Yeung v. Dickman  ◆ Curtis Dickman, M.D., said fellow Phoenix surgeon Tony Yeung, M.D., was a “danger to the public.” Yeung sued him. Their fight is bouncing around the courts and offers important lessons for any physician considering filing a complaint against a colleague. Read the details of the legal battle here.

Leg Reversed and Reattached  ◆ Rotationplasty puts the foot where the knee joint used to be with the heel in front, toes pointed back—rotated in other words. For 10-year-old Dugan Smith this was the surgery that got him back on the baseball diamond. Read on about this rare and amazing procedure.

The Economics of Adult Reconstruction  ◆ The recession, declines in reimbursement, retiring surgeons, and less interest in adult reconstructive surgery…all mean that patients will likely have to wait longer and longer to see a total joint specialist. Learn about the AAHKS survey…

Dr. Charles Epps, Part II  ◆ Dr. Charles Epps, the first African American president of the AOA, has counseled families through the process of understanding and accepting a child with limb deformities, and helped establish the National Rehabilitation Hospital. His is a legacy of advancement.

Singing Decreases BP in OA Patients
Disc Replacement Tops Fusion
New Study Targets PRP for Knee Pain
Wright Medical in Turmoil
Les Cross Joins Alphatec’s Board
Generic Implants Hit Market
J&J Settles Bribery Charges

For all news that is ortho, read on.
Orthopedic Power Rankings
Robin Young’s Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Did not see Wright Medical’s abrupt management turn-over coming. Wall Street’s analysts are interpreting the events as putting WMGI in play. With several outstanding products in key strategic markets, that interpretation has a certain logic to it. We think, however, that everyone needs time to digest events.

<table>
<thead>
<tr>
<th>Rank</th>
<th>Last Week</th>
<th>Company</th>
<th>TTM Op Margin</th>
<th>30-Day Price Change</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>Orthofix</td>
<td>14.49%</td>
<td>2.99%</td>
<td>Tough spine headwinds these days, so expectations are for flat overall sales in Q1. OFIX has regularly beat expectations</td>
</tr>
<tr>
<td>2</td>
<td>7</td>
<td>Alphatec</td>
<td>1.11</td>
<td>6.18</td>
<td>Les Cross is a great add to ATEC’s board. Les Cross + Dirk Kuyper should make savvy investor’s drool.</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>Medtronic</td>
<td>31.23</td>
<td>0.66</td>
<td>Upgraded by Wells Fargo’s Biegelsen this week to Outperform. Momentum building for MDT on Wall Street.</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>Zimmer</td>
<td>27.38</td>
<td>(4.57)</td>
<td>Consensus opinion is that Zimmer's sales growth rate will accelerate through the course of 2011 from 2.80% to 5.00%.</td>
</tr>
<tr>
<td>5</td>
<td>5</td>
<td>Stryker</td>
<td>25.61</td>
<td>(7.97)</td>
<td>Expectations are high for SYK’s first quarter. Analysts looking for 11% YOY sales growth.</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>Smith &amp; Nephew</td>
<td>23.22</td>
<td>(1.25)</td>
<td>Like Zimmer, analysts are looking for SNN’s sales growth rate to also increase significantly this year.</td>
</tr>
<tr>
<td>7</td>
<td>10</td>
<td>Integra LifeSciences</td>
<td>15.18</td>
<td>(4.61)</td>
<td>IART’s spine division received FDA clearance for three new spine implants. Up three spots this week. One for each implant.</td>
</tr>
<tr>
<td>8</td>
<td>NR</td>
<td>Symmetry</td>
<td></td>
<td>9.51</td>
<td>Back on Power Rankings this week. One of the best performing ortho stocks this past month.</td>
</tr>
<tr>
<td>9</td>
<td>8</td>
<td>NuVasive</td>
<td>6.69</td>
<td>(6.23)</td>
<td>How will NUVA do? Better than expected. Strong distribution + innovative products are why.</td>
</tr>
<tr>
<td>10</td>
<td>9</td>
<td>Exactech</td>
<td>9.66</td>
<td>(3.21)</td>
<td>Last year, EXAC delivered a big upside surprise in Q1. Would be hard to repeat, we think, but not impossible.</td>
</tr>
</tbody>
</table>
# Top Performers Last 30 Days

<table>
<thead>
<tr>
<th>Company</th>
<th>Symbol</th>
<th>Price</th>
<th>Mkt Cap</th>
<th>30-Day Chg</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAKO Surgical</td>
<td>MAKO</td>
<td>$26.15</td>
<td>$1,070</td>
<td>30.4%</td>
</tr>
<tr>
<td>TranS1</td>
<td>TSON</td>
<td>$4.45</td>
<td>$93</td>
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<tr>
<td>Symmetry Medical</td>
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<td>$9.90</td>
<td>$360</td>
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<td>Alphatec Holdings</td>
<td>ATEC</td>
<td>$2.92</td>
<td>$259</td>
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<td>Tornier N.V.</td>
<td>TRNX</td>
<td>$19.28</td>
<td>$753</td>
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<tr>
<td>Orthofix</td>
<td>OFIX</td>
<td>$33.05</td>
<td>$596</td>
<td>3.0%</td>
</tr>
<tr>
<td>ConMed</td>
<td>CNMD</td>
<td>$27.20</td>
<td>$769</td>
<td>2.8%</td>
</tr>
<tr>
<td>Synthes</td>
<td>SYSTVX</td>
<td>$139.12</td>
<td>$16,513</td>
<td>2.4%</td>
</tr>
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<td>RTI Biologics Inc</td>
<td>RTIX</td>
<td>$2.74</td>
<td>$150</td>
<td>1.9%</td>
</tr>
<tr>
<td>Medtronic</td>
<td>MDT</td>
<td>$39.67</td>
<td>$42,420</td>
<td>0.7%</td>
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</table>

# Worst Performers Last 30 Days

<table>
<thead>
<tr>
<th>Company</th>
<th>Symbol</th>
<th>Price</th>
<th>Mkt Cap</th>
<th>30-Day Chg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterin Intl Holdings</td>
<td>BONE</td>
<td>$3.40</td>
<td>$124</td>
<td>-17.1%</td>
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<tr>
<td>Orthovita</td>
<td>VITA</td>
<td>$2.06</td>
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<td>$59.71</td>
<td>$23,360</td>
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<td>TiGenix</td>
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<td>$1.82</td>
<td>$57</td>
<td>-7.3%</td>
</tr>
<tr>
<td>Wright Medical</td>
<td>WMGI</td>
<td>$15.47</td>
<td>$588</td>
<td>-7.1%</td>
</tr>
<tr>
<td>Kensey Nash</td>
<td>KNSY</td>
<td>$25.14</td>
<td>$214</td>
<td>-6.5%</td>
</tr>
<tr>
<td>NuVasive</td>
<td>NUVA</td>
<td>$25.74</td>
<td>$1,020</td>
<td>-6.2%</td>
</tr>
<tr>
<td>ArthroCare</td>
<td>ARTC</td>
<td>$33.24</td>
<td>$905</td>
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</tr>
<tr>
<td>Integra LifeSciences</td>
<td>IART</td>
<td>$47.14</td>
<td>$3,150</td>
<td>-4.6%</td>
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<tr>
<td>Zimmer Holdings</td>
<td>ZMH</td>
<td>$59.91</td>
<td>$11,510</td>
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# Lowest Price / Earnings Ratio (TTM)

<table>
<thead>
<tr>
<th>Company</th>
<th>Symbol</th>
<th>Price</th>
<th>Mkt Cap</th>
<th>P/E</th>
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<td>$42,420</td>
<td>11.67</td>
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<td>12.79</td>
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<tr>
<td>Johnson &amp; Johnson</td>
<td>JNJ</td>
<td>$59.46</td>
<td>$162,640</td>
<td>12.81</td>
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<tr>
<td>Average</td>
<td></td>
<td>$11,943</td>
<td>13.18</td>
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# Highest Price / Earnings Ratio (TTM)

