

Orthopedics This Week

week in review

4 The Top 21 U.S. Hip Surgeons ♦ And you thought it was hard to get into the country club...think again. This is the most elite group we've come across...the hip surgeons. Thought leaders tell us their thoughts....

7 Re-Thinking Surgeon Industry Relationships ♦ Five years after the government forced industry and surgeons to redefine their relationship, orthopedic surgeons have come out with their own Manifesto for managing those relationships. How did we get here and what's the Manifesto say? Read it here.

12 One Price Knee Replacement Surgery Debuts ♦ In an industry built on the religion of individualized treatment, a program touting single priced surgery is either apostasy or game changing or both. A Minnesota orthopedic practice has that vision and may have more in common with Target Stores than Mayo Clinic. Is this the future? See for yourself.

16 Holy Cow! CME Credit on the Fast Track? and more... ♦ STOP Courting Disaster With Kids and Football ... Holy Cow! CME Credit on the Fast Track? ... Boden Laments Innovation Slowdown ... Powerfully Sensitive New Tool Measures Meniscal Trim vs. Repair



19 Paprosky, Kyle Debate Extended Trochanteric Osteotomy ♦ With extended trochanteric osteotomy you get unparalleled exposure. What's not to like?" asserts Wayne Paprosky. "There is a place for the slot...100% union rate, no problem with ingrowth and the intraoperative fracture is less," counters Richard Kyle.



breaking news

- 22 Medtronic Sues NuVasive, Again**
- FDA Calls Public **Postmarket Surveillance Meeting**
- MedCure Opens European Tissue Bank**
- Female Athletes More Vulnerable to ACL Tears**
- Blood Cells Reprogram Into Embryonic State**
- LDR Introduces FDA-Cleared Lateral Lumbar Cage**
- Federal Judge Rejects Orthofix/DOJ Deal**

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Globus Medical debuts on the Power Rankings in the #1 spot—the first company to ever achieve that distinction. With a 30% operating margin, Globus is the most profitable company in orthopedics. With a forecasted growth rate in excess of 20%, it is also one of the fastest growing firms. Finally, highest consensus analyst rating (1.3, BUY) of all orthopedic equities.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	NR	Globus Medical	30.06%	21.93%	Even though the stock is up 22%, GMED's P/E ratio is still 7th cheapest in ortho.
2	1	Medtronic	28.65	3.00	The glow over Q2 is over and we're back to what have you done lately. Can MDT hold its recent gains? We think yes.
3	5	Zimmer	26.37	6.76	The three most profitable orthopedic companies are 1-2-3 this week. Cash is king, again.
4	4	Symmetry Medical	5.63	6.37	FDA approves SMA's Flash Back, er Pak which will further bolster Symmetry Surgical and its Codman brand.
5	9	Orthofix	16.23	3.11	Cash flow baby. It's what's going to make OFIX the eventual darling of all value investors.
6	2	Integra LifeSciences	13.36	4.13	Tale of two quarters. This one ending in September, consensus says down earnings. Q4, big increase. Market's confused too.
7	6	Smith & Nephew	21.36	3.58	No real news although buying interest has pushed SNN's overall valuation down to 11th out of 27—not the bargain bin.
8	10	ArthroCare	(0.80)	4.25	ARTC surprised this past week with a sudden surge of new buying interest. Most buyers expect ARTC's earnings to break out soon.
9	3	Stryker	23.68	2.19	No new CEO. Guidance at the analyst meeting last week was straightforward. Needs a catalyst.
10	7	Exactech	7.68	1.44	From Wall Street's perspective a lot is riding on the 4th quarter. Consensus of analysts is 50% earnings growth for Q4.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Globus Medical	GMED	\$16.40	\$1,484	21.93%
2	MAKO Surgical	MAKO	\$16.78	\$716	17.75%
3	Alphatec Holdings	ATEC	\$1.74	\$156	13.73%
4	TiGenix	TIG.BR	\$0.67	\$61	12.02%
5	Bacterin Intl Holdings	BONE	\$1.68	\$71	11.26%
6	NuVasive	NUVA	\$21.47	\$933	8.98%
7	RTI Biologics Inc	RTIX	\$4.14	\$231	8.38%
8	Zimmer Holdings	ZMH	\$65.22	\$11,394	6.76%
9	Symmetry Medical	SMA	\$9.52	\$349	6.37%
10	Tornier N.V.	TRNX	\$19.07	\$757	5.97%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TranS1	TSON	\$2.33	\$64	-13.38%
2	Johnson & Johnson	JNJ	\$67.88	\$187,148	-0.69%
3	Exactech	EXAC	\$16.86	\$224	1.44%
4	Stryker	SYK	\$54.15	\$20,601	2.19%
5	Conmed	CNMD	\$27.51	\$782	2.19%
6	Medtronic	MDT	\$41.61	\$42,448	3.00%
7	Orthofix	OFIX	\$43.43	\$824	3.11%
8	Smith & Nephew	SNN	\$54.40	\$9,783	3.58%
9	Wright Medical	WMGI	\$20.77	\$823	4.06%
10	Integra LifeSciences	IART	\$40.63	\$1,098	4.13%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	\$41.61	\$42,448	12.35
2	Zimmer Holdings	ZMH	\$65.22	\$11,394	12.89
3	Johnson & Johnson	JNJ	\$67.88	\$187,148	13.47
4	Stryker	SYK	\$54.15	\$20,601	13.92
5	Orthofix	OFIX	\$43.43	\$824	14.82

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	\$20.77	\$823	79.88
2	NuVasive	NUVA	\$21.47	\$933	65.06
3	Symmetry Medical	SMA	\$9.52	\$349	56.00
4	RTI Biologics Inc	RTIX	\$4.14	\$231	23.00
5	Exactech	EXAC	\$16.86	\$224	20.81

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	ArthroCare	ARTC	\$29.90	\$829	0.97
2	Orthofix	OFIX	\$43.43	\$824	0.97
3	Globus Medical	GMED	\$16.40	\$1,484	1.19
4	Zimmer Holdings	ZMH	\$65.22	\$11,394	1.34
5	Stryker	SYK	\$54.15	\$20,601	1.37

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	\$20.77	\$823	8.26
2	NuVasive	NUVA	\$21.47	\$933	6.91
3	CryoLife	CRY	\$5.61	\$154	4.68
4	Symmetry Medical	SMA	\$9.52	\$349	4.67
5	Smith & Nephew	SNN	\$54.40	\$9,783	3.86

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	\$1.74	\$156	0.79
2	Symmetry Medical	SMA	\$9.52	\$349	0.97
3	Conmed	CNMD	\$27.51	\$782	1.08
4	Exactech	EXAC	\$16.86	\$224	1.09
5	CryoLife	CRY	\$5.61	\$154	1.29

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$0.67	\$61	53.19
2	MAKO Surgical	MAKO	\$16.78	\$716	8.47
3	Globus Medical	GMED	\$16.40	\$1,484	4.48
4	TranS1	TSON	\$2.33	\$64	3.32
5	Tornier N.V.	TRNX	\$19.07	\$757	2.90

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

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The Top 21 U.S. Hip Surgeons

By OTW Staff



Wikimeida Commons and Jaime de la Fuente

And you thought it was hard to get into the country club...think again. This is the most elite group we've come across...the hip surgeons.

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

In alphabetical order, here are the top 21 hip surgeons in the United States.

Robert L. Barrack, M.D. is the Charles F. and Joanne Knight Distinguished Professor of Orthopedic Surgery at Washington University School of Medicine in

St. Louis. He is also the chief of staff for orthopedics at Barnes-Jewish Hospital, as well as chief of Adult Reconstructive Surgery. "He has made major contributions to the hip field in terms of surface replacement...and he has done a great job of following up on problems that have occurred with those. He is a critical thinker who has looked carefully at patient outcomes with regard to different technologies and devices...and provided great information about the ways of judging the work we do."

Daniel J. Berry, M.D. is the chair of orthopedic surgery at Mayo Clinic in Rochester, Minnesota, and is a former president of The American Academy of Orthopaedic Surgeons (AAOS). He is also a past president of the American Association of Hip and Knee Surgeons

(AAHKS). "He has done it all...when he speaks people listen. He is an outstanding surgeon and a tremendous thinker."

John J. Callaghan, M.D. is professor in the Department of Orthopaedic Surgery and Biomedical Engineering at the University of Iowa. He is an adjunct assistant professor at Uniformed Services University of the Health Sciences and is a former president of AAOS. "He is a very smart man...extremely detail oriented. He is a very good technician and has done superb work with the follow-up of cemented stems, with a very high success rate."

John C. Clohisy, M.D. is a professor of Orthopedic Surgery at Washington University School of Medicine in St.

Louis and director of the Center for Adolescent and Young Hip Disorders. Dr. Clohisy is co-chief of the Adult Reconstructive Surgery Service and director of the Fellowship in Joint Preservation, Resurfacing and Replacement. “He is known for hip osteotomy, is very experienced, and is highly regarded. He reports it like it is with regard to data and outcomes.”

Lawrence D. Dorr, M.D. is founder and medical director of The Arthritis Institute at Good Samaritan Hospital Arthritis Institute in Los Angeles, California. He is a past president of the AAHKS and The Hip Society. “He has been very innovative in the world of robotic hip surgery and computer assisted surgery. His humanitarian work is legendary in our field.”

Thomas K. Fehring, M.D. is co-director of the Hip and Knee Center and director of the Adult Reconstructive Fellowship at OrthoCarolina in Charlotte, North Carolina. He is First Vice President of the AAHKS. “He has a no nonsense approach and is willing to ask questions that sometimes aren’t asked by others. He is willing to be critical in examining his own work and reports honestly if something doesn’t work. He has contributed to infection management overall, and specifically obesity and its impact on arthroplasty.”

Kenneth A. Gustke, M.D. is an orthopedic surgeon with the Florida Orthopaedic Institute; he is a founding member and past president of this practice. He is a founding member of the AAHKS. “He has a wonderful reputation, is a great technical surgeon, and has made major contributions to hip implant design.”

Carlos J. Lavernia, M.D., F.A.A.O.S. is medical director of the Orthopaedic Institute at Mercy Hospital in Miami,

Florida, and adjunct clinical professor of orthopedic surgery at the University of Miami. Dr. Lavernia is an immediate past president of the AAHKS. “He is known for making quality improvements to hip surgery. He has a tremendous practice and does a good deal of humanitarian work. He is a leader of leaders and a role model for others.”

David G. Lewallen, M.D. is an orthopedic surgeon with Mayo Clinic in Rochester, Minnesota. He is the current president of The Hip Society, and is a past president of the AAHKS. “He works incredibly hard and leaves no stone unturned with regard to patient care. He is very personable, tackles extremely hard cases—including revisions—and is an innovative thinker.”

Jay R. Lieberman, M.D. is director of the New England Musculoskeletal Institute and professor and chairman of the Department of Orthopaedic Surgery at the University of Connecticut Health Center. He is a past president of The Hip Society and is the Third Vice President of the AAHKS. “He has done extensive basic and clinical research, in particular helping us to understand the basic science of biologic issues related to hip surgery. He is also an excellent surgeon.”

William J. Maloney, M.D. is professor of orthopedic surgery and chair of the Stanford University School of Medicine. He is a past president of The Hip Society. “He has had a career long impact on hip surgery; he has increased our understanding of osteolysis and its management. He is very straightforward, very bright, and he is usually right. He is very involved in the American Joint Replacement Registry.”

