VOLUME 11, ISSUE 5 | FEBRUARY 10, 2015

Orthopedics This Week

WEEK IN REVIEW

BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Despite the currency headwinds, analysts have been raising their underlying sales growth forecasts for ortho. This week, Glenn Novarro from RBC Capital Markets says ortho is his favorite med-device sub-sector. He points to this year's AAOS where investors will see the underlying strength of products, companies and care givers. Two of the least expensive equities return to the Power Rankings: MicroPort Scientific and Orthofix.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Integra LifeSciences	12.57%	4.75%	Investors are offering just $16.50 per future $1.00 in earnings. Also just $1.97 for every $1.00 in sales. That makes IART cheapest equity in orthopedics.
2	2	ConMed	10.51	5.86	Still basking in the glow from JP Morgan. As the second least expensive equity in ortho, this qualifies as a honeymoon.
3	5	Medtronic	28.84	2.01	With, still, the largest share of the spine market, MDT+COV delivers a level of scale never before seen in spine.
4	4	Stryker	11.52	(1.54)	"SNN can prosper on its own" – SNN CEO Olivier Bohoun. Yup. Likewise SYK has beaucoup growth drivers without SNN.
5	NR	Orthofix	7.46	10.19	Issues press release: sales about $397 million in 2014. Most impressive, however, were the yearend cash and credit facility numbers.
6	NR	MicroPort Scientific	16.53	10.20	Not a lot of news from Memphis-based MicroPort lately. But at these valuations and AAOS on the horizon, time to return to the Power Rankings.
7	3	Zimmer	29.12	(2.13)	Unimpressive revenue performance to close out 2014. Looking ahead to AAOS. Should be interesting, for sure.
8	8	Smith & Nephew	19.92	0.25	SNN CEO also said: "Despite what many people say about needing to be big, we have beaten the market in hips and knees."
9	9	Exactech	10.44	(3.26)	EXAC, at least in terms of its equity, defines volatility. Operationally, however, it remains a multi-faceted gem.
10	6	NuVasive	8.01	(3.63)	Investors had a very nice run and appear to be taking some chips off the table. At these prices NUVA is back to a premium valuation.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$0.88	$142	34.75%
2	MicroPort Scientific	853	$0.46	$657	10.20%
3	Orthofix	OFIX	$32.13	$592	10.19%
4	Bacterin Intl Holdings	BONE	$3.10	$21	8.77%
5	LDR Holding Corp.	LDRH	$36.92	$962	8.59%
6	ConMed	CNMD	$48.23	$1,328	5.86%
7	Integra LifeSciences	IART	$56.92	$1,866	4.75%
8	Medtronic	MDT	$74.47	$105,660	2.01%
9	Globus Medical	GMED	$24.94	$2,443	1.34%
10	Smith & Nephew	SNN	$36.34	$16,245	0.25%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	K2M Group Holdings	KTWO	$18.82	$743	-17.46%
2	MiMedx Group	MDXG	$8.22	$879	-14.91%
3	Wright Medical	WMGI	$24.75	$1,264	-8.94%
4	Aurora Spine	ASG	$1.21	$20	-4.67%
5	RTI Biologics Inc	RTIX	$4.80	$273	-4.57%
6	Johnson & Johnson	JNJ	$101.10	$282,990	-4.23%
7	Tornier N.V.	TRNX	$24.79	$1,212	-3.99%
8	NuVasive	NUVA	$46.73	$2,198	-3.63%
9	Exactech	EXAC	$22.29	$308	-3.26%
10	Alphatec Holdings	ATEC	$1.34	$133	-2.19%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$101.10	$282,990	16.90
2	Medtronic	MDT	$74.47	$105,660	18.65
3	Exactech	EXAC	$22.29	$308	19.55
4	Zimmer Holdings	ZMH	$116.15	$19,670	20.06
5	Globus Medical	GMED	$24.94	$2,443	20.51

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MiMedx Group	MDXG	$8.22	$879	819.62
2	RTI Biologics Inc	RTIX	$4.80	$273	401.91
3	Orthofix	OFIX	$32.13	$592	205.26
4	NuVasive	NUVA	$46.73	$2,198	120.62
5	CryoLife	CRY	$11.51	$322	39.41

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Exactech	EXAC	$22.29	$308	1.30
2	CryoLife	CRY	$11.51	$322	1.31
3	Globus Medical	GMED	$24.94	$2,443	1.54
4	Medtronic	MDT	$74.47	$105,660	1.65
5	ConMed	CNMD	$48.23	$1,328	2.03

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MiMedx Group	MDXG	$8.22	$879	54.64
2	RTI Biologics Inc	RTIX	$4.80	$273	26.79
3	Orthofix	OFIX	$32.13	$592	11.16
4	NuVasive	NUVA	$46.73	$2,198	10.55
5	Smith & Nephew	SNN	$36.34	$16,245	4.77

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	$3.10	$21	0.60
2	Alphatec Holdings	ATEC	$1.34	$133	0.65
3	RTI Biologics Inc	RTIX	$4.80	$273	1.08
4	Exactech	EXAC	$22.29	$308	1.25
5	Orthofix	OFIX	$32.13	$592	1.49

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.88	$142	24.81
2	MiMedx Group	MDXG	$8.22	$879	9.10
3	LDR Holding Corp.	LDRH	$36.92	$962	8.62
4	Medtronic	MDT	$74.47	$105,660	6.08
5	Globus Medical	GMED	$24.94	$2,443	5.30

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

19 of the Best Orthopedic Traumatologists in North America

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

From the treatment of wounded warriors to domestic violence victims to auto accident patients, orthopedic traumatology has experienced significant advances in the science and treatment of trauma over the last 15 years. Much of this progress is due to the people who appear on this list. Those in the know about trauma gave us their thoughts on the some of the top orthopedic surgeons in their subspecialty.

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 orthopedic trauma surgeons in the country. The information in quotes is what we heard about these surgeons.*

Photo creation by RRY Publications, LLC/Source: Andrew Huth

This information was obtained via a telephone survey of thought leaders in the field. No one at OTW names anyone to the list.

In alphabetical order, here are 19 of the top orthopedic traumatologists in North America.

David P. Barei, M.D. is a professor of orthopedics and sports medicine at the University of Washington in Seattle/Harborview Medical Center. He is also program director of the traumatology fellowship at that institution. "Dr. Barei is a consummate thinker, and is technically gifted in the surgical management of complex fractures. His research has moved our understanding of tibial plateau fractures and their treatment to another level."

Brett R. Bolhofner, M.D. is an orthopedic trauma surgeon at All Florida Orthopaedic Associates in St. Petersburg. He also holds an appointment with Bayfront Health. "He is one of the unsung heroes of orthopedic trauma in North America and Europe. He is a true 'out of the box thinker' who develops new paradigms and ways of addressing difficult orthopedic trauma problems and issues. His calm, thoughtful demeanor makes him a pleasure to work with and his surgical skills are amazing. He has been referred to by some as the 'Wizard of West Florida.'"

Mark R. Brinker, M.D. is an orthopedic surgeon with the Texas Orthopedic Hospital in Houston; he also holds appointments with Hermann Hospital, The Methodist Hospital and Texas Children's Hospital. "Dr. Brinker is known for his excellence in the management of complex nonunions and malunions. He manages the worst of the worst and has outstanding outcomes for patients who would otherwise lose their limbs."

Lt. Col. Jean-Claude D'Alleyrand, M.D. is chief of orthopaedic trauma at Walter Reed National Medical Center. "He leads the care of our wounded warriors, especially multiple amputees, including their initial treatment and their continued rehabilitation. He is a highly decorated officer and a medical champion for America's heroes."

Gregory J. Della Rocca, M.D., Ph.D. is co-chief of orthopedic trauma at the University Missouri. "He is known for his extensive research, teaching, and patient care of all kinds of fractures. He is also known for his research on how common orthopedic injuries occur after domestic violence and for educating the public and other orthopedic surgeons about the extent of this problem."

A. Alex Jahangir, M.D., M.M.H.C. is an associate professor of orthopaedic

surgery and rehabilitation at Vanderbilt University Medical Center. "Dr. Jahangir is a crucial member of a highly-respected orthopedic trauma group in Nashville. He is poised to lead the group to a higher level. Dr. Jahangir is not only an outstanding fracture surgeon, but also is highly regarded in the business of medicine."

Bradley A. Jelen, D.O. is an orthopedic trauma surgeon with OrthoIndy. "He is not only an experienced traumatologist, but he is a fantastic adult educator and collaborates with other leading trauma surgeons in his area and throughout North America to improve patient care."

Brian H. Mullis, M.D. is chief of the orthopedic trauma service and an associate professor at Indiana University. "He is an outstanding orthopedic traumatologist and educator. He is a highly skilled clinically and continues to gain leadership roles with the OTA."

