VOLUME 10, ISSUE 33 | OCTOBER 21, 2014

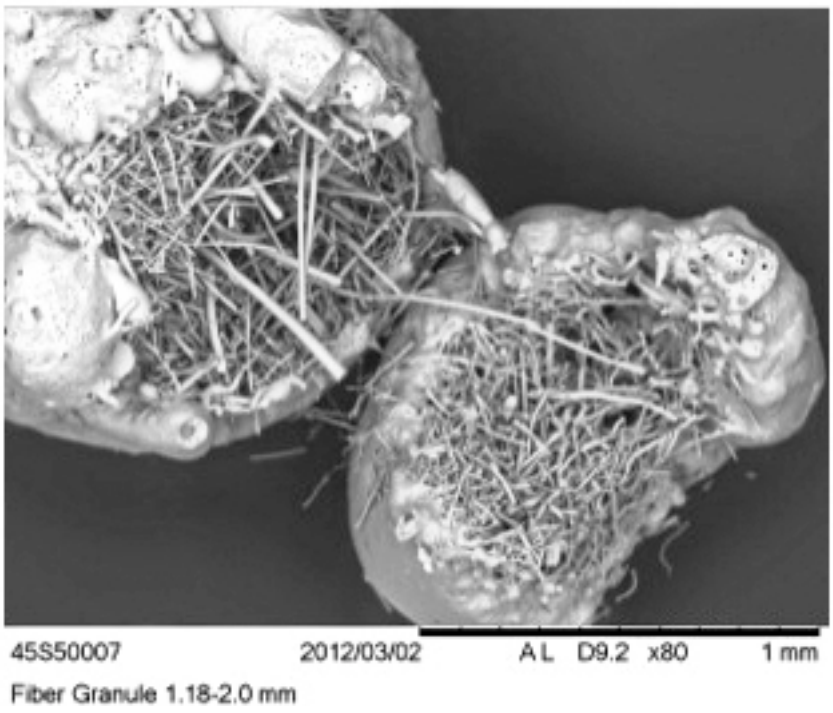
Orthopedics This Week

WEEK IN REVIEW

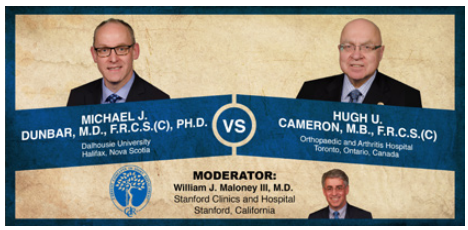
4 BioGlass Is Back – In an Incredible New Form >> Two of the most biologically active implants ever sold to orthopedic surgeons emerged from the U.S. government's atomic energy research of the 1950s and 1960s. The first was Marshall Urist's discovery of bone morphogenic proteins (BMP). The other is the subject of this article.

9 Hofmann, Callaghan Debate the Posterior Stabilized Knee >> "I haven't saved a cruciate ligament in the last five years. It's more difficult and less predictable. It's more forgiving to take the PCL," argues Aaron Hofmann. "A recent study found that ROM was better with the posterior stabilization," counters John Callaghan. "And Chit Ranawat has had a 95% satisfaction rate with a PS knee… no revisions at 10 years."

12 MRI From Your Smartphone? Auto Billing When You Step Out of the Exam Room? Yes! // New HSS Study to Tackle Critical ACL, UCL Failure Issue // First-Ever Step-by-Step Measurement of Operative Time in Scoliosis >> "Failure is the dirty underwear drawer of orthopedic surgeons," says David Altchek, M.D. of HSS. So his study at HSS will tackle a crucial ACL, UCL failure issue. Time and motion study for scoliosis surgery? The results from Beth Israel are fascinating. New smartphone app gives surgeons increased flexibility while also saving time.



15 Dunbar, Cameron Debate Modular Necks >> "No modular necks for routine primary hip arthroplasty!" argues Michael Dunbar. "We have no proof of superiority and there is an increased risk of fracture and fretting, ion debris, etc." Hugh Cameron counters, "Look, I've done more than 350 cases with no incidents of delayed metal hypersensitivity and no pseudotumors."



BREAKING NEWS

19 Analysts Read Tea Leaves of **Biomet's 6% Quarter**

Study: **Preop Physical Therapy Saves** $1,215 per Patient

FDA Challenges RTI Over "Minimal Manipulation"

DePuy Synthes Cuts Hip Pricing in **Third Quarter**

Marriage Made in Biomaterial Heaven: **Amedica and Spinal Kinetics**

"Top" **Ortho Docs Online** for Self-Pay

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Fact: More insured workers, rising premium income at payers, costs are coming down and, as a result, demand for orthopedic implants is rising with conviction. Piper's Matt Miksic makes the call: "Our survey of 50 orthopaedic surgeons' points to another strong finish in 2014, and stable expectations for patient behavior (i.e., deferrals). All indications point to strong results from ZMH, ATEC, BAX, CNMD, GMED, IART, JNJ KTWO LDRH, NUVA, SMA, SNN, SYK and TRNX"

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Symmetry Medical	6.55%	2.44%	SMA seems immune to the general market malaise due to its sale of the OEM solutions.
2	2	Stryker	11.52	(4.36)	Remember fundamentals? Sales, earnings. You know—the reason we're in business. Major ortho is about to report its best Q3 in years.
3	5	Zimmer	29.12	(6.20)	There is a strengthening tail wind to ortho. It is here now. ZMH buying BMET is like raising the big sail on the clipper ship.
4	10	ConMed	10.51	2.45	No company can swing with improving economic conditions more than CNMD. That, plus new management, has investors excited.
5	NR	MicroPort	16.53	6.28	Top performer this week and that purchase of Wright's large joint business looks really smart now.
6	6	Integra LifeSciences	12.57	(4.10)	Still the cheapest overall equity in orthopedics. Three things can change that for IART: sales growth, better profit margins or both.
7	3	NuVasive	8.01	(6.53)	Brean Capital upgrades. But on a valuation basis, spine companies are generally expensive.
8	7	Globus Medical	29.68	(0.81)	GMED is the most expensive equity on the Power Rankings. But with 30% operating margins, GMED qualifies as a premium equity.
9	4	Medtronic	28.84	(6.05)	The Shire tax inversion deal falls apart. Wall Street is starting to have doubts about MDT/COV.
10	8	Exactech	10.26	(14.74)	Overreaction by the market. How do you lose nearly 15% of your value but nothing fundamentally has changed?

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	LDR Holding Corp	LDRH	$33.30	$865	18.93%
2	MiMedx Group	MDXG	$8.29	$876	16.27%
3	MicroPort Scientific	853	$0.52	$733	6.28%
4	CryoLife	CRY	$10.15	$283	3.57%
5	K2M Group Holdings	KTWO	$14.66	$544	3.39%
6	ConMed	CNMD	$39.31	$1,075	2.45%
7	Symmetry Medical	SMA	$9.64	$362	2.44%
8	Globus Medical	GMED	$19.56	$1,846	-0.81%
9	Wright Medical	WMGI	$30.51	$1,539	-3.88%
10	Integra LifeSciences	IART	$48.20	$1,571	-4.10%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Baxano Surgical Inc	BAXS	$0.12	$6	-58.79%
2	RTI Biologics Inc	RTIX	$3.72	$211	-26.63%
3	Alphatec Holdings	ATEC	$1.45	$142	-22.46%
4	Aurora Spine	ASG	$1.47	$23	-20.22%
5	Bacterin Intl Holdings	BONE	$4.02	$27	-19.44%
6	Exactech	EXAC	$20.48	$282	-14.74%
7	Orthofix	OFIX	$28.04	$517	-12.73%
8	Smith & Nephew	SNN	$30.42	$13,591	-10.94%
9	TiGenix	TIG.BR	$0.65	$104	-10.37%
10	Johnson & Johnson	JNJ	$98.70	$278,362	-7.05%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$61.99	$60,720	15.93
2	Johnson & Johnson	JNJ	$98.70	$278,362	16.44
3	Globus Medical	GMED	$19.56	$1,846	16.60
4	Zimmer Holdings	ZMH	$97.52	$16,510	17.49
5	Exactech	EXAC	$20.48	$282	17.66

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$28.04	$517	179.13
2	NuVasive	NUVA	$34.51	$1,621	66.84
3	Symmetry Medical	SMA	$9.64	$362	49.76
4	CryoLife	CRY	$10.15	$283	30.49
5	Integra LifeSciences	IART	$48.20	$1,571	27.07

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Exactech	EXAC	$20.48	$282	0.98
2	CryoLife	CRY	$10.15	$283	1.02
3	Globus Medical	GMED	$19.56	$1,846	1.24
4	ConMed	CNMD	$39.31	$1,075	1.71
5	Zimmer Holdings	ZMH	$97.52	$16,510	2.05

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$28.04	$517	9.74
2	NuVasive	NUVA	$34.51	$1,621	5.37
3	Symmetry Medical	SMA	$9.64	$362	4.15
4	Smith & Nephew	SNN	$30.42	$13,591	2.57
5	Johnson & Johnson	JNJ	$98.70	$278,362	2.51

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Baxano Surgical Inc	BAXS	$0.12	$6	0.30
2	Alphatec Holdings	ATEC	$1.45	$142	0.69
3	Bacterin Intl Holdings	BONE	$4.02	$27	0.79
4	RTI Biologics Inc	RTIX	$3.72	$211	0.87
5	Symmetry Medical	SMA	$9.64	$362	0.90

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
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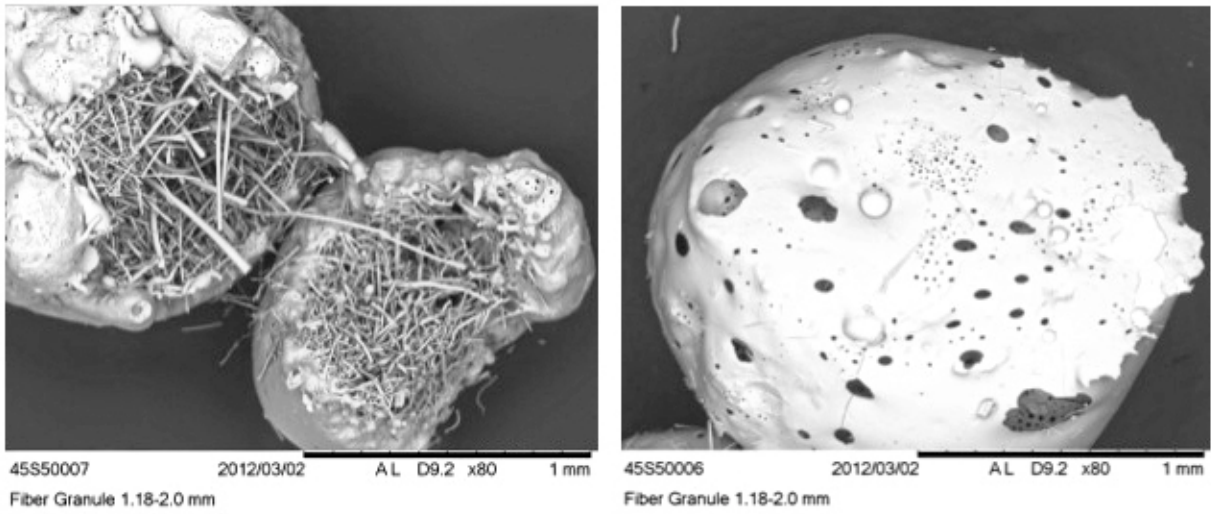
2	MiMedx Group	MDXG	$8.29	$876	11.06
3	LDR Holding Corp	LDRH	$33.30	$865	7.75
4	Wright Medical	WMGI	$30.51	$1,539	5.72
5	Globus Medical	GMED	$19.56	$1,846	4.10

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

BioGlass Is Back – In an Incredible New Form

BY ROBIN YOUNG



Courtesy of Prosidyan

Two of the most biologically active implants ever sold to orthopedic surgeons emerged from the U.S. government's atomic energy research of the 1950s and 1960s. The first was Marshall Urist's discovery of bone morphogenic proteins (BMP). The other is the subject of this article.

