Integra LifeSciences	IART	$48.84	$1,583	8.53%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Alphatec Holdings	ATEC	$1.26	$123	-44.00%
2	Aurora Spine	ASG	$3.25	$51	-30.07%
3	ArthroCare	ARTC	$48.21	$1,657	-2.61%
4	MiMedx Group	MDXG	$7.24	$764	-1.50%
5	CryoLife	CRY	$9.87	$275	-0.90%
6	Tornier N.V.	TRNX	$18.97	$920	0.80%
7	NuVasive	NUVA	$37.13	$1,705	3.20%
8	Exactech	EXAC	$23.14	$314	5.13%
9	Stryker	SYK	$81.64	$30,849	6.03%
10	Zimmer Holdings	ZMH	$98.06	$16,603	6.38%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$22.96	$447	9.22
2	Medtronic	MDT	$59.91	$59,959	16.25
3	CryoLife	CRY	$9.87	$275	16.33
4	Johnson & Johnson	JNJ	$93.32	$263,993	17.04
5	Zimmer Holdings	ZMH	$98.06	$16,603	17.07

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$37.13	$1,705	103.14
2	Symmetry Medical	SMA	$10.55	$393	79.44
3	ArthroCare	ARTC	$48.21	$1,657	31.84
4	Integra LifeSciences	IART	$48.84	$1,583	30.79
5	Conmed	CNMD	$46.68	$1,270	25.64

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Exactech	EXAC	$23.14	$314	1.07
2	Orthofix	OFIX	$22.96	$447	1.32
3	Globus Medical	GMED	$25.30	$2,359	1.58
4	Zimmer Holdings	ZMH	$98.06	$16,603	1.77
5	Conmed	CNMD	$46.68	$1,270	1.97

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$37.13	$1,705	9.94
2	Symmetry Medical	SMA	$10.55	$393	6.62
3	CryoLife	CRY	$9.87	$275	4.08
4	Integra LifeSciences	IART	$48.84	$1,583	3.24
5	Smith & Nephew	SNN	$78.05	$13,953	2.92

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.26	$123	0.63
2	Orthofix	OFIX	$22.96	$447	0.97
3	Symmetry Medical	SMA	$10.55	$393	0.98
4	RTI Biologics Inc	RTIX	$3.90	$220	1.11
5	Bacterin Intl Holdings	BONE	$0.76	$39	1.19

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.25	$200	49.07
2	MiMedx Group	MDXG	$7.24	$764	12.92
3	Wright Medical	WMGI	$31.77	$1,574	6.50
4	Globus Medical	GMED	$25.30	$2,359	5.43
5	ArthroCare	ARTC	$48.21	$1,657	4.38

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

Can ConMed's Founding Family Survive? PART I

BY ROBIN YOUNG

The Corasanti Family runs Utica, New York-based ConMed, Inc., one of the largest ($1.3 billion market capitalization) diversified orthopedic companies in the world. Eugene Corasanti founded ConMed when he has 39-years-old after years of serving as an independent public accountant in the small city of Utica, New York. He is 83-years-old now and to this day, one of the hallmarks ConMed is its accounting culture.

Four members of ConMed's seven member board of directors are accounting professionals—Eugene Corasanti (CPA), Bruce Daniels (former Controller of Chicago Pneumatic Tool), Jo Ann Golden (CPA and former managing partner of Dermody, Burke and Brown) and Mark Tryniski (former Chief Financial Officer of Community Bank and partner with Price Waterhouse).

One of the other hallmarks of ConMed is an insular corporate culture. And it is on this petard that a group of dissident shareholders are trying to hoist the Corasanti family.

Lending voice to ConMed's dissident shareholders is Voce Capital (Italian for "voice") and its managing parnter J. Daniel Plants.

Voce is petitioning ConMed's shareholders to wrest control of their company away from the Corasanti family.

Wikimedia Commons and Howard Pyle/Logos courtesy of ConMed, Inc. and Voce Capital

The Coming Battle for Control of ConMed

That ConMed is undervalued is not disputed. By the cumulative measure of P/E ratio, Price-to-Sales ratio and a comparison of P/E to expected earnings growth rate, ConMed is cheaper than 83% of all other orthopedic companies (see our Power Rankings).

Clearly San Francisco-based Voce Capital sees much more value in ConMed than its Wall Street brethren. But Voce Capital is claiming that ConMed's management and, more specifically, the Corasanti family, is blocking the company from realizing its true (and higher) value.

Said Voce's managing partner J. Daniel Plants in a letter he wrote to ConMed this past November 2013, "ConMed suffers from a culture of nepotism, patronage and dystopian corporate governance that would be corrosive in a closely-held corporation but which

is utterly corrupting in a public company."

Since Voce Capital surfaced, two other well-known corporate raiders Camber Capital (5.1% owners of ConMed shares) and Coppersmith (5.9% of ConMed shares) have also begun buying shares. Combined the three firms own nearly 12% of ConMed's shares—which is 4x the number the Corasantis own.

From all appearances, a bruising fight is shaping up for this coming May's annual shareholder meeting.

Can the Corasantis survive?

Family and Friends

One of Voce's most pointed criticisms concerns ConMed's insular and family dominated corporate culture.

At ConMed many members of the Corasanti family have senior employment positions. When Eugene Corasanti, ConMed's founder, stepped down as CEO in 2006, his son Joseph J. Corasanti, Esq. became his father's successor. Eugene Corasanti's other son, David Corasanti, also works at ConMed. ConMed's head of corporate and business development activities is 82-year-old William W. Abraham whose two sons-in-law are also employed by the company.

Joseph Corasanti's sister-in-law Heather L. Cohen is a member of ConMed's senior management team and serves as Executive Vice President, Human Resources, Deputy General Counsel and Secretary. In this role, she's involved in managing the personnel dynamics and conflicts of interest at ConMed, including those between the Corasantis (her family) and the company.

In its public filings with the SEC, ConMed has disclosed that, addition to salaries and equity participation programs, ConMed's top executives also receive country club memberships, automobile leases and special insurance policies. ConMed made payments to other Corasantis including E. Corasanti's brother-in-law; to J. Corasanti's father-in-law and brother-in-law; and to the law firm of a former director, Robert E. Remmell, throughout his tenure on the board. Most recently, J. Corasanti used ConMed assets to promote the book of his wife, Michelle Cohen Corasanti, including the use of his staff's time, corporate letterhead and company email accounts.

Said Voce Capital's Plants:

> "Shareholders wonder where the line is drawn between the assets of ConMed and the interests of the

Corasanti family, or if there's a line at all."

The elder Corasanti, now 83-years-old, continues as both Chairman and Vice-Chairman of the board. As Chairman he receives an annual board retainer. As Vice-Chairman he has an employment agreement with ConMed and receives a $100,000 annual salary and equity compensation which in 2012 totaled almost $150,000. His job is to make himself "available to advise the Chief Executive Officer" (i.e., his son).

Said Voce's Plants:

"Isn't that what all directors are supposed to do as part of their job? But it doesn't stop there. Eugene Corasanti is collecting $3.7 million of deferred compensation as if he had retired in 2006, even though as a current employee of the Company he's not retired and otherwise would not be entitled to receive it at this time. He also continues to enjoy "an automobile allowance, club memberships and life and health insurance benefits." These benefits continue "during E. Corasanti's life and the *life of his wife*. Mrs. Corasanti's specific contributions to ConMed's success are unclear to us."

