VOLUME 9, ISSUE 15 | MAY 14, 2013

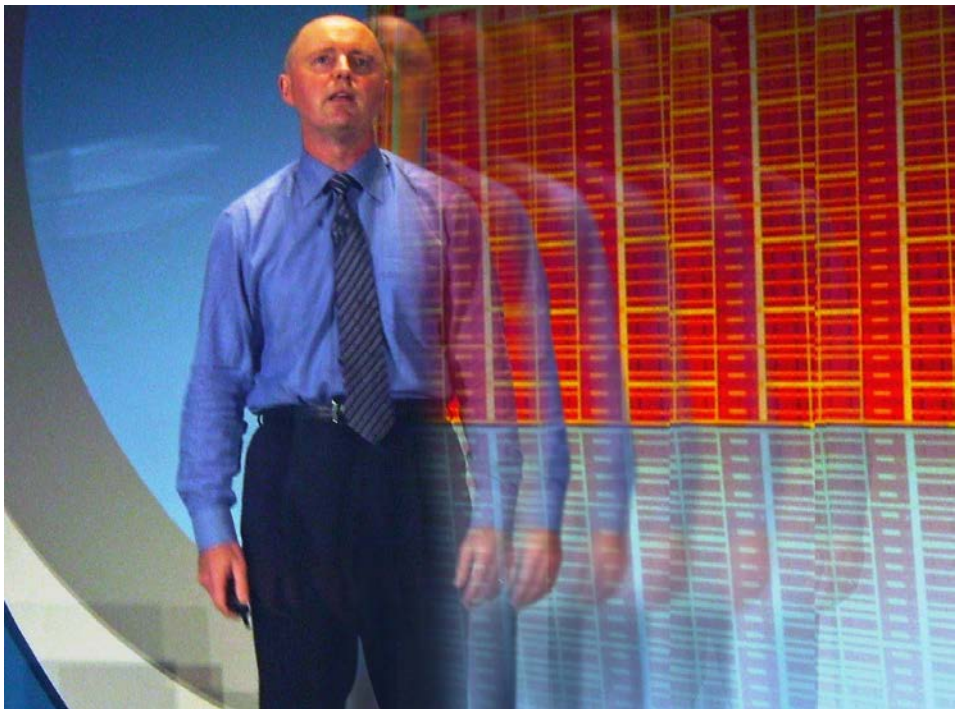
Orthopedics This Week

week in review

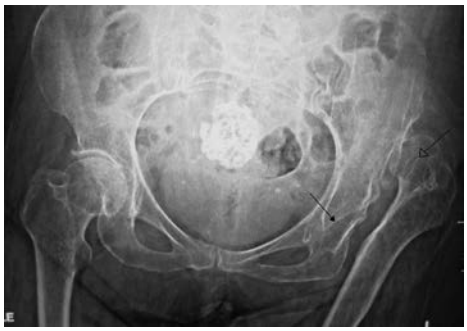
4 Death of the Device Salesman ♦ As if orthopedic device sale reps don't have enough to worry about, Wright Medical's CEO, Robert Palmisano announced on April 30, that the company would now be marketing and selling their orthopedic devices directly to the hospital's paymasters. Read the details here.

8 NEW Smart Memory Nail Changes Shape–*in-vivo!* ♦ A great deal of force can be produced by preventing NiTiNOL from returning to its original shape. In an intramedullary nail NiTiNOL creates constant compressive forces during bone remodeling. Cool, yes? See it this week at AOFAS. Or here, in *OTW.*

12 Here Come the Quality Police ♦ Three aspects of CMS' proposed payment system stand out to us. First orthopedics did ok, not great, but ok. Second the quality police are coming and 25% of all hospitals can expect to be penalized. And finally, the definition of "inpatient" is being tweaked. Oh, oh.



16 Government Forcing Orthopods Into Primary Care? 500th O-Arm Installed and Genetics of Hip Dysplasia Decoded ♦ A disconnect between the number of medical school graduates and residency slots means the government could force orthopedic surgeons into primary care. Medtronic Spine installs its 500th O-Arm using GPS-like mapping. Javad Parvizi, M.D. saysEureka!, finds THE gene for hip dysplasia…and more.



breaking news

19 Surgeon Transplants Shin Bone With Meniscus

DePuy's Ceramic Hip Gains FDA Supplemental Approval

NuVasive Goes Vertical in Manufacturing

SpinalMotion's Kineflex to FDA Panel in July

CMS Lifts Veil From Hospital Charges

Zimmer Cuts Jobs in Warsaw

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Ok, What's wrong with this picture? Deficit is declining due to recently raised taxes and spending cuts. The U.S. government just sold bonds at 0% interest. Free money. U.S. is nearly energy independent. CMS raised reimbursement rates for most ortho procedures. Dow is hitting record highs. Every headline is bullish. Where's the cloud in this silver lining? It's there somewhere.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Globus Medical	29.54%	(0.98%)	Short-sighted sellers. Want to know how to make money in medical technology? Follow cash flow. GMED is exhibit A.
2	3	Zimmer	29.49	4.67	Hits 52-week high and P/E is less than S&P P/E. Also 2nd lowest P/E in ortho—yet still kicks out 29% (of sales) profits.
3	5	NuVasive	7.53	6.18	Buyers really do like Alex and Co. Will recent ANC purchase raise gross margins? Key for NUVA is EPS growth.
4	2	Johnson & Johnson	25.58	4.56	JNJ's dividend expected to grow 8.2% annually for the foreseeable future. With a yield of 3.10%, it's better than the bank.
5	4	Stryker	23.68	2.20	Like ZMH, SYK also hit a 52-week high. But SYK's equity is more expensive than ZMH despite earning less on sales. Seems counter intuitive.
6	6	Medtronic	28.65	4.09	While ZMH has the lowest future P/E in ortho, MDT is 2nd lowest. Means MDT is a cheap stock. Why? Lagging sales growth.
7	10	Orthofix	19.68	(25.16)	This is a big fat gimme. Unloved, unwanted. Big sell off. But fundamentals are improving. Come to daddy!!
8	7	Wright Medical Group	(0.35)	3.23	Beat the Street's estimates in the most recent quarter. Is beginning to feel like an undiscovered value to investors.
9	8	Conmed	11.20	(4.79)	CNMD's past moves have set the company up for higher operating margins. In Q1, they increased 70 basis points.
10	9	Alphatec	(4.29)	(14.01)	Smart investors always look at management first. ATEC's Les Cross is reason enough to bet on ATEC.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	$6.50	$624	35.42%
2	Bacterin Intl Holdings	BONE	$0.84	$36	11.48%
3	RTI Biologics Inc	RTIX	$4.18	$235	8.32%
4	MAKO Surgical	MAKO	$12.20	$573	8.25%
5	NuVasive	NUVA	$22.52	$996	6.18%
6	Zimmer Holdings	ZMH	$79.39	$13,366	4.67%
7	Johnson & Johnson	JNJ	$85.76	$240,890	4.56%
8	Medtronic	MDT	$49.17	$49,849	4.09%
9	Wright Medical	WMGI	$24.60	$1,149	3.23%
10	Stryker	SYK	$68.21	$25,724	2.20%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Orthofix	OFIX	$26.44	$514	-25.16%
2	Symmetry Medical	SMA	$10.43	$389	-17.87%
3	Alphatec Holdings	ATEC	$1.78	$172	-14.01%
4	TranS1	TSON	$1.91	$52	-13.57%
5	TiGenix	TIG.BR	$1.02	$103	-11.83%
6	Tornier N.V.	TRNX	$16.66	$773	-8.91%
7	Exactech	EXAC	$18.09	$243	-8.59%
8	Integra LifeSciences	IART	$35.48	$996	-7.56%
9	Conmed	CNMD	$32.37	$909	-4.79%
10	Globus Medical	GMED	$15.20	$1,399	-0.98%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$26.44	$514	10.29
2	Zimmer Holdings	ZMH	$79.39	$13,366	12.78
3	Globus Medical	GMED	$15.20	$1,399	13.32
4	Medtronic	MDT	$49.17	$49,849	14.01
5	Smith & Nephew	SNN	$59.06	$10,709	14.69

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$22.52	$996	59.26
2	Symmetry Medical	SMA	$10.43	$389	35.97
3	RTI Biologics Inc	RTIX	$4.18	$235	24.59
4	ArthroCare	ARTC	$34.86	$983	22.78
5	Exactech	EXAC	$18.09	$243	18.09

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$26.44	$514	0.82
2	Globus Medical	GMED	$15.20	$1,399	0.89
3	Exactech	EXAC	$18.09	$243	1.29
4	Conmed	CNMD	$32.37	$909	1.34
5	Zimmer Holdings	ZMH	$79.39	$13,366	1.35

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$22.52	$996	4.78
2	CryoLife	CRY	$6.23	$171	4.33
3	Symmetry Medical	SMA	$10.43	$389	3.00
4	Johnson & Johnson	JNJ	$85.76	$240,890	2.62
5	Medtronic	MDT	$49.17	$49,849	2.15

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.78	$172	0.88
2	Symmetry Medical	SMA	$10.43	$389	0.95
3	Exactech	EXAC	$18.09	$243	1.08
4	Bacterin Intl Holdings	BONE	$0.84	$36	1.08
5	Orthofix	OFIX	$26.44	$514	1.11

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.02	$103	25.17
2	MiMedx Group	MDXG	$6.50	$624	23.05
3	MAKO Surgical	MAKO	$12.20	$573	5.58
4	Globus Medical	GMED	$15.20	$1,399	3.63
5	Johnson & Johnson	JNJ	$85.76	$240,890	3.58

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

Death of the Device Salesman

By Walter Eisner

"The Death of the Salesman? Change Coming to Ortho Sales Model," was the provocative headline of Bank of America analyst Bob Hopkins' investor note on May 1, 2013.

