

Orthopedics This Week



week in review

4 Orthopaedic Crossfire®: Bigliani vs. Flatow in Fracture Debate ♦ Will the student out debate the teacher? Former student Dr. Evan Flatow goes toe to toe with the inestimable Dr. Louis Bigliani. Dr. Bigliani maintains that replacement is the way to go with four part fractures. Not so fast! counters Flatow. It's a knockdown, drag out debate between two of the best in orthopedics.

8 Hip and Back Care Under Bundled Payments ♦ Can bundled payments reign in rising health care spending including surgeon payments? New study sheds light on where cost savings in hip and back care might lie. Guess what? It's not with the surgeon.


12 Orthopaedic Crossfire® Bell vs. Brems in Cuff Repair Debate ♦ Dr. Robert H. Bell argues that arthroscopic repair saves time, money and tissue damage while Dr. John J. Brems maintains that open repairs stand the test of time. Both physicians "cuffed" the other round the ears in this spirited exchange. You don't want to miss this Crossfire exchange.

16 On (and Off) the Record ♦ Spine surgeons getting flack from hospitals? Spine surgeons guessing at diagnoses? Dr. Javad Parvizi homes in on periprosthetic joint infection, Drs. Russell Warren and Gunnar Andersson receive awards, and more...





Louis U. Bigliani, M.D.
Columbia Presbyterian
Medical Center
New York, New York

VS



Evan L. Flatow, M.D.
The Mt. Sinai
School of Medicine
New York, New York



Moderator:
Thomas S. Thornhill, M.D.
Harvard Medical School
Boston, Massachusetts



breaking news

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Knee Hospitalization Rates Soar
.....
TranSI Goes "Lateral"

For all news that is ortho, read on.



Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Does any of this sound familiar? Rising gold and oil prices, squeezing disposable income, rising deficits and worldwide protest movements (including a government change in Greece). It should. It happened in 1973. Like now. For the next seven years there was zero economic growth. Could that happen again? Wall Street is worried it might. So sellers are driving equity prices lower.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Zimmer	27.75%	(8.64%)	Now down to 9.2x P/E on forward earnings, ZMH remains the least expensive of all orthopedic equities.
2	2	Medtronic	28.63	0.89	New "outperform" ratings from Credit Suisse and Cowen right in front of this week's earnings release.
3	3	Orthofix	14.72	(0.09)	Three analysts raised their EPS estimate for 2011. Smart move considering OFIX has beaten the analysts every quarter.
4	5	Conmed	9.65	0.15	The key to CNMD is profitability. PSR is 2nd lowest in ortho. As margins expand, EPS will grow and valuation should rise.
5	7	Johnson & Johnson	26.33	1.93	We're back in choppy investment waters so the urge to retreat to safe havens like JNJ is back.
6	4	Stryker	25.23	(3.24)	The only reason SYK is at #6 is because, on a comparative basis, SYK's valuation is getting slightly rich.
7	6	Exactech	7.69	3.16	Headwinds are particularly difficult for smaller ortho companies like EXAC, yet sales last quarter rose 13%.
8	8	Kensey Nash	34.24	(3.97)	The area where KNSY is #1 is expected earnings growth. Analysts are forecasting 20% earnings growth this year.
9	9	Smith & Nephew	22.8	0.62	SNN's competitors are both acquiring new technologies and slimming down. What's SNN doing?
10	10	Integra	15.38	(18.53)	IART has declined like this 4 times in the past. Each time, once bottom was hit, the stock began a sustained 1-2 year run.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 Bacterin Intl Holdings	BONE	\$2.88	\$117	25.22%
2 RTI Biologics Inc	RTIX	\$4.30	\$237	14.97%
3 Exactech	EXAC	\$15.01	\$197	3.16%
4 Johnson & Johnson	JNJ	\$63.85	\$174,365	1.93%
5 Medtronic	MDT	\$33.94	\$35,840	0.89%
6 Smith & Nephew	SNN	\$45.42	\$8,115	0.62%
7 Conmed	CNMD	\$25.97	\$725	0.15%
8 Orthofix	OFIX	\$32.58	\$600	-0.09%
9 Synthes	SYSTVX	\$162.81	\$19,338	-0.13%
10 Alphatec Holdings	ATEC	\$1.99	\$178	-2.45%

Worst Performers Last 30 Days

Company	Symbol	Price	Mkt Cap	30-Day Chg
1 MAKO Surgical	MAKO	\$28.87	\$1,203	-25.97%
2 NuVasive	NUVA	\$13.97	\$590	-20.13%
3 Integra LifeSciences	IART	\$30.25	\$811	-18.53%
4 Wright Medical	WMGI	\$14.44	\$568	-18.42%
5 TranS1	TSON	\$1.63	\$44	-12.83%
6 Tornier N.V.	TRNX	\$19.34	\$759	-12.80%
7 ArthroCare	ARTC	\$26.70	\$735	-10.58%
8 Symmetry Medical	SMA	\$7.53	\$273	-9.50%
9 Zimmer Holdings	ZMH	\$48.44	\$8,679	-8.64%
10 TiGenix	TIG.BR	\$0.92	\$84	-4.77%

Lowest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Zimmer Holdings	ZMH	\$48.44	\$8,679	10.28
2 Medtronic	MDT	\$33.94	\$35,840	10.32
3 Integra LifeSciences	IART	\$30.25	\$811	12.50
4 Orthofix	OFIX	\$32.58	\$600	12.63
5 CryoLife	CRY	\$4.35	\$122	12.79

Highest Price / Earnings Ratio (TTM)

Company	Symbol	Price	Mkt Cap	P/E
1 Wright Medical	WMGI	\$14.44	\$568	30.72
2 RTI Biologics Inc	RTIX	\$4.30	\$237	26.88
3 NuVasive	NUVA	\$13.97	\$590	20.85
4 Synthes	SYSTVX	\$162.81	\$19,338	20.61
5 Exactech	EXAC	\$15.01	\$197	19.00

Lowest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG
1 Orthofix	OFIX	\$32.58	\$600	0.77
2 RTI Biologics Inc	RTIX	\$4.30	\$237	0.95
3 Zimmer Holdings	ZMH	\$48.44	\$8,679	1.10
4 Stryker	SYK	\$47.81	\$18,296	1.24
5 Exactech	EXAC	\$15.01	\$197	1.36

Highest P/E to Growth Ratio (Earnings Estimates)

Company	Symbol	Price	Mkt Cap	PEG
1 NuVasive	NUVA	\$13.97	\$590	4.68
2 Wright Medical	WMGI	\$14.44	\$568	3.38
3 Kensey Nash	KNSY	\$25.16	\$218	2.97
4 Johnson & Johnson	JNJ	\$63.85	\$174,365	2.15
5 Smith & Nephew	SNN	\$45.42	\$8,115	2.06

Lowest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 Symmetry Medical	SMA	\$7.53	\$273	0.76
2 Conmed	CNMD	\$25.97	\$725	1.02
3 Alphatec Holdings	ATEC	\$1.99	\$178	1.03
4 Exactech	EXAC	\$15.01	\$197	1.04
5 CryoLife	CRY	\$4.35	\$122	1.05

Highest Price to Sales Ratio (TTM)

Company	Symbol	Price	Mkt Cap	PSR
1 TiGenix	TIG.BR	\$0.92	\$84	134.84
2 MAKO Surgical	MAKO	\$28.87	\$1,203	27.15
3 Synthes	SYSTVX	\$162.81	\$19,338	5.25
4 Bacterin Intl Holdings	BONE	\$2.88	\$117	4.44
5 Tornier N.V.	TRNX	\$19.34	\$759	3.34

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

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Orthopaedic Crossfire®: Bigliani vs. Flatow in Fracture Debate

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

Louis U. Bigliani, M.D.
Columbia Presbyterian
Medical Center
New York, New York

VS

Evan L. Flatow, M.D.
The Mt. Sinai
School of Medicine
New York, New York

Moderator:
Thomas S. Thornhill, M.D.
Harvard Medical School
Boston, Massachusetts

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Proposition

Four Part Fractures Require Replacement: Once is Enough

For the Proposition:

Louis U. Bigliani, M.D.
Columbia Presbyterian Medical Center
New York, New York

Against the Proposition:

Evan L. Flatow, M.D.
The Mt. Sinai School of Medicine
New York, New York

Moderator:

Thomas S. Thornhill, M.D.
Harvard Medical School
Boston, Massachusetts

This debate was held in May 2009 in an Orthopaedic Crossfire® session at the 10th Annual Current Concepts in Joint Replacement™ (CCJR) Spring meeting

in Las Vegas, Nevada. The CCJR meetings are organized by A. Seth Greenwald, D.Phil. (Oxon) and the Orthopaedic Crossfire® debates serve to frame contemporary controversies and contribute information in a uniquely compelling format within the very popular CCJR meetings (www.CCJR.com).

Dr. Bigliani: "I'll talk today about four part proximal humerus fractures, and that a humeral head replacement [HHR] is the way to go. The indications for four part fractures for me are lateral displacement of the head in a four part fracture, metaphyseal bone comminution, a dislocation, older osteoporotic patients, and certain head splitting fractures."

