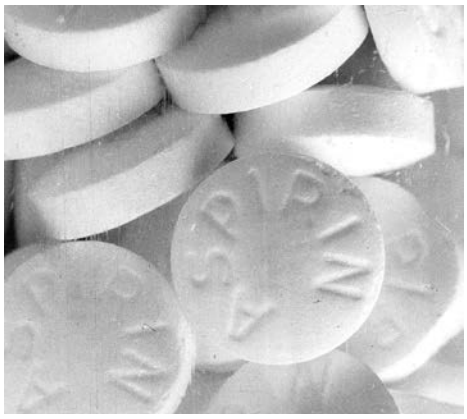
VOLUME 8, ISSUE 33 | OCTOBER 16, 2012

# Orthopedics This Week

## week in review






## breaking news



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

# Orthopedic Power Rankings

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

**THIS WEEK:** Something good is happening among orthopedic companies. We think. Companies with cash to spend are starting to buy. Certainly valuations are attractive. But something has shifted, we think, in board room thinking. We are picking up an increased willingness to buy orthopedic products, distribution or entire companies.

| RANK | LAST WEEK | COMPANY | TTM OP MARGIN | 30-DAY PRICE CHANGE | COMMENT |
|---|---|---|---|---|---|
| 1 | 1 | Globus Medical | 30.06% | 8.16% | FDA's PMA approval of Globus' artificial cervical disc is significant. Especially in front of the NASS meeting later this month. |
| 2 | 2 | Medtronic | 28.65 | 3.36 | MDT entering the broader orthopedic market? Wall Street traders hint that MDT is eyeing smaller, cheaper ortho franchises. |
| 3 | 3 | ArthroCare | (0.80) | 7.65 | Everything's riding on the longer term growth rate for ARTC. Consensus is for a 19% annual sustainable earnings increase. |
| 4 | 4 | Orthofix | 16.23 | (0.12) | JMP Securities initiates coverage with an Outperform. Analysts predicting double-digit earnings growth this year. |
| 5 | 10 | Conmed | 10.39 | 2.94 | CNMD is one of those companies that is starting to buy assets. Most recently Viking Systems. |
| 6 | 8 | Exactech | 7.68 | 0.12 | EXAC is a company whose valuation, in terms of price-to-sales, is low—3rd lowest in ortho. |
| 7 | 7 | Symmetry Medical | 5.63 | (0.51) | Like ARTC, Wall Street is expecting above average earnings growth from SMA—which hinges largely on Codman's integration. |
| 8 | 5 | Zimmer | 26.37 | (4.90) | $1.3 billion in cash and $1.1 billion in annual cash flow. ZMH should be buying small to medium size ortho assets. |
| 9 | 6 | Smith & Nephew | 21.36 | (4.65) | While ortho companies are starting to buy, SNN is selling/spinning off. Could wound care split from ortho? |
| 10 | 9 | Stryker | 23.68 | (3.90) | How will Lobo make his mark at SYK? There are plenty of valuable ortho assets available. Will SYK also step up M&A? |

# Robin Young's Orthopedic Universe

## TOP PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|---|---|---|---|---|---|
| 1 | TiGenix | TIG.BR | $1.07 | $102 | 54.44% |
| 2 | TranS1 | TSON | $2.95 | $80 | 22.92% |
| 3 | RTI Biologics Inc | RTIX | $4.56 | $255 | 13.72% |
| 4 | CryoLife | CRY | $6.12 | $168 | 9.68% |
| 5 | Globus Medical | GMED | $17.63 | $1,595 | 8.16% |
| 6 | ArthroCare | ARTC | $32.50 | $901 | 7.65% |
| 7 | Medtronic | MDT | $43.05 | $43,917 | 3.36% |
| 8 | Conmed | CNMD | $28.37 | $806 | 2.94% |
| 9 | Alphatec Holdings | ATEC | $1.75 | $157 | 1.74% |
| 10 | Wright Medical | WMGI | $21.33 | $845 | 1.62% |

## WORST PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|---|---|---|---|---|---|
| 1 | NuVasive | NUVA | $14.08 | $612 | -34.78% |
| 2 | Bacterin Intl Holdings | BONE | $1.37 | $58 | -16.97% |
| 3 | MAKO Surgical | MAKO | $14.95 | $638 | -16.34% |
| 4 | Zimmer Holdings | ZMH | $62.26 | $10,876 | -4.90% |
| 5 | Smith & Nephew | SNN | $52.29 | $9,421 | -4.65% |
| 6 | Stryker | SYK | $52.30 | $19,897 | -3.90% |
| 7 | Tornier N.V. | TRNX | $18.88 | $750 | -3.13% |
| 8 | Integra LifeSciences | IART | $39.01 | $1,055 | -2.89% |
| 9 | Symmetry Medical | SMA | $9.75 | $357 | -0.51% |
| 10 | Johnson & Johnson | JNJ | $67.97 | $187,396 | -0.26% |

## LOWEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|---|---|---|---|---|
| 1 | Zimmer Holdings | ZMH | $62.26 | $10,876 | 12.30 |
| 2 | Medtronic | MDT | $43.05 | $43,917 | 12.77 |
| 3 | Stryker | SYK | $52.30 | $19,897 | 13.44 |
| 4 | Johnson & Johnson | JNJ | $67.97 | $187,396 | 13.49 |
| 5 | Orthofix | OFIX | $42.13 | $799 | 14.38 |

## HIGHEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|---|---|---|---|---|
| 1 | Wright Medical | WMGI | $21.33 | $845 | 82.04 |
| 2 | Symmetry Medical | SMA | $9.75 | $357 | 57.35 |
| 3 | NuVasive | NUVA | $14.08 | $612 | 42.67 |
| 4 | RTI Biologics Inc | RTIX | $4.56 | $255 | 25.33 |
| 5 | Exactech | EXAC | $16.99 | $225 | 20.98 |

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

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|---|---|---|---|---|
| 1 | Orthofix | OFIX | $42.13 | $799 | 0.92 |
| 2 | ArthroCare | ARTC | $32.50 | $901 | 1.05 |
| 3 | Zimmer Holdings | ZMH | $62.26 | $10,876 | 1.27 |
| 4 | Globus Medical | GMED | $17.63 | $1,595 | 1.28 |
| 5 | Stryker | SYK | $52.30 | $19,897 | 1.36 |

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

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|---|---|---|---|---|
| 1 | Wright Medical | WMGI | $21.33 | $845 | 7.96 |
| 2 | CryoLife | CRY | $6.12 | $168 | 5.10 |
| 3 | Symmetry Medical | SMA | $9.75 | $357 | 4.78 |
| 4 | NuVasive | NUVA | $14.08 | $612 | 4.05 |
| 5 | Smith & Nephew | SNN | $52.29 | $9,421 | 3.72 |

## LOWEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|---|---|---|---|---|
| 1 | Alphatec Holdings | ATEC | $1.75 | $157 | 0.80 |
| 2 | Symmetry Medical | SMA | $9.75 | $357 | 0.99 |
| 3 | Exactech | EXAC | $16.99 | $225 | 1.10 |
| 4 | Conmed | CNMD | $28.37 | $806 | 1.11 |
| 5 | NuVasive | NUVA | $14.08 | $612 | 1.13 |

## HIGHEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|---|---|---|---|---|
| 1 | TiGenix | TIG.BR | $1.07 | $102 | 89.13 |
| 2 | MiMedx Group | MDXG | $2.70 | $231 | 29.73 |
| 3 | MAKO Surgical | MAKO | $14.95 | $638 | 7.55 |
| 4 | Globus Medical | GMED | $17.63 | $1,595 | 4.81 |
| 5 | TranS1 | TSON | $2.95 | $80 | 4.20 |

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

# The Top 29 Orthopedic Traumatologists in the U.S.

By OTW Staff

*Andrew Huth for RRY Publications LLC*

Orthopedic traumatology has made great strides in the last 15 years. Much of this progress is due to the people who appear on our list this month. Those in the know about trauma gave us their thoughts on the best orthopedic surgeons in their subspecialty.

*Here is that list. We don't have "the market" on lists…this isn't the be-all and end-all list—but it is a list of the most impressive orthopedic trauma surgeons in the country. This information was obtained via a telephone survey of thought leaders in the field. The information in quotes is what we heard about these surgeons.*

In alphabetical order, here are the top 29 orthopedic traumatologists in the United States.

**Jorge E. Alonso, M.D.** is a professor of orthopaedic surgery and director of orthopaedic trauma at the University of South Alabama, College of Medicine in Mobile, Alabama. "He does great pelvic and acetabular work; he is also known for some minimally invasive and computer assisted work. He is a great teacher, an engaging person, and has a super work ethic."

**Jeffrey O. Anglen, M.D.** is a professor in the department of orthopaedic surgery at the Indiana University School of Medicine. He is a past president of the Orthopaedic Trauma Association (OTA). "He has been a leader in orthopedic trauma education, was previously chairman of orthopaedic surgery at Indiana University, and has developed training modules for residents and attendings, and has been integral in trauma education throughout the world, especially in underprivileged countries."

**Michael T. Archdeacon, M.D., M.S.E.** is director of the Division of Musculoskeletal Traumatology at the University of Cincinnati Medical Center. He

is also professor and vice chairman of orthopaedic surgery at the University of Cincinnati College of Medicine and chief of staff at University Hospital of Cincinnati. "He is very talented and approaches cases in a very thoughtful manner. He has published in the areas of the pelvis and acetabulum. It's also nice that he's a humorous guy without any hint of cockiness."

**David E. Asprinio, M.D.** is chief of orthopaedic surgery at Westchester Medical Center in New York. He is also Chairman and Program Director of New York Medical College - Department of Orthopaedic Surgery. He is an attending orthopedic surgeon at Sound Shore Medical Center in New Rochelle and the Hospital for Special Surgery in Manhattan. "He is a renowned orthopaedic trauma surgeon who is an excellent and most exacting surgeon. He is actively involved in training orthopaedic residents and fellows in trauma care and surgery and is sought after nationally and internationally as an educator. He is also extensively involved in the medical management of The Westchester Medical Center."

