

# Orthopedics This Week

## week in review

**4 The 28 Top U.S. Shoulder Surgeons** ♦ If a shoulder specialist has a torn rotator cuff, whom do they go to for advice? Shoulder surgeons at the top of their game let us know their thoughts on the best orthopedic surgeons in their subspecialty.

**8 Lifetime Ban for Plagiarism** ♦ A group of Tunisian researchers have been accused, for a second time, of plagiarism. Now the *Indian Journal of Dermatology* has imposed a lifetime ban on the authors. Is a publishing “death sentence” appropriate? See what Retraction Watch reported and what the Committee on Publication Ethics (COPE) has to say.

**10 Device Tax Repeal Stayin’ Alive** ♦ The House repealed the 2.3% medical device tax on June 7. Senate leaders said it was DOA in the Senate and the White House said the President would veto the bill. But, Democratic Senators from medical device manufacturing states want to dump the tax. Read what our political and markets experts say about its chances.

**14 On (and Off) the Record** ♦ Tony Viscogliosi Touts PMA Over 510(k)... It’s Official! Double-Bundle Superior...Infuse Critics Guilty of Loose Talk...4 New Japanese/U.S. Fellows Announced...Amazing Clinical Success with Bone Marrow Concentrate... Interdisciplinary Team Wins Team Science Award...and more.



**18 Burkhead v. Sperling on Lesser Tuberosity Osteotomy** ♦ “Good studies show that LTO is the best method of treating subscapularis insufficiency at the time of total shoulder,” says Buz Burkhead. “Osteotomy is complex,” counters John Sperling, “and there is a lack of strong evidence of superiority.”

## breaking news

- 21 Biomet 4Q12 Results Point to Recovery** .....
- Aesculap’s “Breakthrough” Knee Replacement Debuts** .....
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**For all news that is ortho, read on.**

# Orthopedic Power Rankings

## Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**THIS WEEK:** Two anticipated pieces of news drove buyers to add ortho stocks to their portfolios last week. The Supreme Court's expected rejection of the HealthCare Reform Act and the anticipated repeal of the medical device tax. For the last couple of weeks, ortho has been a singular bright spot in an otherwise shaky, insecure market.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	ArthroCare	(0.67%)	15.82%	ARTC has one of the most liquid balance sheets in ortho. Still #1 in this week's Power Rankings.
2	2	Johnson & Johnson	24.93	5.31	DePuy is the new titan astride the global orthopedics industry. Wouldn't it be ironic if former Stryker CEO MacMillan turned up to run it?
3	3	Stryker	23.68	6.42	One commentator wrote this week: "Stryker is a Jim Collins classic Great company that is also Built to Last"
4	4	Zimmer	24.95	5.28	Under appreciated, ZMH has higher operating margins than any other diversified ortho company.
5	5	Orthofix	16.23	3.06	Strong week last week as new buyers emerged. Legal overhang lifted with DOJ settlement. We also expect good news for the quarter.
6	6	Smith & Nephew	21.50	3.01	Two new plating systems for foot and ankle surgeons were launched at last week's AOFAS meeting.
7	7	Symmetry Medical	5.29	7.11	Impressive sales growth occurring at SMA's surgical unit. This is where management put their Codman (formerly JNJ) purchase.
8	8	NuVasive	6.63	23.19	Wall Street firm Leerink raised NUVA's target price while First Analysis admitted to concern with valuation. Either way, NUVA has been rewarding.
9	10	Integra LifeSciences	13.34	5.18	Wall Street firm Argus upgraded IART last week to BUY. For the 2nd quarter most analysts are forecasting 6% sales growth.
10	9	Conmed	10.09	0.07	In the midst of ortho's rebound, CNMD is largely ignored. Why? EPS expected to jump 29% this quarter.

## Robin Young's Orthopedic Universe

### TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	NuVasive	NUVA	\$23.32	\$1,007	23.19%
2	ArthroCare	ARTC	\$28.85	\$798	15.82%
3	Alphatec Holdings	ATEC	\$1.77	\$159	10.63%
4	MAKO Surgical	MAKO	\$26.06	\$1,109	10.10%
5	CryoLife	CRY	\$5.00	\$138	8.93%
6	Symmetry Medical	SMA	\$8.44	\$309	7.11%
7	TiGenix	TIG.BR	\$0.59	\$54	6.83%
8	Stryker	SYK	\$54.57	\$20,788	6.42%
9	Tornier N.V.	TRNX	\$21.78	\$862	5.63%
10	Johnson & Johnson	JNJ	\$66.63	\$196,579	5.31%

### WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Bacterin Intl Holdings	BONE	\$1.31	\$56	-21.56%
2	TranS1	TSON	\$2.54	\$69	-18.85%
3	RTI Biologics Inc	RTIX	\$3.56	\$199	-1.11%
4	Kensey Nash	KNSY	\$38.46	\$335	-0.03%
5	Conmed	CNMD	\$27.32	\$773	0.07%
6	Exactech	EXAC	\$16.95	\$223	1.44%
7	Synthes	SYST.VX	\$166.16	\$19,817	1.98%
8	Smith & Nephew	SNN	\$48.33	\$8,667	3.01%
9	Orthofix	OFIX	\$40.02	\$750	3.06%
10	Medtronic	MDT	\$38.16	\$39,579	3.72%

### LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	\$38.16	\$39,579	11.49
2	Zimmer Holdings	ZMH	\$63.17	\$11,127	12.81
3	Johnson & Johnson	JNJ	\$66.63	\$196,579	13.27
4	Stryker	SYK	\$54.57	\$20,788	14.32
5	Orthofix	OFIX	\$40.02	\$750	14.34

### HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	\$23.32	\$1,007	54.23
2	Wright Medical	WMGI	\$20.60	\$810	52.82
3	Symmetry Medical	SMA	\$8.44	\$309	33.76
4	Kensey Nash	KNSY	\$38.46	\$335	26.90
5	Exactech	EXAC	\$16.95	\$223	23.87

### LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	\$40.02	\$750	0.80
2	ArthroCare	ARTC	\$28.85	\$798	1.14
3	RTI Biologics Inc	RTIX	\$3.56	\$199	1.16
4	Stryker	SYK	\$54.57	\$20,788	1.33
5	Zimmer Holdings	ZMH	\$63.17	\$11,127	1.37

### HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	\$20.60	\$810	6.27
2	NuVasive	NUVA	\$23.32	\$1,007	5.51
3	CryoLife	CRY	\$5.00	\$138	4.46
4	Symmetry Medical	SMA	\$8.44	\$309	2.81
5	Medtronic	MDT	\$38.16	\$39,579	2.33

### LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	\$1.77	\$159	0.80
2	Symmetry Medical	SMA	\$8.44	\$309	0.86
3	Conmed	CNMD	\$27.32	\$773	1.07
4	Exactech	EXAC	\$16.95	\$223	1.09
5	CryoLife	CRY	\$5.00	\$138	1.15

### HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$0.59	\$54	46.95
2	MAKO Surgical	MAKO	\$26.06	\$1,109	13.13
3	Synthes	SYST.VX	\$166.16	\$19,817	4.99
4	Kensey Nash	KNSY	\$38.46	\$335	4.67
5	TranS1	TSON	\$2.54	\$69	3.61

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

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## The 28 Top U.S. Shoulder Surgeons

By OTW Staff



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If a shoulder specialist has a torn rotator cuff, whom do they go to for advice? Here are the answers! Shoulder surgeons at the top of their game let us know their thoughts on the best 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 shoulder surgeons in the country. This information was obtained via a telephone survey of thought leaders in the field. The information in quotes is what we heard about these surgeons.*

In alphabetical order, here are the top 28 shoulder surgeons in the United States.

**Joseph A. Abboud, M.D.** is an orthopedic surgeon at the Rothman Institute

in Philadelphia and associate professor of Orthopaedic Surgery at Thomas Jefferson University Hospital. "He is an extremely talented clinician and researcher with a lot of funded research projects. He is an innovator and has been involved in designing new shoulder prostheses."

**April D. Armstrong, M.D.** is associate professor of Orthopaedic Shoulder and Elbow Surgery at Penn State Hershey Bone and Joint Institute in Pennsylvania. "She is a rising star, and has developed several models of glenoid bone loss. She is very involved in resident education and instructs other faculty on how to best educate residents."

**John-Erik Bell, M.D.** is an orthopedic surgeon with Dartmouth-Hitchcock Medical Center in New Hampshire. He

is also assistant professor in the Department of Orthopaedic Surgery and The Dartmouth Institute. "He is getting a masters degree in epidemiology specializing in public health outcomes. Basically, he is helping to determine whether or not what we do as surgeons is cost effective. He has also made a significant contribution to our understanding of the geographical distribution of shoulder problems."

**Louis U. Bigliani, M.D.** is the Frank E. Stinchfield Professor and chairman in the Department of Orthopaedic Surgery at Columbia University Medical Center. He is also chief of the Shoulder Service at the Center of Shoulder, Elbow and Sports Medicine at Columbia University Medical Center and is a past president of the American Shoulder and Elbow Surgeons (ASES). "He

is a great educator, researcher, and clinician with a tremendous amount of experience. He is well regarded and is a thoughtful leader."

**Stephen S. Burkhart, M.D.** is an orthopedic surgeon with The San Antonio Orthopaedic Group in Texas. He is also clinical assistant professor in the Department of Orthopaedic Surgery at The University of Texas Health Science Center at San Antonio and is a past president of the Arthroscopy Association of North America. "He is a real innovator and has advanced all aspects of arthroscopic surgery throughout his career."

**Brian J. Cole, M.D.** is an orthopedic surgeon at Midwest Orthopaedics at Rush, as well as professor in the Departments of Orthopaedics and Anatomy and Cell Biology. Dr. Cole is section head of the Cartilage Restoration Center at Rush (Rush University Medical Center). "He

is known for his deep understanding of cartilage repair. He is really on the cutting edge of what is out there."

**Edward V. Craig, M.D., M.P.H.** is an orthopedic surgeon at Hospital for Special Surgery in New York and professor of Clinical Surgery (Orthopaedics) at Weill Cornell Medical College. Dr. Craig is a past president of the ASES. "He is phenomenal. He has a wide breadth of experience and has particularly good interpersonal skills...a fantastic person."

**T. Bradley Edwards, M.D.** is an orthopedic surgeon with Fondren Orthopedic Group, LLC in Dallas, Texas, and a clinical instructor in the Department of Orthopedic Surgery at the University of Texas at Houston. He is also clinical assistant professor in the Department of Orthopedic Surgery at Baylor University, and clinical professor in the Department of

Orthopaedic Surgery and Rehabilitation at the University of Texas Medical Branch. "He is outstanding. He has a very broad practice, but is best known for arthroplasty and for his publications on reverse shoulder arthroplasty. He is a thoughtful scientist."

