

Orthopedics This Week

week in review

4 Metal-on-Metal Trial Underway – How Strong is DePuy’s Case? ♦ Orthopedics’ biggest trial is finally underway. The first witness has been called. The plaintiffs say that DePuy’s ASR metal-on-metal hip had a flawed design which the company knew about. The defendants have a strong counter argument. Bottom line: what did DePuy know and when did they know it?

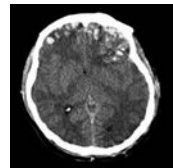
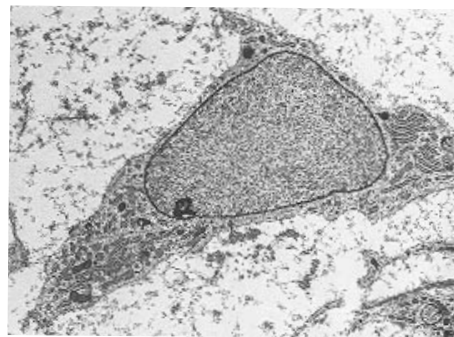
7 The Top 19 U.S. Sports Medicine Specialists ♦ What do the Dallas Cowboys, the Pittsburgh Steelers, and New York Giants have in common? They all have sports medicine doctors on this list! Here are the 19 superstars we heard about...

10 Computer Navigation in TJA: Thumbs Up or Down? ♦ “It’s 2011 and we have no proven benefit of computer assisted total knee surgery. And we’re well into the second decade of use,” states Robert Trousdale. “Wait,” says Arun Mullaji, “There are pros to this. It helps alignment; it also helps balance the knee.”

14 Stem Cells for Tendonitis Study at HSS...To Avoid Overly Aggressive Anticoagulation Ignore Small Clots?...Disaster Certification: Where Are We? ♦ Paul Tornetta, III, M.D., a former president of the OTA, says size matters when it comes to pulmonary emboli.



Scott Rodeo, M.D. updates his very important stem cell tendon study at HSS. Chris Born, M.D. updates us on the AAOS, OTA, and SOMOS project to credential orthopedic surgeons for disaster situations.



breaking news

- 17 Zimmer Steady in 4Q – New Knee Arriving**
- Solvay Biomaterials Enters Huge China Market**
- Stryker’s 6.7% 4Q Recon Growth Raises Bar**
- DePuy Synthes Results Points to Recovery**
- Strong Support for Surgeons in Patient Survey**
- Six Doctors Join Mount Sinai**
- First Device Taxes Paid. Spine Likely To Benefit**
- Mesoblast Tees Up Phase 3 Stem Cell Spine Test**
- NFL Brains Show Signs of CTE**

For all news that is ortho, read on

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: The Dow Jones index is now over 14,000 and a mere 150 points away from its all-time high. Last week the Dow rose 149 points. What's pushing the Dow higher? Increased consumer spending—particularly for housing. The consumer's balance sheet is looking healthier. Orthopedics, of course, is a consumer product.

| RANK | LAST WEEK | COMPANY | TTM OP MARGIN | 30-DAY PRICE CHANGE | COMMENT |
|------|-----------|----------------------|---------------|---------------------|---|
| 1 | 1 | Stryker | 23.68% | 12.81% | In the last two weeks SYK has raised the dividend, bought major distribution in China and beat estimates. |
| 2 | 10 | Globus Medical | 29.39 | 17.92 | Pre-announced much better sales numbers than expected. Doesn't take a genius to see what this means for earnings. |
| 3 | 2 | NuVasive | 7.08 | 9.42 | NUVA sales also beat analyst's lowered estimates. In the era of the device tax, better-than-expected sales is the key to sustaining earnings. |
| 4 | 3 | Zimmer | 25.45 | 8.52 | 1% sales growth. Ugh. But lower expenses helped earnings. ZMH needs to make a strong strategic move—a la SYK, MDT or DPU. |
| 5 | 6 | Medtronic | 28.65 | 12.03 | MDT makes ANOTHER major China purchase. LifeTech Scientific Corporation. If MDT isn't #1 in China now, it will be soon. |
| 6 | 7 | Exactech | 8.64 | 13.92 | Most analysts are expecting a 10% sales growth and 50% earnings growth in Q4. |
| 7 | 4 | Integra LifeSciences | 13.73 | 6.96 | Analysts think that IART's sales growth may slow from Q4's 6% to Q1's 5%. Year-over-year comparisons. |
| 8 | 5 | Symmetry Medical | 5.63 | 2.23 | With 5.63% operating profit margins, investors are curious about how the device tax will affect SMA. |
| 9 | 9 | Johnson & Johnson | 25.58 | 4.71 | DePuy is bearing the brunt of the bad press from metal-on-metal trials. But will it affect sales or earnings? Doubtful. |
| 10 | 8 | ArthroCare | 18.04 | 4.05 | Department of Justice agrees to a one month tolling extension. Frustrating. But the end is in sight. |

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|----|----------------------|--------|---------|----------|------------|
| 1 | Globus Medical | GMED | \$12.90 | \$1,176 | 17.92% |
| 2 | Exactech | EXAC | \$19.15 | \$255 | 13.92% |
| 3 | Stryker | SYK | \$63.04 | \$23,968 | 12.81% |
| 4 | RTI Biologics Inc | RTIX | \$4.95 | \$277 | 12.50% |
| 5 | Medtronic | MDT | \$46.92 | \$47,453 | 12.03% |
| 6 | NuVasive | NUVA | \$17.54 | \$763 | 9.42% |
| 7 | MiMedx Group | MDXG | \$4.32 | \$375 | 9.37% |
| 8 | Zimmer Holdings | ZMH | \$73.47 | \$12,747 | 8.52% |
| 9 | Integra LifeSciences | IART | \$42.28 | \$1,143 | 6.96% |
| 10 | Conmed | CNMD | \$29.50 | \$840 | 5.17% |

WORST PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|----|------------------------|--------|---------|---------|------------|
| 1 | MAKO Surgical | MAKO | \$11.24 | \$516 | -13.47% |
| 2 | Orthofix | OFIX | \$38.42 | \$742 | -3.81% |
| 3 | CryoLife | CRY | \$6.56 | \$180 | -1.65% |
| 4 | Alphatec Holdings | ATEC | \$1.71 | \$155 | -0.58% |
| 5 | TranS1 | TSON | \$2.48 | \$68 | 0.00% |
| 6 | TiGenix | TIG.BR | \$1.22 | \$122 | 0.43% |
| 7 | Wright Medical | WMGI | \$21.78 | \$864 | 0.69% |
| 8 | Bacterin Intl Holdings | BONE | \$1.30 | \$55 | 0.78% |
| 9 | Tornier N.V. | TRNX | \$17.42 | \$727 | 1.04% |
| 10 | Symmetry Medical | SMA | \$10.98 | \$404 | 2.23% |

LOWEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|-------------------|--------|---------|-----------|-------|
| 1 | Orthofix | OFIX | \$38.42 | \$742 | 12.76 |
| 2 | Medtronic | MDT | \$46.92 | \$47,453 | 13.76 |
| 3 | Zimmer Holdings | ZMH | \$73.47 | \$12,747 | 13.81 |
| 4 | Johnson & Johnson | JNJ | \$74.18 | \$205,572 | 14.52 |
| 5 | Stryker | SYK | \$63.04 | \$23,968 | 15.45 |

HIGHEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|-------------------|--------|---------|---------|-------|
| 1 | Wright Medical | WMGI | \$21.78 | \$864 | 68.06 |
| 2 | NuVasive | NUVA | \$17.54 | \$763 | 62.64 |
| 3 | Symmetry Medical | SMA | \$10.98 | \$404 | 47.74 |
| 4 | RTI Biologics Inc | RTIX | \$4.95 | \$277 | 23.57 |
| 5 | CryoLife | CRY | \$6.56 | \$180 | 23.43 |

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|-------------------|--------|---------|----------|------|
| 1 | Orthofix | OFIX | \$38.42 | \$742 | 1.11 |
| 2 | Globus Medical | GMED | \$12.90 | \$1,176 | 1.36 |
| 3 | Conmed | CNMD | \$29.50 | \$840 | 1.37 |
| 4 | Zimmer Holdings | ZMH | \$73.47 | \$12,747 | 1.47 |
| 5 | RTI Biologics Inc | RTIX | \$4.95 | \$277 | 1.57 |

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|------------------|--------|---------|----------|------|
| 1 | NuVasive | NUVA | \$17.54 | \$763 | 7.48 |
| 2 | Wright Medical | WMGI | \$21.78 | \$864 | 7.42 |
| 3 | CryoLife | CRY | \$6.56 | \$180 | 5.86 |
| 4 | Symmetry Medical | SMA | \$10.98 | \$404 | 3.98 |
| 5 | Smith & Nephew | SNN | \$57.44 | \$10,394 | 3.15 |

LOWEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|-------------------|--------|---------|---------|------|
| 1 | Alphatec Holdings | ATEC | \$1.71 | \$155 | 0.79 |
| 2 | Symmetry Medical | SMA | \$10.98 | \$404 | 1.13 |
| 3 | Conmed | CNMD | \$29.50 | \$840 | 1.16 |
| 4 | Exactech | EXAC | \$19.15 | \$255 | 1.24 |
| 5 | Orthofix | OFIX | \$38.42 | \$742 | 1.28 |

HIGHEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|----------------|--------|---------|---------|--------|
| 1 | TiGenix | TIG.BR | \$1.22 | \$122 | 106.48 |
| 2 | MiMedx Group | MDXG | \$4.32 | \$375 | 48.29 |
| 3 | MAKO Surgical | MAKO | \$11.24 | \$516 | 6.11 |
| 4 | Globus Medical | GMED | \$12.90 | \$1,176 | 3.55 |
| 5 | TranS1 | TSON | \$2.48 | \$68 | 3.53 |

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

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Metal-on-Metal Trial Underway – How Strong is DePuy’s Case?

By Walter Eisner

Sixty-six year old DePuy ASR hip implant recipient Loren Kransky has smoked since he was 12, served in Vietnam as a U.S. Air Force mechanic, suffers from diabetes, coronary artery disease, high blood pressure, and kidney disease. He’s had two strokes and is dying of kidney cancer.

He had his hip replaced with DePuy Orthopaedic Inc.’s metal-on-metal ASR hip in 2007. In 2012 he required a revision, claiming he was being poisoned by chromium and cobalt released by the device.

Case Goes to Jury

On January 25, 2013, in a Los Angeles County Superior courtroom, Kransky became the first of roughly 10,000 nationwide patients to get his case in front of a jury. Two previously scheduled trials in Las Vegas and Maryland ended with a settlement and withdrawal of the complaint.