<table>
<thead>
<tr>
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<th>Symbol</th>
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<th>Mkt Cap</th>
<th>P/E</th>
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<td>SNN</td>
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# Lowest P/E to Growth Ratio (Earnings Estimates)

<table>
<thead>
<tr>
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<th>Price</th>
<th>Mkt Cap</th>
<th>PEG</th>
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<tbody>
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<tr>
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<tr>
<td>NuVasive</td>
<td>NUVA</td>
<td>$25.74</td>
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# Highest P/E to Growth Ratio (Earnings Estimates)

<table>
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<th>Price</th>
<th>Mkt Cap</th>
<th>PEG</th>
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<tbody>
<tr>
<td>Kensey Nash</td>
<td>KNSY</td>
<td>$25.14</td>
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<td>7.60</td>
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<tr>
<td>CryoLife</td>
<td>CRY</td>
<td>$5.63</td>
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<td>$769</td>
<td>2.11</td>
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# Lowest Price to Sales Ratio (TTM)

<table>
<thead>
<tr>
<th>Company</th>
<th>Symbol</th>
<th>Price</th>
<th>Mkt Cap</th>
<th>PSR</th>
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<td>1.01</td>
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<td>1.11</td>
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# Highest Price to Sales Ratio (TTM)

<table>
<thead>
<tr>
<th>Company</th>
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<th>Mkt Cap</th>
<th>PSR</th>
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<tbody>
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<td>$26.15</td>
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<td>$57</td>
<td>17.58</td>
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<td>3.46</td>
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Advertise with Orthopedics This Week
It may be modern day Phoenix, Arizona, but a bitter fight between two spine surgeons in the city feels more like an Old West gunfight. The outcome may provide important legal lessons for physicians who are contemplating filing a complaint against a colleague with their state’s medical board.

The Patient

James Lester was suffering from back pain in 1998 and went to see Phoenix spine surgeon, Tony Yeung, M.D. Yeung determined that Lester had a bulging disc. After doing a discography, Yeung treated Lester with a procedure known as “thermal modulation” or “thermal annuloplasty” whereby a heating probe is inserted into the spinal disc space to heat the area’s ligaments.

Yeung told OTW on April 6 that his patient was the first with a stable mild spondylolisthesis treated under a St. Luke’s [Phoenix hospital] IRB (Investigational Review Board) to test the Oratec temperature controlled probe. Yeung said Lester developed a 3/5 neuropraxia, but resolved his back pain. The probe was withdrawn from investigation because it was found that the temperature could not be controlled.

According to Arizona court documents, Lester suffered “permanent nerve damage [during the surgery] that resulted in numbness, weakness, and debilitating pain in his right leg and foot.” Lester sued Yeung for malpractice in 2001. After a jury trial in September 2005, Lester received a $1.4 million award, which Yeung paid.
The physician who testified at Lester’s trial as an expert witness was Curtis Dickman, M.D., a Phoenix neurosurgeon who operated on Lester after Yeung.

**Dickman’s Formal Complaint**

After the Lester trial, Dickman filed a formal complaint against Yeung with the Arizona Medical Board. William Jones, Dickman’s attorney, told OTW on April 4 that Arizona law mandates physicians to report what they consider improper actions by their peers.

In his complaint filed in December 2005, Dickman accused Yeung of “dangerous, inappropriate, negligent and reckless medical treatment.” In Dickman’s opinion, Yeung “is a danger to patients and to the public.” He said “many” patients who were treated by Yeung had come to his office. He added that Yeung’s treatment of Lester was the “most grossly negligent care” he had ever encountered.

The Board took no action because, according to court documents, the Board had already investigated the matter based on a previous similar complaint.

But this wasn’t enough to placate Yeung. He didn’t like being called a danger to the public, wanted to clear his name and take on Dickman, who at Lester’s trial had acknowledged “animosity” toward Yeung.

**Yeung Sues Dickman**

On September 13, 2006, Yeung sued Dickman alleging he was defamed in Dickman’s letter to the Board.

Dickman’s lawyer argued that Yeung couldn’t sue because Dickman’s statements to the Board were substantially similar to his testimony at the Lester trial. He claimed that common law absolute privilege to communications made in judicial proceeding immunized him from civil liability. The trial judge agreed and summarily dismissed the suit without a trial.

Yeung was undeterred and wanted his day in court. So he appealed, and won.

**Immunity: Absolute and Privileged**

The Appeals Court said that a complaint to the Board was not covered by a common law absolute privilege or immunity, but that physicians had “qualified immunity” in making a report to the Board. The Court sent the case back to the lower court.

When the case went back before the trial judge, Dickman again argued that he is immune from liability because, according to his motion, “there is no evidence, let alone clear and convincing evidence, that he acted in bad faith or with actual malice.”

Again, the court ruled in Dickman’s favor. And again, Yeung is not willing to give up his quest to clear his name.

Jones, Dickman’s attorney, told OTW that it seems unfair to mandate physicians by law to file complaints, and then sue them. That’s why Arizona state law provides for “qualified” immunity from lawsuits.

**Truth and Good Faith**

Larry Cohen, Yeung’s attorney told OTW on April 7 that he agrees with Jones, but that immunity only exists if the complaint is based on truth and absent of actual malice. Cohen argues that when Dickman filed the complaint against Yeung, Dickman entertained doubts about his claims or knew, or should have known they were false.

Cohen says Yeung will file a new motion with the trial judge in early April to reverse her second decision to dismiss Yeung’s case and allow a jury to decide if Dickman’s statements to the Board were false and made with malice. Cohen says Yeung has offered ample evidence, including an email survey Dickman sent to 32 other spine surgeons asking about Yeung’s treatment of Lester. Dickman sent the emails after Yeung had a complaint filed against Dickman with AANS (American Association of Neurological Surgeons).

Yeung requested that the emails be disclosed as evidence of Dickman’s state of mind when filing his complaint to the Arizona Medical Board. But Dickman told the court that he had

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deleted the emails. He had promised anonymity to the email recipients. Yeung then asked the court to compel Dickman to turn over the hard drive that contained the deleted emails. The court agreed. However, Dickman notified the court that the hard drive had been destroyed.

Cohen says those emails could provide evidence that Dickman harbored doubts about his complaint to the Medical Board. So Yeung has asked those surgeons to contact him and share the contents of their communications with Dickman.

Beyond Yeung and Dickman

Yeung told OTW that this case is bigger than just him and is being played out in a larger context over the appropriateness of fusion surgery and the willingness of some surgeons to offer expert testimony at trial for personal gain.

As a recognized leader in the field of minimally invasive spine surgery, Yeung clearly didn’t like being called a danger to the public and believes he is fighting this case for all surgeon/scientists who chart new waters.

The Scientific Fight

According to Dickman’s original motion to dismiss Yeung’s suit, he testified at the Lester trial that Yeung’s decision to perform this procedure on Lester fell below the standard of care. He testified that thermal modulation does not treat spondylolisthesis, does not relieve nerve compression, and does not stabilize instability. He testified that “from a theoretical standpoint, this [procedure] doesn’t have a chance of helping this problem.”

The “Reasonable Physician” Affidavit

We won’t settle the scientific argument of what constituted standard of care in 1998 in this article. But in an affidavit filed in December 2010, Hansen Yuan, M.D., a former President of NASS and SAS (North American Spine Society and the Spine Arthroplasty Society), stated, “it is clear from the records that Dr. Yeung was treating Mr. Lester for a bulging disk and mild lysthesis and degenerative disk disease. No reasonable physician in December 2005 could believe that Dr. Yeung’s treatment was directed at relieving spinal stenosis or spondylolisthesis with instability. Dr. Yeung was treating the patient for a disk disruption with discogenic low back pain radiculitis.”