In 1967 a University of Florida professor, Dr. Larry Hench, was heading to a U.S. Army Materials Research conference in Sagamore, New York, when he chanced to sit next to an Army colonel just back from Vietnam.

"We can save lives but we cannot save limbs."

After listening to Hench describe his radiation resistant ceramic the colonel posed a question that would change Hench's life—and the lives of thousands of doctors and patients—forever. He said: "If you can make a material that will survive exposure to high energy radiation can you make a material that will survive exposure to the human body?"

The young colonel had witnessed numerous amputations in Vietnam. On that ride to the conference he told Hench "We can save lives but we cannot save limbs. We need new materials that will not be rejected by the body."

It's now been 45 years since that conversation and the new class of materials that it stimulated may well, finally, be ready to take the stage as the most exciting biologically active bone void fill since BMP.

BioGlass Is Born

Back at work after the conference, Hench recruited Ray Spintler and Drs. Ted Greenlee and Bill Allen to find an answer to the colonel's question. The U.S. Army funded it.

In 1969 Hench, Spintler, Greenlee and Allen came up with a unique ceramic material which was a combination of CaO (calcium oxide), P2O5 (phosphorous pentoxide) in a Na2O-SiO2 (sodium silicate solution) matrix. They melted it into little squares and implanted them, along with a control, into a rat bone model.

Six weeks later Dr. Greenlee reported his results:

> "These ceramic implants will not come out of the bone. They are bonded in place. I cannot push on them. I can't shove them. I can hit them and they do not move. The control implants easily slide out."

The U.S. Army Medical R&D Command would continue to fund this strange and obscure project for ten more years.

The new material proved to be extremely biocompatible, and integrated very well

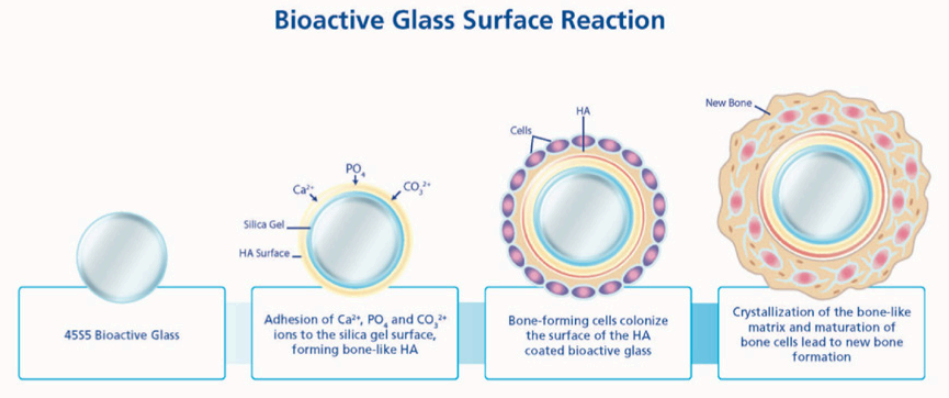
with surrounding bone or soft tissue by forming strong mechanical bond.

At some point someone named the stuff BioGlass.

So Close, Yet so Far

Some of the key discoveries about BioGlass which occurred between 1970 and 1980 were:

- The strength of the bond with bone was equal or greater than the strength of host bone.
- BioGlass's bone bonding was the result of a rapid formation of hydroxy carbonate apatite bi-layer on the implant surface.
- The reactive layers of the ceramic enhanced absorption, desorption of growth factors and synchronized proliferation and differentiation of osteoblasts.
- Everything happens in 6-12 days in vitro and in vivo.



Courtesy of Prosidyan

BioGlass came to market as a bone void fill. There was, however, a problem. Bone void fill is a non-load bearing application. Furthermore, any material used as bone void fill must be able to be resorbed over time.

And BioGlass did not resorb well, if at all.

Back then, BioGlass was essentially a form of crushed glass or glass microspheres. Porosity, such as it was, came in the form of the space between the small particles of bioactive glass.

Micro-channels in bone void fills ("porosity" in other words) are critical to bringing nutrients and cells to

native bone for healing and eventual bone void fill resorption. While this worked with DBM (demineralized bone) or calcium based fills it didn't with BioGlass.

Researchers tried to solve this problem by playing with the formulation. The next generation of BioGlass was, in effect, mostly calcium phosphate with a small amount of BioGlass. That solved the porosity problem. But it reduced the material's bioactivity—which is the whole point of BioGlass.

So close, yet so far.

A New Way to Look at BioGlass

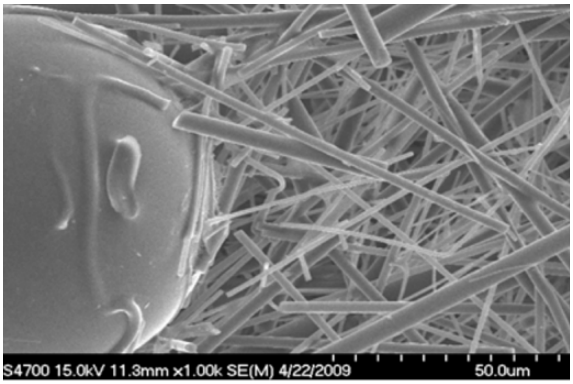
Charanpreet Bagga ("CB" to his friends and colleagues) in collaboration with Dr. Hyun Bae and MoSci Healthcare (which is the largest producer of BioGlass in the world) decided to look at BioGlass a new way.

CB, by the way, is the "go-to" guy for synthetic bone void fill research with 31 issued patents and another 44 in process. He spent the last quarter century leading product development at companies like Howmedica, Spinetech, Orthovita and Orthofix Spine. Dr. Hyun Bae is a world renowned orthopedic surgeon and scientist. Among his other accomplishments (which would take pages to list) is a research fellowship with the NIH (National Institutes of Health).

The CB/Bae/MoSci team decided to look at BioGlass in terms of surface area.

More surface area, more bone bonding. More bone bonding, more secure and long lasting the bone void fill.

BioGlass vermicelli.



Courtesy of Prosidyan

The Vermicelli Solution

Looking at FIBERGRAFT through an electron scanning microscope it looks like vermicelli gone wild.

But each fiber is 100% bioactive glass. FIBERGRAFT leap frogs all other BioGlass type bone void fills.

The team then encased the miles and miles of winding strands into porous

beads which they called "morsels" or BG Morsels.

In May 2014 this invention was implanted for the first time in humans by Dr. Daxes Banit in Georgia. Since then it's been used in more than 200 surgeries.

BioGlass's Anti-Microbial Effects

One of the likely side effects of increasing the surface area of BioGlass is that it will significantly increase the material's natural anti-microbial effects as well. In a study titled: "Antimicrobial Effect of Nanometric Bioactive Glass 45S5" and authored by T. Waltimo, T.J. Brunner, M. Vollenweider, W.J. Stark, and M. Zehnder the authors wrote:

> "The antibacterial effect of nanoparticulate bioactive glass appears to be directly linked to its high surface area."

The authors went on to say high surface area BioGlass has the twin attributes of being able to re-mineralize bone as well as to dis-infect and increase the anti-bacterial efficacy of BioGlass.

FDA Cleared and Bone Formation Data

On March 14, 2014 BG Morsels were cleared by the FDA for commercialization as a 510(k) implant:

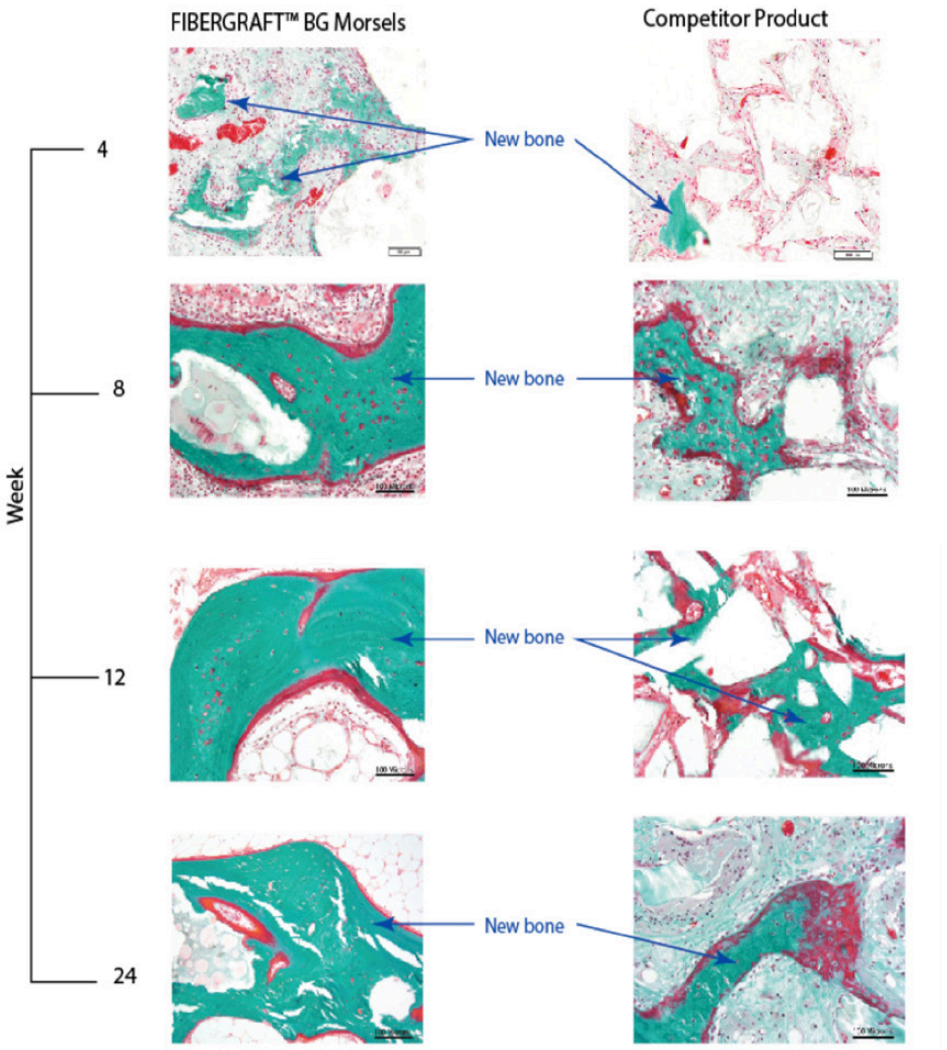
> "…for bony voids or gaps that are not intrinsic to the stability of the bony structure. BG Morsels is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void fill that resorbs and is replaced with bone during the healing process. BG Morsels is not indicated for use in load-bearing applications; therefore, standard internal or external stabilization techniques must be followed to obtain rigid stabilization."

