VOLUME 6, ISSUE 23 | JULY 20, 2010

Orthopedics This Week

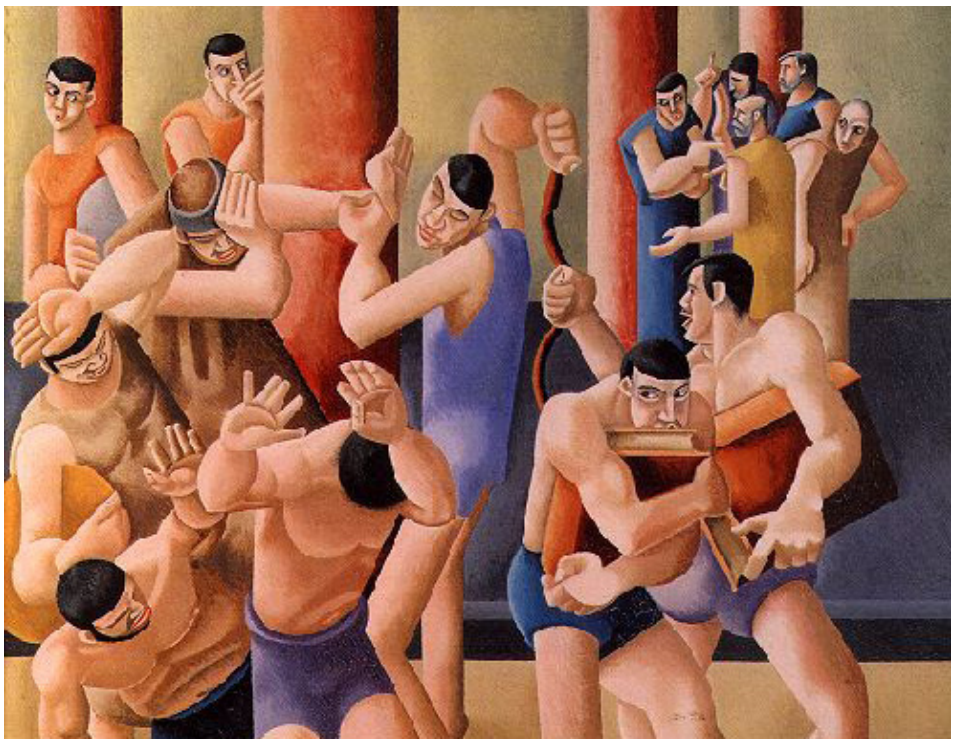
week in review

4 **Chicago Whistleblower Fracas** ◆ Robert Goldberg, M.D., wanted his day in court. He got it and lost. Now he's amending a whistleblower suit to make his case in a new court—the court of public opinion. He's accusing former colleagues of cheating Medicare. The government hasn't joined in. His former colleagues say he has a vendetta. It's an Ortho Rumble, Chicago style.

9 **#1 Private Equity Firm Bets on Spine** ◆ Welsh, Carson, Anderson & Stowe (WCAS) -- the largest and most successful private equity firm focused on information/business services and healthcare – just laid a big bet on spine and selected the Virginia based upstart K2M as its platform company. Smart money.

13 **Revitalizing Regeneration Research** ◆ Last week *OTW* took you inside the Armed Forces' ambitious Institute of Regenerative Medicine (AFIRM) project. Now one of its leaders, the dynamic Dr. Joachim Kohn, talks about the high-tech New Jersey Biomaterials Center, current projects and how the research teams are playing nice together.

17 **The Role of Physician Assistants in Orthopedics** ◆ The future is here…and it is physician assistants. Roderick Hooker, Ph.D., PA, along with Charles Cornell, M.D., delineate the roles and skills of PAs and how the field is changing.



picture of success

30 **Dr. Robert B. Anderson** ◆ Whether helping someone walk for the first time in years, or participating in an NFL Foot and Ankle Subcommittee meeting, Dr. Robert Anderson, an orthopedist with OrthoCarolina, leads the pack.