**David P. Barei, M.D.** is an associate professor of orthopaedics and sports medicine at the University of Washington in Seattle/Harborview Medical Center. "He is a terrifically hardworking traumatologist, a solid clinician, and a very good teacher. I would say that clinically, he is one of the best in the country."

**Stephen K. Benirschke, M.D.** is a professor of orthopaedics and sports medicine at the University of Washington in Seattle/Harborview Medical Center. "He is THE technical wizard in Seattle. He is an outstanding person, and is known for his work with intra-articular fractures."

**Mark R. Brinker, M.D.** is an orthopedic surgeon with the Texas Orthopedic Hospital in Houston; he also holds appointments with Hermann Hospital, The Methodist Hospital and Texas Children's Hospital. "He is a very interesting person who is an expert in Ilizarov techniques. He is very smart, and does a huge number of posttraumatic reconstructions. He is also more well published than people realize."

**Lisa K. Cannada, M.D.** is an associate professor of orthopaedic traumatology at the St. Louis University School of Medicine in Missouri. She is also an orthopaedic traumatologist at St. Louis University Hospital and St. John's Mercy Medical Center in St. Louis. Dr.

Cannada is on the board of directors of the Orthopaedic Trauma Association. "She consistently delivers high quality results, is a real luminary in our field, and has altered how we handle trauma cases."

**Cory A. Collinge, M.D.** is an orthopedic surgeon with Orthopedic Specialty Associates in Fort Worth, Texas. He is director of orthopaedic trauma at Harris Methodist Fort Worth Hospital. "He is a very good traumatologist who has published quite a lot. He does good design work, and does a consistently high quality surgery work."

**James A. Goulet, M.D.** is a professor of orthopaedic surgery at the University of Michigan. He serves on the board of directors of the OTA. "He has meticulous attention to detail, and is very thoughtful. Instead of focusing on innovation, he makes sure that our generation of surgeons is learning to do things right. He is known for his pelvic and acetabular surgery."

**David J. Hak, M.D., M.B.A.** is professor and associate director of orthopaedics at Denver Health Medical Center/ University of Colorado. He is the chief financial officer of the OTA. "He is an excellent orthopedic trauma surgeon who won't accept reductions that aren't where they need to be. He is a real leader who shows a great attention to detail."

**David L. Helfet, M.D.** is professor of Orthopaedic Surgery at Weill Cornell Medical College and director of the Orthopaedic Trauma Service at both Hospital for Special Surgery and New York-Presbyterian Hospital. He is a former president of the OTA. "He is known for pelvic and acetabular fracture work, as well as nonunions. He has done a lot of research looking at DVT [deep vein thrombosis] prevention in those patients and did a lot of the early work in techniques of reconstruction. He is a recognized leader."

**Clifford B. Jones, M.D.** is an orthopedic surgeon at Orthopaedic Associates of Michigan in Grand Rapids. He is also an adjunct professor at the Van Andel Research Institute. "He is underappreciated, and is in fact one of the most clinically active trauma surgeons around. He has been working hard for six years to develop good prospective outcome data. He is really a phenomenal surgeon and we will hear a lot about him in the next five years."

**Philip J. Kregor, M.D.** is an orthopedic surgeon with the Hip and Fracture Institute in Nashville, Tennessee; he is the founder of this practice. "He is known for surgeries around the hip, pelvis and acetabulum, as well as the anterior approach for joint replacement in hip fractures. He is technically a very good surgeon."

**Mark A. Lee, M.D.** is an associate professor of orthopaedic surgery and trauma fellowship director at the University of California, Davis. He is chair of the Fellowship and Career Choices committee of the OTA. "He is an excellent clinician, and a good researcher who has been very active in the OTA. He has done a lot towards organizing the OTA fellowship."

**David Lowenberg, M.D.** is a clinical professor of orthopaedic surgery and chief of the orthopaedic trauma service at Stanford University. "He does a lot of work on nonunions, infections, segmental defects and bone transport; he has published extensively. He has done a lot in concert with plastic surgeons… a lot of collaborative reconstruction work. And he does not have a big ego, even though he has every reason to be a total jerk."

**J. Lawrence Marsh, M.D.** is a professor of orthopedic surgery and the Carroll B. Larson chair of orthopedic surgery and director of the Orthopaedic Residency Training Program at the University of Iowa Hospitals and Clinics. "He has done a lot with external fixation and is a phenomenal researcher. He is a well respected surgeon who has done a lot of translational work, finding clinical problems and then going to lab and working through them."

**Robert F. Ostrum, M.D.** is professor of orthopaedic surgery and director of orthopaedic trauma at Cooper University Hospital in Camden, New Jersey. "He is an excellent clinician and researcher who has refined techniques for femoral nailing. He is very active in the OTA and is a very reliable guy."

**Robert A. Probe, M.D.** is chair of the department of orthopedic surgery at Scott & White Healthcare in Temple, Texas. He is also director of the Scott & White Healthcare Board of Trustees, and chairman of the Memorial Hospital Board. He is currently president of the OTA. "He is known for osteotomies and complicated trauma cases. He has outstanding leadership skills and has really helped the OTA get to the next level… and get more activities finished."

**William M. Ricci, M.D.** is a professor of orthopedic surgery, chief of the orthopedic trauma service, and director of the orthopedic trauma fellowship at Washington University in St. Louis. He is chair of the education committee for the OTA. "He is a tremendous researcher, and has designed implants and successfully brought advances to the field. He is also a phenomenal educator and just last year won the teaching award from the residents at his institution."

**M.L. Chip Routt, Jr., M.D.** will soon join the University of Texas at Houston/Memorial Hermann-Texas Medical Center Hospital where he will be a professor of orthopedic surgery. "He is known for his pelvic and acetabular work, has published extensively, and has developed important procedures. He has done a lot basic research on how to do pelvic surgery correctly."

**Roy W. Sanders, M.D.** is president and cofounder of the Florida Orthopaedic Institute in Tampa. Dr. Sanders is a past president of the OTA and is currently serving as director of the Orthopaedic Trauma Service, and chief of the department of orthopaedics at Tampa General Hospital. "He is known as an innovator, and has defined treatment for calcaneal fractures; he also does great foot and ankle surgery."

**Andrew H. Schmidt, M.D.** is a professor of orthopaedic surgery at the University of Minnesota in Minneapolis. He is president-elect of the OTA. "He is an all around traumatologist, but does especially good work around the shoulder and knee. He has great leadership and organizational skills."

**Alexandra Schwartz, M.D.** is clinical professor of orthopaedic surgery and chief of orthopaedic trauma at the University of California, San Diego. "She is known as an orthopedic trauma educator and for doing all types of complex fractures. She is an excellent clinical traumatologist."

**James P. Stannard, M.D.** is chair of the department of orthopaedic surgery and the J. Vernon Luck Sr. Distinguished Professor in Orthopaedic Surgery at the University of Missouri School of Missouri in Columbia. He is chair of the Bylaws and Hearings committee of the OTA. "He has changed traumatology, and has given us information on the way we should treat dislocated knees. He does a good job of combining sports medicine and trauma."

**Adam Starr, M.D.** is a professor of orthopaedic surgery at the University of Texas Southwestern Medical Center. "He is a very accomplished traumatologist, particularly in the pelvic and acetabular realm; he is well published in these areas. He is a pioneer in percutaneous fixation of the pelvis and acetabulum."

**David C. Templeman, M.D.** is an assistant professor in the department of orthopaedic surgery at the University of Minnesota; he practices at the Hennepin County Medical Center. Dr. Templeman is a past president of the OTA. "He has a good old fashioned way of training fellows so that they learn the importance of surgical planning."

**Paul Tornetta, III, M.D.** is a professor, vice chairman, and residency program director in the department of orthopaedic surgery at Boston University School of Medicine; he is also director of orthopaedic trauma for the Boston Medical Center. Dr. Tornetta is a former president of the OTA. "He has an endless amount of energy and has made tons of contributions to our field. He selects an area of the body and researches it exhaustively."

**J. Tracy Watson, M.D.** is a professor of orthopaedic traumatology, fellowship director, and chief of the orthopaedic traumatology division at the St. Louis University School of Medicine. He is a former president of the OTA. "He specializes in tibial fractures, has developed an external fixator system and retrograde nails. He has published extensively and is very involved in orthobiologics. He is a real surgeon's surgeon in terms of fixing nonunions and malunions." ♦

# Investigator Hits Back at Study Sponsor

By Walter Eisner

*Wikimedia Commons and ArtBrom*

*The New York Times* published a story in early September about a disagreement between Daryl Fourney, M.D. and Vertos Medical, Inc. over the publication of a case study of patients undergoing Vertos' "mild" procedure. On September 18, Vertos' CEO Jim Corbett told us his side of the story.

Corbett cited errors on the *Times* story and left us wondering why this ten person case study was worthy of coverage in America's "Newspaper of Record."

This week Dr. Fourney tells his side. He had a lot to say.

*Daryl Forney, M.D./University of Saskatchewan*

## The "Mild" Study

A quick review.

In November 2007, the University of Saskatchewan approved a pilot study of ten patients who were on a waiting list for laminectomy with fusion surgery. The University reviewed the proposed study protocols, including a six-month endpoint, and approved the study plan.

Vertos' "mild" procedure treats lumbar spinal stenosis by removing portions of the lamina and ligametum flavum to restore space in the spine.

## Publishing Disagreement

After the endpoint of the study was hit, Dr. Fourney wanted to include infor-

mation obtained after the study that six out of the ten patients needed surgery. The company objected to including post-study data. Dr. Fourney disagreed and the company filed a complaint with Dr. Fourney's University. His study was eventually published in the journal *Neurosurgery* as a case study and included his information about the needed follow up surgery.