In animal models, BG Morsels have shown to grow new bone more effectively than either other forms of BioGlass or other bone void fill materials. The histologies on belowt illustrate this.

In animal tests (sheep and rabbit) BG morsels demonstrated impressive performance. One study (see chart on page 8) compared BG Morsels to a positive control, the most popular BioGlass implant to date and then to a negative sham control (untreated defect) in a sheep model.

Make that a 58 skeletally mature sheep model. After 24 weeks with several interim evaluation points; (4, 8, 12, and 24 weeks) including a minimum of three animals per time point per treat-

Sheep Study: Histology Images of Bone Formation at Defect Site
(Goldener's Trichrome Stain)



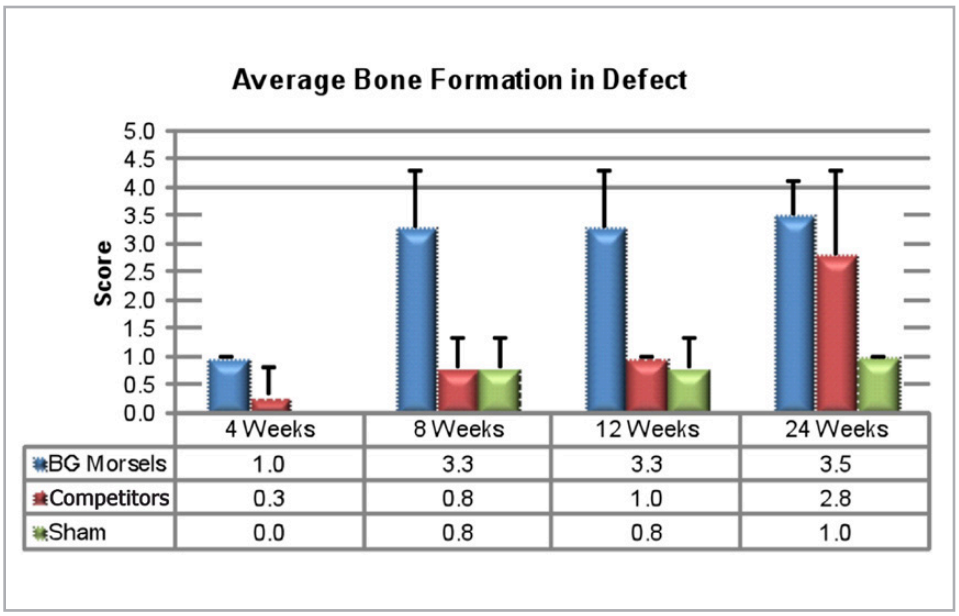
Courtesy of Prosidyan

ment group, BG Morsels device demonstrated clearly superior bone formation in a defect.

In other animal studies where BG Morsels were compared to other popular synthetic bone void fills, BG Morsels were also able to stimulate higher rates of bone formation.

Fibergraft and Prosidyan

CB founded a company to bring his BG Morsels to market. He named it Prosidyan and he located it about 40 miles due west of New York City in Warren, New Jersey.



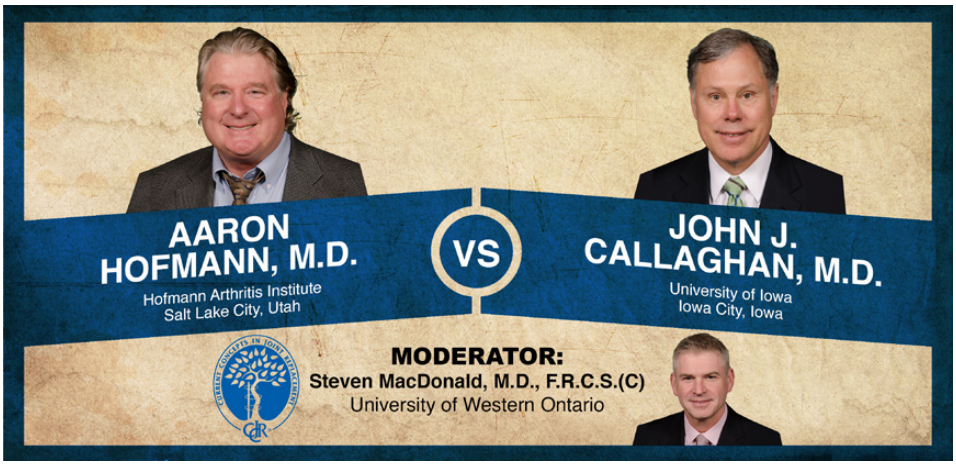
	4 Weeks	8 Weeks	12 Weeks	24 Weeks
BG Morsels	1.0	3.3	3.3	3.5
Competitors	0.3	0.8	1.0	2.8
Sham	0.0	0.8	0.8	1.0

Courtesy of Prosidyan

As he describes his new product, FIBERGRAFT BG Morsels is, in effect, a matrix of bioactive glass microfibers and microspheres, encapsulated inside a porous egg shell. FIBERGRAFT creates an ultra-porous granular structure with, of course, miles of surface area. Without a doubt, this has to be one of the most innovative synthetic bone void fill product of the last 30 years. ♦

Hofmann, Callaghan Debate the Posterior Stabilized Knee

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



Current Concepts in Joint Replacement/RRY Photo Creation

This week's Orthopaedic Crossfire® debate is "The Posterior Stabilized Knee: No Post Required." For the proposition is Aaron Hofmann, M.D. of the Hofmann Arthritis Institute in Salt Lake City, Utah. Against the proposition is John J. Callaghan, M.D. of the University of Iowa. Moderating is Steven MacDonald, M.D., F.R.C.S.(C) of the University of Western Ontario.

Dr. Hofmann: "I used to drink *this* Kool-Aid—saving the posterior cruciate on every patient—but I got over that and I did some cruciate saving and some cruciate sacrificing. I was a maniac about how to do it. We used a fourth-inch osteotome, placed it in front of the posterior cruciate ligament [PCL] to ensure that we didn't cut it. Then I began agreeing with Dr. Insall, who said, 'Exact tensioning of the PCL is often difficult and to some extent depends on luck…'"

"About 3% of the patients whose PCL I saved lost function of the PCL. Posterior substitution seemed to be the logical thing because of better operative exposure, easy balancing of the collaterals, reduced poly wear, greater contact area, and lower normal forces (Scuderi, Insall, *Clinical Orthopaedics and Related Research*, 1992). I began agreeing with that to the point where I designed one, but there are problems with these things."

"In 1982 Insall found an 11% patella stress fracture rate; in 1993 Lombardi noted stress fractures, and in 1989 Hozack found patella clunk. These are old references, but we're fooling ourselves if we think that this has gone away completely."

"I saw a patient last year with a dislocation and flexion instability who had an anesthetic reduction in the OR because you can't get these posts back sometimes. As for patella clunk, our cutouts on the implants have gotten smaller and so this is less of a problem. I just operated on a patient with a patella clunk last week…and they hate the rattle! This doesn't occur if you do a cruciate saving operation or if you use an ultracongruent insert. The latter is a deep dish poly—cruciate sacrificing—with an anterior buildup and a congruent articulation (a 1:1.2 ratio between the femur and the tibia) and there's no box cut needed."

"When I visited Australia I was inspired by the horseback riders. Their saddle doesn't have a saddle horn; it has a congruent surface and the ultracongruent poly does exactly the same thing. In 1991 Dr. A. Seth Greenwald did a study showing that if the strength of the PCL is 350 pounds, then the ultracongruent design is above that. There are at least seven companies that have copied this."

"In 2006 Brian Parsley published work comparing PS [posterior stabilized] to ultra (both sacrificing the posterior cruciate ligament). It was on 219 knees and they found equal results, but improved range of motion (ROM), function, and satisfaction in the patients that had the ultracongruent version."

"In 2012 Lombardi reported on 312 knees that were 'anterior stabilized' (an ultracongruent type of dished component with the highest ROM and the lowest manipulation). They found that the posterior stabilizing post is not required. Chris Peters from the University of Utah recently presented findings showing no difference between deep dished, ultracongruent and cruciate retaining (CR) designs. If you have a PCL that's absent during the operation you can put this in and be assured that you're going to have a stable articulation. You can get great stability just from the conformity of the poly against the femoral component."

Dr. Callaghan: "I know Aaron Hofmann…and I know that when he rides a horse he uses a saddle with a horn! So why would he think he should put a knee replacement in without one?"

"I looked up ultracongruent liners on PubMed. I looked up 'Hofmann ultracongruent liners' and found one liner in 2000…so I don't have enough ammunition. So then I searched on 'ultracongruent insert and total knee replacement' and I saw two old references. Then I did 'Hofmann and deep dish' and found a couple of references there. If you search on 'posterior stabilized total knee' there are over 500 references. I felt a little behind the eight ball, but I'm going to catch up."

"We know there is mobility without congruity in CR knees. Others have shown that you can have congruity, but there is potential for high stresses at the next interface down. If you were going to use this concept on a mobile bearing I could understand it because you can get the low contact stress as well as low constraint forces."

"I'm not going to tell you that you can't use a conforming surface. We have reported on our LCS (low contact stress) rotating knees; you remove the cruciate and it's a very conforming surface with no post. But the average motion in those knees was only 105 degrees. The knee needs rollback into order to get motion. On the medial side you actually pivot until you get back into flexion and then you start rolling back—on the lateral side you roll back throughout (Freeman et al., *Clinical Orthopaedics and Related Research*, 2003 as well as the *Journal of Bone and Joint Surgery*)."

"There has been a lot of work done on deep flexion of the knees with fluoroscopic modeling techniques by Rick Komistek. He showed me what happens with the ultracongruent; it stays right in the middle of the dish and that's why you can't get the motion that you can get if you have rollback."

"There isn't much on ultracongruent liners in the registries, but the American Orthopaedic Association (AOA) registry shows that there's not much difference between PS and CR. But in the most recent meta-analysis (Bercik et al., *Journal of Arthroplasty*, 2013) ROM was better with the PS design. Chit Ranawat has had excellent results, both clinically as well as functionally…95% satisfaction rate with a mobile bearing PS type of knee. At minimum 10 year follow-up there were no revisions. This is similar to our LCS data, but Chit reported an average ROM of 119 degrees. That's because the PS post gives you rollback."

"But there are problems with PS designs. Aaron alluded to the fact that the cam post can impinge, which causes backside wear issues. You do get patella clunk. In another series (Hart, et al., *Knee*, 2008) there was a 1.2% prevalence. Those done arthroscopically (one debridement) had a 79% success rate; those with two debridements had a 95% success rate."

"As Aaron noted, it's somewhat related to the box. You want a long patellofemoral groove; most of the newer devices have these. So, good is the enemy of great. And Aaron, ultracongruent is good, but PS is great."

Moderator MacDonald: "John, do you think in general that a PS knee gets better flexion than a CR knee?"

Dr. Callaghan: "In general, probably so. In the beginning of my career I used a lot of CR knees and in general they did well. But whenever I had a problem with motion I was concerned about whether I did it right. I'm kind of a 'slop in the system' guy, and I think the PS is slop in the system—to make sure that at least one technical aspect of the operation isn't important."

