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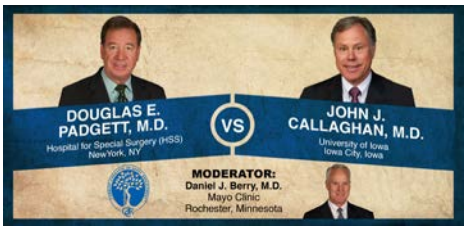
Orthopedics This Week

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: OFIX decides to delay second quarter results in order to double check revenue numbers. Bad sign. Shareholder lawsuits have started. Short sellers have pounced. OFIX is now the most shorted ortho stock. But, here's the interesting point. Insiders are buying stock. When the short sellers look on the other side of their trades they see management!! Now THAT is a good sign.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	5	Zimmer	29.49%	11.38%	Q2 sales were better than forecasted and management raised the 2013 revenue guidance. #1 on the Power Rankings.
2	1	Globus Medical	29.00	1.42	Earnings were a penny better than forecast but those profit margins continue to surprise and amaze.
3	8	Stryker	23.68	11.01	Looks like big, diversified ortho is coming back in favor. Stryker's quarter wasn't great shakes, but again those margins look really good.
4	9	Integra LifeSciences	12.44	2.99	Could IART's product shortage headache be ending? Most analysts think so—which means rebound in the second half.
5	7	Johnson & Johnson	25.58	8.77	Trauma growth now hitting at 4% YOY rates. And those hips and knees are clocking in at 5% and 3%, respectively. Spine? Not so good.
6	6	Medtronic	28.65	6.62	The storm over Infuse is now history and MDT's focus is on getting the basics right—in spine, and everything else.
7	2	Wright Medical Group	6.84	1.75	The honeymoon seems to be over, for now. Next big event is the actual closing of the Microport deal.
8	3	NuVasive	7.53	(9.64)	OIG subpoena caught most investors by surprise. On the more positive side, PODs continue to be pummeled.
9	4	Alphatec	(4.29)	8.49	Most investors expect ATEC to report a small loss on about $50 million in sales. Not so exciting, but Les could surprise.
10	NR	Symmetry	7.49	8.25	SMA beat BOTH sales and earnings forecasts for the second quarter. This is a clear positive for SMA and its shareholders.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MAKO Surgical	MAKO	$15.62	$735	28.88%
2	Bacterin Intl Holdings	BONE	$0.67	$29	27.62%
3	CryoLife	CRY	$7.05	$195	12.08%
4	Zimmer Holdings	ZMH	$84.00	$14,143	11.38%
5	Stryker	SYK	$71.27	$26,949	11.01%
6	Smith & Nephew	SNN	$61.16	$11,025	9.19%
7	RTI Biologics Inc	RTIX	$4.10	$231	9.04%
8	Exactech	EXAC	$21.59	$291	8.99%
9	Johnson & Johnson	JNJ	$94.39	$265,998	8.77%
10	Alphatec Holdings	ATEC	$2.30	$222	8.49%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$0.32	$40	-60.50%
2	Orthofix	OFIX	$22.79	$443	-16.76%
3	Baxano Surgical Inc	BAXS	$1.86	$84	-16.59%
4	NuVasive	NUVA	$22.96	$1,023	-9.64%
5	MiMedx Group	MDXG	$6.31	$605	-4.83%
6	Tornier N.V.	TRNX	$16.51	$766	-3.96%
7	Globus Medical	GMED	$17.15	$1,579	1.42%
8	Wright Medical	WMGI	$27.36	$1,278	1.75%
9	Integra LifeSciences	IART	$38.52	$1,425	2.99%
10	Conmed	CNMD	$32.95	$906	4.01%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$22.79	$443	8.87
2	Zimmer Holdings	ZMH	$84.00	$14,143	13.57
3	Medtronic	MDT	$54.94	$55,347	14.78
4	Globus Medical	GMED	$17.15	$1,579	15.03
5	Smith & Nephew	SNN	$61.16	$11,025	15.12

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	$27.36	$1,278	118.96
2	NuVasive	NUVA	$22.96	$1,023	82.00
3	Symmetry Medical	SMA	$9.05	$337	35.45
4	RTI Biologics Inc	RTIX	$4.10	$231	24.12
5	ArthroCare	ARTC	$36.72	$1,035	23.84

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$17.15	$1,579	1.00
2	Orthofix	OFIX	$22.79	$443	1.27
3	Conmed	CNMD	$32.95	$906	1.36
4	Exactech	EXAC	$21.59	$291	1.39
5	Zimmer Holdings	ZMH	$84.00	$14,143	1.47

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	$27.36	$1,278	11.15
2	NuVasive	NUVA	$22.96	$1,023	7.01
3	CryoLife	CRY	$7.05	$195	5.04
4	Symmetry Medical	SMA	$9.05	$337	2.95
5	Johnson & Johnson	JNJ	$94.39	$265,998	2.84

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$9.05	$337	0.82
2	Bacterin Intl Holdings	BONE	$0.67	$29	0.85
3	Orthofix	OFIX	$22.79	$443	0.96
4	Alphatec Holdings	ATEC	$2.30	$222	1.13
5	Conmed	CNMD	$32.95	$906	1.18

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	$6.31	$605	22.38
2	TiGenix	TIG.BR	$0.32	$40	9.85
3	MAKO Surgical	MAKO	$15.62	$735	7.15
4	Baxano Surgical Inc	BAXS	$1.86	$84	5.77
5	Globus Medical	GMED	$17.15	$1,579	4.09

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

The Top 25 U.S. Hospitals for Total Hip Surgery

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

RRY Publications

Dealing with osteoarthritis (OA)/rheumatoid arthritis (RA)/avascular necrosis? If you need a total hip replacement, you might want to consider one of the top 25 facilities in the country. They have done their homework, and figured out how to deliver expert care and relatively reasonable prices.

What these hospitals have in common:

- High volumes: these 25 hospitals average 394 total hip surgeries per year, whereas the U.S. average is 43.
- Low prices: the average charge was $27,786 compared to the national average of $54,050.

Here's how four of these top hospitals become the best in the country: *(See table on page 5)*

Indiana Orthopaedic Hospital

Frank R. Kolisek, M.D. is a joint replacement specialist at Indiana Orthopaedic Hospital. We asked Dr. Kolisek, past president of "OrthoIndy," what his facility did to make it one of the top 25 in the United States for this surgery. He told *OTW*, "We focus on the care of the patient and their family. We want the patient to receive the best possible orthopedic care and we want them and their families to have a great experience while 'visiting' our facility. We believe that if you take good care of the patient and do what is necessary to achieve this goal, then everything else takes care of itself. We don't focus on the bottom line, but rather we focus on getting the patient treated for their orthopedic problem in the best way possible. Doing this rather than cutting corners makes a big difference in patient outcomes as far as we are concerned. I'm proud that

Provider Name	State	Average Charge	Complication Rate
Anne Arundel Medical Center	MD	$19,619.94	5.0%
Ch Allied Services, Inc.	MO	$27,129.06	5.4%
Christiana Care Health Services, Inc.	DE	$34,145.86	5.5%
Community General Hospital Of Greater Syracuse	NY	$26,736.70	1.0%
Indiana Orthopaedic Hospital	IN	$30,031.31	4.7%
Kansas Surgery & Recovery Center Llc	KS	$21,888.61	4.4%
Lucy Webb Hayes National Training School For Deaconesses & Missionary – Sibley Memorial Hospital	DC	$29,799.22	6.1%
Mayo Clinic Florida	FL	$35,755.46	3.7%
Mayo Clinic Health System – Mankato	MN	$28,507.21	4.7%
Mayo Clinic – Methodist Hospital	MN	$29,628.47	4.5%
Mid-Michigan Medical Center – Midland	MI	$26,969.26	2.9%
New England Baptist Hospital	MA	$24,204.64	4.6%
Robert Packer Hospital	PA	$33,020.57	3.4%
Saint Joseph Medical Center, Inc.	MD	$17,520.97	6.8%
Saint Joseph's Hospital Of Atlanta Inc.	GA	$29,482.06	6.3%
Sanford Medical Center Fargo	ND	$30,773.53	6.1%
Spectrum Health Hospitals	MI	$27,118.74	7.3%
St Francis Hospital And Medical Center	CT	$23,335.40	4.6%
St Joseph's Hospital Health Center	NY	$28,042.71	5.6%
St Vincent Infirmary Medical Center – St. Vincent Health System	AR	$35,143.85	4.5%
St. Mary's Hospital & Medical Center Inc.	CO	$34,277.13	2.0%
Suburban Hospital Inc.-Suburban Hospital Health System	MD	$17,807.29	7.4%
The Moses H. Cone Memorial Hospital Operating Corp.	NC	$25,353.04	4.6%
The Union Memorial Hospital	MD	$24,355.49	4.0%
Tucson Medical Center	AZ	$33,998.33	6.1%

Source: PearlDiver Data Technologies, Inc.

our staff being so efficient that there is no duplication of services. The staff is just wonderful, and makes patients feel like VIPs; and we don't wait for patients to hit the buzzer to provide pain medication. Overall, if we can deliver great outcomes, then the patient will benefit, they and their families will have a great experience and we will help lower health care costs by providing high quality care with low complications."

We then asked Dr. Kolisek about his hospital's average charge for this surgery—$30,031. "What is interesting is government insurance programs and insurance companies have negotiated rates for elective orthopedic procedures such as a hip or knee replacement," he said. "Therefore, they pay the hospital a set fee regardless of what the hospital charges actually are, so charges in and of themselves are not useful. Bundled pricing is catching on at this time as well. We look at what resources it takes to deliver a high quality orthopedic procedure and we don't 'add on' to cover something else. Certainly, we hope the reimbursement we receive covers our costs."

As for how they get patients discharged as soon (and as safely) as possible, Dr. Kolisek explained, "Patient education and having a team that understands the game plan are the most important factors in achieving good outcomes with timely discharges to home. When patients understand what they are getting ready to go through and what is expected of them, then things go better as surprises have been eliminated. Get-

ting their families and friends involved in their care is also quite helpful."