**Neal S. Elattrache, M.D.** is an orthopedic surgeon and director of the Sports Medicine Fellowship at the Kerlan Jobe Orthopedic Clinic in Los Angeles. He is also associate clinical professor in the Department of Orthopaedic Surgery at the University of Southern California. "He is a leader in arthroscopic surgery of the shoulder and elbow and is the team doctor for the Los Angeles Dodgers. He is truly an outstanding doctor and surgeon."

**Evan Flatow, M.D.** is the Bernard J. Lasker Professor and Chair of the Department of Orthopaedics and chief of Shoulder Surgery at The Mount

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Sinai School of Medicine in New York. Dr. Flatow is a past president of the ASES. “He is a talented clinician, scientist, researcher, and educator...he is the whole package. He is especially known for his work on ways of better understanding rotator cuff repair and healing.”

**Mark A. Frankel, M.D.** is an orthopedic surgeon with Florida Orthopaedic Institute in Tampa and director of the Biomechanical Shoulder and Elbow Research Lab at the University of South Florida College of Engineering. “He is known for reverse shoulder replacement, and has designed his own prosthesis for DJO (it is different and controversial). He is not afraid to go against the tide. He has had such success that other product designers have modified their prostheses to look a bit more like his.”

**Leesa M. Galatz, M.D.** is associate professor of Orthopedic Surgery and Program Director of the Shoulder and Elbow Fellowship at Washington University School of Medicine in St. Louis. “She is probably on everyone’s list of the best shoulder surgeons in the U.S. She has a deep understanding of the complexities of shoulder problems and will tackle any type of problem.”

**Ruben Gobezie, M.D.** is director of the Cleveland Shoulder Institute University Hospitals of Cleveland and fellowship director at the Cleveland Akron Shoulder & Elbow Fellowship. Dr. Gobezie is also head of the Cartilage Transplant Center of Cleveland. “He is a younger surgeon...very innovative and skillful. He does a lot of allograft bone grafting for isolated cartilage lesions through a minimally invasive approach—not many people are doing that now.”

**Joseph P. Iannotti, M.D., Ph.D.** is chairman of the Orthopaedic and Rheuma-

tologic Institute at Cleveland Clinic in Cleveland. He is also co-director of the Orthopaedic Research Center and has a joint appointment in the Department of Biomedical Engineering. Dr. Iannotti is a past president of the ASES. “He is one of the most knowledgeable people in the world on shoulder replacements. As far as how to do complex revisions he is ‘the man’...the court of last resort.”

**Jay D. Keener, M.D.** is assistant professor of orthopedic surgery at Washington University School of Medicine in St. Louis. “He is a very intelligent guy and is doing some great research on rotator cuff repairs and healing—these are prospective randomized trials.”

**William N. Levine, M.D.** is professor of Clinical Orthopaedic Surgery at Columbia University in New York. He is also vice chairman of Education in the Department of Orthopaedic Surgery at Columbia, as well as director of Sports Medicine. In addition, Dr. Levine serves as associate director of the Center for Shoulder, Elbow & Sports Medicine and director of the orthopedic surgery residency program at Columbia University Medical Center. “He is very dedicated to teaching residents, fellows, and medical students. He is a great surgeon, and is very involved with the American Academy of Orthopaedic Surgeons (AAOS) on continuing education for practicing shoulder surgeons.”

**Frederick A. Matsen, III, M.D.** is an orthopedic surgeon with the University of Washington Bone and Joint Center in Seattle and is the Douglas T. Harryman II Endowed Chair in Shoulder and Elbow Research. Dr. Matsen is a past president and founding member of the ASES. “He is not only innovative, but he possesses an incredible understanding of the way the shoulder works. He has trained some of the top shoulder surgeons that are currently in practice.”

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**Peter J. Millet, M.D., M.Sc.** is an orthopedic surgeon and partner at the Steadman Clinic in Vail, Colorado. “He is a well-recognized shoulder expert in all areas. He has developed a select practice that includes many high end athletes. He is on the forefront of several advanced arthroscopic shoulder techniques that are used to treat athletes.”

**Anand M. Murthi, M.D.** is attending orthopedic surgeon and chief of the Shoulder and Elbow Service at Union Memorial Hospital in Baltimore, Maryland. He is also director of Shoulder and Elbow Research at that institution. “He is a younger generation shoulder surgeon and is someone to be watched. He is a dedicated clinician and educator who has been actively involved with AAOS. He is a tremendous resource to his colleagues.”

**Bradford O. Parsons, M.D.**, is assistant professor of Orthopaedics at the

Mount Sinai hospital in New York. "He is an up and coming surgeon with outstanding skills. He is very conscientious, involved in research, and in the next five years will be at the forefront of the field."

**Matt Provencher, M.D., M.C., U.S.N.** is director of Orthopaedic Shoulder, Knee, and Sports Surgery at the Naval Medical Center San Diego Department of Orthopaedic Surgery. He is also professor of Surgery and Orthopaedics at the Uniformed Services University of Health Sciences. "He is one of the most influential shoulder surgeons that the military has produced in the last 10 years. He has published more than 100 articles and he is only in his early 40s. His expertise is in managing complex problems that happen to soldiers, including unstable shoulder with bone loss. This is very hard to treat and he is one of the world's leaders in this area."

**Anthony A. Romeo, M.D.** is an orthopedic surgeon at Midwest Orthopaedics at Rush. He is also associate professor and director in the Section of Shoulder & Elbow at Rush University Medical Center. "He is a consummate technical surgeon and a very good teacher. He is a thought leader in shoulder stability, rotator cuff repair, and shoulder arthroplasty."

**Edwin E. Spencer, Jr., M.D.** is an orthopedic surgeon at Knoxville Orthopaedic Clinic in Tennessee. "He is a phenomenally talented surgeon and a very dedicated scientist. He has worked on the natural history of rotator cuff injuries and tears, and has been involved in the design of innovative shoulder prosthesis."

**John W. Sperling, M.D.** is professor of orthopedics at Mayo Clinic. "He has



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a very focused practice...he takes on extremely hard cases. He has published more on arthroscopy than anyone else has recently."

**Robert Z. Tashjian, M.D.** is assistant professor of Orthopaedic Surgery at the University of Utah School of Medicine in Salt Lake City. "He is a talented researcher and has done a lot of work on rotator cuff healing and fractures. He has also done research on the clinical evaluation and biomechanics of reverse shoulder replacement."

**Jon J.P. Warner, M.D.** is chief of the Harvard Shoulder Service and director of the Harvard Combined Shoulder Fellowship. He is also the current president of the ASES. "He is very knowledgeable, and has pioneered work on nerve problems around the rotator cuff. He has done a lot of research on shoulder

arthroplasty, and has published more than most on the kinematics of the shoulder."

**Gerald R. Williams, Jr., M.D.** is director of the Shoulder and Elbow Center at Rothman Institute in Philadelphia and professor of Orthopaedic Surgery at Jefferson Medical College. He is a past president of ASES. "He is a thought leader and genuine innovator."

**Ken Yamaguchi, M.D.** is the Sam and Marilyn Fox Distinguished Professor of Orthopedic Surgery and chief of the Shoulder and Elbow Service at Washington University School of Medicine in St. Louis. "He has a good grasp on rotator cuff disease and his research has helped us all learn about much more about this problem. He has the largest database on the natural history of rotator cuff tears." ♦

## June 22, 2012

# Retraction of the Week – Lifetime Ban for Plagiarism

By Walter Eisner

Each week, *OTW* publishes a recent scientific journal retraction arising from shoddy, lazy or downright fraudulent research. These are examples of researchers who omitted or falsified data, used data out of context or employed such awful logic that they were forced to retract their study.

These examples are collected by *Retraction Watch* and we are honored to be able to present them with permission from *Retraction Watch* to our readers. *Retraction Watch* was started in 2010 by Adam Marcus and Ivan Oransky, M.D.

### *Indian Journal of Dermatology* Retractions and Lifetime Ban

A medical journal in India has imposed a professional death sentence on a group of Tunisian researchers by forever banning them from publishing in the journal, “on all future articles in which they are assigned/mentioned as an author or coauthor.”

*Retraction Watch's* (RW) Ivan Oransky, M.D., reported on June 20, 2012 that the *Indian Journal of Dermatology* (IJD) found a group of Tunisian researchers guilty of plagiarism. Last August, Oransky said RW brought the news that the IJD had banned the researchers from publishing in the journal for five years because they had plagiarized in a 2009 study. (<http://retractionwatch.wordpress.com/2012/06/20/serial-plagiarizers-banned-from-dermatology-journal-forever/>)



*Indian Journal of Dermatology and*

Oransky writes that the journal's editors had found another case where the researchers had plagiarized, and were now banned for life.

Here's what the IJD editor wrote:

*In the background of serial academic dishonesty, the authors were initially served with a show-cause notice and on receipt of their clarification (deemed inadequate), based on unanimous decision of the Editorial Board, a complete restriction on the part of the journal on all future articles in which they are assigned/mentioned as an author/coauthor was imposed and the corresponding author was communicated accordingly.*

*Now the second article is also being formally retracted from the online and offline version of the journal.*

*IJD maintains a strict principle of absolute zero tolerance in matters like these.*

*The journal unconditionally apologizes to all concerned for this unintended oversight on its part.*

The following articles were retracted:

1. Jalel A, Soumaya GS, Hamdaoui MH. Dermatology life quality index scores in vitiligo: Reliability and validity of the Tunisian version. *Indian J Dermatol* 2009; 54(4):330-3 (<http://www.e-ijd.org/>)

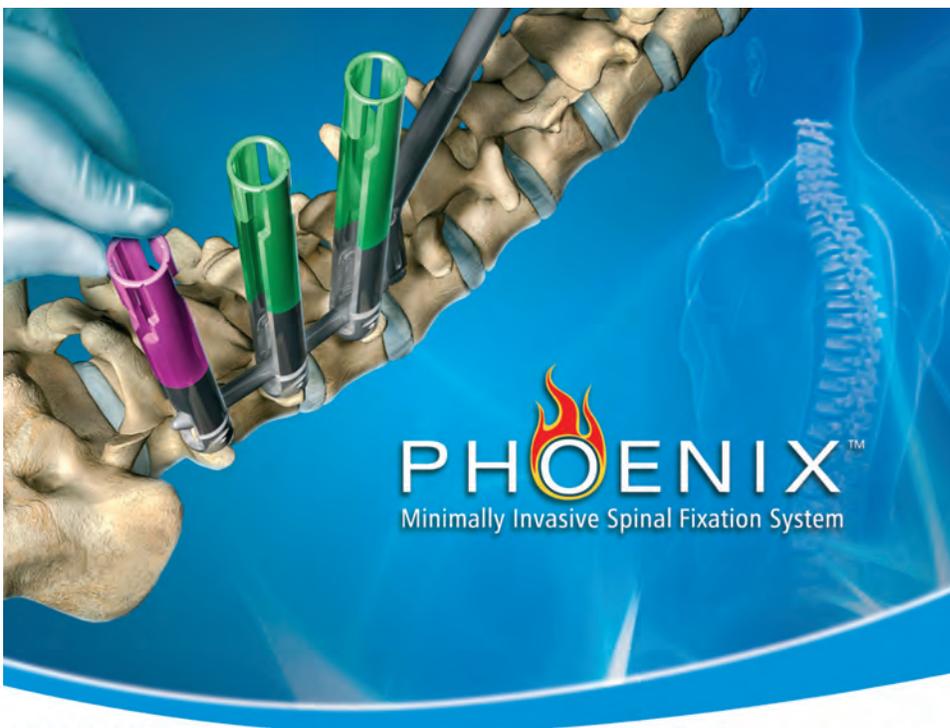
article.asp?issn=0019-5154;year=2009;volume=54;issue=4;spage=330;epage=333;aulast=Jalel)

Based on the report of a fact finding committee as appointed by the editorial board of Indian Journal of Dermatology and in consultation with the journal Ombudsman last year (2011) the above article was retracted (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3108510/>) from the online and offline version of Indian Journal of Dermatology and the authors were barred from submitting their manuscript(s) to IJD for the next 5 years on the charges of plagiarism as the presented patients, data, results and discussion were identical with those of an article published in BMC Dermatology in 2004 cited below.

