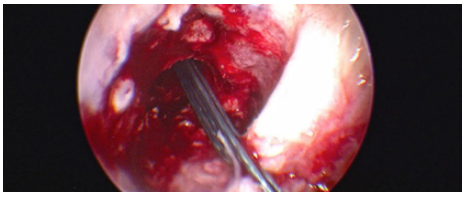
VOLUME 10, ISSUE 14 | MAY 6, 2014

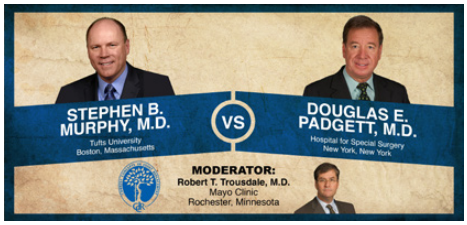
# Orthopedics This Week

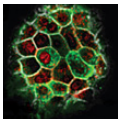
## WEEK IN REVIEW







## 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:** It's been a difficult trailing 30 days for orthopedic equities. Of the 23 companies we track in our Power Rankings, only 6 increased in value. That means that nearly three quarters (74%) of all orthopedic stocks fell in price. Institutional investors will chase deals or the prospects of deals (i.e., the rise in ConMed's shares) but overall seem to be treating orthopedics as if companies are facing pricing pressures and low, single-digit growth rates. Which is pretty much on target.

| RANK | LAST WEEK | COMPANY | TTM OP MARGIN | 30-DAY PRICE CHANGE | COMMENT |
|---|---|---|---|---|---|
| 1 | 1 | Zimmer | 27.31% | 1.59% | Still in the honeymoon phase. This merger gives ZMH operational efficiencies which translate into pricing power. On paper, anyway. |
| 2 | 3 | ConMed | 10.19 | 7.54 | Did the Biomet deal take ZMH out of the running for CNMD? If so, too bad. It would be almost poetic if Linvatec wound up back at ZMH. |
| 3 | 5 | Smith & Nephew | 20.25 | 1.82 | The answer to ZMH + Biomet could well be SNN for one or more of the competing large joint suppliers. |
| 4 | 2 | Johnson & Johnson | 26.58 | 1.10 | For the first time in memory, JNJ is NOT in the top 10 in terms of valuation. In one year, this stock is up 19%. With dividend, make that 22%. |
| 5 | 7 | Alphatec Spine | (5.21) | (2.67) | Les, don't go! Another CEO in a long line of replacement CEO's takes over. This time it's James Corbett. Les will be a hard act to follow. |
| 6 | 9 | Integra LifeSciences | 11.77 | (2.37) | IART is the least expensive equity among diversified orthopedic companies. Needs a catalyst. |
| 7 | 4 | Medtronic | 28.84 | (5.00) | Unfortunately, compared to its comparable companies, MDT is weak. Its "relative strength" is low. |
| 8 | 6 | Stryker | 15.71 | (5.43) | SYK's sales and earnings lagged behind Wall Street's estimates for the first quarter. With ZMH's moves, investors are on the sidelines for SYK. |
| 9 | 10 | NuVasive | 6.30 | (14.90) | At these prices, NUVA is getting into value territory. Q1 report was solid and beat published expectations, but Wall Street is focusing on the challenges ahead. |
| 10 | 8 | Orthofix | 6.75 | (6.22) | Everyone is waiting for Q1 2014 results—which are due mid-week, this week. Last year, Q1 results were $91 million in product sales and net income from operations of $7.6 million. |

# Robin Young's Orthopedic Universe

## TOP PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|---|---|---|---|---|---|
| 1 | RTI Biologics Inc | RTIX | $4.62 | $262 | 16.08% |
| 2 | ConMed | CNMD | $47.19 | $1,284 | 7.54% |
| 3 | Smith & Nephew | SNN | $77.97 | $13,948 | 1.82% |
| 4 | Zimmer Holdings | ZMH | $98.11 | $16,537 | 1.59% |
| 5 | Johnson & Johnson | JNJ | $99.31 | $280,958 | 1.10% |
| 6 | ArthroCare | ARTC | $48.48 | $1,673 | 0.37% |
| 7 | Integra LifeSciences | IART | $44.87 | $1,461 | -2.37% |
| 8 | Alphatec Holdings | ATEC | $1.46 | $143 | -2.67% |
| 9 | Exactech | EXAC | $21.48 | $293 | -4.53% |
| 10 | Medtronic | MDT | $58.77 | $58,818 | -5.00% |

## WORST PERFORMERS LAST 30 DAYS

| | COMPANY | SYMBOL | PRICE | MKT CAP | 30-DAY CHG |
|---|---|---|---|---|---|
| 1 | TiGenix | TIG.BR | $0.67 | $108 | -18.29% |
| 2 | Tornier N.V. | TRNX | $17.97 | $872 | -17.11% |
| 3 | Symmetry Medical | SMA | $8.19 | $307 | -16.68% |
| 4 | NuVasive | NUVA | $33.40 | $1,556 | -14.90% |
| 5 | Baxano Surgical Inc | BAXS | $0.93 | $44 | -14.68% |
| 6 | Bacterin Intl Holdings | BONE | $0.71 | $39 | -14.68% |
| 7 | CryoLife | CRY | $9.03 | $254 | -14.49% |
| 8 | Aurora Spine | ASG | $4.05 | $64 | -14.38% |
| 9 | MiMedx Group | MDXG | $5.56 | $587 | -9.74% |
| 10 | Globus Medical | GMED | $24.79 | $2,316 | -8.01% |

## LOWEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|---|---|---|---|---|
| 1 | Medtronic | MDT | $58.77 | $58,818 | 15.94 |
| 2 | CryoLife | CRY | $9.03 | $254 | 16.43 |
| 3 | Zimmer Holdings | ZMH | $98.11 | $16,537 | 16.81 |
| 4 | Johnson & Johnson | JNJ | $99.31 | $280,958 | 17.59 |
| 5 | Exactech | EXAC | $21.48 | $293 | 17.67 |

## HIGHEST PRICE / EARNINGS RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | P/E |
|---|---|---|---|---|---|
| 1 | Orthofix | OFIX | $30.02 | $546 | 158.26 |
| 2 | NuVasive | NUVA | $33.40 | $1,556 | 107.75 |
| 3 | Symmetry Medical | SMA | $8.19 | $307 | 52.37 |
| 4 | ArthroCare | ARTC | $48.48 | $1,673 | 36.64 |
| 5 | ConMed | CNMD | $47.19 | $1,284 | 26.69 |

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

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|---|---|---|---|---|
| 1 | Exactech | EXAC | $21.48 | $293 | 0.98 |
| 2 | Globus Medical | GMED | $24.79 | $2,316 | 1.58 |
| 3 | Zimmer Holdings | ZMH | $98.11 | $16,537 | 1.98 |
| 4 | ConMed | CNMD | $47.19 | $1,284 | 2.05 |
| 5 | Stryker | SYK | $77.82 | $29,501 | 2.07 |

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

| | COMPANY | SYMBOL | PRICE | MKT CAP | PEG |
|---|---|---|---|---|---|
| 1 | NuVasive | NUVA | $33.40 | $1,556 | 9.72 |
| 2 | Orthofix | OFIX | $30.02 | $546 | 8.42 |
| 3 | Symmetry Medical | SMA | $8.19 | $307 | 4.36 |
| 4 | CryoLife | CRY | $9.03 | $254 | 4.11 |
| 5 | ArthroCare | ARTC | $48.48 | $1,673 | 3.05 |

## LOWEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|---|---|---|---|---|
| 1 | Alphatec Holdings | ATEC | $1.46 | $143 | 0.70 |
| 2 | Symmetry Medical | SMA | $8.19 | $307 | 0.76 |
| 3 | Bacterin Intl Holdings | BONE | $0.71 | $39 | 1.17 |
| 4 | RTI Biologics Inc | RTIX | $4.62 | $262 | 1.20 |
| 5 | Exactech | EXAC | $21.48 | $293 | 1.22 |

## HIGHEST PRICE TO SALES RATIO (TTM)

| | COMPANY | SYMBOL | PRICE | MKT CAP | PSR |
|---|---|---|---|---|---|
| 1 | TiGenix | TIG.BR | $0.67 | $108 | 18.82 |
| 2 | MiMedx Group | MDXG | $5.56 | $587 | 8.74 |
| 3 | Wright Medical | WMGI | $30.04 | $1,499 | 5.83 |
| 4 | Globus Medical | GMED | $24.79 | $2,316 | 5.33 |
| 5 | ArthroCare | ARTC | $48.48 | $1,673 | 4.38 |

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

# State-of-the-Art Solutions in Hip and Knee Reconstruction

## June 26-28, 2014

*Fairmont Chicago at Millennium Park*

### Invited Faculty

*Course Chair, Hips*

Paul Beaulé, MD, FRCSC

*Course Chair, Knees*

J. David Blaha, MD

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# Expedited PMA On the Way?

**BY WALTER EISNER**

Many, including *OTW*, have been critical of the FDA's oversight in getting new medical devices to patients. It seems the agency's dual mission of protecting and promoting public health has been heavy on the protect side and light on the promote side.

The results are that clinical trials move to other parts of the world, capital is invested elsewhere and U.S. patients have to travel outside the country to get cutting edge treatments. Look no further than high profile professional athletes going to Europe for stem cell therapies.

Who can blame the agency? There are no pats on the back when another patient walks without pain, returns to work or saves insurance companies billions because keeping fit reduces expensive chronic conditions.

But when a device fails, the clamor for someone's head at the agency is deafening. No wonder they are risk averse.

Yet, the agency continues to promise to speed up promoting lifesaving and enhancing devices. We've heard from sources familiar with internal discussions at the FDA that agency leaders have told their staffs that they recognize that medical device start-ups have slowed and they have to find ways to lean on the "promote" pedal.

