

# Orthopedics • This Week

## WEEK IN REVIEW

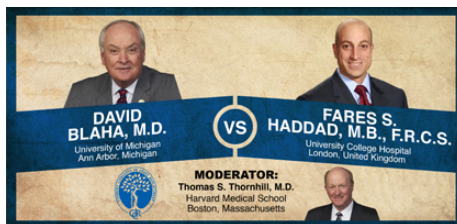
**5 Study: Patients, Not Surgeons, Driving Demand for Surgery // President of the NFL Physicians Society Says ACL Injuries NOT on the Rise // ZERO Pain After Knee Replacement Thanks to “God-send” Drug >>** New Duke Study: patients opt for surgery more often than previously thought. Surprise! ACL injuries in the NFL are *not* increasing. Great news for physicians and patients, liposomal bupivacaine can get patients to the point of being pain free.

**8 Six Questions Top Surgeons Ask About Stem Cells >>** “Stem cells” have been in orthopedic use since before World War II. We just didn’t know they were “stem cells.” In fact, we probably still don’t know what the heck those cells are. Two of the top surgeons/scientists tackled the problems of understanding “Stem Cells” at AAOS and came up with six questions every physician should ask. Here goes, and take notes.

**11 Nine Rules for Surviving CMS’s New Data Dump >>** CMS just released the mother lode of payment and billing data to the public. Now lawyers, payers, bookkeepers and reporters can see what CMS claims surgeons did and how much they were paid. But watch out. Here are 9 essential facts every surgeon should know and prepare for.



**14 Blaha, Haddad: Four Rounds Over Femoral Neck Modularity >>** “This is an unnecessary evil. It’s not required for function and may be associated with implant failure,” says David Blaha. Fares Haddad notes, “There are still indications for modularity, but we need to get the design right and simplify the technique. And it has to be generalizable.”



## BREAKING NEWS

**17 Errata: “Alphatec’s \$49 Million French Adventure”**

Artificial Knee Climber Attempts Everest

Adult Offspring of Those With Addictions are Prone to Arthritis

Lizard Tails Prompt Cartilage Study

Cayenne Medical Claims MedShape Violates Fixation Patent

MicroPort Orthopedics Adds Star Power

**For all news that is ortho, read on.**

# Orthopedic Power Rankings

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

**THIS WEEK:** The stock market is correcting. All bull markets have corrections. The typical correction is defined as a decline of 10% or less in a relatively short period of time. This correction started on March 21, when the NASDAQ index was at 4,276 and volume clearly showed sellers dominating trading. A 10% drop from there would take the index to 3,850. Most vulnerable? Growth company stocks.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Zimmer	27.31%	(5.48%)	Knees, baby. Anecdotally, the Persona knee is one of the most successful new product launches in ortho history.
2	3	Johnson & Johnson	26.58	3.49	Scared investors are liking the JNJ dividend. At 2.70% it's a warm, dry haven to weather out this correction.
3	2	Stryker	15.71	(2.78)	This year and next will be integration years for SYK's recent acquisitions. This year, EPS expected to rise 12-16%.
4	4	Medtronic	28.84	(1.05)	All news is about MDT's cardiovascular business. Where's spine? New products, new studies, new anything.
5	6	Orthofix	6.75	33.29	The way this stock jumped is testament to how depressed it was while OFIX was fixing its record keeping.
6	7	Alphatec Spine	(5.21)	2.50	Broken stock. Not broken company. In fact, we see signs of continuously strengthening management and company.
7	8	Smith & Nephew	20.25	(4.01)	One little known fact about SNN is its extraordinarily high payout ratio—42% of its earnings are paid out to shareholders.
8	5	Integra LifeSciences	11.77	(8.94)	Get ready for a big earnings jump in Q1. The consensus of analysts is that IART will report \$0.57 per share up from \$0.39 in last year's Q1.
9	9	NuVasive	6.30	(12.27)	This is the one year anniversary of Japanese approval for NUVA's line. Japan will be an important driver of future NUVA sales growth.
10	10	Globus Medical	28.29	(11.65)	Most analysts expect GMED to post an 8% Q1 sales increase and only a penny increase in Q1 earnings. Again, overly conservative expectations.

# Robin Young's Orthopedic Universe

## TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Orthofix	OFIX	\$31.55	\$574	33.29%
2	Aurora Spine	ASG	\$4.86	\$76	15.71%
3	Johnson & Johnson	JNJ	\$96.87	\$273,980	3.49%
4	Alphatec Holdings	ATEC	\$1.44	\$140	2.50%
5	CryoLife	CRY	\$9.63	\$270	1.16%
6	ArthroCare	ARTC	\$48.50	\$1,667	0.73%
7	Tornier N.V.	TRNX	\$18.81	\$913	-0.58%
8	Medtronic	MDT	\$59.20	\$59,248	-1.05%
9	Stryker	SYK	\$79.36	\$30,014	-2.78%
10	Smith & Nephew	SNN	\$73.75	\$13,191	-4.01%

## WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	\$5.68	\$600	-22.09%
2	TiGenix	TIG.BR	\$0.69	\$111	-21.48%
3	Baxano Surgical Inc	BAXS	\$1.05	\$50	-14.63%
4	Wright Medical	WMGI	\$28.49	\$1,420	-13.27%
5	Bacterin Intl Holdings	BONE	\$0.63	\$35	-12.50%
6	NuVasive	NUVA	\$32.88	\$1,530	-12.27%
7	Symmetry Medical	SMA	\$9.01	\$338	-12.18%
8	Globus Medical	GMED	\$22.97	\$2,146	-11.65%
9	Integra LifeSciences	IART	\$43.99	\$1,426	-8.94%
10	ConMed	CNMD	\$42.68	\$1,161	-6.20%

## LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Zimmer Holdings	ZMH	\$91.50	\$15,423	15.93
2	CryoLife	CRY	\$9.63	\$270	15.93
3	Medtronic	MDT	\$59.20	\$59,248	16.06
4	Johnson & Johnson	JNJ	\$96.87	\$273,980	17.64
5	Exactech	EXAC	\$22.63	\$309	18.84

## HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	\$32.88	\$1,530	87.63
2	Symmetry Medical	SMA	\$9.01	\$338	67.87
3	ArthroCare	ARTC	\$48.50	\$1,667	32.03
4	Integra LifeSciences	IART	\$43.99	\$1,426	27.73
5	Smith & Nephew	SNN	\$73.75	\$13,191	23.73

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

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Exactech	EXAC	\$22.63	\$309	1.05
2	Globus Medical	GMED	\$22.97	\$2,146	1.44
3	Zimmer Holdings	ZMH	\$91.50	\$15,423	1.74
4	ConMed	CNMD	\$42.68	\$1,161	1.80
5	Stryker	SYK	\$79.36	\$30,014	2.17

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

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	\$32.88	\$1,530	8.44
2	Symmetry Medical	SMA	\$9.01	\$338	5.66
3	CryoLife	CRY	\$9.63	\$270	3.98
4	Integra LifeSciences	IART	\$43.99	\$1,426	3.26
5	Johnson & Johnson	JNJ	\$96.87	\$273,980	2.96

## LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	\$1.44	\$140	0.68
2	Symmetry Medical	SMA	\$9.01	\$338	0.84
3	Bacterin Intl Holdings	BONE	\$0.63	\$35	1.04
4	RTI Biologics Inc	RTIX	\$3.80	\$215	1.08
5	Exactech	EXAC	\$22.63	\$309	1.30

## HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$0.69	\$111	19.41
2	MiMedx Group	MDXG	\$5.68	\$600	10.13
3	Globus Medical	GMED	\$22.97	\$2,146	4.94
4	Wright Medical	WMGI	\$28.49	\$1,420	4.64
5	ArthroCare	ARTC	\$48.50	\$1,667	4.41

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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# Study: Patients, Not Surgeons, Driving Demand for Surgery // President of the NFL Physicians Society Says ACL Injuries NOT on the Rise // ZERO Pain After Knee Replacement Thanks to “Godsend” Drug

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

**S**tudy: Patients Want MORE Surgery According to a new study, it's not the doctors that are pushing for surgeries. It's the patients! Chad Mather, M.D., an attending orthopedic surgeon at Duke University, and a former AAOS [American Academy of Orthopaedic Surgeons] Washington Health Policy Fellow, tells OTW, “We are working on an exciting new area of study in the field of personalized and customized medicine. This is an effort that grew out of my policy work in traditional economic analysis which commonly compares two interventions. I observed that in simulations of these models that while we could determine if strategy A or B was better for a population of patients, some patients had better outcomes with A and some with B. Therefore, the best strategy was not to pick between treatment A or B, but rather to get treatment A and B to the right patients. Our current work utilizes a common marketing research tool, conjoint analysis which involves a personalized assessment of risks and tradeoffs to measure patient preferences. Our pilot work focuses on the treatment decision for a first time anterior shoulder dislocation and over 50% of respondents chose surgery with cost sharing at \$1,000 cost share and 42% at \$2,000. A full 90% of patients chose surgery if they had only one more recurrence.”