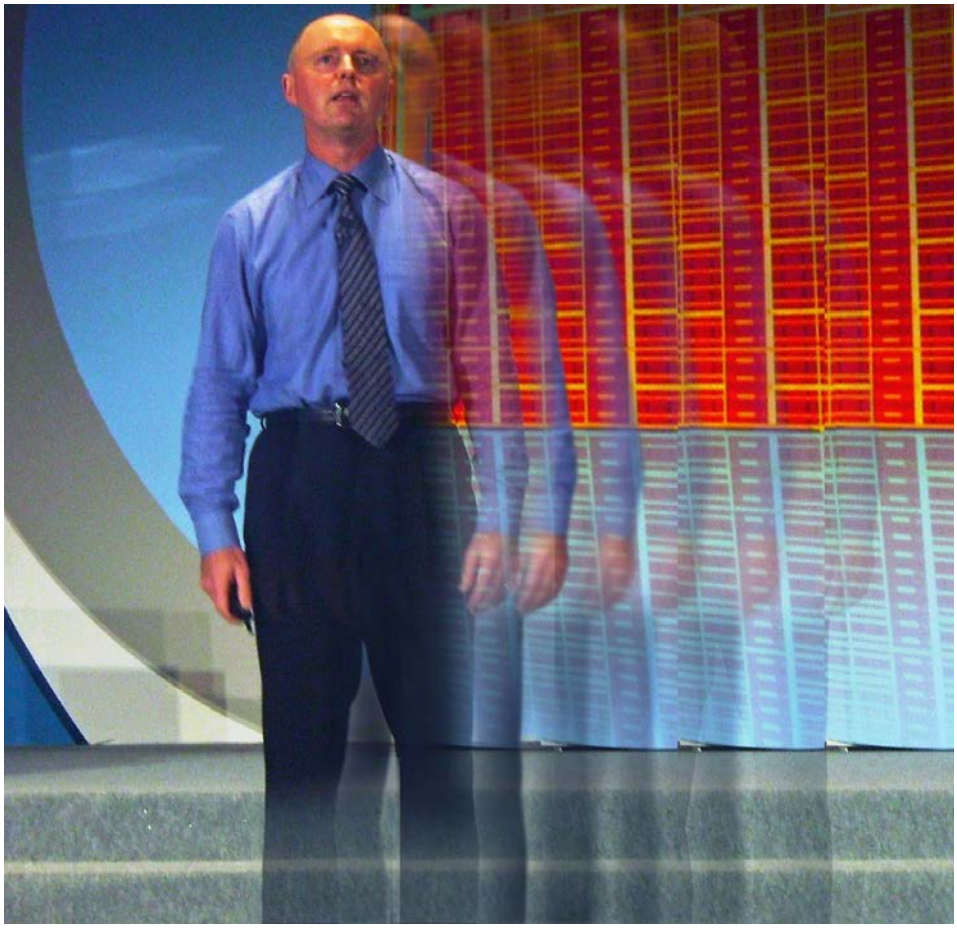
Robert Palmisano, CEO, Wright Medical Technologies, Inc.

Hopkins was referring to the April 30 announcement by Wright Medical Technologies, Inc.'s CEO Robert Palmisano that Wright is beginning to sell their orthopedic devices directly to hospitals without using sales reps.

Disintermediation

The news continues a story of changing dynamics in the sales and marketing of orthopedic devices. We like the term "disintermediation." It was only a couple of years ago since the then-CEO of Medtronic, Inc., Bill Hawkins, declared the end of the surgeon champion era as the company shifted its sales focus from surgeons to hospital paymasters.

Device reps caught in that changing dynamic have also had to deal with the rise of physician-owned distributorships which further impacted their value in the distribution chain.



Wikimedia Commons and Rico Shen

Palmisano's announcement added another chapter (or nail in the coffin) to the disintermediation story.

Wright Direct

During a call with analysts, Palmisano announced the early stages of a new program called Wright Direct. In short, the program sells certain orthopedic devices directly to hospitals and requires them to own and manage the inventory. He said the program is taking advantage of changing dynamics in U.S. healthcare and the resulting cost pressures being faced by many hospitals.

"Hip and knee replacement procedures are one area where a growing segment of hospitals are looking for a comprehensive solution to help solve this problem. This creates a compelling opportunity for a device company such as Wright that can offer a total solution, including high-quality, clinically-proven products at low prices, training and logistic support."

Wright had a similar program a couple of years ago. Palmisano told analysts that program "didn't work all that well," because it wasn't complete enough.

Institutional-Driven Purchasing

This time the company studied the market and saw a movement to institutionally driven purchasing decisions as opposed to physician-drive decisions. Wright hired Mitt Romney's old company, Bain & Company, to help figure out how to segment the 6,000 hospital market in the U.S.

The report came to the conclusion that about 10% of the U.S. hip and knee procedure market is institutionally driven. That, according to Palmisano, is up from about 5% only two or three years ago. And it's looking to be 15% to 20% in the next couple of years. "So there's a clear drift towards institutions gaining more control over the purchasing decisions."

He noted that institutions are controlling more of the physicians by buying physician practices and gaining alignment in the institution to make sure that they operate more profitably.

Price Reduction

The Wright Direct program is a turnkey operation where an institution takes over the responsibilities that are currently borne by the company.

For example, currently there's a rep in every case. Under the Wright program, that won't be the case. Also, currently inventory is held by the distributor or the company. In the Wright program, the inventory will be held by the institution. In return there would be a price negotiated meant to compensate the institution for taking on their additional costs.

Palmisano said he thinks Wright is particularly well situated to do this because this would not conflict with the company's other business (such as extremities and biologics). "We do not have a lot of business today in these institutions that will be cannibalized as other companies might. So I think that this is Wright healthcare going lower-cost. We will be able to provide very clinically proven, very effective products, and the institution would take over some of the logistics and some of the in-case support. And it will turn out to be a win-win between us and the institution."

The company is just launching the program as it builds an organization that is

used to calling on hospital CEOs and CFOs instead on physicians. "We're building an organization that knows the ins and outs of the C-Suite in hospitals."

Wright has most of the people hired and expects to start seeing the effects of this later in the year. The company also has a couple of pilot programs up and running. Palmisano said they've gotten a "very good" reception to the concept and it's a matter of having the people on the ground. "We don't want to go too fast and just try to get some quick sales. The object is to be a long-lasting business solution to institutions."

Dividing Up Savings

How will the commission structures change for distributors?

During a question and answer session with analysts, Palmisano acknowledged that 10-15% on the dollar for these implants is paid out on the commission for sales and distribution. He was asked if that's the 10-15% that the company will be sharing with the hospitals.

Palmisano said that there will still be a distributor area that will get a portion of what they used to get. "Not the whole thing, but they'll get a portion of it because they will still be needed, in some ways, to help the account in certain situations. But the majority of the distributors today do not get commissions. So it's nothing but a positive to them to some extent, that they would get some commission to help us out when needed. But the discount rate (to the hospital), I'm sure, will be more than the 10-15% that we save in commissions."

The program is not an order online program added Palmisano. "It is a program for which we have a different organization than our current organization, calling on these accounts and interacting with them at just a higher or different level than the current distributor organization interacts with physicians."

He added, "We don't do a lot of bundling and those kinds of things. So I think that offering a solution to these institutions [where they] can get products at a very different cost structure than they currently have…doing some of the work themselves and carrying the inventory and those kinds of things, we think that will provide us with an entry into those institutions that we don't currently have."

Impact on Ortho Market

Bob Hopkins said the program will have no impact on Zimmer Holdings, Inc. or Stryker Corp. as the roll out will take time. "Wright is a small hip/knee player (less than 5% share) and the target list will be focused given that a minority of hospitals will initially want to take on the costs and infrastructure demands that will go along with this type of model. But longer term this type of model would likely put more pressure on orthopedic pricing and we do think it will gain traction over time."

Hip/knee market growth has fallen from the high teens to the low single-digits over the last several years, said Hopkins, "Yet the ortho companies are spending more today on SG&A as a percentage of sales than they did when growth was robust."

"From a total spending perspective there has been no real change to the high-touch, relationship driven orthopedic sales model despite an enormous change in the growth dynamics of the industry."