"Case #1: Consider a 68-year-old neurologist with an isolated four part fracture of the proximal humerus. She's got

some osteoporosis, but there's a lot of medial comminution so this is somebody who I would replace because your first shot is your best shot. We've seen that people with malunions don't do well. A delto-pectoral approach is what I like to use...important to find the biceps and if you can, preserve some of the greater tuberosity with the lesser tuberosity."

"Big sutures need to go around both the lesser and greater tuberosity to be able to get traction and to be able to pull the rotator cuff out to length. When you do dislodge the head it's important to keep all the bone...you need bone graft."

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“Case #2: Consider a 46-year-old male who fell from a ladder and sustained a four part fracture. He didn’t have anything done, and went on to a malunion which was treated with a tuberosity osteotomy and a prosthesis in 1983 when Dr. Flatow was a resident with Dr. Neer. At 26 years the patient is satisfied, has 160° of forward elevation, 30° of external rotation, internal rotation of T10, good rotator cuff strength with mild subacromial pain.”

“If we look at the literature, great results when it comes to pain relief and improved function, although it can be variable. In a meta-analysis of 808 patients the Constant Score was 56.63, with tuberosity complications being the biggest factor. Avascular necrosis [AVN] occurs when we revise three and four part fractures previously treated with open reduction and internal fixation [ORIF]. Resch’s work shows a Constant Score of 49.5% with internal fixation. If we use plate fixation we see that 79% have varus angulation, so in my estimation multiple studies over time have demonstrated that HHR for proximal humerus fractures provides reliable pain relief and improved function. Therefore, HHR is a reasonable treatment for the management of four part proximal humerus fractures, especially in older patients.”

Dr. Flatow: “I’m going to speak against this. The question is, ‘Is a big hunk of metal the best treatment for proximal humerus fractures...or can we do better?’ The issue is, ‘Have things changed in the debate between a prosthesis and internal fixation?’”

“It’s hard to debate one’s teacher—and I trained with both Drs. Neer and Bigliani—I will try to debate my mentor with tact and discretion and respect.”

“The results of HHR for fracture are important because if it’s such a miraculous operation then why wouldn’t we want to do it in every case? *The literature suggests that there is consistent pain relief, but there is variable function. When it says ‘variable’ in an article it usually means that ‘variable’ is another word for ‘not so good.’* The most common problem is stiffness; the worst problem is failure of tuberosity repair. The ‘old’ thinking is that AVN is a big risk in complex fractures, that AVN is a clinical disaster, that doing an HHR later is very hard, and that doing a HHR first works well.”

“I’ve watched the evolution of these ideas. Dr. Bigliani was once a young man with young thinking; he is now very distinguished in his career and his thinking. But as he has gotten a bit

older perhaps he is stuck in this older thinking, and needs to look forward to the recent, ‘young’ thinking that AVN is not always a disaster. We consider the work of Hertel and Jakob where they subdivide AVN risk in four part fractures so that some four parts like a classic dislocated four part have a very high risk of AVN, and others like an impacted valgus fracture with some soft tissue attachment which are on a spectrum with lateral displacement fractures, have less of a risk. Other, more recent concerns are that less AVN occurs with minimally invasive techniques, as Resch and Benirshke have argued. Gerber has argued that AVN is better tolerated if internal fixation is anatomic.”

“I think that AVN is better tolerated in Switzerland than it is in New York City, but his point is that many of the articles about AVN after fracture included people with malunited tuberosities, loose hardware, nerve injuries and scar. And finally, the realization that if you have to do a hemiarthroplasty later, if you did a more minimal internal fixation earlier, the results may be better.”

“So perhaps a classic four part head dislocated fracture is not a good case for internal fixation. But this is not as common as other patterns such as a valgus impacted fracture, which may have a medial hinge. And we’ve learned how to hit it up with elevators and put in pins and place screws in the tuberosity without making incisions, so there’s less scarring. And the lesser tuberosity can be reduced, so the technologies have been expanding. Fixed angle plates can be a problem in these fractures because the screws wind up sticking up in the air if there is collapse.”

“As an example, a patient with a three part fracture was pinned. At 1.5 years

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she was doing well, but nothing ruins results like follow up, and out at two years she had AVN. But her hemiarthroplasty went almost like a primary osteoarthritic replacement because she had not had a big, open incision at her initial surgery.”

“So percutaneous pinning and minimally invasive surgery (MIS) has become reliable and reproducible, and stiffness is rare. Leesa Galatz, Jerry Williams and I reported on this from three centers, and we have found excellent results, and the AVN rate has been fairly low. Also, the complications are less complicated than after traditional plating, so this has changed some of our thinking because of the lack of scarring in these situations.”

“So proximal humerus fractures...I think there are fewer indications for primary hemiarthroplasty, perhaps true four part dislocations and head splits. MIS/ORIF [open reduction, internal fixation] is growing, and I think late humeral head replacement is certainly an option.”

“Dr. Bigliani has tremendous prestige. He is the president of the American Orthopaedic Association, a prestigious organization...it's a very old organization. It reminds me of the Freemasons, and so I think there is a rationale for some new thinking on this important topic.”

Moderator Thornhill: “Louie, you listed some of the four parts you would replace with a humeral head replacement. Which ones would you repair?”

Dr. Bigliani: “I think Evan's right... that minimally invasive techniques in younger patients with good bone where their soft tissue attachment sort

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of escaped the four part classification. When someone gets older, when they have osteoporotic bone, when they just need one operation rather than two... and Evan has been double dipping as you can see from his talk—doing two operations on one patient. When you have older individuals I would go with HHR, but for younger people it's worth it to try and put it back together. And I'm dead set against these big plates... too much metal, too little bone."

Moderator Thornhill: "You talk about one or two operations...how about no operations? How about in a valgus impacted four-part, when would you treat the patient nonoperatively?"

Dr. Flatow: "I think a valgus impacted fracture can be tempting to treat nonoperatively because it looks like all the pieces are close together. But the head is usually not at all in contact in the socket and so for an active, healthy person they really don't do very well. They may be pain free, but they usually don't have good motion. But unlike a four part with the head and the axila, if you have a demented or a very elderly sick patient, you can get by because it is impacted, the pieces are close together, it's not going to erode into an artery or cut a nerve."

Dr. Bigliani: "There's a lot of literature out on that and if patients are willing to accept less range of motion and limited function then it's a reasonable alternative."

Dr. Flatow: "It works better in Scotland than in Manhattan."

Moderator Thornhill: "Well, I think under comparative effectiveness we may be facing that even more. Louie, what would be the de minimis x-ray

evaluation you want on someone with a four part fracture?"

Dr. Bigliani: "Get the three trauma series views—axillary, lateral in the scapular plane, and an AP view. And you should get a good CT scan. And then you can get more extravagant with other reconstructions, but reconstructions are fairly easy to get right now."

Moderator Thornhill: "CT scan on everyone with these?"

Dr. Flatow: "I don't think everyone, but I agree completely with Louie...when there is any question or imprecision I think a CT scan can be very helpful."

Moderator Thornhill: "What's harder, a total shoulder or fixing a four part?"

Dr. Flatow: "I think it's harder to get a good result, so I don't know about the effort at surgery, but the learning curve and doing a good job with the tuberosities and getting a good result after fracture is a little more challenging than an osteoarthritic total shoulder."

Dr. Bigliani: "Four part fracture is hard. There are a lot of technical steps that I left out...I just had a patient two years ago who had a massive pulmonary embolism—still alive—and we couldn't rehab her for awhile. The other thing I want to say is that anatomical fracture in young people really isn't anatomical. There is always some soft tissue attached and I think those really need to be fixed."

Moderator Thornhill: "Louie, who exactly should be doing these fractures?"

Dr. Bigliani: "The person that really thinks that he's qualified to do it. It

could be a trauma surgeon or shoulder surgeon...someone who understands the pathology, understands what needs to go into the operation, and understands the rehab."

Moderator Thornhill: "I think you both agreed that all these fancy new plates and stuff may have some downside, and that minimal is the way to go?"

Dr. Bigliani: "These reconstruction plates...it's a million screws into osteoporotic bone and it's probably not the greatest alternative."

Dr. Flatow: "Shoulders aren't apples and everyone's seen that video of the plate with the apple but you can get some bad results with a plate."

Moderator Thornhill: "That 26-year-old case had a cemented humeral component...I've seen several cases of four parts where in an uncemented humeral component it tends to spin out because you lose the rotational stability with your tuberosities off. Yet the case you showed used cement. When do you decide to cement?"

Dr. Bigliani: "If you've got osteoporotic bone and you don't have good fixation a little cement never hurts."

Dr. Flatow: "Almost always cement a fracture."

Moderator Thornhill: "Thank you for a very good discussion, gentlemen." ♦

Please visit www.CCJR.com to register for the upcoming 2011 CCJR Winter Meeting, December 7-10 in Orlando, Florida and the 2012 CCJR Spring Meeting, May 20-23 in Las Vegas, Nevada.

Hip and Back Care Under Bundled Payments

By Walter Eisner

How do spine and hip surgeons fare under a bundled payment system?

A recent study published in *Health Affairs* was the first detailed study to specifically look at back and hip surgeries and answer that question.

The authors of the study (*Large Variations In Medicare Payments For Surgery Highlight Savings Potential From Bundled Payment Programs Health Affairs*, 30, no.11 (2011):2107-2115), looked at variations between high and low cost hospitals for a full episode of back and hip surgical care and determined that current Medicare episode payments for certain inpatient procedures varied by 49% to 130% across the hospitals.