Thomas Vail, M.D./UCSF



Thomas Schmalzried,
M.D./Joint Replacement
Institute

Kransky and his wife Sheryl are suing DePuy, SFG Medical, Inc., Thomas Schmalzried, M.D. and Thomas Vail, M.D. (among others) for failure to warn, negligent recall and manufacturing defects of the device and essentially



Los Angeles Superior Courthouse Source: Wikimedia Commons and John O'Neill/RRY Publications LLC

serve as proxies for cases yet to go to trial.

At issue for this and upcoming trials isn't exclusively whether Kransky was specifically damaged by the ASR, but what did company officials know about the safety of the device, when did they know it, and what actions did they take with that information?

Opening Statements

In opening statements to the jury, Kransky's lawyer, Michael Kelly told jurors that DePuy was aware of the defects when the company started selling the device. He introduced documents which allegedly suggest that company executives knew there were serious

problems with the ASR because internal testing in 2007 revealed that the device had a critical design flaw. He charged the company with hiding information from doctors complaining about the device.

Alexander Calfo, DePuy's lawyer told jurors that the evidence will show that the device was not the cause of Kransky's failed hip and that it was properly designed. He claimed Kransky was exposed to Agent Orange in Vietnam and all his other chronic illnesses were the cause of the hip failure. He also attributed the failure to improper placement of the hip by the surgeon and that the amount of metal shown in Kransky was not high enough to cause his device failure.

“Mr. Kransky did not get worse because of the (implant) and did not get better when it was removed,” he said. Calfo said that Kransky’s kidney problems compromised his body’s ability to flush chromium and cobalt, which weren’t at high enough levels to cause health problems.

Calfo said that cobalt and chromium from the ASR hips don’t poison patients. “The ASR was thoroughly tested and was researched before it was ever used.”

Before getting to the documented evidence and witnesses after four days of the trial (many testifying via videotaped depositions available to future trials), let’s review the timeline of the device.

DePuy ASR Timeline

The device was introduced in 2004 in Europe and 2005 in the U.S. Eventually over 36,000 U.S. patients received the hip. Worldwide, over 90,000 implants were sold.

By 2009, national registries in Australia and elsewhere began reporting high failure rates. Australian national registry data showed that the implant failed at a rate of 22% after five years and 44% after seven years.

In 2009, the FDA rejected DePuy’s request to clear its resurfacing version of the ASR. The agency cited concerns over high concentrations of metal ions.

The company recalled the device in 2010, citing, among other things, poor sales.

In 2012, British experts at the world’s biggest artificial joint registry said doctors should stop using all (not just DePuy’s) metal-on-metal hip replacements after a study found that, after five

years, about 6% of people who had the implants needed the device replaced.

Plaintiff: DePuy Knew of Design Flaws

To prove that the company knew of design flaws long before recalling the device in 2010, Kelly called his first witness, Magnus Flett, to tell the jury how DePuy analyzed what might cause the ASR hips to fail. Flett led a design team and oversaw a group conducting a failure mode and effect analysis.

In his opening statement, Kelly had displayed a DePuy document from September 27, 2007, describing how “massively increased wear” can occur when the cup is “oriented at a steep angle.” The company could “significantly redesign” the ASR to remove a groove, or ridge, that was part of the cup’s design, according to the document.

Kelly said that while DePuy advised doctors ideally to place the cup at a 45 degree angle in the hip, a study showed more than half of implants were placed at wider angles.

“Isn’t it true that DePuy didn’t know in 2008, 2007, 2006, 2005, ’04, all the way down to the design, DePuy had no idea what the acceptable range was for the placement of the ASR?” Kelly asked Flett. “Isn’t that the simple and plain truth?”

“I think the data as we started to get it indicated angles above 55 gave us increased ion results,” Flett responded.

Who Knew What and When?

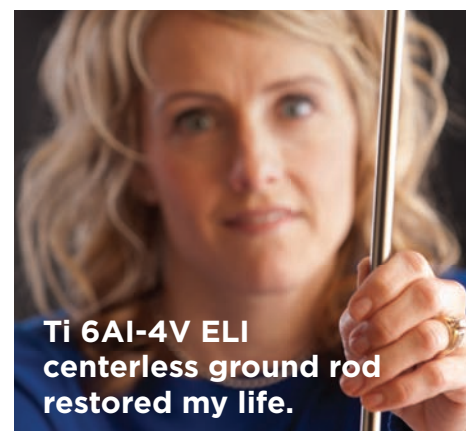
Kelly referred to a May 2, 2008, email in which Paul Berman, DePuy’s head of U.S. marketing, wrote, “We will ultimately need a cup redesign but the

short term action is to manage perceptions.”

Kelly also referred to a Berman email of July 2, 2008, about sales representatives “telling surgeons DePuy is making an emergency change to the ASR cup. We must keep the ASR 2 project under total wrap, particularly in the U.S. where we will not make the change immediately. As expected, the competition will use this information against us.”


Andrew Ekdahl, the current president of DePuy and in charge of the 2005 introduction of the device in the U.S., was also told by a company consultant that the ASR was flawed, according to another document.

“The issue seen with the ASR today, over five years post-launch, are most likely linked to the inherent design of the product and that is something we



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should recognize,” company executive, Raphael Pascaud reportedly wrote in March 2009.

DePuy Pulls Device off Market

Flett said DePuy scrapped efforts to redesign the ASR cup because of financial and business reasons. He said that DePuy never told surgeons that the ASR failed and required revisions at a rate that was eight times that of another company hip device, the Pinnacle.

He said DePuy stopped selling the ASR in late 2009. “We didn’t see the sales of the product continuing the way we wanted, so we took it off the market,” Flett said.

A memo from Berman to the company sales force read, “This global rationalization is consistent with DePuy’s strategy to streamline its portfolio, reduce cost and reallocate resources to high growth brands and technologies that best meet the current and future needs of surgeons and patients.”

According to Kransky’s lawyers, DePuy “has consistently claimed it recalled the ASR for purely ‘financial reasons.’” They claim DePuy then “attempted to pivot off that position, claiming the real reason it recalled the ASR was for a ‘remedial or precautionary measure.’”

They argue that DePuy sought to deem the recall a “remedial measure” so that it could exclude certain evidence from the trial.

Ekdahl Testimony

Then it was time for the jury to hear from Ekdahl himself via videotaped deposition taken in December 2012.

Ekdahl testified the company recalled the 93,000 implants because they “did

not meet the clinical needs for the product,” not because they were unsafe. In answering Kelly’s questions about the recall, Ekdahl said that the ASR didn’t have an acceptable revision rate.

“What was the acceptable revision rate?” Kelly asked.

“I don’t think we put a revision rate on paper and said this is a revision rate that was acceptable,” responded Ekdahl. Kelly asked how many revisions DePuy forecasts for the U.S. “We’re not forecasting a revision rate,” Ekdahl said.

Kelly asked why the U.S. rate of revision wouldn’t reach 40%, as in Australia. Ekdahl said he doesn’t know what the rate will be. About 32,000 patients had ASR devices implanted in the U.S., said Ekdahl, and that “somewhere in the neighborhood of 15 to 20%” of those hips had failed.

Handling of Safety Concerns

Kelly questioned Ekdahl about DePuy’s handling of safety complaints that surgeons filed with the company about the device. Kelly noted that one surgeon, William Griffin, emailed Ekdahl and others on December 18, 2008, to say he had “concerns about the design and have started to see failures consistent with my concerns.”



Andrew Ekdahl

Ekdahl acknowledged, “I believe this was reported to our clinical team. I just don’t recall who did it. We should have done it. I’m assuming that we

did it. I don’t recall.” Ekdahl said that in response to the email, he spoke to people on the marketing team.

Kelly asked about DePuy discussions in 2008 to redesign the ASR cup. A company engineer, Graham Isaac, emailed Ekdahl on April 30, 2008, to say the ASR is “susceptible to extreme metal ion levels,” which a competitor product didn’t face.

“We need to discuss that at the earliest possible opportunity as I believe it means that we need to start any ASR upgrade sooner than our previous plans had suggested,” Isaac wrote.

At a September 2009 meeting of the company’s U.S. board overseeing joint devices, officials said the revision rate of the ASR device was two or three times that of another DePuy implant, the Pinnacle. It said that the impending publication of Australian registry data would be “very damaging to the ASR.”

Thomas Vail, M.D., testified that the device was not defective. He also told the jury he received almost \$2 million in royalty payments. During the recall, he said he did not experience any safety issues with his patients.

Settlement Rumored

So concluded the fourth day of the biggest trial in orthopedics in decades.

Legal experts have said they are certain that ultimately there will be some sort of global settlement after some of the cases are litigated. DePuy can fight each case said one expert. News reports have said that DePuy has offered to settle the cases for \$200,000 per case or about \$2 billion. The plaintiff lawyers have turned that down.

The trial continues in Los Angeles. ♦

The Top 19 U.S. Sports Medicine Specialists

By *OTW* Staff

What do the Dallas Cowboys, the Pittsburgh Steelers, and New York Giants have in common? They all have sports medicine doctors on this list! According to those in-the-know, there are 19 high echelon sports medicine specialists in the U.S. who are extraordinarily equipped to meet the needs of athletes.

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 sports medicine specialists 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 is *OTW's* list of the top 19 sports medicine specialists in the United States.

David W. Altchek, M.D. is an attending orthopedic surgeon and co-chief in the Sports Medicine & Shoulder Service at Hospital for Special Surgery. He is the medical director for the New York Mets and a medical consultant for the NBA. Dr. Altchek is a professor of Surgery in Clinical Orthopaedics at the Weill Cornell Medical College. "He has vast experience in treating baseball injuries, and has developed a popular variation on the Tommy John surgery. He is very active in research and education and is a real sports medicine innovator."

James R. Andrews, M.D. is one of the founding members of the Andrews Sports Medicine & Orthopaedic Center in Birmingham, Alabama. He is a past president of the American Orthopaedic Society for Sports Medicine (AOSSM).



Wikimedia Commons and U.S. Navy photo by Photographer's Mate 2nd Class Jayme Pastoric

He is clinical professor of Orthopaedic Surgery at the University Alabama Birmingham Medical School, the University of Virginia School of Medicine, the University of Kentucky Medical Center, University of South Carolina Medical School and adjunct professor in the Department of Orthopaedic Surgery at

the University of South Alabama. Dr. Andrews is senior consultant for the Washington Redskins, medical director for the Tampa Bay Rays, team physician for the Birmingham Barons Double A Professional Baseball Team, and medical director of the Ladies Professional Golf Association. "He taught us how to man-

age and think about the entire system that surrounds professional athletes, i.e., that in addition to working with the athlete, we must also know how to work with trainers and coaches. He is a charismatic leader who has helped us get better outcomes in the field.”

