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# Orthopedics This Week

## week in review






## breaking news



**For all news that is ortho, read on.**

# Orthopedic Power Rankings

## Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**THIS WEEK:** This quarter's reports prompted an extensive reshuffling of the Power Rankings. A resurgent Symmetry pushed still struggling ArthroCare off the rankings. Orthofix, true to form, surprised investors and now the upgrades are streaming in. Notably, most every company reported reduced profit margins except two: OFIX and CNMD.

| RANK | LAST WEEK | COMPANY | TTM OP MARGIN | 30-DAY PRICE CHANGE | COMMENT |
|---|---|---|---|---|---|
| 1 | 8 | Orthofix | 16.23% | 5.91% | 200 basis point increase in operating margins and sale of Breg sets stage for even stronger operating results. |
| 2 | 5 | Conmed | 10.09 | (3.54) | Operating margins rose this quarter, rare and good news for sure. But 16% earnings growth? Investors should be cheering. |
| 3 | 3 | NuVasive | 6.63 | 0.24 | With Globus coming to market, NUVA has a new comp. But 22% sales growth is impressive. Stock is off 50% from its 52-week high. |
| 4 | 1 | Zimmer | 24.95 | (0.96) | Better sales growth than expected but profit margins slipped. Pricing is tough for everyone. Also 4th least expensive ortho stock. |
| 5 | 6 | Johnson & Johnson | 24.93 | (1.17) | Raises its dividend by 7%. Impressive. Forward yield is now 3.50%. JNJ also beat EPS estimates in the quarter. |
| 6 | 2 | Stryker | 23.68 | (0.85) | Stryker's business is healthier than the stock. Respectable quarter with revenues up 7% despite tough pricing. |
| 7 | 7 | Integra LifeSciences | 13.34 | 8.13 | Integra beat analyst's expectations to start the year and then raised guidance. No wonder buyers are returning. |
| 8 | 9 | Smith & Nephew | 21.50 | (1.08) | Analysts expect SNN to report results in line with the overall single digit industry growth rate. Okay, then. |
| 9 | NR | Symmetry Medical | 5.29 | (3.10) | There have been a couple of surprises this earnings season and SMA may join OFIX and CNMD. This week tells the story. |
| 10 | 10 | Medtronic | 28.24 | (4.44) | The key to MDT's report later this month will be margins. Not sales. This quarter the Street wants to see profit growth. |

# Robin Young's Orthopedic Universe

## TOP PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|---|---|---|---|---|---|
| 1 | TranS1 | TSON | $3.69 | $101 | 12.84% |
| 2 | Integra LifeSciences | IART | $38.18 | $1,031 | 8.13% |
| 3 | Orthofix | OFIX | $40.29 | $753 | 5.91% |
| 4 | CryoLife | CRY | $5.37 | $148 | 1.32% |
| 5 | MAKO Surgical | MAKO | $42.42 | $1,806 | 1.05% |
| 6 | NuVasive | NUVA | $17.06 | $733 | 0.24% |
| 7 | Synthes | SYST.VX | $172.72 | $20,515 | 0.05% |
| 8 | Stryker | SYK | $54.58 | $20,791 | -0.85% |
| 9 | Zimmer Holdings | ZMH | $63.01 | $11,224 | -0.96% |
| 10 | Smith & Nephew | SNN | $49.63 | $8,896 | -1.08% |

## WORST PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|---|---|---|---|---|---|
| 1 | TiGenix | TIG.BR | $0.76 | $69 | -15.25% |
| 2 | ArthroCare | ARTC | $25.27 | $699 | -6.92% |
| 3 | Bacterin Intl Holdings | BONE | $2.00 | $84 | -6.54% |
| 4 | Medtronic | MDT | $37.69 | $39,220 | -4.44% |
| 5 | Tornier N.V. | TRNX | $23.92 | $940 | -4.01% |
| 6 | Alphatec Holdings | ATEC | $2.25 | $202 | -3.85% |
| 7 | Conmed | CNMD | $29.13 | $816 | -3.54% |
| 8 | Exactech | EXAC | $16.00 | $211 | -3.38% |
| 9 | Symmetry Medical | SMA | $7.20 | $263 | -3.10% |
| 10 | Wright Medical | WMGI | $18.78 | $738 | -2.80% |

## LOWEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|---|---|---|---|---|
| 1 | Medtronic | MDT | $37.69 | $39,220 | 11.74 |
| 2 | Zimmer Holdings | ZMH | $63.01 | $11,224 | 12.81 |
| 3 | Johnson & Johnson | JNJ | $64.85 | $178,018 | 12.92 |
| 4 | Stryker | SYK | $54.58 | $20,791 | 14.33 |
| 5 | Orthofix | OFIX | $40.29 | $753 | 14.44 |

## HIGHEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|---|---|---|---|---|
| 1 | Wright Medical | WMGI | $18.78 | $738 | 56.91 |
| 2 | NuVasive | NUVA | $17.06 | $733 | 34.12 |
| 3 | Symmetry Medical | SMA | $7.20 | $263 | 24.00 |
| 4 | Exactech | EXAC | $16.00 | $211 | 21.62 |
| 5 | RTI Biologics Inc | RTIX | $3.62 | $201 | 21.29 |

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

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|---|---|---|---|---|
| 1 | Orthofix | OFIX | $40.29 | $753 | 0.89 |
| 2 | Kensey Nash | KNSY | $28.99 | $251 | 1.27 |
| 3 | Stryker | SYK | $54.58 | $20,791 | 1.33 |
| 4 | ArthroCare | ARTC | $25.27 | $699 | 1.36 |
| 5 | Zimmer Holdings | ZMH | $63.01 | $11,224 | 1.37 |

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

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|---|---|---|---|---|
| 1 | Wright Medical | WMGI | $18.78 | $738 | 6.03 |
| 2 | NuVasive | NUVA | $17.06 | $733 | 3.87 |
| 3 | CryoLife | CRY | $5.37 | $148 | 2.74 |
| 4 | Johnson & Johnson | JNJ | $64.85 | $178,018 | 2.20 |
| 5 | Smith & Nephew | SNN | $49.63 | $8,896 | 2.20 |

## LOWEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|---|---|---|---|---|
| 1 | Symmetry Medical | SMA | $7.20 | $263 | 0.73 |
| 2 | Alphatec Holdings | ATEC | $2.25 | $202 | 1.02 |
| 3 | Exactech | EXAC | $16.00 | $211 | 1.03 |
| 4 | Conmed | CNMD | $29.13 | $816 | 1.13 |
| 5 | RTI Biologics Inc | RTIX | $3.62 | $201 | 1.19 |

## HIGHEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|---|---|---|---|---|
| 1 | TiGenix | TIG.BR | $0.76 | $69 | 60.08 |
| 2 | MAKO Surgical | MAKO | $42.42 | $1,806 | 21.37 |
| 3 | TranS1 | TSON | $3.69 | $101 | 5.25 |
| 4 | Synthes | SYST.VX | $172.72 | $20,515 | 5.16 |
| 5 | Tornier N.V. | TRNX | $23.92 | $940 | 3.60 |

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

# Better Outcomes. Lower Costs. A Radical Redefinition of Orthopedic Care

By Biloine Young

What do 140 nursing homes, retirement facilities and assisted living establishments within a 30 mile radius of Regions Hospital in Saint Paul, Minnesota have in common? They all have—posted in a prominent location—the phone number of Region's GFP. (GFP stands for Geriatric Fracture Program, the bureaucratic-sounding name assigned, nationally, to a handful of hospital-based orthopedic care programs for the elderly.)

When a nursing home patient falls or otherwise sustains an injury, the staff calls, not an ambulance to take the patient to the hospital, but the Regions GFP number. In response a portable x-ray machine is dispatched to the nursing home, along with a nurse practitioner or an orthopedic physician's assistant, both of whom have been trained in frontline medical care and orthopaedics. They do an onsite evaluation, take pictures, and discuss the situation with any one of nine orthopedic surgeons at Regions who cover the program. Then, as likely as not, right there in the nursing home, they will set the fracture, put a cast on the injury and leave the patient resting in his own bed.

Not for this patient is a harrowing ambulance transfer and emergency room work-up.

If the break turns out to be a fracture of the hip, an ambulance is called, but instead of taking the patient to the hospital's emergency room, it takes the patient directly to the orthopedic floor of the hospital. Peter A. Cole, the orthopedic surgeon who conceived the program, says that now 60% of the elderly patients who used to be taken to the emergency room of Regions Hospital are now being successfully treated for their fractures at the nursing or residential home where they live.


*Source: Morquefile and click*

*Dr. Peter A. Cole*

Ten years ago Marc Swiontkowski, chairman of the University of Minnesota Orthopaedic Department, recruited Cole to build a program at Regions Hospital that could better address the volume of trauma cases that were coming in to this Level I trauma center. Cole dreamed of a trauma program that would care for patients from "infancy to grave." To him that meant developing "bookend programs" for both pediatrics and geriatrics. It was not lost on Cole that the cares of fractures in the elderly was relegated to the most junior person on the staff, or to off-hour care after elective surgeries were completed.

It was never anyone's priority to take care of what some looked on as" inconveniences" that would come through the emergency room door.

