WEEK IN REVIEW

4 Chinese Increasing Inspections at U.S. Ortho Facilities
   >> In the middle of the U.S. China tariff fight, the Chinese government has decided to shift its regulatory philosophy from “stringent” pre-approval to “rigorous” post-approval and increased scrutiny of U.S. based medical device companies. Should you be worried? Here are the details.

6 Dr. A. Seth Greenwald Sells CCJR®
   >> Seth Greenwald, the founder of Current Concepts in Joint Repair® (CCJR®), has agreed to sell his educational organization—now the largest independent education meeting dedicated solely to joint arthroplasty in the world—to the Hip and the Knee Societies.

10 Meneghini v. Padgett: Posterior Stabilized Knee Designs: Vestigial Organs
   >> Posterior Stabilized or Cruciate Retaining? Have designs progressed to the point where cruciate retaining deserves more support? Meneghini is a strong “yes” while HSS’ Padgett sticks with the post. Who won their case? You be the judge.

BREAKING NEWS

14 FDA Finally Issues Site Change Notification Requirements

14 Anthem Caves in Spine Surgery Lawsuit. Must Pay.

16 Cementless TKA vs Cemented in Morbidly Obese Patients…New Data

17 How to Cut 1 Hospital Day in Revision TKA/THA Cases

19 Elegant New Work From Rutgers Explains Implant Loosening

21 Single-Use Implants and Instruments Cut OR Time 33%

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

**THIS WEEK:** The largest integrated orthopedic suppliers—DePuy Synthes, Zimmer Biomet and Stryker—reported strong earnings and solid sales growth for the final quarter of 2018. While orthopedic sales growth rates remain in the low single digit range, cash flows are strong and the business of supplying orthopedic physicians remains highly stable and predictable. In the current environment, that’s attractive for investors. Stable. High cash flow. And rising demand for products for as long as anyone can forecast.

<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>4</td>
<td>Zimmer Biomet</td>
<td>20.80%</td>
<td>14.00%</td>
<td>Mike Matson, top healthcare analyst at Needham, said it best. Zimmer's supply issues are done and the company is shifting to offense for 2019.</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>Stryker</td>
<td>22.01</td>
<td>14.76</td>
<td>Sales rose about 8% in the final quarter of 2018. The big news, Stryker sold 54 MAKO robot assist devices to hospitals in Q4.</td>
</tr>
<tr>
<td>3</td>
<td>1</td>
<td>Integra LifeSciences</td>
<td>16.97</td>
<td>8.39</td>
<td>IART stock price is rising nicely. Investors expect sales will increase about 8% in 2019 and, with Codman doing well, that should be achievable.</td>
</tr>
<tr>
<td>4</td>
<td>3</td>
<td>ConMed</td>
<td>8.97</td>
<td>10.09</td>
<td>ConMed's sales rose 8% in 2018. At the start of the year, management guided 4-5% sales growth for 2018. Analysts are now raising all their estimates for 2019.</td>
</tr>
<tr>
<td>5</td>
<td>7</td>
<td>Johnson &amp; Johnson</td>
<td>24.44</td>
<td>5.05</td>
<td>In 2018, DePuy Synthes reported flattish knee implant sales (+0.2%), 2.0% hip implant sales growth, a decline in spine sales and a 2.2% rise in trauma sales.</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>Orthofix</td>
<td>7.92</td>
<td>0.78</td>
<td>Just acquired one of its more successful distributors—Options Medical. For 2019, most analysts expect that sales will rise about 6%.</td>
</tr>
<tr>
<td>7</td>
<td>5</td>
<td>Medtronic</td>
<td>22.84</td>
<td>0.44</td>
<td>Medtronic Spine's sales numbers for Q4 in a couple weeks. Most analysts expect a solid sales growth and new details on Mazor's next gen robotic assist device.</td>
</tr>
<tr>
<td>8</td>
<td>8</td>
<td>NuVasive</td>
<td>10.14</td>
<td>1.36</td>
<td>New CEO Berry is resetting expectations. That means lowering sales growth rate guidance for 2019. Wall Street likes Berry and is giving him a honeymoon to see what he can do.</td>
</tr>
<tr>
<td>9</td>
<td>9</td>
<td>Smith &amp; Nephew</td>
<td>17.31</td>
<td>3.68</td>
<td>SNN is expected to report its Q4 results the first week in February. Most analysts are expecting 1-2% recon sales growth and 3-4% sports medicine sales growth.</td>
</tr>
<tr>
<td>10</td>
<td>10</td>
<td>Flexion Therapeutics</td>
<td>(1267.00)</td>
<td>9.95</td>
<td>Flexion is experiencing a period of explosive sales growth. Sales for 2018 were under $1 million. Sales for 2019 are expected to clear $20 million by a consensus of Wall Street analysts.</td>
</tr>
</tbody>
</table>
## Robin Young's Orthopedic Universe

### 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>MiMedx Group</td>
<td>MDXG</td>
<td>$2.67</td>
<td>$296</td>
<td>45.11%</td>
</tr>
<tr>
<td>Lattice Biologics</td>
<td>LBL.V</td>
<td>$0.02</td>
<td>$1</td>
<td>38.87%</td>
</tr>
<tr>
<td>Nevro Corp</td>
<td>NVRO</td>
<td>$48.01</td>
<td>$1,448</td>
<td>31.35%</td>
</tr>
<tr>
<td>RTI Surgical</td>
<td>RTIX</td>
<td>$4.37</td>
<td>$277</td>
<td>18.11%</td>
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<tr>
<td>Stryker</td>
<td>SYK</td>
<td>$177.31</td>
<td>$66,347</td>
<td>14.76%</td>
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<tr>
<td>Zimmer Biomet</td>
<td>ZBH</td>
<td>$116.60</td>
<td>$23,784</td>
<td>14.00%</td>
</tr>
<tr>
<td>SINTX Technologies</td>
<td>SINT</td>
<td>$0.22</td>
<td>$5</td>
<td>13.47%</td>
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<tr>
<td>Globus Medical</td>
<td>GMED</td>
<td>$43.87</td>
<td>$4,319</td>
<td>10.75%</td>
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<tr>
<td>ConMed</td>
<td>CNMD</td>
<td>$69.81</td>
<td>$1,964</td>
<td>10.09%</td>
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<tr>
<td>Flexion Therapeutics</td>
<td>FLXN</td>
<td>$13.70</td>
<td>$519</td>
<td>9.95%</td>
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### WORST PERFORMERS LAST 30 DAYS