Robert F. Ostrum, M.D. is a professor of orthopedic surgery and director of orthopedic trauma at Cooper University Hospital in Camden, New Jersey. Dr. Ostrum also directs Cooper's orthopedic trauma fellowship. "He is one of the most conscientious orthopedic traumatologists around. He is a critical thinker, an excellent technician, and a fantastic educator."

Robert V. O'Toole, M.D. is an orthopedic trauma surgeon with the University of Maryland Medical Center in Baltimore. "He is a young, energetic researcher at Shock Trauma who possesses exceptional surgical skills. He will be instrumental in changing standards of practice in poly-trauma patients in the next ten years within North America."

William M. Ricci, M.D. is chief of the division of orthopedic trauma at Washington University in St. Louis. He was just named second president elect of the Orthopaedic Trauma Association (OTA). "Bill has spent his entire career, teaching and training both residents and fellows. He is extremely well published and is an outstanding surgeon, clinician, design surgeon, teacher and mentor. He is most well known for his work on peri-prosthetic fracture fixation."

H. Claude Sagi, M.D. is director of Research and Fellowship Training for the Orthopaedic Trauma Service at the Tampa General Hospital, and Assistant Clinical Professor with the University of South Florida Depart-

ment of Orthopaedic Surgery and Sports Medicine. "He is an emerging leading in our understanding of pelvic trauma; he is active in research leading to a better understanding of pelvic ring stability."

Roy W. Sanders, M.D. is president and cofounder of the Florida Orthopaedic Institute in Tampa. Dr. Sanders is a past president of the OTA and is currently serving as director of the Orthopaedic Trauma Service, and chief of the department of orthopedics at Tampa General Hospital. "You need look no further than Roy when it comes to excellence in the field. He exemplifies a meticulous attention to detail and a high level of professionalism."

Stephen A. Sems, M.D. is an assistant professor of Orthopedics at Mayo Clinic Rochester Minnesota. "He is a compassionate surgeon who has considerable expertise in the management of fracture malunion and nonunions. He maintains a common sense approach that is tailored to each patient."

David C. Templeman, M.D. is an assistant professor in the department of orthopedic surgery at the University of Minnesota; he practices at the Hennepin County Medical Center. Dr. Templeman is a past president of the OTA. "He is an outstanding acetabular surgeon and has had a primarily pelvic and acetabulum practice for 25 years. He has been a leader and is on the board of the American Academy of Orthopaedic Surgeons and chair of the Board of Specialty Societies."

Paul Tornetta, M.D. is chief of orthopedic trauma at Boston City Hospital and program director of the orthopedic residency at Boston University. He is a past president of the OTA. "Paul is one of the most well-known orthopedic trauma surgeons in the U.S., having written extensively on almost every subject in the field. He created and runs the annual OTA fellows course, and is a senior editor of Rockwood and Green. Paul is best known for his work on pelvic and acetabular fractures, syndesmotic injuries and tibial intramedullary nailing, and as a lead researcher in the SPRINT study."

Heather Vallier, M.D. is an orthopedic trauma surgeon at MetroHealth Medical Center and holds the inaugural Clyde L. Nash M.D. Professorship in Orthopaedic Education at Case Western Reserve University. "She is doing an excellent job of evaluating the timing of multiply injured patients. She has done complex statistical analysis of multiply injured patients in order to refine the indications on both a physiologic and timing basis."

John C. Weinlein, M.D. is an orthopedic trauma surgeon at the Campbell Clinic in Memphis, Tennessee. "He is a devoted clinical traumatologist who is accomplished at providing complex fracture care. Dr. Weinlein is an excellent educator who excels in teaching the technical details that are critical to fracture care."

David B. Weiss, M.D. is an assistant professor and director of the orthopedic trauma division at the University of Virginia School of Medicine. "In addition to being a skilled surgical technician, Dr. Weiss is highly dedicated to education in orthopedic trauma. He has consolidated orthopedic trauma care in central Virginia with his leadership skills, surgical acumen, teaching abilities, and bedside manner." ♦

Uncle Sam and FeeFee File for Divorce

BY WALTER EISNER

After 50 years of marriage, Uncle Sam and FeeFee (fee-for-service) are getting a divorce. Uncle Sam is trying to move the $2.9 trillion U.S. health system to a new partner, PayFee (pay-for-performance). FeeFee is out, PayFee is in.

Everybody saw it coming. It was a long relationship but it had been going south for years. As the medical arms race took off, Uncle Sam's family grew to over 68 million beneficiaries and the old passion started to fade away. "We've grown apart," Uncle Sam told FeeFee. "I've changed and you've gotten more and more needy."

Photo creation by RRY Publications, LLC/Niek Verlaan and pixabay

The "Quality" Siren

Uncle Sam couldn't resist the allure of PayFee and her siren song of "quality." They would share in the payment risks, and in fact, the new couple had already set up house and talked openly about how happy they were together and how much money they were already saving.

Health and Human Services Secretary (HHS) Sylvia Burwell informed us of the planned split on January 26, 2015 as she announced "a timeline to move the Medicare program, and the health care system at large, toward paying providers based on the quality, rather than the quantity of care."

HHS Secretary Sylvia Burwell/Source: hhs.gov

The Divorce

Within four years, all but 10% of traditional Medicare payments are to be linked to new quality and efficiency standards, including most of those still billing by the old fee-for-service method.

By 2016, 30% of payments will be tied to alternative payment models, such as Accountable Care Organizations (ACOs) or bundled payment arrangements, rising to 50% by the end of 2018. HHS also set a goal of tying 85% of all traditional Medicare payments to pay-for-performance by 2016 and 90% by 2018 through programs such as the Hospital Value Based Purchasing and the Hospital Readmissions Reduction Programs.

Physicians and Hospitals Respond

"This is a bless-your-heart day," Doug Henley, M.D., the executive director of the American Academy of Family Physicians, told Burwell when she announced the Obama administration's plan.

The American Medical Association (AMA) wasn't so sure. The AMA, you may recall was never a fan of Medicare. When President Truman first proposed Medicare in 1945, the AMA denounced it as "the first step in a plan for the socialization not only of the medical profession, but all professions, business and labor." So much for a measured response.

Robert Wah, M.D., the AMA's current president reportedly said the association is looking forward to hearing more details behind the percentages as well as the plans to reach the targets.

American Hospital Association (AHA) Executive Vice President Rick Pollack said that the group wants to learn more on how these new goals will be phased in.

The American Academy of Orthopaedic Surgeons(AAOS) was unable to provide us with a comment.

Coaxing Private Payers

To push private payers to join in the new marriage, Burwell announced the creation of the Health Care Payment Learning and Action Network. Through the network, HHS will work with private payers, employers, consumers, providers, states and state Medicaid programs, and other partners to expand alternative payment models into their programs. The network will hold its first meeting in March 2015.

A coalition of large providers and payers including, Partners HealthCare, the Boston health system that oversees Brigham and Women's and Massachusetts General hospitals; Ascension, the nation's largest Catholic and nonprofit health system; Aetna, a national for-profit insurer; and Health Care Service Corporation, which operates five state Blue Cross plans, have all committed to changing their financial incentives to move the bulk of their payments to pay-for-performance by 2020. The coalition, proposed by Richard Gilfillan, M.D., a former Medicare official and the chief executive of Trinity Health, is called the Health Care Transformation Task Force. It hopes to help find some kind of consensus on payment models so doctors and hospitals don't have to negotiate multiple arrangements with Medicare and each private insurer.

New Payment Models

The Affordable Care Act created new payment models that move payment systems toward rewarding so-called "quality." These models include ACOs, primary care medical homes, and new models of bundling payments for episodes of care. In these new models, providers are given a lump sum for the care they deliver and have a financial incentive to get rid of duplicative or unnecessary X-rays, screenings and tests.

Some of these new models also have resulted in insurers being cut out as the

middle man. In Seattle, Boeing Company contracted directly with a local ACO to provide care for its employees for a fixed fee. No insurance company was involved.

The move to embrace pay-for-performance has moved quickly. In 2011 Medicare made almost no payments to providers through alternative payment models, but today such payments represent approximately 20% of Medicare payments, according to HHS. The goals announced by Burwell represent a 50% increase by 2016. To put this in perspective, in 2014, fee-for-service payments were $362 billion.

Happy New Marriage – So Far

But what about the kids, the 68 million beneficiaries covered by Medicare and Medicaid? Will they be better off?

So far, Uncle Sam says the experiment is working as Medicare has seen combined total program savings of $417 million due to existing ACO programs. The government also claims that the programs have "helped reduce hospital readmissions in Medicare by nearly 8%—translating into 150,000 fewer readmissions between January 2012 and December 2013—and quality improvements have resulted in saving 50,000 lives and $12 billion in health spending from 2010 to 2013, according to preliminary estimates."