As he looked ahead at the demographics, Cole realized that "an orthopedic tsunami was about to hit us." To prepare for it he wanted a system in place so that when there were reams of elderly fracture patients coming in, the hospital would be able to take are of them. "We can't simply be inconvenienced with every hip fracture that comes in the ER," he said. "Unfortunately that is what occurs in most hospitals. What was always treated as a relatively manageable inconvenience has become an unmanageable albatross to many hospitals because of the increasing numbers of patients."

*Dr. Julie Switzer*

The Regions-HealthPartners GFP got its start when Cole hired Julie Switzer, M.D., "a wonderful fracture surgeon, exceptional in treating broken bones, who loves to treat elderly patients", he said, and Jay Noel. Noel is an orthopedic physician's assistant who, Cole said, "is a real dynamo, willing to partner with me in initiatives, even to the extent that he carries a beeper 24 hours a day 365 days a year to go out to nursing homes and do consults."



Switzer and Cole's geriatric program now conducts more than 300 nursing home and assisted living consultations a year, in what he calls "a radical redefinition of the way we would traditionally address an orthopedic situation." There is no charge to the nursing home for the service and the patients own health

insurance pays for their medical care. Regions Hospital pays all of the costs of the service including the salaries of the staff people running the program. Cole estimates the cost savings to the insurance providers to be in the hundreds of thousands of dollars annually.

According to Cole, the program has raised the quality of care for the elderly. "It is an adverse situation," he says, "to take residents out of a nursing home and put them in a completely foreign environment, start them on a myriad of drugs for pain control and startle every sensory system they have with alarming stimuli. Many get confused, delirious. Patients become de-conditioned and this can lead to having to monitor patients more carefully to keep them from falling in the hospital, developing pneumonia and bed sores. They aspirate their food or don't eat because they have lost their appetite, develop situational depression and spiral downward. Then there are the problems of transitions of care when you have a medical team, a cardiology team and an orthopaedic team—all of whom are working on a patient who easily could have had a simple treatment in the nursing home."

Despite these benefits, Cole says the model, as it is now, is not repeatable. "I cannot take this program and sell it to my colleagues in other hospitals in other states," he said, "because it reduces the number of tests and procedures which the hospital can bill for to be reimbursed." It works in Saint Paul because the program saves money for Health Partners, which owns the hospital. "We are saving a substantial cost of care for the health plan," he said.

Cole and Switzer are applying for a CMS (Centers for Medicare and Medicaid Services) Innovation Grant to help devise a workable financial model. "We must discover the exact value of this program. We want to be able to put a dollar value on every step of this model. What are the savings when patients avoid going to the ER, when post-operative patients can avoid going to the clinics, when patients are treated in nursing homes instead of coming to the hospital, when there are decreased lengths of stay because patients are admitted directly to Regions Hospital?"

According to Cole the staffs of the nursing homes and senior residences love the program. "They get a free consultative service and it is so much better for them to do it this way," he says. "Imagine all of the communication with families that needs to occur when patients are moved in and out of nursing homes, the logistical transfers of care, discharge orders, the medication sheets."

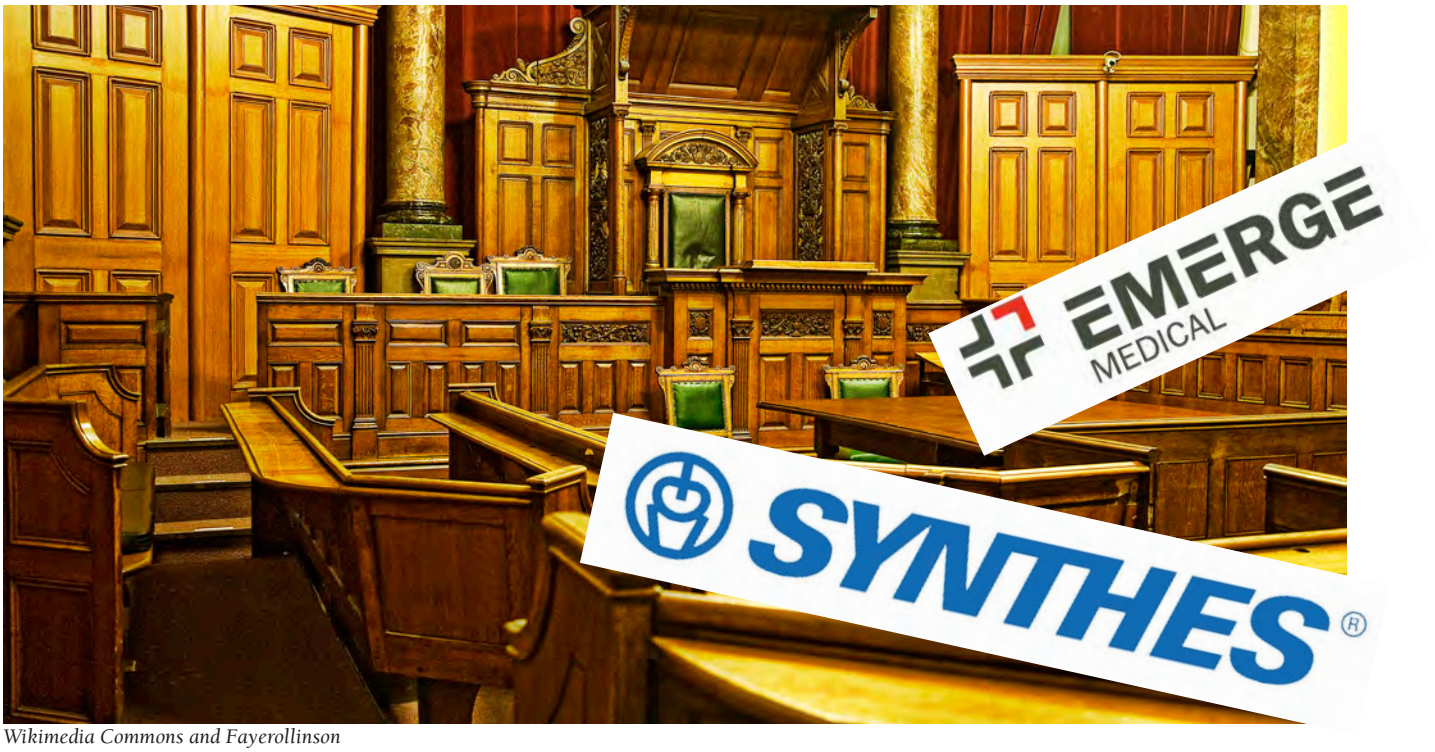
Since the end of World War II, life expectancy rates have increased significantly in the U.S. and age-adjusted death rates have dropped for eight of the top ten diseases. The average American is living longer. As the overall U.S. population ages, demand for orthopedic services for the elderly will increase at a faster pace than the population growth rate. In fact, the growth rate in demand for orthopedic services will grow exponentially faster. For example, there are just under 6 million people 85 year of age or older today. By 2050 that number will triple. Yet the amount of orthopedic healthcare services this group will require will at least ***quintuple***.

According to the United States Census Bureau, about 40 million, or just under 13% of Americans are currently age 65 and older. By 2050, however, that number is projected to expand to 88.5 million—roughly 20% of the country's population. People 75 years old are becoming the United State's fastest growing age group.

Cole and Switzer have become national leaders in a movement to create a subspecialty within orthopedics, to be called Geriatric Orthopaedics. "Just as you have sports surgeons, and hand and spine surgeons, we want to recognize and develop a new specialty for geriatric surgeons with training programs, societies and journals—all the distinguishing elements of a subspecialty", he said. It was in conversation with these other thought leaders that Cole learned that his team is the only one in the country doing this kind of outreach program for the elderly. "All of the other models are hospital based." he said. ♦

# Orthopedic Generics on Trial

By Walter Eisner



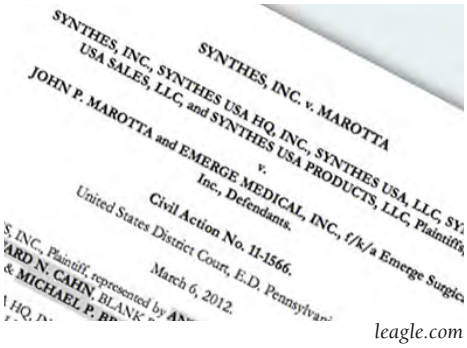

*Wikimedia Commons and Fayerollinson*

John Marotta made Synthes, Inc. a lot of money after he joined the company in 2004 as a Trauma Sales Consultant in Arizona and later as a Regional Manager.

According to court documents, when Marotta first arrived in Arizona, Synthes was selling $389,000 worth of its product, per year. By 2008, Synthes sales in the state had increased by 15-fold to $6 million per year.

## Marotta Competes

Marotta resigned in March 2010 and later that year became CEO of Colorado-based Emerge Medical, Inc. Emerge incorporated in January of the same year. The company was formed to produce and sell generic device fixation hardware (generics) such as drill-bits, guide-wires and screws for the orthopedic trauma market.


SYNTHES, INC. v. MAROTTA

JOHN P. MAROTTA and EMERGE MEDICAL, INC., f/k/a Emerge Surgic

Civil Action No. 11-1566,

United States District Court, E.D. Pennsylvan

March 6, 2012.

leagle.com

Synthes didn't take kindly to Marotta's departure and competing with them, so in March 2011 they sued him and Emerge Medical.

## Breach of Contract or Monopoly

Synthes accuses Marotta and Emerge of, among other things, a breach of fiduciary duty; breach of contract under the Non-Competition and Non-Disclosure Agreements; tortious interference with contracts and fraud. Eric W. Brown, Zachary W. Stassen, and Charles Q. Powell were later added as defendants in an Amended Complaint.