It is in these variations that the authors believe bundled payments can realize the biggest cost savings and which could also affect hip and back surgeons.

It turns out that it wasn't surgeon payments that varied widely, but pre-op and post-op care. As Kevin Bozic, M.D., MBA, told us on November 16, this is an opportunity for physicians to have an impact on costs because they have substantial influence over roughly 80-90% of decisions around an entire episode of care.

Bundled Payments: Past, Present and Future

Before diving into the specifics of the bundled payment study, we need a little history and background on the subject.

Bundled payments, also known as episode-based payments, reimburse

health care providers (such as hospitals and physicians) on the basis of expected costs for episodes of care. It has been described as a middle ground between fee-for-service reimbursement (in which providers are paid for each service delivered to a patient) and capitation (in which providers are paid a lump sum per patient regardless of how many services the patient receives).

The fee-for-service system has been blamed for rewarding volume of care instead of quality.

The idea of bundled payment reaches back to the mid-1980s when Medicare's hospital prospective payment system using diagnosis-related groups was put into place. Some believed the new payment system caused hospitals to dump

patients into skilled nursing facilities more quickly than appropriate to save money. It was then suggested that Medicare bundle payments for hospital and post hospital care. But that was never done.

In 1984 The Texas Heart Institute began to charge flat fees for both hospital and physician services for cardiovascular surgeries. The Institute claimed that it was able to maintain quality care while lowering costs. The Institute's flat fee for surgery was significantly lower than the average Medicare payment for the procedure.

Currently, the Centers for Medicare and Medicaid Services (CMS) has initiated the Medicare Acute Care Episode demonstration project, which involves



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a single payment for both Part A and Part B services for beneficiaries undergoing a variety of orthopedic and cardiac inpatient procedures. The project is scheduled to begin next year.

Under one model of the pilot project, physicians and hospitals would split a single payment—determined prospectively—for an inpatient episode, such as a hip replacement, that would include post discharge services. The hope is that hospitals and physicians will work together more closely to coordinate a patient's care after discharge so that the patient will not bounce back as a readmission several weeks later.

The results of the study published in Health Affairs indicate that this model offers the best opportunity to save costs. Two of the CMS bundled payment models focus on inpatient stays, a third involves postdischarge services only, and a fourth combines inpatient and postdischarge services. The earliest a group participating in the project could get started with the first inpatient-only model in January 2012, said Richard Gilfillan, M.D., acting director of the CMS Innovation Center. The other three models require more analysis and would not become active until later in 2012.

In the future, The Affordable Care Act requires a plan to reform Medicare payments for post-acute services, including bundled payments.

Miller Study

Now back to the study led by David Miller, M.D., MPH, an assistant professor of urology at the University of Michigan Medical School.

Miller and five coauthors found that post-discharge care was the leading



David J. Miller M.D., Ph.D.
Source: www.med.umich.edu

cause of payment differences among patients receiving hip replacement surgery or back surgery, accounting for 40.7% to 85.2% of the variation, depending on the kind of surgery. Physician services only accounted for 8.6% to 12.8% of the variation among surgeries.

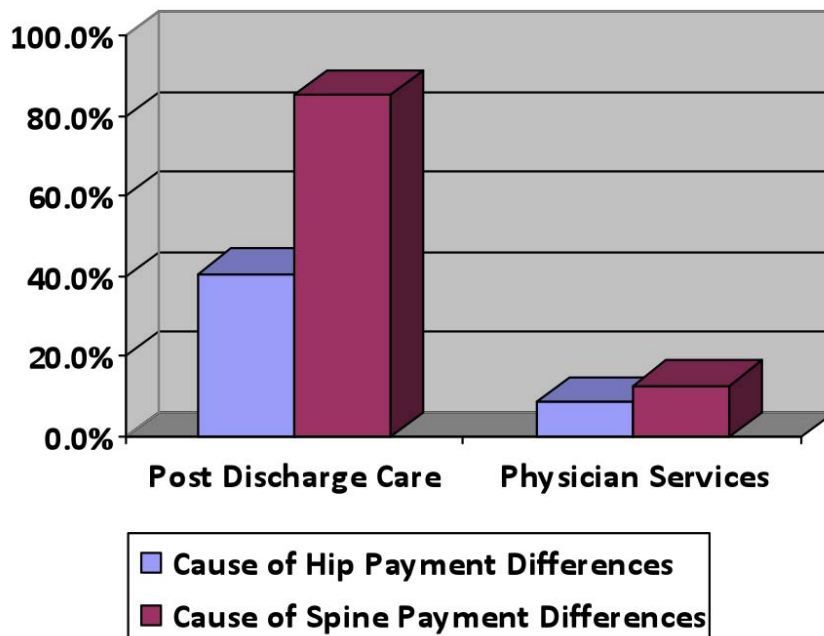
The authors studied Medicare claims for four surgeries (back, hip, colectomy and coronary artery bypass grafting) from January 2005 through November 2007. They tallied payments for hospital, physician, and postdischarge

care from the date of admission to 30 days after discharge. Excluded from the analysis were patients enrolled in Medicare managed care plans, those younger than age 65 years or older than age 99 years, and patients not enrolled in both Part A and Part B of Medicare at the time of the procedure.

The average Medicare payments were \$20,807 for elective hip replacement and \$26,540 for back surgery.

Hospitals were ranked according to total episode payments and assigned to five groups, or quintiles, adjusting the results for price, differences in demographic characteristics, comorbidity, and illness severity. After these adjustments, payments for hospitals in the highest-cost quintile were still 10% to 40% higher than those for hospitals in the lowest quintile, depending on the procedure. The biggest difference dollar-wise between the top and bottom hospitals was \$7,759 for back surgery.

“Intentional differences in payments attributable to such factors as geogra-



Data Source: Study led by David Miller, M.D., MPH./ Image created by RRY Publications LLC

phy or illness severity explained much of this variation,” wrote the authors.

“But after adjustment for these differences, per episode payments to the highest-cost hospitals were higher than those to the lowest-cost facilities.... Postdischarge care accounted for a large proportion of the variation in payments, as did discretionary physician services, which may be driven in turn by variations in surgeons’ practice styles.”

Postdischarge care for hip replacement accounted for a greater share—85%—of the difference in total payments to hospitals in the first and fifth payment quintiles than for any of the other procedures, according to the Miller study. Physician services variations ranged from 9% for hip replacement to 13% for back surgery.

“Sizable Savings for Payers”

“Our study suggests that bundled payments could yield sizable savings for payers, although the effect on individual institutions will vary because hospitals that were relatively expensive for one procedure were often relatively inexpensive for others. More broadly, our data suggest that many hospitals have considerable room to improve their cost efficiency for inpatient surgery and should look for patterns of excess utilization, particularly among surgical specialties, other inpatient specialist consultations, and various types of postdischarge care.”

Bozic, Chair of the American Academy of Orthopaedic Surgeons Healthcare Systems Committee, told Medscape Medical News that the Miller study shows that there is “significant



Kevin Bozic, M.D., MBA
Source: ihs.medschool.ucsf.edu

variability in the types of resources that patients utilize.... Some are under the control of the physician, and some are under control of the patient.”

He said factoring a surgery patient’s living status into discharge plans is critical for both quality of care and cost control.

“Let’s say a patient lives alone in a walk-up apartment where there is no elevator. If you can come up with a plan to get him or her up and down the stairs, and have someone provide meals, and other home services, you might be able to keep the patient out of a post-acute-care facility, which would drive up costs,” he told Medscape.

He said physicians should look at every step of patient care to determine whether it adds value.

“If we routinely order a lab test, and it doesn’t change how we manage the patient, we should eliminate it,” he said. “But don’t eliminate it just on the basis of cost. You’ll end up cutting corners and potentially compromising outcomes.”

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

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Shifting Power

Cutting corners or skimping on care to save money is a concern raised as physicians and hospitals stand to gain financially from the cost savings associated with a bundled payment. That's where defining best practices comes in, Bozic told *OTW*.

The University of Minnesota's spine chief, David Polly, M.D. told *OTW* that physicians in this system will no longer be looking at what's best for a particular patient, but will be making decisions about a patient group. Bozic agreed with that assessment.

Polly and Bozic also agree that the bundled payment system shifts risk from payers to providers for managing the costs associated with an episode of care for specific procedures. But they see the

trade-off of more control over managing the care of the patient.

"Episode of care payments offer orthopaedic surgeons a tremendous opportunity to control their own destiny in terms of their future reimbursement," said Bozic.

