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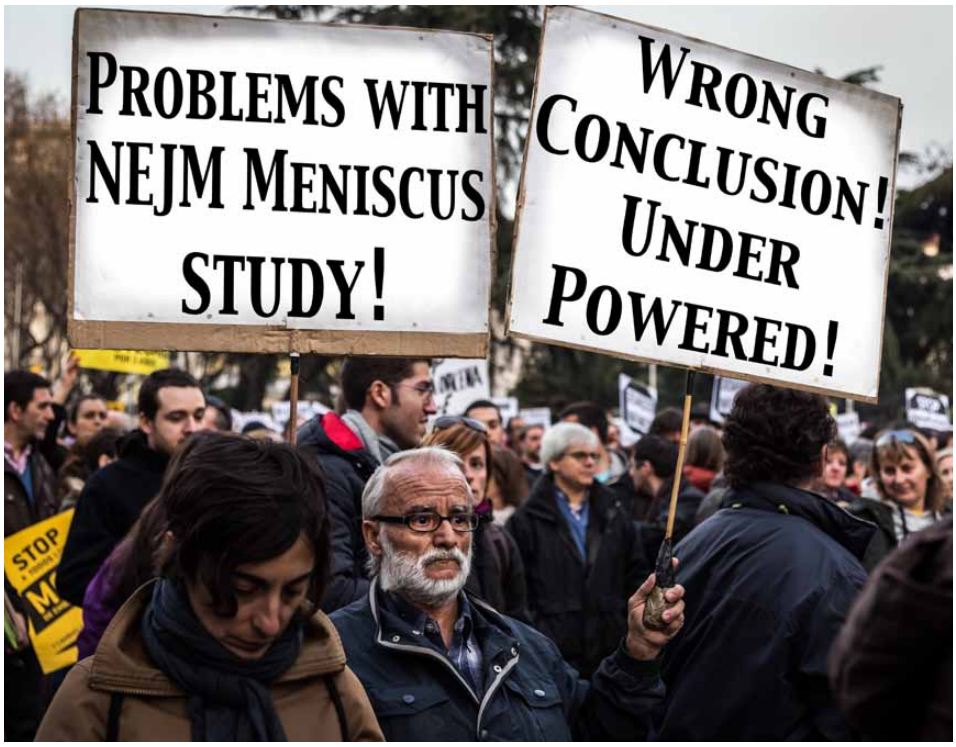
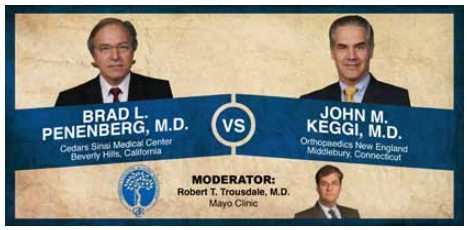
Orthopedics This Week

WEEK IN REVIEW





BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Betting on healthcare in general and orthopedic in particular is a very good sector bet this second week in January 2014. NASDAQ is beating the Dow and a bias is clearly emerging in favor of growth stocks. Ortho benefits from this sentiment in part due to its positive correlation to higher employment and more insured. Time is ripe for orthopedic equities.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Orthofix	16.25%	14.21%	At $447 million market value, OFIX remains the least expensive ortho equity.
2	3	Conmed	10.37	12.05	CNMD shares up 56% in the last 12 months—which is more than twice the performance of the S&P 500.
3	2	Integra LifeSciences	11.77	7.05	By contrast, IART underperformed the S&P in 2013. This year, however, consensus estimate is for 23% earnings gains.
4	6	Stryker	15.22	7.45	Buys patient safety company. Part of presenting a fully integrated solution to hospitals and clinics.
5	4	Symmetry Medical	6.50	5.51	Debt reduction deal major positive for SMA. Stock is starting 2014 with an upward bias.
6	5	Zimmer	27.31	7.02	Wall Street brokerage house, Needham, told investors that ZMH likely to beat estimates for Q4.
7	10	Medtronic	28.84	6.56	While MDT stumbles in nerve denervation for cardio, spine keeps trundling along. At 16x P/E, MDT a value.
8	9	NuVasive	6.30	10.68	In valuation terms, NUVA is still in the upper 50% of all ortho equities. Wall Street is giving NUVA a management premium.
9	8	Globus Medical	28.53	5.47	GMED buys developer of a "next generation" spine robot. Interesting.
10	7	Exactech	10.00	2.98	Most analysts expect a 6% to 7% sales rise in 2013. For 2014, more of the same. Steady as she goes.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$0.94	$151	42.29%
2	Bacterin Intl Holdings	BONE	$0.55	$28	34.15%
3	ArthroCare	ARTC	$46.48	$1,319	21.07%
4	Alphatec Holdings	ATEC	$2.13	$208	17.68%
5	Baxano Surgical Inc	BAXS	$1.12	$51	16.67%
6	MiMedx Group	MDXG	$8.11	$839	16.36%
7	Orthofix	OFIX	$22.99	$447	14.21%
8	Tornier N.V.	TRNX	$19.40	$941	12.33%
9	Conmed	CNMD	$43.98	$1,214	12.05%
10	NuVasive	NUVA	$34.81	$1,553	10.68%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Aurora Spine	ASG	$3.11	$39	-5.74%
2	MAKO Surgical	MAKO	$29.99	$1,544	0.03%
3	Johnson & Johnson	JNJ	$94.74	$267,303	1.75%
4	Exactech	EXAC	$23.86	$323	2.98%
5	Globus Medical	GMED	$20.07	$1,871	5.47%
6	Symmetry Medical	SMA	$9.96	$371	5.51%
7	Smith & Nephew	SNN	$73.23	$13,074	6.12%
8	Medtronic	MDT	$59.95	$59,851	6.56%
9	Zimmer Holdings	ZMH	$96.68	$16,530	7.02%
10	Integra LifeSciences	IART	$49.48	$1,590	7.05%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$22.99	$447	9.23
2	Medtronic	MDT	$59.95	$59,851	16.13
3	Zimmer Holdings	ZMH	$96.68	$16,530	17.29
4	Johnson & Johnson	JNJ	$94.74	$267,303	17.67
5	Globus Medical	GMED	$20.07	$1,871	17.90

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$34.81	$1,553	91.61
2	Symmetry Medical	SMA	$9.96	$371	50.20
3	Integra LifeSciences	IART	$49.48	$1,590	31.58
4	ArthroCare	ARTC	$46.48	$1,319	29.76
5	CryoLife	CRY	$11.00	$304	28.40

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$20.07	$1,871	1.19
2	Orthofix	OFIX	$22.99	$447	1.32
3	Exactech	EXAC	$23.86	$323	1.60
4	Conmed	CNMD	$43.98	$1,214	1.72
5	Zimmer Holdings	ZMH	$96.68	$16,530	1.82

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$34.81	$1,553	7.45
2	CryoLife	CRY	$11.00	$304	7.10
3	Integra LifeSciences	IART	$49.48	$1,590	4.22
4	Symmetry Medical	SMA	$9.96	$371	4.18
5	Johnson & Johnson	JNJ	$94.74	$267,303	2.76

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	$0.55	$28	0.86
2	Symmetry Medical	SMA	$9.96	$371	0.90
3	Orthofix	OFIX	$22.99	$447	0.97
4	RTI Biologics Inc	RTIX	$3.33	$188	1.05
5	Alphatec Holdings	ATEC	$2.13	$208	1.06

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.94	$151	37.04
2	MiMedx Group	MDXG	$8.11	$839	31.02
3	MAKO Surgical	MAKO	$29.99	$1,544	15.03
4	Globus Medical	GMED	$20.07	$1,871	4.85
5	Johnson & Johnson	JNJ	$94.74	$267,303	3.98

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

Mounting Criticism of *NEJM*'s Flawed Meniscectomy Study // AO Spine's Global Survey Results Are In // PE, DVT Rates NOT as High as Previously Thought

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

Criticism of *NEJM* Partial Meniscectomy Mounting Rapidly

Let's take a closer look at the recent *New England Journal of Medicine* article on arthroscopic partial meniscectomy, says Brian Cole, M.D. Dr. Cole, Professor in the Departments of Orthopaedic Surgery and Anatomy & Cell Biology at Rush University Medical Center, tells *OTW*, "There are a number of problems with this study. It took five years to enroll patients in the study, so there should have been a denominator amongst the five sites of several thousand potential meniscectomy patients in the practices of the investigators. In fact there were less than 200 enrolled; add to that the fact that almost 25% were dropped from the study. Then there is the issue that these were not acute, dramatic tears…they were degenerative menisci. This brings into question the generalizability of the population studied to the population at large with acute and chronic meniscal tears."

Wikimedia Commons and Barcex

"And their conclusion that 'arthroscopic partial meniscectomy is of no value' is not what the study showed. They looked at two surgical procedures, that had the common factor of irrigation and lavage with the only difference being one group underwent a concomitant debridement of the meniscus. If you want to know the impact of the different aspects of the treatment then a true 'sham' group would be needed where an incision is made without entering the joint. That said, both groups improved with surgery compared to their baseline clinical presentation."

"Let's say that the study had been appropriately powered. Then you can say that doing something to the meniscus may or may not make a difference. But arthroscopy did seem to make things better. It is a nuance because half of the patients had the meniscus treated and half did not…and these are degenerative, not traumatic, injuries."

"I do congratulate the authors for the rigor in which the study was performed. I share concerns, however, with other orthopedic surgeons that this study could cause problems. If policy makers or insurers take the message away that surgery for meniscal tears isn't effective when in fact this and several other studies have shown that it is effective when appropriately indicated, then I worry that coverage decisions may be erroneously made."