Marotta and Emerge fought back by not only denying Synthes' allegations, but filing a counterclaim in federal court in Philadelphia, accusing Synthes of, among other things, antitrust violations, making misleading statements to Emerge customers, and trying to crush Emerge through litigation.

That's where this story gets interesting. Why would Synthes, a multibillion dollar company pull out a bazooka to swat away a fly?

A Synthes spokesperson told us that the company doesn't comment on ongoing litigation. But others spoke to *OTW* on and off the record.

## A Bazooka for a Fly

It turns out that Synthes has pulled out the litigation bazooka in similar cases with similar charges against defendants 19 times since 2007, according to an analysis of Synthes lawsuits reviewed by *OTW.*

According to Marotta and Emerge, "this tactic stems from Plaintiffs' [Synthes] dilatory ulterior motive: 'to continue Synthes['s] well established litigation plan against start-up competitors...[by] driv[ing] up the costs of litigation and wear[ing] down its young opponents with a call for an unnecessary preliminary injunction...[and then] mov[ing] to amend their complaint.'"

Synthes says nonsense and they deny any such legal gamesmanship and claim they filed the amended complaint based on the limited information gained from their own investigation.

The court declined to find that Synthes engaged in any "undue delay or dilatory tactics."

## Supply Chain Disintermediation

But legal gamesmanship aside, there is more at stake here than just a few generic guide-wires, screws and drill-bits.

Disintermediation in the orthopedic implant supply chain is taking place in an environment that the former CEO of Medtronic, Inc. called the "End of the Surgeon Champion". Hospitals are swallowing independent orthopedic practices and buying decisions, particularly for generic hardware items, are coming from hospital committees and group purchasing organizations instead of individual surgeons.

Just last month Emerge announced a deal to sell its devices to Premier, Inc., the nation's second largest healthcare group purchasing organization (GPO) with over 2,500 hospital members at specially negotiated pricing and terms. Emerge guarantees customers annual cost reductions for the term of their contract.

Marotta and Emerge acknowledge that their generic hardware is fully interchangeable with Synthes hardware and can be used with Synthes inventory management systems and surgical sets. The competition is getting fierce.

Synthes claims that by November 2010, Emerge representatives began placing labels for reordering Synthes' surgical drill bits in Synthes' inventory cabinets, directing Synthes' customers to reorder surgical drill bits from Emerge instead.

As a result, those Synthes customers have begun to order replacement drill bits directly from Emerge rather than from Synthes.

## Fair Competition

Synthes' lawsuit, claim Marotta and Emerge, is an "effort to crush infant Emerge and punish former Synthes employee Marotta for daring to form a company that competes, no matter in how small a part, with Synthes, and to ensure that Synthes has no real competitors in the market for Generic Device Fixation Hardware."

Synthes has, according to the suit, "wrongfully and intentionally attempted to thwart Emerge's rise in the orthopedic device business by engaging in a continuous course of conduct involving disseminating false and malicious information about Emerge's personnel and products while using oppressive litigation tactics aimed at intimidating and eliminating Emerge." They also accuse Synthes of, "Wrongfully obtaining trade secret and other confidential information from Emerge, and unfairly competing in the orthopedic device business."

"In an attempt to maintain a controlling monopoly, Synthes engaged in predatory anti-competitive conduct that is harmful to the market for GDFH, the consumer, and contrary to the universal public policy goal of lowering the cost of healthcare in the U.S."

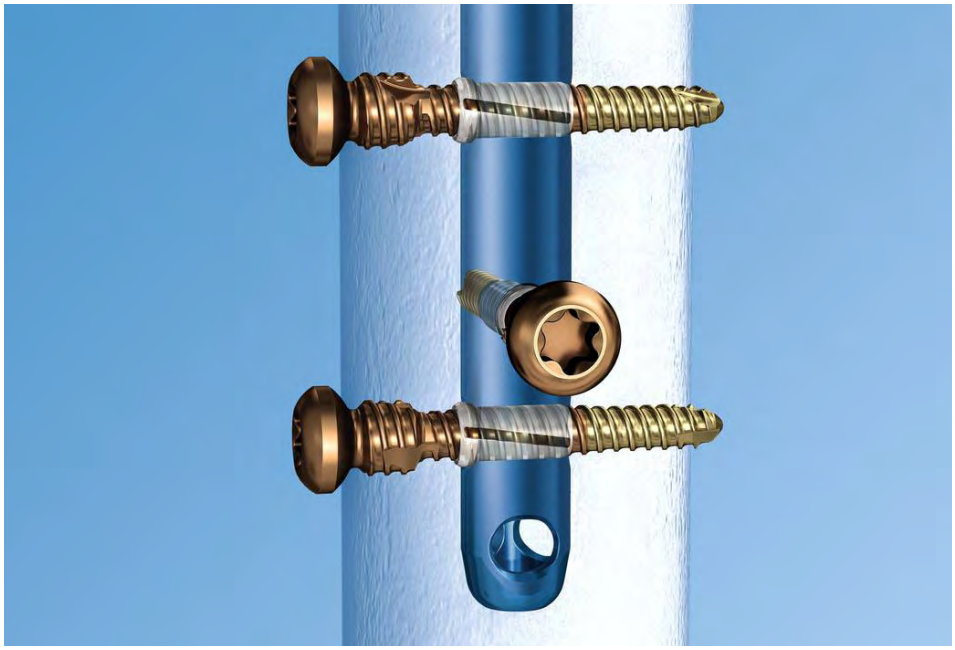
"Synthes is engaging in this conduct to drive competitors, specifically Emerge, out of business. There is a dangerous probability that Synthes will achieve a monopoly in the market."

## Trauma Market

What market are they fighting over? How big of a deal can guide-wires be?

The approximately $3 billion orthopedic trauma market (in 2011) is comprised of products like screws, plates, nails and drill bits used to repair broken bones and is led by Synthes, which Johnson & Johnson is buying for $21.3 billion. According to *Orthopedic Network News*, a publication that tracks device costs, individual devices can be relatively inexpensive, but a trauma case with a variety of parts can cost thousands of dollars.

Low-cost orthopedic parts are cheaper versions of existing products and the company typically doesn't send sales representatives into operating rooms



*Angular Stable Locking System (ASLS)/ © Synthes*

*Synthes DLS - Dynamic Locking Screw/ © Synthes*

to advise surgeons, which is a common but cost- and labor-intensive practice.

## Squeezing the Middle Man

"In certain cases the reps are getting paid more than the surgeons, and they're also trying to up-sell pricier wares," said Itai Nemovicher, president of another recent start-up called The Orthopaedic Implant Company in a *Dow Jones* interview with Jon Kamp in 2011. Nemovicher is a former Smith & Nephew PLC, representative.

In the same article, Gene Kirtser, president and CEO of Research Optimization & Innovation, the supply chain manager for the non-profit Sisters of Mercy Health System in the Midwest, said, "Providers are looking for more and more ways to take costs out." Kirtser said Emerge will get a tryout in one of the system's 30 hospitals, and could go system-wide.

Marotta says the company can save their hospitals' customers up to 50% off their current costs. He told *OTW* in an interview last year that the company's vision is to apply its generic device platform to the larger orthopedic, sports medicine, and spine market and ultimately to the entire $92 billion medical device industry.

One of the big manufacturers, Wright Medical Group, Inc. has also gotten into the generic game by launching a business called "White Box Orthopedics" in 2010 that offers cheaper versions of the company's replacement hips and knees through a more bare-bones sales approach.

## Cost of Sales

Stan Mendenhall, publisher of *ONN*, wrote in August 2010 that the largest component of a medical device is not research and development or manufacturing costs, but "SG&A" (selling, general, and administrative expenses). The average SG&A for seven orthopedic companies was 43.3% in 2009, with the largest element of that being payment to the sales group.

Mendenhall says that many hospitals that he talks to question the value of the rep in the first place.

"I have heard from some manufacturers that hospitals treat the reps as 'unpaid' labor, and dump all sorts of responsibilities on them, which would normally belong to the hospital." He notes that

the labor costs are, of course, included in the price of the product.

He says the rep service that seems most valuable from the hospitals standpoint is training hospitals and surgeons in the use of new implant systems. However for generic products and disposable hardware, there is less need for training.

## The Value of Instruments

Mendenhall wrote in 2011 that in recent years, the number of disposable instruments has soared as hospitals have reduced the costs of implants. The net result is an ever-growing percentage of the OR budget dedicated to instruments.

He found that instruments accounted for less than 3% of the total implant costs for joint replacement and spine cases; however they accounted for almost 13% of the implant costs in trauma cases.

At the high end trauma cases with nails, cannulated screws and hip pins all had over 20% of their costs assigned to instruments.

The parts identified as instruments were the second highest dollar value of components charged to hospitals after cortical screws in trauma cases. The types of devices assigned to this code are predominately drill bits and guide-wires, with a smattering of saw blades.

The major manufacturers selling trauma devices to hospitals, according to Mendenhall, had over 10% of their sales of trauma cases in instruments, with Stryker Corporation having the highest (18%), and Zimmer Holdings, Inc. with the lowest at 10%. Sixteen percent of market leader Synthes' sales were attributed to instruments.