Joel M. Matta, M.D. is an orthopedic surgeon with the Hip and Pelvis Institute at St. John’s Health Center in

Santa Monica, California. “He has been a real leader in the anterior approach movement. He is probably the leading surgeon for acetabular fractures in the U.S.”

Joseph C. McCarthy, M.D. is vice chairman of the Department of Orthopaedic Surgery, a hip and knee replacement orthopedic surgeon, and a Lecturer on orthopedic surgery at Harvard Medical School. Dr. McCarthy is a past president of the AAHKS. “He is one of the pioneers of hip arthroscopy; he does a substantial amount of arthroplasty work. Before it was fashionable Joe was the only one involved in credible publishing on arthroplasty. He has a balanced approach, is a prolific textbook author, and is a real leader.”

Michael B. Millis, M.D. is an orthopedic surgeon at Boston’s Children’s Hospital and is a professor of orthopedic surgery at Harvard Medical School. “He does a lot of hip osteotomy work on children and adults; he also does a lot of periacetabular orthopedic work. He has had a prolific academic career, and is very talented at sorting out what works and what doesn’t in the realms of developmental hip disorders and congenital deformities.”

Wayne G. Paprosky, M.D. is an orthopedic surgeon at Midwest Orthopaedics at Rush in Chicago, and a professor at Rush University Medical Center. “He is a pioneer in revision hip surgery, and has developed a lot of techniques that many of us have used for over two decades. He is known for his work on complex problems, including extensively coated femoral implants in difficult acetabular reconstructions.”

Brian S. Parsley, M.D. is an orthopedic surgeon in private practice in Houston, Texas; he is also clinical associate professor in the department of orthopedic

surgery at Baylor College of Medicine. Dr. Parsley is the Second Vice President of the AAHKS. "What incredible surgical technique he has. He has had a huge impact on the quality of care in our field."

Chitranjan S. Ranawat, M.D. is an attending orthopedic surgeon at Hospital for Special Surgery and professor of orthopedic surgery at Weill Cornell Medical College in New York. He is a past president of AAHKS and The Hip Society. "He has made an enormous contribution to the field, and is recognized as one of the best technical surgeons around. He is a quintessential surgeon and has contributed much to our understanding of the principles of hip replacement."

Richard F. Santore, M.D. is an orthopedic surgeon with the Orthopedic Medical Group in San Diego, California; he is also an orthopedic surgeon with Sharp Memorial Hospital. Dr. Santore is a past

president of the AAHKS. "He does osteotomies as well as hip replacements; he is one of only about six surgeons doing hip osteotomies in the U.S. He has been a real innovator in that area. He is an outstanding surgeon, a critical thinker, and an honest presenter of his data."

Steven F. Schutzer, M.D. is an orthopedic surgeon with Orthopedic Associates of Hartford, PC with St. Francis Care in Connecticut. He is also associate clinical professor of orthopedic surgery at the University of Connecticut School of Medicine. Dr. Schutzer is a founding member and Co-Director of the Connecticut Joint Replacement Institute at St. Francis Hospital. "He has helped developed a unique model for a joint replacement program—it is exceptionally patient focused. And Steve is just a great, humble man."

Thomas P. Sculco, M.D. is surgeon-in-chief and Korein-Wilson Professor of Orthopedic Surgery at Hospital for

Special Surgery in New York. He is the chairman of the Department of Orthopedic Surgery and a professor of orthopedic surgery at Weill Cornell Medical College. "He is an excellent primary hip surgeon, and does a great job of balancing the roles of chair and clinician. He is innovative in the MIS realm and has long been out in front of others on this issue...and patients love him because he is an affable guy."

Robert T. Trousdale, M.D. is an orthopedic surgeon with Mayo Clinic in Rochester, Minnesota. He is the Education Committee Chair of The Hip Society and is the Treasurer of the AAHKS. "He has done significant studies on the hip, including work on how much muscle injury there is with different surgical approaches. He has done randomized studies on hip replacement, and has been involved in the use of computerization in the OR. He has the kind of personality that allows him to take risks." ♦

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Re-Thinking Surgeon Industry Relationships

By Walter Eisner



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It's been five years since former U.S. Attorney Christopher Christie filed criminal charges against orthopedics' largest device manufacturers for allegedly paying kick-backs to surgeons to use their products.

"This industry routinely violated the anti-kickback statute by paying physicians for the purpose of exclusively using their products," Christie said. "Prior to our investigation, many orthopedic surgeons in this country made decisions predicated on how much money they could make—choosing which device to implant by going to the highest bidder."



*U.S. Attorney Christopher Christie
Wikimedia Commons and Luigi Novi27*

Saving the Industry

Christie later told Congress that the evidence was so egregious that had he

proceeded with prosecutions, the largest device makers would have lost their Medicare credentials and the entire industry would have collapsed. By forcing companies, through deferred prosecution agreements, to pay modest fines, accept federal monitors and revamp consulting contracts with surgeons, the industry was saved.

No one challenged the then U.S. Attorney. No one was prosecuted and the supposed egregious evidence never saw the light of day. The biggest complaint we heard from surgeons was that the tens of millions of dollars paid to the Christie-approved lawyers was far more

than surgeons received for doing actual consulting work which improved medical technology. But that's another story.

Consulting Decline

As a result of the government's intervention, consulting payments to surgeons by all of the companies went from \$272 million in 2007 to \$105 million in 2008. The total number of physicians receiving payments from the companies went from 1,693 in 2007 to 628 in 2008. Current figures are hard to come by as some companies stopped reporting payments until a new federal "Sunshine" law takes effect in 2013.

"We are confident that the industry, which had been engaged in illegal kick-back practices to secure market share, has made significant changes," said

Christie's successor after the deferred prosecutions agreements expired two years later.

Task Force Report

Where are we now? Have orthopedic surgeons and their professional societies stepped up and figured out how to police their own? What is the state of the relationship today from the orthopedic surgeon's perspective?


July 16 edition of *The Journal of Bone and Joint Surgery—American*. You can read the full report here http://ryortho.com/AOA_OIOM_Report.pdf

Surgeon Ethical Manifesto

The report explores dozens of levels of interaction between surgeons and industry from education to company reps in the OR to surgeon ownership and participation in the business of health care. The report offers unmis-

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We found out in a recent report released by the American Orthopaedic Association (AOA) Task Force on Orthopaedic Surgeon-Industry Relationships. The report was produced under the aegis of the Orthopaedic Institute of Medicine (OIOM). The purpose of the Task Force was to explore the critical topic of industry relations with orthopedic surgeons.

The report is the result of 22 months of study and includes 16 recommendations. The full report appeared in the

takable rules for proper conduct of a surgeon.

The authors of this landmark report were:

- G. Paul De Rosa, M.D. (Chair)
- Robert Barrack, M.D.
- Jonathan Braman, M.D.
- Nancy Cummings, M.D.
- Edward Hanley Jr., M.D.
- E. Anthony Rankin, M.D.
- Surgeon-ethicist Peter Angelos, M.D., Ph.D.



AOA/OIOM Report

- Cardiologist Robert Califf, M.D.
- Attorney David Hyman, JD
- Pathologist David Korn, M.D.
- Industry representative Stephen Peoples, VMD
- Susan Roberts, Ph.D.

The report acknowledges the value of industry/surgeon relationships, but does not shy away from the potentials of abuse.

Differing Missions, Necessary Collaboration

At the core of the relationship, say the authors, surgeons and industry have very different missions. Industry's primary mission is to expand market share and return profits to investors. The surgeons' primary mission is to do what's in the best interest of the patient.

Surgeons need industry to manufacture their innovations and industry needs surgeon input to increase market share.

According to study co-author Dr. Rankin, preserving the status quo is unacceptable and changes are needed. He said the report's recommendations build on previous work by the American Academy of Orthopaedic Surgeons (AAOS) and emphasize that surgeons should get paid for work, not volume. He believes surgeon behavior has changed, in part, because doctors are more aware that their industry relationship is more transparent.



E. Anthony Rankin, M.D.;
courtesy of American
Academy of Orthopaedic
Surgeons

"We all know that self-regulation is not only desired and preferred, it is also the right thing to do," said Dr. Rankin in an article in *AAOS Now*. "I am confident that the efforts made by the AAOS, and now the AOA, in providing clarity and direction to our profession regarding appropriate physician–industry relationships will enable orthopaedists to better address this issue going forward."

Recommendations

What does the report recommend?

Among the 16 recommendations, the report calls for the orthopedic specialty "to aspire to reduce, and eventually eliminate, industry's financing of orthopaedic educational activities, gifts, meals, and the use of prescription drug samples."

The following are among the recommendations from the OIOM:

- Payment from industry for advice, expertise, or other services in the context of product development should be fee-for-service or hourly consulting fees based on fair market value and well-defined contractual obligations with pre-specified timelines and deliverables.
- Regarding clinical studies: surgeons should only participate in research that meaningfully contributes to the professional literature, is adequately powered to clinically important endpoints, and be designed, structured, and managed to minimize bias and ensure patient safety. Analysis and reporting of research data must be independent of industry influence.
- Residency, fellowship, and other training programs should receive funds from unbiased, independent, third party organizations or through central administration of

the institution. Residency and fellowship training programs should stop accepting individual-focused grants from companies and require companies to submit funding through either of the aforementioned approaches.

- Industry funds should not be used to develop clinical practice guidelines. When forming guideline committees, individual and composite numbers of financial ties to industry should be evaluated and minimized to avoid actual or perceived industry influence on the resultant guidelines.

History of Collaboration

The report also provides a detailed history of the relationship between surgeons and industry.

Companies rely heavily on surgeons to assist them as they develop new devices and implants. In fact, surgeons have

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proven to be critical in literally every stage of product design and development and that active involvement is, said the report, unique to the surgical fields of medicine.



Professor Sir John Charnley;
courtesy of johncharleytrust.org

This model, notes the report, has created a steady stream of new innovation none more dramatic than the development of the total hip replacement by Professor Sir John Charnley in 1962, which revolutionized the field of orthopedic surgery. The biomedical device industry, with annual revenues of nearly \$30 billion, has flourished from this collaboration.

The collaborative relationship between industry and surgeons is a necessary and mutually beneficial relationship. However, states the report, there is also the opportunity for conflict of interest to “erode beneficence and the integrity of the patient-physician relationship.”

Rise of Implantation

In recent decades, the practice of orthopedic surgery has evolved into one that relies heavily on device implantation to improve quality of life for patients with severe musculoskeletal disease. Prior to 1970, says the report, most orthopedic

Orthopaedic Institute of Medicine Surgeon-Industry Relationships in Orthopaedic Surgery

Recommendations (Condensed)

1. Understand the distinction between industry relationships that are gratuitous, self-indulging, and potentially corrupting, and those that improve the care of patients.
2. Refrain from establishing the former classes of vendor relationships.
3. Payment for consulting with industry should be fee-for-service or hourly consulting fees.
4. Recuse from decision-making when involved in institutional purchasing decisions.
5. Don't profit from patients if involved in product development activities, in which genuine IP [intellectual property] is transferred and royalties are paid.
6. Avoid investigator-initiated grants for “weak” research projects.
7. Only participate in research that meaningfully contributes to the professional literature, are adequately powered, have a study design, operational structure, and oversight mechanism to minimize bias.
8. Avoid participation in speaker's bureaus.
9. The use of ghostwriters is always unacceptable.
10. Developing a standardized core curriculum for inculcating professionalism and ethics in GME [Graduate Medical Education] programs.
11. Industry relationships with universities must be premised on the charitable and educational uses to which a university may put a tax-subsidized industry gift, not to a product endorsement.
12. Industry funds for residency, fellowship, and other training programs should be distributed through unbiased, independent, third party organizations.
13. Reliance on prescription drug samples should be eliminated.
14. Encourage industry to support research in multi-center networks to improve transparency and objectivity.
15. Industry funds should not be used to develop clinical practice guidelines.
16. Societies should measure and report the percentage of industry support received for their operating budgets.

interventions consisted of non-operative treatment and surgical procedures that did not involve total joint replacement devices. “In the ensuing decades, numerous technologic breakthroughs resulted in the development of hip and knee implants that have dramatically improved the quality of life for millions of patients. Total hip replacement has been termed the ‘Operation of the Century.’”