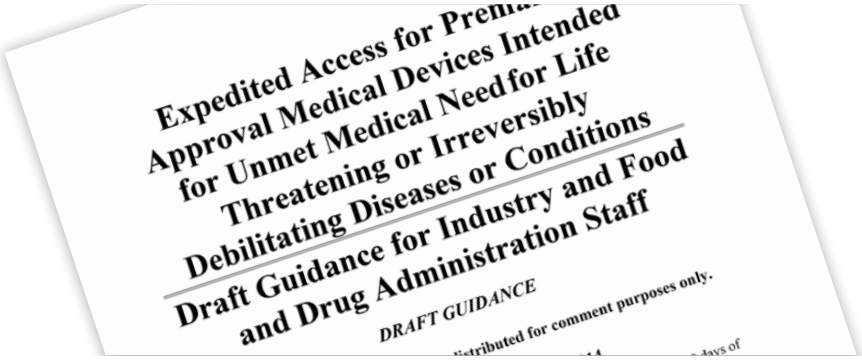

*Photo created by RRY Publications and logo courtesy of the FDA*

## The "Expedited PMA"

The latest effort is the proposed Expedited Access Premarket Approval Application for Unmet Medical Needs for Life Threatening or Irreversibly Debilitating Diseases or Conditions program, also called, "Expedited Access PMA" or "EAP" program

The proposal was released for comment on April 22, 2014. The EAP seeks to speed up approvals for patients who have no other treatment options and focuses on earlier and more frequent interactions between companies and FDA staff. It calls for the involvement of senior management and a collaboratively developed plan for collecting the scientific and clinical data to support approval.

The idea is similar to the process the agency uses to speed access to innova-




*Expedited Access PMA*

tive drugs that address serious unmet medical needs such as Fast Track and Breakthrough Therapy designations.

## Product Development Focus

The FDA says EAP is not a new pathway to market, but rather a collaborative approach to facilitate product development under the agency's existing regulatory authorities. While other existing device programs have focused on reducing the time for the premarket review, EAP also seeks to reduce the time associated with product development.

As part of the EAP program, FDA looks to provide more "interactive communications" during device development and more interactive review of Investigational Device Exemption (IDE) applications and premarket approval applications (PMA). In addition, FDA states that it "intends to work interactively with the sponsor to create a data development plan specific to the device."

Morningstar analyst Debbie Wang told *Reuters* that this is, "yet another aspect of how FDA is trying to work in a more coordinated fashion so they can reduce the number of false starts and situations of reinventing the wheel, and to help put some priority on which therapies are going to affect the most patients with the greatest need."

## Breakthroughs and Unmet Needs

A device can be eligible for the program if it features breakthrough technology with significant benefits over existing products and are intended to treat or diagnose patients with serious conditions whose medical needs are unmet by current technology.

"We expect most devices that enter this program will be in the preclinical trial phase, says Jeffrey Shuren, M.D., director of the FDA's Center for Devices and Radiological Health."

## Eligibility

To be eligible for participation in the program, the device must meet one of the following challenging conditions:

First, the device must be intended to treat or diagnose a life-threatening or irreversibly debilitating disease or condition.

Second, the device must meet at least one of the following criteria for addressing an unmet need:

1. The device represents a "breakthrough technology" that provides a clinically meaningful advantage over existing technology; or
2. No approved alternative treatment or means of diagnosis exists; or
3. The device offers significant, clinically meaningful advantages over existing approved alternatives; or
4. The availability of the device is in the best interest of patients (e.g., addresses an unmet medical need).

*Jeffrey Shuren, M.D.*

Third, the sponsor submits an acceptable draft Data Development Plan that has been approved by FDA.

## More Data, Not Less

In addition to the three prong test to qualify for the EAP program, device companies have to be prepared for some hands on collaboration with FDA. *Health Data Management* interviewed Bradley Merrill Thompson, a D.C.-based attorney, who questioned the value of EAP.

He said the possible speed of the approval—and there are no guarantees of course that it will in fact turn out to be quicker—comes at the cost of FDA looking over your shoulder the entire way. "Thus, while most devices get approved based on data that the manufacturer develops with modest input from FDA, here the agency potentially micromanages the manufacturer all along the way, potentially driving up the cost of the data development."

"I see these programs rolled out by FDA every few years; indeed, this program is just the formalization of something that the agency started in 2011. Unfortunately, for the vast majority of companies, these initiatives really do not prove to be useful. As I recall, when the pilot program came out in 2011, there was only one company that participated. A couple years later, when they revised the program, they got only a couple more."

The problem, he says, is that the bar for the EAP program is too high and the vast majority of medical device developers will not qualify.

Thompson also pointed out that a product has to be a breakthrough technology that is above and beyond currently existing therapies. "Frankly, most

medical devices represent incremental improvements." He says most entrepreneurs proudly tout the benefits of their new products, but when the FDA looks at them it characterizes the gains as more modest.

Mark DuVal, a well-known industry attorney, agrees with Thompson. He told us the proposal requires more premarket work for companies, not less as was recommended by Institutes of Medicine. DuVal also said while it's important for the agency to encourage breakthrough technologies and orphan drugs and devices, most of innovation comes in increments through the 510(k) program. He fears the agency is increasing resources for fewer and smaller niches.

*Mark DuVal*

## Review Times

The narrative about the FDA is that in recent years, review times dragged out as the agency faced a rising number of new product applications.

So what's the record?

On March 13, 2014, Margaret Hamburg, M.D., the agency's commissioner told Congress that since 2010, the FDA has improved its performance in reviewing device applications

Specifically, she said the agency has achieved:

- 27% decrease in the backlog of lower device applications
- 10% decrease in average total review time
- 43% decrease in higher risk devices backlog
- 32% decrease in average total review time

Hamburg said the agency is at the "cutting edge in terms of review and approv-

al of new products," compared to the rest of the world. "If you look at drugs approved in recent years, I think about three-quarters of them were approved in the United States first and on devices, apart from the highest risk devices, we are I think at par with comparable other countries in terms of review times. We do ask for more clinical data often on the higher risk devices. But, I think there's some urban mythology about where we stand in comparison to review times and leadership."

Under the most recent user fee agreement (MDUFA III) with the device industry, the FDA will collect almost $600 million in fees over five years. The agency plans to hire an additional 200 full-time employees over that time to speed up review times. Hamburg added that since October 1, 2013, the agency has already hired 90 of those employees.

After Hamburg's testimony, Janet Trunzo, senior executive vice president, technology and regulatory affairs of AdvaMed, told us, "AdvaMed is encouraged by the progress FDA has made in meeting its commitments under the new user fee agreement, but we all recognize there is a long way to go. So far, the agency appears to be meeting its MDUFA III decision goals and commitments for substantive interactions with submission sponsors. Initial data from FDA shows marked improvement in total review times for PMAs and modest improvement in total review times for 510(k)s compared to the historic highs seen in 2010."

## A Better Way?

But maybe there are other solutions to speeding up device reviews.

The EAP proposal came out at the same time the Manhattan Institute for Policy Research (MIPR) published a research report entitled "An FDA Report Card: Wide Variance in Performance Found Among Agency's Drug Review Divisions."

The MIPR found a wide gap in the approval rates of different drugs. The report notes that "[s]ome review divisions, such as the Center for Drug Evaluation and Research's (CDER) oncology and antiviral divisions, approved drugs with nearly twice the speed as the next-fastest divisions, and nearly four times

as quickly as CDER's slowest division." The neurology division took nearly 600 days to approve a drug, and the two fastest units, oncology and anti-viral, took under 200 days.

The authors of the report said their analysis of performance has "revealed large differences among the FDA divisions. High-performing divisions are several-fold better on output measures than low-performing divisions, and they perform better without commensurately greater resources or less complexity of tasks or reduced safety. Inconsistent performance across divisions is thus a strong indication of inefficiency, but also of opportunity. A careful comparison of the performance of the agency's drug review divisions suggests that agency performance can be dramatically improved at little cost to taxpayers."

## Speak Your Piece

You've got 90 days after publication of the draft guidance in the Federal Register to review the proposal and submit comments. The proposal is available here.

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM393978.pdf

Submit electronic comments to http://www.regulations.gov.

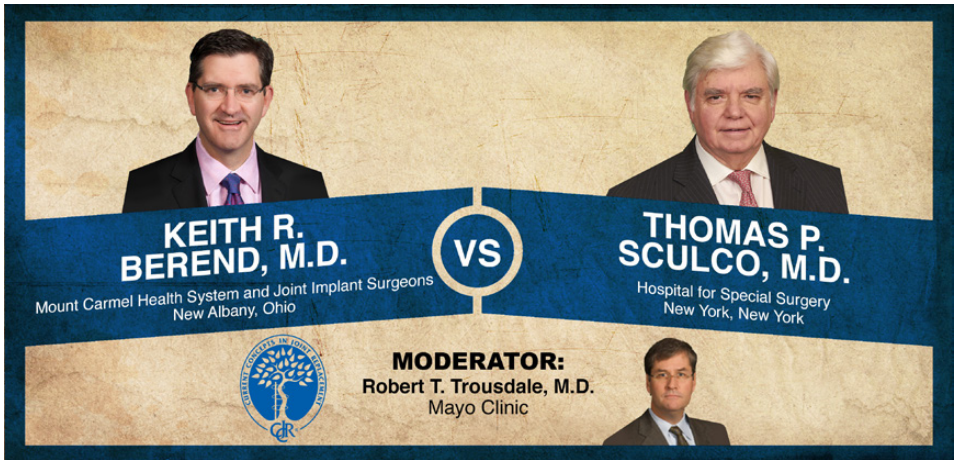
Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the Federal Register. ♦

# Berend v. Sculco: Four Rounds Over Anterior Approach

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

"The anterior approach has a faster recovery and optimizes outcomes when compared with a direct lateral approach," says Keith Berend. Hold on, says Tom Sculco. "The posterolateral approach is a common approach that can easily be extended, involves less blood loss, and is expeditious."

This week's Orthopaedic Crossfire® debate is "The Mini-Anterior Approach: Optimizes THA Outcomes." For the proposition is Keith R. Berend, M.D. from Mount Carmel Health System and Joint Implant Surgeons in Ohio; against the proposition is Thomas P. Sculco, M.D. from the Hospital for Special Surgery in New York. Moderating is Robert T. Trousdale, M.D. from Mayo Clinic.




