

# Orthopedics • This Week

## WEEK IN REVIEW

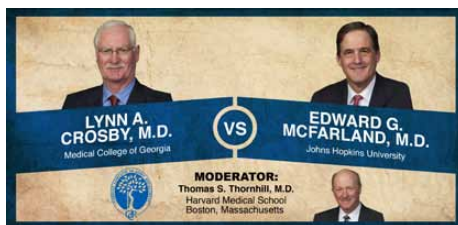
**4 Is MAKO Stryker's Trophy Wife? >>** Seventy-two-year old Stryker just agreed to acquire much younger MAKO Corporation—the pioneer of orthopedic robotics for a jaw dropping \$1.65 billion. s MAKO Stryker's Trophy Wife? What does buying MAKO say about Stryker's strategic plans? Read on, the answer might surprise.

**8 More Patients, But 30% LESS Pay: The Health Exchange Paradox >>** Will physicians accept a 30% cut to treat patients enrolled in state health exchanges? About 20 million new patients are expected to be enrolled via exchanges by 2016. But most physicians aren't aware of the coming changes. Maybe they need to buy a clue.

**13 Instant Autologous Chondrocyte Repair // New Trick for Returning Throwing Athletes to Play // JBJS Review has Launched! >>** UMC Utrecht in the Netherlands has accomplished the near impossible—a single step autologous chondrocyte repair. Are the days of the two-procedure Carticel coming to an end? The head orthopedic surgeon for the Pittsburgh Steelers, James Bradley, M.D., shares his trick for getting pro-throwing athletes back to pre-injury levels.



**16 Crosby Takes on McFarland Over Reverse Shoulder >>** “In an older person with good glenoid bone a reverse is the best option for cuff tear arthropathy,” states Lynn Crosby. Ed McFarland counters, “No. These patients need to suck it up and try nonoperative treatment first.”



## BREAKING NEWS

**20 Change the Hip, Improve the Heart**

MoM Hips: Banned in Britain

Spine Case Goes to New Jersey Supremes

Lawyers Set to Earn \$1 Billion in DePuy ASR Deal

Stark Law Exemption Deadline Looming for Physician-Owned Hospitals

It's Probably a Fact: Men Are Hard Headed

For all news that is ortho, read on.

# Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**THIS WEEK:** Symmetry Medical and Conmed replace Smith & Nephew and JNJ on the Power Rankings this week coming in at #8 and #10, respectively. SMA has its fair share of struggles in 2013 but seems to be clearing the decks for a rebound in 2014. CNMD's valuation is now so low that it's hard to ignore. This is, after all, the season for bargain hunting.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Exactech	10.00%	12.12%	Smallest diversified orthopedic company in our Universe. It's a unique position and may well prove to be a strength in 2014.
2	4	Orthofix	16.25	3.20	'Tis the season for rebounding companies. OFIX, SMA and CNMD. OFIX has 2nd lowest valuation in all orthopedics.
3	1	NuVasive	6.30	5.93	High flying NUVA is stretching the limits of valuation. Of course, if you want a Mercedes you pay Mercedes prices.
4	3	Integra LifeSciences	11.77	1.55	With last month's sale of 3.5 million shares the expectations for earnings growth in 2014 and beyond increased.
5	6	Zimmer	27.31	3.62	ZMH is officially the least expensive equity in orthopedics. Why? With U.S. headwinds (CMS, etc.) investors want more strategic moves at ZMH.
6	5	Globus Medical	28.53	7.60	GMED's future P/E to growth is the best in ortho, BUT Price-to-Sales is 4.28x, the 20th most expensive in all of ortho.
7	7	Stryker	15.22	0.45	CMS cut hip and knee payment rates. Not unexpected and SYK will be affected less than, for example, ZMH.
8	NR	Symmetry Medical	6.50	25.29	At some point SMA is due to bounce back from the fire and integration issues. After Q3 write-off, time might be now.
9	8	Medtronic	28.84	(1.07)	Not a great quarter. MDT spine is a company in transition.
10	NR	Conmed	10.37	11.66	CNMD comes late to the 2013 ortho equity party but at these valuations plus a 33% cash dividend jump, better late than never.

# Robin Young's Orthopedic Universe

## TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	\$0.68	\$86	76.19%
2	Symmetry Medical	SMA	\$9.81	\$365	25.29%
3	CryoLife	CRY	\$11.05	\$305	22.91%
4	MiMedx Group	MDXG	\$6.30	\$616	17.98%
5	Exactech	EXAC	\$24.88	\$337	12.12%
6	Conmed	CNMD	\$40.71	\$1,124	11.66%
7	Wright Medical	WMGI	\$29.81	\$1,404	9.80%
8	Alphatec Holdings	ATEC	\$1.99	\$194	9.34%
9	Globus Medical	GMED	\$19.26	\$1,796	7.60%
10	NuVasive	NUVA	\$33.25	\$1,484	5.93%

## WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	\$0.41	\$21	-30.02%
2	Baxano Surgical Inc	BAXS	\$1.02	\$46	-16.39%
3	Tornier N.V.	TRNX	\$18.09	\$877	-15.39%
4	Medtronic	MDT	\$57.32	\$57,175	-1.07%
5	ArthroCare	ARTC	\$37.72	\$1,070	-0.66%
6	Stryker	SYK	\$74.42	\$28,162	0.45%
7	MAKO Surgical	MAKO	\$29.96	\$1,542	0.50%
8	Integra LifeSciences	IART	\$46.45	\$1,492	1.55%
9	Johnson & Johnson	JNJ	\$94.66	\$267,077	2.02%
10	Orthofix	OFIX	\$21.63	\$421	3.20%

## LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	\$21.63	\$421	8.69
2	Medtronic	MDT	\$57.32	\$57,175	15.52
3	Zimmer Holdings	ZMH	\$91.41	\$15,629	16.35
4	Smith & Nephew	SNN	\$66.88	\$11,958	16.40
5	Globus Medical	GMED	\$19.26	\$1,796	17.18

## HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	\$33.25	\$1,484	87.50
2	Symmetry Medical	SMA	\$9.81	\$365	49.45
3	Integra LifeSciences	IART	\$46.45	\$1,492	29.64
4	CryoLife	CRY	\$11.05	\$305	28.19
5	ArthroCare	ARTC	\$37.72	\$1,070	24.15

## LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	\$19.26	\$1,796	1.15
2	Orthofix	OFIX	\$21.63	\$421	1.24
3	Conmed	CNMD	\$40.71	\$1,124	1.59
4	Exactech	EXAC	\$24.88	\$337	1.66
5	Zimmer Holdings	ZMH	\$91.41	\$15,629	1.72

## HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	\$33.25	\$1,484	7.11
2	CryoLife	CRY	\$11.05	\$305	7.05
3	Symmetry Medical	SMA	\$9.81	\$365	4.12
4	Integra LifeSciences	IART	\$46.45	\$1,492	3.96
5	Johnson & Johnson	JNJ	\$94.66	\$267,077	2.79

## LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	\$0.41	\$21	0.65
2	Symmetry Medical	SMA	\$9.81	\$365	0.89
3	Orthofix	OFIX	\$21.63	\$421	0.91
4	RTI Biologics Inc	RTIX	\$3.08	\$174	0.98
5	Alphatec Holdings	ATEC	\$1.99	\$194	0.99

## HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	\$6.30	\$616	22.79
2	TiGenix	TIG.BR	\$0.68	\$86	21.01
3	MAKO Surgical	MAKO	\$29.96	\$1,542	15.02
4	Globus Medical	GMED	\$19.26	\$1,796	4.65
5	Johnson & Johnson	JNJ	\$94.66	\$267,077	3.97

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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# Is MAKO Stryker's Trophy Wife?

BY ROBIN YOUNG

**B**orn in 1941, Stryker Corporation celebrated its 72nd birthday this year and coincidentally entered into a strategically interesting new marriage with much younger MAKO Corporation.

MAKO is, of course, the pioneer of robotics in orthopedic surgery while Stryker is one of the five companies that supplies 90% of all orthopedic implants and instruments in the world.

Together they are...an intriguing combination.

## A December / May Romance

He likes Mantovani, she likes Kanye West. Now they must find areas of common interest and start building a life together.

As a general proposition, big company purchases of young, entrepreneurial companies turn out better for the shareholders of the young, entrepreneurial company than the big company. DePuy's purchase of Synthes is going through a depressingly typical period of integration snafus. Medtronic's purchase of Kyphon has been a hard slog.

Why do big companies struggle so hard with trophy acquisitions?

There are, according to the academics who study such things, five basic mistakes that large acquirers make:

1. **Stray too Far From Core Competencies:** A company whose traditional strength is selling products to businesses would not likely do well buying a consumer-oriented



Image created by RRY Publications, LLC / Sources: Corporate logos, Morguefile and earl53

business. In Stryker's case, one of its core competencies is selling hospital equipment and surgical navigation systems, endoscopic and communications systems, patient handling and emergency medical equipment. These are large fixed asset sales—similar to MAKO's robots.

2. **Putting Cost Savings Ahead of Sales:** About ten years ago the business consulting firm McKinsey published an insightful analysis of M&A failures and concluded that the most common cause of failure was putting cost savings ahead of sales. The acquiring company's management is under pressure to make an acquisition pay for itself with earnings. So most acquirers cut costs in the acquired company. Big mistake. Here's why. Small changes in sales easily trump major cost savings. According to

that McKinsey study, a 1% shortfall in revenue growth required a 25% improvement in cost savings to stay on-track. Oops. But... if the acquired company exceeds its revenue-growth target by only 2% to 3%, then it can offset a 50% failure on cost reduction. Lesson learned: the worst thing you can have is a sales drop-off immediately after the acquisition. Feed the sales beast!

3. **Getting the Earn-Outs Wrong:** When buyers and sellers can't get to pricing agreement, they use milestones and associated earn-outs to get to "yes." Too many earn-out structures, however, back fire when the key people responsible for achieving the earn-out milestones either are not aware of them or have not been incentivized to support them. Stryker and MAKO sidestepped that issue by getting

to agreement on price—no matter how tortuously—up front with no earn-out milestone provisions.