Aghaei S, Sodaiji M, Jafari P, Mazharinia N, Finlay AY. DLQI scores in vitiligo: reliability and validity of the Persian version. *BMC Dermatology*; 4: 8. Published online 4 August 2004

- Jalel A, Yassine M, Hamdaoui MH. Oxidative stress in experimental vitiligo C57BL/6 mice. *Indian J Dermatol*. 2009;54(3):221-4 (<http://www.e-ijd.org/article.asp?issn=0019-5154;year=2009;volume=54;issue=3;spage=221;epage=224;aulast=Jalel>)

It has come to our notice that almost the same set of authors in that same year published another article (as above) which contains identical introduction, identical table and most of the discussion of an article published in *Acta Dermatovenerol Alp Panonica Adriat* in 2008 cited below.



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Arıcan O, Kurutas EB. Oxidative stress in the blood of patients with active localized vitiligo. *Acta Dermatovenerol Alp Panonica Adriat*. 2008 Mar; 17(1):12 -6.

*Retraction Watch* has written about bans before and is in favor of them. Although, Oransky notes, “the Committee on Publication Ethics (COPE) is against them. RW has heard of one ban of ten years but this is the first time they’ve heard of a lifetime ban.

COPE, a forum for editors and publishers of peer-reviewed journals, was established in 1997 by a small group of medical journal editors in the UK but now has over 7000 members worldwide from all academic fields. Membership is open to editors of academic

journals and others interested in publication ethics. Several major publishers (including Elsevier, Wiley-Blackwell, Springer, Taylor & Francis, Palgrave Macmillan and Wolters Kluwer) have signed up their journals as COPE members. COPE also advises editors on how to handle cases of research and publication misconduct.

The *Indian Journal of Dermatology* has been published since 1955 and is, according to the journal, the oldest living journal of dermatology in Asia and one of the oldest peer-reviewed journals dedicated to this particular discipline. ♦

## Device Tax Repeal Stayin' Alive

By Walter Eisner

The U.S. House of Representatives voted 270-146 on June 7, 2012, to repeal the scheduled 2.3% medical device excise tax that is to take effect in 2013.

The vote was bipartisan with 37 Democrats joining Republicans to repeal. There are now nervous Democrats in the U.S. Senate from medical device manufacturing states up for reelection in November who want to show voters they're looking out for jobs back home.

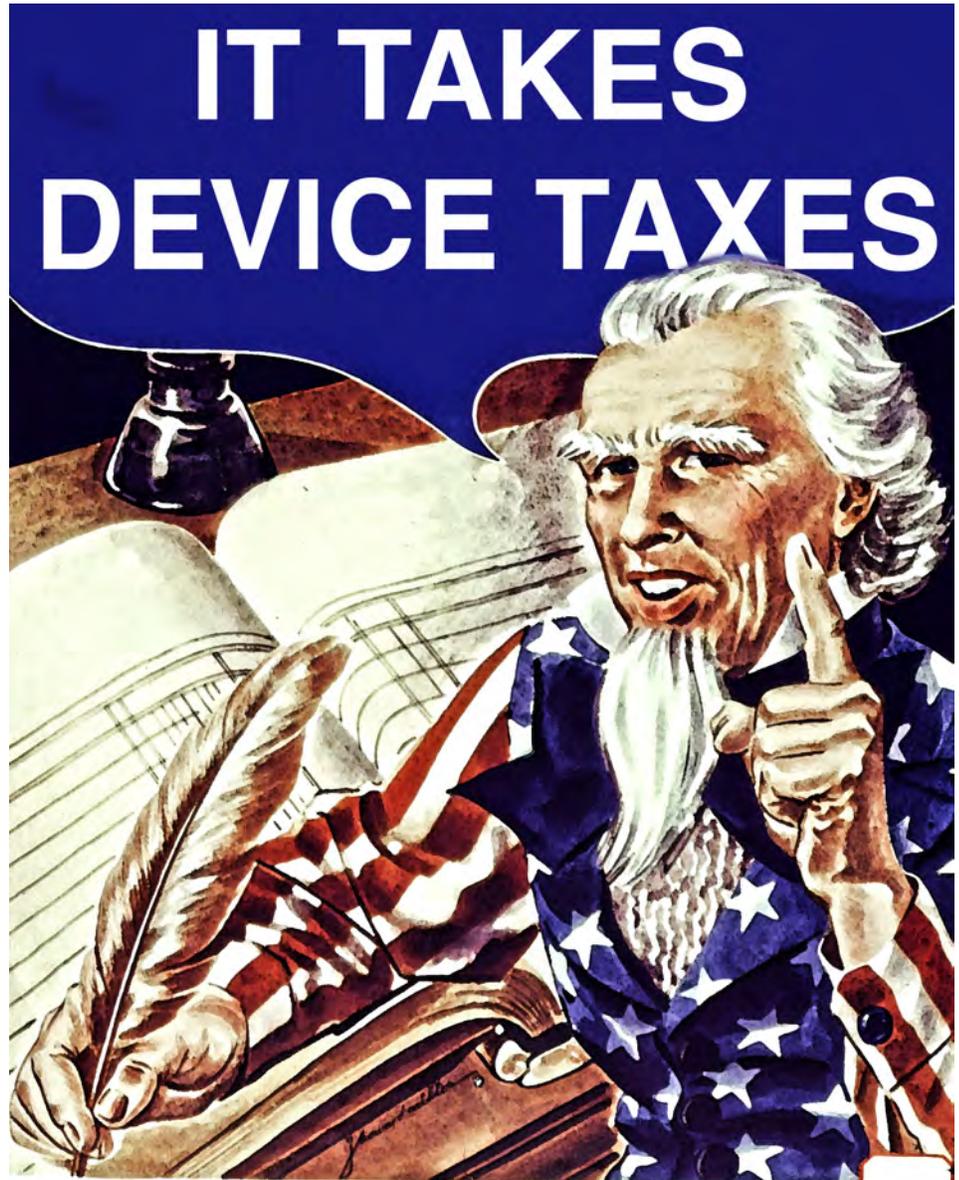
Bipartisanship, jobs and an American industry that is still leading the world would seem like a good recipe for a compromise to get the bill heard and passed in the Senate.

### DOA in Senate?

However, the Democratic-controlled Senate, immediately after the House vote, said through a spokesperson that there would be no hearings scheduled. The White House then jumped in to say the veto pen was waiting for the bill if it reached the President's desk.

It would seem the repeal of the device tax has no chance, but some of those nervous Democratic senators want to revisit the issue before having to explain themselves to voters in the fall.

When the health care reform law, referred to as "Obamacare," was being negotiated a couple of summers ago, the medical device industry, led by AdvaMed, successfully negotiated a proposed \$40 billion device tax down to \$20 billion over ten years. When



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the midterm elections in 2010 gave Republicans control of the House, device manufacturers redoubled efforts to repeal the tax.

Does repeal have a chance?

### Nervous Senate Democrats

Former Democratic Congressman and deficit-hawk Tim Penny from Minnesota told OTW that it seemed unlikely that the Senate would act on this before



Tim Penny/Wikimedia Commons

the presidential election. But given the noise influential Democratic Senators like Amy Klobuchar of Minnesota and John Casey of Pennsylvania are making, Senate leadership might have to give the bill some acknowledgment to protect those members. Even Massachusetts' Republican Senator Scott Brown's high profile Democratic challenger, Elizabeth Warren, is calling for repeal of the tax.

As a percentage of total employment, Minnesota, Utah, Delaware and Massachusetts have the largest concentrations of medical technology jobs, according to AdvaMed. The top 10 states, including New Jersey and California, have 12 Democratic senators.

Because Republicans have made repealing "Obamacare" a top legislative priority, many Democrats are afraid to vote to dismantle any part of the Affordable Care Act (ACA) and having to admit the law isn't perfect.

### Democrats: Offset Must Be Sound

But, says Penny, this is not a vote against "Obamacare," and strengthens the ACA by giving it the right revenue stream. Penny said the repeal bill is good public policy because it recovers overpayments from people who received too much in subsidies to buy health insurance.



Senator Al Franken/Wikimedia Commons

When the bill to repeal was proposed, the main argument made by Democrats was that loss of the tax revenue would add to the national debt. "I still think we need to eliminate the tax," said Minnesota Democratic Senator Al Franken, "But any plan to do so must be offset in a responsible and fiscally sound way." Republicans found the money to cover the estimated \$29 billion, ten-year cost of repealing by changing rules governing what happens when taxpayers qualify for insurance subsidies under a prior year's lower income and then make more money than expected.

The law limits what those people would have to repay. The House bill would make them return all overpayments. The White House called this a tax increase.

### Killing the Goose

Whether or not this issue becomes electorally relevant in November, the narrative of killing the goose that continues to lay golden eggs of profits and jobs in places like, Indiana, Massachusetts, Minnesota and California, is a powerful economic story in an election about the economy. Mitt Romney went out to NuVasive, Inc. in San Diego this spring and praised the work of device companies while criticizing the heavy regulatory burden and taxes on companies in the U.S., citing how Europeans seem to do it better.

### Tax Impact Debated

The potential impact of the device tax has been hotly disputed. The device industry already announced layoffs, citing the anticipated tax, as a reason.