Essentially the vast majority of musculoskeletal technology breakthroughs were developed by surgeons. The report notes, for example, that modern fracture fixation devices were largely developed by a group of Swiss surgeons with contributions from German and Russian surgeons.

“Industry was enlisted in these efforts primarily to manufacture and distribute the devices, but the vision that led to these breakthroughs that have advanced the discipline to its current state, came largely from innovative surgeons who sought to improve the quality of care for patients.”

Marketing to Colleagues Versus Patient Quality of Care

As the practice of orthopedics has evolved from a largely non-interventional practice to a surgical one, the siren song of sales and marketing has begun to compete with patient quality of care considerations among some surgeons and in some practices.

According to the report, “More recently, the surgeon-industry relationship has evolved from the past model. In many cases, this relationship appears to prioritize influence over surgeon decision-making rather than improving the quality of devices in the marketplace.”

Dr. Rankin, who previously chaired the AAOS Conflict of Interest Project Team, which developed recommendations that led to the establishment of the AAOS Disclosure Database, concluded: “This document from the OIOM puts forth recommendations and considerations designed to protect the core values of orthopedic surgery as a discipline and to reaffirm and strengthen profes-

sionalism and integrity among orthopedic surgeons.”

The OIOM Task Force said further that conflict of interest does exist in the discipline of orthopedic surgery and while the impact of those conflicts of interest on patient care is uncertain, it is clear that “industry has grown to expect some orthopedic surgeons to facilitate their marketing objectives in exchange for monetary payments, income-earning opportunities, gifts, privileges, and prestige.”

“Relationships with industry are necessary, valuable and productive when ethical, transparent, and managed appropriately with recognition of and respect for the very different values and missions of the profession and the industry.”

Will surgeons live by these recommendations? Who knows, but as the report warns, “Failure to regulate ourselves will inevitably lead to increasingly more intrusive external regulation.” ♦

One Price Knee Replacement Surgery Debuts

By Biloine W. Young

Where's the catch? In an industry built on the religion of individualized treatment, a treatment program based on single-priced surgery is either apostasy or game changing or both.

A Minnesota orthopedic practice has a vision that may have more in common with Minnesota-based Target Stores than it does with the Mayo Clinic. The Twin Cities Orthopedics (TCO) Excel Program wants to make the process of ordering a new knee as uncomplicated as "buying a carton of milk off the shelf." That is how Troy Simonson, practice administrator, describes this unconventional new program in which total knee replacement patients pay one bill that covers everything—the surgery, the anesthetist, nursing care in a luxury spa setting, medications, physical therapy, even check-ups after discharge. The all-inclusive set price? \$21,000.

One of the surgeons behind the concept, Owen R. O'Neill, M.D., says, "This is one of the most innovative advancements we've seen in raising quality while reducing costs. There's nothing like it. We've seen surgical centers across the country outsourcing recovery to hotels. But a hotel room can feel almost as impersonal as a hospital and certainly doesn't meet the sanitary qualifications nor the onsite medical rehabilitation the Excel program offers."

Here is how the Excel program works. The patient meets first with his surgeon and Justine Lehman, the nurse practitioner, who will follow the patient through

the entire experience. She will work with the patient's primary care doctor to make certain that there are no unforeseen risk factors. About two weeks before the surgery is scheduled the patient is called in to attend the Excel education camp. Here patients are introduced to the exercises they are to perform both pre- and post-surgery and to hear the entire process carefully explained.

"Our goal with Excel is for the patient to anticipate every single step," Lehman said. "We want our patients to know what is coming next." Surgery takes place at one of Twin Cities Orthopedics Surgery Centers. Four hours following surgery the patient is moved in a special van about three blocks to York Gardens, a premium recovery retreat with suites equipped with wireless, flat screen TV's and kitchenettes. Patients have 24-hour medical and nursing care. Surgeons do rounds daily and an internal medicine group is on call.

Simonson explains that the more they have under their control the more able they are to manage the patient experi-

ence. "We control what the nursing staff is doing at York Gardens, how the pre-operation teaching is done, how prepared the patients are coming in to it, how the physical therapy is going to be done. All of the nurses and therapists have been trained by us and we designed the clinical pathways they follow. They spend time in the surgery center so they understand where the patient is. Everyone is on the same team."

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York Gardens Premium Recovery Suite; Courtesy of Twin Cities Orthopedics Surgery Centers

He credits the role of the nurse practitioner as being a key to the success of the program. Hers is the face patients see from the day they decide to have

surgery all the way through to their post-operative care. She is the one who calls them at home, 24 hours and 48 hours after their return, to run through

a check-list of screening to make sure there are no complications. Nurses at York have 24 hour access to her.

America's Response to Medical Tourism?

Simonson estimates Twin Cities Orthopedics has reduced the cost of the knee replacement procedure by as much as 30% to 50%. "We eliminate the hospital stay cost," he says and "we have gone to two vendors for implants." The program has caught the attention of providers of medical tourism, Simonson notes, "There is an insurance plan here in the Twin Cities that covers an employer in Arizona. They have sent employees to Costa Rica for knee surgery for \$18,000. We are close to matching the Costa Rica cost."

According to a 2009 Deloitte study of medical tourism, 1.3 million patients travel to destinations outside the U.S. for medical care annually. Increasingly U.S. employers have begun exploring medical travel programs as a way to cut employee health care costs. For example, in January 2008, Hannaford Bros., a supermarket chain based in Maine, began paying the entire medical bill for employees to travel to Singapore for hip and knee replacements, including travel for the patient and companion.

In 2000 Blue Shield of California began the United States' first cross border health plan. Patients in California could travel to one of the three certified hospitals in Mexico for treatment under California Blue Shield. In 2007, a subsidiary of BlueCross BlueShield of South Carolina, Companion Global Healthcare, teamed up with hospitals in Thailand, Singapore, Turkey, Ireland, Costa Rica and India.

But what happens when the cost of care in the United States begins to rival that in Costa Rica?

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No Medicare Coverage

And what about Medicare? Medicare pays for a majority of orthopedic reconstruction surgery in the United States. Excel, however, is not covered by Medicare, in part because the surgery is carried out at a day surgery center. “We are trying to figure out where to have that discussion with Medicare,” Simonson said. At present costs are covered by one insurance provider, Medica. Simonson says talks are going on and are close to resolution with other insurance providers. “It will save money but, operationally, they are trying to figure out how we process this one bill. It’s crazy.”

While “innovation” and “Medicare” may appear to be conflicting concepts, the Patient Protection and Affordable Care Act is trying to arrange a shot gun marriage for this odd couple. The union has a name—it is “The Center for Medicare and Medicaid Innovation” and it is a branch of the United States government.

Let’s call it “CMMI”

CMMI was created by the 2010 U.S. health care reform legislation and its stated purpose is “to test innovative payment and delivery system models that show important promise for maintaining or improving the quality of care in Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP), while slowing the rate of growth in program costs”. — said authors Guterman, Davis, Stremikis and Drake in a 2010 article titled “Innovation in Medicare and Medicaid will be central to health reform’s success” which appeared in journal *Health Affairs*.

Finding the front door into the Center may prove to be difficult, however. Also from the *Health Affairs* article, the Cen-



PreOp Room; Courtesy of Twin Cities Orthopedics Surgery Centers

ter “is to give priority to twenty models specified in the law, including medical homes, all-payer payment reform, and

arrangements that transition from fee-for-service reimbursement to global fees and salary-based payment”.

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While pursuing payer support, Simonson is nonetheless planning to simultaneously expand services and says that Twin Cities Orthopedics will soon begin doing hip, shoulder and other orthopedic surgeries in the Excel program.

Their first knee patient, Sharelle Peterson, is an enthusiastic supporter. “Being part of the Excel program, I was able to stay in a place where I didn’t feel sick. I was there because I was recovering. The environment was much more comfortable than the hospital and I received assistance when I needed it much quicker than in my hospital experience in the past. I also saw my surgeon every day.”

Who are These Guys?

For over 60 years Twin Cities Orthopedics has offered a full spectrum of medical care, devoted to the diagnosis, treatment, rehabilitation and prevention of injuries and conditions that affect the body’s muscles, joints and bones. TCO runs 28 clinics located throughout the Minneapolis/St. Paul metropolitan area.

Indeed, Twin Cities Orthopedics is either the second or third (depending on how one counts) largest orthopedic practice in the U.S. with over 83 physicians.

Like Target in Minnesota or Wal-Mart in Arkansas, sometimes the key to delivering consistently high quality ser-



Recovery Room; Courtesy of Twin Cities Orthopedics Surgery Centers

vices and products is logistics. Twin Cities Orthopedics, like other innovative health care providers in this country are exploring innovative, even disrupt-

tive, approaches to changing healthcare delivery in the United States—despite what happens in Washington. ♦

Holy Cow! CME Credit on the Fast Track? and More...

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

STOP Courting Disaster with Kids and Football ... Holy Cow! CME Credit on the Fast Track? ... Boden Laments Innovation Slowdown ... Powerfully Sensitive New Tool Measures Meniscal Trim vs. Repair

Powerfully Sensitive New Tool Measures Meniscal Trim vs. Repair

Christina R. Allen, M.D. is an orthopedic surgeon with the University of California, San Francisco (UCSF). She has received a grant from the Orthopaedic Research and Education Foundation (OREF) for her work on imaging. Regarding her project, "Quantitative MR Imaging Evaluation of Articular Cartilage and Kinematic Changes in the Knee After Meniscectomy," Dr. Allen told *OTW*, "We are looking at changes in cartilage stresses in knee loading conditions after surgery...examining the differences between the surgical knee and the opposite knee. We don't know how long it will take to develop changes on a microscopic level, but this allows us to track how things are changing. Also, we will be able to get information on whether it is best to trim or to repair the meniscus."

"Our system is very sensitive to cartilage changes. The imaging system—"T1-rho"—will pick up structural changes and will let us know how much stress the cartilage is under. We need to know if we are really helping by repairing the meniscus. What about the long term health of the knee? We will have more answers after this work is complete."



Wikimedia Commons and Josh Adkins

STOP Courting Disaster With Kids and Football

Paul Saluan, M.D. is an orthopedic surgeon at Cleveland Clinic Sports Health. He tells *OTW*, "My thoughts turn to football at this time of year. My son started playing football this year, his eighth grade year, for the first time. I was in discussion with one of my co-team physicians on the sidelines of an intersquad collegiate scrimmage over the weekend as well, and our discussion turned to my son starting play at the eighth grade level. We went further and got onto the topic of 1st and 2nd graders in full equipment and full contact football. We both agreed that

this is a recipe for disaster on multiple levels. Kids this age, typically 6-9 years old have a larger head to body ratio than their more fully grown counterparts in 6-8th grades. This leads to less neck control and theoretically more concussion risk. I am not aware of any studies to date on this age group yet, but I have a feeling we will be seeing some evidence in the near future of increased injury risk. It is also hard to refute the fact that these kids will have 4-5 more seasons of lifetime head trauma at a young age than their peers who started playing in 6th grade. We all know that the younger you are when you sustain

your first concussion, the more significant the injury.”