4. **Cultures That Don't Mesh:** Just because MAKO is in the same business as Stryker doesn't mean they have the same culture. MAKO makes its living by selling expensive capital equipment where service and implants are add-ons to the main event. Implants, in other words, are in the service of the capital equipment—the million dollar robot. Stryker, too, sells capital equipment. In fact, Stryker's capital equipment sales are a bigger percent of Stryker sales than such other diversified orthopedic companies as Zimmer, DePuy or Biomet. Unlike MAKO however, Stryker's capital equipment sales are in the service of implants. Stryker will cut deals on capital equipment sales in order to

build up implant orders. The one key aspect, however, of Stryker's culture which should play well at MAKO is its decentralized operating model. To a great extent, MAKO will be more autonomous at Stryker than it would have been, for example, at JNJ or Medtronic.

5. **Integration for Its Own Sake:** Stryker has the established brand, for sure. But RIO and MAKO have built a brand synonymous with successful robot sales and improved rates of implant accuracy and surgical consistency. Stryker will have to impose its standard operating procedures onto MAKO. That's just how it goes at a big company. MAKO is now a Stryker business unit. But this aspect of integration risks demoralizing the small MAKO sales team that has account authority. Stryker's reputation for

autonomous operating units will help but...here is where the hardest post-deal work could be.

**Six Percent of Stryker**

The final price tag for MAKO was \$1.65 billion or \$30 per share. At that price MAKO represents about 6% of Stryker's overall market value. MAKO's sales are but a rounding error for Stryker and MAKO's operating losses should not prove to be material. (See table on page 6)

Stryker's return on equity is 10.41%. Stryker's shareholders probably hope MAKO will generate around \$170 to \$200 million in incremental earnings eventually. Not all of those sales need to come specifically from MAKO, however. They can come from pull-through sales of Stryker implants and other capital equipment due to MAKO's RIO sys-




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	2013 Sales est.	2013 Profit (Loss) est.	Total Assets	Cash on Balance Sheet	Market Value
<b>MAKO</b>	\$125 million	\$(38) million	\$137 million	\$53 million	\$1.65 billion
<b>Stryker</b>	\$8.99 billion	\$1.6 billion	\$14.9 billion	\$5.1 billion	\$28.11 billion

Source: RRY Publications, LLC

tems. Clearly, MAKO's value to Stryker is strategic.

**\$1.65 Billion**

\$1.65 billion is a lot of money for a 9-year-old firm. But surgical robotics companies operate in a different universe than implant suppliers. Intuitive Surgical, the supplier of the da Vinci surgical robot and related instruments and accessories is 18-years-old yet has a \$14.8 billion market value—about 50% less than Stryker. Intuitive's sales are \$2.2 billion, which is 75% less than Stryker's. *So, one fourth the sales but just half the valuation.* Wall Street puts a much higher value on surgical robotics than on implant suppliers.

How did MAKO's CEO Maurice Ferré, M.D., and Stryker's CEO Kevin Lobo agree on \$1.65 billion (\$30 per share)?

It all started with a phone call from Lobo to Dr. Ferré in early August 2013. Lobo opened the bidding at \$21 per share in cash.

Dr. Ferré told Lobo that \$21 wasn't going to get much board support. Dr. Ferré reviewed it with his board chairman, Charles W. Federico, and it was a non-starter.

Lobo responded quickly and increased the offer to \$24 – \$26 per share, in cash. This time, he put the offer in writing and said that it could go even higher if there were some new opportunities or product capabilities disclosed by MAKO.

Between August 16 and August 19, 2013, the whole MAKO team along with their advisors reviewed Stryker's letter and decided to take Lobo up on his offer to show off their new opportunities or products.

A week or so later, on August 26, 2013, the respective corporate teams met in person for several hours to review any heretofore unknown opportunities and future product capabilities. After the meetings ended, Dr. Ferré told Stryker that MAKO's board would be meeting the following week to make a go/no go decision regarding Stryker. Dr. Ferré

told Stryker that if they were going to increase their bid, they'd better do it before the MAKO board meeting.

Just three days later, August 29, 2013, Lobo called Dr. Ferré and moved his bid up to \$30 per share, in cash.

On September 4, 2013, the MAKO board met in person and reviewed Stryker's new offer with their advisors. Their conclusion? Stryker's price would be more favorable to MAKO's stockholders than staying independent. After the board meeting ended Dr. Ferré contacted Lobo to find out if a higher price



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was possible. Lobo said that the \$30 per share was pretty much it. But he'd check with his guys further.

Sure enough, on the next day Lobo moved the price to \$31 per share—but that price was subject to due diligence. Lobo also told Dr. Ferré that no further increases would be forthcoming.

For the next three weeks Stryker's team poured over MAKO's books and records.

Then, on September 19 Lobo called Dr. Ferré and asked for a face-to-face meeting. The next day Lobo was in MAKO's Florida office. After looking at everything, Lobo said, Stryker had decided to LOWER its price from \$31/share to \$29/share. According to Lobo, his team had found several business- and performance-related issues. In addition, MAKO had been planning to acquire Pipeline Business and that if MAKO went ahead with that purchase, the additional costs were on Stryker's books.

Dr. Ferré told Lobo that \$29 per share was not going to pass MAKO's board.

Lobo told Dr. Ferré that he did not have authority from Stryker's board to raise the offer.

MAKO and its board together with their advisors went back and reviewed everything again. Was there any way to accept the \$29 offer? After long hours of debate, discussion and analysis, the MAKO board could not pull together enough votes to approve the \$29 offer. So MAKO's board told Dr. Ferré to call Lobo before Stryker's September 24 board meeting and to try again to move the purchase price up to \$30 per share, or more.

After Stryker's board meeting, Lobo had some good news for MAKO. Stryker's board was willing to pay \$30/share but asked that the size of the termination fee that would be payable by MAKO to Stryker in certain situations (generally involving the existence of a superior proposal to acquire MAKO from a third

party) would be 3.7% of the transaction value, up from the 3.0%–3.25% .

With that, the deal was sealed at the board levels.

Thirty dollars per share was 84% higher than MAKO's stock price just before the deal was announced. It was also about 113% higher than the three-month average MAKO closing price.

### PostScript

Stryker's purchase of MAKO will likely close in mid-December.

One recurring question from surgeons—who are all dealing with the realities of an increasingly cost conscious health-care system—is why would Stryker acquire a company which sells million dollar robots in this period of health-care cost reduction?

Stryker's answer is that MAKO will simplify joint reconstruction procedures, reduce variability and enhance the surgeon and patient experience.

In dollar terms, Stryker's implants comprise about 18% of the total cost of a large joint replacement. The rest of the cost of surgery is everything else including the surgery itself, rehab and any problems that come up. Small gains in the non-implant portion of surgery—like fewer errors, more consistent outcomes—can have a huge effect on overall costs.

At a time when insurance companies are asking hospitals, surgeons and implant suppliers to virtually guarantee outcomes and eliminate variability...Stryker's purchase of MAKO is a \$1.65 billion bet that robots are the answer. ♦

The advertisement features a close-up photograph of a silver and black microphone. A bright yellow banner is overlaid on the left side of the image, containing the text "INTRODUCING PODCASTS LISTEN NOW." in bold, black, sans-serif font. Above the banner, the word "Orthopedics" is written in white on a dark red background, with "This Week" in smaller white text to its right. The background of the entire advertisement is a light gray surface.

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# More Patients, But 30% LESS Pay: The Health Exchange Paradox

BY WALTER EISNER

**W**ill physicians make it up in volume?

Under the state health exchange system of the Affordable Care Act (ACA), as many as 20 million new patients are expected to have insurance coverage and, no doubt, will be showing up for hip, knee and other musculoskeletal treatment.

That's the good news.

The bad news is that the private health plans that will cover these new patients want to slash reimbursement rates for physicians who will be caring for those new patients.

Do orthopedists know about these coming changes? Apparently not.

## Slashing Rates

In California, Blue Shield of California sent amendments to its providers asking them to accept rates up to 30% lower for insurance-exchange patients.

In New York, UnitedHealthcare's amendments offer "less than \$40 for a typical office visit and about \$20 for reading a mammogram," according to a November 26, 2013 article in *The Wall Street Journal*. The fees for some office visits are less than half of what physicians in the city say they receive for treating people covered by employer-sponsored insurance.

While individual physicians may be unaware of the impact of the state exchange reimbursement rates, their



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societies are putting up red flags. On November 26, 2013, numerous physicians' groups told Obama administration officials that they are worried that new insurance plans offer only limited networks of providers and low reimbursement rates for physicians, and that could make it difficult for millions of those enrolled to actually get health care.

But individual physicians will have to decide on their own if he or she will participate.

## Uninformed and Unprepared Providers

According to a recent report titled: *Understanding Obamacare: Politico's Guide to the Affordable Care Act* a lot of

physicians are all over the map in their knowledge of the new law, and some are falling for the same ideological myths as the general public.

"It's not clear that many of them understand how it's going to affect them," said the report.

"As a group, they are incredibly uninformed about a lot of aspects of the law," said Shane Jackson, president and COO of LocumTenens.com, a physician recruiting firm based in Georgia that has conducted surveys to measure doctors' knowledge of the law.

He said the surveys have found that physicians are "not at all prepared" to walk their patients through the main parts of the law, and that there's a "real

unfamiliarity” with the changes the law could create in their own medical practices.

Physicians don't even have a clear handle on the changes that will affect them directly—like the payment reforms, which are supposed to pay them for giving better medical care, not just more of it

One survey this past summer found that more than six out of ten physicians said they were “not at all familiar” with issues like what the health exchange plans would cover, what the payment rates would be and how the process would work to get their medical claims paid.

Some physician group leaders are worried that their members don't seem curious to learn more.