"Like his father, J. Corasanti has a pretty nice gig. His annual compensation is approximately $2.5 million. Just like dad, he earns additional payments for his Board service—despite the fact that he's also an employee. This is both inappropriate and unnecessary, given how handsomely he's already paid as CEO. The Company continues to carry as a loan to father and son premiums paid by ConMed to purchase multi-million "split-dollar" life insurance policies for their benefit. In addition to the other perquisites lavished on top ConMed executives, J. Corasanti also has access to special life and health insurance policies and benefits for himself and his wife should she outlive him (coincidentally, just like her mother-in-law). And finally, he's protected by a generous ($15 million) golden parachute. The apple, they say, never falls far from the tree."

So What?

The Corasanti family hires its relatives and pay themselves well. So what?

Nepotism is not, a priori, a bad thing. Two firms which the managers at Voce are no doubt familiar with—Piper, Jaffray and Hopwood and Stephens Inc.—are famous for their family hiring. Within the financial community both firms enjoy exceptional reputations.

Voce Capital, however, maintains that ConMed's familial and insular hiring patterns are directly linked to ConMed's poor performance.

Said Voce in a November, 2013 letter to ConMed's management:

"In the last ten years, ConMed's organic growth has slowed considerably, from high single digits early in the prior decade to essentially flat to down this decade. These results significantly underperform orthopedic industry leaders such as Smith & Nephew, Stryker and Zimmer. Zooming in on 2013, ConMed is the only one of its peers to report negative revenue growth."

Furthermore, alleges Voce:

"Throughout 2009 ConMed declared the worst [of the 2008 recession] was behind it, yet went on to fall short of its revenue guidance for FY 2009. In February 2010 it confidently announced 'the economic effects on the company had reached a welcome turning point' and in July went on to say 'our business is stabilizing and returning to a state of steady consistent growth.' Yet ConMed missed both its 3Q10 and 4Q10 revenue targets (4Q10 actually shrank 3.5% year-over-year). As a result, ConMed subsequently fell short of its full year 2010 revenue guidance, then missed it again in 2011…and yet again in 2012. While 2013 is not formally over, it's not too early to write its epitaph because management has already lowered its full year revenue target below the bottom end of its original forecast—*making six straight years ConMed has missed its revenue projections.*"

Annual Meeting in May

Voce Capital has proposed four independent directors to replace some of the existing directors on ConMed's board of directors. The annual meeting is set for May 22 in Utica, New York.

The owners of ConMed—its shareholders—will have an opportunity to vote at that meeting. Since Voce launched its challenge to ConMed's management, the value of the shareholder equity has risen by 30.0%. Love them or hate them, investors like Voce do generally have the effect of pushing equity prices up. ♦

Next week: *One of the dissenting shareholders throws in the towel and ConMed adds two outside members to its board of directors.*

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Zimmer Accuses Stryker of Trojan Horse Attack

BY WALTER EISNER

Zimmer Holdings, Inc. says there is a "Trojan Horse" being built in Amarillo, Texas to sneak sales reps into the operating room to attack their business and steal their money and customers. Who, allegedly, are the Greeks in this Trojan War? Stryker Corporation.

Wikimedia Commons and Giovanni Domenico Tiepolo (1727–1804) / The Procession of the Trojan Horse in Troy

Cody Stovall Comes to Amarillo

The tale begins in February 2008, when a medical device sales rep from New Mexico named Cody Stovall joined Zimmer Southwest in Amarillo, Texas.

Zimmer Southwest was a former distributor of Zimmer products in the southwestern portion of the U.S. Stovall was assigned to be a sales representative in territory made up of Amarillo and the surrounding areas. He joined Team Brittain, led by longtime Zimmer sales representative, Carla Brittain. His job was to assist Brittain in managing and maintaining her Zimmer territory.

Brittain, along with other tenured Zimmer representatives from outside Amarillo, allegedly mentored and trained Stovall and introduced him to Zimmer's long-standing and, according to Zimmer lawyers, "near-permanent" customer relationships.

Zimmer Invites Stovall Inside

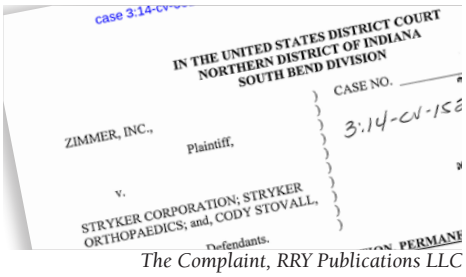
In October 2012, Zimmer decided to bring its southwestern U.S. sales force inside and offered Stovall employment as a sales representative directly with Zimmer. One year later, Zimmer adjusted the Amarillo territory, allegedly at Stovall's request, and split the territory between Stovall and Brittain.

After the split, Stovall was assigned and compensated for sales of reconstructive orthopedic implants to all of Zimmer's surgeon customers in the Amarillo territory, with the exception of five specific surgeon customers who Brittain had called on for years.

By 2013, according to court documents, Stovall was earning nearly $240,000 a year and revenues generated by surgeon customers within his territory generated sales in excess of $6 million in that year.

Stovall Defects to Stryker, Zimmer Sues

But, according to a lawsuit filed against Stovall and Stryker in a Michigan fed-


case 3:14-cv-
IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION
CASE NO.
3:14-CV-152
ZIMMER, INC.,
Plaintiff,
v.
STRYKER CORPORATION; STRYKER ORTHOPAEDICS; and, CODY STOVALL,
Defendants.

The Complaint, RRY Publications LLC

eral district court on January 29, 2014, Stovall resigned from Zimmer on January 10, 2014 and went to work for Stryker.

In addition, says Zimmer, Stovall and Stryker came up with a scheme to steal Zimmer's customers and, ultimately, revenue, by recruiting the top competitive sales representatives from Zimmer and by offering them a guaranteed six figure salary and a $30,000 bonus for every $500,000 in business they convert from their former Zimmer customers to Stryker.

Zimmer says they found out about the plan when Stovall allegedly bragged about the scheme to his former colleagues when he solicited them to join him, and when Stryker pitched this exact scheme to current Zimmer sales representative Carla Brittain—telling her, she too could switch to Stryker and attend surgeries with her former Zimmer customers by "selling" a Stryker RegenKit Platelet-rich Plasma spray.

The Plasma Spray Trojan Horse

Here is where Zimmer's complaint gets original. According to Zimmer's lawyers, Stovall initiated his and Stryker's attack on Zimmer before he ever resigned from Zimmer. Says Zimmer's lawyers, the plan of attack called for Stovall to sell the Stryker biologic plasma spray product in an effort to place him into joint replacement surgeries with his former Zimmer surgeon customers in violation, allegedly, of his post-employment restrictive covenants.

Andrew Huth and RRY Publications LLC

Zimmer claims Stovall meant to use that deception as a "Trojan Horse" to solicit reconstructive implant business away Zimmer's customers on Stryker's behalf.

Injunction Sought

Zimmer is suing for breach of contract, breach of fiduciary duty, tortious interference with contract, unfair competition and civil conspiracy. It also seeks damages from Stovall and Stryker for its lost business, and wants the court to issue an injunction to stop the alleged "Trojan Horse" attack.

Every surgeon has his or her own protocol and preferences in the oper-

ating room, which vary from surgeon to surgeon. Therefore, says the Zimmer complaint, a critical element in maintaining strong customer relationships is the knowledge of a surgeon's preferences and method of operating to make the surgeon's use of Zimmer's products seamless.

The Hospitals in Question

Stovall, claims Zimmer, knew its confidential information, including: sales and marketing information, organizational and sales employee information, advertising information, pricing, customer lists, marketing and sales techniques, confidential consumer information, territory sales plans, product development and delivery schedules, and product technical information.

