VOLUME 9, ISSUE 16 | MAY 21, 2013

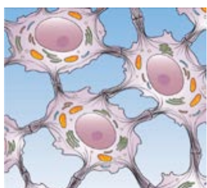
Orthopedics • This Week

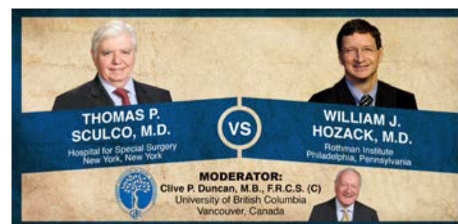
week in review

4 Did the FDA Kill This Company? ♦ Did the FDA kill CoAxia using the new de novo process? Despite reducing mortality rates in patients 2 to 1 over standard of care, the FDA pushed CoAxia into the new de novo process. In retrospect, it also killed the company. Attorney Mark DuVal, is warning clients to beware the de novo process lest it devours you too.

8 Surgeon Skill vs. Patient Outcome: That's the Posterior v. Anterior Debate as Sculco Takes on Hozack ♦ "Is the anterior approach good for the everyday orthopedic surgeon who is doing 25-30 hip replacements a year," says Tom Sculco. Bill Hozack counters, "With anterior you preserve the posterior capsule, eliminate the need for post-op restrictions, and speed recovery."

11 Doctor Led Business Models Proven Superior, Dump the Spine Chainsaw! And Local Anesthesia Beats General – Like a Drum! ♦ Health policy expert says orthopedic surgeons will have more say in patient care. HSS surgeon discusses how you can dramatically decrease complications and mortality… and more.





breaking news

15 Natural Fibers Good **Stem Cell Matrix**

Researchers Create **Bone From iPS Skin Cells**

OrthoView Advances Pre-Operative Planning

Healthcare Spending Slowdown Continues

Best Chance for **Doc Fix**

Limbs Will Be Spared: New Clamp Approved

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: 93% of S&P 500 companies have now reported quarterly results. 67% beat earnings expectations, 24% missed. Overall, U.S. corporate earnings up 4.8% YOY. Plus this—the Fed's easy money policy has made borrowing dirt cheap. What does this mean? Strong earnings + low cost debt = corporate stock buyback binge. And a looming stock shortage. Investors can either buy low interest debt or chase stocks.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	3	NuVasive	7.53%	15.15%	Two of the most dynamic ortho companies happen to be in spine. This week, strictly on valuation, NUVA takes #1 from GMED.
2	2	Zimmer	29.49	9.78	Hit new 52-week high last week. But still the 2nd lowest priced ortho company. With #1 op profit margins no less.
3	1	Globus Medical	29.00	4.25	Trading at 19x trailing earnings. Consensus 5-year EPS growth rate is 15%. Street still doesn't quite "get" GMED.
4	6	Medtronic	28.65	7.53	MDT to announce results this week. Most analysts expect flat to slightly higher spine hardware sales. Infuse expected down 10%.
5	5	Stryker	23.68	6.99	SunTrust downgrades to Neutral. We, on the other hand, find paying 15x earnings for 24% profit margins attractive.
6	8	Wright Medical Group	6.84	7.13	Reporting better numbers than expected after the BioMimetics purchase. Impressive.
7	7	Orthofix	19.68	(19.39)	Look who is buying OFIX. Directors Gero and Mainelli. A bit over 20,000 shares last week. What do they know?
8	10	Alphatec	(4.29)	5.29	Piper's analyst quoted as saying that ATEC's pipeline looks strong. Again, this is the LC pattern emerging.
9	4	Johnson & Johnson	25.58	4.99	If the market is shifting to more dynamic, volatile growth stocks, then JNJ is back into Dow Dog territory.
10	NR	Integra LifeSciences	12.44	14.37	Yes, product recalls hurt this past quarter. But the pipeline is strong. Back on the Power Rankings at #10.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	$7.26	$697	45.49%
2	RTI Biologics Inc	RTIX	$4.33	$244	15.78%
3	Bacterin Intl Holdings	BONE	$0.75	$32	15.38%
4	NuVasive	NUVA	$23.26	$1,029	15.15%
5	Integra LifeSciences	IART	$36.53	$1,025	14.37%
6	CryoLife	CRY	$6.34	$174	12.81%
7	Zimmer Holdings	ZMH	$80.34	$13,526	9.78%
8	Medtronic	MDT	$49.84	$50,528	7.53%
9	Wright Medical	WMGI	$24.64	$1,151	7.13%
10	Stryker	SYK	$68.90	$25,984	6.99%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$0.87	$87	-24.75%
2	Orthofix	OFIX	$26.53	$516	-19.39%
3	TranS1	TSON	$1.70	$46	-15.00%
4	Symmetry Medical	SMA	$10.43	$389	-13.23%
5	Exactech	EXAC	$18.00	$242	-7.46%
6	Tornier N.V.	TRNX	$16.42	$762	-4.42%
7	MAKO Surgical	MAKO	$11.14	$523	0.72%
8	Conmed	CNMD	$33.44	$939	3.75%
9	Globus Medical	GMED	$15.69	$1,445	4.25%
10	ArthroCare	ARTC	$34.65	$977	4.30%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$26.53	$516	10.32
2	Zimmer Holdings	ZMH	$80.34	$13,526	12.93
3	Globus Medical	GMED	$15.69	$1,445	13.75
4	Medtronic	MDT	$49.84	$50,528	14.24
5	Smith & Nephew	SNN	$58.94	$10,681	14.65

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$23.26	$1,029	61.21
2	Symmetry Medical	SMA	$10.43	$389	35.97
3	RTI Biologics Inc	RTIX	$4.33	$244	25.47
4	ArthroCare	ARTC	$34.65	$977	22.65
5	Exactech	EXAC	$18.00	$242	18.00

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$26.53	$516	0.83
2	Globus Medical	GMED	$15.69	$1,445	0.92
3	Exactech	EXAC	$18.00	$242	1.29
4	Zimmer Holdings	ZMH	$80.34	$13,526	1.37
5	Conmed	CNMD	$33.44	$939	1.38

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$23.26	$1,029	4.94
2	CryoLife	CRY	$6.34	$174	4.40
3	Symmetry Medical	SMA	$10.43	$389	3.00
4	Johnson & Johnson	JNJ	$88.09	$247,435	2.69
5	Medtronic	MDT	$49.84	$50,528	2.18

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$10.43	$389	0.95
2	Bacterin Intl Holdings	BONE	$0.75	$32	0.97
3	Alphatec Holdings	ATEC	$1.99	$192	0.98
4	Exactech	EXAC	$18.00	$242	1.08
5	Orthofix	OFIX	$26.53	$516	1.12

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	$7.26	$697	25.75
2	TiGenix	TIG.BR	$0.87	$87	21.42
3	MAKO Surgical	MAKO	$11.14	$523	5.09
4	Globus Medical	GMED	$15.69	$1,445	3.74
5	Johnson & Johnson	JNJ	$88.09	$247,435	3.68

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

Advertise with Orthopedics This Week

Click Here for more details
or email tom@ryortho.com
Tom Bishow: 410.356.2455 (office)
or 410.608.1697 (cell)

Did the FDA Kill This Company?

By Walter Eisner

CoAxia, Inc. is out of business because the FDA lured the company into the de novo process.

That's the warning from industry lawyer Mark DuVal of DuVal & Associates, P.A, in a May 2013 "Client Alert."

Mark DuVal

De Novo Process

The de novo process was intended to be applied when a predicate device does not exist and the device was not so risky that it required the PMA (Premarket Approval) pathway.

Duval warns companies considering entering the de novo process that while the program looks like a benign substitute for the 510(k) program, in reality, it disguises PMA-like data requirements and "may devour your company."

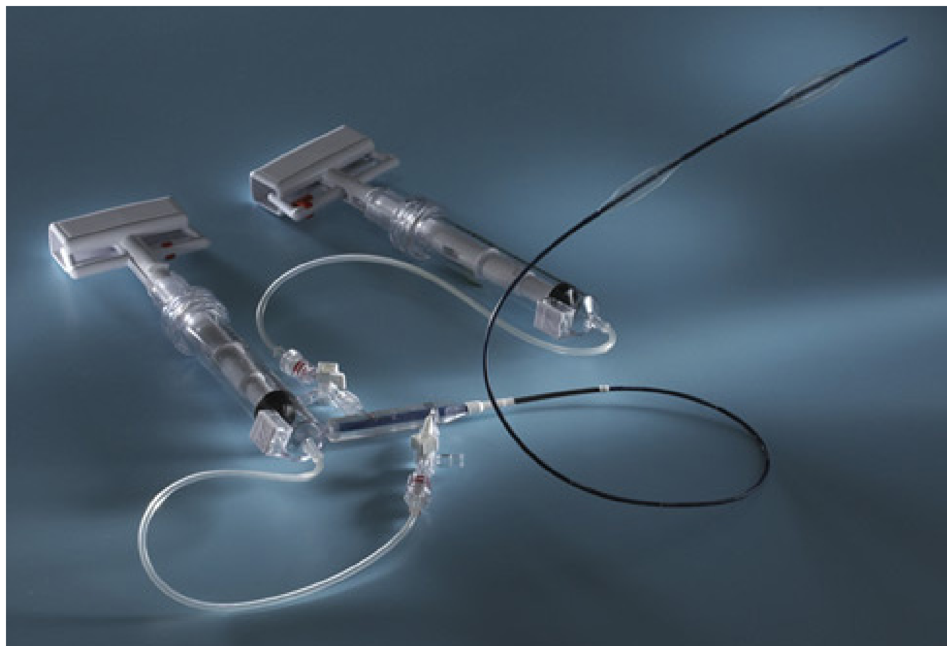
And CoAxia NeuroFlow is exhibit A.

Logo courtesy of CoAxia, Inc. and photo creation by RRY Publications LLC

Serving CoAxia Up

CoAxia was the first company to receive an FDA offer of a de novo panel. And they were the first to accept the offer. It occurred after CoAxia failed a de novo approval with divisional staff alone. Says Duval: "The prospect of an independent expert advisory panel was appealing to the company. That was before we discovered how manipulated it could be by divisional staff. The device did not get approval for the labeling the company sought—first as an extension of the 510(k) labeling, and second, as part of a de novo reclassification and approval."