“We're not hearing a huge amount. That concerns me a bit,” said Molly Cooke,

president of the American College of Physicians.



Molly Cook, M.D./American College of Physicians

Perhaps those findings aren't all that surprising given a recent Mayo Clinic survey of physicians who say controlling health care costs is not their responsibility. They say their job is to treat patients, not populations and fix flawed public policy. That's the jobs of the lawyers, insurers and regulators.

### Get Informed, Dispel Myths

But, warns the Politico Guide, the Affordable Care Act will also set in motion big changes in how physicians are paid and how they deliver care. “There's not a lot of evidence yet of how well, or how badly, those changes will work—so that leaves lots of room for doctors to fill in the lack of knowledge with their worst fears.”

For example, Aaron Carroll, M.D., a physician and professor at the Indiana University School of Medicine who



Aaron Carroll, M.D./Indiana University

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speaks to physician groups about the law, says the questions he's hearing suggest that some physicians have been influenced by the talking points used by the law's opponents.

They ask whether fee-for-service medicine will go away completely, for example, and whether all of their medical decisions will be second guessed.

Getting rid of fee-for-service is not part of the new law. "But those concerns are a clear sign of the anxiety about moving away from the payment system doctors know best—and about where, exactly, the future savings are going to come from," continued the Guide.

"Everyone seems to be in favor of less spending, but no one can make less money," Carroll said.

### To Join or Not to Join

Which brings us back to private insurer attempts to slash reimbursement rates.

The exchange plans are expected to cover more than 20 million people by 2016. Physicians have long been concerned about declining or stagnant rates from government programs such as Medicare and Medicaid, and have looked to the exchanges to bring in more privately insured patients.

But, according to physicians and experts interviewed in the *Wall Street Journal* article, more physicians may leave the plans as awareness of the new rates spread. Many physicians surveyed in September by the Medical Group Management Association said they weren't aware of the fees they would be offered for treating patients on the exchanges. Of those that had heard, 37% said the rates offered were lower than Medicare, and 18% said they were lower than Medicaid rates.

In order to keep prices low for exchange plans, many health insurers cobbled together narrow networks of physicians who agreed to lower their fees.

Some insurers have contractual arrangements with physicians that allow them to automatically include doctors in a new plan, unless the physician requests to opt out in writing, according to Mike Scribner, CEO of Strategic Healthcare Partners, a health care consulting firm based in Savannah, Georgia., that represents about 700 physicians and 30 managed care hospitals in the state.

Physicians told *Kaiser Health News* that the Blue Cross Blue Shield Association plans have generally been more straightforward about the discounted rates—and some doctors who had the opportunity to "opt out" of their exchange plans did so.

UnitedHealthcare's move in New York, affecting plans designed around

broader physician networks, is meant to rein in costs. Some physicians said they learned of the fee cuts while the new consumers starting picking health plans. As a result, consumers may end up selecting physicians who haven't even agreed to participate in the plans. UnitedHealthcare is giving physicians who don't want to accept the rates 30 days to opt out.

If few people enroll in coverage, insurers may not need broad networks, but, according to *The Wall Street Journal* article, if enrollment soars, they may have to return to the negotiating table.

### California Docs: "Hell No!"

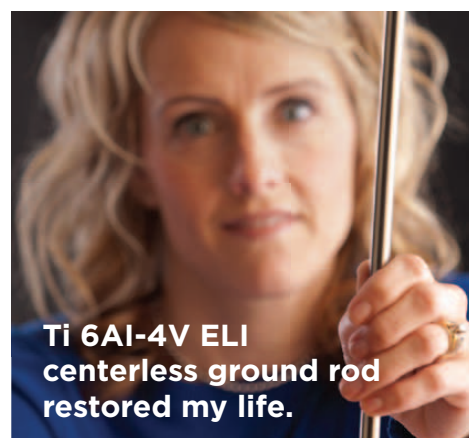
So far, problems with the federal exchange web site have kept enrollment numbers down on a national level, but some individual state exchanges, like California, are reporting enrollment numbers as expected.

When Blue Shield of California sent physicians contract amendments earlier this year allowing them to opt in to treat exchange patients and accept the 30% lower fees than their normal commercial rates, California's physicians said, "Hell no!"

"We said, this doesn't make a whole lot of sense for us," said Richard Thorp, M.D., an internist in Paradise, California, and president of the California Medical Association. Too few physicians agreed to the change in some mostly rural areas, so Blue Shield had to agree to continue usual rates for some physicians, said Steve Shivinsky, a spokesman for the insurer.


### New York Insurer Reacts

In New York, physicians are also questioning their participation in exchange plans.



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“We have heard from a lot of physicians the rates [insurers] are offering them are very low, and physicians are questioning whether they are going to participate,” said Sam Unterricht, M.D., a Brooklyn ophthalmologist and president of the Medical Society of the State of New York.

That seemed to get UnitedHealthcare’s attention.

“Our goal is to provide exchange members with a robust choice of providers,” said a statement issued by UnitedHealthcare. The insurer added that it would “offer physicians the choice of participating at rates that are above Medicaid and comparable to historical rates.” Few New Yorkers have historically purchased coverage on the individual market, and doctors say their rates for most employer-sponsored plans are much higher. The company initially notified doctors of new rates in April.

Many doctors say they have not decided if they will participate in the new plans—in some cases, even when an insurer is including them in their provider list.

A survey by the Medical Society of the State of New York found that 40% of more than 400 physicians who had responded so far said they chose not to participate in a health insurer’s exchange plan, and one-third said they did not know whether they were participating or not.

### Be Curious, Pay Attention

That means consumers should be wary of information in plan directories and confirm participation with their physicians. And physicians should know if they have been corralled into an exchange run plan.

The California Medical Association is so concerned about errors that it has asked Covered California, the state’s insurance marketplace, to remove a search function that lets buyers plug in the names of physicians and get a list of all the plans that they participate in, said

Lisa Folberg, vice president for medical and regulatory policy for the California Medical Association.

The best piece of advice for physicians is, be curious and pay attention. ♦



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feasible or are not expected to promote fusion and who have at least one of the following compromising factors: osteoporosis, diabetes or nicotine use. The effectiveness of OP-1 PUTTY for this use has not been demonstrated.

Brief summary of contraindications and warnings:

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treatment (5) have a known hypersensitivity to the active substance or to collagen (6) have an autoimmune disease or immune suppression (7) have been previously treated with OP-1 IMPLANT or OP-1 PUTTY.

- The use of OP-1 IMPLANT/OP-1 PUTTY may result in (1) the formation of localized ectopic or heterotopic bone outside of the treatment site (2) development of an immune response against BMP-7 or Type I collagen.

- There are no adequate well controlled studies of OP-1 IMPLANT/OP-1 PUTTY in (1) pregnant women (2) patients with autoimmune disease or immune suppression (3) patients with renal impairment.

Please see the package insert for the complete indication, contraindications, warnings, precautions, adverse events and other important medical information.

**Caution:** Federal law restricts this device to sale by or on the order of a physician.

# Instant Autologous Chondrocyte Repair // New Trick for Returning Throwing Athletes to Play // JBJS Review Has Launched!

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

**Instant Autologous Chondrocyte Repair!** The orthopedics department at UMC Utrecht in the Netherlands has just figured out how to do autologous chondrocyte knee repair in a ONE procedure. Up until now, using the patient's own chondrocytes to repair knee cartilage required two operations—one to harvest the chondrocytes and after culturing, another procedure to implant them (aka: Carticel).

The team, led by Professor Daniël Saris, bypassed most of the Carticel approach by surgically removing cartilage cells from damaged knees and then mixing them with specially selected donor stem cells. This cell mixture was then applied to the damaged area in the knee during the same operation. The advantage for patients is that only one procedure is required instead of the usual two operations. The new surgical technique will be less burdensome on patients, reduced treatment time. And it costs 75% less than the current two operation standard.

This new procedure is called 'Instant MSC Product Accompanying Autologous Chondron Transplantation' (IMPACT). Professor Saris told *OTW*,

"IMPACT is a new treatment that we are using in a first-in-man trial for patients 18-45 years old with a single full cartilage defect on the femoral condyle or trochlea. The stem cells are cultured from bone marrow of healthy adults undergoing surgery. We mix them with patient own

chondrons (chondrocyte with pericellular matrix) and implant them in fibrin glue in one procedure. We have treated six patients now with early signs of success and are planning to do 35 in this study. This is the first time this technique has been used worldwide and could have serious effects on cost-effectiveness in the future compared to normal cell transplantation.

The interesting findings are that mixing a low number of chondrocytes with stem cells result in cartilage regeneration. Recent research has led us to believe that mesenchymal stem cells primarily stimulate cartilage regeneration by trophic factor extrusion while at first it was thought stem cells differentiate. Also, while the stem cells are allogeneic, the lack of MHC class II markers result in no immune response as we have seen preclinical and now clinical for the first few patients.

The next steps will be to develop the air-brush technique to be fully arthroscopically

applied and after completing this unique first-in-man trial we will seek further support for efficacy evaluation and many commercial parties have expressed interest in this innovative academic development."



Wikimedia Commons and ErinNik

**Steelers Surgeon Shares Key Trick for Getting Throwing Athletes Back**

The head orthopedic surgeon for the Pittsburgh Steelers, James Bradley, M.D., has just come out with a new study looking at throwing and non-throwing athletes with posterior instability of the shoulder. Dr. Bradley, a sports medicine specialist with Burke & Bradley Orthopedics at the University of Pittsburgh Medical Center, tells OTW,

“Our prospective study included 200 shoulders involving all types of athletes; we performed arthroscopic posterior capsulo labral reconstructions on all of these shoulders for unidirectional posterior instability. Then we evaluated them according to the American Shoulder and Elbow Society (ASES) scores; we then examined stability, range of motion (ROM), strength, and pain.

In past studies throwers didn't meet the same standards when they returned to play as non-throwers. But in our recent study we found that at a mean follow-up of 36 months—looking at the ASES score and all subjective scores (ROM, etc.)—there was no statistical difference between throwers and non-throwers...and that was very surprising.