“It is a shame that we continue in the direction of pushing the envelope in younger and younger individuals, because the reality is that once these leagues start, it then becomes the standard approach to the grooming process of that particular sport. It becomes almost impossible for young individuals to competitively progress to the next level without becoming involved in one of these leagues. We need to let kids play more and train less. There is such a thing as ‘too much, too soon.’”

Holy Cow! CME Credit on the Fast Track? Ted Miclau, M.D. is professor and vice chair of Orthopaedics at UCSF and director of the UCSF/San Francisco General Hospital Orthopaedic Trauma Institute (OTI); he has recently led a webinar on technology in orthopedics. He tells *OTW*, “Aside from new implants, technology continues to grow in orthopedics, and there are lot of new resources available to surgeons. They are not only available to those who can go to meetings or live in urban areas...

those in rural areas and those abroad can benefit as well. Mo Bhandari, M.D., who is with McMaster University, has spearheaded a novel online resource called MyorthoEvidence.com. It allows doctors throughout the world to look up the best evidence available for any given orthopedic problem. The site emphasizes the vast growth in the amount of papers available, and attempts to help interpret them.”

“Another terrific web based option is VuMedi.com, a surgical video site established by Roman Giverts when he was a graduate student at Berkeley. He has an enormous amount of videos from academic institutions and he has a database of 40,000 surgeons who have signed up from all over the world. Remote conferences are also the wave of the future. I recently moderated a session on current controversies in orthopedics where we had four panelists who were all participating remotely. We had some of the most interesting talks I’ve ever heard on the subjects. The project ran quite smoothly, and we had substantial participation—220 people from around the globe. There were live, interactive

question and answer sessions; also, CME credit was available.”

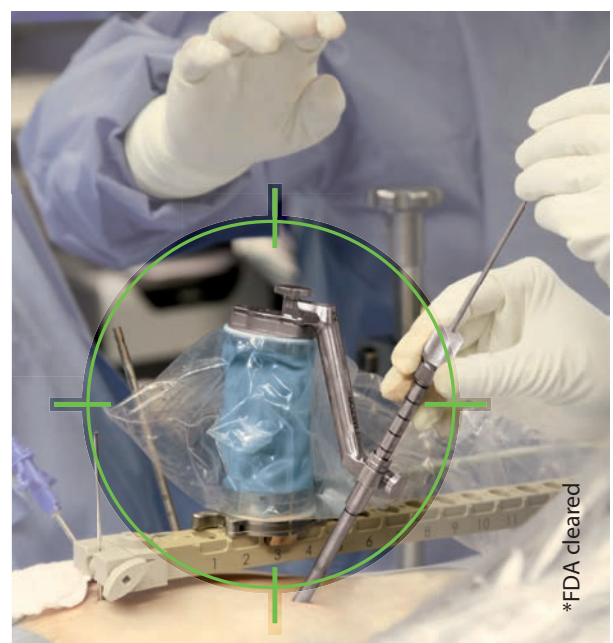
“In addition to surgeon education, technology is also burgeoning in that more and more journals are available online, and thus an increasing number of surgeons abroad are able to access top orthopedic publications. Additionally, there is telemedicine, wherein we use the Internet to provide clinical care at a distance. Our program has just received a grant to use telemedicine to improve clinical treatments, and this technology can also be used following disasters. There are obstacles to the adoption of telemedicine, however, such as infrastructure development. You could do rudimentary telemedicine if you had a simple Internet connection, but the important thing is that both places—the location that is broadcasting and the location that is ‘receiving’—are compatible. There is also an issue with lack of acceptance by government payers or insurers, medicolegal liability (because you’re not actually seeing the patient), the regulatory challenges involved in treating patients across state lines, etc. Given these challenges, the low lying

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fruit for telemedicine is to treat patients within one's own state, and to treat people in rural areas where there is no specialist care. “

“Lastly, technology is progressing in the area of global research. We are working with Mo Bhandari's group to develop a global database of the incidence of global trauma. More and more surgeons abroad have access to the Internet, but they still need direction and a coordinating center to maintain the database. In due time, this will progress as well.”

Newly Minted Orthopedists Establish Three Awards Mark Morrey and Matt Abdel met at the University of Wisconsin (UW) School of Medicine and Public Health, and were both drawn to the idea of helping others. Both Drs. Abdel and Morrey have recently completed their orthopedic surgery residencies at the Mayo Clinic and have just begun the terms as Mayo Scholars, which involves traveling the globe to further their education. Not wanting

to leave their UW medical students behind, the duo has established three endowed scholarship funds to benefit medical students from the University of Wisconsin. Students may apply for the Abdel-Morrey Orthopedic Surgery Award, the Class of 2007 Excellence in Orthopedic Surgery Award, and the Philip M. Abdel Memorial Scholarship.

Boden Laments Innovation Slow-down Scott Boden, M.D. is director of The Emory Orthopaedics & Spine Center and professor of Orthopaedic Surgery at Emory University School of Medicine. Dr. Boden has been thinking a lot lately about innovation. He tells *OTW*, “My concern in the current financial and regulatory climate is that few device companies are willing to make the longer term investments in highly innovative new products and technologies, but instead are focusing on 510(k)-approvable often ‘me too’ type products with a shorter approval process. A second concern stems from the potential impact on health care

consolidation over the next few years and what the impact will be on smaller start up companies that are often the source of some of the more innovative advances.”

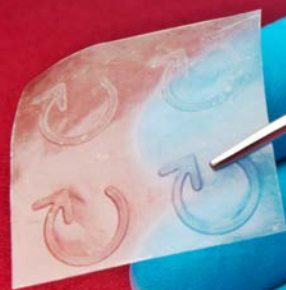
“I think the rate of new technology innovation will slow for a couple reasons. The economy is causing much pressure for companies to produce short term numbers. Also, major innovations often require long PMA [premarket approval] approval process, and with the uncertainty of health care reform and pricing pressure, companies are more reluctant to make those longer term investments.”

Asked how he would proceed if he were at the helm of a commission to promote innovation in the field, Dr. Boden told *OTW*, “One of the biggest challenges to new technology is the cost required to actually prove their value. I think I would try to incentivize value-based products somehow rather than me-too products.”

Tim Morris New VP at EOS Tim Morris, formerly the General Manager at Trumpf North America, is now Vice President, EOS of North America, Inc. Morris spent ten years at Trumpf, where, among other things, he oversaw the sales and service activities of the Laser Technology Division. Morris has worked in a wide range of other fields, including aerospace, automotive, medical, and consumer electronics. At EOS, Morris will be involved in managing sales/marketing, service/application engineering and administration. He will also oversee the EOS of North America, Inc. family of companies such as Advanced Laser Materials (ALM) and Integra, which specialize in researching and developing engineered materials for additive manufacturing processes, along with providing comprehensive customer support. ♦

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Paprosky, Kyle Debate Extended Osteotomy

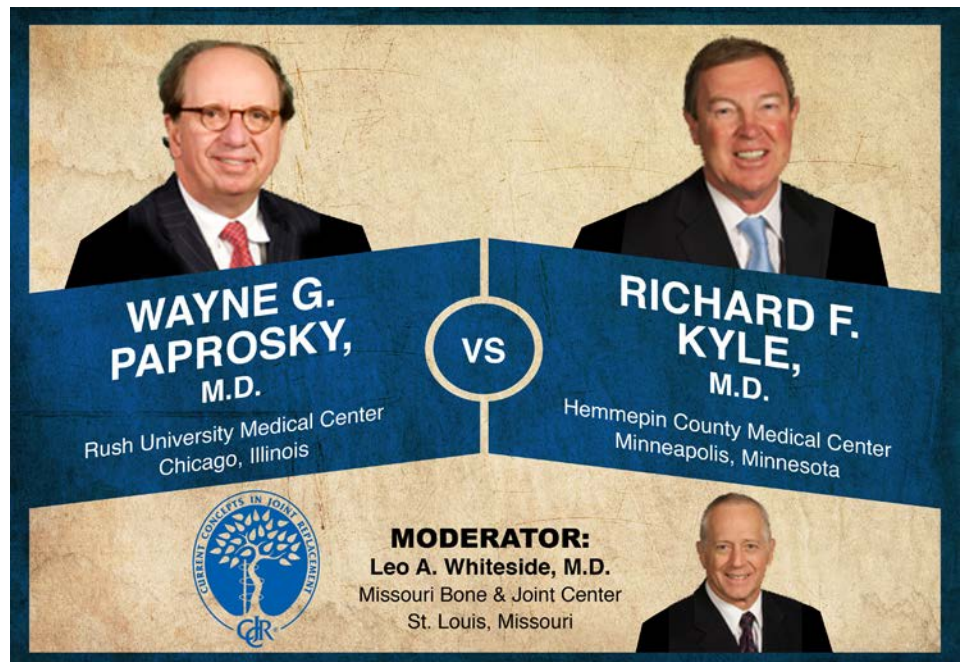
By Elizabeth Hofheinz, M.P.H., M.Ed.

With extended trochanteric osteotomy “You get unparalleled exposure and it addresses all of these issues to enhance the potential for results. What’s not to like?” asserts Wayne Paprosky. “Osteotomy is the gold standard, but there is a place for the slot... 100% union rate, no problem with ingrowth and the intraoperative fracture is less,” counters Richard Kyle.

This week’s Orthopaedic Crossfire® debate is “Cemented Stem Failure Requires Extended Trochanteric Osteotomy.” For the proposition was Wayne G. Paprosky, M.D. from Rush University Medical Center in Chicago. Against the proposition was Richard F. Kyle, M.D. of Hennepin County Medical Center in Minneapolis; moderating was Leo A. Whiteside, M.D. from Missouri Bone & Joint Center in St. Louis.

Dr. Paprosky: “You must look at the main problem when revising the cemented stem. You want improved exposure... don’t break the greater trochanter, be able to get the component out as well as the cement. Ideal conditions would certainly be to put the component back in, so you need a straight tube. Try to use the shortest possible stem that gives you fixation. You want the trochanter to heal, so it should have a broader surface area to heal... and you don’t want it to dislocate.”

“Over the years we have published data on several studies; our average from the time of beginning the osteotomy to prosthetic insertion is about 35 minutes—this is after the acetabulum is done. We know that the proximal femur isn’t supportive anyway in most of these



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cases where you’re going to consider doing an osteotomy. Many of these are remodeled into varus, and we’re using distal fixation so basically that upper circular femur really isn’t providing a lot of value to the situation.”

“You can do an extended osteotomy before dislocation, such as when you have a subsided stem, a lot of scarring, heterotopic ossification, a protrusion-migrated acetabular component and so forth. You can also do it after dislocation, when the stem is well fixed. The most common time to do this with respect to cement is when the stem is loose and after dislocation. This has become very attractive procedure in dealing with cement removal. We go along the posterior linea... we do the distal feathering to avoid propagation stress fractures and then we can do a microsaw to open it up. Now we can advance the oste-

otomy when we reattach the greater trochanter, making sure that we advance it posteriorly somewhat to increase the tension. And it is kind of like an orthopedic orgasm, removing that cement under direct vision. You can get access to the distal cement as well, and those little areas of well-fixed cement that can get you in trouble, especially when the femur is remodeled.”