## *NY Times*: Intimidation, Cover-Ups and Product Safety

The *Times* reported, the situation was, "a glimpse into the sometimes contentious world of medical testing and the federal rules that allow device makers to market new products with little or no data about their long-term effectiveness or safety."

The *Times* further reported that the company tried to intimidate Dr. Fourney by filing a formal complaint with the University of Saskatchewan. "Vertos accused Dr. Fourney of scientific misconduct and violating 'research ethics' by failing, among other things, to follow the study's original protocol and by independently deciding to follow his patients for added time without seeking agreement from Vertos," wrote Barry Meier, the *Times* reporter.

The *Times* also quoted *The Spine Journal* Editor Eugene Carragee, M.D. saying, that the intensity of the complaints by Vertos about Dr. Fourney reminded him "of a time not that long ago when a manufacturer could prevent a study with negative results from being published."

Charges of intimidation, cover-up of clinical evidence and federal rules allowing products with no data about safety and effectiveness got our attention and we dug in.


*Wikimedia commons and Haxorjoe*

## Intimidation

Was this, as Dr. Carragee asserts, an example of corporate misconduct? Or is it a case of a misunderstanding?

Vertos' Corbett told us that the company did not file a formal complaint against Dr. Fourney and only sent a letter to him and the University about his plan to include data in his report past the study endpoint.

Dr. Fourney says that isn't true and the company did indeed file a formal complaint against him with his employer.

"The *Times* characterized this correctly. Mr. Corbett does not," said Dr. Fourney. He said the letter referenced by Corbett was not where the company lodged the complaint against him to the University.

"The formal registration of complaint of scientific misconduct from Mr. Corbett and Vertos is in a separate letter…It was addressed to the President of the University of Saskatchewan with a copy to the Chair of the Research Ethics Board. It states, 'Dear Peter [MacKinnon]: I am writing to register a formal complaint of scientific misconduct against your faculty, Dr. Daryl Fourney.'"

"Either Mr. Corbett has forgotten about his own letter or he is attempting to mislead readers of *Orthopedics This Week*," said Dr. Fourney.

## "I Forgot"

Corbett went with the memory excuse.

"For clarification, I did forget that I sent this additional letter," Corbett said. "That was my mistake. At the end of the day, none of this changes the fact that my concerns were based on a sincere disagreement over the science, or lack thereof, behind Dr. Fourney's study."

Did Dr. Fourney think the company was trying to intimidate him? Was he intimidated?

"Yes and yes. Any professor would feel intimidated by an allegation of scientific misconduct. This was not a mere disagreement regarding 'the science' as Mr. Corbett attempts to portray. Rather, Vertos has questioned my credibility," said Dr. Fourney.

## Unsafe Devices Without Data

Did Dr. Fourney agree with the *Times*' characterization of this being an example of implanting new products into patients with no data about safety?

"I generally agree with this statement from *The New York Times*, said Dr. Fourney. "However, the published data on "mild" shows that it is safe in large numbers of patients. There is only one anecdotal note from BNI in a letter to the editor of *Pain Physician* that really questions safety. However, BNI has not done a clinical study as of yet. I have never disputed that "mild" appears to be relatively safe in the published studies—the main question is how effective it is. If the effectiveness long term is low, then it is questionable how much risk, if any, is acceptable."

## Study Disagreements

What about including data after the endpoint of the study was hit?

Dr. Fourney says whoever tipped off the *Times* must have read his response to Dr. Chopko's letter to *Neurosurgery*. (See Fourney DR. In reply *Neurosurgery* 2012; 71:E526-8.)

"Dr. Chopko asked why the article included data after the study closure at six months. I explained that after the study closed, I kept seeing patients with refractory neurogenic claudication. I felt this was important for patients and physicians to know about this, and my Research Ethics Board (REB) agreed. Although Vertos did not want to extend the study protocol, the REB determined that it was my ethical obligation to include the reoperation results as 'post-study' outcomes."

## Cover Up?

Corbett said that he didn't try to keep Dr. Fourney from publishing his results in a report. He just didn't want it part of the study because revising the protocol retrospectively would have been difficult.

"[That's] not entirely true, said Fourney. "They did not want me to report on the need for reoperation after six months, despite the Research Ethic's Boards' confirmation that it was my ethical obligation to report it.

Did he speak with Dr. Carragee about this?

"I spoke to several academic colleagues, in confidence, about my problems with Vertos trying to prevent my results from being published through several means including the misuse of allegations of academic misconduct." He agrees with Dr. Carragee's description on the *Times* that Vertos has a "poor or odd understandings of what the ethical responsibilities of a researcher are or this was a naked attempt at intimidation."



Dr. Fourney said he believed the *Times* story was fair because both side were able to weigh in. "Your method of interviewing me with these questions after publishing Vertos' side is clearly biased."

## Fourney's Rebuttals

Dr. Fourney added that he went to his Research Ethics Board to get their opinion on what to do about the post-study need for reoperation, and received their memorandum agreeing that it was his ethical obligation to report this data. "We never breached the protocol of the original study. The findings after six months were described in the article as 'post-study outcomes.'" He disputes the suggestion that his study was not FDA-registered, but it was only post-study events that were not part of the FDA-registered protocol."

## Study Size

He takes issue with the description of the study as having methodological limitations because it only involved ten patients, while the limitations of the Vertos-funded research, which he described in detail in his response to Dr. Chopko's letter, including serious conflict of interest oversights, have not been mentioned. (See Fourney DR. In reply Neurosurgery 2012;71:E526-8.).

He points out that enrollment was ceased after he realized that MRIs showed no decompression and many patients had refractory neurogenic claudication."

## Case Series Versus Clinical Study

He also takes issue with Vertos' description of the study as a "case series" rather than a clinical study. "All studies lacking a control group are essentially case series. This includes all of the "mild" studies with the exception of one small randomized trial that compared "mild" to epidural steroid injection. Despite the positive 'conclusions' of that study, after analysis of variance with repeated measures, there were no significant between group differences (PRLL vs. ESI) for average VAS improvement ($P = 0.54$) or ODI ($P = 0.86$). The mean ZCQ patient satisfaction score also showed no statistically significant between group differences at week six ($P > 0.05$). (See Brown LL. A Double-blind, Randomized, Prospective Study of Epidural Steroid Injection vs. The mild® Procedure in Patients with Symptomatic Lumbar Spinal Stenosis. Pain Pract 2012.)"

Dr. Fourney says a key finding of his study, which he says has not been challenged, is that the "mild" procedure did not produce any measurable decompression on post-op MRI.

## Corporate Sponsorship

Vertos said Dr. Fourney received a grant to fund his work, but that the grant did not come from them.

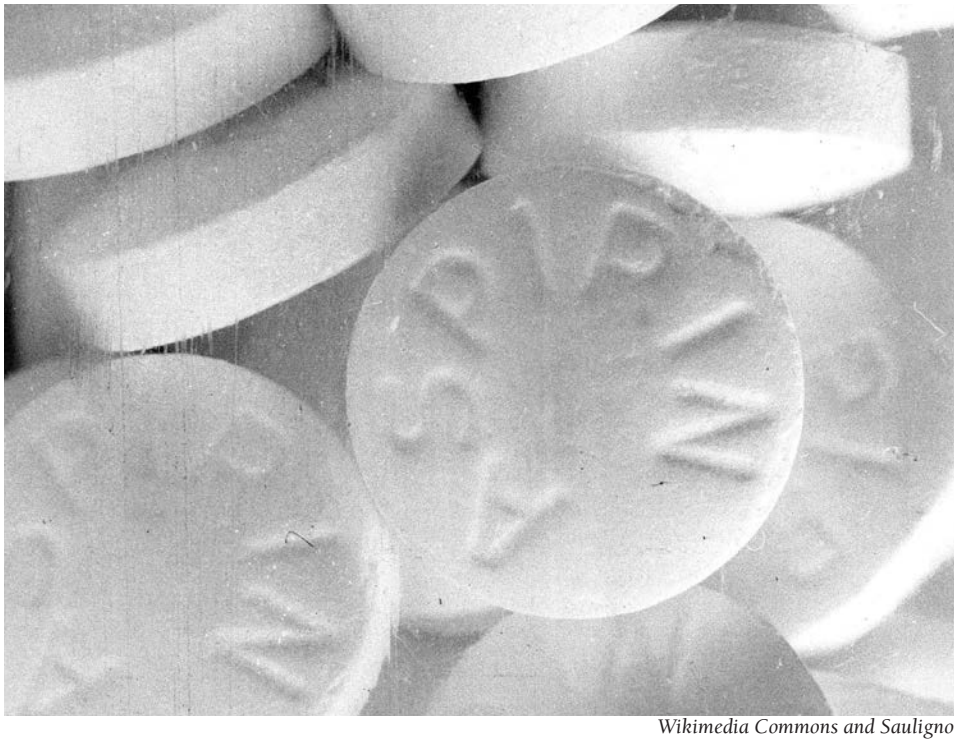
Dr. Fourney said this is "another key factual flaw." He said this suggests that some other competitor may have funded this work. "The contract with the University of Saskatchewan clearly names Vertos as the sponsor."

After hearing directly from the company and Dr. Fourney, we are still left scratching our heads wondering who wanted this in *The New York Times* and why the paper saw this case in Canada as an example of U.S. rules that "allow device makers to market new products with little or no data about their long-term effectiveness or safety." ♦

# Surprise! No Surgery for Epidural Abscesses, All You Need Is Aspirin!...and More

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

Surprise! No Surgery Required for Epidural Abscesses...All you need is Aspirin!? Really?...Traumatologists Tests Generics and Report Huge Savings….and More…



*Wikimedia Commons and Sauligno*

**Surprise! No Surgery Required for Epidural Abscesses** Christopher Bono, M.D. is chief of orthopaedic spine at Brigham and Women's Hospital. In collaboration with one of his partners, Mitchel Harris, M.D., the principal investigator of the study and one of their outstanding residents, Sang Kim, M.D., Dr. Bono has found a way to spare patients unnecessary surgery. He tells *OTW*, "We see a lot of patients with epidural abscesses in our hospital; in addition, there has been some recent literature suggesting that nonoperative treatment might be a good option for these patients, instead of 'surgery for all.' Interestingly, physicians on the medical service feel uncomfortable if we do not operate on these patients. The fact is, however, that many patients can be successfully treated with antibiotics alone."