Where's the Surgeon?

One person no stranger to the disruption of the distribution chain in orthopedics is John Steinmann, M.D., a founder of the physician-owned distributor concept.

Steinmann told us that the Wright model, while an attempted response to a demand for lower costs, "has some serious flaws that will considerably dilute its effectiveness."

John Steinmann, M.D.

He says the model is directed toward those institutions that are in a position to drive 10% of decisions in implant choice. "The obvious problem is that it does not address the other 90%."

In addition, Steinmann says this model makes an incorrect assumption that the hospital has the expertise to identify quality and to appropriately value newer technologies. "Surgeons are the only individuals that can identify appropriate quality and the only individuals that can appropriately value newer technologies. Every model that I have seen that takes surgeons out of the equation fails. This is inappropriate."

The answer, he says, is to align the surgeon, hospital and device company in a manner whereby each demonstrates a meaningful interest in the well-being of the others. "The surgeons need to hold device companies accountable to

fair pricing, through value based competition, while helping to reduce the need for device companies to expend inordinate amounts of money on sales, promotion and inventory. Device companies, relieved of considerable inventory, sales and promotional costs, need to adhere to fair pricing while enjoying a reasonable profit for further research and development efforts. Hospitals need to respect and pay fair pricing while focusing on providing efficient assistance to the surgeons."

"The Wright model falls far short in achieving meaningful alignment and meaningful healthcare savings primarily because they have shut the surgeon out of the equation and failed to gain sustainable alignment."

Wright: Surgeon Already Involved

Ted Davis, president of Wright OrthoRecon, told us the institutionally driven

Ted Davis, President, Wright OrthoRecon

hospitals in the Wright model include those where the surgeon is ***already*** an advocate of a differentiated business model.

He added that an important component of the Wright Direct model is that it will be targeted at, "institutions where meaningful alignment ***already exists*** between the hospital and the surgeon, who remains an important and integral part of the decision-making process. Based on the data, approximately 10% of the hip and knee procedures in the U.S. are being done in hospitals that are institutionally driven, which includes the core tenet of physician/hospital alignment. This is up from about 5% only two or three years ago and could double in the next couple of years. As this transition occurs, surgeons will continue to play an important role in product selection at these hospitals."

Davis continued that the Wright program provides 'clinically proven products at low prices and the training and logistics support for successful hospital implementation and surgeon collaboration."

While Hopkins' provocative title of the death of the device salesman may be dramatic, the sales model for orthopedic sales continues to change as payers and hospital paymasters take over purchasing decisions. ♦

NEW Smart Memory Nail Changes Shape–*in-vivo!*

By Robin Young

Wikimedia Commons and Petermaerki

A great deal of force can be produced by preventing a deformed piece of NiTiNOL from returning to its original shape—sometimes as much as 100,000 psi. The atoms in the nickel and titanium (NiTi) that make up NiTiNOL work extremely hard to get back into their original, very specific locations.

And it doesn't even require heat. Just the right implant design.

Atlanta, Georgia-based MedShape Inc. is introducing an tibial-talo-calcaneal (TTC) fusion nail made of this remarkable shape memory metal at this week's American Foot and Ankle Society Trauma (AOFAS) course in Durham, North Carolina.

Called DynaNail, this intramedullary nail is made of NiTiNOL which has been encased in a rigid titanium body. When implanted, the NiTiNOL inner core exerts constant compressive force to accommodate implant loosening and/or resorption and drive fusion.

How cool is that?

Think about it. Because of the shape memory metal core, this implant will maintain compression throughout the bone healing and fusion process. Those atoms of nickel and titanium are working very hard to get back to their original locations so this implant keeps a tight fit, constantly working to stabilize the bone as the patient puts on the loads and stresses from walking, stepping, pivoting—in short, daily life.

NiTiNOL

The shape memory alloy that is at the base of DynaNail is NiTiNOL—an increasingly common medical grade implant. Its greatest successes have historically been for cardiovascular use, but MedShape has innovated several ways to adapt shape memory implants to the unique demands of orthopedics.

Unlike orthopedics, cardiovascular applications require very small forms—like stents, guidewires or embolic protection filters. Orthopedic implants, however, have more complex performance requirements—like load bearing, metal bone interactions, sheer and torsional stresses.

NiTiNOL is also a difficult alloy to fabricate. Making a small embolic filter is very different from a bone plate or intramedullary nail.

MedShape has come up with a clever solution by housing NiTiNOL in a titanium shell. DynaNail embodies the best of both metals—titanium strength with NiTiNOL shape memory.

Nickel and titanium is not an obvious alloy. The inventor, William J. Buehler, stumbled across it while working on nose cones for the Navy's Polaris reentry vehicle. About 50 years ago he discovered that hot and cold forms of the nickel/titanium alloys had different properties.

His theory was that nickel and titanium, when combined as an alloy, underwent

some sort of atomic structural transformation and became, in effect, elastic at different temperatures. In fact, he found, self-forming elastic!

Buehler found that NiTiNOL "remembers" and recovers its original shape when it warms up. In engineering terms, the alloy transforms at the atomic level from martensite (the lower temperature phase) into austenite (the higher temperature phase).

Superelasticity

The "killer app" was that NiTiNOL was superelastic. That means that the alloy would change dynamically and dramatically from austenite to martensite and back again repeatedly, back and forth, back and forth, applied stress, and released stress, again and again. The same every time.

It was SUPER elastic. In fact, NiTiNOL turned out to have roughly ten times the deformation recovery capability of a typical stainless steel.

In the 1980s, NiTiNOL was a hit for cellular telephone antennas and eyeglass frames. The two original landmark NiTiNOL-based medical devices were the Homer Mammalok for breast tumor localization, developed by Mitek in Westwood, Massachusetts, and the Simon NiTiNOL Filter, which traps potentially deadly blood clots in the venous system, developed by NiTiNOL Medical Technologies in Boston, Massachusetts.

Since the late 1990s, NiTiNOL medical devices were predominately peripheral vascular products like stents and guidewires. Johnson & Johnson's (JNJ) Cordis unit released their version of the NiTiNOL self-expanding stent with the 1998 release of the SMART Stent. Total worldwide sales of the SMART Stent are estimated to be about $1 billion.

More recently, NiTiNOL mesh inferior vena cava filters and embolic protection devices became commercially successful products. In 2006, NiTiNOL-based devices accounted for over $750 million of the U.S. peripheral vascular device market. The extended worldwide market for these devices has been estimated by some analysts to be as large as $1.1–1.5 billion.

Tough to Fabricate

Imagine the head scratching that comes with this request: "Frank, melt down some NiTiNOL and make a shape like this." To start with, the basic metallurgical mechanisms in NiTiNOL make such

DynaNail/MedShape Inc.

activity very susceptible to impurity contamination. Too many impurities and NiTiNOL's functionality is severely compromised.

Even after the high purity requirements are met, an even higher manufacturing hurdle remains. NiTiNOL is an extremely difficult material to machine into final shape. It is for the reason that most orthopedic implants, given the requirements for reasonable cost relative to, say, cardiovascular implants, are of very simple geometries such as a staple, and are most often formed from wire.

MedShape's engineers, including its CEO and Chairman Kurt Jacobus, (who has a Ph.D. in mechanical engineering from the University of Illinois and sits on the advisory board for the Georgia Tech College of Engineering) and CTO Ken Gall (a Georgia Tech professor and world renowned expert in shape memory materials) bring advanced processing technology to their implants. "We have discovered unique ways to process the NiTiNOL to make it as easy to machine and grind as free-machining steels. And in the process we have created an economical path to create complex shapes like the NiTiNOL element that powers DynaNail", say Jacobus. And this processing brings with it an additional bonus: better strength and durability than normal NiTiNOL. So DynaNail is only the start of the potential orthopedic applications.

Trauma Applications

DynaNail can be used for the following indications:

- Post-traumatic and degenerative arthritis
- Post-traumatic or primary arthrosis involving both ankle and subtalar joints
- Revision after failed ankle arthrodesis with subtalar involvement
- Failed total ankle arthroplasty
- Non-union ankle arthrodesis
- Rheumatoid hindfoot
- Absent talus (requiring tibiocalcaneal arthrodesis)
- Avascular necrosis of the talus
- Neuroarthropathy or neuropathic ankle deformity
- Neuromuscular disease and severe deformity
- Osteoarthritis
- Charcot foot
- Previously infected arthrosis, second degree

Because of its NiTiNOL core, DynaNail sustains compressive loads during bone resorption/implant loosening. Most other nails lose all of their compression after 1mm of resorption and often behave as distracton devices. DynaNail sustains its compression for up to 7mm of resorption at a sustained load of 600N. And in the process behaves like an external fixator embodied in an intramedullary nail.

Shape Memory Polymers?

In addition to NiTiNOL, MedShape also has an entirely new class of smart materials—shape memory polymers. MedShape's shape memory polymers can deform up to 400% and still recover their original shape without losing their mechanical integrity. What is especially interesting about these polymers is that they can be triggered by heat or light or mechanical force.