“At the same time, epidemiological data suggests only 37% of patients ever have surgery after a first time anterior shoulder dislocation. These findings suggest that according to patient pref-



Andrew Huth and RRY Publications LLC

erences, we are actually *underutilizing* not overutilizing surgical treatment. We are still in the early stages of this project and more testing is required to confirm these early results. However, if these trends continue and occur in other orthopaedic conditions, this data could refute the influence of supplier induced demand causing over-utilization of orthopaedic surgery. Orthopaedic surgeons continue to argue that current utilization is appropriate, but we might be wrong after all—in fact, some orthopaedic surgeries might be actually be underutilized!”

**ACL Injuries NOT on the Rise** In contrast to what many think, ACL injuries in the NFL are *not* increasing, says Matthew Matava, M.D., President of the NFL Physicians Society. Dr. Matava, an orthopedic surgeon with the Washington University School of Medicine and Team Physician for the St. Louis Rams,

tells OTW, “While the general impression is that ACL injuries in the NFL are increasing, in fact they have remained consistent. In 2011 (preseason and regular season) we saw 55 such injuries; in 2012 it was 63, and in 2013 it was 57.”

“Players are being very up front, saying, ‘We can’t hit each other in the head, so we have to hit lower in order to make a tackle.’ So naturally, it would seem that we would see an increase in knee injuries. I think the ACL tears have remained relatively constant because the new concussion rules haven’t caused players to hit as low as perhaps they fear. However, any rule change has to be examined after being in affect several years in order to truly assess its effect on the game. Each and every player will tell a doctor, ‘I would rather be hit in the head than in the knees. I’ll take my chances with a concussion... that wouldn’t be career-ending.’ I tell

them, ‘I can reconstruct your knee, but I can’t reconstruct your brain.’”

“And you would think that we would see more injuries in Thursday night games as compared to Sunday and Monday night games, but that has not been the case. While I do not have any theories as to why injuries remained the same, it could be that the three days between games is enough to recuperate from the prior week’s injuries. It is important to note that even if the numbers increase that all of this data represent a snapshot in time and should be analyzed after several years of data collection in order to truly assess any negative effects on injury rates.”

“Unfortunately, football is a collision sport and will always be associated with the risk for injury. The NFL and NFL Physician Society have committed significant resources and effort to reduce this risk. In addition, the collection of injury data is done in a scientifically

rigorous fashion by an independent organization with significant experience and expertise in biomedical data collection.”

**ZERO Pain After Knee Replacement Thanks to “Godsend” Drug**

Want happy patients? Do something that frees them of their pain. John Barrington, M.D., an orthopedic surgeon at Texas Center for Joint Replacement in Plano, Texas, tells OTW, “Pain relief after joint replacement is strongly correlated with patient satisfaction. Unfortunately, in the past we haven’t done very well in this regard; about 20% of patients have chronic pain after knee replacement. And we know that short term, severe pain can lead to chronic pain. The goal is to create a painless experience, something that is hard to achieve because often what we use—local numbing or an epidural—doesn’t work long enough...then we are left with narcotics. More recently surgeons have used things like regional blocks

with femoral nerve catheters, but those can increase the risk of falls, which can lead to reoperation.”

So what is the answer? “Liposomal bupivacaine,” says Dr. Barrington. “It is a Godsend in that it provides 72 hours of pain relief. In our study, up to 65% of patients experienced zero pain while in the hospital. The average pain score for those treated with Liposomal Bupivacaine was 1.6 on a scale of 0 to 10 (measured on the Visual Analog Scale). There were also secondary positive effects such as a decrease in length of stay, an increase in patient satisfaction as measured by the Press Ganey satisfaction scores, and lower costs. We decreased the overall cost to the hospital by \$1,250 per patient. We increased the pharmacy cost by \$280, but we saved \$1,500 in other medications. Overall, this meant a \$1.24 million saved in this study (1,000 patients treated with liposomal bupivacaine versus 1,000 patients without this drug).

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I was pleasantly surprised as I thought that this would be cost neutral.”

“One of the most exciting things is that this opens up the world of joint replacement to same day procedures. I am pleased to say that I am often asked to speak on behalf of surgeons and hospital groups. Surgeons often come watch the procedure, and frequently ask me to facilitate conversations about this between their hospital administrators and ours.”

“This study gives hospitals a more thorough understanding of pain control. If we can have a win for the patient and a win for the doctors... *and* a win for the hospital, then why not use this medication?”

**OrthoWorx Forms University/Industry Advisory Board** OrthoWorx, Inc. has announced that it has formed a University/Industry Advisory Board to better connect the technology and talent needs of Indiana’s orthopedic medi-

cal device industry with the assets and capabilities represented by Indiana’s higher education institutions.

“We believe this is the right time and the right group of partners to address critical economic and educational challenges facing the State of Indiana,” said Sheryl Conley, President and CEO of OrthoWorx, in the March 20 news release. “Indiana is known for its great universities and, in fact, it produces more graduates than the state is currently able to employ. The orthopedic device industry has many needs that can be met by resources within our state, but a great number of its relationships with academia have evolved over time with out-of-state institutions—we intend to address that missed connection for the benefit of students, employers and the State’s economy overall.”

Colleges and universities that are currently committed to joining OrthoWorx as part of the University/Industry Advisory Board include: Indiana Uni-

versity; University of Notre Dame; Ivy Tech Community College; Manchester University; and Trine University. Discussions regarding membership are still underway with Ball State University, IPFW (Indiana University-Purdue University Fort Wayne) and Purdue University. Grace College, a founding member and frequent collaborator of OrthoWorx, also will be a member of this new Advisory Board.

Conley added, “Many companies would like a stronger recruiting presence at Indiana schools and many Indiana schools desire to create more experiential learning experiences for students, as well as to place more graduates in our industry. What has been lacking is an appreciation on both sides of the strengths and capabilities of each other. We think that should change and we are grateful to those universities who have committed their time and resources to joining us in this important collaboration.” ♦







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# Six Questions Top Surgeons Ask About Stem Cells

BY ROBIN YOUNG



American Academy of Orthopaedic Surgeons (AAOS)

**B**one morphogenic proteins (BMP) were not a failure, but they didn't live up to their promise. With that observation, Tom Einhorn, M.D., and George Muschler, M.D., opened up a very interesting seminar regarding the use of stem cells in orthopedics at the recently concluded American Academy of Orthopaedic Surgeons (AAOS) meeting in New Orleans. The lessons learned from BMP, in other words, can help guide physicians as they contemplate using stem cells in their practice.

In fact, these two top surgeons and scientists listed six basic questions which every practitioner should ask about so-called "stem cells."

But first, here is a little background about these top physicians and researchers—Tom Einhorn and George Muschler.

## Tom Einhorn, M.D.

Dr. Einhorn is Boston University's Chairman of the Department of Orthopaedic Surgery and Professor of Orthopaedic Surgery, Biochemistry and Biomedical Engineering. He's a graduate of both

Rutgers University and Cornell Medical College. He interned at the University of Pennsylvania Hospital, completed his residency at St. Luke's—Roosevelt Hospital in New York City and did a fellowship at the Hospital for Special Surgery (HSS).

His research has focused on repairing and regenerating bone and cartilage as well as reconstructive surgery of the hip and knee and treating metabolic bone disease.

Dr. Einhorn is the former Chairman of the Orthopaedics and Musculoskeletal Study Section of the National Institutes of Health, President of the Orthopaedic Research Society, President of the International Society for Fracture Repair and Chairman of both the Committee on Examinations and the Council on Research and Scientific Affairs of the American Academy of Orthopaedic Surgeons.

Among his many awards are the Marshall R. Urist Award and the Alfred R. Shands, Jr. Award from the Orthopaedic Research Society, the Kappa Delta

Award from the American Academy of Orthopaedic Surgeons, the Dr. Marian Ropes Physician Achievement Award from the Arthritis Foundation and the Marshall Schiff Award from the American College of Rheumatology. He is Deputy Editor for Current Concepts Reviews for *The Journal of Bone and Joint Surgery*, and serves on the Editorial Boards of *The Journal of Bone and Mineral Research*, *Journal of Orthopaedic Research* and *Bone*.

## George Muschler, M.D.

George F. Muschler was researching stem cells before it was fashionable and is one of a small handful of researchers who've defined therapeutic stem cells and their potential. When he is not serving as Vice Chairman of the Orthopaedic and Rheumatologic Institute in the Cleveland Clinic, Dr. Muschler sees patients requiring adult reconstructive surgery or treatment of fracture non-union among other musculoskeletal problems.

Dr. Muschler's lab in the Department of Biomedical Engineering at the Cleveland Clinic has consistently led the way in researching adult stem cell biology, tissue engineering, and regenerative medicine. He's Director of the Clinical Tissue Engineering Center (CTEC) and also serves as Co-Director of the Armed Forces Institute of Regenerative Medicine (AFIRM), a national network funded by the Department of Defense and dedicated to accelerating better therapies to serve wounded warriors.

Dr. Muschler is a member of the American Medical Association, American Orthopaedic Association, Association

of Bone and Joint Surgeons, Orthopedic Research Society, American Society for Bone and Mineral Research, International Society for Stem Cell Research, Tissue Engineering and Regenerative Medicine International Society, and International Society for Fracture Repair.