As we have reportedly extensively, providers and payers say they are able to squeeze out costs to the system, not by cutting back on patient care, but by eliminating "defensive medicine" tests and procedures, holding physicians to strict protocols that eliminate mistakes and reduce adverse event costs. The Institute of Medicine estimates we spend $210 billion annually on medicine that doesn't make us any healthier.

Surgeons Skeptical

But many specialty physicians, like surgeons, remain unconvinced the new marriage really delivers on the promises of "quality." They say new care models have shown limited progress in controlling costs and little evidence of being able to sustain cost savings. If hospitals and insurers, who are out to make a buck, like it, physicians who are duty bound to do what's best for the patient, are skeptical. But as physicians become employees of health systems and those systems are being acquired by insurers, they have less clout on business and financial decisions.

whitehouse.gov

The cost savings are there, but evidence of improved patient outcomes is sketchy.

It's been over 20 years since the country's first pay-for-performance programs were started (1992) and researchers have started to look back to see if they lived up to their promise.

Aaron Carroll, M.D., of Indiana University School of Medicine wrote on July 28, 2014 in *The New Health Care*, that we're seeing disappointingly mixed results of improved patient care. Sometimes, he said, it's because providers don't change the way they practice medicine; sometimes it's because even when they do, outcomes don't really improve.

Carroll cited one study in particular which appeared in *Health Affairs* and looked at the effects of a government partnership with Premier Inc., a national hospital system. Initially, the study found the 260 hospitals in the pay-for-performance project improved patient care more than the 780 not in the project. BUT, five years later all those differences were gone.

A New Role – The Specialist Primary Care Doc

The effect on physicians and their practices is even murkier.

According to the 2014 Annual Fee Schedule Survey from *Physicians Practice* covering 1,616 medical practices, 20% of respondents thought the shift away the from fee-for-service will be good for their practice, with 23% saying it will be a detriment with 44% "not sure" of the effect. That is a 10% increase from the 2013 survey.

Specialists find the changes the most disruptive because they are largely

paid based on how many services they perform. Primary physicians, on the other hand, expect a new system will compensate them for work they haven't historically been paid for doing, such as monitoring their patients' health between office visits.

"It's not clear to me in this proposal how they [specialists] would be included or even participate," Lou Goodman, the president of the Physicians Foundation, based in Columbia, South Carolina, said in a phone interview with *Bloomberg*.

Centers for Medicare and Medicaid Services (CMS) says it wants to experiment with ways to pay specialists and plans to start with oncologists.

According to *Bloomberg*, Tennessee Oncology, a group of cancer doctors based in Nashville, is testing an arrangement with the insurer Blue Cross Blue Shield of Tennessee in which oncologists act as primary care physicians for people with advanced cancer, monitoring their health, trying to prevent expensive emergency room visits and hospitalizations.

Even the group of McAllen, Texas, physicians who found themselves the subject of an unflattering *New Yorker* story a couple of year ago are getting into that act. They formed an ACO and saved Medicare $6 million in their first year. They got to keep $1.6 million after paying back a government loan.

This year, the McAllen group is targeting overuse of hospital services, including emergency rooms. "Hospitals won't like that too much, but that's the way it goes," said Ken Oates, the group's administrator.

Specialists like orthopedic surgeons get paid for the quantity of work and reducing the use of health-care services is a problem for them.

But if they can reduce admissions, ER visits, procedures and imaging, Goodman says "the specialists should be paid to be available whether they perform a service or not. That's a complicated concept. I haven't seen any government programs that do that."

Embrace the New Marriage

Uncle Sam is clearly moving ahead with PayFee. The kids are deciding whether they like this new arrangement. And everyone else, particularly providers, are being forced to start making changes to their current compensation models.

If they don't adjust, they could be stuck paying expenses based on a fee-for-service model but being reimbursed on a pay-for-performance model.

In short, between FeeFee and PayFee. ♦

Surprising Data on Elderly Shoulder Surgery Outcomes // Retain BOTH Cruciates and Have a Natural Feeling? // Knee World: Perioperative Management Trumps Technology

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

Photo creation by RRY Publications, LLC / Source: Wikimedia Commons

New Study: Excellent Outcomes for 70-Year-Old Patients With Rotator Cuff Surgery To settle the issue—or at least put many minds at ease—Peter J. Millett, M.D., M.Sc., director of Shoulder Surgery at The Steadman Clinic in Vail, Colorado, got to work on the issue of whether older patients benefit from rotator cuff repair. Dr. Millett tells *OTW*, "There is a fair amount of debate about whether older people with rotator cuff injuries will heal well after surgery. 'Just send them to physical therapy,' is what many surgeons say. Our new 44-patient (49 shoulders) study, which has just been accepted for publication by the *American Journal of Sports Medicine*, proves that rotator cuff repair is effective in recreational athletes over the age of 70. We found excellent clinical results as measured by the American Shoulder and Elbow Standardized Shoulder Assessment Score; the average score was 90 on a scale of 100. When you look at our overall cohort of patients after rotator cuff repair, we find a mean score of 92, so the results in these active older patients were especially good."

"We also found high levels of return to functional activity (skiing, golf, tennis, and cycling); a full 77% of the patients were able to return to their desired level of sports activity. In addition, the decrease in pain levels was highly statistically significant…and there were no revisions."

"If the patient has good tissue quality at the time of arthroscopic repair, then we will take an aggressive approach to rehabilitation after surgery. We begin early passive motion on the same day of surgery, and get the person to active motion by three to four weeks postoperatively."

"To my colleagues who are concerned about performing these surgeries on older patients I say, 'If your patient is active, healthy, motivated, and has good tissue quality, then age should not be a factor.' Sometimes the older athlete is written off. But these people look in the mirror and do not see themselves as older. They are young at heart! As long as the conditions are right, we should

give them our best shot…and fix their rotator cuff tears!"

Teasing Out the Answer to: Should We Retain BOTH Cruciate Ligaments? When it comes to knee replacement, a successful outcome is not synonymous with a pain-free, natural feeling knee. Gwo-Chin Lee, M.D. is an assistant professor and program director of the Adult Reconstruction Fellowship program at the University of Pennsylvania in Philadelphia. Dr. Lee and his team are in the process of studying whether it is feasible to retain both cruciate ligaments during knee replacement in order to give a more physiologic feeling to an artificial knee. He tells *OTW*, "For whatever reason, one of five patients who undergo conventional knee replacement is dissatisfied despite reporting significant pain relief and improved function following surgery. I think part of the problem is that the current knee replacements we have available today don't reproduce normal knee kinematics and aren't designed for the higher demand patients. There are currently some designs on the market that attempt to reproduce individual anatomy and even retain both cruciate ligaments but there is relatively little data on whether these newer implants function significantly different compared to our traditional knee implants."

"I believe that there are currently several barriers that may prevent successful retention of both cruciate ligaments with traditional condylar femoral component and monoblock tibial base plate designs. Natural knee kinematics is complex and the movements of the natural knee are guided by the interplay between functioning cruciates and collateral ligaments and the articular surface geometries of the distal femur and the tibia. For these reasons, simply preserving the cruciate ligaments during TKA [total knee arthroplasty] may not be sufficient to restore physiologic kinematics."

"Today, the technology is available to customize femoral implants to individual patient anatomy but there are no options available on the tibial side. We have previously studied and published the complex anatomy of the distal femur, and now we are looking to see what are the anatomic relationships on the tibial side of the equation. We recently performed an anatomic study using 3D MRI technique of normal non-arthritic knees to defined the complex topography of the proximal tibia, mainly to see if a single piece tibial base plate could accurately reproduce normal anatomy. In this study, we found that there was great variability in the tibial anatomy. In 40% of patients, there was a significant difference greater than 3 degrees between the posterior slopes of the medial and lateral tibial plateaus. So, in this situation, a monoblock tibial

component may not be able to reproduce normal anatomy."

"Conversely, in the rest of this sample, a single piece tibial component could closely restore the proximal anatomy of the tibia. I think that if a bi-cruciate retaining TKA is contemplated, one should preoperatively obtain advanced imaging (i.e., MRI) in order to determine whether there are significant differences in the medial and lateral slopes of the tibia. This emphasizes the point that as we move to produce a more anatomic reconstruction, we need to have a less cookie cutter approach."

"Future areas of research involve determining the best way to balance the cruciate ligaments against the collaterals if preserved. Determining the changes in ligament tension and function and their respective tolerances to changes in alignment and rotation will be crucial towards developing a reproducible surgical technique for retaining both cruciates in TKA. The best way to study this is undetermined but may involve the use of implantable sensors to study the lengths and tensions of each ligament, dynamically throughout knee motion. It is not going to be easy, but it is necessary information."