Ned Amendola, M.D. is professor and director of the University of Iowa Sports Medicine Center. He is a professor at The University of Iowa Department of Orthopaedic Surgery. Dr Amendola is the Kim and John Callaghan Endowed Chair in Sports Medicine. He is the head team physician for the Hawkeye football team. “He is well respected, and has done a lot of biomechanical and clinical research in knee surgery techniques. He is an honest man with great integrity... and he is a super educator.”

Robert A. Arciero, M.D. is professor and chief of the Sports Medicine Division of the Department of Orthopaedic Surgery at the University of Connecticut Health Center. He is also the director of

the Orthopaedic Sports Medicine Fellowship program at the UConn Health Center. Dr. Arciero is a team physician for the University of Connecticut athletic programs. He is also an orthopedic team physician for USA Hockey.” “He has won numerous awards for his knee and shoulder research, and is in the presidential line for AOSSM. He is very well respected, honest, bright, a good leader, and a good teacher.”

James P. Bradley, M.D., M.S. is a sports medicine specialist with Burke & Bradley Orthopedics at the University of Pittsburgh Medical Center. Dr. Bradley is head orthopedic surgeon for the Pittsburgh Steelers. He is a past president of the National Football League Physicians Society and of Herodicus. “He is extremely experienced in the professional athletic realm and has very clear and consistent judgment with regard to patient care. Surgically, he is excellent.”

Daniel D. Buss, M.D. is the founder of Sports and Orthopaedic Specialists

in Minneapolis, Minnesota. He is an orthopedic consultant to the University of Minnesota varsity athletes, Macalester College and Northshore Gymnastics. He is also a team physician for the Minnesota Twins. “He is an expert in shoulder injuries in all kinds of athletes (throwing athletes or those in contact sports). He is outstanding and has contributed greatly to our understanding of shoulder injuries.”

Brian J. Cole, M.D., M.B.A. is a sports medicine and cartilage restoration orthopedic surgeon at Midwest Orthopaedics at Rush. Dr. Cole is a professor in the Department of Orthopedics with a conjoint appointment in the Department of Anatomy and Cell Biology at Rush University Medical Center in Chicago, Illinois. In 2011, he was appointed as chairman of surgery at Rush Oak Park Hospital. He is the section head of the Cartilage Research and Restoration Center at Rush University Medical Center. Dr. Cole is the team physician for the Chicago Bulls, co-team physician for the Chicago White Sox team and for DePaul University in Chicago. “He is known for doing important basic science research—as well as clinical research—and has brought many innovations to our field. He is a real leader and is widely respected.”

John E. Conway, M.D. is a sports medicine specialist with Orthopedic Specialty Associates, Texas Health Physicians Group in Fort Worth, Texas. He also serves as medical director for Ben Hogan Sports Therapy Institute at Texas Health Harris Methodist Hospital Fort Worth. He is Team Orthopedic Consultant for the Fort Worth Cats Professional Baseball Team, the University of Texas at Arlington, and is Baseball Orthopedic Consultant for Texas Christian University. “He is well known for baseball medicine involving the shoulder and elbow. He is an outstanding

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surgeon with meticulous training...and he does sports medicine for all the right reasons.”

Daniel E. Cooper, M.D. is a sports medicine specialist with the Carrell Clinic in Dallas, Texas. He is a past president of the Texas Sports Medicine Society and is an independent consultant to numerous collegiate and professional teams, sports agents and their players. He is also the head team physician for the Dallas Cowboys. “He has great judgment, is a logical thinker, and is a talented surgeon. He is also known for his research and teaching activities.”

Neal S. ElAttrache, M.D. is a sports medicine specialist with the Kerlan-Jobe Orthopaedic Clinic in Los Angeles, California. Dr. ElAttrache is chairman of the Board of the Kerlan-Jobe Orthopaedic Foundation and program director for the Kerlan-Jobe Fellowship. He is the team physician for the LA Dodgers and is an orthopedic consultant to the Anaheim Mighty Ducks, St. Louis Rams, LA Lakers, LA Kings and the PGA Tour. “He is a master when it comes to the shoulder, elbow, and knee. He is an extremely thoughtful surgeon and is technically excellent.”

Freddie H. Fu, M.D. is the David Silver Professor and Chairman of the Department of Orthopaedic Surgery, University of Pittsburgh School of Medicine. Dr. Fu specializes in sports medicine and holds secondary appointments as professor of Physical Therapy, Health & Physical Activity, and Mechanical Engineering and serves as the head team physician for the University of Pittsburgh’s Athletic Department. He is a past president of the AOSSM. “He is the primary person that came up with the concept of anatomic ACL reconstruction. He is world famous and is a major influence in sports medicine.”

Christopher D. Harner, M.D. is medical director for the Center for Sports Medicine at the University of Pittsburgh. He is also the current president of the AOSSM. Dr. Harner is the Blue Cross of Western Pennsylvania Professor of Orthopaedic Surgery at the University of Pittsburgh School of Medicine. He holds a secondary appointment as professor of Physical Therapy, Health, and Physical Activity. “He is known for his leadership and co-directs one of the most prestigious fellowships in the country. He has also been a prolific author.”

Darren L. Johnson, M.D. is professor and chair of the Department of Orthopaedic Surgery at the University of Kentucky. He is director of sports medicine and serves as head orthopedic surgeon for the Kentucky Wildcats. “He is a great teacher; he is also known for his important work on the ACL. He is a major proponent of the newer anatomic technique.”

Walter R. Lowe, M.D. is the Edward T. Smith Professor & Chair, Chairman & Professor in the Department of Orthopaedic Surgery at the University of Texas Medical School at Houston. He is also the medical director of the Memorial Hermann Sports Medicine Institute and the chief of Orthopaedic Surgery at the Memorial Hermann Hospital - Texas Medical Center & LBJ Hospital Houston. He is the head team physician for the Houston Texans and the Houston Rockets. “He is extremely experienced with sports injuries, especially those in the knee. He is a very caring doctor and knows how to develop a great rapport with patients/players.”

C. Benjamin Ma, M.D. is the chief of sports medicine and associate professor in residence at the University of California, San Francisco. “He is doing impressive research in cartilage knee and is tal-

ented leader. He is a very vibrant part of the sports medicine community.”

Mark D. Miller, M.D. is the S. Ward Casscells Professor of Orthopaedic Surgery at the University of Virginia and a team physician at James Madison University. “He is very prolific in terms of his work on review courses; he is an excellent teacher and clinician.”

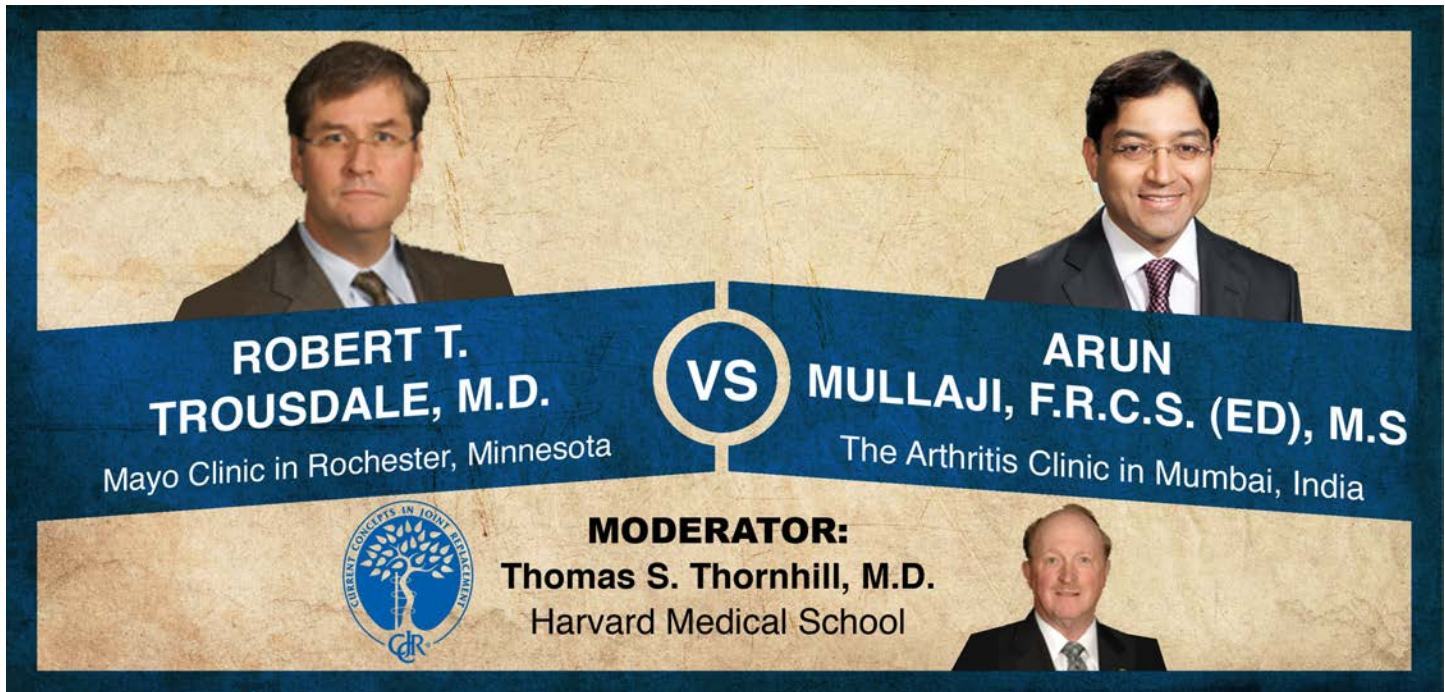
Marc Safran, M.D. is associate chief of sports medicine, fellowship director of sports medicine, and professor of Orthopaedic Surgery at Stanford University. “He is known for his research on clinical outcomes in hip arthroscopy. He is well respected and is highly sought after for meetings and speaking engagements.”

Russell F. Warren, M.D. is surgeon-in-chief emeritus of Hospital for Special Surgery, attending orthopedic surgeon and professor of orthopedics at the Weill Medical College of Cornell University. He is a former president of the American Orthopaedic Society for Sports Medicine and the American Shoulder & Elbow Society (ASES). He is the team physician for the New York Giants football team. “He is a great educator and is always a student. He has stayed ‘on the curve’ despite being a veteran in orthopedics. He is known for being innovative and forward thinking; he has solid clinical judgment.”

Lewis A. Yocum, M.D. is a sports medicine specialist with the Kerlan-Jobe Orthopaedic Clinic in Los Angeles. He is the team physician to the Los Angeles Angels. “He is reknown for treating baseball athletes; he is very respected for his work on the shoulder and elbow, particularly in overhead throwing athletes. He is a resource for the diagnosis and treatment of injuries that involve complex decision making.” ♦

Computer Navigation in TJA: Thumbs Up or Down?