Moderator MacDonald: "Aaron, do you think it's more reproducible to release the PCL?"

Dr. Hofmann: "I don't think I've saved a PCL in the last five years. It's more difficult, less predictable. It's more forgiving to take the PCL; every time I train a fellow they leave my umbrella of care and then start doing ultracongruents on every single patient."

Moderator MacDonald: "John, the registry data shows a slightly higher revision rate for PS over CR knees."

Dr. Callaghan: "Early on you do see a few clunks, etc., and you probably do have a couple of reoperations. Some of the early designs were related to that. It shouldn't be instability."

Dr. Hofmann: "We all have some patients with instability; I think a PS knee is less forgiving if you get flexion instability because they get the rattle, then the post wear. I've seen many patients that don't have a PCL. They thought it was saved—and they have some flexion instability—but the patients don't really know it."

Dr. Callaghan: "Aaron, I think that today, most of us need a tight flexion gap when you're doing a PS knee. Some people left them relatively loose because they thought the peg would help with that, but it doesn't."

Moderator MacDonald: "Aaron, John pointed out that the post has a role kinematically. Do you agree?"

Dr. Hofmann: "I mostly agree. The guys that have the best deep dished poly have put the null point—the center of rotation—not in the center, but about 6mm back toward the posterior side. So you're actually rolled back a little to start with. Then you remove the posterior lip of the ultracongruent so that it doesn't cause impingement. One of the available implants even professes to be high flex (beyond 125 degrees)."

Moderator MacDonald: "John, you believe the post has a role?"

Dr. Callaghan: "It's been shown—not promoted. If you don't have a post then it's questionable as to whether you can get rollback."

Moderator MacDonald: "Do you ever use a true PS with a post in your primaries?"

Dr. Hofmann: "No, I use it on every revision—either a big or a little post—but not on a primary."

Moderator MacDonald: "Thank you gentlemen." ♦

Please visit www.CCJR.com to register for the 2014 CCJR Winter Meeting, December 10 – 13 in Orlando, Florida.

MRI From Your Smartphone? Auto Billing When You Step Out of the Exam Room? Yes! // New HSS Study to Tackle Critical ACL, UCL Failure Issue // First-Ever Step-by-Step Measurement of Operative Time in Scoliosis

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

The 45 Second Exam Note Want an ortho-specific app that lets you peel back the skin and zoom in on joints? Wishing you could order an MRI from your smartphone? The time has come… and the app was developed by practicing orthopedic surgeons. Matthew Stiebel, M.D. is an orthopedic surgeon with Jupiter Medical Center in Jupiter, Florida. Dr. Stiebel, a sports medicine specialist who has been an instructor for the AANA (Arthroscopy Association of North America) and AOSSM (the American Orthopaedic Society for Sports Medicine), tells *OTW*, "I have used several electronic medical record (EMR) systems, all of which came up short. When approached by Dan Cane (co-founder of Modernizing Medicine and past co-founder of Blackboard) to help develop a radically different EMR system for orthopedic surgeons, I listened, and then I got involved."

Modernizing Medicine/ EMA Orthopedics

"EMA Orthopedics is a native iPad app with an easy interface that maximizes screen space. Surgeons who are 60 and older are very comfortable navigating the programs. In orthopedic surgery practices there is no time to be leisurely between patients, so we need something that stays on the move with us. As for speed, it takes me approximately four minutes to dictate a note; with this app I tap right through the form in 45 seconds! And EMA Orthopedics, which is cloud based, makes it easy for surgeons to remain connected to the Internet as they move easily between exam rooms."

"So you carry the iPad all day, and as you walk out of an exam room you can fill out the physical, and then the program automatically bills for me and sends the necessary forms to the billing department. No other EMR does this. I can take a picture of, for example, a swollen knee, and add it to the chart. Sometimes I even draw on the pictures when I'm telling a patient where the ACL graft will go—then that goes in the chart as proof that I have explained things to the patient. I even bring it into the OR because I can read all the notes, take pictures of the radiographs, and make them part of the chart."

"One thing that truly differentiates this program is the way it holds data. We put data in that is structured. It is not like data you have from dictation where if you want to do research, then you must pull out all the cases with, for example, broken arms, and subdivide them into type X. That is very difficult to do when the data isn't

structured. With this program you can perform searches based on the type of fractures, on all ICD-9 or ICD-10 codes. You can also see what all other users of EMA Orthopedics have done using de-identified data. If we can take advantage of this opportunity to perform such a large meta analysis of data then we will have a great chance to see what is working and what is not."

"We are partnering with IBM Watson to create something known as schEMA, which will be powered by Watson and will expand the power of what we are doing now. This will allow users to interact with the system in a way that's cognitive…like Siri on the iPhone. With schEMA, users can pose queries, describe symptoms or search for information and statistics about various conditions and matches those queries with clinically useful content. schEMA will use medical journals and other to parse the current evidence and present relevant answers. We have started developing schEMA for dermatology and plan to further develop into other specialties."

New HSS Study Tackling Critical ACL, UCL Failure Issue "Failure," says a savvy surgeon, "is the dirty underwear drawer of orthopedic surgeons." David Altchek, M.D. is an attending orthopedic surgeon and co-chief in the Sports Medicine and Shoulder Service at Hospital for Special Surgery (HSS). He is also the Medical Director for the New York Mets. Dr. Altchek tells *OTW*, "In both the anterior cruciate ligament (ACL) of the knee and the ulnar collateral ligament (UCL) of the elbow we now have solid techniques and we are getting good outcomes. So now, we are getting greedy—appropriately so—and we want 'no' failures. We are doing MRIs postop to look at reconstructing ligaments in both the UCL of the elbow and the ACL of the knee. We need to determine when the ligament starts to mature and when we can start loading it. Perhaps some people are returning to pivoting and throwing before they are ready."

"In this study, which involves five HSS surgeons, we are aiming for 200 ACLs and 100 UCLs. We hypothesize that some people heal slower and therefore the ligament doesn't mature as fast. By taking MRIs a month postop, then at three months, seven months, and one year, we will have a solid idea of what these ligaments look like in periods of healing. We will be able to pinpoint the junctures at which they change and mature."

"Our study population is young athletes between skeletal maturity (approximately 15 to 25 years of age). They must have had no prior surgeries and no significant associated injuries. In the ACLs we are studying the hamstring and patellar tendon; we will compare

them to each other and to each group. Then we will study two groups of grafts in the UCL, comparing them to each other and to their own group. We will use the same graft in all subjects."

"Return to play is confusing and we need more accurate information. Failures are the dirty underwear drawer of orthopedic surgeons; they don't talk about them much. We need to turn that around."

First-Ever Step by Step Measurement of Operative Time in Scoliosis Apparently, when it comes to idiopathic scoliosis, there is room for improvement in making the operation more efficient which has important implications for the patient. Baron Lonner, M.D. is the chief of the Division of Spine Surgery in the Department of Orthopedic Surgery at Beth Israel Medical Center and director of the hospital's Spine Institute of New York. He and his colleagues at Rady Children's Hospital in San Diego and at Nemours Children's Hospital in Delaware set out to get the details. Dr. Lonner tells *OTW*, "We divided adolescent idiopathic scoliosis surgery into 14 clear steps and measured the time associated with each step. We also measured blood loss because prolonged operative times lead to more blood loss, more potential for infection, and more anesthesia."

"You also want to minimize time in the OR because of increased costs that then take away from other services the hospital can provide for patients. We found that there are four main components in terms of operative time. The first is exposing the spine to put an implant in and the second is putting the screws in—each step takes 15-20% of the overall operative time. The third component is putting the rods in and performing manipulations for correction of the spinal deformity. The fourth component is closure of the soft tissue compartments."

"We are now working on the use of power tools in the OR because we have found that they increase accuracy. But I am also seeing a significant decrease in operative time because I and some other surgeons are using these tools (approximately 30-50% faster). We are also going to be looking at ways to improve the efficiency of closing the spine. One option is sutures that you can run continuously; another possibility is to use skin glue and a special mesh that holds the skin edges together."

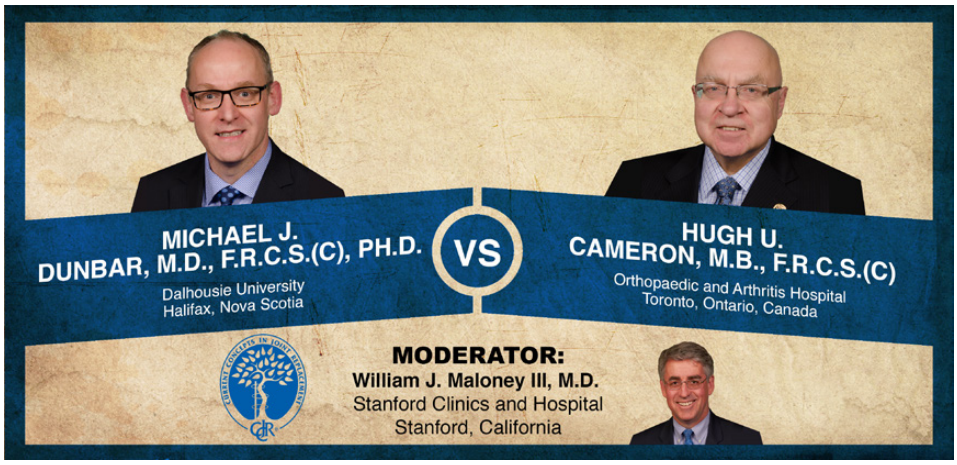
"One way to decrease postoperative pain and blood loss is to not expose the spine as far out to each side. To do that, however, we must develop new tools for insertion of the screws and new soft tissue guides. There are techniques where the muscle and skin are not fully exposed but that has not taken hold for idiopathic scoliosis because our results are so good with standard "open" approaches. We might need to consider some hybrid of traditional open and MIS (minimally invasive surgery)… something that will involve less dissection of the musculature, less bleeding, and less pain, but with reliable deformity correction, good fusion, and healing. We are also working on improving the implants themselves so as to facilitate correction maneuvers and decrease the amount of dissection required to get to the spine."

"Interestingly, we found some variation amongst surgeons as far as the order of the steps performed and in the time it takes to do the steps. So here we have an opportunity to standardize the procedure such that those surgeons who perform fewer of these surgeries can be successful in improving outcomes for their patients. The bottom line is that more experience in performing these 14 steps also impacts how accurately and efficiently surgery is performed." ♦

Dunbar, Cameron Debate Modular Necks

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

This Orthopaedic Crossfire® debate is "Abandonment of Modular Necks: The Baby and the Bath Water." For the proposition is Michael J. Dunbar, M.D., F.R.C.S.(C), Ph.D. of Dalhousie University in Halifax, Nova Scotia. Against the proposition is Hugh U. Cameron, M.B., F.R.C.S.(C), of the Orthopaedic and Arthritis Hospital in Toronto. Moderating is William J. Maloney III, M.D. of the Stanford Clinics and Hospital.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Dunbar: "There are three proposed advantages to modularity: reduction of impingement, reduction of dislocations, and better balancing of leg length and offset with subsequent improved function. As for impingement, it can be an issue if you use ceramics. And as impingement is related to femoral component positioning, your job is to get the component right."