"Our research, which we will soon submit for publication, was a very large retrospective study; in this first phase we looked at patients treated nonoperatively, and specifically examined which characteristics led to failure and which led to success. We found that diabetes, age greater than 65 years, MRSA infection, and neurological compromise were associated with failure of nonoperative treatment. Conversely, if someone did not fulfill these criteria then they had a high chance of succeeding with nonoperative care. It was really surprising how strong of a cohort of patients we found that could be treated nonoperatively. Honestly, if you ask 8 out of 10 spine surgeons about what to do in these situations, they would say, 'Operate!' We will continue to develop this instrument, have it published, and analyze it to see how well it works prospectively."

**All You Need Is Aspirin!? Really?** Javad Parvizi, M.D., director of research for The Rothman Institute in Philadelphia, tells *OTW* of his revolutionary new work. "My colleagues and I have just completed a study showing that aspirin is as good as any other medication at preventing blood clots in joint replacement. We looked at 26,000 patients in this single center study; the fact that aspirin can prevent DVT [deep vein thrombosis] or pulmonary embolism is a huge revelation. This means that going forward we can avoid giving toxic drugs to our patients. Those at the highest risk will still need something more than aspirin, of course."

"My colleagues and I undertook this study because we were seeing a lot of patients coming in with bleeding after taking drugs that were aimed at pre-

venting them from developing problems in the first place. It was surprising to see that the majority of patients were returning to us due to bleeding issues and hematomas as opposed to venous thromboembolism. We will be presenting our results at the American Academy of Orthopaedic Surgeons meeting in 2013; this is very exciting indeed, and it will be practice-changing."

**Rick Epstein New President, CEO at Sonoma** Sonoma Orthopedic Products, Inc. has announced that Rick Epstein will lead the company as President and Chief Executive Officer, thus succeeding Glen Coleman. Epstein was also named to the Board of Directors.

Prior to joining Sonoma Orthopedic Products, Epstein was CEO at Ellman International, a privately held medical device company. He has also served as Vice President and General Manager at V. Mueller (Cardinal Health) and has held senior executive positions at Cardinal Health, Intuitive Surgical and Baxter Healthcare. Epstein earned an MBA from University of Chicago, an MS in Mechanical Engineering from Stanford University and a BS in Engineering from the University of Illinois.

**Traumatologists Test Generics and Report Large Savings** Peter Althausen, M.D. is lead author on a new study that may lead the way in cost savings for the U.S. healthcare system. Dr. Althausen, a traumatologist with the Reno Orthopaedic Clinic tells *OTW,* "This year the Orthopaedic Trauma Association announced that its new focus is on safety, quality, and cost containment. This is critical because over the past ten years payments to doctors and hospitals have decreased while payment to implant companies have increased. My trauma colleagues and I are extremely concerned that our system can't pay for the patients we are taking care of. In some markets, six out of nine emergency rooms have closed in the last ten years because they can't pay for indigent care."

"We worked with colleagues from the University of Nevada School of Medicine and did two studies where we utilized generic screws from The Orthopaedic Implant Company (OIC). What we are extremely interested in is helping to decrease the cost of medical care. In a system where implant companies and reps are paid regardless of whether or not the providers and facilities get paid, something is wrong."

"In the first study we had 45 femoral neck fracture patients treated with generic 7.3 mm cannulated screws made by OIC that were compared to 50 patients treated with screws made

by traditional companies. We examined things like time in the OR, blood loss, complication rate, and length of stay. Everything was the same except for cost…the hospital saw a 67% cost reduction by using OIC's generic screws! This resulted in an annual savings of $34,653 for the hospital…and that's just for ONE operation."

"In the other study we compared 35 patients treated with generic cannulated screws from OIC with 44 patients treated with conventional screws for posterior pelvic ring injuries. In the generic group, surgeons implanted 45 screws and 40 washers. In the conventional group surgeons implanted 59 screws and 50 washers. A blind reviewer found there was no increase in operative time, estimated blood loss, complication rate, screw cutout, screw deformation or screw loosening. For the hospital this meant a 73% cost reduction, which translates to an annual savings of $14,472."

"The average drill bit we use costs around ten dollars to make—the big manufacturers sell it for $96—it's just crazy. Note that these generic implants were biomechanically tested by an independent lab before we used them. The average doctor doesn't know that all of the big companies make their screws, plates, and rods in the same manufacturing facilities…the one selling for $1,000 was made on the same machine that the one selling for $200. Final thought: the market for cannulated screws is $393 million. Just imagine how much can be saved by using generics."



**Stem Cells for Extreme Foot and Ankle Problems** Chris Coetzee, M.D. is a foot and ankle specialist at Twin Cities Orthopedics in Minneapolis. He tells *OTW*, "My colleagues and I were seeing a number of complex nonunions and there were just not many options if someone has already had multiple surgeries. I had a patient who was scheduled for an amputation; this person was obviously interested in another option. I had just heard about using stem cells in these situations and we went forward and we were able to save this person the trauma of an amputation."

"This study evolved from that experience, and is the first prospective randomized study to compare autologous bone graft to stem cells for fusions (the study only involves subtalar fusions). We are two-thirds of the way through the study, but at this point we can say that the stem cells are at least equal to the autologous bone graft. Each patient will be followed for three or four years afterwards, and will undergo periodic CT scans to evaluate their progress."

**Lawrence Crossett, M.D. To Be Honored** The University of Pittsburgh has announced that Dr. Lawrence Crossett, chief of the Adult Reconstruction Division within the Department of Orthopaedic Surgery at the University of Pittsburgh Medical Center, is the medical honoree for the 2012 Bone Bash. Dr. Crossett is also Assistant Professor of Orthopaedic Surgery at the University of Pittsburgh School of Medicine. He specializes in joint replacement surgery of the hip and knee as well as complex revision/reconstruction of those joints. Dr. Crossett has been consistently named as one of America's Top Doctors and one of Pittsburgh's Top Doctors. This event will take place at the Clear Story Studio in Pittsburgh on October 19, 2012. ♦

# Murphy v. Dunbar on Femoral Neck Modularity in THA

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

"These types of implants have served patients well, and we have good clinical data to support that," argues Stephen Murphy. "No!" counters Michael Dunbar. "The use of modular necks in primary routine arthroplasty isn't justified because there's no proof of superiority, increased risks, and increased cost."

This week's Orthopaedic Crossfire® debate is "Femoral Neck Modularity in THA: The Missing Link." For the proposition was Stephen B. Murphy, M.D. from Tufts University in Boston. Against the proposition was Michael J. Dunbar, M.D., F.R.C.S.(C), Ph.D. of Dalhousie University in Halifax, Nova Scotia; moderating was Steven J. MacDonald, M.D., F.R.C.S.(C) of the University of Western Ontario.


*Current Concepts in Joint Replacement/RRY Photo Creation*

**Dr. Murphy:** "Proper reconstruction of femoral pathomechanics has always been determined by control at the neck shaft junction. In my practice measuring anteversion on CT the variation is from 4 degrees to 61 degrees and I don't think it's possible to properly reconstruct the hip during total hip replacement [THA] in all patients without control above the medullary canal."

"You can do a lot of that by putting a junction at the base of the neck. For example, you can preserve tissue to a greater extent. The technique we use is behind the abductors right through the piriformis and an incision in the superior capsule…ream through the top, cut the neck off, take the neck out without dislocating the hip, reaming the cup and putting it in with a double angle cup impactor. When we do this with a modular neck we can assemble the hip in situ and better preserve the surrounding soft tissues and close the capsule anatomically. We've shown in a prospective, peer-reviewed study that it's a faster recovery, less morbidity, and a lower complication rate using those methods."

"In terms of revisions, having a neck you can remove facilitates revision. You can take the neck off and revise a cup. If you have a problem with the neck you can change the neck angle/length without revising the stem; and no other design will allow you to do this other than one with a junction at that level."

"In terms of the regular long necks and short necks, beginning in 2002 we have experience with 960 cases, 73% of which are long necks…almost 600 are more than two years out and a number of them are over 300 pounds. There have been no neck fractures in this group with a standardly available titanium neck since 2002. We have had no failures or revisions in the standardly available neck lengths because of a modular neck, and we have four revisions that were much easier because of a modular neck."

"I understand that Michael's group in Halifax has had problems with neck fractures, and it's largely one particular implant combination…and all of the case reports in the past year related to

neck fractures concern the same device. All of these are a particular implant and any others have also been titanium necks that have broken. There haven't been any cobalt chrome necks that have broken. A Garbuz article showed higher metal levels in these metal-metal bearings and I don't feel that there's any evidence that the metal ions were coming from the neck taper rather than from the articulation itself."

"So we had 0% fractures, they had 3% fractures; we had different stems with the same neck so I think that's clearly a stem related issue. It reminds me of the ceramic squeaking issue—it took awhile to realize that it was a small number of specific implants that had the problem."

"Recommendations Dr. Dunbar has made in the past: 1) Cement a stem in varus. We know that a varus stem predisposes to thin cement mantles and has a higher failure rate and predisposes to stem fractures. So I'd say this is a biomechanically imprudent recommendation. 2) Control version with a cemented stem. I'd say that's the same thing. Thin cement mantles lead to higher failure rate and controlling version extremely through the cement mantle is biomechanically imprudent."

"Recommendation 3) Use a transgluteal exposure…if you can't properly control version your hip is going to stay stable anyway if you preserve the tissues. My take? Soft tissue preservation and component placement are both important and just because you do a good job on one doesn't give you the license to do a poor job with the other."

"Torque: if you can control version better through modularity then torque can be controlled more into anatomic levels rather than in the wrong direction. In our experience using tissue preservation and in situ assembly of the component over half the patients go home the next day, 85% go home by day two; only 3% go to rehabs and some are back to work at a week. This is much less expensive than conventional alternatives."