The "top 10" instruments by sales in Mendenhall's analysis were led by Stryker's guide-wire used for implanting a femoral nail. Other devices in the top 10 were 5 drill bits sold by Synthes, a Stryker modular shaft for a reamer, a Synthes guide-wire, and two Smith & Nephew devices.

No court date for a hearing has been announced. But if Marotta and Emerge win this case, the opportunities for disruption in the manufacturing and distribution of generic devices, instruments and hardware in orthopedics will be richer. ♦

# Paprosky vs. Mears: MIS Hype or Help?

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

"Patient selection is key," says Wayne Paprosky, "And the skinny, passive, depressed individual is not going to do well no matter how small the incision." Dana Mears counters, "Wait. Let's look at the economics of this…there are not going to be enough healthcare dollars to support this proliferating number with the techniques we're currently using."

This week's Orthopaedic Crossfire® debate is "MIS: More Hype Than Help." For the proposition was Wayne G. Paprosky, M.D., F.A.C.S. from Midwest Orthopaedics at Rush in Chicago. Against the proposition was Dana C. Mears, M.D. of the University Pittsburgh; moderating was Cecil H. Rorabeck, M.D., F.R.C.S.(C) of the University of Western Ontario.


*Wikimedia - KaihsuTai and Current Concepts in Joint Replacement/RRY Photo Creation*

**Dr. Paprosky:** "MIS can stand for several things: Maybe It's Safe. Maybe It's a Scam; maybe it's just for people who aren't terribly normal (Mainly Insane Surgeons). I think it's mostly selection."

"One of the main goals should be early return to function. All the other things are nice, but are variable with respect to assessment. No matter the approach or size of incision, we must remember that we are dealing with patients—they are our focus, not individual outcomes."

"Same day discharge: I come from an institution where patients go from the OR table to a taxicab. Discharge within 24 hours doesn't affect the outcome; patients spending 2-3 days in the hospital after MIS procedures have outcomes as good as 24-hour patients. Patients must be properly anticoagulated, have good pain management with oral medication, and be proficient with physical therapy before they are turned loose."

"It was said that the 2-incision was 'it,' however that has turned out to not be the case. Mayo Clinic has shown slower recovery after 2-incision in a mini posterior-incision total hip arthroplasty (THA)—this was a randomized clinical trial (RCT). Patients actually felt the mini posterior was better than a 2-incision, which was going to revolutionize total hip surgery in general."

"Then you have [a study showing that] the minimal incision technique in THA doesn't improve postoperative outcome (an RCT). The Rothman Institute found that with minimally invasive surgery 80% of the patient data that has been published regarding MIS surgery was inaccurate. Larry Dorr has shown very good results with the mini posterior in a blinded study. So it's a difference of opinion with respect to what should be done. [de Beer] says forget the incision, it doesn't matter."

"Joel Matta has introduced a different technique for those people who do not believe that the posterior approach is indicated. Generally, the indication for choosing anything from the front is because of a low dislocation rate, and that this is superior. He's reported 0.61%, but you have to use a device that looks like something I've seen in a dungeon in New Orleans."

"We've shown with a posterior approach with a capsular repair—on almost 1,000 cases—dislocation rate was virtually the same. So that's not an

argument to choose one over the other. If you are going to do this…stick with what you know."

"Patient selection and attitude are critical. Body habitus is not the only criteria. Pre-op education, pre-op analgesia, as well as perioperative anesthesia protocols are critical to the success of both procedures. If you load these people up with all of these chemicals, interoperatively you run more chemicals, giving more afterward is not going to hurt."

"Motivated Interested Sharing Risk, Mainly In Shape. And the skinny, passive, depressed individual is not going to do well no matter how small the incision. Aggressive, exuberant [skinny] person…going to do it. Beware of the guy who may seem normal. He may not be, and may end up complaining about everything."

"In conclusion, be honest, know your limitations…these perfect results that you see on TV may be 10-15% of the population. But MIS surgery does not benefit all THA candidates."

**Dr. Mears:** "In attempting to define that MIS is more help than hype, I want to take a slightly different vantage point… the concern with the proliferation of numbers and the economics therein. Currently the estimated numbers are 250,000 per annum total hips in the U.S. and 450,000 total knees. Worldwide it's 3x these numbers; there are not going to be enough healthcare dollars to support this proliferating number with the techniques we're currently using."

"To me, an outpatient procedure looms to consider no matter the surgical approach. As Wayne outlined, what are the attributes where this could be done in an outpatient setting truly at lesser expense? However you do it, some pain management modality is crucial. We've used peripheral nerve blocks and multimodal technique; we have a separate nursing unit with high intensity therapy, combined with preoperative education."

"The patients get out of bed rapidly the day of surgery. Postural hypotension is a problem; they undertake activities consistent with home transfer using aspirin as a basis and attempting to have 23-hour discharge—some on the day of surgery."

"With my anesthesiologist we set out a working hypothesis that we could attempt to identify where it would be feasible to have a protocol for outpatients, even though we would assess it inpatient in view of financial considerations…recognizing that subsets of patients would require longer inpatient stay. We assess, determine preoperatively gender, age, weight, ASA [American Society of Anesthesiologists] status, preoperative hemoglobin, as well as those during and after surgery."

"Recently this work was approved for publication based on 676 consecutive patients at UPMC prospectively studied; 665 unilateral and 66 bilateral hips, with 11 preoperative exclusions. The mean age was 62, mean weight was 190lbs…followed for 3.5 years. The mean length of stay was 1.8 days for unilateral and 2.8 days for bilaterals, with 394 discharges the day after surgery."

"Post discharge home support: 44% were discharged home within 23 hours. 87.8% had no home support, 12% went to a rehabilitation center. We compared this with our preoperative results for tra-

ditional methods, showing a substantial improvement. Our local insurance carrier, UPMC identified the finances, saving $2,300 per patient, $6,000 per bed, $2,400,000 per year. The main impact was cutting the rehabilitation centers—that amounted to $7,000,000 per year."

"The problem with this is that it requires identification of patients. We had not assessed opioid abuse or dementia. These methods have not achieved widespread use; surgeons are resistant to techniques, and many patients have surgery performed in sites with small numbers of procedures. And you must change the pain management, therapy, nursing, and administration, along with a lot of other factors. To me, the worst problem is the lack of third-party payers; our payers have not gotten on board for changes that would save them money. I think that will change in the future."



**Moderator Rorabeck:** "Help us define the indication for this operation."

**Dr. Mears:** "In terms of patient size, we had set up prospectively a series of factors, including patient weight, that we thought would be germane to the distinction of short or long stay. Apart from the patients with the most severe forms of morbid obesity, weight was not a factor. Age was a factor over age 65, but mainly over the age of 75. But the two we have not considered, unfortunately, that we're now attempting to study prospectively, was occult dementia and habituation to opioids."

**Moderator Rorabeck:** "Is the driver here to improve the economics or patient care?"

**Dr. Mears:** "I think the patient care at the end of the day in terms of the quality of results, the potential complications, are not compromised in this way. But you do have to identify those patients where this would be realistic. At our site, a transplant center, if someone has had a heart/liver/lung transplant I would never dream of doing this procedure in an outpatient setting."

**Moderator Rorabeck:** "Wayne, maybe you could encapsulate this. When does Wayne Paprosky do an MIS hip replacement in a routine case?"

**Dr. Paprosky:** "First of all, length of stay is down in general. If there aren't medical complications it's rare no matter what kind of incision you do. It's clear that if you select a patient that appears motivated and is not obese, that is the patient to put the effort into to try and get that patient back to work in 8-10 days. But you cannot do this for all patients. If someone comes in and says, 'I'm highly independent,' but there are five people accompanying him, don't waste your time trying to get that patient back to work because he is getting a secondary gain out of getting breakfast in bed for a month (instead of going back to work). The other thing is you can't dig 2.5 hours in a Medicare patient who may not be qualified for this and the hospital loses money."

**Moderator Rorabeck:** "Dana, when you think about the potential costs in terms of an operation that may take an hour longer, does that factor into the economic analysis?"

**Dr. Mears:** "The surgery doesn't take any longer for an established hip surgeon with any of these methods. When

I was a resident a carpal tunnel release had to be done as a three day inpatient admission; complications would be accepted. Well now we look at that as patently absurd. You then look at ACL repair; that went to what is mainly now an outpatient procedure…technically more demanding, initially very controversial, now accepted. I see this driven in the same way and it will be driven by economic issues. Now, the U.S. payers largely don't pay for an outpatient procedure in an outpatient setting. If they were to change and you selected the patients appropriately, that would change everything."

**Moderator Rorabeck:** "How is navigation going to fit into this?"

**Dr. Paprosky:** "I don't think navigation for this type of surgery is going to offer a whole lot. If you choose patients correctly and you're doing a lot of them you can get real good at it. The question is…you've got to get there first. It's like surface replacement. There is a learning curve. A guy who's going to do 20 hips a year is not going to ever get real good at this so that he can take advantage of the potential economic gains of a patient going home the same day. I discharged about two dozen patients the same day and I had sphincter tightening and I was worried about someone popping off a PE…that just makes me nervous, especially in the elderly person."

**Moderator Rorabeck:** "I think the message is that it's an operation that has its place, particularly in the hands of an experienced hip surgeon. Thank you." ♦

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# On (and Off) the Record

By Elizabeth Hofheinz

Joints Failing Due to Oral Bacteria… Nonoperative Care Trumps Operative Care?...Now Where Did That Needle Go?..."Unprecedented" OA Pain Marker Initiative at Duke…MRSA Vaccine Coming?...and more.