*Current Concepts in Joint Replacement/RRY Photo Creation*

**Dr. Berend:** "There are results in the literature over the past decade that taught the benefits of the direct anterior approach. Such as: it's safe and reproducible, there may be less blood loss, less pain, shorter hospital stays, fewer readmissions, perhaps better implant positioning because of visualization or fluoroscopy, less muscle damage, and overall better recovery compared with other approaches."

"The problem is that there are an equal number of studies that are very well designed and performed and that show that it can be dangerous and difficult to teach…that show a chance of more blood loss, there's no benefit over more common approaches, there are more outliers in terms of implant positioning because of decreased visualization, perhaps more or different muscle damage, and that there's no significant difference between recovery with an anterior approach versus some of the other approaches."

"My *JBJS* study from 2009 compared the less invasive direct lateral approach with my early experience with the anterior supine intermuscular (ASI) approach. We found that early on there was a slight trend toward picking lighter patients for this approach—although I don't do that any longer. The OR time was very similar in both of these approaches, but there was more blood loss intraoperatively with the ASI. And there was nearly double the transfusion rate with that approach (although it wasn't statistically significant)."

"We did see a slightly shorter length of stay, a significantly better discharge deposition (meaning that patients were more likely to go straight home and less likely to need rehab). And we showed that preoperatively their Harris Hip Scores were identical…but that as early as six weeks those scores were already better with the anterior supine compared with a muscle-splitting direct lateral."

In our initial series—published this year [2013] in *Instructional Course Lectures*—we had 1,035 consecutive ASI on 906 patients. The transfusion rate leveled off at around 5%, we had an average 40-month follow-up, and there were only four complaints of lateral femoral cutaneous nerve issues. There was a 2.4% revision/reoperation rate, only four dislocations, and only one deep infection in this unselected series of over 1,000 patients."

"So we concluded that the ASI has a faster recovery and optimizes outcomes when compared with a direct lateral approach. In the early postoperative period periprosthetic fracture occurs in 0.86% of cases. This may be an actual increased risk with the anterior approach, but it's just on the outside of that which has been published in other series and registries. Infection is extremely uncommon with this approach, and it seems to be less than

that published in registries and other large series—0.1% as compared to 0.6-3% in certain registries."

"Neither Dr. Lombardi nor I have done a posterior approach in 25 years. But if we were to randomize our patients, the question is, 'Having done thousands of anterior approaches and no posterior approaches, which would end better?' Clearly, the anterior approach in our hands would be much better. Perhaps you could design a study where it's not surgeons who have no experience, and you randomize patients into the hands of surgeons who do a posterior approach and those who do an anterior approach. The question remains, 'How many cases must you do to be proficient? How many years of practice do you have to have under your belt in order to say that this is going to be a fair comparison…and that there's not a learning curve bias, a patient selection bias, or even a surgeon experience/skill bias?"

**Dr. Sculco:** "The posterolateral approach is a common approach that can easily be extended, involves less blood loss, and is expeditious. Its main disadvantage has been a question of increased dislocation rate."

"Some years ago we looked at about 1,500 hips done through this less invasive approach, followed out to 10 years. Radiographically, we found that the position of our stem and socket were quite good. We did have a 1.2% dislocation rate, five femoral fractures, and five neuropraxias (we were pushing this procedure through too small an approach). There were very few wound complications. So last week I looked up Internet searches for the anterior approach, and found over three million sites; there is a tremendous interest in this approach."

"The claims made are that it's tissue sparing, involves less pain, and provides faster recovery. But there is not a lot of evidence to support these assumptions. The disadvantages of the anterior approach? You need a special OR table as well as intraoperative fluoroscopy; femoral exposure is more problematic, OR time is increased in many studies, and complications may be greater."

"Is it more muscle-sparing? In 2006 a cadaveric study came out from Dr. Menghini of the Mayo Clinic. There was significant damage to the tensor (31%) and the conjoined/piriformis tendon through the anterior approach (50%)."

"Dislocation rates...Siguier showed 0.96% in 1,037 THR [total hip replacements]; Matta found 0.61% among 437 THR; Kennon found 1.3% among 2,132 THA [total hip arthroplasty]; Sariali found 1.5% among 1,374 THA; these are similar to the 1.2% I found among 1,465 THA from my series."

"Periprosthetic fracture rate…Dr. Matta had a 2.4% fracture rate—significantly greater than the 0.3% posterior fracture rate that I reported."

"In videos of Keith doing the procedure with Dr. Anderson, I noted what I call the 'fluoroscopy machine dance.' This is where the fluoroscope comes in, goes out, comes in, goes out throughout the procedure. Then there was the complete excision of the anterior capsule and much of the superior capsule. That is not tissue-sparing. Then there is this medieval winch that Keith puts on the table…the hook grabs the femur and pulls it up into the wound…a bit primitive."

"Then there's what I call the Hobbit—the diminutive femoral prosthesis that you can stick in because you really can't see very well into that femur. And Keith said that his learning curve is 35 cases, and he certainly is an expert at this approach. So if the average orthopedic surgeon in the U.S. does 25-50 hip replacements a year it's going to take one to two years before you are comfortable."

**Moderator Trousdale:** "Can we agree that both exposures are pretty reliable?"

**Dr. Sculco:** "Yes."

**Moderator Trousdale:** "Can we agree that both cause some muscle damage?"

**Dr. Sculco:** "Yes."

**Dr. Berend:** "Yes."

**Moderator Trousdale:** "Can we agree that that the recovery rate may be the same or may favor the direct anterior approach (at least the first six weeks)?"

**Dr. Sculco:** "It's about the same."

**Dr. Berend:** "It's about the same. The only question is, 'Do you use hip precautions on your posterior approach?'"

**Dr. Sculco:** "I do, but we're more conservative than we need to be."

**Moderator Trousdale:** "Tom, your precaution may be if you use one to avoid hyperflexion, abduction, leg propulsion for posterior instability. Keith, is it not rational for the direct anteriors to tell them to avoid extension and external rotation of the hip joint?"

**Dr. Berend:** "The only thing the physical therapists teach them differently is how to get in and out of bed."

**Moderator Trousdale:** "Tom, why is blood loss less with a posterior approach than with an anterior approach?"

**Dr. Sculco:** "I think the suction is less. It's an atraumatic, clean approach. You don't cut much muscle; you release piriformus and conjoined tendons. A little bit of the quadratus is released, but not much. And usually there aren't a lot of big vessels that you can damage. We've documented that blood loss is significantly less with this approach."

**Moderator Trousdale:** "So where does the blood loss come from? It can't be the socket or the femur because that should be the same (theoretically), right?"

**Dr. Berend:** "It may or may not be. If you hyperextend the table…the leg, could there be some type of venous phenomenon that causes more bleeding from the capsule or the femur during femoral prep. That's one theory. The other theory is that in any of the studies we've done looking at the changes in blood loss, the most important variable is hypotensive anesthesia—Tom's group pioneered that. If we use this there's such little blood loss anyway; adding tranexamic acid…blood loss isn't an issue for me regardless of the approach."

**Moderator Trousdale:** "Keith, why would the infection rate be lower with the direct anterior approach?"

**Dr. Berend:** "There may be a surrogate variable in that dataset I presented. I was selecting out thinner patients. Using any lateral based approach on the obese patient you have a lot more tissue to heal…there's a lot more fat and a longer incision versus the anterior approach where there's little fat."

**Moderator Trousdale:** "Would you agree that if you have a complex hip that the posterior approach may win out if you need more extensile exposure?"

**Dr. Berend:** "No question on the femoral side. I will say that I've gotten more comfortable with complex acetabulum issues."

**Moderator Trousdale:** "Both approaches seem to work well. Why do you think the anterior approach—if it's so good—hasn't been more widely adapted?"

**Dr. Berend:** "Because the posterior approach is outstanding and if you're happy with your results and you're not solving a problem there may not be a reason to change."

**Dr. Sculco:** "There's a lot of marketing out there, and patients say to me all the time, 'I want you to do the anterior approach.' So a lot of young surgeons going into practice are being pushed to do it."

**Moderator Trousdale:** "Thank you gentlemen." ♦

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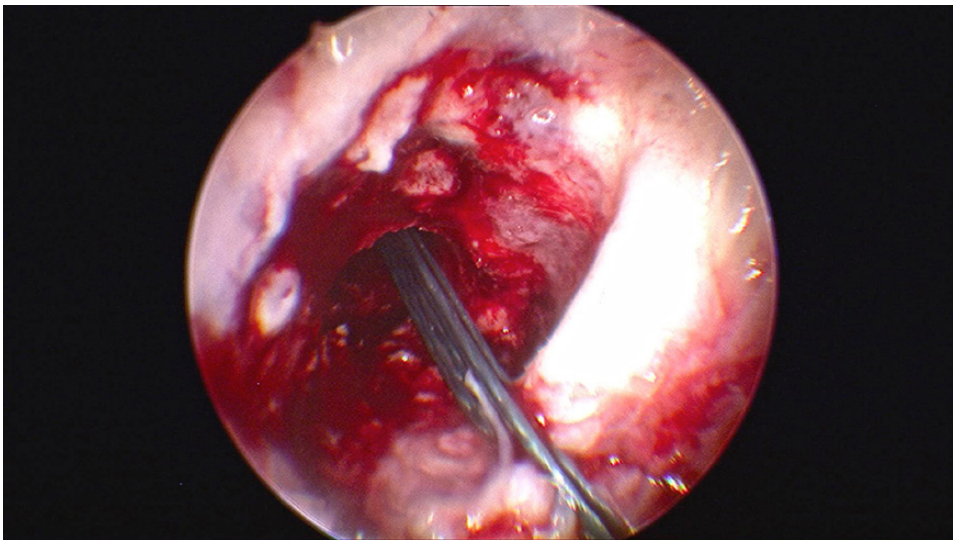
# New Program Makes Better Arthroscopists // Lateral Meniscus Guide 30% – 50% Off?! Study Must Read // Steve Haddad, M.D. Reports on AOFAS Expanding Fellowships

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



*Anterior cruciate ligament/Wikimedia Commons and Arthroscopist*

**New Program Makes Better Arthroscopists. It's an ASSET!** Knot tying, triangulation, etc.…the basics. Are all orthopedic surgeons in training reaching proficiency? A new arthroscopic assessment tool, meant for residents, is hoping to ensure that this is the case. Gregg Nicandri, M.D., an orthopedic surgeon with the University of Rochester Medical Center in New York, tells *OTW*, "Arthroscopic training remains a delicate task, and it is challenging to determine if an orthopedic resident is making the appropriate amount of progress. The Arthroscopic Surgery Skill Evaluation Tool (ASSET), a video based program, allows for the assessment of a surgeons' arthroscopic skill level. It measures, among others things, how well the surgeon to use the arthroscope in a way that doesn't damage the soft tissue and cartilage; the ability of the surgeon to use the instruments within the joint; and the ability of the surgeon to triangulate within the joint and coordinate the use of both hands."