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



Current Concepts in Joint Replacement/RRY Photo Creation

“It’s 2011 and we’ve got no proven benefit of computer assisted total knee surgery. And we’re well into the second decade of use,” states Robert Trousdale. “Wait,” says Arun Mullaji, “There are absolute pros to this. Intra-operatively we know that it helps alignment, but more importantly it helps balance the knee. And there is more.”

This week’s Orthopaedic Crossfire® debate is “Computer Navigation in TJA: More Bother Than It’s Worth.” For the proposition was Robert T. Trousdale, M.D. from Mayo Clinic in Rochester, Minnesota. Against the proposition was Arun Mullaji, F.R.C.S. (Ed), M.S. of The Arthritis Clinic in Mumbai, India. Moderating was Thomas S. Thornhill, M.D. from Harvard Medical School.

Dr. Trousdale: “In 2011 we’ve got no proven benefit of computer assist-

ed total knee surgery. That might be alright if it was a new technology, but we’re now well into the second decade of use.”

“There’s been a meta analysis looking at 11 level one studies—randomized controlled trials—and their conclusion was that, ‘Navigated knee replacement provides few advantages over conventional surgery. Its clinical benefits are unclear and remain to be defined.’”

“What has been demonstrated with the computer is that it’s a better tool to hit a specific target than manual instruments. The problem is that we don’t know what the right target is for each individual patient. And there may be factors other than mild malalignment that may be important for durability. But it’s a good tool for research information, and it can help us learn what

the optimal alignment of a total knee replacement is.”

“Demonstrated negatives to computer assisted surgery (CAS): increased surgical times, increased cost, and an increased prevalence of specific complications. The fundamental premise of CAS is that it will improve our alignment for a large cohort of patients, and that is going to improve survivorship of our knee replacements. I’m not sure that’s been well shown.”

“As for the data looking at survivorship relative to overall knee alignment, the studies have been relatively poor... using short X-rays. And John Moreland’s was a review...not a great way to look at the mechanical axis. Mark Pagnano spearheaded this study, which had 399 knees and 275 patients.”

“Postoperatively, we broke down the patients into five zones: 300 [knees] were in the middle, 60 were in a bit of valgus and 35 were in varus. At 15-year follow-up we were unable to show any survival free of revision for any reason on postop alignment...any difference between the well aligned knees and the outlier knees. So the survivorship at 15 years—with revision as the endpoint—was the same. Survivorship, using aseptic loosening or wear osteolysis as an endpoint—again, no difference. The malaligned knees did the same as the well aligned knees.”

“This study told me three things: one, that there may be factors other than alignment that may be important for a 15-year survival. Also, total knees can do alright in the long term with mild malalignment. Lastly, we don't know where the alignment should be in our total knee replacements.”

“Navigated knees can be tricky. In the OR we now have tracking devices, camera, additional OR traffic. I think the future of computer/robotic assisted surgery is going to be out of the OR. If you move the computer out of the OR it will save time and resources. And it will save your mental energy to do the important part of the operation which is the soft tissue balancing.”

Dr. Mullaji: “Let's start with the cons. Does CAS take more time? Most surgeons don't take a lot more time—0-5 minutes at most. There are two studies showing that most surgeons become time neutral within 20-30 total knees. We also have much faster software and much smarter hardware.”

“There are a lot of studies showing that there is a cost effectiveness to the use of navigation for total knee replacement. This is impacted by the hospi-

tal volume and the initial cost of the equipment. Is there a learning curve? There are two recent studies showing that when you take experienced versus novice surgeons or centers, there is no difference in accuracy, outcomes, or complications from the first case onwards. In my own series of nearly

1,500 CAS total knee cases there has been no learning curve and you get very good results in terms of alignment.”

“Intraoperatively we know that it helps alignment, but more importantly it helps balance the knee. It also helps in the assessment that you've corrected

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the deformity. There are many papers saying that alignment is achieved with navigation. There is our own paper of nearly 500 cases where we've shown that navigation can reduce the number of outliers. And we've extended these over a much larger series, and we've reduced the outliers to under 8%."

"It has particular value in the obese; you can't really determine where the femur is, where the hip center is in these cases. There are two studies showing that in conventional surgery when you analyze these patients there are nearly 40% outliers with conventional methods...we can drastically reduce this with navigation."

"You can verify your accuracy before and after you perform the cuts—you can't do that with patient specific instrumentation. More importantly, it helps to reduce the number of femoral components which are internally rotated as compared to conventional surgery."

"Soft tissue balancing: You can check your medial and lateral gaps, not only at 0 and 90 degrees of flexion, along with the alignment, but throughout the range of motion. Once you've achieved a rectangular extension gap, CAS can help to achieve an equal flexion gap. You can play on the computer screen, anteriorly or posteriorly shift the component, flex or extend it, up/downsize the femoral component, ensure your gaps are perfectly equal and then cut."

"There is a study showing that if you have better aligned knees, the International Knee Scores are better, the SF-12 Physical Scores are better, as well as the SF-12 Mental Scores. Gait analysis studies have shown improved outcomes with daily activities when you use navigation versus conventional surgery. Moreover, you have reduced blood

loss, a reduced incidence of fat emboli, and a reduced incidence of notching."

"As for the long term, the main indication for navigation is to try and stem this rising tide of revisions. If you look at 60,000 revisions performed across the U.S., 42% are due to mechanical causes...so alignment and stability do matter."

"We've shown with radiostereometric analysis studies that there's less tibial subsidence if you use navigation as compared to conventional means. And I've looked at my own revision rate for mechanical causes before we started using CAS (so in the last 1,000 conventional total knees) and we had 15 revisions. Compare this to our first 1,000 with navigation where we reduced it to just three revisions for mechanical causes."

"When you combine technique with technology you have an unbeatable combination. People may tell you it takes time...find the time!"

Moderator Thornhill: "Thirty second rebuttal, Rob?"

Dr. Trousdale: "In specific circumstances a computer can help, such as with previous complex hip surgery or malalignment from trauma to the femur or tibia. Having said that, we don't know where exactly to put the mechanical axis. We don't know where the rotation of the femoral tibial component should be. Nor do we know where the balance should be. This is a tool that may help us get there, but in 2011 it's not for routine clinical usage."

Moderator Thornhill: "Arun?"

Dr. Mullaji: "We don't know what the exact mechanical axis should be, but

that's not a fault of the tool. But if you have data as to what is the best axis to target I think there's no better tool than navigation. Even if you want to go by the soft tissues and say, 'This is how I want to balance my knee. I want to leave it in two degrees of varus,' then this is a tool that's going to be able to get you there."

Moderator Thornhill: "Rob, when would you use it?"

Dr. Trousdale: "I've used it for big deformities, I would use it for big varus bow of the femur/tibia. If you don't have access to that then intraoperative fluoroscopy is not as precise as the navigation, but it's certainly more precise than eyeballing the cuts and intramedullary guides. I'd have no qualms about intraoperative X-ray either if I didn't have access to navigation."



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Moderator Thornhill: “What would it take for you to use it routinely in the OR?”

Dr. Trousdale: “A lot of medicine for myself.”

Moderator Thornhill: “You’re on a lot of medicine, right?”

Dr. Trousdale: “It would have to be time neutral and efficient and show proven long-term benefits.”

Moderator Thornhill: “I’ve never seen—when I add equipment—that the cost remains neutral?”

Dr. Mullaji: “There are enough studies to show that if you factor in your hospital volume, your initial costs are not that high. The economists are saying that it is a very cost effective tool.”

Moderator Thornhill: “But aren’t they saying that it will increase your hospital volume?”

Dr. Mullaji: “I don’t think the studies are showing that, but if you have a large

number of cases then your initial cost is reduced.”

Dr. Trousdale: “I think some of those make the assumption that it may decrease your revision rate. You’ve got to prove that before you can make that assumption. But on the front end it’s a more expensive technology.”

Moderator Thornhill: “Will we all be using some form of navigation in the future?”

Dr. Mullaji: “Yes, whether you’re going to be using navigation from home trying to figure out these cutting blocks or intraoperatively. I suspect that a lot of us will continue to use navigation for every case, especially as it gets more portable and the software is improved.”

Moderator Thornhill: “I’ve not used navigation, but I’ve been told that you’re not as good with soft tissues with navigation. If it’s a loose knee I put it in tighter than I would in a knee that is tight. Do you agree that you can balance the soft tissues as well?”

Dr. Trousdale: “With navigation?”

Moderator Thornhill: “Yes.”

Dr. Trousdale: “I didn’t use it for soft tissue balancing. I just use it for sagittal and axial alignment. Arun, why don’t you think there is penetration in the U.S. and Canada with that technology if it’s that great?”

Dr. Mullaji: “It’s partly related to the perception people have that navigation is more cumbersome, more time consuming, and that it’s not easy to learn.”

Dr. Trousdale: “Every surgeon has different error points. Mine in total knee surgery appear to be on my tibial slope and that is where navigation did help me.”

Dr. Mullaji: “In our cases we have a lot of deformity in the femur...in the coronal plane...and this technology helps us put the distal resection at 11 degrees if necessary, something you can’t do with conventional surgery.”

Moderator Thornhill: “Thank you.” ♦

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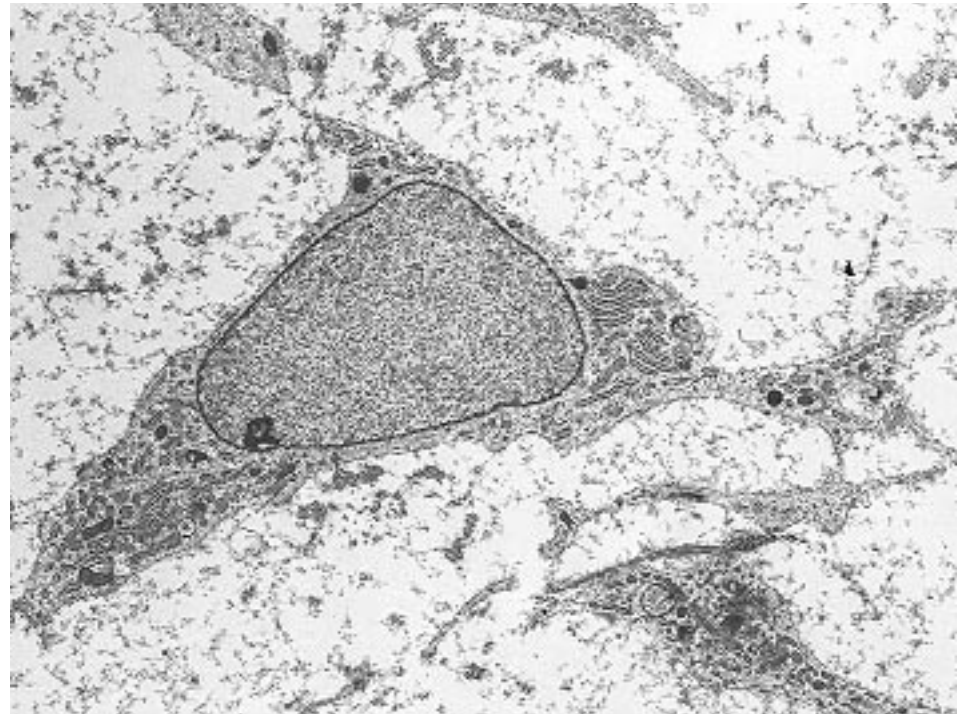


Stem Cells for Tendonitis Study at HSS...To Avoid Overly Aggressive Anticoagulation Ignore Small Clots?...Disaster Certification: Where Are We?

