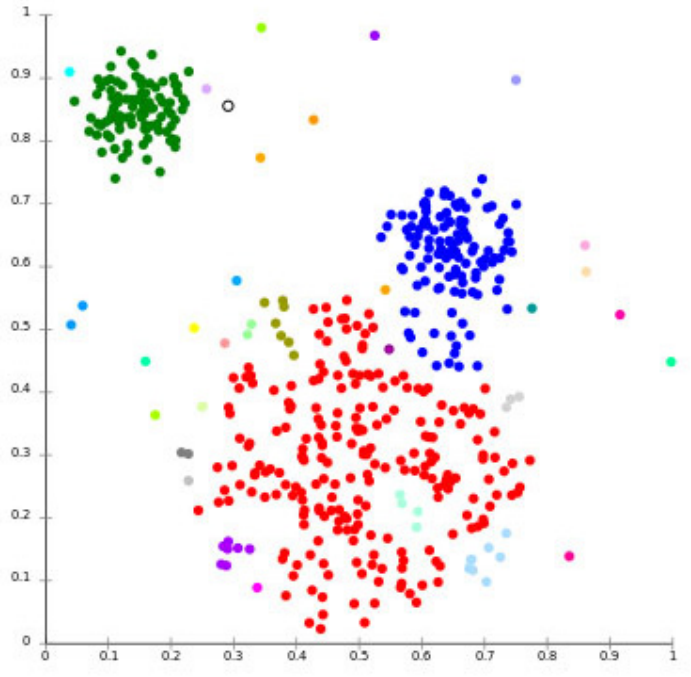
VOLUME 8, ISSUE 36 | NOVEMBER 13, 2012

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: Fiscal Cliff. Wall Street assumes a deal will happen, but the #1 worry is that entitlement cuts won't be high enough to reduce deficit meaningfully. Entitlements mean Medicare and Social Security. It means patients over 65. So, either way, orthopedic stocks have a wall of worry to scale between now and January. We simply don't expect much upside to orthopedic stock valuations in the next couple of months.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Johnson & Johnson	25.58%	2.42%	Jefferies downgrades on reimbursement worries (see entitlement comment above). Diversification, however, in the form of Pharma keeps JNJ #1.
2	2	Zimmer	26.37	3.32	Up 3.32% in the past month, this 4th least expensive company in orthopedics has more than $1 billion in cash and annual cash flows.
3	3	Stryker	23.68	0.59	Precious few orthopedic stocks are finding buyers these days—but SYK, with a new CEO, is one of the lucky companies.
4	9	NuVasive	7.08	(5.85)	Big jump this week for NUVA. Great NASS —as we've confirmed independently—from a slate of strong new product launches.
5	4	Medtronic	28.65	(3.27)	Infuse data was reassuringly positive at NASS—lower complications, NO retrograde ejaculation risk and really good cancer data.
6	7	Conmed	10.39	(17.50)	Rough month in the stock market, but 10%+ sales growth in both endoscopy and arthroscopy is a notable bright spot.
7	8	Symmetry Medical	5.63	(11.91)	The one good thing about SMA is that they will show stellar year-over-year earnings growth for several quarters.
8	10	Smith & Nephew	21.36	(0.69)	Very slow sales grower and flat to down earnings expectations. Time to roll up these large, cash rich slow growers?
9	5	Globus Medical	30.06	(17.50)	GMED has so much percolating that when these profit takers wash out, GMED should bounce—in 2013.
10	6	ArthroCare	18.04	(0.06)	Slow sales growth. Down earnings this quarter. But that cash and cash flow make ARTC M&A fodder.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TranS1	TSON	$2.69	$73	5.49%
2	Zimmer Holdings	ZMH	$64.69	$11,224	3.32%
3	Johnson & Johnson	JNJ	$69.87	$193,628	2.42%
4	Stryker	SYK	$52.53	$19,972	0.59%
5	ArthroCare	ARTC	$31.99	$892	-0.06%
6	Smith & Nephew	SNN	$51.98	$9,372	-0.69%
7	MiMedx Group	MDXG	$2.72	$236	-2.16%
8	RTI Biologics Inc	RTIX	$4.18	$234	-2.56%
9	Medtronic	MDT	$41.16	$41,989	-3.27%
10	CryoLife	CRY	$5.81	$159	-3.65%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Globus Medical	GMED	$13.86	$1,263	-17.50%
2	MAKO Surgical	MAKO	$14.36	$617	-12.06%
3	Symmetry Medical	SMA	$8.43	$310	-11.91%
4	TiGenix	TIG.BR	$1.02	$93	-11.28%
5	Orthofix	OFIX	$38.70	$748	-9.73%
6	Tornier N.V.	TRNX	$17.48	$729	-8.82%
7	Alphatec Holdings	ATEC	$1.64	$149	-7.87%
8	Bacterin Intl Holdings	BONE	$1.29	$55	-7.86%
9	Exactech	EXAC	$16.14	$215	-7.82%
10	Wright Medical	WMGI	$20.05	$795	-7.56%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$41.16	$41,989	12.21
2	Zimmer Holdings	ZMH	$64.69	$11,224	12.49
3	Orthofix	OFIX	$38.70	$748	12.86
4	Stryker	SYK	$52.53	$19,972	13.27
5	Johnson & Johnson	JNJ	$69.87	$193,628	13.84

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$20.05	$795	62.66
2	NuVasive	NUVA	$13.51	$588	48.25
3	Symmetry Medical	SMA	$8.43	$310	35.13
4	Globus Medical	GMED	$13.86	$1,263	20.78
5	CryoLife	CRY	$5.81	$159	20.75

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$38.70	$748	0.92
2	ArthroCare	ARTC	$31.99	$892	1.00
3	Conmed	CNMD	$26.86	$765	1.24
4	Zimmer Holdings	ZMH	$64.69	$11,224	1.34
5	Exactech	EXAC	$16.14	$215	1.36

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$20.05	$795	6.19
2	NuVasive	NUVA	$13.51	$588	5.20
3	CryoLife	CRY	$5.81	$159	5.19
4	Smith & Nephew	SNN	$51.98	$9,372	3.22
5	Symmetry Medical	SMA	$8.43	$310	2.93

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.64	$149	0.75
2	Symmetry Medical	SMA	$8.43	$310	0.86
3	Exactech	EXAC	$16.14	$215	1.05
4	Conmed	CNMD	$26.86	$765	1.06
5	NuVasive	NUVA	$13.51	$588	1.09

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.02	$93	81.40
2	MiMedx Group	MDXG	$2.72	$236	30.40
3	MAKO Surgical	MAKO	$14.36	$617	7.30
4	TranS1	TSON	$2.69	$73	3.83
5	Globus Medical	GMED	$13.86	$1,263	3.81

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

Infuse Inhibits Cancer?

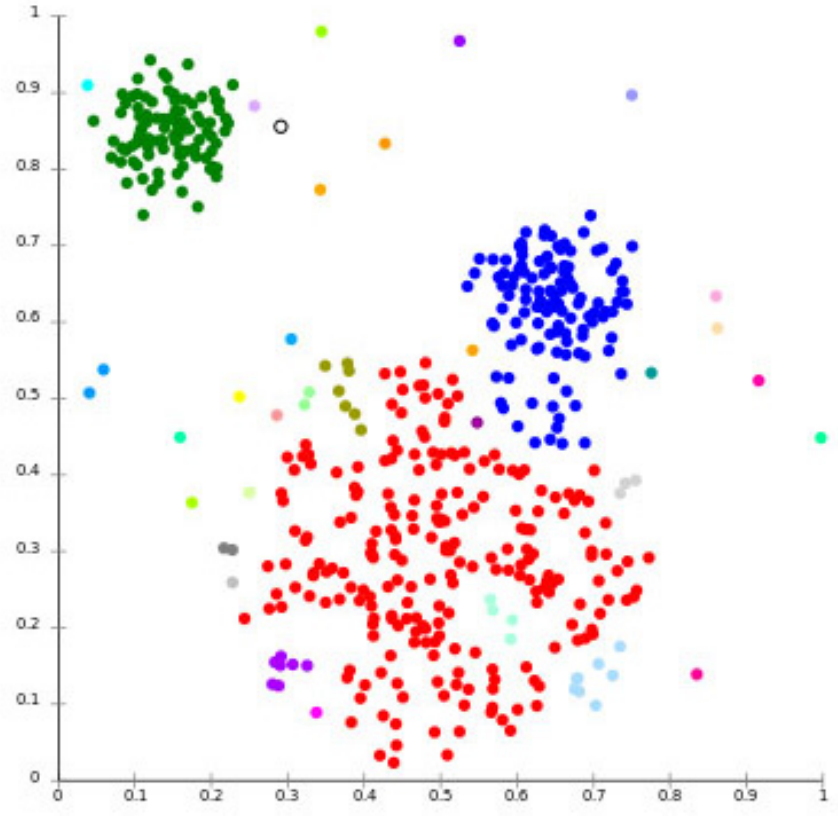
By Robin Young

Can 467,916 spine fusion patients be wrong? Eugene Carragee, M.D., thinks so. Especially when a study powered by half a million patients didn't agree with his analysis of the 463 patient AMPLIFY[8] study. Dr. Carragee's disappointment was in full view.

We begin our report with the presentation given at the recent North American Spine Society (NASS) meeting by Paul Anderson, M.D., Professor of Orthopedic Surgery at the University of Wisconsin. On the morning of October 24, he presented a retrospective study of 467,916 Medicare patients who'd had a spine fusion between 2005 and 2009.

Approximately a quarter of those patients (110,808) received BMP-2 and the remainder (357,108) did not.

At 467,000 patients, Dr. Andersons's study was the largest yet attempted to find a link between the use of BMP-2 and cancer.



Source: Wikimedia Commons and Chire

As Dr. Anderson noted in his opening discussion, BMPs are powerful biologic agents which can induce bone formation. And there is an intuitive appeal to the argument that such bone inducing biologics could play a role in tumor formation.

But 463 patients in the AMPLIFY study just can't provide statistically significant data about BMP-2 and cancer. In Dr. Anderson's words, "The absolute risk of cancer promotion from BMP-2 may be small but could be significant at the population level. Small risks are difficult to detect in Phase 3 controlled trials. The effects on cancer risk may only be measurable using large sample sizes."

Nearly half a million Medicare patients between 2005 and 2009 is a large sample size.