"At present, we are validating the ASSET, and having residents from PGY1-5 [post graduate year 1-5] complete simulated and live diagnostic arthroscopies of the knee and shoulder. We are attempting to determine whether performance as determined by ASSET on simulated surgery correlates to performance in real surgical cases and how well skills transfer from various simulated to live surgical environments. We are collecting this data in an effort to develop benchmarks and proficiency criteria; that will help us provide guidance to other programs as far as how they can determine the progression of their residents."

"This is a novel tool, not only because it allows for an objective assessment of the trainee's progress, but because it can be used to assess multiple arthroscopic procedures as well as proficiency in common simulated environments. For example the ASSET can be used to assess proficiency when performing a diagnostic knee arthroscopy on a dry anatomic model, on a cadaveric specimen, and on a virtual reality simulator. There has been an increased emphasis on surgical skills education outside of the operating room and a tool like the ASSET allows us to assess the efficacy of various skills curricula on arthroscopic proficiency."

"For example, the ABOS (American Board of Orthopaedic Surgery) recently published a recommended PGY-1 [post graduate year 1] curriculum for arthroscopy and we have initiated a study to determine the effect of completing this curriculum using the Arthroscopy Association of North America's FAST (Fundamentals of Arthroscopic Surgery Training workstation on PGY-1 proficiency when performing diagnostic knee arthroscopy."

"At this point the ASSET is being used primarily for the assessment of basic diagnostic arthroscopy however we intend to assess its validity for more

advanced procedures such as menisectomy, ACL reconstruction, and labral repair"

**Lateral Meniscus Guide 30-50% off?! Better Read This Study** In what is likely the first such study of its kind, researchers have found that using the lateral meniscus as a guide for ACL (anterior cruciate ligament) tibial tunnel placement may not be such a great idea. Mark Miller, M.D. is the S. Ward Casscells Professor of Orthopaedic Surgery at the University of Virginia. He tells *OTW*, "First of all, there is a dearth of research on tibial tunnel placement in ACL reconstructions (as opposed to quite a lot of work that has been done on the femoral side). We have just completed a study in which we took intraoperative lateral radiographs for 100 consecutive primary ACL reconstructions using guidelines commonly recommended for placing the tibial tunnel. It turns out that when you use the lateral meniscus as a guide for tibial tunnel placement, the resultant location on lateral X-rays is highly variable… anywhere from 30 to 50% of the way across the tibial plateau."

"We are now about to complete a cadaveric study where we will investigate anterior tibial tunnel placement with newer independent drilling femoral tunnel techniques and see whether there is graft impingement. Previous research suggests that if you drill the femoral tunnel through the tibial tunnel and you put the tunnel too far anteriorly, then notch (roof) impingement is common. Everybody was placing the tunnel posteriorly but biomechanically it may not be the best place because studies say that anterior placement is more effective. It turns out that with this independent femoral drilling you get less roof impingement…so you CAN put it more anteriorly."

"Despite this new evidence, people are still going to be concerned about roof impingement. Thus, we must continue to work on proving that this is not a problem. Our hope is to expand this into clinical studies soon."

**Steven Haddad, M.D. Driving for Expanded Education and Fellowship Under AOFAS** Under President Steven Haddad's leadership, the American Orthopaedic Foot & Ankle Society (AOFAS) is developing resources to expand education and assist fellowship programs as they train the next generation of orthopedic foot and ankle specialists. "The number of foot and ankle fellowship positions offered in the match has increased 90% over the past 10 years, and the number of applicants has exceeded the number of positions," Dr. Haddad told *OTW*. "More important, the educational experience provided through our fellowships continues to strengthen as we add AOFAS

resources to complement the fellowship directors' dedication. The Society's outreach through our Resident Scholarship Program has encouraged interest in the specialty. These Resident Scholars attend the AOFAS Annual Meeting largely free of financial obligations, and are paired with a mentor to enhance their experience. This year the number of Resident Scholars coming to our annual meeting is more than double that of four years ago, and a high number apply for our fellowships. We are committed to providing resources to build on the excellent broad-based educational experience our fellows receive. "

"We are also expanding our public outreach on our Society's patient education website www.FootCareMD.org," he continued. "More than 50 new articles on foot and ankle conditions and treatments have been added to the site by our committees this year. To increase understanding, photos are being added to this peer-reviewed content. Patients now have a place to go to achieve a validated understanding of their condition and proposed treatment options."

Another important focus for the AOFAS is research. "A successful 10-site pilot study collected data from more than 300 patients using the PROMIS (NIH Patient Reported Outcome Measurement Information System)," Dr. Haddad explained, "and soon the AOFAS will launch a broader initiative by expanding its OFAR (Orthopaedic Foot & Ankle Outcomes Research) Network. It will provide the mechanism for members to collect patient-reported outcomes and assess their results. This database will allow our members to evaluate their own success in achieving the desired surgical goals."



"This is a time of significant growth for the AOFAS in terms of membership engagement and building for the future. Our annual meeting attendance jumped 26% last year over the previous year, and abstract submissions this year are up 50% over last year. We upgraded our journal, *Foot & Ankle International*, last year with a new publisher, and the number of manuscript submissions increased 17% during that first year. Simply put, the AOFAS has never been stronger in membership advocacy."

**AMSSM Announces Traveling Fellows** The American Medical Society for Sports Medicine (AMSSM) has selected Chad Asplund, M.D. and Irfan Asif, M.D. as the first two Junior Traveling Fellows for AMSSM's new International Traveling Fellowship program tour to Australia. Drs. Asplund and Asif will join AMSSM Founder Jim Puffer, M.D., who will serve as the first Senior Traveling Fellow for the July 9-23, 2014 tour. This program is supported by DJO Global, Inc.

The Traveling Fellowship program is an academic exchange and clinical immersion initiative for sports medicine physicians to teach and learn sports medicine on a global level. The purpose of the program is to encourage academic interchange, share research and explore common clinical interests amongst international sports medicine leaders.

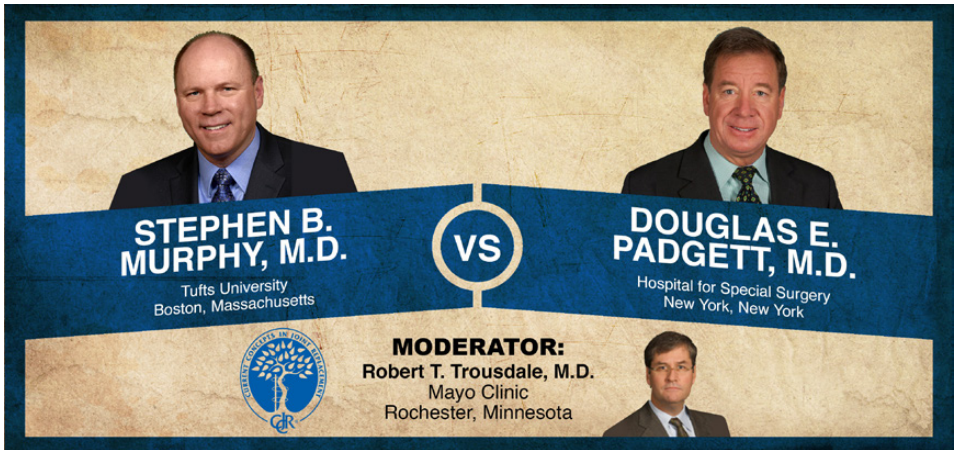
Dr. Asplund serves as medical director of Student Health Services and associate professor at Georgia Regents. He is the team physician for Georgia Regents, Paine College and the Augusta Greenjackets baseball team. Dr. Asif serves as director of the Sports Medicine Fellowship Program and assistant professor at the University of Tennessee Department Of Family Medicine. The Traveling Fellowship tour will include stops in Melbourne, Canberra and Sydney. ◆

# Murphy, Padgett Debate Ceramic-Ceramic

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

"Ceramic-ceramic bearings are exceptionally reliable in young, high demand patients," says Steve Murphy. "Cross-linked polyethylene is a better option," says Doug Padgett. "There is a lot of basic science behind it, we can measure its performance, and people tolerate it well."

This week's Orthopaedic Crossfire® debate is "COC Bearings in the Young Patient: A New Standard Emerging." For the proposition is Stephen B. Murphy, M.D. from Tufts University in Boston; against the proposition is Douglas E. Padgett, M.D. from the Hospital for Special Surgery in New York. Moderating is Robert T. Trousdale, M.D. from Mayo Clinic.




*Current Concepts in Joint Replacement/RRY Photo Creation*

**Dr. Murphy:** "Our experience is with high demand patients (307 hips) less than 50 years of age of whom 60% were male. Most of these were part of a prospective FDA/IDE [investigational device exemption] study. We had uncemented femoral and acetabular components, a flush-mounted liner, and an 18 degree taper with no metal backing or elevated metal rim. Of this group, 17% had at least one prior surgery; all had preservation of the posterior capsule and short rotators. Bearings were small: 28mm (29%), 32mm (69%), and 36mm (2%). "

"In that group, out to 16.5 years, nine hips were revised. There were three fractures, two of which were high energy polytrauma, three osseo-integration failures, two modular neck fractures, and one was revised at an outside institution for unknown reasons. Fourteen year survivorship with revision for any reason, any component was 96%. If you exclude the two prosthetic neck fractures, the survivorship at 14 years is 97%. There were no dislocations, no revisions for infection, and no osteolysis."

