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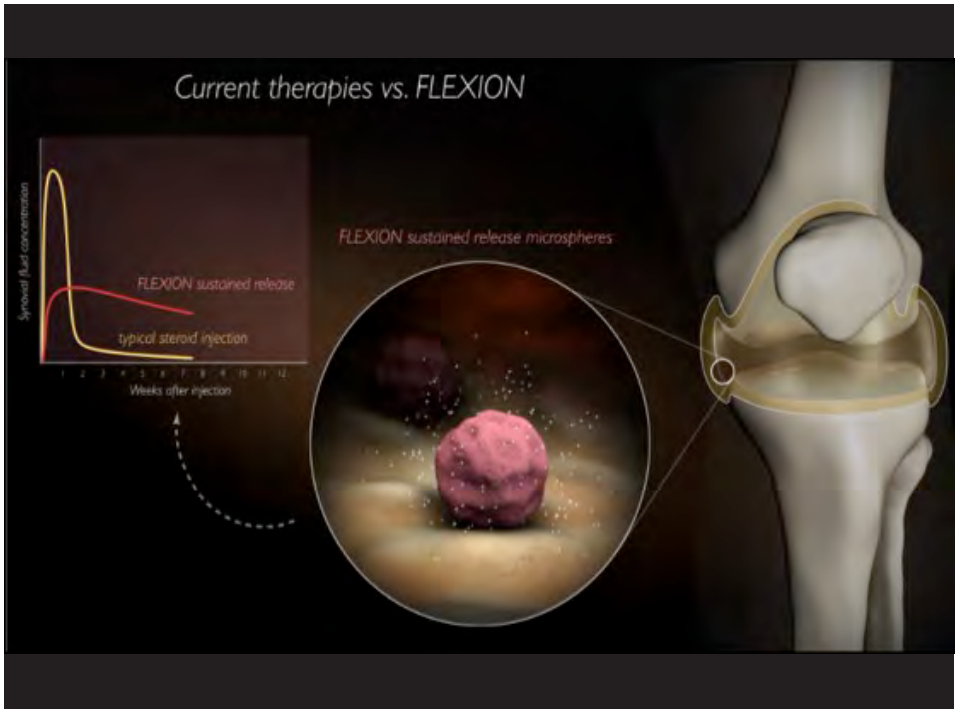
Orthopedics This Week

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: This market reminds me of the Mississippi River—deceptively calm on the surface, powerful currents underneath. Two crosscurrents that demand investor respect are: deleveraging sovereign debt in Europe and the economic pause in China. Either one could pull us underwater. Stay close to shore.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Integra LifeSciences	14.81%	10.86%	Northland Securities, the latest incarnation of Minnesota's sell side broker market, initiates coverage—"Outperform" rating.
2	1	Zimmer	24.95	(1.46)	Second lowest P/E in orthopedics with a real chance to beat analysts EPS estimates in 2012.
3	7	Conmed	9.65	(1.49)	Consensus of analysts is that CNMD will have the strongest earnings growth rate in orthopedics in 2012.
4	4	Stryker	25.23	(3.38)	Free cash flow at SYK is a delight to behold. Clean balance sheet and a highly diversified product line.
5	3	Smith & Nephew	22.80	(2.57)	Goldman drops rating to Neutral from Buy. Strong on fundamentals, but Goldman not impressed with share price value.
6	6	Johnson & Johnson	26.33	(0.77)	54,000 patents. 230 subsidiaries. $62 billion in sales—all before acquiring Synthes. Too big to manage?
7	5	Orthofix	14.72	(5.44)	Only IART is cheaper by way of five valuation measures yet OFIX gets only fleeting respect. Maybe it's the Netherland Antilles address.
8	9	NuVasive	7.26	(4.95)	Stock is settling down after getting knocked around in January. Growth story still among the best in spine.
9	8	Medtronic	28.63	(6.96)	Very few believe that MDT can stabilize spine market share. Time to march to a different drummer. MDT may be back.
10	10	ArthroCare	(0.95)	(19.90)	No one likes this stock. Only 18x forward earnings. 2x sales. ARTC looks cheap. But may require patience...lots of patience.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TranS1	TSON	$3.45	$94	37.45%
2	Tornier N.V.	TRNX	$23.46	$922	18.07%
3	Bacterin Intl Holdings	BONE	$3.37	$137	17.83%
4	MAKO Surgical	MAKO	$38.05	$1,614	11.35%
5	Integra LifeSciences	IART	$34.20	$919	10.86%
6	Wright Medical	WMGI	$18.07	$710	4.88%
7	Kensey Nash	KNSY	$24.10	$209	0.12%
8	Johnson & Johnson	JNJ	$64.74	$177,716	-0.77%
9	Synthes	SYST.VX	$169.71	$20,158	-0.98%
10	Zimmer Holdings	ZMH	$61.56	$10,965	-1.46%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	ArthroCare	ARTC	$26.05	$719	-19.90%
2	TiGenix	TIG.BR	$0.85	$78	-14.35%
3	Symmetry Medical	SMA	$6.62	$240	-10.78%
4	RTI Biologics Inc	RTIX	$3.73	$207	-8.80%
5	CryoLife	CRY	$5.37	$149	-8.67%
6	Medtronic	MDT	$37.67	$39,199	-6.96%
7	Exactech	EXAC	$16.60	$218	-5.95%
8	Orthofix	OFIX	$39.99	$748	-5.44%
9	NuVasive	NUVA	$15.54	$663	-4.95%
10	Stryker	SYK	$52.90	$20,156	-3.38%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$37.67	$39,199	11.74
2	Zimmer Holdings	ZMH	$61.56	$10,965	12.80
3	Johnson & Johnson	JNJ	$64.74	$177,716	12.95
4	Stryker	SYK	$52.90	$20,156	14.26
5	Orthofix	OFIX	$39.99	$748	14.81

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$18.07	$710	54.76
2	NuVasive	NUVA	$15.54	$663	31.08
3	RTI Biologics Inc	RTIX	$3.73	$207	24.87
4	Exactech	EXAC	$16.60	$218	22.43
5	Symmetry Medical	SMA	$6.62	$240	22.07

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Integra LifeSciences	IART	$34.20	$919	0.68
2	RTI Biologics Inc	RTIX	$3.73	$207	0.88
3	Orthofix	OFIX	$39.99	$748	0.90
4	Kensey Nash	KNSY	$24.10	$209	1.06
5	Stryker	SYK	$52.90	$20,156	1.32

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$18.07	$710	5.79
2	CryoLife	CRY	$5.37	$149	2.32
3	Johnson & Johnson	JNJ	$64.74	$177,716	2.27
4	Smith & Nephew	SNN	$49.27	$8,828	2.12
5	NuVasive	NUVA	$15.54	$663	2.07

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$6.62	$240	0.67
2	Alphatec Holdings	ATEC	$2.07	$185	0.94
3	Exactech	EXAC	$16.60	$218	1.06
4	Conmed	CNMD	$29.74	$833	1.15
5	Integra LifeSciences	IART	$34.20	$919	1.18

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.85	$78	125.12
2	MAKO Surgical	MAKO	$38.05	$1,614	19.10
3	Bacterin Intl Holdings	BONE	$3.37	$137	5.19
4	Synthes	SYST.VX	$169.71	$20,158	5.07
5	TranS1	TSON	$3.45	$94	4.90

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

Could This Be Orthopedics' Future?

By Robin Young

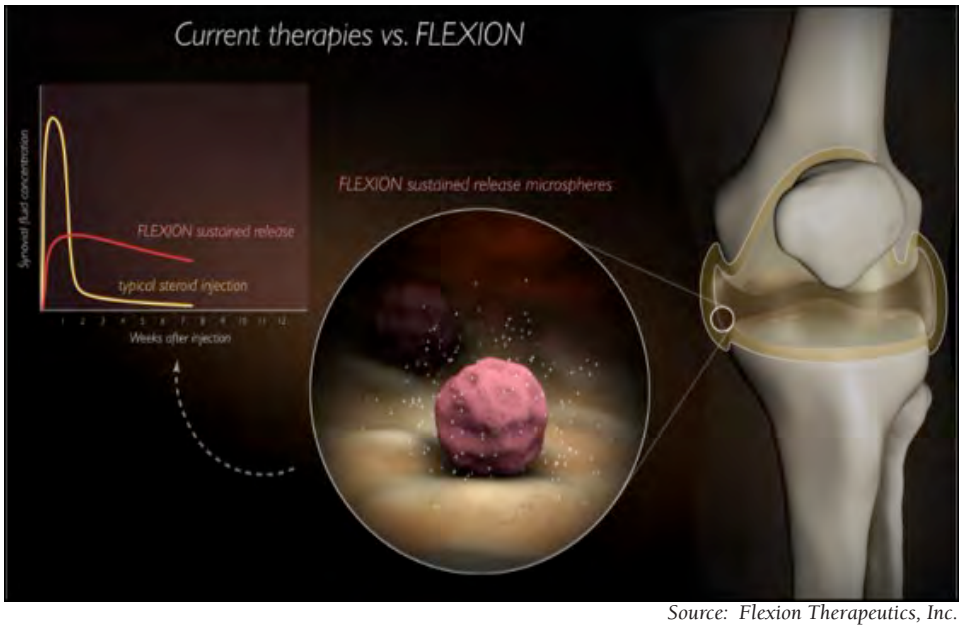
What if steroid pain relief lasted months instead of weeks? Or what if an inhibitor of TrkA, a pathway known to have the largest pain relief signal ever seen in osteoarthritis, was injected intra-articularly with little or no systemic effect?