CoAxia NeuroFlow is a dual balloon catheter which the FDA twice cleared for use in the descending aorta to divert



CoAxia NeuroFlow/CoAxia, Inc.

blood flow from the lower extremities to the upper extremities, such as in the cerebral, cardiac and pulmonary vasculature.

In addition to two 510(k) clearances, the device has a Humanitarian Device Exemption (HDE) for use in patients with cerebral vasospasm.

The device would be used in patients who need more blood in the head, such as those with cerebral ischemia or, arguably, ischemic stroke. After its two clearances and HDE approval, CoAxia conducted a 500+ patient randomized trial which demonstrated that the device was safe when used in ischemic stroke patients.

Furthermore, CoAxia's study documented a 2 to 1 **reduction** in mortality over standard of care.

So, what happened?

For many companies with FDA experience, this will sound depressingly and alarmingly familiar.

First, the FDA's staff recommended a particular endpoint for the study which was different than the endpoint the company wanted. Staff wanted "return to normal." Says Duval: "This is a very difficult endpoint to demonstrate and one to which the company, in hindsight of course, should not have acquiesced." Sure enough, even though twice as many patients lived versus standard of care, the number who "returned to normal" did not meet the pre-study target. In the FDA's view, the study did not meet the endpoint—their endpoint.

From PMA to 510(k) to De Novo to Oblivion

CoAxia missed the FDA's efficacy endpoint but, DuVal points out, the body of clinical data still had substantial worth. Based upon this clinical data, the company abandoned its PMA submission and simply asked to extend the current 510(k) labeling for use in ischemic stroke patients.

The FDA said "no" and fought CoAxia's request over the course of several years.

The question considered by the FDA was whether the company should be able to clarify the labeling to state the device is a "tool" and not a "treatment."

The company argued the tool claim is a specific indication falling under the general intended use. However, the FDA's review division ruled that the device was NSE (not substantially equivalent) because the proposed use constituted a new intended use and therefore was a "treatment."

DuVal: "FDA's decision shows how subjective this determination/interpretation is because this device certainly can be used by physicians today in ischemic stroke patients."

"If FDA wanted to embrace the 510(k) program and Least Burdensome requirements, it could just as easily have justified a decision to find that the proposed

VerteBRIDGE®
PLATING TECHNOLOGY
ROI-C®
CERVICAL CAGE
ROI-A®
ALIF CAGE
Avenue® L
LATERAL LUMBAR CAGE
LDR
a passion for innovation
www.ldrmedical.com
Advertisement

use fell comfortably within the general use and made a substantial equivalence determination."

"Instead, FDA forced the device onto the PMA path (with a de novo stop in between) and to support a request for yet another large clinical trial, thus effectively killing the company and the use of its technology in stroke patients," charges DuVal.

ReGen Deja Vu

This should remind readers of the Regen Biologics, Inc.'s 510(k) clearance case where the FDA staff ignored two orthopedic panel recommendations that the device was safe, and probably effective, and in violation of its own rules revoked the company's existing clearance status. That company also went out of business after the FDA action.

DuVal warns companies that the CoAxia case demonstrates how the FDA can use its power to support a request for more and more data and make a decision that is more Class III, PMA-like than a Class II, moderate risk de novo decision; and how the panel process can be manipulated by divisional staff to achieve the end they desire.

Off-Ramp to De Novo

The agency is "subtlety and indirectly redirecting many submissions that normally would have been effectively handled by the 510(k) program on to the de novo path," said DuVal.

Why would the FDA do that?

DuVal says it is because de novo path provides the agency more administrative control to dictate the quality and quantity of data than would otherwise be necessary under the 510(k) path. When FDA asks for data under the de novo path it is not tethered to the 510(k) standard of "substantial equivalence," which requires an applicant to demonstrate safety and effectiveness in a comparative sense to a predicate device.

The de novo path, claims DuVal, allows FDA to use the same standard as with a PMA, albeit in the context of a moderate risk (Class II) device.

By diverting as many 510(k) applications as possible to the de novo path, DuVal says the FDA can require as much data as it wants for approval. "Although FDA may disagree, the de novo path is PMA-like. Some would say it is PMA-lite. FDA finds it difficult to hold itself to a moderate risk (Class II) standard," added DuVal.

Photo manipulation by RRY Publications. Source: Wikimedia Commons and ReGen Biologics

Under the de novo path, the FDA can get into many definitional battles with applicants regarding the interpretation over the elements of the 510(k) program, i.e. whether a device has the same intended use, same technological characteristics, or has different characteristics and/or the question of whether the new technological characteristic raises new types of questions of safety and effectiveness.

De Novo Trap

"If you thought FDA's seemingly benign offer to pursue de novo to keep your device dream alive because your device was not going to survive the 510(k) path (i.e. an NSE letter), think again," warns DuVal.

"Let's face it, no matter what path your device is on, FDA wants to ask for whatever information it desires, even if it exceeds the statutory construct for a moderate risk device; even if it exceeds the demands of good scientific judgment; even if it looks like a science project; even if it far exceeds what was required to obtain a CE Mark in Europe. Once FDA has an applicant in the de novo world the only limitation on its far-reaching administrative judgment is the well-intentioned, but often loosely defined and infrequently applied, Least Burdensome requirements."

DuVal writes that some would say FDA is doing indirectly what it cannot do directly, i.e. require the "science project-like" data it prefers of many applicants of PMAs.

The FDA Angst

"One also suspects that the real reason for asking for a clinical trial is that FDA seems to be attempting to shore up past regulatory clearances where no clinical data was required."

He believes today's FDA often feels the "old" FDA did not do its job and should have required far more data for clearance of the previous generation of 510(k)s. "Never mind that the predicate devices have not demonstrated any safety issues or, in the rare case where there are some safety issues, they are not significant enough to merit a clinical trial as solution."

Changing the Predicates on the Fly

He says the FDA now seems to be asking for clinical data from new 510(k) applicants to create new predicates in the predicate family for which clinical data are required. This will, in turn, enable FDA to request clinical data of future device applicants, whether such data are truly needed or not. Frequently, that desire to have clinical data as the norm, where none was required in the past, seems to be another reason for pushing devices down the de novo path.

Internal FDA Politics

There are also internal FDA political issues here.

DuVal observes that applicants often disagree with a review team regarding the appropriate pathway for a device and makes its case that the device has a legitimate predicate(s) and deserves to be considered under the 510(k) path. "And it seems there are also internal disagreements within the Agency about whether a device belongs on the 510(k) path."

It is industry's impression that when internal disagreements occur, management will tend to side with the most conservative view, in many cases regardless of the merits of the various arguments. The dynamic at play with the de novo path is that it has become something it was not intended to be—a convenient "out" for the Agency.

"What seems to happen is that review staff and management debate internally whether a device belongs on the 510(k) path and as they struggle with the definitions of same intended use, etc., FDA often comes to an internal stalemate. Rather than management having the courage to break the stalemate and leave the device on the 510(k) path, they simply punt and suggest or direct the applicant to pursue the de novo path."

This makes de novo an escape valve for internal disagreement and potential strife, says DuVal. "The de novo program was never intended to be a default position for making tough decisions or a tie-breaker for moments when there is internal controversy over whether or not a device belongs on the 510(k) path."

DuVal says this is one of the reasons why Congress recently passed Section 603 of the FDASIA. It requires FDA to produce documents to show the various internal opinions expressed during the review process.

He says it is industry's hope that this provision will help to reduce bad decisions aimed more to minimizing internal controversy than in making the correct decision. "These bad, politically motivated decisions frequently lead to the use of the de novo process as an escape valve. In doing so, the de novo process becomes a de facto substitute for 510(k) reviews."

"Grandma, What Big Teeth You Have"

DuVal warns his clients to remember the story of Little Red Riding Hood and the Big Bad Wolf as a metaphor for the de novo process. He says don't be fooled by the wolf dressed like Grandma. ♦

Denver Health Medical Center is seeking a Spine Surgeon. This academic position encompasses a broad spectrum of spinal pathology focusing on spinal trauma and adult degenerative disorders. Partnership would be established with the current Chief of Orthopedic Spine Surgery and the Neurosurgical Division. The Orthopedic and Neurosurgery "Spine Team" has been recognized as a model for the Nation by the American College of Surgeons. A formal affiliation with the University of Colorado, School of Medicine means faculty surgeons receive an academic appointment to help guide the resident training program for Orthopedic Surgery. Denver Health is a National model for integrated urban safety-net health care systems that serves as a Level I Trauma Hospital. Our Rocky Mountain Regional Trauma Center is the busiest hospital in Colorado.

MD Candidates should be BE/BC in Orthopedic Surgery or Neurosurgery and have completed fellowship training in Spine Surgery. Ideal candidates will have a strong desire for consistent involvement in ongoing academic productivity, strong patient-care and surgical skills, and a strong committed interest to education. A high ethical and moral standard is required. Honesty, integrity, and reliability are demanded of this future teammate who should possess a passion to serve the underserved.

Interested candidates should contact Jeanette.Moore@dhha.org.

Denver Health is an equal opportunity employer.

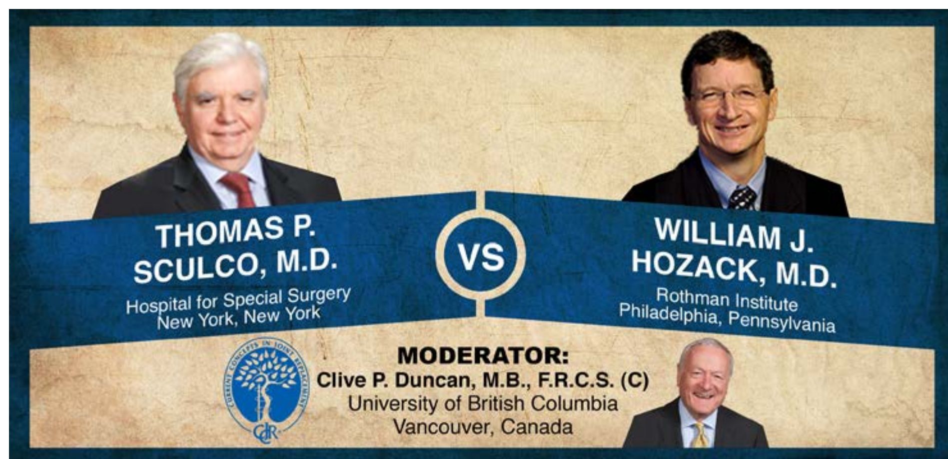
© 2013 Denver Health

Advertisement

Surgeon Skill vs. Patient Outcome: That's the Posterior v. Anterior Debate as Sculco Takes on Hozack

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

Is anterior too difficult for the rank and file surgeon? "We must ask whether the anterior approach is good for the everyday orthopedic surgeon who is doing 25-30 hip replacements a year," says Tom Sculco. But that's not the point, counters Bill Hozack, patient outcomes are why the anterior approach is the way to go. "With the anterior approach you preserve the posterior capsule, eliminate the need for restrictions after surgery, and this approach enhances patient confidence and speed of recovery."