He added that no reasonable physician could believe that the care provided by Yeung caused, “complete foot drop or severe reflex sympathetic dystrophy, or destroyed Mr. Lester’s L5 nerve root.”

In sum, Yuan said that no reasonable physician could believe Yeung’s care was, “blatantly negligent, dangerous and inappropriate”...or any other of additional accusations in the complaint to the Arizona Medical Board.

Yeung and Dickman are well known and highly regarded physicians in their fields.

Curtis Dickman, M.D.

According to Dickman’s website, he is a New York native who came to Phoenix’s Barrow Neurological Institute (BNI) in 1985 as a resident, and has practiced neurosurgery at BNI since 1992 where he has served as Director of Spinal Research and Associate Chief of the Spine Section within the Division of Neurological Surgery.

He subspecializes in spinal surgery and performs comprehensive spinal surgery and has special interests in the treatment of tumors of the spine and spinal cord, spinal trauma, surgery of the upper cervical spine, endoscopic spinal surgery, herniated thoracic discs, spinal fixation and fusion, spinal deformity and instability, artificial disc replacement, and hyperhidrosis.
Dickman has authored six medical textbooks and over 175 scientific articles. He is on the editorial boards for several major spinal and neurosurgical journals. He has held executive leadership positions in several spine societies and has been the scientific program director for several major spine societies.

Tony Yeung, M.D.

Yeung has authored over 70 scientific publications on his minimally invasive techniques, and was named a “Health Care Hero” by the Phoenix Business Journal. Yeung served as the President of the Maricopa County Medical Society, The Arizona Orthopedic Society, The Western Orthopedic Society - AZ Chapter, and the Board of the Arizona Medical Association. He is currently the President of the World Congress of Minimally Invasive Spine Surgeons, and Executive Director of the Intradiscal Therapy Society.

The Lesson

At this point we don’t know how the trial judge will rule on Yeung’s motion to let a jury decide whether or not Dickman’s statements were true and made without malice. We do know there are important lessons to learn here by any physician considering filing a complaint against a colleague to their state’s medical boards.

Yeung’s attorney, Cohen said it best: “Make factual statements and make them in good faith.” ♦
Leg Reversed and Reattached
By Biloine Young and Robin Young

When Dugan Smith, an active fourth-grader fell and broke his femur, he and his parents found he had a bigger problem than a broken leg. Just above Dugan’s knee lay a softball-sized malignant tumor.

His doctor, Joel Mayerson, M.D., Associate Professor of Orthopedic Surgery and Director of the Ohio State University’s (OSU) Division of Musculoskeletal Oncology and Director of OSU’s Orthopaedic Residency Program, reduced Dugan’s fracture, put him in a cast and started four months of chemotherapy. But that was just the beginning.

“For a ten-year-old child like Dugan with osteosarcoma we were facing essentially four treatment options. We could remove the tumor and fill the void with allograft or we could replace the distal femur with prosthesis or we could amputate above the knee or, finally, we could do a procedure called rotationplasty” recalls Dr. Mayerson.

“We discussed the options with Dugan’s parents, we conducted a psychology evaluation of Dugan, we talked about the cosmetics and functional aspects of each option but probably the most important consideration for Dugan was his activity level both now and in the future. Dugan told us that he wanted to be able to play baseball. After reviewing the options, Dugan’s parents actually let him make the final decision. He said to me ‘Doc, do whatever you have to do to get me back to playing baseball’.

Rotationplasty

Rotationplasty is where the foot is attached to where the knee joint used to be. The foot’s heel is in front and the toes are pointing back—rotated in other words. In this new position, the ankle joint now functions in place of the knee joint. Surprisingly to people who are unfamiliar with the approach, the ankle joint will, over time, create a functional, natural knee and the toes actually provide a vital sensory feedback to the brain.

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**Long-Term Results**

Several studies have reviewed the long-term results of rotationplasty on skeletally immature patients. One published in the journal *Clinical Orthopedics and Related Research*, author Hanlon M. Krajbich reviewed the cases of 21 skeletally immature patients with a Grade IIB osteosarcoma about the knee who’d been treated with a modified Van Ness rotationplasty. Fourteen patients were followed up for 4 to 10.5 years (mean follow-up, 8 years). Functional assessment using Enneking’s method showed all had good or excellent results. No patient thought that the reconstruction affected their ability to achieve recreational, sporting, or career goals. The reconstruction is durable and is not associated with an increase in late complications.

Another study published in the same journal in June 2007 by authors Agarwal, et al., offered a more detailed review of rotationplasty. These authors evaluated the disease status and functional results in 30 patients (range, 6-25 years) who underwent rotationplasty for bone sarcomas from January 2000 to February 2004. The surgeons in these cases used plating in all 27 distal femur resections. In the proximal femur tumor, the surgeons contoured the distal femur and fixed it to the ilium with cancellous screws. In two cases which involved the entire femur, the surgeons articulated the upper end of the tibia with the acetabulum in one case and inserted an Austin Moore prosthesis in the upper end of the tibia in the other.

According to Agarwal, et al., two patients underwent an amputation after postoperative vascular compromise. The authors also noted that two patients had venous congestion complications but they both recovered after exploration. The authors also
reported that one patient experienced partially recovered nerve palsy. Two patients had wound infection. One patient had a nonunion which was treated with subsequent bone grafting. The authors were able to follow up and document outcomes in 26 of the 30 patients in the study. Follow-up periods ranged from 24 to 60 months. Finally, the authors used the Musculoskeletal Tumor Society scoring system.

Agarwal, et al., found that 20 of the 26 patients who’d been treated with rotationplasty and had been evaluated for the study had a follow-up score of 25 or greater. The authors’ conclusions? “Rotationplasty provides good local disease control and good function for young patients with a primary bone sarcoma.”

**Cosmetics**

The main drawback to this operation is cosmetic.

The cosmetics of a foot at the knee position and then pointed backwards takes getting used to and some patients never get there. Typically, as was the case for Dugan, the patient’s calf muscle now serves as the thigh, while the ankle and foot act as knee and shin.

In Dugan’s case, Dr. Mayerson dedicated quite a bit of time with both Dugan and his parents to make sure they understood the cosmetic issues. But for Dugan, the chance to be fully mobile quickly outweighed any concerns over appearance. He and his parents knew that he had a lifetime in front of him and the freedom that a functional joint via rotationplasty represented a significant improvement over the use of traditional above-knee prosthesis.

**Managing Growth**

Dr. Mayerson’s second greatest concern, after cosmetics, was managing Dugan’s expected bone growth. “Most boys stop growing around age 17. In Dugan’s case, his untreated leg will grow faster than his rotationplasty leg. So we made Dugan’s rotationplasty leg approximately 7 centimeters longer than his other leg. By the time he is 17 years old, hopefully both legs will be of equal length at the level of the knee.”

The key for Dr. Mayerson was to determine Dugan’s skeletal age at the time of surgery and then make an accurate as possible guess at his amount of skeletal growth remaining until maturity. What complicates this algorithm is that growth plates at different parts of the leg and hip grow at different rates. Of the total growth that a patient can expect, the plates at the hip account for 30% of that future femur growth while plates at the knee contribute the remaining 70%. In the lower leg, plates at the ankle account for 40% of growth in the tibia and fibula,
while those at the knee contribute the remaining 60%.

Since Dr. Mayerson and his team removed growth plates on either side of Dugan’s knee Mayerson compensated by making Dugan’s residual limb longer.

“The whole surgery took 8-9 hours and was performed at Nationwide Children’s Hospital in Columbus, Ohio,” remembers Mayerson.

Rehabilitation

Mayerson’s team fitted Dugan with a prosthetic leg that fits over his foot and ankle, allowing him to walk, run and play sports. Recalls Mayerson: “The ankle joint functions exactly as a knee joint although it is not as stable side-to-side as a knee joint. The prosthesis helps to manage the side-to-side stability.”