“In the case of an encased heterotopic ossification, you have well fixed cement and the stem has subsided. You can do the osteotomy down to the tip of the stem; grab the stem by the tail, pull it out, making reinsertion very easy. With long cement canals it makes a lot of sense. We feel now that almost 45-50% of these canals are remodeled in varus. To try and achieve 4 cm of distal fixation with an 8 or a 10 inch stem... well, it is difficult to get it in. You’re likely to

break the trochanter or it's going to go out the side of the femur.”

“Osteopenic or osteolytic greater trochanters are at risk. Most importantly, an extended proximal trochanteric osteotomy allows for neutral reaming because of the remodeled femur. Our average 12-year follow up: we had only two non-unions, bone ingrowth was present 92% of the time and there are fairly low complications so we feel this is a safe, efficient and accurate method of revision of cementless or cemented stems. You get unparalleled exposure and it addresses all of these issues to enhance the potential for results.”

Dr. Kyle: “Removal of well fixed cement is daunting, especially when there's a very long cement tail and a well fixed cement column—I've seen these a lot when we were doing hybrids with very small stems and in bigger people with very thick cortical canals. The blind technique has been abandoned: it's spe-

cialized hand tools, ultrasound, fluoroscopic guidance, and some laser. The biggest problem is postoperative fractures at 28%, and fractures are problematic because most of the time they need to be fixed—particularly if it's in a postoperative period, it's a disaster.”

“I agree...the extended trochanteric osteotomy is the gold standard. There is an alternative, and one of the problems I've seen are iatrogenic fractures during surgery, which is a much better deal than postoperatively with the blind technique—and it's been reported up to 20%. Femoral windows can be an alternative...introduced by Muller in 1970. Harry Rubash did a study in 1993 and had no intraoperative fractures and very good results. We've looked at a small series and reported on those: the results are similar to Wayne's. We've had excellent results, but the difference is the complication in intraoperative fractures, which was only 3%.”

“We did some biomechanical studies...we looked at an intact femur, a cut and a wired construct. The slot was biomechanically stronger in bending. The biggest difference was in torsion where with the slot we retained about 60% strength compared to 20% with the slide. Then after wiring it was still quite a bit stronger.”

“The slot technique is not in the varus femur, it's in the straighter femur. We measure down to the cement canal, remove the cement proximally as needed and then extend the incision. We open up the vastus lateralis and take a Christmas tree burr and measure preoperatively the length of the cement mantle, and particularly the very long cement mantles that go all the way down to the diaphysis are problematic. I use mostly curved revision prostheses that are fully coated. Once that window is outlined we can remove that window,

look at the cement, and use a small hook osteotome to remove the cement.”

“The femoral component is inserted, and again you can see it bypass the window, but you've maintained the tube all the way down. The key is to get the prosthesis back into valgus and then put the slot back in. Lateral trochanteric bone is removed, you use an extensively porous coated canal filling stem. You bypass the slot by at least two femoral diameters and you reinforce the slot with cortical strut only if the bone is very osteoporotic and deficient.”

“I use the slot frequently: 100% union rate, no problem with ingrowth and the intraoperative fracture rate is less. Osteotomies are length limited because you don't want to go down into the metaphysis in difficult cases...and there is a slight increase in incidence of fractures. The slot is a bit stronger and all cement, including the very distal tip, is removed under direct vision. In conclusion, the extended femoral slot is a safe and effective technique for cement removal during revision total hip arthroplasty.”

Moderator Whiteside: “Wayne, how often in the process of elevating that extended osteotomy does the greater trochanter fragment, fall off and actually separate from the diaphyseal segment?”

Dr. Paprosky: “It's not going to happen very often when the stem is out because then you can increase the thickness of the osteotomy fragment. However, when you have a large, bulky stem, especially cementless that's ingrown, and an osteolytic greater trochanter, the chance of fracture is higher. In those cases removing a well fixed stem, it's probably in the range of 15%.”

Moderator Whiteside: “What happens when you break off the greater trochan-

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ter? You've elevated your osteotomy and you find the greater trochanter just breaks into an osteolytic lesion and separates. How do you repair that later?"

Dr. Paprosky: "In many of these revisions when the fracture occurs it's almost like a trochanteric slide. You have the abductor mechanism intact with the vastus lateralis and by the time you put your new implants in, and with the scar tissue that's there, it often is not a big problem."

Moderator Whiteside: "So you don't do a big repair on that?"

Dr. Paprosky: "If I can, but I'll certainly do the repair but most of the time there's nothing there—there's not a big downside to it."

Moderator Whiteside: "That may be a significant difference between the slot and the greater trochanteric slide. What do you think, Dick?"

Dr. Kyle: "I try to ensure the slot is below the lesser trochanter and then I'm very careful when I ream. I'll protect it so when you're reaming you protect it against hoop stresses. I haven't had a problem, but the one fracture we had was of the trochanter. I agree with Wayne completely...if it's just a crack and seems stable I might use a cerclage wire and leave it alone. But if it's completely dissociated then I'll use a hook plate."

Moderator Whiteside: "But my impression from your talks is that you're probably less likely to break off the greater trochanter."

Dr. Kyle: "I've actually used the slot a lot and it's rare that I break the trochanter off, but I pay particular attention—and this is where the difference is—you must get back into the trochanter to get a long stem down and not put it in varus. So you have to clean out the bone in the back of the trochanter. If you don't, you'll break the trochanter—in a primary or a revision."

Moderator Whiteside: "Which is an advantage of the extended trochanteric osteotomy?"

Dr. Kyle: "In the varus hip, yes."

Moderator Whiteside: "Infection: you have a well fixed cement mantle, but an infected total hip...do you still feel free to do a big slot osteotomy, lift off that bone and put that dead bone piece back in (in the face of a cleaned up infected area)?"

Dr. Kyle: "In an infected total hip I think either a slot or an osteotomy is problematic. I'd try to get it out from the top, but personally I would rather have the slot down there and not put it back in right away."

Moderator Whiteside: "You'd leave the slot out?"

Dr. Kyle: "I'd do as small of a slot as I could and probably leave it out when I go back in...put an allograft on it. Sometimes I've actually put either a prosthetic that's coated with cement so it bridges that or I'll take an intermedullary rod and coat it with cement."

Moderator Whiteside: "That may be one of the differences between the two

techniques. Wayne, do you think you preserve the vascularity of this greater trochanteric slide such that you could open a femur in the face of infection and then put that back down?"

Dr. Paprosky: "Yes, we maintain the vascularity. Craig Della Valle and I published a paper on this and they all healed...all different organisms...and we reosteotomized in many of the cases. Actually, I think because of vascularity it's probably safer to put it back and let it heal in the face of infection."

Moderator Whiteside: "Wayne, when you put everything back together and the tip of the stem is at the end of your osteotomy, do you ever leave it like that?"

Dr. Paprosky: "If you're using a fully coated stem you should have bypassed it."

Moderator Whiteside: "But you can't do it...too far down."

Dr. Paprosky: "Then you've probably done the osteotomy too far down."

Dr. Kyle: "I like to have the ability to keep that tube intact and go all the way down and that's the limitation of the osteotomy."

Moderator Whiteside: "Thanks, gentlemen." ♦

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

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Federal Judge Rejects Orthofix/DOJ Deal in Boston

A federal judge in Boston has rejected a previously signed plea agreement between the Department of Justice and Orthofix, Inc. to resolve a bone growth stimulation criminal investigation.

“It seems in this case the court’s hands ought not be tied,” U.S. District Judge William Young told prosecutors and Orthofix lawyers at a September 6 hearing, according to a Bloomberg report. “I have extreme unease of treating corporate criminal conduct like a civil case.”

The Bloomberg report said:

“It is unclear whether Young’s refusal to accept the plea also scuttles Orthofix’s agreement to pay \$34.2 million to resolve civil claims first raised in a whistleblower’s lawsuit that the company defrauded the federal Medicare program through payments to doctors who used its bone-growth stimulators.

“It’s an unusual situation,” David Schumacher, an assistant U.S. attorney handling the Orthofix case, said in an interview after Young rejected the plea.

Neil Getnick, a New York-based lawyer representing the whistleblower, said in a telephone interview with Bloomberg that he couldn’t immediately comment on whether Young’s rejection of the plea would affect the settlement of the whistleblower claims.”

Orthofix Remains Confident

Robert Vaters, Orthofix International N.V.’s president and CEO, said the company and the government stand behind their agreements and continue to discuss a resolution to the matter following the court’s rejection of the plea. “We remain confident that this matter will be resolved amicably and in a manner that is in the best interests of our shareholders,” said Vaters in a September 6 press release.

In a September 7 press release, the company also noted, “As matter of law,

a federal court must determine whether there is a factual basis for a criminal plea offered by a defendant and, if it accepts the plea, will then impose its sentence. Federal Rule of Criminal Procedure 11(c)(1)(C) allows criminal defendants to agree with the government, before offering a plea, on a recommended sentence, which becomes binding on the court if it accepts the plea. Orthofix Inc., like other corporate defendants, had previously entered into such an agreement as part of the resolution of the government’s investigation.”

—WE (September 7, 2012)



Orthofix International N.V.

LDR Introduces FDA-Cleared Lateral Lumbar Cage

LDR Holding Corporation says it is the first company to introduce a lateral lumbar cage with integrated in-line plating into the U.S. market.

So says, Christophe Lavigne, president and CEO of LDR as the company announced FDA clearance of the Avenue L Lateral Lumbar Case System on September 4, 2012.

The system, according to the company, “represents the pinnacle of lateral lumbar fusion, featuring enhanced in-

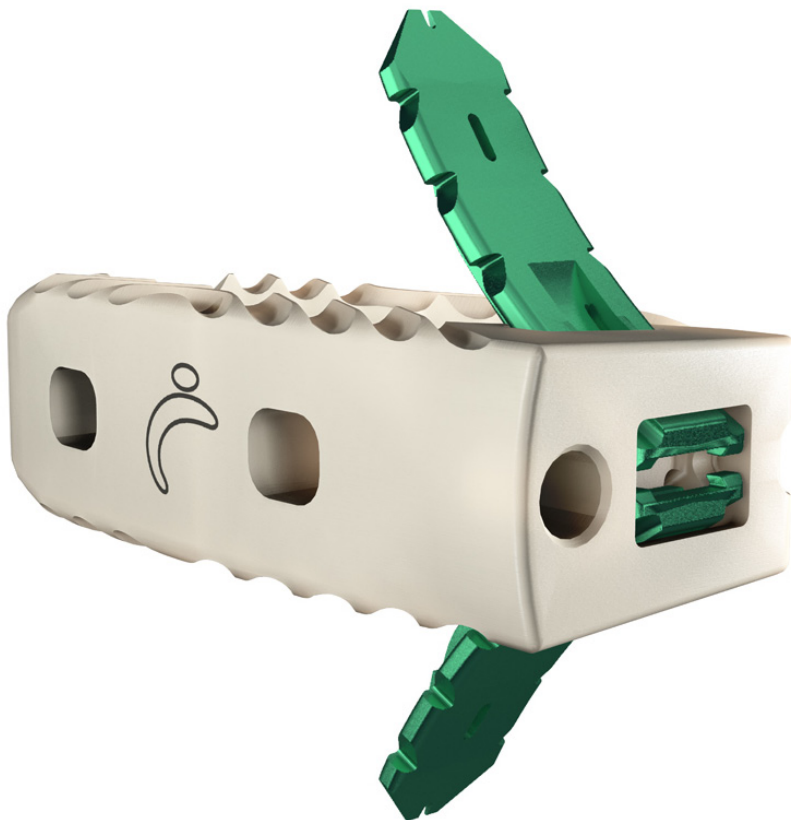
line, self-guided VerteBRIDGE plating technology to facilitate simplified cage insertion and zero-profile, intradiscal, integrated fixation all through a direct, minimally invasive approach.”