**Joints Failing Due to Oral Bacteria?** Case Western University (CWU) researchers say that we may need to look to the mouth to find the source of joint failure. A team from the CWU School of Dental Medicine has found that bacteria from the fluid that lubricates hip and knee joints had bacteria with the same DNA as the plaque from patients with gum disease and in need of a joint replacement. These bacteria cannot be detected using routine lab tests, thus researchers used polymerase chain reactions and DNA sequence analysis of specific genes (16S-23S rRNA) in order to locate the bacteria in the plaque and fluid. The researchers suggest it might be the reason why aseptic loosening or prosthetic wear of the artificial joints fail within 10 years when no infection appears to be present.

**Nonoperative Care on the Rise** Brian Cole, M.D., a sports medicine and cartilage restoration orthopedic surgeon at Midwest Orthopaedics at Rush, says that patients are "hungry" for alternatives that are nonsurgical. Dr. Cole, who serves as a clinical trial advisor for one such nonsurgical option, tells *OTW*, "We are seeing increased patient demand for alternatives to the operating room. Fortunately, there is an emergence of new solutions that may be particularly helpful with high volume problems. One involves the use of electric energy to reduce pain. The technology has been shown to reduce biochemical markers for inflammation, and is now in clinical trials and producing data."

"Another new technology emanates from the pharmaceutical industry, and provides the ability to take medications currently used and prolong their activity by chemically surrounding them in

polymers…essentially prolonging the amount of time in the joint. Additionally, there are some early growth factor studies in the OA arena…ones that are related to disease modification. Why now? Well, on the device side, some of these things have been suppressed because of the economy and the availability of dollars to drive things from conception to manufacturing, etc. Things are changing, however, and in the next five years we should better understand the impact of OA [osteoarthritis] on the general population and hope for it to decrease."

**"Unprecedented" OA Pain Marker Initiative at Duke** Virginia Kraus, M.D., Ph.D., Professor of Medicine in the Division of Rheumatology at Duke University Medical Center is leading a novel effort to validate biochemical markers for osteoarthritis (OA). She tells *OTW*, "This initiative represents a triumvirate of academics, industry and the Foundation for the National Institutes of Health (FNIH), and is a substantial effort to bring together government and industry funding to tackle a major chronic disease, OA. One of the components of the FNIH is a biomarkers consortium whose goal is to advance biomarkers for drug development, as well as the advancement of therapies for different diseases. The Foundation had a real success story in the development of biomarkers to monitor harmful effects of drugs on the kidney, so we are using that success as a paradigm for our OA project."

"At present we are evaluating 600 individuals (who are already part of the NIH funded OA Initiative), using existing blood and urine specimens, X-ray and MRI imaging data, to qualify biochemical and imaging biomarkers for OA indications. We will be evaluating 12 biochemical markers and a host of imaging markers; our hypothesis is that the change in one or more, over 12 to 24 months, will predict pain and structural deterioration of the knee at four years. We plan to evaluate markers of cartilage degradation, inflammation, and cartilage repair. While many of the markers may have capability of predicting progression individually, we think that the combination of many markers will provide the strongest predictive capability."

"After this study we plan to validate the results in additional cohorts, including clinical trial cohorts to determine whether the biomarkers change in conjunction with clinical improvements in response to the therapy. We are engaging in discussions with the FDA regarding this work and the steps necessary to ultimately gain FDA approval of a set of markers of OA disease progression that could be used in clinical trials. This is an important collaboration for our field that includes major support from industry and donations of kits from biomarker assay manufacturers. All this combined makes for an unprecedented opportunity and a promising project."



**It's 8am in the OR…Where Exactly is Your Needle?** Robert Stanton, M.D., a former President of the American Orthopaedic Society for Sports Medicine, tells *OTW*, "We are seeing a trend toward the use of in-office diagnostic ultrasound to help with guided injections. More accuracy is warranted… while orthopedic surgeons are trained to do joint injections, there is no question that mistakes are made when it comes to needle placement. This is not to be used on every single patient, but it is helpful, for example, with heavy patients where the anatomy is less clear."

"Ultrasound is particularly valuable for use by anesthesiologists placing regional blocks. You can verify that the needle

is adjacent to the nerve. For all ultrasound guided procedures, patients are very satisfied because of the visual feedback of seeing exactly where the needle is. Fortunately, most insurers are covering this…and the prices have come down significantly. At the same time, more educational courses are being offered and people are not hesitating to sign up."

**All Aglow in the OR? Radiation and Cone-Beam CT Technology** Jeffrey Lange, M.D., a second-year orthopedic research resident at the University of Massachusetts Medical School, was first author on a study that is garnering much attention. Dr. Lange tells *OTW*, "In spine specifically there are a lot of intraoperative imaging options that can help us with instrument positioning. These techniques mostly require radiation (X-ray or CT scan). Cone beam CTs are an attempt to make a lower radiation dose CT scan. Our question, which has attracted some interest, was, 'How much radiation does a patient see from that interoperatively?'"

"These were all estimated dosages because we studied only simulated surgical scenarios. The take home message was that this type of CT scan does not appear to increase exposure to radiation over traditional CT scans in single scan usage. We also wanted to know what happens in a typical spinal surgery (which might use multiple scans). Although it depends on patient- and scenario-specific factors such as weight or number of spinal levels involved, there appear to be many full procedures for which the radiation dose does not exceed that of typical CT. It is especially important when discussing radiation risk to make sure that you're talking about a risk profile rather than an absolute (safe versus dangerous). This is a widely used tool and people have had great success. The important thing is to be clear as to your goals up front."



**MRSA Vaccine Coming?** A research team from the University of Rochester Medical Center (URMC) will be leading an international consortium of trauma surgeons, infectious disease specialists, and translational scientists…all in an effort to tackle infections from complex orthopedic surgeries. The team, led by Stephen L. Kates, M.D., will be working with $3 million from AOTrauma, which is part of the Switzerland-based AO Foundation. Dr. Kates, Professor of Orthopaedics at URMC, will oversee 8 research projects involving 21 medical centers. The researchers will be focusing on:

- identifying the best ways to prevent infection and create an education template for medical providers everywhere
- develop a diagnostic test to demonstrate a patient's immunity to Staphylococcus infections
- develop a novel, MRSA passive immunization (vaccine) to prevent MRSA infections during total joint replacement
- use animal models to study the best ways to deliver antibiotics to deep wounds and to study a possible vaccine against staph
- analyze all current treatment protocols for patients suffering from severe bone and joint infections
- create an international infection registry to help with the study and treatment of infections in a standardized manner
- disseminate study results and discoveries about best clinical practices in a six-part educational series to be available through the AO Trauma Foundation.

**R. Barkley Payne New VP at OREF** R. Barkley Payne, former vice president of development for the American College of Healthcare Executives, is the new VP of corporate development and strategic philanthropy for The Orthopaedic Research and Education Foundation (OREF). Payne's 10+ years of experience in cultivating partnerships for nonprofit health care entities includes the five years he spent as executive director of the American Dental Association Foundation—as well as the five years he spent as senior director of fundraising and development. In 2009, he was awarded honorary fellowships by the American College of Dentists and International Academy of Dental Facial Esthetics, their highest awards for non-DDS professionals. *Association Trends Magazine* named Payne a 2004 young and aspiring association professional. Payne earned a BA in public relations at Western Kentucky University. ♦

company

# Zimmer Results Confirm Stability in Ortho

Zimmer Holdings, Inc.'s sales for the first quarter rose 2.7% to $1,141 million, which was slightly better than last quarter's growth of 2.4%.

Hips were up 2.5, knees up 2.4, and spine was down 6%. Extremities and trauma did better, growing 4.8% and 7.7%, respectively. Revenues were generally in line with consensus.

As noted by all their competitors, Zimmer management pointed to delayed procedures due to high unemployment and challenged spine sales due to pricing pressure and payer pushback.

### Recon Market

With Zimmer's report on top of results from Biomet, Inc., DePuy Orthopaedics, Inc. and Stryker Corporation, the orthopedic market's current growth rate is coming into focus with 80% of the market reporting.

Analysts pretty unanimously echoed all the company's cautiously optimistic outlook on the recovery of the recon market. Knees are showing signs of improvement, while hips remain relatively stable.

Wells Fargo Analyst Larry Biegelsen estimates that on a constant currency basis, the global knee market grew 2-3% in the first quarter, largely due to the recovery of the U.S. knee market. He estimates the global hip market grew about 2% during the quarter, which was marginally worse than the fourth quarter of 2011.

*Wikimedia Commons and Chrome23*

| Zimmer 1Q12 | Sales ($ in millions) | % Change* |
|---|---|---|
| **Total Reported Sales** | **$1,140** | **2.7%** |
| Reconstructive | $860 | 3.0% |
| Knees | $471 | 0.0% |
| Hips | $344 | 5.0% |
| Trauma | $76 | 12.0% |
| Spine | $53 | down 6% |
| Extremities | $45 | 10.0% |
| Other | 51.4 | 8.0% |

*Source: Zimmer Holdings, Inc.*
** In constant currency*

### Zimmer's Quarter

David Dvorak, Zimmer's president and CEO, said the company delivered year-over-year sales growth in all geographic segments and in most product categories in the quarter. "Looking forward, our new product introductions and progress in our transformation programs will enable the company to generate increased value to stockholders."