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

Key Stem Cell Tendon Study at HSS The labs at Hospital for Special Surgery (HSS) are humming these days, as clinician scientists delve into soft tissue healing...specifically, in the identification of cell based approaches. Scott Rodeo, M.D., co-chief of the Sports Medicine and Shoulder Service at HSS tells OTW, “We have a rat model of tendonitis where we are evaluating the role of stem cells in improving the structural changes in the tendon. Thus far we have learned that these implanted cells do have the ability to modify tissue. Next, we will determine how to direct the cells to act like a tendon cell. We need to find out the exact signals needed to push the cells down the appropriate pathway. We are seeing that these cells have a positive role in improving the structural and biomechanical properties.”

“Our team is poised to begin a meniscus repair model in rabbits which we will ultimately transfer to humans. We are also looking at the initial feasibility of using bone marrow derived cells for the improvement of rotator cuff healing in humans. We will take a sample of cells that we use in each patient and look in the lab and measure the cell concentration and specific cell surface markers. The fact of the matter is that we don't truly know what these cells are. We call them stem cells, but we don't know how accurate that is. It's also not yet clear how well they proliferate in cell culture. There appears to be tremen-



Wikimedia Commons and Robert M. Hunt

dous variability in the behavior of these cells between different individuals.”

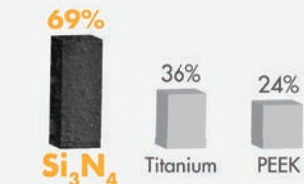
“Then there is the other side of the equation, namely, the effect of mechanical loading on these tissues. How the cells behave may depend on the mechanical load on the cells. We are doing ACL reconstructions in rats where we use an external fixator on the knee, and control the knee's motion and ligament loading. Thus far we have found that excessive or early post-op motion is likely to have a detrimental effect on healing. We are excited by the fact that this has tremendous clinical applicability.”

Disaster Certification: Are You Ready? While “help” is not a dirty word, heading into a disaster zone unprepared can get you—and the people you are trying to assist—into loads of trouble. To avoid such scenarios, the American Academy of Orthopaedic Surgeons (AAOS), the Orthopaedic Trauma Association (OTA) and the Society of Military Orthopaedic Surgeons (SOMOS) have developed a certification process and database for orthopedists who want to respond to disasters. Christopher Born, M.D., chief of Orthopedic Trauma at Rhode Island Hospital within the Department of Orthopaedic

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Surgery of Brown University, updates us on the status of this program. “This project emanated from our experiences in Haiti, where we found that despite good intentions, many surgeons didn’t know what they were getting into. It became clear that some major issues could best be addressed through an educational program. These include working with the government/military as well as Nongovernmental Organizations (NGOs), the organization of disaster response, personal safety and security as well as ethical/cultural considerations when treating people in an austere environment.”

“To date the disaster preparedness course has been given three times, with the fourth session planned for the AAOS meeting next month [March 19-23] in Chicago. A total of 179 par-

ticipants have attended the course and the one scheduled for March is full at 75 attendees. Of this pool, AAOS has started the first responder database and thus we now have a ‘bank’ of 130 surgeons willing and properly trained to do disaster work.”

“One of our goals is to educate surgeons as to what they might expect...what to bring, what not to bring, etc. Doctors have to be physically fit, and know the ins and outs of their personal liability. Their malpractice insurance may not cover this work; the same is true of their life insurance and disability insurance. Then there are the proper immunizations, i.e., those required by government teams.”

“We are encouraging orthopedic surgeons to get involved with some of the

government disaster response teams like Disaster Medical Assistance Teams (DMATS) or the Department of Health and Human Services’ (HHS) IMSuRT team. Unfortunately, the government is still not well organized in terms of incorporating civilian responders into the military or HHS for the purposes of surge coverage in the event of a national or international disaster. The AAOS, OTA, and SOMOS continue to work on a number of levels to move the ball downfield toward pre-credentialing surgeons in order to work with government teams. Frankly, this may require some sort of legislative action. The educational programs that have been enacted by the orthopedic professional organizations may help to ease some of the government’s fears of incorporating civilians in the disaster response programs. By setting an example, it is also

hoped that other professional medical organizations will also actively engage their memberships in this type of activity.”

Pass on Small Clots? Clot size does differ, but what to do with the smaller ones? 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 and a former president of the OTA. He tells *OTW*, “The sizes of pulmonary emboli (PE) vary, with smaller, subsegmental clots having a much lower pulmonary risk than larger lobar or central clots. With advent of the CT pulmonary angiogram we are seeing many more PE being diagnosed...but most of this increase are smaller sized clots. There are multiple papers in the literature showing that the rate of PE is increasing but death from PE is not. This has been termed “overdiagnosis” due primarily to the diagnosis of very small and possibly clinically irrelevant clots. Some of these are likely normal anatomic variants that are being called subsegmental PE.”

“At present there is not much agreement as to what to do with these small clots, and while there is some data suggesting that they are not dangerous most physicians are immediately responding by aggressively anticoagulating patients. This approach carries its own risks, primarily that of increased bleeding, which may lead to other complications, including death.”

Yelena Bogdan, M.D., a PGY3 resident at Boston University Medical Center, led a multicenter evaluation looking at the complication rates in orthopedic trauma patients who were diagnosed with a PE. She states, “Our team has

examined data from multiple trauma centers, looking at DVT prophylaxis, the tests used to diagnose PE, the treatment instituted and the complications of both the PE (pulmonary) and the treatment (bleeding, infection, etc.). We found that all of the centers are responding similarly and are performing very aggressive anticoagulation irrespective of the size of the clot. Interestingly, the complication rate of the anticoagulation was 12%; these rates were the same regardless of the size of the clot, but the pulmonary complications varied. The bigger the clot the worse the pulmonary complications.”

Dr. Tornetta added, “This work is essentially a snapshot of how trauma centers are diagnosing and treating PE. Based on this review, we have a better idea of the risks of aggressive anticoagulation. However, we don’t yet know the true risk of using a different protocol. We will approach our next study in a prospective manner with careful monitoring. We have formed a committee on this topic and they are taking a hard look at how to most appropriate way to proceed. Perhaps we will choose one anticoagulant for a trial and only address subsegmental clots as a first measure. No one center sees a lot of these, meaning that we would need multiple centers. But wouldn’t it be great if we found that anticoagulation wasn’t necessary in some cases...then we could eliminate certain risks for some patients.”

Patent Alert: Statins for Tendonitis

High cholesterol could be a real drag on your tendons, says a shoulder surgeon from the Rothman Institute in Philadelphia. Joseph A. Abboud, M.D. is an orthopedic surgeon at Rothman, as well as an associate professor of Orthopaedic Surgery at Thomas Jefferson University Hospital. He tells *OTW* about their news. “We recently had a patent

approved for the application of cholesterol lowering agents—statins—for the treatment of patellar tendon injury. Through work done at the University of Pennsylvania, Louis J. Soslowsky, Ph.D. and I have demonstrated an association between elevated cholesterol and tendon disease. In mice, rats, pigs, and monkeys we have shown altered tendon mechanical properties; we are also seeing altered tendon healing properties in animals exposed to high cholesterol diets versus animals on a regular diet. We believe intrinsic changes happen over the lifetime of a tendon leading to its degeneration and possibly ultimate failure. One of the factors that predisposes a tendon to degenerative processes may be years of elevated cholesterol. In the near future, we are looking to initiate a clinical trial looking at the use of cholesterol lowering agents for the prevention of tendon injury.” ♦

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**Zimmer Steady in 4Q
– New Knee Arriving**

Zimmer Holding Inc.'s fourth quarter revenue came in at \$1.18 billion, up 2.1% on a constant currency basis over the previous year's quarter.

Hips and knees came in down 1% and up 1%, respectively. The company likely lost some market share during the quarter.

Based on results from Biomet, Inc., Johnson & Johnson's DePuy Synthes Companies, Stryker Corporation, Zimmer and estimates for other companies, Mizuho Securities USA analyst Mike Matson estimates that, on a constant currency basis, global knee growth was 2% and hip growth was 1% during the fourth quarter. Wells Fargo's Larry Bielsen believes that the hip and knee markets, on a constant currency basis, grew 2.2% and 2.8%.

Persona Knee - "Largest Launch Ever"

Company officials told Wall Street analysts on January 31, 2013 that the company began to expand the release of its new knee, Persona, "The Personalized Knee System." Dave Dvorak, company CEO and president said the new knee builds on the clinical legacy of the Nex-Gen and Natural-Knee systems and provides surgeons with "unprecedented options to personalize each patient's treatment."

"It's going to be the company's largest launch ever," said Dvorak. He added that launching a system of this magnitude will involve multiple stages over the next several years. Also in the quar-

ter, iASSIST Knee, the personalized guidance system, received FDA clearance.

Hip sales grew in the Americas by 1.8%, but declined 5.2% in Europe, Middle East and Africa.

Extremities sales improved 7.5%. "We continue to generate strong sales of our Trabecular Metal Reverse Shoulder System, Trabecular Metal Humeral Stem and our recently introduced Sidus Stem-Free Shoulder System," said Dvorak.

Zimmer Spine's \$96 Million Goodwill Charge

The spine franchise continued to be a challenge as Dvorak announced that the company would be taking a \$96

million goodwill impairment charge against the value of the business. He said the change in outlook for the U.S. spine market, together with ongoing company-specific challenges, contributed to the decrease in the implied fair value of the U.S. spine business.

Joint Preservation

Forecasting that the joint replacement industry is moving towards becoming a joint preservation business, Dvorak said the company was continuing to make progress building out early intervention portfolio of products. "These products extend our reach into joint preservation earlier in the continuum of care for arthritis and specifically, knee arthritis. In the fourth quarter, we began the broader introduction of our Gel-One hyaluronic acid injection product to promising early feedback."

The company expects full year revenues in 2013 to increase between 2.5% and 4.5% in constant currency when compared to 2012.