"I am not sure that a bi-cruciate retaining knee implant is quite ready for prime time in 2015. There are questions of alignment, laxity, and design that remain unanswered. Additionally, the instrumentation necessary to precisely reproduce anatomy may not be widely available or cost effective yet. Finally, we all know that a significant number of patients requiring knee replacements will not have intact or functioning cruciate ligaments, so the precise patient population that would benefit from these newer technologies remains undefined. Perhaps the best way to achieve this would be to use unlinked unicompartmental knee replacements to resurface the arthritic knee. I don't know."

"What I do know and believe that we need to introduce new technologies and surgical techniques responsibly with good science behind it. Conventional knee replacements are excellent, durable, and reliable at relieving pain and improving function in patients with knee arthritis. Any new technology will need to be benchmarked against 40 years of clinical results prior to wide adoption in the best interest of the patient."

Knee World: Perioperative Management Trumps Technology After several years of reviewing the knee literature, one surgeon-pundit points to clear patterns in the data. Carl Deirmengian, M.D. is an orthopedic surgeon at the Rothman Institute in Philadelphia. For the past six years Dr. Deirmengian has co-authored a review article on what is new in adult knee surgery for *The Journal of Bone and Joint Surgery* (*JBJS*). He tells *OTW*, "The goal of the article is to look back at the last year of knee surgery articles in several top journals and review all of the prospective level one studies to provide my opinion. This year my colleagues and I reviewed 25 papers and grouped them into several categories."

"One such category was minimization of blood loss, where the standout item appears to be the use of tranexamic acid. As for patient specific instrumentation, one study found no difference in clinical outcomes or component alignment between a group treated with traditional instruments and another with customized cutting blocks. Another study found that patient specific instrumentation didn't reduce operative time. They did say, however, that this may change as surgeons acquire more experience."

"In general, I am seeing a major change in thinking in our field. We had always previously assumed that the success of surgery has something to do with a given implant, technology, or approach to surgery. For many years in the joint replacement world we have been trying new methods such as minimally invasive surgery, or new technologies such as 'high-flexion' knees. Despite our tremendous efforts to develop these technologies and surgical approaches, there is no evidence to suggest that they result in any clinically significant benefit for the patient. If anything, increasing problems may have arisen, such as the risk of malalignment that has been described in some minimally invasive surgery studies."

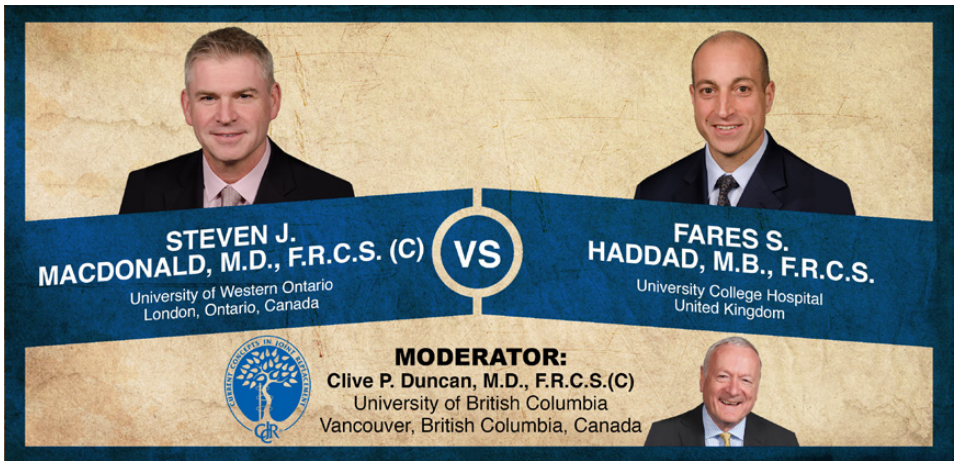
"What is clear now is that it's not the technology that has made the difference for patients…it's the perioperative management. We get patients walking faster, we pre-emptively treat pain and nausea, we avoid intravenous narcotics, and they are discharged more quickly, etc. This is what really makes the difference. It is easy to say, 'oh, here is this new implant,' or 'wow, this minimally invasive approach to the knee is amazing,' but the data shows that patients don't get better faster with these innovations. We must accept that most of the variability in joint replacement results are not due to differences in technology or surgical technique. As long as there are no major complications during a knee replacement, I believe that the patients' early outcomes are mostly due to peri-operative management and biological variation in the response to surgery. Unfortunately, even developments in the realm of biologics have failed to be fruitful for patients with end-stage osteoarthritis. I don't see any reasonable hope of implant-free treatments for end-stage osteoarthritis any time soon." ♦

MacDonald, Haddad Debate Femoral Head Materials

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

"Why choose a delta (ceramic) versus a cobalt-chrome head? There's no evidence of decreased revision rates with a delta head and it's more expensive," says Steve MacDonald. "If you look at the level one data that is available," says Fares Haddad, "and look at the long term outcome, you will move away from cobalt-chrome heads."

This week's Orthopaedic Crossfire® debate is "Femoral Head Materials… No Difference in Outcomes." For the proposition is Steven J. MacDonald, M.D., F.R.C.S. (C) of the University of Western Ontario. Fares S. Haddad, M.B., F.R.C.S. from University College Hospital in the UK. Moderating is Clive P. Duncan, M.D., F.R.C.S.(C) of the University of British Columbia.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. MacDonald: "The debate is cobalt-chrome versus a ceramic or delta head. About five years ago we were at the peak of hard-on-hard bearings, with metal-metal and ceramic-ceramic constituting about a third of the total hips done. That's changed substantially as currently about 92% are highly cross-linked polyethylene (XLPE). Now the debate is, 'Against what counter surface? "

"A recent publication from the Australian registry includes 250,000 total hips taken out to 10 years. The lowest cumulative revision rate was cobalt chrome on XLPE (4.3%); in second place was ceramic on XLPE (4.6%). So clinically, they seem to be doing pretty much the same. If you look at the head size in XLPE at seven years there is no difference in the cumulative revision rate for 36 and 32mm…not the really large heads."

"So what's the trend in femoral head material choice? Increasingly, it is towards the use of a ceramic head and away from a metal head. But not all ceramics are created equal. About 90% of the market is using a mixed ceramic (delta) head…so why choose a delta versus a cobalt-chrome head? There's no evidence of decreased revision rates with a delta head, and there's no evidence for decreased, clinically relevant wear rates. And you can show hip simulators against XLPE where there are subtle differences, but both cobalt chrome and ceramic are well below the osteolysis potential, and it's hard to imagine that this is going to bear out clinically."

"One of the challenges is that in many countries and institutions the delta ceramic comes at a significant price premium. At my institution ceramic heads are twice the cost of cobalt-chrome heads. So why choose delta? Taper corrosion. A case series from Rush Orthopedics (nearly 20 patients) found taper corrosion with a cobalt-chrome head against XLPE. They weren't all large heads; most were 28mm. Clive Duncan and his group published a case series (retrieval study) on hip arthroplasty and found that even a ceramic head had taper corrosion."

"What is the actual corrosion rate of a cobalt-chrome ball and a standard taper? We have no idea. So let's be clear that corrosion is multifactorial. While head material may be clinically relevant at this point we don't have any evidence of that. We have no idea of the global incidence or prevalence, and no idea of the true clinical reduction that a delta head would give you over cobalt chrome."

"Regarding cost benefit analysis, here is the challenge at my institution: it's a $400 premium to do a delta head. What is the reduction in the incidence of clinically relevant taper corrosion with a delta? I don't know. Is it 1 in 1,000? That would be a cost of $400,000 to prevent one case."

"Delta ceramic is not the ultimate solution. As for the issue of fracturing, the delta ceramic fracture rate is rare. In Australia it's about 1 in 70,000. So

if you choose a delta head you must accept that there's no clinical superiority; you're hoping for a lower corrosion rate, but who knows. And you have to accept the cost differential. I think you choose a cobalt-chrome head because you do have evidence for clinical superiority or at the very least, equivalence. In summary, choosing a cobalt-chrome head means that you're inherently more intelligent."

Mr. Haddad: "You could be fooled by Steve's intelligence and charm, but I took the issue to my children. When they looked at the different types of heads it was clear that they preferred the pink and black ones. I will share the literature and you will see why."

"The difference depends on what you look at…and especially how hard you look. You have to look at wear, corrosion, and high level activities—and you have to look long-term. Steve can get away with what he is saying because we as a profession haven't done enough robust, level one studies. And, when you look at registries in particular, you must look beyond the femoral head material. There are many confounders: the stem and the socket, the way they are fixed, what happens on the acetabular side, the local biomechanics, and patient's biomechanics."

"There are a few studies that try to compare into the longer term. What we see there are only slight differences in favor of ceramic. Chit Ranawat did a nice case controlled study with follow up of over 17 years. In his group wear was lower with ceramic (same approach, same surgeon, same stems)."

"I agree with Steve. The data for XLPE is compelling, so the wear that we're measuring is very small—which makes it difficult. A number of studies have come out showing that this is a change for the better."