St. Francis Hospital and Medical Center

The Connecticut Joint Replacement Institute (CJRI) at St. Francis Hospital and Medical Center is also amongst the best in the U.S. Steven F. Schutzer, M.D. is medical director of the CJRI and president of Connecticut Joint Replacement Surgeons, LLC. He told *OTW*, "Since CJRI's inception on July 31, 2007, our prime focus has been on generating sustainable healthcare value for our patients. We have been successful in doing so by a strong commitment to standardizing our approach to the delivery of care for our joint replacement patients; our care plans are all protocols driven. We have established a continuous process improvement methodology that follows this scheme: 'measure…assess….adjust….implement….adjust… measure…'"

"Also, we pay careful attention to cost and supply chain spending; this is guided by evidence-based decision making. We have created a culture of excellence throughout CJRI…one that every member of our diverse family of dedicated staff helped write and now live; this captures broad buy in. In addition, we provide real time feedback to our surgeons on outcomes and cost, and make it a point to engage the patient and family in their care. We also think it's important that we have a cadre of high quality fellowship trained arthroplasty surgeons managing the service line."

We also asked him about his facility's charges—a quite modest $24,355.49. Dr. Schutzer told us: "The answer to the question has to be predicated upon an assumption that we are comparing 'apples to apples,' an assumption that I suspect is flawed. Hospital charges are meaningless. As you likely know, hospital charges and their costs have very little correlation. At CJRI and St. Francis Hospital, we have an outstanding finance department with whom we have worked with for many years now to 'clean up' our cost data. So, we know, with substantial accuracy the cost of delivering total hip and knee arthroplasty. Having access to clean

cost and outcomes data, three years ago, we implemented a bundled payment program for primary THA [total hip arthroplasty] and TKA [total knee arthroplasty] based on real costs of delivering this service. We run a lean, highly efficient, high quality arthroplasty institute. I would urge you and your readers to not place much credibility on published hospital charges for these or other procedures."

Concerning discharge, Dr. Schutzer stated, "The answer to this can be traced to the responses to your first question. Reducing length of stay is a complex undertaking with multiple nodes and decision points any one of which can affect the success of the effort. That said, in six years, as a result of our care plans, we have reduced the LOS [length of stay] from 4.2 to 2.7 days for our total joint patient population. Safety is a key issue and is part of the CJRI culture that has been cultivated since we opened. To address one of the most devastating safety issues for hospitalized patients... in-hospital falls...we have implemented a 'Call, don't fall' program. This is actually a contract between our staff and our patients that they sign on admission in which they agree NOT to get out of bed or chair without assist (until deemed safe by our safety team) and in which we agree to respond to their calls for service in a timely fashion. This has reduced the incidence of our falls by 60%."

Sanford Medical Center Fargo

Arlene Biberdorf is vice president of Ortho/Neuro/Rehab for Sanford. Regarding all they are doing right in the realm of total hips, she told *OTW*, "Total hip patients come to their surgery prepared. All patients are encouraged to attend pre-op class in a group setting and/or a 1:1 learning session. Literature reveals patients who attend a pre-op class are more confident in their ability to recover from surgery with encouraged independence. By reducing anxiety, patients are engaged in their care and have a sense of improvement in their quality of life. We have earned The Joint Commission's Gold Seal of Approval for the total hip replacement program. We voluntarily seek national certifications to validate our commitment to practicing the best standards of care so we can achieve the best outcomes possible."

Regarding their charge for this procedure—$30,773.53, Biberdorf stated, "The total charges for these cases is a total of the individual services provided to the patients, while receiving care. The services can range therefore the cost changes."

As for getting patients sent home in a timely and safe manner, Biberdorf commented, "Pre-op discharge planning is

essential so that the transition from the hospital setting is seamless, and patients are aware, before their surgery of the 2 night/3 day length of stay. During their stay, transition rounds are performed daily, with the patient and our interdisciplinary team (nursing/PT/OT/Case Management/Pharmacy). By having consistent communication between the patient and all the team members, this ensures a safe and timely transition from the inpatient setting."

New England Baptist Hospital

David A. Mattingly, M.D. is chief of adult reconstruction and director of the Otto E Aufranc Fellowship at New England Baptist Hospital (NEBH). He told *OTW*, "We rank in the top 25 because we provide high quality and high value with low complication rates. All surgeons are fellowship trained and work together to establish protocols that produce high patient outcomes and satisfaction. And our educational program, including the training of five fellows each year, provides a knowledge base that is stimulating and current."

Concerning this facility's charge for total hip surgery—$24,204.64, Dr. Mattingly told *OTW*, "The price of a surgery varies based on the individual needs of each patient. Some patients are more complex with comorbidities such as diabetes or cardiology issues. These patients require additional services to support their surgery. NEBH always makes an effort to provide high quality and high value. We do everything we can to keep costs down through increased efficiency and evidence-based protocols."

To the point about safe and timely discharge, Mattingly noted, "Our preadmission screening process is very thorough. It is designed to keep infection rates low and eliminates some of the potential complications post-surgery. We also spend a lot of time educating our patients prior to surgery. By doing this patients are better prepared for surgery both physically and mentally. Empowering the patients and making them partners in the surgical process helps to get them ready to go home faster. Our active physical therapy program also helps. Working with patients before the surgery and getting them mobile quickly after the surgery also contributes to a shorter hospital stay." ♦

The research for this ranking was performed by PearlDiver Technologies, Inc., a company with a proprietary database that includes more than one billion patient records and includes Medicare (deidentified) and private payer data as well as specific industry data as compiled by PearlDiver's team of analysts. (PearlDiver Technologies, Inc. is affiliated with Orthopedics This Week.)

Ripped From the Headlines – The Ten Best Doctor Movies

BY ROBIN YOUNG

Wikimedia Commons

Passions unbridled! Doctors and nurses! Saving lives and making love, often simultaneously. Stories ripped from headlines. Damn the rules, damn the system. "Make love to me Harold. I know I'm just a surgeon and you're a hotshot payables manager! I must have you, right here, right now!" "But we're in the cafeteria, Sylvia…"

When it comes to drama, nothing delivers the goods so well as an outbreak, an emergency, a fatal condition, a stigma, a loss of function and eye candy actors and actresses in war (MASH), out west (Medicine Woman) or a gritty urban hospital (ER, Grey's Anatomy, Chicago Hope).

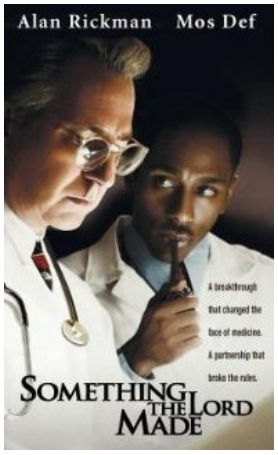
There is something deeply satisfying about a good medical drama.

So, who does this best?

Yes, you guessed it. We have the answers. For the first time, here in the convenient framework of the number ten, are the absolute best, most satisfying medical movies—of all time!

Don't agree? Feel free to post your favorites below.

Number 1: *Something the Lord Made*



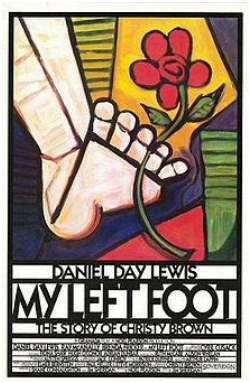
Something the Lord Made is the richly satisfying story of a 34-year partnership that begins in Depression Era Nashville in 1930 when Blalock (Alan Alan Rickman) hires a young black man Thomas (Mos Def) as an assistant in his Vanderbilt University lab, expecting him to perform janitorial work. But Thomas' remarkable manual dexterity and intellectual acumen confound Blalock's expectations, and Thomas rapidly becomes indispensable as a research partner to Blalock in his forays into heart surgery.

The film traces the two men's work when they move in 1941 from Vanderbilt to Johns Hopkins, an institution where the only black employees are janitors and where Thomas must enter by the back door. Together, they attack the heart problem of Tetralogy of Fallot, also known as Blue Baby Syndrome, and in so doing they open the field of heart surgery.

After Blalock's death, Thomas continued his work at Johns Hopkins training surgeons. At the end of the film, in a formal ceremony, Hopkins recognized Thomas' work and awarded him an honorary doctorate. A portrait

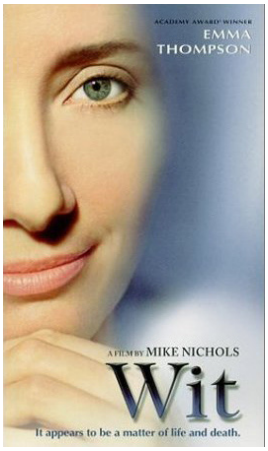
of Thomas was placed on the walls of Johns Hopkins next to Blalock's portrait, which had been hung there years earlier.

Number 2: *My Left Foot: The Story of Christy Brown*



This film received five academy award nominations and won two—Best Actor for Daniel Day Lewis and Best Supporting Actress for Brenda Fricker. *My Left Foot* tells the true story of Christy Brown who was born with a severe form of cerebral palsy. Except for his left foot, Christy is paralyzed. Written off as retarded and helpless, Christy nevertheless learned to write and paint using his left foot and along the way falls in love with his nurse. There is no sugar-coating in this this movie. Brown, who became a heavy drinker, is not lovable. His mother (played by Brenda Fricker) never gives up and, eventually, Christy becomes a well-known author, painter and fundraiser for cerebral palsy causes. This is terrific movie that will inspire all who are in the healing professions.

Number 3: *Wit*

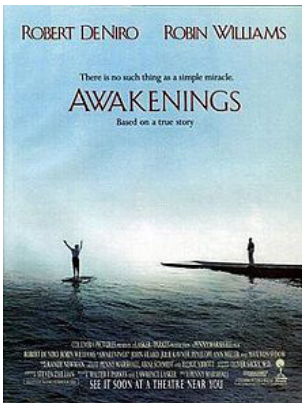


Actually, nearly any move with Emma Thompson is worth seeing. In this drama she plays an increasingly ill victim of Stage IV ovarian cancer named Vivian Bearing. As she undergoes ever more tests and experimental treatments, she begins to realize that the doctors treating her, including a former student of hers, see her less as someone to save and more as a guinea pig for their treatments. The only person who seems to care for her as a person is Susie Monahan (Audra McDonald), one of the nurses on the staff.