"So it's possible to design implants that are strong and don't break. Our patients have been well served by these types of implants, and we have good clinical data to support that. Using basic biomechanics it's clear that the neck-shaft junction is the place to be."

**Dr. Dunbar:** "Advantages to modularity: reduced impingement, reduced dislocations, and better balancing of leg length and soft tissue through offset. Impingement: it can be an issue, but it's mostly been driven by the ceramic audience with respect to the tension that can occur on the neck of the ceramic liner. But you don't have to use

ceramic. Impingement is very based on component positioning."

"Stability: Steve [MacDonald] and Bob Bourne have reported on a very low incidence of dislocation when you have meticulous attention to detail with respect to closure of the soft tissue through the direct lateral approach. Dislocation doesn't have to be a clinical issue, however if you look at all comers with respect to modular versus nonmodular necks with the Australian registry—and you look at reasons for revisions—dislocation stands out as a higher incidence with a modular neck."

"I do think that the ability to fine tune leg length and offset are important. I think you can do it through a cemented stem…there are differences in cemented stems and how they behave through radiostereometric analysis (RSA) migration. A stem with a flat, cross-sectional area has been shown to be resistant to aseptic loosening."

"Disadvantages: we're adding a new mechanical interface. Also, we think there is a risk of dissociation and fracture. Also, some of the data coming out now, particularly with the nine year midterm results, are describing worse outcomes…and I think there is an unintended adverse effect by decreasing the anteversion of the component through RSA data—and certainly there is increased cost."

"What about fretting? In a paper by my colleagues from Vancouver and Montreal (Garbuz, et al.) they looked at a resurfacing bearing—same cup versus a total hip. In this case the only difference was a modular junction allowing them to put on a larger head. They found a 4.6x increase in incidence of metal ion production, particularly cobalt. So it's not benign to add another interface."



"What about the fractures? There are several series now, with the largest being from Europe, on a different kind of stem…5,000 patients with a 2.4% fracture rate. I think that's probably an unacceptable rate. At our center we have reported a case study with pitting corrosion with tension fracture on scanning electron microscopy (SEM). Unfortunately we've had a larger series now with 16 fractures in 452 implants (3.5% fracture rate)."

"What about the effect of retroversion? In a paper by Richie Gil and others from Oxford they looked at the RSA migration patterns of two different stems, one with a round cross-sectional area and one with a flat cross-sectional area… and it was stem dependent. But in the round cross-sectional area stem, as you decrease the anteversion you have the unintended effect of increasing the lever arm which is particularly important for getting out of a chair or stair climbing in terms of the posterior migration pattern. And they found a deleterious effect with respect to the RSA migration pattern, particularly in the round cross-sectional stem."

"There's supporting data from the Australian registry—in this case a modular neck versus fixed neck, and you find that the number one reason for revision is not fracture, but loosening. So this is indirect evidence that we're creating unintended adverse biomechanical forces on these components."

"These are premium products and what we all must be aware of is that the market has tanked and the appetite for adding more bells and whistles to our implants that drive up costs probably isn't there. So I think the use of modular necks in primary routine arthroplasty isn't justified because there's no proof

of superiority, increased risks, and increased cost."

**Moderator MacDonald:** "Mike, a couple of the main reasons for doing a modular neck junction are improvements in stability, perhaps decreased impingement. Do you think there's any clinical evidence that they do that?"

**Dr. Dunbar:** "There's no clinical paper I could find showing that they've decreased the incidence of impingement. There's one biomechanical study that shows they do that, but it's yet to be translated. There's also one other paper that looks at reconstitution of leg length and offset and it does appear that in that case—that series—there was improved reconstitution of leg length and offset. This is a three dimensional problem and we're measuring it with plain films in that study. He [Dr. Murphy] is measuring it with CT scan which is probably the only way you can do it."

**Moderator MacDonald:** "Steve?"

**Dr. Murphy:** "If a patient has 60 degrees of anteversion and you're using an uncemented stem, you just cannot put that stem in the right place if it's fixed. So that hip will be malpositioned and can impinge posteriorly. There are many examples of hard bearings impinging in the back or the neck, rubbing against the rim. You can attribute a lot of that to femoral component and acetabular component malposition… and the combined positioning is critical. In our group of tissue preserving patients that's over 900, the dislocation rate is less than 0.3%, and I think the tissue preservation has something to do with it…femoral component also does."



**Moderator MacDonald:** "Mike, are you concerned about corrosion, fretting, ions, at that second junction?"

**Dr. Dunbar:** "Not overly concerned, but we need to be aware of it. Every time we add a new interface or junction we should be studying it rigorously. What I'd object to is that we're putting it in without knowing. And I don't think that Garbuz's group was expecting to find that just putting this little junction on might increase the ion level."

**Moderator MacDonald:** "Steve, regarding fretting and ions, you said you don't think it's much of an issue."

**Dr. Murphy:** "In terms of fretting and metal debris, that was a titanium junction and you were talking about cobalt and chromium levels. Certainly, if you have a high degree of fretting and corrosion at the junction you might have problems, but it wouldn't be cobalt and chromium unless it was affecting bearing wear. Every one of those case reports was one particular implant combination so it wouldn't be surprising that you'd find corrosion in that particular combination since that's the one that's having a problem."

**Moderator MacDonald:** "Thank you, gentlemen." ♦

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

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company

# Biomet's Growth Rate Slowing

Biomet, Inc., often seen as the canary in the orthopedic coalmine, was first to report revenue for the last quarter. The privately-held company's results are closely watched by analysts to see where the broader orthopedic market is heading.

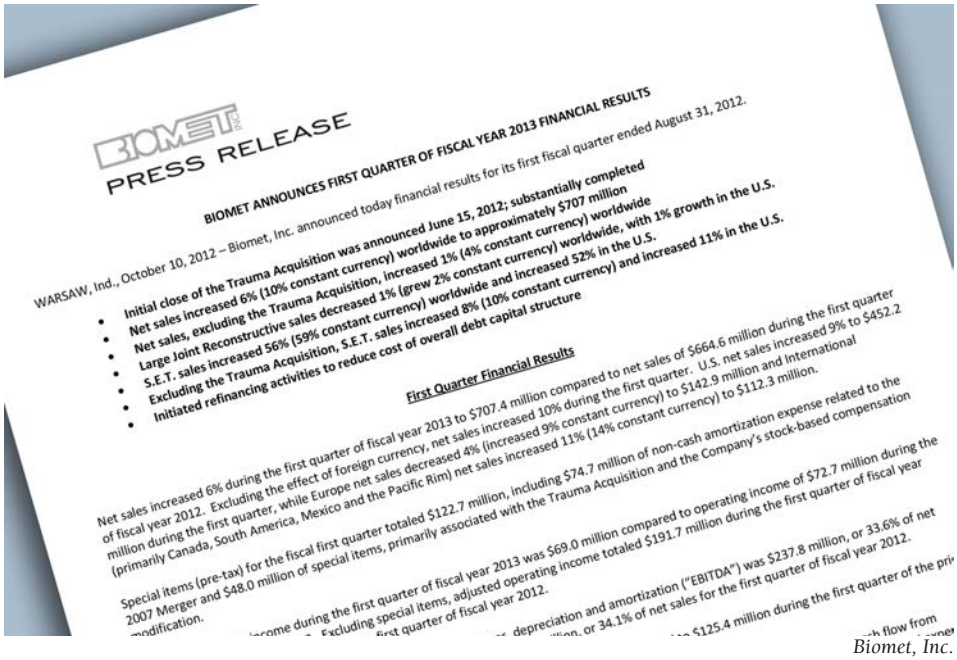
Reported sales of $707 million for the company's first quarter of 2013, excluding the acquisition of DePuy's trauma business, was up 1% from the previous year's first quarter. Including the acquisition increased reported sales by 6%.

Hips and knees both declined 1% on a reported basis. Spine and extremities were bright spots, increasing 10% and 13%, respectively.

"After three consecutive quarters of robust growth, taking market share, it is not terribly surprising that Biomet's growth rate has slowed, as the company's growth reverts to the mean," wrote BMO Capital Markets analyst Joanne Wuensch.

Wuensch also said that the company's results have become, "less correlated with other orthopedic companies. This is particularly true given the company's odd quarter-end and lumpiness from periodic sales initiatives. This said, [first quarter] large joint results [down 1%] give us pause."

Bob Hopkins of Merrill Lynch said Biomet's results are as often misleading as they are predictive when it comes to read-throughs for the other hip and knee players. "We do not believe hip and knee market trends changed materially from last quarter."


BIOMET
PRESS RELEASE

BIOMET ANNOUNCES FIRST QUARTER OF FISCAL YEAR 2013 FINANCIAL RESULTS

WARSAW, Ind., October 10, 2012 – Biomet, Inc. announced today financial results for its first fiscal quarter ended August 31, 2012.

- Initial close of the Trauma Acquisition was announced June 15, 2012; substantially completed
- Net sales increased 6% (10% constant currency) worldwide to approximately $707 million
- Net sales, excluding the Trauma Acquisition, increased 1% (4% constant currency) worldwide
- Large Joint Reconstructive sales decreased 1% (grew 2% constant currency) worldwide, with 1% growth in the U.S.
- S.E.T. sales increased 56% (59% constant currency) worldwide and increased 52% in the U.S.
- Excluding the Trauma Acquisition, S.E.T. sales increased 8% (10% constant currency) and increased 11% in the U.S.
- Initiated refinancing activities to reduce cost of overall debt capital structure

First Quarter Financial Results

Net sales increased 6% during the first quarter of fiscal year 2013 to $707.4 million compared to net sales of $664.6 million during the first quarter of fiscal year 2012. Excluding the effect of foreign currency, net sales increased 10% during the first quarter. U.S. net sales increased 9% to $452.2 million during the first quarter, while Europe net sales decreased 4% (increased 9% constant currency) to $142.9 million and International (primarily Canada, South America, Mexico and the Pacific Rim) net sales increased 11% (14% constant currency) to $112.3 million.