"In a prospective, multicenter study with over 400 hips that were randomized into three groups: cobalt chrome on XLPE and oxidized zirconium (similar to ceramic) on XLPE and conventional polyethylene. These were safe hips, i.e., we didn't see any disastrous, bearing related complications. The groups all improved in terms of their hip scores and general quality of life scores. But when you look at wear at five years you find a dramatic change from standard poly to XLPE…and a further improvement with oxidized zirconium. Steve would be right to say that this is not statistically significant, but I will expect to report in a few years that there is a statistically significant difference."

"A study from Moussa Hamadouche in France looks at 22mm heads and compares standard polyethylene and XLPE on oxidized zirconium and cobalt chrome. And because his study is out about eight years he does see a statis-

tically significant difference with less wear with the oxidized zirconium, both with standard polyethylene and, to our surprise, as early as seven years with XLPE."

"Steve showed the Australian registry data, but in reality it shows that coupling with ceramicized metal with a lower failure rate out to 10 years. That may be because of the stem or the bearing or both, but the reality is that this is the lowest wear rate."

"As for corrosion, retrieval data shows that oxidized zirconium has much lower rates of change and material loss (when you look at retrievals). Data from our lab shows the same thing. We have a lab model to simulate corrosion and we've tested many materials in it. It has been validated over a number of taper changes and material changes. Steve is right…you do see some changes with ceramic, but it's a decimal point difference… significantly less with ceramic than you see with cobalt chrome."

"So in 2014 we have to heed health economics. But we want low wear, low corrosion, something that is safe and long lasting. If you look at the level one data that is available, and look at the long term outcome, you will move away from cobalt-chrome heads."

Moderator Duncan: "Steve?"

Dr. MacDonald: "We've quoted similar research. The questions are, 'Is it clinically relevant?' and 'To what population?' And the cost differential is huge. We are trying to prevent theoretical revisions (which haven't been borne out) and a theoretical corrosion rate (which we're not sure about). We're in the realm of opinion because we just don't have much data."

Mr. Haddad: "Roughly $400 difference in cost over the lifetime of a patient isn't very much. It's different if the patient has a limited life expectancy. But from what we know now and the problems that we are starting to see, the issues with the taper that we still don't understand—particularly if we're going to high offsets—I think the data is pointing towards ceramic. We as a profession have failed to generate the data."

Dr. Duncan: "Steve, if the patient will pay for it will you use ceramic and under what situations?"

Dr. MacDonald: "If the cost doesn't impact your practice and/or the patient will bear that cost, I would use ceramic. I use it in patients who are under 50 (for the reasons Fares mentioned)."

Dr. Duncan: "Fares, the nickel allergy question comes up in clinics all the time. What do you say?"

Mr. Haddad: "In the hip it's easier because you can avoid it so easily. It's a much bigger issue if someone is having a knee replacement. With the hip we would use a titanium stem and use a non-cobalt chromium head. It removes that concern for the patient and for us."

Moderator Duncan: "Thank you, gentlemen." ◆

Please visit www.CCJR.com to register for the 2015 CCJR Spring Meeting, May 17 - 20 in Las Vegas, Nevada.

COMPANY

Zimmer Keeps Market Share Ahead of Biomet Merger

Image created by RRY Publications, LLC / Sources: Zimmer Holdings, Inc., ptdh and pixabay

Zimmer Holdings, Inc. "held reconstructive share in the fourth quarter of 2014 with a slight share gain in knees offsetting a slight share loss in hips," according to Needham & Co. analyst, Mike Matson. Joanne Wuensch of BMO Capital Markets called it a "solid quarter" as Zimmer prepares for Biomet, Inc.

That's how the two analysts described Zimmer's $1.22 billion fourth quarter sales results. With disruptions anticipated from the proposed merger with Biomet, Inc., that's a pretty good quarter for Zimmer CEO Dave Dvorak and company.

On a reported basis, those sales decreased 1.6% from last year's red hot fourth quarter. On a constant currency basis, sales rose 2.4%.

Dvorak expects sales in the first quarter of 2015 to increase 1.5% and 2.5% on a billing day and constant currency basis. The strong U.S. dollar is expected to cause sales to decrease by approximately 6% in that first quarter. Then they expect the merger with Biomet to be approved.

Zimmer 4Q14	Sales $ in million	% Change
Total Reported Sales	**$1,223.0**	**down 1.0%**
Reconstructive	$911.0	down 2.0%
Knees	$519.0	down 1.0%
Hips	$338.0	down 4.0%
Extremities	$54.0	4.0%
Trauma	$80.0	down 1.0%
Spine	$56.0	6.0%

Source: Zimmer Holdings, Inc.

Matson noted that, on a constant currency basis, Zimmer's fourth quarter recon growth slowed to 2% from 5% in third quarter. Knee growth slowed to 2% vs. 6% and hip growth slowed to 1% vs. 3%, from the third quarter. In particular, added Matson, U.S. recon growth slowed to -1% from 3% in [the third quarter] as Zimmer lapped an 8% comparison from the fourth quarter of 2013. Spine, which had been a problem child for Zimmer for some time, pulled up sales by climbing 6% on a reported basis.

Global Recon Growth

Based on results from Biomet, DePuy Synthes, Stryker Corporation, and Zimmer and estimates for the others, Matson believes that on a constant currency basis, global recon growth was 2% in fourth quarter vs. 4% in the third quarter. "We estimate that global knee growth was 1% and that global hip growth was 2%."

RBC Capital Markets analyst Glenn Novarro says given recent commentary from orthopedic management teams as well as overall healthcare utilization trends, he believes that the U.S. recon market is stable. "We expect these trends to continue into 2015 as the U.S. jobs outlook and overall economy continues to slowly improve."

Healthcare Reform Upside

Novarro makes an indirect comment about claims that the medical device tax was hurting the device industry. He says he believes the Street has little (if any) volume benefit from healthcare reform in its models in 2015. "Accordingly, any pickup would represent upside to current 2015 Street estimates for Zimmer. We believe that a ~1% volume benefit for the hips/knee market could add ~$25 – $30 million in revenues for Zimmer" before factoring in the Biomet acquisition.

After surviving the "Tyranny of the Comps" and sidestepping potential merger sales disruptions, as we saw when Synthes merged with DePuy, Dvorak appears to be steering his ship to calm and steady waters. The lights of the end of the first quarter, when he's promised to consummate the Biomet deal, are closing in. — *WE*

Titan Spine Hits 27,000 Implantations of Endoskeleton!

Titan Spine, LLC has announced that it has achieved 27,000 implantations of its Endoskeleton interbody fusion devices, a figure which represents an increase of 25% from 2013.

Titan President Kevin Gemas commented, "The significant growth of Titan Spine observed in 2014 alone has been tremendous, and we are extremely well positioned to continue our momentum in 2015 and beyond. Over the past year, Titan achieved several milestones that attributed to our global growth and further validated our position as the leader in surface technology. These include the expanded use of our devices in Europe, securing market registration approval in Australia and New Zealand, and obtaining FDA clearance for both the Endoskeleton TL, the first lateral device to feature surface technology, as well as our next generation nanoLOCK surface technology, the first FDA-cleared interbody fusion devices to feature nanotechnology."

The company says that it has greater than 220 hospital customers (an increase of 40% from 2013), with more than 90 U.S. distributors. It has plans for a full launch of Endoskeleton TL lateral device for the first quarter of 2015.

Gemas told *OTW*, "Essentially the ultimate goal for Titan this year is to change the status-quo in the spine industry with the purpose of providing better care for more patients. In our view, the industry has become complacent and accepts PEEK (a plastic material) as the standard material to provide surgeons and their patients for a fusion procedure. We see this as totally unacceptable and we as an industry can do much better for patients in need of spinal fusion."

"Titan will continue to be the leader in 2015 as the most highly-differentiated interbody spinal fusion device company. We will accomplish this objective in a number of ways. First, by applying our new proprietary and improved FDA-cleared nanoLOCK surface technology—the only nano surface FDA cleared in the spine industry—to all of our interbody devices this year."

"Second, Titan is investing significant capital and engineering/quality resources to produce devices that will be sterile packed and delivered to hospitals in a more efficient and effective method. In addition, we are also exploring areas of our manufacturing processes where we can be more cost-effective for hospitals around the world in order to reach and better serve more fusion patients."

"Third and equally important as reaching more people, in 2015 Titan will continue to invest in additional top field professionals to educate and communicate our interbody device's benefits to more surgeons and patients that currently rely on a plastic spacer. We believe that the time has finally come for a fusion device that is designed and engineered to ***participate*** in the fusion process by promoting the upregulation of osteogenic and angiogenic growth factors for bone development."