"The Australian Joint Replacement Registry (2013) shows that modular necks have a higher dislocation rate. With regard to leg length and offset, with a cemented stem you don't need this because within the envelope you can broach it up and down, and change the varus and valgus; you can also play with the version. There are no advantages to the modular neck."

"There is the potential for fretting and ion debris (and associated corrosion). There's also dissociation and fracture. In my opinion, the midterm outcomes at 10 years are worse than fixed necks; they are also more expensive. A 2009 paper that won the John Charnley Award (Garbuz et al., The Association of Bone and Joint Surgeons) found that the issue wasn't the metal-metal bearing, but the coupling. So there is the potential to generate metal ions."

"A 2010 series on 5,000 hips with a titanium neck had a fracture rate of 2.4% (Grupp et al., *BMC Musculoskeletal Disorders*). That's not an extremely high rate, but it's unacceptable. We reported on the PROFEMUR Z fractures at the tension interface of the modular neck (2010, *The Journal of Bone and Joint Surgery*). We have had over 452 implanted and had a fracture rate of 4.5%. These are big revisions because you can't get them out the way you normally do because there is no neck to grab onto. You're often forced to do extended trochanteric osteotomies. We now have patients with 'time bombs' inside of them and they are upset about it, and are in fact undergoing counseling."

"The Australian Registry shows that the fixed neck has better survivorship than the modular neck. One reason that there may be a higher revision rate is due to retroversion. Gill from the Oxford lab (*The Journal of Arthroplasty*, 2002) looked at the effect of retroversion on radiostereometric (RSA) migration patterns. As you retrovert, you extend the lever arm thus generating more retroverting forces. This would be germane when you're getting out of a chair, climbing stairs, etc."

"Australian Registry data from 2012 shows reasons for revision in modular versus fixed necks, and there was a much higher incidence of aseptic loosening with the modular necks. This may in part be due to this retroverting effect."

"Finally, these are expensive. Would the money have been better spent on surgical technique/training?"

Dr. Cameron: "The modular neck in most common use is the Cremascoli; the one I use is different, but has the same concept. All of the companies think that the bigger the stem, the longer the neck, but a big stem with a longer neck results in leg length problems."

"The Rizzoli Institute researchers looked at this (*The Journal of Bone and Joint Surgery*, 2009) and found that without a modular neck it is not possible to rec-

reate length, offset, and version…especially in women. Impingement is also an issue; it can cause dislocation, noise, particle generation, and locking mechanism failure. In the past I never heard bad things about the Cremascoli. What has changed?"

"The taper has been shortened, the neck is longer, the version angles have been increased, head sizes bigger than 32mm have been introduced, and there have been some surface changes."

"The one I'll discuss here is cobalt chrome, not titanium. It's a standard Morse taper reinforced with anti-rotation cogs. It's the R-120, a conventional stem with a proximal satin finish. Once the stem was in the neck length variation was a huge bonus, but the main advantage was version change. I can put it in 8 degrees and 12 degrees of version; more isn't necessary."

"It is possible to change version after stem insertion. You can't use a pure Morse taper because it won't withstand the rotational forces; that's where the rotational cogs come in. The original cemented stem I used between 2002 and 2005 was polyethylene cemented sockets. The neck length was usually 32mm, but 35mm was also available, as was 38mm in a couple of cases. I anteverted it in only two cases; it was neutral in 39% of cases and retroverted in 59% of cases. This means that if the necks were not modular it would not have been possible to place them in the optimal position."

"We had two bisphosphonate fractures and one late sepsis, as well as two taper fractures at the neck/stem junction and one taper dissociation. All had long necks and heads. The stem was reintroduced in 2007 and between then and 2011 I did 188 cases. All stems were cemented and all cups were not cemented. The early complications were six calcar fractures, all of which were wired. There was one dislocation at two years and zero taper problems. Neck version was even more surprising; almost none of them were anteverted. Less than 30% were neutral and about 75% were in retroversion. Some of these were in maximal retroversion, meaning that if the cup was nonmodular then I would have placed only 30% in an optimum position."

"The taper problem has been solved. My caveat is that I've never used a head >32mm. In a series from 2002 I've done more than 350 cases with no incidents of delayed metal hypersensitivity and no pseudotumors. Columbus had problems finding America and Charnley had issues with his initial hip joint. My friends embrace the future!"

Dr. Dunbar: "I'm taking an international approach with all comers through registry data and he is showing his excellent series. He is better than the average surgeon, so it doesn't reflect in his data."

Dr. Cameron: "You must impact the taper. They must be put in properly, especially if it's an offset taper. And you can't just tap it a little bit. When you're locking a taper the heaviest hit is the only one that's important."

Moderator Maloney: "Mike, Dr. Cameron said to get the offset leg length correct you must use a modular neck."

Dr. Dunbar: "That's the argument for a cemented stem. If the argument is that an old osteoporotic femur gets a big patulous canal, therefore I get a big stem with a big offset because that's the linear scale up with the companies, the answer is, 'forget the uncemented stem, put a cemented stem in and within the cement envelope you can put in any size offset and fine tune it.'"

Dr. Cameron: "The problem is that in North America residents aren't taught cemented stems. And cementing a stem properly is much more difficult than locking a taper properly."

Dr. Dunbar: "That would go to your point earlier about not being afraid of the taper. In the long term it won't be acceptable to say that because we're in North America and we haven't taught our residents how to do cemented stems that we must abandon it and develop new technologies. We have technologies that have been around for 35 and 40 years. It seems that every time we introduce a new technology we mess it up."

Moderator Maloney: "Hugh, you look at the registry data and it's clear that modular necks are having problems. How do you respond to someone saying, 'How can you justify using a modular neck when we're having fractures, taper corrosion, and adverse local tissue reaction?'"

Dr. Cameron: "There are some tapers and stems available that aren't very good. But in the Australian Registry, if you're doing a revision and remove the neck, but leave the stem alone, then that's counted as a revision."

Moderator Maloney: "There are other ways to get around the version and neck angle issue. Don't you think we

have enough options without making it modular?"

Dr. Cameron: "I've been using S-ROM for 25 years and I could always change the version and the offset. But I couldn't do it with a cemented stem."

Moderator Maloney: "You're both from Canada and have issues about who is paying. If payers are looking at this data, then what are they going to do with modularity?"

Dr. Dunbar: "I would restrict it to a single use individual case that is justified with a submission to Health Canada. At our center, the reason we put in a modular neck is that it was part of an RSA [Royal & Sun Alliance Insurance Company of Canada] study. It's really hard to print the RSA study on 0.8 micromotion when we're reporting a 5% fracture rate. The cost for the neck was more than the entire construct of the cemented hip that I use."

Dr. Cameron: "We do more joints than any other hospital in Canada and I'm the only one who still uses cement on a regular basis. So when I'm gone I suspect this argument will go too."

Moderator Maloney: "Are you going to fill out a form for your hospital administrator in order to use a modular neck?"

Dr. Cameron: "I already do."

Dr. Dunbar: "There is a class action lawsuit over this in our province."

Moderator Maloney: "Hugh, what about assembly?"

Dr. Cameron: "It must be done properly, especially if it's offset because when you're hitting it down you're losing half the force. I wonder how many of these head/neck junction problems are because they're not being hit hard enough. And it's not as crucial to keep it dry in the body as it is to hit it hard."

Moderator Maloney: "Mike, what about in vivo assembly?"

Dr. Dunbar: "It brings complexity and it's just another variable that can go wrong."

Moderator Maloney: "Thank you gentlemen." ♦

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COMPANY

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"The world's top doctors at your fingertips, from the comfort of your own home," boasts the latest Internet online concierge medical services for patients. "We provide priority access Telehealth Consultations & Second Opinions from the world's leading doctors."

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On October 8, 2014, HelloMD announced the release of its Telehealth services. The company claims their doctors are in the top 1% worldwide. The website is peppered with the logos of Stanford, UCSF, Harvard Medical School, Mayo Clinic and UCLA, among others.

Priority Access

"We have already selected the best of the best, for each major category of orthopedic surgery. Our experts are world-renown, often performing hundreds procedure [sic] each year. Many top doctors have long waiting lists for appointments. Our doctors will prioritize their schedules to ensure you get priority access, fast."

Participating Surgeons

The following orthopedic and spine surgeons shown on the website are from San Francisco and Los Angeles.

- Elly LaRoque
- Justin Saliman
- Nicholas Mast
- Piers Barry
- Youjeong Kim
- Nicholas Colyvas
- Leonard Gordon
- Gordon Lundy
- Jason Snibbe
- Kenneth Light
- Hyun Bae

International Referrals

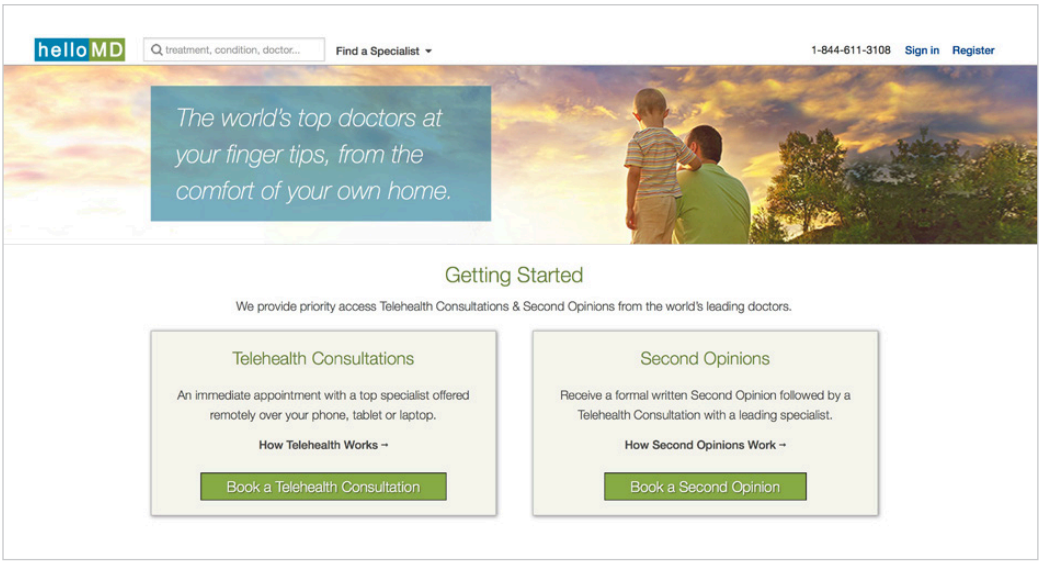
Lundy, an orthopedic surgeon from San Francisco said, "I recently used HelloMD to connect with a prospective patient in Hong Kong. The Telehealth capabilities allowed for an in-depth discussion of treatment options, and this patient will likely travel to my office in San Francisco for treatment. This is a powerful way of expanding my access to international patients."

"Strict" Surgeon Selection Process

The company says it follows a "strict" selection process to ensure that just the top 1% of doctors are represented. They don't disclose how you get on the list because the selection process is proprietary. The selection process includes consideration of "both subjective and objective measures, including peer nomination and review." Thus far, they claim to have enlisted top neurosurgeons, orthopedic specialists, cardiovascular, plastic surgeons ophthalmologists, and others.