No Corporate Funding

In addition to Dr. Anderson, Jason Savage M.D. and Mick Kelly, a University of Wisconsin medical student, also worked on the study and the University of Wisconsin Medical School's IRB (institutional review board) panel provided oversight.

Medtronic, Inc., the supplier of Infuse, had no financial or other role in this study. As far as we know, the company was not even aware of it. Anderson and his colleagues did not receive corporate support of any kind for this study.

Between 2005 and 2009, 467,916 Medicare patients had spinal fusions and BMP-2 was used in 110,808 of those patients. The remainder, 357,108 patients, did not receive BMP-2.


Eugene Carragee, M.D.


Paul Anderson, M.D.

The average follow up was 2.85 years in the BMP-2 cohort and 2.94 years in the control cohort. The patient demographics were similar in the BMP-2 and control group. Females were 62.5% of the BMP-2 cohort compared to 58.4% of the control group. Both groups had similar age distributions. Most of the patients in the study were under 65 years of age.

Study Findings

Here's what this study of 467,916 spine fusion patients found:

1. Of the patients who were treated with BMP-2, under six percent (5.9%) or 6,557 developed a cancer2 during the study period.
2. Of the patients who were NOT treated with BMP-2, more than six percent (6.5%) or 23,232 developed a cancer2 within the study period.
3. For each 100,000 patients the incidence per year exposure of cancer was less in the BMP-2 group (2,076 per 100,000) than in the non-BMP-2 group (2,212 per 100,000).
4. The relative risk (RR) of developing cancer in the BMP-2 group compared to the control group was 0.938 (95% Confidence Intervals (CI): 0.913, 0.964). This was statistically significant (P=5.32E-06).
5. The BMP-2 group had a 6.2% reduced risk of cancer than in the control group.
6. The relative risk of developing cancer in males exposed to BMP-2 vs. control was 0.98 (CI: 0.94-1.02), which was not statistically significant.
7. The relative risk in females was 0.93 (CI: 0.90-0.97).
8. "We calculated relative risk of new neoplasms of 19 of 24 most common SEER cancer types. Patients exposed to BMP-2 had a relative risk less than one (indicating lower risk than control)—*in 18 of the 19 neoplasms.*" — Dr. Paul Anderson, et al.
9. **"We found that exposure to BMP not only was not associated with increased cancer but that the opposite was true with a relative risk reduction in the BMP group of 6.2%."** – Dr. Paul Anderson, et al.
10. "Although this association was present, we cannot identify any biologic explanation for this effect. Further investigations are warranted." – Dr. Paul Anderson, et al.

Present at Dr. Anderson's talk at NASS was Dr. Eugene Carragee, Chief of Spinal Surgery at the Stanford University School of Medicine and managing editor of NASS's peer review journal, *The Spine Journal*.

Dr. Carragee has written extensively regarding BMP-2 and cancer saying in previous podium presentation at NASS and elsewhere that BMP-2 may fuel existing cancers (see the November 5 article in the *Milwaukee Journal Sentinel* written by John Fauber). Specifically Dr. Carragee cited the 463 patient AMPLIFY study (239 patients with BMP-2 and 224 without) to support his opinions.

Carragee Reacts

Dr. Carragee's reaction to Dr. Anderson's data? He called it irresponsible.

Dr. Andersons's response? I see your 463 patient study with my 467,916 patient study.

And then raise you with decades of oncological research.

Dr. Anderson had the winning hand.

Bone Morphogenic Growth Factors and Cancer

Dr. Marshall Urist, who first described bone morphogenetic proteins (BMPs) in the mid-1960s, started his inquiry into BMPs as a result of a commission from the U.S. Atomic Energy Commission to research strontium 90, tetracycline, and the treatment of osteogenic sarcoma—cancer.

He was deeply aware of BMP and cancer yet he believed that BMP would transform orthopedics for the better. "The availability of the protein [BMP]," Dr. Urist told the *Los Angeles Times* in 1987 as his "bone glue" was undergoing testing by the Food and Drug Administration, "will make it possible to repair large bone defects caused by old infection, injuries, removal of tumors and congenital deformities in children and adults."

The FDA eventually approved BMP for bone growth in the spine and fractures. So while orthopedists went to work using BMP for tough cases, oncologists continued to research BMP's links with cancer.

In fact, at the original FDA Panel when Infuse was first evaluated for commercial use in spine surgery, cancer was discussed in detail and the data at the time suggested that in most cases BMP-2 actually slowed cell growth. As the body of oncological research shows, this makes biologic sense since BMP-2 is a morphogen. Morphogens promote cell differentiation. Differentiation is a **mutually exclusive** from cell division. Cancer is about pathological cell division.

Of course, Dr. Carragee's arguments have been that BMP-2 could be leaking off the collagen sponge carrier and thereby have the opportunity to promote cancer—anywhere in the body since it could, in theory, travel throughout the body. But, as was discussed at the original FDA Panel, most of the Infuse in the collagen carrier eluted in the first 5 days and rapidly cleared the blood in hours. It was very hard to make a case that there was a high enough Infuse dose at the surgery site much less at the site of any nascent tumor somewhere downstream to even in theory contribute to tumor promotion.

Hundreds of peer reviewed studies of BMP and tumors were published. As a body of work they taught that BMPs play a role in both tumor formation AND inhibition.

Top Ten Findings From 50 Years of Oncological BMP Research

10. "BMPs are a double-edged sword in tumor biology: they function both as tumor promoters and tumor suppressors depending on the type of cell or tissue and the BMP dosage in the micro-environment. Additionally, we found no clear-cut pro- or anti-carcinogenic BMP's in the oncogenic process, although some BMPs appear more often on the side of tumor promotion than others and vice-versa."[2]
9. BMPs can act as growth and proliferation inhibitors. In different cancer environments, BMP-2 and -5 can inhibit proliferation, and modulate steroidogenesis of human adrenocortical tumor cells in vitro through a BMP dependent pathway. [2]
8. BMP2-CEA expressing positive cells drive differentiation of mesenchymal stem cells to bone lineages.[3]
7. BMP-2 decreases the proliferation of MCF-7 breast cancer cells suggesting a crucial role of BMP-2 in repressing the activity of growth inhibitory pathway such as TGF-β. [4]
6. In gastric cancer, BMP-2 act as growth inhibitor in a dose dependent manner by cell cycle arrest in the G1-phase mediated by p21/WAF1/CIP1, and enhances the pepsinogen II gene a differ-

entiation marker of glandular cells of stomach, suggesting role in gastric cancer cell modulation. [5]

5. It is common in advanced phases of prostate cancer to find BMPs associated with bone metastasis. BMP-2 produced by tumor cells is involved in heterotopic ossification in metastatic lesions from several types of cancerous cells such as urothelial bladder carcinoma. [2]
4. BMPs are known to be associated with angiogenesis, particularly during embryogenesis. However, BMPs and their role in the process of angiogenesis in cancer remain to be determined. [6]
3. Tumors adopt angiogenesis as a survival mechanism. Tumors secrete growth factors to induce blood vessel formation. Angiogenesis normally becomes quiescent during adulthood except for healing and some pathological conditions, including cancer. Onset of angiogenesis can occur at any stage of tumor progression but depends on the tumor type and micro environment. Angiogenesis is orchestrated by a diverse set of activators and inhibitors—which include the BMP family of proteins. [7]
2. BMPs behave differently at different doses, cell types, and cellular environments. This affects cellular attributes such as cell movement, adhesion, invasiveness, epithelial to mesenchymal transformation (EMT) and mesenchymal to epithelial transformation (MET). [2]
1. In complex oncogenic processes such as angiogenesis or metastasis, the role of individual BMPs may be direct or indirect. Further in vitro and in vivo studies are required to determine a mechanism in a specific type of cell, tissue or cancer. More study is needed to determine the combined effects of multiple BMPs on normal or cancer tissue, as the synergistic effects on cells may be different compared to individual effects. Such experiments would provide support (or lack thereof) for using BMPs in cancer therapy as an inhibitor. [2]

Where to Now?

Dr. Paul Anderson's study was the first large scale review of patients who'd received BMP-2 for bone formation. It shows that patients who've been administered BMP-2 to grow bone for spine fusion have a reduced risk of cancer. This is consistent with much existing oncological research. Furthermore, Dr. Anderson's study, when examined within the context of existing and long standing oncological research, illustrates clearly that forming ANY conclusions from a 463 patient study is premature.

Dr. Carragee, who is the editor of *The Spine Journal*, stands in contrast to Dr. Anderson who approached this subject with thoughtfulness, objectivity and detail. As one would expect from a scientist.

Obviously more study is required. The good news is that the oncological community has laid an impressive foundation of BMP research. The other good news is that Dr. Paul Anderson and his team decided to actually look at 467,000 patients and see if a link between BMP and cancer might be teased out of the data. Their work and this study is clearly a step in the right direction.

Finally. ♦

References:

[1] 24 cancer types as defined by the National Cancer Institute's Surveillance Epidemiology and End Results (SEER). Brain and other nervous system, breast, cervix uteri, colorectal, corpus uteri, esophagus, Hodgkin Lymphoma, Kaposi's Sarcoma, kidney and renal pelvis, larynx, leukemia, liver and bile duct, lung and bronchus, melanoma, myeloma, non-Hodgkin lymphoma, oral cavity and pharynx, ovary, pancreas, prostate, stomach, testis, thyroid, and urinary bladder.

[2] (Ashok Singh and Rebecca J. Morris, The Yin and Yang of Bone Morphogenic Proteins in Cancer, Cytokine Growth Factor Rev. 2010 Aug;21(4):299-313. Epub 2010 Aug 4.)

[3] (Fong S, Chan MK, Fong A, Bowers WJ, Kelly KJ. Viral vector-induced expression of bone morphogenetic protein 2 produces inhibition of tumor growth and bone differentiation of stem cells. Cancer Gene Ther. 2010;17(2):80–5)

[4] (Arnold SF, Tims E, McGrath BE. Identification of bone morphogenetic proteins and their receptors in human breast cancer cell lines: importance of BMP2. Cytokine. 1999;11(12):1031–7.)

[5] (Wen XZ, Miyake S, Akiyama Y, Yuasa Y. BMP-2 modulates the proliferation and differentiation of normal and cancerous gastric cells. Biochem Biophys Res Commun. 2004;316(1):100–6.)