"This year, Titan will continue to be laser-focused on providing devices that allow patients to heal faster, and that is why we are always investing in making the best fusion devices possible." — *EH*

Kevin Gemas, Titan Spine, LLC

ChoiceSpine Buys Baxano's VEO Lateral Fusion System

Knoxville, Tennessee-based, ChoiceSpine, LP has acquired Baxano Surgical Inc.'s VEO Lateral Access & Interbody Fusion System.

The principals of ChoiceSpine, Marty Altshuler and Rick Henson, said they look forward to building relationships with previous VEO users and this provides a great opportunity to grow their Western footprint. "By adding a lateral system to our product offerings, as well as launching 4 new products in 2015, we can easily say that we are moving forward in the spinal marketplace."

Baxano filed for Chapter 11 Bankruptcy late in 2014 and put its assets up for auction.

Baxano's major assets included the AxiaLIF family of products for single and two level lower lumbar fusion, the VEO lateral access and interbody fusion system featuring the REVEAL retractor, the iO-Flex system, a set of flexible instruments used by surgeons during spinal decompression procedures, the iO-Tome instrument, which removes the facet joints and Avance, an MIS pedicle screw system used in lumbar fusion procedures.

No price was noted for the VEO system in the February 2, 2015 ChoiceSpine press release. In August and September 2014, ChoiceSpine announced FDA 510(k) clearance for its Lancer pedicle screw system and the Thunderbolt minimally invasive pedicle screw system. The company, which acquired Orthotec, was founded in 2006. — *WE*

ChoiceSpine, LP

LEGAL

FTC Biting at Wright and Tornier's Ankles

Wright Medical Group, Inc. has received a "Second Request" from the Federal Trade Commission (FTC) regarding its proposed merger with Tornier N.V.

Second requests are typically made when the FTC staff has heard from potential customers that there may be some difficulties in replacing products sold by the merged entity. Zimmer Holdings Inc. received such a request from the FTC over their plan to merge with Biomet, Inc.

According to the company, all product lines identified in the Second Request are lower extremity products. Tornier said its lower extremity product lines in the Second Request accounted for approximately $14.9 million in U.S. revenue for the identified period.

Federal Trade Commission, United States of America

Needham & Co. analyst Mike Matson says he suspects that the product lines in question consist of Tornier's ankle products because that is an area of overlap between the two companies. Both have around 30% of market share. He now thinks it's likely that the FTC will require Wright to sell one of the two companies' total ankles. He views this as a modest negative since it would mean the ankle could end up in the hands of a competitor like Smith & Nephew plc or Zimmer.

Wright President and CEO Robert Palmisano stated, "We just received the Second Request and are evaluating our options. We will continue to work cooperatively with the FTC to resolve this as quickly as possible. Whatever the final resolution, we do not expect it to have a material impact on the strategic rationale or economics of the proposed merger, and we remain firmly committed to the transaction."

Augment FDA Approval Delay

The February 2, 2015 announcement by the company also included news that a Wright vendor received a Form 483 at completion of a recent FDA pre-approval inspection for Augment Bone Graft. Wright management believes the response from the vendor will satisfy the FDA and the agency will give final approval to Augment by the end of June.

An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. — *WE*

BIOLOGICS

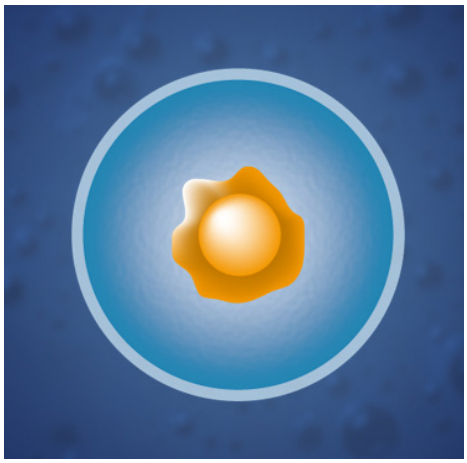
Bone and Cartilage Creating Cell Discovered

Scientists at Columbia University Medical Center (CUMC) have identified a stem cell in the bone marrow of mice that is capable of regenerating both bone and cartilage. They report their study ("Gremlin 1 Identifies a Skeletal Stem Cell with Bone, Cartilage, and Reticular Stromal Potential") in the online issue of *Cell*.

They discovered the cells, called osteochondroreticular (OCR) stem cells, by tracking a protein expressed by the cells. Using this as a marker, the researchers found that OCR cells self-renew and generate key bone and cartilage cells, including osteoblasts and chondrocytes. The researchers also showed that OCR stem cells, when transplanted to a fracture site, contribute to bone repair.

"We demonstrate here that expression of the bone morphogenetic protein (BMP) antagonist gremlin 1 defines a population of osteochondroreticular (OCR) stem cells in the bone marrow," wrote the investigators. "OCR stem cells self-renew and generate osteoblasts, chondrocytes, and reticular marrow stromal cells, but not adipocytes. OCR stem cells are concentrated within the metaphysis of long bones not in the perisinusoidal space and are needed for bone development, bone remodeling, and fracture repair."

"We are now trying to figure out whether we can persuade these cells to specifically regenerate after injury. If you make a fracture in the mouse, these cells will come alive again, generate both bone and cartilage in the mouse—and repair



Wikimedia Commons and Diabetes Center for Life Sciences

the fracture. The question is, could this happen in humans," said Siddhartha Mukherjee, M.D., Ph.D., an assistant professor of medicine at CUMC and a senior author of the study.

The researchers believe that OCR stem cells will be found in human bone tissue, as mice and humans have similar bone biology. "Our findings raise the possibility that drugs or other therapies can be developed to stimulate the production of OCR stem cells and improve the body's ability to repair bone injury—a process that declines significantly in old age," said Timothy C. Wang, M.D., the Dorothy L. and Daniel H. Silberberg Professor of Medicine at CUMC, who initiated this research.

The study also showed that the adult OCRs are distinct from mesenchymal stem cells (MSCs), which play a role in bone generation during development and adulthood. Researchers presumed that MSCs were the origin of all bone, cartilage, and fat. However, recent studies have shown that these cells do not generate young bone and cartilage. The CUMC study suggests that OCR stem cells actually fill this function and that both OCR stems cells and MSCs contribute to bone maintenance and repair in adults. —*BY*

New Technology Doubles Life of Tissue

Thanks to researchers at the University of Missouri School of Medicine, doctors will not have to jettison tissue that is donated for joint replacements. At present, says the January 28, 2015 news release, doctors have to throw away more than 80% of donated tissue used for joint replacements because the tissue does not survive long enough to be transplanted. With a new technology known as the Missouri Osteochondral Allograft Preservation System, (MOPS), the life of donated tissue is more than doubled—without a decrease in quality.

James Cook, D.V.M., Ph.D. courtesy of University of Missouri School of Medicine

"It's a game-changer," said James Stannard, M.D., co-author of the study and J. Vernon Luck Sr. Distinguished Professor of Orthopaedic Surgery at the University of Missouri School of Medicine, news release. "The benefit to patients is that more graft material will be available and it will be of better quality. This will allow us as surgeons to provide a more natural joint repair option for our patients."

To date, donated tissues have been stored within a medical-grade refrig-

eration unit in sealed bags filled with a standard preservation solution. With MOPS there is a new preservation solution and special containers—designed by the research team—that allow the tissues to be stored at room temperature. When the scientists compared the two preservation techniques, they found that the MOPS technology allowed for clinical outcomes to be extended to at least 60 days, versus the current storage time of approximately 28 days. The study also found that the MOPS preservation system resulted in a 100% rate of usable tissue grafts at 60 days after procurement.

"Time is a serious factor when it comes to utilizing donated tissue for joint repairs," said study co-author James Cook, D.V.M., Ph.D. director of the University of Missouri Comparative Orthopaedic Laboratory and the Missouri Orthopaedic Institute's Division of Research. "With the traditional preservation approach, we only have about 28 days after obtaining the grafts from organ donors before the tissues are no longer useful for implantation into patients. Most of this 28-day window of time is used for testing the tissues to ensure they are safe for use. This decreases the opportunity to identify an appropriate recipient, schedule surgery and get the graft to the surgeon for implantation."

Dr. Cook told *OTW*, "The Missouri Osteochondral Allograft Preservation System was developed to extend the storage time of donor tissue and preserve it at a higher quality level than with current methods. The new system includes a serum-free specialized culture media with numerous FDA-approved additives stored in a filtered chamber that does not require specialized incubation conditions."