Finally, what if these injections modified the disease of osteoarthritis?

There's a Boston-based company named Flexion Therapeutics, Inc. whose products could well extend steroid effectiveness dramatically, bring other novel therapies to the physician office and deliver new levels of pain relief to patients suffering from osteoarthritis. The products, which have yet to be properly branded, are:

1. FX005 – an anti-inflammatory, sustained release, intra-articular injection for patients with osteoarthritis (second-line treatment)
2. FX006 – a first-line sustained release, intra-articular steroid injection for pain associated with osteoarthritis
3. FX007 – a non-narcotic analgesic, sustained release, intra-articular injection for pain associated with end-stage osteoarthritis and for patients who are headed for joint reconstruction surgery.

By licensing therapies from AstraZeneca and Merck and then combining them with known and FDA-approved sustained release formulations, Flexion appears to be well on its way to bringing to market three novel, longer lasting and more effective intra-articular treatments for pain associated with osteoarthritis.



Source: Flexion Therapeutics, Inc.

If these compounds successfully make it through the FDA gauntlet, they could change current care patterns by delaying joint recon surgeries and increasing care incidence at such front line care centers as the physician office or pain clinic.

Just before the American Academy of Orthopaedic Surgeons (AAOS) annual meeting, *OTW* sat down with Flexion CEO Michael Clayman to learn more about these compounds and his company's progress.

OTW: It's been two years since Flexion acquired FX005 and FX007 from Astra Zeneca and originated FX006 itself. Can you describe these anti-inflammatory and other compounds and which orthopedic indications they address?

Michael Clayman: To frame this discussion, since we acquired those compounds we decided to focus on the intra-articular treatment of osteoarthritis and we added a new sustained release product.

We are attracted to the osteoarthritis space due to the enormous size of the unmet medical need. There are well over 100 million people worldwide with symptomatic osteoarthritis with approximately 27 million in the United States. Available pain relief therapies for joint osteoarthritis are, to put it diplomatically, imperfect. Oral therapies have modest efficacy and have black box warnings for organ toxicity. Intra articular injections consist of steroids and hyaluronic acid. Steroids actually

work quite well in terms of pain relief but last only a couple of weeks on average and hyaluronic acids, while very popular, hardly separate from placebo in controlled clinical trials.

We embraced a sustained release approach to intra-articular therapies which we expect will deliver persistent therapeutic concentrations of drug in joint for months and yet with vanishingly low systemic concentrations which should provide desirable safety profiles.

Our first product, the one that is in clinical study now, FX005, is a p38 Mitogen-Activated Protein (MAP) kinase inhibitor. The p38 target is an enzyme that plays an important role in the inflammatory cascade. It also plays an important role in processing pain signals.

So p38 is an attractive target at two levels (mediating the inflammatory cascade and processing pain signals). In the past, industry developed p38 inhibitors that were given systemically. The problem was that systemic use of p38 inhibitors was associated with unacceptable toxicities despite the fact that it demonstrated anti-inflammatory and pain relief effects. We think a sustained release, intra-articular approach might afford physicians the opportunity to give a p38 inhibitor its best chance to work locally while avoiding those systemic toxicities.

OTW: Mike, that particular p38 inhibitor, is that the one you're thinking about as a second-line therapy for joint pain associated with osteoarthritis?

Michael Clayman: Correct. It is the first that we've placed into clinical development and we expect it to be used for those patients who have advanced to needing something beyond the intra-articular steroids.

CEO Michael Clayman/Source: Flexion Therapeutics, Inc.

Of course, one of the other two products we have in the pipeline is FX006, a sustained release steroid. As I mentioned, while steroids work quite well in terms of pain relief because they are out of the joint in a matter of days they don't deliver persistent pain relief. The pain relief they do deliver wanes, on average, in about two weeks. We think that our sustained release steroid has the opportunity to prolong that benefit out to three months or more. It would be positioned more toward front line therapy.

We expect that we will be in clinical development with our steroid product this year. The initial study will be a Phase 2b dose ranging study comparing three different doses of our sustained release steroid intra-articularly to the very commonly prescribed immediate release intra-articular steroid, Kenalog. The study would be powered to demonstrate superiority to Kenalog at time points beyond two weeks in terms of pain relief.

The third product we have in the pipeline is FX007, a TrkA antagonist. TrkA is the receptor for nerve frowth factor (NGF). We know that the nerve growth factor/TrkA pathway is an important one for mediating pain because Pfizer, for example, and other companies have developed monoclonal antibodies to NGF and when administered systemically in clinical studies, you see the largest pain relief signal ever seen in osteoarthritis.

The problem with systemically administered anti-NGF monoclonal antibodies is that they are associated, in a small

percent of patients, with accelerated progression to joint replacement. As a result, the FDA put all the anti-NGF programs targeting osteoarthritis on clinical hold.

So why would we be interested in interrupting a pathway which has this potential cloud over it?

Three reasons:

1. **We're local.** With the sustained release format we would expect no meaningful systemic exposure and thereby avoid any systemic adverse events associated with the anti-NGF.
2. **We're intermittent** as opposed to the anti-NGFs which were administered every 60 days for up to two years. That approach essentially created a 100% blockade of NGF. By contrast we would be giving our drug intermittently every several months to allow the drug to ultimately come off the receptor.
3. **We're focused on end-stage patients.** These are patients who've progressed to the point of needing knee replacement. These are patients who have crossed the pain threshold and there is nothing that is really helping them adequately in terms of pain relief except knee replacement. We would offer this therapy as a way of addressing their pain while they wait for the surgical intervention. By focusing on that end-stage knee patient population we would hope to limit the potential regulatory concerns about accelerated progression to joint replacement because we would be treating a joint that was already on the path to replacement.

OTW: Do you have a good guess as to why anti-NGF would accelerate the path to joint replacement?

Michael Clayman: There are two dominant theories:

1. By so effectively relieving pain you've created the conditions for over-use of the affected joint. An osteoarthritic joint which would otherwise have provided pain feedback signals is now rendered almost pain free. And the patient does things with that joint that they wouldn't normally have been able to do.
2. The other theory is that there is a systemic effect associated with blocking NGF. NGF has trophic effects. It may be involved importantly in neuro-vascular remodeling. One clue that this might be the case comes from anti-NGF clinical trials where patients who enter with index knee pain, leave the trial with a shoulder replacement.

OTW: Let's go to the regulatory question—it's seems to us that your first compound, FX005, the intra-articular, sustained release p38 MAP kinase inhibitor, is furthest along to commercialization.

Michael Clayman: While it is the first product that we've advanced to clinical development, we think the path to commercialization may actually be faster with FX006, our sustained release steroid. That's because FX006 may quali-

fy for so called 505(b)(2) status since it represents a new formulation of an already approved drug, triamcinolone acetonide. Because the p38 inhibitor in FX005 is a new chemical entity it will likely require more extensive clinical testing.

But as it relates to FX005, the proof of concept study, which followed a single ascending dose study, will deliver its data in the second quarter of this year. A total of 140 patients will have been assessed. Assuming we have a positive signal in terms of clinically meaningful pain relief we will progress that compound to Phase 2b dose ranging.

These studies are powered to demonstrate a magnitude of pain relief substantially in excess of that shown with hyaluronic acid in controlled clinical trials. So, assuming the study is positive, we should have a pretty encouraging pain relief signal and we would advance it to Phase 2b dose ranging and then Phase 3.

OTW: FX005, is it being compared against hyaluronic acid?

Michael Clayman: Actually, in our initial trials of FX005 we're comparing it to placebo but we're looking for a magnitude of pain relief that would be two to three times that seen with hyaluronic acid. We are considering comparing it head-to-head with hyaluronic acid at the right time.

OTW: Any evidence that these compounds might be disease modifying?

Michael Clayman: We believe that both the p38 inhibitor (FX005) and the sustained release steroid (FX006) have the potential to be disease modifying.

There's actually a substantial amount of pre-clinical data that suggest that blocking the p38 pathway would translate into a disease modifying effect. And increasingly there is a clinical view that synovitis is an important driver to joint destruction. So, quelling synovitis for a prolonged period of time has the potential to be disease modifying.