Rehab for Dugan was slow at first. “Dugan had to undergo six more months of chemotherapy. During that period he fell down a couple of times. Once he broke his hip and another time he fell and broke his distal tibia just above the ankle (new knee). Dugan didn’t tell me about his fall and painful hip for a month. It wasn’t until we saw an X-ray that we discovered that he’d incurred a new fracture.”

When OTW commented that Dugan sounded like a pretty active 10 year old, Dr. Mayerson laughed and said, “Yes, you can’t keep Dugan still very long.”

Dugan also went through a long period of gait training but in 2010, Dugan returned to playing baseball and this year, according to Dr. Mayerson, “Dugan’s knee joint bends fully, so he’s recovered. Bottom line, this is an extremely functional operation if a patient is committed, as Dugan and his parents were, to really stick to it and to get past the cosmetics of it.”

So how do Dugan’s parents like it? “They think it’s great.”
In the past, not being able to get an appointment with Dr. X for three months said something about the good doctor’s talents and/or popularity. No more, say our experts. The economics of the recession—both now and for a long time to come—may just mean that not getting prompt treatment by any adult reconstructive specialist isn’t about cache…it’s reflective of a stark new reality.

In 2009, the American Association of Hip and Knee Surgeons (AAHKS) set out to assess the effects of the recent recession, with an eye towards the years to come. Of the 953 AAHKS members surveyed, a full 458 (48%) responded to questions regarding issues such as surgical and patient volume, hospital relationships, total joint arthroplasty cost control, potential impact of Medicare reimbursement decreases, and attitudes toward retirement planning.

The study’s lead author was Dr. Richard Iorio, the director of adult reconstruction at the Lahey Clinic Medical Center and professor of orthopaedic surgery at Boston University Medical School. He told OTW, “Because of the economic downturn, plummeting reimbursements, and total joints being an area open to significant legal risk, adult reconstructive surgery is not something that is appealing to up-and-coming orthopedic surgeons. Combine this with the fact that a multitude of reconstruction specialists will reach retirement age in the next few years, and we are headed for a crisis—patients will just not be able to be seen in a timely fashion…and they will suffer.”

Commenting on the study findings, Dr. Iorio says, “Due to the economic downturn, 30% of surgeons surveyed reported that their surgical volumes decreased and 29% reported that outpatient visits also decreased. The changing economic realities of today’s retiree were also apparent in the study, with a mean loss of 29.9% of retirement savings and a reported planned retirement age that has increased to 65.3 years from 64.05 years. These more difficult economic realities have decreased demand for adult reconstruction services. As the economy improves, demand for adult reconstruction services will again outpace the supply of surgeons willing to supply these services.”

A co-author, Dr. Mary O’Connor, associate professor of orthopedics at Mayo Clinic in Jacksonville, Florida, also waded through the disconcerting data. She notes, “The time is on the horizon when patients are going to have to wait longer and longer to see a total joint specialist; when they can’t get the care they need, most likely it is only then that the reasons for the delay in care will (hopefully) be addressed.”

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Photograph by Mark Wolfe/Wikimedia Commons
to wait longer and longer to see a total joint specialist; when they can’t get the care they need, most likely it is only then that the reasons for the delay in care will (hopefully) be addressed. We are trying to address this workforce shortage with efforts to recruit more young surgeons into adult reconstructive fellowships. It really is a great specialty. But the problem is multifactorial and I’m skeptical that substantial improvement will occur until there is a real patient access crisis. At present there is no clear recognition on the insurer level that reimbursements for total joint surgery should be increased, particularly for revision procedures. Those of us who do revision surgery, which is especially complex, do it because we are deeply dedicated to our patients.”

On this point, Dr. O’Connor adds, “These are difficult surgeries that involve a lot of time and effort, in addition to a substantial risk of litigation. So if you wanted to be a productive surgeon with less stress and better reimbursement, you would not do revision joints. Again, these are very complex cases; I tell my staff not to put more than one revision surgery a day on my schedule because revisions simply take more out of me...they are more physically and mentally demanding.”

Digging into the political fundamentals, Dr. Iorio states, “The government must come to a conclusion as to how healthcare will be funded; part of this is taking a hard look at how much of our Gross Domestic Product they are willing to commit to it. Total joint replacement is one of Medicare’s most expensive Diagnosis-Related Groups, a cost that will only increase if patients are not treated and then become disabled. Politicians understand that these services are desired by their constituents, but the way government resources are distributed at present means that we don’t have enough money to pay for them. We need a new funding mechanism for healthcare.”

Of the data, Dr. O’Connor says, “Although we saw a slight increase in the planned retirement age it is unlikely that this is enough to offset the access problem. Even though the surgeons (on average) said that they would work one year longer than before the economic downturn, we can’t assume that they will do the same volume of work. In their preretirement year in particular they won’t be doing as much surgery. We also found that there is a reimbursement threshold at which point our members will say ‘Enough. I won’t operate on patients if you’re going to pay me less than XYZ amount.’ At least 50% of the orthopedists in our survey said that they are no longer operating on Medicare patients…the population that is most adversely impacted by declining reimbursements.”

Surgeons aren’t the only ones watching this tumble...hospitals as well are taking note of where exactly the money is leaking out of their institutions. Of the doctor/hospital relationship, Dr. O’Connor says, “As providers and hospitals become even more aligned there may be an increased recognition by hospital administrators regarding the cost of performing revision joints and caring for infected joint patients, particularly those with Medicare. The trend could be that hospital administrators will say, ‘Dr., if one of your surgical patients returns with an infected knee, you can do the revision surgery. But I don’t want you doing these surgeries on patients who had their now infected joints put in at other institutions.’ In fact it would be interesting to ask providers in a future survey, ‘Has your hospital’s...
Bringing the implant manufacturers into the picture, Dr. Iorio advocates for consistency and clarity. “One way to control costs is for hospitals to put a ceiling on the amount that they will pay for implants...perhaps using a system whereby hospitals choose one implant system and manufacturers bid for the contract. The problem in joint replacement is that there are a lot of technologic innovations that require an incremental cost increase. But, we need to figure out what a good implant is, i.e., one that lasts a long time and cuts down on the complication rate. Also problematic for hospitals is that manufacturers aren’t transparent. For example, hospital X in Chicago doesn’t know what hospital Y in a neighboring city is paying for the same implant. Complicating the situation is that if all doctors in a hospital want a different company’s implants then this lessens the institution’s purchasing power.”

Dr. Iorio adds, “We conducted this survey before President Obama’s new healthcare initiatives were signed into law. Once we figure out where all of this is going, then we will have a better sense of how to respond. The fact is that if we extrapolate nationwide from what has been done in Massachusetts—my state—the system will likely go broke.”

And, says Dr. Iorio, the average person—understandably—isn’t shedding any tears over orthopedic surgeons’ situation. “What gives me hope is that joint replacement surgeons delivery quality care day in and day out. Although our patients are our strongest advocates they usually don’t understand the inadequacies of the funding mechanisms...and no one is crying for surgeons. Yet we have to acknowledge that we accumulate—on average—14 years of extensive training before we can begin to work. Once in practice we are working with patients who tend to be heavy, whose problems require a high degree of skill, and—unlike many other subspecialties—must be followed for 15 to 20 years. But change will not come from doctors as we are a small portion of the population. There are about 20,000 orthopedic surgeons in the U.S. doing close to a million joint replacements each year. Only 2,000 of those surgeons perform more than 50 total joint surgeries per year...change will come from the patients.”