Late in Vivian's illness, the only visitor she receives in the hospital is her former graduate school professor and mentor, Evelyn Ashford (Eileen Atkins), who reads her excerpts from Margaret Wise Brown's *The Runaway Bunny*. As she nears the end of her life, Vivian regrets her insensitivity and realizes she should have been kinder to more people. In her time of greatest need, she learns that human compassion is of more profound importance than intellectual wit.

Vivian dies at the end of the film, with her voiceover reciting "death be not proud."

Number 4: *Awakenings*



Robin Williams as Oliver Sacks? Yes, and it works very, very well. Williams, playing a version of the absent minded klutzy professor and real life neuro scientist Oliver Sacks (named Malcolm Sayer in the film), takes a job at a Bronx psychiatric hospital in 1969. He is charged with the care of a group of apparently catatonic and unresponsive patients—one of whom is Robert DeNiro. Of course, we've seen DeNiro give interviews. Also unresponsive. Sayer tests a new drug, L-DOPA on one of his patients—as played by DeNiro. Gradually, his patients begin to emerge from their living-dead states under the influence of L-DOPA, but complications develop. *Awakenings* was nominated for three academy awards. Directed by Penny Marshall, the performances by Williams and DeNiro are two of their best ever and definitely Oscar worthy.

Number 5: *MASH*

One of the greatest medical movies ever produced, this black comedy launched the careers of Donald Sutherland, Elliott Gould, Sally Kellerman, Tom Skerritt and Robert Duvall. Director Robert Altman's style captured the casual, chaotic atmosphere with its constant noise, activity and gore of a mobile army surgical hospital (MASH) three miles from the Korean War front lines. Altman experimented with widescreen photography, zoom lenses and overlapping sound and dialogue along with improvisational ensemble acting. These techniques were revolutionary 40 years ago (and still fresh today) and have influenced movies ever since. Nominated for five academy awards and winner of Best Screenplay, many of its lines are now part of the popular culture.

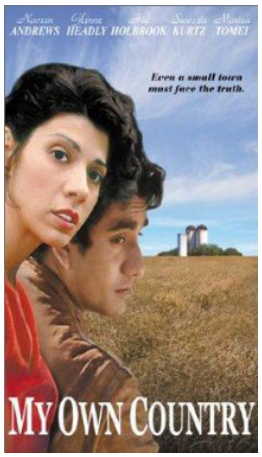
Hotlips O'Houlihan: "I wonder how a degenerated person like that could have reached a position of responsibility in the Army Medical Corps!"

Father Mulcahy: "He was drafted."

Number 6: *Red Beard*

This 1965 film by famed Japanese director Akira Kurosawa is about the relationship of a town doctor and his new trainee. The story is set in 19th century Edo (now Tokyo). A Dutch-trained young doctor, who aspires to become personal physician to the Shogun, is disappointed to find that he's been assigned to train in a rural clinic under the autocratic "Red Beard." Dr. Niide (aka: Red Beard) seems like a tyrannical task master, but is really a compassionate clinic director. Through working with patients at the clinic and learning to work under the rules, the young doctor begins to learn the magnitude of his patient's suffering as well as his power to ease that suffering. The young doctor begins to regret his earlier vanity and selfishness. Through observing his mentor, Dr. Niide, the young doctor discovers what being a doctor really means—that the lives of his patients are more important than wealth or status.

Number 7: *My Own Country*



Directed by Mira Nair—one of the most talented directors working today—*My Own Country* tells the true story of an East Indian doctor who settles in Johnson City, Tennessee, and become one of the great crusaders against AIDS. This film is more than a "fish out of water" story. Dr. Verghese, who trained in infectious diseases and received his medical degree from Madras Medical College, Chennai, India, is an extraordinarily talented and courageous scientist who confronted a true plague. The film is set in 1985. AIDS is spreading from the big cities to the rural areas. Dr. Verghese takes this implacable disease on as his personal crusade. He soon has as many as 82 patients under his care. His wife, who is very pregnant, worries that he may contract the AIDS virus through contact with patients. At the same time, he is confronted with hospital administrators who are worry about the cost of all this care. Starring Marisa Tomei, this is a great and undiscovered gem of a movie.

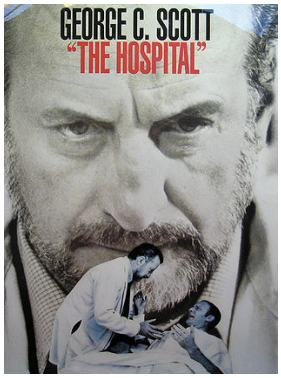
Number 8: *The Doctor*

What happens when the doctor becomes the patient? This film, which is based on the book "A Taste of My Own Medicine" by real-life surgeon Ed

Rosenbaum, explores that dynamic in an extraordinarily powerful way that resonates strongly with patients and physicians alike. In this movie William Hurt plays an arrogant doctor who cares little about the emotional welfare of his patients. When he discovers that he has a malignant tumor, he learns what patients endure—long lines, callous attitudes and the indignities of illness. Through his own experiences and those of his fellow cancer patients, the doctor learns to be a more caring healer. I wonder how many surgeons will see themselves in the Hurt's character.

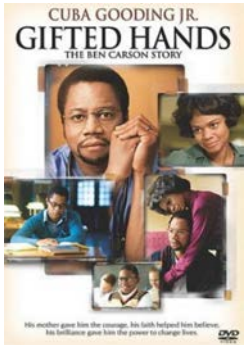
Number 9: *The Hospital*

At the time of its release, this 1971 movie received almost universal critical praise. *The Hospital*, which is loosely based on New York's Lennox Hill hospital in the early '70s, won the Academy Award for its screenplay by Paddy Chayefsky. The movie stars George C. Scott as a bitter, suicidal Dr. Bock, Chief



of Medicine. The movie opens with the mysterious deaths of two doctors and a nurse. Both seem to have died from staff ineptitude and extreme carelessness. Dr. Bock complains of impotence and has thoughts of suicide. Into this mess comes a new patient, a physician who has retired to Mexico. His adult daughter, the alluring Diana Rigg, brings him to the hospital for treatment. Literally in minutes, Dr. Bock and the patient's daughter fall in lust. The enduring strength of this movie is its screenplay. Forty years on, it still snarls and bites.

Number 10: *The Gifted Hands of Ben Carson*



This 2009 movie starring Cuba Gooding Jr. is based on the life of world renowned neurosurgeon Ben Carson. Sponsored by Johnson & Johnson, the movie aired on TNT. Ben Carson started out life as a child in a single parent home. His mother, who dropped out of school in the third grade, is the principal driver pushing her children to achieve in school. Despite stints in a mental institution, Carson's mother persevered. Carson eventually goes on to medical school and rises to become a famed neurosurgeon at Johns Hopkins hospital in Baltimore. Occasionally syrupy, this movie still documents the struggle and focus required to become a successful surgeon and leader. In Ben Carson's story are the elements of many of the stories of great physicians. ♦

Docs on Controlling Costs – "Not My Job"

BY WALTER EISNER

Make the lawyers, insurance companies, hospitals, device makers and patients do it.

That's the opinion of most of the 2,500 physicians surveyed by Mayo Clinic researchers about who is most responsible to reduce health care costs.

Jon Tilburt, M.D.

Wikimedia Commons

Jon Tilburt, M.D., a general internist at Mayo Clinic and his colleagues set out to discover what physicians thought their role is in controlling health care costs, and which strategies they thought were most promising. In 2012 they sent out 3,897 surveys by mail using the American Medical Association's (AMA) Physician Masterfile. Over 65% of those surveyed responded.

Survey Says

Besides discovering that only a third of the respondents thought they had a major responsibility in controlling costs, the researchers found:

- Few physicians expressed enthusiasm for eliminating fee-for-service payment models (7%)
- Most physicians reported being aware of the costs of the tests/treatments they recommend (76%)
- Agreed they should adhere to clinical guidelines that discourage the use of marginally beneficial care (79%)
- Agreed that they should be solely devoted to individual patients' best interests, even if that is expensive (78%)
- Doctors need to take a more prominent role in limiting use of unnecessary tests (89%)

So if these physicians don't think they bear "major responsibility" to control costs, who do they think does?

- Trial lawyers (60%)
- Health insurance companies (59%)
- Hospitals and health systems (56%)
- Pharmaceutical and device manufacturers (56%)
- Patients (52%)

Paycheck Divide

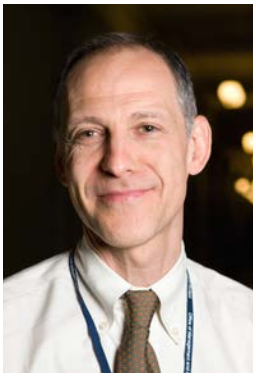
Where one stands apparently depends upon where one sits. Tilburt said that whether physicians were salaried or not was a major predictor of their enthusiasm for cost control strategies. For instance, salaried physicians were three to four times more likely to be ok with eliminating the fee-for-service system.

Overall, just 30% of the surveyed docs supported eliminating fee-for-service. Penalizing clinicians for avoidable readmissions received just 6% support. Bundled payments received a mere 6% support.

Emanuel: "Denial of Responsibility"

Ezekiel Emanuel, M.D., Ph.D. calls this attitude "a denial of responsibility... In the face of this new and uncertain moment in the reform of the health

care system, physicians are lapsing into the well-known, cautious instinctual approaches humans adopt whenever confronted by uncertainty: blame others and persevere with 'business as usual.'"



Ezekiel Emanuel, M.D., Ph.D.

In an accompanying editorial in the July 24, 2013 edition of the *Journal of the American Medical Association* (*JAMA*), Emanuel, wrote that controlling health care costs is the fundamental domestic policy challenge facing the U.S. Increasing costs are crowding out spending on other public priorities like education, defense, law enforcement, environmental protection and other important public purposes.