breaking news

For all news that is Ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Orthopedic stocks joined the bear market last week. Analyst forecasts for 2011 turned decidedly negative. That, in turn, pushed orthopedic valuations down across the board. Investors appear to be looking past the current quarter's sales and earnings performance.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	13.51%	(4.99%)	The new EPS range for 2011 is $0.88 and $2.90. Almost guarantees that OFIX will outperform.
2	2	Kensey Nash	38.72	(1.64)	Two new agreements—Arthrex and St. Jude—belie consensus that sales will be down 2.50% this year.
3	3	Johnson & Johnson	27.1	0.34	One of the only stocks that appreciated over the past 30 days. A 3.60% forward dividend yield helps tremendously.
4	5	Symmetry	11.48	(6.38)	Consensus is that sales will be down almost 6% this quarter, but up 8% next year.
5	NR	Medtronic	32.48	(4.14)	Medtronic has replaced JNJ as the lowest P/E or future P/E among ortho stocks. Now MDT needs to up the dividend to JNJ levels.
6	8	Stryker	24.71	(1.67)	Over the last 30 days, 3 analysts have raised the estimates for SYK. Up two spots this week.
7	9	Zimmer	27.69	1.36	ZMH is one of the few orthopedic companies expected to increase its growth rates in 2011. UP two positions this week.
8	7	Smith & Nephew	22.83	(6.49)	The American analyst corps may be missing SNN, but the Europeans are all over it. Future P/E is 4th best among all ortho companies.
9	4	Exactech	12.72	(10.02)	Drops this week as sentiment shifts to large caps. Consensus is 10% revenue growth this year but essentially flat EPS
10	10	Integra LifeSciences	15.37	(8.21)	Sales and earnings call set for next week (July 29). Consensus is 6% sales growth—for basically every quarter this year.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Synthes	SYST.VX	$120.19	$14,264	9.0%
2	Capstone Therapeutics	CAPS	$0.73	$30	4.3%
3	Zimmer Holdings	ZMH	$55.91	$11,340	1.4%
4	Johnson & Johnson	JNJ	$59.44	$163,940	0.3%
5	*Average*			*$11,061*	*-0.6%*
6	Kensey Nash	KNSY	$22.14	$215	-1.6%
7	Stryker	SYK	$51.20	$20,310	-1.7%
8	Medtronic	MDT	$37.27	$40,360	-4.1%
9	Orthofix	OFIX	$30.25	$533	-5.0%
10	TiGenix	TIG.BR	$2.23	$69	-5.7%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Orthovita	VITA	$1.87	$144	-22.4%
2	Mako Surgical	MAKO	$11.60	$392	-17.0%
3	TranS1	TSON	$2.41	$50	-16.9%
4	CONMED	CNMD	$17.03	$497	-15.3%
5	ArthroCare	ARTC	$26.54	$715	-14.3%
6	CryoLife	CRY	$5.31	$152	-14.2%
7	RTI Biologics Inc	RTIX	$2.80	$153	-13.6%
8	NuVasive	NUVA	$35.57	$1,390	-12.8%
9	Exactech	EXAC	$16.08	$207	-10.0%
10	Alphatec Holdings	ATEC	$4.55	$397	-9.9%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Medtronic	MDT	$37.27	$40,360	11.25
2	Kensey Nash	KNSY	$22.14	$215	12.02
3	Johnson & Johnson	JNJ	$59.44	$163,940	12.74
4	*Average*			*$11,061*	*12.85*
5	Exactech	EXAC	$16.08	$207	13.06

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$46.08	$8,190	65.07
2	RTI Biologics Inc	RTIX	$2.80	$153	46.56
3	NuVasive	NUVA	$35.57	$1,390	32.16
4	Symmetry Medical	SMA	$10.12	$364	20.19
5	Synthes	SYST.VX	$120.19	$14,264	17.31

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CryoLife	CRY	$5.31	$152	0.65
2	Orthofix	OFIX	$30.25	$533	0.66
3	Alphatec Holdings	ATEC	$4.55	$397	0.87
4	NuVasive	NUVA	$35.57	$1,390	0.93
5	Exactech	EXAC	$16.08	$207	0.93

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CONMED	CNMD	$17.03	$497	6.55
2	Symmetry Medical	SMA	$10.12	$364	2.09
3	Johnson & Johnson	JNJ	$59.44	163,940	1.87
4	*Average*			*$11,061*	*1.65*
5	RTI Biologics Inc	RTIX	$2.80	$153	1.50

Lowest Price to Sales Ratio (TTM)

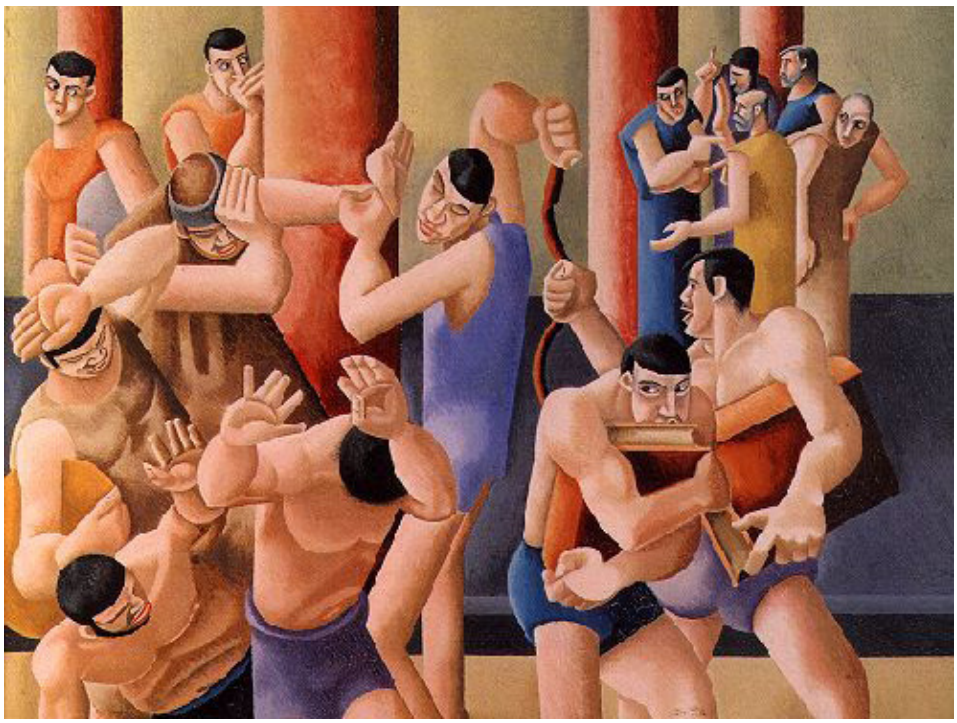
	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$2.99	$54	0.58
2	CONMED	CNMD	$17.03	$497	0.72
3	RTI Biologics Inc	RTIX	$2.80	$153	0.96
4	Orthofix	OFIX	$30.25	$533	1.00
5	Symmetry Medical	SMA	$10.12	$364	1.10

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$2.23	$69	66.77
2	Mako Surgical	MAKO	$11.60	$392	10.54
3	Synthes	SYST.VX	$120.19	$14,264	4.20
4	NuVasive	NUVA	$35.57	$1,390	3.58
5	Stryker	SYK	$51.20	$20,310	3.01

Chicago Whistleblower Fracas

By Walter Eisner



Morguefile

Two court dramas involving orthopedic surgeons are playing out in Chicago this summer. One is taking place in a court of law. The other, in the court of public opinion.