Dr. O’Connor: “To help facilitate that change, I have seen some orthopedists in private practice distributing educational handouts on Medicare reimbursement and issues of access. We clearly need to educate the public better than we have. Last year Dr. Neil Sheth surveyed patients in Chicago to understand what they think their surgeon was paid to perform a total joint and then if they felt the Medicare reimbursement level was appropriate. Most patients felt the reimbursement was too low. This paper has been submitted for publication.
My fellow, Dr. Joel Tucker, and I are partnering with Dr. Sheth to perform a similar survey at our institution which will provide a broader base of data. In addition to education, we need both surgeons and patients to become and remain politically engaged. Fortunately, the AAHKS is particularly advocacy oriented: we have the highest donations to the orthopedic political action committee of any specialty group. But this is going to be a long haul—for everyone.”◆
Generic Implants Hit Market

Generic drugs have been on the market for a long time. What about generic orthopedic implants and instruments?

In an April 4 press release sure to cause as much controversy with medical device sales reps as physician owned distributorships, Denver-based Emerge Medical, Inc. announced the "first-ever line of high-quality generic implants and instruments" for the $2 billion orthopedic trauma market. The company saves customers money by cutting out the middle man and selling directly to hospitals and providers.

Products noted on the company's website and manufactured in the U.S., include cannulated screws and guide wires, as well as drill bits. Company CEO and former Synthes sales rep and sales manager John Marotta told OTW that the company focuses on core devices that are easily standardized and have low physician preference. In other words, physicians are not partial to a specific brand of product.

Marotta says the company can save its hospitals customers up to 50% off current costs. "Hospitals are increasingly pressured to cut costs while continuing to deliver quality medical care. Emerge Medical was created to meet this critical need."

The company sells directly to hospital administrators, department heads and surgeons to reduce, what Marotta called, "the add-on expenses typically associated with medical device sales forces."

Company CFO Zach Stassen, said, "High selling, general and administrative costs are built into the price of many medical devices, yet there has been little innovation in many core, basic products for over a decade."

While the company believes it has a good business model with current product offerings, they have no intention of stopping there. Marotta says the company's vision is to apply its generic device platform to, "the larger orthopedic, sports medicine and spine market; and ultimately to the entire $92 billion medical device industry."

The goal, says Marotta, is to allow "hospitals and physicians to deliver premium patient care without having to pay premium prices. This vision is akin to other game changing moments in industry, whether it's the introduction of generic pharmaceuticals or the Michael Dell vision that helped to revolutionize the PC [personal computer] market."

—WE (April 5, 2011)

Trans1’s Clearance, Paper Approvals and Guidance

Trans1 Inc. had two pieces of good news and a little sobering news at the end of March.
First, the company announced the FDA granted 510(k) clearance for its next-generation AxiaLIF 1L+ product line, an instrumentation and implant system for L5-S1 lumbar fusion. The original AxiaLIF 1L system was launched in 2005.

Second, the company announced that two clinical papers highlighting the efficacy and safety of the AxiaLIF spinal fusion procedure have been approved for publication in leading spine peer-reviewed journals.

The company says the first paper reviews efficacy data from a four site, 156 patient study with two-year follow up and demonstrates a 94% fusion rate. This paper has been accepted for publication in SPINE. The second paper is a 9,152 patient retrospective safety study that shows a 1.3% complication rate. This paper has been accepted for publication in the SAS Journal.

Ken Reali, Trans1’s president and CEO said, "The publication of significant clinical data supporting the use of our AxiaLIF approach is critical to our reimbursement strategy. We believe that these papers will be important as we pursue additional payer coverage decisions for our Category 3 CPT code and seek to gain society support for the graduation of the current Category 3 code to a Category 1 code."

Guidance Lowered

There was some sobering news too. Reali announced that the company's expected revenue for the first quarter of 2011 would come in about $1.2 million lower than expected, due to "general spine market conditions and ongoing AxiaLIF physician reimbursement pressure."

According to the DOJ charges, DePuy authorized the payment of about $16.4 million in cash incentives between 1998 and 2006 to publicly employed Greek healthcare providers to induce the purchase of DePuy products including surgical implants. To conceal the payments, DePuy units "falsely recorded the payments in their books and records as 'commissions.'"

According to the SEC’s complaint, "Public doctors and administrators in Greece, Poland, and Romania who ordered or prescribed J&J products were rewarded in a variety of ways, including with cash and inappropriate travel. J&J subsidiaries, employees and agents used slush funds, sham civil contracts with doctors, and off-shore companies in the Isle of Man to carry out the bribery."

A resolution of a related investigation by the United Kingdom Serious Fraud Office is anticipated.
"The message in this and the SEC’s other FCPA cases is plain—any competitive advantage gained through corruption is a mirage," said Robert Khuzami, Director of the SEC’s Division of Enforcement. “J&J chose profit margins over compliance with the law by acquiring a private company for the purpose of paying bribes, and using sham contracts, off-shore companies, and slush funds to cover its tracks.”

Credit for Self Reporting

The government gave J&J credit for voluntarily disclosing some of the violations and conducting a "thorough internal investigation to determine the scope of the bribery and other violations, including proactive investigations in more than a dozen countries by both its internal auditors and outside counsel. J&J’s internal investigation and its ongoing compliance programs were essential in gathering facts regarding the full extent of J&J’s FCPA violations."

As part of the settlement, the company has entered into a Deferred Prosecution Agreement (DPA) with the DOJ and a "Consent to Final Judgment" with the SEC.

Bill Weldon, company chairman and CEO said, “More than four years ago, we went to the government to report improper payments and have taken full responsibility for these actions. We are deeply disappointed by the unacceptable conduct that led to these violations. We have undertaken significant changes since then to improve our compliance efforts, and we are committed to doing everything we can to ensure this does not occur again.”

A former marketing director at DePuy in Europe, Robert Dougall, was sentenced to a year in prison in England last year after admitting to paying bribes in Greece. His sentence was overturned by an appeals court.

Michael Dormer, the former J&J Worldwide Chairman, Medical Devices & Diagnostics, resigned in February 2007, immediately after the company reported the violations to the SEC.

—WE (April 8, 2011)◆

Avoiding the FDA “AI” Letter

Here’s some advice from the FDA if you want your 510(k) application to sail smoothly through the review process:

1. Address appropriate guidance documents
2. Provide an adequate device description
3. Identify the appropriate indications with a predicate device

If you don't do those things, you will receive an "AI" (additional information) letter from the FDA.

The FDA requests additional information when the 510(k) lacks information necessary for the agency to begin, continue, or complete the review and make a determination as to whether the device is, substantially or not substantially, equivalent to a predicate and receive clearance for marketing. Getting an AI letter from the FDA stops the review clock and marks the end of the review process.

Analysis of AI Reasons with 2 or More Requests

Source: FDA
a review cycle. It will slow your process and cost you money.

At a recent AAMI (Association for the Advancement of Medical Instrumentation) meeting, Christy Foreman, the Acting Director—Office of Device Evaluation, reported on an internal reviewed of 134 applications that had at least two AI requests.

Foreman noted the following six reasons for an AI:

• Inadequate performance testing
• Inadequate device description
• Inadequate/missing predicate comparison
• Missing standards form 3654 (when standards were used)
• Inadequate/missing biocompatibility information
• Inadequate/missing instructions for use

Of those reasons, almost 60% of the 134 applications with two AIs were noted for a failure to address guidance documents or recognized standards. Almost 50% were identified for inadequate device descriptions and over 40% were cited for a lack of identifying indications of use where a predicate device was missing.

—WE (April 8, 2011) ~

ReGen Rejects FDA

ReGen Biologics has rejected the FDA’s offer for another hearing to make the case for the Menaflex device, 510(k) cleared by the agency in 2008. The agency has said it intends to rescind that clearance.

The Menaflex Collagen Scaffold is an absorbable mesh implant designed to encourage the re-growth of damaged knee cartilage.

"Enough is enough," said Gerald Bisbee, Jr., Ph.D., the company's chair, president and CEO.

He says safety and effectiveness issues were settled at a November 2008 FDA Advisory Panel meeting. "The only issues that require remediation are the blatantly arbitrary and unfair processes of the FDA, and those aren't on the table in a Part 16 review...enough is enough."