Opponents of repeal say the device industry is trying to renege on a deal they agreed to when the ACA was passed. They also point out that device makers will benefit because tens of millions of currently uninsured potential customers will now have the resources to pay for new hips and knees. When the law passed, Bill Frist, M.D., the Senate's former Republican Majority Leader proclaimed that the new law was good for everyone involved in health care. Steve Ubl, head of AdvaMed told investors that the added tax combined with additional patients is probably a wash for device makers.

But the Medical Device Manufacturers Association (MDMA) and AdvaMed issued statements and published research that claims to show that the tax hurts the industry and disputes that there will be new, if any, business from the additionally insured. They say the newly insured aren't the demographic age and health group for which devices are developed.

Companies also object to paying 2.3% of total revenue, regardless of whether or not the business made money. This will hurt innovation, they say, as companies with small margins or trying to get profitable, will be hurt most.

### Industry Corporate Tax Rate

The device industry reported taxable income of \$13.7 billion in 2006 and paid \$3.1 billion in corporate taxes. That's a roughly 23% effective tax

rate—right around the 25% average for all industries, said a study by the Tax Foundation. Add a \$3 billion annual new tax on top of that, and the industry would pay more like \$6 billion in taxes or a roughly 45%—well over the industry-wide average.

The report said industry will likely be able to pass along the cost of the tax increase to consumers because it is unlikely patient demand for devices, particularly life-saving, devices will decline dramatically.

### Matson: Impact on Earnings and Volumes

So who's right? What is the most probable impact of the tax on industry and procedure volumes?

We turn to Mike Matson of Mizuho Securities, one of orthopedics' most senior Wall Street analysts.



Mike Matson

In a March 21, 2012 analyst note, Matson stated, "Assuming reform remains unchanged, the medical device excise tax...will only be partially offset by an increase in procedures as the uninsured gain coverage".

Matson expects 2013 earnings by device companies he covers, to be reduced by 5%. However, he says Stryker Corporation and Zimmer Holdings, Inc. have indicated they fully expect to offset the tax, while NuVasive and Orthofix International, NV expect to partially offset the tax.

In general, Matson says larger-cap companies more likely to offset the tax than smaller-cap companies given a smaller impact and greater P&L flexibility.

However, Matson anticipates the tax to be somewhat offset by increased procedure volume as the uninsured start to gain coverage in 2014. "In the longer run, health reform should decrease the uninsured population by around 30 million people in 2016. While the uninsured group tends to skew younger, middle-aged individuals (45-64 years old) make up 27% of the uninsured population."

He therefore expects the number of insured middle-aged people to increase by 7.5 million or 9%. "Since we estimate that middle-aged people account for 36% of med tech procedures, we expect this to result in a 3% increase in med tech procedures between 2014 and 2016." (See Table Below)

Company	Ticker	Rating	CY13E Excise Tax (\$M)	CY12 EPS	No Tax		With Tax (No Offset)		Tax % Reduction to CY13E EPS	Management Plus
					CY13E EPS	EPS Growth	CY13E EPS	EPS Growth		
Wright Medical Group	WMGI	Neutral	6.5	\$0.16	\$0.31	95%	\$0.21	32%	(32%)	Unknown
NuVasive	NUVA	Buy	13.4	\$0.92	\$1.08	15%	\$0.89	(4%)	(16%)	Partially Offset
Boston Scientific	BSX	Neutral	92.7	\$0.42	\$0.50	20%	\$0.45	7%	(11%)	Fully Offset
Orthofix International	OFIX	Buy	11.8	\$3.05	\$3.48	14%	\$3.10	2%	(11%)	Partially Offset
Stryker	SYK	Buy	131.2	\$4.12	\$4.52	10%	\$4.26	3%	(6%)	Fully Offset
C R Bard	BCR	Neutral	48.4	\$6.65	\$7.28	9%	\$6.86	3%	(6%)	Unknown
ResMed	RMD	Neutral	19.6	\$1.63	\$1.85	13%	\$1.75	7%	(5%)	Unknown
Covidien	COV	Buy	126.3	\$4.24	\$4.74	12%	\$4.52	7%	(5%)	Fully Offset
Medtronic	MDT	Neutral	205.6	\$3.45	\$3.82	11%	\$3.66	6%	(4%)	Unknown
Zimmer Holdings	ZMH	Buy	56.8	\$5.30	\$5.75	8%	\$5.51	4%	(4%)	Fully Offset
St. Jude Medical	STJ	Buy	64.2	\$3.47	\$3.79	9%	\$3.63	5%	(4%)	Fully Offset
Intuitive Surgical	ISRG	Neutral	40.2	\$14.68	\$17.19	17%	\$16.49	12%	(4%)	Unknown
Baxter International	BAX	Buy	40.4	\$4.59	\$5.07	10%	\$5.01	9%	(1%)	Unknown
<b>Average</b>						<b>19%</b>		<b>7%</b>	<b>(8%)</b>	
<b>Median</b>						<b>12%</b>		<b>6%</b>	<b>(5%)</b>	

Source: Company reports and Mizuho Securities USA estimates

While Matson says it's straightforward to calculate the impact of the tax (see Table), what's less clear is the companies' ability to offset it.

One way to pass it on is through a price increase. "But given a lack of pricing power, we think that this is highly unlikely. So we think the com-

panies must either offset the tax with cost reductions or see their earnings reduced. We expect most companies to attempt to do the former but not all will be successful."

Here is how some companies have said they intend to deal with the tax during quarterly conference calls with analysts:

**NuVasive:** "We will figure out what we can with regard to offsets. But we don't expect to be able to dramatically offset the tax... There are just not enough levers for us to pull."

**Orthofix:** "One of the major initiatives and goals of improving our operating margins was to absorb [the tax]... It is certainly harder for a company that is smaller than a company that is bigger, but we have been planning on it for quite a bit of time and continue to look for efficiencies to cover it."

**Stryker:** "We expect to be able to deliver greater than double-digit or greater growth in 2013, inclusive of absorbing the med device tax."

**Zimmer:** "We do expect to be able to fully offset the medical device tax in 2013 through the savings that we'll be achieving both in cost of goods and SG&A."

### More Procedures Not Enough

While expecting a 3% increase in procedures, Matson estimates there would have to be an average 8% increase in procedures to fully offset the impact of the tax. He also notes the volume benefits will come several years after the companies begin paying the tax.

The repeal effort could become moot depending on the outcome of the Supreme Court ruling expected in late June on the law's constitutionality. The court could overturn the entire reform package or eliminate selected provisions, including a mandate that requires individuals to have health insurance.

That would be the worst outcome for companies, says Matson—the tax without the extra business. ♦



# ON AND OFF THE RECORD

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## On (and Off) the Record By Elizabeth Hofheinz, M.P.H., M.Ed.

**T**ony Viscogliosi Touts PMA Over 510(k)...It's Official! Double-Bundle Superior...Infuse Critics Guilty of Loose Talk...4 New Japanese/U.S. Fellows Announced...Amazing Clinical Success with Bone Marrow Concentrate...Interdisciplinary Team Wins Team Science Award...and more.

**Amazing Clinical Success With Bone Marrow Concentrate** Lew Schon, M.D. is director of Foot & Ankle Services at

MedStar Union Memorial Hospital in Baltimore, Maryland. These days, Dr. Schon is getting better, faster healing thanks to something he's quite excited about—orthobiologics. He tells *OTW*, "Despite the controversies and major problems we have had with BMPs, there are still a lot of great opportunities to improve the magnitude and speed of healing with orthobiologics. I've been focusing on using bone marrow concentrate as a source of the body's own stem

cells, and to date have done over 1,000 cases—and will soon begin publishing them. I am using these cells for bony healing in challenging nonunions, malunions, and reconstructions in locally or systemic compromised patients—and also for soft tissue healing. The early results show that in cases where we used bone marrow concentrate for treating tendinopathy, the success rate is better than with platelet rich plasma for peripheral blood. In cases where the

patient had bilateral posterior tendinopathy or a broken Achilles tendon, I reconstructed the worst side and on the other I used bone marrow concentrate alone...the clinical success is pretty amazing.”

“This is so promising that I have cofounded a new company called Bio-active Surgical, through which we are developing stem cell sutures. So far it has been used for rats in a gap tendon model; we have shown better, faster healing with better tissue organization and mechanical properties within the gap treated with stem cell sutures over a gap treated with sutures with injections of stem cells alone.”

**Nassr, Klineberg, Smith and Costouros Picked as 2012 Traveling Fellows**

The American Orthopaedic Association-Japanese Orthopaedic Association (JOA) Exchange Traveling Fellowship has announced the four fellows who will be visiting top Japanese academic centers and historical landmarks for the JOA Traveling Fellowship. **Ahmad Nassr, M.D.** is a consultant and assistant professor of orthopedic surgery at the Mayo Clinic in Rochester, Minnesota specializing in spine surgery. He completed his residency at Rush University Medical Center and his fellowship at the University of Pittsburgh Medical Center. He received his M.D. from the University of Pennsylvania and his undergraduate degree from the Massachusetts Institute of Technology. **Eric Klineberg, M.D.** is an assistant professor and fellowship director for the Department of Orthopaedic Surgery at the University of California, Davis. Dr. Klineberg is a fellowship trained Orthopaedic Spinal surgeon. He attended the University of Maryland to obtain his M.D. and completed an Orthopaedic Surgery Residency at the University of

Washington Medical System. In 2007, he completed his fellowship at The Cleveland Clinic Foundation for combined Neurosurgery and Orthopaedic

Surgical Spine. **Jordan Smith, M.D.** attended medical school at the University of Washington in Seattle, and completed his residency at the University of

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Arizona. This was followed by fellowship training in orthopedic trauma at Carolinas Medical Center and computer navigated orthopedic surgery in Ulm, Germany. He has returned to serve on the faculty at the University of Arizona as one of four orthopedic traumatologists with a focus on pelvic and acetabular reconstruction. **John Costouros, M.D.** specializes in the arthroscopic and open treatment of complex shoulder disorders including sports injuries, degenerative conditions, fractures, and compressive neuropathies. He graduated with honors from Stanford University in Biological Sciences followed by medical school and residency at the University of California, San Francisco (UCSF). He completed fellowships with Drs. J.P. Warner and Christian Gerber at Harvard and the University of Zurich. He is currently assistant professor at Stanford University School of Medicine in the Department of Orthopaedic Surgery.

#### **It's Official! Double-Bundle Superior**

Freddie Fu, M.D. is the renowned chair of the department of Orthopaedic Surgery at the University of Pittsburgh. He has recently published two papers in the *American Journal of Sports Medicine* on single- versus double-bundle reconstruction. Dr. Fu tells *OTW*, “We have published—and are currently conducting—multiple high level studies comparing the anatomic single-bundle technique with the anatomic double-bundle technique. One of our recently published studies has demonstrated that anatomic double-bundle ACL reconstruction is significantly better than conventional single-bundle ACL reconstruction and superior to anatomic single-bundle reconstruction. These studies are important in order to begin to understand and to appreciate the significance of recon-

structing the native anatomy of each individual patient and to change the surgical paradigm.”