In the finest tradition of brawling Chicago-style politics, an orthopedic surgeon named Robert Goldberg—and June Beecham, a former director of real estate at Rush—filed an original whistleblower (qui tam) lawsuit in 2004 against Goldberg's former colleagues at Midwest Orthopaedics and Rush University Medical Center. Goldberg originally alleged improper patient referrals. It was not the first legal fight between Goldberg and his colleagues.

Last month, Goldberg's original 2004 whistleblower lawsuit was unsealed. In an amended suit, Goldberg now accuses six of his colleagues and Rush of cheating Medicare by billing for surgeries where the attending surgeon was not present for critical elements of the surgery.

In June, some of Goldberg's accusations, related to the use of office space in return for patient referrals, were settled by the Justice Department, with the medical center agreeing to pay more than $1.5 million but not admitting to wrongdoing.

But now, in the amended suit, Goldberg launches another haymaker and says that the defendants scheduled multiple surgeries in various operating rooms to pump up procedure volumes to curry favor with Zimmer Holdings. The defendants say their surgery scheduling is common and complies with Medicare reimbursement rules.

They also insist this is just another chapter in a long line of fights with Goldberg.

In the Name of the King

What does Medicare, through the Justice Department say about this alleged cheating?

Qui tam is a Latin phrase meaning, "in the name of the King." Goldberg is alleging that the King was cheated. However, the King's men, through the Justice Department, have not only been silent about the new allegations of cheating and settled the previous charges, but have declined to join Goldberg in the amended suit. Their silence is deafening.

When the well-informed victim of the alleged cheating doesn't agree that he's been cheated, the hurdles for the accuser become exponentially higher.

In fact, the hurdles are so high, that the statistics of settled whistleblower lawsuits demonstrate that the prospect of a successful suit without government participation is staggeringly low.

Whistleblower

The 6% Case

Between 1986 and 2008, according to the Justice Department, there were about 4,600 qui tam cases settled or dismissed. When the government participated, the success rate for the whistleblower was about 95%. When the government stayed silent, the success rate was a measly 6%.

Goldberg's allegations of improper Medicare payments will be settled in a court of law as the arcane rules governing Medicare payments in teaching hospitals get dissected and adjudicated. His past rocky relationship with his colleagues is largely irrelevant to the question of proper or improper Medicare billings.

Court of Public Opinion

However, Goldberg's relationship with his colleagues is important in the court of public opinion as other teaching hospitals and surgeons around the country read about this case and have to wonder if they are in a similar situation.

Charles Bush-Joseph, M.D., the managing partner at Midwest told *OTW* in an interview on July 14 that when the news of Goldberg's amended suit was reported in the *Chicago Tribune* and *Wall Street Journal*, other administrators, gathering for an annual meeting, wanted to know what the "bleep" was going on. The suit is being watched carefully by large teaching hospitals all over the country because many have surgical schedules similar to those at Rush.

Our conversations with other medical facilities showed that Rush's surgery schedules were a common practice.

Bush-Joseph told us that all a physician has is his reputation. He said Goldberg has a vendetta against his former colleagues and they will defend themselves vigorously.

Goldberg/Midwest: A Rocky Marriage

Goldberg has had a litigious relationship with his colleagues. Midwest Orthopaedics is one of the largest orthopedics practices in the country. Rush is a highly respected and regarded teaching hospital. In fact, Goldberg earned his medical degree at Rush Medical College and has been a member of the Rush medical staff since 1995.

Goldberg has had a series of claims, allegations, grievances, and lawsuits against the medical center and his colleagues going back over a decade.

An Illinois Supreme Court decision over a previous Goldberg suit against his partners noted that Goldberg had repeatedly voiced complaints about his assignments and treatment at Rush. He complained that he had not been assigned an equitable share of calls in the emergency room, did not have access to orthopedic residents and, among other things, had not been given the opportunity to perform teaching duties.

In 2003, Goldberg initiated a formal grievance raising these issues. A five-member grievance committee, with two members selected by Goldberg heard the complaints. Several of Goldberg's complaints were dismissed because they were not alleged to have affected his practice.

Round One: Midwest/Rush

Goldberg was unsatisfied and sued Midwest and Rush in 2004 for, "tortious interference with contractual relations, tortious interference with prospective economic advantage, and breach of contract." That case went all the way to the Illinois Supreme Court. The court ruled against Goldberg.

Rush Hospital - Chicago, Illionois

In February 2005, the defendants filed a motion to dismiss the suit. In April 2005, the court agreed and dismissed the case. Subsequently, on March 10, 2006, the Circuit Court denied Goldberg's appeal.