Both groups showed significant improvement in all scores with p-value greater .01 so all values improved in both cohorts equally so our good and excellent results were 91% and 89% percent, respectively. The most important thing is that throwers were equally likely to return to their pre-injury sports *at the same level as non-throwers* and critically the athlete on which we did suture anchor capsulo labral repairs had significantly higher return to sport at the same level versus non-anchor repairs.

The message to my colleagues is that if you are in doubt about using suture anchors, don't be. I now use suture anchors in all my posterior repairs.

Going forward we will separate out pitchers from other throwing athletes. My gut says that the pitchers will fare worse than other throwing athletes because of the amount of abuse those arms take.”

**JBJS Reviews Now Online** *The Journal of Bone and Joint Surgery, Inc.*, is pleased to announce that *JBJS Reviews*, an innovative online and tablet journal, is now live.

“With *JBJS Reviews*, we are continuing to respond to the information needs of our audience,” commented Kent Anderson, CEO and Publisher at *JBJS, Inc.*, in the November 21, 2013 news release. “We know that review articles are essential reading for orthopaedists at all stages of their careers. With *JBJS Reviews*, we are committed to providing quality review content authored by recognized experts, and publishing online enables us to publish continuously, accelerating information transfer,” added Anderson. “We also have seen an increase in the number of orthopaedic surgeons adopting tablets like the iPad and the Galaxy in the clinical setting and to access information. *JBJS Reviews* has been built with both iOS and Android apps. Users can access articles and take integrated CME exams to affirm their knowledge. We think this will put important information even closer to our users and increases its interactivity.”

“I am excited to be working on this project,” added Thomas A. Einhorn, M.D., editor of *JBJS Reviews*. “The mission of *JBJS Reviews* is to publish the best evidence and most compelling clinical information in an easy-to-read format

that is optimized for tablet, mobile, and online use,” added Dr. Einhorn. The *JBJS Reviews* app for the iOS and Android platforms is expected to be approved and available shortly.

Kent Anderson told OTW, “The timing for *JBJS Reviews* matches a number of trends in the marketplace. First, there is the growing amount of orthopaedic information, which has created a need among orthopaedic surgeons and others for review articles. Second, there are only a few orthopaedic review journals, and while they do an excellent job in general, the audience need is growing. Third, *JBJS* sets a quality standard that's a little different, and our research showed that readers wanted the kind of thoroughness and readability a *JBJS* product brings. Finally, there is the trend in the orthopaedic market toward tablet devices like iPads, so building a review journal with iOS and Android



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apps made a lot of sense. Ultimately, it was all about market needs—for review articles, for *JBJS* standards, and for new delivery media.”

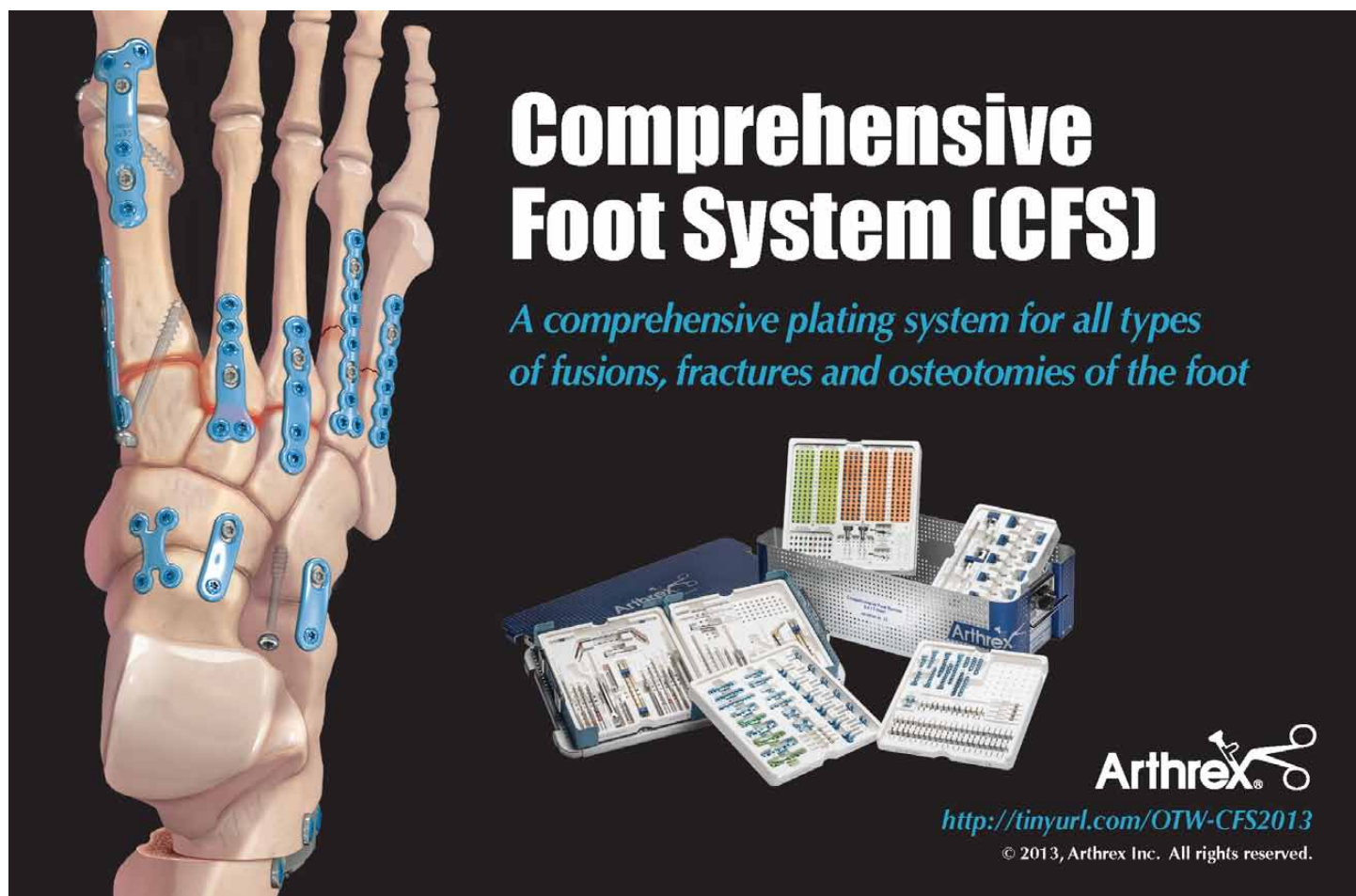
He added, “As a long-standing organization, we look beyond the one-year timeframe to judge success. That said, in one year, we expect *JBJS Reviews* to have attained strong recognition in the market, to have become a natural complement to other review journals and products in the market, and to be attracting some of the better review articles. We also hope that our integrated CME proves popular, and that our

tablet apps are widely adopted. Those will be how we measure success, and we will adapt based on what we learn.”

**Korsh Jafarnia, M.D. Joins Weill Cornell Medical College** Dr. Korsh Jafarnia, an orthopedic surgeon and hand and upper extremity specialist at Houston Methodist Orthopedics & Sports Medicine has joined the faculty of Weill Cornell Medical College. Dr. Jafarnia, who has accepted the appointment as assistant professor for clinical orthopedic surgery, was a clinical assistant professor of Baylor College of Medicine for the past 11 years. Dr. Jafarnia spe-

cializes in injuries and conditions of the hand, wrist and elbow and is a former chief of staff at Houston Methodist Willowbrook Hospital.

Dr. Jafarnia studied advanced techniques in hand surgery at the French Institute for Hand Surgery in Paris before completing a residency program at Baylor College of Medicine. He then completed a fellowship in Hand and Upper Extremity Surgery at Massachusetts General Hospital at Harvard Medical School. He has a Certificate of Added Qualifications (CAQ) in Surgery of the Hand. ♦



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# Crosby Takes on McFarland Over Reverse Shoulder

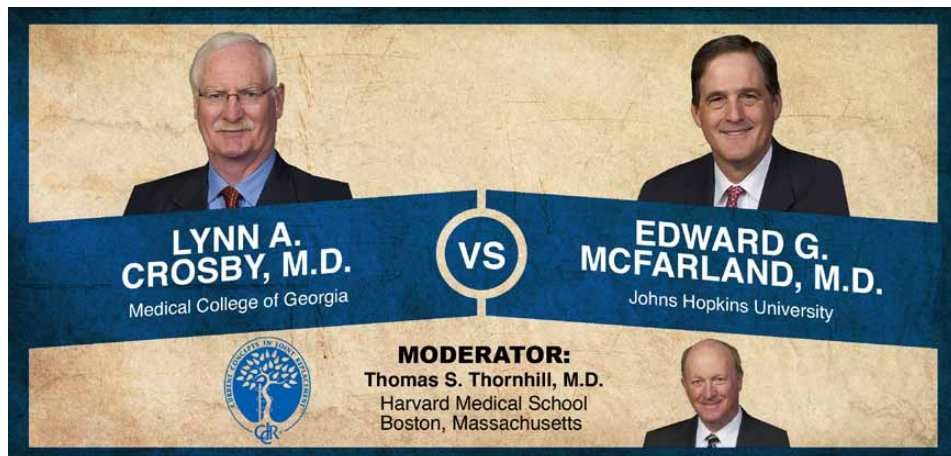
BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

**I**n an older person with good glenoid bone a reverse is the best option for cuff tear arthropathy,” states Lynn Crosby. Ed McFarland counters, “No. These patients need to suck it up and try nonoperative treatment first.”

This week’s Orthopaedic Crossfire® debate is “This Cuff Tear Arthropathy Is Best Treated With a Reverse Shoulder.” For the proposition is Lynn A. Crosby, M.D. of the Medical College of Georgia; against the proposition is Edward G. McFarland, M.D. from The Johns Hopkins University. Moderating is Thomas S. Thornhill, M.D. from Harvard Medical School in Boston.