<table>
<thead>
<tr>
<th>COMPANY</th>
<th>SYMBOL</th>
<th>PRICE</th>
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<tbody>
<tr>
<td>Alphatec Holdings</td>
<td>ATEC</td>
<td>$1.30</td>
<td>$56</td>
<td>-41.70%</td>
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<tr>
<td>AxoGen</td>
<td>AXGN</td>
<td>$16.36</td>
<td>$633</td>
<td>-20.70%</td>
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<tr>
<td>SeaSpine Hldgs Corp</td>
<td>SPNE</td>
<td>$15.33</td>
<td>$284</td>
<td>-12.65%</td>
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<tr>
<td>Aurora Spine</td>
<td>ASG.V</td>
<td>$0.24</td>
<td>$10</td>
<td>-10.21%</td>
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<tr>
<td>Pacira</td>
<td>PCRX</td>
<td>$39.26</td>
<td>$1,614</td>
<td>-6.05%</td>
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<tr>
<td>Xtant Medical Hldgs</td>
<td>XTNT</td>
<td>$2.25</td>
<td>$30</td>
<td>0.00%</td>
</tr>
<tr>
<td>Medtronic</td>
<td>MDT</td>
<td>$88.31</td>
<td>$118,604</td>
<td>0.44%</td>
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<td>Dynatronics Corp</td>
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<td>$2.77</td>
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<td>-38.87%</td>
</tr>
<tr>
<td>NuVasive</td>
<td>NUVA</td>
<td>$49.13</td>
<td>$2,526</td>
<td>1.36%</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>MDXG</td>
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<td>Johnson &amp; Johnson</td>
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<tr>
<td>Smith &amp; Nephew</td>
<td>SNN</td>
<td>$37.74</td>
<td>$16,527</td>
<td>21.55</td>
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<tr>
<td>Zimmer Biomet</td>
<td>ZBH</td>
<td>$116.60</td>
<td>$23,784</td>
<td>21.96</td>
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<td>Medtronic</td>
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### HIGHEST PRICE / EARNINGS RATIO (TTM)

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<th>P/E</th>
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<td>CryoLife</td>
<td>CRY</td>
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<td>$1,030</td>
<td>150.92</td>
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<tr>
<td>MicroPort Scientific</td>
<td>853</td>
<td>$0.98</td>
<td>$1,566</td>
<td>83.20</td>
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<tr>
<td>Orthofix</td>
<td>OFIX</td>
<td>$53.97</td>
<td>$1,021</td>
<td>69.44</td>
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<tr>
<td>RTI Surgical</td>
<td>RTIX</td>
<td>$4.37</td>
<td>$277</td>
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### LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

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<th>SYMBOL</th>
<th>PRICE</th>
<th>MKT CAP</th>
<th>PEG</th>
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<td>3.72</td>
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### LOWEST PRICE TO SALES RATIO (TTM)

<table>
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<th>MKT CAP</th>
<th>PSR</th>
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<td>DYNT</td>
<td>$2.77</td>
<td>$23</td>
<td>0.35</td>
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<tr>
<td>Xtant Medical Hldgs</td>
<td>XTNT</td>
<td>$2.25</td>
<td>$30</td>
<td>0.36</td>
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<tr>
<td>SINTX Technologies</td>
<td>SINT</td>
<td>$0.22</td>
<td>$5</td>
<td>0.42</td>
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<td>0.55</td>
</tr>
<tr>
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<td>LBL.V</td>
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<td>$1</td>
<td>0.96</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
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<th>SYMBOL</th>
<th>PRICE</th>
<th>MKT CAP</th>
<th>PSR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion Therapeutics</td>
<td>FLXN</td>
<td>$13.70</td>
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<td>1460.95</td>
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<td>5.63</td>
</tr>
<tr>
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<td>CRY</td>
<td>$27.86</td>
<td>$1,030</td>
<td>5.43</td>
</tr>
</tbody>
</table>

**PSR**: Aggregate current market capitalization divided by aggregate sales and the calculation excluded the companies for which sales figures are not available.
**Note**: Amedica Corporation name has changed to SINTX Technologies, Inc.
Chinese Increasing Inspections at U.S. Ortho Facilities

BY WALTER EISNER

Get ready for more frequent and rigorous Chinese inspections at your manufacturing facility in Warsaw, Indiana, Memphis, Tennessee, or wherever orthopedic devices are made for distribution in China.

The Chinese government has been inspecting overseas drug companies since 2011 and device companies since 2015. Now, in the middle of a tariff fight, the government is shifting its regulatory philosophy from "stringent" pre-approval supervision to "rigorous" post-approval enforcement and is signaling "increased scrutiny" of foreign orthopedic companies.

That's the warning from Ropes & Gray Attorney Katherine Wang.

New Chinese Inspection Regulations

Wang, based in Shanghai, wrote on January 18, 2019, that the National Medical Products Administration (NMPA) just released the Regulations for Drug and Device Overseas Inspection (regulations). The regulations set out a working procedure for the Chinese government to use at foreign facilities to verify whether foreign drug and device companies' research and development (R&D) and manufacturing activities adhere to Chinese statutory requirements and standards.

"In recent years," wrote Wang, "the NMPA began to regulate the entire life cycle of imported drug and device products." As of December 2018, it had inspected 131 drug products produced in 25 countries. So far, it has inspected 90 device products produced in 13 countries. "Experiences derived from past inspections enabled the NMPA to formalize a set of working procedures in the regulations."

The regulations, she says, echo the NMPA's risk-based regulatory approach. The selection of companies inspected largely depends on the company product's overall risk level. "The NMPA generally considers red flags such as concerns expressed by the Chinese Center for Drug Evaluation (CDE) or Center for Medical Device Evaluation (CMDE) or foreign regulators, past violations, adverse events and quality complaints. The NMPA may also conduct random checks on foreign manufacturers."
Inspection Scope

According to Wang, the government’s inspections look to verify authenticity, reliability and compliance of R&D and manufacturing activities. "The NMPA usually focuses on (i) consistency of actual manufacturing process with the processes registered with the NMPA, and (ii) China GMP compliance."

During on-site inspections, she notes that foreign manufacturers must give the government full access to all relevant premises and documents, including real-time manufacturing processes of the product in question. She adds that the government may also extend its inspections to R&D partners and third-party vendors, such as suppliers of active pharmaceutical ingredients (API), excipients or packaging materials. "Foreign manufacturers should coordinate with their partners and vendors to enable these extended inspections. Any foreign manufacturers that do not cooperate with the inspection team will receive a failure notice from the NMPA."

Inspection Results and Penalties

Wang says the government’s inspection results include (i) “pass,” (ii) “corrective action,” and (iii) “fail.” Penalties include corrective actions, warning letters, suspension of import and sales, product recall and rejection of product license renewal.

"In practice," she writes, "most manufacturers have been required to take corrective actions in order to close deficiencies. For severe deficiencies, the NMPA would order manufacturers to suspend importation and sales of their products in China. Since the end of 2018, the NMPA has banned importation of 19 drug products and two devices that were affiliated with severe deficiencies."

Wang adds that while domestic Chinese drug and device manufacturers have been frequently inspected by the government, foreign manufacturers experienced a "much lower" frequency of inspections. But the announcement of the new regulations signals the government's desire to treat foreign and domestic companies equally.

She advises drug and device companies to carefully study the statutory requirements and standards, perform internal audits on the relevant facilities, and identify and close potential gaps as soon as possible to mitigate enforcement risks.