An NIH [National Institutes of Health] grant was awarded recently to look at exactly that question as it relates to immediate release steroids. The grant funds a clinical study in which clinical investigators will give immediate release steroids every three months for two years with imaging evaluations along the way. If that approach shows any beneficial effect it would be quite logical that a sustained release steroid might actually improve on that.

So I think the scientific view is leaning increasingly toward the potential of steroids, delivered in the proper way, having disease modifying potential.

OTW: Is it your plan to go for an indication for osteoarthritis in any joint—regardless of whether it is knee, hip, shoulder or facet?

Michael Clayman: Our clinical development programs are aimed at osteoarthritis of the knee, which is the most commonly injected joint. We anticipate that in time we will also be doing clinical studies of other joints.

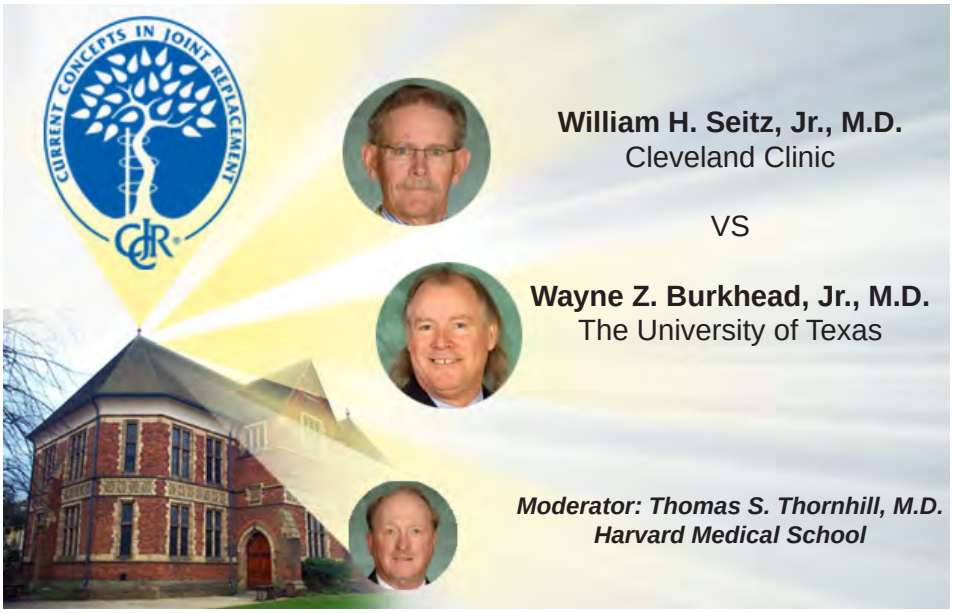
OTW: Thank you very much Michael. These are very interesting products and best of luck. ♦

Burkhead vs. Seitz in Shoulder Reaming Debate

By Elizabeth Hofheinz, M.P.H., M.Ed.

"There is a shit storm ahead of arthritis in young people," states Dr. Burkhead. "True," says Dr. Seitz, "And frankly, I've drunk your Kool-Aid."

This week's Orthopaedic Crossfire® debate is, "Ream and Run: Best Management Option for the Young Arthritic." For the proposition was William H. Seitz, Jr., M.D. from Cleveland Clinic. Against the proposition was Wayne Z. Burkhead, Jr., M.D. of The University of Texas; moderating is Thomas S. Thornhill, M.D. of Harvard Medical School.



Wikimedia - KaihsuTai and Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Seitz: "Dr. Matsen is responsible for the concept of 'ream and run,' but that was reaming the glenoid to centralize the head. However, we want to do everything possible to save glenoid bone. So the issue is, 'Should we do a hemi-arthroplasty in the face of various forms of arthritis in the young patient?' There is a fair amount of agreement in the types of cases that we would do a hemi-arthroplasty. The bigger question is how we do it, and what we do to preserve the bone stock of the glenoid."

"So what do we do with the glenoid? We can do some soft tissue coverage and preserve bone stock, as Dr. Burkhead will tell you. And I frankly have drunk his Kool-Aid. But we do need to correct the glenoid version if there's significant wear…and center the head."

"For example, after a capsulorraphy with posterior subluxation and erosion, we may need to do a bit of glenoid reaming, but in that situation I would do what Dr. Burkhead mentioned and put some soft tissue there. In many young patients this will give early good results, but the problem is that these patients are living longer."

"The disadvantages: blood loss, longer operation, requires more dissection, and you must remove a significant amount of glenoid bone stock if you put a polyethylene glenoid in. And revising these is harder and it burns bridges."

"The real problem is if you put a glenoid component in and the patient lives quite awhile, and you get loosening and poly particulate debris, what's going to happen is that you have little glenoid bone stock left. So when there is posterior wear I remove a bit of the glenoid, but try to leave as much of the canal as possible, and do a resurfacing. What I really ream is the humeral side. I do a cup arthroplasty and try to preserve as much humeral bone stock as possible."

"Young patients with cuff tear arthropathy (CTA)…if you put a reverse in, they're not going to reduce their activities."

"Avascular necrosis is a very good indication for doing ream and run. Contraindications for this technique include: poor bone stock, an unstable joint, and inadequate peripheral support such as in a fracture. I've learned from Dr. Burkhead that it's good to use the patient's own fasciae to resurface the glenoid if possible. If not, we can use other tissues such as an Achilles tendon allograft."

"In cuff tear arthropathy, as long as the head is captured, and we have a patient

who wants to return to being active, we can also resurface the coracoacromial arch. You surface ream, fit, and get your implant on, and then get it centered again. But you must have superior subluxation without escape…that way you'll get good pain relief and good motion…but you need to be centered well below the coracoacromial arch."

"This is a crossfire, so have at it, Buz."

Dr. Burkhead: "I think Bill and I agree that there is a shit storm ahead of arthritis in young people. Our colleagues in the arthroscopic arena have created a new condition for us—chondrolysis—and we will be reaping their sad harvest for many years. If you haven't stopped using polylactic acid anchors in the glenoid, please do so today."

"We know that total shoulder arthroplasty in the first five years is superior in every parameter to hemi-arthroplasty. But in longer term follow-up this trend isn't statistically significant. Total shoulders deteriorate with time, glenoids get loose, and cuffs tear…and many times the results equalize. The goal is to relieve pain and improve motion to the extent that total shoulder arthroplasty does. We want to create a durable surface on the glenoid side that is cartilage-like; a smooth, wettable surface with a low coefficient of friction…and you can do that better with an interposition than you can with a native glenoid."

"The goal is to try to get to the mould arthroplasty by Smith Peterson…his goal of obtaining hyaline cartilage, and with some of the newer materials we are seeing chondroblasts and chondrocytes. You can't leave a hemi-arthroplasty, or even a biologically resurfaced shoulder in the operating room stiff. You have to gain motion—even if you must go back to some of the old fashioned Z lengthenings."

"You may have to correct version on the humeral side, and you may have to adjust that to what you have to work with on the glenoid side if you're not going to bone graft. You've got to ream the glenoid, you've got to change the version, but we ream only to subchondral bone; we don't ream into cancellous bone, which is the principle that Rick Matsen has postulated and really this microfracture over a broad area is trying to create fibril cartilage as part of the fracture healing. The key is to create drill holes…you must drill past the subchondral plate because pain doesn't come from cartilage…pain doesn't come from the surface of the bone."

"Rick Matsen's data had only 72% satisfactory rates. If you compare that to our article where we had up to 15 years' follow up, we had an 86% successful rate. So just in reviewing the historic literature it makes sense to put a biologic surface on the glenoid. There are several people who are now doing interposition grafting with osteochondral grafts…press fit into the glenoid. With newer materials like dermal matrix allograft we're seeing some plump chondrocyte-looking material in that, and achieving Smith Peterson's goal. Thank you."

Moderator Thornhill: "Bill, where are you reaming?"

Dr. Seitz: "I have a hard time telling people to go in and ream beyond the subchondral bone in a glenoid. It's dangerous and takes away much of the strength. The reality is that sometimes you do have significant posterior wear and you must ream down a bit of the front, but then I would do a fascial resurfacing. I ream the humeral head and I don't put a stem in—a conservative procedure in young folks."

Moderator Thornhill: "So you're folding like a $3 suitcase?"

Dr. Seitz: "A few years ago Buz sent everybody in the Shoulder and Elbow Society his CD and when I played it in the OR the next thing I knew I was putting fascial arthroplasties in."

Moderator Thornhill: "Bill, are you now over on his side…that interposition is better than just reaming?"

Dr. Seitz: "Yes."

Moderator Thornhill: "Do you ever combine that with a bony block to restore glenoid height and put an interposition on top of that?"

Dr. Seitz: "Not to restore the height, but if I'm revising a shoulder with a failed glenoid component, and I have a big void, then I'll do a graft into the void and then do a fascial resurfacing over that…with the anticipation that I could come back once that bone got incorporated and put a glenoid in."

Moderator Thornhill: "So why would you even put a fascia on that? Why not just put the bone in if you're going to come back?"