Dvorak reaffirmed full year 2012 constant currency revenue growth guidance of 2-4% but now expects currency translation to decrease revenue by 1.5-2.0%

Overall pricing was down 2.0%, worse than the last quarter primarily due to increased pricing pressure in knees and spine. Hip pricing was relatively flat compared to the last quarter. Knee pricing declined slightly.

### Hip and Knee Product Outlook

The company expects to introduce significant implant and instrument additions to its knee business over the rest of the year. In the first quarter, Zimmer introduced new patient specific instruments for its unicompartmental knee system and received FDA clearance for the first phase of its, yet to be named, next generation knee system which is to be available on a limited basis in 2012 before a broader commercial launch in 2013.

In hips, management highlighted its efforts in personalized product lines such as the Continuum Acetabular Cup, which is helping the company gain hip market share. In addition, the company's Vivacit-EVitamin E Highly Crosslinked Polyethylene cup liner is expected to rollout later this year

**Money to Shop**

Finally, with free cash flow of almost $1 billion in 2011 and $1.2 billion of cash on the balance sheet, BMO Capital Market Analyst Joanne Wuensch says management has the capacity and continues to pursue a bolt-on acquisition strategy to complement its orthopedic businesses. Over the last five years Zimmer has purchased two companies: ExtraOrtho, Inc. in November 2011, a manufacturer of external fixation devices and Synvasive Technology, Inc. in January 2012, a manufacturer of patient specific knee instrumentation as well as surgical cutting blades.

With markets stabilizing, competitors buying and selling each other and money in the bank, eyes will be on CEO Dvorak to see what he'll do with his resources.

*—WE (April 27, 2012)*

## LDR Cervical Cage Cleared by FDA

The FDA has granted clearance to LDR Holding Corporation's ROI-C Lordotic Cervical Cage.

The cage adds to the company's stand-alone portfolio and, according to an April 24 company announcement, complements the existing ROI-C anatomically shaped cage introduced in 2009.

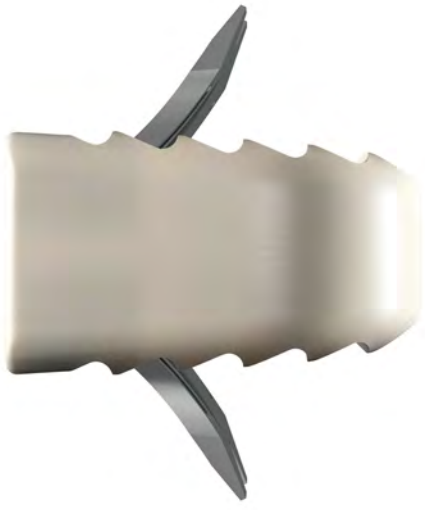
"When used with the company's integrated VerteBRIDGE plating technology, both cages offer a zero profile, stand-alone construct for fusion in the cervical spine. The design of the ROI-C Lordotic Cervical Cage provides and additional option during surgery allowing surgeons to treat patients with more varied anatomy and reduces the need for thick cervical plates that may contribute to dysphagia, or difficulty swallowing," continued the statement.

Robert Jackson, M.D., Chief of Neurosurgery at Mission Hospital Regional Medical Center and Assistant Clinical Professor of Neurosurgery at the University of California - Irvine, implanted the first ROI-C Lordotic Cervical Cage in the U.S. "A critical aspect of anterior cervical fusion is providing excellent stability through good bone-implant contact and primary stability with immediate loading. That is best achieved by matching the cage to a patient's specific anatomy...LDR's cervical offering addresses the anatomical challenges I encounter and allows me to deliver better care to my patients."

LDR President and CEO Christophe Lavigne said the introduction of the cage will:"…strengthen our worldwide leadership in stand-alone device innovation. LDR has led the way in providing surgeons with a broad selection of implant geometries for stand-alone cervical and lumbar fusions. The ROI-C Lordotic Cervical Cage represents the latest application of VerteBRIDGE Plating technology which has been successfully used in more than 25,000 cervical and lumbar cage implantations worldwide since 2008."

The company said the shapes of both of the ROI-C Cervical Cages and their integrated plating system are designed to match the patient's anatomy and provide initial and long-term stability. The self-guided, curved plating is delivered in the plane of the disc through a direct anterior approach, so that the surgery can be achieved with less exposure than may be required to implant a traditional cervical plate, or even contemporary stand-alone systems with screws that must be inserted at oblique and challenging angles. The system features instrumentation including an inserter that protects anatomical structures when placing the cage and VerteBRIDGE Plating.

*—WE (April 25, 2012)*



*LDR Corporation/ROI-C Lordotic Cervical Cage*

# Orthofix Sale of Breg Opens Options

Orthofix International N.V. is selling Breg, Inc., the company's sports medicine business.

Orthofix acquired Breg in 2003 for around $150 million and is selling the company for $157.5 million to the private equity firm, Water Street Healthcare Partners. While making a little money on the transaction and recognizing operating income since 2003, Mizuho Securities USA, Inc. analyst Mike Matson agreed that the most valuable thing Breg may have done for Orthofix was to provide profits while the company's spine business was struggling during the Blackstone acquisition.

Matson said Breg has historically been a very profitable business with operating margins of around 22% (excluding corporate expenses). Lately however, its operating margin has fallen due to product liability litigation from the pain pump product Breg used to sell. On an April 24 conference call with analysts , management stated that Breg's operating income was just $1.2 million last year and indicated that the deal should increase both its gross and operating margins.

### Deleveraging Opens Options

Bob Vaters, Orthofix's president and CEO, said the divestiture of Breg will allow the company to focus its full resources and attention to, "Strengthening our value proposition around our repair hardware and regenerative biologics and stimulation solutions. We believe this deleveraging event and resulting borrowing capacity will allow us to expand and enhance both our Spine and Orthopedic business units in a way that accelerates our ability to create shareholder value."

Founded in 1989, Breg offers cold therapy, knee, shoulder, spine, elbow/wrist, foot/ankle bracing and orthopedic practice solutions. The company's products are sold through more than 100 distributors in 36 countries. Breg is based in Carlsbad, California, with approximately 500 employees in the U.S. and Mexico.

Matson does not expect the sale of Breg to cause a significant change to Orthofix's growth profile but the sale should allow the company to focus on its implant businesses that have been consolidated in Lewisville, Texas.

It wasn't just Wall Street analysts that liked the deal, as the company's stock shot up between 5-10% after the announcement. Overall, the deal looks like the company sold off a business that got it through some tough times, but was now causing a drag on margins. With the proceeds, management will now be able to lower debt, increase margins and have more ammunition to make acquisitions or internal improvements to its core spine business.

Matson indicates the company is on the right side of history as the challenging spine market has reduced private company valuations significantly and made it ripe for consolidation by larger, public companies such as Orthofix.

*—WE (April 24, 2012)*


*Image creation by RRY Publications, LLC. Source: Corporate logos*

# Stryker 1Q12: Flat and Stable

Bank of America Analyst Robert Hopkins asked Stryker Corporation's Chief Financial Officer Curt Hartman, who is serving as interim CEO, the question on everyone's mind. No, not about Steve MacMillan's "family" reasons for resigning as head of the company, but whether or not hip and knee sales rates went up from the last quarter of 2011.

### Sales "Flat and Stable"

Hartman passed to Katherine Owen, Stryker's VP of Strategy. She told Hopkins and the other analysts on an April 17 conference call that sales were "probaby closer to flat and stable. It feels like the environment may be getting a little bit better, but with just one quarter and some of the seasonality, seasonal anomalies that happen between Q4 and Q1, it's probably too soon to say we've seen a real change in the trend, but it certainly feels very stable at the moment."

However, Owen seemed quite happy to point out that Stryker's non metal-on-metal hip products did very well for the quarter. "Our hip sales continue to see the benefit from the uptick of both the ADM and MDM mobile bearing systems that allow for a large hip head without the need for a metal-on-metal component. Combined, ADM and ADM (sic) [MDM] represented approximately 21% of our U.S. hip cup procedures exiting the quarter, up from 17% at the end of 2011, underscoring the market's receptivity to an ultimate large-head implant system.

Net reported sales during the first quarter of 2012 grew 7.2% to $2.2 billion. Reconstructive sales increased 5.2%. MedSurg increased 7.5%. Neurotechnology and Spine increased 12.4%.

### Knees Rebound

On a constant currency basis knees were the big winner going up by 5%, representing an acceleration after four consecutive quarters of negative growth. Management said OtisMed is steadily gaining traction and is largely responsible for the gains in knees. Hips were up 3.1%. Trauma and extremities were up 9.7 and spine, excluding the impact of acquisitions, was up 4.3%. Spine growth was due to sluggish volumes and especially pricing, which got incrementally worse in the quarter.

Larry Biegelsen, Wells Fargo's analyst, said the quarter was so strong that he was raising his 2012 sales estimates by $51 million and 2013 estimates by $61 million.