Approved in Europe in 2000 for use in medial, and in 2006, for lateral meniscus injuries, the device has been used in over 3000 European surgeries. “With no safety issues,” added the company statement. “In fact, a recent independent publication from a prestigious European academic center shows that 10 years after surgery, Menaflex patients show superiority [outcomes] to patients receiving the standard of care, partial meniscectomy.”

FDA

After the introduction in Europe, the device underwent one of the most scrutinized and contentious FDA clearance processes in recent memory and was cleared for the U.S. in 2008. But in 2010 the FDA said the 2008 clearance was tainted by the agency's response to outside political pressure. The agency's own review found the company had done nothing wrong during the clearance process, offered no direct evidence of "political" pressure and essentially agreed with the company's side of the story of the appeals process.

The company points out that, according to the internal review there was "...widespread internal disagreement and confusion about the legal standard for 510(k) review within the agency… and there was no legal foundation for requiring a company to demonstrate clinical benefit in a 510(k)."

It still feels a little Kafkaesque. Two FDA ortho panels said the device is safe, there's no evidence the company,
nor anyone, did anything wrong, and no safety concerns now. The agency just says it screwed up internally and will rescind clearance.

“Chill U.S. Investors”

Bisbee says the FDA actions have unsettled the FDA regulatory community.

"It's unbelievable that after more than five years of review of this product—and after being told [by the FDA] to file two separate 510(k) submissions for this device as a surgical mesh—Dr. Shuren [current FDA device head] now says that they were wrong. This arbitrary and unsubstantiated intention is an example of why the investment community is increasingly wary of investing in companies with products requiring FDA approval."

The company says the FDA's decision that device clearances can be reviewed and rescinded..."Will chill U.S. investors' enthusiasm for investing in the development and distribution of new devices."

"After six years of unthinkable bias, mistakes and blunders, we are opting out of the FDA's administrative process and pursuing other legal options for continuing to market Menaflex to U.S. orthopedic surgeons and their patients," said Bisbee.

What those legal options are was not addressed in the company statement.

—WE (March 31, 2011)

New Study Targets PRP for Knee Pain

Will platelet-rich plasma (PRP) relieve knee pain in patients with osteoarthritis? Researchers at Chicago-based Rush University Medical Center intend to find out. For years doctors have used PRP to promote healing after surgery, but results have remained inconclusive. PRP, which doctors have used to treat sports injuries in professional athletes, contains growth factors that promote cell proliferation. The substance is prepared from the patient's own blood.

The present standard of care for knee pain is either corticosteroid injections, which may provide relief for about three months, or synthetic lubricants containing hyaluronic acid, which can last for up to a year.
In the double-blind, randomized, controlled study of PRP, 100 patients will receive either hyaluronic acid or PRP. The PRP is prepared from 10 millimeters of the patient's own blood which is spun in a centrifuge to separate the platelets from the red and white blood cells. The platelets are then injected into the knee joint using ultrasound imaging to guide placement.

The patients receiving PRP will receive three injections over a three week period and will be monitored for two years. Physicians will assess pain and knee function. In addition, a teaspoon-size sample of the synovial fluid will be taken from around the knee joint to test for molecular changes that may indicate a shift in the balance of anabolic factors that increase the buildup of tissue and catabolic factors that break it down. An imbalance in these factors has been implicated in the deterioration of cartilage that leads to osteoarthritis.

"There have been few controlled clinical trials...but data so far suggests that it could be a promising treatment for healing in a variety of tissues," said Dr. Brian Cole, orthopedic surgeon, professor of orthopaedic surgery, head of the Cartilage Restoration Center at Rush and head team physician for the Chicago Bulls. "The therapy will not be a cure for osteoarthritis, but it could help put off the day when a patient will need to get a knee implant," he said. Rush is a not-for-profit academic medical center comprising Rush University Medical Center, Rush University, Rush Oak Park Hospital and Rush Health.

—BY (April 4, 2011)
the orthopedic industry try to digest the stunning news, Wall Street’s analysts are already speculating that the cause of these abrupt changes are tied to the firm’s ongoing Department of Justice investigation.

Wright fell 10% to $15.38 at 9:32 a.m. in Nasdaq Stock Market composite trading, after touching $15.28 for the biggest intraday decline since April, 28, 2009.

Last September 30, Wright Medical joined a long list of orthopedic firms that agreed to settle claims brought by the Department of Justice which accused companies of inducing doctors to use their devices through the mechanism of medical consulting programs. Prosecutors had agreed to drop Wright Medical’s case in 12 months if an independent monitor agreed that Wright has reformed the way the company hires its medical consultants.

The press release and the way this is all being handled is stunning and implies that the monitor had something to do with the abrupt departures of CEO Henley and CTO Bono. Losing, in our view, such veteran and well regarded managers raises questions not only about the departed employees but also about the way this was handled and the people who caused this outcome.

In its press announcement this morning, the company said that the management changes were not related to its operational performance, financial condition or financial reporting. Furthermore, the company reiterated that its first quarter 2011 adjusted earnings per share* (both including and excluding non-cash stock based expense) and revenue, when reported, will be in line with current consensus estimates.

The Board of Directors has formed a committee comprised of Directors David D. Stevens, Robert J. Quillinan, Lawrence W. Hamilton and John L. Miclot to undertake a search for a permanent CEO. Stevens has asked not to be considered for the permanent CEO position but will serve as interim CEO until the selection process is completed. Candidates from both inside and outside the company will be considered.

Said Stevens; “I look forward to leading the company on an interim basis and working with my fellow directors to identify a permanent CEO. Given my experience as Chairman of Wright Medical, and previously as CEO of Accredo Health Group, Inc., I am very familiar with both this company and the industry. I am impressed by the depth and talent of the senior leadership team, and will work closely with them to ensure that our success continues. Wright Medical is committed to maintaining the highest standards of ethical conduct and to complying strictly with the laws and regulations that govern our business practices.”

Stay tuned, for sure.

—RRY (April 5, 2011)◆

Singing Decreases BP in OA Patient

Whether you’re hitting the high notes or the low notes, go ahead and sing before surgery...Researchers from Harvard are reporting that singing reduced the blood pressure of a 76-year-old OA patient who had experienced severe preoperative hypertension prior to total knee replacement. When medications didn’t help with the hypertension, the patient asked the doctors if she could sing. The result: the woman’s blood pressure dropped dramatically when she sang several religious songs.

For those patients who don’t respond to traditional preop treatments, other ways of addressing hypertension need to be utilized. In the news release, lead author Nina Niu, a researcher from Harv...
vard Medical School, states, “Several studies suggest that listening to music can be effective in reducing blood pressure by calming or diverting patients prior to surgery, which lessens stress and anxiety. Our case study expands on medical evidence by showing that producing music or singing also has potential therapeutic effects in the pre-operative setting.”

This case-report, which appears in the April issue of Arthritis Care & Research, discusses the treatment of a 76-year-old woman from the Dominican Republic who had hypertension and a 15-year history of bilateral knee OA. The patient was treated with ACE inhibitors and calcium-channel blockers for high blood pressure and diclofenac, a non-steroidal anti-inflammatory drug (NSAID), for knee pain. She was accepted into Operation Walk Boston, a philanthropic program providing total joint replacement to poor Dominican patients with advanced OA of the hip or knee. The case study authors served as members of her medical team.

At the time of hospital admission the patient’s blood pressure was 160/90 mm Hg, controlled by her normal regimen of nifedipine and lisinopril. Soon, however, the patient’s blood pressure increased to 240/120 mm Hg and persisted, requiring doctors to postpone surgery.