His undergraduate degree was in chemistry from the University of Illinois. His medical degree is from Northwestern University School of Medicine. His residency was at the University of Texas Southwestern Medical Center in Dallas, Texas. Like Dr. Einhorn, he completed a fellowship at the Hospital for Special Surgery. After HSS, Dr. Muschler went on to complete an additional fellowship at the Memorial Sloan Kettering Cancer Center.

### Six Stem Cell Questions (Commentary by RRY)

1. How do you know the viability of stem cells and their ability to express phenotypes?

Let's face it. If you're planning to put these cells into painful joint or disc, you're sending them directly into a hypoxic and harsh line of fire. Even worse, transporting your stem/progenitor cells from point A (like a donor or bioreactor in Kalamazoo) to point B (your patient in Bakersfield) can cut the herd pretty significantly.

This is a tough, but critical question. Direct injection is the clinically preferred method to transplant cells and, for sure, the clinical studies of the past decade have clearly shown that these stem and progenitor cells have immense potential to improve tissue and organ function for multiple debilitating diseases and injuries.

But moving from the hot house of a well-controlled study to the real world

of a busy clinic is not so easy. At a minimum, physicians need to find ways to improve the viability of cells after implantation. Many studies, including some from both Einhorn and Muschler's labs, have correlated symptomatic relief with higher cell viability after transplantation. Cell injection procedures can kill lots of cells. Some studies have reported that as few as 1%–32% of cells survive post-transplantation.

2. How can we use stem cells to prevent osteo-arthritis?

Top researchers are increasingly concluding that "stem cells" are not the main event but rather part a multi-dimensional therapeutic solution.

Osteoarthritis is caused by any number of triggers including mechanical and oxidative stresses, aging or apoptotic chondrocytes. Biologists who study these biologic processes point to articular chondrocytes within diseased cartilage as main actors. Specifically there are a couple of nasty little buggers in the knee called matrix metalloproteinases (MMPs) and aggrecanases which don't just degrade the cartilage, they also contribute to a toxic joint environment. Stem cells have been shown in animal and some human studies to inhibit inflammation and to help restore damaged cartilage. But the results, while promising, are also a little confusing. Bottom line: "Stem cells" may well be but one component of a more complex treatment program.

3. What do stem cells do when they get into an arthritic joint?

If only we had a super slow motion camera to film these cells in action. The best thinking today about what stem cells do comes from Mark F. Pittenger, Ph.D. – whose 1999 paper "Multilineage potential of adult human mesen-

chymal stem cells" is probably the most cited stem cell paper ever (as of April 8, 15,604 citations). In 2004, he wrote the following about stem cell activity for the journal *Blood* ("Human mesenchymal stem cells modulate allogeneic immune cell responses"):

In his study "hMSCs (human MSCs) altered the cytokine secretion profile of dendritic cells (DC), naive and effector T cells and natural killer cells to induce a more anti-inflammatory or tolerant phenotype. Specifically, the hMSCs caused mature DCs type 1 (DC1) to decrease tumor necrosis factor  $\alpha$  (TNF- $\alpha$ ) secretion and mature DC2 to increase interleukin-10 (IL-10) secretion; hMSCs caused T<sub>H</sub>1 cells to decrease interferon  $\gamma$  (IFN- $\gamma$ ) and caused the T<sub>H</sub>2 cells to increase secretion of IL-4; hMSCs caused an increase in the proportion of regulatory T cells (T<sub>Regs</sub>) present; and hMSCs decreased secretion of IFN- $\gamma$  from the NK cells."

Simply put, Dr. Pittenger is saying that MSCs reduce inflammation and lay the foundation for tissue regeneration and repair.

4. What is the right nomenclature?

What is color? Same problem with the words "stem cell." You and I can tell what is "blue." Scientifically, however, the color blue is a set of wavelengths in the electromechanical spectrum somewhere between 430 and 790 THz. There are more colors within that range than one person can count in an afternoon. Same for "stem cells." So-called "stem cells" are actually progenitor cells which exist on a very wide spectrum of potentiality. The total number of cell types which could be progenitors or express growth factors or in some manner act like the cells described in Dr. Pittenger's paper probably number in the hundreds of thousands.

Calling these cells “stem cells” is like saying every color is blue.

The nomenclature or the names we use to describe these cells does not really describe their true capabilities or functions.

5. What are the standard ways to test that the cells will do what we want?

First of all, “stem cells” are loaded with a wide range of expectations from patients, sales people and physicians. What patients want is to get back to normal. What physicians want is something safe and effective and affordable. Step one is figure out the base line expectations for these progenitor cells.

Is it fair to expect either off the shelf, cultured MSCs or autologous progenitor cells to stop and reverse osteoarthritis? No. Is it fair to expect them to behave along the lines described in Dr. Pittenger’s paper? Yes, as adjusted for each patient’s biology and the broader eco-system of their joint. Safety first. Then pain relief. In stages, led by the data, built to a standard way to test how one or more of these progenitor cells perform. No question, there are lots of moving parts in this puzzle.

6. What clinical infrastructure do we need to do proper clinical studies?

Well, first there is the issue of money. Then we could try to clone a few of the

key researchers like Muschler, Einhorn and Pittenger and sprinkle them around the country in about 100 clinics. But, perhaps most important (or second after money), is a data infrastructure which would support a comprehensive, complete, longitudinal registry and would have the support of most patients, clinicians, health systems, and payers in the research process.

What clinical infrastructure do we need? We need money. Researchers like Muschler, Einhorn and Pittenger. And a massive comprehensive longitudinal data registry.

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# Nine Rules for Surviving CMS's New Data Dump

BY WALTER EISNER

The Centers for Medicare and Medicaid Services (CMS) just released the mother lode of data on individual payments and bills submitted and collected by physicians participating in the Medicare program.

CMS said this unprecedented release of the information is to help consumers make better choices. Not everyone agrees.

## The Data Set

The data, which is called the Carrier Standard Analytical File, was released to the public as a result of various requests under the Freedom of Information Act (FOIA). These requests, in effect, were seeking to overturn a 33-year-old court injunction which prevented CMS from giving public access to the data.

That original injunction came from a lawsuit filed by the American Medical Association (AMA) and the Florida Medical Association in 1981 to prevent then President Jimmy Carter's administration from publishing these data files.

A year ago (May 2013) a federal judge lifted that 33-year ban.

This week the data set was released. All billion plus data points.

The data set included the names and work addresses of about 880,000 physicians and other health care providers. It also provides how much each physician received of the \$80 billion paid out under Medicare Part B Fee-for-Service Program for 6,000 different types of services (per the National Provider

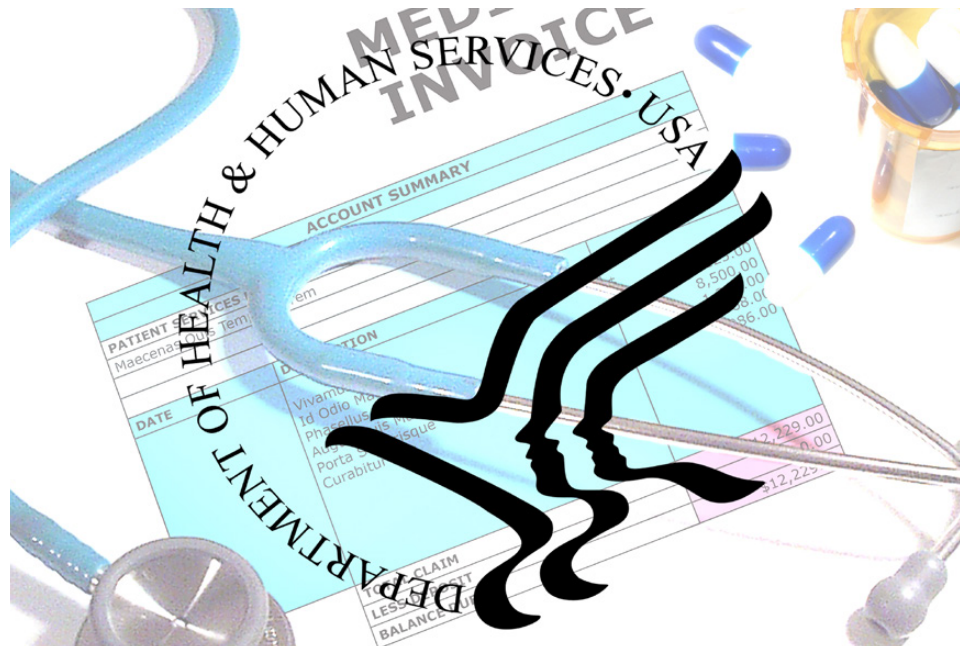


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Identifier (NPI), Healthcare Common Procedure Coding System (HCPCS) code system).

But wait, there's still more.

In addition to names, addresses and dollar amounts, the data set also gives the number of services, average submitted charges and standard deviation in submitted charges, average allowed amount and standard deviation in allowed amount, average Medicare payment and standard deviation in Medicare payment, and a count of unique beneficiaries treated.

## Use or Misuse?

CMS has been using this data for years to compare hospitals. Last May, for example, the agency released hospital charge data allowing consumers to compare charges for common inpatient

and outpatient services by hospital and location.