[6] (Langenfeld EM, Langenfeld J. Bone morphogenetic protein-2 stimulates angiogenesis in developing tumors. Mol Cancer Res. 2004;2(3):141–9.) and (Valdimarsdottir G, Goumans MJ, Rosendahl A, Brugman M, Itoh S, Lebrin F, et al. Stimulation of Id1 expression by bone morphogenetic protein is sufficient and necessary for bone morphogenetic protein-induced activation of endothelial cells. Circulation. 2002;106(17):2263–70.) and (Raida M, Clement JH, Leek RD, Ameri K, Bicknell R, Niederwieser D, et al. Bone morphogenetic protein 2 (BMP-2) and induction of tumor angiogenesis. J Cancer Res Clin Oncol. 2005;131(11):741–50.)

[7] (Bergers G, Benjamin LE. Tumorigenesis and the angiogenic switch. Nat Rev Cancer. 2003;3(6):401–10.)

[8] Administration FDA Panel, Executive Summary for P050036 Medtronic's AMPLIFY rhBMP-2 Matrix. Food and Drug Administration, 2010.

Medicare Showing Orthopods the Love

By Walter Eisner

The election is over. Unless a lame-duck Congress acts between now and the end of the year, more than one million physicians and providers will be subject to a 26.5% across-the-board cut to their Medicare payments in January as required by the Sustainable Growth Rate (SGR). In addition, there's a "fiscal cliff" waiting to take an additional 2% out of Medicare's total budget in 2003.

Sounds ominous. But what can orthopedic surgeons really expect to be paid in January 2013?

Morguefile and RRY Publications LLC

Behind the Curtain of Codes

There's some good news.

While the focus is on the larger federal budget issues, the real calculations of payments, reimbursements and public healthcare policies that affect a surgeon's bottom line take place behind the curtain of codes and relative values of procedures, commonly referred to as "RUCs", determined by the American Medical Association (AMA) and adopted by the Centers for Medicare and Medicaid Services (CMS).

We got our first look into 2013 when CMS issued a final physician payment rule on November 1, 2012 for Medicare's payments for physician fees for 2013. The physician payment rule is not to be confused with CMS' August 1 announcement that they will increase hospital payments for orthopedic surgeries in 2013 by on average 4.4%. The surgeons' portion of those payments depends on their individual hospital negotiations.

Winners and Losers

Payments to family practitioners will increase by 7%, while other primary care providers will receive a 3-5% increase. Since the physician payment bucket is a zero-sum proposition, higher payments for some mean lower payments for others. For instance, independent laboratory providers (14% payment declines), neurologists (7% reductions), radiation oncologists (down 7%), pathologists (down 6%), interventional radiologists (down 3%) and cardiologists (down 2%) will all experience pay cuts.

But the headlines don't tell the whole story for orthopedics.

Orthopedic Opportunities

According to the American Academy of Orthopaedic Surgeons (AAOS), the procedures and services most utilized by orthopedic surgeons are listed in 28 new or revised work RVUs (relative value units). AAOS presented these RVUs to the AMA/RUC and which then presented them to CMS. There were no procedures or services where CMS did not accept the RUC/AAOS recommendations.

The estimated cumulative impact on orthopedic surgery is 0% meaning CMS doesn't expect that there will be any large changes for orthopedic surgery payments—positively or negatively.

The rule also includes a new policy to pay a patient's physician or practitioner to coordinate the patient's care in the 30 days following a hospital or skilled nursing facility stay. "Recognizing the work of community physicians and practitioners in treating a patient following discharge from a hospital or nursing facility will ensure better continuity of care for these patients and help reduce patient readmissions," said CMS in the rule to justify higher payments for primary care physicians.

But primary care physicians aren't really getting more money as much as the codes they submit are being reimbursed at higher rates. And there is an increased number of codes to use to report their services. The real impact on orthopedic surgeons has to do with the RVUs that Medicare accepted from the AMA and are used to reimburse surgeons.

The good news for orthopedic surgeons is that they perform many of the procedures that are described in these new codes. So orthopods may well receive more income if they also perform those procedures and submit the associated new codes.

The Top Orthopedic Policies

From the perspective of the orthopedic surgeon, the major policies promulgated in the rule are the following.

1) Creation of relative value units and payment for transition of care services (i.e., non face-to-face patient encounters). The AAOS supported this initiative.
2) The extension of the multiple procedure reduction rule (MPRR) to apply to certain diagnostic testing. Even though this isn't relevant to orthopedic surgery, AAOS commented in opposition to the proposal because it is similar to a previous CMS action that extended a payment reduction for multiple imaging or therapy services provided by the same provider on the same day.
3) Updated interest rate assumption for practice expense inputs. AAOS supported the CMS proposal to update their interest rate assumptions for equipment. CMS switched to a more current rate and AAOS supported this because it is more accurate and fair.
4) Proposed inputs for the Medicare value-based modifier. The Affordable Care Act (ACA) required CMS to create a modifier to provide differential payment rates based on "value." CMS has announced they intend to start implementing the payment modifier in 2015. The AAOS supports the payment modifier in theory but has called for changes to the inputs and methods as proposed.

Dale Blasier, M.D. MBA, is chair of the AAOS Coding, Coverage and Reimbursement Committee. Dr. Blasier told us that the RUCs did not have any great gains or losses for orthopedics. "That's good news."

R. Dale Blasier, M.D., MBA

The next big thing on the horizon for coding and reimbursement, according to Dr. Blasier, has to do with "non-face-to-face" services. Those are services where orthopedic surgeons are providing oversight and managing transitional work and chronic care conditions. In effect, billing for the "in-between" services.

Dr. Blasier also wants to be sure surgeon payments remain fair while hospitals continue to acquire private orthopedic practices and while payers move to bundling payments for the hospital (parts) and the physician (labor). He said that AAOS will be vigilant in assuring that payments to surgeons are fair because hospitals seem to have better representation.

A Good Trend

Tim Hunter, vice president MCRA, LLC

Maintaining the orthopedic payment status quo is significant considering that CMS enacted considerable pay cuts in other specialty areas, said Tim Hunter, vice president of Health Economics, Reimbursement & Public Policy at MCRA, LLC. "It also means that orthopedic surgery as a whole has maintained the positive gains from the 2011 rule." He shared the following summary with us:

Estimated Impact on Total Allowed Charges-Orthopedic Surgery

CY 2013	
• Allowed Charges:	$3,643 (million)
• **Combined Impact:**	**0%**
CY 2012	
• Allowed Charges:	$3,584 (million)
• **Combined Impact**	
o **Fully implemented:**	**0%**
o **Transition:**	**-1%**
CY 2011	
• Allowed Charges	$3,432 (million)
• **Combined Impact**	
o **Fully implemented:**	**4%**
o **Transition**	**3%**
CY 2010	
• Allowed Charges	$3,261 (million)
• **Combined Impact**	
o **Fully implemented:**	**2%**
o **Transition:**	**0%**

Courtesy of MCRA, LLC

Hunter said the obvious focus within the rule is the improvement in payments for frontline care—internal medicine, family practice, and geriatrics (though the total expenditure for this line is relatively small). "However, this focus on direct physician-patient interaction also has a positive impact on orthopedic practices. CMS has increased the practice expense of RVUs associated with non-facility physician office visits for new and established patients, which positively impacts that portion of the orthopedic practice associated with non-surgical and conservative care treatment."

The Rest of the Rule

In non-orthopedic specific areas, the final rule continues efforts by CMS to align quality reporting across programs to "reduce burden and complexity." The rule makes changes to the PQRS (Phy-

sician Quality Reporting System) and the Electronic Prescribing (eRx) Incentive Program. These changes, says the agency, will simplify reporting and align the various programs' quality reporting approaches so they support the National Quality Strategy.

The final rule also lays out next steps to enhance the Physician Compare website, including posting names of practitioners who, as part of the Million Hearts campaign, successfully report measures to prevent heart disease. These are recommended measures under PQRS as well.

Among other changes, the final rule expands access to services that can be provided by non-physician practitioners. The rule allows Certified Registered Nurse Anesthetists (CRNAs) to be paid by Medicare for providing all services that they are permitted to furnish under state law. This change will allow Medicare to pay CRNAs for services to the full extent of their state scope of practice. The rule also allows Medicare to pay for portable X-rays ordered by nurse practitioners, physician assistants and other non-physician practitioners.

Another rule outlines how Medicaid reimbursements will be brought on par with those of Medicare for primary care providers in 2013 and 2014, as outlined in the Affordable Care Act. The federal government will pay for 100% of the difference between the Medicaid state plan payment as of July 1, 2009 and the applicable Medicare rate.

Of particular interest to surgeons participating in ambulatory surgery centers is a 0.6% increase in payments. Hospital outpatient departments get an additional 1.8% in 2013. CMS also makes some changes to the quality reporting programs for both types of facilities.

Finally, the rule explains how Medicare will pay for molecular pathology services, which the agency says is the next innovation of clinical laboratory tests that will foster the development of personalized medicine. These tests will be paid under the Clinical Laboratory Fee Schedule with 2013 payment set by the gap filling method. The final rule also requires a face-to-face encounter as a condition of payment for certain durable medical equipment (DME) items for orders written on or after July 1, 2013.

Keep on Movin'

Relatively speaking, orthopedic surgeons and procedures have done well by Medicare for 2013. The agency seems to be saying it favors therapies which keep seniors moving and active over labs and testing procedures. Some might call this rationing. Orthopedists should call it effective medicine.

The final fee schedule rule will be published in the Federal Register on November 16 and take effect January 1, 2013. ♦

Outcome Based Liability Ready or Not!...Ideal Treatment or Best Value?

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

Here Come Outcome Based Financial Liabilities – Ready or Not!

David J. Jacofsky, M.D. is an orthopedic surgeon and the Chairman of The Center for Orthopedic Research and Education (CORE) in Arizona. He is also a SHRI Senior Scientist and Head for SHRI/CORE Orthopedic Research Lab. He tells *OTW*, "I don't think that all orthopedic surgeons are fully aware of reality of changes that are coming regarding payor reform. Many doctors lack the infrastructure to be able to be successful in a world where we have to directly manage costs and take significant financial risk on our complication rates, the post discharge period, and on readmissions for any reason. How many surgeons and hospitals really have a deliberate, automated, and coordinated effort to follow evidence based protocols? Hip and knee arthroplasty are the best examples in healthcare of how bundled payments for the full episode of care can be piloted. It's a very distinct surgical procedure, it's planned and elective, and there are significant societal costs associated with them that are largely in control of the provider (patient selection, implant costs, length of stay, whether a patient is discharged home or to a skilled care facility, preoperative optimization, preoperative education of the patient and preparation of family members who can assist with aftercare, etc.)."