### First Quarter Orthopedic Market

Looking at the overall orthopedic market, Jefferies Analyst Raj Denhoy wrote that Stryker's results taken together with the most recent quarterly results from DePuy Orthopaedics, Inc. and Biomet, Inc. point to a stabilizing market. "Though implant volumes for large joints remain below historic trend as macroeconomic headwinds weigh on these end markets. In aggregate, hips appear stable while knee growth

| Stryker 1Q12 | Sales ($ in millions) | % Change* |
|---|---|---|
| **Total Reported Sales** | $2,161 | **7.4%** |
| Reconstructive | $958 | 5.2% |
| Hips | $312 | 3.1% |
| Knees | $352 | 5.0% |
| Trauma/Extremities | $243 | 9.7% |
| Med Surg | $821 | 7.9% |
| Neurotech/Spine | $382 | 12.3% |
| Spine | $181.0 | 12.2% |

*Source: Stryker Corporation*
** Constant currency*

*Stryker Board of Directors*

does appear to have ticked up a notch, although the sustainability of any trend is wholly unknown. So, while volumes could ultimately rebound to more normalized levels over the coming quarters, there is little visibility on the timing and extent of such a recovery."

Mike Matson, Mizuho USA's analyst estimates that the recon market grew by 1% on a constant currency basis in first quarter. He estimates that global knee and hip growth were both at 1% on a constant currency basis.

Hartman told the analysts that the search continues for a permanent replacement for MacMillan and the board was comfortable with the pace of the search effort. In the meantime, he said the company's game plan will stay the same and will continue to "run the offense." That's a change as MacMillan was fond of baseball metaphors.

*—WE (April 23, 2012)*

## DePuy Results Show Market Stabilizing

Johnson & Johnson's reported sales for the first quarter of 2012 declined by 0.2% to $16.1 billion. The company's Medical Devices and Diagnostics division's sales fell 0.3% to $6.4 billion. Within that division, DePuy Orthopaedics, Inc.'s reported sales dropped 0.7% to $1.493 billion.

### Utilization Stabilizing

While sales fell, company CFO Dominic Caruso told analysts on April 17 that utilization rates have stabilized and for the first time in nine quarters, utilization rates climbed slightly in U.S. hospitals.

On an operational basis, the company's knee sales grew 1.6%. Caruso said sales benefited from overall market improvement and positive impact from mix driven by an increased number of revision surgeries. Hip sales rose 1% while spine fell 2.6%. In the U.S., spine sales dropped 7.6% due to pricing pressure, while rising 5.4% elsewhere. But Caruso noted that utilization may be starting to stabilize, telling analysts, "We're not seeing the rapid declines." Spine pricing was comparable to the prior quarter and was down in the mid-single digits.

The company took $271 million in charges during the quarter to pay for ongoing litigation and recall expenses related to their ASR metal-on-metal hips.

### Waiting for Synthes

Caruso said the pending Synthes, Inc. acquisition should be completed in the second quarter. Japanese, Canadian and Chinese regulators have all approved the deal and the company is waiting for approval from the EU and U.S. The expected sale of the company's trauma business to Biomet should, said Caruso, satisfy remaining regulatory concerns.

### Analysts Positive

Mike Matson, Mizuho Securities USA analyst, viewed the results as positive for orthopedic companies but neutral for spine companies. After seeing DePuy's numbers, Matson now thinks the first quarter's operational spine market growth rate could be worse than his original 0% forecast.

BMO Capital Market's Joanne Wuensch pointed to management's "cautiously optimistic" orthopedic outlook, with commentary from the field reflecting "early signs of some positive trends," similar to Biomet's previous commentary.

*—WE (April 17, 2012)*

| J&J Orthopaedics 1Q12 | Sales ($ in millions) | % Change* |
|---|---|---|
| **Total Reported Sales** | **1,493** | **-0.7%** |
| Knees | 363 | 1.6%* |
| Hips | 328 | 1%* |
| Spine | 265 | down 2.6%* |
| Bone Cement | 206 | down 6%* |
| Sports/Mitek | 172 | 1%* |
| Extremities | 86 | 5%* |
| Trauma | 72 | 1%* |

*Source: Larry Biegelsen, Well Fargo Securities*
** Operational*


*Wikimedia Commons and Photo Creation by RRY Publications LLC*

## Medtronic Spinal's New Electronic Instruments

Medtronic, Inc. has launched a system of electronic instruments. The company says the system has shown to save time, increase control and reduce wobble of instrument movement during spine surgery.

The POWEREASE System is specifically designed for use in instrumented or reconstructive surgery for drilling, tapping and driving specialized implants. The company says the system brings a new capability to the operating room through compatibility with two pedicle screw platforms, the CD Horizon Solera and the TSRH 3Dx Spinal Systems, and integration with the company's Nimeclipse neuromonitoring, O-Arm imaging and Stealthstation navigation systems.

Through biomechanical testing versus manual instruments, the Powerease system, according to the company, demonstrated 51% less time required for tapping the pedicle and 55% less time required for placing pedicle screws. This testing also showed greater control with 38% less wobble, defined as maximum radial movement of the instrument from the center axis of the instrument or screw when placing pedicle screws, compared to manual instruments. The company cautions that biomechanical testing is not necessarily indicative of human clinical outcome.

In the April 16 press release Doug King, head of Medtronic Spinal, says the system reduces surgeon's fatigue associated with repetitive hand motion and enhances surgeon control, including in complex reconstructions of the spine. "We're pleased to couple advanced power technology with our proprietary neuromonitoring and surgical navigation systems, which enable a more informed procedure."

*—WE (April 16, 2012)*

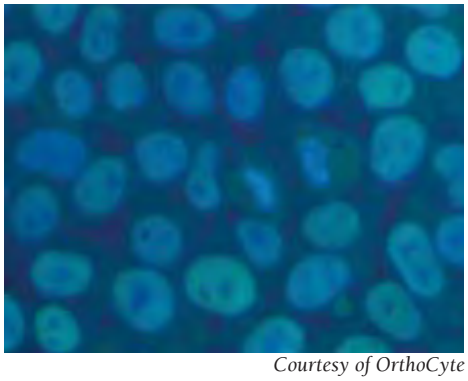

*Medtronic, Inc. /POWEREASE™*

biologics

## OrthoCyte Close to Stem-Cell Cartilage Breakthrough

OrthoCyte Corporation, a subsidiary of BioTime, Inc. reports that it has found a way to manufacture cartilage from human embryonic stem cells that can be scaled up for industrial production. The product would be used for the treatment of osteoarthritis.

The study is published online in the peer-reviewed journal *Regenerative Medicine*. Scientists reported on the ACTCellerate line designated 4D20. 8.The proprietary cell line is the cellular component of OrthoCyte's product in development, OTX-CP07. The report demonstrates that 4D20.8 cells possess site-specific markers of craniofacial mesenchyme, markers of proximal mandibular mesenchyme.



*Courtesy of OrthoCyte*

This tissue is significant because it naturally produces one of the strongest joint cartilages of the body. The study documented the conditions in which the cells can be propagated on a large scale, the conditions in which the cells can be differentiated into cartilage in the laboratory, and evidence that the cells could repair damage to knee joints in rat models.

Another significant finding reported in the study is that the OrthoCyte 4D20.8 cells lacked certain mesenchymal stem cell (MSC) markers. MSCs have the ability to proliferate in response to fractures and to generate a transient type of cartilage called "hypertrophic cartilage" that functions as a temporary repair of the fracture. Over time, however, this hypertrophic cartilage is transformed into bone. Because of their propensity to hypertrophy, MSCs have not been an effective source of cartilage for joint repair. When compared to MSCs in studies published in the current paper,

4D20.8 cells displayed markers consistent with definitive cartilage progenitors and showed a marked decrease in the expression of hypertrophic chondrocyte markers.

Arnold Caplan, Ph.D., OrthoCyte's Chief Scientific Officer, noted in the April 23 press release, "The long-stated goal in orthopedic research has been to isolate the progenitors to specific and diverse types of cartilage in the body, such as those of the ear, nose, trachea, sternum, and weight-bearing joints. Cloning progenitors derived from hES cells is a novel method of obtaining these cells, which will be of great interest to those in the research community and those seeking to cure the debilitating disease of osteoarthritis."

The economic implications of the research are not lost on Michael D. West, Ph.D., BioTime's chief executive officer. "We see osteoarthritis as one of the low-hanging fruits in regenerative medicine. The rapid rise of this market due to the aging of the baby boom population, the current lack of a cure for the disease, and the ease of scaling our product has led to our prioritizing this product for development."

Age-related degenerative disease is the largest category of unmet medical needs. The most common complaint of an aging population is the disease known as osteoarthritis, for which there is currently no cure. An estimated 27 million Americans suffer from it, and the number is rapidly growing with the aging of the population. A safe and effective means of regenerating functional cartilage cells in human patients could therefore address a significant market.

*—BY (April 26, 2012)*

large joints

## Genes Help Detect OA Early

Researchers from the Washington University School of Medicine in St. Louis have discovered that the same genes that promote healing after cartilage damage also appear to protect against osteoarthritis (OA). The researchers reported their findings in a pair of studies, published online in the journals *Arthritis & Rheumatism* and *Osteoarthritis and Cartilage*. The team conducted their research in mice, but indicate that the genes also are likely to be important in people.

*Wikimedia Commons and Nevit Dilmen*

"Our goal is to see whether we can protect cartilage in people by detecting the early biological changes that occur in osteoarthritis and prevent it from progressing to the stage where joint replacement becomes necessary," says principal investigator Linda J. Sandell, Ph.D., the Mildred B. Simon Professor of Orthopaedic Surgery, in the April 26, 2012 news release. "The main problem with biological treatments is that currently, we can't detect osteoarthritis in its early stages. Better understanding of the genes that influence the disorder may help us do that."