But now the public can mine and manipulate the data. National Public Radio said that CMS was relying on a form of "crowd sourcing" to uncover potential fraud, waste or abuse. The way in which the data is organized, virtually anyone will be able to compare physicians (who accept Medicare patients), specialties, locations, types of medical services and procedures delivered, Medicare payment amounts, and submitted charges.

Principal CMS Deputy Administrator Jonathan Blum, said that the information would allow for a more informed debate about appropriate Medicare payments for particular services. He cited the example of *The Wall Street Journal* which had used similar payment information to identify and report on a num-



Jonathan Blum  
Principal CMS Deputy  
Administrator/CMS

ber of instances of Medicare fraud, waste, and abuse, using Medicare payment data.

Blum also said the information will allow a more informed debate about the appropriate Medicare payment for particular services.

Notably, the AMA and thousands of individual physicians are concerned that the plaintiff's bar, payers, reporters, hospital administrators or others could use the information to reduce pay or change work rules or generally bash physicians.

The AMA provided a list of nine items of caution that physicians or other

### AMA's Nine-Step Program for Physicians and Other Providers

healthcare providers can use when discussing the data with either patients or reporters:

1. Errors — Data being released may contain errors because there is currently no mechanism for physicians and other providers to review and correct their information.

2. Quality — The data does not include explicit information on quality of care provided or quality measurement. It solely focuses on payment and utilization of services so it cannot be used to evaluate the value of care provided.

3. Number of Services — Residents, physician assistants, nurse practitioners and others under a physician's supervision can all file claims under that physician's NPI; the data may not properly detail the services performed and who performed them. Additionally, there

are several instances in which it can appear that two surgical procedures were done when in fact there was only one. For example, when there are co-surgeons or an assistant at surgery, the procedure should be counted as only one surgery, not two.

4. Charges vs. Payment — Medicare and other payers pay fixed prices for services based on fee schedules; therefore the amount paid to physicians is generally far less than what was charged and is not an accurate portrayal of payment.

5. Patient Population — The data is an incomplete representation of the services physicians provide, as it is not risk adjusted. Additionally, it does not include care for private insurance patients or Medicaid beneficiaries, making it a limited view of the patients a physician cares for.

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6. Site of Service — Payment amounts vary based on where the service was provided. Medicare pays physicians less for services provided in a hospital outpatient department than for services in the physician's office. However, for services in the outpatient department, another payment is made to the facility to cover its practice costs so that, in reality, the total costs to Medicare and to the patient may be higher when a service is provided in a facility setting.
7. Provider Comparisons — There is a lack of specificity in specialty descriptions and practice types in the data, which could be misleading when making comparisons between physicians. In some cases, physicians who appear to have the same specialty can serve very different types of patients, thus impacting the mix of services provided.
8. Missing Information — The data does not account for patient mix and demographics or drug and supply costs.
9. Coding and Billing Changes — Any analysis using the data should take into account changes in Medicare's coding and billing rules that may be different over time and across regions of the country (e.g., local coverage determinations).

### Wrestling With the Data Yourself

The data is, of course, available to anyone. Charles Ornstein, a senior reporter with *ProPublica* and Pulitzer Prize-winning writer, offered six suggestions to anyone who seeks to mine and learn from these massive data files.

1. Have a strategy for storing and opening the data. — This data set is big. About 10 million rows.

Because of that, you won't be able to analyze it in Microsoft Excel and you might not be able to open it in Microsoft Access. You'll want to upload it onto a data server and analyze it in a more powerful program such as SQL or SPSS.

2. Know what the data covers—and what it doesn't. — This data covers services and treatments provided by doctors and other health professionals who treated the 33 million beneficiaries in Medicare Part B in 2012. It doesn't include expenses incurred by the 13.6 million people in Medicare Advantage plans (managed-care plans) in 2012 nor does it include any private insurance costs/payments. Moreover, this data doesn't cover payments for inpatient hospitalizations, skilled rehabilitation, durable medical equipment or prescription drugs.
3. There are many reasons why a doctor may receive large payments from Medicare. — For one, the doctor may treat exclusively Medicare patients. In such cases, the doctor's payments would naturally look larger compared to peers who also see a lot of privately insured patients (this is called a provider's payer mix). Another explanation is that the doctor may provide services that are reimbursed at higher rates than typical office visits. A

third explanation is that the provider may have other professionals billing under his/her Medicare number, which is allowed in some circumstances. Of course, there may be other reasons that raise questions of fraud, but don't just assume that because a number is large, a doctor has done something wrong.

4. Quantity and quality are not the same. — Doctors who perform a lot of surgeries generally have better outcomes than those who perform fewer procedures. But because of the payer mix problem mentioned in the last paragraph, you won't necessarily know from the Medicare data alone how many procedures a doctor performs across his practice. As health care data expert Fred Trotter notes, a surgeon who has "low volume" in this data might be actually be doing the procedure a lot, but just for commercial payers primarily.
5. Not everyone can be compared head to head. — It doesn't make sense to compare the billings/services provided by a neurologist to those of a primary care doctor.
6. Medicare coding and billing is complex. — Take the time to familiarize yourself with...billing codes, some of which seem almost identical. Medicare also has a series of adjustments to the data that take into account where the service is being performed (hospital vs. office), geographic differences in costs between regions, etc.



Charles Ornstein  
 Lars Klove and ProPublica

To view the physician dataset, visit:  
<http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html> ♦

# Blaha, Haddad: Four Rounds Over Femoral Neck Modularity

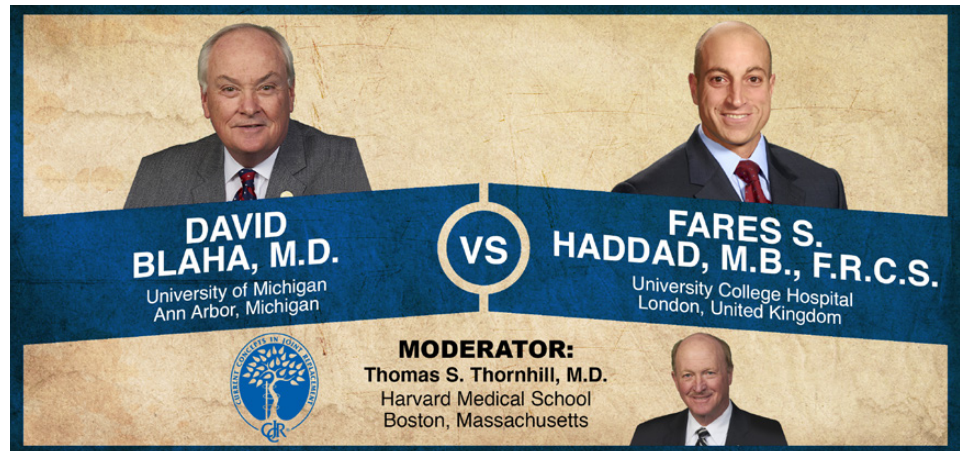
BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

“**T**his is an unnecessary evil. It’s not required for function and may be associated with implant failure,” says David Blaha. Fares Haddad notes, “There are still indications for modularity, but we need to get the design right and simplify the technique. And it has to be generalizable.”

This week’s Orthopaedic Crossfire® debate is “Femoral Neck Modularity: An Unnecessary Evil.” For the proposition is J. David Blaha, M.D. from the University of Michigan; against the proposition is Fares S. Haddad, M.B., F.R.C.S. from University College Hospital in London, United Kingdom. Moderating is Thomas S. Thornhill, M.D. from Harvard Medical School in Boston.

**Dr. Blaha:** “At previous meetings I’ve been quoted as saying, ‘The modular neck is the keystone to the functional restoration of the hip...period.’ I never really said that. (Picture of President Obama appears onscreen.) What I said was, ‘The modular neck is the keystone to the functional restoration of the hip—if it doesn’t turn out to have a problem with fracture and corrosion...period.’”

“All taper junctions corrode. The question becomes, ‘Is the advantage provided by the modular neck worth the corrosion?’ The advantages of the modular neck are that you can uncouple the placement of the stem and final position of the head. Also, you can fine tune the ‘sweet spot’ where all of the muscles have the most normal lever arms. They also allow implantation of a total hip



Current Concepts in Joint Replacement/RRY Photo Creation

stem through a smaller, less invasive approach, but that’s not something that I’ve found to be an advantage.”

“The disadvantage of the modular neck is corrosion. Titanium alloy, cobalt chromium and all biocompatible metals corrode when exposed to the oxygen in room air. This chemical reaction ‘passivates’ the material and renders it resistant to further corrosion. If the passivation layer remains intact nothing else happens.”

“The modular neck, however, is in a mechanically disadvantageous position, with the loads at the head potentially moving the male portion of the taper and knocking off the passivation layer. If this continues, corrosion releasing titanium, hydrogen gas and chloride will result in hydrogen gas collecting below the implant; and the entire effects of this mechanically accelerated crevice corrosion is that it can ruin the entire fixation of the modular neck. You can change the material, the shape, and the roughness, etc. to change the

modular neck. Ions from metal-metal articulations can make it worse. Still, corrosion is inevitable.”

“We’ve had several cases where we had gas in the joint without fracture; when we aspirated the gas it turned out to be hydrogen gas. To remove a fractured modular neck you must drill through it. When you do that you find some combustion of the hydrogen gas. And if you use a slap hammer to remove a well fixed neck the combustion can be impressive in the OR.”