You can reach Ms. Wang at Katherine.Wang@ropesgray.com — WE
Dr. A. Seth Greenwald Sells CCJR®

BY ROBIN YOUNG

D
r. A. Seth Greenwald, founder of the Current Concepts in Joint Replacement® (CCJR®) meetings, has agreed to sell his educational asset—now the largest independent education meeting dedicated solely to joint arthroplasty in the world—to The Hip Society and The Knee Society, in partnership.

The Hip Society, which started in 1968 to advance the knowledge and treatment of hip disorders to improve the lives of patients, will co-own CCJR with The Knee Society, which was organized to advance the care of patients with knee disorders through leadership in education and research.

Notably, eight members of the Knee Society’s board and seven members of the Hip Society’s board as well as numerous Society members are contemporary faculty members for the CCJR meetings.

This combination has a sense of inevitability.

“We’re very excited” said Douglas E. Padgett, M.D., president of The Hip Society. “The significance of this milestone in the history of both organizations cannot be overestimated. We are embarking on a new chapter in pursuing our mission of leadership in arthroplasty education.”

Dr. Padgett has been a CCJR faculty member for more than a decade.

Robert Barrack, M.D., president of The Knee Society, who’s been a CCJR faculty member for almost 30 years, chuckled when we asked him about this deal.

“I remember when Seth first asked me to be a faculty member. He called me up and we talked for three hours about the meeting agenda. I felt as though Seth and I were creating the CCJR agenda. When I arrived at the meeting, however, I found that he’d spent three hours with each of the other 20 faculty members and they all thought that they had created the program.”

Dr. Greenwald agrees. “I’m relentless on the telephone and by email. My interactions with the faculty do create the program, foster my orthopaedic education and the growth of the meetings reflects their ongoing commitment to orthopaedic education.”
As does CCJR’s reputation. Today, getting Seth's phone call, lending your hand to the agenda and being asked to serve as a member of the CCJR faculty is an honor. No accident that so many of the board members of these top societies are also CCJR faculty.

As Dr. Barrack told OTW, “CCJR's legacy is the gold standard in arthroplasty education, nationally and internationally.”

Furthermore, said Dr. Barrack, “Merged with The Knee Society, and its partner, The Hip Society, creates an unprecedented opportunity for us to collaborate and to carry that legacy successfully well into the future.”

Greenwald’s two annual CCJR meetings (Spring and Winter, Las Vegas/Cleveland and Orlando) are literally treasured by the global community of orthopedic physicians, nurses and suppliers for their independence, quality of lectures, debates and ability to remain clinically relevant for 36 years.

Here’s how a surgeon from Chile, who’d paid $850, plus airfare, hotel and other expense to attend, described CCJR to OTW:

“This is the most up-to-date meeting in the world for surgeons. Everyone on the podium is an expert. This is different from AAOS [American Academy of Orthopaedic Surgeons] where the speaker’s level of expertise is more uneven. Seth’s meeting is free of commercial bias. At other meetings, market forces cause devices to be introduced to surgeons without critical judgment. At this meeting, experts debate and we can make up our minds.”

A Typical CCJR

Sitting in a CCJR meeting is like learning from a curriculum designed by an educator. Not a surgeon. Not a committee. Not a manufacturer.

That’s because CCJR is the singular vision of Oxford University and M.I.T educated, bushy-haired, crinkly-eyed A. Seth Greenwald, D.Phil.(Oxon).

Greenwald starts every meeting by calling his 1,000 – 1,500-member class to order. On time. In 36 years, he’s never been late.

CCJR typically opens with three debates. Point. Counterpoint. One faculty member affirms one side of a current issue. Another takes the other side. Full contact. “This is going to be like taking candy from a baby.” “Are you kidding me? Get real!”

That is only the first step in Dr. Greenwald's master plan. Step two is a literature critique and review or as Seth puts it, “What do the outcomes tell us?”
A panel of his faculty members dissect the latest studies. “This data is at odds with my clinical experience.” “Solid study design, sample size is bit small.” “While the numbers may not be on target, the conclusion mirrors my own outcomes.”

Step three is live surgery. Not just any live surgery. At one memorable CCJR, Russell Warren, M.D., from the Hospital for Special Surgery performed a reverse shoulder reconstruction live, in full color with Evan Flatow, M.D., providing colorful commentary and channeling questions from the audience for Dr. Warren while he was operating.

That was as much performance art as surgery.

Thirty-six years of CCJR have educated, we estimate, 15,000-20,000 orthopedic surgeons, nurses, and, yes, company executives, engineers and sales people as well as regulatory agency personnel from all over the world and—helped the careers of more than a few faculty members.

A Little History

Turn the clock back to 1967 when a young M.I.T-educated aeronautical engineer from New York and his young wife (expecting their first child) have just arrived in the United Kingdom. Seth Greenwald had been accepted at Oxford University to study the effects of vibration on nuclear power plant cooling towers and, in the process, read for a Doctorate from one of the most prestigious educational institutions in the history of man.

But, waiting for engineer Greenwald was a note from his would be mentor saying, in effect, “sorry old chum, but I’m off on my sabbatical and you’ll have to fend for yourself.” Stranded and abandoned Seth walked into a pub, The King’s Arms, to mull his future with the assistance of a pint of best bitter. This is Oxford, England, of course, and the denizens of pubs are not exactly like those in, say, Oxford, Mississippi.

Joining Seth that very day, at the specific hour and at that exact pub were two other gentlemen with their own set of problems. Mr. John Goodfellow (orthopedic surgeon) and Dr. Peter Bullough (pathologist) were wallowing in the deep end of a conceptual question: “How does weight bearing across articulating human hip joint surfaces contribute to cartilage degeneration resulting in arthritis?”

A pint or so later and young Mr. Greenwald found himself signing up to work on a doctoral thesis in orthopedic and engineering sciences—the first received at Oxford University in this newly emerging cross discipline.
Starting CCJR

We asked Dr. Greenwald how he started CCJR. Here’s his story.

“After I returned to the United States, I was, as with any scientist, dependent on the federal government to help support my research activities. My only funding came from either NIH [National Institutes of Health] or the Department of Defense. By the early 1980s, I had three grants going for me. One from the Department of Defense and two from NIH.”

“Then one was deferred for six months because they ran out of money. I went to my institution and asked if they’d carry me and they said ‘no.’ They didn’t mind paying my salary, but not my lab assistants. I had to let two people go.”

“I said to myself that’s the last time I’m ever going to be dependent on anybody to facilitate my ongoing research interests.”

“I love to teach. So, I said to myself, why can’t I put an educational meeting on? I put my first CCJR on in 1982 or ’83 at the Americana Hotel in Miami Beach. Looking back, I realize it was a shot in the dark.”

“Twenty-eight people showed up—including faculty.”

“It wasn’t exactly a success. I tried a second time and, I believe, 30 people came. I was about to quit when somebody said to me, ‘You know Seth, they have a new theme park in Orlando, and you might want to go up there.’ The theme park was Disney World. If a change to Orlando didn’t work, I was going to give up—250 people came.”

“After that the meeting just began to grow.”

Today, CCJR meetings host 1,500-2,000 attendees annually from, literally, all over the world.