HIPAA Compliant Care Team

A special "care team," is created which has access to each patient case. "The care team can span geographic borders, and includes secure (HIPAA compliant) medical records management, and communications between consulting doctors, the patient and care coordinators. These capabilities ensure that the continuum of care is not compromised as the patient transitions from one provider to another," stated the company announcement.



HelloMD

Targeting China

The company is building an international doctor referral network and says it already has formal alliances with "significant" physician groups in China. In addition, the company's proprietary library of over five hundred doctor videos will be converted to Chinese, with other languages to follow.

"Our Chinese alliances efforts are well underway, and we see this as a growth market for leading U.S. doctors," stated Nicholas Colyvas, HelloMD chief medical officer. "Rather than compete with Chinese doctors, we are enrolling them in collaborative patient services, bringing the best of east and west medical thinking to each patient engagement."

"The business of medicine in America is changing rapidly," stated Mark Hadfield, founder of HelloMD. "The best doctors are increasingly aware of a significant global market for their services; a market that will self-pay in order to access the best of the best. Our vision is of a global marketplace with easy access to the top 1% of doctors worldwide."

To see the website for yourself, click on www.hellomd.com. — *WE*

DePuy Synthes Cuts Hip Pricing in Third Quarter

Johnson & Johnson's DePuy Synthes' orthopedic sales increased 2.7% to $2.344 billion during the third quarter of 2014. Currency cut revenues by 0.2%.

Hip Prices Cut

The company cut hip prices by 5% during the quarter but still logged a 4% increase in hip sales. Knee sales jumped 6% and trauma sales rose 3%. Only spine sales showed a decline, dropping 1%. Chief Financial Officer Dominic Caruso told analysts on an October 14 conference call that the company cut hip prices as it attempted to renew contracts with hospitals and other customers.

Sales growth, according to the company, was driven by trauma, sports medicine, knees and hips. Trauma's increase was due to market growth and new product launches, while the launch of Monovisc, coupled with the continued strong growth for Orthovisc drove results for sports medicine.

Hip sales were driven by strong volume growth, partially offset by continued pricing pressure. Primary stem platform sales were major contributors to the results. The company attributed the increase in knee sales to the launch of Attune, partially offset by pricing pressure across the regions.

DePuySynthes 3Q2014	Sales ($ in millions)	% Change
Total Reported Sales	**2,344**	**2.7%**
Knees		6.0%
Hips		4%
Spine		-1%
Trauma		3%

Source: Johnson & Johnson

Photo creation by RRY Publications LLC/Logo courtesy of DePu

Caruso told analysts the industry has now seen two consecutive quarters of positive momentum in hospital utilization rates, which is in line with recently published analysts' reports noting the strength. "We continued to remain confident that as economies recover and as healthcare reform continues to gain momentum here in the U.S. and abroad, utilization rates are going to increase."

A New Seasonality

Analysts asked Caruso what the company expected to see on the U.S side in terms of hip and knee volumes after a soft first half of the year.

"We did see increased volume in the third quarter," said Caruso. He said this was consistent with what the company expected in that the second half of the year would be stronger than the first half of the year. He added that the company experienced 70% of its hip and knee growth in the fourth quarter.

"So obviously, we've now seen a new seasonality that's very clear in the hip and knee market. And we've seen an uptick in the third quarter or in the back half of the year as we expected, we would see."

Market Growth and Pricing

Louise Mehrotra, vice president of J&J investor relations added that their best

estimate of U.S market growth for the third quarter was that hips grew about 3%. "We grew slightly faster and knees about 4%, which we also grew slightly faster. But that's again, just a big estimate because we're the first or second [to report]."

Hip pricing in the U.S., said Mehrotra, was minus 5%. For knees, pricing was negative 2.2%, a little better than the second quarter. "Mix coming in about 1.5% positive so negative minus 0.6 on the quarter price and mix together and that's better than the second quarter."

Spine pricing was down 5%, more negative versus the second quarter. Mix is up a positive of 1%. Pricing on trauma was roughly 2% positive.

"Surgery Is the Place to Be"

Caruso told analysts that the company made the determination some time ago that it was going to focus on surgery, general surgery, and specialty surgery, and orthopedics and have less of a focus on cardiovascular. J&J got out of the drug-eluting stent business as it saw it becoming a commoditized business.

"Within the overall approach to medical devices, we still believe surgery is the place to be. We're obviously very happy with our market position there. We made a big bet as you know in orthopedics and we're continuing to see the benefits of that combination with Synthes."

"I think our competitors have basically followed suit in terms of these combinations in orthopedics as you know, and there is also combinations along with a current large player in cardiology now acquiring a major player in surgery, again confirming our approach that in fact surgery is the place that we're going to see sustainable growth going forward."

Synthes Integration

Asked when special charges for integrating Synthes will stop, Caruso said the company has been "very careful" to integrate this business in a way that wouldn't be disruptive to customers. "There are a number of sites that we have to consolidate. These are two very large businesses as you can imagine. So these integration activities are winding down and we should see less of the special charges going forward. And I would say that we're very close to actually completing the full integration of Synthes."

Lower Extremities and Robotics

Addressing question about whether or not the company needs to add robotics to its portfolio, Caruso said, "I don't think we need a robotics platform of our own to effectively compete in the future. We are in fact utilized in the robotic platform that exists today with our product, but I'll view it as a critical enabler of growth for us in particular."

He offered that the only place the company sees some weakness in their offerings is in the extremities portion of trauma. "So, lower foot and ankle kind of trauma products, that market seem to be growing more rapidly than the overall market and we have some new innovations coming to market, but not yet there. So we are not yet participated in that growth, but we will be going forward." — *WE*

Marriage Made in Biomaterial Heaven: Amedica and Spinal Kinetics

Amedica Corporation, the leading developer of innovative forms of silicon nitride ceramics has entered into a multi-year private labeling agreement with Spinal Kinetics, Inc., one of the leading innovators of artificial spinal disc technology.

Wikimedia Commons and danielclauzier

Amedica will now provide Spinal Kinetics with sterile packed silicon nitride spinal interbody fusion devices for sale in worldwide markets.

This is huge news.

Amedica's spinal interbody fusion devices are made of a micro-composite silicon nitride biomaterial—a ceramic that has unmatched strength, durability and reliability. Its surface texture and hydrophilic nature attract both osteoblasts and physiologic proteins to ensure reliable osteointegration, while its surface biochemistry inhibits bacterial biofilm adhesion.

"The Spinal Kinetics team is very excited to add Amedica's silicon nitride spinal fusion technology to our product portfolio," said Spinal Kinetics President and CEO Tom Afzal. "This agreement is a critical additional step in broadening the range of uniquely innovative technologies we bring to the spine surgery community."

Located in Sunnyvale, California, Spinal Kinetics, a privately held medical device company that developed the M6-C cervical and M6-L lumbar artificial discs, was founded in 2003. The company reports that it has over 31,000 implants to date.

Amedica Corporation, a public company based in Salt Lake City, Utah, recently added Sonny Bal, M.D., .J.D, MBA, as its new President and Chief Executive Officer. Just a week ago, the company lost its legendary chairman, Max Link, who unexpectedly passed away at 74 years of age.

For Amedica, this is a major announcement and, along with its new CEO, portends many more positive developments. — *BY*

Analysts Read Tea Leaves of Biomet's 6% Quarter

Biomet, Inc.'s most recently completed quarterly sales rose 6% over the same quarter last year.

Wall Street analysts pore over Biomet's results like gypsies reading tea leaves at the bottom of the tea cup to divine where orthopedic sales for the entire industry are heading. The leaf reading will come to an end soon as Biomet is betrothed to Zimmer Holdings, Inc., which usually reports later in the season.

This quarterly result released October 9, 2014, can be "tricky" according to BMO Capital Markets analyst, Joanne Wuensch. She said the quarter included summer months, "which are usually seasonally soft, but last year we saw an increase in ortho sales in the [quarter] heading strong into the end of the year, creating tough year-over-year comps for the industry."

Biomet's total sales for the quarter were $774.8 million. U.S. sales rose 5.4% to $495.1 million, while European sales increased by 6.5% (3.2% constant currency). International sales climbed 8.3% (10% constant currency).

Sales Rising, Slowing

Knee sales rose 4.3%, hips were up 3.8% and sports, extremities and trauma (S.E.T.) sales increased 3.4%.

Reported net income for the quarter dropped from $31.1 million the previous year to $7.3 million. Cash flow fell to $2.4 billion compared to $50.4 million the previous year.

Wuensch noted that knee sales slowed from the previous quarter due to difficult comps. Management attributed the rise in sales to its Oxford Partial Knee system, citing more than 300 professionals trained during the quarter, and expectations for up to 400 in the next quarter, as well as its Vanguard XP Bicruciate Knee (which was introduced at AAOS in the spring). European knee sales increased between 6-10% over the last several quarters.

Hip sales also slowed from the previous quarter. Sales in the quarter were driven by the Taperloc Hip System, G7 Acetabular System, and Arcos Modular Femoral Revision System.

The 20.9% increase in spine sales was primarily due to the November 2013 acquisition of Lanx, which the company said added 200-250 basis points to net sales in the quarter. The company said integration is moving forward according to plan, providing for cross synergies in the segment.

Biomet 1Q 2015	Sales ($ in millions)	% Change
Total Reported Sales	**774.8**	**6.0%**
Knees	234.7	4.3%
Hips	155.3	3.8%
Sports, Extremities, Trauma	154.5	3.4%
Spine & Bone Healing	122.8	20.9%
Dental	53.7	down 0.5%
Biologics and Other	53.8	5.5%

Source: Biomet, Inc.

Reading Tea Leaves, source: Wikimedia Commons and Harry Herman Roseland

S.E.T. also slowed from the previous quarter. Sports medicine saw increased demand for the company's JuggerKnot brand. Extremities sales were up double digits, leading to 27 consecutive quarters of double-digit growth, primarily powered by the Comprehensive Reverse Shoulder System. Management also pointed to its Comprehensive Convertible Glenoid system, its Signature Patient –Specific glenoid instruments launched a couple of quarter ago, and highlighted that it is enrolling patients into its U.S. IDE for a comprehensive anatomical stemless shoulder system. The company also launched a new cannulated screw system for lower-extremities during the quarter.

Second Half Market Recovery?

Glenn Novarro at RBC Capital Markets said he would characterize Biomet's U.S. results as better than the previous quarter and sees it as a potential sign that the U.S. market may be recovering after a slow first half of the year.

He believes the U.S. recon market has to come in slightly better than expected. He models approximately 3% constant currency growth for the worldwide recon market in the quarter and believes the underlying health of the worldwide recon market will improve sequentially. His tea leaves say Biomet is getting the reporting season off to a good start for orthopedics. — *WE*

Cedars-Sinai Now Affiliated With Kerlan-Jobe, Santa Monica Orthopaedic and Sports Medicine

There's a new orthopedic triumvirate in Southern California these days. Cedars-Sinai Health System has just announced an agreement with the Institute for Sports Sciences that clears the way for a formal affiliation with the Kerlan-Jobe Orthopaedic Clinic and Santa Monica Orthopaedic and Sports Medicine Group.