Having more power to manage a patient's care within economic realities is the carrot in a health care system that is increasingly using the stick to impact physician practice. But as the Miller study shows, the cost savings in a bundled pay system that looks to close the gap in variances between high cost and low cost hospitals are likely to come from post-op care. ♦

Health Affairs

At the Intersection of Health, Health Care and Policy

David C. Miller, Cathryn Gust, Justin B. Dimick, Nancy Birkmeyer, Jonathan Skinner and John D. Birkmeyer
Large Variations in Medicare Payments For Surgery Highlight Savings Potential From Bundled Payment Programs
Health Affairs, 30, no.11 (2011):2107-2115
doi: 10.1377/hlthaff.2011.0783

The online version of this article, along with updated information and services, is available at:
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by guest

Health Affairs

Orthopaedic Crossfire® Tackles Arthroscopic Cuff Repair

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

Robert H. Bell, M.D.
Crystal Clinic
Akron, Ohio

VS

John J. Brems, M.D.
Cleveland Clinic
Cleveland, Ohio

Moderator: Thomas S. Thornhill, M.D.
Harvard Medical School
Boston, Massachusetts

Image created by RRY Publications, LLC. Source: Wikimedia - KaihsuTai and Current Concepts in Joint Replacement

Proposition

Cuff Repair Should be Done Arthroscopically: Body of Evidence

For the Proposition:

Robert H. Bell, M.D.
Crystal Clinic
Akron, Ohio

Against the Proposition:

John J. Brems, M.D.
Cleveland Clinic
Cleveland, Ohio

Moderator:

Thomas S. Thornhill, M.D.
Harvard Medical School
Boston, Massachusetts

Dr. Bell: “Arthroscopic approaches allow us to look at and treat additional pathology. Chondral lesions, biceps lesions, AC [acromioclavicular] joint problems, and of course, articular side partial thickness tears, which we would not visualize if it were mainly bursal lesions. Mobilization...very selective releases...you can do these open, but arthroscopically you can do them even in a more selective, less traumatic fashion. Paralabral capsulotomies...much as we do for adhesive capsulitis. Anterior interval releases for the leading edge of the supraspinatus, and then posterior interval releases (in this case of a supraspinatus lesion which is retracted anteriorly and medially).”

“So the question is, ‘Does the arthroscopic approach affect rehab?’ This isn’t an evidence based Level I study, but I looked at a large group of patients—open and arthroscopic—and we looked at the total number of visits, average cost per visit, total cost of rehab, and compared those to subsets. We found that the arthroscopic group had significantly fewer visits, were discharged over a month sooner, and their average total charge was less than the open repairs. That still doesn’t save you a great deal of money, but it did lessen the time in rehab.”

“What about OR charges? We compared ‘time in’ to ‘time out’ for an arthroscop-

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ic and an open group of patients...the open group was about an hour and a half; arthroscopic was about an hour.

The 30% decrease against what your OR charges are, that can translate into reasonable savings.”

“As for the case we’re discussing today, it was an active older gentleman with significant functional limitations who wanted to get back to playing tennis. I can almost guarantee you he’d have intra-articular pathology, with a biceps lesion. I would debride and perform a concomitant decompression to open up his subacromial space. I’d do a paralabral release if need be...if the cuff was retracted, anterior and posterior interval releases. A Mumford, possibly, if symptoms dictated and not relying on a radiographic picture. And then the repair itself would be a double row repair. In an active individual like this, two anchors medially, two to three anchors laterally; we’d pass all the medial sutures through in a mattress fashion...tie those first, creating a medial row and coupling those laterally to recreate the footprint, realizing a stable construct that we could get going fairly quickly.”

“Re-tear rates are improving as we obtain better materials; better anchors with better pullouts, enhanced suture materials...our suture passing devices are improving...double row reconstructions...less early postop issues with adhesive capsulitis. Cost issues will improve as we lessen the time in surgery. Biologics are going to enhance this a great deal in terms of platelet rich plasma. There is no question in my mind that arthroscopic rotator cuff repair is the way to go.”

Dr. Brems: “I’m taking the tack that in a specific case, open repair would offer the better option. Consider a 60-year-old male executive who is an avid tennis player. He’s had two years of minor symptoms while playing tennis, several injections of steroids over the last 12 months, physical therapy, sleep interruption, many oral anti-inflammatories,

and the MRI scan which showed supra- and intra-spinatous tears, 2 cm retraction, and mild muscle atrophy. Some cuff tears can be treated arthroscopically, but not all cuff tears should be treated arthroscopically.”

“In this tear, why is open the better option? Considerations: patient’s age and physical demands; tear size and configuration; tissue quality; fat replacement of the muscle can be suggestive of size and chronicity of tear; quality of the bone to which it has to be reattached; delamination issues, which are commonly seen in large cuff tears.” “Except in acute tears—which we rarely see—‘retraction’ is an orthopedic myth. In chronic tears—which we see commonly—the tendon is gone... it’s not just pulled back and retracted where you can pull it back and sew it. The bony footprint is often osteopenic and anchor failure is not uncommon. So now we recommend the double row technique, but some studies showed as recently as 2008 the double row technique suggests there’s now hypovascularity imparted by the newer suture techniques, and may damage the repaired tissue. The open technique can permit large bone tunnels and transosseous fixation with lower risk of fixation failure.”

“In an arthroscopic situation, when people have gone back in and looked at it in revision situations you’ll get a spot welding where the anchors may be. Whereas an open technique along a large bony trough using a transosseous suture technique in a horizontal mattress fashion obtains a seam...considerably more durable in tension than the spot welding may be.”

“There are three major differences between open and arthroscopic techniques...two are permanent and one

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is temporary...one is very significant. With one difference, arthroscopic wins: the length and permanency of the scar. Another difference: there is no doubt that arthroscopic surgery is less painful, but pain can be a good thing... and perhaps some of the failure rates in arthroscopic surgery are because patients without pain think they are healing and they feel better before they really are better. Difference three: in this case, open is the clear and convincing winner—definitely better outcomes, especially when considering cuff integrity. Many arthroscopists will acknowledge that cuff integrity fails, but because the pain has not returned they consider it a good outcome.”

“What is *not* different? Patients do not heal faster...they don’t return to work sooner, they don’t return to sports quicker; they should not resume strengthening any sooner because the rate limiting

step is the time it takes a tissue to heal to the bone. And some argue that the healing is more robust with the open technique because of the better blood supply in the bone trough.”

“In an ultrasound follow-up of 127 patients in 2009—Dr. David Altchek from New York—found that the progression from a single tendon tear to a multiple tendon tear increased the likelihood of re-tear by at least nine times. If we look at Dr. Brian Cole, 47 shoulders, two year follow-up, all arthroscopic repairs, 22% re-tear rate in two years. Dr. Leesa Galatz looked at 18 patients with single and two tendon tears, ultrasound analysis, where 94% failed in a two year follow-up.”

“Open repairs do stand the test of time. Dr. Joseph Iannotti looked at 40 patients and had 88% good/excellent outcomes; Dr. Francis Cuomo looked at

30 patients and had 100% good/excellent outcomes...and on and on.”

“So this man’s large, 2 cm tear should be treated open.”

Moderator Thornhill: “Rob, do you ever do open repairs?”

Dr. Bell: “Absolutely. And John and I don’t disagree as is often the case in a situation like this. Certain cuff tears I will address open...not infrequently a combined subscapularis/ supraspinatus that I need to work on lateralizing, I do open. But the majority I fix arthroscopically. I think the data—even though John nicely demonstrated this—the reports on the efficacy of the open repairs in the last group was based not upon the confirmed integrity of the repair, but the outcomes, and I think the outcomes now are very similar between the two groups.”

Moderator Thornhill: “So what is the learning curve? Who should be able to do this and what should be our level of training?”

Dr. Brems: “I appreciate the question because we had a discussion in our residency program last week about this issue. I wonder...at how many training programs are the residents even being exposed to open techniques anymore? Are we soon going to be graduating residents who’ve never even seen an open rotator cuff repair? As we’ve tried to show today, there are situations, and I think—from my heart—the case that I’ve just showed I would do that open. There are tears that are smaller and less complex—if there’s an acute tear which can and should be treated arthroscopically—my point is that we should not always do it, and not be considered inadequate if we don’t. The issue is when to do what.”

Moderator Thornhill: “Rob, I had the pleasure of going to Columbia, sort of the birthplace of acromioplasty, and Dr. Bill Levine gave a talk suggesting that we’re doing too many acromioplasties. In the case that you talked about today you did a rotator cuff repair, you did a Mumford procedure, you did several other things. Do you think we’re overdoing these?”

Dr. Bell: “No. It’s a good question and I put that up there as an option that would be part of it. If I look statistically at the Mumford, for instance, it’s probably less than ten...I do fewer Mumfords now arthroscopically than I did open. I do decompression acromioplasty still in the majority of chronic tears. If I have a younger individual under the age of 40, which is infrequent in an acute tear, I would not do a decompression. But I see very little morbidity associated with doing a decompression in the face of a chronic lesion. In fact, I think it enhances the outcome.”

Dr. Brems: “I would argue the opposite. With open repairs—Dr. Evan Flatow taught me this—when I do an open repair for large cuff tears, I will do an acromioplasty, but when I take the coracoacromial (CA) ligament off the acromion I keep it intact with the deltoid undersurface and clearly reconstruct the CA arch when I close the deltoid. In larger tears it becomes incumbent to maintain that arch because of the potential problems down the line. If the cuff fails again you want the arch intact to try to minimize superior escape that might occur.”

Dr. Bell: “I agree with that and Evan and I had this conversation ten years ago when he first started talking about CA ligament reconstructions and I said, ‘I don’t know why you have to reconstruct them, just don’t resect them!’

And so my acromioplasty is peeling it back, not resecting it and when we come back—God forbid I’d ever have to re-scope a shoulder—I can see that the CA ligament attachment is back to the decompressed acromion.”