On April 7, 2006, Goldberg appealed that decision in the Appellate Court of Illinois. That court affirmed the Circuit Court's order of dismissal. On March 27, 2007, Goldberg appealed to the Illinois Supreme Court. By the end of May, the court had denied his appeal.

Psychology of Whistleblowing

What motivates a whistleblower? In the now famous case of Mark Whitacre, former president of the BioProducts Division of Archer Daniel's Midland (ADM) in the mid-90s, the whistleblower himself proved to be an extraordinarily complex psychological study. In that case, the whistleblower was so profoundly conflicted that he served eight years in federal prison. The entire story was the subject of the Steven Soderbergh movie *The Informant* starring Matt Damon.

In a study titled *Science and Engineering Ethics*, author Joan E. Sieber, Professor Emerita of Psychology at California State University, writes that there are seven "psychological processes involved" in whistle blowing:

1. Fundamental attribution error – the whistleblower assumes that someone is engaged in a willful act of fraud or harm
2. False consensus – when the whistleblower assumes that others agree with their interpretation of events
3. Self-serving bias – the whistleblower takes credit for praise-worthy actions, but rejects responsibility for blame-worthy ones
4. Self-presentational concerns – the whistleblower tries to "recoup lost ground by making claims that favor him even if the evidence turns out to be shaky or nonexistent"
5. Motivation – a complex mix of need for love, revenge, material advantage, prestige and so on.
6. Control – need for a sense of control
7. Belief – the "irrational" belief in a just world

And when those conditions exist in sufficient force, a whistleblower is created.

Goldberg Tries Again

After Goldberg's 2004 whistleblower suit was settled with the feds last March, Goldberg amended the now unsealed suit and charged six of his colleagues at Midwest and Rush with the Medicare billing cheating allegations.

The surgeons named in the suit include Richard A. Berger, who helped develop products for Zimmer and once ranked among its highest-paid consultants, along with Brian J. Cole, Aaron G. Rosenberg, Craig J. Della Valle, Wayne G. Paprosky and Mitchell B. Sheinkop.

The allegations were a bombshell in the press. Stories highlighting surgeons not present at critical moments of surgery, monitoring residents by video hookups caught the public's attention. Even web sites such as InsideSurgery.com, run by a physician, erroneously reported that Goldberg's "inside information" had been used by the feds to file fraud charges against the surgeons. The feds of course declined to join Goldberg.

The *Wall Street Journal* reported, "According to the suit, financial ties with device maker Zimmer Holdings Inc., spurred bad behavior."

The surgeons "knew that in order to maintain their celebrity status with Zimmer, they would have to continue to be among Zimmer's biggest customers, and they accomplished this goal by scheduling and billing Medicare for hundreds, if not thousands, of joint replacements surgeries annually that did not comport with the Medicare Rules and Regulations," the complaint alleges.

The complaint continues, "To obtain the incredibly high volume of orthopedic surgeries…doctors would schedule as many as five or six orthopedic surgeries in a morning in two (and occasionally three) different operating rooms."

Surgery Schedules

Specific allegations in the complaint center on Medicare rules that requires the teaching physician to "be present during all critical portions of the procedure and immediately available to furnish services during the entire service."

On April 22, 2004, for instance, the complaint alleges, "Sheinkop never entered operating room 9 to perform a knee replacement on a 67-year-old patient. He performed another procedure in operating room 7."

According to the complaint, one of the residents who performed the surgery, "admitted that Sheinkop had never been present for any of a particular patient's surgery, but stated that he had been instructed by Sheinkop to falsify the medical record."

In another allegation, the complaint states, "On Oct. 21, 2004, Cole had five surgeries scheduled; two at 7:30 a.m., another at 8 a.m., another at 8:30 a.m. and another at 9:30 a.m. The 8 a.m. operation was in Rush's operating room 5, while the others were in the outpatient SurgiCenter."

When Cole had concurrent surgeries, the complaint states he would, "remain physically present in one operating room, while 'monitoring' a second operating room through an electronic video link that projected images through the fiber optic arthroscopy camera onto a large monitor."

Midwest Slugs Back

Jeffrey Rogers, Midwest's attorney, said the video system was used "to determine room readiness, such as when it was clean for another patient and sometimes also for teaching purposes." Rogers said it wasn't used to remotely manage surgeries.

"It's a big mistake" to rely on a schedule to determine when "critical portions" of a surgery took place, said Rogers.

Rogers also said, "We note that the government has declined intervention in these allegations (regarding patient safety), and we also want to point out that we had no participation in the settlement (involving office space) whatsoever."

Midwest: Where's the Proof?

"I don't know what their proof is or where they get this. It's too early to tell; we've only had this complaint a week. But we would deny that there were any overlapping surgeries that violated applicable rules and regulations, or threatened the health or safety of any patient," added Rogers.