Cedars-Sinai Health System

In 2014, the Institute for Sports Sciences was formed by Kerlan-Jobe and Santa Monica Orthopaedic and Sports Medicine Group so that together these high level entities could work toward innovative clinical, research and training programs in sports medicine and orthopedics. Last year, the Institute for Sports Sciences announced that it had selected Cedars-Sinai as a partner in these efforts. Going forward, the Institute for Sports Sciences will continue to manage Kerlan-Jobe and Santa Monica Orthopaedic and Sports Medicine Group.

"Cedars-Sinai's orthopedic program is already ranked as the best in the West and is in the top 10 nationally, so when we partner with such outstanding orthopedic groups as Kerlan-Jobe and Santa Monica Orthopaedic and Sports Medicine, the possibilities for taking orthopedics and sports medicine to an unprecedented new level for patients

are extraordinary," said Thomas M. Priselac, president and CEO of Cedars-Sinai, in the October 8, 2014 news release.

"The Institute for Sports Sciences represents a new model for how physician specialists in different groups can come together and help shape the healthcare landscape in some very impactful ways," said Jeremy Hogue, CEO of the Institute for Sports Sciences.

Bert Mandelbaum, M.D., chair of the Santa Monica Orthopaedic and Sports Medicine Group Foundation, and head of its fellowship program, told *OTW*, "We have a lot of parts to our overall enterprise, and we have some exciting priorities within each domain. From a clinic standpoint, we will be adding physicians and groups which are a good match to our culture and share our mission and vision. From a surgery center standpoint, we are looking to add service lines like outpatient spine and joint replacement, as well as look to expand to other surgery centers. And from a research standpoint, the partnership with Cedars-Sinai, which is one of the premier research hospitals in the world, is really exciting as we take advantage of this combination and work on some game-changing developments."

Neal ElAttrache, M.D., chair of the Kerlan-Jobe Orthopaedic Foundation and head of its fellowship program, commented to *OTW*, "And one overriding priority is to truly integrate our organizations so that—while they remain separate in ways that are good for each group—we ensure that our leadership and strategic planning is part of a singular focus and we truly take advantage of the collective strength we have assembled. The long-term goals for this partnership are very big and bold, but also very attainable. It's exciting to see the way our leadership is already coming together to ensure we meet our potential." — *EH*

LEGAL

FDA Challenges RTI Over "Minimal Manipulation"

The definition of "minimal manipulation" of cells is rearing its head again as the FDA has sent RTI Surgical Inc. (RTI) a letter regarding the company's map3 cellular allogeneic bone graft.

"Altering Characteristics"

An October 9, 2014 letter sent by Mary A. Malarkey, Director Office of Compliance and Biologics Quality Center for Biologics Evaluation and Research said the company's processing "does not meet the definition of minimal manipulation for cells or nonstructural tissues." Specifically, the FDA says the company's process "alters the relevant biological characteristics of the cells."

map3 Chips Allograft

map3 Chips Allograft consists of a scaffold composed of demineralized bone matrix and cortical cancellous chips, as well as cultured bone marrow-derived multipotent adult progenitor cells, cryopreserved in a suspension. All these constituents are processed from the same human donor. The final packaged product includes the demineralized bone matrix, cortical cancellous chips and the multipotent adult progenitor cells.

The FDA says the multipotent adult progenitor cells included as a component in map3 "do not meet all of the criteria in 21 CFR 1271.1 O(a)."

Failure to Perform Tests

Additionally, Malarkey's letter said it appears that RTI is not performing all of the necessary donor testing for the bone marrow component of the product. "You must test a specimen from the donor of viable, leukocyte-rich cells or tissue for evidence of infection due to cytomegalovirus (CMV), to adequately and appropriately reduce the risk of transmission."

Company Response

Company President and CEO Brian Hutchison said in a press release that the company will work "diligently" to fully address any concerns or questions

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the FDA has. "We have carefully considered the regulatory pathway of this important implant from the beginning of development, and we continue to be confident in the science behind our map3 allograft."

According to the statement, the company has submitted an initial response to the FDA letter, and is preparing a "comprehensive package of data to address the Agency's comments and provide clarifying information regarding the technical components of the implant processing. We believe we understand the basis for questions and points raised by FDA in the letter and at this time, we feel confident that in developing map3 and processing of map3, we properly considered the relevant regulatory questions. Additionally, the company has removed the website pending thorough review and revisions as needed."

The website had included information that the multipotent adult progenitor cells, "provide a unique set of angiogenic cytokines that affect the regulation and differentiation of vascular endothelial cells, thus promoting the growth of new blood vessels." Therefore, argues the FDA, the multipotent adult progenitor cells are dependent on the metabolic activity of living cells for their primary function. "This cellular product is not intended for autologous use or allogeneic use in a first or second degree blood relative; accordingly it does not meet the criterion in 21 CFR."

The company has 32 other orthobiologic products on its website.

The entire FDA letter can be read here: http://www.fda.gov/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/complianceactivities/enforcement/untitledletters/ucm418126.htm — *WE*

"FDA 9" Whistleblower Lawsuit Tossed Out

The "FDA 9" whistleblowers who accused the FDA of spying on them have had their lawsuit tossed out by a federal judge in Washington because they did not exhausted all other administrative avenues of redress within the FDA.

According to an October 3, 2014 story in *Mass Device*, Judge Reggie Walton ruled on September 23, 2014 that although the plaintiffs "alleged no shortage of facts establishing that the defendants took, or threatened to take, a variety of prohibited personnel actions against them for their whistleblower activities," his court lacked jurisdiction.

On January 25, 2012, FDA "whistleblower" scientists filed a suit in federal court, accusing FDA Commissioner Margaret Hamburg, M.D., Jeff Shuren, M.D., the head of the Center for Devices and Radiological Health (CDRH) and Kathleen Sebelius, the then-head of the Department of Health and Human Services of illegally spying on them and using the ill-gotten evidence to retaliate against them.

The scientists said the government violated their constitutional rights and protections against reporting government corruption. And most importantly, claimed the illegal spying activity would chill future federal employees from reporting official misconduct.

According the lawsuit, on January 29, 2009, the FDA "commenced a covert and secret search and seizure operation" on the "FDA 9" to intercept private communications sent by the scientists to Congressional representatives created on government issued computers, sent through government networks, or remotely connected to government networks.

The agency allegedly set up a secret file on its database labelled "FDA 9" to collect the surveillance data. The agency, according to their suit, took screenshots of their computers as they accessed their private Gmail accounts. "Although the government has the right to surveil any activity on the computers it issues, it's unclear whether it's legal to secretly gain access to private email accounts used on government-issued devices," wrote Brad Perriello of *Mass Device*.

Judge Walton wrote that "If the administrative and remedial scheme set forth under the [Civil Service Reform Act] can resolve the claims that the plaintiffs have alleged in their complaint before this court, then the plaintiffs must use that scheme to seek redress and the court is precluded from exercising jurisdiction over the plaintiffs' claims." — *WE*

Gavel/Creative Commons

BIOLOGICS

Novel Way to Get Bone-Producing Cells From Fat

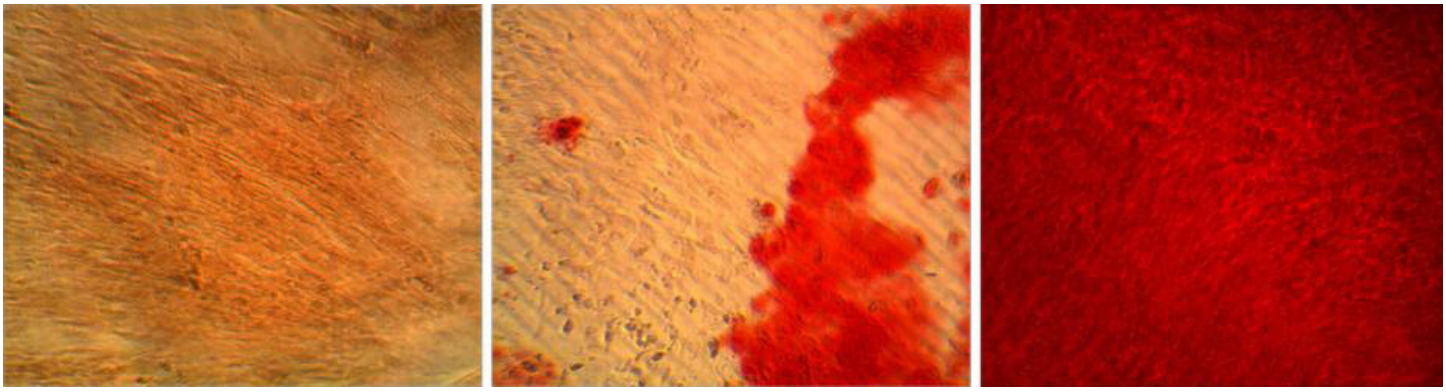
Brown University researchers have found a new way of extracting bone-producing cells from human fat, even developing a fluorescent tag that could locate and identify cells expressing the gene known as ALPL (alkaline phosphatase). If the tag finds the RNA (ribonucleic acid) produced when the gene is expressed, it attaches and glows.

Hetal Marble, lead author and Brown graduate student, said in the October 6, 2014 news release "targeting gene expression rather than surface proteins for the purpose of gathering cells to make a new tissue is a 'paradigm shift' in the following regard: Gene expression provides a way to target any cell based on whether it can produce another tissue, while targeting surface proteins limits researchers to harvesting cells that fit a presumed definition of being a stem cell. The new approach, she said, is more pragmatic for the purpose."

The team had a four-day wait period because that's how long it takes for the maximum number of cells to express ALPL when cells are chemically primed to do so. In future research, said senior author Eric Darling, Ph.D., the Manning Assistant Professor of Molecular Pharmacology, Physiology and Biotechnology and a member of the Center for Biomedical Engineering assistant professor of medical science, the team would like to target a gene expressed much earlier in the differentiation process to see if they can avoid a priming period.

Asked what should orthopedic surgeons know about this work, Dr. Darling commented to *OTW*, "The effectiveness of cell-based therapies depends to a great extent on the quality of the cell population used. If you treat a bone defect with cells incapable of producing bone, your outcomes will be poor. Mesenchymal stem/stromal cell populations include many different cell types. Our work showed that a fluorescent marker could be used to identify which cells could positively express a gene associated with bone, and in combination with a fluorescence-activated cell sorter, could enrich for bone-forming cells. Enriched cells were shown to deposit up to eight-times more calcified matrix than unsorted cells, which is hypothesized to translate into quicker and/or stronger tissue formation. The fluorescent marker degrades and has no effect on the differentiation capability or viability of treated cells. The cell yield was also much higher than conventional approaches, which moves us closer to our eventual goal of making single-surgery procedures possible, i.e., autologous cells taken from a patient, purified, and re-implanted within one surgical session."

He added, "The techniques used in this study could theoretically be used to sort cells based on the expression of any gene (mRNA [messenger RNA], actually). We targeted alkaline phosphatase, liver/bone/kidney (ALPL gene), which is expressed soon after stem cells are exposed to chemicals that induce osteogenesis. It should be possible to target earlier genes in the osteogenic differentiation cascade, although further work would need to be done to determine whether there is a sufficient difference in expression between cells that can and cannot differentiate along that lineage. Genomic studies can help in identifying highly expressed genes that should be targeted, with empirical measurements being the ultimate decider on whether sorting/enrichment produces an increase in ostegenesis while not compromising cell yield to a great extent." — *EH*



Darling Lab/ Brown University

LARGE JOINTS

Activity Trackers: Boon or Fitness Fad?