AO Spine's Global Classification Survey Results are in. Now Comes the Hard Part.

Alexander R. Vaccaro, M.D., Ph.D. is a spine surgeon with the Rothman Institute in Philadelphia. He is also vice chairman of the Department of Orthopaedics at Thomas Jefferson University. Dr. Vaccaro tells *OTW*, "In the trauma world spine surgeons are always searching for the most user friendly, universally accepted spinal classifica-

tion system. The recently completed AO Spine Thoracolumbar Classification System, incorporating principles of the original AO and TLICS systems is now being validated, with the Rothman Institute being one of the study sites. The system, which was sent to 100 facilities in seven regions of the world, allows a validated assessment of the systems applicability in spinal trauma care as well as allows everyone to see how different regions of the world perceive the severity of injury through the development of a severity score. Does XYZ culture view a particular fracture pattern to be severe? Do they opt more for aggressive treatment or do they usually go the nonoperative route?"

"We are still working with the data, but thus far I've noticed that different regions of world look at spine injuries differently. Some societies regard specific injuries as being more unstable than others, therefore they opt for surgical intervention more often than other societies. That's why we often notice that a surgery rate is higher in certain countries for specific spinal injuries. So we're seeing that with these trauma cases people in some areas of the world are describing things as being more severe than people in other areas. It's not like they think that it's necessary to operate on everything, it's that they perceive the injury as being more severe."

"So are they right? To find out we must do well designed studies with evidence that rivals level I and level II data as RCTs [randomanized controlled trials] are difficult to do in the setting of trauma. I can say this, though. The European surgical community sees specific injuries as being more unstable than surgeons in North America. We don't know why this is, but we have a meeting coming up that will hopefully shed light on this and other issues."

"Traditionally, we would think that nonoperative care costs less, but that may not be the case if the person has to remain in a brace for an extended period of time and cannot work. There are others who say that surgery is less expensive because that person can return to work sooner. So the question is, 'is acute care more expensive than nonoperative care, and if so, who pays? Is this an investment by insurers or does society pay for this?' It will certainly take a while to come to these answers."

Shake Up in Blood Clotting Numbers What do you do when published data doesn't match your clinical experience? You do your own study. Robert Z. Tashjian, M.D. is Associate Professor of orthopedic surgery at the University of Utah. Dr. Tashjian, a shoulder specialist, tells *OTW*, "My partners and I noticed that our clinical experience regarding blood clotting after total shoulder did not match the data in the literature. Most of the work in this area has been done by Mayo Clinic and Hospital for Special Surgery, which have reported great variability in DVTs [deep venous thrombosis] and pulmonary embolism (PE): the incidence ranges from .1% to 10-15%. We undertook a retrospective study of 10 years of shoulder replacement data, and examined 533 patients who underwent a shoulder arthroplasty evaluating for the incidence of venous thromboembolism (deep venous thrombosis and pulmonary embolism) as well as risk factors for the development of clotting. Examples of risk factors evaluated included comorbidities, smoking status, medications prior to surgery, hormone replacement, past cancer status, etc."

"We found an overall clotting rate of 2.6%, which was more in line with our clinical experience, and PE was much more common than DVTs (2.3% versus 0.9%). Then we looked at factors affecting clotting and found that those with comorbidities and heavier patients were more likely to have a problem. Other factors we found associated with clotting included revision surgery and diabetes. One of the more interesting things was that surgeries in which patients had a higher preoperative hematocrit had a higher incidence of clotting. Here in Salt Lake City we are at a higher altitude and we have always wondered whether our clotting rate differ because of this. There is some data for other procedures indicating that a high pre-op hematocrit and hemoglobin can be a risk factor for clotting. Finally, we did find that patients with a history blood clotting prior to surgery had an increased risk for clotting after surgery similar to other authors."

"So clotting—either PE or DVT—is not nominal…but it may not be significant enough to require therapeutic Lovanox or Coumadin on every shoulder replacement patient. Surgeons need to look for risk factors and not necessarily treat it preoperatively but be more aware of this postoperatively."

Ojedapo Ojeyemi, M.D Has Joined the Team at American Spine. Ojedapo Ojeyemi, M.D., a board certified orthopedic surgeon, has joined the team at American Spine. American Spine has 10 multi-disciplinary locations in the Maryland and Pennsylvania area.

Dr. Ojeyemi obtained his Bachelor's Degree with Honors/Cum Laude from Stony Brook University. He completed his Medical Degree at SUNY Health Science Center in Brooklyn, New York. Dr. Ojeyemi then specialized in orthopedics and completed his residency at Howard University Hospital in Washington, DC. He went on to subspecialize in spine and did his fellowship at the world renowned Texas Medical Center in Houston. Dr. Ojeyemi held academic clinical appointments at Howard University Hospital prior to joining American Spine. At Howard University, Dr. Ojeyemi was actively involved in medical student and resident education and research, as well as patient care.

Dr. Ojeyemi practices general orthopedic surgery, but his subspecialty and main focus is leading minimally invasive spine surgery at American Spine. He is passionate about using the least invasive surgical approach while removing the pain source from a degenerated spine. He lectures worldwide about his success in using minimally invasive spinal techniques. Dr. Ojeyemi regularly performs complex open and minimally invasive spine procedures, minimally invasive and complex joint surgeries, sports medicine, hand and foot surgery, as well as orthopedic trauma surgery.

He is an active member of the American Academy of Orthopaedic Surgeons, J. Robert Gladden Orthopaedic Society, AO Spine, and North Atlantic Spine Society. Dr. Ojeyemi is dedicated to promoting minimally invasive spine surgery, motion preservation and percutaneous fusion, including endoscopic and laser thermodiskoplasty. In addition to his work at American Spine, Dr. Ojeyemi is involved in humanitarian medical missions work in Africa, particularly Nigeria. During these trips, his teams have performed advanced orthopedic care for trauma victims and children with deformities. ♦

Device Tax and Physician Pay: Congress' Chew Toys

BY WALTER EISNER

"If you want a friend in Washington, get a dog," said President Harry Truman.

And right now, physicians and medical device companies are looking for political friends to replace the (un) sustainable growth rate (SGR) formula and repeal a politically unpopular medical device tax. But those friends are hard to find in a "pay-as-you-go" federal budget process that requires cuts for new spending.

Everyone is a competitor when the cost for getting what you want is a price someone else has to pay at the public healthcare trough.

Illusion of Bipartisanship

A brief outbreak of bipartisanship seems to have garnered enough momentum to repeal the 2.3% device tax and replace the SGR that will cut physician Medicare reimbursements by 24% this spring.

But hospitals and insurers already coughed up billions when the Affordable Care Act (ACA) was negotiated three years ago. They don't want to kick in more and are not friendly to efforts that will help device companies and physicians at their expense. And lawmakers have gone on record to say they are not going to ask grandma and grandpa to pay more or take cuts on services.

2014 is a mid-term election year in the second term of a lame-duck president who doesn't want to do anything to unravel his signature domestic policy achievement.

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Show Me the Money

So where will the $30 billion to repeal the device tax and the $116 billion to replace the SGR come from? Nobody has come up with an answer.

Surprisingly, the prospects for the $116 billion SGR fix seem slightly brighter than repealing the tax. The $116 billion can come from the entire healthcare federal budget, while the device tax fix blows a $30 billion hole in the ACA and threatens the president's legacy.

It's Different This Time

Gail Wilensky, Ph.D. a former CMS [Centers for Medicare and Medicaid Services] Administrator wrote in the December issue of the *New England Journal of Medicine* (*NEJM*) that this year is different when it comes to the SGR.

"This year, for the first time, bipartisan, bicameral attention is being directed toward developing an alternative reimbursement system that rewards physicians who improve the quality and efficiency of care, rather than just kicking the proverbial SGR can down the road for one more year."

On December 26, 2013, President Obama signed into law the Pathway for SGR Reform Act of 2013. The new law prevented a scheduled payment reduction for physicians and other practitio-

Gail Wilensky, Ph.D./ www.gailwilensky.com

ners who treat Medicare patients from taking effect on January 1, 2014. The law provides for a 0.5% update for such services through March 31, 2014 and gives lawmakers more time to work on fixing the SGR.

Congress has been granting pay hikes to physicians while bypassing the SGR formula and declaring it unworkable for a decade now. Only once have scheduled cuts actually gone into effect. *FierceHealthFinance.com*, in a January 1, 2014 article, predicted that since that method appears to work and most of the proposals for SGR replacement begin with freezing physician payments for the rest of the decade, don't expect lawmakers to make big changes here.

The Proposed Fix

In the meantime, both houses of congress are working on similar, but ever-changing bills that would:

- Increase payments by 0.5% through 2017 and flat payments through 2023
- Mandate "appropriate use criteria for advanced diagnostic imaging"
- Simplify current payment incentive programs by combining them into one value-based program
- Increase the public availability of provider payment data
- Give physicians who privately contract with Medicare patients the option to automatically renew their two-year opt out
- Provide 5% bonuses for doctors who use a qualifying alternative payment model and
- Give electronic health record (EHR) vendors until 2017 to make their EHRs interoperable.

After loud cries from physician groups against initial proposals that contained no Medicare payment increase for 10 years, lawmakers in both chambers provided a 4-year period of 0.5% payment increases.

Both proposals encourage the use of alternative payment models such as accountable care organizations, combine three quality incentive programs into one, and make numerous other

changes to the way Medicare pays for the delivery of healthcare.