MedShape is the only company with an FDA cleared shape memory polymer implant based on PEEK or PMMA chemistries. Medshape's PEEK Altera is a biomedical polymer which can be triggered to deploy after implant by the physician into the precise geometry for fixation. MedShape's PEEK Altera is biocompatible, biostable, radiolucent and MRI safe.

Outside of the medical device industry, shape memory polymers are being tested as automobile fenders which could self-repair using a common household hairdryer to remove dents.

MedShape has three product families based on its proprietary shape memory polymers: ExoShape, Eclipse and Morphix.

ExoShape is a soft tissue fastener for fixing soft tissue grafts on the tibial side of the knee joint during ACL (anterior cruciate ligment) reconstructions. It is made from MedShape's proprietary

MedShape Inc.

shape memory polymer, PEEK Altera. ExoShape is delivered pre-compressed in a low profile geometry that inserts between the graft bundles.

Eclipse is a simple soft tissue anchor for surgical use between the tendon and the bone and, of course, since it is made from shape memory polymers, it stays in place and applies a constant compressive force to hold the soft tissue grafts in place.

Morphix is a very small polymer anchor for foot and ankle and sports medicine surgeries. It is designed to anchor into the cancellous bone beneath the cortical shelf. Again, because it utilizes a shape memory polymer, the Morphix anchor applies a constant level of force against the bone. Most suture anchors, by contrast, can pull out after about 1,000 cycles at loads which are less than 50% of initial pull out strength. Morphix, on the other hand, keeps its initial pull out strength.

MedShape

MedShape is one of these small, innovative manufacturers are innovating its way into the orthopedic industry. CEO Kurt Jacobus, who spent about five years at McKinsey & Company focusing on developing start-up businesses, joined MedShape in 2006 and has built the firm to the stage where, this year, it should generate around $10 million in sales. He and the MedShape team have done this in a very rough economic environment and in an unusual way: they have financed the business privately, meaning the company has taken no venture capital financing. At six years old, MedShape is one of the more interesting young companies successfully bringing innovation to orthopedic surgeons.

So, when you're at AOFAS this week look up MedShape and ask for Kurt. Ask him to show you how these shape memory materials work and see if he'll give you a sample to take back to the hospital so you can amaze your friends and colleagues. ♦

Here Come the Quality Police

By Robin Young

No hospital wants to land in the bottom 25% of CMS' (Centers for Medicare and Medicaid Services) quality rankings. But for more than 750 hospitals, it will be unavoidable. Twenty-five percent of all hospitals receiving Medicare reimbursements will be penalized by CMS starting FY2015. In total, more than 3,000 U.S. hospitals receive inpatient payments from Medicare each year. CMS has started to measure these hospitals according to eight metrics and those who land in the bottom quartile will be penalized financially. There's no way around it. CMS grades on a curve.

Effects of Sequester on CMS's Payments

On April 26 the Centers for Medicare and Medicaid Services released the 2014 Medicare Inpatient Prospective Payment System (IPPS) rule. The federal government's fiscal year starts in October, so these new prospective payments would—if they survive in the their proposed form—take effect in the final quarter for 2013 and for the first nine months of 2014.

In its press release, CMS announced that proposed payments overall for fiscal 2014 would increase by 0.8% from current levels but…because of the government sequester earlier this year, the base line dropped 2.0% meaning that the proposed new levels are still 1.2% ***below*** payment rates on December 1, 2012.

Because of the sequester, facilities receiving Medicare funds face a negative 0.8% "recoupment adjustment" and CMS alerted its healthcare provider network that it will make similar reductions in FY2015, 2016 and 2017. In total, CMS is trying to cut costs by $11 billion in order to meet the mandate in the American Taxpayer Relief Act of 2012—aka: The Sequester.

DHHS

Orthopedics Did OK

Three aspects of the FY2014 proposed payments stand out, we think:

1. Orthopedics was treated well—at least as compared to other specialties
2. CMS is putting hospitals on a grading curve and penalizing them for *comparatively* poor quality of care
3. The definition of "inpatient" is narrowing so that more and more patients will be treated as "outpatient" even if they are spending a couple or three nights at the healthcare facility.

Lower extremity joint replacement (including hip and knee) with major complications reimbursement increases 1.4% and without major complications increase 3.3%. Upper extremity joint replacement—shoulders, elbows, clavicle—with complications or major complications up 5.7% and without complications or major complications increase 7.5%. Finally hip or knee revision procedures with major complications increase 6.1% and without complications or major complications up 7.0%.

Selected CMS Orthopedic Reimbursement Payments 2012-2014					
MS-DRG	Description	Severity	Proposed 2014 IPPS Payment Change	2013 DRG Payment	2012 DRG Payment
469	Lower Extremity Joint Replacement w/cc	MCC	1.4%	$19,746	$19,381
470	Lower Extremity Joint Replacement wo/cc	No MCC	3.3%	12,099	11,750
483	Upper Extremity Major Joint	CC/MCC	5.7%	14,617	13,522
484	Upper Extremity Major Joint	No MCC/CC	7.5%	12,097	11,228
466	Hip or Knee Revision	MCC	6.1%	28,916	28,050
467	Hip or Knee Revision	No MCC	7.0%	18,776	14,472
459	Spine Fusion exc Cervical	MCC	(2.3%)	37,758	36,557

Source: CMS and Orthopedic Network News / Stan Mendenhall

As the table above illustrates, this year's proposed increases are decent unless you are a spine implant supplier.

Change is constant at CMS—which causes no end to anxiety throughout orthopedics. The majority of patients receiving a large joint implant in any given year are over the age of 65 and eligible for Medicare reimbursement. The percentage of large joint reimbursement paid by Medicare has declined pretty steadily since 1970—when it peaked at 70%—to 60% in 2001 and, no doubt, less than that now. Over this same period of time physician payments for performing a large joint replacement have fallen significantly. Since 1990, according to a recent study, the average Medicare physician reimbursement for large joint surgery declined about 40%.

Two Nights Is "Outpatient?"

CMS is proposing to make a significant change to the criteria for inpatient admission designation. As we know, outpatient reimbursement is very different from inpatient reimbursement. Under the proposed new rule, to be "inpatient" would require "more than 1 Medicare utilization day"—which is defined as crossing two midnights in the hospital receiving medically necessary services.

There are a couple of interesting cross currents happening with this proposed new ruling. Medicare, it appears, thinks

that this change to two midnights will shift care to the inpatient side and, as a result, made a slight downward payment adjustment to account for it in the inpatient rates.

BUT…since under Part B, hospitals can self-deny inpatient cases and rebill under Part B, this new ruling will probably mean that every stay less than two midnights will always be billed outpatient.

And when does the starting point for inpatient stay begin? CMS is saying in the proposed new rule, "The starting point for this time-based instruction would be when the beneficiary is moved from any outpatient area to a bed in the hospital in which the additional hospital service will be provided."

That, in fact, is usually when the physician orders observation services because observation is usually done using a hospital bed—not, for example, propped up against the wall in the hallway or in the outpatient area. If CMS interprets this rule in the manner that "observation" equals inpatient care, then it is clear. But if CMS interprets "observation" as an extension of outpatient care…then we could be talking more than two midnights.

Either way, the trend to reduced length of stays seems to be pushing more and more reimbursement to an outpatient basis—at least so far as CMS is concerned.

Don't You Hate Curve Grading?

Now come the grades. Under the Affordable Care Act (ACA), CMS is required to reduce payments to hospitals that fall into the bottom 25% of eight specific quality measures also known as Hospital Acquired Conditions (HACs). Grading on a curve, in other words. So, no matter how much any hospital improves their rate of HACs, if they land in the bottom 25%, they are penalized. Beginning in 2015, facilities in the bottom quartile will receive 99% of what they would otherwise be paid. And CMS is planning to divide these HACs into two categories.

The first category of HACs is:

1. Rates of pressure ulcers
2. Number (not rate) of foreign surgical objects left inside patients
3. Rate of iatrogenic pneumothorax (when air or gas is left in the pleural cavity due to mechanical ventiliation, tacheostomy, tube placement or other intervention)
4. Rate of postoperative physiologic and metabolic derangement (when patients experience problems with blood sugar control or kidney failure after having an operation)
5. Rate of postoperative pulmonary embolism or deep vein thrombosis
6. Rate of accidental puncture or laceration

The second category of HACs include rates of central line associated bloodstream infections and catheter associate urinary tract infections.

CMS is proposing to calculate an overall score for each hospital where each category of HACs would make up 50% of each hospital's score. To be fair, CMS will consider in its scoring the patient's age, gender and/or comorbidities so that hospitals which serve sicker patients are not unfairly penalized.

There was a bit of good news in that CMS did not create or modify the HACs. So, it is eight hospital-acquired conditions. Just eight.

And, of course, there was a bit of confusion too. No codes for the last two HACs. That's right, two of the HACs cannot be coded. Those HACs are catheter-associated urinary tract infections and vascular catheter associated infection.