Dr. Seitz: "It holds it in better; it acts as a retaining wall."

Moderator Thornhill: "Buz, let's say there's enough posterior glenoid wear that to get a good surface you would have to go through the subchondral bone anteriorly. What would you do?"

Dr. Burkhead: "I usually just burr down the ridge, do the drill holes, ream down the high side. When you ream the high side you end up with a central ridge…you have about 19 degrees of version that you can safely ream. And I burr down that central ridge. I alter the version on the humeral side, even though Christian Gerber showed that limits abduction and increases your force. I've always made my changes on the humeral side. I've not tried to graft these with bone and then put a surface over it."

Moderator Thornhill: "My German knee colleagues don't resurface the patella and they say that one of the ways they prevent postoperative pain is to use an electrocautery and to circumferentially go around the soft tissues of the patella. Have you done that?"

Dr. Burkhead: "We do it inadvertently because that's how you release the labrum."

Dr. Seitz: "I've never thought of it in terms of the plexus of nerve endings around there, but Buz is right. The other thing is that the glenoid isn't a fixed structure. The scapula is a moving target."

Dr. Burkhead: "Also, cysts in the glenoid are common, and in the equine literature they've measured substance P within the cyst. One of the things ream and run doesn't always do is that if you ream down past those cysts you're really getting into thin bone. If you see a cyst on the surface, make sure you curette it all out and drill a separate hole in the cyst."

Moderator Thornhill: "Would you both agree that yes, we can make chondrocytes, Type II collagen, etc. but we've yet to take these structures and get the ultra structure of articular cartilage?"

Dr. Burkhead: "Yes."

Dr. Seitz: "Yes."

Moderator Thornhill: "Thank you both." ♦

Please visit www.CCJR.com to register for the 2012 CCJR Spring Meeting, May 20-23 in Las Vegas, Nevada.

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BCBS Threatens to Deny Entire Surgery Over BMP

By Walter Eisner

RRY Publications and BCBS of Minnesota

Imagine you are a 62-year-old diabetic patient who's been in a car accident and you are on the way to the hospital for emergency spine surgery.

The surgeon determines you need spinal instrumentation and fusion, but he's worried about your ability to generate bone growth given your diabetes and other comorbidities. He determines that the risks of harvesting bone graft are too high and that, in his best medical judgment you are a good candidate for BMP (bone morphogenetic protein) to promote bone growth and fusion—but in your case such a use would be "off-label".

In Minnesota, Blue Cross Blue Shield (BCBS) is threatening to deny your entire treatment from the car accident if your surgeon uses BMP off-label.

Off-Label Usage and Coverage

The FDA has approved two BMPs and associated carrier/delivery systems. One is osteogenic protein-1 (OP-1) consisting of rh-BMP-7 and bovine collagen, which is reconstituted with saline to form a paste. The addition of carboxymethylcellulose forms a putty. The other is the Infuse system which consists of rhBMP-2 on an absorbable collagen sponge carrier.

But because the BMP used in the emergency surgery was used off-label, the insurance carrier calls you soon after and says the spinal surgery you just had, and all the associated expenses will not be paid because your surgeon used the BMP off-label.

That's what Blue Cross Blue Shield of Minnesota (BCBS MN) set in motion when the insurer issued a new coverage decision (policy number IV-85) effective on November 13, 2011. The policy stated the following:

> *"When BMP is used for indications that are considered investigative or*

not medically necessary, any procedures performed in conjunction with BMP will not be covered. This includes, but is not limited to, professional, facility, and anesthesia services as well as supplies."

Surgeons Cry Foul

Surgeons from the Scoliosis Research Society (SRS) and International Society for the Advancement of Spine Surgery (ISASS) responded to say the insurer has crossed the line.

"They're trying to force us to practice yesterday's medicine tomorrow, to maximize insurer's profits today," said SRS member and University of Minnesota spine chief David Polly, M.D."

David Polly, M.D

Polly told *OTW* that when a spine surgeon fixes a patient who has a complex problem, he or she uses a series of surgical approaches, various screws, rods and cages, and bone graft. "The use of BMP is only a very small part of the surgery and treatment process. Emerging data in complex cases suggests that it may help many people avoid the need for repeat surgeries if the bone does not heal. The use of BMP may constitute 5 minutes of a 10-hour surgery and a full-week hospital stay. The BCBS policy would deny payment for the entire hospitalization."

""They [BCBS MN] are directly interfering with the doctor/patient relationship here and are (de facto) attempting to practice medicine without a license," added Tom Errico, M.D. former president of both ISASS and the North American Spine Society (NASS). He's currently heading the nascent International Advocates for Spine Patients (IASP) along with ISASS colleague, Gunnar Andersson, M.D. "This coverage policy is exactly why patients need their physicians standing up for them."

OTW contacted the insurer on March 6 and asked if the surgeons were right and if the policy went too far?

Blue Cross Blue Shield Considers Revisions

We received this reply from Blue Cross Blue Shield of Minnesota on March 7:

"All medical policies are written with the goal of ensuring the safest and most effective care for our members. We are taking feedback on our BMP policy under advisement and will consider making immediate revisions if the current language has unintentionally created confusion about approvals for other covered services."

Tom Errico, M.D.

Commenting on the BCBS MN response, Errico told *OTW* that surgeons have to remain vigilant and respond immediately and forcefully with the best interests of the patients at heart. "They [the insurers] will learn to go elsewhere to save money. Spine surgeons simply cannot continue to keep their heads buried in the sands of clinical work and not pay attention to the whirling winds around them."

Nontransparent and Ill-Defined Process

In a joint letter, SRS and ISASS say their concerns with the new policy were twofold.

Their first concern involves the "lack of a transparent and clearly elucidated rationale for the decision to severely restrict access to BMP." The societies write that a critical tenant of evidence-based decision making is that the methodology and process are available for review and discussion. "We strongly believe that this approach must be applied in a fair and uniform manner. It is unreasonable to hold physicians to a standard of transparency and academic rigor if [BCBS MN] is permitted to make payment decisions based upon a nontransparent and ill-defined process."

Punishing Patients at Risk

Their second concern is over the policy itself, which they believe to be "completely unjustified and inappropriate." They say the policy puts patients with severe and complex spine deformities for which BMP may be a necessary component of their treatment regimen at risk for inadequate medical care. "Whether or not [BCBS MN] of Minnesota finds it necessary to restrict payment for a device that it deems too costly, it is unconscionable to use that as a basis in denying payment for the underlying medically necessary procedure."

Polly doesn't buy the reported rationale for this denial as being simply about off-label use. He told *OTW* that the FDA has specifically stated that the agency does not regulate physicians' practice of medicine. The FDA only regulates how companies can advertise their products. Physicians are free to do what is best for their patients.

Off-label use can, sometimes, even be the standard of care. He noted that the initial use of aspirin to prevent heart attacks and strokes was off label but the standard of care. Oftentimes the use of medical devices, potentially even lifesaving use in children, is off label because there is not a business case to be made for the companies to do the studies in children since the companies will never get a return on their investment. He added that cancer chemotherapy for unusual or advanced cancers are often off label but may be the only hope for patients in these settings.

"BCBS [BCBS MN] could have taken a number of steps," says Polly," that would have been reasonable. They could have partnered with physicians to create a registry of off-label use and looked at the results. They could have created a category of coverage with evidence determination where the physician could use the product but have to report the outcomes back to BCBS [MN]. They could have chosen to say that they would pay for everything except the BMP and put the physicians and hospitals at the financial risk for the decision."

"But instead they have chosen to fully deny coverage for the standard of care practice when there is only a very small variation in that care that physicians do to improve patient outcomes. Physicians do not get paid any extra money for the use of BMP; in fact they get paid less than if they harvested the patient's own bone, a procedure which causes its own pain and morbidity. BCBS of MN did not ask for input from the professional medical associations on this decision. They have specifically refused to talk to key opinion leaders and academics on this topic."

Profit Enhancing Strategy?

"So," concluded Polly, "one is left to draw the conclusion that BCBS [MN} did this as a pure profit enhancing strategy. Patients may think that when they pay for an insurance policy that this will cover the treatment that their doctor thinks is best for them, clearly this decision demonstrates otherwise. Insurance companies ARE regulating the practice of medicine right now!"

Interfering With Doctor/Patient Relationship

Errico is not a big fan or user of BMP. If anything, he says he's biased against BMPs.

"But BCBS MN has crossed the line. This should be about the relationship between a patient and his doctor who is ethically and morally bound to do what's in the best interest of the patient."

"With this policy," said Errico, "the insurance company is punishing patients for using BMP. This policy is directly interfering with the doctor/patient relationship and is going down a very slippery slope and sets a dangerous precedent."

Need for Structured Responses

Errico said surgeons respect the needs of insurers to spend money based on the "best practice of medicine". He added, "Let's all agree however that this is NOT best accomplished by unilateral, arbitrary, punitive insurance directives but by insurers collaborating with the medical professional societies to arrive at justifiable practice guidelines when confronted with clinical cost effectiveness dilemmas."