The hospitals which are the subject of this lawsuit and account for approximately $6 million in annual revenue to Zimmer are:

- Baptist St. Anthony's
- VA - Amarillo
- Golden Plains Community Hospital
- Coon Memorial Hospital
- Hereford Regional Medical Center
- Hutchinson County Hospital
- Ochiltree General Hospital
- Dr. Dan C. Trigg Memorial Hospital
- Wilbarger General Hospital
- Memorial Hospital of Texas County
- Memorial Hospital
- Childress Medical Center
- Pamap Regional Medical Center
- Amarillo Bone and Joint Clinic
- Physician's Surgical Hospital
- Northwest Texas Healthcare System
- Surgery Center on Soncy
- Northwest Texas Surgery Center
- Panhandle Surgical Center

Stryker's Incentives

In addition to a purportedly guaranteed $27,000 per month salary, Zimmer is also accusing Stryker of promising to pay Stovall the same $30,000 promised other Zimmer sales representatives for every $500,000 worth of Zimmer business he is able to convert.

Then, says Zimmer, Stryker also made a similar offer to Carla Brittain while she was employed by Zimmer. In fact, continues the complaint, Stryker's territory sales manager Lance Cowart offered Brittain a position with Stryker and an annual salary of $300,000 to participate in the "Trojan Horse" scheme.

Zimmer also alleges that Stovall and Stryker's Cowart said that they'd employed this same scheme to unfairly compete with Zimmer in other parts of the country.

Trash Talking

And, of course, Zimmer is accusing its former sales rep of trash talking the company to its customers.

Finally, Zimmer is accusing its former rep of soliciting other Zimmer sales representatives in Texas to join him in the "plot" to take Zimmer customers and destroy Zimmer's goodwill and business in northwest Texas.

We're Shocked! Shocked! This Has Happened Before?

Actually, this is not the first time these two companies have tangled over sales reps and customer poaching.

In October 2013, Stryker and Zimmer settled a suit brought by a Stryker unit, accusing Zimmer of poaching its employees and stealing trade secrets. The settlement came the week before the suit was scheduled to go to trial.

In that suit, according to a *Law360* story on January 30, 2014, Stryker unit Howmedica Osteonics Corp. lodged trade secrets and breach of contract claims against Zimmer and several people who had been employed by Howmedica but went to work for its competitor. Zimmer had allegedly convinced more than a dozen of Stryker's managers and sales representatives to jump ship, a scheme that purportedly allowed Zimmer to create its own spinal products business based on expertise and company secrets developed by Stryker.

Zimmer Filed Six Counts Against Stryker

Zimmer's lawsuit consists of six counts:

Count I: Breach of Contract Against Stovall

Count II: Breach of Fiduciary Duty Against Stovall

Zimmer claims that by virtue of his access to Zimmer's confidential information and customers for nearly six years, Stovall owed Zimmer a duty of loyalty.

He allegedly breached his duty by:

- Not devoting his best efforts to Zimmer
- Diminishing the goodwill Zimmer has established with its customers by disparaging Zimmer and unexpectedly and immediately resigning and, thereby, leaving a profitable Zimmer territory unserviced and unsupported
- Usurping sales opportunities from Zimmer
- Planning a coordinated effort on behalf of Stryker to convert Zimmer's customers during his employment and in contradiction to his Agreement with Zimmer.

Count III: Unfair and Deceptive Trade Practices Against Stryker and Stovall

In an intentional effort to destroy near-permanent business relationships in Stovall's assigned territory, and know-

ing of the Agreement, Stryker allegedly recruited and hired Stovall.

Count IV: Tortious Interference With Contracts Against Stryker

Stryker allegedly knew Stovall had an agreement with Zimmer, but hired him anyway.

Count V: Tortious Interference With Contract and Business Relationships Against All Defendants

Zimmer says it had the reasonable expectation that relationships with customers would continue and would not be unjustifiably disrupted.

Count VI: Civil Conspiracy

Stryker and Stovall allegedly entered into an agreement to breach the agreement. They are accomplishing the aims of their conspiracy by using the plasma spray as a cover for Stovall to solicit his former customers.

Zimmer's Demands

Zimmer wants Stovall to be permanently enjoined from:

- Working with Stryker in the Amarillo area, or any sales capacity in which his knowledge would benefit Stryker
- Contacting any Zimmer customers or active prospect
- Solicit anyone at Zimmer to leave Zimmer
- Disclosing any confidential information
- Possessing any Zimmer confidential information

Additionally, Zimmer wants actual and punitive damages to be proven at a trial by jury, legal costs and anything else the Court deems "equitable and just."

Stryker's Answer

Stryker is still formulating its answer. Our guess? They'll deny the vast majority of Zimmer's allegations. Or not. We don't know. But what we're pretty sure of is that these two firms will figure out a way to settle this dispute and get back into the fray again on many other fronts.

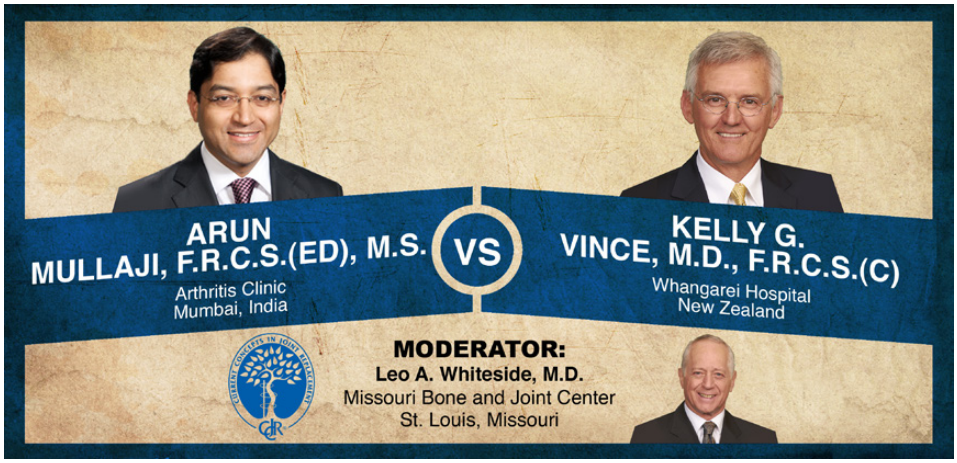
Going out on a limb here, we'll predict that this isn't the last time two orthopedic companies come to legal blows over sales reps switching sides. ♦

Mullaji and Vince Debate Cemented Stems

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

"Cemented stems are versatile, surgeon-friendly, and mechanically sound." says Arun Mullaji. Kelly Vince prefers uncemented saying, "There are times when cement is best, but for the vast majority of cases I find that uncemented, long diaphsyeal engaging stems are preferable."

This week's Orthopaedic Crossfire® debate is "Cemented Stems: A Requisite in Revision TKA [total knee arthroplasty]." For the proposition is Arun Mullaji, F.R.C.S.(Ed), M.S. from The Arthritis Clinic in Mumbai, India; against the proposition is Kelly G. Vince, M.D., F.R.C.S.(C) from Whangarei Hospital in New Zealand. Moderating is Leo A. Whiteside, M.D. of the Missouri Bone and Joint Center in St. Louis.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Mullaji: "Why should you use a stem in revisions at all? To enhance fixation of implants when there is Type 1 or Type 2 bone loss. If it's more than that you'll use sleeves or cones or other devices. Also, when you're using a more constrained device you need better fixation."

"I think there are five key benefits to cemented stems. They are versatile, particularly in altered patho-anatomy. Mechanically, they provide sound and immediate fixation with less stress shielding, stem tip pain, and a lower fracture risk. They help technically in facilitating balancing a much larger flexion gap, and they allow antibiotics to be mixed in the cement for revisions related to infection. Clinical results show that there is less loosening and radiolucency. Lastly, they're surgeon-friendly (easier to insert or revise and cheaper)."