Current Concepts in Joint Replacement/RRY Photo Creation

This week's Orthopaedic Crossfire® debate is "The Posterior Approach: Optimizes THA [total hip arthroplasty] Outcome." For the proposition is Thomas P. Sculco, M.D. of The Hospital for Special Surgery in New York and against the proposition is William J. Hozack, M.D. from the Rothman Institute in Philadelphia. Moderating is Clive P. Duncan, M.B., F.R.C.S. (C) from the University of British Columbia in Vancouver.

Dr. Sculco: "There are many ways to get into the hip joint, and in expert hands all will yield excellent results. The two most common in the U.S. now are the anterior approach and the posterolateral approach. The latter can be easily extended, the blood loss is less, and it's expeditious. Its main disadvantage is that it's been reported to have a higher dislocation rate."

"The incision I use is primarily a lateral approach, although I come in posteriorly for my deep dissection. One-third of the incision is above the greater trochanter, two-thirds below; it's a linear approach. On the femoral side your visualization should be a full circumferential view of the neck of the femur so that you won't violate the neck on the insertion of your femoral component."

"Some years ago we looked at almost 1,500 total hip replacements through this less invasive posterolateral approach. Follow-up was about 10 years, and the skin incision was 8.4 centimeters. The radiographic evaluation was quite good: abduction (42.2), cement (95% A or B), stem (93% neutral). Complications: dislocation rate was 1.2%, femoral fracture rate was 0.3%, and neuropraxias of the sciatic nerve is a problem if you put excessive tension posteriorly. We learned that early on when we tried to make these incisions too small. Wound complications were dramatically small: four hematoma and three infections. Many of these patients only stay in the hospital for two days."

"As for anterior hip replacement, it has been popularized on the Internet in the U.S. There are 62,000 Web sites. But is this a good approach for the everyday orthopedic surgeon who is doing 25-30 hip replacements a year? The claims made are that it is tissue sparing and there is no injury to muscle, that there is less pain, and that the recovery is faster. Is there really evidence to support these assumptions? There is actually very little in the literature."

"The disadvantages: Most patients are placed on a special OR table which must be purchased for this approach; many surgeons use intraoperative fluoroscopy; the femoral exposure is more difficult, particularly in larger patients and male patients; the OR time is increased…and are the complications higher?"

"A cadaveric study by Meghini disputes the fact that there is no muscle injury in the anterior approach. In the posterior approach there is injury to the glutei and the abductors; however, in the anterior approach there was significant injury to the tensor fascia lata and the external rotators."

"In another study, Pilot looked at a cytokine evaluation of muscle injury. When comparing the anterior and posterior approaches there was no difference in these sensitive markers of tissue injury in either approach. As for dislocation, that's been advocated as an advantage of the anterior approach. Looking at several studies advocating anterior approaches, we see that the dislocation rate is not significantly different from my series I reported earlier (Siguier, 0.96%; Matta, 0.61%; Kennon, 1.3%; Sariali, 1.5%; Sculco, 1.2%)."

"Periprosthetic fracture: Dr. Matta is the advocate and early developer of the anterior approach. In a paper he published he had a 2.4% fracture rate in an expert's hands; my fracture rate with the posterolateral approach was 0.3%. Lateral femoral neuropraxia is also a problem; that's been reported in as high as 67% of patients. Much of it is transitory, but it is still bothersome to the patient."

"In a series of five community surgeons in five community hospitals with 250 hip replacements done anteriorly, the surgical time is nearly three hours; blood loss was nearly two units, with a 9% complication rate. In summary, keep it simple…disaster is always a threat."

Dr. Hozack: "As Clive knows, we Canadians have a different perspective on things. The goal of total hip replacement should be a perfect result. But we don't always achieve that goal. What is perfect? No pain at any time, no restrictions at any time, a faster recovery (days not months), no muscle damage, normal range of motion (ROM), no second operation, no complications."

"Obviously there are certain things that are unrelated to the approach, such as the amount of pain you experience, the ROM you achieve, and the need for a second operation. But the other four may give you pause and make you think of trying a different approach. These are: no restrictions at any time postoperatively, the speed of recovery, the level of muscle damage, and the lack of early or late complications."

"Hip restrictions that are imposed on the patient are not good for that patient. We force them to buy certain devices

Introducing Cellentra™ VCBM (Viable Cell Bone Matrix)

The Triad of Bone Remodeling

The Complete Bone Remodeling Triad

- Viable Osteogenic Cells: ≥ 250,000 cells per cc including mesenchymal stem cells (MSCs), osteoprogenitor cells and pre-osteoblasts
- Verified Osteoinductivity: Demineralized component provides additional inherent growth factors. Demineralized bone has been shown to include BMP-2, 4, 7, VEGF, TGF-ß, PDGF, IGF-1, FGF[1, 2, 3]
- Osteoconductive Scaffold: Cancellous bone matrix offers an interconnected trabecular structure

Biologics • Bone Healing • Microfixation • Orthopedics • Spine • Sports Medicine • Trauma • 3i

biomet.com • 800.526.2579

©2013 EBI, LLC. All rights reserved. All trademarks are the property of Biomet, Inc. or one of its subsidiaries unless otherwise indicated. Rx Only.

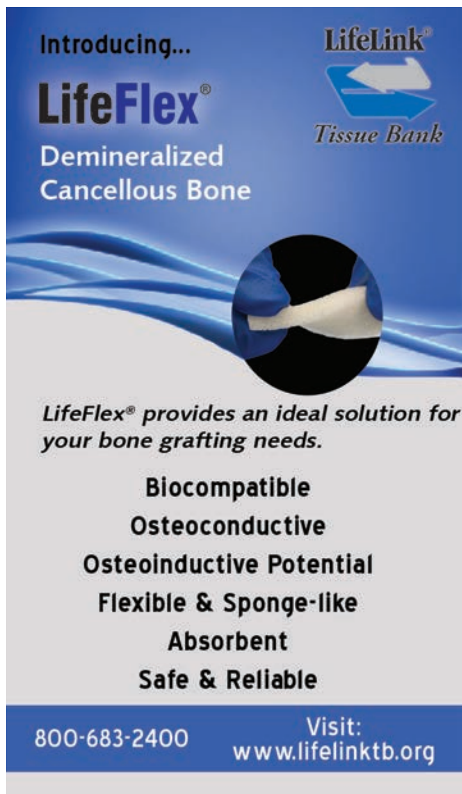
1. W.S. Pietrzak, J. Woodell-May, N. Mcdonald. Assay of Bone Morphogenetic Protein -2, -4 and -7 in Human Demineralized Bone Matrix. J. Craniofac Surg. 2006 Jan;17(1):84.90.***
2. B. Wildemann, A. Kadow-Romacker, N.P. Haas, G. Schmidmaier. Quantification of Various Growth Factors in Different Demineralized Bone Matrix Preparations. J. Biomed Mater Res A. 2007 May;81(2):437-42.
3. B. Blum, J. Moseley, L. Miller, K. Richelsoph, W. Haggard. Measurement of Bone Morphogenetic Proteins and Other Growth Factors in Demineralized Bone Matrix. Orthopedics. 2004 Jan;27(1Suppl): S161-5.

*** FINANCIAL: In support of their research or for preparation of this work, one or more of the authors may have received, in any one year, financial remuneration from Biomet, EBI, LLC or Bioelectron, Inc.

Pre-clinical studies are not indicative of human clinical outcomes.

BIOMET® SPINE
One Surgeon. One Patient.®

Advertisement



Advertisement

that are difficult to transport out of the house to restaurants, etc., and are actually very expensive. People like to cross their legs, get in their cars and drive, etc…and the posterior approach limits that in the very beginning because it violates a significant number of structures. If you add up the number of muscles that are cut, you see that the posterior approach cuts the most number of muscles."

"So there is a rationale for an anterior approach of some sort. It preserves the posterior capsule, eliminates the need for restrictions after surgery, and it enhances patient confidence and speed of recovery. There are data in the peer-reviewed literature (Nakata et al, *JOA* 2009) suggesting that in the early post-operative time there is a faster recovery with an anterior approach as opposed to a posterior approach."

"Soft tissue damage affects functionality and the consequences are severe: weakness, limp, soreness, heterotopic bone formation, and general disappointment for the patient and the surgeon. And there are good alternative approaches available that go between muscles, between nerves, that don't damage muscle, and create less muscle trauma."

"So consider an alternative approach that spares one of the biggest muscles around the hip—the gluteus maximus. We always forget to talk about that muscle, and this is routinely violated in the posterior approach. And another approach might spare the gluteus medius and minimus muscles during surgery."

"Bergin et al published an article in the *Journal of Bone and Joint Surgery* in 2011 suggesting that inflammatory markers are decreased with a less invasive approach. And if you're worried about instability…if you look at causes for revision in the U.S. the number one cause is instability of the hip. In expert hands it's not a problem, but in the general population of surgeons instability is a big deal."

"So consider coming over from the back side…don't fight it so much. If you learn it from experienced surgeons then you don't need a special table—you can do it on a regular table and it doesn't require any special expenses. It does require special instrumentation, but that is true of every approach."

Moderator Duncan: "Bill, when can we expect the first prospective randomized study which is really going to put this issue to bed once and for all?"

Dr. Hozack: "There is one prospective randomized study that I did comparing it to direct lateral."