**Dr. Crosby:** “Cuff tear arthropathy is the arthritic eroded collapse of the glenohumeral joint, with superior migration of the humeral head after a massive rotator cuff (RC) tear. This was first described by Charles Neer and Ed Craig in 1972. The acromial humeral distance we get on a normal X-ray is 7-14 mm; if we look at the sagittal view on an MRI, the supraspinatus should fill that entire fossa. If the acromial humeral distance is decreased less than seven, but is five or less, the supraspinatus is usually retracted and the humeral head on a plain X-ray shows us that the acromial humeral distance is decreased. And in the sagittal MRI fatty atrophy is noted in the fossa.”

“If it goes on longer and the acromial humeral distance is less than 5mm on the plain X-ray, then this is a massive tear, including the infraspinatus. If you do get an MRI you’ll see that usually on the axial view the infraspinatus is usually retracted and gone. Coronal view: if you look at certain cases on an



Current Concepts in Joint Replacement/RRY Photo Creation

MRI you would say there is a massive tear that’s irreparable with the supraspinatus retracted up over the head...but the head is still located and the acromial humeral distance is still relatively normal. On the MRI, if the fatty atrophy has not decreased the muscle mass, and it’s at or below the line of the acromion coracoid line then this is still a repairable situation. But if it’s less than 5mm conservative care would be recommended, namely injections and deltoid rehab.”

“If that fails you can think about an arthroscopic debridement if they are male, the ROM [range of motion] is above 100 degrees, and they have good deltoid tone. But most of the time in these patients if they’ve failed that we discuss arthroplasty.”

“If we look at the old classification for these, this helps make the decision. We used to have Type 1A and Type 1B, and you could do a hemi. In Type 1A the head is still centered and there is still motion, and it’s using the whole undersurface of the acromion as the new joint.

Type 1B is still centered, but the erosion has occurred more medially, but there’s still active elevation because they are still using this space to elevate off of.”

“If you just replace the head the patient will get some pain relief, but the wear is going to be in the same place and it will continue. If you just replace the head, it’s still rotating under the acromion and the superior aspect of the glenoid continues to wear. When this happens, and that fails and you have to reconstruct the hemiarthroplasty, you have less bone to deal with.”

“If you have to do a reconstruction with a reverse you may have to use augments because you want this inferior tilt. If you put a glenoid in an eroded superior glenoid your forces are superior and you’re going to get a shear force.”

“In the patient with Grade IV fatty infiltration who is 69, retired, a previous tennis player, has pain with or without activity, and he still has well preserved glenoid bone. In this case I think there is only one option...a reverse.”

**Dr. McFarland:** “There are many things short of a reverse, including non-operative treatment, arthroscopic debridement, cup arthroplasty, etc. It depends a lot on patient characteristics. This is a very heterogeneous group; many patients have full range of motion and fairly decent function. I tell my residents and fellows that these lesions are attached to a person, so what’s important are the demographics and the radiographs. How much arthritis is there? How much pain, loss of motion, and loss of function?”

“Other variables to consider in making a treatment plan are their age, whether it’s their dominant arm, other medical conditions, their activity level, and the surgeon’s expertise. I tell patients that come in with RC tears that have arthritis that this is not heart disease, and that they have time to make a decision. There is nothing in the literature indicating that a patient with cuff tear arthropathy is doomed to shoulder purgatory. There is no compelling reason in this patient to have surgery based on the information that we’ve been given.”

“So I begin with nonoperative treatment. If the patient wants to play sports and be active then the best thing is that he or she *not* have surgery. The goal of nonoperative treatment is to maintain ROM (these patients often have pain when they get stiff); we work hard to get them pain relief; we have them avoid lifting overhead and away from their body. They can use non-steroidals if there are no contraindications, chondroitin sulfate, cortisone dose packs, glenohumeral joint injections (sometimes helps, depending on the degree of arthritis), hyaluronic acid injections.”

“As for surgery, only about 80% of people get pain relief, and by five years most will have an arthroplasty. I tell



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patients, particularly the older ones, that it's not going to buy them much time. Regarding the indications for tendon transfers, it should be a younger patient...but the results aren't as predictable as we would like them to be. They are better for regaining external rotation as opposed to pain relief. But all you have to do is get an infected one and you will change your mind. I don't do them anymore."

"As far as humeral resurfacing, this is for a younger, active patient who is not ready for joint replacement. The resurfacing options are cup arthroplasty, cuff tear arthroscopy head, or hemiarthroplasty. The results are unpredictable. But for patients who want to stay active they are probably a better choice than a reverse. With humeral resurfacing of any type you want to put them in patients who are going to do sports where they're not going to break things."

"A great study by Lawrence et al. from Mayo found that the most common activities after a reverse total shoulder arthroplasty were cooking, baking, and driving. The most high demand things were snow shoveling, wheelbarrow use, and dirt shoveling. Maybe at Mayo—where I trained—that's all you have to do up there. But you don't want to put a reverse total shoulder arthroplasty in someone who wants to be at all athletic."

"So the reservations about reverse now are that there are no results beyond 10 years and that the effect of notching is not known. Also, could it some day be the equivalent of metal on metal hip? Maybe 20 years from now if these things are all falling out—hopefully I will be retired—but there will be plenty of attorneys ready to take us on."

"So if these patients do get a resurfacing it should be a procedure that is convertible to a reverse. Dr. Crosby needs to admit defeat."

**Moderator Thornhill:** "Lynn, Ed says that he is going to do a conservative therapy and when that doesn't work he'll do a resurfacing that could be converted to a reverse. Your response?"

**Dr. Crosby:** "Those are all good options. It depends on what he wants. If he wants a procedure that's going to give consistent pain relief, early results show that 10 years isn't unreasonable if it is put in correctly and watched. Contrast this with a surface replacement or a hemiarthroplasty you're probably going to get it converted at some point. Ed made a good point: if you use a system that is convertible that would be much easier and you wouldn't have to remove the stem. But still, in a patient who is nearly 70, you'd probably do better with a reverse."

**Moderator Thornhill:** "Ed, now they have these convertible implants. What are issues of converting a failed hemiarthroplasty with this stem?"

**Dr. McFarland:** "If you're going to convert them, unfortunately every time you operate on the shoulder the results get a bit worse. One of the problems with converting a hemi to a total is that the subscapularis becomes dysfunctional in a large percentage of those patients. The reverse has allowed us to convert a hemi to a functional arthroplasty. In the past it was totally unpredictable in terms of results. It also deals with bone loss better than a conventional total shoulder. So revising these hemis to a reverse is not that big of an operation. In a patient who wants to stay active they can go with a hemi first. But as Lynn said the pain relief is still a bit unpredictable with hemis."

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**Moderator Thornhill:** “Lynn, what is it that makes a shoulder that’s a 1A or even a 1B progress? Some of them don’t necessarily progress to get out of the glenoid. Is there any predictability about this?”

**Dr. Crosby:** “I don’t think there’s any information on that, but activity level is important. Are they loading that area? Are they trying to use it with resistance over time? I think the more active individual that is lifting is likely to progress faster than someone who is sedentary.”

**Dr. McFarland:** “I think the thing that determines how much pain someone has is how they use their shoulder.”

**Moderator Thornhill:** “Ed, if your other shoulder is normal are you less likely to proceed with a more aggressive procedure?”

**Dr. McFarland:** “We see a lot of patients with bilateral disease, and it’s not uncommon to replace one of them and have them able to just tolerate the other one. We have a conversation with them as far as what their priorities are. The only time I’ve had to worry about dominance or non dominance is with patients who have had strokes or those who are very dependent on their arms for gait (such as patients with wheelchairs). Most of the time we address the one that hurts the most and go from there.”

**Moderator Thornhill:** “Lynn, what about the CTAs...the implants that will hinge off the subacromial area?”

**Dr. Crosby:** “We toyed with a lot of different options before the reverse was allowed back into the U.S. For me the procedure that worked the best was Buz

Burkhead’s Achilles tendon allograft. Patients were satisfied, their activity level was high...and I think the reason that worked so well was that you took the pressure off the bone superiorly. So if I still had to use a procedure I would use a hemiarthroplasty with an Achilles tendon allograft. As far as the hooded ones, the reason those were semi-successful is that they didn’t catch as they rotated.”

**Moderator Thornhill:** “Thank you both.” ♦

*Please visit [www.CCJR.com](http://www.CCJR.com) to register for the 2013 CCJR Winter Meeting, December 11–14 in Orlando, Florida.*

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COMPANY

## RMH Medical Center Breaks Ground for Orthopedics

RMH Medical Center in Harrisonburg, Virginia has recently broken ground on its health campus for a state-of-the-art facility dedicated to better serving the needs of advanced imaging, orthopedics and sports medicine patients. The free-standing, two-story, 52,000 square-foot facility is planned to open in September 2015.

“We are pleased to have an extremely talented staff of medical professionals who are able to offer a comprehensive range of high-quality orthopedic services to our growing community,” said Carrie Willetts, program director for Orthopedics, Sports and Spine Services, in the November 13, 2013 news release. “The increasing need for these services, and our expansion of staff to meet the growing need for them, led the Sentara RMH Board to approve construction of this new facility.”

“This will be a place where all of the patient’s orthopedic, sports medicine, physical therapy, hand therapy, and imaging services needs can be met in one location,” Willetts added. “As a center of excellence, it will not only offer convenience but will enhance continuity of care. Medical professionals in the building can easily communicate across services to coordinate patients’ care and be aware of their progress.”

Key features of the new facility include the following:

- **More space for patient care.** With more than 52,000 square feet, plus room for future expansion,



Wikimedia Commons and Chad Halford

tion, the new Center will allow complementary services, such as orthopedics and imaging, to be together in the same building.