"We need cemented stems in Asia where we often see distorted anatomy in the form of saggital and coronal bowing of the femur, a larger valgus correction angle, and tibial bowing. We've reported these in our previous publications (*Journal of Arthroplasty* 2009 and 2013), both noting femoral bowing and valgus correction angle in our patients that can vary from 2-12 degrees. Cementless stems—or any other stems—can only provide 5/6/7 degrees of valgus. Lastly, metaphyseal or even diaphyseal bowing is common, and in our recent publication we've shown the influence of tibial plateau inclination."

"So in these conditions if you use a long press-fit cementless stem you can have malalignment, penetration of the cortex, or periprosthetic fractures… and end up with a much larger flexion gap. When you put in a long cementless stem you are anteriorizing the femoral component, and you end up with a huge flexion gap."

"Most of these cases require a revision on the femoral side. You have a trumpet shaped canal, and on the tibia you have ice-cream cone defects. This means that if you're going to use a cementless stem you're going to put in a thick, long one and fix it distally. That way you increase the length of the canal that you're violating and you will have stress shielding. This was shown in the 2008 study by Completo et al. published in *The Knee*. They showed that the amount of load being transferred distally by the cementless stem is minimal—just 6% as compared to 24% with cemented stems."

"Likewise on the femoral side, a short cemented stem can provide as good a fixation as a long cementless one. A 2012 study by Conlisk et al. in *Bone and Joint Research* showed that the relative motion is least for cemented stems on the femur. You have more stem tip pain with cementless stems—11-20%. There is also a much higher incidence of radiolucency (10-74% with cementless stems; 32-61% with cemented)."

"Most of our revision cases will have a larger flexion gap than extension gap. If you're using a cemented stem you can flex it, posteriorize it, and close that

gap. If you use a cementless stem—which is usually long—it will follow the bow and move the femoral component anteriorly. With a cemented one you can fudge and adjust it."

"In infections it's useful to be able to mix antibiotics with cement. And the clinical evidence shows a much higher loosening rate with cementless stems—7% versus 29% (Fehring et al., *CORR*, 2003). There is a much higher mechanical failure rate, with more re-revisions with cementless stems. Lastly, these are surgeon-friendly because they are easy to insert, easy to remove, a reduced risk of fracture, and they are cheaper."

"There are caveats. Use mobile-bearing inserts to reduce fixation stresses on the bone-cement interface. Use the optimum cementing technique, and ensure accurate implant position."

Dr. Vince: "We need to remember where the diaphysis is, as well as the metaphysis. Also note that the diameters of the funnel shaped bone differ significantly in these locations. In revisions I would opt for a diaphyseal engaging press fit stem; a metaphyseal length press fit is not recommended. What is necessary is some increase in fixation when constraint is used. I do agree that *some* kind of stem fixation is required in revision TKA."

"By 1987 I was using the Insall Burstein modular revision system; by 1995 I had acknowledged that the short stems weren't working that well. With failures you can either use more cement or you can use a different technique, which is what I chose to do."

"The available research is full of bad information. The paper by Fehring et al. entitled 'Stem Fixation in Revision TKA: A Comparative Analysis' should be called 'Metaphyseal Stem Fixation in Revision TKA: A Comparative Analysis.' They've excluded the diaphyseal length stems. And they had higher failure rates with their uncemented stems, but they weren't long enough."

"The Mayo Clinic study by Shannon et al. (*JOA*, 2003) again shows metaphyseal length stems with a 10% failure rate…I'd stop doing it if I had a 10% failure rate. Their lengths were too short; the fill of the canal was too narrow."

"The technique would be 145mm stem on the tibia, 200mm on the femur. When you do revisions involving big deformity you really need to fully cement a shorter stem to get the alignment that you want. Metaphyseal fully cemented stems are a reasonable choice if you're very concerned about loosening. I'd favor the diaphyseal length stems to guide position and enhance fixation. My colleagues and I have studied the technique. The tibia is an asymmetric bone, and the stem is best placed in an asymmetric medial position."

"I also found that I could manipulate femoral position by eccentric reaming. If you use a straight stem on the femur it may not be in the correct position, but we can increase valgus by reaming eccentrically to the lateral side. If you use a straight stem with this technique it will overhang on the lateral side. But if you ream eccentrically to the lateral side you can increase valgus with a long stem; then you can centralize the component by using an offset stem."

Moderator Whiteside: "Arun?"

Dr. Mullaji: "If you have access to offset stems I think you can modify your reaming technique and you can use long, cementless stems. The problem is that in our part of the world you often don't have offset stems available…they also add an expense. What about the larger flexion gap? You'd need to use offset stems to do the same thing. So when you're dealing largely with the older population, low demand, osteoporotic patients you don't want to put in these long, thick stems which are likely to fracture the bone…then have a problem with mismatch of your flexion and extension gaps."

Moderator Whiteside: "Kelly, your rebuttal?"

Dr. Vince: "Leo, I don't want anyone using fully cemented stems for the wrong reason. The majority of revisions done with fully cemented smaller stems are actually put in the wrong position. The component is floating around the cement mantle, and the surgeon is poorly informed as to where it should be. The diaphsyeal engaging stem actually guides you. But if you have to remove a fully cemented stem you may believe Arun that it's easier to take out…but come and talk to me after you've tried it."

Moderator Whiteside: "I couldn't agree more. Arun, when you get an infection in these cemented, pressure-injected stems how do you get that thing out of there?"

Dr. Mullaji: "If it's an early infection then I'll use your technique and put in these antibody infusions. It can be challenging to remove, but it's not difficult in an infection situation. If it's uninfected, yes."

Moderator Whiteside: "'Infected' was my question."

Dr. Mullaji: "By the time most of these patients come to us they are already loose."

Dr. Vince: "We have a strong bias in our literature against publishing bad results, and I'd suggest that there is no publication of the treatment of infected fully cemented long stems because the results are bad."

Moderator Whiteside: "Kelly, you use cementless long stems often. Do your patients have end of stem pain?"

Dr. Vince: "If you say you have a patient with an uncemented stem that is diaphyseal engaging with this technique with end of stem pain, you're going to have to prove that the component is not loose before I believe that there's end of stem pain. There is no *good* study on end of stem pain."

Moderator Whiteside: "And you have no anecdotes where you removed a stem or cut a stem in two because of end of stem pain?"

Dr. Vince: "No."

Moderator Whiteside: "I must say that I do. Thank you both." ♦

Please visit www.CCJR.com to register for the 2014 CCJR Spring Meeting, May 18 - 21 in Las Vegas, Nevada.

Depressing Question: Could You Handle a Shooter in Your Hospital? // New Study Shows XLIF Works in Degenerative Scoliosis Cases // New Research From Rush: You CAN Operate on Obese Patients

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

Depressing Question: Could You Handle a Shooter in Your Hospital? An urgent public emergency probably isn't on your radar screen… until it lands in *your* hospital. No one knows that better than the medical and administrative staff of Boston hospitals. A new special report, "It Takes a Team—The 2013 Boston Marathon: Preparing For and Recovering From a Mass-Casualty Event," is pointing the way forward for hospitals everywhere. Lloyd Resnick, developmental editor at the *Journal of Bone and Joint Surgery* (*JBJS*), was intimately involved in the preparation of this report, a collaboration between *JBJS* & the *Journal of Orthopaedic & Sports Physical Therapy* (*JOSPT*). Resnick tells *OTW*, "The 2013 Boston bombing galvanized a lot of people, especially the multiple disciplines involved in emergency preparedness. In talking to numerous emergency preparedness people this theme rang throughout: hospitals must *regularly* drill for mass casualty events, despite how challenging it is to create time, space, and resources to do that. A large level one trauma center like Mass General runs three to five full scale exercises per year involving actors and mannequins, plus five to ten tabletop exercises. The front line people we spoke with also drove home the point that it is critical to get senior executives at these hospitals on board."