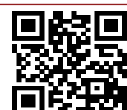
Moderator Duncan: "Because the prospective randomized studies comparing things to the direct lateral usually wins because of the transgluteal is so disruptive to the function of the hip. I mention that because the G3—the Watson Jones approach—which is really just two fingerbreadths behind what you use—showed that there is really no advantage to changing your approach mid-career. Tom, you're the leader of a prominent residency program in New York. Are we now at a point where we should introduce this to our residency programs?"

Dr. Sculco: "I've done the anterior approach to the hip, and we have a number of surgeons at our facility that use the anterior approach…so my residents do see the approach. As they rotate through my service I always ask them what they think. They say that they think anterior is a more difficult approach than posterior. I think surgeons should know all the approaches to the hip, but they should find an approach that they're most comfortable with and they get the best results."

Moderator Duncan: "Thank you." ♦

Please visit www.CCJR.com to register for the 2013 CCJR Winter Meeting, December 11–14 in Orlando, Florida.

"You may now view content from the CCJR Meetings on the CCJR Mobile™ App. Please scan the QR code to download the CCJR Mobile App to your Android or iOS mobile device, or visit www.ccjrmobile.com."



Doctor Led Business Models Proven Superior; Dump the Spine Chainsaw!; And Local Anesthesia Beats General – Like a Drum!

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

Doctor-Led Models Superior! A certain in-the-know health policy expert is predicting a pendulum shift—back towards orthopedic surgeons having more say in the care of their patients. Chad Mather, M.D. is an attending orthopedic surgeon at Duke University. Dr. Mather, an AAOS (American Academy of Orthopaedic Surgeons) Washington Health Policy Fellow, tells *OTW*, "Right now, orthopedic surgeons are mobilizing toward adapting to different payment models, much of which requires more integrated care for episodic payments. What we're starting to see is that physician-led models deliver more cost efficient and convenient care. My health policy colleagues and I were just in Washington, D.C. discussing how to protect access to in-office ancillary services, and we are convinced from examining the evidence that doctor-led initiatives will soon emerge as the most successful models of care. In episodic payment models, reimbursement could go to the orthopedic surgeon, the hospital, or a primary care doctor. We believe that the orthopedic surgeon is the best equipped provider to manage the pathway of care. For example, the facility where a procedure is performed a major driver of the cost of care. Orthopedic surgeons can get patients to the least expensive facility that is safe for them.

Andrew Huth and photo creation by RRY Publicaitons LLC

"It's early, but one reason we know that this is imminent is because market conditions favor physician led models—most hospital-based services cost significantly more than office-based services. Perhaps the most important piece of this is that orthopedic surgeons are in a unique position of knowing more about both primary and specialty musculoskeletal care than any other provider. The musculoskeletal system is widely known to be underrepresented in medical school—as opposed to the cardiopulmonay system, for example—yet one out of every five presenting complaints to primary care physicians in this country is musculoskeletal. Primary care doctors are just not as well equipped to manage orthopedic issues as they are equipped to handle, for example, cardiology or GI problems. I think it will become increasingly clear to payers as they scrutinize different care models that orthopedic surgeons are best equipped to deliver high value musculoskeletal care."

Dump the Chainsaw in Spine Surgery Why use a chainsaw, says Izzy Lieberman, when you can use precision technology? Isador Lieberman, M.D. is an orthopedic surgeon with the Texas Back Institute. He tells *OTW*, "I've been emphasizing more and more lately about the importance of pre-operative planning for spinal surgery. This is an evolving process; surgeons have always done this to a certain extent, using X-rays and CT scans to estimate what we think we should do in the OR. That was the state of the art for the last 25 years. Now we have at our disposal technology to help us measure and apply implants within

1 millimeter tolerances; we are beyond using a chainsaw. At this juncture in our field, the placement of instruments and implants is so much more critical. We are fortunate to have much improved imaging and software to help us plan operations, determine the degree of correction for sagittal or coronal balance, and figure out the size and placement of the implant. Then we take this information to the operating room and combine it with navigation and robotics to facilitate the pre-operative plan. Why not take advantage of these tools? Why not go into the OR as prepared as possible?"

"If a contractor was going to redo your kitchen and he looked around and said, 'Yeah, we'll move this about six inches,' and wanted to proceed without a blueprint, would you let him remodel your kitchen? Probably not. It's the same thing with a pilot. If you heard that the pilot didn't do a preflight plan you wouldn't get on the plane with him. We need to be able to say, 'I'm going to cut from point A to point B, take out a 20 degree wedge here, decompress L1-2, etc.' With robotics and navigation we have that capability."

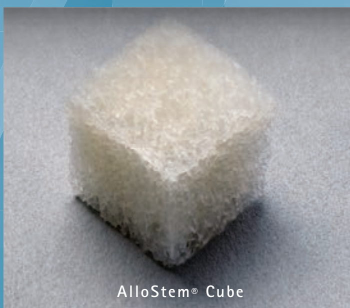
"I often hear, 'But does this really save time in the OR?' 'Absolutely!' is my response. Recently I did a complex revision and spent 35 minutes developing my pre-operative plan. I booked the case on the basis of experience with other such cases…I allotted seven hours and ended up finishing in four hours. When I finish a case early I can be more efficient with hospital resources, be cost effective, and minimize the patient's operative risk. And from a systems viewpoint, OR efficiency is being scrutinized more, so it is increasingly important to plan your time."

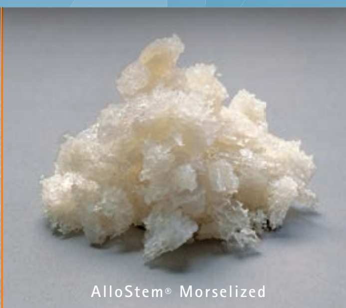
"With a pre-operative plan my team works like an orchestra. The anesthesiologist knows at what point to expect hemodynamic issues, the scrub tech knows exactly what size screws need to be ready, the circulating nurse knows exactly what equipment I need and has everything ready to go (i.e., nobody is running around mid-surgery looking for xyz gizmo). And if your plan doesn't go as expected, you call the audible, which is also pre-operatively planned. All surgeons must know how to get into trouble and how to get out of trouble. With a pre-operative plan you have thought about it even before you set foot in the operating room. I suspect that this kind of pre-operative planning and precision will ultimately be required by the FDA and licensing boards, very similar to the pre-operative time out."

Local Beats General – Like a Drum

Know about neuraxial anesthesia? You should! A full 95% of anesthesiologists and surgeons at Hospital for Special Surgery (HSS) are using it for joint

WE'VE ADVANCED THE NATURE OF BONE.





Natural bone is a miracle. AlloSource has discovered a way to capture the essential qualities of natural bone in a cellular allograft tissue.

AlloStem combines partially demineralized bone with adult mesenchymal stem cells to create an allograft tissue that is a natural scaffold to support new bone formation. All in a tissue with superior handling properties.

AlloStem. It's an advancement of which nature would approve.

For more information, please visit
allosource.org
or call 720. 873. 0213

Advertisement

replacements. Stavros Memtsoudis, M.D., Ph.D. is director of Critical Care Services at HSS in New York; he has just published his work in the *Anesthesiology*. He tells *OTW*, "While the majority of joint replacements in the U.S. are performed under general anesthesia, we at HSS have found that using neuraxial anesthesia—as opposed to general anesthesia—decreases the risk of blood transfusions, decreases length of stay, as well as a host of organ related complications."

So why isn't everyone using it? "There are a multitude of things that come into play, namely, patient, institutional, and surgeon preferences. And unless you work in a place where a lot of knee and hip arthroplasty is done, then most likely everyone is accustomed to general anesthesia. Then there is the issue of anticoagulation; neuraxial techniques that are used for postoperative pain control, such as epidurals, are considered contraindicated with potent anticoagulants. I just spoke with physicians in Canada who are reviewing an enormous amount of national data and trying to come up with best practices for hip and knee arthroplasty. They are using our paper to guide them and hope to increase their rate of utilization of neuraxial anesthesia—which now stands higher than in our study in U.S. hospitals but may be as low as 50%."

"This type of anesthesia requires a certain level of expertise and is quite involved as the patient has no feeling below the waist but often requires sedation especially for longer surgeries. The process requires a team approach and mutual understanding of the roles of every individual to make neuraxial anesthesia successful. I encourage my colleagues to look at the outcomes beyond the OR. From our end, we have seen a dramatic decrease in complications and mortality rates, as well as even better implant performance. We just may find that insurers will start paying close attention to the type of anesthesia used. Interestingly, one of the first people to contact me was someone from a risk management journal. The reporter asked how these findings may affect medical litigation issues; my answer was that it will be no different than with competing medications or

Comprehensive Foot System (CFS)
A comprehensive plating system for all types of fusions, fractures and osteotomies of the foot
Arthrex
http://tinyurl.com/OTW-CFS2013
© 2013, Arthrex Inc. All rights reserved.
Advertisement

interventions that are used to treat a specific condition. The patients must be informed of risks, benefits and alternatives and complications may occur irrespective of the intervention."

Capture the Fracture One fracture is bad enough, but two or three is, well, common in some places. The International Osteoporosis Foundation (IOF) is attacking this gap in fracture care with a new program—Capture the Fracture. Carey Kyer, science project manager for the IOF tells *OTW*, "Capture the Fracture will reduce secondary fractures by promoting the development of Fracture Liaison Services (FLS) worldwide. We are setting international standards for FLS, and have developed a Best Practice Framework (BPF), a set of 13 standards outlining the essential and aspirational components of a successful FLS. We are making the BPF a 'living' document by putting it into action through our program: 'Capture the Fracture Best Practice Recognition.' Via this program, FLS submit their system to Capture the Fracture, we assess it using the BPF and award the FLS a gold, silver or bronze achievement level in accordance with the BPF."

"The FLS is recognized on our web-based map which allows FLS the opportunity to showcase their achievements, lets policy makers/healthcare systems to see a visual representation of FLS services and service gaps worldwide, and serves as a resource. Among other things the Web site includes audits and surveys from around the world, implementation guides and toolkits, and future plans for a mentorship and grant program for developing systems."