There are two every year in the United States. One in the Spring in Las Vegas/Cleveland. The other in Winter in Orlando. International meeting venues inclusive of Greece, China and Brazil have added to the recognition of the CCJR brand.

CCJR’s DNA

“Over the years CCJR’s program has reflected innovations in orthopedics. We began many years ago teaching cemented hips and then we went to cementless hips. We’ve gone from cemented knees to, now, cementless knees are on the rise. We’ve moved through dozens of different surgical approaches, innovative instrumentation inclusive of today’s emerging interest in robotics.”

“As physicians become more familiar and more sophisticated about the nuances of what it takes to drop the knife and minimally assault the soft tissues, orthopedic surgery outcomes consistently improve.”

“A CCJR meeting comes down to three ingredients. 1) You have to have an appreciation of orthopedics as an emerging discipline and how it is always changing. You have to be up on that. 2) You also have to figure out how you can get people to sit in a room from 7:30 in the morning to 6:00 at night and come back for 2-1/2 days. You have to have a diverse program. Presentations, debates, literature reviews, problem cases where you’re trying to stump the experts, live surgeries and video surgical techniques and 3) The sine qua non of each successful CCJR meeting is the staff around me that for over 30 years has continually contributed to optimizing the meeting logistics. They have bought into it, in much the same way as the faculty, recognizing that CCJR’s continued success rests, in large measure, on all of their shoulders.”

What’s Next?

The terms of the sale were not disclosed, but we do know one thing.

The most important condition of the sale was that Greenwald’s reputation for being the “Switzerland” of orthopedics—unbiased and unbought—would remain the foundation of the meeting.

Greenwald is not retiring. He will continue to play his customary role of rounding up the faculty and with their help crafting each meeting’s agenda.

“I’m remembering Robert Frost, a great American poet, and I’m dating myself, but back in the 1960s, shortly before he died, I had a chance to hear him speak. He recounted his life as an American poet laureate. Then he read one of his most famous poems called The Road Not Taken.”

“It really stuck in my gut. Life is like that. You’re in the woods, you come to a bifurcation, crossroads in the road, and they are pathways. Which one are you taking? Go left? Go right? You can’t really see beyond the trees. Sometimes you just go and take a chance.”

Early in his career, Seth reached a bifurcation on his road and has paraded on it for more than four decades.

No doubt spending dozens of hours on the phone with each faculty member, he and they put together what is essentially the succession plan for CCJR. The faculty, who understand the unique and monumental value of the educational experience he has created, will make sure it will always be Seth’s meeting.
Meneghini v. Padgett: Posterior Stabilized Knee Designs: Vestigial Organs

BY OTW STAFF

This week’s Orthopaedic Crossfire® debate was part of the 34th Annual Current Concepts in Joint Replacement® (CCJR®), Winter meeting, which took place in Orlando. This week’s topic is “Posterior Stabilized Knee Designs: Vestigial Organs.” For is R. Michael Meneghini, M.D., Indiana University School of Medicine, Indianapolis, Indiana. Opposing is Douglas E. Padgett, M.D., Hospital for Special Surgery, New York, New York. Daniel J. Berry, M.D., Mayo Clinic, Rochester, Minnesota is serving as the moderator.

Moderator Berry: Maybe surprisingly or shocking, “Posterior Stabilized Knee Designs: Vestigial Organs” is an interesting topic because 60% of the knees in the United States are now posterior stabilized [PS] knees. Speaking in the affirmative with a bit of an uphill battle is Michael Meneghini.

Dr. Meneghini: Yeah, an uphill battle. More importantly an uphill battle because moderator Berry taught me years ago during my fellowship to use a posterior stabilized design. Awkward? We’ll see.

I truly admire and respect Dr. Padgett, so it's really going to hurt me to crush him in this debate. Well, not that much.

Twenty years ago, a younger looking Tom Thornhill and a very distinguished Robert Booth debated cruciate retaining versus posterior stabilized tibial inserts. Why are we bringing it back 20 years later? Why did even it fade away?

I would argue that total knee replacement has evolved. Twenty years ago, there was no clear advantage of cruciate retaining or posterior stabilized designs. The pros and cons were largely theoretical. The focus was on survivorship, not on patient outcomes. The metrics that we used back then were not sensitive enough to pick up small differences between implant designs.

I would argue that newer tibial inserts have enhanced sagittal conformity with anterior lipped designs to substitute for the posterior cruciate ligament, if it’s not competent. The cam-post mechanism is now obsolete.

So vestigial organ, appropriately named, what is that actually? The definition is “a structure in an organism that has lost all or most of its original function in the course of evolution.”

I'm going to use two arguments. An intuitive argument and then a scientific and data-driven argument.

The intuitive one starts something like this. So, the total knee, all of our body, is more fluid. The four-bar linkage, the total knee moves in very fluid, smooth mechanisms. So, it doesn't really seem intuitive that you would replace that with something like a cam and a post.

I would argue that nothing in the human body really wants to slam into a post repetitively, over and over again as you walk or bend. That can't be good either externally or internally in the long-term. The post-cam mechanism is not benign. You can have post wear and impingement. You can have fatigue fractures; patella clunk, which albeit has improved over time. And then just removing the extra step…removing the bone for the box prep…you can have additional bone loss at revision and a potential for condyle fracture, which has also been seen in PS designs.

Let's look at the science.

In a recently published study by my senior partner (Biyani, et al., Surg Technol Int 2017) who did PCL [posterior cruciate ligament] resection in two different knees. He took away the cruciate ligament and replaced it with either an
anterior lipped or a PS tibial insert. No functional differences reported at one year.

Brian Parsley and co-authors reported the same thing years ago using an ultra-congruent bearing versus posterior stabilized (J Arthroplasty 2006).

David Scott, et al. presented at AAHKS [American Association of Hip and Knee Surgeons] and subsequently published in the Journal of Arthroplasty, a prospective, randomized study of approximately 50 knees in each group, anterior lipped total knee versus PS total knee. The PCL was resected in all cases. There was no difference in functional outcomes at two years.

An elegant Mayo Clinic study of 8,000 total knees (Abdel, et al., JBJS-Am 2011). Fifteen years survivorship; 90% for cruciate retaining; 77% for posterior stabilized; and the risk of revision was lower in the cruciate retaining knees.

Finally, as we continue to evolve total knee designs, we bring technology into the picture. One of the big advances will be highly cross-linked polyethylene. It minimizes wear. But its Achilles heel is the fatigue properties. So, you cannot use a post in those designs. Long-term—you’ll see issues.

The emergence of anterior lipped cruciate retaining inserts obviates the need for a posterior stabilized total knee replacement with a cam and a post.

Surgical technique remains critical because the knee must be balanced in flexion whether you use a cruciate retaining or posterior stabilized design.

There is currently no scientific evidence to support a cam and post mechanism to replace a posterior cruciate ligament in total knee arthroplasty.

Dr. Padgett: Vestigial, according to Webster, is “an organ or part of the body that becomes functionless, such as your recta pilae muscles, male nipples, tonsils.” Is the post-cam vestigial? This is the debate. I respect Michael and we are friends. But Michael on this—you are wrong.