“Recently, the editors of one of the leading scientific journals in our field, *Arthroscopy*, called for high level studies that would prospectively compare anatomic single- and double-bundle reconstructions. In a letter to the editor written by our head of clinical research, Dr. James Irrgang, we were happy to be able to reply directly that we are in the middle of a NIH [National Institutes of Health] funded trial that does exactly that. The purpose of this randomized clinical trial is to determine whether double-bundle ACL reconstruction is better than single-bundle ACL reconstruction in terms of dynamic knee function and clinical outcomes. For this trial we are prospectively randomizing patients with an ACL size that we can restore with both single- and double-bundle reconstruction. Since the clinical exam alone oftentimes is unable to pick up on differences in knee function between the two, Dr. Scott Tashman has developed a machine (one of only a few of its kind worldwide) that can measure *in vivo* knee kinematics very accurately.”

“In general, the goal that we set for ourselves is to provide the patient with the best potential for a successful outcome. In orthopedic surgery this starts with approximating the native anatomy as closely as possible. Individual anatomical characteristics should be meticulously identified and objectified before and during surgery and should ultimately be restored with respect to size, shape and function.”

**Tony Viscogliosi: Touts the 4P's—PMA Preferred so Payers Pay** Tony Viscogliosi, founder and executive chairman of

Small Bone Innovations (SBI), has been thinking a lot lately about clinical superiority. Viscogliosi, whose company owns the STAR Ankle, tells *OTW*, “First of all, insurers, surgeons, hospital purchasing authorities and workers compensation consultants are increasingly responding to the government's call to prove comparative effectiveness before paying for innovative treatments. The fact is that investing in the FDA's Pre-market Approval (PMA) pathway with well-researched and clinically proven technologies is vastly better than the conventional 510(k) option because the latter is all about equivalency and not clinical superiority.”

“Today's ankles are based on 510(k) clearances that required—then and now—use of cement to implant the device. Why aren't these devices that existed prior to 1976 available anywhere else in world today? Because they didn't work effectively and did not last, leading to their withdrawal from the market. So why would patients be implanted with 510(k) technologies that are based upon a heritage of failure? With the STAR, payors are recognizing the difference between a clinically proven PMA ankle technology versus the 510(k) equivalents.”

“Payers are looking for solutions superior to fusion—the existing gold standard. We own the only technology to achieve that goal with the STAR Ankle's independently documented superiority to fusion. No other total ankle device can make that claim and that's why the STAR is getting exclusivity in the market as a preferred solution. It is a reward for the tens of millions of dollars SBI spent on development and rigorous clinical trials. In the new era of comparative effectiveness, manufacturers do have an obligation to bring

to market what works. Unfortunately, the bigger companies have not fully embraced the value of demonstrating clinical superiority.”

“The STAR is a great example of a gamble on funding clinical research in an unproven market that suddenly, when research demonstrates superiority, causes market growth to explode because patients, doctors, payers and hospital purchasing committees will readily pay for something that works. It is radical from a business standpoint because it’s high risk, big return. I challenge and welcome other manufacturers to subject their products to the PMA pathway. It’s the best option for everyone so let the best technology win!”

#### **Infuse Critics Guilty of Loose Talk**

Facts, not innuendo should rule the day, says a celebrated spine surgeon. He tells *OTW*, “It was a big turn events when the Department of Justice (DOJ) decided that there was no cause for further action against Medtronic regarding ‘off label’ use of BMP-2. This clears the air because there has been a lot of loose talk and innuendo, with certain parties inappropriately using their pulpits to deliver accusations of wrongdoing and conspiratorial behavior. The DOJ’s decision removes the unscientific ‘guilty by media trial’ bit from the con-

versation and allows us to get back to fact driven scientific dialogue about the place for BMP and related technologies in responsible patient care. The issues of potential carcinogenesis at high doses are importantly undergoing further independent scrutiny. We all await further data and objective input to the discussion. As for the issue of retrograde ejaculation being BMP versus exposure related...there was one article published and trumpeted to the media by the author/editor. That led to a slew of coverage in the lay press that was unprecedented and inappropriate. That one paper’s findings based on clinical observations at one institution were presented to the media as if they were fact is disappointing. Moreover, where was the press coverage of more recent studies which refute that conclusion? In a true scientific dialogue one set of observations doesn’t carry the day. An accumulated body of data/observations will ultimately lead to consensus. In this age of mass media and sensationalism, we must try to safeguard the scientific method.”

**Interdisciplinary Team Wins Team Science Award** Researchers from four institutions—Weill Cornell, Hospital for Special Surgery (HSS), University of Massachusetts Medical School and Mathematica Policy Research—have

won a prestigious award recognizing the team’s success in translation of research discoveries pertaining to perioperative outcomes in orthopedic surgery into clinical practice. The team, which included Dr. Alejandro Della-Valle, an orthopedic surgeon at HSS, was recognized for studying various aspects of the perioperative epidemiology including the incidence, risk factors and trends of morbidity and mortality, changes in the population receiving care and outcomes associated with different orthopedic surgical approaches and anesthetic techniques. Looking first at bilateral total knee replacement, the researchers discovered that the procedure carries a three-fold adjusted risk for in-hospital mortality, even when performed on younger and healthier patients. Moreover, the researchers found that staggering the procedure across several days produced even greater risk for morbidity and mortality. As a result, HSS revised its guidelines on who is an appropriate candidate for same stage bilateral knee replacement surgery and who would benefit from having two procedures staged months apart. HSS also discontinued the protocol of staging procedures only days apart. The team moves forward now with an effort to develop national guidelines, and will host a symposium at HSS this September.” ♦

## Burkhead v. Sperling on Lesser Tuberosity Osteotomy

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

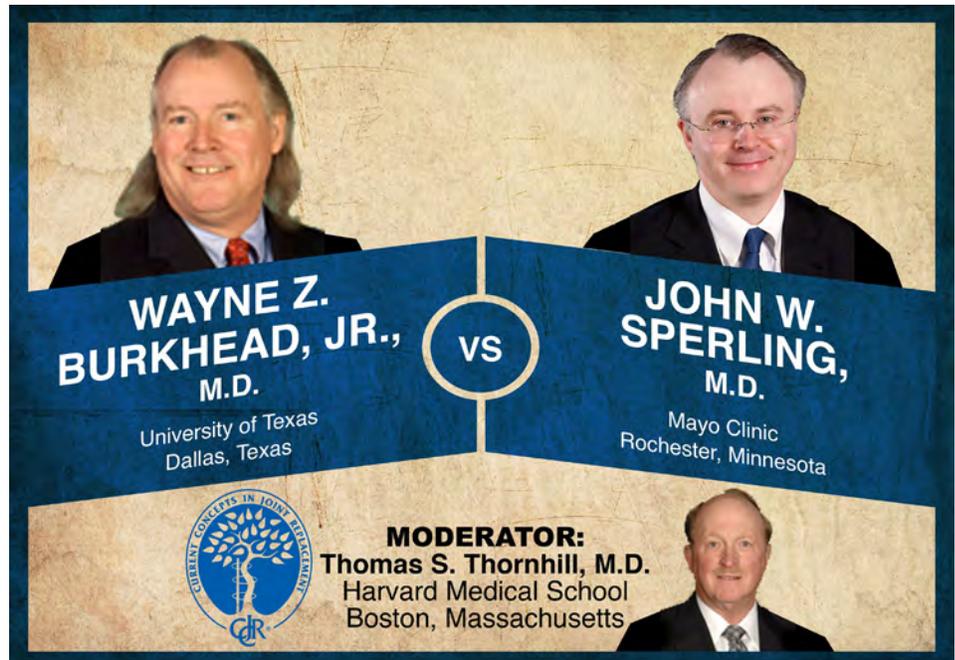
“**G**ood studies show that LTO is the best method of treating subscapularis insufficiency at the time of total shoulder,” says Wayne “Buz” Burkhead. “Osteotomy is complex,” counters John Sperling, “and there is a lack of strong evidence of superiority.”

This week’s Orthopaedic Crossfire® debate is “LTO Minimizes Subscapularis Insufficiency in Shoulder Replacement.” For the proposition was Wayne Z. Burkhead, Jr., M.D. from the University of Texas in Dallas. Against the proposition was John W. Sperling, M.D. of Mayo Clinic in Rochester, Minnesota; moderating was Thomas S. Thornhill, M.D. of Harvard Medical School.

**Dr. Burkhead:** “First of all, I love John. So I won’t refer to him as a minion from a well known institution or what Marlon Brando said to Martin Sheen...an errand boy sent by postal clerks. But I did plan on eviscerating him—then I got the case. This is a new technique... they’re handicapping this thing now.”

“The case illustrates: First, the importance of a good history, physical, and old records. Second, the importance of an historical perspective. Third, post reconstruction instability is a subset of osteoarthritis (OA) with its own unique features.”

“This is a Putti-Platt. This man has horrible external rotation, and what he probably has is scapulothoracic. So in regards to this case I surrender. I would go so far as to say that this case is a relative contraindication for lesser tuberosity osteotomy (LTO). The Putti-Platt creates an extremely thick anterior segment that’s almost the exact same thing



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you would do if you did a Z plasty of the tendon. So the subscapularis capsule construct should be gained with a soft tissue approach.”

“The Magnusen Stack is a contraindication that most people probably haven’t heard of. The subscapularis is taken lateral to the lesser tuberosity, so if you do a lesser tuberosity on this patient you’ve amputated two centimeters of the subscapularis.”

“Who is the ideal candidate for LTO? Nearly everybody else with OA and mild to moderate internal rotation contracture. The subscapularis footprint has been well described, and it can generate 250 Newtons and that’s key because every repair gives you at least 250 Newtons. But that’s just of an internal rotation moment that’s created by the subscapularis. That doesn’t measure the strength of an over-aggressive

physical therapist early on after the procedure.”

“We’ve done a number of the ‘Fleck’ osteotomies with anatomic dual row repair, taking the position that a dual row repair is stronger—and clearly it is in every study that’s been shown. We did a human cadaveric shoulder study with a dual row repair and compared it to a tenotomy group. To be fair, they were Mason-Allen sutures with the more simple stitch component placed on the tendinous side. So there wasn’t a huge difference between double and single row techniques as we had done the single row technique...or the tenotomy in terms of the ultimate strength. But the tenotomy just barely got you to the critical amount.”

“Double row: no gross rotational motion. Clearly, both techniques control the moment of the internal rotation

and the medial pull of the subscapularis, but this technique controls the rotation of that fragment much better.”