The patient asked doctors if she could sing—something she often did as a stress reliever and sleep aid. The medical team encouraged her ‘raise her voice,’ and after two songs checked her blood pressure which had lowered to 180/90 mm Hg. With continued singing for 20 minutes, the patient’s blood pressure remained lower and persisted for several hours after. Under doctors’ orders, the patient sang periodically through the night which kept her blood pressure at acceptable levels. The following morning, the woman was cleared for knee replacement surgery and had a successful operative experience.

—EH (April 1, 2011) ◆

Blood Test Detects Joint Loosening

The Times of India is reporting on a blood test, devised by four doctors from the Royal Liverpool University, U.K. that can, within 48 hours, detect if an artificial joint is coming loose or not. Speaking to the Times reporter about the test, Professor Simon Peter Frostick, an orthopaedic surgeon specializing in shoulder injuries said, "The test is very much like what we undergo for testing blood sugar level or any other blood tests. By just testing a sample of five milliliters of blood, we can tell whether some part of the transplanted artificial joint is getting loose or not."

The principal investigator is Dr. Margaret Roebuck. She, with her team of four doctors, spent three years and half a million Pounds (about $800,000) analyzing 2,500 patients before they came up with their blood test.

Talking about the economical viability of the test, Frostick said that it is a simple test and would not make a hole in the common man's pocket. "We believe that once the kit is available for commercial use, the cost could be around 10 Pounds (about $16). The technique can be easily adopted."

"As there are more chances of artificial joints becoming loose after, say, 10 years of daily wear, the test would come as a boon and every patient would be able to keep a close eye on the condition of his artificial joints."

Source: Jeremy Grisham and Wikimedia Commons
According to Tripathi “loosening is the major reason for the failure of artificial joints and the joints loosen when the metal and cement come in contact with the bone.”

—BY (April 1, 2011)

CMS ACO Recommendations Issued

The Centers for Medicare and Medicaid Services (CMS) has issued a 429-page draft of how Accountable Care Organizations (ACO’s) will be implemented under the Affordable Care Act on March 31.

The agency also, jointly with the HHS Office of Inspector General, published its proposals for waivers of certain federal laws, including the physician self-referral law, the anti-kickback statute, and specific provisions of the civil monetary penalty law.

The Federal Trade Commission (FTC) and the Department of Justice also jointly issued an Antitrust Policy Statement, and the Internal Revenue Service published its guidance needed for tax-exempt organizations that participate in ACOs.

Advertisement
**Big Is Better**

A quick analysis by Kaiser Healthnews stated that under the proposed rule, Medicare would continue to pay ACO providers seeing at least 5,000 patients on a fee-for-service basis—as it currently does under the traditional Medicare system. But CMS envisions some ACOs caring for 60,000 or more beneficiaries and acknowledged that its rules encourage such larger organizations, which could realize bonuses more easily than would smaller ACOs.

Kaiser noted the rules would give ACOs two routes to participate in a three-year arrangement, starting as early as next January.

Aggressive ACOs could opt for potential bonuses of up to 60% of savings. But they would have to agree to repay Medicare for cost overruns. At most, a badly performing ACO would have to repay the government 10% of what Medicare would have spent on those patients if they weren’t in the ACO.

CMS said this approach was designed for health care systems where doctors and hospitals already operate like ACOs—places such as the Mayo Clinic in Minnesota and Intermountain Healthcare in Salt Lake City.

According to Kaiser, ACOs that are less experienced or more risk adverse could choose an alternative path to avoid any financial risk for the first two years. They would be eligible for smaller bonuses, up to 50% of the savings they achieved for Medicare. Even those ACOs would still face potential penalties in the third year of up to 7.5% of what CMS estimated their patients should have cost.

**Antitrust Issues**

The proposed rules also include provisions to relax antitrust rules that now prohibit many doctors and hospitals from collaborating to the degree required for an ACO. New ACOs that account for fewer than 30% of a local market would be given leeway from prosecution unless they engaged in deliberately anticompetitive behavior. The FTC would evaluate larger proposed ACOs within 90 days to determine if they would violate antitrust laws. Providers in rural areas may get additional exemptions.

You have until June 6 to make comments. The agency will issue a final rule later this year.

To read the proposed rules, click here: [http://ryortho.com/ACO_Recommendations.pdf](http://ryortho.com/ACO_Recommendations.pdf)

—WE (April 5, 2011) ◆

**Disc Replacement Tops Fusion**

What to do about back and neck pain is the problem. When drugs and physical therapy fail to provide relief patients often turn to spinal fusion surgery. Studies by Rick Delamarter, M.D., co-director of the Cedars-Sinai Spine Center, suggest there is a lower cost and more effective remedy for pain than spinal fusion or artificial disc replacement.

Delamarter compared disc replacement surgery with spinal fusion operations by examining 209 patients with damaged cervical spine discs who received either minimally invasive disc replacement or spinal fusion surgery. A separate group of 136 who received an artificial disc two years after the first group were also a part of the study. Four years after surgery, he found that the fusion patients were four times more likely to need additional surgery than did the disc replacement patients. Half of the additional spinal fusion operations were necessary because of new disc complications occurring at adjacent levels to the fusion. Nearly 88% of the disc replacement patients reported high satisfaction with the surgery compared to 76% of fusion patients.

A second study focused on those patients suffering from three-level lower back disc disease. The study compared the difference in the cost of care between disc replacement and fusion. The total...
hospital costs for the disc replacement patients were, on average, 49% lower than it was for fusion patients.

Both studies compared disc replacement surgery with the more common fusion operation to treat degenerative disc disease and deterioration caused by aging, wear and tear. All patients were assessed on their satisfaction with the results of the procedure. The second study focused on 53 patients suffering from three-level, lower back disc disease and looked at cost comparisons for length of hospital stay, resources used, and other factors.

Dr. Delamarter said in his report: "Healthcare expenditures for back pain have exceeded $91 billion annually over the past few years, indicating that an expanded use of artificial disc replacements could help lower this cost."

"Back pain is the fifth leading cause of hospital admission and the third most common reason for surgery," said Delamarter. "Estimates vary and are probably understated, but health care expenditures for back pain top $91 billion a year, not including indirect and societal costs such as time lost from work and worker's compensation. It is crucial that we develop surgical procedures that are cost effective without sacrificing high-quality results." Delamarter is the lead author of the two studies, which were published in the SAS Journal of the International Society for the Advancement of Spine Surgery and the Society for Minimally Invasive Spine Surgery.

—BY (April 4, 2011) ◆

Les Cross joins Alphatec’s Board

Leslie Cross, the nearly 30-year veteran of DJO’s (nee Smith & Nephew) bracing business has agreed to become Alphatec Spine’s tenth director, sixth independent director.

Leslie Cross is one of the legends of orthopedic company management and his decision to join Alphatec’s board of directors is a significant vote in favor of CEO Dirk Kuyper’s vision and management. Les brings solid, practical management experience to an otherwise Wall Street heavy board. You would think with so many Wall Street Masters of the Universe on Alphatec’s board, the stock would perform better.

Welcome, Les.
Leslie Cross earned his medical technology diploma from a technical school—specifically the Sydney Technical College in Sydney, Australia. He later learned the basics of business management at the University of Cape Town in Cape Town, South Africa. Les’ post graduate work, at which he would not only excel but rise to become one of this industry’s best known and most successful leaders, started at the famous and tough American Hospital Supply finishing school.

In 1982, Leslie Cross found a home at London-based Smith & Nephew. Smith & Nephew was at the time a wound care company which had recently acquired the Memphis, Tennessee-based orthopedic company, Richards and had tucked away in a corner was a little bracing division which, in 1982, had just been named DonJoy.

Initially, Smith & Nephew made Les a Managing Director in charge of two different DonJoy divisions. Eight years later Les was asked to take on the job of senior vice president of marketing and business development for the DonJoy bracing and support division of Smith & Nephew.

In 1995, Les was promoted to President of the DonJoy but very quickly rose to the position he would hold until just this year—CEO.