Meneghini says, “cruciate retaining works.” Padgett says, “posterior stabilized post not only works, it predictably works.”

Mike let’s agree on this. The best knee is the natural knee. It’s the number one knee. It’s the bomb, right? No question about that. And the best gait data, is the
bi-cruciate retaining gait. This goes back to Cloutier in the 80s. The problems with the bi-cruciate knees—they are technically difficult and while the gait data supports its more normalcy, clinical results demonstrate no advantage.

Modern day total knee. What’s the first step? We reset the ACL. And what happens with that? The kinematic data shows an increase in the degree of anterior translation in the ACL-deficient knee. Which, by the way, is what the cruciate retaining knee is, right?

But we want to drive contact posterior. How do we do this? Articular geometry, reliance on the PCL, or perhaps a post/cam mechanism.

So, what about that PCL? In most cases, in my experience, it’s degenerative, and it’s the Goldilocks effect. It’s too loose. It’s too tight. Ah, yes, it’s just right. Despite this though, let’s save the PCL. Michael has a bumper sticker on his car that says that.

Let’s assess TKR kinematics. Fluoroscopic and intraoperative sensor studies. Fluoroscopically it’s a loaded environment, reproducible by following the contact point through motion and the use of assessment to determine the impact of design variables on rollback.

In one prospective, randomized study—cruciate retaining versus posterior stabilized—at 5 years, taken through range of motion (Victor, et al., JBJS-Br 2005). The results showed greater rollback with the posterior stabilized. Greater amount of posterior translation. Forward displacement in the cruciate retaining knee. However, I will admit the clinical outcomes were similar.

What about more novel ways to assess this—intraoperative sensing? Michael, you’re familiar with this…right? I think you’ve actually written about this. Three pieces of work (J Arthroplasty 2017 and 2016).

Summary of Michael’s work … Early phenomena of lateral rollback equals better clinical outcomes in the cruciate retaining anterior lipped design. Getting a tighter grouping of the differences in the pressures on the medial and lateral sides yielded better UCLA scores. I think that’s important.

My problem with the cruciate retaining—with or without an anterior lip—
is that the kinematics are unpredictable and you’ve got the risk for later dysfunction. Tearing. Stretching out.

What do you get with a posterior stabilized knee? You get a post-cam mechanism that’s durable. A post-cam mechanism that’s predictable. And a post-cam mechanism that’s reliable.

We started on the subject of vestigial structures. It is my suggestion, ladies and gentlemen, that the PCL in the total knee is the vestigial structure. That, in fact, the post lives on…long live the post.

Moderator Berry: Alright, gentlemen. Thank you both. You’ve made your points quite well. So, Mike people gradually have, not altogether, moved away from them to a PS design. Why? My guess is that it’s probably for two of the reasons Doug mentioned. One, is the PCL is kind of tough to balance and it’s easy to get a little too loose. There is unpredictability to that process. And then fluoroscopic data showed unpredictable kinematics once the PCL is gone. Can you address those two? Is the world different now? Or have you just decided it doesn’t matter?

Dr. Meneghini: To your first point, I think that the anterior lip gives those surgeons who want to try and retain the cruciate ligament a factor of safety. There is a factor of safety built in with modern designs that can help people transcend that. We’ll see if that maintains…if the world continues to be 60% PS, which it may do for the foreseeable future.

The second comment on the kinematic data…and its great fluoroscopic kinematic data…and that there is no correlation with that data and outcomes.

We’ve talked about anterior paradoxical translation and femoral rollback for 30 years. Great work. But we have yet to correlate with outcomes. And our patients have changed. Our patients now come into our office with high-end activity levels.

Moderator Berry: I think you make a really good point.

Doug let’s look at the downside of the PS knee. Virtually every big, big, big registry study shows a slight—1 or 2% at 5-10 years—advantage of cruciate retaining versus posterior stabilized knees in terms of survivorship. Do you think a cruciate retaining knee, just because it’s a little less constrained, has a slight survivorship advantage or not? And if so, does it matter?

Dr. Padgett: I think that your points are appropriate, Dan, and it’s obviously hard to tease that out of the data. It doesn’t make a lot of sense to me that the survivorship would be matched for the degree of deformity and complexity of the patients. Quite frankly, it should be different for the two groups. Institutional data, larger registries certainly support that concept. Unclear exactly what the etiology is behind that.

Moderator Berry: Fair enough. Is there a functional difference or advantage to the type of implant that you’re advocating compared to the one your opponent is advocating? I’ll start with Michael and then we’ll go back to Doug.

Dr. Meneghini: My argument is that there is absolutely no difference. With our current metrics and the data we have to date they are equivalent. There is data that if you resect the PCL or recess the PCL in cruciate retaining knees you get better motion. But they may also have less stability.

Dr. Padgett: I’ll tell you the one functional advantage of a posterior stabilized knee is that you’re not re-operating on posterior stabilized knees because of flexion instabilities. Mike, I think you’d agree with that.

Dr. Meneghini: Doug, I know that you live in Manhattan and seeing all those skyscrapers and the posts and all those things it makes sense. But those of us in the Midwest, that makes no intuitive senses to us. You guys walk into buildings all the time. We don’t want to do that. We like smooth transitions. I would argue that that mechanical device is showing up in the registries as less durable over 10-20 years.

Moderator Berry: Doug, so let’s go back to the post for just a quick second. The post does seem like a primitive way of getting rollback, I have to admit, even though I am a posterior stabilized user. Is there anything on the horizon that’s going to move us beyond the post but still get the kind of predictable kinematics that a PS knees gives us?

Dr. Padgett: I think unless we get over the first step of the total knee replacement, which we do right now, which is quite frankly resection of the ACL, and basically having a cruciate deficient knee, then what we have to use is what’s in our armamentarium.

Moderator Berry: Gentlemen, thank you very much.

Please visit www.CCJR.com to register for the 2019 CCJR Spring Meeting, May 8 - 11 in Cleveland, Ohio.
**LEGAL**

**FDA Finally Issues Site Change Notification Requirements**

When the FDA approves or clears a device, the FDA blessing is specific to a manufacturing site.

What constitutes a manufacturing site change and when should you submit a premarket approval application (PMA) supplement for a site change? What documentation should you submit in a site change supplement?

Three years ago, the agency issued a draft guidance to help industry figure out the answers to those question. On December 14, 2018, the agency finally issued a 19-page final guidance on the subject.

The final guidance deviates from the draft in that it includes a few new clarifications around whether a change to a manufacturing site is likely to require a PMA supplement or is eligible for a 30-day notice. Certain policies were added to the draft section on whether a preapproval inspection may be needed.

“An applicant should submit a 180-day PMA supplement for using a different site...that affects the device’s safety or effectiveness. Manufacturing process changes that are not directly associated with the facility move should be submitted separately [via a 30-day notice or a PMA annual report] and are not considered part of the manufacturing site change supplement,” states the guidance.