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"Because it is a distinct episode of care, unlike more chronic and variable conditions such as congestive heart failure or diabetes, it is easy to tell the doctor that they are fully responsible for all the patient costs from three days prior to surgery until 90 days post-discharge. If you send the patient to a nursing home you are effectively paying for it, as you or the hospital receives the same fixed total dollar amount for a given episode of care. The good news is that there is a significant opportunity for doctors to see an increase in income based upon taking a financial risk with these sorts of procedures if they are prepared."

"Our group has seen an increase in reimbursement rates for four years because we are able to take outcomes-based risks. We tell the insurance companies, we will take a marked reduction in guaranteed reimbursement at the time of service, i.e., instead of paying 'x' for a knee replacement you pay us half up front, BUT, here are ten quality metrics and if we hit these targets for each of them then we save the insurer this amount of money. We want half of that. This is working very well for us. Admittedly, we are a larger practice of 50 doctors and 26 physician assistants. As always, there is strength in numbers, but the key lies in a coordinated strategy and the creation of an infrastruc-

ture to make such pay for performance programs viable. We are hopeful that smaller groups will continue to partner with us to improve the ability of physicians to 'take health care back.'"

Ideal Treatment or Best Value? Anthony Romeo, M.D. is an orthopedic surgeon at Midwest Orthopaedics at Rush. He is also Professor of Orthopaedic Surgery at Rush University Medical Center, and director of the Section of Shoulder & Elbow. Dr. Romeo tells *OTW*, "A recurring theme now in all aspects of orthopedic surgery is the movement toward determining the value of healthcare. At the recent American Shoulder and Elbow Surgeons (ASES) meeting we spent a lot of time discussing how that applies to us. There is an increased emphasis on our role as orthopedic surgeons in helping to define the value of care that we provide. The ASES has done a great job of looking at outcomes that define care in terms surgeons are comfortable with. However, we must get better at defining this value in a way that patients understand. Why? Because there are a number of players at the table, including insurers, government, and other third party reviewers. The most alarming part is that these reviewers—who are most often NOT orthopedic surgeons—don't often understand the value of the care we provide. And because to date we have had a hard time describing it they go about making decisions based entirely on cost. We need our patients as allies and advocates. Patients can request and lobby for care that is valuable for them."

"For example, we are really under siege with regard to reverse shoulder arthroplasty. It is twice as expensive in terms of implants as compared to a standard total shoulder, but the coding and billing result in the same reimbursement in insurance. Then we are told, 'Well, since you haven't shown that it's valuable why should we pay the extra cost?' It's maddening because we know without question that a reverse shoulder is the ideal treatment for arthritis combined with a nonfunctioning rotator cuff. There is no better operation for those who fail conservative management. While a standard total shoulder may have good pain relief it is more likely to be ineffective as far as the ability to perform daily life activities. The solution is to collect the proper outcome data before surgery, including patient specific satisfaction scores and quality of care scores like those used in Europe. And, we need to do a better job of presenting our data."

Career Debut: Some Tips Scott Tucker, M.D. is winding up his last year of residency and next year will begin a fellowship at the Andrews Institute for Orthopaedics and Sports Medicine. We've followed Dr. Tucker through his years of training and check in with him now as he winds up his formal education and prepares to embark on his career. He tells *OTW,* "I know that hospital employment is increasingly popular, but honestly, my contemporaries are leaning toward private practice. Many people say, 'Join a hospital… you'll have more security.' But maybe it's because we're emerging from training with around $300,000 in debt that we're willing to take our chances with private practice. There is more risk, but there is also a much higher earning potential."

"As for how I will approach practices next year, I honestly wish that we were given more guidance on this in residency. However, I have heard from many who have gone before me that when considering a practice it is important to ask to see their books. It's easier for me to say that now, but when I am sitting across the table from the senior partner it might be a bit harder. The older doctors I know, however, say, 'You will eventually become a partner, so it is reasonable to make this request.' I also plan on asking about how best to market myself, how much call I would be taking, and, perhaps most importantly, how long does it typically take to get one's practice to the level where you're doing the kind of surgery you set out to do.' I'll keep you posted, Elizabeth."

Epidural Steroid Injections on Hold? Alan Hilibrand, M.D. is a professor of Orthopaedic Surgery and Neurosurgery at the Rothman Institute in Philadelphia. He is also Director of Medical Education for the Department of Orthopaedic Surgery at the Rothman Institute and Jefferson Medical College. Dr. Hilibrand tells *OTW*, "I think it's fascinating that people are taking a second look at the role of epidural steroid injections in the treatment of spinal disorders. This is to a great extent due to the recent fungal meningitis outbreak…and while this could happen with any injection,

when it involves an injection where the benefits are unclear it becomes more of an issue. The other reason that orthopedic surgeons are questioning this treatment is because of a recent study that we published looking at the option of using these injections on weekend warriors with spinal stenosis. It looks like this treatment option is not as effective for individuals with spinal stenosis as with those who have a herniated disc. In cases involving a herniated disc people often get better so you are quieting down pain and giving them a chance to get better on their own. For spinal stenosis epidurals are used to help avoid surgery, thus it's more of a temporizing measure. Our study suggests that epidurals may not be benefitting people in significant way in terms of functional outcomes or in preventing surgery."

"Patients themselves are coming into our offices at Rothman and saying, 'We're not so sure about epidurals anymore.' We surgeons do feel a compulsion to offer people nonoperative treatment before surgery, but at this point we are becoming less likely to recommend steroid injections. We need answers in the form of a prospective randomized trial comparing operative care to these injections. This is often difficult because patients come in with their own preferences for a certain treatment. I don't see us altering course in the next year or so unless we can get some data that makes us more comfortable recommending this nonoperative treatment. Until then, there will increasingly fewer epidurals."

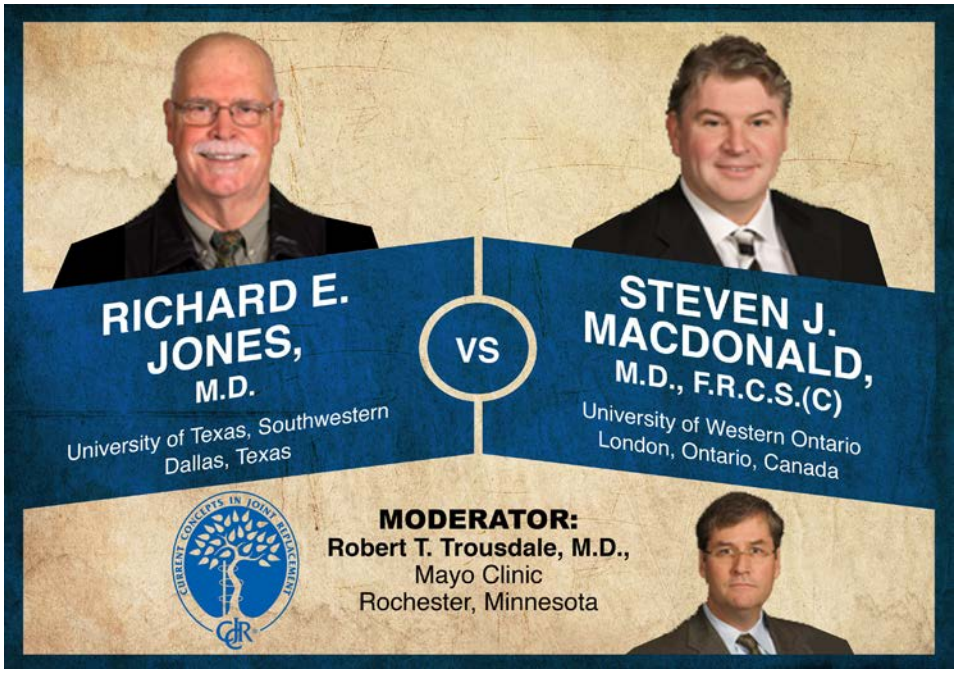
Darren Johnson, M.D. Named Team Physician of the Year University of Kentucky (UK) team orthopedic surgeon Dr. Darren Johnson has been named the 2012-13 Southeastern Conference Team Physician of the Year by SEC member institution athletic training staffs. This award is chosen by the athletic training staffs at SEC member institutions and is given annually to recognize a team physician who has contributed greatly to his or her school's teams and to the SEC sports community. Voting criteria includes reliability to the physician's athletic department and noted involvement in the field of sports medicine. A $1,000 award will be given to the University of Kentucky Athletic Training Education Program in Dr. Johnson's name for student athletic trainer scholarship or education. Currently, Dr. Johnson serves as the chair of the Department of Orthopaedic Surgery and Sports Medicine at the University of Kentucky and the head orthopedic surgeon for UK Athletics. Dr. Johnson earned his degree from the UCLA School of Medicine before doing his residency at the University of Southern California and his fellowship at the University of Pittsburgh. ♦

Jones Debates MacDonald Over Tourniquets

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

"There are many disadvantages of a tourniquet," says Richard Jones. "Let it bleed!" "Wait," says Steve MacDonald, "There can be no argument that a tourniquet reduces intra-operative blood loss. You use a tourniquet if you're good looking and highly intelligent."

This week's Orthopaedic Crossfire® debate is "TKA Sans Tourniquet: Let it Bleed." For the proposition was Richard E. Jones, M.D. of the University of Texas, Southwestern. Against the proposition was Steven J. MacDonald, M.D., F.R.C.S.(C) from the University of Western Ontario. Moderating was Robert T. Trousdale, M.D., of Mayo Clinic in Rochester, Minnesota.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Jones: "The benefits of TKA [total knee arthroplasty] with tourniquet: you could operate in a bloodless field and potentially there's a better bone-cement-implant interface for fixation. The potential problems: 1) Neuromuscular: direct nerve damage secondary to pressure and indirect nerve damage secondary to hypoxia; also, a delay in recovery in muscle function. 2) Vascular: altered hemodynamics with limb exsanguination…you actually increase the circulatory volume by 15-20% when you're putting your tourniquet up. When you release it you get reactive hyperemia which gives you a 10% increase in limb size. That may increase soft tissue tension and it may give you secondary pain."