Special items (pre-tax) for the fiscal first quarter totaled $122.7 million, including $74.7 million of non-cash amortization expense related to the 2007 Merger and $48.0 million of special items, primarily associated with the Trauma Acquisition and the Company's stock-based compensation modification.

...come during the first quarter of fiscal year 2013 was $69.0 million compared to operating income of $72.7 million during the ... Excluding special items, adjusted operating income totaled $191.7 million during the first quarter of fiscal year ... first quarter of fiscal year 2012.

... depreciation and amortization ("EBITDA") was $237.8 million, or 33.6% of net ... or 34.1% of net sales for the first quarter of fiscal year 2012.

... $125.4 million during the first quarter of the pri... ...h flow from ...

*Biomet, Inc.*

| Biomet 1Q 2013 | Sales $ in million | % Change* |
|---|---|---|
| **Total Reported Sales** | **$707.4** | **1%*** |
| Large Joints | $393 | down 1% |
| Knees | | down 1% |
| Hips | | down 1% |
| Sports, Extremities, Trauma | $127.3 | 8%* |
| Spine & Bone Healing | $77.9 | 4.0% |
| Dental | $57 | down 4% |
| Other | $52.2 | 1.0% |

*Source: Biomet, Inc.*
** excluding DePuy Trauma Acquisition*

Jeff Binder, Biomet's president and CEO, was "generally pleased" with the results. "The completion of the trauma acquisition bolsters our S.E.T. (Sports, Extremities, Trauma) product category to annualized sales in excess of $500 million in an attractive segment of the orthopaedic market. The team has executed well on the integration and our investment in building a great S.E.T. business is paying off. We did experience some deceleration in growth for our hip and knee business, but until others report their results we won't know whether market growth has slowed or our growth has come back to market."

The company reported a loss of $31.5 million, compared with a loss of $39.2 million a year earlier.

The *Wall Street Journal*'s MarketWatch.com reported that, "Biomet has been in the red for over four years, weighed down by charges related to its 2007 buyout by a private-equity consortium. A weak economy has also caused some patients to put off hip and knee-replacement procedures. But strong sales in the sports-medicine and extremities segments have helped to drive Biomet's top-line growth in recent quarters."

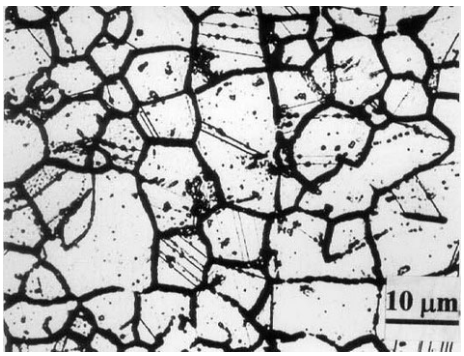
*—WE (October 12, 2012)*

large joints

## Hip Resurfacing Fails Major British Test

Because 72% of traditional implants have lasted only ten years surgeons, when dealing with patients younger than age 55, have explored hip resurfacing as an alternative to conventional total hip replacement, according to Todd Neale, writing in *MedPage Today.*

That has not worked out too well, reports a study conducted at the University of Bristol, England, and detailed in *The Lancet*. Researchers found that, for male patients with smaller femoral heads, the hip resurfacing was not as effective as total hip replacement. Implant survival was also poorer with hip resurfacing than with other surgical techniques when the femoral head was less than 54 mm. (For larger head sizes, implant survival was comparable.) For




*Wikimedia Commons and webcorr/Caption: A heavily sensitized microstructure of the surface of type 304 stainless steel*

women the five-year implant survival was worse with hip resurfacing regardless of head size.

To assess implant survival, Ashley Blom, Ph.D. lead researcher and his colleagues, looked at data from the National Joint Registry for England and Wales. Their analysis included 434,560 primary total hip replacements performed from 2003 through 2011. Of these, 7.3% were resurfacings.

An unadjusted analysis showed that five-year revision rates were higher for resurfacing than for stemmed total hip replacement (5.2% versus 2.8%). The unadjusted five-year revision rate was 8.5% for women and 3.6% for men, a difference not attributed to the smaller head sizes in women. "Women might have an increased risk of osteoporotic fractures of the femoral neck or a greater predisposition to reactions to metal debris," the authors suggested.

The median age of the patients who had a resurfacing was 55. The predicted five-year revision rates in 55-year-old women were 8.3% with a 42 mm resurfacing head, 6.1% with a 46 mm head, and 1.5% with a 28 mm cemented metal-on-polyethylene stemmed total hip replacement. That is the most common type of traditional implant. Similar differences were seen for 55-year-old men with smaller head sizes.

Blom recommended that resurfacing not be undertaken in women and that preoperative measurement be used to assess suitability in men. "Before further new implant technology is introduced we need to learn the lessons from resurfacing and metal-on-metal bearings," he said.

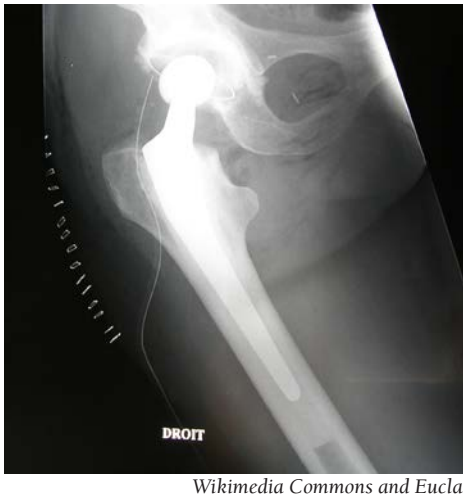
"Although our analysis focused on medium-term failure rates, other considerations need to be taken into account," the authors noted, including the conservation of femoral bone with resurfacing, differences in patient outcomes, and the release of metal into the patients' tissues, which can cause end-organ damage and DNA changes.

*—BY (October 11, 2012)*

## Mega Study Evaluates Joint Patient Outcomes

More than 100 orthopedic surgeons and nearly 7,000 patients are participating in a study conducted by the University of Massachusetts Medical School to better understand the outcome of total joint replacement surgeries—from the perspective of the patient. The study is in its second year of a four-year project that is funded by a $12 million federal grant. As explained by Brian Boyd, writing in *Business Telegram.com*, the researchers hope to learn, in fine-grained detail, what practices and circumstances contribute to a successful replacement.

The participating surgeons perform a total of 15,000 operations or more a year, so the project leaders expect to reach their goal of enrolling 33,000 patients by the end of the four-year period, indicated Patricia D. Franklin, M.D. a professor of orthopedics, physical rehabilitation, family medicine and community health, who is the primary investigator. The highest volume and costliest procedure in the Medicare budget is joint replacement, and it is projected to grow exponentially. At the same time, 40% of




*Wikimedia Commons and Eucla*

people who underwent the procedure last year were younger than 65, Franklin said. The medical school's data so far shows people younger than 65 are going through the procedure for similar reasons as older patients, because of arthritic pain and disability.

"What's different about this approach is that it is patient-centered," said David Ayers, M.D., chairman of orthopedics and physical rehabilitation at the medical school. "In the past, orthopedic registries focused on the implants, not the patients, and replacement surgeries were deemed a success or failure simply depending on whether or not the implant was removed at a later date," he said. The approach to creating a registry takes into account whether the quality of life for the patient with the implant is improving, in terms of pain relief and their ability to function.

The medical school staff plans to contact joint recipients at regular intervals—six months, a year, two years and longer—after their surgery to find out how they are managing pain and their physical functioning.

The data gathered should help researchers learn more about which circumstances lead to better outcomes—from patient factors, such as lifestyles and weight, to different surgical approaches and hospital settings. Prior to the publication of the study findings, participating surgeons will have access to the raw data collected on their patients, allowing them to monitor the effectiveness of surgeries that they have performed.

"The analysis will tell us is what is the best practice, what gets the best results after hip or knee replacement," Ayers said. "It has enormous potential to be used to help hospitals or insurance companies to look at their patients and determine what their patient outcomes are in comparison to our national sample."

The medical researchers will publish their findings, along with a summary of the data. In the meantime, participating surgeons have access to the raw data collected on their patients, allowing them to monitor the effectiveness of surgeries that they have performed.

The school's efforts could provide the health care industry with useful information, Dr. Ayers said.

"It has enormous potential to be used to help hospitals or insurance companies to look at their patients and determine what their patient outcomes are in comparison to our national sample," he said.

*—BY (October 12, 2012)*

## Stryker's "Revolutionary" Computer-Assisted Surgery System

Stryker Corporation says it's "revolutionary" and can helping avoid revision hip surgery.

On October 4, the company announced the launch of a computer-assisted surgery system called the Stryker Adapt for the Gamma3 Locking Nail System.

Jim Bruty, senior director of Marketing, Stryker Navigation, said the system allows surgeons to more accurately position nail and lag screws with no significant difference in procedure time during hip surgery.

Proper positioning of the lag screw in the femoral head is an important aspect of achieving positive patient outcomes, according to the company. Failure of a cephalomedullary nail may occur if the lag screw has not been properly placed within the femoral head. A "cut out" of the lag screw in the femoral head is one potential result, which may necessitate a revision surgery.


*Stryker Adapt/Stryker Corporation*

During conventional hip fracture surgery, surgeons use mechanical instruments and x-ray images to place the nail and lag screw. Stryker's new system is a computer-assisted surgery system designed to help surgeons in lag screw positioning by using Stryker's proprietary adaptive positioning technology. The system, according to the company, automatically identifies the Gamma3 Locking Nail relative to the patient's anatomy and provides computer guidance to assist the surgeon with implant alignment, lag screw length and lag screw positioning.

The Gamma3 Locking Nail System consists of a cephalomedullary nail, a lag screw and a distal locking screw. The cephalomedullary nail is placed into the canal of the femur, and then the lag screw is placed through the nail and into the neck and head of the femur. The lag screw and nail together help unite the fracture, allowing it to become more stable to help promote proper healing.