He said health care must be transformed in at least six ways.

1. More value consciousness in medical decisions
2. Keep patients healthy to avoid chronic illnesses
3. More team care and away from individual practitioners
4. More organized and coordinated systems
5. More process standardization
6. Greater price and quality transparency

Captains of the Ship

"Physicians must lead," said Emanuel, "They are the captains of the health care ship." He added that physicians decide who gets seen, how often and by whom. They decide who gets hospitalized, which tests are ordered and which diagnostic procedures and surgical operations are administered. They decide which medications to prescribe. "If physicians oppose the changes, reform will fail."

With only about a third of physicians believing they bear some major responsibility, he asks if they can really be "both the captain of the ship and cede responsibility to almost everyone else?"

Unless physicians want to be marginalized, Emanuel writes that physicians must accept that they are responsible for controlling health care costs.

Emanuel wasn't all negative and found some good news in that physicians seem to recognize that health care costs are important with 51% strongly agreeing that the cost of a test or medication is only important if the patient has to pay for it.

Steinmann: "We're Doing a Miserable Job"

John Steinmann, D.O., who has been one of the most active physicians in challenging existing health care cost structures in device distribution, agrees that this study is discouraging and not reflective of the mindset he and his fellow physicians and surgeons should have at this time.

John Steinmann, D.O.

In a response to *OTW*, Steinmann wrote that treatment decisions that physicians make on behalf of their patients, ranging from which tests and procedures to perform to which drugs and medical devices to use, account for 60% of the health care spend in America. "Couple that with the fact that health care spending per capita in the U.S. is nearly twice that of the next closest country with no evidence of any superiority in quality. Then ask, if an individual were making purchase decisions for a company and that company spent twice as much as their competitors to produce the same product, would not that individual who was responsible for making those purchase decisions have to be replaced?"

"Like it or not, we as physicians, far more than anyone else, have the responsibility to spend the countries health care dollar wisely and current data would suggest that we are doing a miserable job of this. As a result, we should understand that we are at serious risk of losing this responsibility—a direction that would have equally disastrous effects on health care in America."

Gross Market Failure

In the area of orthopedic and spinal devices, Steinmann writes that surgeons know that the majority of devices have reached a status whereby there are a number of quality manufacturers making products that will perform equally well. "Yet this commoditization of this industry has not resulted in any cost savings."

Steinmann says physicians owe it to the American public to "correct the gross market failure that has persisted in this area and cause products and manufacturers to compete on value. If we continue to ignore the fact that our decisions cause the U.S. health care sys-

tem to spend twice what it should for medical devices we should be subject to losing the privilege of making that decision."

He says there is no disputing that physicians are the most qualified individuals to make health care treatment decisions including decisions on which drugs and devices to use. "But what is becoming clear is that if we cannot demonstrate greater responsibility in ensuring those decisions are made on the basis of value, then we as physicians will assuredly and rightfully lose that right."

Loss of Control

Why might physicians think other stakeholders have a greater responsibility?

"They could have a highly virtuous view of themselves—that they are trying to do the right thing and are victims in a system of villains," Tilburt said. "Or they might say: 'Look, I'm a cog in a wheel of a large system that I don't really control.'"

"They see drug company profits going up and hospital executives taking seven digits (of income), and the only patients they remember from the previous day in clinic were the super-demanding ones."

Patients Come First

For what did physicians in the survey think they are responsible? Well, patients.

"Most physicians say that trying to address health care costs is part of their job," Tilburt said. "On the other hand, physicians have no problem at the same time saying: 'Look, when push comes to shove, my patients come first and I don't care how much it costs.'"

Physicians also hold nuanced views about their perceived responsibility for health care costs. Most (78%) agree that they should be solely devoted to their individual patients' best interests, even if that is expensive, whereas 85% disagree that they should sometimes deny beneficial but costly services to certain patients because resources should go to other patients that need them more.

Society Second

Yet 85% also agree that trying to contain costs is the responsibility of every physician, and 89% agree that doctors need to take a more prominent role in limiting use of unnecessary tests.

This apparent inconsistency, write the survey authors, "May reflect inherent tensions in professional roles to serve patients individually and society as a whole."

They note that previous studies have suggested that U.S. physicians endorse the ideal of prudent stewardship but are reluctant to withhold available but costly services that could benefit individual patients.

"Similarly, Campbell et al. found that 98% of physicians endorse 'just distribution of finite resources' but 36% would order magnetic resonance imaging that is not indicated. Antiel et al. found that a majority of U.S. physicians were willing to accept lower reimbursement for expensive drugs and procedures if that would expand health insurance coverage, but 55% also objected to using cost-effectiveness analysis to guide what treatments are used in practice. Physicians clearly struggle with these tensions and how they can act individually and collectively to provide optimal, sustainable quality care," wrote the authors.

What Do Docs Want?

Moving toward cost-conscious care starts with strategies for which there is widespread physician support, says Tilburt. Those efforts may include improving quality and efficiency of care and bringing transparent cost information and evidence from comparative effectiveness research into electronic health records with decision support technology. More aggressive (and potentially necessary) financing changes may need to be phased in, with careful monitoring to ensure that they do not infringe on the integrity of individual clinical relationships.

The authors conclude that health reform efforts that don't create a stress test for physicians to choose against the needs of patients would be the first step physicians would want to see. ♦

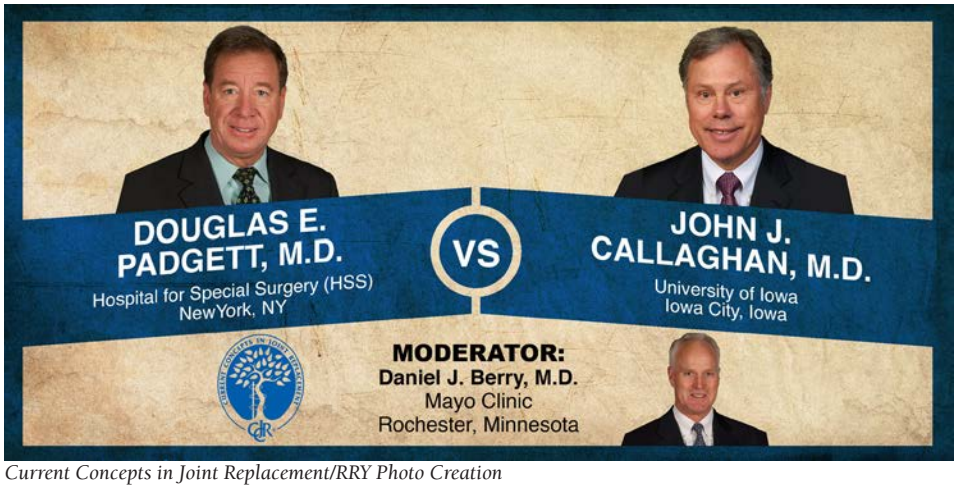
You can read the details of the survey here: http://jama.jamanetwork.com/article.aspx?articleid=1719740#joi130031r19

Padgett, Callaghan: Three Rounds Over Constrained Liners

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

Doug Padgett says, "Constrained liners are problematic. We looked at 70 liners and found a mean length of implantation of only 26 months. We noted a tremendous amount of wear on both the outer and inner rims." "But some do need a constraint," argues John Callaghan. "And when we looked at the tripolar design out to ten years there was a 93% success rate."

This week's Orthopaedic Crossfire® debate is "Constrained Liners in Revision THA: More Problems than They Solve." For the proposition is Douglas E. Padgett, M.D. of Hospital for Special Surgery (HSS); against the proposition is John J. Callaghan, M.D. from the University of Iowa. Moderating is Daniel J. Berry, M.D. from Mayo Clinic in Minnesota.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Padgett: "Today's thesis is that it's better to avoid/prevent than treat in terms of instability, and constrained liners are the last resort. Dislocation remains a problem for surgeon and patient. Kevin Bozic has taught us that instability remains the number one reason for revision in the U.S. It's so prevalent that at the Hip Clinic at the University of Iowa they are very proactive in this regard. This was noted by Dr. Callaghan recently, who advised a patient, 'And when your hip pops out, go to the ER and ask for the resident on call and tell them you came from Mayo.'"

"The factors associated with instability are complex, and include patient, surgeon, and implant issues. Thirty years of THA [total hip arthroplasty] data from Mayo on the cumulative dislocation rate show that head size influences instability; the cumulative risk was estimated to be about 7% at 25 years. If you dislocate once you have at least a 50% chance of dislocating again."

"And bracing? The data is awful…there's about a 50/50 chance that bracing will help. If you determine that the cause of instability is component orientation, then changing components should solve the problem. Unfortunately, it was only successful in 70% of cases in the original Mayo study."

"This led us to the age of constraint… poor results with revision. Most manufacturers had at least one type of constrained design. Our group—and John—reported on the high success rate at two to three years (94-96%). Unfortunately this is subject to the effect of time. At HSS we wrote up the modes of failure of the constrained implants whether they were pulled out of pelvis, whether or not they re-dislocated, whether there were material problems."

"We looked at our retrieval collection—70 liners. The mean length of implantation was only 26 months in this group. The indications for the use of these constrained liners were: prophylaxis in a third and prevention of recurrent instability in another third. We noted a tremendous amount of wear on both the outer and inner rims. Obviously, with these well-functioning liners that were removed for infection, there was no difference in the extent of damage between the two."

"Recently we had a 71-year-old female with rheumatoid arthritis who at four years postop had recurrent dislocations. It was revised to a dual mobility last year, had a closed reduction in the ER. The liner was sitting in the flank, so I'm not sure if the dual mobility is going to solve the problem."

"If we do a critical analysis of the unstable THR [total hip replacement] I would suggest using these radiographic criteria: looking at the socket, stem, and true lateral to assess version. In most cases you will find a problem. We looked at 700 hips from our registry; the biggest issue was the failure to reconstruct proper offset on both the socket and the femoral head side."