"Vascular injury is higher in patients that have atherosclerotic or calcified arteries. Also, increased risk of DVT with direct trauma for the vessel walls, increased levels of thrombin-antithrombin complexes, and a 5.3 times greater risk for large venous emboli propagation and transesophogeal echogenic particles. 3) Furthermore, you get an increase in wound healing disturbances and a higher propensity for wound leakage. Early experience for us with no tourniquet was in the high risk patient with a previous DVT or PE, multiple scarring, or compromised cardiovascular status. For the last eight years we have used no tourniquet on all comers."

"The operative protocol is regional anesthesia to control blood pressure and reduce bleeding; incision and approach made with 90 degrees of knee flexion; meticulous hemostasis—all vessels readily seen and coagulated with an argon beam coagulator. We use 0.25% ropavicaine with epinephrine injected peri-articular to diminish some of the bleeding. We coagulate all the posterior tissues at the flexion-tension balancing stage after you've cut your tibia and your femur. And we use saline jet lavage. We then use filtered carbon dioxide which is delivered through a high pressure Carbo-Jet to dry and prepare bone ends for cementation. We do a routine closure and we use a compressive dressing."

"Our observations: no differences in blood loss or transfusion rates; less postop pain, faster straight leg raise and knee flexion gain; fewer wound heal-

ing disturbances; consistent cement penetration and mantles, so we see no changes in our X-rays and in our follow up in the tourniquet phase and in the post no tourniquet phase. So our recommendation is: give it a try…let it bleed. Thanks to the Rolling Stones."

Dr. MacDonald: "I have performed TKAs without tourniquets in a select few patients: vasculopaths with no distal pulses and the non-complaining patient in the cadaver lab. There are pros and cons, and there are few randomized clinical trials (RCTs) to guide us in this; there is no registry data. Why use it? There can be no argument that a tourniquet reduces intra-operative blood loss. In a paper published this year—a meta analysis of 15 papers including 1,040 TKAs there was significantly greater blood loss."

"However, if you look at overall blood loss—intraop and postop—there was not a significant difference between the two groups. So you have a choice… you can have bleeding in your operative field or you can have bleeding later when you're finished. I'll take it later—not in my operative field. But I can't make an argument that tourniquet use reduces overall blood loss."

"It's a given that we want a dry bone surface for cementing. If you don't have a dry bone surface there is the risk of late loosening. So without a tourniquet you need an alternative…meticulous hemostasis and this crazy thing about filtered carbon dioxide. But they all come with the following: a dollar cost and a time cost. If you don't have a tourniquet it's probably going to take you a bit longer."

"There's an excellent paper that was published just a couple of months ago showing a direct correlation between OR time and infection in TKA (Willis-Owen CA, et al., *JBJS*[Am]). Their recommendation was that 'Steps to minimize intra-operative delay should be instigated.' and 'Care should be exercised when introducing measures which prolong the duration of joint replacement.'"

"The proposed downsides to a tourniquet? They're either basic science theories or they're rare or short term in my opinion. Vessel wall damage leading to increased DVT…is there a single clinical paper supporting this? There is a paper that refutes that—a tourniquet versus no tourniquet RCT where their outcome measure was to evaluate any evidence of vessel damage using an ultrasound. There was no difference in the incidence of DVT or thrombis between the two groups. This paper showed less intraoperative and total blood loss with a tourniquet."

"Another proposed downside to a tourniquet is an increase in wound healing disturbances, but there is no clinical evidence for this. Another is delay in muscle function recovery; there is no clinical evidence for that theory. Nerve damage…true…you can get transient changes, but I'm unaware of permanent ones."

"It's a judgment call. You don't use a tourniquet if you are concerned about the theoretical risks and you have alternatives to achieve a dry field…and they are cost neutral…and you don't increase the OR time…and you don't need published data on the long term results. So Dickie, there you go. You do use a tourniquet if you're good looking and highly intelligent."

Moderator Trousdale: "Dickie presented 15—and granted, you stated some are theoretical—disadvantages of a tourniquet. The one potential advantage—the drier surgical field—you look at Dickie's intraoperative surgery and his field is pretty dry. Its blood loss… that meta analysis is good. It implies the postop blood loss is lower if you don't use the tourniquet…so the real issue is transfusion. What are your transfusion rates?"

Dr. MacDonald: "It's dependent upon a lot of things. We have a protocol… based on their preop hemoglobin we use tranexamic acid in every case… which significantly changes your blood loss. Our transfusion rate in a primary total knee setting is between 3 and 4% depending on the quarter. We get quarterly analysis and it's variable surgeon to surgeon."

Moderator Trousdale: "Dickie?"

Dr. Jones: "Same."

Moderator Trousdale: "Both of these guys are using tranexamic acid. Dickie's using it topically. Steve?"

Dr. MacDonald: "IV during the OR. With a knee it's when we're cementing the patella."

Dr. Jones: "I've been chicken to use it systemically because of possible complications. We've used it topically and found that there're no issues."

Moderator Trousdale: "Last month a group from Toronto (Wong J, et al., *JBJS*[Am]) showed that topical use is very effective…and there's very good data in multiple surgical subspecialties documenting the use of that in an IV. We use a gram at the beginning of the case and a gram at the end."

Dr. Jones: "One of most specious arguments I've ever heard is increased time in the OR. There's no increased time. Don't you jet lavage your total knee patients before you cement?"

Dr. MacDonald: "Yes. That's not really evidence of no increased OR time. I think it's a hard argument to tell somebody if they stop using a tourniquet it's going to be exactly time neutral."

Moderator Trousdale: "Dickie, without a tourniquet you showed us you're cementing the cobalt chrome tray in flexion. Do you bring the knee in extension when you cement it?"

Dr. Jones: "Yes."

Moderator Trousdale: "And you don't think that affects your cement mantle at all?"

Dr. Jones: "No."

Moderator Trousdale: "You'd think in theory the blood would permeate…"

Dr. Jones: "You would, but it does not. We do it at about 15-20 degrees of flexion and axial compression so that we ensure we're equivalent with our pressure on both sides. If you cement an extension and you haven't fully released a valgus or varus deformity, then you'll end up with an uneven cement mantle. We saw no difference in cement penetration looking at the lateral X-rays and the spot laterals in the OR of the patients that were with tourniquet or without."

Moderator Trousdale: "Steve, in defense of Dickie, does cement mantle make a difference in total knee replacement? Do we have data in the knee about what thickness cement mantle we want to get?"

Dr. MacDonald: "I would say no. There's been RSA [radiostereometric analysis] studies done on different things like whether you should cement the keel or the post, and I think we have evidence for micromotion with that. But that's not a surrogate measure for absolute tray cement mantles."

Moderator Trousdale: "There are two issues with bleeding. One is hemoglobin and transfusion rates and most of the studies look at tourniquet/no tourniquet, pre- and post-op hemoglobin. That's a very weak surrogate because the hemoglobin rates both pre- and

post-op are directly related to hemodilution issues. Same with the transfusion triggers--it's different from every hospital and every surgeon. Part of that is how you use drains."

Dr. MacDonald: "We use a drain for 24 hours—no, actually, until the next operative day. They pull the drains somewhere between 8 and 9am the following day. Every single person gets a drain."

Dr. Jones: "I haven't used a drain in a hip or a knee in 20 years; we use compressive dressings."

Moderator Trousdale: "How do you handle a patient with a PFO [patent foramen ovale]?...25% of our patients have a little atrial septal defect and when you let the tourniquet down you get a showering effect of some emboli. Do you look for patients with a PFO prior to surgery? Do you change your tourniquet based on a cardiac situation or previous embolic stroke?"

Dr. MacDonald: "We don't look. Do you?"

Moderator Trousdale: "I don't look."

Dr. MacDonald: "You don't know. Trousdale's trying to sound smart? He has no idea what he just said."

Dr. Jones: "The good news for me is since I never used a tourniquet I don't have to worry about all of those issues."

Moderator Trousdale: "Dickie, you won hands down. You should all stop using tourniquets unless you're from Canada. Gentlemen, thank you." ♦

Please visit www.CCJR.com to register for the 2012 CCJR Winter Meeting, December 12 - 15 in Orlando, Florida.

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company

DePuy's Personalized Knee Adds Options

DePuy Orthopaedics, Inc. is now offering the Trumatch Pin Guide for use with their Sigma Fixed Bearing Total Knee System. The guide recently received for 510(k) clearance from the FDA, according to a November 7 press release from the company.

With this offering, the company says surgeons now have the option to choose whether to utilize a pin guide or cutting guide in their procedure. The guide is part of the company's personalized solutions portfolio which includes surgical instrumentation and a computer software system that is designed to aid in knee implant positioning.

Specifically, the company says the pin guide offers surgeons:

- Intra-operative flexibility for surgeons desiring to make changes during the surgical procedure
- A smaller, lower profile jig for less invasive procedures
- An integrated alignment guide to improve ease of use
- Reusable, re-sterilizable metal guides for pin drilling

Michael Swank, M.D., Medical Director of Research for Joint Preservation, Restoration and Reconstruction at the Christ Hospital in Cincinnati, Ohio, said that in a recent study that he conducted on the benefits of customized patient instrumentation, he found that DePuy system provided his patients, "not only a potentially faster operation, but also a shorter hospital stay without sacrificing clinical outcome or clinical alignment."

Trumatch Personalized Solutions originally launched in 2009 and is now available in 24 countries. The Sigma knee system, which includes fixed bearing and rotating platform options, is, according to the company, the leading knee system in the U.S. and has been provided for nearly 1.7 million patients.

—WE (November 9, 2012)

Trumatch Pin Guide/DePuy Orthopaedics, Inc.

Symmetry Partnering With MTG Medical

Symmetry Medical Inc. has announced that its subsidiary, Symmetry Surgical, has entered into an exclusive distribution agreement with MTG Medical Technologies (MTG), subsidiary of Neuro-Competence, in Germany, Austria, Switzerland, Czech Republic, Hungary and Slovakia. Under terms of the agreement, MTG will distribute Symmetry Surgical's portfolio of surgical instruments, which includes all brands and products of the recently acquired Codman surgical instruments portfolio from Johnson and Johnson.

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"Partnering with MTG and bringing the Symmetry Surgical portfolio to Europe is an exciting milestone in expanding our global presence," said Chris Huntington, chief operating officer of Symmetry Surgical, in the October 31, 2012 news release. "Their expertise and mission align with our own values, which are focused on improving patient care and outcomes. We look forward to working with MTG to achieve strong growth in these key markets as we continue our expansion into other European countries in the coming months."