“Stryker has recalled their modular neck because of corrosion. We put in 390; 275 were in primary cases. In order to get a unified series we looked at just those with the PROFEMUR-Z and with the large diameter metal-metal head. This is the same metal-metal that we used for the surface replacement; 21.5% of our cases required revision. With the exception of limb length discrepancy, everything else such as modular neck fracture and gas in the joint can be an effect of corrosion.”

“If we compare our large femoral head stem replacements to our surface replacements, the latter only had a 7% failure rate. Amstutz had a low failure rate (94.4% survival at four years), as did McMinn (99%, 97%, 96% survival at 5, 10, 13 years, respectively). The addition of the modular neck seems to increase the failure rate.”

“Mike Berend and Adolph Lombardi did 810 stem replacements with a fixed neck and a 38mm metal-metal articulation; they had a failure rate of 7.8%. And because of the corrosion they abandoned this.”

“We want to know, ‘Could the corrosion products from the modular neck be increasing the problems associated with large diameter metal-metal?’ Is the modular neck necessary? The majority of my necks were varus; a few were varus retroverted, which I could have done by rotating the stem slightly in the canal.”

**Mr. Haddad:** “First of all, I know very little about flip-flopping. Also, we never allow explosions in our operating theater. In order to give patients functional hips, we have to tailor implants to their bone stock and anatomy. Here, modularity has advantages in terms of addressing version, length, and offset. If we fail to balance the hip, we get impingement, loss of soft tissue tension, and instability. We also get increased wear, and we get those patients who limp or are unhappy with their prosthesis.”

“The early solution that we used for these problems was customized stems...but having one bullet when you go to battle seems suboptimal. Modularity gives us more intraoperative options, allows us to hit the sweet spot by uncoupling the head from the stem, and allows us to correct deformity. Also, we have better

stability, less impingement, more inventory, and if you have to do a revision it is easier.”

“My particular argument is that in revision surgery this is something you really want because modern revisions have aimed much higher by allowing us constructs that adjust for leg length and stability. The problem here has occurred due to some uncontrolled introductions of suboptimal implants in the primary setting. We’ve seen failures in the Australian registry, but bear in mind that a lot of these failures are due to loosening and instability...not necessarily due to corrosion. Nevertheless, they are failures. But if you drill down and look at the implants, you see that the ones recalled account for a big proportion of the failures. There are some long term studies with modular necks that show good results for instability and survivorship.”

“We need to look at how we innovate, but also be careful not to get rid of things just because we don’t understand them. We have to take a step back and understand the taper. The taper relies on frictional interlock, and that is dependent on a number of factors. These include taper size, taper length/engagement, the material, surface finish, neck length and offset.”

“In our quest for thinner femoral necks, greater offsets, and bigger femoral heads, we have created an environment that can generate fretting corrosion at modular junctions and leads to premature implant failure. If we take a step back and see that tapers are complex systems, we can begin to see how we can use them now and in the future. We have the data...the science is there, and we know what the important factors are. The way you clean the area before impacting the taper, how you position

it, the impaction force, and the environment are under your control.”

“There is a risk-benefit equation here. We’ve been looking at this in the lab, specifically examining the electrochemical nature of this. The biggest key is the bending moment. The greater the bending moment the higher the risk of corrosion. The more the torque, the higher the risk of corrosion. That’s where metal-metal large heads possibly come in. The higher the offset, the bigger the head size, the greater the torque, the greater the current, the greater the corrosion. We can establish patterns for that...depending on the scale you get and on the materials that you use.”

“If you use ceramic or a different surface you will see that the scale is much less. There is potential for alternative surfaces to allow us to continue to use these tapers. Jacob Cartner and colleagues did a retrieval study comparing cobalt chrome and oxidized zirconium. Their conclusion was that offset was important, but also that head material was important. In 2013 we’re beginning to understand why corrosion happens at the taper. It’s partly due to large femoral heads, high offsets...partly surface area and surface finish...and to a great extent it’s surgical technique.”

“I think we have to be careful in how we innovate, but we should also take care not to overreact. We’ve created a problem; we have to understand it and not lose its advantages when we move forward with the next generation of hip implants.”

**Moderator Thornhill:** “Why can’t we model these things better so that this doesn’t occur?”

**Dr. Blaha:** “I don’t know. The data from the Rizzoli Institute convinced

me that the production of wear debris was going to be minimal, as was the corrosion. The difference here is that when I assembled the modular necks with a slight varus and slight retroverted neck, when I impacted that firmly and according to instructions I probably didn't get the neck exactly down the pocket. And that left room for corrosion. So we didn't model the way we put it in the OR; instead we modeled perfect implantation of the modular neck."

**Mr. Haddad:** "We have a great operation, but we're in danger of ruining it by not evaluating and innovating carefully."

**Moderator Thornhill:** "Should we have something that controls impaction force?"

**Mr. Haddad:** "You must make sure you're completely clean at the taper junction and that you're hitting it hard in the right direction. If you're going to do sequential taps the last one has to be the hardest."

**Dr. Blaha:** "It's important that the impaction be directly along the length of the taper."

**Moderator Thornhill:** "David, can you—by serum levels of cobalt and chromium and the differential between the two—have some determination of whether this is coming from the articulation or from one of the modular junctions?"

**Dr. Blaha:** "I don't know any way to do that. What I'm using is cobalt and chromium to look at articulation...and the cobalt chromium ball on the titanium neck. But I'm looking at titanium levels as a surrogate for corrosion at the pocket junction."

**Moderator Thornhill:** "Does it matter whether it's a titanium stem with a cobalt chrome neck or a cobalt chrome stem with a cobalt chrome neck?"

**Dr. Blaha:** "Yes, but I don't know how it matters."

**Mr. Haddad:** "There is a difference between what you see with a mechanical effect load edge bearing at a surface like metal-metal where you get both cobalt and chrome elevated. When you're looking at this sort of phenomenon at a taper, the chromium precipitates so you get a differentially high cobalt and a low chromium. And you should not be reassured by the low chromium. We don't have any data to be able to look at that differential and say, 'This is good. This is bad.'"

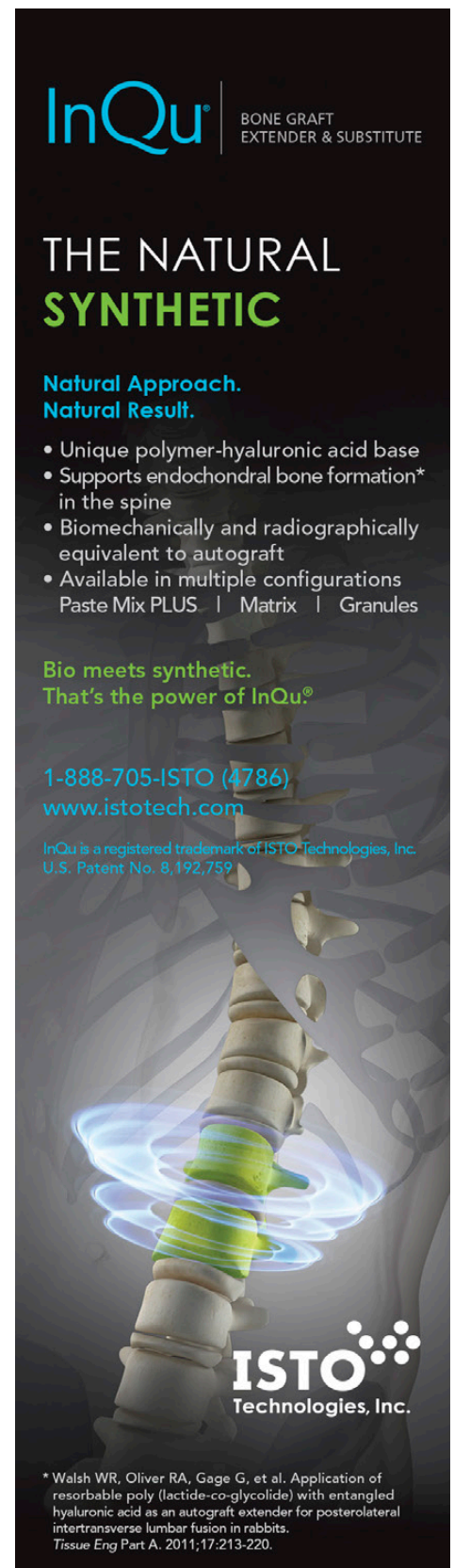
**Moderator Thornhill:** "David, at the head-neck junction are we better off using ceramic?"

**Dr. Blaha:** "There's no question that at that junction ceramic has a lower amount of corrosion. There's no way to test that with a modular neck. If we found some way to use ceramic there it might be better...but we have to test that in the lab and in limited clinical situations...and see if it fails in the long term."

**Mr. Haddad:** "That's what the electrochemical tests will tell you. If you put a ceramic head—same torque, same bending force—you will get less of a current."

**Moderator Thornhill:** "Thank you gentlemen." ♦

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\* Walsh WR, Oliver RA, Gage G, et al. Application of resorbable poly (lactide-co-glycolide) with entangled hyaluronic acid as an autograft extender for posterolateral intertransverse lumbar fusion in rabbits. Tissue Eng Part A. 2011;17:213-220.