“Tenotomy fails at the tendon—single row was variable, double row always failed at the bone. So it improves a reproducible restoration of subscapularis integrity. Scott Simon showed that a tenotomy was just as good. He used a figure eight suture—tendon to tendon repair; I suggest a figure of eight suture. But the model that he tested for the LTO is simple drill holes...this is not the way Christian Gerber described it and it's not the way we do it. This is ineffective. This is not going to control rotation of that fragment because you only have one plane of control. So if you want to do an LTO you should use Gerber's technique, 632 Newtons, with only 4.6mm of displacement after millions of cyclic loads.”

“Conclusions: Biomechanical studies and reasonably well designed high level evidence-based studies would lead

an intelligent orthopedic surgeon to assume that LTO is the best method of treating the subscapularis at the time of total shoulder. But there are situations where it's not the best choice. Recognition of the unique features of soft tissue, soft tissue to bone, and bone to bone fixation will allow you to choose the best method for your patient.”

**Dr. Sperling:** “I'm going pro-tenotomy...subscapularis tenotomy really is the optimal approach to shoulder arthroplasty. Very little attention was directed at subscapularis integrity in the past; recent papers have highlighted abnormal subscapularis function following shoulder arthroplasty.”

“Subscapularis compromise can be due to re-rupture, poor quality tissue, excessive tension at time of surgery in regard to overstuffing, and nerve injury during mobilization.”

“LTO was described as an effort to minimize subscapularis repair failure.

The goal is bone to bone healing, and it's thought by many to be superior to bone to tendon healing. The challenges of LTO: it's more complex, you may crush the metaphyseal bone, possible fragmentation of the lesser tuberosity, as well as the potential for non-union.”

“The benefits of tenotomy: it's simple, reproducible, and a time efficient method to provide a secure repair of the subscapularis. Tony Romeo's group: tenotomy versus osteotomy with 24 pairs of cadaveric shoulders. They underwent cyclic loading; there was no difference comparing tenotomy versus osteotomy in regard to stiffness, elongation amplitude, or cyclic elongation.”

“Akin Cil looked at a cadaveric study comparing osteotomy to tenotomy. Tenotomy did better than osteotomy in regard to displacement and maximum load to failure. George Athwal did a prospective, double blind, randomized trial comparing these two groups. He found no difference at two year follow-up in regard to strength and outcomes scores. George also looked at a follow-up biomechanics study—he found there was no difference.”

“This is the classic study that's been used to defend tenotomy—it was by Dr. Nevaizer. Forty-five patients with a total shoulder arthroplasty that underwent a tenotomy and repair; protected post-operative motion. What he found in regard to clinical testing in this tenotomy group, 41/45 had a negative lift-off test and 45/45 had a negative belly-press test. The authors thought that the issue of subscapularis healing really is related to the postoperative rehabilitation.”

“Another concerning study was by Christian Gerber, a large proponent of this. He looked at CT scans after an osteotomy, and there was a 44% rate

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of progressive fatty infiltration. Clearly, damage is being done to the subscapularis with an osteotomy.”

“Conclusion: the complexity of an osteotomy, together with concerns over non-union, fragmentation, fatty infiltration, as well as a lack of strong evidence of superiority don’t warrant changing from tenotomy.”

**Moderator Thornhill:** “Buz, what percentage of total shoulders now are done with LTO versus tenotomy—in the world?”

**Dr. Burkhead:** “I don’t know.”

**Moderator Thornhill:** “John?”

**Dr. Sperling:** “It’s hard to give a number...30%?”

**Moderator Thornhill:** “Would it be fair to say that the movement has been away from tenotomy and that younger guys are doing more LTOs?”

**Dr. Sperling:** “It’s split. Some people who try to do an osteotomy and then sometimes see the problems associated with it—fragmentation of the lesser tuberosity, nonunion.”

**Moderator Thornhill:** “So Buz, you folded up like a \$3.00 suitcase on this argument.”

**Dr. Burkhead:** “At least I didn’t give up in the ready room like Seitz did last year.”

**Moderator Thornhill:** “One of the problems following Putti-Platts is residual posterior subluxation of the shoulder and oftentimes even instabil-

ity. So your reason for not doing that would be to allow you to lengthen the subscapularis?”

**Dr. Burkhead:** “I’d reverse the Putti-Platts. Subscapularis Z lengthening is a lost art. It got an unfair, bad reputation. Rockwood and Neer did it from different sides. I think Rockwood would start laterally and move medially and Neer did the opposite. You could see how that surgery was done, that you probably would want to start laterally, dissect it down and then have two good levers. For every centimeter of length that you get you have gained 20 degrees of external rotation. In someone like this I would try to get about two centimeters of length. And I’d even be willing to augment that with one of the dermal matrices if I was concerned about the thinness. But usually in these patients who have had a Putti-Platt, it is so thick that you really have plenty of tendon to work with. You would sew these together with figure of eight sutures to maximize your strength.”

**Moderator Thornhill:** “What about rheumatoids?”

**Dr. Burkhead:** “If you ask me who I do the osteotomy on...male, osteoarthritis with minimal internal rotation contracture of about 30 degrees. You can’t medialize the osteotomy. If you do that you’re creating a situation similar to a lesser tuberosity malunion where they’re going to have loss of internal rotation.”

**Moderator Thornhill:** “When you do your tenotomy do you try to close the rotator interval, move it, or put it back anatomically?”

**Dr. Sperling:** “I put a few stitches in the rotator interval, but I put them on before I put the real head on. If you try to put those interval stitches once you have the real humeral head on it can be difficult. So I put maybe two stitches in the interval, put the real humeral head on, start closure. You have to dial in the amount of external rotation you want. If you close the interval with the arm at the side you’ll never get the external rotation.”

**Moderator Thornhill:** “Buz, if you do a well-fixed LTO you can start external rotation earlier, and if so how early? Also, do you think your ultimate subscapularis strength by lift off or belly press is better?”

**Dr. Burkhead:** “The answer to the first question is, ‘No, I don’t think you should start it that much sooner. But you can strengthen them sooner and you have a radiographic endpoint, so once you see that your LTO has healed it’s much like a Bristow procedure versus a soft tissue reconstruction. Once the bone is healed and the tendon intact that patient can be strengthened, stretched aggressively if they need that.”

**Moderator Thornhill:** “If you do a LTO your ultimate strength of the subscapularis is better?”

**Dr. Burkhead:** “Yes.”

**Dr. Sperling:** “No.”

**Moderator Thornhill:** “Now that we have consensus, thank you.” ♦

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## company

**Precision Spine Buys Spinal USA**

Spinal USA, LLC and Precision Medical of Mississippi, LLC, have been sold to Precision Spine, Inc. of Parsippany, New Jersey.

The transaction is valued at approximately \$72 million. A statement from Precision Spine said the company plans to continue the growth fueled by the 2011 releases of the Vault Stand Alone ALIF System and the S-LOK PC Posterior Cervical System, and aims to offer several additional new products in the second half of 2012.

Spinal USA is the physician-founded spine company unfairly scorched by the *Wall Street Journal* last October when

Adam Lewis, M.D., a neurosurgeon investor in the company was accused of allegedly performing unnecessary surgery because he was using the company's devices.

The *Journal*, in an ongoing critique of physician-owned health care business, cited Charles Rosen, M.D., founder of the Association for Medical Ethics, who reviewed the medical records of one of Dr. Lewis' patients and said the patient was a poor candidate for a 360-degree spinal fusion.

James Pastena, president and CEO of Precision Spine said the company is well positioned to address the needs of the aging population in a cost effective manner. "Our subsidiaries have a proven track record of lowering manufacturing costs while delivering high quality medical products and reducing costs for local and national health care provid-

ers and their respective patients. These achievements have driven a growth rate of more than 30% in a market experiencing overall negative growth. We believe we can accelerate that rate, with several initiatives planned that will build on our strengths, expand our product lines and allow us to deliver even greater value to communities hard hit by the current economy."

Spinal USA was founded in March of 2005, by a group of medical professionals.

Pastena, according Spinal USA, was president of EBI, and a corporate vice president of Biomet, Inc., its parent company. During his tenure with EBI he lead the company growth from \$85 million in 1993, to \$500 million with a +20% return at his departure. The company also says Pastena brought the company spine segment to the #4 market share position in the

world. They say he organized the largest company owned hybrid direct sales force in orthopedics, and established unilateral external fixation for limb lengthening, trauma and Colles' fracture repair as standards of orthopedic care, resulting with EBI becoming the market leader.

Precision Spine, Inc. is a privately held company and is the parent company of its wholly owned subsidiaries, Spinal USA, Inc. and Precision Medical, Inc.

—WE (June 24, 2012)



Source Spinal USA, LLC

## Aesculap's "Break-through" Knee Replacement Debuts

Aesculap Implant Systems debuted a new knee replacement system at the recent Current Concepts in Joint Replacement Spring meeting that promises, according to the company, to recreate a natural pivotal motion while greatly reducing surface stress. Additionally, the narrowed design combined with smoother transitional radii reduce soft-tissue infringement.

The company says the VEGA System Posterior Stabilized Knee Replacement System is based on a patent-pending post-cam mechanism and is a "pivotal breakthrough" in knee replacement technology. The design facilitates a large range of motion and optimized surface contact between the femoral component and gliding surfaces. The surface contact between the articulating

components maximizes bearing surface stress distribution, reducing the risk of delamination.

The system offers 13 femoral and 11 tibial sizes and uses the company's Advanced Surface (AS) multi-layer coating which, the company says, has demonstrated reduce wear results and increased longevity. Noting that wear is the number one reason for knee revisions in the long term, the company says an AS coated knee prosthesis, "demonstrates 60% reduction in wear when compared to a CoCr [cobalt chrome] prosthesis, as demonstrated in testing with other Aesculap knee designs. The hard ZrN [zirconium nitride] ceramic surface can lead to improved scratch resistance and good wettability for better articulation between bearing surfaces."

The system design team was led by William Mihalko, M.D., Ph.D., Professor and J.R. Hyde Chair and Director of Bio-

medical Engineering at the University of Tennessee Campbell Clinic Department of Orthopaedics and Biomedical Engineering and K.J. Saleh, B.Sc., M.D., M.Sc. (Epid), FRCS(C), MHCM. Dr. Mihalko said, "The breakthrough design concepts found in the VEGA System knee replacement allows the patient to regain their natural motion while the Intuitive and Quick instrumentation leads you through a logical step-wise progression during surgery, reducing steps in the Operating Room for optimum outcomes."

The system's instrumentation platform, says the company, is highly intuitive and reduces steps in the workflow to save time and money. The platform contains dual-purpose instruments, fewer trays, and a simplistic design that allows surgeons to operate quickly and easily resize.

—WE (June 24, 2012)



Aesculap Implant Systems/VEGA System

## Biomet 4Q12 Results Point to Recovery

There's nothing better than getting to pre-announcing good news for your own company and your industry.