"We found that at our institution the majority of unstable hips were in sub-optimal implant position. We now advise that if it's sub-optimal, fix it! The options are to revise the cup, revise the stem, use larger diameter heads, and potentially offset liners. In a case of recurrent instability following revision we had a retroverted cup…we revised the cup. In another case there was a retroverted stem; we revised the stem."

"Constraint should be used when there is no other option. In conclusion, constrained liners create more problems than they solve."

Dr. Callaghan: "There's no question that larger head sizes can control a lot of the problems today. The larger heads don't appear to be wearing. In a hip simulator they do still show that there's more wear with these larger heads, but I'm not sure we can say that this will definitely be the case with larger heads."

"Our biggest problem now is becoming the trunion issues with the larger heads…especially as you get up around 40mm. There is good clinical evidence showing that big heads are not enough. In work by Lachiewicz where they used 36 and 40mm heads there was a 4.6% early dislocation rate. Beaule was one of the first to use large heads in revision surgery; he had a 9% prevalence of dislocation."

"King and Ries have shown that the problem becomes greater when your abductors are off. In one group of 28mm heads there was an absent abductor and a 40% dislocation rate. In another group of 36mm heads there was an absent abductor and a 33% dislocation rate. We must remember to always check the patient during the physical exam and ensure that their abductor is functioning. With metal-metal we've been

seeing situations where the abductors are completely necrotic. I've been putting in constrained liners in a number of those folks."

"So why have constrained liners gotten a bad rap? There are different kinds of constrained liners; some capture between the head and polyethylene and some capture at a distant site. When you look at those that capture between the head and the liner there's no question a very high re-dislocation rate. We looked at those with tripolar type of designs and found that about 70-90% of the movement is at the bipolar, so they don't actually lose the constraint. When we looked at the tripolar design out to ten years there was a 93% success rate; it was only the younger patients that had failures.

"The acetabular and femoral revision rates at ten years were reasonable (5% and 3%)…just a bit higher than in revision surgery, but these were also complex cases. Osteolysis was low (2%). You can also cement a liner into the shell if you use a number of techniques."

"Yes, we had failures, but they were related to technique such as an abducted cup, one where there was an extended lip down inferiorly (the bipolar will pop out of the tripolar), and you can't put it on a bunch of bone graft."

"Some people do need a constraint. Doug would sleep a lot easier if he would use it on occasion. We are still liberal with the use of constrained liners with elderly patients, especially in people with deficient abductor musculature."

Moderator Berry: "Can we come to some agreement on current indications for a constrained implant? Doug?"

Dr. Padgett: "I think that would be neuromuscular patients and perhaps those with deficient abductors."

Moderator Berry: "How about the patient who's got all the other implants and you can't determine why they're coming out?"

Dr. Padgett: "That becomes problematic in my hands because that's not going to prevent dislocation. The issue I have with constrained liners is that when they dislocate that's not a, 'I'm going to Dr. Doug's clinic at New York Hospital.' Rather we're not able to successfully close reduce those patients and they buy themselves another operation. My concern is the overutilization of this technology. So I don't think identification of what you see as the high risk patients—like a hyper mobile woman who's undergoing primary hip replacement. As a prophylactic measure I think that is overused."

Moderator Berry: "Good point. Just because you're afraid that someone might become a dislocator you're worried about overusing technology that has accompanying risks? John, who do you think should not get a constrained liner?"

Dr. Callaghan: "Any patient under age 50 I would try these other things… tripolar, dual mobility. Maybe I'll be back in there, but I'll accept it in those patients…with those other patients I mentioned I just want one operation. You should avoid constrained liners when you do a big acetabular revision. You've got all these screws in there—and screws can be problematic—and you have bone graft. I think nowadays you should put a tripolar in and see how it does…if you must revise so be it."

Moderator Berry: "Let's say you've done a big acetabular revision and you're worried about cup fixation. That's the one you're going to worry about going to constrained because that's going to stretch those interfaces in that first year?"

Dr. Callaghan: "Absolutely."

Moderator Berry: "Give me you're top technical tips on avoiding failure of a constrained implant."

Dr. Callaghan: "I used to think that the extended lip on the tripolar was a bad idea. Now I think it's a very good idea… because usually there's going to be one direction that's the biggest problem for the patient. The problem with some of the newer cups—even the tripolar one—is that they have a rim on both sides and you can impinge on the other side of that. I don't use those; I use the old style. I put the extended lip in the direction that the patient's been dislo-

cating. I accept the fact that you could have a problem the other way."

Dr. Callaghan: "Absolutely."

Moderator Berry: "Doug?"

Dr. Padgett: "You heard what John said. You ignore that and do the opposite. Don't use an elevated liner because in our series that's where they all wore… and you have broken rings, poly wear, etc. I think that it actually has been an advantage with the lower profile devices."

Dr. Callaghan: "There's not enough experience with those yet for you to have in your lab, but you'll get more of those."

Moderator Berry: "So we all agree that constrained implants are more at risk for impingement than nonconstrained, just by virtue of the way they're designed. Would you agree that if you're going to do constrained you should put trials in and try to figure out how to position them?"

Dr. Callaghan: "I agree."

Dr. Padgett: "I agree 100%.

Moderator Berry: "Thank you both." ♦

Please visit www.CCJR.com to register for the 2013 CCJR Winter Meeting, December 11–14 in Orlando, Florida.

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COMPANY

Zimmer Sales Accelerate Best in Years

Zimmer Holdings, Inc., according to Bank of America analyst Bob Hopkins, just reported the company's best revenue growth in years.

The reported second quarter 4% increase in sales to $1.17 billion by the largest hip and knee maker in the industry continued the theme of stability in orthopedics. Net currency impact for the quarter decreased company revenue by 1.6% or $18 million.

Zimmer President and CEO David Dvorak told Wall Street analysts on July 25, 2013, the company expects to "sustain this accelerated top line performance in the second half of the year." Full-year revenues for 2013 are now expected to increase between 4.0% and 5.0% on a constant currency basis from 2012. Previously, the company had estimated full-year revenues would increase between 2.5% and 4.5% constant currency.

Dvorak continued that in the second quarter, musculoskeletal markets demonstrated stability with modest improvements over the first quarter. This was in line with trends from the previous several quarters, as well as company management expectations for the full year.

Knee sales rose 4% to drive overall reconstructive sales up 2%. Hip sales remained relatively flat. Trauma was flat and spine sales climbed 3%. The big winner was extremities, which rose 14%. Knee growth, said Dvorak, benefited from promising sales of Gel-One, Zimmer's single-injection hyaluronic acid treatment. It was too early to see any impact from the introduction of the company's Persona knee.

Spine's growth rate represents a "noteworthy turnaround" from recent quarters with significant performance improvements from all geographic regions, added Dvorak. Zimmer Spine's return to growth has been led by a focus on the company's core fusion products, such as the inViZia Anterior Cervical Plate Systems, as well as the TM Ardis and TM-S Interbody Fusion devices.

During the quarter, the company announced the acquisition of Knee Creations, LLC, with its joint preservation procedure called Subchondroplasty and NORMED Medizin-Technik GmbH, with trauma and extremities products.

Zimmer 2Q13	Sales $ in million	% Change
Total Reported Sales	**$1,169**	**4.0%**
Reconstructive	$868	2.0%
Knees	$481	4.0%
Hips	$338	flat
Trauma	$74	flat
Spine	$54	3.0%
Extremities	$49	14.0%

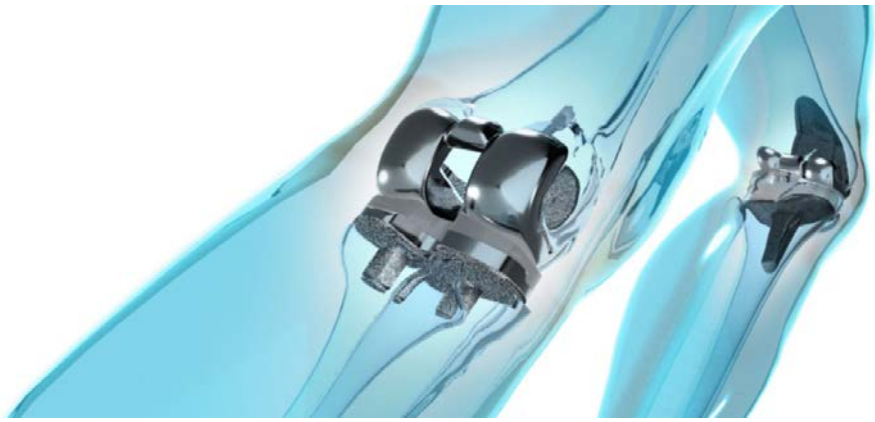
Source: Zimmer Holdings, Inc.

The company also set aside $47 million for worldwide claims related to the Durom Acetabular Component.

Joanne Wuensch of BMO Capital Markets said it is hard to argue with revenue increasing 5.5% on a constant currency basis. She said while it looks like the company lost some share in hips during the quarter, it looks like knees increased at greater than two times the market rate constant currency.

Matt Miksic, senior analyst with Piper Jaffray, said he viewed the most important near-term metric for Zimmer and the ortho group as a return to top-line growth and end-market demand in the U.S. "On that front the company delivered significant upside, raising outlook for the remainder of the year. The results in the quarter put our 'turning the corner call' for orthopedics on track and confirm our recent survey work which points to stable and improving trends in the U.S. orthopedics market."

—WE (July 26, 2013)



Zimmer Holdings, Inc.

Stryker 2Q: Hips and Trauma Shine

Stryker Corporation's reconstructive sales climbed 5.6% to $979 million in the second quarter of 2013.

"We delivered another solid quarter of operational results with balanced sales growth across all segments and geographies, as well as strong cash flow performance," said the company's President and CEO Kevin Lobo, on July 18, 2013.

On a reported basis, hips were up 3.5%, knees up $3.4, trauma up 14.4% and spine rose 3.8%.

On a constant currency basis, total sales rose 7.6% during the quarter. Excluding the expected impact of foreign currency and acquisitions, projected 2013 sales growth is 4.0% to 5.5% for the full year.