Advertisement

**ERRATA**

**Errata: “Alphatec’s \$49 Million French Adventure”**

On April 8, 2013 in an article titled, “Alphatec’s \$49 Million French Adventure,” we reported, “A jury found Alphatec Holdings, Inc., and its owners, HealthpointCapital, LLC, guilty of transferring assets for less than fair market value and millions would have to be paid to OrthoTec, LLC, the injured party.”

We erred. None of those parties were found guilty.

Ebun S. Garner, Esq., General Counsel and SVP Alphatec Spine, Inc., wrote to tell us that the trial was between OrthoTec and Surgiview SAS, a subsidiary of Scient’X SAS. “None of Alphatec, Healthpoint, John Foster or Tim Berkowitz were defendants in this trial. Thus, the jury did not make any findings with respect to Alphatec, Healthpoint or Messrs. Foster or Berkowitz.”

He also objected to the use of the word “guilty” in the article in that the term is used in criminal proceedings, not civil proceedings.

He points out that Surgiview has limited assets all located in France. “It is unlikely that a judgment against it could ever be collected upon.” Mr. Garner also points out that following the trial, there was to be a second trial “in which it would be determined whether Alphatec could be held responsible for the judgment against Surgiview under a theory of piercing the corporate veil. Thus, nobody was sprinting to the appeals court. A judgment had not even been entered against Surgiview yet, let alone the beginning of the Alphatec trial.”

Mr. Garner tells us that the plaintiff contacted Alphatec to settle following the verdict, “because of the uncertainty in the OrthoTec, Surgiview, Scient’X, Alphatec and Healthpoint made a collective decision to settle the case.”

While Alphatec agreed to pay the plaintiff \$49 million, Mr. Garner says that Messrs. Forster and Berkowitz have not

agreed to pay anything to OrthoTec in the settlement. He said they are two of nine directors of Alphatec. “They are not managing partners of Alphatec.”

Mr. Garner also pointed out mistakes about the timing and nature of the relationships between the companies involved in the story. For instance, EuroSurgical sold its interests in Surgiview to a Swiss company called Indev in 2004 and Indev sold its interests to Scient’X in 2005. Alphatec acquired Scient’X in 2010, not 2006, as we erroneously reported. Therefore, OrthoTec did not sue Alphatec until 2011.

In previous court documents, it was alleged that Olivier Carli, one of the founders of Scient’X, was the sole director of Surgiview. “Surgiview is an SCS, which under French law means that it does not have a board of directors. You mention that Olivier Carli is the sole director. That is not possible,” wrote Mr. Garner.

Finally in response to our report that OrthoTec’s attorneys stated that the case will now move to New York, Mr. Garner says “the settlement included the matter in New York against Healthpoint and Messrs. Forster and Berkowitz.”

We appreciate Mr. Garner’s corrections and clarifications and apologize for our errors.

—WE (April 11, 2014)



Photo Creation by RRY Publcaitions / Napoleon Bonaparte and Wikimedia Commons

COMPANY

## MicroPort Orthopedics Adds Star Power

MicroPort Orthopedics, Inc. (MPO), recently established through MicroPort Scientific's acquisition of Wright Medical's OrthoRecon business, has added more star power to its management team. The new leader at the helm of the MPO management team is Ted Davis, CEO, who has led the OrthoRecon business for Wright Medical Technology, Inc. since 2012. Davis is leveraging the company's 60 years of successes and its ability to attract seasoned additions, while retaining current leaders, in order to transform MPO into a global growth company.

Prior to assuming leadership of the OrthoRecon business, Davis led Wright's Corporate Development and Research & Development functions, with responsibilities for the Business Development, Government Affairs, National Accounts, Reimbursement, Medical Education and Global Research & Development teams from 2010 through 2012.

Jason G. Jones, M.S., CCRP, Vice President of Clinical Affairs, brings over 20 years of experience in the clinical research industry. He specializes in innovative clinical development planning and clinical operations with

advanced knowledge of FDA approval criteria. Jason has worked in the clinical departments of Zimmer Holdings, Inc., C.R. Bard, Inc., Mediscis Pharmaceutical Corporation, Smith & Nephew, Inc. He is adept at leveraging quality clinical evidence to drive product adoption through published peer-reviewed articles that not only report safety and efficacy but also include health economic deliverables which demonstrate hospital efficiency and/or cost effectiveness.

Ben Hutson, the new Vice President of Manufacturing has 25 years of medical device experience in operations, manufacturing and sterilization. Prior to joining MicroPort, Ben served as Executive Vice President of American Operations for 28 facilities for Sterigenics International, Inc.. As Group Director, Trauma Global Operations with Smith & Nephew, Ben was responsible for manufacturing and supply chain operations, supporting \$600M in sales with operations in the U.S., Germany, Switzerland, Italy and Malaysia.

Kamaal Anas, Vice President of Regulatory Affairs, has over 18 years of experience in Regulatory Affairs (RA), Quality Assurance (QA) and Product Development for Drugs, Biologics and Medical Devices. Prior to joining MPO, Kamaal was Senior Director of Regulatory Affairs and Quality Assurance for the International AIDS Vaccine Initiative (IAVI). Prior to joining IAVI, Kamaal was the Senior Director of Reg-

ulatory Affairs and Quality Assurance for Meridian Life Science, Inc. In this capacity, he helped Meridian expand facilities, increase product offerings, improve quality systems, and collaborated with business development to increase business. Before joining Meridian, Kamaal held positions of increasing responsibility, culminating in Vice President of Technical Operations for Equi-Tox, Inc., a pharmaceutical company. Kamaal has also provided ad hoc Regulatory Affairs and Quality Assurance consulting services to the drug, biologic and medical device industries.

Don Hilliard, Sr. Director of Global Customer Experience has over 20 years of customer service experience, with 13 of those years being in the medical devices industry. Don has held various positions of increasing responsibility in customer service departments at General Electric Appliances and Smith & Nephew Orthopedics, most recently as the Director of Global Order Management. He has built world class service departments through benchmarking and hiring talented employees.

"Developing a world class clinical program, ensuring our customers have the best experience every time they call our customer service team, and managing the challenging global regulatory landscape are vital elements to our future success," said CEO Davis.

—EH (April 8, 2014)



Left to right: Ted Davis, Kamaal Anas, Ben Hutson, Jason Jones and Don Hilliard/Photos courtesy of MicoPort Orthopedics

LEGAL

## Cayenne Medical Claims MedShape Violates Fixation Patent

Attaching tendons to bones is one of the most common needs in orthopedic surgery. Companies fight hard to protect their proprietary methods for accomplishing such fixation.

Cayenne Medical, Inc. claims MedShape, Inc. has violated one of their soft tissue reconstruction patents.

### Infringement Alleged

The company filed suit in federal court in Arizona, alleging that MedShape's ExoShape Femoral Soft Tissue Fastener infringed and continues to infringe Cayenne patents (United States Patent Nos. 7,651,528 and 8,435,294) that broadly cover Cayenne Medical's novel AperFix System and methods for attaching soft material to bone, such as in an anterior cruciate ligament (ACL) reconstruction procedure.

Cayenne's '294 patent was filed in 2009 by Ken Montgomery, Sidney Fleishman, James Whayne, Kevin Ohashi, Nicanor Domingo, John Wright, Derek Harper and Heber Crockett.

### Cayenne Medical's Invention

The invention relates generally to devices, systems and methods for material fixation. More specifically, the invention relates to a technique that can be used to firmly hold a soft tissue or graft against bone tissue within a bone tunnel.

According to the abstract submitted to the patent office, the invention is

an "exemplary surgical implant" with a modified bone anchor that is able to grasp the tendon and hold it firmly in a bone tunnel. "Once deployed, the anchor delivers lateral compression to the tendon, providing direct tendon to bone compression to facilitate healing. The anchor has different versions which allow it to be attached to the tendon prior to insertion into the bone tunnel, or be inserted between tendon arms when the surgical procedure dictates. The resulting tendon to bone compression allows for the firm fixation in a manner markedly simpler than traditional techniques. A modification of this anchor can also allow the anchor to grasp and hold suture. This variation facilitates the technique for knotless rotator cuff repair."

### Pros and Cons of Conventional Methods

The patent holders, in their application, noted that there are many conventional techniques used for the fixation of tendon to bone, each having some advantages. "The disadvantages of each such technique present a need in the art for a simple and universal technique to fixate tendon to bone such that the device is easy to use, the process is simple to follow, and the result is a firm and secure tendon to bone fixation with minimal negative effect on the tendon. Further, such device should be easy to manufacture, universally applied to different tendon to bone sites, and require

minimal effort to understand and use in practice."