That's what Jeff Binder, head of Biomet, Inc., got to do on June 15 as he announced the company's quarterly growth had accelerated significantly both in the U.S and worldwide. The company said revenue for the quarter ending in May rose 5% on a constant currency basis to \$740 million.

Analysts were quick to jump on the news saying Biomet most likely took market share in the quarter. Mike Matson, Mizuho Securities Analyst, said he believes that Biomet's results are, "still probably indicative of some degree of improvement in the recon and spine markets."

Larry Biegelsen of Wells Fargo noted that the results mark the fourth consecutive quarter of growth acceleration in the U.S., while the spine numbers represent, "a significant turnaround" after four straight quarters of negative growth and sees this as another data point pointing towards a recovery in the spine market.

Biomet 4Q 2012	Sales \$ in million	% Change*
<b>Total Reported Sales</b>	<b>740.0</b>	<b>5.0%</b>
Large Joints	439.6	6.0%
Knees		6.0%
Hips		6.0%
Sports, Extremities, Trauma	96.2	16.0%
Spine & Bone Healing	83.9	5.0%
Dental	69.2	down 4%
Other	50.6	down 1%

Source: Biomet, Inc.  
\* Constant Currency

# BIOMET®



MorgueFile and Alvimann/Biomet/RRY Publications LLC

Biomet is the number four recon company with 13% market share and will release full fourth quarter results on July 17.

Binder said in a prepared statement, "I'm extremely pleased with our fiscal fourth quarter sales results, which were strong across numerous product categories. In a separate release today, we announced the initial closing of the DePuy [Orthopaedics, Inc.] trauma acquisition and we're very excited about the additional opportunities we believe this business will bring

to Biomet. As we exit fiscal year 2012 with a strong finish to our consolidated sales results and welcome the addition of our new trauma team members, we look forward with much enthusiasm to the possibilities in fiscal year 2013."

The company also announced that preliminary full-year results showed a 3% constant currency increase to \$2.838 billion.

Sherry Slater of the *Ft. Wayne Journal Gazette* noted that Biomet, Inc. was mum on whether it earned a profit on that revenue and that last year the company reported an annual loss of \$843.5 million, almost \$800 million more than the previous year.

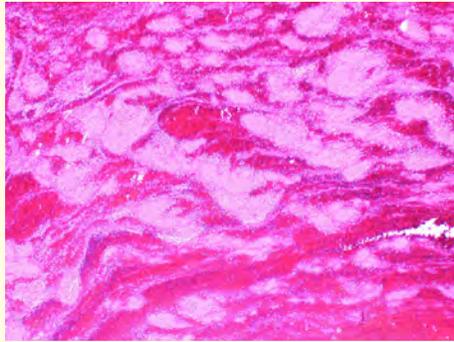
—WE (June 24, 2012)

## biologics

**Blood Clots Heal Rotator Cuff Tears**

Can a blood clot help heal a rotator cuff tear? Christopher S. Proctor, M.D., writing in *Arthroscopy Techniques*, believes it can. In his article he notes that a significant number of rotator cuff repairs re-tear in the first six months. To resolve this problem, Proctor refers to recent research that has focused on the use of platelet-rich plasma (PRP). Platelets contain and release a number of growth factors and studies indicate that these growth factors benefit tendon healing.

But not every time. Results of rotator cuff repairs that have been augmented by PRP have been mixed with some showing lower re-tear rates and others showing no change in the re-tear rate at all. Proctor acknowledges that part of the problem may be that not all PRP



Wikimedia Commons and Yale Rosen

preparation process are alike, appropriate dosing has not been established and techniques for applying PRP have not standardized. He proposes a new procedure.

Proctor urges the application of fibrin blood clots to the tendon, noting that the clots are a rich source of platelets and a reservoir of platelet-derived growth factor. He writes that clots can provide a scaffold for cell migration and proliferation and “may biologically affect the healing process in a much broader fashion than the simple appli-

cation of PRP.” A final benefit is that a properly prepared fibrin clot has structural integrity and can hold sutures.

A Stowe, Vermont company, Pierce Surgical Corporation has devised the “Clot-Master Hula Cup” that will produce a blood clot in ten minutes. A technician in the operating room puts from 10 to 60 cc of blood or bone marrow aspirate into the container, closes the lid, adjusts a glass rod that runs through the center of the cup and swirls it for 10 minutes. This creates the blood clot and aligns the fibers so that the clot has sufficient structure that it can be sutured onto the tendon-bone repair site.

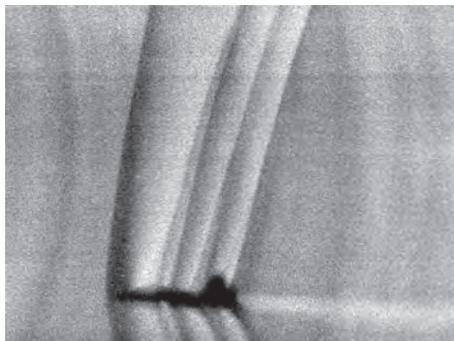
Proctor writes, “Using an endogenous fibrin clot to augment rotator cuff repair not only has the advantages of being reproducible, quick and inexpensive but also provides a method of securely fastening the biologic material at the repair site.”

—BY (June 22, 2012)

## large joints

**Shock Waves May Prevent Osteoarthritis**

SANUWAVE Health, Inc, a Georgia company, reports that a peer-reviewed, preclinical osteoarthritis research project demonstrated the ability of the company’s shock wave therapy to prevent the onset of osteoarthritis. The therapy, called Extracorporeal Shock Wave Technology (ESWT), was the subject of a recent clinical study titled; “Extracorporeal Shock-wave Therapy Shows Time-Dependent Chondroprotective Effects in Osteoarthritis of the Knee in Rats,” and which was published in the online edition of the *Journal of Surgical Research*.



Wikimedia Commons and NASA/Dr. Leonard Weinstein

While osteoarthritis of the knee is considered primarily a cartilage disease, company officials report that emerging evidence suggests that changes within the subchondral bone (below the cartilage) play a corresponding role in the onset and progression of the disease. As a result, they assessed six different

parameters in this study—three for cartilage and three for subchondral bone.

The researchers performed surgical trauma to the anterior cruciate (ACL) ligament of research animals to induce osteoarthritic changes in the knee in two study groups. One of these groups subsequently received ESWT treatment of the subchondral bone. A third group, used as a control, included healthy animals that did not receive surgical trauma or ESWT treatment.

The group that received ESWT treatment had results comparable to the control group of normal, healthy animals across all six assessed parameters, strongly suggesting that ESWT treatment prevented the onset of osteoarthritis.

The group that received ESWT treatment compared with the non-ESWT group showed statistically significant improvements in the structure and overall health of cartilage, together with improvements in vascular function and new microvascular activity within bone, and new bone formation. Researchers evaluated the subjects at 2, 4, 8 and 12 weeks.

Investigators interpreted the results as demonstrating that the beneficial effects of ESWT occurred as early as two weeks after treatment, maximized between two and four weeks, and continued for at least 12 weeks, which was the longest time point analyzed in this study.

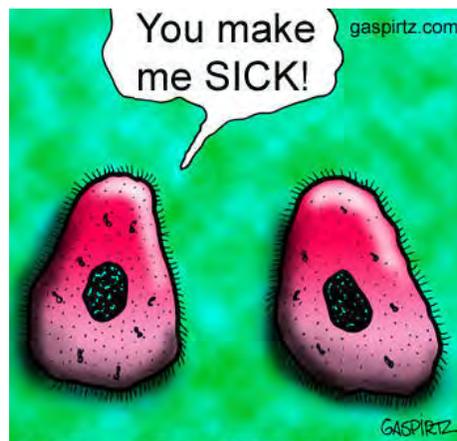
Commenting on the study, the lead investigator, C. J. Wang, M.D. an orthopedic surgeon at Chang Gung Memorial Hospital in Kaohsiung, Taiwan said, “We showed that a single ESWT procedure applied after the onset of osteoarthritis delays, and can even regress, osteoarthritic changes to the knee. Our results clearly show that ESWT treatment provides early and sustained benefits to both cartilage and bone that together prevent osteoarthritis in the knee.”

Wang concluded, “Our research is perhaps the first to use acoustic shock waves to prevent osteoarthritic changes to the knee and the results are similar to those seen with pharmacotherapy. Based on our positive study results to date, I believe that SANUWAVE’s platform of proprietary ESWT devices, known as PACE® technology, may offer an effective, noninvasive and low-cost treatment option in humans that carries little risk compared with other treatments.”

—BY (June 22, 2012)

## Gut Bugs Participating in RA!

According to researchers at Mayo Clinic and the University of Illinois at Urbana-Champaign, unusually large populations of specific gut bacteria may trigger the development of diseases such as rheumatoid arthritis (RA). It may also fuel disease progression in people genetically predisposed to this crippling and confounding condition, say the researchers, who are participating in the Mayo Illinois Alliance for Technology Based Healthcare.



When germ relationships go bad

Wikimedia Commons and Gaspirtz

“A lot of people suspected that gut flora played a role in rheumatoid arthritis, but no one had been able to prove it because they couldn’t say which came first—the bacteria or the genes,” says senior author Veena Taneja, Ph.D., in the June 11, 2012 news release. Dr. Taneuz is a Mayo Clinic immunologist. “Using genomic sequencing technologies, we have been able to show the gut microbiome may be used as a biomarker for predisposition.”

Researchers also found that hormones and changes related to aging may further modulate the gut immune system

and exacerbate inflammatory conditions in genetically susceptible individuals.

Dr. Taneja and her team genetically engineered mice with the human gene HLA-DRB1\*0401, a strong indicator of predisposition to rheumatoid arthritis. A set of control mice were engineered with a different variant of the DRB1 gene, known to promote resistance to rheumatoid arthritis. Researchers used these mice to compare their immune responses to different bacteria and the effect on rheumatoid arthritis.

“The gut is the largest immune organ in the body,” says co-author Bryan White, Ph.D., director of the University of Illinois’ Microbiome Program in the Division of Biomedical Sciences and a member of the Institute for Genomic Biology. “Because it’s presented with multiple insults daily through the introduction of new bacteria, food sources and foreign antigens, the gut is continually teasing out what’s good and bad.”

The mice used mimic human gender trends in RA, in that females were about three times as likely to generate autoimmune responses and contract the disease. Researchers believe these “humanized” mice could shed light on why women and other demographic groups are more vulnerable to autoimmune disorders and help guide future therapies.

“The next step for us is to show if bugs in the gut can be manipulated to change the course of disease,” Dr. Taneja says.

Asked how they will go about this, Dr. Taneja told OTW, “There are many ways of changing gut flora. We plan to make gut flora of susceptible mice more like resistant mice to see if we can change

the course of disease. This can be done by giving bugs to the susceptible strains that are less abundant when compared to the resistant mice. These studies are in progress in our laboratory.”