The final guidance added a criterion under the approach used by FDA’s Center for Devices and Radiological Health (CDRH) and its Center for Biologics Evaluation and Research (CBER) to determine whether to conduct an inspection of a new manufacturing site associated with a site change supplement to evaluate implementation of quality system requirements under 21 CFR Part 820.

The agency said the guidance “should help firms manage the timeframes associated with implementing the changes in the manufacturing site and any processes, methods, procedures, qualifications and validations.”

The guidance only applies to a manufacturer of a device with an approved PMA, a product development protocol, or a humanitarian device exemption (HDE). The guidance does not address manufacturing site changes for devices cleared under premarket notification (510(k)) submissions, granted premarket authorization through the De Novo pathway, or approved and distributed as part of an investigational device exemption (IDE).

To read the entire guidance, [click here](#).

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**Anthem Caves in Spine Surgery Lawsuit. Must Pay.**

Between August 2013 and August 2016 Anthem, Inc., one of the largest medical insurers in the United States, categorically DENIED all requests to reimburse two-level cervical artificial disc replacement surgery (2C-ADR) because, they said, it was “investigational.”

Between August 2013 and August 2016, Anthem, Inc., one of the largest medical insurers in the United States, categorically DENIED all requests to reimburse two-level cervical artificial disc replacement surgery (2C-ADR) because, they said, it was “investigational.”

In July 2017, Lawrence Bradford filed a class action suit against Anthem Inc. on behalf of all similarly situated plaintiffs, seeking declaratory and injunctive relief. Bradford claimed that Anthem categorically denied all requests for two-level cervical artificial disc replacement surgery (2C-ADR) surgery because the procedure was “investigational.” Failing to state a specific reason or reasons for denying claims and failing to provide the specific plan provisions on which a determination is based is a violation of the Employee Retirement Income Security Act of 1974 (ERISA).

Because Anthem failed to state a specific reason or reasons for labeling cervical artificial discs as “investigational” and therefore denied claims and failed to provide the specific plan provisions on which a determination was based, claimed Bradford, is a violation of ERISA.
The two parties mediated and came to a settlement.

According to the terms of the settlement, all class members (“class members” are defined as patients who were denied two-level cervical artificial disc treatment from August 2013 when the FDA approved the surgery to August 2016 when Anthem began to cover the surgery) who paid out-of-pocket for 2C-ADR can make claims for reimbursement and class members who have not yet undergone 2C-ADR and are still covered by Anthem can submit their requests for approval. Anthem will reimburse class members for out-of-pocket expenses up to a maximum of $35,000. Anthem also agreed to pay the class counsel’s attorney fees.

But Anthem was not done playing games.

The massive insurance company decided to notify patients who’d been denied treatment by first class mail.

The terms of the settlement did not specify how patients were to be notified, it only said that the proposed settlement be mailed no later than 28 days after the entry of the preliminary approval order.

Back to court the attorneys went, and a federal court judge just ruled that Anthem, Inc. cannot use first class mail to notify the members of class about a spinal surgery settlement.

Judge Andre Birotte, Jr. of the United States District Court for the Central District of California said that notifying a class by a single piece of first-class mail was inadequate.

Judge Birotte ordered Anthem to at least use Priority Mail Flat Rate Envelopes and mark the envelopes with “attention-getting text” to maximize the likelihood that the class members would pay attention to the notice. — KD

**COMPANY**

**Medovex Corporation Raises $4.9 Million**

Alpharetta, Georgia-based Medovex Corporation, developer of a novel, non-invasive treatment for back pain, announced that it has raised $4.9 million from investors in two transactions.

In the first transaction, the company received $1,800,000 in cash and $200,000 by cancellation of debt from four separate purchasers. In the second purchase agreement, announced 10 days later, the company received $2.9 million from six investors. Medovex had offered a minimum of $1,000,000 and a maximum of $6,000,000 of units at a price of $50,000 per unit.

Medovex is a corporation that was formed to acquire and develop a diversified portfolio of medical technology products and services. The company’s first product, the DenerveX System, is intended to provide long-lasting relief from facet joint syndrome pain.

The system “…is a rotational, monopolar, radiofrequency [RF] denervation device, powered by a dedicated DenerveX Pro-40 generator. It is designed to ablate the nerve and capsular tissue on the posterior surface of the facet joint. Denervation is achieved through Rotacapsulation, a combination of high heat and rotational tissue shaving.” The device is currently in Pre-Submission with the FDA.

William “Bill” Horne, Medovex CEO and chairman, said, “In just recent weeks, we have announced the completion of the transaction of [Regenerative Medical Solutions], appointed two new high-quality board members, and secured nearly $5 million in financing allowing us to execute our business plan going forward.”

“Soon, you should expect to see additional communications that will further bolster and speak to the quality of our team, what our business will look like going forward, and most importantly, how we intend to build long term sustainable shareholder value. It’s an exciting time here at Medovex and we are grateful for both the continued support of our existing shareholders as well as those who have just recently joined us.”

— KD
Cementless TKA vs Cemented in Morbidly Obese Patients…New Data

A new study from the University of Louisville Adult Reconstruction Program has collected survivorship data for both cementless total knee arthroplasty (TKA) and cemented TKA in morbidly obese patients. The data is in a new study which appears in the February 2019 edition of the Journal of Arthroplasty.

The retrospective study, “Increased Survivorship of Cementless versus Cemented TKA in the Morbidly Obese: A Minimum 5-Year Follow-Up,” was co-authored by Arthur Malkani, M.D. of the University of Louisville Adult Reconstruction Program.

Dr. Malkani explained the issue that he and his colleagues were expecting to address in the study. “We were seeing higher failure rates following primary cemented TKA in our morbidly obese patients and young active males due to aseptic loosening despite well aligned knees.”

The authors compared five-year survivorship data for 108 morbidly obese patients (BMI ≥ 45.6) who’d received a cemented primary TKA with 85 morbidly obese patients (BMI = 45) who’d received a cementless TKA.

They found: “There were 5 failures requiring revision in the cementless group, including 1 for aseptic tibial loosening. In the cemented group, there were 22 failures requiring revision, including 16 implants for aseptic loosening. Survivorship with aseptic loosening as the endpoint was 99.1% in the cementless group vs 88.2% in the cemented cohort at 8 years.”

Dr. Malkani summarized the data from this study to OTW, “Our results demonstrated that survivorship with aseptic loosening as the endpoint was 99% using a modern design cementless total knee arthroplasty compared to 88% in the cemented cohort at eight years.”

“Morbidly obese patients have a higher failure incidence due to aseptic loosening with cemented TKA with decreasing survivorship over time. The use of cementless TKA using a modern design implant in the morbidly obese with the potential of durable long-term biologic fixation and increased survivorship is an excellent alternative to the use of mechanical cement fixation.”