Huntington told *OTW*, "Through our partnerships with MTG Medical Technologies and a growing number of stra-

tegic distribution partners throughout Europe, Asia Pacific, South America and North America, we are committed to giving healthcare professionals around the world access to new and innovative surgical instruments that can benefit their patients. We are investing in the research and development of new surgical instruments—monitoring the marketplace and working with top surgeons and industry leaders to broaden our already diverse portfolio with medical devices that meet real-world needs."

—EH (November 7, 2012)

legal

LDR's Mobi-C Receives "Approvable Letter"

The Food and Drug Administration (FDA) has continued its slew of cervical disc approvals by notifying LDR Spine USA, Inc. that it has given the firm an "Approvable Letter" for the company's Mobi-C cervical disc. The firm made the announcement on November 6.

First Two-Level Approval

The Mobi-C is a metal and polyethylene mobile bearing prosthesis specifically designed as a low-profile cervical intervertebral disc replacement for both one and two level applications. A company spokesperson said the Mobi-C is the first and only cervical disc to receive an approvable letter for two-level use in the treatment of cervical degenerative disc disease (DDD) in the U.S. The approval follows a 600 patient concurrent IDE (investigational device exemption) clinical trial for one- and two-level cervical disc replacement.

FDA has determined that Mobi-C is approvable for two-level indications, subject to the satisfaction of all applicable requirements of the Quality System Regulations (21 CFR Part 820), as well as finalization of the labeling and post-approval study. FDA will issue an approval order, allowing commercial sale and distribution, after said requirements have been reviewed and determined to be acceptable.

By the age of 50, 85% of the population will show evidence of disc degeneration, according to the company. "Two-level disease is by far the most prevalent and the IDE trial showed that Mobi-C is clinically superior compared to the gold standard treatment, fusion. This is a large market of patients for which currently there are no devices approved," continued the company statement.

2013 Launch Expected

"We are confident that we can efficiently complete the remaining requirements inherent in the full approval process and we anticipate commercial U.S. availability of Mobi-C in 2013," said Christophe Lavigne, president and CEO of LDR. "Given the high incidence of two-level cervical disease, we are proud that Mobi-C may become the first cervical disc available to treat patients on-label that suffer from two-level pathology.

This is the third FDA approval of a cervical disc in the last month. Also approved were Globus Medical, Inc.'s Secure-C and NuVasive, Inc.'s PCM.

—WE (November 6, 2012)

Mobi-C Cervical Disc/LDR Spine USA, Inc.

biologics

Advanced Biologics Validates Growth Factor in OsteoAMP

Advanced Biologics, LLC has succeeded in the validation of its OsteoAMP process which showed no clinically relevant donor-to-donor variation. The testing used 100 consecutive allograft donors whose gifts were processed into products that resulted in 100% clinical success in 300 lumbar and cervical spine fusions, according to a company release.

Company officials describe OsteoAMP as an allogenic growth factor that is a lower-cost alternative to recombinant growth factors, such as rhBMP-2 (Infuse, Medtronic). OsteoAMP's four distinctive formats—granules, compressible sponges, putty, and structural grafts—allow surgeons to tailor deliver of the technology according to their needs in surgery.

Through Advanced Biologics proprietary process, allograft and its native bone marrow are processed and the BMPs (Bone morphogenetic protein) and growth factors found within the bone marrow cells are extracted and bound to the allograft. This process results in an end product that, company officials claim, has shown to contain 500 to 1,000 times the BMP and growth factor amounts of any autograft or allograft derived biologic on the market.

Founded in 2009 and located in Ladera Ranch, California, Advanced Biologics is a privately held company focused on developing innovative and clinically relevant biologic solutions across a wide degree of medical specialties. The company was awarded the Best New Regenerative Technology award in 2009, Best New Biomaterial Technology Award in 2010, and 2011 Best New Technology in Biomaterials and Biologics by the Orthopedics This Week Spine Technology Awards.

Courtesy of Advanced Biologics

—BY (November 7, 2012)

Biomet Spine Introduces Living Cell Product

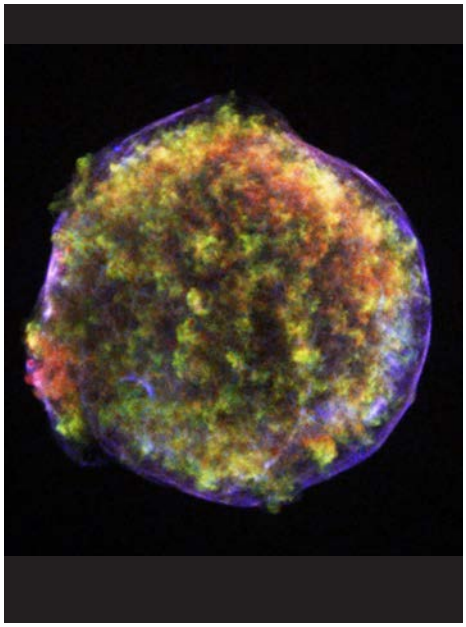
Biomet Spine introduced Cellentra VCBM (Viable Cell Bone Matrix), the third cell spine market entrant, at this year's annual meeting of the North American Spine Society (NASS) in Dallas, Texas. The introduction of Cellentra was Biomet's twelfth new product introduction in the past 12 months.

"Cellentra™ VCBM offers the complete bone healing triad, including viable osteogenic cells, verified osteoinductivity, and an osteoconductive scaffold" said Jennifer Grasso, Director of Marketing at Biomet Spine & Bone Healing Technologies. "Every lot of Cellentra™ VCBM is proven to contain at least 250,000 viable cells per cc, including mesenchymal stem cells (MSCs), osteoprogenitor cells and pre-osteoblasts."

Grasso further defined the new product. "The demineralized component of Cellentra™ VCBM provides additional inherent growth factors, including BMP-2, 4, 7, VEGF, TGF-β, PDGF, IGF-1 and FGF." She said that the cancellous bone matrix of Cellentra VCBM, offers an interconnected trabecular structure for optimal osteoconductivity.

Biomet officials believe that the introduction of Cellentra VCBM complements Biomet Spine's line of Biologics and Implantable Stimulation products which includes the Indux Cortical Strip and SpF Implantable Spine Fusion Stimulator. Jennifer Grasso went on to state: Biomet, located in Warsaw, Indiana, was founded in 1977. It presently distributes products in 90 countries.

—BY (November 5, 2012)



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Stem Cells Treat Hip Necrosis

Increasing numbers of doctors and hospitals are treating patients with stem cells and providing anecdotal evidence of their results. In Bangalore a multi-specialty hospital claims to have successfully used stem cells to cure a hip joint disorder.

"We have so far treated seven patients, including two non-resident Indians (NRIs) suffering from hip joint disorder using their stem cells and helped them to resume normal life within months," said the hospital chairman H.N. Nagaraj.

He described avascular necrosis as a disease leading to a loss of blood supply to the hip joint. If not treated early, the dislocation of the hip bone can result in disability. He said that any serious injury, medications such as steroids, blood coagulation or excessive alcohol can cause blood loss.

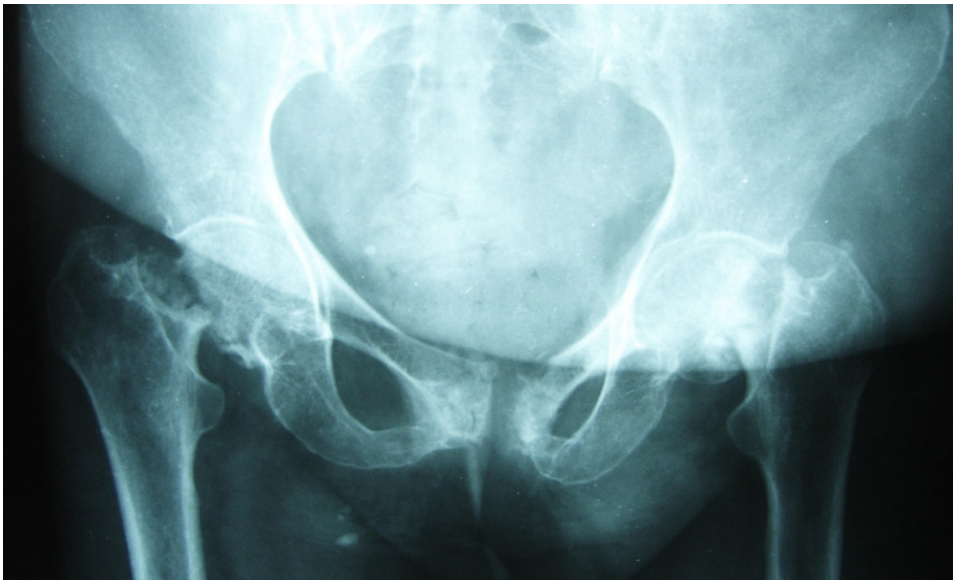
"Stem cell therapy has been used for the first time in the world to treat the hip bone disorder by rejuvenating its tissues with the bone marrow of the patient. Stem cells in the marrow of the affected bone are separated from red blood cells and blood plasma through a clinical process and injected into the hip joint of the patient," Nagaraj said.

The private hospital on the city's outskirts has contracted with a Pune-based laboratory to harvest the stem cells and transplant them through four injections over four weeks to restore the hip joint function lost due to damage to its cartilage. The stem cells also repair bone cells as they can differentiate between bone and cartilage cells.

"The novel treatment has no bleeding or scar formation as the process does not involve surgery. The patient has to visit our hospital for a day in a week for each of the four injections," Nagaraj said.

The hospital plans to submit its therapy treatment protocol for publication in the *Journal of Mass & Heat Transfer* in the United States and Britain and file for an international patent and intellectual property rights.

—BY (November 5, 2012)



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large joints

FDA Approves Xeljanz for RA

The FDA has announced the approval of twice daily Xeljanz (tofacitinib) for adults suffering with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to, or who are intolerant of, methotrexate. Xeljanz works by blocking molecules called "Janus kinases," which are important in the joint inflammation of RA.

Wikimedia Commons and Ayena

"Xeljanz provides a new treatment option for adults suffering from the debilitating disease of RA who have had a poor response to methotrexate," said Badrul Chowdhury, M.D., Ph.D., director of the Division of Pulmonary, Allergy, and Rheumatology Products in the FDA's Center for Drug Evaluation and Research, in the November 6, 2012 news release.