Neither bill specifies how to pay for the proposals.

Not all medical societies are on board. The American Urological Association, American College of Surgeons, and several other surgical groups—16 in total—wrote congressional leaders to urge them to oppose the bills or postpone markups.

The groups were concerned with the Value-Based Performance Incentive Program and low or no payment increases in the bills.

The North American Spine Society (NASS) and the Alliance of Specialty Medicine are also hesitant. NASS is concerned that certain provisions will have unintended consequences on patient access. In addition to the low or zero payment updates, the society is concerned that there are no assurances of a viable fee-for-service system; no inclusion of at least a five-year transition period to a new payment system; and the creation of a new budget-neutral, tiered quality payment program that measure an individual's performance relative to others.

They say the proposals ensure that physicians become competitors, rather than collaborators, on quality improvement.

Bigger Is Better

Wilensky wrote that the incentives that the SGR presents to the individual physician are incompatible with the formula's objective of controlling aggregate physician spending. "The SGR is driven by the aggregate spending of all physicians. Since no one physician or physician group is large enough to affect aggregate spending, good behavior can't be rewarded and bad behavior can't be penalized at the level of the physician or the group associated with the good or bad behavior."

She added that the challenge is to determine which alternative payment or care-delivery models warrant increased reimbursement. "The hope is that some of the pilot projects currently under way sponsored by the Center for Medicare and Medicaid Innovation (Innovation Center) or by private payers will provide insights to answer this question. For example, can the various models for medical homes and accountable care organizations (ACOs) or other strategies being tested consistently produce savings, and are any early savings that are produced by voluntary participants likely to be generalizable and sustainable?"

"Obviously, the results for these activities are years off. Specialists may need to consider whether they will be able and willing to accept more financial risk than they have in the past. The success of physician-led ACOs may clarify their ability to do this successfully."

Senator Max Baucus, one of the architects of the SGR fix, said, "We all share the same goals: improve the fee-for-service system, reward value over volume, and encourage physicians to transition to alternative payment models, such as medical homes and accountable care organizations."

In other words, continue the strategy of having physicians become employees of larger healthcare systems and making treatment decisions based on the evidence of "Big Data."

Maybe this year will be different, but don't bet your practice on it.

Repealing the Device Tax: A Bridge too Far

The device tax has a bigger bridge to cross.

The recent budget signed by the president included a tax repeal, but only if spending cuts can be found elsewhere in the ACA. Hospitals, insurers and physicians aren't volunteering to chip in.

The Curse of Success

Large medical device companies are perceived by some in Congress as a highly profitable cartel that drives up device costs through a lack of transparency. The companies impose secrecy agreements on their customers, so buyers can't compare prices. The large companies are not seen just as innovators bringing new devices to patients, but as a central problem to high healthcare costs.

Proponents of the tax cite a McKinsey & Company study that says the U.S. spends about 50% more than expected on the top five medical devices, compared with Europe and Japan. McKinsey calculates that this amounts to $26 billion in excessive spending each year.

AdvaMed: Outside the Tent

The medical device lobby (AdvaMed) also culled itself from the herd by sitting on the sidelines when the ACA was being put together three years ago.

While hospitals and insurers struck deals, AdvaMed, did not, and balked when lawmakers proposed legislation that would require producers to pay a tax on sales. They have been fighting it ever since, claiming that the tax will cost jobs, harm smaller companies and slow innovation.

Stephen Ubl

Stephen Ubl, president of the association, said one reason the industry had not offered a cost-savings plan was that hospitals, which had already agreed to cost cuts, would seek price breaks from device producers. A separate tax on device sales would effectively result in "double taxation," he said.

Cash and Advertising Campaign

The industry has reportedly distributed at least $10 million in campaign contributions to lawmakers and kicked off a new advertising campaign in late September.

"Save 43,000 jobs, save billions for investments in tomorrow's treatments and cures, improve our global competitiveness," the advertisement said. The ad campaign was followed by a letter signed by nearly 1,000 device manufacturing companies nationwide that was sent to leaders in both the House and Senate.

AdvaMed has few friends outside of senators from states that employ lots of medical device employees. Those senators, like Amy Klobuchar of Minnesota and Elizabeth Warren of Massachusetts have been able to cast symbolic, but meaningless votes, to repeal the tax.

The ad campaign started on the same day that *The Wall Street Journal's MarketWatch* ran a story by Russ Britt saying the device tax was put in place in the first place because device makers had "soaring margins" in the decade prior to the passage of Obamacare.

Lukewarm Leaders

Then there are the personal politics of some industry leaders unwilling to invest their time to push for the repeal. The biggest dog on the block, Omar Ishrak, CEO of Medtronic, Inc. told an audience in Minnesota last summer at an AdvaMed event that he is not spending any time pushing for repeal because it's the law of the land and the companies have to learn to manage the tax.

Unless AdvaMed can find cost savings from other healthcare providers or industry, or cut back on coverage under the ACA, Steve Ubl is going to have to get a dog. ♦

FDA Rolls Fernstrom's Ball

BY ROBIN YOUNG

Fernstrom, Nachemson and Harmon are long gone now.

Ulf Fernstrom, M.D., died a couple decades ago. Alf Nachemson, M.D. in 2006. Paul H. Harmon, M.D., long before that. But the 'Ball'—the implant they invented, manufactured, declared war over and implanted in about 100 patients—finally made it to an FDA panel meeting. Fifty-seven years after it was first implanted in a human.

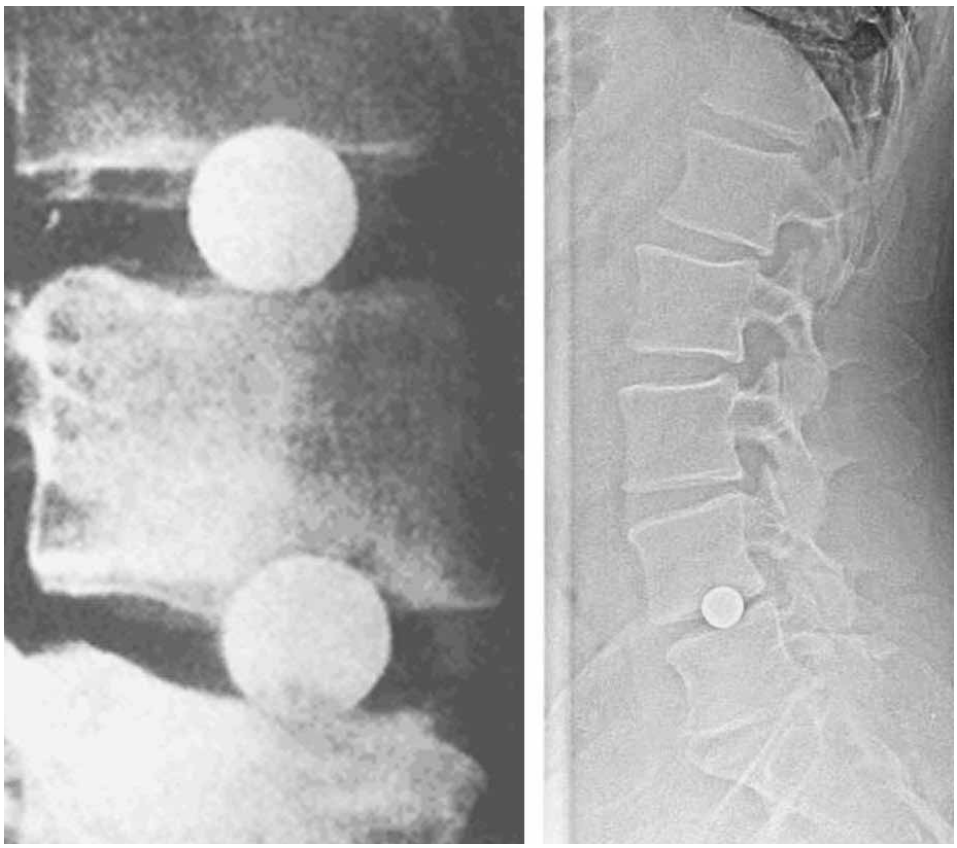
The panel convened its meeting on December 12, 2013 to consider the use of spinal spheres…and a stair climbing wheelchair. Almost no one attended. In fact it was the shortest Panel meeting in recent memory. Done before lunch.

Twice the panel's chair (John Kelly, M.D., associate professor, orthopedic surgery, Hospital of the University of Pennsylvania's Sports Medicine Center, Philadelphia) said, "ok, we all agree, that does it" before the FDA staff said they still had to answer a couple of questions on the agenda.

At one point panel member Bernard A. Pfeiffer, M.D., looked out at the comparatively empty room and commented that no one from industry was around. He asked if that was a sign that spheres had come and gone for industry.

The panel's industry representative said she spoke to a number of the companies and none were marketing spheres currently. Although, if the FDA had any guidance, they were all ears.

In the panel's view Fernstrom's ball exists somewhere in spine's rear-view mirror. Far, far back. As one panel member said: "It's come and gone (replaced by cages) and I don't want it back."



Courtesy of The Burton Report and European Spine Journal

Well, sort of.

The Old Academic Brawl

Fernstrom and Nachemson were Swedish contemporaries. Alf Nachemson was a research assistant for Dr. Carl Hirsch at Uppsala University, Sweden's first University. Ulf Fernstrom was a surgeon.

Both Fernstrom and Nachemson invented an intervertebral implant and each implant reflected the respective professional focus of the two physicians.