Moderator Thornhill: “I thought I had it. I went from single row to double row, and so to increase the footprint, look to see if there’s fat in the muscle...and then I heard that they all fall apart anyway. So tell me, do I do double row, give as big of a footprint as I can and be very judicious about rehab?”

Dr. Bell: “There probably is not a significant difference in the outcomes on double versus single. Early, biomechanically there is. One thing we’re not doing is releasing these cuffs the way we used to do open so I would do single row in the majority of cases.”

Dr. Brems: “As would I...single row in the majority of cases.”

Moderator Thornhill: “Gentlemen, thank you.” ♦

Please visit www.CCJR.com to register for the upcoming 2011 CCJR Winter Meeting, December 7-10 in Orlando, Florida and the 2012 CCJR Spring Meeting, May 20-23 in Las Vegas, Nevada.



On (and Off) the Record By Elizabeth Hofheinz

Dear OTW Reader: Spine surgeons getting flack from hospitals? Spine surgeons guessing at diagnoses? Dr. Javad Parvizi homes in on periprosthetic joint infection, Drs. Russell Warren and Gunnar Andersson receive awards, and more...

Spine Surgeons Getting Flack From Hospitals? A spine surgeon tells OTW, “Those of us in private practice—especially those of us who are just starting out—are really disheartened about reimbursement. I’ve been in practice for a year and a half...in that short period of time I’ve seen reimbursements for our procedures change twice. We have multiple codes for procedures, and the powers that be are starting to bundle

those codes such that we are getting paid not for four procedures, but for two. Another issue is that my hospital, like many, is tightening controls and limiting our independence in terms of what products we want to utilize. My colleagues and I are getting flack along the lines of, ‘We don’t want you to use this bone graft because it is too expensive and insurance won’t pay. Every time you put this into a patient it’s a pure loss for us.’ In this environment, we can’t do what is optimal for patients.”

OrthoData: New President and CEO Ric Navarro has come aboard OrthoData as the new president and chief executive officer. Navarro, who will also serve on the company’s board of directors,

has over 25 years of medical device and implant experience. Most recently he served as the VP and Site Manager for Integra LifeSciences spine division in Akron, Ohio. Prior to that, Navarro, who is an inventor on 21 patents, was in senior management at Theken Spine and was a co-founder and VP R&D for Theken Disc, a company that developed the first lumbar artificial disc to incorporate microelectronics. In addition he has held senior engineering, quality, and operations roles with Integra, Biomec, Allen Medical Systems, AcroMed and the Cleveland Clinic.

VBrothers Could Benefit From Fire Sale An ortho PR insider tells OTW, “The recent troubles of Japan’s Olympus

Corp., a world leader in medical imaging (as well as in cameras), may thwart its ambitions to become a major player in the orthopedics sector. The company is alleged to have made several high ticket investments for which it overpaid and circulated cash back to various employee-related entities. Although its U.S. investments in Stryker's biomaterials business and device companies such as SBi are not the focus of investigations, Olympus's \$100 million pitch into orthopedics now may well unravel. Should this occur, New York-based Viscogliosi Bros. LLC—the original suitor for the Stryker business—could benefit from any fire sale of those assets.”

Gunner Andersson Honored by Museum

Dr. Gunnar Andersson, of Midwest Orthopaedics at Rush (MOR) fame, was recently honored by the Swedish American Museum for his support of the organization and contributions to the field of spine care, according to an MOR news release. Dr. Andersson is the co-chair of the board of trustees for the Swedish American Museum and remains active in the Swedish American community. He was recently recognized with the 2010 Freedom of Movement Award from the Arthritis Foundation and the Lifetime Achievement Award from the International Society of the Study of Lumbar Spine. Dr. Andersson earned his medical degree at the University of Goteberg and completed his residency at Sahlgren Hospital in Sweden. He also completed a fellowship in orthopedics at The London Hospital in the United Kingdom.

Tackling Periprosthetic Joint Infection

The esteemed Javad Parvizi, M.D., director of research for The Rothman Institute in Philadelphia, tells *OTW*, “If you ask any orthopedist what are his or her three biggest challenges, peripros-

thetic joint infection (PJI) will be one of the things they mention. Next year I will assume the presidency of the Musculoskeletal Infection Society (MSI); we have made it our mission to address all of the issues that face orthopedic surgeons at present. To this end, we are focusing on defining PJI, and well as developing a standardized protocol for treatment. As it is now, an orthopedist in Cleveland is likely treating a PJI differently from one in Seattle. A huge challenge is that there is not a substantial amount of evidence out there... and whatever evidence we have is low level. So, we have launched multiple randomized controlled trials to address the lack of evidence. The studies will show whether we need intravenous versus oral antibiotics, determine the length of antibiotic treatment, define the role of washing out infected joints as opposed to removing them and so on. The mission is underway.”

Innovative Ortho Leader Recognized

The Minnesota Medical Association has presented its Physician Leadership in Quality Award to Paul Dale, M.D., for his leadership and direction in establishing the Joint Replacement Center at Douglas County Hospital in Alexandria, Minnesota. Dr. Dale, the center's orthopedic medical director, promoted an innovative treatment approach at the center, which has a camp-like atmosphere and a lake-lodge motif. Before the center was established, patients underwent their procedures and rehabilitation individually. Now, the patients are oriented in groups, eat meals together, and rehabilitate together. The approach has paid off with lower complication rates, improved patient satisfaction scores, and better treatment outcomes.

Changes at Northwestern Orthopedics

Michael Schafer, M.D. tells *OTW*,

“After 32 years of serving as the department chairman, I have stepped down but am still active in the department as program director. I am working with the new chairman, Terry Peabody, to implement programmatic changes. For example, he now holds a weekly meeting with residents, known as, ‘Conversations with Terry.’ I sit in, and we listen to residents' concerns, we provide feedback, and try to promote an open dialogue. This is going a long way toward getting everyone comfortable with the new chair, and has decreased the overall anxiety level. I'm pleased at the way this is working out... previously, I was doing both roles. This is more appropriate because the chair has so many tugs on him that it is almost impossible to give the necessary attention to a residency program. There are a lot of requirements coming down the pike that haven't been implemented yet... these include changes in how residents will be trained, so there will be lots of work for me as program director.”

Russ Warren, M.D. Receives Award

The Orthopaedic Foundation for Active Lifestyles (OFALS) recently held its seventh anniversary gala fund-raiser at The Harvard Club of New York City. During the event, Dr. Russell Warren received the Excellence in Sports Medicine Award. Dr. Warren is Surgeon-in-Chief Emeritus of the Hospital for Special Surgery in Manhattan and Professor of Orthopedics at the Weill Medical College of Cornell University. He has been the team physician for the New York Giants for 20 years, and has been named *New York Magazine's* Best Doctor for many years. He is currently the Team Physician for the New York Giants. He is the past President of the American Orthopaedic Society for Sports Medicine and the American Shoulder and Elbow Society.

OREF has New CEO The Orthopaedic Research and Education Foundation (OREF) board of trustees has announced the appointment of Sharon Mellor, Ph.D., CAE as chief executive officer. Mellor, who will assume leadership of the foundation on December 1, 2011, brings with her a vast experience in fundraising for medical and educational foundations. She was most recently associate vice president for resource development at the College of DuPage (COD) and executive director of the COD Foundation. She has also served as CEO for the American Academy of Periodontology Foundation, as associate executive director of the Oral and Maxillofacial Surgery Foundation, and in executive positions in development and communications for the American Osteopathic Association. Mellor, a MENSA member, earned a Ph.D. in interdisciplinary studies with an emphasis in organizational behavior and development from Union Institute & University, Cincinnati; an MBA from Loyola University, Chicago; and a BA in journalism and organizational communications from Purdue University.

Spine Surgeons Guessing? A spine surgeon tells *OTW*, "We are no good at determining the origin of patients' pain...to the point where we are probably occasionally treating patients for the wrong diseases. We look at an imaging study and say, 'Oh, it's degenerative disc disease' when it may actually be facet osteoarthritis or a muscle problem. Relying on imaging is not sufficient because discs are *supposed* to degenerate as we get older. To validate the diagnosis we often do injections, but those are not well validated...you get a lot of

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false positives and negatives. There are efforts being made to improve imaging, but we need to accelerate the effort and make more research funding available. Unfortunately, I think there is a lack of interest in determining new diagnostic methods. The fact is that we are better at developing treatment methods. This situation reminds me of the old adage, 'If all you have is a hammer, everything looks like a nail.'"

Mark Drakos, M.D., Joins HSS Dr. Mark Drakos, a foot and ankle surgeon who also specializes in sports related injuries, has joined Hospital for Special Surgery (HSS). He did his undergraduate work in biomedical engineering at Harvard University, then obtained a medical degree from the State Univer-

sity of New York at Stony Brook where he was elected a member of the Alpha Omega Alpha Medical Honor Society. Dr. Drakos completed his orthopedic training at HSS, during which time he received several research grants as well as the Jean McDaniel Award for the chief resident who best exemplifies professional skill, dedication to the ethics of medicine and commitment to resident education. He also received the Lewis Clark Wagner Award for excellence in orthopedic surgery research. Following residency he did a sports medicine fellowship at the HSS where he was an assistant team physician for the New York Giants. He followed that with a second fellowship in foot and ankle surgery at Brown University. ♦

company

Stryker Sues Zimmer, DePuy, S&N and Wright Over Hip Patent

Stryker Corp. claims that DePuy's, Wright Medical's, Zimmer's and Smith & Nephew's hip replacement systems utilizing a dual-locking mechanism, all infringe on Stryker's '243 patent.