"There are no studies of cross-linked poly (XLPE) at 14 years; we do have some studies with high survivorship (100% at 10 years, but only 50 patients and 56% of the hips were excluded from the study)."

"Why would people elect not to use ceramic-ceramic bearings? Cost, fracture, squeaking, dislocation. The cost is similar to most ceramic on XLPE; the cost is less than many with ceramic on XLPE with newer porous coatings. And with cobalt chromium (CoCr) we have taper corrosion at a higher incidence with those bearings, so CoCr is used less and less in hips. So you're really talking about cost of ceramic on poly versus ceramic-ceramic. In fact, if you use enhanced porous coating with those constructs they're actually more expensive than ceramic-ceramic."

"The fracture rate in this high demand group is infrequent and associated with life-threatening trauma. The incidence of poly fracture may actually be higher. And if you do have to repair a fractured ceramic liner head, generally it's an uninflamed joint and it's a relatively simple procedure."

"As for squeaking, we all know that's a design issue. If you use the correct designs such as flush mounted liners without elevated metal rims…or you use standard titanium components rather than beta titanium alloys then this isn't a clinically significant problem. Dislocation: In this particular study of 262 hips there were no dislocations, so I think stability is a function of soft tissue technique and component placement."

"Regarding XLPE, lipids and loading reduce the oxidative stability of these bearings. Also, they have decreased tensile strength and edge loading; all retrievals show some subsurface oxidation in all types of XLPE. Vitamin E poly may be a good solution, but it has

less cross-linking and short follow up. So I think these are exceptionally reliable bearings in young, high demand patients."

**Dr. Padgett:** "Let's look at the 2000 national registry from Sweden. While we knew that each decade we were getting better in terms of reducing our revision rates, there was one group—those under the age of 55—where they concluded that younger, more active patients were at greater risk for problems related to hip arthroplasty. And those problems from the 80s into the new millennium included older generation polys, the effect of sterilization, and the effect of shelf life. This led to an orthopedic fork in the road: either make a better poly or forget about poly and go to the alternatives."

"MoM [metal-on-metal] bearings appeared to have lower wear rates, low rates of osteolysis, larger heads for stability, and no risk of fracture. The disadvantages were theoretical tumor induction, possible metal ion release, probable metal debris, and inevitable adverse tissue reaction. We know from multiple reports that the revision of these pseudotumors have done poorly. "

"Looking at ceramics, alumina-alumina has extremely low wear rates, is wettable, and is hard. Then there is Murphy's Law. There are the clickers and the squeakers. The former may represent a little microseparation. And regardless of the etiology of the squeaking everyone finds it annoying. As for fractures, whereas they used to be about 1/1,000 now it's down to 1/25,000 but it's still not zero."

"We reported our experience with mal-seating. We don't know what the significance of the metal jackets are. This may be a problem. We know that impingement is a problem, and marginal chipping can occur with ceramics. Metal transfer as a result of the impingement clearly affects the surface roughness. These observations support our long-held hypothesis that hard-on-hard bearings are extremely sensitive to component position."

"So this leaves us with XLPE. There is a lot of basic science behind it, we can measure its performance, people tolerate it well, and it reduces strain due to both adhesive and abrasive wear mechanisms. There is 10 year data from Massachusetts General Hospital on the Longevity/Durasul method showing no increase in head penetration since the beginning of the first year (the bedding in period)."

"So based on the lack of apparent wear at 10 years and the absence of identifiable lysis…based on the ability to use larger heads and the rare catastrophic events, it is apparent that XLPE is indicated in young patients."

**Moderator Trousdale:** "Steve?"

**Dr. Murphy:** "Squeaking is totally design related, and every case that Doug showed where there is mal-seating, metal transfer, squeaking, etc… that is all elevated metal liners and is a different issue. Regular flush mounted liners don't have a significant problem with squeaking and I've never revised anyone for that reason."

**Moderator Trousdale:** "Doug, what about the 20-year-old that needs a THR [total hip replacement]?"

**Dr. Padgett:** "You might consider a ceramic-ceramic bearing. The harder bearings are more sensitive to position; I would use enabling technology to make sure it's right down the pike."

**Moderator Trousdale:** "Steve, would you use ceramic on that kid?"

**Dr. Murphy:** "Sure."

**Moderator Trousdale:** "And for a 50-year-old?"

**Dr. Padgett:** "Ceramic on poly."

**Moderator Trousdale:** "Justify why you would use ceramic on poly versus metal on poly. Ten year survivorship data seems to be the same."

**Dr. Padgett:** "I think something's happened in the last ten years as far as the trunion/taper design."

**Moderator Trousdale:** "Steve, when do you stop using ceramic on ceramic?"

**Dr. Murphy:** "Anyone who is old enough so that there's no possibility that ceramic on poly would wear out. Depending on their medical history it would be somewhere between 65 and 75."

**Moderator Trousdale:** "Steve, a lot of the data you gave was on alumina-on-alumina so can you discuss the differences of alumina, etc.?"

**Dr. Murphy:** "Delta-Delta and alumina-alumina wear are almost identical. Delta is stabilized to reduce the possibility of crack propagation, so it's about twice as strong. Because of that the designs have changed so that they're stressed more… so the fracture rate is no lower because they're designed close to the edge. If you use the exact same design then the fracture rate would go down."

**Moderator Trousdale:** "So the head fracture seems to be lower, but the socket Delta fractures are pretty similar to the alumina?"

**Dr. Murphy:** "They are very similar. That's a design issue. Doug mentioned the Mass General study at 10 years where they had virtually no wear. Even though that was a perfect polyethylene they don't use it anymore. Why is that?"

**Moderator Trousdale:** "So Doug there are some downsides to the Delta. It's got almost 20% zirconia. Should we be concerned about that?"

**Dr. Padgett:** "We have about 40 retrieved Deltas at this point—the longest is at 5.5 years. We looked at phase transformation in terms of maybe the roughness changes, and the good news is that there seems to be little of that phase transformation. So at this point I'm cautiously optimistic."

**Moderator Trousdale:** "Steve, if we're using a ceramic-ceramic should we use alumina-alumina or Delta-Delta where there's no 10 year data?"

**Dr. Murphy:** "If you design the Delta-titanium junction to be as strong as the one for alumina then it would be a great bearing. If it's the same bearing distribution (28-32-36) then that's all you need."

**Moderator Trousdale:** "Doug, Steve mentioned that fracture was relatively easy to handle. Some people would argue that. How do you handle a patient who is young, with a ceramic-ceramic bearing whose head has exploded?"

**Dr. Padgett:** "Tough question. The problem is that these are small shards of glass, and if you wind up going back to a metal or ceramic-poly bearing then the wear rates could be exceedingly high. The key for me is a meticulous debridement. As for the bearing option at that point, if you've already exploded one ceramic-ceramic then do a complete synovectomy. Then probably consideration of either the ceramic or metal on poly."

**Moderator Trousdale:** "Steve, would you go back to ceramic-ceramic in a fracture?"

**Dr. Murphy:** "If it's a head fracture—like a fall from a height on concrete—and there's polytrauma, but the hip is pristine and the liner is fine, then I'd change to a Delta with a titanium sleeve…quick case, quick recovery. I'd go Delta against alumina."

**Moderator Trousdale:** "There have been rumors about ceramic creating a suction effect for stability."

**Dr. Padgett:** "We did about 800 ceramic-ceramic hips, and of all the subgroups our dislocation rate in the ceramic-ceramic group is the lowest. This was four surgeons. I don't know why…same approach as we've always done. There may be something to that."

**Moderator Trousdale:** "If ceramic-ceramic is so good why aren't all the hip surgeons doing it for most of their patients?"

**Dr. Murphy:** "There's a myth that it's more expensive, but when compared to a lot of the stuff people are using now it's less expensive. It is more technique sensitive, so it's more forgiving for a lower volume surgeon."

**Moderator Trousdale:** "Thank you." ♦

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COMPANY

# First Quarter Ortho Decelerates, Biomet Tops Growth

*Wikimedia.org and RRY Publications, LLC*

All the major orthopedic companies have reported first quarter sales. How did the Big Six (soon to be Big Five) fare after a great fourth quarter of 2014?

Bob Hopkins, senior analyst at Bank of America/Merrill Lynch did the numbers. But Hopkins cautions that he hesitates to read too much into quarterly market share assumptions because companies only report revenue, not unit data. He says this can be misleading because relative mix cycles can vary meaningfully.

**Biomet Grew 7.3%**

Overall, the hip and knee market grew 3.4% in the first quarter. Biomet, Inc.'s revenue grew by 7.3%. Hopkins said first quarter sales are down about 2.5 points from a very strong fourth quarter of 2013, "but about in line with hip/knee growth for all of 2013."

**Stryker Takes Hips**

In hips, Stryker Corporation showed the highest revenue increase (4.9%), while in knees, Biomet's revenue rose 9.4%. While overall revenue for the hip market rose 2.7%, only Biomet (4.3%) and Stryker beat the average. Overall revenue for the knee market rose 4%. Only Zimmer Holdings, Inc. (5%) joined Biomet in beating that average.

That makes Biomet the only contestant to beat both averages.

The sequential decline in growth in the quarter, according to Hopkins, was actually on easier comps, and was helped a bit by selling day comparisons (half a day). Weather and seasonality were obvious offsetting negatives.

Hopkins said comps get significantly tougher throughout 2014 and price cuts in Japan kick in, but weather and seasonality ease as headwinds. "Overall we think the Q1 decline was relatively in-line and we remain comfortable with a market growth outlook for hips/knees in the 3-4% area."

**U.S. Decline Drove Deceleration**

Importantly, notes Hopkins, U.S. declines drove all of the sequential first quarter growth deceleration in global hips/knees combined as Europe appears to be rebounding.

Overall, Hopkins says for the U.S. players, global recon market share in the quarter was fairly stable compared to last year's first quarter when adjusting for comps and selling days.