—WE (February 1, 2013)

| Zimmer 4Q12 | Sales (\$ in millions) | % Change* |
|--------------------|---------------------------|-------------|
| Total Sales | \$1,181 | 2.1% |
| Reconstructive | \$872 | Flat |
| Knees | \$476 | 1.0% |
| Hips | \$349 | Down 1% |
| Trauma | \$84 | 10.0% |
| Spine | \$54 | Down 5% |
| Extremities | \$47 | 7.0% |

Source: Zimmer Holdings, Inc.

* In constant currency



Courtesy of Zimmer Holdings, Inc.

Stryker's 6.7% 4Q Recon Growth Raises Bar

Stryker Corporation had a very good fourth quarter. After tamping down expectations during his first quarterly call with analysts in October, Stryker's new President and CEO Kevin Lobo was able to beat expectations in his second analyst call on January 23, 2013.

Stryker's reconstructive sales grew by 6.7% during the quarter. Trauma and extremities led the way with sales growth of 10.2%. But the big surprise and good news for the orthopedic market was that reported knee and hip sales grew 5.4% and 3.6 respectively. The spine division also had a good quarter, growing by 6.4% on a reported basis.

Lobo gave his VP of Strategy and Investor Relations Katherine Owen the chance to give the good news. Owen told analysts that company management is pleased with the momentum it is seeing in the U.S. in both hips and knees, crediting some of that to the company's *GetAroundKnee* campaign.

On the hip side, she noted the Accolade launched in the second quarter of last year. "I think at this point, at the very least, the [recon] market is stable, to maybe modestly improved in the fourth quarter. How much share shifting we've seen, it's just too early to predict until all the numbers come in. But we feel pretty good about the stability of the market and certainly some of the momentum that we're seeing."

Core spinal implant sales accelerated to post mid-single-digit constant currency sales growth, helped by a double-digit increase from the biologics products obtained by the acquisition of Orthovita.

Lobo: "Good Outlook for 2013"

"And if you look at our recon business over the full year," added Lobo, "it was a very strong year. If you go all the way back to January, we've had pretty much a strong year across knees and hips with knees accelerating more. Hips, obviously, had a little bit of a dip in the third quarter and then picked right back up. Hips have been on a pretty good roll for almost eight quarters now. So it's kind of sustained strong performance. I'm very happy with the leadership team we have out there. And so really have a good outlook going into next year."

Some analysts were ready to declare the end of the big dip from the Great Recession.

Piper Jaffray analyst Matt Miksic said that if the remaining manufacturers report results in-line with analyst estimates, constant currency growth for the reconstructive market will be up 2.2%. "For context, this compares to

U.S. recon growth of 0.9% in 3Q12 and 0.1% in 4Q11. We view these trends as supportive of our view that growth trends in the ortho market continues to improve after decelerating and bottoming during the period from mid-2008 through the end of 2011."

Room to Grow

Responding to a question from BMO Capital Market analyst Joanne Wuenssch on how he plans to make his mark on the company, Lobo got to talking about one of his favorite subjects, globalization and the recent acquisition of Trauson, a Chinese orthopedic manufacturer.

"We have a lot of room to grow. There are a lot of products that have been a great success within the U.S. that we have yet to really operationalize outside the U.S. So globalization and innovation is a big area of opportunity," responded Lobo. Expectations for Lobo and Stryker have just gone up.

| Stryker Corporation 4Q12 | Sales (\$ in millions) | % Change* |
|--------------------------------------|------------------------|-------------|
| Reported Reconstructive Sales | \$1,046 | 6.7% |
| Hips | \$325 | 3.6% |
| Knees | \$360 | 5.4% |
| Trauma/Extremities | \$278 | 10.2% |
| Spine | \$190.0 | 6.4% |

Source: Stryker Corporation

For the full year 2013, the company is projecting constant currency sales growth in a range of 3.0% to 5.5%.

—WE (January 25, 2013)



Image created by RRY Publications, LLC. Source: Corporate logo

DePuy Synthes Results Points to Recovery

If Biomet, Inc. is the canary in the coal mine for orthopedics, then DePuy Synthes Companies is the bellwether.

Results for the bellwether were good in the fourth quarter of 2012 as the company reported sales of \$2.388 billion for the quarter. Excluding the impact of the Synthes acquisition in June, those revenues represented a 3.5% increase over the previous year. Reported sales were up 65.1% if Synthes was included.

Company executives told Wall Street analysts on January 22 that they have made significant strides in the integration of Synthes and solidifying their leadership position in orthopedics.

Interestingly, company executives practically swooned over Synthes, mentioning the company's name frequently and in positive terms. DePuy was rarely mentioned.

Hips, Knees and Trauma Up, Spine Down

Operationally, hips were up 6%, driven by 7% growth in the U.S. due to strong results in primary stem platform sales, partially offset by continued pricing pressure. Hips outside the U.S. were up 4% operationally, driven by the growth of cemented stems, heads, and acetabular products.

Knees increased 4.1% on an operational basis, with the U.S. up 7% driven by fixed bearing and revision platforms. Sales outside the

U.S. were up 1% with growth in Asia and Latin America, partially offset by softer sales, primarily in Europe, due to competitive pressures.

Including the Synthes business, and excluding the divested DePuy trauma business, trauma grew approximately 1% on an operational basis, with the U.S. down 4% and sales outside the U.S. up 6% on an operational basis. U.S. growth was impacted by a supply disruption.

Including the Synthes business, spine was down 3% on an operational basis, with the U.S. down approximately 7%, impacted by continued softness in the market as well as the restructuring of the commercial sales organization. Outside the U.S., sales grew approximately 4% operationally.

Share Improvements

Alex Gorsky, the chairman and CEO of DePuySynthes' parent company Johnson & Johnson, said he hasn't seen all of the orthopedic companies report yet, but he was pleased with DePuySynthes' sales results. "It's a little too early for us to know if we've gained share or not. But certainly these results are impressive and our early indications are that we have done better in share in both hips and knees, especially in the U.S... If we look particularly in knees, we're seeing the market come back a bit more than in hips right now."

| J&J Orthopaedics 4Q2012 | Sales (\$ in millions) | % Change |
|-----------------------------|------------------------|---------------|
| Total Reported Sales | \$2,388 | 3.5%** |
| Knees | | 4.1% |
| Hips | | 6.0% |
| Spine | | Down 2.8% |
| Trauma | | 1.0% |

Source: Johnson & Johnson

* Constant Currency

**Excluding Synthes



Image created by RRY Publications, LLC. Source: DePuy Synthes

“You’re going to hear more about a new knee system that we’ll be launching through the course of 2013,” promised Gorsky.

Resurgence and Reform

“We see a lot of reasons to believe in underlying growth...we are very pleased with some of the resurgence that we saw, for example, in the hip and knee categories, especially in the fourth quarter,” said Gorsky.

If the device industry was looking for support in criticizing the new 2.3% device excise tax, they didn’t find it in comments from the company’s leaders.

For 2012, the company’s effective tax rate, excluding special items, was 21.2%. For 2013, the company expects that rate to be approximately 20%. The Johnson & Johnson CFO said this effective tax rate for 2013 includes the federal R&D tax credit renewed by Congress under the American Taxpayer Relief Act for both 2012 and 2013.

“It is important to note that the overall impact to Johnson & Johnson of the provisions of the Affordable Care Act in 2013 is estimated to be the equivalent of \$1 billion of cost, or approximately \$0.25 of earnings per share. While this is a significant cost, we remain committed to the principle of providing broader access to healthcare for all Americans,” added Gorsky.

Piper Jaffray analyst Matt Miksic said he viewed the unexpectedly strong results in U.S. hips and knees as positive for orthopedic utilization as well as broader medical device utilization rates.

—WE (January 23, 2013)

Solvay Biomaterials Enters Huge China Market

High performance polymers, which have allowed orthopedic implants to become routine treatments for the most severe orthopedic products, as manufactured by one of the leading innovators in this are—Solvay Specialty of Alpharetta, Georgia—are now available for the rapidly growing Chinese hospital market.

The percentage of China’s population which is aged 65 and over will double over the next 20 years. By 2050, 27% of China’s population will be elderly. In the first half of 2011, China’s government increased healthcare spending 61.4% to more than 245 billion RMP (source: Standing Committee of the National People’s Congress). China today has 18,396 hospitals with 4.2 beds per thousand people. In the next ten years, 80% of the Chinese hospitals will be rebuilt, expanded or relocated. In ten years, annual healthcare expenditures in China could reach \$1 trillion.

Solvay’s biomaterials line, previously available in the U.S. and Europe, is targeted to meet growing demand for high quality orthopedic implants in China. Company officials say that their biomaterials will primarily be targeted at orthopedic and cardiovascular applications.

“With our broad product portfolio we are firmly positioned as a strategic supplier to the Chinese healthcare industry and this expansion in biomaterials signals our further commitment,” said Shawn Shorrocks, global market manager for healthcare, in a January 13 news release. “We are leveraging our position as a leading supplier of high performance polymers to support applications from instrumentation to implants.”

Among Solvay’s biomaterials line are Zeniva PEEK; Proniva, a self-reinforced polyphenylene; Eviva, a polysulfone; and Veriva, a polyphenylsulfone. Officials say that the biomaterials can be sterilized via all conventional methods including gamma radiation, ethylene oxide, and steam. The products are available in resin for injection molding or extrusion, as well as stock shapes for machined components.

Solvay plans to serve the Chinese market from its Shanghai facility where it operates research and development, sales, and commercial activities. Company officials note that the entire line of thermoplastic biomaterials is manufactured in compliance with the relevant aspects of ISO 13485 and current Good Manufacturing Practices. All materials are tested in an accredited lab that is ISO 17025 compliant.

—BY (January 29, 2013)



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Plastics

Courtesy of Solvay Biomaterials

legal

FDA Won't Appeal First Amendment Off-Label Ruling

The FDA announced on January 23, 2013, that the agency would not appeal the landmark federal circuit court Caronia decision that the First Amendment protects truthful speech about the off-label use of FDA-approved products.

Alfred Caronia was prosecuted and convicted of conspiring to introduce a misbranded drug into interstate commerce. He was caught on tape telling a physician that the drug had uses other than what was on the product's label. The government had wired up a physician under unrelated Medicare fraud charges. That physician eventually committed suicide.

A dissenting judge wrote that the decision may restrict off-label prosecutions in the future. "The majority calls into question the very foundations of our century-old system of drug regulation." The decision only applied in New York, Connecticut and Vermont, the states covered by the appeals court.

After Caronia's victory, the FDA had to decide if the agency wanted to risk appealing the case and losing another round over free speech.

Dramatic Risks of Appeal

Tom Beimers, a former prosecutor in the Department of Justice and now in private practice at Faegre Baker Daniels LLP, told us that had the FDA pursued this case the agency would have risked "dramatically expanding the reach of what they can now plausibly argue is



Wikipedia.org

a narrow precedent with limited geographic and factual scope. For the same reasons this case lacked jury appeal—reliance on technically 'truthful' speech, absence of patient harm, and no 'sweeteners' such as lavish kickbacks—it is also a poor vehicle, from the government's perspective, for broader judicial review of off-label prosecutions."