“Current design cementless TKA are not the same as past generation cementless implants which had poor tibial baseplate-polyethylene locking mechanisms and utilized polyethylene with poor wear characteristics. Similar to the success of cementless THA [total hip arthroplasty], modern design cementless TKA demonstrate excellent clinical results with durable biologic fixation and increased survivorship compared to cemented TKA in the morbidly obese.” — EH

TKA Short-Stay Patients, Higher Readmission Rates. New Study


Alex Bottle, Ph.D. with the Faculty of Medicine at the School of Public Health at Imperial College London and co-author explained the genesis of this study to OTW. “This study arose in part from our realization that, although the 30-day all-cause readmission measure is the one that everyone uses and is the one in pay-for-performance schemes such as in

Photo creation by RRY Publications, LLC

Wikimedia Commons and William Cousins
the U.S., many readmissions are for reasons not directly connected to their arthroplasty."

“We wanted to look at two alternative readmission measures. This study is part of a wider project looking at which are the best measures for surgeon and hospital performance; we compared the statistical properties of these three readmission measures in another recent paper in the same journal (ref #14), which recommended that surgeons, hospitals and regulators monitor ‘surgical readmissions’ alongside all-cause ones.”

The authors wrote, “All primary TKAs recorded in England’s National Health Service administrative database from 2006 to 2015 were included. In total, 566,323 procedures were recorded…”

Dr. Bottle told OTW, “The main result was that predictors of all-cause, surgical, and return to surgical theatre readmission often differed, particularly for return to theatre. We also note that short-stay patients had significantly higher readmission rates than those staying two nights. This is of interest due to the trend towards performing more arthroplasties with same-day discharge. It’s not clear how many and which patients this will be best for.”

“We identified several patient factors such as mental health conditions and neurological conditions that are associated with higher risk; patellofemoral replacements were associated with higher risk of return to theatre (reoperation) readmissions but lower risk of all-cause or surgical readmissions. These findings could help surgeons and their patients with the clinical decision-making process.” — EH

How to Cut 1 Hospital Day in Revision TKA/THA Cases

Surgeons from Florida have come up with some specific suggestions as to how their colleagues can improve treatment metrics for arthroplasty revision patients.


Chancellor Gray, M.D., an orthopedic surgeon at the University of Florida College of Medicine in Gainesville and co-author on the work, told OTW, “We found that the overall environment and culture of care in our health system was improving, favoring increased value for our total joint arthroplasty [TJA] patients, in the wake of our Comprehensive Care for Joint Replacement (CJR) inspired redesign of our total joint program.”

“We were seeing improved quality metrics for our revision patients, though they were not explicitly targeted by our intervention, and wanted to examine the effect of the redesign for these patients in particular. Prior work we published showed the efficacy of the intervention on the intended group, so we were quite curious to see the effect on this other group (the revision patients).”

“We compared quality metrics for all revision TJA patients including readmission rate, use of post–acute care facility after discharge, length of stay, and cost, between the year leading up to the redesign and the two years following its implementation. Changes in the primary TJA group over the same time period were also assessed for comparison.”
Dr. Gray explained to OTW the most surprising results from the study. “The most important results are that, despite no targeting of revision patients, complex revision THA [total hip arthroplasty]/TKA [total knee arthroplasty] patients can see an improvement in length of stay, readmission rate, and home discharge rate largely through a culture change coming from care improvements for primary THA/TKA patients.”

“For instance, we improved length of stay by nearly a day (from 4.8 to 3.9 days) and were able to make a nearly 25% improvement in patients going to home instead of to a facility.”

“Surgeons have an opportunity to improve care for their patients through culture change in their hospital/practice. We found the key elements of the culture change to stem from a monthly multi-disciplinary meeting where the surgeon group: a) controlled the messaging by being the foremost presenting group, b) was a fully invested group willing to share and compare data, and c) was willing to take ownership over the whole patient-care episode, both before, during, and after the hospital surgical experience.”

“Despite putting surgeons in what may, at first, feel like an uncomfortable position, bundled payment programs may offer real opportunities for care alignment and improvement of value in what is a very common and very expensive operation. In fact, handled correctly, these programs give surgeons an opportunity to reassert ownership over the care episode for the benefit of their patients and their health system.” — EH

UK Study: No Difference Between 5 TKA Prophylaxis Regimes

In the constant hunt for the most effective antibiotic prophylaxis for total knee replacement (TKR), a team of UK researchers performed a study titled “A comparative study of 5 different antibiotic prophylaxis regimes in 4500 total knee replacements.” This was published online December 18, 2018 in the Journal of Clinical Orthopaedics and Trauma.

Satish Babu, M.R.C.S. a Specialist Orthopaedic Registrar at Frimley Park Hospital in the UK and co-author explained the rationale behind the study to OTW. “In the institution where the work was carried out, the recommended antibiotic prophylaxis protocol for TKR was changed several times due to side effects and perceived deficiencies of existing regimens.”

“Despite this, there was no obvious difference in observed deep infection rates. Furthermore, there is widespread variation in the antibiotic prophylaxis regimens used between surgeons throughout the UK and we wanted to examine which, if any, were better.”

So Babu and his colleagues put together a retrospective study of prospectively collected data on a total of 4,500 elective knee replacements over a nine-year period at a district general hospital. The investigators collected data regarding an antibiotic regime, patient characteristics, infection (treatment, infective agents, sensitivities) and complications. They then identified five different antibiotic regimes that have been used in elective knee arthroplasty at their institution. In total, the researchers identified 40 patients who had a deep infection.

Interestingly, said Babu, “There were no significant differences in the rates of deep surgical site infection after TKR between the five regimes examined in our study. Rather than adopting a ‘one size fits all’ approach, clinicians should exercise judgment in choosing antibiotic prophylaxis protocols based on patient, surgical and environmental factors.”

“Our study produced no evidence to say one particular antibiotic regimen was superior to another when considering prophylaxis for TKR. We recommend the choice of antibiotic prophylaxis for TKR should be made locally at the institution where the surgery is being done based on pathogen virulence in the area, drug resistance and cost.” — EH

Wikimedia Commons and Tech. Sgt. Tyrona Lawson
Elegant New Work From Rutgers Explains Implant Loosening

A failed joint replacement leaves patients and surgeons with big problems. Rutgers researchers homed in on the role of the immune system in the inflammation and bone loss that can occur after such as surgery.


According to the Rutgers researchers, the study “found white blood cells, called macrophages, respond to the particles as if they were harmful invaders and engulf them. But the cells then die and secrete a specific molecule that triggers an even stronger immune response – including inflammation which can cause tissue damage and bone destruction which leads to loosening of the implants.”

“Bone degradation can occur within 10 to 15 years and often requires complex revision surgery to replace the implant and treat bone loss,” said lead author William Gause, director of the Center for Immunity and Inflammation at Rutgers New Jersey Medical School. “However, many people start experiencing pain from this inflammation shortly after surgery. They are prescribed medications for the pain, but the loosening continues.”

More generally, say the researchers, these studies reveal new insights into how inert and sterile microparticles, including pollutants such as diesel exhaust particles or silica, can cause robust and harmful inflammation, ultimately leading to disease.

“Although we typically think of infectious agents or toxins as causing disease, apparently the response of the body to these particles, which have essentially no intrinsic activities, can result in considerable tissue damage and pathology,” Dr. Gause said.