As for measuring the program's success, Kyer stated, "Initially, we will track the uptake of our program and awareness of the campaign through map growth, i.e., tracking the number of FLS appearing on our map. We started with 10 and have grown to 32 since our launch in March. Success will also be measured by Web site hits/clicks, growth of FLS by country, and citations of Capture the Fracture in publications. Orthopedic surgeons can get involved by endorsing the program, joining the coalition of partners, submitting the FLS at their hospital to be recognized on the Capture the Fracture map, and using the BPF to implement an FLS at their hospital." ♦

Visit Us Online At:
www.centinelspine.com

Experience the
GOLD
STANDARD
In Integrated Interbody Fusion®

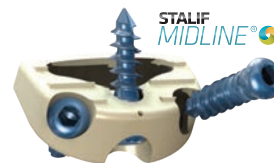
STALIF MIDLINE® & STALIF C®
No Profile® Integrated Interbody Fusion® Systems

Or Call: 484-887-8810

EASE OF IMPLANTATION.
SHORT OPERATIVE TIMES.
SEGMENTAL FIXATION.

These are just 3 of the many reasons why STALIF MIDLINE® & STALIF C® are considered the premier Integrated Interbody Fusion® devices.

STALIF MIDLINE® & STALIF C® are part of totally integrated systems, with implants and instruments designed to work in harmony to reduce surgical times. Utilizing Centinel Spine's™ highly aggressive ABO® anti-backout cancellous screws, the converging 3 screw design of both STALIF MIDLINE® & STALIF C® was engineered with the AO principles in mind to capture areas of concentrated bone density. The devices provide the maximum end plate / implant contact—allowing for "lag fixation". STALIF® devices are meant to rest on the apophyseal rim of the vertebral body, making them both true "no-profile".



Let us show you why your medically indicated DDD patients will benefit greatly from your use of the STALIF® family of Integrated Interbody Fusion® devices. For more information, contact Centinel Spine™ Customer Service at 484-887-8810.

from Centinel Spine™

Advertisement

company

DePuy Dumps Metal-on-Metal

DePuy Orthopaedics, Inc. is discontinuing the use of metal liners in the company's Ultamet metal-on-metal and Complete ceramic-on-metal hip systems.

Not a Recall

In a May 16, 2013 statement, the company said this is not a recall and the decision was made not out of safety concerns, but because of low clinician use of the systems and the availability of other options that meet the clinical needs of patients. The company also noted proposed changes in FDA regulations of the entire class of metal-on-metal products.

The discontinuation will be effective August 31, 2013 so surgeons will be able to plan accordingly for upcoming surgeries. The ceramic head used in Complete will continue to be available for use in other bearing surface combinations.

The discontinued metal liner was designed exclusively for use with DePuy's Pinnacle Acetabular Cup System. The Pinnacle Cup will not be impacted by the move.

Streamlining Portfolio

According to the company, the decision was made in conjunction with an ongoing review of DePuy's product portfolio. "Other worldwide product discontinuations will be announced throughout 2013 and 2014 that will simplify and streamline DePuy's portfolio by focusing on fewer, worldwide strategic product platforms."

DePuy Complete/DePuy Orthopaedics, Inc.

90% Decline in Sales

Clinician use of ceramic-on-metal and metal-on-metal bearings is extremely low and not expected to increase. In the U.S. and Europe in 2012, metal-on-metal bearings comprised less than 2% of the bearings implanted. This, according to the company, represents a 90% decline in industry sales since 2007. Industry sales of ceramic-on-metal bearings have been low since their introduction to the market. Ultamet and Complete now represent less than 1% of DePuy bearings sold in these markets.

Shifting Physician Preferences

The company noted advancements in polyethylene bearing technology and the recent approval of next generation options. "Physician preferences have shifted toward metal-on-polyethylene, ceramic-on-polyethylene and ceramic-on-ceramic [CoC] bearings," said the statement. The options include the newly approved DePuy Ceramax total hip system with Biolox delta ceramic-on-ceramic 36MM large femoral head for use with the Pinnacle system. The company says physician use of ceramic-on-ceramic bearings is widespread in Europe where, in 2012, CoC represented over one in five bearings used. The company believes CoC bearings also have considerable growth potential in the U.S. where new options are coming to market.

Regulatory Changes

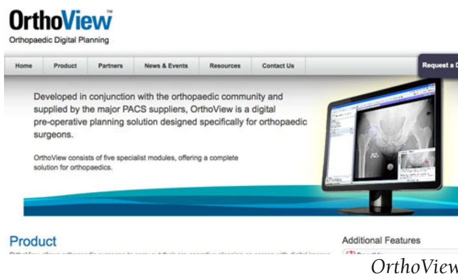
The regulatory changes noted by the company refer to the January announcement by the FDA that the agency plans to require all metal-on-metal hip replacements with existing 510(k) clearances to be approved through the Premarket Approval (PMA) process. Ultamet was first cleared for sale through the 510(k) process in 2000. DePuy has communicated to the FDA its decision not to pursue a PMA submission for Ultamet.

The company made no reference to ongoing metal-on-metal litigation.

—WE (May 17, 2013)

OrthoView Advances Pre-Operative Planning

OrthoView, a company providing digital pre-operative planning software, is announcing the launch of OrthoView PSL (private user license), a subscription-based OrthoView templating solution meant to ease the pre-operative planning process. According to the company, there *are* over 5,000 orthopedic surgeons in the U.S. now using OrthoView, and the software is installed worldwide in over 1,850 hospitals and clinics.



OrthoView

With OrthoView PSL orthopedic surgeons can make the decision to start creating their pre-operative plans by simply downloading the program; templating with digital images is possible within a matter of hours.

Currently only available to orthopedic surgeons in private practice in the U.S., OrthoView PSL is one of a range of purchase and licensing options available from OrthoView, LLC, based in Jacksonville, Florida.

OrthoView PSL is a single-user license without PACS connectivity. Digital x-ray images are imported into the solution from the surgeon's computer or a DICOM CD and the resulting plan can be printed or saved along with the images.

—EH (May 16, 2013)

legal

Nurse Practitioners, Docs at Odds

Board certified surgeons and pain interventionists aren't the only ones having a scope of practice argument over who is best qualified to treat patients.

While some orthopedic surgeons assert that the government is limiting residency slots and could force medical school graduates into primary care, a study reported in the May 16, 2013 issue of the *New England Journal of Medicine*, showed that doctors don't believe nurse practitioners provide the same quality of primary care.

Which raises the question of, if there is a need for more medical school graduates going into specialty residency slots, why would doctors not want nurse practitioners to take over some of the primary care burdens?

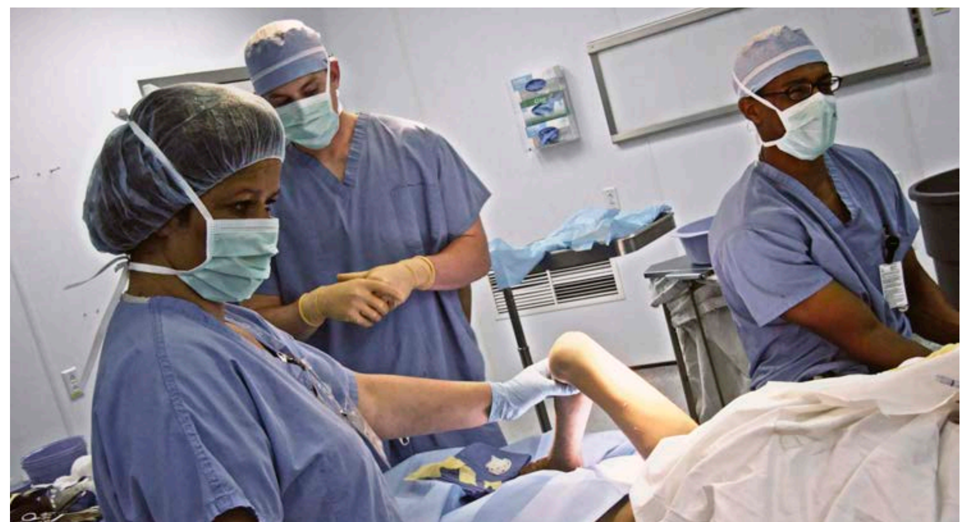
Quality of Care

Nearly 1,000 doctors and nurse practitioners were surveyed in the study. Most were divided on the question of who gives the higher quality of care: Two-thirds of physicians said if a doctor and nurse practitioner provided the same service, the doctor would do it better. The nurse practitioners didn't agree with that. Eighty-two percent of nurse practitioners felt they should lead their own practices, while only 17% of doctors did.

Nurse practitioners go through advanced education and training beyond the requirements to become a registered nurse. In about 16 states, they can do most of what doctors do—including heading their own primary care practices, prescribing drugs and performing medical procedures unsupervised. In other states, nurse practitioners may be required to work with a doctor.

Doctor Supervision

Some doctors' groups, including the American Medical Association and American Academy of Family Physicians, have said that nurse practitioners should be able to practice only under the supervision of a doctor. According to the American Association of Nurse Practitioners, bills have recently been



Wikimedia Commons

introduced in ten states to expand nurse practitioners' scope of practice.

Safety and Effectiveness

According to the survey, the majority of practitioners in both groups agreed that increasing the number of nurse practitioners would improve timeliness of care. However, less than a third of doctors said such an increase would boost safety or effectiveness of care. Nurse practitioners, on the other hand, overwhelmingly felt such an increase would improve care. Close to 81% thought the growth would improve access to health care for the uninsured and 77% said it would result in lower health care costs.

Equal Pay

The doctors and nurses also disagreed about whether nurse practitioners should be paid equally for providing the same health services. More than 64% of nurse practitioners agreed with the idea of equal pay, as opposed to less than 4% of doctors. With an estimated 25 million people gaining insurance under the health care law, nurse practitioners argue they can fill some of those needs if they are granted greater scope of practice.

Karen Donelan, Ed.M., ScD, an assistant professor of medicine at the Harvard School of Medicine and the study's lead author, reportedly said both sides need to "be at the table" in figuring out what primary care will look like in the future. "Achieving collaboration will take a lot of work, and it needs to be based on data rather than rhetoric."

—WE (May 17, 2013)

Bone Growth Stim Convictions Mount

The drip, drip, drip of former Orthofix, Inc. employees convicted of cheating Medicare to sell bone growth stimulator devices continues.