—EH (June 18, 2012)

## extremities

### Android-Controlled Robotic Foot/Ankle Prosthetic Incredible!

A Bedford, Massachusetts, bionics company, iWalk, has developed a foot and ankle combination that, company officials say, allows amputees to walk normally. Called the Powerfoot BiOM, the device is reported to be the first lower leg system to utilize robotics to replace the action of the foot.

Developers explain that the device generates power during any movement in walking that increases the approximate

90 degree angle between the front part of the foot and the shin. They describe it as being akin to depressing an automobile pedal, thus propelling the prosthesis forward. Through a series of sensors, the BiOM can adapt to changing terrain, adjust ankle stiffness and power delivery to ensure a consistent, efficient gait.

“People can get used to it in three to five minutes,” said Rick Casler, iWalk’s vice president for research and development. “It’s great to hear people say, ‘You’ve given my ankle back to me,’” he said.

A study by the Center for Restorative and Regenerative Medicine Department of Veterans Affairs found that amputees



using the Powerfoot BiOM were able to walk at the same speed, using the same amount of energy, as non-amputees. Company officials estimate that amputees wearing artificial limbs expend an estimated 20% more energy walking than do those with a BiOM. The study concluded that amputees using the BiOM “experienced normative ankle mechanics” during walking that “normalized metabolic energy costs compared with non-amputees.”

The developers say that the device is controlled by the same Android software that is used in cell phones so that users can change the amount of power the device uses, and thus their stride. According to iWalk president and CEO Timothy A. McCarthy, the company hopes, in two years, to have a knee system that is fully integrated with the foot/ankle device. The iWalk foot/ankle device costs about \$50,000.

The Powerfoot was developed by Hugh Herr, Ph.D., director of the Biomechanics Group at the Massachusetts Institute of Technology’s MediaLab. He has worked to perfect the bionic ankle ever since he lost both legs in a mountain climbing accident 20 years ago. He describes the action of the device, “When my foot hits the ground it moves as if it has a calf muscle, an Achilles and is being controlled by the spinal cord,” in the June 10 news release. Herr founded the privately held company in 2006. It receives funding from the U.S. Department of Veterans Affairs and the U.S. Army’s Telemedicine and Advanced Technology Research Center.

—BY (June 22, 2012)

Courtesy of iWalk



## Ankle Tissue Anchor Gets 510(k) Clearance

**K**Fx Medical Corporation, a Carlsbad, California, company specializing in tissue fixation in orthopedic surgical procedures performed on the shoulder, knee, foot, and ankle, has received 510(k) clearance from the FDA for its AppianFx Tissue Fixation Anchor.

Company officials say the anchor is easy to use, requires fewer steps and less time for insertion and has great pull-out strength. “This new anchor enables KFx to expand into the rapidly growing foot & ankle repair and reconstruction

market, as well as other applications requiring smaller implants,” said Tate Scott, company president and CEO.

Aron Green, M.D. of Seaview Orthopedics, Ocean, New Jersey said in a June 14 news release, “Use of the KFx AppianFx anchor in foot & ankle procedures makes technically challenging cases significantly easier. There is no whip stitching which saves measurable time, and a reliable and reproducible method of tensioning with excellent fixation strength. This device is a game changer.”

The privately held company was founded in 2003 to develop products for tissue fixation in orthopedic surgical pro-

cedures performed on the shoulder, knee, foot, and ankle.

According to company officials the line of implants from KFx has been used to reattach tissue to bone in shoulder, knee, feet and ankle procedures in well over one million annual cases.

—BY (June 22, 2012)



Courtesy of KFx Medical

## trauma

### Osteoporosis in Men: New Guidelines

**O**steoporosis...don't forget about the men, say experts. The Endocrine Society has just released clinical practice guidelines (CPG): “Osteoporosis in Men: An Endocrine Society Clinical Practice Guideline.” They are published in the June 2012 issue of the *Journal of Clinical Endocrinology and Metabolism (JCEM)*, a publication of The Endocrine Society.

“For men age 50, one in 5 will experience an osteoporosis-related fracture in their lifetime,” said Nelson Watts, M.D. in the June 18, 2012 news release. Dr. Watts is with Mercy Health Osteoporosis and Bone Health Services in Cincinnati, Ohio, and is chair of the task force that authored the CPG. “Mortality after fracture is higher in men than in



Wikimedia Commons, Balinto, and Mrszantogabot

women. Of the 10 million Americans with osteoporosis, 2 million are men. Of the 2 million fractures due to osteoporosis that occur each year, 600,000 are in men.”

Some of the recommendations from the CPG include:

- Men at higher risk for osteoporosis (including men aged 70 years or older and men between the ages of 50 and 69 who have risk factors) should be tested using dual-energy x-ray absorptiometry (DXA);
- Men with low vitamin D levels [ $<30$  ng/ml] should receive vitamin D supplementation to achieve levels of at least 30 ng/ml;
- Pharmacologic treatment should be given to men aged 50 or older who have had spine or hip fractures and men at high risk of fracture based on low bone mineral density and/or clinical risk factors.

Asked what might lead doctors and/or orthopedists to not manage this condition well/thoroughly in men, Dr. Watts told *OTW*, “First of all, osteoporosis is not managed very well in postmenopausal women who have had fractures! Second, it is often considered a ‘woman’s disease,’ although 20% of the 10 million Americans with osteoporosis are men and one-third of the 2 million fractures due to osteoporosis occur in men. Bone density testing equipment is often put in the hospital’s ‘Women’s Center’ or ‘Breast Imaging Center,’ making it awkward for men to be tested. Finally, while Medicare covers bone density testing for virtually all female beneficiaries, coverage for men is quite limited—meaning that men tested (appropriately) at age 70, or sooner if they have other risk factors, often have to pay out of pocket for their first bone density test.”

—EH (June 20, 2012)

## spine

### Hospitals Double Dip on Spine Surgeries

Some California hospitals collect duplicate payments for spinal surgeries—get paid twice—according to a report by California Watch, founded by the Center for Investigative Reporting. Reporter Bernice Yeung writes in the June 19 news release that this practice amounted to additional costs of \$67.5 million in 2010. And it is all due to the way California’s workers’ compensation program reimburses providers for spine surgery.

The California workers’ compensation program pays hospitals 120%, as compared to what Medicare pays, for injured workers’ medical services. However, spinal surgeries trigger additional payments, called “pass-through” payments. These are intended to reimburse hospitals for the cost of the devices implanted in the patients during spinal surgery.

What the California Watch study discovered was the fact that the cost of the instruments was already factored

into the hospitals initial charges and their reimbursement. The report, based on 3,350 surgeries, estimates that the duplicate payments for spinal devices added \$20,000 to the cost of each procedure.

Yeung quotes a representative of the California Hospital Association as saying that pass-through payments are necessary to ensure that injured employees have access to complicated and costly back surgeries. “California Hospital Association’s concern is that the Medicare population is different from the workers’ compensation population... and payments are based on a population of elderly and disabled patients,” said Amber Ott, the vice president of finance for the California Hospital Association. “The clinical approach is different than if it were a young person trying to re-enter the workforce. You are trying to achieve full mobility versus comfort.”

According to data from California’s Office of Statewide Health Planning and Development, there were 5,193 injured workers who had surgeries that qualified for a pass-through payment in 2010.

—BY (June 22, 2012)



RRY Publications and Andrew Huth

## people

**MacMillan to DePuy-Synthes?**

Is Stephen MacMillan in the running to take over the recently created DePuySynthes?

First *The Wall Street Journal* reported that the former Stryker Corporation CEO was gunning for a job with his old employer, Johnson & Johnson. Now *Massdevice.com* reported on June 13, that with the DePuySynthes merger completed and rumors of MacMillan “looking like a good fit” to run the new ortho business, would his two-year non-compete agreement with Stryker stand in the way?

The two-year non-compete clause Macmillan signed with Stryker in his February 2012 separation agreement, which paid him \$5.5 million in cash and the rights to purchase nearly \$65 million worth of stock options seems to be a huge hurdle.

Under the terms of that agreement, which forbids MacMillan directly or indirectly to “own, manage, operate, join, control, be employed by, or participate in the ownership, management, operation or control of, or otherwise be connected in any manner with, including, without limitation, holding any position as a shareholder, director, officer, consultant, independent contractor, employee or partner of, spokesman for, or investor in, any business which is competitive with (x) the businesses of the company or any of its subsidiaries or affiliates,” according to a regulatory filing.

Before joining Stryker and after a stint at Global Specialty Operations of Pharmacia Corporation, MacMillan served



Stephen MacMillan

as president of Johnson & Johnson—Merck Consumer Pharmaceuticals. He had held numerous other roles at Johnson & Johnson since 1989, including vice president, marketing and professional sales at McNeil Consumer Specialty Pharmaceuticals, and managing director of the UK subsidiary of Johnson & Johnson MSD (Merck). He began his career with Procter & Gamble in 1985, where he held various marketing positions.

The MacMillan watch continues.

—WE (June 24, 2012)

**Thomas Prescott and Thomas Wilder Join Benvenue Board**

Benvenue Medical, Inc. is welcoming Thomas M. Prescott and Thomas C. Wilder to its Board of Directors. Prescott is president and CEO of Align Technology, Inc., and Thomas C. Wilder is president and CEO of Sequent Medical, Inc.

Prescott, who will serve as chairman of the board, has been president and CEO of Align since 2002. The company is the



Courtesy of Benvenue Medical, Inc.

inventor of Invisalign and an innovator in digital dentistry, and it has grown significantly under his leadership. Previously, Mr. Prescott was president and CEO of Cardiac Pathways, where he successfully led a turnaround prior to its acquisition by Boston Scientific Corporation. Prior to Cardiac Pathways, Mr. Prescott held various sales, marketing, management and executive roles at Nellcor Puritan Bennett, GE Medical Systems, and Siemens.

Prescott earned a Master of Management from the Kellogg Graduate School of Management at Northwestern University and a bachelor's degree, with emphasis in Civil Engineering, from Arizona State University.

Tom Wilder has served as the president and CEO of Sequent Medical, Inc., a privately held medical device company focused on developing innovative devices for the treatment of neurovascular disease, since 2010.

Prior to joining Sequent Medical, Wilder was president and CEO of Photothera, Inc., a private company developing transcranial laser therapy for the treatment of acute ischemic stroke. His experience also include being president and CEO of Micro Therapeutics, a publicly traded company that provided a broad range of advanced interventional products to neurovascular specialists. Prior to Micro Therapeutics, Wilder held several management positions during an 11-year tenure at Medtronic, Inc.

He holds a Master of Management from the Kellogg Graduate School of Management at Northwestern University, and a BA in Economics from Stanford University. He also serves on the Board of Endologix, Inc.

—EH (June 19, 2012)



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