Alf Nachemson was the lab rat and believed strongly that any implant in the spine disc must mimic the elastic properties of the anatomic disc. His doctoral thesis analyzed the loads and stresses of the spinal disc as derived from detailed studies of cadaveric specimens (Rydevik et al., 2007). Many of today's principles of biomechanic behavior of the spine originated from Nachemson's work and remain, to this day, highly influential.

Ulf Fernstrom was a surgeon and looked for a more basic solution. Building on

the work of Harmon, he came up with a stainless steel ball to implant into the intervertebral disc space. Its purpose was to restore disc articulation and spacing. Two purposes. One implant.

Nachemson was appalled that Fernstrom was actually implanting such a rigid construct into a living human spine. A solid-rigid ball had zero elastic properties. Nachemson's alternative was a silicone ball—which would ultimately fail every cadaveric test (Szpalski et al., 2002).

Fernstrom Balls

Beginning in the late 1950s, Fernstrom implanted 191 of his "Fernstrom Balls" in 101 patients. It was an attempt to achieve arthroplasty in the spine and to create center of rotation that was mobile. President John F. Kennedy is rumored to have been a Fernstrom Ball patient.

Ironically, given Nachemson's focus on biomechanics, X-rays of two- and three-level Fernstrom Ball implants show that the alignment of the spine with the Fernstrom Balls tended to be very good.

The Fernstrom Balls were implanted with minimal disruption to the structures of the spine, including the ligamenture. Later Dr. McKenzie from Alberta, Canada, began implanting the Fernstrom Ball. Interestingly enough, he had two of them implanted in himself.

The Evidence

At a spine meeting five years ago, Art Steffee, M.D., founder of AcroMed Corporation and one of the pioneers of modern spine surgery, shared photos of a patient who'd had the Fernstrom Balls for 35 years and was doing fine.

Reitz and Joubert looked at 75 cervical disc arthroplasties performed with the Fernstrom Ball in 32 patients and reported that at the one year point they had not detected either neurological complications or subluxations of the Balls. In two cases they did find intrusion into adjacent bone, but the clinical results remained excellent in both cases. The authors cautioned about the need for a two-year follow-up period before a final assessment of this surgical technique could be made.

A 2012 study (Eur Spine J. 2012 Mar;21(3):443-8. doi: 10.1007/s00586-011-2040-y. Epub 2011 Oct 19. The Fernstrom ball revisited. Siemionow KB, Hu X, Lieberman IH) reported on four patients who underwent cobalt-chrome sphere implantation and later presented with symptoms of sphere subsidence. All four patients presented with low back pain and/or lower extremity pain, and some with weakness. Imaging demonstrated that all patients had a loss of disc space height with sphere subsidence. Three patients underwent sphere removal, anterior interbody fusion using femoral ring allograft and posterior pedicle or facet screw fixation. In the fourth patient, the sphere was subsided into both the L5 and S1 endplates prohibiting removal.

"The Rape of the Spine"

Dr. Nachemson called the use of the Fernstrom Balls "The Rape of the Spine" and, in the course of authoring more than 400 studies and articles became the dominant critic of spinal fusions and spinal arthroplasty.

His co-author on some of these studies was Richard Deyo, M.D., of the University of Washington. Among his other accomplishments, Dr. Deyo petitioned the Center for Medicare and Medicaid services to deny coverage for the first spinal arthroplasty system approved by the FDA—the Charité.

Two Camps – Elastomeric vs. Rigid Implant

In terms of technical and service characteristics, the spine sphere only has to be mobile.

By contrast, Nachemson's elastomeric implant had to have three functions: mobility, elasticity and shock absorbing.

Over time, both designs added new components to try to correct perceived failures of each.

Nachemson's silicone balls were placed between two metal vertebral plates forming a sandwich structure.

Fernstrom's rigid sphere morphed into lateral versions of the ball-and-socket joint which echoed the success of Sir John Charnley's hip articulating prosthesis in the late 1960s.

The Charité disc, for example, is the natural extension of Fernstrom's solid joint articulating and load bearing surfaces (although not shock absorbing—strictly motion preserving). In 1982 in Charité Hospital at the University of East Berlin, surgeons Kurt Schelznack, M.D., and Karin Büuttner-Janz, M.D., developed the design of the SB Charité, the first artificial disc to be implanted commercially in France in 1989.

In 1986, Waldemar Link, a West German orthopedic implant manufacturer joined the project. Charité was approved for U.S. commercial sale in 2004. Since then 10 other joint articulating intervertebral designs have emerged. Two were approved by the FDA for commercialization in the U.S. Only one remains on the market—the ProDisc.

Discs based on Nachemson's mimetic theories were much slower to reach the market. One of the strongest U.S. projects came from AcroMed (purchased by DePuy, now a JNJ company) and that was the AcroFlex disc project.

AcroFlex was an elastomeric ball sandwiched between two metal plates. It was tested in human trials in 1988-1989, 1993-1994 and 1998-2000. All failed.

Other elastomeric intervertebral implants were developed over the years but none ever made it to market.

FDA's Housecleaning

Since 2005, four manufacturers have submitted 510(k) applications to clear their sphere devices. The companies and their respective spheres are Medtronic, Inc.'s Satellite Spinal System, Biomet Spine's Spinal Stabilization Sphere System, Interbody Innovation LLPs' Spinal Spheres and PEEK Spinal Spheres and Life Spine's Spinal Sphere System.

At the December 2013 panel meeting, Constance Soves, Ph.D., a member of the FDA's Review Team, said "We could not identify any reports specifically describing spinal sphere devices for use in intervertebral fusion procedures. Consequently, we could not obtain any valid scientific evidence regarding the safety and effectiveness of spinal sphere devices when used for intervertebral body procedures based on this review."

Apparently spinal spheres had been marketed for use in intervertebral body fusion procedures before passage in 1976 of the Medical Device Amendment rules for 510(k) clearances. In effect, spinal spheres had been grandfathered in as intervertebral body fusion devices.

The FDA noted the inherent contradiction of clearing for fusion a device (the ball) which is intended for use as a non-fusion device.

Still, the FDA was doing a little housecleaning and asked the Panel to recommend reclassifying spinal spheres as Class III devices. Which the Panel did.

To help put the nail in the 510(k) pathway for spheres, the FDA staff reported that their search of the Manufacturer and User Facility Device Experience (MAUDE) database search up to June 30, uncovered 21 unique medical device reports (MDR) on the spheres. Of those cases, 16 resulted in removal/revision, 10 of pain and 6 of neurological impairment.

So, the Fernstrom Ball will live on as Pro-Disc, Charité and every other metal-on-metal ball and socket motion preserving spinal implant. Fittingly, among the practitioners.

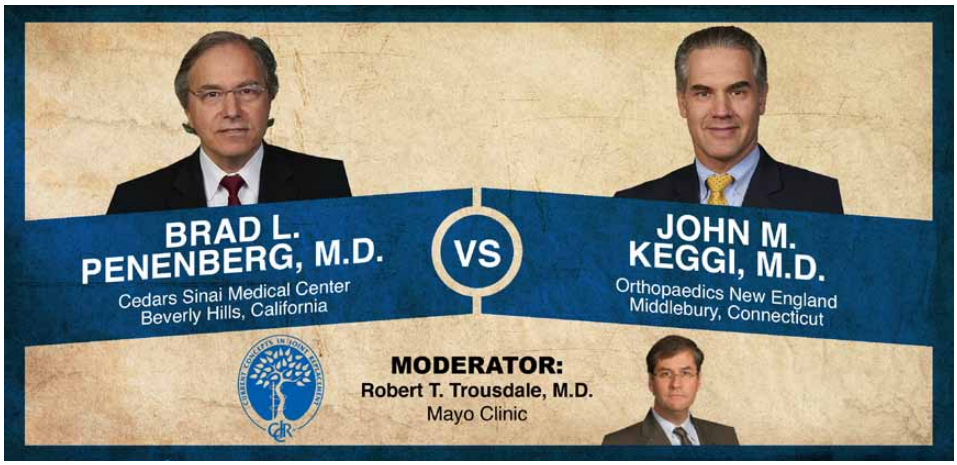
As for Nachemson's mimetic theories—they also live on in the academic literature and from podiums throughout the world. Among the theoreticians. ♦

Penenberg, Keggi Debate the Direct Anterior Approach

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

"Posterior is NOT a four letter word!" says Brad Penenberg. "Why choose an option that's almost guaranteed to result in a life-altering complication?" john keggi retorts, "the DA (direct anterior approach) is here to stay; it is safe and easy, and has been around for 130 years."

This week's Orthopaedic Crossfire® debate is "The Direct Anterior Approach: Here Today, Gone Tomorrow." For the proposition is Brad L. Penenberg, M.D. of Cedars Sinai Medical Center in Beverly Hills, California; against the proposition is John M. Keggi, M.D. from the Orthopaedics New England in Middlebury, Connecticut. Moderating is Robert T. Trousdale, M.D. from the Mayo Clinic.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Penenberg: "The direct anterior (DA) approach. Is it the only choice? Is the learning curve worth the price? But what we're seeing in the hospital, is that maintained?"

"The attraction is accelerated recovery. The idea of unlimited activity immediately postop is another attraction to the concept of a soft tissue sparing approach such as the DA. But you can achieve the same results are possible through a modified posterior approach. This is not a big, open, transgluteal, traditional Moore approach with multiple tendon releases. But posterior is NOT a four letter word!"