"Another recommendation in the report—to practice low-frequency, high-impact scenarios such as an active shooter—arose from an interview with Meg Femino, Director of Emergency Management at Beth Israel Deaconess Medical Center. In the report, Femino also emphasizes the need to 'drill deep into your hospital's system; an occasional decontamination drill in the ED isn't enough.'"

Wikimedia Commons and Aaron "tango" Tang from Cambridge, MA, USA

Resnick added, "Brigham and Women's Hospital in Boston has produced a training video for its 16,000 employees on how to handle a scenario where there is an active shooter in the hospital."

And note that doing just the minimum isn't sufficient, says Resnick. "One of the people I interviewed said that if her hospital had done only what the Joint Commission mandates for emergency preparedness, they would not have been ready for April 15, 2013."

"On the communication front during a disaster, aim to be clear, thorough, and quick. Clear communication is greatly facilitated if you cultivate relationships with people in the emergency preparedness community. Have their phone numbers programmed into your phone, and keep having these conversations so that in the event of a disaster you know whom to call. There is no such thing as being too prepared."

XLIF for Degenerative Scoliosis: It's a Definitive 'Go' To XLIF naysayers out there, Frank Phillips, M.D., an orthopedic surgeon with Midwest Orthopaedics at Rush, has published what is the largest prospective series of degenerative scoliosis (DS) treated with minimally invasive fusion techniques. In the study, published in *Spine*, Dr.

Phillips reported that using the XLIF in the treatment of degenerative scoliosis leads to good outcomes, and lower complication rates than with traditional open surgery.

Dr. Phillips, Professor of Orthopaedic Surgery and Director of Minimally Invasive Spine Surgery at Rush University Medical Center, tells *OTW*, "Many of my colleagues had questioned the role of XLIF in the treatment of DS. Early on in the XLIF experience, I felt that this procedure was a natural fit in the treatment of DS addressing a real clinical need where traditional surgeries were associated with high major complication rates and long recovery periods. We presented the first report of XLIF specifically in DS with two-year follow-up in 2005 at the IMAST [International Meeting on Advanced Spine Techniques] meeting and I was met with skepticism. We decided to put the jury to rest, however, and recruited 107 patients to be involved in the largest prospective, multicenter study to quantify outcomes after XLIF in this patient population. We found rapid and statistically significant improvement in all outcome measures—Oswestry Disability Index, visual analogue scale for back pain and leg pain, and 36-Item Short Form Health Survey mental and physical component summaries. In addition, the procedure was able to address the spinal deformity"

"We are continuing studies to determine when stand-alone lateral interbody fusion is adequate, when we need supplemental instrumentation and direct decompression, and when the patient needs a more extensive surgery to completely correct the deformity. In recent years, larger and larger surgeries are being performed more frequently to address spinal deformity. As we pay more attention to spinal balance and pelvic parameters, the role of less morbid surgeries to address these issues are receiving more attention."

"It is gratifying to see surgeons adopting the XLIF in the treatment of scoliosis with good patient outcomes. When we first discussed this application almost 10 years ago we were met by a lot of skepticism. Now, lateral techniques have become part of the surgeon's armamentarium in treating DS. More recently we have continued to extend the use of XLIF for the treatment of complex spinal deformity. Many surgeons that ignored this technique for years are now on a marketing tear. As long as

we continue to study these procedures thoughtfully and validate outcomes, we will be helping out our patients."

Study: You CAN Operate on Obese Patients When an obese patient is lining up for surgery, many orthopedic surgeons put on the brakes. Now there is evidence that this may not be necessary. Alan Hilibrand, M.D. is a professor of Orthopaedic Surgery and Neurosurgery at the Rothman Institute in Philadelphia. He is also Director of Medical Education for the Department of Orthopaedic Surgery at the Rothman Institute and Jefferson Medical College. He tells *OTW*, "In the SPORT study, looking at patients with a BMI [body mass index] over 30 we showed that discectomy surgery did not involve a higher risk of complications. (That might be a different story with those whose BMI was higher than 40, however.) We found a significant treatment effect among the other group of patients who underwent surgery for spinal stenosis; patients taking the nonoperative route did poorly."

"There has been quite a controversy surrounding this issue because in the joint replacement arena we have evidence that obesity negatively affects outcomes. In some places—like the UK—surgeons won't let someone over a certain BMI have a knee replacement. And aside from the clinical issues, one has to wonder if such spine surgeries are an important use of healthcare dollars."

"I was a bit surprised by the results in that I thought there would be a smaller treatment effect for surgery on obese patients. Going forward I would like to investigate these issues on those patients who have 40 or higher BMI. Based on our data there is a threshold beyond which the complication risk goes up…and maybe the clinical benefits go down."

Freddie Fu, M.D. Named Lifetime Member of ESSKA Freddie Fu, M.D., the renowned chair of the department of orthopedic surgery at the University of Pittsburgh, is being honored by the European Society of Sports Traumatology, Knee Surgery and Arthroscopy (ESSKA). Dr. Fu has been named a Life/Honorary Member of ESSKA, the greatest honor bestowed by this organization. The eight-member ESSKA board voted unanimously to bestow Honorary Membership upon Dr. Fu. The ceremony will be in Amsterdam during the General Assembly during the ESSKA Congress. Dr. Fu will be the third such honoree from the U.S. and the first from Pennsylvania.

Freddie H. Fu is the David Silver Professor of Orthopaedic Surgery and Chairman of the Department of Orthopaedic Surgery at the University of Pittsburgh School of Medicine and University of Pittsburgh Medical Center. Previously, he was the department's executive vice chairman. Dr. Fu has also been the head team physician for the University of Pittsburgh Department of Athletics since 1986 and holds secondary appointments at the university as professor of physical therapy and health physical and recreational education.

Dr. Fu received his undergraduate and post-graduate degrees at Dartmouth College and Dartmouth Medical School before earning his medical degree at the University of Pittsburgh in 1977. Continuing his training at Pitt, he then completed a residency in orthopedic surgery and a fellowship in orthopedic research. Dr. Fu also fulfilled an internship in general surgery at Brown University and an international fellowship at the Hanover Trauma Center in Germany. Dr. Fu is internationally recognized for his pioneering surgical techniques to treat sports-related injuries to the knee and shoulder. He is also an extremely well regarded scientific and clinical researcher. ♦

COMPANY

LDR Implants 50,000 VerteBRIDGE

LDR is celebrating its latest milestone with the announcement that it has reached over 50,000 implantations of its spinal cages utilizing VerteBRIDGE Plating Technology. Since its introduction in France in 2007 and in the United States in 2008, VerteBRIDGE—a novel system for integrated cage fixation—has grown to a comprehensive platform of products with integrated zero-profile plating technology adapted for use in anterior cervical, anterior lumbar, oblique lumbar, and lateral lumbar applications.

ROI-C with VerteBRIDGE Plating Technology/Courtesy of LDR

VerteBRIDGE is a minimally invasive, zero-profile, technology that utilizes a self-guided plating system that requires less exposure than other stand-alone systems on the market that must be secured with screws inserted at oblique angles. It has self-locking plates designed for initial and long-term stability, may be inserted through a mini-open technique in the transverse plane of the disc, and boasts adjustable placement of the cage prior to insertion of the plating. In addition, the inserter provides protection of vascular structures during plate placement.