The Washington University team bred the mice that healed rapidly with other mice that healed more slowly, and they found that the mice that could quickly heal and regenerate cartilage in the knee also were less susceptible to OA.

"Some people—and these mouse studies suggest that someday we may be able to predict which people—fare much better after an injury," said Dr. Sandell. "We want to find a way to identify the genes that protect them."

Dr. Sandell, director of the university's Core Center for Musculoskeletal Biology and Medicine, and co-investigator James M. Cheverud, Ph.D., professor of anatomy and neurobiology, now are studying several other strains of mice on the spectrum between the good healers and those that heal poorly. They've looked at the cartilage tissue under the microscope to determine the extent of osteoarthritis following an injury and analyzed the DNA in cartilage.

"We've identified genes that correlate with healing and with protection from osteoarthritis," Dr. Sandell says. "The work is in its beginning stages, but now that we've found a correlation, we want to look at even more strains of mice so that we can actually map the location of the genes that cause osteoarthritis and help to repair cartilage."

*—EH (April 27, 2012)*

## It's Still the Pain, Stupid

Pain is what drives most patients to their surgeons for hip or knee replacements and experts agree that the patient's level of pain is the best indicator of the need for hip or knee replacement surgery. Where that pain is located may be significant. In the case of hips, the main symptom is pain in the groin, especially when the patient is active and moving the joint.

"If pain is not in this area, it has to be deeply investigated because the worse scenario would be that the patient goes through hip replacement and may still have pain after the surgery because it did not solve the basic problem," says Michaela Schneiderbauer, M.D., a surgeon specialist and assistant professor of orthopedics at the University of Miami School of Medicine.

Discomfort on the outside area of the hips and rear-end could, in contrast, be symptomatic of back problems, she says. In the knees, the pain is acute when walking and present when the knee is resting, which prevents a person from sleeping or resting. In some cases the patient has difficulty standing for long periods of time."

According to the National Center of Health Statistics, 1.1 million patients in the United States undergo hip or knee replacement surgery each year. That number keeps growing because of longer life expectancy as well as the dramatic rise in the rate of obesity. By 2030, the American Association of Hip and Knee Surgeons projects that the number of surgeries will reach 4.5 million.

Schneiderbauer warns her patients of the hazards of excess weight. "People don't expect a surgeon to tell them that they should lose weight, but if they are patients in the first stages of the illness, which is when they can improve the symptoms and keep their natural knee or joint, it is my duty to tell them," Schneiderbauer warns in the April 16 news release. "Excess weight in the body multiplies by four or five times in the knees. If a patient loses 20 pounds, it is as if 80 pounds have been removed from his knees."

*—BY (April 24, 2012)*

*Morquefile and Headache2323*

## Smoking Raises Failure Rate in TKR

Add a ten-fold higher revision rate following total knee replacement (TKR) to the hazards of smoking to patients. A study ("Increased Revision Rates Following Total Knee Arthroplasty in Patients Who Smoke,") found that the patients in the smoking group experienced 13 replacement failures, a failure rate of 10%, compared to five in the non-smoking group, a rate of 1%. The study involved 621 TKR patients, including 131 smokers with a median age of 62.

*Wikimedia Commons and Bachmount*

The medical complication rate in the smoking group also was "significantly higher", with 27 patients (21%) having a medical complication compared to 60 (12%) of the non-smokers. Complications included deep venous thrombosis or blood clots, anemia that required treatment, cardiac problems, and acute renal failure.

Another study, titled, "Smoking is a Harbinger of Early Failure with Ultraporous Metal Acetabular Reconstruction," examined the effects of smoking on patients who underwent reconstruction of the acetabulum. The process involves the coating of the cup-shaped

cavity at the base of the hip bone with ultra porous metal. Between 1999 and 2009, surgeons used ultraporous acetabular components in 533 hip replacements, including 159 primary and 374 revision surgeries. Of these patients, 17% were smokers, 31% were previous smokers, 50% were non-smokers, and the smoking history of 3% was unknown. The failure rate in smokers was 9.1%, compared to 3.4% in non-smokers.

Both studies were presented at the 2012 Annual Meeting of the American Academy of Orthopaedic Surgeons and reported on *PR Newswire*. During a Smoking Cession Forum, Glenn R. Rechtine, M.D., an orthopedic surgeon and associate chief of staff at the University of South Florida, said that surgeons can help ensure optimal care by refusing to perform surgery on patients who smoke. As a result of his refusal, he said that 40% of his patients have stopped smoking.

Richard D. Hurt, M.D., professor of medicine and director of the Nicotine Dependence Center at Mayo Clinic, outlined a three-step process that clinicians can initiate to help their patients stop smoking. "First, ask about tobacco use," said Hurt. "Have your receptionist ask, your nurse ask, your physician's assistant ask, and you ask—even if you already know the answer. Asking shows the patient that smoking is a serious problem that must be addressed. Then, advise the patient to stop smoking. Don't just say, 'you know, you ought to consider stopping someday.' Tell the patient, 'you need to stop smoking.' Finally, because smokers are going to push back, it's important to offer help."

David O. Warner, M.D., associate dean for clinical and translational science at Mayo Clinic, urged the Academy to replicate the American Society of Anesthesiologists' (ASA) Smoking Cessation Initiative which, he said, strives to offer smoking cessation assistance to every patient who smokes. "Smoking is the most costly and most preventable risk factor in postoperative complications," said Warner. "Surgery is a teachable moment—one we need to capitalize on."

*—BY (April 20, 2012)*

## Female Knees More Vulnerable Than Males

If you are a woman skier you are more likely than men to injure a knee while skiing. Moreover, it is likely that the injury will be on your non-dominant leg. Early studies have shown that women are twice as likely as men to hurt a knee during downhill ski crashes, and three times as likely to tear the knee's anterior cruciate ligament, or ACL.

Now the lead author of a study at the University of Innsbruck, Austria, Gerhard Ruedl and his colleagues, have collected information from close to 200 recreational skiers who tore their ACL while skiing in Austria. They found that men were about equally likely to have injured their left knee as their right, although 87% of them were right-leg dominant.

Most of the women studied, 91%, were also right-leg dominant, but twice as many women as men injured their left ACL as their right. Robert Johnson, M.D., a sports medicine physician at the University of Vermont College of Medicine said the discrepancy could be caused by "anatomy, strength patterns, muscle patterns, wider pelvis...it all adds up."

Skiing ability and the skiers' physical fitness did not appear to influence the injury locations, leading the authors of the study to conclude that the sex of the skier was responsible for the differences. Ruedl said that women have greater body asymmetry than men with

*Wikimedia Commons and M.O. Hammond*

regard to strength and proprioception, the sense of how the body—in this case, the knee—is positioned. He suggested that this could make women more vulnerable to the strain that is put on the non-dominant knee as a skier turns.

He recommends that to prevent injuries women skiers should do strength and balance training on their non-dominant leg to reduce differences between the legs. Johnson is skeptical that strength training could reduce ACL injuries for female skiers, "It makes sense that the stronger you are the less likely you are to be injured," he said in the April 6 new release, "but who has the highest incidence of ACL tears? It's ski racers."

*—BY (April 17, 2012)*

trauma

## OA: 32 Genetic Regions Identified

Team OA! A worldwide consortium of researchers—180, in fact—has identified 32 genetic regions associated with osteoporosis and fracture. The research shows that osteoporosis results from the combined contributions of dozens, if not hundreds, of genes. It also suggests many new avenues for anti-osteoporosis drug development.

"We're learning that the genetic architecture of disease is very complex," said John Ioannidis, M.D., DSc., director of the Stanford Prevention Research Center, in the April 15, 2012 news release. Dr. Ioannidis is one of seven senior authors of the study and the methodological leader of the consortium. The research will be published online April 15 in *Nature Genetics*.

*Wikimedia Commons and RSJThompson*

This prospective meta-analysis involved more than 100,000 participants. While the team identified six regions strongly correlated with the risk of fractures of the femur or lower back, they indicate that the predictive power of the study for individuals is relatively low.

"As a result," said Ioannidis, "the next step of incorporating this information into basic patient care is not clear. Each variant conveys a small quantum of risk or benefit. We can't predict exactly who will or won't get a fracture."

"The real power of our study lies in the ability to generate prospectively a huge combined data set and analyze it as a single study," said Ioannidis. "It's likely that our expectations have been too high in terms of what single studies can accomplish. Each one of the many teams identified at most only one or two markers; many found none."

"In reality, there may be 500 or more gene variants regulating osteoporosis," said Ioannidis. "To find all of them, we'll need to study millions of patients. Is this unrealistic? I don't think so. Sooner or later this will be feasible."

In this study, the researchers found that people with the highest number of variants associated with decreased bone mineral density were about 1.56 times more likely than people with an average number of variants to have osteoporosis, and those with the most of those variants associated with fracture risk were about 1.60 times more likely to have experienced fractures. Compared with those who had the fewest associated variants, they were about four times more likely to have either osteoporosis or a fracture.

Asked what he was most surprised to learn, Dr. Ioannidis told *OTW*, "Probably the fact that the genetic architecture of osteoporosis and fracture risk is so complex. In the early years we were thinking of a few genes dictating the process, Nature had even published a paper in the mid-90s that featured in its cover page the title 'the osteoporosis gene' claiming that a single gene had been identified that could account for 75% of the risk of osteoporosis. The picture we get now suggests that several hundreds of genes may be involved in regulating bone density and fracture risk."

*—EH (April 26, 2012)*

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