Polly added this latest episode of coverage denial in one state is a good demonstration of the lack of a structured recourse mechanism for surgeons to be alerted to and respond to various private carriers across the country. He said the staffs of national surgeon societies don't always focus on states. He pointed to the IPAB (Independent Payment Advisory Board) as another example of why societies need to develop such a structured mechanism to respond to payer challenges of physician-directed medical decisions.

Hopefully, the medical societies are listening. ♦

On (and Off) the Record

By Elizabeth Hofheinz

Dear *OTW* Reader: Seven Modes of Metal-on-Metal Hip Failure… These College Students 5x More Likely to Have Shoulder Instability…Another Look at Outpatient Joint Replacement…New Leadership at SBi and SI Bone…Two Reasons Patients Have Higher Rates of Medial Meniscus Injury and more….

The Seven Modes of MOM Failure…

Timothy Wright, Ph.D., Kirby Chair of Orthopedic Biomechanics at Hospital for Special Surgery (HSS), and Douglas Padgett M.D., chief of Adult Reconstruction and Joint Replacement with HSS, have just completed a study that gives the first comprehensive look at the modes of failure in metal-on-metal (MOM) total hip replacements.

Dr. Wright tells *OTW*, "There is a long history of analyzing retrieved implants and making observations about the kinds of damage you see on the surface…but little comprehensive information about the mechanism behind the damage. I think it's fair to say that we don't have our arms around the problem yet…not from an implant standpoint, a surgical technique standpoint, a manufacturing standpoint, or from a patient standpoint (do they have host factors that make them more susceptible to damage?). One of the things that is still unclear is metal ion concentrations in the blood. Yes, patients with higher levels are often symptomatic, but there are also patients with low levels who are symptomatic.

"We looked at how we could begin to match our observations of the damage modes on the surface with quantitative measurements of how much the com-

ponent wore in the damaged areas as well as with other factors such as metal ion levels, MRI imaging, and the surgical positioning of components, manufacturer, and head size. We found seven distinct damage modes, some of them obvious as to the underlying mechanisms of failure. For example, 100% of the heads were scratched, probably due to hard chunks of carbide from the metal component or due to spicules (tiny spike-like structures which are found in many organisms—sponges, for example) of bone.

This is important because in the second part of our study, we are working with a company that has the technology to tell us where material has been removed. So if I'm staring at the head, where is the geometry altered? If you now take the descriptors of what the surface looks like, together with how the material was removed, it gives us more confidence in trying to understand mechanisms."

Freddie H. Fu, M.D. Wins Sports Award The distinguished chair of the Department of Orthopedic Surgery at the University of Pittsburgh—Dr. Freddie Fu—is being honored with the 2012 Dapper Dan Sports Leadership Award for his efforts to improve the health of athletes. Dapper Dan was founded in 1936 by *Pittsburgh Post-Gazette* sports editor Al Abrams. Over time the organization has evolved from a businessmen's sports club into a substantial charity. Dr. Fu is credited with helping to establish the Sports and Preventive Medicine Institute in 1985. He also was instrumental in the establishment of the University of Pittsburgh's Sports Medicine Fellowship Program. Dr. Fu is known far and wide for his novel surgical techniques for treating sports-related knee and shoulder injuries, as well as his extensive scientific and clinical research in the biomechanics realm. Dapper Dan, a charitable organization with six fundraising events per year, will bestow this honor on Dr. Fu March 12, 2012 at the annual Dapper Dan Sportsman of the Year Dinner.

Risk of Shoulder Instability 5x Greater in These College Students U.S. Army LTC Brett Owens, M.D. followed West Point cadets from 2006-2010, comparing cadets with a history of shoulder instability and dislocation to those without such a prior injury. They found that those cadets with a prior history of glenohumeral joint instability were more than five times more likely to experience future instability than their classmates. Dr. Owens told *OTW*, "Before our study, there was only anecdotal evidence of high incidence shoulder instability at West Point...but no one knew how common it was or the risk factors involved. And in the prevention arena, most of the work had been focused on ACL injuries...despite the fact that shoulder instability is also a common reason athletes seek orthopedic care. In our study we had data on 700 individuals (1,400 shoulders). And one of the advantages of our institution is the ability to conduct strict surveillance because it is a closed community.

We were able to correlate baseline characteristics with a history of instability, with those that had ligamentous laxity. Our population is similar to the U.S. collegiate athlete population, and we are hoping that folks who care for young athletes will find our research applicable. There are two important messages I have for my colleagues. First, this work reinforces the importance of early stabilization of first time dislocators. Secondly, we must focus on primary prevention. Most shoulder instability research has been on surgical treatments, but no one has looked at primary prevention. Once you injure yourself you are in a different category; those never before injured are the ones to target for prevention."

Another Look at Outpatient Joint Replacement Dr. Richard Berger, a hip and knee surgeon at Midwest Orthopaedics at Rush, has been doing over 1,200 joint replacement operations a year for the last several years…and 75% of those are outpatient.

Said Dr. Berger to *OTW*: "At Rush we are routinely doing outpatient joint replacement, and in doing so are giving patients not only better health, but more and earlier independence. For patients having their hip or knee replacement complete before noon, 96% are able to go home the day of surgery. In fact,

we have had such success that we have been able to now include just about all patients in this outpatient protocol—regardless of their age. It's a win-win for everyone—patients get the benefit of being less dependent on others and hospitals save money and bed space.

So why hasn't this caught on? Because it's currently very complicated, and requires a team approach that includes anesthetists, physical therapy, discharge planners, etc. We have ten years of data showing that this is a safe, effective approach to joint replacement. I believe that as more surgeons become facile at the surgery and feel more comfortable with the team approach to short stay after joint replacement, this short stay will start to catch on. Once there are enough places around the country doing outpatient total joints, I believe it will become commonplace."

Michael P. Simpson New President, CEO at SBi Small Bone Innovations, Inc. (SBi), a leading, privately held orthopedics company focused exclusively on arthroplasty and joint-related trauma technologies and treatments for the small bones and joints, has appointed Michael P. Simpson as President and Chief Executive Officer, effective February 21, 2012.

Mr. Simpson's appointment enables Anthony G. Viscogliosi, SBi's Founder, Chairman and CEO since 2005, to step up to the new position of Executive Chairman. Mr. Simpson held several senior executive positions during his nine year career at Orthofix, Inc., a unit of Orthofix International NV. During Mr. Simpson's career as a division President at Orthofix, an orthopedic devices company with $575 million-plus revenues in 2011, he managed the global development and distribution internationally of the product portfolio, including foot and ankle technologies, with full P&L responsibility.

These ACL Patients Have Higher Rates of Medial Chondral Injury Guillaume Dumont, M.D. and Philip Wilson, M.D. are orthopedic surgeons with the University of Texas Southwestern Medical Center in Dallas, Texas. Dr. Dumont told *OTW,* "Our recent study found that children who had delayed treatment of an ACL injury more than 150 days were more likely to experience a medial meniscus tear or chondral injury in their knee. Additionally, children more than 15 years old had a higher rate of associated medial meniscus injury. We examined the effect of the child's weight, something that had not been looked at previously; we found that children with ACL tears who weighed more than 143 pounds had an increased rate of medial and lateral meniscal tears at the time of surgery. A complete physical examination of the knee, and often an MRI are important in identifying ligamentous and cartilage injuries in the knee. Our study helped identify factors that are often associated with increased rates of meniscus and chondral injuries. In the future, it would be beneficial to investigate long term functional outcomes in patients who had ACL reconstructions as children.

We know that with ACL reconstruction and a good rehabilitation program, patients have improved knee stability—*however at this point we do not know the long term risk of knee arthritis and overall knee function twenty years down the line.* We should be vigilant about treating our patients with ACL tears to minimize the risk of further cartilage injury, and consider surgical reconstruction even in young patients. It is important to emphasize that surgeons treating pediatric patients with ACL tears should feel comfortable dealing with open growth plates to avoid injuring them."

Daniel Cher, M.D., W. Carlton Reckling, M.D. Join SI-BONE Dr. Daniel Cher, an internist with over 15 years of clinical affairs and research experience in a variety of medical device technology companies, has been named Vice President of Clinical Affairs at SI-BONE. Dr. W. Carlton Reckling, an orthopedic spine surgeon with over 17 years of spine surgery and clinical research experience, was named Vice President of Medical Affairs. Dr. Cher has developed clinical and regulatory strategies, designed and led clinical trials, and directed clinical research. He has worked at early-stage companies developing new minimally invasive therapies for interventional neuroradiology and for spine surgery. Dr. Reckling has worked as a spine surgeon in Wyoming and Colorado, where he utilized a number of minimally invasive therapies for different spinal surgical procedures. Both physicians will work with multiple parties to develop a consensus diagnostic process for identification of SI joint conditions. ♦

company

FDA's Globus Oops

Image created by RRY Publications, LLC. Source: Wikimedia and Corporate Logo

Oops.