Hunter Rigsby Pleads Guilty

On May 14, 2013, the U.S. Attorney's Office in Massachusetts announced that Hunter Rigsby, a former territory manager, pled guilty to health care fraud and paying kickbacks from 2005 through 2011 while selling Orthofix bone growth stimulators in Tennessee.

According to the announcement, Medicare only pays for "long bone" stimulators when at least 90 days have elapsed without clinically significant healing, and it only covers certain types of injuries. Rigsby was well aware of these guidelines, having received training on these guidelines at Orthofix. On numerous occasions, doctors in Rigsby's territory ordered bone growth stimulators that did not satisfy Medicare's guidelines.

Forged Records and Physician Signatures

For instance, some doctors prescribed the device before 90 days had elapsed without any healing, and other doctors prescribed the device for patients who had injuries that were not covered under Medicare's guidelines. When this occurred, Rigsby often forged the patient's medical records to make it appear as though the claim was payable under Medicare's guidelines, when in fact Medicare should not have paid the claim. Rigsby falsified doctors' chart notes to make it appear as though Medicare's 90-day rule was satisfied.

Rigsby also deleted portions of physicians' chart note that described patients'

Morguefile and RRY Publications LLC

injuries which were not covered by Medicare and changed the note to make it appear as though the patients had injuries that were covered. On some occasions, Rigsby submitted orders where the physician had not ordered a bone growth stimulator at all. Rigsby also forged physicians' signatures on prescriptions and Medicare Certificates of Medical Necessity.

Fired, But Continues Fraud

Orthofix fired Rigsby in July 2009 after discovering the fraud.

Rigsby and Orthofix sales personnel then "devised a scheme" to allow Rigsby to continue to submit bone growth stimulator orders to Orthofix through a new front company that Rigsby created. Rigsby took numerous steps to conceal his affiliation with the front company so that Orthofix compliance personnel would not detect that he was still doing business with the company. Rigsby continued to submit orders for stimulators, sending the orders in through separate individuals.

Even though Rigsby had been fired for falsifying medical records, he continued to manipulate patient medical records and forge physicians' signatures until Orthofix finally severed its relationship with him in 2011. Through his scheme, Rigsby caused Medicare and other federal insurance programs to pay more than $400,000 for bone growth stimulators that should not have been paid.

Kickbacks

According to the announcement, Rigsby also paid kickbacks to health care professionals to induce them to order Orthofix stimulators. For instance, Rigsby paid the person who was responsible for ordering stimulators at one of the largest medical practices in Tennessee. Rigsby approached this person and asked if he could pay this person in return for steering stimulator orders to Orthofix. The person agreed, and Rigsby left an envelope with $200 in cash at the person's house. In another instance, Rigsby entered into an arrangement to pay a nurse in Morristown, Tennessee, each time that the surgeon who employed her ordered an Orthofix stimulator. Rigsby left an envelope of cash, between $200-$300, in the back of the nurse's truck after the surgeon began to order stimulators.

Conviction Scorecard

Six other individuals have been convicted and sentenced for committing fraud in relation to Orthofix bone growth stimulator sales. In December 2012, the company was convicted of obstruction of a federal audit and ordered to pay $42 million in criminal fines and civil payments, and was sentenced to probation for five years.

Sentencing is scheduled for August 9, 2013. The maximum penalty for health care fraud is ten years in prison, followed by three years of supervised release, a fine of $250,000 or twice the loss or gain resulting from the crime, whichever is greater, forfeiture, restitution, and a mandatory special assessment. The maximum penalty for paying kickbacks is five years in prison, followed by three years of supervised release, a fine of $250,000 or twice the loss or gain resulting from the crime, whichever is greater, forfeiture, restitution, and a mandatory special assessment.

—WE (May 17, 2013)

Why use a polymer barrier when natural covering is available?
We got you covered!
AmnioClear
FROM
AFcell
For more information
www.afcellmedical.com
Advertisement

biologics

Natural Fibers Good Stem Cell Matrix

Stem cells need a partner if they are to be biologically effective as regenerators of cartilage tissue. University of Bristol researchers in the United Kingdom believe they may have found that partner. In a study published in *Biomacromolecules* they explored the feasibility of using naturally occurring fibers such as cellulose and silk for stem cell scaffolds—the matrix to which stem cells can cling as they grow.

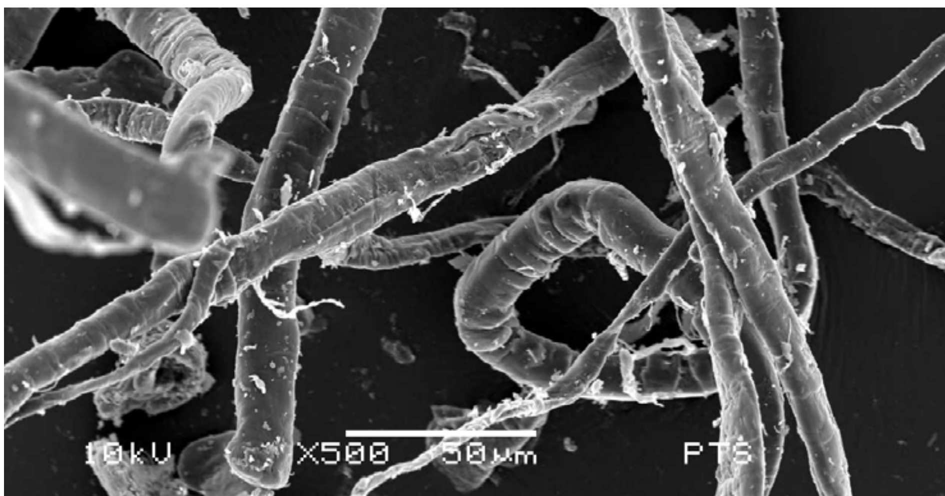
The team treated blends of silk and cellulose for use as a tiny scaffold that allows adult connective tissue stem cells to form into a preliminary form of chondrocytes—the cells that make healthy tissue cartilage—and secrete extracellular matrix similar to natural cartilage.

Wael Kafienah, M.D., lead author from the University's School of Cellular and Molecular Medicine, said: "We were surprised with this finding, the blend seems to provide complex chemical and mechanical cues that induce stem cell differentiation into preliminary form of chondrocytes without need for biochemical induction using expensive soluble differentiation factors. This new blend can cut the cost for health providers and makes progress towards effective cell-based therapy for cartilage repair a step closer."

Sameer Rahatekar, Ph.D., lead author from the University's Advanced Composite Centre for Innovation and Science, added: "We used ionic liquids for the first time to produce cellulose and silk scaffolds for stem cells differentiation. These liquids are effective in dissolving biopolymers and are environmentally benign compared to traditional solvents used for processing of cellulose and silk."

The teams are currently working on the fabrication of 3D structures from the blend suitable for implantation in patients' joints. Future studies will focus on understanding the peculiar interactions between the blend and stem cells towards refining the quality of the regenerated cartilage. Over 20 million people in Europe suffer from osteoarthritis which can lead to extensive damage to the knee and hip cartilage.

—*BY (May 13, 2013)*



Wikimedia Commons and Setral Chemie GmbH

InQu® BONE GRAFT EXTENDER & SUBSTITUTE

THE NATURAL SYNTHETIC

Natural Approach.
Natural Result.

- Unique polymer-hyaluronic acid base
- Supports endochondral bone formation* in the spine
- Biomechanically and radiographically equivalent to autograft
- Available in multiple configurations Paste Mix PLUS | Matrix | Granules

Bio meets synthetic.
That's the power of InQu®

1-888-705-ISTO (4786)
www.istotech.com

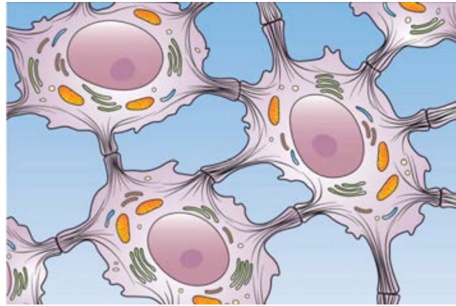
InQu is a registered trademark of ISTO Technologies, Inc.
U.S. Patent No. 8,192,759

* Walsh WR, Oliver RA, Gage G, et al. Application of resorbable poly (lactide-co-glycolide) with entangled hyaluronic acid as an autograft extender for posterolateral intertransverse lumbar fusion in rabbits. *Tissue Eng* Part A. 2011;17:213-220.

Advertisement

Researchers Create Bone From iPS Skin Cells

A group of scientists from the New York Stem Cell Foundation Research Institute (NYSCF) has succeeded in generating patient-specific bone substitutes from skin cells for the repair of large bone defects. The researchers took skin cells and, utilizing an advanced technique called "reprogramming," turned the adult skin cells back into an embryonic-like state. (These induced pluripotent stem cells (iPS) carry the same genetic information as the patient and can become any of the body's cell types.)


Wikimedia Commons and Holly Fisher

The team then guided these cells to become bone-forming progenitors and seeded them onto a scaffold for three-dimensional bone formation. They placed the seeded scaffold into a device called a bioreactor, which provides nutrients, removes waste, and stimulates maturation, mimicking a natural developmental environment. Darja Marolt, Ph.D., and Giuseppe Maria de Peppo, Ph.D., both research fellows of NYSCF, led the study which was published in the *Proceedings of the National Academy of Sciences of the USA.*

"Bone is more than a hard mineral composite; it is an active organ that constantly remodels. Blood vessels shuttle important nutrients to healthy cells and remove waste; nerves provide connection to the brain; and bone marrow cells form new blood and immune cells," said Marolt. The scientists believe that their study represents a major advance in potentially creating personalized reconstructive treatments for patients with bone defects resulting from disease or trauma.

Previous studies demonstrated the bone-forming potential from other cell sources, yet serious caveats for clinical translation remained. A patient's own bone marrow stem cells can form bone and cartilaginous tissue but not the underlying vasculature and nerve compartments. And embryonic stem cell derived bone may prompt an immune rejection. Therefore the NYSCF scientists chose to work with iPS cells to overcome these limitations.

—BY (May 13, 2013)

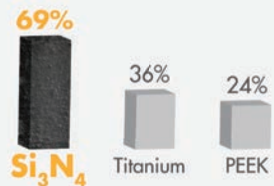
Interbody fusion,
ASAP
Si_3N_4

Call 855.839.3500 or visit us at www.amedica.com
to discover why material matters.