- **Improved efficiency and communication.** With all services in one state-of-the-art building, the orthopedic care team will be able to easily coordinate the patients’ entire spectrum of care, from diagnosis to treatment to recovery.
- **Orthopedic clinic.** The facility will include 38 exam rooms and dedicated space for spine, joint, sports medicine and general orthopedic services.
- **Advanced imaging.** The facility will have two CT scanners, two MRI machines, three ultrasound rooms, one general X-ray room, and an intervention room for image-guided procedures, such as injections and kyphoplasty. Imaging patients will not need to go to the main hospital building for these services.
- **Rehabilitation.** A rehabilitation gym and sports performance arena will provide ready access to physi-

cal therapy and sports medicine. Hand therapy will also have a conveniently designated care area.

- **Convenience.** Features include ample onsite parking with a covered entranceway and a common entrance where patients will be greeted, registered and directed to the appropriate service area.
- **Natural light.** Ample natural light and beautiful views of the surrounding area will enhance health and healing processes.

Carrie Willetts told OTW, “Our orthopedics program has grown to meet an increasing community need, and we now need a larger, more patient-centered space to continue providing exceptional outpatient orthopedic services. This spacious new facility will integrate imaging services and rehabilitation services as well, which means our patients can come to one convenient location to receive comprehensive, high-quality outpatient orthopedic care.”

—EH (November 26, 2013)

LEGAL

## Spine Case Goes to New Jersey Supremes

If you fail to disclose that you don't have medical malpractice insurance before you perform surgery on a patient and something goes wrong, is that fraud?

According to *Law360*, a New Jersey couple named James and Sheila Jarrell were awarded less than \$938,000 by a jury after the jury found their spine surgeon had deviated from accepted standards. The couple appealed the award up to the state's Supreme Court, who agreed on November 22, 2013 to consider the case. The couple is claiming that the physician's failure to disclose his lack of medical malpractice insurance constitutes fraud by the surgeon and the hospital where the surgery took place.

We have heard this story about deviating from accepted standards in New Jersey before.

Regular OTW readers will recognize the name of Richard Kaul, M.D. Kaul is cur-

rently waiting to hear from a New Jersey administrative judge on whether or not the judge will recommend to the State Medical Practice Board that Kaul's medical license be revoked for deviating from accepted standards and guidelines and being a danger to the public. The state's Attorney General and star witness Greg Przybylski, M.D., say Kaul, (and interventional physicians like him) lack the qualifications and training to perform certain spine surgery procedures, such as a lumbar fusion.

Kaul and interventionalists continue to frame Kaul's case as a turf war over who is going to make money from performing certain procedures. Board certified orthopedic spine surgeons say the interventionalist are not trained adequately in surgery to be able to deal with problems that could arise during an endoscopic procedure and an open approach is required.

Dr. Kaul's tribulations or transgressions, depending where you stand, continue to provide fodder for important legal and clinical questions about spine surgery and patient protection. It may not be the last time the New Jersey Supremes see Dr. Kaul.

—WE (November 29, 2013)

## Lawyers Set to Earn \$1 Billion in DePuy ASR Deal

Lawyers representing over 8,000 plaintiffs in DePuy ASR hip lawsuits are recommending that their clients accept Johnson & Johnson's (J&J) \$2.5 billion settlement offer.



Tax Credits/Flickr

For good reason. According to a November 25, 2013 *New York Times* article by Barry Meier, the lawyers stand to earn almost \$1 billion.

Those lawyers have publicly praised the deal and described it as an "innovative plan" that will compensate patients who had to have hip revision surgery. After the lawyers' fees, Meier reported that patients will get about \$160,000 on average to compensate for their pain and suffering. There is also a \$475 million pool for added payments to the most severely injured. In addition, J&J agreed to pay claims from private insurers and agencies like Medicare seeking to recover the costs of operations and other medical treatments related to the device.



New Jersey Supreme Court/State of New Jersey

According to Meier, the lawyers will receive about one-third of the settlement, or about \$800 million. The single biggest chunk of those fees will go to the firms most involved with developing cases and negotiating the settlement; they will get a bonus of about \$160 million.

One lawyer, not involved in the settlement fees, could earn about \$90,000. Meier reported that that lawyer's patient said he believed his lawyer paid about \$400 on filing fees and between \$2,000 to \$3,000 to get copies of the medical records.

But the lawyers will only get paid by J&J if they convince 94% of the 8,000 eligible plaintiffs to accept the deal. J&J can walk away if that threshold is not met. Roughly 4,000 ASR patients who have filed claims against J&J but have yet to have a replacement procedure will not qualify for the plan.

Acceptance does not appear to be a foregone conclusion.

Several patients like Celeste Laney, a former occupational therapist, told Meier it was impossible to know what their claims might be worth if they went forward because the only two cases that went to trial ended with wildly disparate outcomes.

Some patients will see their payouts reduced based on their age, weight, or whether they were smokers. In addition, those who had an ASR for more than five years will get \$25,000 less for each additional year they had the device before its replacement.

"I'm not taking it, it's a joke," said Laney who continues to have significant medical issues.

The \$475 million pool in the settlement will be used to supplement the

basic payouts to patients like Laney. Along with patients who had to have repeated operations, extra payments will also be available to patients who developed infections, experienced joint dislocation or had other problems related to a procedure like a heart attack or a blot clot.

The size of such payments will be determined by how many patients qualify for special funds, a group the lawyers think will be about 10% of claimants.

The lawyers for both sides have convinced and congratulated each other and received the praise of the court. Now, they just have to convince their clients they were worth almost a third of their pain and suffering.

—WE (November 27, 2013)

## LARGE JOINTS

### MoM Hips: Banned in Britain

The United Kingdom has banned metal-on-metal hips.

The UK's National Health Service (NHS), following new guidelines issued by the country's National Institute for Health and Care Excellence (NICE) has banned most metal-on-metal hip implants in all hospitals funded by NHS. Few of the implants would meet the new standards set by NICE. The ban will affect nearly all manufacturers of the devices.

The UK's public health system is fully funded by the NHS, so every hospital falls under the ban.

The new standards, according to *The Telegraph*, say the NHS should stop using any hip implant with a failure rate higher than 5% at five years. It means that almost every type of metal-on-metal hip implant—including five more devices still used—should no longer be fitted in patients. An audit of all hip surgery in England, Wales and Northern Ireland found that most types of metal-on-metal hip devices in use had failure levels below the standards NICE deems acceptable.

*The Telegraph* reported in October that the metal-on-metal resurfacing models found to have the high failure rates are: the Adept; Cormet 2000; Durom; Recap Magnum; and Conserve Plus. A sixth device, the Corail/Pinnacle full hip replacement using ceramic-on-metal, also failed to meet the standard.

Just two types of metal-on-metal devices in current use fall within the proposed national standard.

Stephen Cannon, honorary consultant surgeon at the Royal National Ortho-



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paedic Hospital, said “The figures speak for themselves—even the best metal-on-metals have four times the failure rate of the rest. This is really a significant problem, because these were given to an awful lot of people.” He added, “I think there is a question about whether it goes far enough, but this is definitely a step in the right direction—it amounts to a ban on most of them.”

The devices continue to be sold in the U.S., but demand has dropped significantly after British and Australian surgeon societies first began reporting unusually high levels of failures of the devices. Johnson & Johnson, parent of DePuySynthes, just announced a \$2.5 billion settlement for a vast majority of lawsuits filed by patients with failed revision hips. Other lawsuits continue to work their way towards settlements or trials for the other manufacturers.

—WE (November 26, 2013)

## FDA Clears OrthAlign’s Handheld Navigation Device

OrthAlign Inc.’s handheld navigation device for use with both total hip and total knee arthroplasty surgeries has received clearance from the FDA.

Called the OrthAlign Plus, the palm-sized, single use computer-controlled navigation device is an alternative for surgeons, specifically in total hip arthroplasty, according to Nick van der Walt, OrthAlign’s vice president of engineering. He said, “Many surgeons have shared with us their challenges in being able to consistently position the acetabular cup at the desired inclination and anteversion. We are now uniquely able to provide surgeons with the tools they need to address those challenges and

dramatically improve total hip arthroplasty alignment.”

Company officials report that for total hip arthroplasty surgery, the OrthAlign Plus system provides measurement accuracy of  $\pm 3^\circ$ , with at least 95% confidence when measuring the angle of the shell impactor, relative to the frame of reference defined by the registered landmarks.

in over 12,000 total knee arthroplasty cases, demonstrating its accuracy to be comparable to traditional CAS systems, while providing better accessibility through greater ease of use, no need for capital investment, and significant lower cost per case. OrthAlign is a privately held medical device company.

—BY (November 25, 2013)



“Cup orientation with conventional instruments has been challenging. While navigation systems have been available for over a decade and are known to improve accuracy, adoption has been low due to high capital equipment cost and disruption to surgical workflow. The OrthAlign Plus system provides comparable accuracy without these drawbacks,” said David J. Mayman, M.D., clinical co-director of the Computer Assisted Surgery Center, Hospital for Special Surgery, New York.

According to the company press release, its product called KneeAlign 2, is fully integrated into the OrthAlign Plus system thus providing a reliable and efficient alternative to expensive computer assisted surgery (CAS) systems. KneeAlign has successfully been used



OrthAlign, Inc.

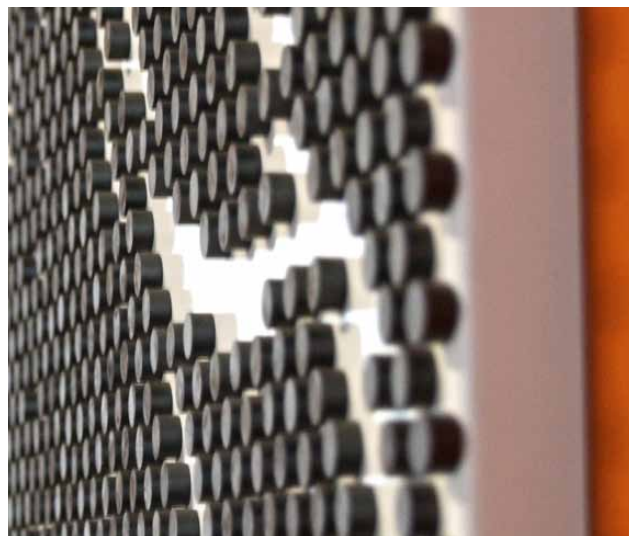
## Magnets Allow Fused Leg to Bend

A locking orthopedics innovation uses magnets to help patients with knee problems. Lindsey Alexander, a writer for *MedCity News*, quotes Eric Lucas, founder of the Engage Knee System, as explaining that many patients with knee dysfunction for whom a knee replacement is not appropriate, choose to have their two leg bones fused together—a knee arthrodesis. This means that the leg cannot bend and is always rigid. The procedure allows a patient to walk around on his own, but it makes some daily activities such as driving, bathing, or sitting in the front seat of a car, difficult.