Several LDR cages are available with VerteBRIDGE plating. The ROI-C Cervical Cage, which is used for anterior cervical interbody fusion, is available in two sagittal profiles that are designed to respect the patient's anatomy and allow close contact between the bone and the implant as well as provide restoration of both height and lordosis.

The ROI-A ALIF Cage, available in midline and oblique designs, is used for anterior lumbar interbody fusion, and provides an optimized cage shape for peripheral coverage of the endplates and strong support on cortical bone. The tapered posterior shape facilitates insertion. The oblique cage can be inserted from a 25° anterolateral angle that may reduce retraction of the great vessels and minimize the associated management of segmental vessels.

The most recent addition to the VerteBRIDGE portfolio is the Avenue L Lateral Lumbar Cage, which incorporates zero-profile, intradiscal, integrated fixation. The minimal, in-plane exposure afforded by VerteBRIDGE plating technology is especially well-suited to the lateral transpsoas approach where surgeons are concerned with minimizing the retraction of the psoas during insertion of the cage and integrated fixation.

Christophe Lavigne, CEO and President of LDR, told *OTW*, "We've seen tremendous success with our VerteBRIDGE Plating Technology and remain committed to developing innovative spinal solutions that benefit the surgeon and patient. We are proud of reaching this milestone and look forward to reporting on future developments and innovations."

—EH (March 7, 2014)

Biomet Going Public to Reduce Debt

It's official. Biomet, Inc. is going public to reduce company debt.

The company announced on March 7, 2014 that its parent company, LVB Acquisition, Inc., has filed a registration statement with the Securities and Exchange Commission (SEC) for a proposed initial public offering of its common stock. In connection with the offering, LVB Acquisition intends to change its name to Biomet Group, Inc.

The number of shares to be offered and the price range for the proposed offering have not yet been determined. BofA Merrill Lynch, Goldman, Sachs & Co., J.P. Morgan, Citigroup, Wells Fargo Securities, Barclays and Morgan Stanley are acting as the joint book-running managers for the offering.

Previous and accurate news reports stated that according to unnamed "people," the public offering that could raise around $1 billion.

The preliminary prospectus was not yet available.

This will bring to full circle the company being a public corporation again aftern being taken private for $11.3 billion in 2007 by four Wall Street buyout firms. The buyout came after company founder, Dane Miller, Ph.D. was removed as the company CEO. He returned with the bankers to retake the public company by buying out the public shareholders. According to securities filings, $5.9 billion of debt still remains on the company's balance sheet.

That debt is in stark contrast to Biomet competitors sitting on huge piles of cash.

Biomet expects to use the net proceeds of the offering primarily to reduce outstanding indebtedness.

—WE (March 7, 2014)

RRY Publications/www.outsidethebeltway.com

Maxx Medical Donates Knee Implants to Ecuadorian Project

Twelve needy patients in Ecuador will get new knees this month thanks to a donation by Maxx Medical, Ltd. and a team of 30 medical professionals who are flying to Machala, Ecuador to install them. Rick Savino, M.D., an orthopedic surgeon with Long Island Bone and Joint in New York, will perform the surgeries which have been arranged by Blanca's House, an organization that provides 21st century medical care for the underprivileged. The operations will take place at the Hospital Militar in Machala.

Courtesy of Maxx Medical, Ltd./Wikimedia Commons and Staff Sgt Alesia Goosic

The medical professionals are paying their own way as well as bringing with them everything necessary to perform the 12 total knee implants. Maxx Medical is donating the implants and surgical instruments required for the surgeries.

"These trips provide me with the opportunity to perform medical procedures for the reason I went into medicine in the first place—to help those who truly need and appreciate it with no insurance issues, documentation worries or attorneys looking over our shoulders. It's as simple as people who need medical help and a team dedicated to making them better," said Savino.

"It feels good to give back to the global patient community, partnering with surgeons and charitable organizations to restore patient mobility," said Ashesh Shah, the CEO of Maxx Medical.

—BY (March 3, 2014)

MedShape's New Technology: PEEK Scoria

MedShape, Inc. now has a new material platform known as PEEK Scoria, which involves a new process to grow a controlled porous layer on the surface of PEEK. While porous metals have found their way into clinically used devices, MedShape is the first company to develop and clear through the FDA devices manufactured with porous PEEK. The Morphix SP Suture Anchor, the first device manufactured from PEEK Scoria, recently received FDA 510(k) clearance.

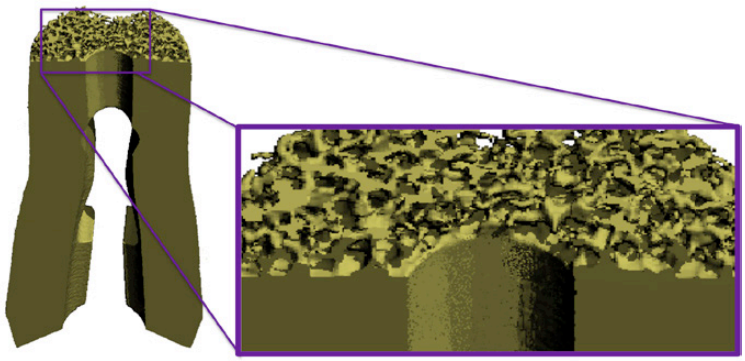
Developed by a group of scientists and engineers at the Georgia Institute of Technology, PEEK Scoria contains pores only on the top millimeter of the surface. PEEK Scoria is processed using Zeniva PEEK resin from Solvay Specialty Polymers, a world leader in high-performance polymer technology. The technology was also developed at Georgia Tech through a grant from Solvay.

The proprietary technology, licensed from Georgia Tech by MedShape, increases the contact area with adjacent biologic tissue without compromising the mechanical integrity of the device itself. PEEK Scoria has the following key material characteristics:

- 65% porosity
- 300um average pore size
- 99% interconnectivity
- 2X shear strength of trabecular bone
- Comparable fatigue strength and modulus to traditional PEEK

The presence of an open cell structure has shown to be advantageous for supporting biologic tissue in-growth around a material. Porous materials are a class of structured materials associated with promoting adjacent tissue in-growth. However, the mechanical properties of porous materials, particularly porous polymers, are inherently reduced compared to their bulk material counterpart, limiting their use, to date, in load-bearing applications. Unlike traditional porous materials, PEEK Scoria contains porosity only on the top 1mm surface layer and exhibits mechanical strength and fatigue resistance comparable to regular PEEK and greater than clinically-used porous metals. PEEK is a widely used material in biomedical implants because of its excellent mechanical properties, radiolucency, and biocompatibility. However, PEEK does not actively interact with bone tissue.

Professor Bob Guldberg, is the director of the Parker H. Petit Institute for Bioengineering and Bioscience at Georgia Institute of Technology, and a world-renowned expert in biomaterials and device osseointegration. Professor Guldberg has recently studied bony ingrowth in PEEK Scoria and results of his work will be presented at the Orthopaedic Research Society Annual Meeting in March. "The preliminary data demonstrate bony ingrowth into the porous PEEK network. Future studies will include a fundamental understanding of the extent of osseointegration and soft tissue attachment and the impact of the release of biologic agents from the porous network."



MedShape, Inc.

Morphix SP is the first product to feature the technology. Morphix SP has the same design and performance benefits as its predecessor (Morphix) but includes a porous layer at the top of the implant at the interface between soft tissue and bone.

MedShape will be showcasing PEEK Scoria and Morphix SP at the upcoming American Academy of Orthopaedic Surgeons Annual Conference in New Orleans.