NYSE EURONEXT

Stryker 2Q13	Sales $ in million	% Change
Reported Reconstructive Sales	**$979**	**5.6%**
Hips	$319	3.5%
Knees	$340	3.4%
Trauma/Extremities	$266	14.4%
Spine	$187.0	3.8%

Source: Stryker Corporation

William Jellison, the company's new chief financial officer, told analysts that a $170 million increase associated with the voluntary recall of the Rejuvenate and ABG II modular hip stem and an increase of $19 million for estimated settlement expectations for previously disclosed regulatory issues, depressed profits by 35%.

Analyst Reactions

Jefferies analyst Raj Denhoy said recon growth came in higher than expected due to growth in extremities (and an extra selling day), which remains one of the few growth areas in orthopedics and where Stryker is now a market leader. He noted several positive developments, including hip/knee market stabilization; progress in the company's turnaround efforts in Europe; and limited impact thus far from major knee launches from Zimmer Holding, Inc. and DePuy Synthes Companies.

Joanne Wuensch, BMO Capital's analyst, said hip sales came in above the market growth rate, driven by the launch of the Secure-Fit Plus Stem (launched at AAOS in March 2013), following the Accolade II launch in the second quarter of 2012, and, most importantly, "just good ol' execution." With three of the manufacturers having reported so far, Wuensch said it looks like the company gained a bit of share during the quarter, "Impressive given the Rejuvenate and ABG II modular neck hip stems recalls in July 2012."

Strong trauma sales were driven by the Trauson acquisition, and, according to Wuensch, an impressive demand for its foot and ankle products. She noted that U.S. foot and ankle sales were up 34% in a market increasing in the 10%-15% range. "Stryker is clearly taking market share in a fragmented market."

"Management delivered a very 'Stryker-like' quarter, showing solid execution and upside across a wide range of business lines, including the company's hospital capital business lines, where many investors had been bracing for downside," added Piper Jaffray's Matt Miksic. "Management's commentary regarding the tone of the orthopedics market was similar to Johnson & Johnson and Biomet, Inc., describing a stable or potentially improving environment in the U.S."

—WE (July 23, 2013)

Biostat Study Ends in Disappointment

A Phase III study to demonstrate the efficacy for Spinal Restoration, Inc.'s Biostat systems has ended in disappointment.

One of our readers in the study posted on July 7, 2013 that he had been notified the study was being discontinued due to no significant difference between the test group and control group, the company issued a formal announcement on July 18, confirming the disappointing results.

"While the study outcome is unfortunate for our investors, clinical investigators, employees and many potential patients," said company President and CEO Gary Sabins, "the study data provide valuable insights into the nature of discogenic back pain and patient response to treatment. The results emphasize the critical importance of rigorously conducted, multicenter, randomized, controlled studies to demonstrate true efficacy of proposed therapies for discogenic low back pain."

According to the company, the success criteria for primary analysis of the Phase III Investigational New Drug (IND) study of the system were not met. The proportions of successful patients that received the Biostat Biologx Fibrin Sealant or saline injection were not statistically significantly different when analyzed at the 26-week primary endpoint.

The Phase III IND study was conducted at 20 centers in the U.S. and randomized 220 subjects with single-level discogenic low back pain in a 3:1 ratio to injection of Biostat fibrin sealant or saline using the Biostat System. An additional 40 nonrandomized subjects received the sealant injections at two lumbar levels in a separate safety arm of the study. Study enrollment was completed in July 2012 and the study data was unblinded in early 2013 to conduct the primary endpoint analysis. Ninety-six percent of subjects completed the 26-week visit and 50% of subjects had completed the final 78-week extended follow-up visit at the time of the analysis.

At 26 weeks, 33.5% of subjects who received the fibrin sealant met the prespecified composite definition of subject success compared to 39.3% of subjects in the saline control arm. Clinically meaningful improvements in low back pain were achieved in 42.1% and 50.0% of Biostat and control subjects, respectively. Clinically meaningful improvements in the Roland-Morris Disability Questionnaire were achieved in 52.4% of Biostat subjects and 50.0% of control subjects. The outcomes reported in the subjects treated at two lumbar levels were very similar to the results of the one level subjects.

Sabins said the outcomes of the Phase III study are obviously very disappointing. "We were very encouraged by the results obtained in our preclinical studies and pilot clinical trial and expected the Phase III study to provide clear evidence of efficacy for the Biostat system. Many subjects achieved significant, long-lasting improvements in their condition. Unfortunately, the benefits provided by injection of [the fibrin sealant] with the Biostat System could not be distinguished from the benefits provided by injection of saline."

Spinal Restoration was formed to identify and develop new, early intervention, minimally invasive therapies for the treatment of chronic low back pain. The Biostat system was the first endeavor. The company is currently determining the appropriate next steps for the Biostat system and the company.

—WE (July 22, 2013)

Spinal Restoration, Inc./Biostat System

LEGAL

Device Tax Hits $1 Billion

The 2.3% medical device excise tax required by the Affordable Care Act aka "Obamacare," has cost device companies an estimated $1 billion since the start of the year.

That's according to a July 15, 2013 report from three Washington, D.C.-based lobbying groups, the Medical Imaging & Technology Alliance (MITA), the Advanced Medical Technology Association (AdvaMed) and the Medical Device Manufacturers Association (MDMA). The figures were not verified by the Internal Revenue Service.

"The $1 billion threshold is frightening as every dollar spent paying for this medical device tax threatens medical innovation and American jobs," said Gail Rodriguez, executive director of MITA. AdvaMed's Stephen Ubl and MDMA's Mark Leahy also issued statements noting bipartisan support to repeal the tax.

The Republican-controlled House of Representatives has voted dozens of times to repeal Obamacare and the tax and the Democrat-controlled Senate overwhelmingly passed a non-binding resolution last month to repeal the tax.

The tax requires device manufacturers to pay an estimated average of $194 million per month in medical device tax payments (with a payment of approximately $97 million due semimonthly). This tax, according to the industry lobbying groups, threatens a medical device industry that helps employ 2 million nationwide, generates approximately $25 billion in payroll, pays out salaries that are 40% higher than the national

Washington State Dental Association

average ($58,000 vs. $42,000) and invests nearly $10 billion in research and development annually.

Tax Impact Disputed

The device lobbying groups and Wall Street analysts have not seen eye to eye on the impact of the tax.

On April 1, 2013, Wells Fargo analyst Larry Biegelsen issued an analysis which showed the cumulative benefit to U.S. volume surgical procedures due to Obamacare will increase 3.6% by 2022 and will likely offset the 2.3% medical device tax under the new healthcare law.

Biegelsen estimated the increased healthcare coverage of tens of millions of newly insured patients represents a 1.5% tailwind to U.S. volumes across 10 key device categories in 2014, the first year coverage is expanded.

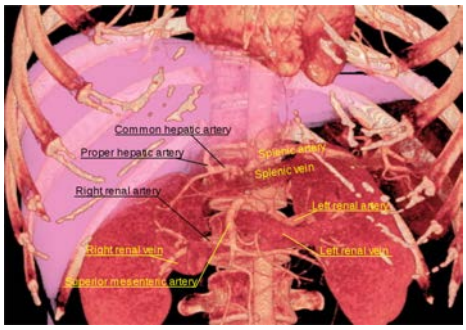
Smaller manufacturers have told us that the tax has hurt them because the tax is on revenues not profits. Larger manufacturers have attributed some job cuts to the device tax. At a meeting sponsored by AdvaMed in St. Paul, Minnesota last month, Medtronic, Inc. CEO Omar Ishrak told the audience that he has not personally been active to repeal the tax because it's the law and it's unlikely that spending any of his time working to repeal the tax would be effective.

—WE (July 23, 2013)

BIOLOGICS

Med Students Delight – Cadaveric Vessels Colorized

Med students will be grateful as will surgeons developing less invasive surgical techniques. The object of their appreciation is ChromaVasc, a technique developed by MedCure, Inc. that highlights the arterial and venous system throughout the entire body of cadaveric, whole body donors.



Courtesy of Wikimedia Commons and Mikael Haggstrom

To the dismay of medical students, the veins and arteries in a cadaver look quite different from how they look in a living patient. In a cadaver the veins and arteries tend to collapse and deteriorate making them difficult to identify. When colorized through ChromaVasc they regain their normal contours and more closely resemble living veins and arteries, even with elasticity and flexibility, according to a company release.

"This procedure offers tremendous benefits to the students, staff, and faculty of any medical/nursing schools, universities, training centers, and surgeons/physicians in practice," says Karim Muradian, M.D., lab manager of MedCure's Surgical Training Center in Henderson, Nevada. "The brightly colored vessels will allow the medical practitio-

ner to immediately identify any vessel and easily follow its entire course from the heart to the target organ," he said.

Company officials claim that Chroma-Vasc provides information that would be difficult to observe in a non-injected cadaveric specimen which is helpful to physicians in surgical training. Blue color is injected into the venous system while red color is injected in the arterial. The color solution is as far reaching as the arteries of the sclera, finger and toe tips as well as the brain, digestive, renal, and neurological systems.

"Anatomical knowledge will always remain integral to surgical training and as surgical practices evolve and innovate, so must our tools," say MedCure officials.

—BY (July 26, 2013)

LARGE JOINTS

Medical Tourism – U.S. the Next India?