With a 94% chance of success, it appears likely that Rush/Midwest will prevail in court. But now the case is also being played out in the court of public opinion and here Goldberg has an advantage. In many ways, and as we have seen repeatedly, in the court of public opinion the rules of evidence and fair play don't exist. All-in-all, there is no winner here and perhaps most unfortunately, the sterling reputation of one of this country's great teaching hospitals is on the line. ◆

Orthopedics This Week

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#1 Private Equity Firm Bets on Spine

By Robin Young

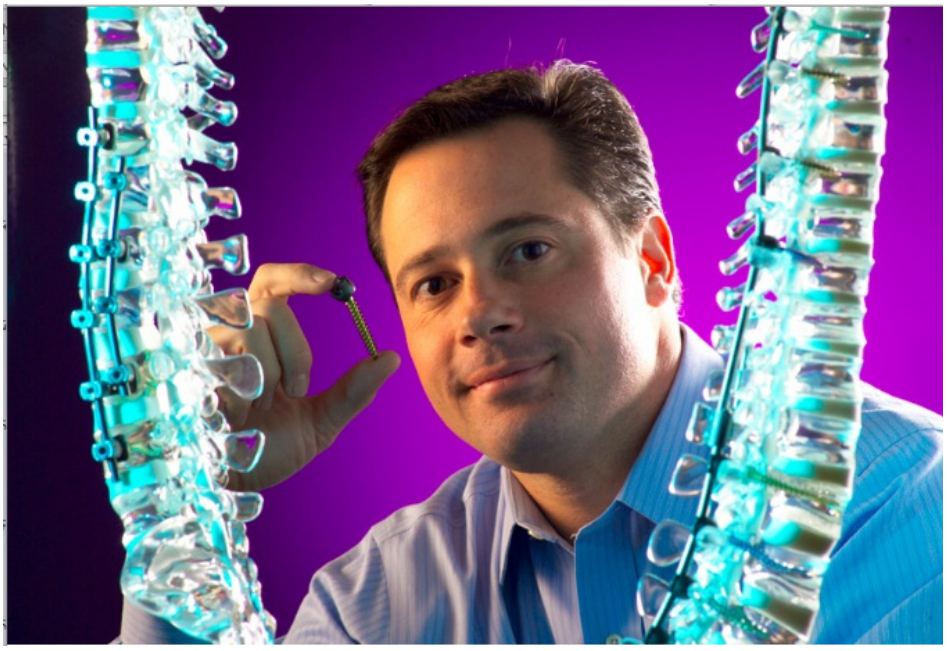
Thirty-six years ago the United States was fighting its way through a particularly severe recession. Unemployment was spiking, the stock market was tanking. In the midst of the doom and gloom Warren Buffet told a reporter "I feel like an oversexed guy in a whorehouse. Now is the time to invest and get rich." and he started buying.

Kind of reminds us of the spinal implant industry today. Hospitals are demanding lower prices, Medicare (CMS) is cranky, the FDA is flailing around, several small spine technology firms have left the pitch and one of the most important new technology initiatives—motion preservation implants—was mugged in the alley.

Then, like Buffett in 1974, the $20 billion private equity firm of Welsh, Carson, Anderson & Stowe (WCAS)—the largest and most successful private equity firm focused on information/business services and healthcare—lays a big bet on one of the fastest growing young spine technology companies in the industry—K2M, Inc.

Welsh Carson logo

Who are these guys at WCAS? What do they see, that orthopedic-specific private equity firms and the boards at the Big Five are missing?



Eric Major, CEO, K2M

So we did a little investigating.

WCAS is about 31 years old. Their modus operandi is to pick one company in an industry sector, put a bet down, keep management intact and tell them to build, build, build. With the fat checkbook managements are offered an opportunity to build out product lines and distribution whether through organic growth or via acquisition. But, and this may be the key, WCAS bets on strong jockeys to ride a thoroughbred company to the finish line.

Case in point: AGA Medical. This Minnesota-based cardiovascular implant company was generating about $100 million in revenues and growing fairly rapidly (although, not as fast as K2M) when WCAS made their investment in 2005. In the intervening five years, AGA invested in distribution and product line expansion. Last year AGA went public. Today it has a market value of $650 million and an enterprise value of $825 million. Its sales have more than doubled to $220 million (consensus estimate by analysts this year). While WCAS didn't disclose its 2005 purchase price, we can reasonably estimate that WCAS' investment in AGA has appreciated roughly 400%.

WCAS' investment in K2M is expected to close later this month. Investors who are NOT selling include K2M's management, employees and its other major investor, Ferrer Freeman, who has two seats on K2M's board. One of Ferrer Freeman's principals is former Wright Medical CEO Tom Patton. Patton has built a remarkable track record since pulling Wright Medical out of its

downward spiral some ten years ago. In addition to selling Wright to another private equity firm, Warburg Pincus, he went on to run and sell three other companies.

But why K2M? "When Welsh Carson looked at us, they saw a company with the potential to be a platform investment in spine." recalls K2M CEO and Co-Founder, Eric Major. "They saw in us, I think, a mature management team, the kind of processes and structure that can scale to the next level and beyond that a strong regulatory and compliance organization."

We also suspect that WCAS saw a management team that tackled tough projects—like products for complex surgery and then successfully navigated the pathway to market, wining design awards in the process. One surgeon who has used K2M's products wrote this on an anonymous blog this past February:

> "The system is incredible. I am a deformity surgeon and I "gave it a go" to see what all the talk was about. I thought I would use it once and that it would be a joke. How wrong was I. It is incredibly powerful and fast. I can do monster reductions very quickly, far easier that the previous system that I used. I had to do a revision using my old system last week—what a nightmare. It reminded me what a frame-shift this pedicle screw is."

Last year K2M won a "Best Spine Technology Award" from this publication and then earlier this year won the 2010 Medical Design Excellence Award (MDEA) for the SERENGETI Minimally Invasive Retractor System. The SERENGETI features a unique flexible polymer retractor which is captured under the head of a cannulated screw and placed with the screw for secure, spine-based retraction. The retractor provides simplified access to the hard-to-reach L5 - S1 levels, as well as rod introduction for multi-level complex posterior instrumentation procedures.