Other than hospital-acquired conditions, CMS also penalizes hospitals for certain readmission rates. Readmissions for heart attack, heart failure and pneumonia are all subject to penalties. Now CMS is looking at adding elective total hip or total knee arthroplasty to the readmissions penalty calculations for FY2015.

Opening the Data Room

As part of the ACA, CMS is opening its data room to the general public. The most recent example of this was Medicare's release of its Provider Charge Data. Representing almost 7 million discharges, or 60% of the Medicare total IPPS discharges, this is a significant new database. The data is only charging data—not reimbursement data—so it's only part of the story. We know from our PearlDiver database that Medicare typically reimburses about 20-25% of the amount charged.

Here is the link if you have an interest in these databases. http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html

But the trend to open up the Medicare data room is in place and we would expect additional databases will be dusted off and presented for public dissemination.

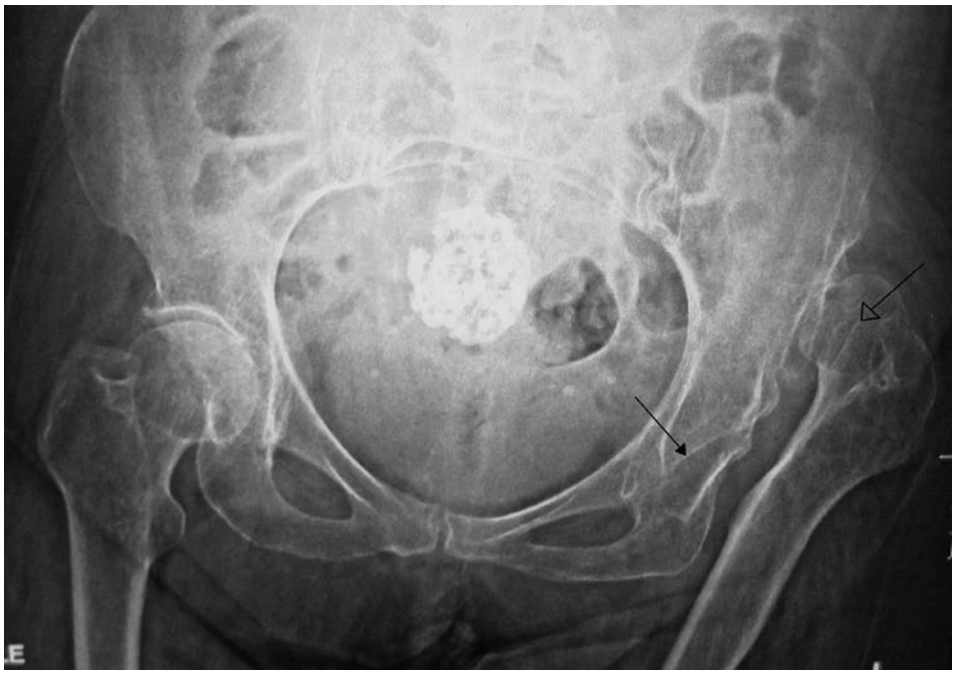
In the most current data base, Medicare released the 100 most frequently billed discharges which are paid under Medicare. Spinal fusions, except cervical without major complications had a charging range of $20,000 on the low end and $300,000 on the high end. Major joint replacement of the lower extremity ranged from $25,000 on the low end to $250,000 on the high end.

It's hard to say how such data might be used. But Medicare is, we expect, hoping that consumers will use this information to find lower cost healthcare. ♦

Government Forcing Orthopods Into Primary Care? 500th O-Arm Installed and Genetics of Hip Dysplasia Decoded

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

500th O-Arm Installed An "O-Arm" by the way is the orange Popsicle-colored portable imaging machine sold by Medtronic Spine for intraoperative imaging. It lets spine surgeons know—before they leave the OR—that everything was well-positioned. How important is that? According to Eric Epperson, senior director of Public relations & communications for Medtronic Spine, who is paid to make sure we know such things, "The challenge with minimally invasive surgery is that it is more difficult to visualize the anatomy; in addition, there is a strong need to keep radiation exposure to a minimum. Medtronic has installed over 500 O-arm imaging systems globally. This is a technology that works in conjunction with our StealthStation Navigation system. The O-arm provides real-time 3D and 2D images…and there is much less radiation for the surgical staff compared to the alternate fluoroscopy approaches. The solution is similar to the concept of a 'global positioning system' in that the surgeon's instruments are tracked in space and are localized to a 'map' of the specific patient anatomy. So, critically, the surgeon is able to confirm the precision of his or her work before the patient leaves the OR. There is no more, 'Maybe I should have repositioned that screw before patient X left.' Surgeons have a larger-than-usual field of view; because of this, and the fact that we use flat panel technology, the chance of error is minimized. When the King of Spain needed spine surgery recently, I'm proud to say that he sought out a hospital that had a Medtronic O-arm."



Wikimedia and James Heilman, MD

Government Forcing Orthopods Into Primary Care? There is some concern and even skepticism out there these days about the disconnect between the number of medical school graduates and residency slots. You might say that Richard Iorio, M.D. is one of the conspiracy theorists. Dr. Iorio is the Dr. William and Susan Jaffe Professor of Orthopaedic Surgery and the chief of adult reconstructive surgery at NYU Langone Medical Center. He tells *OTW*, "The number of medical school graduates continues to rise, while the number of residency slots has remained frozen for roughly 10 years. This clearly creates competition—not necessarily a bad thing—but it also means that there may come a time when these graduates are struggling to put a career together. And frankly, it's unclear if the government is interested in rectifying this situation. The fact is that if they can limit the number of residency slots then that could force these graduates into primary care. And with primary care as the key to controlling costs and referrals to specialists in the age of heath care reform, by limiting the number of specialists, the lack of access will ultimately decrease health care expenditures to these specialists. We already don't produce enough orthopedic surgeons as it is. So, the government may see decreasing access to care for older orthopedic patients as a viable way to save a substantial amount of money. But I'm a cynic…or maybe a realist."

Genetics of Hip Dysplasia Decoded Javad Parvizi, M.D., director of research for The Rothman Institute in Philadelphia, tells *OTW*, "My team and I are working on the genetics of developmental dysplasia of the hip…and we have located the gene. We would have never guessed that this gene could influence joint development. It controls a very specific transcription factor that is critical for the development of the joint; those with dysplasia either lack the gene or the ability to have it expressed. It's a great story, really. Our work is based on our experience with a large family (70 members) in Utah. We went to their family reunion, rented an X-ray machine, and lined everyone up for DNA samples and X-rays. This has allowed us to sequence this gene (which is for the Caucasians). This means that developmental dysplasia of the hip is a genetic disorder, something never before proven. It also means that this particular gene can be used as a screening when children are growing, thus replacing our currently crude screenings. And if we can detect this condition early then we can intervene to prevent osteoarthritis at a young age."

Compensating for the ACGME An orthopedic surgeon who directs a major residency program tells *OTW*, "The biggest change I'm seeing in graduate medical education is that it is becoming increasingly formalized. Fifteen years ago there was little structure and it was more experience-based where you were exposed to whatever you were supposed to be learning. The ACGME (Accreditation Council for Graduate Medical Education) has altered its focus; it used to concentrate on whether or not the facility had the necessary components for education. Then it switched to looking at whether the educational components were being used well, and now they are moving away from that and towards looking at the finished product, i.e., 'Are residents adequately educated?' Along with this they are moving away from worrying about how it's done. Twenty years ago there was a requirement that

you hold resident conferences and then 10 years ago they required that you take attendance. Now they are more interested in if the residents actually learned anything at those conferences."

"This is all very stressful for residency programs, partly if not totally because for years academic medical centers have run on the efforts of residents. Now with the duty hour restrictions and more rigorous requirements for educating residents it means they are not available to do as much work. The programs have basically handled this by hiring huge numbers of physician assistants. And frankly, there are a fair number of residents who are violating duty hour restrictions and not attending all the conferences. This is a patient care issue because these are often residents who would ideally have more supervision. And as many of us know, there is no evidence that duty hour restrictions improve patient safety. If the ACGME could develop a better means of improving patient safety then the duty hour restriction might be lifted. This restriction is a blunt tool for what they want—patient safety—but related to that is resident fatigue. So ideally you would just focus on fatigue and make programs figure out how they can be assured that residents are not overly tired. Even though the idea was that they would go home and sleep more we know they are not doing that…they're just doing something else."

Freddie Fu, M.D. et al. Win Prestigious Hughston Award The team at Pittsburgh—along with colleagues from Slovenia—has done it…they have walked off with the 2013 Hughston Award, an honor bestowed on the most outstanding paper that appeared in *American Journal of Sports Medicine* in the year 2012.