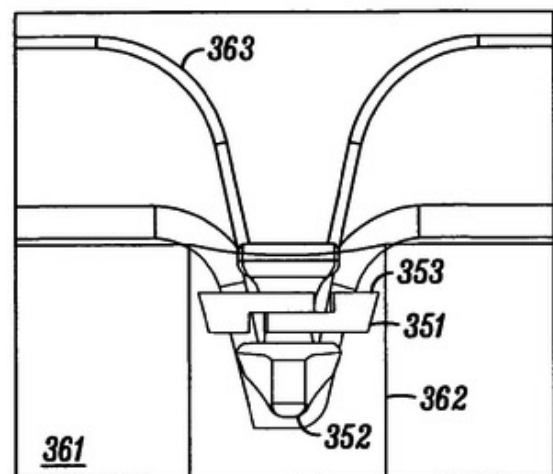
### "Elegant Simplicity"

They said their invention uses a device that is "easy to manufacture and use. In particular embodiments, the present invention is a modified anchor. The elegant simplicity of this invention eases the complexity of tenodesis procedures and its basic but effective design and use will make it readily adopted by the orthopedic community."

David Springer, Cayenne Medical's president and CEO said the company will use, "all reasonable measures to ensure that violators, such as MedShape, stop the infringement of our patented inventions."

The company, privately held and headquartered in Scottsdale, Arizona, develops innovative soft tissue ligament and tendon repair and reconstruction products for the knee and shoulder.

—WE (April 7, 2014)



US 8,435,294 B2  
**DEVICES, SYSTEMS AND METHODS FOR MATERIAL FIXATION**  
 Assigned to Cayenne Medical, Inc.

'294 Patent/US Patent Office

LARGE JOINTS

## Weight Loss Makes a Difference

If you failed to lose some weight before your joint replacement surgery, do not give up. Losing weight following the surgery has clear benefits.

According to a study by Geoffrey Westrich, M.D., research director of the adult reconstruction and joint replacement service at New York's Hospital for Special Surgery (HSS), patients who lost weight after knee surgery suffered less pain, enjoyed better function and exhibited higher activity levels than those who maintained the same weight or gained. Weight gain also led to poorer outcomes for hip replacement patients.

The paper, titled, "Weight Change after Hip and Knee Arthroplasty: Incidence,

Predictors and Effects on Clinical Outcomes," was presented at the annual meeting of the American Academy of Orthopaedic Surgeons in New Orleans on March 14.

Previous studies provided conflicting evidence regarding whether patients lose or gain weight after lower extremity joint replacement, according to Dr. Westrich. And prior to his study, there was little research examining whether weight change after joint replacement was associated with a difference in clinical outcomes. HSS researchers aimed to answer these questions, and also see if there are factors that predispose patients to gain or lose weight after surgery.

Dr. Westrich and his colleagues reviewed 3,036 knee and 3,893 hip replacement surgeries and found the following:

- Seventy-four percent of total knee replacement patients and 84 percent of total hip replacement

patients did not demonstrate a change in BMI following surgery.

- Patients who underwent knee replacement surgery were more likely to lose weight after surgery than those who had hip replacement surgery.
- Patients who were obese before their joint replacement surgery were MORE likely to lose weight than those patients who were either normal weight or overweight, but not obese.
- Overweight or obese females who had joint replacement surgery were more likely to lose weight than their male or normal weight counterparts.
- Patients with higher pre-operative activity scores were more likely to maintain their weight than to gain or lose weight.

Researchers considered a number of other factors to see if they were associated with a change in weight. These factors included patient scores on pre-operative surveys to assess pain, stiffness, and physical function; whether the patient was discharged to home or a rehabilitation facility; whether or not the patient smoked; and co-existing health problems such as diabetes, hypertension and depression. None of these factors was determined to predispose patients to experiencing weight gain or loss after joint replacement.

Dr. Westrich and his colleagues reviewed the body mass index of nearly 7,000 patients in the two years after their surgeries and found that most remained at the same weight levels. "We should convey to our patients the importance of maintaining good health and an appropriate weight, and we should help them in any way we can," said Westrich.

—BY (April 10, 2014)



Wikimedia Commons and Petr Kratochvil

## Finger Length a Predictor of OA?

Is there significance to the length of the index finger? Yuanyuan Wang, M.D., from Monash University's Department of Epidemiology and Preventive Medicine, decided to find out. He put together a study to determine whether the ratio of the lengths of the index and ring fingers was associated with the risk of knee or hip osteoarthritis (OA) severe enough to require joint replacement.

"We assessed the ratio of the lengths of the index finger and ring fingers of middle-aged and older people participating in the long established Melbourne Collaborative Cohort Study using photocopies that were taken of their hands," Wang said. "This was compared to the incidence of total knee and hip replacements between 2001 and 2011. We achieved this by linking the cohort records to the Australian Orthopaedic Association National Joint Replacement Registry."

In the 11 years following the initial finger measurements, doctors reported a total of 580 knee replacements and 499 hip replacements. "This indicates that lower index to ring finger ratio is associated with a higher incidence of total knee replacement," Wang said. "The results were consistent when the ratio was examined both on the right and left hand, with the risk being stronger for the right hand."

Wang's findings supported the belief that hormonal factors play a role in the origin and development OA, and may possibly account for gender differences in the prevalence of OA. "Although our study's results may in part be explained by joint injuries associated with high-level physical activity in those with a lower 2D:4D and the greater susceptibility of knee OA in response to injury than hip OA, they may also reflect hormonal influences on the growth of the bone, cartilage and soft tissue," Wang said.

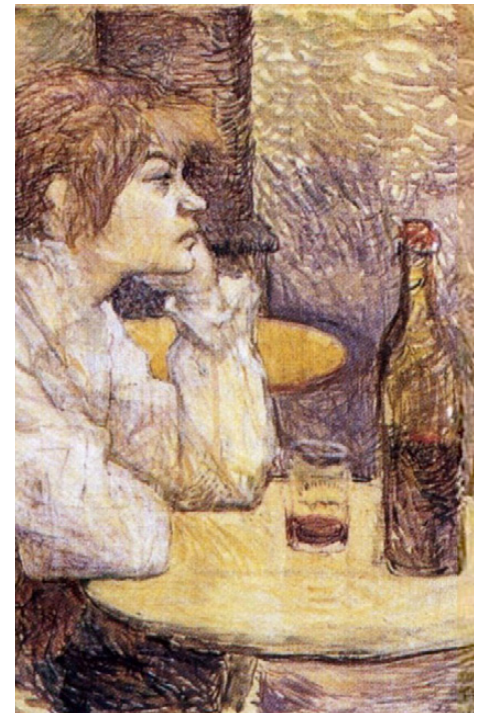
—BY (April 9, 2014)



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## Adult Offspring of Those With Addictions are Prone to Arthritis

Researchers from the University of Toronto have released a new study indicating that the adult offspring of parents who were addicted to drugs or alcohol are more likely to have arthritis.



*The Hangover, Portrait of Suzanne Valadon by Henri de Toulouse-Lautrec/Image source: Wikimedia Commons and Toulouse-Lautrec*

Investigators examined a group of 13,036 adults and found that 20.4% of respondents had been diagnosed with arthritis by a medical professional. Investigators found that 14.5% of all respondents reported having at least one parent whose drug or alcohol use caused problems while they were under the age of 18 and still living at home.

After adjusting for age, sex, and race, parental addictions were associated with 58% higher odds of arthritis, says

lead author Esme Fuller-Thomson, Ph.D., Professor and Sandra Rotman Endowed Chair in the University of Toronto's Factor-Inwentash Faculty of Social Work and the Department of Family and Community Medicine.

“We had anticipated that the adult offspring's health behaviors such as smoking, obesity and alcohol consumption might explain the strong link between parental addictions and arthritis, however we did not find this to be the case. Even after adjusting for these adult health behaviors, as well as income, education, a history of childhood maltreatment and mood and anxiety disorders, we found that parental addictions was still a statistically significant factor associated with 30% higher odds of arthritis,” explained study co-author and recent

MSW graduate, Jessica Liddycoat, in the March 26, 2014 news release.

Future prospective studies are needed because the survey nature of the data makes it impossible to determine whether the relationship between parental addictions and arthritis is causal.

“However, there is ample evidence from other studies to support the provision of efficacious interventions to treat addictions,” says co-author Maria Stefanyk. “Although we do not know if these interventions will impact the development of arthritis in adulthood, we do know that children do much better on a wide range of outcomes when parents are no longer abusing drugs and alcohol.”

—EH (April 8, 2014)

## Lizard Tails Prompt Cartilage Study

Lizards are not cuddly creatures but they can do something humans cannot—grow cartilage. If a lizard loses its tail it can regrow another one. The new tail will not have any bones in it, but the regrown cartilage will be strong enough the support the new tail.



Wikimedia Commons and Thomas Brown

The lizard's ability to regenerate cartilage has grabbed the attention of researchers because scientists, so far, have been unable to successfully replicate this lizard cartilage-growing ability in humans.

Two of those researchers are Thomas Lozito, Ph.D. and Rocky Tuan, Ph.D. of the Center for Cellular and Molecular Engineering at the University of Pittsburgh. As reported by the Orthopaedic Research Society, Lozito explained, “We study lizard cartilage to understand how it is able to be maintained in such a robust state. We have identified several key molecules known to play roles in normal skeletal development that are turned on in unusual and interesting patterns during lizard tail cartilage growth. These molecules are respon-

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sible for the unique tissue properties of regenerated lizard cartilage.”

Lozito noted that scientists’ attempts to engineer cartilage tissue in the lab, “often results in cartilage that eventually calcifies and is replaced by bone,” he said. This, of course, is of little help for those who suffer from degenerative joint diseases, such as osteoarthritis.