K2M was founded in 2004 by John Kostuik, Eric Major, Lew Parker, Andrew Rock, and Richard Woods of the management team and others. Dr. John Kostuik, who serves as K2M's Chairman and Chief Medical Officer, was previously Chief of Spine Surgery at The Johns Hopkins University School of Medicine and he was once President of the Scoliosis Research Society and the North American Spine Society. In fact, Dr. Kostuik was one of NASS' original members and organizers.

This is the second company Eric Major has started. We first got to know the then 29-year-old Eric Major as CEO of American Osteomedix (AOM). This was around 2000 when Kyphon was just emerging as a treatment for vertebral compression fractures. Eric had an alternate, less expensive approach and it created significant buzz at the small NASS meeting in Chicago that year. Eighteen months later, Interpore Cross bought Eric's company for US$8 million in cash and about 2.4 million shares of Interpore Cross common stock. AOM became

a wholly owned subsidiary of Interpore Cross. The company's revenues before selling to Interpore were about $1.2 million. Eric worked about two years at Interpore. And then disappeared.

In 2004, along with Dr. Kostuik, Major quietly started K2M. K2M did not hit most spine surgeons' radars until 2005 when the company started selling its first products and hit the bricks looking for capital. The company snared $21.5 million from a number of investors including some surgeons and the private equity firm, Ferrer Freeman & Company that same year. Sales in 2006 were, we estimate, about $22 million and it was that same year that the FDA granted K2M clearance for its Denali Deformity Spinal System.

Over the next four years, sales at K2M rose at an average annual rate of about 50% and this year, we estimate, K2M will report more than $100 million in sales.

What's Next for K2M?

K2M's global headquarters will remain in Leesburg, Virginia, and it will continue to operate under its existing management team. But, the scope of the company's growth and vision will likely change. One clue as to where K2M may be looking came last October when the firm announced that it had opened a direct sales and distribution office in the United Kingdom. K2M's expansion into the UK had actually started in 2008 when it received the CE Mark clearance and successfully introduced its RANGE Spinal System, MESA Spinal System, DENALI Spinal System, PYRENEES Cervical Plate System, and ALEUTIAN Interbody Systems.

"Setting up a European base is a clear statement that we are committed to expanding the availability of our innovative technology globally and supporting surgeons treating the most difficult spinal deformities," stated Lane Major, K2M's Senior Vice President or Global Marketing. "Our mission is to be the worldwide leader in providing solutions for complex spinal pathologies and this is a huge step in the right direction."

With WCAS and Ferrer Freeman backing the firm, K2M's future is so bright, management may have to wear sunglasses.

Here is the PearlDiver forecast for the entire spinal implant and related biologics products, including K2M.

Spine Implant and Related Biologics Industry Revenue Forecast 2006-2011

Revenue ($ millions)	2006	2007	2008	2009	2010E	2011E
Medtronic	2,355	2,755	3,389	3,500	3,528	3,722
Depuy	818	870	913	1,002	1,046	1,121
Synthes	630	724	867	955	1,020	1,119
Stryker	340	424	507	558	616	687
Kyphon	408	424	-	-	-	-
Zimmer	177	198	230	254	257	281
Orthofix / Blackstone	145	243	252	279	311	348
Biomet	215	210	210	234	241	258
Abbott	101	111	86	-	-	-
NuVasive	98	154	250	370	497	626
Globus	82	123	178	256	348	460
Alphatec	74	80	101	132	222	259
Pioneer Surgical	53	73	92	112	134	158
K2M	21	35	60	83	112	129
Osteotech	54	57	52	47	48	51
Orthovita	47	58	77	93	104	122
Arthrocare	21	22	23	20	19	28
Scient'X	38	45	47	50	-	-
SeaSpine	20	30	45	60	75	89
RTI Biologics	35	41	42	41	37	42
U.S. Spine	5	17	29	39	50	58
Integra Spine			19	41	46	52
Trans1	6	17	25	30	27	29
LDR		15	21	35	53	73
Spinal Elements	6	12	18	25	33	41
MEDICREA				19	23	30
Exactech (Altiva)			7	7	7	8
Other	300	393	495	550	629	714
Total Revenues	$6,048	$7,130	$8,036	$8,792	$9,480	$10,504
Total Growth	17.6%	17.9%	12.7%	9.4%	7.8%	10.8%