"First of all, there is a 2013 study from Christopher T. Martin supporting the accelerated recovery and shortened length of stay with anterior versus posterior approaches. But if you look at it closer it is in comparison to the more extended tendon release approach. It also brings up the possibility of a significant number of lateral femoral cutaneous nerve injuries."

"The pressure is on in the office as patients come in with articles from the lay press and we are forced to react. One option is to consider the 'direct posterior' approach. In 2008 I published some of the aspects of this technique in JBJS; there were no nerve injuries, no ankle fractures, only the rare trochanteric fracture, rare dislocation, no wound problems, no heterotopic ossification, 90% of patients were discharged after two nights, and 90% required no narcotics at discharge. These results have been duplicated by other authors in the last couple of years."

"The appeal to this approach is the familiar orientation of the patient—lateral decubitus position. The concept that varies now is the gluteal window or transgluteal approach, leaving the iliotibial band (ITB) intact and with a limited short external rotator…release the conjoined tendon only sparing piriformis obturator externus. This affords direct access to the femoral canal, in-line preparation, and in-line implantation. Another option is to use the tip of the greater trochanter as a reference point for insertion of the femoral component."

"The acetabulum is fully and circumferentially visualized and access can be afforded through two options. One is a portal with an 8mm reamer drive shaft; other authors have described access with offset or 90 degree reamers. One of the great advantages is achieving the same results, but that this approach is readily extensile."

"It's also a myth that direct anterior is the only option permitting no postop precautions. Several papers (AAOS, Robertson, 2013; *JBJS*, Penenberg, 2008; Curr Rev MS Med, Chow, 2011) have found no postop precautions."

"Also, we're asked to believe that there's a finite learning curve with DA. There is an example where the surgeon had

done over 100 DA procedures using limited intraoperative fluoroscopy; postop X-rays revealed unsatisfactory results with limited fluoroscopy. Another patient operated on by a surgeon who had done over 300 of these cases came to me after being in a wheelchair for six months with a subsided stem, two large incisions, and a big open reduction and internal fixation (ORIF). And a 2011 study by Jewitt shows us that wound problems continued, even after his 800 cases. So my observation is that the learning curve for the DA is an opportunity to turn routine THA [total hip arthroplasty] into a catastrophe."

"There is no literature supporting use of the DA with severe hip disease and high BMI [body mass index] patients. Any paper from the 21st century shows similar dislocation rates with both approaches. Also, a significant capital investment is not required with a modified posterior approach."

"It's OK not to offer a high risk procedure. And when telling the patient you can reference *The New York Times* article from February 2010 that discusses alternatives to the DA. Why choose an option that's almost guaranteed to result in a life-altering complication?"

Dr. Keggi: "The DA is here to stay; it is safe, easy, and I have always done it that way. The anterior approach has been around for 130 years and it's been around for 42 years in the modern arthroplasty era."

"Briefly, it's an anterior incision; the skin is folded down. Once you're down on the hip you can excise or incise the capsule; the osteotomy is performed in situ. You take out a napkin ring of bone, remove the head and you have a great view of the acetabulum…better than with any other approach."

"The releases that Dr. Penenberg mentioned always involve the posterior capsule and sometimes involve the conjoined tendon of the obturator internis. The anterior approach has increasing use. At least 25% of surgeons who perform more than 50 hip replacements a year use the DA some of the time; at least 20% use it routinely."

"The DA gives you good visibility at all times, the sciatic nerve is well out of your way, as is the femoral bundle. It has a documented lower risk of DVT; anesthesia likes it and likes you for it, and you have good X-ray access."

"We published our results in the early 2000s on all patients (2,132) from 80 to 400lbs. The dislocation rate was 0.1%; fractures requiring fixation were 1%; DVT and PEs were 0.8%. And you don't need any special tools like an expensive table or special OR bed. If you bounce rooms and use two rooms the table is much more expensive. No special instruments or positioning are required; the latter is easy and quick in the OR. The setup is simply a gel bump underneath the SI joint on the affected side; no peg board is necessary. And because the patient is supine you always know where the pelvis is."

"Despite what my colleague said the anterior approach is definitely extensile. We've shown that in our *JBJS* revision paper; even if you have a complication intraoperatively with your anterior primary you can always extend. There is nothing you can't do through the anterior approach, and there's nothing you can't do safely through the anterior approach."

"It does have proven functional benefits…in physical parameters (Nakata, *Journal of Arthroplasty*, 2009). Restrepo's study from 2010 in the *Journal of*

Arthroplasty showed improved SF-36 and WOMAC scores. It's more reliable for placing your cup (Nakata, *Journal of Arthroplasty*, 2009), and there are lower CPK (creatine phosphokinase) levels as a marker of muscle damage (Bergin, 2011 *JBJS*). And Bremer's 2011 work in *JBJS* found that there was less soft tissue damage on an MRI at one year postop compared to other approaches. Oldenrijk's 2010 study in *Acta Orthopaedica* found that the gluteal damage was the least with the DA approach."

"The DA has the lowest dislocation rate, in part because it relieves the anterior capsular contracture; and you maintain the posterior sling of soft tissue. My colleague has become very skilled at the transgluteal posterior approach. It does spare the iliotibial band and releases the conjoined tendon only versus a more extensive external rotation release; and it is gluteal sparing. But these are core features of the DA approach and have been for the last 40 years!"

"His approach, the percutaneous assisted total hip, is cool…but I would argue that it is a posterior hip with an anterior technique. The direct anterior approach is here to stay."

Moderator Trousdale: "Brad, why don't you address his issue with safety?"

Dr. Penenberg: "Safety equates with familiarity and a learning curve. If a surgeon starts off in an orientation and soft tissue anatomy that he's familiar with then he's more likely to be able to avoid risk and complications. The complications I've seen are when surgeons stray from familiar territory; all of a sudden they're not able to see. So being able to scale down in a stepwise fashion and bale out at any moment is where safety comes in."

Dr. Keggi: "A lot of focus gets put on the anterior approach, but troch fractures, etc., exist with all approaches. It's highly surgeon-dependent."

Moderator Trousdale: "That's true. So you must look at randomized, prospective trials. If you examine the data you have to almost get down to muscle enzyme measurements to see a difference between a posterior approach and an anterior approach. So let's take a 40- or 50-year-old surgeon that does 200 hips per year and is good at one approach…are the advantages of the DA strong enough that this surgeon should go through the learning curve of the operation?"

Dr. Penenberg: "Yes. Going forward a lot of people will learn it in residency and it will be one of their familiar approaches. But for the 40-year-old surgeon who is entertaining a change I would say that of those who have changed very few change back."

Moderator Trousdale: "Is there anyone you wouldn't do the DA on? Brad?"

Dr. Penenberg: "There's no concern. I think we can start with a restricted approach posteriorly/transgluteally, and if it's a deep protrusio just cut the neck in situ and we can still retain the IT band. With obese patients it's a longer incision, but the angular access is identical. Those patients can have the same postoperative success so I think it is immediately extensile if necessary, but it still allows the same access and results regardless of the disease severity or BMI."

Moderator Trousdale: "John, do you do the DA on a 400lb patient?"

Dr. Keggi: "We do. We do it on everyone. We do our revisions and resurfacings that way. If you're starting the anterior approach the easiest patients are tall patients, and females that have a relative laxity in anteversion. The most difficult patients are short, compact males with retroversion."

Moderator Trousdale: "Are wound complications higher in obese patients?"

Dr. Keggi: "Yes, but they are for every approach."

Moderator Trousdale: "Radiation issues…what's your average radiation time?

Dr. Keggi: "Zero. We take postoperative films. When someone is starting out there is definitely a benefit to taking an X-ray during the case or using fluoro. I would just take a plain film to confirm component position. It's not mandatory to use X-ray; many people are now using X-ray for the posterior approach as well."

Moderator Trousdale: "Thank you both." ♦

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

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COMPANY

New DePuy Synthes Matrix for Fusion

DePuy Synthes Spine and DePuy Synthes Biomaterials have collaborated to produce a hydrated, pliable and totally demineralized cancellous bone matrix that fills voids during posterolateral spine fusion surgery. Furthermore, the company says the matrix provides a natural scaffold for new bone formation.

The U.S. launch of Conform Sheet was announced on January 6, 2014 and, according to Max Reinhardt, DePuy Synthes Spine worldwide president, is an excellent example of how DePuy Synthes Companies can meet the needs of hospitals and health care systems.

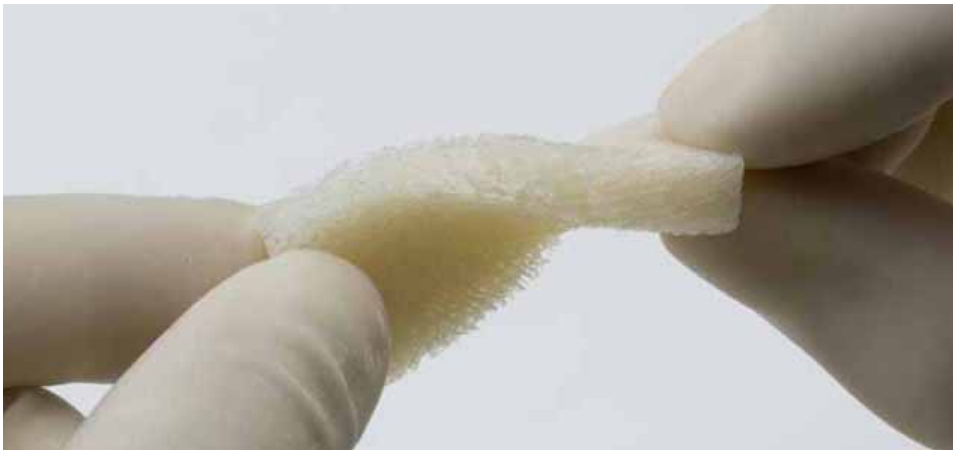
The allograft implant, processed by the Musculoskeletal Transplant Foundation (MTF), has both osteoinductive and osteoconductive properties. Through a unique demineralization process, bone morphogenic proteins (BMPs) are exposed, providing the implant its osteoinductive properties, while the cancellous structure of the scaffold provides osteoconductive characteristics. The product is wickable in that it readily absorbs various hydrating fluids including bone marrow aspirate, blood or saline. When combined with bone marrow aspirate, the implant becomes osteogenic.