The FDA has changed a statement made in a February 28 press release announcing a $1 million dollar penalty settlement with Globus Medical, Inc. and its CEO for marketing an unapproved medical device.

The agency originally wrote: "The device-clearance process assures the quality and safety of devices before they reach the market. Firms can't simply choose to sell devices that FDA has found are not safe and effective."

In fact, the agency made no such finding. The FDA did not determine that the product was not safe and effective and Globus asked the FDA to change the statement. The agency changed the language on February 29 from: "devices FOUND NOT to be safe and effective," to; "devices NOT FOUND to be safe and effective."

Ed Joyce, Director of Investor Relations & Business Development at Globus, contacted *OTW* and asked us to note the change. He also told us that the NuBone Osteoinductive Bone Graft, the product in question, was on the market since 2007 and had "an excellent safety record, with no implant-related adverse reactions or patient issues."

Joyce also noted another change in the original FDA announcement. The agency's original statement; "During an inspection of Globus Medical in September 2010, FDA investigators learned that the company had marketed its NuBone Osteoinductive Bone Graft product without proper premarket approval or clearance, as required by law," was changed to: "This action is in response to FDA learning that the company had marketed its NuBone Osteoinductive Bone Graft product without proper premarket approval or clearance, as required by law."

The company issued a statement on February 29 after the FDA posting. The statement said that David Paul, Chairman and CEO of Globus Medical, and the company have reached a settlement with the FDA to resolve, "an administrative complaint alleging Food, Drug and Cosmetic Act violations regarding Globus' former product, NuBone. There were no patient safety issues reported regarding NuBone. Significantly, the Amended Complaint does not allege any intentional wrongdoing by Globus Medical or Mr. Paul."

Dara Corrigan, the FDA's associate commissioner for regulatory affair originally wrote, "This company ignored previous warnings by the FDA and continued to produce and distribute unapproved medical devices."

The company said it had considered NuBone to be minimally manipulated tissue exempt from premarket notification, but in March 2008 the FDA's Tissue Reference Group determined that the product required 510(k) clearance. "Globus and FDA maintained an ongoing dialogue regarding NuBone's regulatory status including two 510(k) submissions with substantial animal data. During that time Globus regularly communicated with FDA regarding NuBone and throughout NuBone's lifecycle believed that it was acting in a manner that was acceptable to FDA. Despite its history of safe use, Globus decided to discontinue NuBone in 2010."

The settlement requires Globus to pay a $550,000 penalty and Paul to pay a $450,000 penalty, for a total of $1 million.

—*WE (March 9, 2012)*

MacMillions for Stryker Separation

Stryker Corporation and ex-CEO Stephen MacMillan have agreed to terms of separation.

Ironically, terms of separation are what got the former Stryker boss into hot water in the first place, as some board members reportedly lost confidence in MacMillan over a marital separation. MacMillan's wife filed for divorce in a Michigan court in September.

In SEC papers filed at the end of February, the company reported that MacMillan will receive $5.5 million in a severance payout. In addition, MacMillan, whose resignation was treated as a "termination without cause," is entitled to payment of his 2011 bonus of $1.1 million. He'll also have two years to exercise vested options for 1.2 million shares.

MacMillan was, however, stripped of 676,644 stock options. Those options had a market value of roughly $6 million according to a compensation consultant quoted in the *Wall Street Journal*. He will get to keep about 1.2 million shares in stock options he's been granted over his seven-year tenure. Those options, valued at about $65 million based on Stryker stock price at the time of his departure, will vest immediately and remain exercisable for two years.

The company will also pay for MacMillan's medical, dental and vision benefits for 18 months and then will provide him with lump sum payments to cover his COBRA benefits for six months. He also gets some office space and outplacement services.

MacMillan agreed not to sue the company, disclose any confidential information or compete directly with Stryker for a period of two years.

To read the Separation Agreement, click here.http://sec.gov/Archives/edgar/data/310764/000031076412000085/sykexhibit02212012.htm

—WE (March 7, 2012)

Stephen MacMillan, CEO

FDA Warns Synthes

The FDA has sent Synthes, Inc. a warning letter accusing the company of doing an "inadequate" job of handling surgeon complaints over some of its products. That can't be welcomed news at Synthes headquarters in West Chester, Pennsylvania, after former executives were recently sentenced to jail for getting into trouble with the FDA. It also can't be good news across the river in New Jersey where Johnson & Johnson, with its own ASR hip recall problem, is in the process of purchasing Synthes.

Synthes, Inc, West Chester, PA/Synthes, Inc.

Failure to Report

A warning letter posted online on Tuesday, March 6 accused the company of failing to report serious complaints about its devices to the FDA within 30 days, as required by law. The devices noted by the agency included: Click'X 3-D Polyaxial Heads, Click'X 3-D Pedicle Screws, and N-Hance Rods.

"Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice,"

Kirk Sooter, director of the FDA's Philadelphia district office, wrote in the letter.

"We will co-operate and work diligently with the FDA until these deficiencies are fully resolved," Synthes spokesman Gilgian Eisner said in an email reported by Reuters.

Specifically the agency noted the firm was aware of one particular event on July 1, 2009. But the FDA said it didn't receive the report until July 14, 2011.

Inadequate Complaint Procedures

The FDA warning letter included other "inadequate" procedures for "receiving, reviewing, and evaluating complaints for a formally designated unit." The warning also cited a "Failure to maintain a record of the investigation of a complaint" and failing or refusing to furnish material or information respecting the device that is required.

The FDA found the Synthes violations during an inspection of its plant in West Chester, carried out June 22 through September 15 of last year. The FDA said Synthes responded to its initial complaints on September 29 but the agency did not have evidence that the company had corrected the problems.

Quality Assurance Problems

The letter concluded that observations issued at the closeout of the inspection, "may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance."

—WE (March 6, 2012)

biologics

Cultured Cells Injected to Repair Knee

Faced with a patient with a severely disabling injury on her left knee, doctors at JPN Hospital in New Delhi successfully performed their first "third generation autologous chondrocyte implantation." According to the report in *The Hindu*, doctors used the patient's own cultured cells to repair damage to the cartilage in her knee.

"This advanced surgery is being probably done for the first time in any government set-up in the Capital and we are proud to announce that the patient is recovering well," said Professor incharge of the sport injury and arthroscopy unit, Department of Orthopaedics, Vinod Kumar.

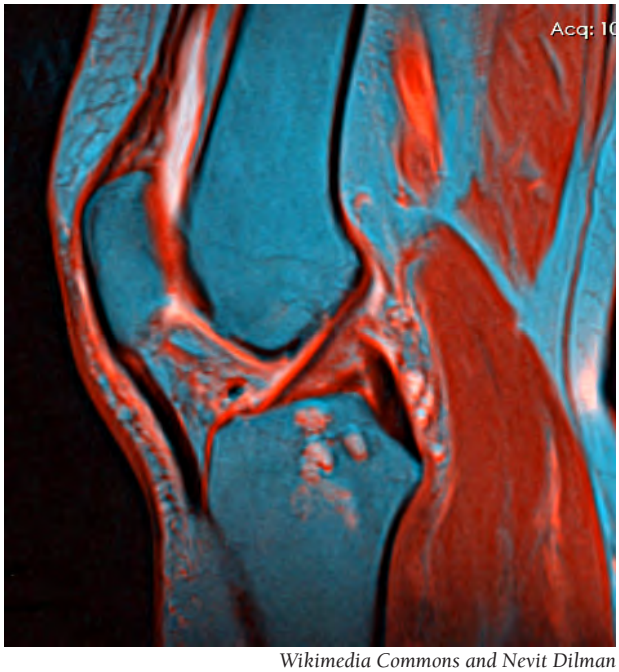
Explaining the procedure Kumar said: "The patient injured her knee while participating in a dance program in August 2011 at her home town in Uttar Pradesh. Her knee developed swelling and she had constant pain. They brought her to this hospital in Delhi and after investigations we found that the patient had damaged her cartilage of the knee joint which doesn't repair by itself.

"Since the patient was very young we decided that she is suitable to undergo this latest procedure where healthy cartilage cells are taken, grown and reintroduced into the injured area to repair it. In this case we performed an arthroscopy procedure where natural cells from the cartilage were taken and these were transported by a private company to Korea where these cells from the patient's knee were cultured, processed and grown and then delivered back to our hospital.

"We got four vials of the cultured cells with each vial containing 12 million cells which when introduced would, we believed, repair the damaged cartilage of the knee. This procedure was performed on the patient on February 11 and the patient has been kept under observation at the hospital," said Kumar.

The patient, who is still admitted to the hospital, is recovering well and, according to Kumar, "after the operation we are sure that the girl will be able to go back to her normal life," he said. He added that the hospital has trained a group of doctors to conduct the cellular repair procedure.