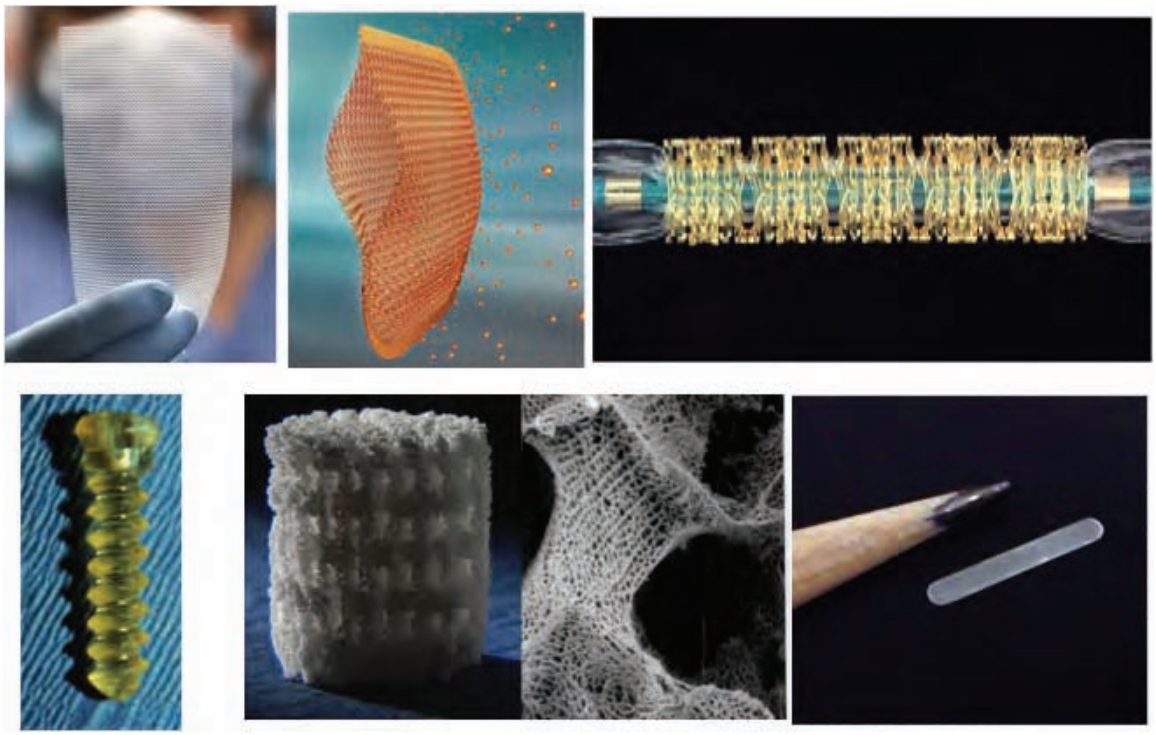
Source: PearlDiver Technologies estimates

◆

Revitalizing Regeneration Research

By Jacqueline Rupp

As it became clear from last week's article, "Orthopedics on the Edge," the Armed Forces Institute of Regenerative Medicine (AFIRM) is a multi-layered organization chocked full of pioneering projects and fast-tracked research.



Medical devices developed with biomaterials. Source: NJ Center for Biomaterials

Time is ticking for the group.

The AFIRM project has a five-year life and it is two years into it. In many ways, the Institute has already fulfilled some of its biggest goals. Technology is heading for trials and market and there is now evidence that public and private institutions can collaborate and divergent research teams are in fact able to make things happen…quickly!

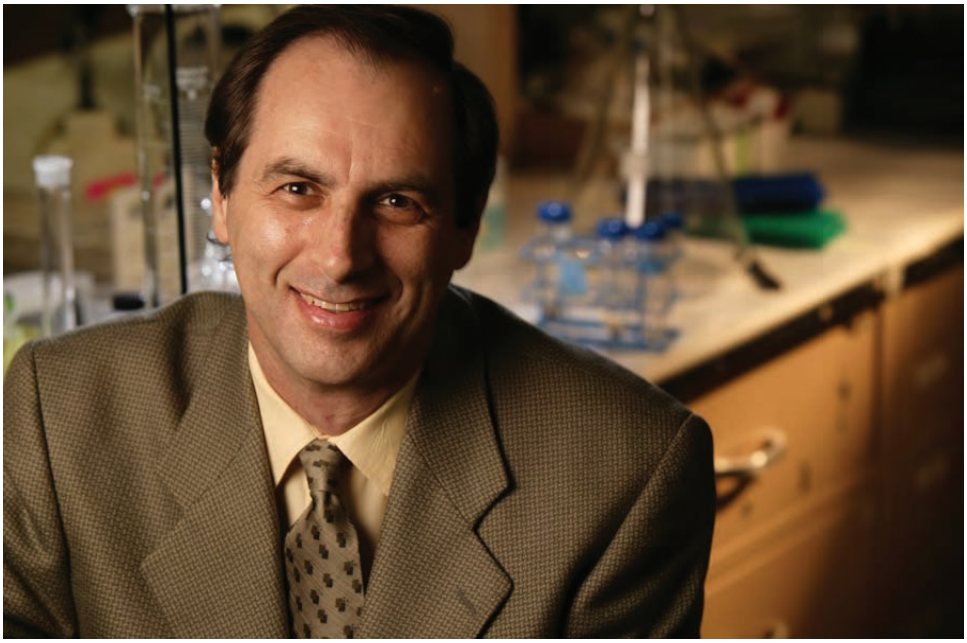
The AFIRM is composed of two consortia—the Rutgers/Cleveland Clinic Consortium and Wake Forest/Pittsburgh Consortium. Within these two branches lie individual projects and research teams from dozens of universities. The Rutgers Consort is led by Dr. Joachim Kohn, Ph.D. and includes a network of institutions from Rutgers, in collaboration with the New Jersey Center for Biomaterials (NJ CBM) in Piscataway, New Jersey, the Cleveland Clinic, the Mayo Clinic, Northwestern University to 12 other universities.

The New Jersey Center for Biomaterials

NJ CBM is a particularly interesting facet of AFIRM. Not a university like most of the other contributing research facilities, NJ CBM is actually a consortium in and of itself, comprised of top "Garden State" public universities that work in conjunction with industry to bring products to the patient's bedside. Begun in 1997, the Center works on many fronts, from the development of new materials for tissue engineering to new medical implants and devices.