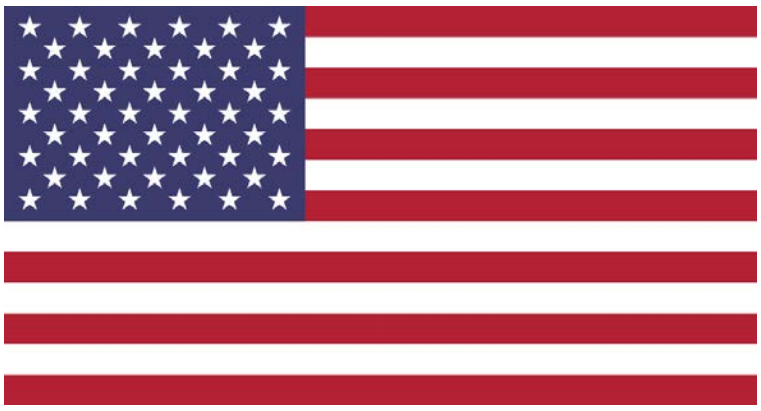
Forget Singapore or Costa Rica for medical tourism. If patients are looking for a bargain in joint replacement, they should first research the U.S. The Chickasaw Nation Medical Center in Ada, Oklahoma, charges $5,304 for a knee replacement, according to the consumer comparison site *nerdwallet.com*. Bruce Watson, of *Daily Finance*, reports that the next most expensive hospital for a knee replacement is Medina Memorial in Medina, New York, where the tariff is $14,788.

Watson calls the variation in medical pricing within the U.S. "stunning" noting that Monterey Park Hospital in Monterey Park, California charges $223,373—or 42 times as much as Chickasaw and 15 times as much as Medina Memorial for that knee replacement.

Hips and knee replacements are not the only high ticket items. Major differences in price exist for most surgical procedures. Watson wrote that prices for angioplasty range from $13,314 to $203,522 and the cost to have a pacemaker installed can vary from $15,128 to $167,628.

Obviously, not all hospitals or surgeons have the same expertise or experience with complex procedures. Patient outcomes vary from institution to institution. But if medical tourism is a temptation, prospective patients should look to what is available in the U.S. before purchasing their tickets to India.

—BY (July 29, 2013)



Wikimedia Commons and Dbenbenn

Elderly Do Just Fine With Joint Arthroplasty

Give the elderly a break! Healthy patients in their 80s and older do just as well after joint arthroplasty as do younger patients. Researchers at the University of Alberta, Edmonton, Canada, checked on 454 patients who had received either a hip or a knee replacement. Sixty-nine of the patients were 80 years old or older while the remainder were between the ages of 55 and 79.

Library of Congress and Harris & Ewing Collection

Researchers evaluated them one month before their surgery and six months postoperatively for pain, function and health-related quality of life, according to Geof Michaels, writing in *News Fix*. The researchers found that there was no age-related difference in joint pain, function or quality of life and that their age did not significantly determine the patients' pain or function.

On the negative side, they found that, regardless of age, when they matched the patients with the general population for age and sex, no subject who had received a joint replacement achieved comparable overall health. At the conclusion of the study, the Canadian researchers said that age should not be the only limiting factor when considering who should have joint replacement surgery.

—BY (July 29, 2013)

New Study Challenges Rheumatoid Arthritis Myth

Patients with rheumatoid arthritis (RA) who undergo hip and knee replacements are just as pleased with the results as are patients who have osteoarthritis (OA) and undergo the same surgeries, according to studies presented at the European League Against Rheumatism's annual congress. The studies found that RA patients were as likely as OA patients to see improvements in pain and function after either surgery, even though some RA patients did not do as well as OA patients after hip surgery, wrote Jennifer Davis for *Arthritis Today*.

The findings refute earlier beliefs that RA patients who undergo joint replacement surgery have less favorable outcomes than do OA patients. Davis points out that many of the studies on which this idea is based were done before biologics were in widespread use.

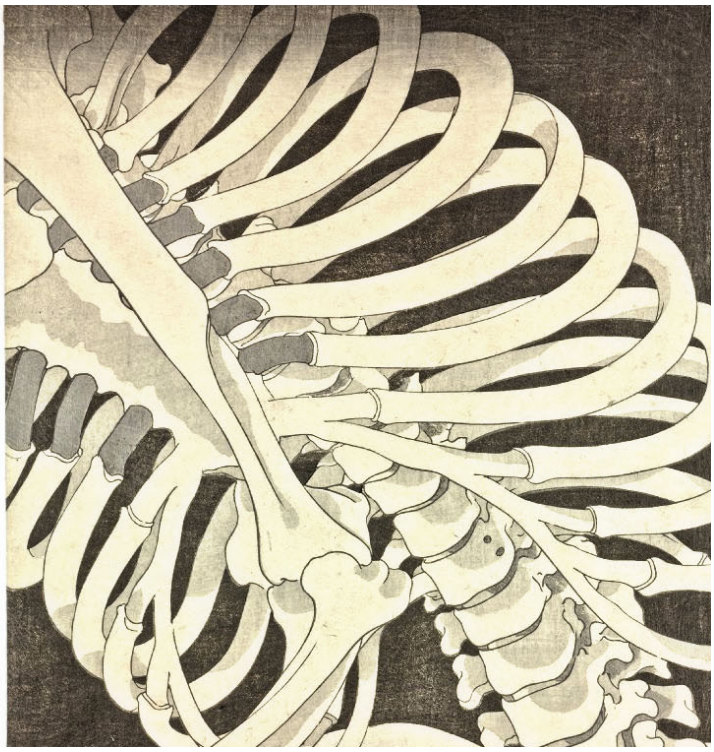
"RA patients were just as likely to have significant improvement and on the questions of satisfaction, they were as satisfied. They were doing much better than when they went into the surgery," explains lead author of both studies Susan M. Goodman, M.D., a rheumatologist at Hospital for Special Surgery in New York City. Davis quotes Goodman as saying, "The likelihood of not doing well is higher for that RA group even though their absolute improvements are the same. They improve and are very satisfied with it—they just aren't doing as well as OA patients."

The knee study was based on records of 178 RA patients and 5,206 OA patients from the Hospital For Special Surgery Replacement Registry who had total knee replacement surgery. While RA patients had worse pain and function before the surgery, after the procedure they had similar outcomes and satisfaction. Both the knee and hip studies documented patient's pain, functional abilities and satisfaction before surgery as well as two years later.

Davis reported that the study also looked at patients who had revision knee replacement surgery. The 32 RA patients and 342 OA patients studied had similar pain and function before the second surgery. But two years later, RA patients were doing better than OA patients and 90% of the RA patients were satisfied with the outcome compared with 67% of the OA patients.

The situation with hip replacement patients was another matter. Among 202 RA patients and 5,810 OA patients having hip replacements, the RA patients had worse function and greater pain before surgery. Two years later, all patients in both groups showed a 10 point improvement in their function scores. However, 18% of the RA patients still had poor function compared to only 4% of OA patients.

—BY (July 21, 2013)



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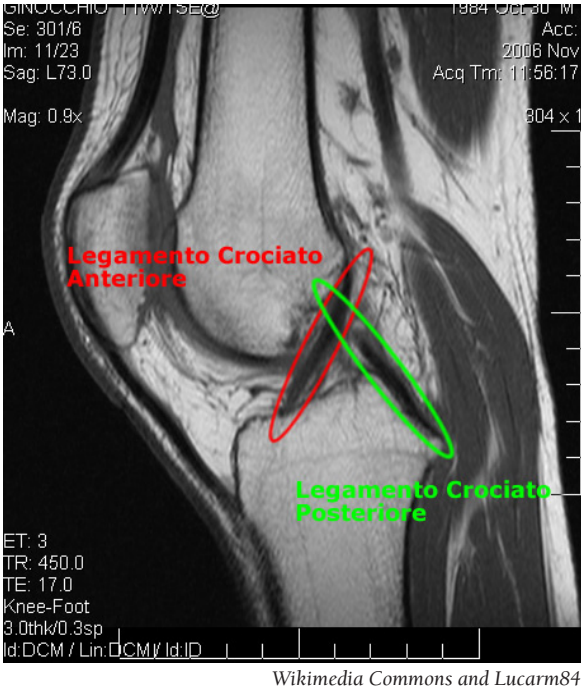
TRAUMA

One ACLR Tear Leads to Another

One anterior cruciate ligament reconstruction (ACLR) often leads to another, according to a study presented at the American Orthopaedic Society for Sports Medicine's (AOSSM) Annual Meeting and reported in *Science Daily*. The study revealed that the chance of having to go through the surgery again within 24 months is six times greater than it is for someone who had never had an ACL tear.

The study also found that female athletes, after experiencing an ACLR demonstrated a more than four times greater rate of injury within 24 months than did their healthy counterparts. This data highlights the fact that ACLR patients who return to playing sports are at greater risk for injury and should take appropriate precautions to prevent injury," said lead author, Mark V. Paterno, Ph.D., from the Cincinnati Children's Hospital.



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Researchers analyzed data from 78 subjects, 59 were female and 19 were male. All were between 10 and 25 years old, all had undergone ACLR and all were ready to return to a pivoting/cutting sport. There were also 47 healthy, control individuals. Each subject was followed for injury and athletic exposure for a 24-month period after returning to play. Twenty-three of the ACLR individuals and four of the control subjects suffered an ACL injury.

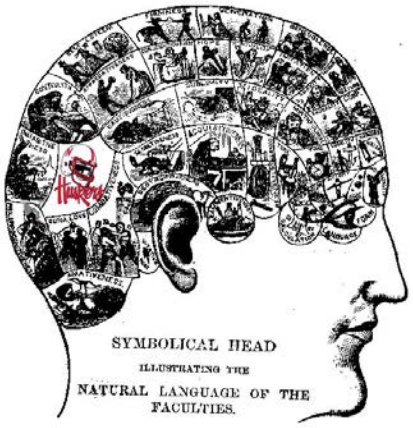
Within the ACLR group, there appeared to be a trend for female subjects to be two times more likely to suffer an injury on the opposite knee than on the previously injured one. Overall, 29.5% of athletes suffered a second ACL injury within 24 months of returning to activity with 20.5% sustaining an opposite leg injury and 9.0% incurring graft re-tear injury on the same leg. A higher proportion of females (23.7%) suffered an opposite leg injury compared to males (10.5%).

"Our study represents the first report of subsequent ACL injury incidence rate focused on two-year outcomes of young, active patients returning to sport. Even though additional research still needs to be performed to support our findings, our data does provide early evidence for re-examining current rehabilitation and return to sport protocols following ACLR," said Paterno.