The researchers plan to examine the properties of the regenerated lizard tail that make it conducive for cartilage growth. Lozito said, “We have evidence that lizard cells themselves are particularly primed for differentiating into cartilage and that lizard cartilage itself contains a population of stem cells that readily forms new cartilage in response to trauma. This is practically the opposite of what occurs following damage to human cartilage.”

Lozito said the group’s goal is to “identify the signals and cellular properties underlying the regenerative power of lizard tail cartilage which will afford new insights into actual cartilage regeneration and potentially yield lizard-inspired therapeutics and treatments for human cartilage diseases.”

—BY (April 4, 2014)

## Artificial Knee Climber Attempts Everest

Greg Paul, a 59-year-old Utah mountain climber with two artificial knees, will attempt to reach the summit of Mount Everest in May. If he succeeds he will be the first known climber to attempt to summit Everest with two artificial knees.

Paul told a writer for *Digital Journal*, “If I can get to the top of Everest with my

Ortho knees, anybody ought to be able to climb stairs or play a round of golf with them. I want to be a role model for all those baby boomers who think or feel they are too old to pursue their passions and dreams. Where there is a will there is a way!”

Paul left for Nepal on March 25 where he will meet his climbing team and its experienced leader Sherpa Phurba Taski. (Taski has climbed more 8,000 meter peaks than anyone else in the world.) The party will climb the south (Nepal) side of the mountain on the route first pioneered by Sir Edmund Hillary. The expedition is expected to take 71 days, and the climbers hope to summit during a window between May 12 and May 29 when winds at the top recede.

The manufacturer of his knee replacements, Ortho Development Corporation, of Draper, Utah, is sponsoring his

2014 Everest summit attempt. Brent Bartholomew, president of the company, said, “Ortho Development is passionate about developing products that alleviate pain and improve the quality of life for patients suffering from limitations brought on by arthritis. Greg Paul is an inspirational embodiment of our company’s vision. We are proud to have designed and manufactured the knee replacement implants, right here in our Utah facility that will help a fellow Utahnian reach the top of the world.”

“My knees feel really good, and I’m feeling ready to go,” said Paul. “It has been an intense 16 months of training. Other than the period between Thanksgiving and Christmas 2012, I have done something related to training six days per week. The closer to departure dates the more focused and determined I become.”

—BY (April 9, 2014)



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EXTREMITIES

## Research Ends Shoe Sole Debate

Still trying to decide if hard or soft soles on their shoes protect runners from injury? If so, give up because a new study published in the *British Journal of Sports Medicine* has found that the hardness of the sole makes no difference.

According to Stephen Kasica, writing for *Outside*, researchers at the Sports Medicine Research Laboratory in Luxembourg hypothesized that runners training on a hard midsole had a higher risk of running-related injuries than did runners running in soft shoes. To test their assumption they monitored 247 runners wearing 12mm-drop trainers from “a renowned sports equipment

manufacturer.” Some subjects wore cushioned shoes, and others wore a midsole that was 15% stiffer in the heel.

When they examined the runners five months later, the researchers found that the runners who wore the cushioned shoes had just as many injuries as did the group wearing the harder shoes. They also found that soft shoes did not protect the heavier runners from injury.

“Midsole hardness of modern cushioned running shoes did not influence running-related injury risk,” researchers wrote. More relevant to the prediction of injury was the runner’s body mass index, his or her history of injury, rate of exertion, history of regular running and involvement in other sports on a regular basis.

—BY (April 4, 2014)



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## Smoking Slows Bone Healing

Here is additional incentive—if more is needed—to quit smoking. A British study has found that bone-healing cells in nonsmokers were of better quality, were more active and divided more quickly than did those in smokers. Researchers learned this by analyzing the bone-healing stem cells taken from blood samples from the area of the fractures in 50 smokers and nonsmokers with broken legs.



Wikimedia Commons and Bibliothèque nationale de France

“After growing and harvesting the stem cells from the tissue, we were able to closely analyze and monitor how cigarette smoking had a detrimental impact on stem cell growth and development, giving rise to abnormal bone repair,” said Andrew Sloan, a researcher at the University of Lincoln, UK, in a university news release. “We also showed how the molecules that [affect] certain cellular processes were being hampered by the toxic effects of the tobacco smoke and its constituent components.”

The researchers have presented their findings at a number of medical conferences in Europe. The next step, according to the press release, will involve finding out if the harmful effects of smoking can be reversed.

—BY (April 4, 2014)

REIMBURSEMENT

## McKesson Jumps on Bundled Care Bandwagon

The McKesson Corporation, a healthcare services and information technology company currently ranked 14th on the Fortune 500, has joined the Employers Centers of Excellence Network (ECEN) to provide its employees increased access to affordable high quality hip and knee replacement care.

As earlier reported by OTW, the Pacific Business Group on Health developed ECEN. Other members of the organization are Wal-Mart Stores, Inc. and Lowe's Companies, Inc. A 2013 study that found the cost of a hip or knee replacement varied up to 10 fold across the country with no direct correlation to care quality spurred the development of ECEN. To deal with this variable cost situation ECEN negotiated a fixed bundled payment rate for all procedure-related costs at five carefully selected hospitals located throughout the country.

The result is that employees benefit from access to high quality care at reduced or no cost to them as McKesson and other participating employers will not only cover the majority of the cost, but also support travel costs for patients and a caregiver.

"We are proud to offer our employees the opportunity to be treated by top surgeons at distinguished medical centers that are committed to the highest quality standards and have demonstrated excellence in joint replacement surgery," said Gerri Burrue, vice president of benefits, McKesson Corporation. "In addition to cost benefits, the ECEN



Courtesy of McKesson Corporation

program provides support for patients at every step, and we expect that our employees will be enthusiastic about the guided ECEN experience."

ECEN centers to date are, Johns Hopkins Bayview Medical Center, Baltimore, Maryland; Kaiser Permanente,

Irvine Medical Center, Irvine, California; Mercy Hospital, Springfield, Missouri; Virginia Mason Medical Center, Seattle, Washington. According to the press release, expansion to additional centers is underway.

—BY (April 10, 2014)

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SPINE

**Benvenue Medical:  
 Full Launch of Kiva  
 VCF**

Benvenue Medical, Inc. has announced the full commercial launch of the Kiva VCF Treatment System for the reduction and treatment of spine fractures. Recently released results from KAST (Kiva System as a Vertebral Augmentation Treatment—a Safety and Effectiveness Trial) demonstrated the Kiva System met or exceeded the performance of the Medtronic, Inc. balloon kyphoplasty (BKP) system. The Kiva System is an implant-based solution for vertebral augmentation and a next-generation alternative to BKP, making it the first clinically proven new approach to the treatment of VCFs in over a decade.

The Kiva System features a proprietary, cylindrical implant made from a medical polymer that is designed to provide a very predictable structural support for the vertebral body and a reservoir to contain and direct the flow of bone cement. This new implant approach allows the treating doctor to deliver a much more consistent result. BKP inserts a bolus of bone cement directly into a vertebral cavity without an implant to hold it, making the control of the bone cement less predictable. The company continues to expand its direct sales distribution, network of physicians using Kiva and hospital contracting agreements in response to initial demand.

Benvenue CEO Robert Weigle told OTW, “Our booth at the Society for Interventional Radiology conference was surrounded by companies that have balloon kyphoplasty products. Literally there were six companies right

around our booth all offering balloons, with no discernible difference between any of them. Then along comes Benvenue with our new implant technology and with clinical data showing distinct clinical benefits and outcomes. You can imagine the response. We had physicians coming to the booth saying our implant really makes sense and when can they learn this technique.”

Asked where he hopes to be in one year with this product, Weigle commented, “As we are in the full swing of launching Kiva commercially this month, it’s difficult to think about a year from now. What I can share is that the reception among physicians we’ve been talking to has been very positive and there is substantial interest in Kiva as a new, implant-based approach to vertebral augmentation.”

—EH (April 8, 2014)



Benvenue Medical, Inc.

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410-356-2455 • 410-608-1697



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**Robin R. Young, CFA**

*Editor and Publisher*  
[robin@ryortho.com](mailto:robin@ryortho.com)

**WRITERS**

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

*Senior Writer*  
[elizabeth@ryortho.com](mailto:elizabeth@ryortho.com)

**Walter Eisner**

*Senior Writer*  
[walter@ryortho.com](mailto:walter@ryortho.com)

**Biloiné W. Young**

*Senior Writer*  
[bgwy@msn.com](mailto:bgwy@msn.com)

**ADVERTISING**

**Tom Bishow**

*Vice President of Sales*  
[tom@ryortho.com](mailto:tom@ryortho.com)

**PRODUCTION**

**Suzanne Kirchner**

*Production Manager*  
[suzanne@ryortho.com](mailto:suzanne@ryortho.com)

**Jayne Johnson**

*Email, Web, & Conference Coordinator*  
[jayne@ryortho.com](mailto:jayne@ryortho.com)

**Dana Bader**

*Graphic Designer*  
[dana@ryortho.com](mailto:dana@ryortho.com)

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116 Ivywood Lane • Wayne, PA 19087  
TOLL FREE: 1-888-749-2153  
[www.ryortho.com](http://www.ryortho.com)