The system’s cage and self-guided, curved VerteBRIDGE plating are delivered in the plane of the disc through a minimally invasive direct lateral approach, so that the implantation may, according to a company press release, be achieved with less exposure than may be required of other lateral systems with integrated screws that must be inserted at divergent angles. “The system features thoughtfully designed instrumentation including an inserter

that protects anatomical structures while implanting the cage and plating. Avenue L has been implanted via a prepsomatic approach without neurological monitoring in Europe, and is also compatible with the direct lateral transpsomatic approach common in the United States. The Avenue L lateral cage has been used in Europe since 2010 with over 300 cases completed.”

Faissal Zahrawi, M.D., founder of the Celebration Minimally Invasive Spine Institute in Celebration, Florida implanted the first Avenue L lateral lumbar cage in the U.S. He said, “Direct lateral lumbar surgery is the perfect application of LDR’s integrated VerteBRIDGE plating. I appreciate that the in-line plating can be deployed in the plane of the disc without requiring additional or prolonged retraction of the Psoas. Avenue L with integrated VerteBRIDGE plating gives me confidence in the stability of the cage, increases my treatment options and allows me to deliver better care to my patients.”

A French surgeon, Alexis Faline, M.D., of the Centre Orthopédique SANTY, one of the initial users in Europe, said, “I have found Avenue L to be an extremely versatile and reliable system. The cage design includes a generous surface area which may help to promote solid fusion, and a wide variety of sizes that addresses diverse patient anatomy. The VerteBRIDGE plating provides immediate, additional stability without having to alter my exposure. Avenue L has been an important addition to my surgical practice for lumbar degenerative conditions, through a prepsomatic approach, and I am very pleased with the clinical results that I have observed in my patients.”



Avenue L Lateral Lumbar System / LDR Holding Corp.

—WE (September 4, 2012)

MedCure Opens European Tissue Bank

MedCure, Inc., a non-transplant tissue bank that connects whole-body donors to medical research and education, will open a tissue bank in Amsterdam, Netherlands, in September. This tissue bank will be the first of its kind in the region and will provide human cadaveric tissue specimens to universities, researchers and educators in Europe.

April Salisbury, CEO of MedCure, says “This is an exciting opportunity for the firm’s European partnerships. Access to quality cadaveric anatomical specimens is fundamental to medical health technology advancement. Our European location will provide greater access to our services and enhance research within the medical community.”

Company officials note that traditionally it has been difficult for researchers and physicians in Europe to acquire un-

embalmed cadavers for their research, education or surgical training. Salisbury notes that, “Un-embalmed cadavers provide an exact representation of human anatomy, including the variation from individual to individual, unlike any available anatomical models.”

Orhan Arslan, M.D., course director of anatomy at the University of Southern Florida Health, agrees that there is no substitute for a human cadaver for teaching. “The virtual approach cannot substitute for the real thing,” he says. “It cannot be taught by looking at slides or listening to a lecture.”

MedCure was founded in 2005. The corporate office is located in Portland, Oregon with additional sites in Florida, Rhode Island and Nevada. Surgical Training Centers for physicians to learn advanced surgical procedures are located in Henderson, Nevada; Cumberland, Rhode Island; and Portland, Oregon.

—BY (September 2, 2012)

Medtronic Opens Chinese Innovation Center

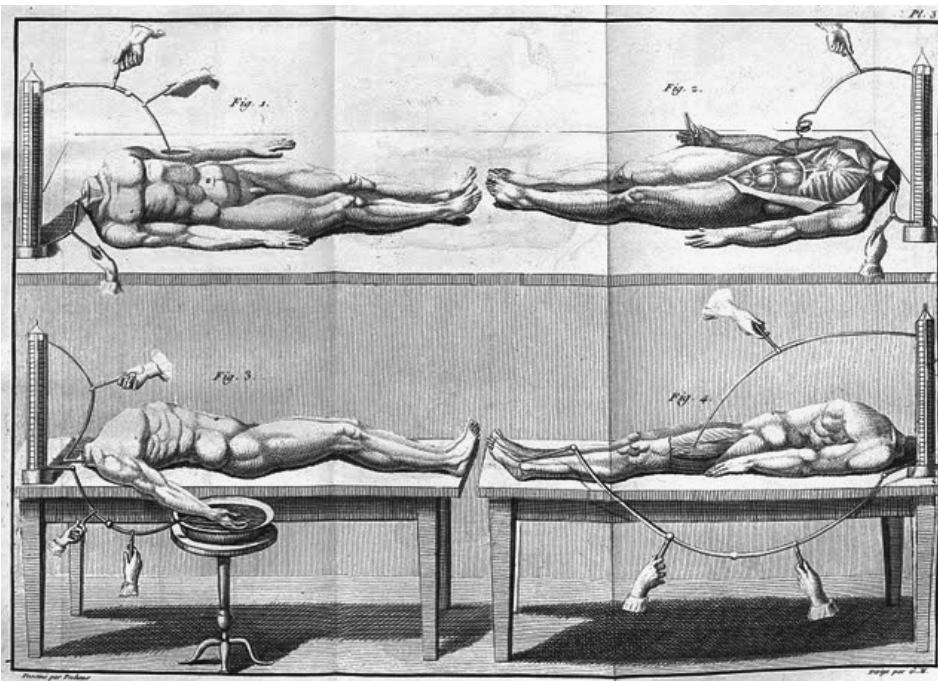
Medtronic, Inc. has officially opened an Innovation Center in Shanghai, China.



Innovation Center, Shanghai, China / Courtesy Medtronic, Inc.

In an August 27 announcement, the company said the new facility, located in the company’s China headquarters and the first outside the U.S. and Europe, “represents the company’s initial step in creating local product research and development in China.” The Center will work closely with Medtronic’s global research and development teams, as well as local universities and research institutions.

More importantly, said Medtronic Chairman and CEO Omar Ishrak, the Center will allow the company to partner with Chinese physicians to create innovative solutions for patients. “It



Experiments with headless cadavers (1804) Source: Wikimedia Commons and Giovanni Aldinni

allows us a unique opportunity to leverage local talent and expertise to increase our growth in China and link it to our larger global capabilities,” said Ishrak.

Medtronic Greater China is headquartered in Shanghai and has business operations at mainland, Hong Kong and Taiwan offices. Medtronic opened its first office and built a pacemaker assembly line at Shanghai Zhangjiang High Tech Park in 1996. In 2008, Medtronic made a 15% equity investment in Weigao Group, a local leading medical device company, and formed a joint venture with Weigao. In August 2010, Medtronic opened the company's first patient care center in Beijing, China,

The Weigao joint venture markets China Medtronic's spinal products and Weigao's orthopedic products which include therapies for the hip, shoulder, spine and trauma.

Ishrak has said globalization is a key strategy and driver of growth for Medtronic. “We have already accelerated our efforts to expand in emerging markets, including China, through additional investments in people and infrastructure, and the Shanghai Innovation Center is an example of our work to transform ourselves into a truly global organization.”

The company press release noted that China has become the fastest growing region among all the emerging economies. To serve the ever-growing Chinese healthcare sector, Medtronic will hire and train an additional 1000 skilled staff over the next five years, hundreds of which will work toward the development of new medical technologies within the Innovation Center.

—WE (August 30, 2011)

legal

FDA Calls Public Postmarket Surveillance Meeting

The Food and Drug Administration (FDA) is holding a public meeting on September 10, 2012 to solicit public feedback regarding FDA's proposal to strengthen the national medical device postmarket surveillance system.

Prior to this public meeting, FDA intends to issue a preliminary report on plans to strengthen the medical device postmarket surveillance system in the U.S.

You can attend the meeting in person in Greenbelt, Maryland, or attend via a Webcast.

There have been some high profile cases of approved devices having to go back and perform 522 Postmarket Surveillance Studies. Makers of metal-on-metal hips and certain spine stabilization systems are currently undergoing postmarket studies.

Medical device manufacturers as well as other firms involved in the distribution of devices must follow certain require-

ments and regulations once devices are on the market. These include such things as tracking systems, reporting of device malfunctions, serious injuries or deaths, and registering the establishments where devices are produced or distributed. Postmarket requirements also include postmarket surveillance studies required under section 522 of the act as well as post-approval studies required at the time of approval of a premarket approval (PMA), humanitarian device exemption (HDE), or product development protocol (PDP) application.

If you wish to attend this meeting in person, you must register online by September 10, 2012. If you wish to view this meeting by Webcast, you must register by close of business on September 5, 2012.

There is no fee to register for the meeting and registration will be on a first-come, first-served basis. Early registration is recommended because seating is limited.

If you wish to make an oral presentation during an open comment session at the meeting you must indicate this at the time of registration. FDA requests that presentations focus on the areas defined in the Federal Register Notice.

You should also identify which discussion topic you wish to address in your presentation and you must submit a brief statement that describes your experience and/or expertise relevant to your proposed presentation. In order to keep each open session focused on the discussion topic at hand, each oral presentation should



Source: FDA.gov

address only one discussion topic. FDA will do its best to accommodate requests to speak.

Meeting Topics

Specific topics of interest include, but are not limited to, the following:

1. The unique device identifier system and its incorporation into health-related electronic records;
2. national and international device registries for selected products;
3. adverse event reporting and analysis; and
4. developing and using new methods for evidence generation synthesis and appraisal.

These topics will also be discussed in relation to the Sentinel provision in the FDA Safety and Innovation Act calling for the expansion of the postmarket risk identification and analysis system to include devices.

Key questions for feedback include:

- Are these the right efforts?
- What principles should drive these efforts?
- What are the attributes of an effective “active surveillance” system for devices?
- How can the device active surveillance system leverage existing systems (e.g., Sentinel)?

Following public comment, FDA intends to have a moderated discussion session.

For further information, click here: <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm300721.htm>

—WE (August 30, 2012)

Medtronic Sues NuVasive, Again

NuVasive, Inc. and Medtronic, Inc. are in a dispute again over some Gary Michelson-based technology.

NuVasive disclosed in an 8-K SEC filing on August 23 that Medtronic, through its subsidiary, Warsaw Orthopedic, Inc., was asserting additional patent claims against the company in ongoing patent litigation.

Specifically, the complaint filed by Medtronic in the U.S. District Court for the Northern District of Indiana alleges that various NuVasive spinal implants (including its CoRoent XL family of spinal implants) infringe U.S. Patent No. 8,021,430, and that NuVa-

sive's Osteocel Plus bone graft product infringes U.S. Patent No. 5,676,146 C2. These additional patents expire in the next three to four years. Osteocel Plus is the product NuVasive acquired from Osiris Therapeutics Inc. and was called Trinity.

NuVasive strongly denies infringing any valid claims of these additional patents and intends to defend the lawsuit vigorously. NuVasive is assessing all offensive and defensive measures available to it, including the assertion of counterclaims and the use of administrative reexamination procedures available through the U.S. Patent and Trademark Office.