—BY (July 24, 2013)

Nebraska Develops Concussion Detector

It looks like an oversize hairnet covered with hundreds of bottle caps. But the bottle caps are electrodes and the hair net is a mesh that a football player can slip over his head following a hit. If the device works as planned, a football player who takes a hit to the head will come to the sideline, remove his helmet and slip on an electrode-covered mesh cap.



Wikimedia Commons and courtesy of the University of Nebraska

The team's medical staff will analyze the player's brain waves on the spot and determine within minutes if he can safely return to the game or whether he has sustained a concussion. If it is a concussion, the electrodes will indicate the extent of the injury, and, if there is one, how severe it is.

The device, still under development, is a product of the University of Nebraska's Center for Brain, Biology and Behavior, called the CB3, headed by Dennis Molfese. "There has been great concussion research that's been going on for decades," said Molfese, "It's disconcerting to realize just how little we really know."

CB3's main attraction is the mesh cap studded with electrodes making it a type of magnetic resonance imaging machine—known as a functional MRI—that tracks the brain's blood flow. Developers hope it will help define what is and is not a concussion.

Brian Hainline, M.D., chief medical officer for the NCAA, is supportive of the research. "Concussion is right up there as first and foremost. It's the elephant on the table, and we, with everyone else, we have to solve it," he said. "The big, hoped-for dream would be, let's have a biomarker in brain imaging. If you're to the left of that, you're safe; if you're to the right of it, you're not. That's probably a few years out. But functional brain imaging and blood flow are going to be a very important part of that."

About 300,000 sports-related concussions are reported annually in the United States. They became a major concern after the publicity given the number of brain injuries reported by former NFL players. Thousands of former players are presently suing the league, claiming that the NFL did not adequately protect players from concussions.

—BY (July 22, 2013)

SPINE

Protein Dip Speeds Bone Growth

Bone fractures in the elderly are slow to heal. Now researchers at Stanford University School of Medicine have come up with a simple and effective way to speed up the growth of healthy new bone. As explained by Stanford University writer Krista Conger, researchers have found that a quick immersion in a signaling protein solution called Wnt3a can speed up the growth of healthy bone in response to a break.

If this simple treatment works on humans, it will improve the outcomes of the more than 500,000 bone grafts performed each year in the U.S. "We're very focused on designing a treatment that could be easily employed by orthopaedic surgeons in the normal course of bone grafting," said professor of surgery Jill Helms, D.D.S., Ph.D.

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Bone grafting involves transplanting whole marrow—which is rich in stem cells that form bone, blood and the cells of the immune system—into a fracture site. Doctors prefer using a patient's own marrow to avoid the problem of rejection. Unfortunately, marrow from older patients does not work like marrow from younger patients does. So orthopedic surgeons often use donor bone or marrow and rely on drugs to stimulate bone growth. The hope is to find alternatives that allow the use of a patient's own cells without medications.

They may have found it. The researchers discovered that a quick dip in a bath of a signaling protein called Wnt3a can rev up sluggish bone-forming cells in older animals that would normally be unable to heal a fracture. "We've shown that when we temporarily treat bone marrow from aged animals with Wnt before transplanting the cells into a

fracture site, we see really robust bone formation," said Helms.

In the current study, Conger explained, the researchers harvested bone marrow from laboratory mice genetically engineered to express a fluorescent protein. They then transplanted this marrow into 2-millimeter holes they'd created in the skulls of anesthetized mice and followed the fate of the transplanted cells.

Within seven days, the transplanted marrow cells had begun to divide. The defects in the mice that had received the treated bone graft healed completely while the untreated mice were unable to fill the hole with new bone.

When the researchers repeated the experiment with marrow from older animals they found that they generated much less bone at the site of the injury. The older animals also expressed lower levels of the Wnt protein than did the younger ones. The researchers exposed the aged donor marrow to a brief bath of either Wnt3a or a control solution before transplanting them into the recipients. Within seven days, animals that received the Wnt-treated marrow had twice as much new bone at the injury site as did the control animals.

The researchers then repeated their experiments on rabbits, which have longer bones that more closely resemble those of humans. Again, they found that treating old marrow briefly with Wnt3a significantly improved the cells' ability to heal a fracture in the leg. Helms is the senior author of the study, published in July in the *Journal of Bone and Joint Surgery*. Philipp Leucht, M.D., a resident in orthopedic surgery at Stanford, is the lead author.

—BY (July 29, 2013)

Titan Spine Awarded 4 (!) New Patents

Titan Spine, LLC of Mequon, Wisconsin, is celebrating the awarding of four new patents by the U.S. Patent and Trademark Office. The patents relate to the surface textures of the firm's spine implants as well as the design of its ENDOSKELETON interbody device and system instrumentation. Titan Spine now holds 10 patents and has an additional 14 applications under review.

One patent covers aspects of the roughened surface of the implant. The implant features a combination of macro, micro and cellular-level textures on its surface which, company officials say, help induce the production of biologically active proteins necessary for bone growth.

Barbara Boyan, Ph.D., Dean of the School of Engineering at Virginia Commonwealth University, said, "The specific combination of Titan Spine's surface textures produces a distinct biological response at the implant site . In-vitro research supports this difference between Titan's devices and other interbody cages beginning at the cellular level, which may extend to an improved environment for fusion."

Paul Slosar, M.D., orthopedic surgeon at SpineCare Medical Group and medical director for Titan Spine, commented, "The science behind Titan Spine's implants is translating into significant clinical benefits. In my experience, patients are fusing more quickly and exhibiting robust fusion, with meaningful, sustained pain reduction and functional improvement. While traditional interbody cages serve mainly to provide structure to the fusion site, Titan's devices also enhance the fusion process and represent the future of spine implant development."

Chad Patterson, director of Product Development and Operations for Titan Spine, said, "Our surface treatment technology and interbody device design are truly unique in spinal care, as confirmed by the award of these new patents. We are pleased to be a leader in interbody IP and excited to continue to innovate and expand our portfolio to further pioneer the application of surface technology, implant design and advanced surgical techniques speeding patient recovery in spine care."

—BY (July 26, 2013)

Courtesy of Titan Spine, LLC

Ti-Bond PEEK 5X Stronger Than Naked PEEK

Spinal Elements, Inc. reports on the results of a test comparing its Ti-Bond porous titanium coated PEEK interbody implants with PEEK implants without the coating. The company release defines the coating as random unconnected titanium pores that are biomechanically adhered through a plasma vacuum spray to the surfaces of its PEEK-OPTIMA interbody implants.

William Walsh, Ph.D. of the University of New South Wales, Australia, performed the device testing. He found that the devices coated with Ti-Bond had a shear strength approximately five times that of the PEEK devices. Histologic review showed that fibrous tissue had formed around the PEEK implant devices while the devices with Ti-Bond coating had bone forming in the porosity of the coating. Walsh examined the samples at the end of four weeks.

"It was very compelling to see the difference between the two specimen groups at such a short time period. The integration of bone into the Ti-Bond coating stands in sharp contrast to the barrier of tissue that formed around the PEEK device," commented Walsh on the testing.

Spine surgeon Scott H. Kitchel, M.D. of Eugene, Oregon said, "The potential clinical benefits of this technology are tremendous. Now we have a device that is participating in the fusion process where we did not previously have that option. The ability to get stable fixation in a spinal fusion earlier in the post-operative healing process may lead to improved long-term patient outcomes." Spinal Elements is headquartered in Carlsbad, California.

—BY (July 31, 2013)

Courtesy of Spinal Elements, Inc.

PEOPLE

Jo A. Hannafin, M.D., Ph.D.: First Female President of AOSSM

Jo A. Hannafin, M.D., Ph.D., an orthopedic surgeon at Hospital for Special Surgery (HSS), has been named the first female president of the American Orthopaedic Society for Sports Medicine (AOSSM). Dr. Hannafin is director of Orthopedic Research at Hospital for Special Surgery and prthopedic director of the Women's Sports Medicine Center at HSS.

Jo A. Hannafin, M.D., Ph.D./Hospital for Special Surgery

Dr. Hannafin is head team physician for the Women's National Basketball Association New York Liberty; she also serves as a team physician for the United States Rowing Team. She previously was an assistant team physician for the New York Mets and team physician for the WUSA NY Power.

She has a personal goal as president. "I would like to focus on improving member fellowship. The missions of the AOSSM include education, research, patient care and fellowship. By fellowship, I don't mean fellowship train-

ing, but fellowship in a community of like-minded people—the fellowship among sports medicine physicians," she explained in the July 10, 2013 news release. Dr. Hannafin also wants to further strengthen the organization and to ensure that it offers innovative and intellectually challenging meetings that are well attended.

Dr. Hannafin told *OTW*, "The quality of the research abstracts received and accepted for presentation set the tone of the meeting. The use of symposia reviewing the latest surgical treatments that incorporate scientific data, surgical video and debate provide an excellent educational forum. My goal for the AOSSM Specialty Day and the Annual meeting is to optimize the use of available time to provide high quality information to our members. This will take the form of research presentations, symposia, live surgical demonstrations and high level debate on controversial or cutting edge topics."

Asked about her research goals for AOSSM, Dr. Hannafin commented to *OTW*, "Research has been a critical component of my academic career and forms the basis for what we do as sports medicine surgeons. When I chaired the Research Committee, we created and the Board agreed to fund a three year research initiative. This program has been expanded and strengthened by the Research Committee Chairs who followed me. The Research Committee of the AOSSM is one of our strengths and will be led for the next three years by Rob LaPrade, M.D. We are fortunate to have Bart Mann, Ph.D. as our full time Research Director. The Research Committee formulates a plan and topic for our three year research initiative which is supported by a 250,000 grant awarded during each cycle. There is a research meeting held which will bring together experts in the selected topic and researchers interested in that area. We have traditionally invited members of the scientific staff at the NIH to attend these meetings. The goal of this 'think tank' is to bring together investigators from different institutions and to facilitate proposals for funding that are multi-institutional or multi-disciplinary in design. This process has been a springboard for application for federal funding by our members. In addition, in the appropriate forum I will continue to lobby for the importance of support of both clinical, translational and basic research which provide an essential foundation for appropriate patient care."

—EH (July 23, 2013)

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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

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