Dr. Cook, who also serves as the William and Kathryn Allen Distinguished Professor in Orthopaedic Surgery at the University of Missouri School of Medicine, leads the research team that developed the new bone-and-cartilage-preservation technology. — *EH*

LARGE JOINTS

Study: Penalizing Hospitals for Readmissions Is NOT the Answer

Using data from 346 U.S. hospitals, researchers from Northwestern Medicine and the American College of Surgeons have just published work

Photo creation by RRY Publications, LLC
Source: Wikimedia Commons

suggesting that it may be not be useful to penalize hospitals for patient readmissions following surgery. They even learned that it may be counterproductive for improving the quality of hospital care. According to the February 3, 2015 news release, the researchers found that "most surgical readmissions are not due to poor care coordination or mismanagement of known issues. Instead, readmissions were due to expected surgical complications, such as wound infections, that occurred after discharge and were not present during

a patient's hospital stay more than 97% of the time."

"There has been a growing focus on reducing hospital readmissions from policymakers in recent years, including readmissions after surgery," said lead author Karl Y. Bilimoria, M.D., M.S., a surgical oncologist and vice chair for quality at Northwestern Memorial Hospital and director of the Surgical Outcomes and Quality Improvement Center at Northwestern University Feinberg School of Medicine. "But before this study, we didn't really understand the underlying reasons why patients were being readmitted to hospitals following surgery."

The researchers collected data from the American College of Surgeons' National Surgical Quality Improvement Program for all of 2012. These data did include the underlying reason for why the readmission occurred based on the medical record, discussions with treating doctors, and the patients themselves. This data, according to the news release, are not available elsewhere. Six different surgical procedure types were reviewed based on their clinical and CMS [Centers for Medicare and Medicaid Services] policy relevancy, resulting in a total of 498,875 separate patient cases being analyzed for the study. Total hip and knee replacement procedures were among the procedures reviewed. Others were bariatric surgery, colectomy or proctectomy, hysterectomy, ventral hernia repair, and lower extremity vascular bypass.

Researchers found that 5.7% of the patient cases had unplanned readmissions. Of those unplanned readmissions, only 2.3% of patients were readmitted due to a complication that occurred during their initial stay in the hospital. The common cause for unplanned readmissions was surgical-site infections at 19.5%, followed by delayed return of bowel function with an overall rate of 10.3%. The study's add that while these two post-surgical complications are the top two causes for readmissions, compliance with available quality measures to reduce these complications is often already high among hospitals in America and implementing, "policies requiring reductions in readmissions without understanding how to impact improvement could be counterproductive."

Other complications that resulted in readmissions were dehydration or nutritional deficiency, bleeding, an intravenous blood clot and prosthesis or graft issues. The authors note that some of these complications, such as dehydration, are worth addressing as there might be opportunities to reduce their occurrence through better communication with patients, patient education, and innovative care redesign.

Dr. Bilimoria told *OTW,* "Readmissions for orthopedic procedures are due to well-known and well accepted risks of surgery, primarily wound infections. Thus readmissions are simply a proxy for complications. Since CMS already measures complications after surgery, measuring readmissions simply penalizes hospitals twice for complications. Readmissions should certainly be avoided where possible but these results question whether there is merit to the tremendous focus on readmissions in pay for performance programs." — *EH*

EXTREMITIES

Stiletto Heels Harbinger of Osteoarthritis

Most women who wear high heels know, from the pain in their feet, that the heels are not good for them. Radhika Sanghani, an admitted lover of stilettos, writing for *The Telegraph* in the UK reports that Stanford University scientists have found that when a woman puts on a pair of high heeled shoes she is putting dangerous levels of strain on her joints. If the woman is overweight, the damage is even worse.

Sanghani quotes a study published in the *Journal of Orthopaedic Research* in which scientists scanned the knees of 14 women as they walked wearing different types of shoes.

When they examined the angle of the knee as the women's feet struck the ground they found that the higher the heels, the more likely it was the knees were bent when shoes touched ground—increasing the strain on the knee joint. The wearing of heels of three or more inches made the women's knees look, to them, more like aged or damaged joints.

"Wearing high heeled shoes has been implicated as a potential contributing factor for the higher lifetime risk

Wikimedia commons and Oxfordian Kissuth

of osteoarthritis in women," said lead author Matthew Titchenal, Ph.D. candidate of Stanford University's Biomotion Laboratory. "In this study, many of the changes observed with increasing heel height and weight were similar to those seen with ageing and osteoarthritis progression. This suggests high heel use, especially in combination with additional weight, may contribute to increased risk," he said.

According to Sanghani, Jane Tadman at Arthritis Research UK has implicated high heels as a probable risk factor for osteoarthritis of the knee, and back pain. "Wearing high heels shortens the Achilles tendon, causing restriction in ankle movement, and jams the toes into the front of the shoe, which can cramp and deform them" she said.

Sheila Jeffreys, author of *Beauty and Misogyny*, said that even successful women still feel compelled to wear heels which "'make walking difficult, distort women's gait, make it difficult to run or escape danger and cause falls." She is critical of the promotion of footwear that cripples one half of the population and makes it increasingly difficult for them to walk. — *BY*

REIMBURSEMENT

Chronic Conditions, Not Surgical Failure Cause Most Hospital Readmissions

Hospitals have been hit with Medicare payment penalties ranging from 1% to 2% of all Medicare payments for readmissions following surgery associated with the management of myocardial infarction, heart failure, and pneumonia. Hip and knee surgeries are expected to be added to the list in the coming year.

Fred Pollock, M.D. and colleagues studied causes for readmissions of patients with a primary admission diagnosis of hip fracture at a level I trauma center in rural Appalachia. The study findings "provide novel data on patients from rural Appalachia who require hospital readmission after initial repair of a hip fracture. This study also provides insight into risk factors and/or patient-specific conditions that may place members of the rural geriatric community at higher risk for hospital readmission after initial management of hip fracture," according to the authors.

The study institution was a large facility that serves approximately one-third of West Virginia as a tertiary care facility and level I trauma center. The patient base was primarily rural and spread over a large geographic area. The authors said their patients are often frail with "diminished physiologic reserves as a result of multiple pre-existing medical problems that complicate recovery and lead to hospital readmission. Pre-existing comorbidities often include cardiovascular and pulmonary disease, diabetes, dementia, and osteoporosis that increase the risk of morbidity and prolong recuperation after surgical intervention."

They published their results in the January 2015 issue of *Orthopedics* (*Orthopedics*. 2015; 38(1):e7–e13).

Readmission Rate – 25% Surgical Failure

Here's what they found in their retrospective cohort study which included 1486 patients who were 65 years or older and had a surgical procedure performed to treat a femoral neck, intertrochanteric, and/or subtrochanteric hip fracture during an eight-year period:

- A 30-day readmission rate of 9.35% (n=139)
- Patients in the readmission group had a significantly higher rate of pre-existing diabetes and pulmonary disease and a longer initial hospital length of stay
- Readmissions were primarily the result of medical complications, with only one-fourth occurring secondary to orthopedic surgical failure
- Pre-existing pulmonary disease (odds ratio [OR], 1.885; 95% confidence interval [CI], 1.305–2.724), initial hospitalization of 8 days or longer (OR, 1.853; 95% CI, 1.223–2.807), and discharge to a skilled nursing facility (OR, 1.586; 95% CI, 1.043–2.413) were determined to be predictors of readmission.

"Accordingly," concluded the study, "patient management should be consistently geared toward optimizing chronic disease states while concomitantly working to minimize the duration of initial hospitalization and decrease readmission rates."

The researchers are from the Orthopedic Trauma Group-Charleston Area Medical Center (FHP, JPM), Charleston; and CAMC Health Education and Research Institute-Center for Health Services and Outcome Research (AB, DS, AM, JTC), Charleston, West Virginia. — *WE*

Kaiser Health News

SPINE

Moth Creates Novel Peptide for Spine Fusion

Cerapedics, Inc., a privately-held orthobiologics company located in Westminster, Colorado, has received CE Mark rating in Europe and Therapeutic Goods Administration listing in Australia for the firm's new i-FACTOR Flex FR biologic bone graft. The new biologic bone graft, designed primarily for spinal fusion surgery, features the company's proprietary synthetic small peptide bone graft technology with the addition of purified silk fibers. The silk is claimed to provide enhanced cohesion, improved mechanical properties, and handling characteristics.

Jeff Marx, president and chief operating officer of Cerapedics, told *OTW* that, to the best of his knowledge, though silk has historically been used in medicine, his company is the first to use silk in allografts. The product contains silk from larva of the bombyx mori moth. The silk is purified to remove the protein sericin, which results in biocompatible fibroin fibers that enhance cohesion and mechanical properties.

Wikimedia commons and CSIRO

As Marx explained, while the original product worked well in confined spaces, such as cages, "the addition of silk improved interoperative handling characteristics allowing doctors to use it in a broader array of indications."

"Based on our clinical experience thus far, the new i-FACTOR Flex FR biologic bone graft appears to offer significant advantages in handling while maintaining the safety and efficacy of the first generation i-FACTOR with P-15 technology," said Niall Craig, M.D. consultant orthopedic surgeon for the United Kingdom's National Health Service.