The article, "Prospective Randomized Clinical Evaluation of Conventional Single-Bundle, Anatomic Single-Bundle, and Anatomic Double-Bundle Anterior Cruciate Ligament Reconstruction: 281 Cases With 3- to 5-Year Follow-up," is by Mohsen Hussein, Carola F. van Eck, Andrej Cretnik, Dejan Dinevski and Freddie H. Fu. This collaboration between Pittsburgh and Slovenia began almost 10 years ago, at which time Dr. Hussein was a fellow at the University of Pittsburgh in the Department of Orthopaedic Surgery. The team indicates that great lengths were taken to design this level I trial to the highest standards possible. They cite Slovenia as being an ideal country to perform a randomized controlled trial, as it is a socialized medicine system with only three trained ACL (anterior cruciate ligament) surgeons in the entire country. Thus, they found recruitment and follow-up of patients to be excellent. ♦

company

Zimmer Cuts Jobs in Warsaw

Almost 50 full time employees have lost their jobs at Zimmer Holdings, Inc.'s Warsaw, Indiana, operations.

The *Journal Gazette* of Ft. Wayne, Indiana, reported on May 10, 2013 that Zimmer cut less than 50 full-time jobs at its Kosciusko County operation, which employed about 1,500 as of December 31, 2012. Worldwide, the company employs over 9,300 workers in more than 25 countries.

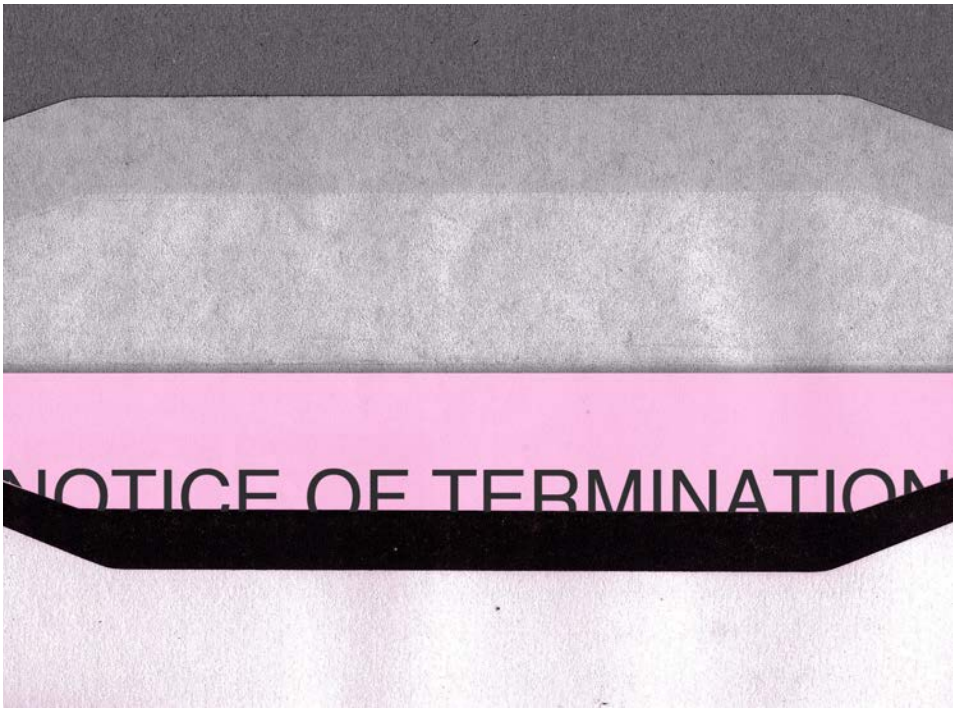
Garry Clark, the company's spokesman, told the *Gazette* that the job reductions were made May 9 across corporate and operational functions but didn't include Warsaw production workers.

He said the company has been restructuring itself to position it for sustained growth.

"These programs have enabled Zimmer to increase the productivity of our new product development programs and better meet the needs of our customers. As part of these ongoing efforts, the company today implemented certain actions that resulted in employee reductions across its businesses and geographic segments. All affected employees will be supported with a range of severance and outplacement benefits," said Clark.

Local media noted that the new medical device tax was a concern to local leaders about future job cuts. Zimmer's CEO Dave Dvorak is head of AdvaMed, the largest trade group of medical device makers and has been critical of the tax. However, the company did not cite the tax as a reason for the job cuts.

—WE (May 10, 2013)



Morguefile and solrac_gi_2nd / Photo Creation by RRY Publications LLC

NuVasive Goes Vertical in Manufacturing

NuVasive, Inc. is verticalizing its manufacturing model by buying one of its implant suppliers.

On May 6, 2013, the company announced it was acquiring ANC, LLC, a spine implant manufacturer based in Dayton, Ohio. NuVasive has been involved with ANC since ANC became a manufacturing partner with NuVasive three years ago. The company announcement said the relationship expanded over that time period to make ANC one of NuVasive's "significant implant suppliers."

NuVasive, Inc.

Alex Lukianov, NuVasive's chairman and CEO, welcomed ANC's 65 member team into the NuVasive family. "Over the past three years, we have been very impressed with ANC's progression as a quality manufacturer and their cultural fit with NuVasive. The facility will be designated NuVasive Manufacturing, LLC, and we look forward to expanding their capacity and systems as we grow together. Bringing portions of our manufacturing in house is a key element of our ongoing commitment to improve operating profitability as we grow toward $1 billion in revenue and

beyond. The acquisition will reduce the time from the concept of a new idea to ultimate market introduction, enabling development and manufacturing to work seamlessly in launching our innovative solutions."

In total consideration for ANC, NuVasive will reportedly pay approximately $4.5 million, around half of which will be in the form of loans forgiven to the company. No debt will be assumed in the deal. The company anticipates the transaction will be neutral to earnings in fiscal year 2013. Over the long term, however, the company expects vertical integration will provide opportunities to drive profitability improvements.

Piper Jaffray analyst Matt Miksic said NuVasive will continue to make modest investments in the facility throughout this year, which he estimates to be in the neighborhood of $1 million or less in capital expense related to IT systems.

He believes the facility, which currently represents around 10% of NuVasive's manufacturing sourcing, could reach 20% without significant capital expansion, and is well-aligned with the company's higher growth, higher margin CoRoent and Precept implant lines.

—WE (May 8, 2013)

MedShape: FDA Nod for Eclipse

MedShape, Inc. has announced the receipt of FDA 510(k) clearance for its Eclipse Soft Tissue Anchor, a new shape memory fixation device designed to attach a tendon, ligament or soft tissue to bone. The product is made of MedShape's proprietary PEEK (polyether ether ketone) Altera material, and offers a non-rotational insertion method that allows for improved fixation strength.

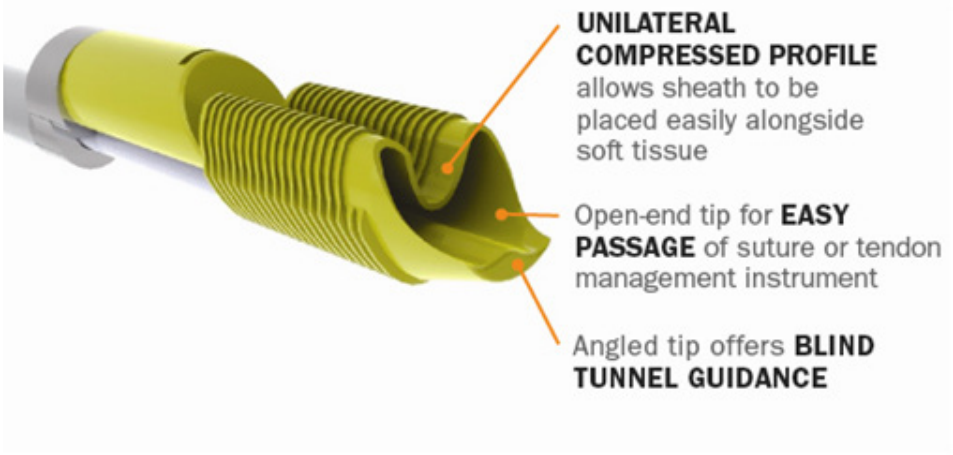
Because it is compressed on one side, Eclipse allows more space for surgeons to accommodate a tendon alongside the implant. It also incorporates an open tip in the sheath for a suture to be fed through the implant, and its non-tapered shape provides more soft tissue compression across the bone. In addition, the Eclipse anchor offers a wider choice of sizes—it is available in diameters 4 through 9 mm, and 10 through 20 mm in length allowing for its use in a variety of soft tissue repair procedures in the shoulder, knee, hand/wrist, and foot/ankle. Like ExoShape, the Eclipse Soft Tissue anchor offers strong fixation, easy insertion and procedural versatility.

"The Eclipse Soft Tissue Anchor provides a non-rotational insertion and fixation method that maintains graft bundle orientation and tension with simplified delivery," said Jack Griffis, lead development engineer for Eclipse, in the April 18, 2013 news release. "Because it is compatible with both arthroscopic or mini-open procedures, it allows surgeons the freedom to select their own preferred soft tissue management strategy."

The Eclipse is loaded on a disposable gun, and is a two-part sheath-and-bullet device made from MedShape's proprietary PEEK Altera material, a strong, yet highly deformable shape memory polymer (SMP). As indicated by the company, the Eclipse anchor can be compressed into a compact temporary form to facilitate easy insertion into a target surgical site and later expanded into its final functional geometry for fixation without loss of mechanical integrity. The PEEK Altera material is biocompatible, biostable, radiolucent and MRI safe.