Within the U.S., Stryker has gained share in the hip market at the expense of Smith & Nephew and Zimmer, while in knees, Biomet appeared to gain share although their print did not include March.

—*WE (May 2, 2014)*

| First Quarter 2014 Revenue Growth | | | |
|---|---|---|---|
| | **Hips** | **Knees** | **Combined** |
| Biomet | 4.30% | 9.40% | 7.30% |
| Zimmer | 2.00% | 5.00% | 3.80% |
| Stryker | 4.90% | 2.30% | 3.50% |
| **Overall Market** | **2.70%** | **4.00%** | **3.40%** |
| DePuy Synthes | 2.00% | 3.00% | 2.70% |
| Smith & Nephew | 0.00% | 0.00% | 0.00% |

*Source: Bank of America/Bob Hopkins*

## gSource Donates Instruments to Ghanaian Orthopedic Hospital

gSource, LLC is pleased to announce a fourth donation of their surgical instruments to the Foundation of Orthopedics and Complex Spine (FOCOS), a 501c3 nonprofit organization. The donated instruments, valued at $5,730, will be provided to the FOCOS Orthopedic Hospital in Accra, Ghana, for use in orthopedic procedures to help alleviate musculoskeletal problems including complex spine and pediatric orthopedic disorders. To date, gSource has donated instruments valued at $25,400. Surgical instruments are in need as FOCOS hopes to complete more than 150 surgeries in 2014.

"Once again we are pleased to be able to donate gSource instruments to the FOCOS Orthopedic Hospital in Ghana. It gives us great satisfaction to know our donation provides the FOCOS volunteer surgeons with the finest instruments to perform the corrective orthopedic surgeries needed by their patients in order that they may live a life free of pain and incapacitating disability," commented Gerd Billmann, president of gSource in the April 28, 2014 news release.

Oheneba Boachie-Adjei, M.D. is the founder and president of FOCOS and the chief emeritus of the Scoliosis Service at Hospital for Special Surgery. He told *OTW*, "Instruments donated by gSource are used in complex spine surgical procedures at the FOCOS Hospital in Ghana, West Africa. Resources are very limited and the cases are very complex requiring sophisticated equipment. gSource instruments are durable to withstand the wear and tear of extreme use and conditions at FOCOS."

Asked about their instrument needs for the next year, Dr. Boachie-Adjei commented to *OTW*, "We expect to perform around 200 surgeries at the FOCOS Orthopedic Hospital over the next year. It is difficult to predict our exact instrument needs as this will vary depending upon the complexity of the surgeries performed. Some instruments can be re-used while others are only good for one procedure. Our main focus right now is to expand our repertoire of tools—we have thousands of instruments but many are duplicates of the same tool, and much of our inventory is not of high quality. Thanks to the support of gSource, we have been able to begin to expand our instrument list and have replaced old, outdated tools with top of the line quality."

*—EH (May 2, 2014)*

*FOCOS*

## NuVasive's Double-Digit First Quarter

NuVasive Inc.'s first quarter sales rise of 11.3% made Wall Street happy and prompted Piper Jaffray analyst Matt Miksic to write that the results demonstrate the company's aptitude for "sustainable execution and share gains." It sounds like he was channeling company Chairman and CEO Alex Lukianov's mantra of, "Onwards and Upwards."


*NuVasive, Inc.*

| NuVasive, Inc. 1Q14 | Sales ($ in millions) | % Change |
|---|---|---|
| **Total Reported Sales** | **$177.5** | **11.3%** |
| U.S. Lumbar/ Cervical | $119.4 | 9.0% |
| U.S. Biologics | $26.2 | 9.0% |
| U.S. Monitoring | $11.0 | 11.0% |
| International | $21.0 | 34.0% |

*Source: NuVasive, Inc.*

Sales of $177.5 million included a 9% increase in lumbar and cervical core fusion sales, a 9% rise in biologic products and 11% in intra-operative monitoring (IOM). The company's focus on going international produced a 34% increase in sales. During a conference call with analysts on April 29, 2014, Lukianov reiterated the company expects to reach revenue of $725 million for the year.

Lukianov pointed to increased physician training in Japan, the world's second larg-

est spine market, and increased international adoption rates as reasons for the rise in overseas sales. Overall growth was driven by new product launches and increasing productivity from new sales reps hired over the last year.

**Stable and Improving Spine Market**

The tone of the spine market, according to Lukianov, remains stable and improving with physician-owned distributor (POD's) sales flattening or declining, and payor pressure generally stable. He noted that the North American Spine Society (NASS) and other spine societies are becoming increasingly active on the advocacy front to fight payor pushback. Lukianov also said that numerous hospital networks have increased disclosure requirements for physicians and spine companies making it more difficult for PODs to do business within these networks. He believes that the prevalence of PODs has likely peaked, but does not expect any material impact on growth in 2014.

Larry Biegelsen of Wells Fargo wrote that smaller spine companies continue to take share. In the first quarter, NuVasive (+11%), Globus Medical, Inc. (+9%) and LDR (+20%), grew significantly faster than DePuy Synthes (flat) and estimated flat Medtronic, Inc. core spine growth.

Looking ahead to the remainder of 2014, Biegelsen said AttraX biologic, which "had moved to the side for several quarters now appears to be not-dead." Management is continuing to work with the FDA, submitting additional preclinical work. The company hopes to receive an answer from the FDA by end-2014. In addition, the launch of Osteocel Pro is "going well."

**Lukianov: "Evolving the Organization"**

"Results in the first quarter of 2014 were solidly in line with our expectations, and place us on track to achieve full year guidance by continuing to execute our share-taking strategy. While staying true to NuVasive's core philosophy of driving innovation to improve spine patient outcomes, we are evolving our organization to maintain a start-up mentality and to continue to lead spine innovation as a much larger, and increasingly profitable, global organization," said Lukianov.

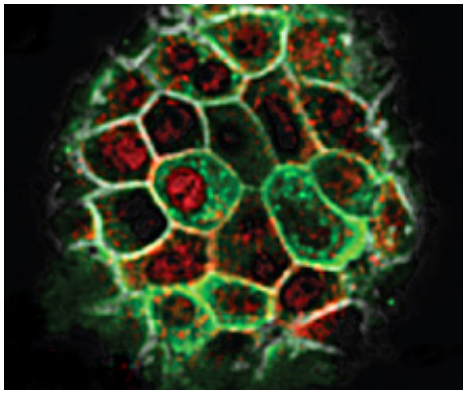
*—WE (April 30, 2014)*



BIOLOGICS

## FDA Scientists Studying Stem Cells

Scientists at the FDA are studying stem cells. They are part of FDA's MSC Consortium, a large team of FDA scientists studying adult mesenchymal stem cells (MSCs) that could eventually be used to repair, replace, restore or regenerate cells in the body, including those needed for heart and bone repair. The scientists claim that their investigational work is unprecedented. Seven labs at FDA's Center for Biologics Evaluation and Research formed the consortium to fill in gaps in knowledge about how stem cells function.


*National Institutes of Health*

"This research aims to facilitate development of this important class of innovative medical products," explained Carolyn A. Wilson, Ph.D., associate director for research at the center. "It's the first time we've done anything like this, and it's proven to be a very useful approach."

Steven R. Bauer, Ph.D., chief of the Cellular and Tissue Therapy Branch in FDA's Office of Cellular Tissue and Gene Therapies, said, "It's not science fiction. For me, regenerative medicine is the most exciting part of what we regulate in our office."

One reason why stem cell based clinical trials have not yet resulted in a marketed product is that growing the cells and making sure their use is safe and effective has been a challenging problem. Bauer explained, "The major challenge is that cells are much more complex than traditional products that FDA regulates. And they have the ability to respond to their environment. Taking them out of the body and manufacturing them—that is, growing large numbers of them—or isolating them can change their biology. And it can change the way they behave if they are put back into the patient."

The consortium's research has shown that widely accepted ways to identify and characterize MSCs do not reveal some important biological differences between batches of cells. According the Bauer, the consortium is seeking to better characterize MSCs that will be used in clinical trials. If investigators can improve the tools used to characterize MSCs, the data generated from their studies could also improve because their MSC products will be more predictable, he says.

The improved predictability of their products will, in turn, allow FDA scientists to more easily evaluate the safety and effectiveness of new stem cell technologies—a key part of the regulatory science that is the foundation of FDA decisions.

"My colleagues and I hope our scientific findings will be helpful in the field of regenerative medicine," Bauer said. "Although there are many scientific hurdles to overcome before the use of stem cells reaches its full potential, I think this medicine will eventually have the capacity to do that."

*—BY (May 1, 2014)*

**LARGE JOINTS**

## Trial Tests Regeneration of ACL Tissue

A medical device company called Soft Tissue Regeneration, Inc. has completed enrollment for a clinical trial of the company's L-C Ligament, a bioresorbable scaffold for soft tissue regeneration of the anterior cruciate ligament (ACL) of the knee.

The clinical trial is a prospective, multicenter test to evaluate the safety profile of the L-C Ligament in 15 males and females with acute ACL injuries. The effectiveness of the treatments will be judged by the rate of revision surgery in the treated patients, as well as their radiographic, clinical and subjective outcomes.

"The first patient was implanted on June 18, 2013, and is now out more than 10 months," said Joseph Reilly, president and CEO of Soft Tissue Regeneration. "All 15 patients are doing extremely well and are following a normal course of physical rehabilitation. This is the first step in a process that will help improve patient outcomes on many levels."