The company claims the system has been proven to assist surgeons in more accurately positioning the lag screw, regardless of their level of clinical experience. "Optimal lag screw placement has been identified as the primary factor in prevention of lag screw cut out," said James Maxey, M.D., orthopedic surgeon in Peoria, Illinois. "The combination of clinical research, trauma engineering and elegant positioning technology allows novice and expert surgeons to accurately place the lag screw. The Stryker Adapt system is a great innovation and advance in hip fracture repair."

Stryker Adapt was designed specifically for use with Stryker's Gamma3 Locking Nail System and does not work with any other device.

*—WE (October 10, 2012)*

## Inflammation: New Mechanism Discovered

Scientists affiliated with VIB and UGent in Belgium have discovered a mechanism used by the protein A20 to combat inflammation. This news is timely for those suffering from rheumatoid arthritis (RA)…Friday, October 12 is World Arthritis Day.

Rudi Beyaert, Deputy Department Director at VIB – UGent said in the October 9, 2012 news release, "We hope that our research can eventually contribute to the development of new therapies against rheumatoid arthritis and other auto-immune conditions." Beyaert and his research team previously identified the molecule A20 as an important point of focus for the development of new medicines against RA and other autoimmune diseases. A20 appears to exert an anti-inflammatory effect in white blood cells.

Previous research has demonstrated that A20 interferes with specific "signaling pathways" in our cells that stimulate the activity of a DNA binding molecule (NF-κB). NF-κB plays a key role in many immunological processes and excessive activation of NF-κB can result in a whole range of "inflammatory diseases," including arthritis. However, it is still largely unknown how A20 interferes with the activity of NF-κB.

Kelly Verhelst and other scientists on the team of Rudi Beyaert have now mapped the specific interaction between A20 and the NF-κB "signaling pathway." They demonstrated that a small particle (ZF7) at the end of the A20 protein binds to certain small molecules (ubiquitin chains), which are attached to specific NF-κB signaling proteins in the cell. This makes it impossible for these proteins to communicate with other proteins, thereby disrupting the signal that would normally result in inflammation.

Rudi Beyaert said, "Now that we know the importance of this small fragment (ZF7) of A20 for the anti-inflammatory effect, we can also use it as a point of focus for the development of medicines against various auto-immune diseases. This is one step closer, but we still have a long way to go."

*—EH (October 9, 2012)*

*morguefile and pixelrave*

extremities

## Typing Prevents, Not Causes, Carpal Tunnel

Cracking your knuckles does not lead to arthritis nor does typing cause carpal tunnel syndrome. In fact, says Jessica Frankenhoff, M.D., "Typing actually helps prevent carpal tunnel." A specialist in carpal tunnel syndrome and hand-related surgery at Stony Point Surgery Center, Frankenhoff says that the sound we hear when someone "cracks" his knuckles is popped "air bubbles from a created vacuum" surrounding the knuckles.

An inevitable symptom of carpal tunnel is tingling due to a lack of blood flow to the hands. "Eventually the tingling progresses and you get permanent numbness," said Frankenhoff, who added that the numbness can turn into pain within months, or take several years. While some have carpal tunnel syndrome in one hand, Frankenhoff said that most patients have it in both. Some find that they can ease the pain by wearing splints on their hands at night, but if the pain increases surgery is required. According to Nathan Cushing, writing in *RVANEWS,* about 3% of women and 2% of men will develop the condition.

The carpal tunnel is a narrow space in the wrist through which tendons and nerves pass. The syndrome develops when those nerves and tendons become inflamed, creating pressure in the wrist. "Because there is a fixed space" in the carpal tunnel, said Frankenhoff, "the pressure goes up and collapses the blood vessels" causing the tingling, numbness, and pain.

"The surgery itself is literally cutting the ligament," said Frankenhoff, adding that that a recurrence post-surgery is extremely rare. She says that a way for patients to avoid the likelihood of developing carpal tunnel syndrome is to watch their weight. Obese individuals have increased odds of developing carpal tunnel syndrome, as do women. There is one thing that people can do to keep from developing carpal tunnel and that is yoga. "Yoga is the one thing that has actually been shown to help," she said.

*—BY (October 9, 2012)*

*Wikimedia Commons and German Federal Archives*

trauma

## Effervescent Tablet for Osteoporosis: FDA Approved

Mission Pharmacal Company has announced that BINOSTO (alendronate sodium) Effervescent Tablet is now available by prescription in the U.S. The FDA has approved BINOSTO—now in a once weekly, buffered solution—to treat osteoporosis in postmenopausal women and to increase bone mass in men with osteoporosis.

BINOSTO delivers osteoporosis treatment and fracture prevention at the hip and spine—alendronate sodium—in a once weekly, buffered solution. BINOSTO is a strawberry flavored tablet containing alendronate (70mg) that rapidly dissolves in half a glass (4 oz.) of plain room temperature water to make a buffered solution.

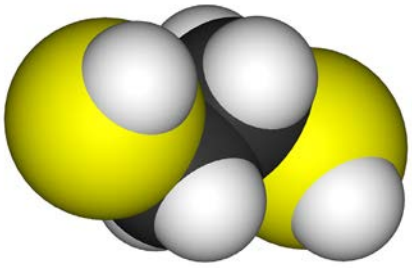
"We are very pleased to add BINOSTO to our line of bone health products," says Terry Herring, President of Commercial Operations at Mission Pharmacal, in the October 11, 2012 news release. "With this exciting new treatment option, physicians can rest easily, knowing they are prescribing an easy-to-take and proven therapy for their osteoporosis patients that protects against fracture risk at the hip and spine."

*—EH (October 12, 2012)*


*Mission Pharmacal Company*

## Infection Fighting Gel Tested

With studies showing that patients requiring orthopedic surgery may be three times more likely to experience post-operative infections than patients undergoing other forms of surgery, the Perelman School of Medicine at the University of Pennsylvania has accepted a $2.5 million grant for a study. The grant is from the Congressionally Directed Medical Research Program (CDMRP) and will be used to begin Phase II human trials of the effectiveness of treating post-surgical orthopedic infections with Microbion Corporation's topical BisEDT drug. Phase 1 human trials of BisEDT were successfully completed in 2011. Clinical studies for Phase 2 will begin in 2013 at the Hospital of the University of Pennsylvania, and at UCSF/San Francisco General Hospital.



*Wikimedia Commons and Benjah-bmm27*

"We're honored to be given this award from the Department of Defense (DoD), and are hopeful that the Phase 2 trial will allow us to offer improved treatments and standards of care to a significant number of patients," says Samir Mehta, M.D., chief of the Orthopedic Trauma and Fracture Service at Perelman. "Orthopedic trauma and fracture patients are at an increased risk for infection. If successful, this new treatment strategy could be a significant step toward reducing instances of amputation, disability and even death."

"The goal of our study is to examine the efficacy and safety of administering a single application of Microbion's topical BisEDT gel to infected extremity wounds," said Annamarie Horan, MPA, Ph.D., director of Clinical Research for Penn Orthopedics. "The gel is not a replacement for standard antibiotics, but the promising results of the Phase 1 trial provide strong evidence suggesting the drug may be an effective supplemental treatment."

Orthopedic extremity injuries also constitute the majority (65%) of combat casualties experienced in recent U.S. military conflicts. The risk of infection developing after surgical treatment of traumatic, open military wounds represents an extremely serious threat. Reports indicate that military wound infection rates may be as high as 77%.

*—BY (October 12, 2012)*

spine

## Vexim Records Record Year With SpineJack

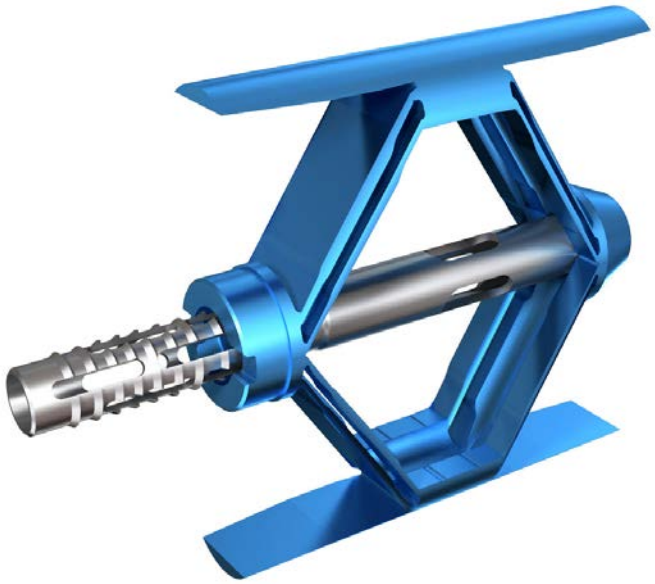
Vexim, a French medical device firm specializing in the minimally invasive treatment of vertebral fractures, reports a 93% sales growth for the first half of 2012 as compared to the same period in 2011. First half sales totaled 1.1 million Euros. The company's domestic sales (in France) increased by three and half times its levels from the prior year while international sales rose by a very respectable 42%.

Company officials attributed the sales growth, in part, to the fact that it obtained CE marking in January 2012 for the new 4.2 mm diameter SpineJack implant, adding it to the company's existing line of 5 mm and 6.5 mm diameters. Officials say that this new diameter makes it possible to treat pathologies on high thoracic vertebrae as well as on all small vertebrae. The company trained over 40 surgeons in the use of Vexim's technology during the first half of the year alone. Guided by X-ray, physicians insert the implants in less than 30 minutes enabling the patient to be discharged shortly after surgery.

During the year, Vexim also launched two new subsidiaries, one in Germany in March and the second, based in Milan, in June. The company reports that it is now ahead of its business plan.