—BY (March 9, 2012)



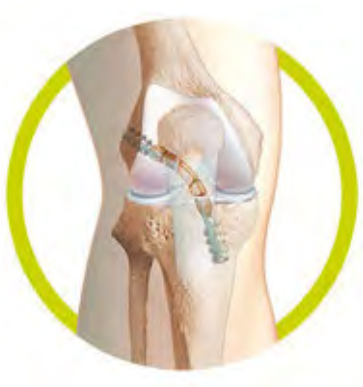
Wikimedia Commons and Nevit Dilman

large joints

Alternative to Patella-Tendon Bone Adopted at HSS

For roughly 15 years, Dr. Michael Maynard, attending orthopedic surgeon at the Hospital for Special Surgery (HSS) in New York, used the bone patella-tendon bone autograft technique almost exclusively for his anterior cruciate ligament (ACL) reconstructive surgeries. No longer. Today Dr. Maynard is a believer in an innovative ligament repair system which was developed in France in 2003 called the CoLS technique.

New to the U.S., the CoLS technique is an approach that requires harvesting of just a single hamstring tendon which can then quadruple to produce the graft.



FH Orthopedics, Inc.

One of the benefits of this approach is that patients can put weight on the ACL almost immediately and reduce their reliance on braces or crutches.

Dr. Maynard (see attached interview with *OTW*) first learned about the CoLS technique two years ago at the American Academy of Orthopaedic Surgeons (AAOS) convention. Since it was developed in France, Dr. Maynard had to travel to France to receive training. He brought the technique back the Hospital for Special Surgery in New York. After about six months, he said that he was especially impressed by his patients' post-operative response. "It is such a clear difference in how much less pain they have, how much quicker they have return of their quad function, how soon they could get off crutches, and stop using a brace. There's no doubt that this is the superior way to go."

In the intervening period Dr. Maynard has performed more than 50 CoLS procedures and has dropped the use of the bone patella-tendon bone autograft technique from his armamentarium. Beyond improved healing, he was also pleased with the strength of the graft and stability it provided to the knee. Said Dr. Maynard, "At six months, I got some objective evidence using the KT1000 Arthrometer and they [CoLS patients] were doing at least as well as the people who had what had before been considered a stiffer, stronger graft. So, at six months, I switched over entirely."

The company that is promoting and training surgeons in the CoLS technique is FH Orthopedics which is headquartered in Mulhouse, France. The U.S. subsidiary of the French company was set up in 2002 and is building a whole line of innovative orthopedic products for U.S.-based physicians. But the flag ship product is clearly CoLS which is a key advancement in knee ligament implant procedures. Since receiving FDA clearance in 2008, the CoLS technique has been performed in close to 1,000 patients in the U.S. and is now used by over 35 surgeons across the country. The CoLS technique has been performed in over 20,000 patients worldwide.

—RRY (March 8, 2012)

Symmetry Launches Offset Reamer Driver

Symmetry Medical, Inc.

Want easier access to the acetabulum? You may want to check out Symmetry Medical Inc.'s new Offset Reamer Driver. This new product, which features an ergonomic silicone overmolded handle, is used in minimally invasive surgical techniques, such as the direct anterior approach, to introduce acetabular reamers to the hip joint. The driver features a drive shaft designed and tested to meet the demands of total hip arthroplasty (THA) surgery.

President and Chief Executive Officer Thomas J. Sullivan, , said in the February 28, 2012 news release, "The launch of the Offset Reamer Driver is an example of Symmetry's commitment to further expanding our line of acetabular preparation instrument products to support our OEM customers and the surgeons they serve. The driver is the most tested instrument ever developed by Symmetry and highlights our commitment to develop state-of-the-art, durable instruments that will be well received as a valuable additions to our customers' surgical instrument sets for total hip replacement surgery."

He added, "The launch is also consistent with our strategy to increase sales of proprietary, IP-backed innovative medical device solutions, which drive improved gross margins and profitability."

Tom Sullivan told *OTW*, "This product has undergone the most stringent durability testing of any innovation in Symmetry history. The unique drive linkage makes cleaning a much simpler process."

—EH (March 6, 2012)

It's Official: TKA Patients Have More Life to Live

Wikimedia Commons and HuHu Uet

Replacing an arthritic knee joint may do more for patients than eliminate their pain—it may save their lives, according to a study presented in February at the annual meeting of the American Academy of Orthopaedic Surgeons and reported by Tara Parker, writing February 28 in *The New York Times*. This outcome turned up when, using Medicare records, researchers from Philadelphia and Menlo Park, California, examined the results of joint replacement on 135,000 patients. All had received diagnoses of osteoarthritis of the knee between 1997 and 2009.

Of the 135,000 patients with arthritis, 54,000 had opted to have their knees replaced while 81,000 had not. Three years after their arthritis diagnosis, researchers discovered that the knee replacement patients had an 11% lower risk of heart failure than did those who had done nothing. Seven years later the

knee replacement patients' risk of dying for any reason was 50% lower.

The researchers attempted, with limited success, to control for differences in age and overall health between the two groups. Nevertheless, their findings are consistent with studies of knee replacement and mortality in Scandinavia. The theory behind knee replacement, said the study's lead author, Scott Lovald, senior associate at Exponent, a scientific consulting firm in Menlo Park, is that the surgery improves quality of life. "At the end of the day, we're trying to figure out if quantity of life increases as well," he said, adding that the team was conducting a similar review of Medicare data on the long-term benefits of hip replacement surgery.

The founder of the Rothman Institute, Dr. Richard H. Rothman, urged caution in interpreting data that are not randomized and controlled, noting that not every patient with knee arthritis is a candidate for joint replacement surgery. "People can tolerate a lot of knee disability for reasons we don't totally understand," he said. "If the pain is acceptable, you live with it."

Rothman believes that whether patients experience better health after surgery depends on motivation—how motivated they were to stay fit before surgery and how motivated they are afterwards to become more active. "For the motivated patient, it allows them to walk through that portal and become better conditioned and lose weight," he said. "It (joint replacement surgery) is not a weight-reduction program. It's a potential avenue to improve your level of fitness, weight, cardiovascular health and mental health."

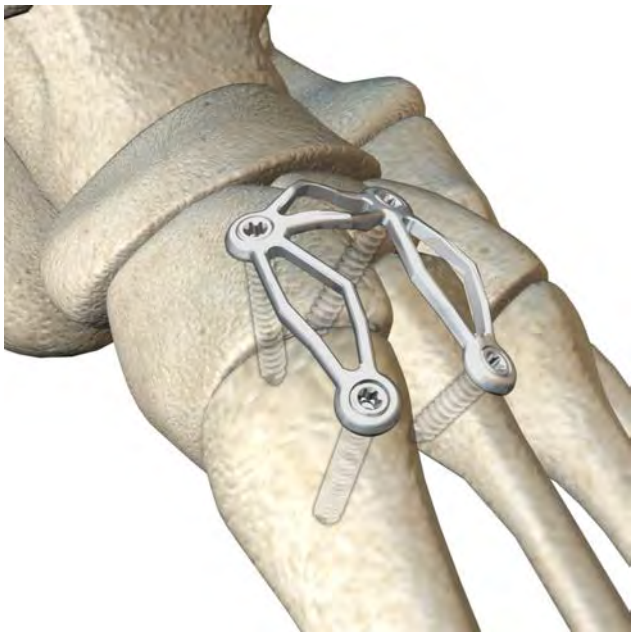
—BY (March 9, 2012)

extremities

Wright Launches CLAW II Plating System

The CLAW…part deux…Wright Medical Group, Inc. has announced the full commercial launch of the CLAW II Polyaxial Compression Plating System featuring ORTHOLOC 3DSi Polyaxial Locking Screw Technology. The system will be available this month in the U.S. through Wright Medical's foot and ankle sales force, as well as in select countries outside the U.S. through Wright's direct and distributor-based sales organization.

"Since 2006, the CLAW plating system has combined stable, rigid fixation with controlled joint compression, which are essential when performing fusions in the foot and ankle. The advancements offered with the new CLAW II system, such as variable-angle locking screws and anatomically contoured plates for fusions and osteotomies of the forefoot and midfoot, will enable surgeons to chose the appropriate implants to meet the patient's unique circumstances," noted W. Hodges Davis, M.D. in the March 1, 2012 news release. Dr. Davis is a foot and ankle orthopedic surgeon with OrthoCarolina Foot and Ankle Institute in Charlotte, North Carolina.



Wright Medical Group, Inc.

"The CLAW II Polyaxial Compression Plating System builds upon our successful CHARLOTTE CLAW plating system and further expands our market leading foot and ankle product portfolio," added Robert Palmisano, president and chief executive officer of Wright Medical. "We are now able to offer foot and ankle surgeons expanded plate offerings for specific midfoot fusions that utilize our ORTHOLOC 3DSi polyaxial technology in a stainless steel compression plate."