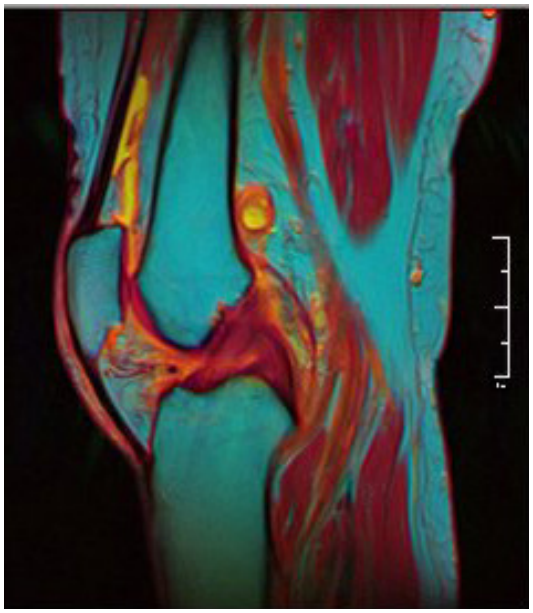
Reilly described L-C Ligament as being a synthetic bioresorbable scaffold that is designed to stabilize the knee after ACL reconstruction surgery. It is a patented technology that uses a clinically-proven polymer called poly(L-lactic acid) (PLLA) that is widely used in orthopedic implantable devices. He said that it addresses known risks and morbidity associated with allograft and auto graft tissues.

"This procedure is straight forward, fast and does not require harvesting of the patient's tendon, thereby eliminating the risks associated with the harvest site", said Kees van Egmond, M.D., who is the first surgeon in the world to implant the L-C Ligament. "This procedure has the potential to facilitate faster, improved healing with very little surgical morbidity for patients."

The L-C Ligament is anticipated to encourage the regeneration of the patient's own ligament tissue. The company reports that, to date, results from large-scale animal testing at two years and longer have demonstrated that the L-C Ligament can successfully regenerate a native ligament intra-articularly.

The trial is being conducted at Isala Klinieken in Zwolle, The Netherlands, by van Egmond and at Martini Hospital in Groningen, The Netherlands by Reinoud Brouwer, M.D. A larger, randomized clinical trial in Europe is anticipated to begin in September 2014.

*—BY (May 1, 2014)*



*Wikimedia Commons and Nevit Dilman*

## Doc Invents Post-Surgery App

Michael Dunbar, M.D., a surgeon at the Queen Elizabeth II Hospital and a professor in biomedical engineering at Dalhousie University, Nova Scotia, Canada, was finding it hard to keep up with the long line of patients needing hip and knee replacements and post surgery check-ups. So he invented a smartphone app.

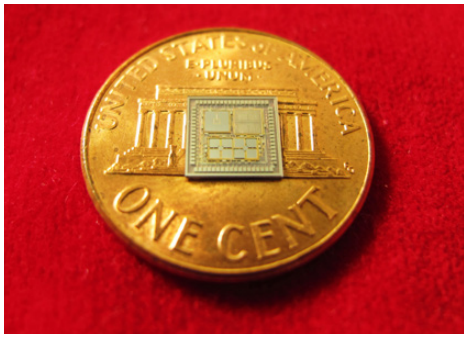
Dunbar's app uses the accelerometer in smartphones to analyze the gait of a patient. "It can measure the centre of mass displacement very accurately" said Dunbar, "The accelerometers are pretty simple and pretty powerful."

Here is how Dunbar envisions it working. Patients would get a text message or phone call from the doctor telling them that it is almost time for a checkup and to strap their phone on and go for a walk within the next week or so.

"It's going to be hard for this not to be more accurate than what we're doing already," said Dunbar. "What we are using now is just a two-dimensional X-ray, which is very blunt, and is just a picture of the patient lying down, and has nothing to do with the patients' walking around and how they get around in space."

The app works by strapping the phone on to the patient's back or hip and having him walk around in his own neighborhood. The results would be shared with the doctor for analysis and a follow-up phone call or message sent to the patient about how he is healing.

"Turns out the majority of people are fine," said Dunbar about the patients he sees currently for post-surgery appointments. He sees his app as a time saving and time effective option. "Because ultimately," he says, "it is going to save a lot of money."




*Caption: The single chip TIMU prototype contains a six axis IMU (three gyroscopes and three accelerometers) and integrates a highly-accurate master clock into a single miniature system, smaller than the size of a penny.*
*Source: Wikimedia Commons and University of Minnesota*

*—BY (May 1, 2014)*

## Joint Replacement Cost Higher Than Annual Income

What should individuals of a certain age do if money is in short supply—save for retirement or a joint replacement? That is the question raised by *NerdWallet* writer Nepala Pratini who points out that the cost of a knee or hip replacement is far above the median annual household income in 18 states. Most of these states are in the southern half of the United States.

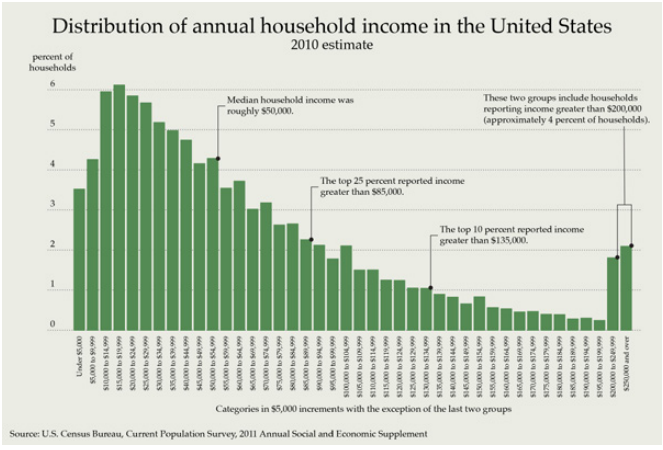
According to the Organization for Economic Cooperation and Development, the number of hip and knee replacements jumped by more than 25% between 2000 and 2009. At a growth rate of 8%, one in 12 adults over the age of 25 will, at some point, have this surgery.

Pratini reports that the average price across the country for a joint replacement is $50,105. Monterey Park Hospital in California charges the most ($223,373) while the Chickasaw National Medical Center in Oklahoma charges $5,303. As Pratini notes, both prices are unmanageable for millions of individuals who may need joint replacements in the coming years.

According to a survey conducted by the Employee Benefit Research Institute and Greenwald and Associates about a third of U.S. workers have less than $1,000 saved for retirement. About 60% have saved less than $25,000. Researchers for *NerdWallet* estimate that, even with insurance, ten million Americans will face medical bills they will be unable to pay. Insurance does not make costly procedures free.

Fidelity estimates couples who retired in 2013 will need $220,000 to cover medical expenses through the end of life. A hip or knee replacement for the uninsured could account for one-quarter of these costs.

*—BY (May 1, 2014)*




*Wikimedia Commons and U.S. Census Bureau*

## Orthopedics Indifferent to Economic Trends

Recent downturns in the economy have had little or no effect on the growth in hip and knee arthroplasty in the United States—which is good news for orthopedic surgeons. Steven M. Kurtz, Ph.D. and his colleagues from Exponent, Inc., in Philadelphia found that the trend for joint replacement surgery in the U.S. population has been "insensitive to economic turndowns."

Their report states, "The total number of procedures increased by 6.0% from 2009 to 2010 for primary total hip arthroplasty, 6.1% for primary total knee arthroplasty, 10.8% for revision total hip arthroplasty, and 13.5% for revision total knee arthroplasty."

"The available data do not support the hypothesis that the anticipated long-term national demand for joint replacements has been fundamentally altered by the current recessionary economic environment," said Dr. Kurtz, who was also lead author of the previous 2007 study. "They suggest instead that the long-term trends for the demand in total joint arthroplasty appear to be recession-proof."

The authors published their study in the April issue of *The Journal of Bone and Joint Surgery*. They used government projections of National Health Expenditure from 2011 to 2021 as well as a regression model to estimate future arthroplasty rates in the U.S.

*—BY (April 28, 2014)*

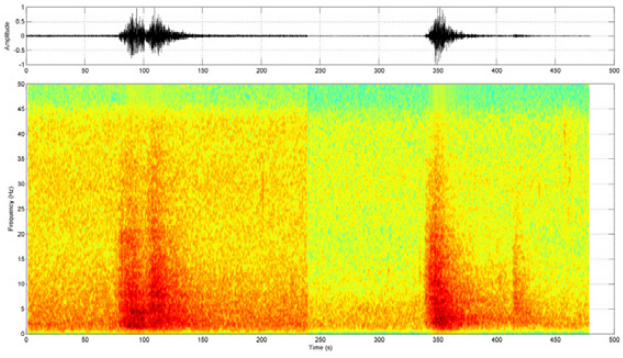
*Wikimedia Commons and Media I am*

**EXTREMITIES**

## Sound Waves May Heal Shin Splints

Irritation of the affected area could be a successful treatment for shin splints, a common running injury also known as medial tibial stress syndrome (MTSS), according to the April 21 press release. Phil Newman, an assistant professor at the University of Canberra, has been using sound waves to stimulate the body's natural repair response. Newman says that the application of sound waves tricks the body into repairing the injury.

"This therapy has been successfully used for the treatment of tendon injuries in the heel, foot and shoulder for many years with an extremely low rate of side effects," he said. Newman has been using the therapy on a trial group of runners with MTSS and he has found the results to be encouraging. "Our research suggests it will be effective in treating the shin splints," he said.



*Wikimedia Commons and Moore JR*

Newman noted that shin splints have been the scourge of runners for a long time and there is not yet an effective, established treatment for this condition which, he says, affects one in three runners.

"Once you get MTSS, it's hard to get rid of it and in many cases, the pain not only disrupts training but it can even affect everyday activities. If we can finally treat this very common injury, we can get more people out enjoying the health benefits of running," he said.

*—BY (April 28, 2014)*

REIMBURSEMENT

# Providers Embracing "The Bundle"

*Wikimedia Commons and RRY Publications*

"Capture the Bundle," Richard Rothman, M.D., founder of the Rothman Institute and one of the most successful physician-owned and led academic orthopedic centers in the U.S., told attendees at the recent annual meeting of the American Academy of Orthopaedic Surgeons (AAOS).

His colleagues appear to be listening.

According to a KPMG LLP poll conducted on March 26, 2014, more healthcare providers are using bundled payment systems. The biggest challenge cited by 42% of the providers is in getting physicians and hospitals aligned and controlling expenditures.

The bundled payment model package out- and in-patient costs, professional fees and post-discharge costs related to specific conditions into one payment.