AMEDICA®
rethink what's possible®

In the race to achieve fusion, material matters. And, unlike spacers made of PEEK or titanium, Silicon Nitride (Si_3N_4) interbody fusion devices feature a demonstrated ability to achieve superior new bone growth and osteointegration, along with proven anti-infective properties and enhanced imaging attributes. All to help you attain and confirm fusion faster than ever before.

Valeo® OL
Interbody Fusion Device



Percent of new bone around implant at 90 days[1]

REFERENCE: 1. Webster TJ, Patel AA, Rahaman MN, Sonny Bal B. Anti-infective and osteointegration properties of silicon nitride, poly(ether ether ketone), and titanium implants [published online ahead of print July 31, 2012]. *Acta Biomater*. http://dx.doi.org/10.1016/j.actbio.2012.07.038. Accessed September 12, 2012.

©2012. AMEDICA Corporation All Rights Reserved. Document #402038

Advertisement

large joints

New Slippery Polymer for Joint Injections?

Creaking joints may get some longer lasting lubricant from work done by biomedical engineering Professor Mark W. Grinstaff and his colleagues at Boston University. They have developed a new synthetic polymer that works like synovial fluid, the natural lubricant in joints.

"From our studies, we know our biopolymer is a superior lubricant in the joint, much better than the leading synovial fluid supplement, and similar to healthy synovial fluid," said Grinstaff. "When we used this new polymer, the friction between the two cartilage surfaces was lower, resulting in less wear and surface-to-surface interaction. It's like oil for the joints." Grinstaff explained that the best fluid supplement now available offers temporary symptom relief but provides inadequate lubrication to prevent further degradation of the cartilage surfaces that cushion the joint.

"You put it between your fingers, and it's slippery," Grinstaff observed. "Once we made it, we wondered if we could use it as a lubricant and where it would be useful. That's how we thought of using it as a potential treatment for osteoarthritis." He said that a characteristic of the biopolymer is its large molecular weight or size, which prevents it from seeping out of the joint, enabling longer lasting cartilage protection. Unlike the leading synovial fluid supplement, which lasts one or two days, he added, the new polymer remains in the joint for more than two weeks.

The most common form of joint disease and a leading cause of disability in the elderly is osteoarthritis. It presently affects about 27 million Americans and 200 million people worldwide. The ailment is characterized by pain and swelling of the hands, hips, knees and other joints where degradation of cartilage and synovial fluid results in bone-on-bone abrasion. While there's no cure, one treatment—injection of a polymer to supplement synovial fluid in the joint—promises to relieve symptoms and slow the disease's progression by reducing wear on cartilage surfaces.

Wikimedia Commons and Michael Perekas

—BY (May 13, 2013)

Weight Gain Likely Following Knee Arthroplasty

As if getting a new knee was not traumatic enough, a new study indicates that a significant post-surgery weight gain is likely to follow. Nancy Walsh, staff writer for *MedPage Today,* reports May 1 that on an adjusted multivariable analysis, recipients of knee arthroplasty were 60% more likely to gain 5% or more of their baseline body weight than were matched controls who did not have the procedure. The weight gain took place over a five-year postoperative period. Daniel L. Riddle, Ph.D., of Virginia Commonwealth University in Richmond, Virginia and his colleagues conducted the study.

Wikimedia Commons and Alisdair Maclean

Individuals who had a second arthroplasty during the subsequent five years found that the chance of experiencing that "clinically important" weight gain doubled. Riddle and his colleagues analyzed outcome data for 917 patients in the Mayo Clinic arthroplasty registry. They matched them with 237 controls from the population-based Rochester Epidemiology Project. A total of 205 of the 917 Mayo patients had a second lower-limb or hip arthroplasty procedure.

The subjects' baseline weight was 89.1 kg (196 lbs) in the arthroplasty group and 76.3 kg (168 lbs) in the control

group. Two-thirds of the subjects were women. Walsh noted that during the first year after the surgery, 22.1% of patients gained 5% or more of their body weight, compared with 16% of the controls. In the fourth year, 32.3% of the surgery patients had that percentage weight gain, as did 22.8% of the controls.

Prior to conducting their study the researchers reasoned that, "The logical assumption may be that persons who are overweight or obese prior to surgery are more likely to lose weight following surgery. Because there is less pain and improved mobility, the impediments to increased activity and exercise are eased following surgery, and weight loss would logically follow." Obviously, they were wrong in their assumptions.

Walsh reported that in the five years after the index date, the controls averaged a mean weight loss of 0.35 kg (0.77 lbs.), while those who had just one arthroplasty gained an average of 1.23 kg (2.7 lbs.). Those patients who had a second arthroplasty experienced a mean weight gain of 2.62 kg (5.77 lbs.).

—BY (May 13, 2013)

trauma

Limbs Will Be Spared: New Clamp Approved

The Combat Ready Clamp, a vise-like tourniquet, has just received new critical indications from the FDA making it the first device of its kind approved to treat unmanageable amputations and pelvic wounds not addressable with standard limb tourniquets. The Combat Ready Clamp is a now approved for use on all five anatomical junctions where life-threatening hemorrhage can occur in the result of such actions as roadside and terrorist bombings. Uncontrolled bleeding is the leading cause of preventable death in combat and remains the top focus of tactical medicine.

Combat Medical Systems, manufacturer of the Combat Ready Clamp, has worked extensively with the U.S. Army's Institute for Surgical Research (USAISR) in San Antonio, Texas, and with the Wake Forest University Baptist Medical Center in Winston Salem, North Carolina, to ensure the device's clinical efficacy.

"The Combat Ready Clamp is the first device available to treat junctional hemorrhage of the upper extremity on the battlefield or anywhere else, and Combat Medical Systems continues to lead the way in the best care for the nation," said Dr. John Kragh of the U.S. Army, in the May 7, 2013 news release. "We in the military also continue to be impressed with their team which includes Wake Forest University in their commitment to the best care for these casualties."

The Committee on Tactical Combat Casualty Care (CoTCCC) recommends the device, which applies in seconds. It has already shown life saving success in limited use in Afghanistan as well as multiple Life Flight cases in the U.S.

"Everyone at Combat Medical Systems is excited about this recent news," said Chris Murphy, vice president of research and development. "This has certainly been a team effort. The support we have received from the USAISR and Wake Forest University has been invaluable in our efforts to deliver this one-of-a-kind device. But it is the early adopters, the military leaders and most importantly our great military medics and corpsman that serve our fallen every day that deserve the most credit."

Combat Medical Systems, headquartered in Fayetteville, North Carolina, was founded in 2008 by a team of experienced military medical personnel and industry product specialists with a mission to simplify tactical medicine.

—EH (May 14, 2013)

Combat Medical Systems

reimbursement

Best Chance for Doc Fix

Improving federal government finances may open a brief window to overhaul Medicare's flawed physician payment system.

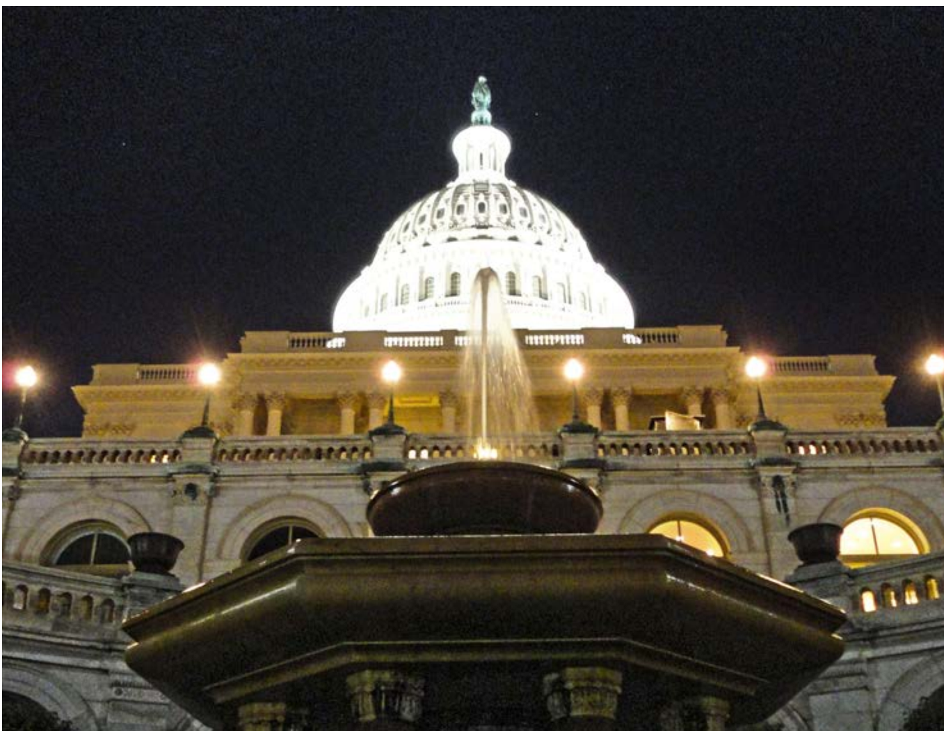
In the midst of rising government revenue from tax collections and bailout paybacks shrinking the federal deficit faster than expected, the Democrat chair and Republican leader of the Senate Finance Committee, Max Baucus and Orrin Hatch, sent letters to providers on May 10, 2013, asking questions about repealing and replacing the sustainable growth rate (SGR).

"Our ultimate goal is for Medicare to pay physicians and other healthcare providers in a way that results in high quality, affordable care for seniors," the senators wrote. "We support identifying alternative models, including those being currently tested, with a clear recognition that these will take time to develop and scale."

Shrinking Deficit

The previous day, Fannie Mae, the mortgage finance giant that got a boatload of taxpayer aid during the recession, said it would pay back $59.4 million to the government in dividends at the end of June. Freddie Mac also said it would pay back at least $7 billion. That along with a 16% increase in tax collections from higher tax rates is resulting in a federal deficit for the first seven months of the government's fiscal year that's $231 billion less than the deficit a year ago, according to the Congressional Budget Office. That's more than enough to pay for a "doc fix."