Medtronic wants compensatory damages from profits lost to the firm and an order to halt the NuVasive's alleged



Image created by RRY Publications. Sources: Corporate logos

infringement. Legal issues between Medtronic and NuVasive date back to 2008 when Medtronic filed an even larger lawsuit involving nine additional instances of alleged patent infringement technology, including NuVasive's MaXcess Retractor System and Helix ACP Cervical Plates.

Rulings on the majority of those counts are still in progress.

The first phase of the trial included three disputed claims by Medtronic and one disputed claim from NuVasive. Each claim had a favorable outcome for the company that filed. In 2011, Medtronic won all three cases entitling it to \$101 million in lost profits and royalties. NuVasive was awarded \$660,000.

Phase II of the trial is set to begin January 2013.

Industry Impact

GlobalData analyst Joseph Gregory writes that the recent string of IP lawsuits has "likely sent a wave of concern and opportunity. Medtronic received a substantial sum in the first phase of the 2008 trial. At the time of the verdict, this was the fourth-largest patent infringement claim in history. Marketplace competitors, such as DePuy Spine, Zimmer and Integra, may see this result as an opportunity to take similar legislative action against other competitors to reap comparable sums. At the same time, these competitors may begin to reexamine their legal coffers to ensure ample funds are available should these types of lawsuits befall them. GlobalData estimates that the global spinal fusion market will grow to a value of \$7.8 billion by 2018."

—WE (August 29, 2012)

large joints

Female Athletes More Vulnerable to ACL Tears

Blame it on Title IX. Soccer, basketball and volley ball—These are sports that require quick turns and abrupt landings. Girls who play these sports are up to eight times more likely than boys to rupture the anterior cruciate ligament of their knee, according to Joe Miller, writing for the *Charlotte Observer*.

In 1971 before the passage of Title IX—the law that mandated equal opportunities for males and females in sports that receive federal funding—approximately 290,000 females participated in high school athletics. After Title IX, by 2010, that number had soared 100 fold to nearly 3.2 million. And so had the number of injuries to female knees.

Miller quotes William Garrett, M.D., an orthopedic surgeon and team physician for Duke University, saying, "When I see the women making sudden stops on hard floors, or the gymnasts make a landing on the floor exercises—I cringe

every time." The reason is the fact that the anterior cruciate ligament, one of four major ligaments in the knee has, since the 1970's, proven to be a ticking time bomb for post-pubescent female athletes.

Why are female athletes more vulnerable to these types of injuries? Doctors speculate that it may relate to biological differences. Since the higher risk does not occur in women until puberty, estrogen may play a key part. Males see an increase in testosterone around this time, girls see an increase in estrogen, which may make tendons such as the ACL more relaxed, and thus more susceptible to injury.

Miller reports on an area of study that looked at the anatomical differences between boys and post-puberty girls. According to James Fleischli, M.D., with the OrthoCarolina Research Institute in Charlotte, females at this age are more apt than boys to be knock-kneed, to have weaker hip muscles and to have dominant quadriceps vs. hamstrings. This causes girls to stand more upright, with knees extended when they land or make sudden turns, which may stress the ACL.

Researchers at the Sports Medicine Research Laboratory at UNC-Chapel Hill have developed a regimen of exercises designed to help prevent ACL injuries. When a tear occurs, treatment typically requires surgery to replace the torn ligament, then months of rehabilitation to restore strength and range of motion. Overall recovery, with rehabilitation, can take seven to nine months, or even up to a year.

—BY (September 2, 2012)



Soccer – USA vs. Japan. Source: Wikimedia Commons and Joel Solomon

Adipose Stem Cells and Musculoskeletal Healing

A research team from the Georgia Institute of Technology Stem has found that stem cells isolated from fat may be a good treatment option for tissue damage and diseases because of their accessibility and lack of rejection. New research published in BioMed Central's open access journal *Stem Cell Research & Therapy* shows that this is not as straightforward as previously believed, and that fat-derived stem cells secrete VEGF and other factors, which can inhibit cartilage regeneration. However pre-treating the cells with antibodies against VEGF and growing them in nutrients specifically designed to promote chondrocytes can neutralize these effects.

The researchers found that adipose stem cells (ASCs) secrete large amounts of factors, especially the growth factor VEGF, which prevent cartilage regeneration and actually causes the death (apoptosis) of chondrocytes along with the formation of blood vessels. Treating ASCs with medium designed to encour-

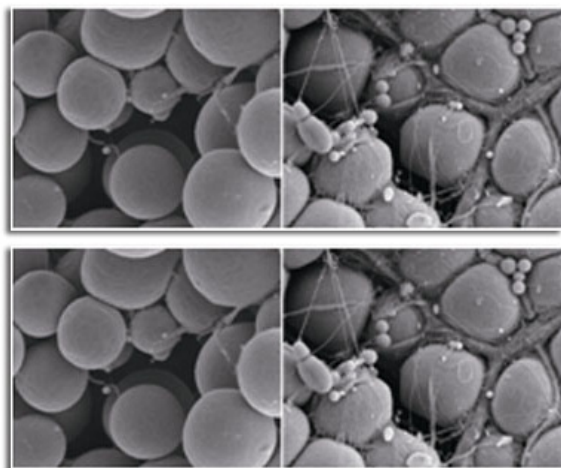
age their differentiation into cartilage cells was able to reduce the amount of these secreted factors and also prevented the growth of blood vessels. Specifically, an antibody designed to neutralize VEGF prevented chondrocyte apoptosis.

Professor Barbara Boyan, who led this research, explained in the August 23, 2012 news release, "Non-treated ASCs actually impeded healing of hyaline cartilage defects, and although treating ASCs improved the situation they added no benefit to compare to cartilage allowed to heal on its own. However we only looked at cartilage repair for a week after treatment, and other people have shown that two to six weeks is required before the positive effect of ASCs on influence cartilage regeneration is seen."

Asked what is the most important thing for orthopedists to know about this work, Dr. Boyan told *OTW*, "Multipotent stem cells are present in fat and have great potential as therapeutics for treating musculoskeletal conditions, but we need to understand much more about them before we use them clinically. While we can manipulate them in many ways in cell culture, their behavior in tissue may be very different than the intended outcome. There is still much to learn."

As for where they go from here, Dr. Boyan stated, "We are studying methods for controlling the delivery of stem cells to treatment sites and for ensuring that the intended clinical outcome can be achieved."

—EH (August 31, 2012)



Fat stem cells. Source: Wikimedia Commons and Mulberrifful

biologics

Windpipe Doc Invents Torn Meniscus Bandage

It sounds like a crazy idea but it should be taken seriously because the proponent, Anthony Hollander, M.D., who was involved in the world's first successful windpipe transplant in 2008. Hollander has used similar technology to develop his latest idea—a stem cell bandage for patients with torn knee cartilage.

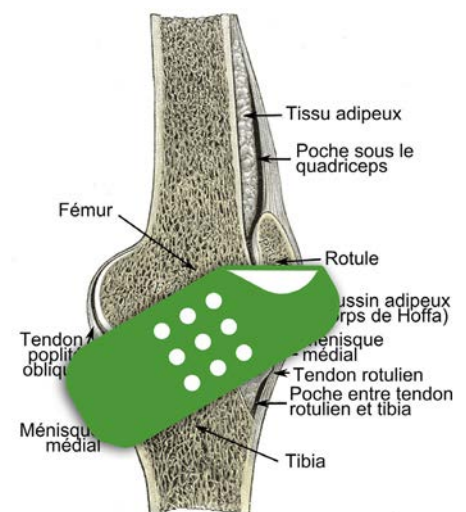


Image created by RRY Publications, LLC Sources: Wikimedia Commons, CDC and Gray's Anatomy

The bandage uses a patient's own stem cells and was developed for commercial use by a Bristol University, England, spin-out company called Azellon Ltd. For the initial phase, Hollander is recruiting 10 patients with torn meniscal cartilage who will have the bandage implanted in their knees in a procedure at Southmead Hospital.

Patients who have been diagnosed with torn meniscal cartilage following an MRI scan will have a small operation to take a sample of bone marrow from their hip. The stem cells taken from the bone marrow will be sent to the lab to grow them on the membrane, called a bio-scaffold, which forms the basis of the bandage. Two weeks later the bandage will be sent back to Southmead for an arthroscopy operation, using a small camera, to implant the bandage into the site of the injury.

Patients will be advised not to stand for a few weeks after the procedure. They will then be followed-up on a regular basis for 7 years. Hollander said, I am very excited. This is the culmination of many years of research. This is about turning science and ideas into reality. We can now begin the process to find out if it is safe and helps these patients.

He went on to explain, “Patients like this because there is no risk of rejection. These patients are often as young as 18, 19, and 20 and within five to ten years of a standard operation to remove the damaged part, they may need an artificial knee by the time they are in their 40s or 50s, which is not a good outcome at all. So the bandage should give these patients quality of life and reduce the cost for the health service.”

The trial will run through the rest of this year and Hollander hopes that, within a year, the researchers will have their first results.

—BY (September 4, 2012)

Blood Cells Reprogram into Embryonic State

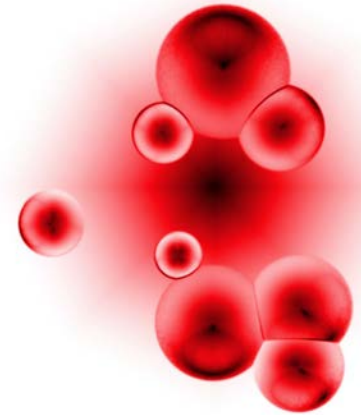
When is a blood cell not a blood cell? When scientists from John

Hopkins turn it into a stem cell that looks and behaves as it did when it was part of a six-day-old embryo. Elias Zambidis, M.D., Ph.D., Assistant Professor of Oncology and Pediatrics at the Johns Hopkins Institute for Cell Engineering and the Kimmel Cancer Center, has coaxed adult blood cells to become induced-pluripotent stem cells (iPS)—adult cells reprogrammed to an embryonic-like state, and bearing unprecedented efficiencies.

Zambidis says his team has managed to develop a “super efficient, virus-free” way to make iPS cells. Generally, out of hundreds of blood cells, only one or two might turn into iPS cells. Using Zambidis’ method, 50-60% of blood cells can be engineered into iPS cells.

Zambidis’ team also found a way around the use of viruses to convert the cells to a stem cell state. Traditionally, scientists have used viruses to deliver a package of genes to cells to turn on processes that convert the cells from one type (such as skin or blood) back to stem cell states. However, viruses used in this way can mutate genes and initiate cancers in newly transformed cells. To insert the genes without using a virus, Zambidis’ team uses plasmids, rings of DNA that replicate briefly inside cells and then degrade. The blood cells were also stimulated with their natural bone-marrow environment.

Here is how they did it. The Johns Hopkins team took cord blood cells, treated them with growth factors, and used plasmids to transfer four genes into them. They then delivered an electrical pulse to the cells, making tiny holes in the surface through which the plasmids could slip inside. Once inside, the plas-



Blood cells/Wikimedia Commons and Gruff 15

mids triggered the cells to revert to a more primitive cell state. The team then grew some of the treated cells in a dish alone, and some together with irradiated bone-marrow cells.

When scientists compared the cells grown using the blood cell method with iPS cells grown from hair cells and from skin cells, they found that the most superior iPS cells came from blood stem cells treated with just four genes and cultured with the bone marrow cells. These cells converted to a primitive stem cell state within 7 to 14 days. Their techniques also were successful in experiments with blood cells from adult bone marrow and from circulating blood.