Vincent Gardès, CEO of Vexim, explained, "The first half of the current financial year saw rich and structuring events for Vexim in all areas of its activity; extension of its range of implants, success of its IPO and the raising of 11 million Euros, strengthening of its management team sand targeted international expansion. The first half financial performances, with sales and the gross margin both doubling, give us much confidence regarding the implementation of our business plan over the years a whole."

*—BY (October 11, 2012)*



*Courtesy of Vexim*

## Generics Pass Quality, Cost Test

Generic implants can deliver significant cost savings without any sacrifice of quality or patient outcomes according to research presented at the 28th Annual Orthopaedic Trauma Association (OTA) meeting in Minneapolis. Two independent Institutional Review Board (IRB)-approved studies conducted by the Reno Orthopaedic Clinic and the University of Nevada School of Medicine examined the costs, implementation and clinical outcomes of the use of the Orthopaedic Implant Company's (OIC) generic screws. The results showed that generic orthopaedic implants provide a high-quality, safe and affordable option for patients and hospitals.

*Courtesy of Orthopedic Implant Company*

The authors concluded that generic screw utilization resulted in hospital cost savings of more than 65%—savings that are similar to those seen within the generic drugs market.

"These studies demonstrate the ability of generic implants to significantly lower implant costs to hospitals, insurance carriers and patients while providing high quality care and potentially saving the health care system billions of dollars in unnecessary costs," said the studies' lead author Peter Althausen, M.D. "We're not surprised by the studies' findings. These results empower

surgeons, hospitals and patients to feel comfortable choosing generic implants without having to worry about sacrificing quality."

The studies looked at the use of generic equivalent 7.3 mm cannulated sacroiliac and femoral neck screws used in orthopaedic trauma procedures. The generic 7.3 mm cannulated screws made by OIC performed as well as conventional screws for the fixation of femoral neck fractures and posterior pelvic ring injuries.

In the first study, 45 femoral neck fracture patients treated with generic 7.3 mm cannulated screws made by OIC were compared to 50 patients treated with conventional screws. The study looked at operative time, estimated blood loss, complication rate, shortening, screw cutout, conversion to arthroplasty and varus collapse. There were no measurable differences between both sets of patients, and the hospital saw a 67% cost reduction by using OIC's generic screws resulting in an annual savings of $34,653 for the hospital.

The second study compared 35 patients treated with generic cannulated screws from OIC against 44 patients treated with conventional screws for posterior pelvic ring injuries. In the generic group, surgeons implanted 45 screws and 40 washers. In the conventional group surgeons implanted 59 screws and 50 washers.

A blind reviewer found there was no increase in operative time, estimated blood loss, complication rate, screw cutout, screw deformation or screw loosening. The hospital realized a 73% cost reduction, which translates to an annual savings of $14,472. Hospital implant costs were decreased significantly without any associated increase in complication rate or radiographic outcome. Both studies concluded that, if generic implants were more commonly used, the results could have profound implications for the treatment of trauma patients.

OIC entered the medical device market in 2010, pledging to save more than a billion dollars in health care costs by 2015. The company's implants are 50% to 60% of the average market price of premium implants, potentially saving health care systems millions of dollars a year. All OIC products are FDA approved and manufactured in ISO 13485 facilities.

*—BY (October 12, 2012)*

## Alphatec Spends $15.2 Million for Phygen

Alphatec Holdings, Inc. parent firm of Alphatec Spine, Inc. is spending $15.2 million in cash and stock to acquire Phygen, LLC, a spine implant manufacturer based in Irvine, California. Upon the recent approval by its board of directors, Alphatec signed a letter of intent to acquire the assets of the Phygen.

Les Cross, who became CEO of Alphatec Spine earlier this year, announced that his growth strategy for the company includes "a focus on new product launches and acquisitions. We have since launched new products such as our BridgePoint™ Spinous Process Fixation System, and acquired exclusive U.S. distribution rights to market a synthetic bone growth biologic under our own brand name of Alphatec NEXoss. It is clear we are executing our new business strategy."

Neurosurgeon, Mark Renfro, M.D., a member of Phygen's Board of Governors, said, "Phygen is delighted by this transaction with Alphatec. Upon closing, Phygen will look to bring its innovative product development process into the Alphatec family. All in all, I believe that this proposed transaction is a real win-win for Phygen and Alphatec."


*Courtesy of Phygen, LLC.*

Alphatec Spine said that it expects the transaction to contribute approximately $15 million in revenue in 2013 and be accretive to fully diluted GAAP earnings per share in 2013. The closing remains subject to the approval of a majority of the members of Phygen and the execution of the definitive documents.

*—BY (October 9, 2012)*



## people

## Yeung Honored by SMISS

Anthony Yeung, M.D., known to his many friends and admirers as "Tony," is the 2012 recipient of the Parviz Kambin Award, given by the Society for Minimally Invasive Spine Surgery (SMISS) to honor outstanding surgeons in the field of endoscopic spine surgery. The Society held the ceremony during its annual meeting, September 23, and Yeung's son, Christopher Yeung, M.D., accepted the award for his father.


*Anthony Yeung, M.D.*

SMISS established the Kambin Award, in collaboration with joimax®, to recognize the surgeons who have successfully performed more than 1,000 cases of endoscopic spinal surgery, trained more than 100 surgeons in the procedure, (in both cases specifically transforaminal surgery), published in numerous scientific publications and professional journals and given presentations at leading congresses. Finally, the recipient must demonstrate a strong commitment to clinical research and training. Choll Kim, M.D. and executive director, Society for Minimally Invasive Spine Surgery, wrote, "Tony is my hero and certainly deserves such an award."

The award is named for Parviz Kambin, M.D. to recognize and honor his pioneering work that paved the way for minimally invasive endoscopic spine surgery. Kambin identified the unique safe access point to the spinal canal now known as the "Kambin Triangle." Previous awardees are Parviz Kambin, M.D., professor of Orthopedic Surgery, Drexel University; Michael Schubert, M.D., APEX Spine Center, Munich, Germany; and Menno Iprenburg, M.D., Veenhuizen, Netherlands.

SMISS is the only society dedicated solely to advancing minimally invasive spine surgery. Endoscopic spine surgery constitutes but a small portion of SMISS' overall educational content regarding minimally invasive spine surgery. SMISS' primary role is to provide a forum for the exchange of ideas and information.

*—BY (October 11, 2012)*

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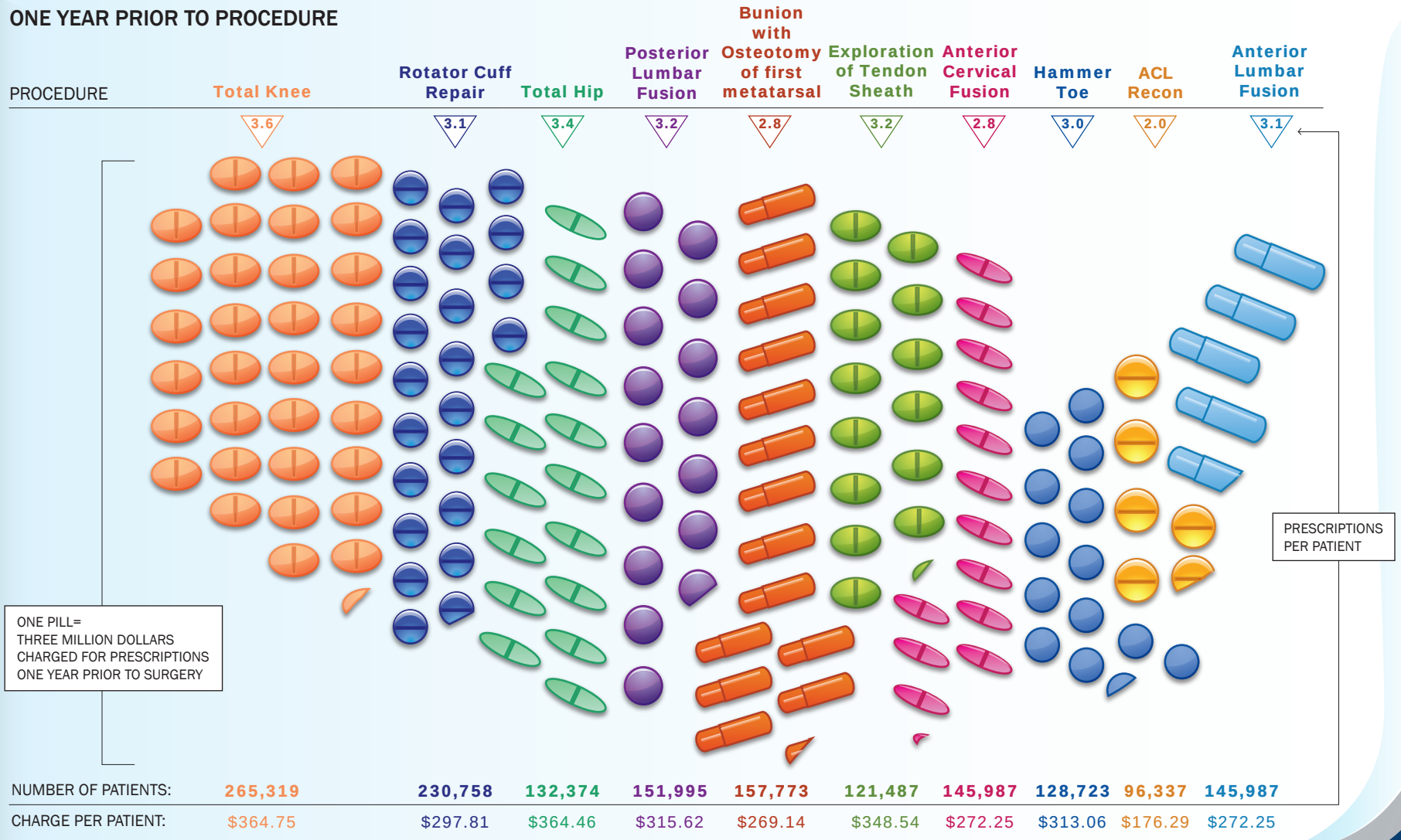


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