During a recent Minnesota LifeScience Alley forum on the potential impact of the decision on the medical industry, Beimers told attendees that he would not have brought a case with these sets of facts to trial. At the same forum, Ralph Hall, a law professor at the University of Minnesota said it was unlikely that device or drug companies were lining up sales reps to test the FDA's off-label promotion position and using the Caronia decision to have the ruling applied throughout the rest of the country. The risk of losing and being given the "death penalty" for participation in federal healthcare programs like Medicare, are too high for companies, he said.

However, said Hall, the right to free speech is not only to speak freely, but also to hear freely. Perhaps, he mused, physicians, with less to risk, would bring charges that they are being denied the right to hear truthful speech from medical product sales people.

FDA: "No Significant Effect"

In a statement, the agency said, "FDA does not believe that the Caronia decision will significantly affect the agency's enforcement of the drug-misbranding provisions of the Food, Drug and Cosmetic Act. The decision does not strike down any provision of the... act or its implementing regulations, nor does it find a conflict between the act's misbranding provisions and the First Amendment or call into question the validity of the act's drug approval framework."

—WE (January 29, 2013)

large joints

One Bill Knee Surgery Gaining Adherents

The one-payment movement for knee surgery is gaining momentum. Blue Cross and Blue Shield of North Carolina announce a deal with Duke University Health System that allows the insurer's customers to make one payment for the procedure. The payment will cover care for a pre-surgical period of 30 days before the hospitalization, the surgery and follow-up care for 90 days after the patient is discharged from the hospital.

Neither the press release nor the report in the January 17 Durham *Herald Sun* disclosed the insurers' or hospitals' charge.

The program became effective at the first of the year and is available to Blue Cross's customers when knee replacements are done by Duke University doctors at Duke University Hospital or at the Durham Regional Hospital.

"These kinds of efforts in new care models that help drive greater efficiencies while increasing quality will become more and more prevalent and clearly represent the future of health care delivery," Victor J. Dzau, M.D., chancellor for health affairs at Duke University, and CEO of Duke University Health System, was quoted as saying in the release.

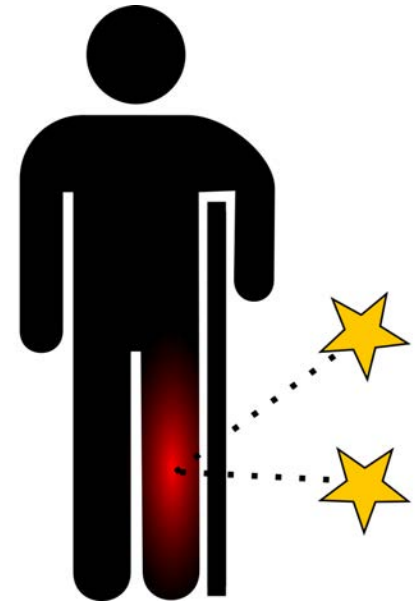
Blue Cross and Blue Shield of North Carolina has made a similar one-payment arrangement with Triangle Orthopaedic Associates when knee replacement surgery is performed at the specialty hospital jointly owned by Triangle Orthopaedic Associates.

As is done at Duke, the bundled payment includes pre-operative tests and office visits within 30 days of the procedure, appointments and care during the hospital stay, and related outpatient care for 90 days after surgery.

—BY (January 29, 2013)

Comorbidities Determine TKA Pain Years Later

Research into a patient's comorbidities when they undergo a total knee arthroplasty may explain pain that occurs two to five years later, according to research reported by Lynda Williams, senior *MedwireNews* reporter. Researchers Jasvinder Singh, M.D. of the University of Alabama, Birmingham, and David Lewallen, M.D., Mayo Clinic College of Medicine, Rochester, Minnesota, found patients who reported pain years after their surgery were also reporting a wide range of comorbidities including heart disease and depression.



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Morguefile and Spike

In their article in *Rheumatology*, the researchers wrote, "Research studies should examine whether preoperative and possibly postoperative optimization of management of these comorbidities can potentially reduce the risk

of poor pain outcomes after TKA [total knee arthroplasty]. With an increasing volume of TKA in the United States, a better understanding of risk factors for poor outcomes is critical to allow patients and surgeons to have realistic and appropriate expectations of TKA.”

To reach their conclusions, the two reviewed data from the Mayo Clinic Total Joint Registry for knee pain as well as function assessments of primary TKA patients two and five years after their surgery. They also examined the revision records for patients at the same two- and five-year intervals.

Singh and Lewallen found that 94% of patients underwent a TKA because they had knee osteoarthritis, 4% had rheumatoid arthritis, and 2% had other indications. The researchers examined patient records for diagnoses of heart disease, peripheral vascular disease, renal disease, chronic obstructive pulmonary disease, diabetes, connective tissue disease, anxiety, and depression.

Analysis showed that the likelihood of moderate to severe knee pain in primary TKA patients at the two-year check-up was significantly predicted by anxiety, implant fixation, and the patient's distance from the medical center. At five years, pain in primary TKA patients was significantly predicted by heart disease, depression and anxiety.

For the revision TKA patients, connective tissue disease and depression were significant predictors of moderate-to-severe pain at 2 years, but no comorbidity predicted the outcome at five years, Williams reported.

—BY (January 30, 2013)

Strong Support for Surgeons in Patient Survey

Laura Miller, writing in *Becker's Spine Review*, reports the encouraging news that only 6% of patients in the United States are concerned about the financial relationships that may exist between their surgeons and representatives of the medical device industry.

However, a study published in the *Journal of Bone and Joint Surgery*, found that a majority of patients believed that surgeons should not accept gifts from representatives of industry.

The study questioned 251 patients in the United States, all of whom had undergone hip or knee arthroplasty, as to their attitudes toward the presumed relationships between orthopedists and representatives of the device industry.

According to Miller, as reported in the *Spine Review*, the survey discovered that:

- 69% of patients thought it was appropriate for surgeons to receive royalties from device companies for their inventions
- 48% thought payment for consultancy was appropriate
- 63% thought it was not appropriate for surgeons to receive gifts from industry
- 76% felt their surgeon would hold the patients' best interest in mind regardless of financial ties to a manufacturer
- 86% wanted professional organizations to ensure financial relationships were appropriate
- 26% supported government oversight of relationships between surgeons and device companies.”

—BY (January 30, 2013)



Wikimedia Commons and Damien Yerrick

trauma

NFL Brains Show Signs of CTE

John Keilman, writing in the *Chicago Tribune* about a study published January 22 in the *American Journal of Geriatric Psychiatry*, suggests that the “Holy Grail” of spotting brain injuries in athletes may have been discovered by work done by renowned researcher Dr. Julian Bailes. Dr. Bailes is a nationally recognized researcher regarding the impact of brain injury on brain function.

Dr. Bailes, who has more than 100 peer review papers to his credit, has

been instrumental in the understanding of the clinical evidence of chronic traumatic encephalopathy (CTE), a progressive degenerative disease found in individuals who have been subjected to multiple concussions and other forms of head injury. Dr. Bailes is also a founding member and director of the Brain Injury Research Institute, which focuses on the study of traumatic brain injuries and their prevention at Evanston’s NorthShore Neurological Institute, Chicago, and the University of California at Los Angeles.

Dr. Bailes and his colleagues used brain scans to look at the brains of five former NFL football players, all of whom had experienced concussions, and compared them with the brains of five

non-football players of approximately the same age. The researchers were looking for signs of the dementia-like condition known as chronic traumatic encephalopathy, or CTE—a condition that is traditionally diagnosed only after death.

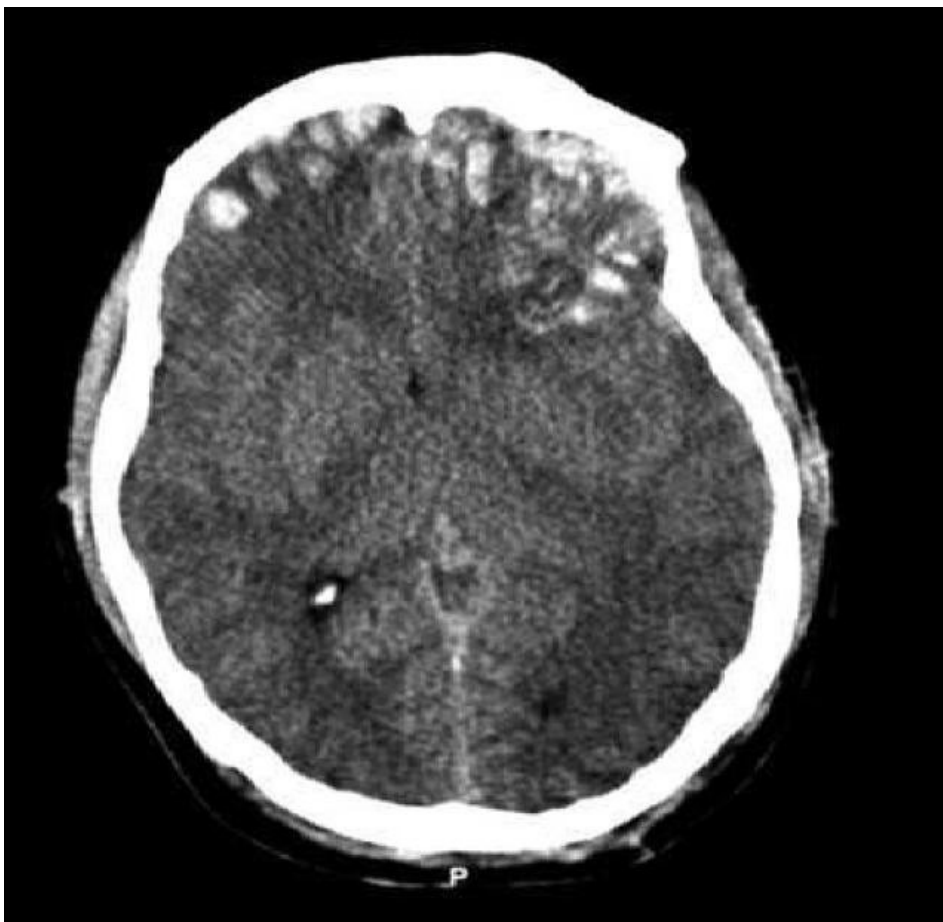
What they found in the scans of the football players was significantly more tau—which is a protein that is believed to build up and coat damaged brain cells—than they found in the brains of the control group. Doctors also found evidence of tau in the brains of retired football players who had committed suicide.

In the study, according to Keilman, the investigators injected the ex-players with a chemical designed to highlight tau deposits during a brain scan. When they compared the players’ scans with those of the control subjects who had not suffered concussions, they found that the players’ scans displayed vivid bursts of red, yellow and green.