In 1998, Les led the spin off and private equity funding of his company. By March, 1999, Les and the newly christened dj Orthopedics was an independent company based in Vista, California. Sales that year were just $103 million. Earnings were $8 million.

Les took his company public in 2001 selling 7.8 million shares to the public at $17 per share. Total shares outstanding after the offering was 10.8 million for a valuation of about $184 million. Sales that year were $169 million and his operating earnings were $23 million.

Much like Alphatec’s stock today, DJO’s stock price declined after its initial offering and, defying the text book logic of valuation, stayed at industry low levels for, if memory serves, a couple of years. In those days Les and his team didn’t hold quarterly conference calls with analysts. It helped the stock.

DJO’s stock price eventually found its bottom and steadily rising sales and earnings fueled an extended period of ever higher DJO stock prices making it one of the best performing stocks in orthopedics between 2003 and 2007. On July 15, 2007, Les agreed to combine his company with ReAble Therapeutics in a merger worth a spectacular $1.3 billion.

Now, after nearly 30 years building this small bracing and support business into a market leading diversified orthopedic company, Les has decided to retire from day-to-day activities and has chosen Alphatec’s board of directors as his next stop.

In 2010, the last full year of Les’s leadership, DJO Global reported sales of $966 million.

Alphatec’s chairman, Mortimer Berkowitz III said he was “very pleased that Les Cross had agreed to join Alphatec Spine’s board of directors.”

Yup.

—RRY (April 4, 2011)◆
Mobility. So much of who we are is based on this concept of “mobility.” As Harry Chapin sang in his famous song “Taxi,”

“You see, she was gonna be an actress And I was gonna learn to fly She took off to find the footlights And I took off for the sky

Here, she’s acting happy And here, she’s acting happy Inside her handsome home And me, I’m flying in my taxi”

As a medical student Dr. Charles Epps earned money for tuition, meals, and rent by driving a taxi. Years later, having risen to the heights of his profession as an acclaimed Professor of Orthopaedic Surgery at Howard University, Washington, D.C., and having defined what upward mobility is possible for a bright, hard working African American, Dr. Epps was back behind the wheel ferrying his charges to their destination—although this time it is his children and he’s a carpool volunteer.

Living a life of mobility and in a most inspirational way, providing it to children and adults would ultimately define one of the most amazing careers in orthopedics.

While most people would focus on Dr. Epps’ remarkable career of forward motion, he himself points to other events in his life. “My most significant accomplishment has been the recognition by my peers. I was very proud to be elected president of the Washington Orthopedic Society, and I was especially pleased to be the first African American named as president of the American Orthopaedic Association (AOA). In my national and international travels for the AOA I made sure to conduct myself with the utmost propriety so that no one would have concerns about having another African American president going forward.”

Dr. Epps is the founder and chief of the region’s only free, multidisciplinary crippled children’s program for limb-deficient children. Dr. Epps helped parents move through the grieving process and aided them in managing the complex emotions that emerge when you learn your child is disabled. “Working with these families was an extremely gratifying experience. The patients felt different because of limb loss, so of course they needed a kind heart in addition to skilled hands. But the parents suffered as well, and often had significant feelings of guilt to contend with when they saw that their baby was born with only a portion of an arm or a leg, or at worst, with all four limbs missing. They would search their mind for something they might have done or not done during the pregnancy, i.e., ‘I didn’t take my vitamins/eat properly, etc.’ It was heart wrenching, but fortunately, there were many times when we were able to help parents reduce the feelings of responsibility.”

Dr. Epps, who was president of the Association of Children’s Prosthetic-Orthotic Clinics, has personally cared for more than 1,000 limb deficient children. “Forty years ago we had such limited information on how to treat these children…now things have improved substantially and the kids can go on to lead rewarding lives. In most cases, we provided the limbs because many of these families were very poor.”

God Doesn’t Make Mistakes

Guiding families through the process of understanding and accepting a child with limb deformities has been one of
Dr. Epps most challenging experiences. “I had worked with many limb deficient children, and I saw a great need in the community. Often, the first orthopedist who was called when a child was born without a limb had never had experience taking care of such a child or interacting with their families. Pediatricians and hospitals started calling me on these occasions and I began going in to talk with the parents (and in some cases the grandparents). I tried to make this traumatic event somewhat less stressful for them; I would invite them to come to my clinic and meet other children and families in similar situations, something that seemed to provide them with great relief. The Howard residents rotated through our clinic and would sit beside me as I tried to comfort and educate the parents.”

“On one occasion the mother of a family that had a limb deficient child called the social worker and said, ‘I don’t know what to do. My older kids are refusing to go to Sunday school because they don’t understand how God could make their brother have only one arm.’ I told them to tell the kids that God made this baby and he is perfect exactly how he is.”

But, as Dr. Epps realized, to bring mobility to those who were born without a limb it also required governmental attention to their mobility needs. Dr. Epps revved his engines. “Years ago I testified before the D.C. City Council and the U.S. Congress to advocate for the establishment of a rehabilitation hospital in Washington, D.C. At the time, there was no hospital in the area that even had a ward dedicated to rehabilitation, so it wasn’t too difficult to make the case for the new facility. We convinced the powers that be to ‘get on board’ with the National Rehabilitation Hospital, and obtained the necessary certificate and funding to go forward. I stayed on the board for more than 10 years...rehabilitation is a natural part of orthopedics, but that is not always recognized.”

As the first African American oral examiner for the American Board of Orthopaedic Surgery, Dr. Epps found that he enjoyed the process and, of course, managed to alter some things along the way. “Every year I would propose one or two other African Americans for the position of oral examiner. What I enjoyed most was that while in the beginning each examiner brought their own cases, later on things were standardized and thus much fairer. I often ran into residents years later at meetings and I was always pleased that they felt I had treated them fairly.”

Dr. Epps and his chosen profession have come a long, long way over
the past decades. Looking forward and considering the trajectory of orthopedics, Dr. Epps thinks that prejudice, while still in existence, may be sharing space with the reality of ‘the market.’ “While I would hope that African American orthopedists would not be considered unique, I don’t think that will come about anytime soon. Years ago the challenge was for minority trainees to be accorded the same opportunities as their Caucasian peers; at that point in time, ‘white’ schools accepted a token African American or two. Now, the issue is largely one of availability. There are so few residency slots available that things are more competitive than ever.”

Aside from what he says made him such a paragon of mobility, namely, hard work, Dr. Epps says that orthopedists coming up through the ranks should always do something else: keep meticulous records. “You must always be honest and thorough with regard to notes, especially in the increasingly common personal injury cases where some parties are less concerned about facts than they should be. And there are those workers compensation cases where some patients don’t really want to work. You must adhere to the truth…you can’t change the facts or tilt them in any manner. Just call it as you see it.”

Citing an extreme example, Dr. Epps notes, “I once told a patient that I thought she was ready to return to work and she replied, ‘Oh no, doctor, this is a workers compensation case. I am entitled to six weeks of sick leave.’ I said, ‘But your injury only took two weeks to heal. Sorry, but I am writing a letter to your employer.’ I later learned that she was furious with me, and was quite emotionally unstable. At one point she said, ‘You can’t do this to me. I know where you live and I’m going to throw a Molotov cocktail through your window.’ I reported her threats and she was soon arrested. Fortunately, such situations are rare.”

Counterbalancing the stress of these situations is the serene home life Dr. Epps has created with his wife. “I met my wife—a pediatrician—in college and she and I attended medical school together. In our early family years I would spend as much time with our four children as possible, managing to eat breakfast with them nearly every morning and driving carpools. They are now well adjusted adults; three of the kids became physicians and one evolved into a computer engineer. We often gather the entire family—including our four grandchildren—at our home in Florida. I also volunteer with the Washington, D.C. Habitat for Humanity, an extremely rewarding endeavor.”

Dr. Charles Epps…for whom mobility became a calling and a dream come true.◆
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