Howmedica Osteonics Corp. in New Jersey, and Stryker Ireland Ltd of Cork, Ireland, (Stryker) is suing DePuy Orthopaedics, Inc., Wright Medical Technology, Inc., Zimmer, Inc. and Smith & Nephew, Inc. for violating Stryker's '243; the "Acetabular Cup Assembly With Selected Bearing," patent.

According to court documents dated November 4, the suit filed in the U.S. District Court for New Jersey involves Stryker's acetabular cup, "featuring a dual-locking mechanism and capable of accommodating a plurality of bearings with different characteristics," [which] has allowed Stryker to achieve "significant commercial success."



Source (clockwise): Wright Lineage, DePuy Pinnacle; Zimmer Continuum/ Image creation by RRY Publications LLC

The allegedly infringing devices are DePuy's Pinnacle and Duraloc acetabular cup systems; Wright's Lineage and Dynasty systems; Zimmer's Continuum system; and Smith & Nephew's R3 acetabular cup.

All of those devices, according to court documents, allegedly contain the dual-locking mechanism claimed in the Stryker patent, are "capable of accommodating one of a plurality of bearing members, and infringe the patent via other aspects."

According to the lawsuits, Stryker received the patent for the surgical device in 2002 and was validated in 2010. The device, according to the company, allows doctors more flexibility in the parts that can be used in hip replacements.

Stryker wants damages, an order to competitors to stop selling their systems, and a jury trial.

—WE (November 16, 2011)

Zimmer Acquires External Fixation Company

Strike one up for the team from Warsaw, the "Orthopaedic Capital of the World," as Warsaw-based Zimmer Holdings, Inc. announced on November 10 that it has acquired Memphis-based ExtraOrtho, Inc. Memphis is home to numerous orthopedic companies and enjoys a healthy competition with its neighbor to the north.

ExtraOrtho makes an external fixation line called Xtrafix External Fixation System.



Xtrafix External Fixation System/ExtraOrtho, Inc.

Zimmer Global Businesses President Jeff Paulsen said the XtraFix technology "is one of the most simple and effective solutions for external fixation...and further enhances Zimmer's position in the vital and growing external bone fixation market." The system can be used for unilateral and multilateral fixation of long bones, wrist, ankle and pelvic fractures.

The company says the acquisition makes Zimmer one of the industry's fastest growing companies in the \$5.5 billion global trauma market, in addition to strengthening its trauma portfolio in the \$820 million external fixation market.

ExtraOrtho was founded in 2007 under the name QFx Technologies, Inc. and launched the patented Xtrafix damage control fixation system in January 2011.

—WE (November 14, 2011)

legal

Supremes to Hear Healthcare Law

It's official. The Supreme Court will take on the constitutionality of the Affordable Care Act in the middle of next year's presidential campaign. Not since 2000 and the controversy over Florida's Electoral votes, will the Court play a potentially central role in influencing the politics of a presidential election.

The Court announced on November 14 that it will hear arguments next March. Historically it would be likely that the Court will issue a decision in late June. By then the Republicans should have a clear frontrunner for their nomination with ten states holding their primary elections on Super Tuesday on March 10. Nine other states will already have held their primaries before Super Tuesday.

The Court and the Election

It's unlikely the timing of the arguments before the Court will impact the Democratic primaries, as President Obama is unchallenged at this point. The timing may however, impact the outcome of the Republican nomination fight. Former Massachusetts Governor Mitt Romney has been criticized by his opponents for signing a health care law while governor that included a health insurance purchase mandate. One of his former opponents referred to the new federal law as "Obamneycare."

Insurance Mandate

The mandate has been at the heart of the constitutional argument from conflicting Appeals Court decisions.



U.S. Supreme Court/Wikipedia.org

Three Appeals Courts have ruled the mandate constitutional, while one has ruled it unconstitutional. The court that ruled the mandate unconstitutional held that the rest of the Act was constitutional.

The justices announced they will hear more than five hours of arguments, an extraordinarily long session.

The 2010 health care overhaul law aims to extend insurance coverage to more than 30 million Americans, through an expansion of Medicaid, the requirement that individuals buy health insurance starting in 2014 or pay a penalty and other measures.

It is not certain the justices will settle the issue now. They might agree with a decision by the federal Appeals Court in Richmond, Virginia. Those judges said arguments over the law's validity are premature because a federal law generally prohibits challenges to taxes until the taxes are paid. The Appeals Court reasoned that the penalty for not purchasing insurance will not be paid before federal income tax returns are due in April 2015.

Judicial Votes

While federal judges voted along party lines in District Court decisions about

the constitutionality of the law, those lines blurred at the Appeals Court level.

In Atlanta, Judge Frank Hull, a Clinton appointee, joined with a Republican colleague in striking down the mandate.

In Cincinnati, Judge Jeffrey Sutton, a Bush appointee, was the deciding vote in upholding the law. And in the District of Columbia, Senior Judge Laurence Silberman, named to the bench by President Ronald Reagan, and Senior Judge Harry Edwards, a Carter appointee, voted together to uphold the law.

Some constitutional scholars have speculated that it will be Justice Anthony Kennedy, a Republican who sometimes joins his four Democratic colleagues, who would hold the deciding vote if there is a split decision.

If the law is held constitutional, President Obama can claim a victory, but would likely energize opponents to turn out on Election Day to elect a Congress and President that could vote to overturn the law that is not yet fully implemented. If the law is held unconstitutional, it would strike a blow to the central domestic achievement of the Administration.

Whatever the Court decides, a future president and Congress will have to deal with an unsustainable growth in American health care spending.

—WE (November 14, 2011)

biologics

Stem Cell “Bandage” Meniscus Trial Set

A British company, the developer of what it calls a “stem cell bandage” which is designed to heal torn meniscal cartilage, is subjecting its technology to a human clinical trial. The trial, believed to be the first of its kind in the world, is made possible by an investment by Sun Capital in Azellon Cell Therapeutics, Ltd., a company spun-off from the University of Bristol in England. The company has received approval from the Medicines and Healthcare Products Regulatory Agency (MHRA) for the trial.

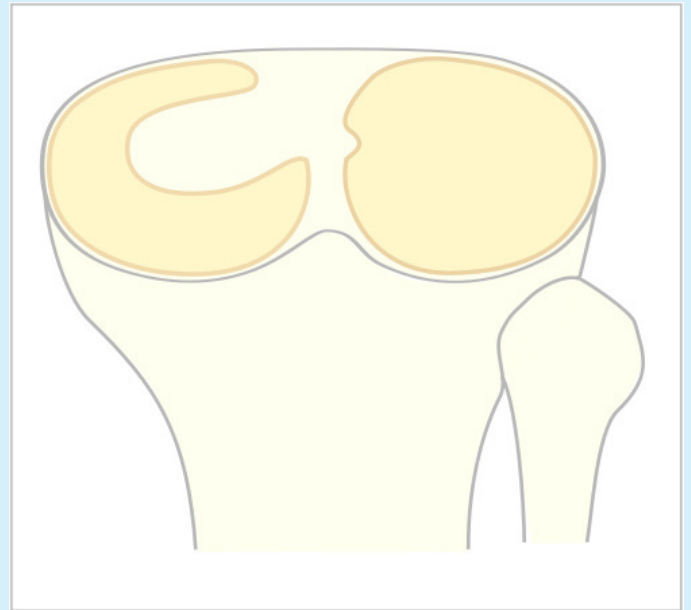
Developers of the Azellon’s Cell Bandage say it is designed as an alternative to the current treatment of surgical removal of the meniscus (meniscectomy), a procedure that more than 1.7 million people around the world undergo. They claim

that this orthopedic procedure often results in the early onset of osteoarthritis, leading to further joint surgery including total knee replacement.

The Cell Bandage, according to company officials in a November 14, 2011 press release, will be grown from the patient’s own stem cells and will be transplanted in the patient’s knee joint within two weeks of extracting the stem cells from bone marrow. The MHRA approved Phase I/IIa trial will treat ten meniscal tear patients with a cell bandage product, seeded with the patient’s own stem cells. The trial will be undertaken at Southmead Hospital in Bris-

tol and is scheduled to begin in May 2012. Interim data is expected to be available within 18 months.

—BY (November 18, 2011)

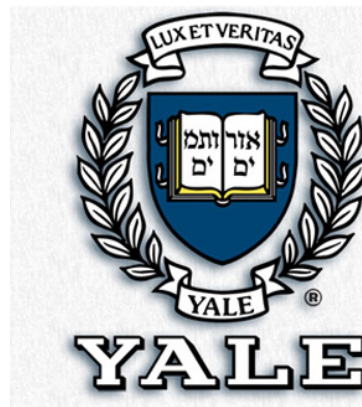


Source: Wikimedia Commons and Uwe Gille

Krumholz Begins Infuse Study

A doctor who *Forbes Magazine* called “the most powerful doctor you never heard of” is the one chosen to evaluate and render a verdict on the product Infuse, manufactured by Medtronic, Inc. In their examination and study of Infuse, Dr Harlan Krumholz, of Yale University, and his colleagues, will address two basic questions: “Does Infuse work? And Is Infuse safe?”