Keilman quoted Dr. Bailes, the principal investigator, as saying that more research is needed to confirm the findings, but if they hold up, they could lead to new therapies and preventive measures to combat the toll of repetitive concussions. “For me, the holy grail of CTE is being able to diagnose it when someone is still alive, where you have the chance to make a difference or help somebody else,” he said.

Critics of the study question its reliability because of the small number of patients participating; that the presence of tau may not correlate with the presence of CTE and that the players’ symptoms of cognitive decline and depression could have other causes.

—BY (January 31, 2013)



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reimbursement

First Device Taxes Paid. Spine Likely To Benefit

The government's take on the first bi-monthly payment of the medical device tax came in at about \$97 million. That's the report from AdvaMed on Tuesday, January 29, 2013. Will orthopedic device makers make up the cost in higher sales?

Wells Fargo's analyst Larry Biegelsen recently took a crack at answering that question and concluded that spine could be a likely winner.

Twice-monthly deposits of the 2.3% tax on device makers' revenue are designed to help pay for changes in the federal health care overhaul. Proponents of the tax claim device makers will recoup their money by selling more devices to 30 million new patients with insurance to pay for their new hips, knees, spinal implants and myriad other devices implanted in humans. Opponents say since most their device sales go to those over 65 who are already covered by Medicare, they won't see any meaningful bump in sales.

Only time will tell who is right.

More Insured = Higher Utilization

Larry Biegelsen and his team looked at the impact on orthopedic sales with the newly insured by analyzing two studies and looking at federal data.

The first study was out of Oregon where the state held a lottery in 2008 for uninsured low income residents to get into the state's Medicaid program and then

compared spending between those that got in and those that didn't.

After one year, those selected had substantial and statistically significant higher healthcare utilization, lower out of pocket medical expenditures and medical debt. Biegelsen reported the study found that insurance was associated with a 20% increase in hospital days, a 40% increase in total list charges, and a 45% increase in the number of hospital procedures. However, the study found a statistically significant increase in hospital utilization for heart

disease but not for the other conditions evaluated.

The second study reported in the *Annals of Internal Medicine* in October 2009 compared 4,567 seniors aged 65-74 in Medicare to their pre-Medicare spending levels to look for increases. The study showed that adjusted annual total Medicare spending was 21% higher for previously uninsured adults than previously insured adults (\$5,796 vs. \$4,773; $P=0.044$) and that hospital stays were 30% higher.



tax collector/trivialdevotion.blogspot

The study also showed that previously uninsured adults had a 42% and a 92% higher adjusted annual hospitalization rate than previously insured adults for complications related to cardiovascular disease or diabetes (9.1% vs. 6.4%; $P=0.002$) and for joint replacements (2.5% vs. 1.3%; $P=0.006$), respectively.

Biegelsen wrote that the general perception among investors is that medical device procedures are done in Medicare covered seniors and will have a minor impact on device utilization. However, after analyzing data from the Healthcare Cost and Utilization Project (HCUP) of the Agency for Healthcare Research and Quality (AHRQ), Biegelsen's team found that although the majority of medical device procedures among the categories looked at are done in elderly patients, a substantial portion are done in nonelderly. The range for nonelderly was 25% (pacemakers/ICDs) to 72% (spinal fusion).

After reviewing Medicaid data, Biegelsen concluded that it is possible that over time the procedure rate among the uninsured may eventually catch up to the rate among Medicaid patients. This suggests that there is significant room for growth in procedures among the uninsured.

Spine Benefits

Biegelsen wrote that Wells Fargo's analysis suggests that the benefit from the newly insured will not outweigh the cost of the 2.3% excise tax in most major device categories with the exception of possibly spinal fusion where the cumulative benefit is 2.5% in 2022. The cumulative benefit for hips and knees was 1.3%.

Let the counting begin.

—WE (January 30, 2013)

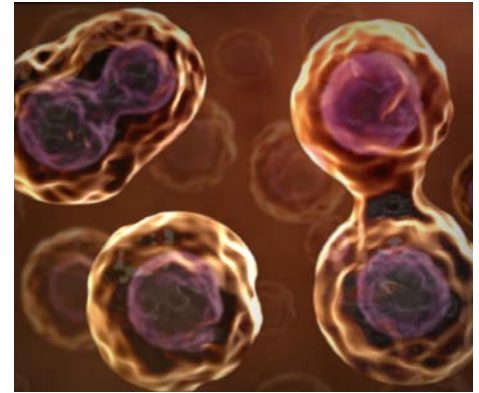
spine

Mesoblast Tees Up Phase 3 Stem Cell Spine Test

Mesoblast Limited's NeoFuse stem cell product showed positive results in the firm's Phase 2 lumbar spinal fusion trial, according Mesoblast Chief Executive Silviu Itescu speaking at the annual JP Morgan Healthcare Conference in San Francisco. The results suggest that Mesoblast's NeoFuse product comprising allogeneic mesenchymal precursor cells (MPCs) is as effective for interbody lumbar fusion as the gold standard, bone autograft, without the need for a second surgical procedure and its attendant morbidity risks. These results, Itescu said, support the progression of NeoFuse to a Phase 3 trial in interbody lumbar fusion.

Researchers enrolled 24 patients in five sites in the United States with 8 patients in each treatment arm—one was bone autograft standard of care, which was the control group, with the second group receiving 25 million MPCs and the third 75 million MPCs. Patients underwent the surgical procedure, one or two level fusions using a posterior approach to the spine, and were evaluated for safety and efficacy. The median follow-up times for the three treatment groups were 23.9, 20.7, and 22.9 months for the bone autograft and the two stem cell groups, respectively.

MPCs were well tolerated with no cell-related serious adverse events and no ectopic bone formation at all. The MPC treated groups had a 30% to 43% lower mean estimated blood loss during surgery compared to the autograft treatment group. At 12 months, fusion was achieved in 85.7% of the patients in the



Courtesy of Mesoblast

25 million treatment group compared to 62.5% in the 75 million and 75% in the control patient groups.

Overall, patients from all three treatment groups had a clinically significant and comparable decrease in low back and leg pain, assessed on the Visual Analogue Scale and functional improvement, assessed by the Oswestry Disability Index questionnaire.

Randall Dryer, M.D., an orthopedic surgeon with the Central Texas Spine Institute and an investigator in Mesoblast's study, said: "For patients whose spinal discs have degenerated too extensively for repair, bony fusion of adjacent vertebra is the primary option to eliminate chronic and debilitating pain. Other than autograft, there is no approved product for posterior spinal fusion, a surgical approach which accounts for 62% of all lumbar fusion procedures. There is a critical unmet need for new technologies to achieve fusion that are safe, effective, and that eliminate the need for bone autograft." Dryer added, "Based upon my experience in the Phase 2 study, Mesoblast's cells may provide a significant and valuable option to achieve fusion in patients with severe spinal disc degeneration and these results warrant progressing to a Phase 3 study."

—BY (January 28, 2013)

people

Six Doctors Join Mount Sinai

Six new doctors are settling into the Mount Sinai School of Medicine's Department of Orthopaedics in New York City. The physicians, including surgeons and physiatrists, come to Mount Sinai from Beth Israel Medical Center.

The new doctors joining Mount Sinai are:

- **Dr. Michael Neuwirth**, formerly Director of the Spine Institute at Beth Israel Medical Center, is now Professor in the Department of Orthopaedics at the Icahn School of Medicine at Mount Sinai. Dr. Neuwirth specializes in complex spinal deformities, cervical spine and lumbar spine issues.
- **Dr. Andrew Casden**, formerly Associate Director of the Spine Institute at Beth Israel Medical Center, is now Associate Professor in the Department of Orthopaedics at the Icahn School of Medicine at Mount Sinai. Dr. Casden specializes in minimally invasive spinal surgery for herniated discs, spinal stenosis and spinal fusion. He has also has extensive experience in spinal deformity surgery.
- **Dr. Paul Kuflik**, formerly Associate Director of the Spine Institute at Beth Israel Medical Center, is now Associate Professor in the Department of Orthopaedics at the Icahn School of Medicine at Mount Sinai. Dr. Kuflik specializes in disorders of the spine with expertise in minimally invasive spine surgery for herniated discs, spinal stenosis, cervical spine disease, spine fusions and spinal deformity.



Dr. Alexander Lee, Physiatrist and Assistant Professor; Dr. Michael Neuwirth, Spinal Surgeon and Professor; Dr. Paul Kuflik, Spine Surgeon and Associate Professor; Dr. Andrew Casden, Spine Surgeon and Associate Professor; Dr. Stuart Kahn, Physiatrist and Associate Professor and Dr. Eugene Bulkin, Physiatrist and Assistant Professor/ Image Credit: Mount Sinai School of Medicine

- **Dr. Eugene Bulkin**, formerly Attending Physician in the Department of Orthopaedics and the Department of Rehabilitation Medicine at Beth Israel Medical Center, is now Assistant Professor in the Department of Orthopaedics and the Department of Rehabilitation Medicine at the Icahn School of Medicine at Mount Sinai. Dr. Bulkin specializes in non-surgical interventions for treatment of spine conditions.
- **Dr. Alexander Lee**, formerly Attending Physician in the Department of Orthopaedics and the Department of Rehabilitation Medicine at Beth Israel Medical Center specializing in interventional physiatry, is now Assistant Professor in the Department of Orthopaedics and the Department of Rehabilitation Medicine at the Icahn School of Medicine at Mount Sinai. Dr. Lee specializes in interventional physiatry: non-surgical treatment of all spine conditions with expertise in radiofrequency neurotomy for neck and low back pain.
- **Dr. Stuart Kahn**, formerly Director of Spine Pain and Rehabilitation Medicine at Beth Israel Medical Center, is now Associate Professor in the Department of Orthopaedics and the Department of Rehabilitation

Medicine at the Icahn School of Medicine at Mount Sinai. Dr. Kahn is both a board-certified physiatrist and board-certified pain management specialist. Dr. Kahn treats acute and chronic pain in patients with spine conditions, specializing in interventional pain.

Dr. Evan Flatow, chair of the Department of Orthopaedics at the Mount Sinai School of Medicine, said in the January 8, 2013 news release, "These renowned surgeons and physiatrists join our existing team of spine specialists to further build our outstanding program of comprehensive operative and non-operative care for patients suffering from spinal disorders. This addition will further cement Mount Sinai's position as the premier center for spine care in the New York region."

Dr. Andrew Hecht, co-director of spine surgery and Director of the Orthopaedic Spine Center at Mount Sinai School of Medicine, said, "We are thrilled to add three superb surgeons to our team as well as three highly skilled physiatrists. Together we will continue to build a spine center of excellence and further our exceptional clinical and research programs."

—EH (January 23, 2012)



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