Ken Gall, Ph.D., professor of Mechanical Engineering and Materials Science at Georgia Institute of Technology and also chief technology officer at MedShape, told *OTW*, "PEEK Scoria is an exciting new technology platform for MedShape that is backed by extensive university biomaterials research. We were excited to discover a new processing method that seamlessly connects a porous surface to a solid base while maintaining the mechanical strength and stiffness of the base material. The clearance of the Morphix SP device represents an important first step in designing future polymer devices to provide both mechanical function along with a local surface that promotes biological repair and function in a high-strength, non-resorbable device."

—EH (March 5, 2014)

BIOLOGICS

Firm Claims TPX-100 Modifies Osteoarthritis!!

OrthoTrophix, Inc., a privately held biopharmaceutical company based in Oakland, California, has started a Phase 2 clinical trial of a cartilage repair therapeutic agent. Called TPX-100, the substance is designed to be used with knee osteoarthritis patients in the U.S.

The purpose of the clinical trial is to demonstrate proof of principle of the safety and knee cartilage repair efficacy of TPX-100 in cases of mild to moderate knee osteoarthritis (DMOAD). The outline of the study is posted at the ClinicalTrials.gov site.

OrthoTrophix reports that it plans to develop TPX-100 as the first disease modifying osteoarthritis or DMOAD drug. Osteoarthritis, a degenerative joint disease, is the most common disease of the joints, and one of the most widespread of all chronic diseases. The company estimates that, in the U.S. more than 27 million people suffer from osteoarthritis with more than half of those individuals being 65 years of age or older.

The joint most affected by osteoarthritis is the knee. Doctors have identified the main cause of the disease to be the degeneration of articular cartilage in the joints by aging, mechanical stress, or both and that repair of such damaged cartilage with new articular cartilage tissue would mitigate such symptoms. While its mortality is low, osteoarthritis presents one of the most critical quality of life problems in all generation with much higher prevalence in the aged population, say OrthoTrophix officials.

Knee osteoarthritis / Source: Wikimedia Commons and Hellerhoff

Company researchers discovered TPX-100 to be a tissue-specific hard tissue regeneration molecule. They say that TPX-100 has demonstrated the ability to repair cartilage and bone by regenerating the respective tissues without affecting soft tissues, and without forming non-relevant tissues in the target site. It forms only cartilage in the cartilage defects without forming bone or other tissues there.

Company officials claim that TPX-100 has demonstrated the ability to promote regeneration of new articular cartilage in the cartilage defects in the knee joints and delay advancement of cartilage damage in multiple cartilage trauma and osteoarthritis models. Company officials have tested TPX-100 in one Phase 1 and two Phase 2 clinical trials to date, and claim that it exhibited an excellent safety profile.

Chief Medical Officer Dawn McGuire, M.D., stated, "A novel DMOAD that promotes articular cartilage formation by simple intraarticular injections would be a revolutionary advance for OA. Current treatments require invasive surgeries or else address only symptoms. We expect to modify the root cause of disability in OA."

—BY (March 5, 2014)

Genes + Scaffold Key to Stem Cell Activity

To get stem cells to repair tissue has, up to the present, required the application of large amounts of growth factor proteins which signal the stem cells to differentiate into cartilage and other tissues. A major difficulty has been delivering these growth factors to the stem cells once they are implanted on a structure into the body. Charles Gersbach, Ph.D., an assistant professor of biomedical engineering at Duke University and an expert in gene therapy, spent years developing biodegradable synthetic scaffolding that mimics the mechanical properties of cartilage.

Wikimedia Commons and Alexandru Darida

As Farshid Guilak, Ph.D., director of orthopedic research at Duke University Medical Center, explains, "There's a limited amount of growth factor that you can put into the scaffolding, and once it's released, it's all gone. We needed a method for long-term delivery of growth factors, and that's where the gene therapy comes in." By introducing new genes and using viruses to deliver gene therapy to the stem cells they have induced the stem cells to make the necessary growth factors all on their own.

What they have is Gersbach's polymer structure for growing cartilage that includes gene therapy vectors to induce the stem cells, themselves, to produce the growth factors they need. The new technique, called biomaterial-mediated gene delivery, is shown to produce cartilage at least as good biochemically and biomechanically as if the growth factors were introduced in the laboratory.

By combining a synthetic scaffolding material with gene delivery techniques, researchers at Duke University believe that they are getting closer to being able to generate replacement cartilage where it is needed in the body. The results show that the technique works and that the resulting composite material is at least as good biochemically and biomechanically as if the growth factors were introduced in the laboratory, according to the researchers. The researchers say that the resulting material acts like a computer—the scaffold provides the hardware and the virus provides the software that programs the stem cells to produce the desired tissue.

"We want the new cartilage to form in and around the synthetic scaffold at a rate that can match or exceed the scaffold's degradation," said Jonathan Brunger, a graduate student. "So while the stem cells are making new tissue (in the body), the scaffold can withstand the load of the joint. In the ideal case, one would eventually end up with a viable cartilage tissue substitute replacing the synthetic material."

While this study focuses on cartilage regeneration, Guilak says that the technique could be applied to many kinds of tissues, especially orthopedic tissues such as tendons, ligaments and bones. And because the platform comes ready to use with any stem cell, it presents an important step toward commercialization.

"One of the advantages of our method is getting rid of the growth factor delivery, which is expensive and unstable, and replacing it with scaffolding functionalized with the viral gene carrier," said Gersbach. "The virus-laden scaffolding could be mass-produced and just sitting in a clinic ready to go. We hope this gets us one step closer to a translatable product." The study appears online in the *Proceedings of the National Academy of Sciences*.

—BY (March 5, 2014)

LARGE JOINTS

Getting the Leg Length Right – Easily!

A concern for surgeons performing hip replacement surgery is to finish the job with both of the patient's legs the same length. The Canadian company Intellijoint Surgical, Inc. (formerly Avenir Medical) has received a Health Canada Medical Device License for its flagship product, Intellijoint HIP, that it claims is significantly more accurate in determining leg length and offset equivalency than traditional measurement methods used in hip replacement.

"Receiving Health Canada's license to launch Intellijoint HIP in Canada, and our ongoing studies in Toronto Area Hospitals are exciting milestones," said Armen Bakirtzian, CEO of Intellijoint. He says that the company's proprietary device enables surgeons to quantify the key measurements needed for accurate primary and revision hip replacement.

"In hip replacement, many surgeons rely on clinical judgment to position implants and determine leg length and offset," said Allan Gross, M.D., orthopedic surgeon at Mount Sinai Hospital in Toronto, and chairman of Intellijoint's Scientific Advisory Board. "However, studies in the U.S. and EU show that after hip replacement over 30% of patients have complaints, one-third of these have complications due to surgical error and 7% are readmitted for high cost revision surgery."

"At the same time," noted Gross, "research shows that accurate measurements in hip replacement improve patients' clinical benefits, and lower hospital costs and liabilities. With Intellijoint HIP, surgeons now have a time and cost saving smart tool for the operating room that enables them to accurately perform hip replacement and enhance patient satisfaction."

intellijoint surgical

Wikimedia Commons and Herbert French/Logo courtesy of Intelligoint Surgical, Inc.

Bakirtzian said that Intellijoint has met the international requirements for its quality management system for the design and manufacture of medical devices and has submitted its application to the FDA for marketing Intellijoint HIP in the United States. Once approved, he added, the firm's products can potentially be used by surgeons to guide over 500,000 hip replacements a year.