"Conform Sheet has excellent handling characteristics. It is compressible for precise placement, where it can then expand to fill the bone void," said Khalid Sethi, M.D., FACS, chief of neurosurgery at United Health Services Wilson Medical Center in Johnson City, New York. "It is packaged in a hydrated state, which eliminates the need for rehydration and there is no implant migration upon irrigation."

The implant is offered in four sizes, can be cut to accommodate irregular shaped anatomy and may be used with the DePuy Synthes Spine Matrix MIS Pedicle Screw System and the Expedium Spine System.

DePuy Synthes Spine also offers Conform Cube Demineralized Cancellous Bone, which launched in 2011. That implant is another fully demineralized cancellous bone product in the form of a cube. It comes in five sizes and has the same properties as the Conform Sheet, but does not come pre-hydrated.

—*WE (January 10, 2014)*



CONFORM SHEET courtesty of DePuy Synthes Spine and DePuy Synthes Biomaterials

Stryker Settles Some Metal Hip Lawsuits

Johnson & Johnson's DePuy division wasn't the only device company settling metal-on-metal hip lawsuits at the end of 2013.

RRY Publications, LLC/Source: Wikimedia Commons

According to the *New Jersey Record,* four patients settled their claims against Stryker Corporation in New Jersey at the beginning of December. The patients alleged that the company's Rejuvenate metal-on-metal hip injured them. Attorneys representing the patients would not disclose the financial terms, citing confidentiality agreements. But they told the newspaper that a deal came through after two weeks of mediation hearings.

J&J recently submitted a $2.5 billion-plus settlement offer to resolve 8,000 lawsuits over its recalled ASR implants.

Stryker is already dealing with 600 metal hip lawsuits and thousands more are anticipated. The company voluntarily recalled the Rejuvenate implant in July 2012. More than 20,000 patients across the country received the implant. The first of the lawsuits against Stryker was filed a month after the recall.

As of the third quarter of 2013, Stryker recorded $700 million in charges relating to the all-metal hip recall effort stemming mostly from expenses relating to the Rejuvenate and ABG II.

Biomet, Inc. is also dealing with its own onslaught of metal hip lawsuits. More than 900 Biomet lawsuits have been consolidated in U.S. District Court in Indiana and a status conference on those cases is scheduled for January 6, 2014.

—*WE (January 6, 2014)*

Solana Cleared for Foot and Ankle Plating System

Memphis-based Solana Surgical, LLC has been cleared by the FDA to market its CrossCheck plating system used by orthopedic and podiatric surgeons in foot and ankle procedures. The company expects to begin commercializing the product in the first quarter of 2014.

According to a December 20, 2013 company announcement, the first phase of commercialization will include plates that will be primarily used for stabilization and fixation (leading to fusion) in the forefoot and mid-foot. Fusion is often the procedure used to relieve pain and correct skeletal alignment issues in patients with arthritis, as well as small joint fractures and bunions.

The company says its system is unlike other plating systems on the market because it offers "unique compression and stabilization features: the plates are manufactured with a Type II anodization, which enhances the fatigue strength of the device, and thus improves stabilization." Additionally, the company's specially designed ridges are built into the plates to enhance grip, and act as a buttress during the compression process. "Studies have shown that similar ridges can also improve host bone health," explains Rebecca Wahl, vice president of Research and Development.

The system offers various sizes and configurations for specific surgical needs and is added to the company's family of products that include a fixation system, TenFuse PIP with sterile instruments, a nail, screw system, a metatarsal decompression implant, a lesser metatarsal head implant, acellular dermal tissue, a cancellous sponge, moldable putty and the Gaitway implant system.

The privately held company was founded in 2008 by former extremity company executives and launched its first product in 2011. In addition to Wahl, current employees include: Alan Taylor, the company's president and CEO; Tommy Turpin, senior vice president of operations and regulatory affairs and Jon Simon, vice president of sales and marketing.

—*WE (January 6, 2014)*

Solana Surgical, LLC

STR Adds Cash and Dane Miller

Soft Tissue Regeneration, Inc., (STR) has added money and expertise to its efforts to offer ACL (anterior cruciate ligament) patients an alternative to autograft or allograft therapies.

STR
Soft Tissue Regeneration

Soft Tissue Regeneration, Inc. and Dane Miller

On January 6, 2013, the company announced the completion of a $5 million financing effort and the addition of Biomet, Inc. founder, Dane Miller, Ph.D. to the company's board of directors. Charles Hart, Ph.D., and Richard Emmitt also joined the board. The first tranches of STR's $5 million financing closed on November 19, 2013.

The company stated the financing commitment will allow for the completion of a European 15-patient Phase I clinical study of the company's L-C Ligament. The first patient was enrolled in June 2013, in The Netherlands. The financing will also support STR's continued regulatory and clinical activities with the FDA in preparation for a global pivotal clinical trial.

Resorbable Polymer Technology

STR focuses on the application of resorbable polymer scaffold technology.

The company's devices are based on proprietary fiber, braid and mesh designs comprised of poly (L) lactic acid (PLLA), a resorbable polymer with a long and proven history of use in implantable medical devices. The company says its device designs are "ideally suited for tendon, ligament, and other soft tissue injuries when an implantable scaffold is required for the reinforcement and/or regeneration of functional tissue."

The first STR device to reach the clinical stage, the L-C ligament, has, according to the company, the potential to advance the surgical repair of torn ACLs by obviating the need to utilize either the patient's own tissue (autograft) with the pain and morbidity of a second surgical site, or the use of cadaver tissue (allograft) with the risks of infection and sub-optimal healing. Following three years of animal testing that demonstrated the ability of the L-C Ligament to remodel and regenerate functioning ligament, STR initiated the clinical study in Europe. As of this date, 10 patients that have received L-C Ligament implants are "all doing well."

Company Co-Founder, President and CEO Joseph Reilly said the company has quickly progressed from a concept to a real product that is "already demonstrating clinically its potential to provide surgeons and their ACL patients with an alternative to the inherent morbidity and risks of autograft or allograft tendon."

New Board Members

Miller is the founder, current member of the board, and former president and CEO of Biomet, Inc. With over 40 years of experience, he is considered one of the most distinguished entrepreneurs and executives in the medical device industry.

Hart is the former chief scientific officer and vice president of two of the pioneer companies in the field of regenerative medical technology, Advanced BioHealing, Inc. and BioMimetics Therapeutics, Inc. He has more than 30 years of experience.

Emmitt is a general partner with The Vertical Group with a 40-year career as an investor and board member of several medical device companies.

Current investors, Connecticut Innovations and Launch Capital led the $5 million financing. Miller and The Vertical Group also participated. "The new members of the board offer years of experience and the guidance and insight that will allow us to continue making clinical and regulatory advances," added Reilly.

—*WE (January 7, 2014)*

Biomet Knee Sales Foreshadow Industry Growth

Biomet, Inc. reported terrific knee sales for the most recent quarter. Reported sales grew by 6.6%, causing Wall Street analysts to predict equally promising results for Biomet's competitors.

Overall reported sales for the companies 2014 second quarter were up 4.5% to $826 million. Reported hip sales rose 2.3%, extremities and trauma climbed 5.3%, spine and bone healing were up 2.3% and biologics rose 3.1%. Excluding currency, total sales increased by 5.4%.

Other highlights of the quarter included the acquisition of Lanx, Inc. and the launch of the G7 Acetabular System.

Reported net income in the quarter was $4.9 million, compared to a net loss of $66.2 million during the second quarter of the prior year. At November 30, 2013, reported net debt was $5.72 billion, compared to $5.61 billion on May 31, 2013.

Jeff Binder, Biomet's president and CEO said the company was "very pleased" with a broad and balanced 6% organic sales growth in the quarter, with strong performance across multiple product segments and geographic regions.

"We're also delivering excellent growth in adjusted net income (ex-specials and amortization), with an increase of 27% to approximately $208 million through the first half of our fiscal year."

Biomet 2Q 2014	Sales $ in million	% Change
Total Reported Sales	**825.7**	**4.5%**
Knees	264.0	6.6%
Hips	167.7	2.3%
Sports, Extremities, Trauma	160.3	5.3%
Spine & Bone Healing	104.9	2.3%
Dental	70.5	4.9%
Biologics and Other	58.3	3.1%

Source: Biomet, Inc.

Wells Fargo analyst Larry Biegelsen said he thinks Biomet's results are a positive sign for the recon market as Biomet's knee and hip results have generally correlated well with the overall market. "It is also important to note that Biomet's [quarter] ends November and we have heard anecdotal reports from several surgeons that procedure volume was very strong in December. This could mean even stronger growth acceleration for the larger recon players."