Dr. Harlan Krumholz is the Harold H. Hines, Jr. Professor of Medicine (Cardiology) and Professor of Investigative Medicine and of Public Health (Health Policy) at Yale University. He is also the Director of Yale’s Clinical Scholars



Source: Courtesy Yale University Caption: Dr. Harlan Krumholz

Program as well as Director of the Yale-New Haven Hospital Center for Outcomes Research and Evaluation

Krumholz is quoted by Janet Moore in the November 14 issue of the *Minne-*

apolis Star Tribune, Medtronic’s home newspaper, as saying, “I’m not seeking to address how the product was marketed. I’m just sticking to the science. I’m trying to set in place a new way of doing business.” His ultimate aim,

according to Moore, is to bring a new level of transparency to the way clinical studies sponsored by drug and medical-device companies are conducted, a process that, she says, is little understood by the public.

The *Star Tribune* has calculated that during Medtronic's 2011 fiscal year it paid \$61 million to doctors for royalties, consulting services, educational talks and training. Of that amount, \$46 million was paid out in royalties, about three-quarters of which went to spine specialists.

Medtronic is one of the few medical-device companies that publicly report these kinds of financial relationships. The company has maintained that collaboration with physicians ensures that medical devices are safe, and that doctors who invent new products or techniques should be fairly compensated.

According to the *Star Tribune* report, Medtronic is funding Krumholz's study with \$2.5 million grant to Yale University to provide the sort of analysis that cannot easily be disputed. Medtronic will provide Krumholz with all of its patient data on Infuse but, with the exception of the funding for the study, will not be involved in any other way.

"We knew we had to take the high road and seek out a third party, a completely unbiased and independent organization," CEO Omar Ishrak said in an interview. "We want to take transparency of clinical data to a whole new level. What we're doing is pretty unprecedented."

—BY (November 18, 2011)

Condoliase Enzyme as Herniated Disc Remedy

According to a November 10 press release, Tokyo-based Seikagaku Corporation has notified the Pharmaceuticals and Medical Devices Agency, that it plans to conduct a Phase III clinical trial for SI-6603, a product with the generic name of *condoliase*. The Phase III trial will be conducted in Japan along with the firm's Phase II trial already in progress in the United States.

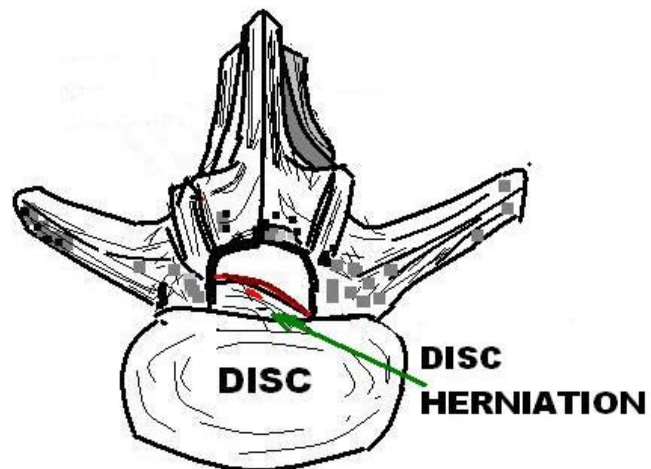
Condoliase is proposed as a treatment for lumbar disc herniation. The purpose of the Phase III trial is to gather further data on the results of an earlier Phase II/III trial, reported in December 2010, and to examine issues of safety and symptom improvement in cases of lumbar disc herniation.

Lumbar disc herniation is the partial protrusion of the nucleus pulposus at the core of each intervertebral disc or

of the annulus fibroses, the disc's outer layer. The resulting pressure on nerves around the vertebra causes pain and numbness. Company officials state that SI-6603 is an enzyme that specifically degrades glycosaminoglycans (GAGs), which are the main components of the nucleus pulposus.

When SI-6603 is injected into the intervertebral disc, researchers expect the resulting dissolution of the GAGs to cause the nucleus pulposus to shrink, relieving the pressure on the nerves. Because SI-6603 does not break down proteins, investigators believe it has no effect on surrounding tissues, such as blood vessels and nerves. Company officials assume that a single dose of SI-6603 could be as effective as surgery in alleviating symptoms. The import of this could be that patients would reap benefits in symptom relief and reduced medical costs.

—BY (November 17, 2011)



Source: Wikimedia Commons and A.E. Francis

large joints

**Bone Graft Market
\$2.3 Billion by 2017**

The market for bone grafts will reach \$2.3 billion by the year 2017 according to a report by Global Industry Analysts, Inc. titled “Bone Grafts: A US Market Report” and reported November 11 by PRWEB. Forecasters base their estimate on the facts of an aging population, rising incidences of degenerative intervertebral disc diseases, a rise in the number of revision orthopedic and dental surgeries, a rise in the number of spinal fusions performed in private healthcare and an increasing number of seniors seeking an active lifestyle.

Approximately one million bone-grafting procedures are performed every year on the pelvis, spine, dentistry and other body extremities in attempts to repair or reconstruct the

bone. The term “Bone Grafts” refers to natural or artificial bones transplanted into the diseased or damaged site to help promote the re-generation of new bone. The market for bone grafts is driven by multiple factors, according to investigators, including the risks associated with the use of auto graft bone, the need to achieve optimum bone fusion, the need to eliminate multiple surgeries, the rising number of spinal fusion procedures, and the growing use of tissue-engineered bone in joint replacements.

Analysts expect the market to gain from the commercialization of next generation bone growth factors, and the launch of innovative new bone products. Bone and joint disorders presently account for almost half of the debilitating conditions experienced by individuals over 50 years of age. With this sector of the population expected to double by the year 2020, analysts expect that the demographics alone will be a key



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growth driver in the global orthopedic market.

With the focus shifting from the mechanics to the biology of bone healing, analysts expect that orthobiologics will gain traction in the bone grafts market. Orthobiologics is defined as a branch of medical science that utilizes biomaterials, and other biological products with regenerative capabilities to fuse, join, and stimulate bone growth. In recent years there has been a rise in the number of bone substitute products commercialized with the intent to improve patients' quality of life and expand treatment options while at the same time bring down healthcare costs.

—BY (November 17, 2011)



Source: Wikimedia Commons and Robert Gougaloff

Knee Hospitalization Rates Soar

Women and men between the ages of 45 and 64 were two-and-a-half times more likely to be hospitalized for knee replacement surgery in 2009 than they were in 1997, according to a November Agency for Healthcare Research and Quality (AHRQ) press release, and reported by *Health News Digest*.

AHRQ's analysis of hospital stays for knee replacement surgery from 1997 to 2009 found that the rate for women ages 45 to 64 jumped from 16 to 42 stays per 10,000 individuals, while for men the same age, the rate climbed from 11 to 28 stays per 10,000.

For women and men 65 to 84, the hospital stay rates rose by 69% and 55%, respectively, from 72 to 122 stays and from 58 to 90 stays per 10,000 people. Among those individuals age 85 years and older, rates increased by 23% for women (from about 27 to 33 stays per 10,000 people) and to 36% for men (from about 27 to 36 stays per 10,000 people).

The AHRQ data is based on Statistics on Hospital-Based Care in the United States, 2009, which provides highlights of the latest data from the 2009 Nationwide Inpatient Sample, a part of AHRQ's Health-

care Cost and Utilization Project. The report provides data on leading reasons for hospitalization, on procedures performed on hospital patients, and other related topics.

—BY (November 14, 2011)



Source: Wikimedia Commons and Haitham Alfalah

trauma

The 'F' Word...Fractures

Fighting the good fight... The National Bone Health Alliance (NBHA) and Kaiser Permanente have just unveiled their "20/20 Vision" for reducing hip and other fractures by 20% by 2020 at a best practices sharing event Monday at the Kaiser Permanente Center for Total Health on Capitol Hill.

"Reducing the expected number of hip and other fractures by 20% by the end of the decade is a public health imperative," said Richard M. Dell, M.D., lead orthopedic surgeon, Healthy Bones Program, Kaiser Permanente, in the November 15, 2011 news release. "It would be a monumental achievement, sparing half a million Americans of horrible pain and suffering and a loss in quality of life—as well as producing



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enormous cost savings throughout the health care system. The time to act is now as a growing number of Americans are reaching the age where hip and other osteoporosis-related fractures are common but are still preventable in many cases."

Dr. Dell told *OTW*, "Fractures should be the new F word for this decade. In the Medicare population, fractures are

often preventable if proper screening and treatment is done. We could prevent 100,000 hip fractures in our Medicare population a year if we reproduce what the Kaiser Permanente Healthy Bones Program has done. If Kaiser Permanente can do this, America can do this."

At the recent meeting, representatives of a number of groups shared best practices and laid out a plan to achieve this nationwide goal. A key element is a proposal to establish a fracture liaison service facilitated by NBHA within Medicare and other health systems modeled on successful programs that currently exist in the United States at Kaiser Permanente, Geisinger Health System the American Orthopaedic Association and the Department of Veterans Affairs as well as internationally in the United Kingdom, Canada and elsewhere. The service would assess patients who suffer a fracture for osteo-

porosis and, if found, provide them treatment and follow-up to manage the disease in an effort to prevent repeat fractures.