The safety and effectiveness of Xeljanz were evaluated in seven clinical trials in adult patients with moderately to severely active RA. In all of the trials, patients treated with Xeljanz experienced improvement in clinical response and physical functioning compared to patients treated with placebo.

The use of Xeljanz was associated with an increased risk of serious infections,

including opportunistic infections, tuberculosis, cancers and lymphoma. Xeljanz carries a Boxed Warning regarding these safety risks. Xeljanz treatment is also associated with increases in cholesterol and liver enzyme tests and decreases in blood counts.

The FDA approved Xeljanz with a Risk Evaluation and Mitigation Strategy (REMS), which consists of a Medication Guide advising patients about important safety information and a communication plan to inform health care providers about the serious risks associated with Xeljanz.

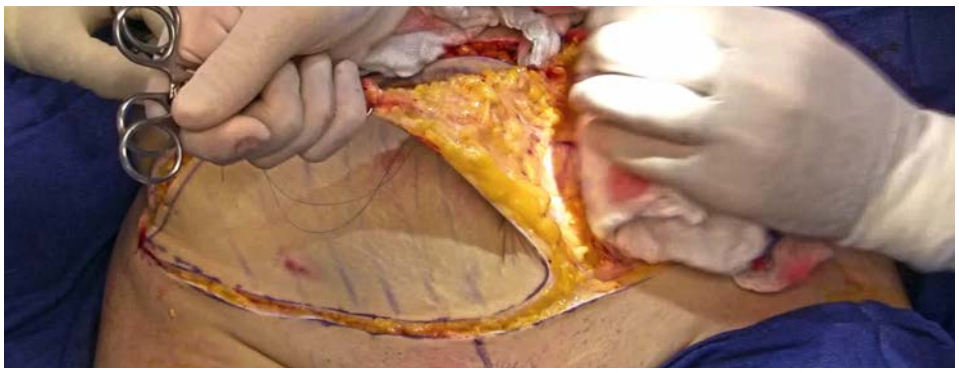
The FDA wants to know the long-term effects of Xeljanz on heart disease, cancer, and serious infections, thus it is requiring a postmarketing study that will evaluate two doses of Xeljanz and include a group of patients on another approved treatment to serve as a comparison.

—EH (November 8, 2012)

Obesity Heightens Knee Replacement Risk

The headline read "Knee Replacement not an easy solution for obese patients." Alas, obese patients have double the rate of infection following knee replacement surgery (compared to non-obese patients) and the rate of infections is higher for both superficial and deep infections. Inevitably, the long-term revision rate for obese patients is nearly double that of the non-obese, according to a study published in the *Journal of Bone and Joint Surgery* that was conducted by Gino M.M.J. Kerkhoffs, M.D., Ph.D., an orthopedic surgeon at the Academic Medical Center Amsterdam, University of Amsterdam.

"Orthopaedic operations can technically be more difficult in obese people, and it is important for us to know whether there is a higher complication rate in the obese, and if the long-term outcome is worse," Kerkoffs said. He notes that obesity is reaching epidemic proportions, particularly in the United States,



Wikimedia Commons and Michael Schwartz MD

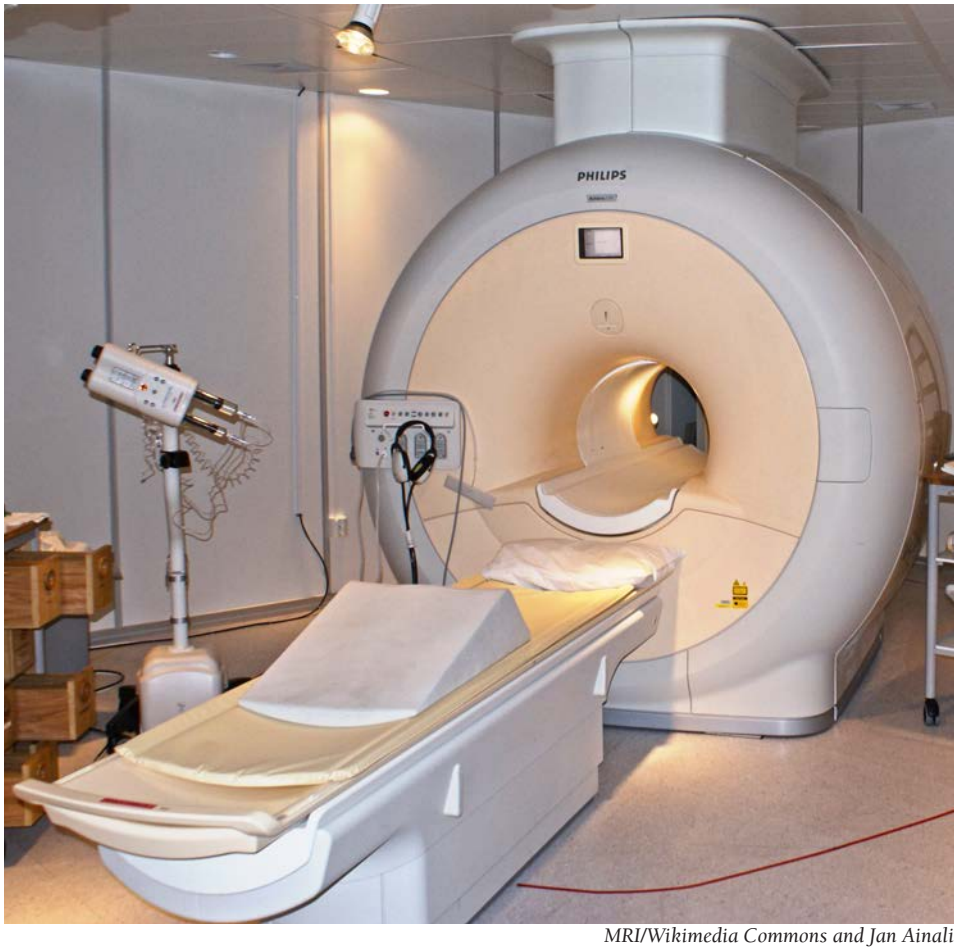
and is a well-documented risk factor for the development of osteoarthritis. While arthritis is initially treated non-surgically, total joint replacement often becomes necessary if the disease progresses.

The paper's authors do not suggest that knee replacement surgery be withheld from obese patients. Instead they recommend that obese patients be well-informed of the likelihood of complications following their total knee replacement, and advised to lose weight before the surgery. Orthopedic surgeons should be prepared to refer them to medical weight-loss professionals, they said. "For the obese patient, this literature sheds new light on treatment options for symptomatic knee osteoarthritis. A total knee replacement is not the easy solution."

—BY (November 7, 2012)

reimbursement

GAO: Imaging Self-Referrals Waste Taxpayers $109 Million



MRI/Wikimedia Commons and Jan Ainali

The U.S. Government Accountability Office (GAO) says that self-referral incentives for physicians for CT (computed tomography) and MRI (magnetic resonance imaging) services are "likely a major factor" in driving an increase in services that cost Medicare an extra $109 million in 2010. The 52-page study was conducted at the request of Congress and released in September.

Self-Referral Increases

The study found that from 2004 through 2010, the number of self-referred services had a larger increase than non-self-referred advanced imaging services and that provider's referrals of those services increased the year after providers gained an ownership interest in the imaging services.

Specifically, the number of self-referred MRI services increased from about 380,000 services in 2004 to about 700,000 services in 2010, an increase of more than 80%. In contrast, the number of non-self-referred MRI services grew about 12% over the same time period, from about 1.97 million services in 2004 to about 2.21 million services in 2010.

"The results of this report are eye opening," said Senator Max Baucus, chairman of the Senate Finance Committee in a press release. "Self-referrals offer an incentive for providers to order more tests than they would otherwise. It's clear they are driving up costs. Providers' bottom lines shouldn't be getting in the way of their patients' care and best interests."

AAOS: Improved Outcomes

John Tongue, M.D., president of American Academy of Orthopaedic Surgeons, responded by pointing out that self-referred imaging services are timely and accessible. He said being able to provide in-office imaging services can lead to greater patient adherence to treatment plans and improved outcomes. "Significant technological advances have been made in our field so that patients can receive timely and accessible screenings from the comfort of their doctor's office. We believe that any restriction on this convenience would threaten the quality of care being delivered to our patients."

Financial Incentives

While acknowledging that these services can help in the early detection and aid in the treatment of certain diseases, the GAO says its findings indicate that factors other than the health status of patients, provider practice size or specialty, or geographic location (i.e., rural or urban) helped drive the higher advanced imaging referral rates among self-referring providers compared to non-self-referring providers.

"We found that providers who began to self-refer advanced imaging servic-

es—after purchasing or leasing imaging equipment or joining practices that self-referred—substantially increased their referrals for MRI and CT services relative to other providers. This suggests that financial incentives for self-referring providers may be a major factor driving the increase in referrals. These financial incentives likely help explain why, in 2010, providers who self-referred made 400,000 more referrals for advanced imaging services than they would have if they were not self-referring."

"These additional referrals cost CMS (Centers for Medicare and Medicaid Services) more than $100 million in 2010 alone. To the extent that these additional referrals are unnecessary, they pose an unacceptable risk for beneficiaries, particularly in the case of CT services, which involve the use of ionizing radiation," stated the study.

Recommendations

The GAO study recommends that the Administrator of CMS take the following three actions:

1. Insert a self-referral flag on its Medicare Part B claims form and require providers to indicate whether the advanced imaging services for which a provider bills Medicare are self-referred or not.
2. Determine and implement a payment reduction for self-referred advanced imaging services to recognize efficiencies when the same provider refers and performs a service.
3. Determine and implement an approach to ensure the appropriateness of advanced imaging services referred by self-referring providers.

The Department of Health and Human Services stated it would consider the first recommendation, but did not concur with the others.

To read the entire study, click here: http://ryortho.com/GAO_Imaging_Self_Referral_Study_2012.pdf

—WE (November 7, 2012)

spine

Safety of Steroid Shots Questioned

How safe are epidural steroids shots when they are injected into the space around the spinal cord? A study by researcher Shalom Mandel, M.D. of Henry Ford Hospital in Detroit, Michigan, presented at the recent meeting of the North American Spine Society, raised new concerns about the injections that are used to treat millions of back pain sufferers.