### 44% Already Bundled

KPMG polled 140 healthcare providers, largely represented by hospitals and health systems and large scale physician groups. Forty-four percent said they are already working with bundled payments. That was up from 38% from last October. Meanwhile, 29% remain undecided, down slightly from 36% in October. According to the poll, 7% said they had no intention to offer bundle payment plans, up from 2% in the October poll. Twenty percent said they're not there yet, but plan to.

The concern over alignment between hospitals and physicians, stated a KPMG press release, reflects a history of misalignment between physicians and hospitals payment methods and operational goals. Nearly 32% of respondents felt control of expenditures throughout the bundle posed the biggest challenge; while 16% believed the ability to harness performance information across the organization as the most significant barrier.

### Key Strategies

Providers were almost equally split when asked about the key components of bundled payment strategies.

- 30% indicated that the ability to harness and manage big data would lead to success
- 28% felt providing resources for program design, administration, and provider contracting were necessary
- 27% cited commitment from top leaders as critical and 15% believed an open mind to new ideas was essential.

### Changing Business Models

"We are seeing a convergence in the market happening where all players—life sciences, payers, providers—are changing their business model to create value for consumers," concluded Marc Berg, KPMG's head of strategy and transformation for Healthcare and Life Sciences. "With bundle options, such as those offered by CMS [Centers for Medicare and Medicaid Services] and private-payer bundles, hospitals can reduce unwarranted admissions and readmissions, decrease lengths of stay, improve cost-effective prescribing and promote volume growth by increasing market share."

—*WE (April 29, 2014)*

# New Weapons for Fighting Insurance Denials

Physicians have a couple of new weapons when fighting insurance carriers who deny claims for payment—their patients and the Affordable Care Act.

Data collected by *Capital Public Radio* in California found that about half the time a patient challenges a denied health care service through a third party, the patient wins.

The Affordable Care Act has made the right to appeal denied health care uniform and universal for every insured person in the U.S. According to healthcare.gov, patients can ask his or her insurance company to reconsider its decision. Insurers have to tell them why the claim has been denied and how to dispute the decisions.

There are two ways to appeal a health plan decision:

Internal appeal: If the claim is denied, the patient has the right to an internal appeal. He or she may ask the insurance company to conduct a full and fair review of its decision. If the case is urgent, the insurance company must speed up this process.

External review: Patients have the right to take an appeal to an independent third party for review. This is called external review. External review means that the insurance company no longer gets the final say over whether to pay a claim.

One patient used as an example in the California story had received four denial letters by the carrier. He filed an appeal with the California Department of Insurance, which regulates his health plan. The insurer's denial was overturned.

Peter Kongstvedt used to manage health plans and is now at George Mason University. He says most health care denials involve administrative errors or mechanical problems. He says patients are often just as successful challenging denials directly to the insurer as they would be through a third party.

"It can be an error on the health plan side," says Kongstvedt. "Maybe they put somebody in the system wrong and they don't know that they're eligible yet. Or it gets a data entry error that occurs, so it doesn't appear that it makes any sense to the system. The computer says 'Oh, we don't pay for this service on that diagnosis,'—that type of thing."

Insurers say only about 3% of claims are denied. Robert Zirkelbach of America's Health Insurance Plans says in the radio program that coverage decisions are based on medical evidence. "It's the medical evidence that drives coverage decisions, and the more evidence that's available about the appropriateness and effectiveness of a particular drug or treatment or technology, that's what drives what's covered."

The lesson for providers is to teach their patients more about how to appeal a denial of service through their individual state health insurance regulators. Keep your state regulator's information handy for patients.

—*WE (April 29, 2014)*


*National Conference of State Legislatures*

SPINE

# Yeung Endoscopic Center Dedicated in New Mexico


*Howard Yonas, M.D., Eileen Yeung, Anthony Yeung, M.D. and Dean Paul Roth/Image Credit: Sara Mota*

The great historian, David McCullough, told a North American Spine Society audience a few years ago that there is nothing inevitable about history. History is made by people who make the best decisions they can with no visibility of the future. Only their character guides their decisions.

It wasn't inevitable almost 30 years ago that Anthony Yeung, M.D. would take the concept of the knee scope and bring it to the spine, using a transforaminal approach and visualized endoscopic instrumentation. It wasn't inevitable that he would develop the FDA-approved Yeung Endoscopic Spine Surgery System (YESS), allowing for outpatient surgery, significantly smaller incisions, preservation of muscle and bone and a quicker recover.

Those decisions led to the dedication on April 25, 2014 of the first academic spine center dedicated to endoscopic spine surgery. The Anthony T. and Eileen K. Yeung Endoscopic Spine Center of the University of New Mexico's (UNM) School of Medicine is located at the Sandova Regional Medical Center in Albuquerque, New Mexico.

### Validating the Field

J. Fred Harrington, M.D., assistant professor of neurosurgery at the medical school and director of the center, told *OTW* that he believes that transforaminal endoscopic spine surgery as practiced by pioneering surgeons such as Dr. Yeung and other endoscopic spine surgeons in Europe and Asia has demonstrated the potential to improve both the subjective patient experience and outcomes after spinal surgery.

"However," added Harrington, "there is a need to increase the amount of scientific data available to validate the field. By carefully studying our patients, we hope to put endoscopic spine surgery in its proper place amongst the tool that spine surgeons can use to alleviate pain and suffering."

Dr. Yeung, a graduate of the UNM Medical School, said he was guided by his own personal experience when his mother had spine surgery when he was a resident and she got worse. "I thought there had to be a better way; I wanted to bring this to UNM because there is already a team of like-minded physicians in place here who are interested in working with patients to find the source of their pain."

### A Better Way

Dr. Yeung's better way was to develop a multi-channel device which marries the laser and the endoscope to allow surgeons to visualize and selectively remove portions of a herniated nucleus contributing to back and leg pain. The 2.7mm operating channel uses a keyhole incision to access the damaged disc, dilating rather than cutting muscle and tissue, resulting in less tissue destruction, no need for general anesthesia, and a quicker recovery. This procedure is used to treat herniated, protruded, extruded, or degenerative discs in the lumbar spine, a very common condition.

"Endoscopic foraminal spine surgery offers the least invasive surgical solution to visualizing and treating the pain generators without burning any bridges for traditional more invasive procedures that have higher surgical morbidity," said Dr. Yeung.

### Multi-Disciplinary Approach

Howard Yonas, M.D., chairman of the department of neurosurgery at UNM explained, "Because we have a very

cohesive multi-disciplinary group in our spine program, it is clear that each part of the breadth of Dr. Yeung's work will be embraced by all members of the team."

"Every patient who comes to us is evaluated by a multi-disciplinary team," added Dr. Harrington. He explained that the Sandoval Regional Medical Center facility is part of the UNM Interdisciplinary Center for Spine Health.

The Interdisciplinary Center for Spine Health at UNM holds a close affiliation with the UNM Pain Center which includes an interdisciplinary team of specialists in neurology, psychiatry, physical medicine and rehabilitation, anesthesia/interventional pain, neurosurgery, internal medicine, family practice, psychology, pharmacy and physical and occupational therapy and chiropractic services.

UNM has equipped a SRMC surgical suite with the unique instruments needed for the surgery and provided special training to operating room nurses assisting with the procedures. UNM surgeons have been operating at SRMC since March.

**Leaving a Legacy**

Dr. Yeung, who practices at the Desert Institute for Spine Care in Phoenix, and his wife, contributed $2.5 million to the Center. "I hope that this is a legacy," said Dr. Yeung.

The decisions which led to the Yeung Center may not have been inevitable, but they are now history.

*—WE (May 2, 2014)*

## Expanding Orthopedics' Cage Presented at ISASS

Expanding Orthopedics Inc. (EOI) is pleased to announce that the FLXfit, TLIF 3D expandable cage will be presented for the first time at the prestigious annual meeting of the International Society for the Advancement of Spine Surgery (ISASS) in Miami. Professor Jean Charles Le Huec will present the work performed with his international colleagues, Dr. Klaus Schnake and Dr. Ory Keynan.

In the April 29, 2014 news release, Professor Le Huec, Head, Ortho-Spine Department, Bordeaux University Hospital, France, former president of ISASS and EuroSpine, explained that "correcting anatomical balance in the lumbar spine is imperative, particularly in the lower disc spaces. The current cages available on the market have limited possibilities for lordosis correction and are sometimes difficult to maneuver. In addition, the contact between the implant and endplate is not always optimal, leading to improper stability after the surgery."

Dr. Keynan, head of Service for Degenerative and Age-Related Spinal Disorders at the Sourasky Medical Center, Tel-Aviv, Israel, noted that "the FLXfit addresses the need for a wide anterior footprint coverage. The design allows a minimal invasive, uni-lateral TLIF approach and its articulated self-guidance feature enables a smooth introduction and an optimal placement after expansion. The lordotic expansion facilitates the lordosis correction at the treated level."

Dr. Schnake, head of the Spine Surgery Center at the Nurenberg Schoen Klinik, Germany, added that "the

*Expanding Orthopedics Inc.*

FLXfit successfully passed all relevant international biomechanical testing, with equivalent or superior results compared to alternative devices in all measures. In cadaver studies performed with my colleagues, all cages were successfully implanted, positioned and expanded with a steep learning curve. Reversibility of the expansion for easy and safe intra-op removal was successfully validated. Lordosis restoration was evaluated at each level and the implant/endplate contact showed good results."

Professor Le Huec, concluded that "initial biomechanical and cadaver testing shows that the FLXfit is a unique three-dimensional expandable articulated TLIF cage that meets the requirements of strength, stability, anatomical benefits and user-friendliness. It combines the benefits of minimal invasive access, optimal footprint, large bone graft chamber, press fit insertion and adaptability to the patients' anatomy while allowing an optimal lordosis restoration."

Ofer Bokobza, CEO of Expanding Orthopedics, told *OTW*, "EOI is currently in the midst of CE and FDA approval processes. The device is getting great feedback from surgeons due to its unique design and ease of use. Once cleared, EOI will be starting clinical use of the FLXfit device in selected centers in Europe and later in the U.S. EOI is also planning to release few additional unique cages based on our 3D expanding technology platform."

*—EH (April 30, 2014)*

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