Dr. Gause told OTW, “We showed that sterile microparticles of a similar size and composition to wear debris particles trigger a type 2 inflammatory response in joint tissue and further showed that this could be inhibited by targeting specific signaling pathways including Bruton’s tyrosine kinase and IL-33.”

“Implant failure may result from harmful inflammation that leads to bone damage and aseptic loosening. This inflammation can be triggered by sterile microparticles that induce a particular type of immune response, which may be controlled by targeting Bruton’s tyrosine kinase or IL-33.” — EH

Does Prior Hip Arthroscopy Affect THA Outcomes?

In what way and how extensively do prior hip arthroscopy interventions and hip preservation surgeries affect total hip replacement surgeries?


John P. Salvo, M.D., associate professor of Orthopaedic Surgery at the Sidney Kimmel Medical College at Thomas Jefferson University Hospital and director of the Hip Arthroscopy Program at the Rothman Orthopaedic Institute in Philadelphia and study co-author told OTW, “The frequency of hip arthroscopic procedures has increased dramatically over the last one to two decades. The short- and mid-terms outcomes have been very good overall with low rates of complications. As more studies are now aimed at long-term outcomes for hip arthroscopy and hip preservation procedures, a question is raised regarding the possible effect of previous hip arthroscopy and hip preservation surgery on total hip replacement (THA).”

“We performed a systematic review of Level I through III studies directly com-
paring outcomes of total or resurfacing hip arthroplasty between patients with and without a history of hip arthroscopy if they reported at least one outcome measure.”

“The mean age in the arthroscopy and control groups was 47.2 years and 49.1 years, respectively. The mean follow-up period after arthroplasty was 3.2 years in the hip arthroscopy group and 3.3 years in the control group. The mean time between arthroscopy and arthroplasty was 1.8 years.”

Salvo and his colleagues noted “…no statistically significant differences in intraoperative measures, postoperative complications, or revision rates, with the exception of one study that reported an increased operative time among controls. Most studies reported similar subjective outcomes between groups.”

“The current literature suggests that short-term and midterm outcomes of hip arthroplasty are comparable in patients with and without a history of hip arthroscopy. However, the available literature is limited given the small sample sizes and therefore greater potential for β error.” — EH

**Exercise Decreases Opioid Use?**

New research examining 88,985 opioid-naive patients with shoulder, neck, knee, or low back pain has found that early physical therapy (PT) could steer patients away from opioids.


Co-author Eric Sun, M.D., Ph.D., with the the Stanford University School of Medicine in California told OTW, “This topic was of interest to us given the growing awareness of opioid use in the United States and recommendations that non-pharmacologic alternatives (e.g., physical therapy) be used instead of (or in addition to) opioids to manage pain conditions.”

The authors found that early PT was associated with approximately 10% reduction in subsequent opioid use.

“Our most important result,” Dr. Sun told OTW, “is that early physical therapy is associated with lower long-term opioid use among patients with severe musculoskeletal pain. Patients with severe musculoskeletal pain (and their healthcare providers) should seek physical therapy as soon as is possible.”

“Our research is one the few large-scale studies to suggest that physical therapy can provide a statistically significant benefit (in terms of long-term opioid use) for patients with severe musculoskeletal pain, and suggests that physical therapy can play an important role for these patients.” — EH

**How Well Do Oral Antibiotics Work in High Risk TJA Patients?**

A new retrospective study has tried to quantify the effectiveness (or not) of oral prophylactic antibiotics on the risk of postoperative infection for high risk total hip or total knee patients. The study researchers were able to look at 2,181 primary total knee arthroplasties (TKAs) and primary total hip arthroplasties (THAs) in an attempt to find an answer.


Co-author Michael Meneghini, M.D., associate professor of clinical orthopedic surgery at Indiana University School of Medicine, explained the purpose and objective of this study to OTW, “Existing research and our anecdotal experience has shown that high risk patients were more likely to get an infection during the early postoperative period after hip and knee arthroplasty. It is our contention that an immunocompromised state during the first week after arthroplasty...”
with edema, fluid and microvascular compromise creates a peri-articular milieu susceptible to infection, particularly in high-risk patients, and protection with prophylactic antibiotics during this first week after surgery minimizes the risk of infection."

According to Meneghini, the research team found that, "The 90-day infection rates were 1.0% and 2.2% after total knee arthroplasty and total hip arthroplasty, respectively. High-risk patients without extended antibiotic prophylaxis were 4.9 and 4.0 times more likely to develop post-operative joint infection after TKA and THA, respectively, than high-risk patients with extended antibiotic prophylaxis."

“We were very encouraged by the statistically significant and clinically meaningful four-fold decrease in 90-day postoperative infection rates in high risk patients, confirming our clinical and experienced-based hypothesis,” said Dr. Meneghini.

“Providing patients who are at high-risk for peri-prosthetic joint infection after hip or knee arthroplasty with a week of oral prophylactic antibiotics can result in a clinically meaningful reduction in postoperative infection. Prevention of even a single devastating joint infection can alleviate suffering for patients and save the healthcare systems millions on a larger scale.”

“The most commonly anticipated hesitation before implementing this protocol into practice is the fear of contributing to antimicrobial resistance (AMR). However, studies have demonstrated that surgical prophylaxis actually contributes minimally to AMR, compared to antibiotics prescribed in the ambulatory and acute-care medical setting.”

— EH

EXTREMITIES

Single-Use Implants and Instruments Cut OR Time 33%

New data regarding single-use, sterile, disposable implant and instrument systems for first metatarsal phalangeal joint (MTP) arthrodesis procedures will be presented at the American College of Foot and Ankle Surgeons (ACFAS) 2019 Annual Meeting held in New Orleans, Louisiana February 13-16, 2019.

But, OTW obtained a preview. It’s interesting.

The study was a 14-month, multi-center prospective trial which compared the use of one of the more popular single-use systems, FlowerCube, to traditional implants in first metatarsal phalangeal joint fusions in 71 consecutive patients.

The lead investigator was John Levin, DPM of the JEM Research Institute located in Lake Worth, Florida.

The investigators found that using FlowerCube lowered intraoperative time by an obviously statistically significant 33% which created $1,300 in cost reductions. The study was conducted at an ambulatory surgery center. The investigators also reported that patient outcomes were equivalent to non-disposable instrumented procedures.

Specifically, 84.51% of study patients experienced union of the joints by 8 weeks post-surgery and 98.59% by 12 weeks post-surgery.

The full study will be presented by Dr. Levin at the ACFAS meeting.

Flower CEO and founder, Oliver Burckhardt, was pleased with the study results. “This study further illustrates and quantifies the savings the Flower-Cube provides, all while maintaining optimal patient outcomes.”

“Flower has long been dedicated to innovative implants and instruments that streamline surgeries and reduce costs of foot and ankle surgeons,” he said.

Flower Orthopedics will also be introducing a new Jones screw for treatment of a fracture in the fifth metatarsal. The company will also introduce a 6.5mm Headless Compression screw at the conference.

For more information about where and when this study will be presented and where to find Flower Orthopedics at the New Orleans meeting, please visit the ACFAS 2019 conference website here. — TR

Courtesy of Flower Orthopedics