—BY (March 4, 2014)

Regional Anesthetic Does NOT Increase Fall Risk

Does the kind of anesthesia used during knee replacement surgery increase the odds that the patient is at risk for a post-surgery fall? Research has shown that regional forms of anesthesia—spinal or epidural (neuraxial) anesthesia and peripheral nerve blocks (PNB)—provide better pain control, faster rehabilitation and fewer complications than does general anesthesia. But surgeons have been reluctant to use them out of a fear that motor weakness, brought on by the regional anesthetic, may cause patients to fall in the first days after surgery.

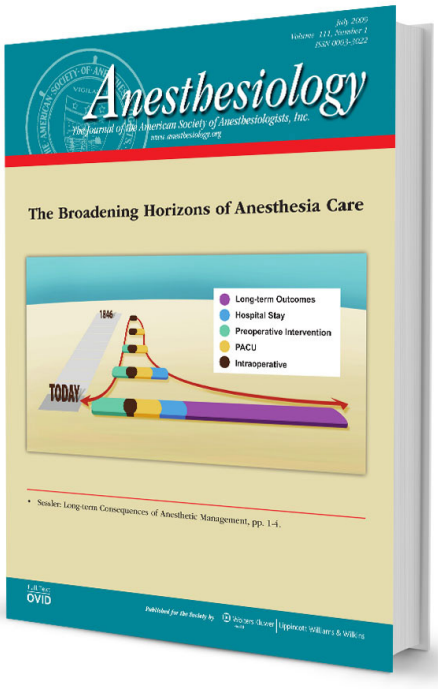
A study based on almost 200,000 patient records, published in the March issue of *Anesthesiology*, debunks that belief. "We found that not only do these types of anesthesia not increase the risk of falls, but also spinal or epidural anesthesia may even decrease the risk compared to general anesthesia," said Stavros G. Memtsoudis, M.D., Ph.D., professor of anesthesiology and public health and director of critical care services, Hospital for Special Surgery, New York, and lead author. "This work suggests that fear of in-hospital falls is not a reason to avoid regional anesthesia for orthopedic surgery."

Surgeons have been right to be concerned about falls. Patients who fall within 30 days of knee surgery are more likely to have worse outcomes, including more heart and lung problems and higher rates of death. As a result doctors have used spinal or epidural anesthesia and PNB far less often than general anesthesia because of concern that regional forms of anesthesia may increase muscle weakness and make patients more prone to falls.

When researchers analyzed the types of anesthesia used in 191,570 knee replacement surgeries in the Premier Perspective database they found that 76.2% of patients had general anesthesia, 10.9% had spinal or epidural anesthesia, and 12.9% had a combination of neuraxial and general anesthesia. In addition, 12.1% of all patients had PNB.

When they examined the type of anesthesia used for those who suffered a fall in the hospital they found that, of patients who had general anesthesia, 1.62% fell, compared to 1.3% of those who had neuraxial anesthesia and 1.5% who had general and neuraxial anesthesia. Patients who received a PNB had a fall rate of 1.58%.

The data used in the study came from a wide range of hospital settings. The researchers found that the fear of patient falls, as related to the kind of anesthetic used, to be unfounded. They noted that hospitals and physicians performing joint replacement procedures use effective fall-prevention programs.



Courtesy of Anesthesiology, the journal of the American Society of Anesthesiologists

—BY (March 4, 2014)

EXTREMITIES

$3.1 Million to Washington University in St. Louis

A team of researchers from Washington University in St. Louis has received a five-year, $3.1 million grant from the National Institutes of Health so that they might discover a better way to improve the outcome of surgical repairs by studying the natural attachment of tendon to bone. An interdisciplinary and multi-institutional group of researchers are reverse-engineering the tendon-to-bone attachment. The work is being led by Stavros Thomopoulous, Ph.D., associate professor of orthopedic surgery in the School of Medicine, and Guy Genin, Ph.D., professor of mechanical engineering in the School of Engineering & Applied Science.

The team will use a variety of imaging methods working with Mark Anastasio, Ph.D., interim chair and professor of biomedical engineering in the School of Engineering & Applied Science. They will use scanning transmission electron microscopy-electron energy loss spectroscopy to determine mineral and collagen distributions at the site of insertion of tendon to bone and perform mechanical testing on the collagen fibers.

In addition, they will use synchrotron X-ray diffraction, Raman spectroscopy and polarized light microscopy to determine the distributions of mineral content and collagen orientation along the tendon-to-bone insertion. They will also use phase contrast X-ray computer tomography to determine the 3-D geometry of tendon and bone and tissue-level testing to determine the mechanics of the tendon-to-bone insertion.

Stavros Thomopoulos, Ph.D., Washington University in St. Louis

Dr. Thomopoulous told *OTW*, "The work was motivated by the clinical need. Rotator cuff tears are prevalent in the population and the incidence increases with age. 20% of people over the age of 60 have tears, and this increases to 50% in those over 80. These tears don't heal, and surgical repair is plagued with high failure rates. We decided to reverse-engineer the young, healthy tissue and figure out what makes that system work so well."

Asked about their first steps, he noted, "The problem is essentially a mechanical one. A compliant rope-like material (tendon) needs to be re-attached to a stiff cement-like material (bone). We are using cutting-edge imaging and modeling approaches to figure out how the body solves this mechanical problem of attaching two dissimilar materials. Experiments will be done at the nanometer through millimeter length scales to understand how the system works."

As for where they hope to be one year from now, Dr. Thomopoulous told *OTW*, "Results from our imaging and modeling experiments will serve as the design criteria for building a tissue engineered replacement for tendon-to-bone attachment, with a particular emphasis on the rotator cuff. We have a five year plan to complete experiments and build mathematical models that describe how the natural tendon-to-bone attachment works. In our first year, we will focus on gaining a nanometer through micrometer scale understanding of how collagen and mineral, the building blocks of this material, interact to produce a tough attachment between tendon and bone."

—*EH (March 5, 2014)*

SPINE

35 Years Later, Patient Sends Love Letter to Art Steffee

Kelly Reisig was in Omaha, Nebraska in the '80s when Arthur Steffee, M.D. came to perform spine surgery on her.

She recently wrote *OTW* to say that 35 years after the successful surgery she is experiencing a "click" in her back and is having trouble finding a spine surgeon to monitor her.

Here is what she wrote:

Flickr and LucasTheExperience/flickr.com/photos/lucastheexperience/3469305764/

I was one of the patients that Dr. Steffee had in the '80s. He actually traveled to Omaha, Nebraska to do the surgery. For me it was a process of three surgeries, and yes, a body cast. I had a fourth surgery when I slipped on the ice. I traveled to Cleveland and Dr. Steffee performed the surgery. I haven't had any problems in nearly 35 years. Recently I have started to hear a "click" in my back. No pain. Just a 'click.'

I remembered that Dr. Steffee cautioned me that the surgery may not last "forever". Because of the recent development, I decided that I would establish a baseline of information with a new surgeon. That way it can be monitored regularly, and if something should happen, it would be much easier to proceed. I am sure you will not be surprised that finding a surgeon willing to be this baseline 'monitor' is impossible. No one wants to touch my back. It's a scary feeling to be unable to find a doctor who wants to treat you.

I'm one of the surgeries that worked. I love Dr. Steffee. I was 16 years old when I had the surgeries and he gave me my life back. I remember the calls from lawyers asking me 'how it went' and 'if I was disappointed.' I had no idea how they got my name but they were most certainly disappointed with my answers. I just wanted to add in my perspective, as a former patient with no past, pending or future lawsuit."

Ms. Reisig is the Donor Research Coordinator for the Foundation for Community Care on Sidney, Montana. Her email is: kreisig@foundationforcommunitycare.org.

—WE March 7, 2014)

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