—WE (January 10, 2014)

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LARGE JOINTS

Study Debunks Arthritis Dietary Supplements

Do the dietary supplements glucosamine and chondroitin sulfate slow joint damage in the knees of people suffering from mild arthritis? Past studies have said "no." A recent new study of the effectiveness of the supplements—that measured more than 30 parts of the knee joint—resulted in a "maybe." Among the people who took the supplements over a period of two years, only a few parts of the knee joint differed from those who did not take any supplements.

The experts continue to differ on the subject. Daniel Solomon, M.D., M.P.H., a rheumatologist and pharmaco-epidemiologist at Brigham and Women's Hospital in Boston (who was not involved in the study) said, "This is yet another set of data arguing against any disease-modifying benefit of glucosamine and chondroitin sulfate."

Another researcher, Krishna Chaganti, M.D., M.S., a rheumatologist at the University of California, San Francisco, who also was not involved in the study, said "[The results] may reflect that drugs or therapies that affect joint structure in osteoarthritis are likely to have an effect earlier in the course of the disease."

Johanne Martel-Pelletier, Ph.D., of the Osteoarthritis Research Unit at the University of Montreal Hospital Research Centre, led the research and was one of the study's authors. The group examined data on 600 participants in an osteoarthritis study sponsored by the U.S. National Institutes of Health Osteoarthritis Initiative. Bioiberica, a Spanish pharmaceutical company that manufactures glucosamine and chondroitin supplements, funded a part of the study.

Some of the study participants were taking bone-building drugs, some were taking pain relievers such as ibuprofen and others were taking glucosamine and chondroitin supplements.

As reported by *Reuters Health*, the researchers used magnetic resonance imaging (MRI) to examine the spaces between the participants' joints and monitored the participants' arthritis symptoms and disease progression over 24 months.

They found that the people who took both anti-inflammatory pain medications and glucosamine and chondroitin supplements had less pain and milder changes due to disease in one part of the knee joint than those who took the pain drugs but no supplements. However, among those who were not taking pain medication, there was no difference in pain between people taking the supplements and those who did not. In the end the people who took supplements had similar disease progression to those who did not take them.

Solomon told *Reuters Health* that the few statistically significant differences in knee anatomy that were seen may have been due to random variation. His belief as a result of the study is that, in general, the results do not change the bottom line for osteoarthritis patients: glucosamine and chondroitin do not help.

—BY (January 7, 2014)

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CMS Picks "Good" and "Bad" Hospitals for Joint Surgery

Medicare (CMS) is using the outcomes of hip and knee replacement surgeries to measure the effectiveness of U.S. hospitals. The agency has identified 95 hospitals where elderly patients are more likely to experience significant setbacks in their recovery and 97 "good" hospitals—meaning that they have a higher recovery rate.

The analysis and reporting is the latest effort on the part of the government to bring about improvement in quality in hospitals. According to Jordan Rau, writing for *Kaiser Health News*, this is the first time Medicare has rated hospitals' performance based on two common elective procedures: hip and knee joint replacements.

Medicare officials downgraded the 95 hospitals because knee and hip surgery patients experienced too many difficulties after their operations. They faulted nine hospitals for having both high readmissions and high complication rates.

In its evaluation of a hospital's professional services and the care provided to hip and knee replacement patients Medicare is using two measures. They are (1) how often patients are readmitted to the hospital within 30 days of their initial discharge and (2) how often patients suffered from one or more of eight complications following their surgery. The complications include a heart attack, pneumonia, excess bleeding at the surgical site, a blood clot in the lung, and infections within 90 days of admission or death within 30 days of the surgery.

Since the fall of 2013 Medicare has been paying less to some hospitals for joint replacement surgeries because those institutions' rebound rates were too high. Beginning in the fall of 2014, when joint replacement surgery will be factored into the penalty program, unless quality improves, hospitals could lose as much as 3% of Medicare payments for each patient stay, Rau estimates.

—BY (January 7, 2014)

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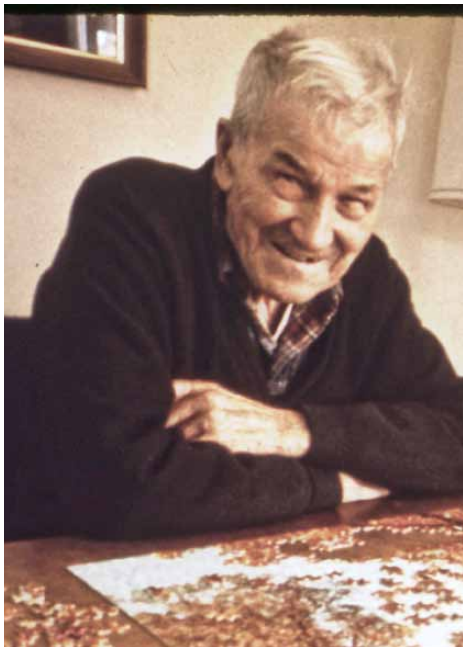
How Old Is too Old for Joint Replacement?

Is one ever too old to get a new knee? Ali Saleh Hussein, whose passport shows that his age is 98, underwent joint replacement surgery on his



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left knee at Breach Candy Hospital in Mumbai in December. His orthopedic surgeon, Amyn Rajani, said, "Hussein's knees are those of a 60-year-old man. While the left one was severely degenerated due to arthritis, his right knee is good for another couple of years." Rajani believes Hussein to be the oldest man in the world to have undergone knee replacement surgery

The oldest individual to have undergone knee replacement surgery in both of his knees is also from India. He is believed to be 94-year-old S.N. Bhatt from Chhattisgarh's Bhilai steel township.

According to the *Times of India*, Kaushal Malhan, M.D. performed joint replace-

ment surgery on both knees of 91-year-old Madhukar Nimdeo. He said that there are many 70-year olds whose joints seem too far gone for them to benefit from replacement surgery. "But there are some like Nimdeo who even at 90 years of age are active enough to benefit from the surgery."

The *Times* writer quoted Pradeep Bhonsale, M.D., who heads KEM Hospital's orthopedic department, expressing a different opinion: "Arthritis is never an emergency like, say, fracture. Moreover, why should a 90-plus patient be put through the risk of a supra-specialty surgery when new medicines and injections can help them equally," he said.

—BY (January 7, 2014)

EXTREMITIES

MedShape: Positive Clinical Results

MedShape, Inc. is reporting on the first wave of clinical outcomes in patients who have received the DynaNail TTC Fusion System. To date during its targeted soft launch period, DynaNail has been successfully implanted in over 100 tibiotalocalcaneal (TTC) fusion procedures. Because the internal nickel titanium (NiTiNOL) element maintains the target fusion bones in close apposition and under sustained compression, fusions are being observed with the DynaNail TTC Fusion System in high-risk patients, specifically those who require bone allografts.

However, a large number of high-risk patients have experienced fusions with DynaNail, as confirmed by CT scan, including many with bulk allografts. Dr. Thomas San Giovanni of the UHZ Sports Medicine Institute in Coral Gables, Florida has implanted DynaNail in five patients, using a femoral head allograft for three, with successful fusion in each.

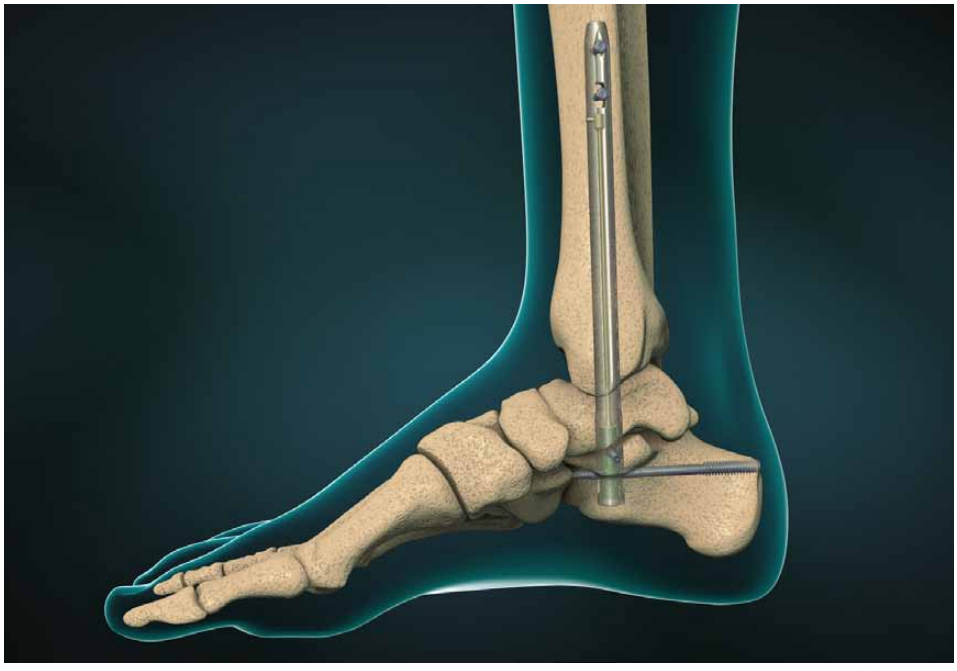
"I believe we may be entering a new era within orthopedics where the unique properties of certain materials such as NiTiNOL will be used to our advantage to assist in the healing of bone—complementing both the mechanical and biologic nature of bone healing," said Dr. San Giovanni in the January 7, 2014 news release. "The DynaNail is the first product of its kind and certainly is on the brink of this technology. I've had very good success with the DynaNail in some of the most difficult clinical scenarios where combined arthrodesis of the ankle and subtalar joint was needed. It has become my preferred fixation method when using a nail for TTC fusions. I have been very impressed by its performance and foresee the technology and unique properties of this nail lending itself to many future applications, even for other conditions."