Lucas explained that the Engage Knee System is a knee replacement that can be locked in place. This is done by waving a handheld device with a magnet

in it over the knee. This pass locks the knee enabling the patient to be stable enough to stand and to be able to walk. When the device is waved over the knee again, the knee unlocks, can bend and the patient can sit comfortably. The mechanical locking system is actuated by a powerful magnet which allows communication of sorts from the implant to the outside of the body.

Lucas developed the Engage Knee System when he was a biomedical engineering graduate student at Clemson University. The medical device company spun out from Clemson a year ago. Lucas and his team are applying



Wikimedia Commons and Johann Addicks

for grants and have built several prototypes. Because other devices use magnets in similar ways, Lucas anticipates a relatively fast path to FDA 510(k) clearance.

—BY (November 26, 2013)

## Obesity in Young Driving TKA Rate

Older people get the blame but it is younger people whose rising rate of obesity is driving the increasing number of knee replacements in the U.S. That is the conclusion of a study that examined data from 9,000 knee replacements gathered by more than 125 orthopedic surgeons from 22 states. The analysis revealed that 55% of patients younger than 65 were obese compared with 43% of those who were 65 or older.

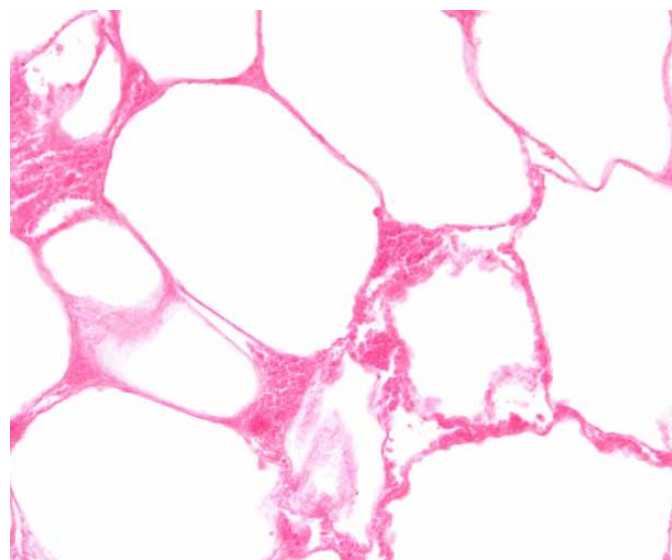
Compared with those 65 and older, twice as many of the patients younger than 65 were severely obese (5% versus 11%). The researchers found that the younger group of patients also had higher rates of smoking and lower mental health scores.

“Our study shows that younger patients are more obese and experience the same amount of pain and functional disability as older patients and in some cases even more,” study author David Ayers, M.D., director of the Musculoskeletal Centre of Excellence at the University of Massachusetts Medical School, said in a university news release.

“What we’re seeing is that the rise in obesity rates in younger people is having a dramatic influence on the number of total joint replacement surgeries,” he said. Surgeons now

perform about 600,000 knee replacement surgeries a year. Ayers expects that number to grow to 3.48 million procedures a year by 2030.

—BY (November 26, 2013)



Fat Cells High Magnification/Wikimedia Commons and Nephron

## Change the Hip, Improve the Heart

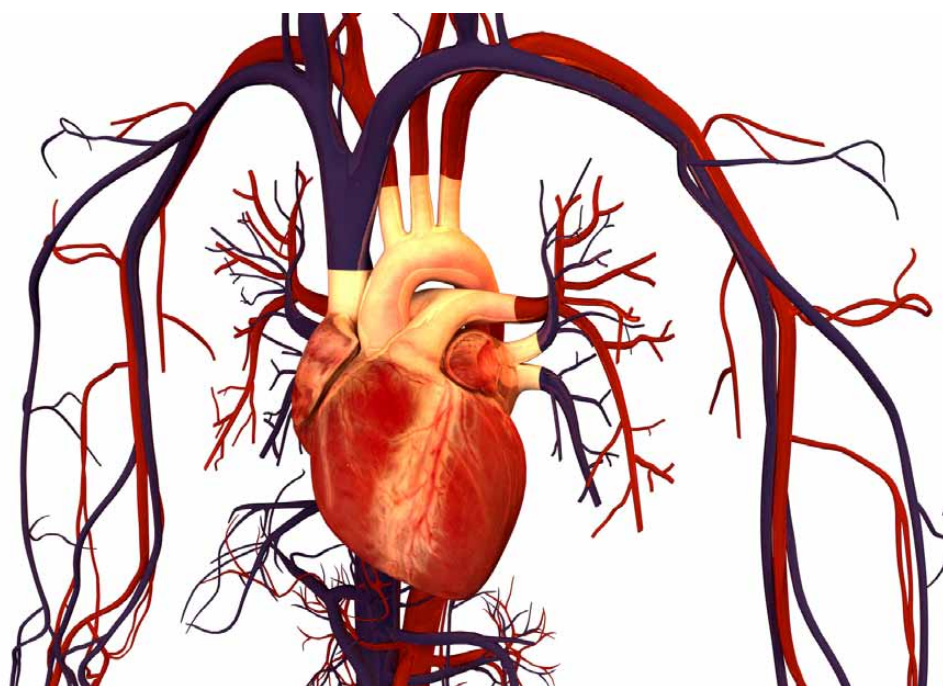
Does having a total hip or knee replacement benefit a patient's heart? It may, according to researchers at the University of Toronto who matched 153 patients who had a joint replacement with 153 who did not. The subjects all had similar health profiles in terms of age, weight, smoking status and the severity of their arthritis. For seven years, the researchers followed both groups to record their rate of serious cardiac events, including heart attacks, heart failures and strokes.

The study author, Bheeshma Ravi, M.D., resident physician in the division of orthopedic surgery at the University of Toronto, reported, "Our study suggested that in persons with moderate to severe osteoarthritis of hip or knee, joint replacement was associated with a greater than 40% reduction in the risk for serious cardiovascular events such as heart attack and stroke." Ravi found

that with knee replacements there was a 54% reduction in heart risk. Hip replacements had a 39% reduction.

The researchers speculate on what caused the reduction in risk. Patients who had the joint replacements may have increased their physical activity, which would have been good for their hearts as well. Or patients who choose joint replacement surgery may simply be more motivated to take care of their health, suggested Trevor Murray, M.D., an orthopedic surgeon at Cleveland Clinic in Cleveland, Ohio. He told Marianne Wait of the Arthritis Foundation, "If [patients] care enough about their musculoskeletal health to go through the pain and suffering of a total joint replacement to try to get better, they're quite possibly the same people who are trying to walk a mile-and-a-half a day and lose weight and eat appropriately, which is really hard to capture." He pointed out that the "whole point of the surgery" is a reduction in pain.

—BY (November 25, 2013)

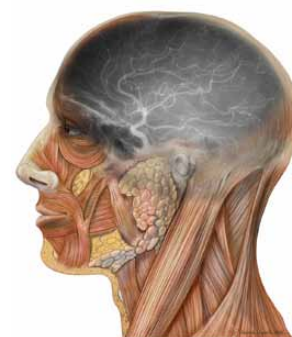


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## TRAUMA

### It's Probably a Fact: Men Are Hard Headed

After experiencing a concussion, do women have worse symptoms than do men? One study says "yes" and another says "no." Tracey Covassin of Michigan State University in East Lansing led a study of 39 male and 56 female soccer players who sustained concussions. All of the players were in high school or college.



Wikimedia Commons and Patrick J Lynch

As reported by Reuters Health, the athletes took computer tests that measured their learning and memory skills, reaction time and physical symptoms before the soccer season started and again eight days after their concussion. On the preseason tests, men and women scored similarly. But eight days after their concussions, women scored 69% on a test that measures a person's ability to remember visual images—as compared to 77% among men. Scores on other thinking and memory tests were still comparable. Women also reported migraines and sleep difficulties more than twice as often as men, according to results published in the *American Journal of Sports Medicine*.

A similar study did not find thinking and memory differences between men

and women after a concussion. The author of that study, Scott Zuckerman, M.D. of Vanderbilt University Medical Center in Nashville, Tennessee, was surprised at the different results. He told Reuters *Health* that the only difference in the studies was that Covassin and her colleagues accounted for athletes' body mass index (BMI), a measure of weight relative to height, in their results. This suggests that larger people have more neck strength and are better able to stabilize the head on impact, therefore suffering a less severe concussion as a result.

—BY (November 25, 2013)

## Orthopedists Missing Domestic Violence Injuries

Domestic violence is the most common cause of nonfatal injuries among women, according to the World Health Organization. Yet only about 25% of orthopedic trauma surgeons have the training required to recognize broken bones caused by domestic abuse.

A study conducted at the University of Missouri found that 74% of orthopedic surgeons believed that only 5% or fewer of their patients were victims of domestic abuse. Yet when the patients were questioned, 40% of North American patients at orthopedic trauma clinics said that they had experienced domestic violence.