Do wearable activity trackers translate into better health and wellness for their wearers? (A confession: your writer wears a Fitbit on her wrist set for 10,000 steps daily.) A study published in the *Journal of Medical Internet Research* concluded that although trackers use evidence-based behavior techniques, according to writer Darius Tahir in *Modern HealthCare*, the authors of the study could not determine if the wearers were healthier because of it.

Wikimedia Commons and MorePix

According to Tahir, the researchers examined 13 wearable activity trackers, including products from Fitbit, Jawbone, Nike and Withings, and categorized them according to their adherence to 93 evidence-based behavior change techniques.

The three systems that utilized the most behavior change techniques came from the brands Jawbone (27 out of 93), Fitbit (20 out of 93) and Nike (19 out of 93). The researchers cautioned that the number of techniques employed may be meaningless. They wrote, "A system with fewer but more effective techniques may ultimately produce a greater impact than a system with more numerous but less effective ones."

While many users find the trackers motivating, including your correspondent, a September 2013 survey conducted by *Endeavour,* revealed that about 20% of users dropped out of the practice after three months. — *BY*

Study: Preop Physical Therapy Saves $1,215 per Patient

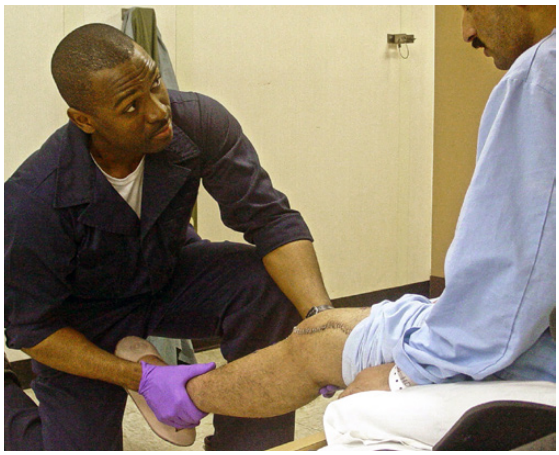
According to a new study that appears in the October 1, 2014 issue of the *Journal of Bone & Joint Surgery* (*JBJS*), joint replacement patients who undergo preoperative physical therapy (PT) are saving "the system" money. As indicated in the October 7, 2014 news release, the researchers demonstrated that preop PT can reduce the need for postoperative care by nearly 30%, saving an average of $1,215 per patient in skilled nursing facility, home health agency or other postoperative care.

Data was obtained for 4,733 total hip replacement (THR) and total knee replacement (TKR) patients (from Medicare claims). "Approximately 77% of patients utilized care services following surgery. Patients receiving preoperative physical therapy showed a 29% reduction in postoperative care use. In addition, 54.2% of the preoperative physical therapy group required postoperative care services, compared to 79.7% of the patients who did not have preoperative therapy."

"The decline in postoperative care services resulted in an adjusted cost reduction of $1,215 per patient, due largely to lower costs for skilled nursing facility and home health agency care. Preoperative physical therapy cost an average of $100 per patient, and was generally limited to one or two sessions."

"This study demonstrated an important opportunity to preempt postoperative outcome variances by implementing preoperative physical therapy along with management of comorbidities before and during surgery," said orthopedic surgeon Ray Wasielewski, M.D., co-author of the study, in the October 7, 2014 news release. Dr. Wasielewski is a physician with OhioHealth in Columbus, Ohio.

Richard Snow, D.O., M.P.H., also with OhioHealth and was a co-author on the study. He told *OTW*, "We were surprised to find the magnitude of the effect that pre-operative physical therapy (POPT) had on the post-acute care, especially considering the number of visits. After thoughtful consideration, the authors agreed that the process of POPT is probably associated with other patient centered processes that providers are using that cumulatively have the effect on post-acute care utilization patterns."



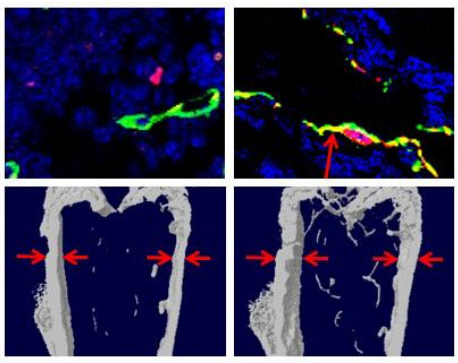
Wikimedia Commons and U.S. Navy photo by Journalist Seaman Erica Mater

Asked about barriers to implementing preoperative physical therapy, Dr. Snow commented to *OTW*, "The major challenges to implementing this type of program are similar to challenges we all face with an increasing demand for delivery of value-based care. First is reducing the fragmentation that comes from the siloed approach to payment. Reengineering care to provide patient centered care across the continuum needs to be facilitated by reengineered payment allowing that care. Second is building the competencies necessary to do adequate pre-operative assessment, both physical and environmental, and building a joint expectation with the patient regarding post-acute recovery." — *EH*

TRAUMA

Overlooked Cells May Be Clue to Osteoporosis

By working with CTSK (Cathepsin K), one of the enzymes used to resorb bone, researchers from Johns Hopkins have found that a group of "scientifically overlooked" cells could be crucial to the process of bone loss caused by osteoporosis. The researchers say that the cells, known as preosteoclasts, also explain the success and activity of an experimental osteoporosis drug—odanacatib.



Xu Cao, Johns Hopkins Medicine

"We didn't know that the drug affects preosteoclasts, nor did we understand how important preosteoclasts are in maintaining healthy bones," says Xu Cao, Ph.D., the Lee H. Riley Jr., M.D., Professor of Orthopaedic Surgery, in the October 6, 2014 news release. "Now drug companies hoping to reverse osteoporosis can look for even more drugs that make use of and target these interesting cells."

Earlier studies had already demonstrated that using the drug odanacatib results in decreased bone resorption by hobbling CTSK. In the current study, odanacatib proved itself as capable of increasing the rebuilding of bone.

To learn how it did this, mice were engineered to have neither bone-dissolving osteoclasts nor preosteoclasts. The team found that the inner layers bones of the mice were abnormal (as they had expected them to be), *and* that the outside layers of the bones were thin. "Moreover, the specialized blood vessels needed to transport bone-building supplies were in scarce supply, suggesting overall that osteoclasts and their precursors regulate bone building and bone resorption."

"The team grew the two cell types separately in the laboratory and collected the liquid around them to test for proteins released by the cells. They found that preosteoclasts—but not mature osteoclasts—secrete a protein called PDGF-BB [platelet derived growth factor], which is a powerful attracter both of cells that make bone-building cells and those that make the specialized blood vessels. As expected, when the preosteoclasts of mice were prevented from making PDGF-BB, the mice had weak bones."

Dosing the mice with odanacatib resulted in an increase in preosteoclasts and osteoclasts; they also secreted more PDGF-BB. "The increased PDGF-BB brought in more cells for making blood vessels and bone, which led to more of the specialized blood vessels and thicker bones."

"To see if the drug could help reverse the increased bone resorption and decreased blood vessel formation of postmenopausal osteoporosis, the researchers simulated menopause in female mice by removing their ovaries. At first, the mice had thinner bones and fewer blood vessels, but treatment with the drug increased the concentration of PDGF-BB in the blood, the number of specialized blood vessels both inside and outside of the bones, and the overall thickness and density of the bone." — *EH*

REIMBURSEMENT

Ortho Hospitals Join Medicare Penalty Hit List

Orthopedic hospitals are now on Medicare's radar and will begin receiving penalties for readmissions.

$428 Million Penalties

In the next year, over 2,600 hospitals are going to lose $428 million in

Bulls eye/Santeri Viinamäki and Creative Commons

expected payments from Medicare as a penalty for having too many patients return within a month for additional treatments. That's 496 more hospitals than last year.

One of the reasons for the increase in the number of hospitals fined from last year is that Medicare began evaluating readmissions this year for patients admitted for elective knee or hip replacements. Also joining the list of patients with heart failure, heart attack, and pneumonia are those suffering from lung ailments such as chronic bronchitis

Nearly three-quarters of hospitals subject to the Hospital Readmissions Reduction Program are being penalized, according to an October 2, 2014, *Kaiser Health News* (*KHN*) analysis. According to KHN, the average fines will be higher than last year, with 39 hospitals receiving the largest penalties allowed. One of those is the oldest hospital in American founded by Ben Franklin in 1751, Philadelphia's Pennsylvania Hospital.

Avoiding Readmissions

The purpose of the penalties is to get hospitals to focus on what happens to patients after they leave the hospital. In a perverse incentive, hospitals used to gain financially from readmissions. Roughly 2 million patients returning per year cost Medicare $26 billion. Officials estimate $17 billion of that comes from potentially avoidable readmissions. Last year, nearly 18% of Medicare patients who had been hospitalized were readmitted within a month.

Not all hospitals are subject to penalties. Certain cancer hospitals and critical access hospitals, as well as facilities dedicated to specific services such as psychiatry or rehabilitation, are exempted from the program.

Socio-Economic Challenges

One group of hospitals, those dealing with low-income and indigent patients, say the penalties aren't fair to them because the socio-economic status of their patients makes follow up care outside of the hospital problematic.

"Low [socio-economic status] patients do often—but not always—have worse outcomes, and yet we know they are often exposed to lower quality of care, whether that's the places that they go or the access to care that have," said Dr. Susannah May Bernheim, director of quality measurement at the Yale School of Medicine's Center for Outcomes Research and Evaluation, which created the method Medicare uses to count readmissions in a *KHN* article. However, she said, "it is important to understand that safety net providers both may be more vulnerable to payment penalties and may in fact need more than average resources to achieve good outcomes for their patients."

Researchers, led by Dr. Karen Joynt and other current and former academics at Harvard's school of public health and the medical school, discovered in a study that one particular hospital was not trying to cut readmissions because its financial stability would be undermined by fewer patients. "It's a quagmire," an anonymous hospital official was quoted in the study as saying. "If you affect the population correctly, you will reduce both readmissions and overall admissions, which is good for the patient but financially bad for the hospital."

Hospital Targets

KHN reports that this year every hospital but one in New Jersey will lose money. So will a majority of hospitals in 28 other states, including California, Florida, Georgia, Illinois, Massachusetts, New York, Ohio, Pennsylvania, Tennessee and Texas, as well as the District of Columbia. Hospitals with the highest readmission rates are losing 3% of each payment, an increase from a maximum punishment of 2% last year.

Another 496 hospitals will lose 1% or more of their Medicare payments. Those include Northwestern Memorial Hospital and Rush University Medical Center in Chicago, Beth Israel Medical Center in Manhattan, Tufts Medical Center in Boston, and a few satellite hospitals owned health systems, including the Mayo Clinic and Geisinger Health System.

Penalty Parameters

A hospital is fined if it had higher than expected readmission rates in any category.

Medicare uses the national readmission rate to decide what is appropriate for a particular hospital, so even if a hospital lowered its readmission rate from the previous year, its payments are lowered if it don't do better than the industry overall.

Round three of the penalties have begun and orthopedics is now on Medicare's radar. We'll report on specific orthopedic hospital penalties as they become available. — *WE*

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