How useful is all of this? If this procedure is indeed an efficient method to produce virus-free iPS cells the researchers believe that it will speed research to develop stem cell therapies, using nearly all cell types, and may provide a more accurate picture of cell development and biology.

—BY (September 3, 2012)

Solomonic Justice for Embryonic Stem Cell Research?

According to an Associated Press report, a federal appeals court on August 24 refused to order the Obama administration to stop funding embryonic stem cell research. The plaintiffs argued that the research relies on destroyed human embryos.

The U.S. Circuit Court of Appeals for the District of Columbia upheld a lower court decision throwing out a lawsuit that challenged federal funding for the research, which is used in pursuit of cures to deadly diseases. Opponents claimed the National Institutes of Health was violating the 1996 Dickey-Wicker law that prohibits taxpayer financing for work that harms an embryo.

The three-judge appeals court panel unanimously agreed with a lower court judge's dismissal of the case. This is the second time the appeals court has said

that the federal funding of embryonic stem cell research was permissible.

Dickey-Wicker permits federal funding of research projects that utilize already-derived cells—which are not themselves embryos—because no ‘human embryo or embryos are destroyed’ in such projects,” Chief Judge David B. Sentelle said in the ruling, adding that the plaintiffs made the same argument the last time the court reviewed the issue. “Therefore, unless they have established some ‘extraordinary circumstance,’ the law of the case is established and we will not revisit the issue,” he said.

Opponents of the research object

because the cells which are being used were obtained from human embryos. They say they fear that success in the research would spur new embryo destruction. Proponents say the research cells come mostly from extra embryos that fertility clinics would have discarded anyway.

—BY (August 25, 2012)



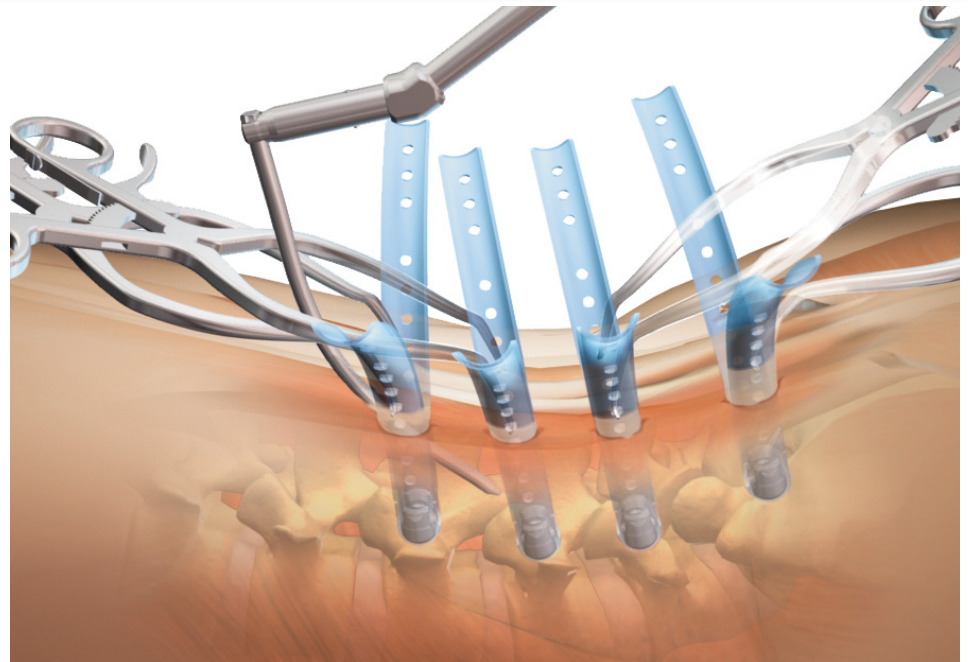
Juicio de Salomon by José de Ribera (1591–1652). Source: Wikimedia Commons

spine

K2M Introduces Retractor System at SRS

K²M, Inc., launched a new retractor system that company President and CEO Eric Major says, addresses complex pathologies within a less invasive environment.

The company introduced the Serengeti Complex Spine Minimally Invasive Retractor System at the 47th Annual Meeting of the Scoliosis Research Society (SRS) in Chicago on September 5, 2012.



Serengeti Complex Spine Minimally Invasive Retractor System / K2M, Inc.

The company announcement states that the system brings K2M's focus on complex spine and minimally invasive together into one system.

The system, according to the company, features "next generation instrumentation to perform complex reduction, controlled manipulation, and above-skin compression and distraction without compromising the option for direct visualization. The system provides the ability to attach and remove the minimally invasive reduction tunnels intra-operatively, combining the benefits of a traditional rigid system with the revolutionary benefits of the flexible, polymer Serengeti Retractor."

Steven DeLuca, D.O., M.S., an orthopedic surgeon with the Orthopedic Institute of Pennsylvania, said that spinal surgery is dynamic and can change mid-course. He said the system, "allows for on-the-spot decision making, providing surgeons the option to attach or remove the reduction tunnels in-situ."

The system features a screw-based method of retraction, allowing for a fixed position to the anatomy. "This simplified design allows for one-step, percutaneous placement of the screw and retractor, providing improved access for rod introduction," stated the company announcement.

Major stated "This important advancement of our already well received [Serengeti system] serves as the intersection of our innovation efforts by combining our core competency in deformity with our award-winning minimally invasive technology...resulting in more options for surgeons."

—WE (September 5, 2012)

people

Polly and Parent Awarded AAOS Grant

Two surgeons, one from Minnesota and the other from Canada, have received the Orthopaedic Research and Education Foundation Prospective Clinical Research Grant for Spine Care. As reported by Laura Miller, writing for *Becker's Spine Review*, David W. Polly, M.D., the chief of spine service at the University of Minnesota, is the Minnesota recipient. Polly has a professional interest in scoliosis and spinal tumors.

The Canadian recipient, Stefan Parent, M.D., is an assistant professor of medicine at the University of Montreal and completed his fellowship in paediatric orthopaedic and spine surgery at the University of California, San Diego.

This is Dr. Polly's 16th award for his scientific work. In 2011 Dr. Polly received the Charles D. Ray Award for Best Clinical Paper-Radiographic Comparison of Lateral Fusion (LLIF) vs. ALIF vs. TLIF vs. Posterior Fusion: Analysis of Segmental Sagittal Contour Change, (SAS11). Dr. Polly is past winner of the White Cloud Award-Best Clinical Paper (co-author) International Meeting on Advanced Spine Techniques (IMAST), the Outstanding Paper, Resident/Fellow Award: 2003 Eastern Orthopaedic/Southern Orthopaedic Association Annual Meeting, Dublin, Ireland. Straight-Forward vs. Anatomic Trajectory of Thoracic Pedicle Screws: A Biomechanical Model (senior author).

Dr. Polly is a graduate of the Uniformed Services University of the Health Sciences Advanced studies which included a residency at Walter Reed Army Medical



David W. Polly, M.D.



Stefan Parent, M.D.

Center and a spine surgery fellowship at the University of Minnesota. Finally, Dr. Polly is lead author or co-author of more than 100 peer reviewed published scientific papers.

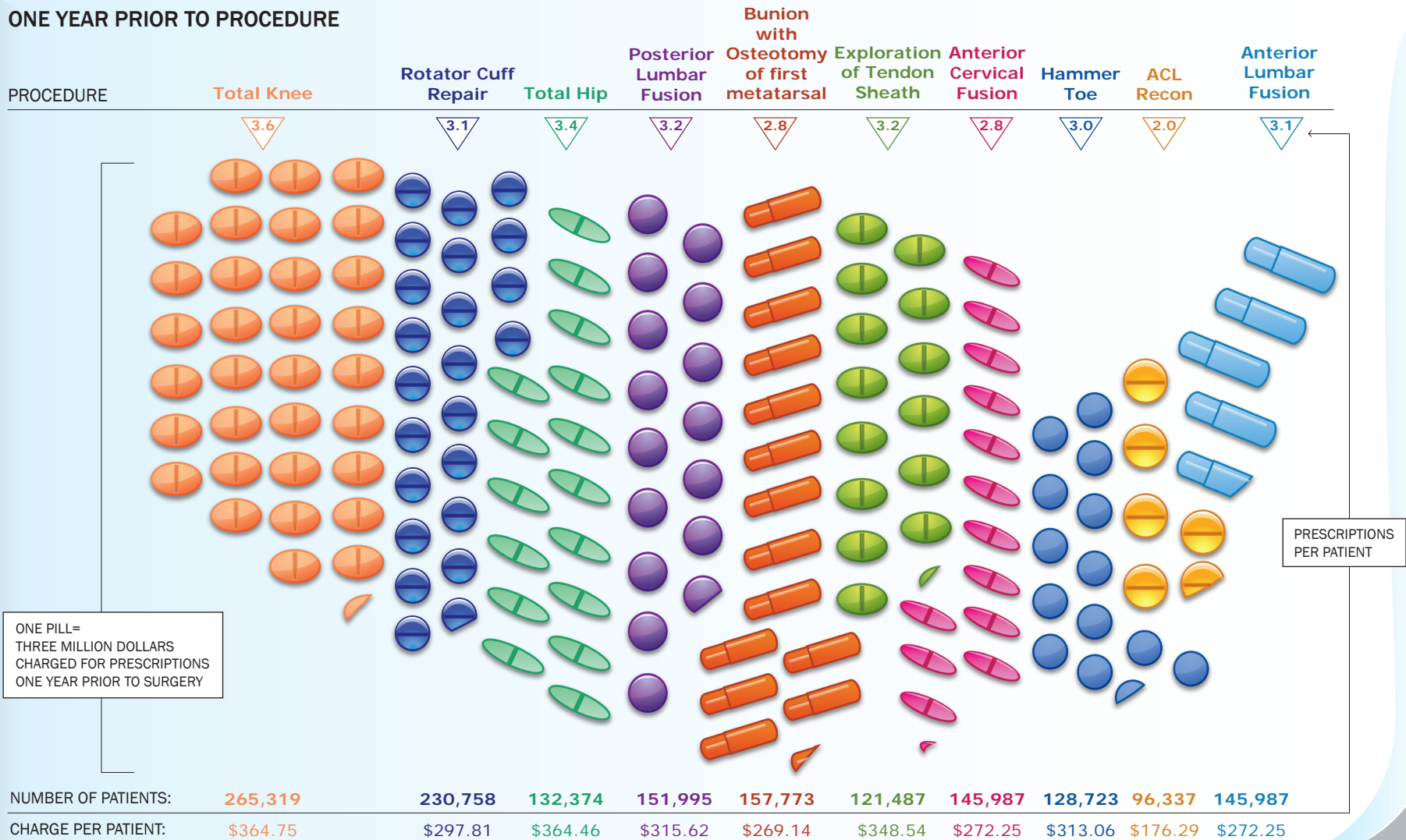
This is also Dr. Parent's 16th grant or award for his research and scientific work. In addition to serving as Assistant Professor, Faculty of Medicine, Department of Surgery, University of Montreal; Dr. Parent is also Chairholder, Depuy Spine Canada Inc.; Academic Research Chair in Spinal Deformities; CHU Sainte-Justine Research Center; and Deputy Head of the axis Musculoskeletal Diseases and Movement Sciences, Research Centre of CHU Sainte-Justine.

—BY (September 1, 2012)

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