"The eccentric shape and 2x sheath expansion provide enhanced soft tissue fixation for surgeons," said Griffis. "As a leader in shape memory devices, we are proud to respond to physician demand with this innovative product."

—EH (May 7, 2013)



MedShape, Inc.

legal

SpinalMotion's Kineflex to FDA Panel in July

Imagine the massive effort required to spend a full day presenting evidence to the FDA orthopedic panel to prove your device is safe and effective. SpinalMotion, Inc. is doubling down and going for two days in July.

The company is going to the panel on July 24 and 25, 2013, to present evidence of the safety and effectiveness of the Kineflex/C Cervical and the Kineflex Lumbar Artificial Discs.

The Kineflex/C is a metal-on-metal (cobalt chrome molybdenum alloy) cervical total disc replacement device. The device is indicated for reconstruction of the intervertebral disc at one level from C3-C7 following single-level discectomy for intractable radiculopathy or myelopathy due to a single-level abnormality localized to the disc space.

The Kineflex Lumbar disc is a metal-on-metal (cobalt chrome molybdenum alloy) lumbar total disc replacement device. The device is indicated for reconstruction of the intervertebral disc at one level (L4-L5 or L5-S1) following single-level discectomy for lumbar degenerative disc disease (DDD) where DDD is defined as discogenic back pain with degeneration of the disc as confirmed by patient history, physical examination, and radiographic studies.

Company President and CEO David Hovda told us he can't say much before the meeting but is looking forward to sharing the company's long term, positive clinical data with the panel.

The company received IDE (Investigation Device Exemption) approvals from the FDA in 2005 to commence studies. The cervical trial involves over 20 U.S. sites. The lumbar trial also involves over 20 U.S. sites, and is a randomized study comparing the disc to another FDA approved lumbar artificial disc. Both trials require a two-year follow-up period.

In June 2007 the company completed enrollment of its cervical clinical trial. Enrollment in the company's first IDE clinical trial, evaluating the lumbar disc was completed in 2006.

On March 20, 2012 the company announced that it received CE Mark for two sub-5mm Kineflex/C cervical total disc replacements.

The company conducted the IDE clinical study of the cervical disc compared to anterior cervical discectomy and fusion in the U.S., and submitted its premarket approval (PMA) application in 2010. A cervical disc paper was selected for the Best Papers section at the 2010 North American Spine Society's Annual Meeting.

In October 2010 the company announced it completed enrollment in an international clinical study evaluating the lumbar disc inserted via a minimally invasive lateral approach.

The meeting will be held at the Hilton Washington DC North/Gaithersburg on 620 Perry Parkway in Gaithersburg, Maryland. The FDA intends to make background material available to the public no later than two business days before the meeting.

—WE (May 10, 2013)

SpinalMotion, Inc./Kineflex Cervical and Lumbar Discs

biologics

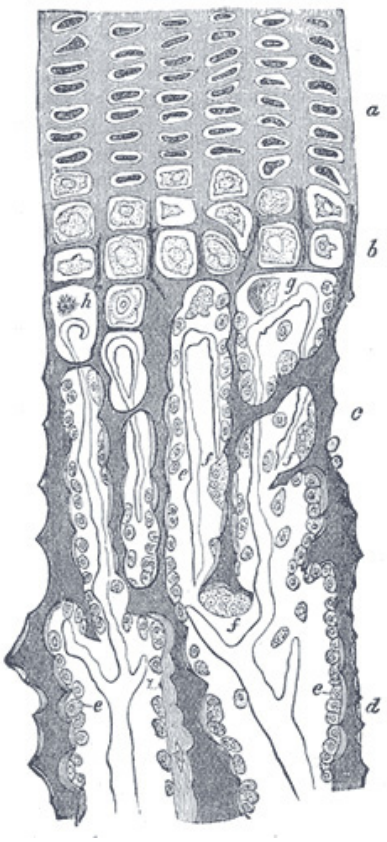
Hydrogel Plus Stromal Cells Repairs Cartilage

Researchers at Micro Orthopaedics, Zhongnan Hospital of Wuhan University, China, led by Ai-xi Yu, M.D., have shown that articular cartilage defects can be repaired by a novel thermo-sensitive injectable hydrogel. The hydrogel is treated with gene modified bone marrow mesenchymal stromal cells (BMSCs).

Researchers injected the chitosan and polyvinyl alcohol (CS/PVA) composite hydrogel containing hTGFβ-1 gene modified BMSCs into rabbits with defective articular cartilage. Sixteen weeks later the defected cartilage regenerated and was proven to be hyaline cartilage. This work can be found in the January 2013 issue of *Experimental Biology and Medicine*.

"No reliable approach is currently available for complete restoration of damaged articular cartilage", said Bai-wen Qi M.D., in a recent press release "In this study, CS/PVA gel was combined with rabbit bone marrow stromal cells (BMSCs) transfected with hTGFβ-1 and used to repair rabbit articular cartilage defects and the repair effect was evaluated".

The researchers believe that tissue engineering combined with gene therapy technology has the potential to manage the repair of defective articular cartilage. In this study, through minimally invasive injection methods, the authors were able to repair rabbit articular cartilage defects with CS/PVA gel and gene modified BMSCs. Qi said "CS/PVA gel can be applied to the repair of articular cartilage defects as an injectable material in tissue engineering, and the regenerated cartilage can secrete cartilage matrix and perform the functions of hyaline cartilage. Use of this gel for cartilage repair has advantages such as the minor surgical procedure required, tight bonding with the damaged tissue and lack of rejection".



Wikimedia Commons and Mangus Manske

Steven R. Goodman, M.D., editor-in-chief of *Experimental Biology and Medicine* said "The study by Qi and colleagues is very exciting as it combines tissue engineering and gene therapy approaches to successfully repair defective articular cartilage. The approach should be adaptable in the future to human tissue repair".

—BY (May 6, 2013)

Children's Stem Cell Treatment Tied to Readmissions

Close to two-thirds of children who received stem cell transplants returned to the hospital within six months for treatment of unexplained fevers, infections or other problems, according to a study at Dana-Farber/Children's Hospital Cancer Center in Boston. Children who received their own cells were half as likely to be readmitted as were children who received donor cells.

Wikimedia Commons and U.S. Navy

"No one had ever looked at these data in children," said Leslie E. Lehmann, M.D., clinical director of pediatric stem cell transplantation at Dana-Farber. "This is very important information and will allow us to counsel families appropriately, as well as try to devise interventions that reduce the rate of readmissions."

A review of the records of 129 children from 2008 to 2011 revealed that 64% had at least one hospital readmission within 180 days of receiving a stem cell transplant. The source of the donor cells was a key predictor. Seventy-nine percent of patients receiving transplants from a related or unrelated donor were readmitted compared to 38% who received their own cells (autologous transplant).

Fever without a documented source of infection accounted for 39% of the readmissions, 24% were for infections and 15% were for gastrointestinal problems. "Most of the patients went on to be successfully treated and ultimately did very well," said Lehmann. He hopes the findings can lead to identifying a group of low-risk children who could be managed at local hospitals rather than transplant centers, reducing costs and inconvenience to families. Lehmann said the goal is to identify which patients could be safely treated without requiring an admission to the hospital.

—BY (May 6, 2013)

large joints

Fat Triggers RA!

University of Colorado scientists have discovered that fat cells in the knee secrete a protein linked to arthritis, offering hope to millions worldwide. Nirmal Banda, Ph.D., is senior author of the study published this week in the *Journal of Immunology*. Dr. Banda, associate professor of medicine in the Division of Rheumatology at the University of Colorado School of Medicine, has spent the last 14 years tracking down the causes of rheumatoid arthritis (RA). He has collaborated with University of Colorado professors Michael Holers, M.D., and William Arend, M.D.

Wikimedia Commons and Enrico

"We found that fat in the knee joints secretes a protein called pro-factor D which gives rise to another protein known as factor D that is linked to arthritis," said Dr. Banda in the May 8, 2013 news release. "Without factor D, mice cannot get rheumatoid arthritis."

Now, with the discovery of pro-factor D in mice with rheumatoid arthritis, Dr. Banda is working on gene therapies to eliminate the protein in localized areas. In studies with arthritic mice, Banda

previously found that the complement pathway involving factor D made the mice susceptible to inflammatory arthritis.

"We are looking at vaccines, drugs or inhibitors to stop the local secretion of pro-factor D in the mouse," he said. "Our goal would be to stop the disease before it progresses and leads to joint destruction."

In his latest study, Dr. Banda found that removing factor D, rather than the entire complement system, achieves the same result without compromising other parts of the system that can fight infection. And, says Dr. Banda, because the fat does the same thing in *all* the joints, not just the knees, new medications resulting from this discovery could treat inflammatory arthritis throughout the body.

"The complement system is both friend and foe," Banda said. "We believe we can shut down one part of the complement system that triggers disease without shutting down the rest. If so, we will be making a major stride toward treating and perhaps even curing rheumatoid arthritis."