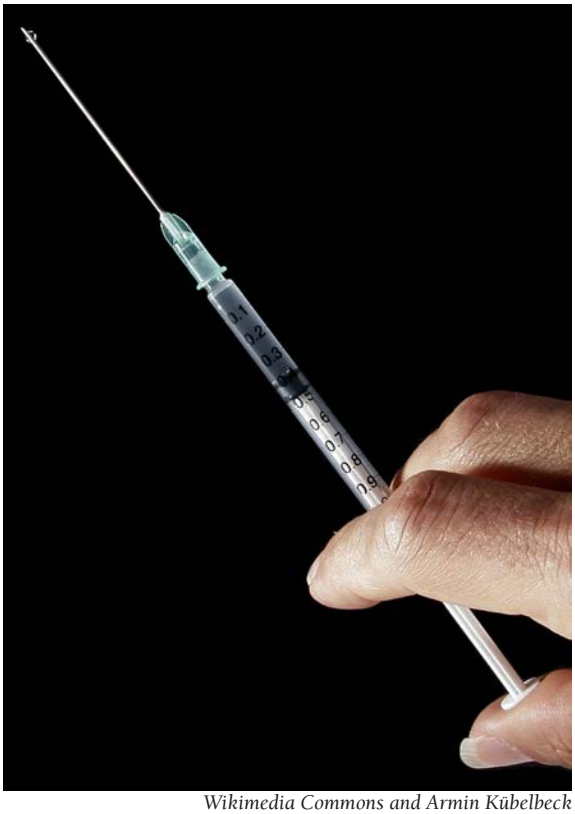
"For a patient population already at risk for bone fractures, steroid injections carry a greater risk than previously thought," said Mandel.

Researchers at Henry Ford Hospital examined data on 6,000 patients treated for back pain between 2007 and 2010. They treated half of the patients with at least one epidural steroid shot and the other half never received the treatment. According to the analysis, spinal fracture risk increased by 29% with each steroid shot. The researchers are quick to point out that this was an association, and does not prove cause and effect.

Steroid treatments, such as those taken orally or by IV, have long been linked to bone loss. However, epidural steroid shots were thought to have little impact on bones because they were delivered directly to the problem area and thus had less effect on the rest of the body. Mandel says this may not be the case.

"If epidural steroids are causing fractures, it is probably because the treatment is not localized," he said. "The drug may be entering the circulatory system." The final word is that more study is needed.

—BY (November 7, 2012)



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Calcium Plus D Cuts Fracture Rate

Women who took calcium and vitamin D cut their risk of vertebral fractures by 13%, according to results from the Women's Health Initiative Calcium plus Vitamin D Supplementation Trial. Nancy Walsh reported the results in *MedPage Today*.

During 12 years of follow-up of almost 30,000 women, there was a significant 13% decrease in risk for clinical vertebral fractures with calcium and vitamin D use, Jane Cauley, DrPH, of the University of Pittsburgh, reported at the annual meeting of the American Society for Bone and Mineral Research. There was no benefit for supplementation for hip fractures, she said.

The original supplement trial assessed whether 1,000 mg per day of calcium plus 400 IU of vitamin D daily reduced the risk of hip fracture and colorectal cancer in more than 36,000 women. The participants were ages 50 to 79 at the time of enrollment at 40 U.S. sites. In the intervention phase of the study they were followed for seven years. When that phase of the study ended, participants were invited to continue in an extension phase, and 29,862 agree to do so.

Those who chose to continue in the trial were healthier and more often white, and 40% were taking more than 1,200 mg of calcium per day, reflecting the fact that they were allowed to use whatever additional dietary supplements they wished. During an additional five years of follow-up, the annualized rate of clinical vertebral fractures was 0.36% for supplement users versus 0.43% for the placebo group.

Cauley noted that, among women who reported taking at least 80% of the study drug, there was a significant 23% decrease for hip fracture, suggesting that the overall benefits outweighed risks among adherent women.

—BY (November 5, 2012)

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people

Lobo Lands Floyd at Stryker

When Kevin Lobo was promoted to the top spot at Stryker Corporation, he moved up from being head of the company's orthopedics business. On November 8, David Floyd, the former head of DePuy Orthopaedics was named to fill the role of group president, Orthopaedics for Stryker.

David Floyd, Stryker Group President, Orthopaedics and Spine and Tim Scannell, Stryker Group President, MedSurg and Neurotechnology

Floyd - Orthopedics and Spine

Lobo also shuffled around responsibilities of his senior managers to give Floyd the added responsibility for the company's spine business.

The spine business was previously assigned to group president of MedSurg and Spine, Tim Scannell.

Scannell – Neurotechnology and MedSurg

So here's Lobo's new line-up. Scannell will continue to head up the company's MedSurg division and take over the Neurotechnology business, which includes the Neurovascular division and Craniomaxillofacial business. Floyd will be in charge of Orthopaedics, which includes Reconstructive, Trauma, Extremities, Joint Preservation, Orthobiologics and Performance Solutions, and Spine. Both men will report to Lobo.

"This realignment will best leverage our leadership talent to drive growth in our Reconstructive, MedSurg and Neurotechnology and Spine segments," said Lobo.

"David brings a strong medical device and orthopedic perspective to Stryker through his successful leadership roles in a broad range of enterprises, including a venture backed startup, middle market med tech and large cap multinationals. He is a proven leader who has demonstrated the ability to drive profitable growth through innovation and we are delighted to have David join our executive team at Stryker," said Lobo. Floyd, said a company statement, has successfully managed global businesses through unprecedented industry change while maintaining strong company, regulatory and customer relationships.

He joins Stryker after 25 years in the medical technology and orthopedics industry where he held a number of senior level leadership roles at DePuy, a division of Johnson and Johnson, Abbott Spine, AxioMed Spine, Centerpulse Orthopaedics and most recently as CEO for OrthoWorx in Warsaw, Indiana.

Scannell began his career with Stryker in 1990 and held various leadership positions within the Endoscopy, Biotech, and Spine divisions before being named group president in 2008.

Lobo and his two key lieutenants make up a streamlined chain of command. From everything we know about these men, it should be a pretty smooth transition.

—WE (November 9, 2012)

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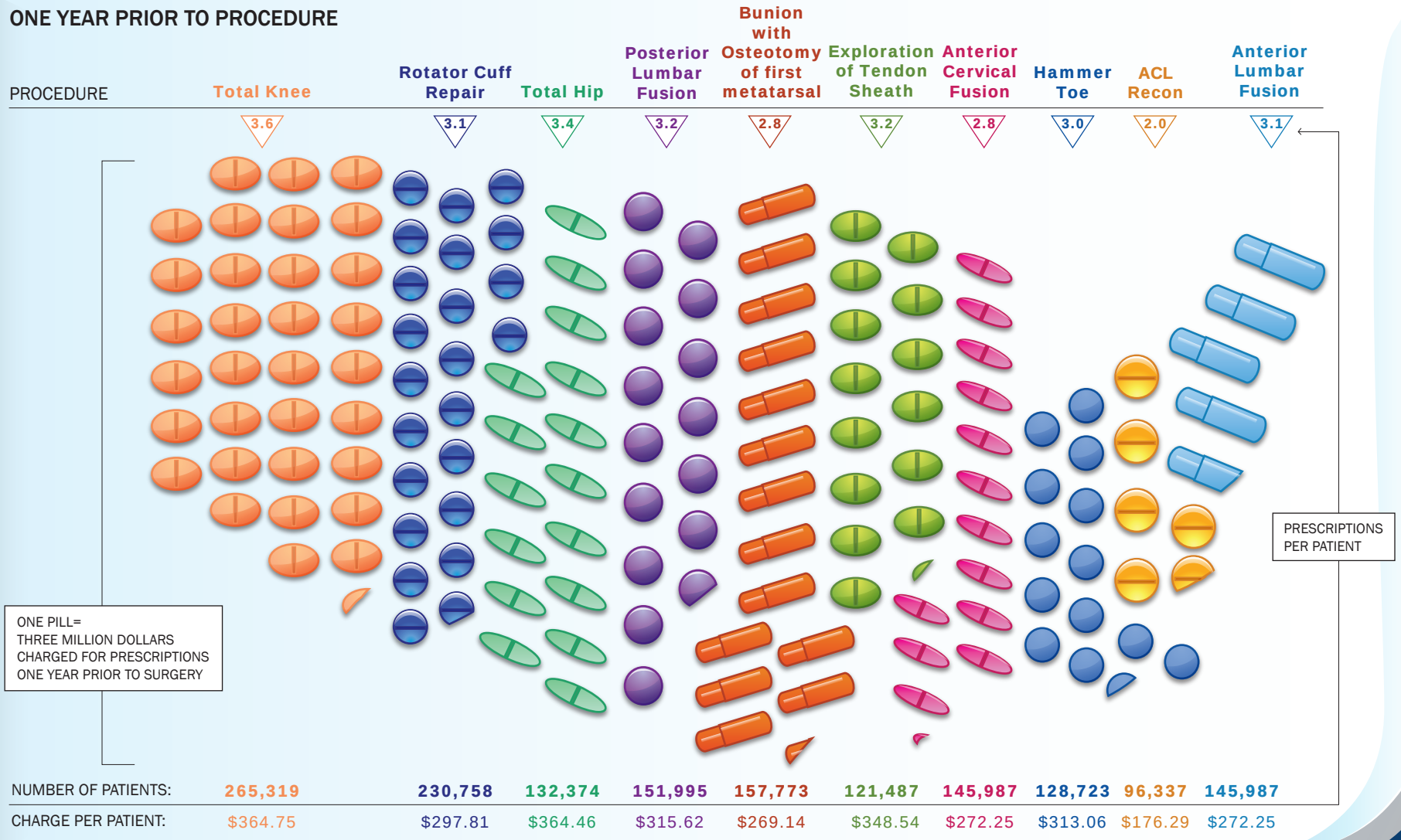

	Total Knee	Rotator Cuff Repair	Total Hip	Posterior Lumbar Fusion	Bunion with Osteotomy of first metatarsal	Exploration of Tendon Sheath	Anterior Cervical Fusion	Hammer Toe	ACL Recon	Anterior Lumbar Fusion
NUMBER OF PATIENTS:	265,319	230,758	132,374	151,995	157,773	121,487	145,987	128,723	96,337	145,987
CHARGE PER PATIENT:	$364.75	$297.81	$364.46	$315.62	$269.14	$348.54	$272.25	$313.06	$176.29	$272.25

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