DynaNail is the only TTC fusion device to harness the superelastic properties of NiTiNOL. Its internal NiTiNOL element allows for compression to be maintained across the joint post-operatively by automatically adapting to loading changes due to settling or resorption. In addition, the ultra-low axial stiffness of the NiTiNOL element automatically dynamizes the joint, and mitigates stress-shielding that is universal to all other intramedullary nails on the market.

Kurt Jacobus, CEO of MedShape told *OTW*, "We are excited to have some of the best surgeons in the world using our unique technology to benefit patients with debilitating foot and ankle conditions."

Asked about the 'hard' release, Jacobus said, "We are planning a multi center clinical study at Duke and an increase of sets in the marketplace to benefit a broader range of patients. A year from now we want to be part way through the Duke clinical study aimed at understanding high fusion rates and resulting benefits of the Dynanail to patients."

—EH (January 8, 2014)



MedShape, Inc.

TRAUMA

Pediatric Fractures: Long-Term Implications for Bone Health?

A recent study at Mayo Clinic indicates that certain types of fractures may have implications for a child's long-term bone health. The study, published in the *Journal of Bone and Mineral Research*, found evidence that children and adolescents whose forearm fractures occurred due to mild trauma had lower bone strength compared to other children. Lower bone strength may predispose children to osteoporotic fractures later in life.

"Our study highlights the need for clinicians to consider the level of trauma preceding the injury, when treating children and adolescents who present with fracture," says Joshua Farr, Ph.D., a research fellow at Mayo Clinic in Rochester and lead author of the study, in the January 7, 2014 news release. "Fractures from moderate trauma appear more likely to occur in the setting of normal bone strength. But fractures resulting from mild trauma suggest an underlying skeletal deficit."

"We can't say with certainty that these skeletal deficits will track into adulthood. They may be transient," Dr. Farr adds. "But we think that trauma classification is a clinical variable that could be used to more closely monitor kids who are suffering mild-trauma fractures. Intervention in terms of diet and physical activity might be used to optimize bone strength."

The Mayo study compared bone strength in children with recent distal forearm fractures due to mild trauma, children with such fractures due to moderate trauma, and children without fractures. Mild trauma was defined as a fall from a standing height, and moderate trauma was defined as a fall from a relatively low height, such as from a bicycle. The children were aged 8 to 15, and included 108 control participants and 115 boys and girls treated for distal forearm fracture at Mayo within the previous 12 months.

Dr. Farr told *OTW*, "We were surprised to find that children with a recent distal forearm fracture owing to moderate trauma did not have skeletal deficits since the relationship between DXA-derived bone measures and fracture risk in children has been previously shown to be independent of the level of trauma preceding the injury."

"Our next step is to define the role of key lifestyle (e.g., diet, physical activity, body composition) and biochemical/hormonal (e.g., sex steroids, parathyroid hormone, vitamin D) factors in modulating the skeletal parameters that discriminate mild trauma fracture patients from non-fracture controls. A better understanding of the modifiable determinants of bone parameters during growth could inform the design of interventions, with the aim of improving skeletal health and reducing fracture risk in children."

—EH (January 10, 2014)

Wikimedia Commons, James Heilman, M.D., Jmlema

Study: Romosozumab Significantly Increases BMD

Amgen and UCB have announced results from a Phase 2 trial evaluating romosozumab, an investigational medicine, in postmenopausal women with low bone mineral density (BMD). Published in the *New England Journal of Medicine* (*NEJM*), the trial demonstrated that, compared with placebo, romosozumab treatment for 12 months significantly increased BMD at the lumbar spine, total hip and femoral neck. Significant increases were also observed in the first BMD assessment at three months. The researchers also observed at the lumbar spine and hip were significantly greater than those observed with current treatments FOSAMAX and FORTEO/FORSTEO.

"The results of the study demonstrate significantly increased BMD and stimulation of bone formation with romosozumab treatment in women with postmenopausal osteoporosis," said Michael McClung, M.D., director of the Oregon Osteoporosis Center and lead study investigator, in the January 1, 2014 news release. "Additionally, romosozumab treatment resulted in greater increases in bone mineral density than those seen with both placebo and the active comparators. These data provide important insight into this medicine being developed for women with postmenopausal osteoporosis at high risk for fractures."

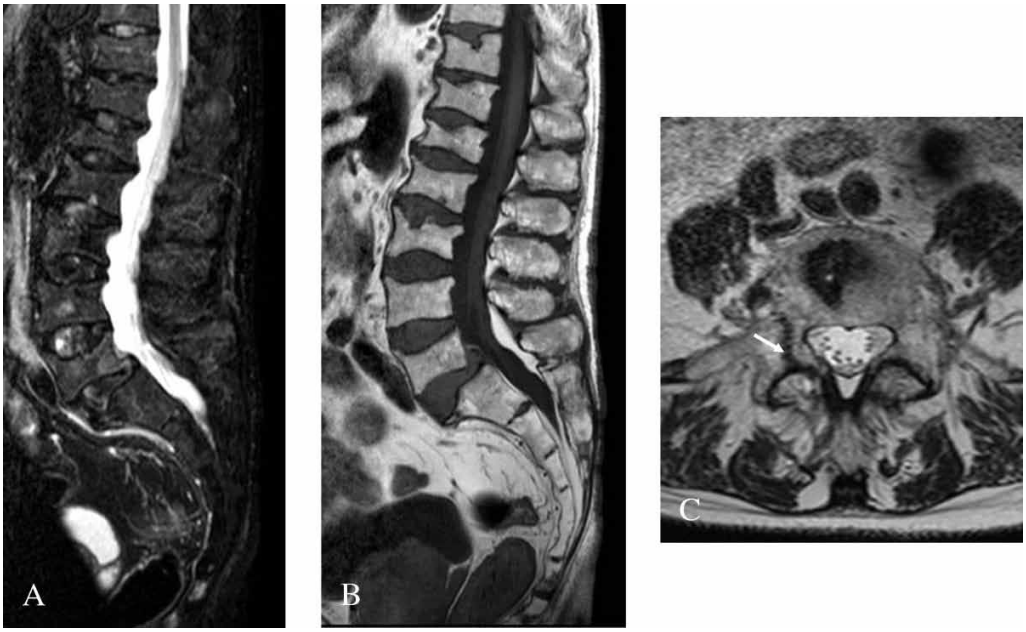
Romosozumab works by inhibiting the protein sclerostin, and is designed to increase bone formation and decrease bone breakdown. Romosozumab is being studied for its potential to reduce fracture risk in an extensive global Phase 3 program.

Asked what he was surprised to learn, Dr. McClung told *OTW*, "Compared to placebo, all doses of romosozumab significantly increased bone mineral density (BMD) in the spine and hip regions. With the largest dose of romosozumab (210 mg given each month) the increase in BMD was significantly greater (11.3%) than were the responses to either alendronate (4.1%) or teriparatide (7.1%). Biochemical indices of bone formation increased during the first 6 months of treatment while markers of bone resorption were modestly decreased during the 12 months of romosozumab therapy. While these results cannot be described as surprising, two aspects of the results stand out: a) the magnitude of the BMD response to romosozumab and b) the fact that the effect on bone formation was transient, with markers of bone formation returning to baseline despite continued therapy with romosozumab."

Regarding future research, Dr. McClung added, "The results of our study provide encouragement to continue to evaluate the potential of romosozumab as a treatment for osteoporosis. The Phase 2 study has been extended to evaluate the effect of longer term treatment with romosozumab, the effects of stopping treatment, of following treatment with denosumab therapy and of re-treatment. Larger Phase 3 studies will evaluate the effectiveness of romosozumab therapy on reducing fracture risk in women with postmenopausal osteoporosis."

The study was a Phase 2, multicenter, international, randomized, placebo-controlled, parallel-group, eight-arm study of 419 postmenopausal women aged 55 to 85 years with BMD. Romosozumab is not currently approved by any regulatory authority.

—EH (January 9, 2014)



Caption:72-year-old patient with severe osteoporosis; Source: Wikimedia Commons and Dr Robert CARLIER, CHU Raymond Poincaré, Garches, France/D.P. Germain: Fabry disease

SPINE

Study: Pinnacle's In-Fill Trumps Traditional Methods

Pinnacle Spine Group, LLC is announcing that an independent study has found that its InFill Graft Delivery System performed better than traditional prepacking methods. The study was designed to evaluate the efficacy of a novel graft filling technique for maximizing interbody space and implant filling and optimizing endplate surface contact with the graft.

The study, conducted by Burak M. Ozgur M.D., FAANS and Erin Gleckman PA-C, of Newport Beach, California, demonstrated a successful increase in interbody space and cage filling, with greatly enhanced endplate surface contact. Volumetric analysis 3-D CT scanning confirmed that up to 94% more graft material can be placed and contained between the vertebrae, including endplate surface contour filling and contact, when compared to traditional prepacking methods.

Zach Sowell, VP of Marketing told *OTW*, "We are very pleased with the outcome of the study. The results prove that a surgeon can achieve greater contact between the graft material and the vertebral bodies when using the InFill Graft Delivery System over the traditional method of pre-packing the implant."

The InFill Graft Delivery System was designed around the concept of placing autogenous graft material into the graft chamber of the implant in situ. It can be used to bulk up a pre-packed implant, or for a complete fill of the implant to maximize contact with the vertebral endplates.

—EH (January 8, 2014)

InFill Graft Delivery System courtesy of Pinnacle Spine Group, LLC

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