Ann Burgess, vice president of biologics and extremities for Wright Medical, told *OTW*, "In designing Wright Medical's new CLAW II system, we were fortunate to have a well-designed first generation product. The technical challenges revolved around making a polyaxial locking mechanism and improving the user interface for the instrumentation and the spreading device. These advancements combine stable, rigid fixation with controlled joint compression, which are essential when performing fusions in the foot and ankle."

—EH (March 9, 2012)

spine

NLT SPINE Secures New Funding

A few million reasons to spur growth…NLT SPINE is announcing that it has secured additional funding from existing investors, Accelmed and Peregrine Ventures. The funds will be used to continue the development of its PROW LIF lumbar fusion product line and additional products, as well as expand its presence in the U.S. market.

This has increased the company's previous rounds of funding from $8.8 million to $14.5 million. According to NLT SPINE, the company's products are based on its non-linear core technology, which allows for inserting large implants and instruments through a small incision. The cornerstone of the PROW LIF product line is the PROW FUSION Transforaminal-Lumbar Interbody Fusion (TLIF) device, which is intended for lumbar fusion procedures. PROW FUSION has recently received 510(k) clearance from the FDA and is currently available under limited release.

Tom Keegan, who brings to the table over 20 years experience in of marketing, technical and clinical experience in the medical device industry a seasoned executive in the medical device industry, is the company's new vice president of business development and U.S. marketing.

Keegan told *OTW,* "The development effort of the PROW LIF lumbar fusion product line has been focused on its cornerstone, the PROW FUSION, Transforaminal-Lumbar Interbody Fusion (TLIF) device. The PROW FUSION has recently received 510(k) clearance from the FDA and the device is now currently being used in select clinical sites in Europe and will begin to be used in select clinical sites in the U.S. in the coming weeks. Clinical experience with the device will be gained during 2012 and full commercialization will take place in 2013. Another key area of development for the PROW LIF lumbar fusion product line is the eSpin disc space preparation tool. The eSpin was recently submitted to the FDA as a 510(k) application and is expected to be introduced as part of the PROW LIF lumbar fusion system later this year. These additional funds will also be used to further the development of other key products based on the non-linear technology platform, including lateral lumbar fusion (PROW FUSION L) and proprietary fixation products, including interspinous fixation and screws for the aging spine."

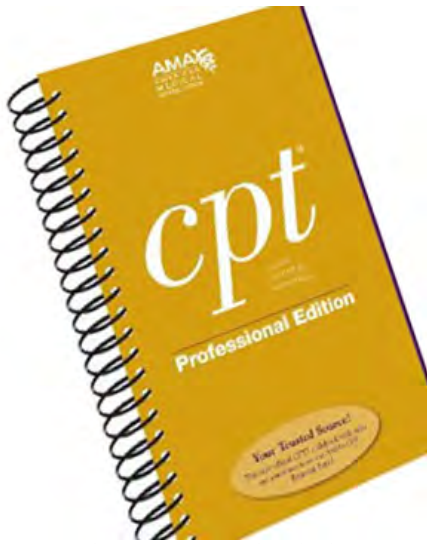
As for how the company will go about expanding its presence in the U.S. market. Keegan commented to *OTW*, "NLT SPINE has initiated its presence in the U.S. market by opening its U.S. offices in Dedham, Massachusetts and will expand this presence with the initiation of the first clinical site in the U.S. in the coming weeks. NLT SPINE will be in a limited release phase in the U.S. for the PROW FUSION during 2012 and full commercialization is planned during 2013. This U.S. expansion will be accomplished with the addition of direct and independent sales specialists to support the growing NLT SPINE customer base."

—EH (March 8, 2012)

Created by RRY Publications LLC, Logo courtesy of NLT SPINE

TranS1 Receives CPT Codes

After years of trying to fit TranS1, Inc.'s unique pre-sacral lumbar interbody fusion procedure into existing CPT (Current Procedural Terminology) codes, the American Medical Association (AMA) has finally approved the company's request for their own code. Physicians generally use the codes owned by the AMA to bill payers for professional services rendered.



CPT Codes Source: Americal Medical Association

On March 5, 2012, TranS1 announced that the AMA's CPT Editorial Panel voted to approve an application for a new Category I CPT code, 225XX1, for L5-S1 spinal fusion utilizing the company's AxiaLIF implant when performing a pre-sacral interbody fusion. In addition, the company said it learned that the CPT Panel also voted to establish a new Category III CPT code, 019XXT, and elected to adopt minor revisions to the company's two current Category III codes, 0195T and 0196T. The new CPT codes, and the revisions to the existing CPT codes, were announced on the AMA's website on March 2, 2012, and will become effective on January 1, 2013.

"This is a significant achievement and an endorsement of the maturation of pre-sacral interbody fusion as a minimally invasive solution at L5-S1," said TranS1 President and CEO, Ken Reali. "The body of peer-reviewed clinical literature that has been published supported the Category I code that was approved."

Reimbursement Clarity

We reported previously that there has been a lack of consistent reimbursement for the CPT Codes 0195T and 0196T used to describe TranS1's fusion surgery. Some physicians found it hard to get reimbursed for the procedure. It's been an important company initiative to get payers to cover the procedures while working with medical societies to clear up coding issues.

Now that the coding issue has been cleared up, the company can focus on convincing more payers to cover the procedure. The company told us that five papers have been accepted for publication this year. Surgeon training efforts have also expanded as the company announced the opening of a new training center in Raleigh, North Carolina, on February 24.

TranS1 currently markets the AxiaLIF family of products for single- and two-level lumbar fusions, the VEO lateral access and interbody fusion system, and the Vectre and Avatar posterior fixation systems for lumbar fixation supplemental to AxiaLIF fusion.

—WE (March 8, 2012)

K2M Corpectomy Cage System Cleared

K2M, Inc. has received its first 510(k) clearance of the year from the FDA to market its Santorini Corpectomy Cage System.

The system is designed to replace collapsed, damaged, or unstable vertebral bodies due to trauma or tumor and provide anterior spinal column support.

Santorini Cage System/K2M, Inc.

Corpectomy is an operation to remove a portion of the vertebra and adjacent intervertebral discs for decompression of the spinal cord and spinal nerves. A bone graft with or without a metal plate and screws is used to reconstruct the spine and provide stability.

Santorini Cage

The Santorini cage is manufactured from biocompatible PEEK polymer and, according to the company's March 1 announcement, allows for an unob-

structed view of the post-operative fusion. It will be available as both solid and expandable options in a variety of sizes. Additionally, the system offers an enlarged graft space and allows for in-situ expansion with a locking clip to secure the desired height.

Charles Theofilos, M.D., founder and director of The Spine Center in Palm Beach Gardens, Florida, said the cage offers, "Precise intraoperative expansion with the stability of a solid peek implant. Its versatility and strength in spinal reconstruction is a welcome addition to the K2M product line."

Eric Major, K2M's president and CEO, said the clearance is an important expansion of the company's complex spine offering, particularly in the areas of trauma and tumor spinal surgeries.

K2M's complete portfolio of products includes: spinal stabilization systems, minimally invasive systems, and other advancing technologies such as motion preservation, annular repair, and nucleus replacement.

—WE (March 5, 2012)

people

Michael P. Simpson Takes Helm at SBi

They are extremely pleased at the extremities company called SBi… Michael P. Simpson, a former division President at Orthofix, Inc., is the new President and Chief Executive Officer of Small Bone Innovations, Inc (SBi). This move will allow Anthony G. Viscogliosi, SBi's founder, chairman and CEO since 2005, to assume the new position of Executive Chairman.

Image Credit: SBi

In the February 22, 2012 news release, Anthony Viscogliosi said, "SBi's revenues, excluding discontinued products, have been growing at a compound average annual growth rate of 27 percent during the period 2006-2011, establishing a platform for continuing growth and profitability. SBi's Board decided that we had reached the point where we needed a leader seasoned in growing a critical mass business into larger scale company. Michael P. Simpson is a great choice to seize this opportunity, based on his track record at Orthofix. He is an experienced professional in the orthopedics industry who understands the extremities market and the demand for evidence-based medicine in terms of pain elimination and joint preservation."

During Simpson's career as a division president at Orthofix, an orthopedic devices company with $575 million-plus revenues in 2011, he managed the global development and distribution internationally of the product portfolio, including foot and ankle technologies, with full P&L responsibility. Mr. Simpson will report to the Executive Chairman and the SBi Board and be a member of SBi's Operating and Executive Committees.

As for what career experience has best prepared him for this new role, Simpson commented to *OTW,* "Having executive leadership roles working for an internal and external foot and ankle company, along with managing both a direct and distributor sales force has given me the experience to lead this organization to reach its full potential. Overall, I have experience managing and leading every operational function in a medical device manufacturing company."

When asked what he will tackle first, Simpson told *OTW*, "In short order, calibrate the operational strategy for sales distribution, product development, product marketing and operations. Additionally, take full advantage of SBI's superior product portfolio in both upper and lower extremity."

—EH (March 5, 2012)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