Robert Preidt, writer for *Long Island Newsday*, quoted Gregor Della Rocca, M.D., an associate professor of orthopedic surgery

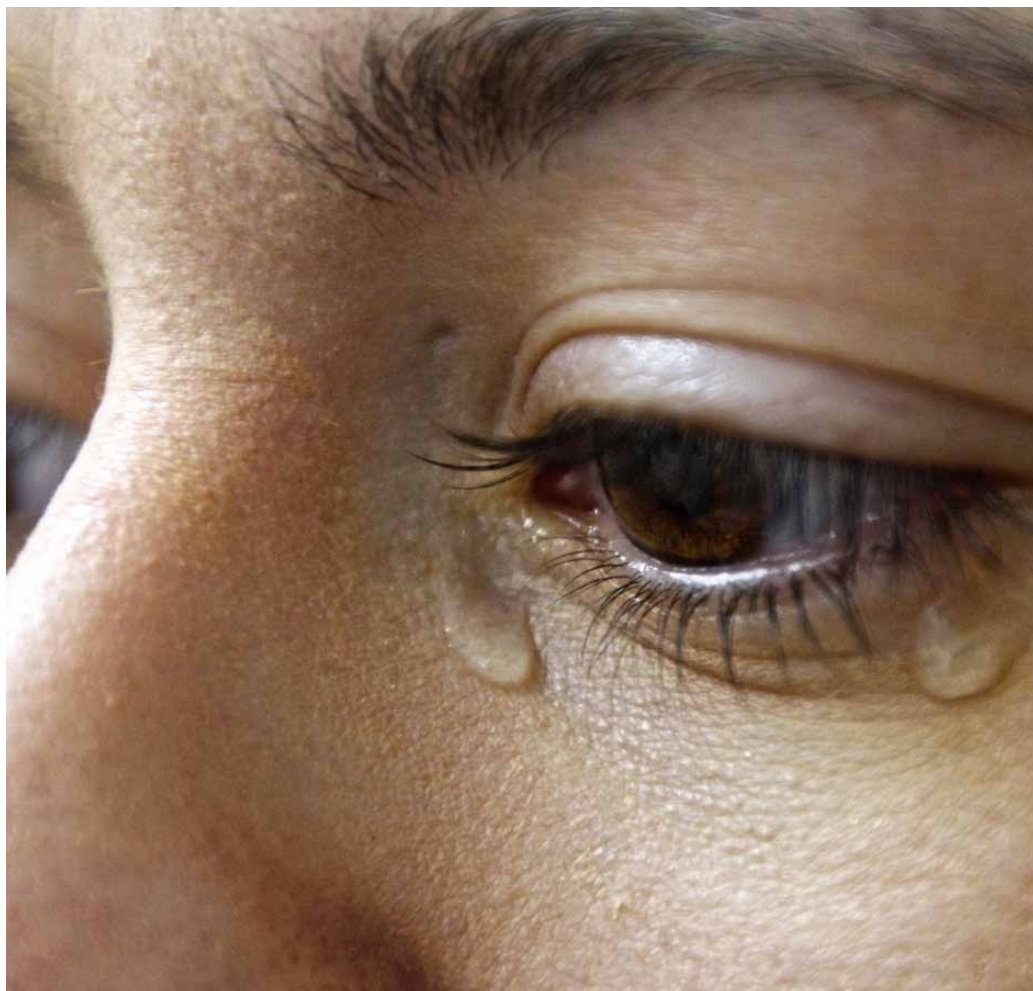
at the University of Missouri School of Medicine as saying in a university news release, "In the United States, most orthopedic surgeons receive training in techniques for recognizing signs of child abuse, but training to recognize abuse of adults is far less common."

Della Rocca's team surveyed 153 orthopedic trauma surgeons, mostly in North America, and asked them about their ability to recognize and respond to signs of intimate-partner violence. They also questioned the doctors about their beliefs about the causes of domestic violence and asked them to estimate how many of their patients suffered these kinds of injuries.

"In our study, we found that most orthopedic surgeons believe identifying injuries caused by domestic violence is an important aspect of providing medical care, and they also believe that receiving education to recognize signs of intimate-partner violence could help them to stop violence in some cases," Della Rocca told Preidt. He added, "only 23% of the surgeons we surveyed had received any training on recognizing and responding to intimate-partner violence."

The researchers published their study in the journal *Clinical Orthopaedics and Related Research*.

—BY (November 26, 2013)



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REIMBURSEMENT

## Stark Law Exemption Deadline Looming for Physician-Owned Hospitals

Physician-owned hospitals that want to keep their “whole hospital” or “rural providers” exceptions to the Federal Stark Law have until December 1, 2013 to report their ownership and investment information to the Centers for Medicare & Medicaid Services (CMS).

The hospitals, according to lawyers from Bradley Arant Boult Cummings LLP, should carefully review their Medicare enrollment files to ensure compliance with a recently imposed reporting requirement. Medicare recently

announced that to satisfy the reporting requirement, physician-owned hospitals must report the ownership and investment information as set forth in the Medicare Enrollment Application (Form CMS-855A), which includes a special attachment for such hospitals.

The lawyers say hospitals that submitted this information on or after December 1, 2012 on Form CMS-855A will be considered to have met the December 1, 2013 deadline. To continue meeting reporting requirements, physician-owned hospitals must either update their information or verify that the relevant ownership and investment information in the Medicare Provider Enrollment, Chain and Ownership System is correct on an annual basis.

The Stark Law prohibits a physician from referring Medicare patients for designated health services to an entity with

which the physician (or the physician’s immediate family member) has a financial relationship, unless an exception applies. To qualify for either the “whole hospital” or “rural provider” exception, the regulations promulgated under the Stark Law require, among other things, that physician-owned hospitals submit to CMS an annual report containing ownership and investment information at such a time and in such a manner as specified by CMS.

To find the CMS announcement and additional references, go to the following link:

<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1332.pdf>

—WE (November 25, 2013)

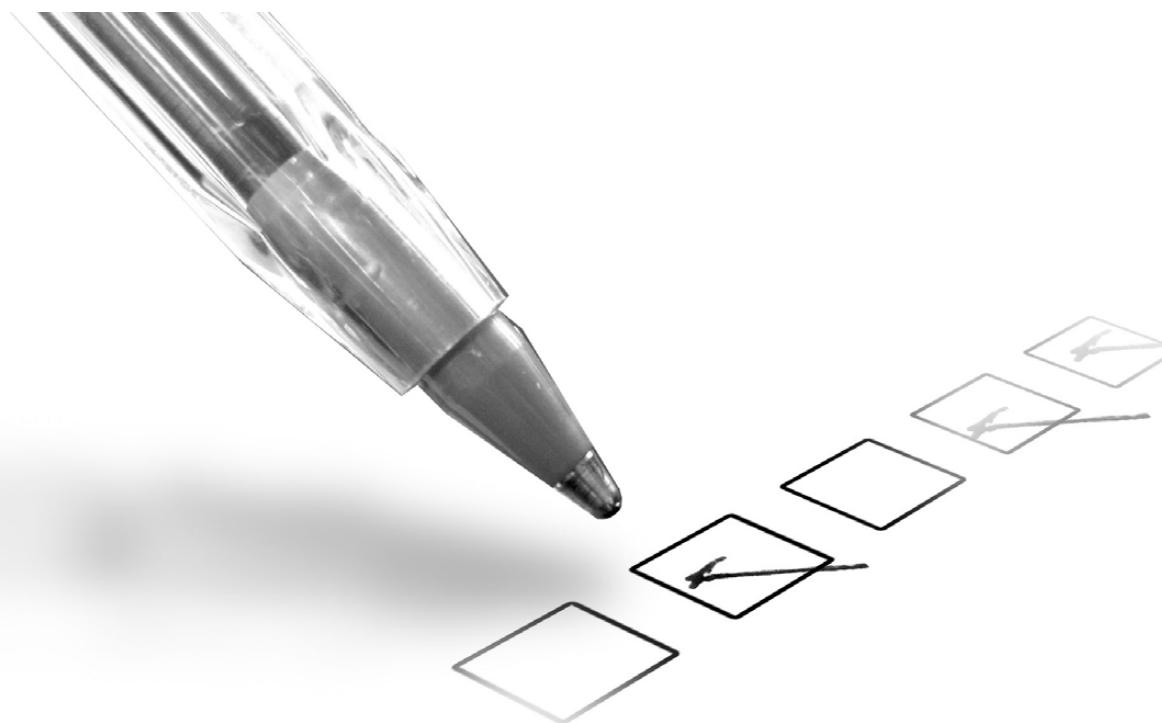


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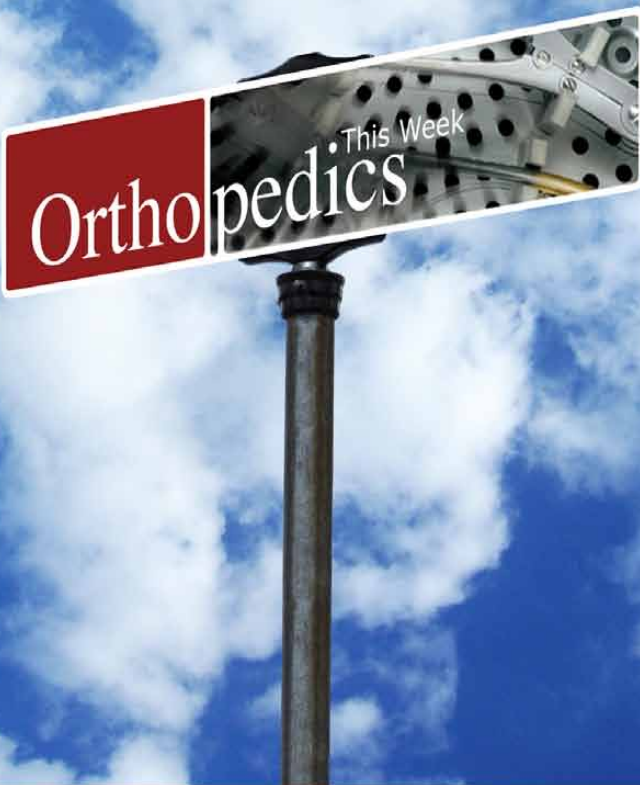
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