The stock market is up, housing prices are rising, consumer confidence is swelling and the number of new workers seeking unemployment benefits has fallen to prerecession levels. Money is so cheap that the government was able to borrow money in early May at no cost for the first time in 17 months and congressional budget auditors recently lowered the price tag for repealing the SGR from over $200 billion to just $138 billion.



Wikimedia Commons and M. Fitzsimmons/U.S. Capitol

Structural and Behavioral Changes

Baucus and Hatch asked providers how Medicare can incentivize providers to "undertake the structural, behavioral, and other changes" necessary for a transition to performance-based payments. "We must improve the current system to ensure that it makes appropriate payments for physician services, reduces unnecessary utilization and improves quality while also easing the transition to new payment models," the senators wrote.

Since the SGR was created by the Balanced Budget Act of 1997, Congress has "patched" mandatory cuts required by the Act. Congress passed the most recent patch on January 1, 2013, as part of the American Taxpayer Relief Act of 2012. The one-year fix cost $25 billion. That patch freezes fees until January 1, 2014, when fees are scheduled to be cut by 26.5%.

The House of Representatives has already acted to fix the SGR, but those efforts have been largely ceremonial and political posturing since their bills have little chance of being heard in the Democratic controlled Senate or signed by the President. This effort by bipartisan Senate leaders has the feel of a serious legislation that can pass the Senate and gain support from the White House.

—WE (May 13, 2013)

Health Spending Slowdown Continues

The nation's health care piggy bank is looking a little better. Health care spending growth slowed in the U.S. by more than $500 billion between 2003 and 2012. If trends continue for the next decade, current projections of spending may be too high by $770 billion.

That's according to two recent studies published in *Health Affairs* (*Health Affairs* May 2013 vol. 32 no. 5.)

Spending Growth Slowdown

The first study led by Harvard Professor Michael Chernew, says that "current trends support cautious optimism that the spending slowdown may persist—a change that, if borne out, could have a major impact on U.S. health spending projections and fiscal challenges facing the country, among other factors."

According to the article abstract, during and immediately after the recent recession, national health expenditures grew exceptionally slowly. During 2009–2011 per capita national health spending grew about 3% annually, compared to an average of 5.9% annually during the previous ten years. Chernew says policy experts disagree about whether the slower health spending growth was temporary or represented a long-term shift.

The study examined two factors that might account for the slowdown: job loss and benefit changes that shifted more costs to insured people. Based on an examination of data covering more than ten million enrollees with health care coverage from large firms in 2007–2011, the authors found that "these enrollees' out-of-pocket costs increased as the benefit design of their employer-provided coverage became less generous in this period. We conclude that such benefit design changes accounted for about one-fifth of the observed decrease in the rate of growth. However, we also observed a slowdown in spending growth even when we held benefit generosity constant, which suggests that other factors, such as a reduction in the rate of introduction of new technology, were also at work.

Wikimedia Commons and GeorgHH

"Our findings suggest cautious optimism that the slowdown in the growth of health spending may persist—a change that, if borne out, could have a major impact on U.S. health spending projections and fiscal challenges facing the country."

Future Savings

The second study led by Harvard Professor David Cutler found that despite earlier forecasts to the contrary, U.S. health care spending growth has slowed in the past four years, continuing a trend that began in the early 2000s.

The study attempted to identify why U.S. health care spending growth has slowed, and explored the spending implications if the trend continues for the next decade.

The researchers found that the 2007–2009 recession, a one-time event, accounted for 37% of the slowdown between 2003 and 2012. A decline in private insurance coverage and cuts to some Medicare payment rates accounted for another 8% of the slowdown, leaving 55% of the spending slowdown unexplained.

They concluded that a host of fundamental changes—including less rapid development of imaging technology and new pharmaceuticals, increased patient cost sharing, and greater provider efficiency—were responsible for the majority of the slowdown in spending growth. "If these trends continue during 2013–22, public-sector health care spending will be as much as $770 billion less than predicted. Such lower levels of spending would have an enormous impact on the U.S. economy and on government and household finances."

This looks like good news for payers and device makers who have stabilized their business models. The impact on patients and providers is yet to be determined.

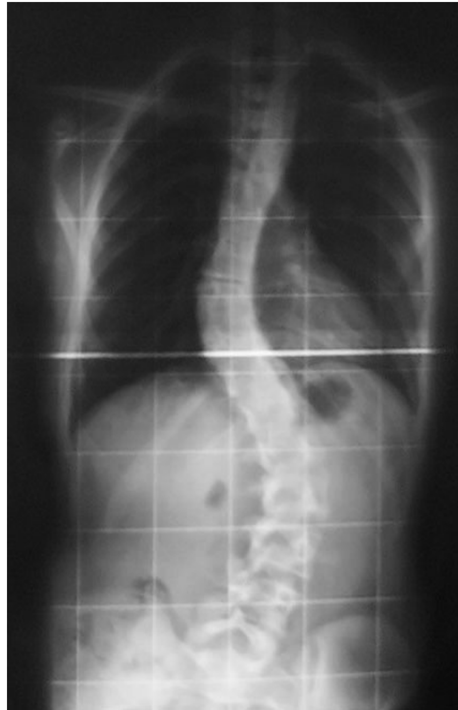
—WE (May 13, 2013)

spine

Adolescent Scoliosis: First Gene Discovered

Big news from Japan…Researchers from the RIKEN Center for Integrative Medical Sciences have identified the first gene to be associated with adolescent idiopathic scoliosis (AIS) across Asian and Caucasian populations. The gene is involved in the growth and development of the spine during childhood. Dr. Ikuyo Kou and Dr. Shiro Ikegawa have just published their work in the journal Nature Genetics.

By studying the genome of 1,819 Japanese individuals suffering from scoliosis and comparing it to 25,939 Japanese individuals, the team identified a gene associated with a susceptibility to develop scoliosis on chromosome 6.



Caption: Posterior-to-anterior X-ray of a case of adolescent idiopathic scoliosis

Image Credit: Wikimedia Commons and Silverjonny

The association was replicated in Han Chinese and Caucasian populations.

The researchers show that the susceptibility gene, GPR126, is highly expressed in cartilage and that suppression of this gene leads to delayed growth and bone tissue formation in the developing spine. GPR126 is also known to play a role in human height and trunk length.

“Our finding suggest the interesting possibility that GPR126 may affect both AIS susceptibility and height through abnormal spinal development and growth,” explain the authors in the May 12, 2013 news release.

“Further functional studies are necessary to elucidate how alterations in GPR126 increase the risk of AIS in humans,” they conclude.

—EH (May 13, 2013)

primaLOK SP
INTERSPINOUS FUSION SYSTEM

brilliantly **Engineered.**
simply **Executed.**

Many patients simply don't need the complexity and risk potential associated with other lumbar fixation methods, like pedicle screws. Learn the facts behind how our **minimally-invasive PrimaLOK SP** Interspinous Fusion System can fit into your surgical plan.

Visit **www.osteomed.com** for patient indications, clinical benefits of our advanced design features, new MIS instrument options, and much more.

OSTEOMED - SPINE | 800.456.7779 | www.osteomed-spine.com | info@osteomed-spine.com

Advertisement

people

David Buche COO of AFCell Medical

AFcell Medical, Inc., a designer and supplier of birth tissue forms under its AmnioClear brand, has hired David Buche as Chief Operating Officer. Buche comes to AFCell Medical with over 25 years experience in the biologics and medical device industry.

Most recently he was vice president for marking and product development instruments of Integra LifeSciences Corporation where he headed the $180 million division. Prior to joining Integra, Buche was vice president and chief operating officer of a 170 employee division of Synovis Life Technologies, Inc. During his 15 year tenure at Synovis, he led consistent growth by driving biological products to market and leading the commercialization of a new regenerative biological technology platform.

Before going to Synovis, Buche held sales and marketing positions for Spectranetics Corporation. He served in the U.S. Navy and earned degrees from the Carlson School of Business, University of Minnesota and California Coast University.

Robin Young, founder and CEO of AFcell Medical said, "David Buche's extensive experience bringing biologic products to market and commercializing regenerative biologic technology platforms fits well with AFcell Medical's culture of innovation for general surgery, wound care and orthopedic indications."

Buche joins AFcell a few weeks after AFcell's board of directors elected Olivier Carli its new chairman. Carli is the president of Denos, Ltd. and founder of Ideal Medical, one of the largest health care service companies in the world. Companies which Carli has founded or led have all become market leaders in more than 64 countries around the world.

David Buche/AFcell Medical, Inc.

—BY (May 13, 2013)

2013 Orthopedics This Week Spine technology Awards
Biomaterials and Biologics
Cervical Care
Diagnostics and Imaging
Minimally Invasive Spine Care
Thoracolumbar Care

2013 SPINE TECHNOLOGY AWARDS
Submissions deadline: August 10, 2013
Awards to be presented: October 10, 2013
For more information visit: spineawards.com

Advertisement

PearlDiver
unfathomably deep data retrieval

Remember the feeling when the data just clicks in place? Markets reveal themselves. Opportunity and risk have measurable dimensions. PearlDiver MAPS markets using actual coded procedures from today's surgeons, hospitals and payers. Isn't it time for real market data?

REAL DATA. REAL REIMBURSEMENT. SOLID MARKET STUDIES.

pearldiverinc.com | scott@pearldiverinc.com | (260) 468-3636

Orthopedics This Week

VOLUME 9, ISSUE 16 | MAY 21, 2013

Orthopedics This Week | RRY Publications LLC

Main Contact Information:
RRY Publications LLC
116 Ivywood Lane • Wayne, PA 19087
TOLL FREE: 1-888-749-2153
Fax: 610-260-6451

Robin R. Young, CFA
Editor and Publisher
robin@ryortho.com

Elizabeth Hofheinz, M.P.H., M.Ed.
Senior Writer
elizabeth@ryortho.com

Walter Eisner
Senior Writer
walter@ryortho.com

Biloine W. Young
Writer
bgwy@msn.com

Tom Bishow
Vice President of Sales
tom@ryortho.com

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Email, Web and
Conference Coordinator
jayme@ryortho.com

Dana Bader
Graphic Designer
dana@ryortho.com

Don't miss your chance!
Advertise with Orthopedics This Week

Click Here for more details or email tom@ryortho.com
Tom Bishow | 410.356.2455 (office) or 410.608.1697 (cell)