Also discussed was the American Orthopaedic Association's Own the Bone Program, a quality improvement initiative introduced in the open health care system that addresses the need to assess and treat patients age 50 and over with osteoporotic fractures and promotes coordination of care between specialties. Own the Bone has touched more than 3,000 patients in 31 states and continues to grow rapidly.

Robert A. Adler, M.D., Richmond Veterans Affairs Medical Center and Virginia Commonwealth University School of Medicine, described an osteoporosis disease-management process as part of the Veterans Affairs Patient-Aligned

Care Team program. "Veterans Affairs pharmacists can use the electronic medical record to identify patients at highest risk for osteoporotic fracture, particularly those who have already suffered a fragility fracture," Adler said.

—EH (November 17, 2011)

Osteoporosis Trial: Negative Results

For some, a disappointing "thud" after three years...Unigene Laboratories, Inc. has announced that Novartis Pharma AG has disclosed to Unigene its first interpretable results from a three-year Phase 3 trial. The trial—Study 2303—is being conducted by its license partner Nordic Bioscience—and assesses the safety and efficacy of an oral formulation of calcitonin (SMC021),

which used Emisphere's proprietary oral delivery technology, in the treatment of post-menopausal osteoporosis.

Study 2303 failed to demonstrate a significant difference between treatment groups at three years for the primary endpoint, with no statistically significant treatment effect observed on the reduction of the occurrence of new vertebral fractures. Similarly no statistical significant response was observed on



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key secondary endpoints such as new non-vertebral fractures or new clinical fractures. According to Novartis, the only statistically significant treatment effect in the first interpretable results dataset, which contains only the most important analyses for expedited review, was an increase in lumbar spine Bone Mineral Density in the SMC021 treatment group relative to placebo. Preliminary analysis of data did show that SMC021 displayed a positive safety profile.

Novartis' Study 2303, evaluating an oral formulation of calcitonin



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(SCM021) for the treatment of osteoporosis, was developed using Emisphere's proprietary oral delivery technology and, under a worldwide licensing agreement, using Unigene's patented peptide manufacturing process to produce calcitonin.

In the November 14, 2011 news release, Ashleigh Palmer, Unigene's President and CEO, stated, "While we would have preferred positive results from this Phase 3 trial, the outcome has very limited impact on Unigene's successful turnaround strategy. Unigene's own oral formulation of salmon calcitonin reached Phase 3 statistical significance for its primary endpoint as presented in detail at the American Society of Bone and Mineral Research in September."

Palmer continued, "Although today's news reduces the likelihood of near-term royalties under our manufacturing license with Novartis, it ironically now places Unigene in an exceptionally strong leadership position with respect to our oral peptide drug delivery platform. In recent months, Unigene has demonstrated that our technology and expertise can overcome Phase 3 development patient compliance and food effect challenges for oral calcitonin; reach Phase 2 oral delivery proof-of-concept for an exacting peptide like PTH; and engage multiple partners in funding feasibility studies for a wide variety of peptides requiring oral delivery across a broad spectrum of therapeutic areas. Without a doubt, Unigene truly is now the industry's peptide development partner of choice!"

—EH (November 14, 2011)

spine

TranS1 Goes "Lateral"

TranS1, Inc. has jumped into the lateral access fusion market with the launch of its own system on November 16.

The company is famous for its minimally invasive AxiaLIF pre-sacral lumbar spine access to the L5-S1 vertebral bodies.

Ken Reali, TranS1's president and CEO said, "The introduction of our lateral system represents an excellent strategic fit with AxiaLIF, as the majority of our current customers utilize a minimally invasive lateral approach for specific pathologies needing interbody spine fusion. This intuitive system demonstrates TranS1's continued commitment to developing less traumatic approaches to lumbar spinal fusion."

The company says its lateral system features an innovative, two-stage retraction method that focuses on nerve visualization and then controlled retraction. The TranS1 lateral system is designed for direct visualization of the psoas

muscles and adjacent nerves prior to muscle dissection. Innovative is the key word here. Medtronic, Inc. and NuVasive, Inc. are involved in a legal battle over intellectual property rights of certain lateral access technologies. Medtronic recently won the first round of that fight.

Reali told OTW that the true innovative quality of the TranS1 system is in the approach to the spine and the psoas muscle.

James Manzanares, M.D. of Orlando, Fl, a surgeon participating in a limited market release of TranS1's system, said: "The key to the TranS1 lateral is that it respects long-held principles for splitting and expanding muscle layers to reduce risk of nerve and muscle trauma. The direct and radiographic visualization of this system allows the surgeon to target specific levels of the spine while potentially avoiding dangerous areas of the psoas muscle."

The system has been in limited market release for the past six months at selected spine centers throughout the U.S. The retractor is complemented by a full range of PEEK lateral interbody

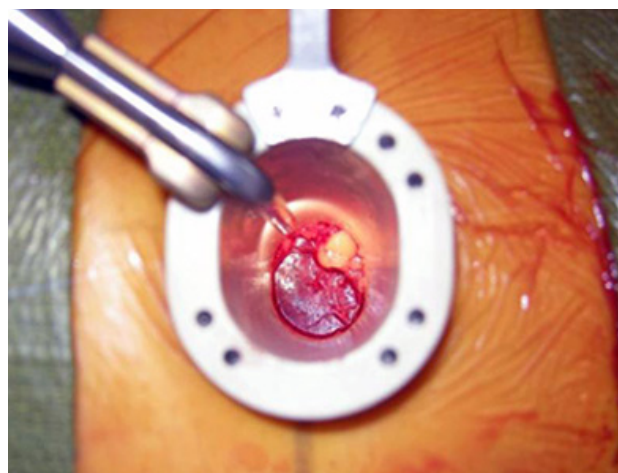


Image Credit: TranS1 Retractor/TranS1, Inc.

implants and a variety of ergonomic instruments. Radiopaque markers are strategically located within the implants to allow proper placement.

The company says its product offerings will continue to grow as it meets new clinical challenges. TranS1 is also developing a motion preservation platform to be delivered through a minimally invasive, trans-sacral approach.

—WE (November 18, 2011)

New Ankylosing Spondylitis Data

Abbott has announced five-year results from the open-label extension of the ATLAS study, which evaluated the long-term impact of treatment with HUMIRA (adalimumab) on disease activity, including spinal mobility in patients with active ankylosing spondylitis (AS). For these patients receiving open-label HUMIRA treatment through year five, improvements were also observed for spinal mobility and quality of life.

ATLAS (Adalimumab Trial Evaluating Long-Term Safety and Efficacy for Ankylosing Spondylitis) is among the first tumor necrosis factor (TNF) inhibitor studies to evaluate five years of efficacy and safety data in AS.

“AS is a potentially disabling disease that can go undiagnosed for up to 10 years, so it is important for people with symptoms to see a rheumatologist early to begin proper treatment,” said Philip Mease, M.D., Chief, Swedish Hospital Rheumatology Clinical Research Division, Seattle, Washington, in the November 8, 2011 news release.

In this study, patients with active AS were randomized to HUMIRA 40 mg every other week or placebo for 24 weeks followed by an open-label extension of up to five years, during which time patients were allowed to escalate to weekly dosing. Of the 125 patients who completed five years of HUMIRA exposure, 30 (24%) received weekly dosing. The recommended dose of HUMIRA for the treatment of AS is 40 mg every other week by subcutaneous injection.

“The controlled portion of the ATLAS study demonstrated improvement in signs and symptoms and other disease measures with adalimumab,” added Dr. Mease.

“HUMIRA’s efficacy and safety has been evaluated across six immune-mediated conditions and its use in rheumatoid arthritis has been evaluated in multiple studies during the past 14 years,” said John Leonard, M.D., senior vice president, Global Pharmaceuticals Research and Development, Abbott. “HUMIRA has been approved for use in people with AS since 2006 and with the open-label extension of the ATLAS trial, HUMIRA is among the first TNF inhibitors to present five years of efficacy data in ankylosing spondylitis.”

Dr. Mease told *OTW*, “Ankylosing spondylitis is a severe disease in which inflammation, predominantly in the spine, causes

chronic pain and progressive fusion of the spine. Adalimumab, like other TNF inhibitors, has demonstrated significant ability to improve pain and mobility, restore function, and improve quality of life. The long-term benefits of adalimumab were reported at this year’s American College of Rheumatology congress, demonstrating that in the 40% of patients still taking the medicine over five years, sustained improvement in pain, mobility, function and quality of life, signifying important durability of effectiveness.”

Dr. Mease also indicated that he receives research grants, consultation fees, and speaker honoraria from Abbott (as well as all other companies that are developing medicines for this disease).

—EH (November 14, 2011)



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

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

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

Walter Eisner
 Senior Writer
 walter@ryortho.com

Tom Bishow
 Vice President of Sales
 tom@ryortho.com

Biloine W. Young
 Writer
 bgwy@msn.com

Suzanne Kirchner
 Production Manager
 suzanne@ryortho.com

Jayne Johnson
 Production Coordinator
 jayne@ryortho.com

Dana Bader
 Graphic Designer
 dana@ryortho.com



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