"The out-of-package handling and in vivo cohesive properties of i-FACTOR Flex FR biologic bone graft are impressive enhancements and can help improve performance in a number of surgical indications," said Gregory Kesteloot, M.D. neurosurgeon at Stedelijk Ziekenhuis Roeselare in Belgium.

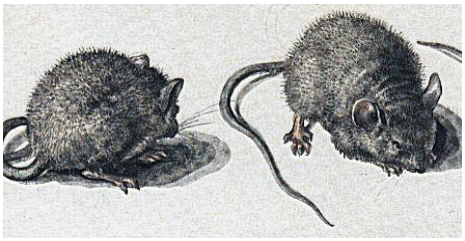
"We are pleased to receive CE Mark approval and TGA listing for the new i-FACTOR Flex FR biologic bone graft," said Glen Kashuba, CEO at Cerapedics. He said that the i-FACTOR Flex FR biologic bone graft is based on original technology developed by Cerapedics to support bone growth through cell attachment and osteoblast differentiation. To date, Kashuba said, more than 60 procedures have been successfully completed using i-FACTOR Flex FR biologic bone graft, primarily in spinal fusion applications.

The company is aggressively pursuing clearance from the U.S. Food and Drug Administration. "We were pleased with the relatively small number of deficiencies with the PMA," Marx said. "None were show stoppers or unanswerable." The company anticipates clearance by the end of 2015 or beginning of 2016. — *BY*

Crippled Mice Walk in Swiss Lab Experiments

Two Swiss researchers at the Ecole Polytechnique Federale in Lausanne, Switzerland, had already earned the world's plaudits when they created an implanted device that allowed paralyzed mice to move their legs. When Gregoire Courtine and Stéphanie Lacour later discovered that their ground-breaking new device eventually caused compression and tissue damage in their subjects because it was too

Wikimedia Commons and Andre Engels



stiff, they decided to invent a flexible implant.

According to Joseph Keenan, *Fierce-Medical Devices*, writing on a study from *MIT Technology Review*, they succeeded. To prevent the damage caused by the rigid implant they invented a flexible product they call an "e-dura" which has a property of human tissue called viscoelasticity. Made of soft silicone, gold wires and rubbery electrodes flecked with platinum, the device is both stretchable and flexible and can be wrapped around the spinal cords of mice. The device also contains a channel that allows the scientists to introduce drugs and medications to the injury site.

When the researchers sent electrical signals through the e-dura, which they had wrapped around the animal's spinal cord, the mice's hind legs moved. After a two month period, the mice showed little sign of any tissue damage—which had not been the case earlier when they had experimented with conventional electrodes.

Keenan quoted Lacour, who is an electrical engineer, as telling *MIT*, "If you want a therapy for patients, you want to ensure it can last in the body. If we can match the properties of the neural tissue we should have a better interface."

The aim of their research, of course, is to create an implant that could restore a paralyzed person's ability to walk. That goal is probably a long way off but Lacour believes that, when it does come, it will involve soft electronics. —*BY*

PEOPLE

Dr. Hamburg Leaving FDA

Margaret Hamburg, M.D., who became the 21st commissioner of the FDA (Food and Drug Administration) almost six years ago, is reportedly leaving the agency. *The Washington Post* reported on February 5, 2015 that Stephen Ostroff, the FDA's chief scientist and a former official at the Centers for Disease Control and Prevention, will take over as acting commissioner.

The *New York Times* reported that Dr. Hamburg told colleagues in an email that she would depart at the end of March. "As you can imagine," she wrote, "this decision was not easy. My tenure leading this agency has been the most rewarding of my career." *Forbes* magazine named her the world's 51st most powerful woman in 2014.

Industry Reaction

The medical device industry seemed to love Dr. Hamburg. After she took over in May 2009, the agency's review times dropped and she was widely praised to fostering a more collaborative environment with industry.

Janet Trunzo, AdvaMed's senior regulatory executive, commended Dr. Hamburg for her years of dedicated service to FDA and to American public health. "It was under her leadership that the historic Medical Device User Fee Agreement III (MDUFA III) was struck, bringing significant new resources, accountability and improvements to the device review process. Much progress has been made, and her legacy will continue in the on-going program which ensures timely patient access to the best in medical care."

The Pharmaceutical Research and Manufacturers of America (PhRMA) also praised Dr. Hamburg for her "thoughtful regulation of medicines" and her "strong leadership." Ian Read, the head of drug giant Pfizer, called Dr. Hamburg "a strong advocate for promoting public health" who supported "innovation in the interest of patients."

Marion Nestle, a prominent nutrition expert and public health professor at New York University told the *Post*, "She's done six years in the hardest job in the world—nobody wants to be regulated and everybody fights the FDA tooth and nail—so I can understand why enough is enough. She managed to

Margaret Hamburg, M.D./Food and Drug Administration

keep the agency funded, avoided scandals, and got [food safety], menu labels, and food labels going. Mostly, she kept Congress and the White House from tearing the agency apart."

Dr. Hamburg: "Place Got Under My Skin"

"The place got under my skin," said Dr. Hamburg in an interview reported by the *Post*. "The honest truth is that I had never expected to stay this long…. It's an extraordinary agency with amazing people, and a unique and essential mission."

She leaves as the longest-serving commissioner in the last few decades after serving as New York City's health commissioner in the 90s. She's the daughter of physicians and a graduate of Harvard Medical School. Her father was a psychiatrist, and her mother was the first African-American woman to attend Vassar College and to graduate from the Yale University School of Medicine.

"There are few harder jobs in this town," said David Kessler, M.D., who was both George H.W. Bush and Bill Clinton's FDA commissioner. "She's pushed the ball uphill in a host of areas…. She's been an excellent steward."

Critics

But everyone wasn't gracious in bidding the Commissioner adieu. If industry liked her, she must be suspect. "I'm pleased to see her go," said Andrew Kolodny, president of Physicians for Responsible Opioid Prescribing and the head of an addiction treatment center in New York. The *Post* said Kolodny clashed with the FDA over its failure to curb abuse of the powerful drugs. "Her administration consistently put the interests of the drug companies ahead of public health."

Michael Carome, director of the health research group at Public Citizen, a nonprofit consumer advocacy organization, said in a written statement reported by the *Post* that Dr. Hamburg's resignation marks the "end of a six-year period of weak and ineffective leadership. Throughout Hamburg's tenure, the FDA has grown even more cozy with the industries that it regulates. Too often, the FDA has succumbed to industry and political pressures, implementing policies and taking actions that tilt too far toward the bottom-line interests of pharmaceutical and medical device companies."

That would get under anyone's skin.

Dr. Hamburg told the *Post* that it's impossible to please all sides in her role, and that an old joke around the agency is that the FDA has two speeds of approving drugs: too fast or two slow.

Promote and Protect

"My goal has always been to try to make sure that patients and consumers have products they need as rapidly as we can responsibly move them through the process, while always adhering to our standards for safety and efficacy," she said.

Inheriting FDA Turmoil

The agency was in some turmoil when Dr. Hamburg arrived in 2009. There were whistleblowers running to Congress accusing the agency's civilian leaders of overruling agency scientists.

"When I came on board, FDA had been through a number of significant crises. There was low morale and a sense that the agency really needed rejuvenation and redirection," Dr. Hamburg said in the *Post* interview. "I think my leadership was important in really strengthening FDA as an institution." Before she arrived, the agency had failed to warn of the dangers of the pain drug Vioxx. In 2005, then commissioner Lester Crawford, who had hidden ownership of stock in companies the agency was regulating, abruptly resigned.

Her immediate predecessor, Andrew C. von Eschenbach, M.D., got ensnared in the ReGen Biologics debacle where the agency deviated from its own processes and inappropriately put a small medical device manufacturer out of business.

Reflect and Relax

Dr. Hamburg said she hasn't spent much time pondering what lies ahead for her. "This is an intense, 24/7 job, where it's very hard to step back and reflect on what it is that I might want to do next," she said. "I just want to take a little time to reflect. And relax."

She's earned her rest…and a skin rejuvenation session. — *WE*

Orthopedics This Week | RRY Publications LLC

Robin R. Young, CFA
Editor and Publisher
robin@ryortho.com

WRITERS

Elizabeth Hofheinz, M.P.H., M.Ed.
Senior Writer
elizabeth@ryortho.com

Walter Eisner
Senior Writer
walter@ryortho.com

Biloine W. Young
Senior Writer
bgwy@msn.com

Sophie Bodek
Writer
sophiebodek@yahoo.com

ADVERTISING

Tom Bishow
Vice President of Sales
tom@ryortho.com

PRODUCTION

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Email, Web, & Conference Coordinator
jayme@ryortho.com

Dana Bader
Graphic Designer
dana@ryortho.com

116 Ivywood Lane • Wayne, PA 19087
TOLL FREE: 1-888-749-2153
www.ryortho.com