—EH (May 9, 2013)

DePuy's Ceramic Hip Gains FDA Supplemental Approval

DePuy Orthopaedics, Inc. actually had some good hip news on May 3, 2013, when the company announced FDA Pre-Market (PMA) Supplemental Approval for its Ceramax ceramic-on-ceramic hip system.

Ceramax Total Hip System

The full product name is the DePuy Ceramax Total Hip System with Biolox delta Ceramic-on-Ceramic 36MM Large Femoral Head. The supplemental approval comes after initial PMA approval of the 28mm size in 2010. Upon launch of the system this summer, the announcement says the company's Pinnacle Acetabular Cup System will offer the only FDA approved ceramic-on-ceramic bearing surface with Biolox delta Femoral Head. The company says that is a new generation nano composite ceramic material.

Simon Sinclair, DePuy Synthes worldwide vice president of strategic medical affairs, said what makes this product unique is the combination of Pinnacle's modular bearing system and the use of Biolox delta ceramic head.

According to the company, the key benefits of the device are very high strength and toughness. These properties are achieved as a result of the high density of the material and the very small grain size of the alumina matrix. Since 1974, previous versions of the heads have been used in millions of implants throughout the world.

"DePuy Synthes Joint Reconstruction continues to advance bearing technology, design, materials and manufacturing to help surgeons choose products based on evolving patient demographics and needs," said Andrew Ekdahl, worldwide president, DePuy Synthes Joint Reconstruction. "Ceramic-on-ceramic bearings represent nearly 20% of all bearings used outside the U.S."

Expands Pinnacle Portfolio

The system expands the Pinnacle portfolio of instruments, implants and materials. The company says the Pinnacle system is the most widely used acetabular cup on the world and has been used in more than 1 million patients worldwide.

The safety and effectiveness of the Ceramax system was evaluated in a prospective, multi-center, non-randomized, controlled clinical study of 264 patients who required hip replacement surgery for non-inflammatory degenerative joint disease that compared the system to ceramic-on-polyethylene hip replacement. According to the company, the study, which was part of the company's PMA application, found no significant differences in adverse events or survivorship between the two groups, and patients experienced similar pain relief, improved function and range of motion. The FDA concluded the system was safe and effective.

—WE (May 8, 2013)

DePuy Orthopaedics, Inc.; Ceramax Hip System

extremities

Surgeon Transplants Shin Bone With Meniscus

The *Edmonton Journal* (Canada) reports an uncommon surgery performed for the first time in the area. Orthopedic surgeon Nadr Jomha transplanted a shin bone, complete with the cartilage and meniscus to reconstruct the knee of a 22-year-old man who had suffered a serious workplace injury.

The patient injured his leg two years ago when a 1,000-kilogram pump jack weight tipped over on his left leg. He had a five-centimeter tear in the main blood vessel in his leg, a dislocated knee, and rips to three of the four ligaments in his knee.

Jomha initially conducted several surgeries to stabilize the leg and repair the blood vessels, after which he reconstructed the torn ligaments using donated tendons. However, he soon realized there was a more serious problem. The top of the patient's shin bone had died and begun collapsing.

Wikimedia commons and Joseph Swafford

Jomha contacted a new tissue program in Calgary to see if it had any donated parts that would fit his patient. It did. Jomha had a good match. In the surgery, Jomha sawed off the dead part of the patient's shin bone and removed it. He made the same cut on the donor bone, leaving the cartilage and meniscus attached.

Jomha transplanted all three components into the leg, securing the donor bone onto the original bone with a plate and screws. Over time, he said, the body replaces the foreign bone with its own bone in a process known as creeping substitution. Unlike live organ transplants, no anti-rejection drugs were required.

Though the patient still has months of rehabilitation ahead, the transplant operation has already made a difference in that he can bend his knee further and with far less pain than before. He hopes he can soon discard his crutches and start to put weight on the leg.

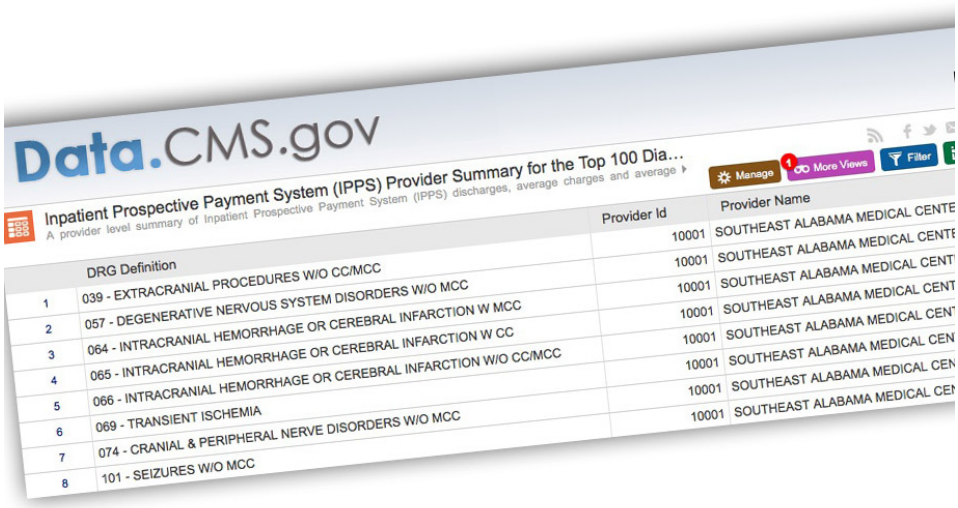
—BY (May 6, 2013)

reimbursement

CMS Lifts Veil From Hospital Charges

On May 8, 2013, the Department of Health and Human Services (HHS) released data showing significant variation across the country and within communities in what hospitals charge for common inpatient services, including orthopedic services.

"Currently, consumers don't know what a hospital is charging them or their insurance company for a given procedure, like a knee replacement, or how much of a price difference there is at different hospitals, even within the same city," said DHS Secretary Kathleen



IPPS Summary for Top 100 Procedures

Sebelius. "This data and new data centers will help fill that gap."

Web Posted Data

The data posted on the Center for Medicare and Medicaid Services' (CMS) website include information comparing the charges for services that may be provided during the 100 most common Medicare inpatient stays. Hospitals determine what they will charge for items and services provided to patients. These charges are the amount the hospital generally bills for an item or service.

Journalists across the country quickly jumped on the data and ran local stories showing wildly different prices for the same procedures in their communities.

For example, the HHS announcement showed that average inpatient charges for services a hospital may provide in connection with a joint replacement range from a low of $5,300 at a hospital in Ada, Oklahoma, to a high of $223,000 at a hospital in Monterey Park, California.

Even within the same geographic area, hospital charges for similar services can vary significantly. For example, average inpatient hospital charges for services that may be provided to treat heart failure range from a low of $21,000 to a high of $46,000 in Denver, Colorado, and from a low of $9,000 to a high of $51,000 in Jackson, Mississippi.

Charges, Not Reimbursement

Often missed was one giant caveat. Payers rarely pay what hospitals charge. PearlDiver Technologies, Inc.'s senior analyst, Scott Ellison, said within the major orthopedic procedures, "We have seen a discrepancy among charges across the U.S. for some time. The variation can occur between two hospitals within miles of each other. Geographically the variation is quite pronounced. For example, hospital charges for a total knee replacement average $41,774 in the Midwest for Medicare patients. The charges for the same procedure average $64,660 in the western portion of the U.S. It must be noted though, these are charges and rarely the amount actually paid to the hospital."

In those same regions Ellison cited, the difference in Medicare reimbursement for a total knee replacement is not so dramatic. "In the Midwest the average reimbursement is $11,549 and the average reimbursement in the West is $13,436," added Ellison.

Ellison said charges can have varying implications depending on how a patient plans to pay for their procedure. "Patients paying the full amount without insurance would clearly see the greatest impact. For these patients especially, transparency in what they will be charged at different hospitals is extremely important."

Data Centers

To make these data useful to consumers, HHS is also providing funding to data centers to collect, analyze, and publish health pricing and medical claims reimbursement data. The data centers' work helps consumers better understand the comparative price of procedures in a given region or for a specific health insurer or service setting. Businesses and consumers alike can use these data to drive decision-making and reward cost-effective provision of care.

The HHS press release noted that the Affordable Care Act also makes available tools to help consumers, Medicare, and other payers get the best value for their health care dollar. "Medicare is beginning to pay providers based on the quality they provide rather than just the quantity of services they furnish by implementing new programs such as value-based purchasing and readmissions reductions. HHS awarded $170 million to states to enhance their rate review programs, and since the passage of the Affordable Care Act, the proportion of insurance company requests for double-digit rate increases fell from 75% in 2010 to 14% so far in 2013," stated the release

To view the new hospital dataset, go to: http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html.

To read a fact sheet about the Medicare data showing variation in hospital charges, see: http://www.cms.gov/apps/media/fact_sheets.asp.

—WE (May 10, 2013)

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