"By fostering relationships within academia, industry, and government, the New Jersey Center for Biomaterials harnesses its scientific, technical, commercial and educational resources to take innovative ideas from the proposal phase, through research and development, publication or patent, technology transfer, and ultimately to the prototype engineering and clinical trial stage in a relatively compressed period of time," explains Dr. Kohn.

"Its structured research, educational, and outreach programs, as well as its industrial partnerships provide researchers, students, postdocs, faculty, clinicians,



Joachim Kohn, PhD

and entrepreneurs—the necessary elements to develop important research skills, to advance and disseminate their technologies, to seed new projects and to make career connections."

Kohn says the Center delivers two key qualities to the AFIRM roster. "The Center brings together the best set of multi-disciplinary researchers with private industry to work toward the military's therapeutic targets for serving the unmet needs of wounded warriors. This net-centric effort is unprecedented in merging the resources of academia, private industry and the military in specific combinations to serve each project's goals."

Full and Complete Funding

The second quality is full and complete funding. Yes you heard correctly, full *and* complete. The NJ CBM is like a researcher's proverbial candy store. "The entire development process of these materials, from the earliest bench-top research to translation into bedside use through clinical trials, is supported. Most centers receive funding for only one stage of the process, but the NJ CBM has received funding for each stage of the process."

"This allows materials in development to progress from one stage to the next seamlessly, without waiting to identify new partners or new sources of support at each step." This has led to some big developments, including the birth of four start-up companies, with around 50 patents being licensed to several companies. "Currently about 10,000 patients carry products invented in the NJ CBM in their body."

A Leader on a Mission

Professor Kohn is himself a major figure in the world of biomaterials. As the Board of Governors Professor of Chemistry and Chemical Biology at Rutgers University he has been the Director at the NJ CBM since its inception 13 years ago. A Fellow of both the American Institute for Medical and Biological Engineering (AIMBE) and the International Union of Societies for Biomaterials Science and Engineering (IUSBSE), Kohn wears many hats as a principal investigator for several major federally-funded R&D programs, including:

- The NIH-funded postdoctoral Tissue Engineering training program
- The National Resource for Polymeric Biomaterials, also NIH-funded
- The NSF-funded Partnership for Innovation, which is actually investigating plant-synthetic hybrid biomaterials

These roles are in addition to his involvement with the military as principal for the Department of Defense's (DoD) Center for Military Biomaterials Research (CeMBR) and of course his leadership role at AFIRM.

Even though he is not a physician and didn't attend medical school, Kohn's work has focused on biomaterials for many years. He actually pioneered significant work in the field, and is perhaps best known for his contributions working with "pseudo-poly (amino acids)," materials that are both benign and non-toxic but feature the benefits of plastics. This includes poly (DTE carbonate), a tyrosine-derived polycarbonate, which is currently awaiting clinical use in medical implants, with a Materials Master file in to the FDA.

Kohn has enjoyed funding that would make most researchers jealous, netting over $25 million since 1993 from government agencies. As if that wasn't enough, Kohn has also founded two companies and serves on the scientific advisory boards of three—so far.

Yeah, he's got awards too: New Jersey High-Tech Hall of Fame inductee and two-time Thomas Alva Edison Patent Award for best patent in New Jersey in medical research among many others.

Hanshella Magno, graduate student in the Kohn Laboratory, working with prototype scaffod for bone regeneration in the craniomaxillofacial complex.

But Kohn's early background makes him all the more the perfect candidate for leading an organization to aid wounded soldiers. Born in Germany and holding dual citizenship, Kohn grew up amidst the aftermath of World War II, the only Jewish student in his high school class of several thousand. His father had lost both parents and a startling seven siblings in the Holocaust. But Kohn's story is one of triumph. Becoming the first in his family to go to college, his initial foray into military medical research was with the Israeli army nearly three decades ago.

Looking to the Future

There are several exciting research projects just getting underway in the Rutgers/Cleveland Consortium. A clinical trial to assess the safety of a novel biomaterial for nerve regeneration is set to begin recruiting patients at the Mayo Clinic in association with industrial partner, BonWrx of Phoenix, Arizona, in 2011.

2010 marks the beginning for two bone regeneration projects with a goal of FDA market clearance.

The first involves a team from Rutgers developing a tyrosine polycarbonate bone pin for small fracture fixation in conjunction with Trident Biomedical of Bridgewater, New Jersey.

Vanderbilt University working with Osteotech of Eatontown, New Jersey, hosts the second project, which looks to establish a GMP (Good Manufacturing Procedure) manufacturing facility for a new bone void filler.

Finally the Cleveland Clinic is partnering with Kalamazoo, Michigan-based Tolera Therapeutics to achieve DoD approval for a therapeutic antibody, TOL101 that enhances the body's tolerance of Composite Tissue Allograft Transplantation. This therapy would take away the need for life-long immune-suppression. Enrollment may begin in early 2011.

Secrets of Rapid Research

Kohn points out there are several key reasons why AFIRM has been successful in pushing progress through. Here is his formula for swift research success:

1. Identify and run with the most promising projects. "The Rutgers/Cleveland Clinic Consortium of AFIRM has moved four projects towards clinical trials (some trials are already recruiting patients, and others are funded but are waiting for final regulatory approval, and some are currently waiting for final funding approval)."

2. Scientific rigor. "The natural opportunities for collaboration that arise as a result of the consortium structure are invaluable. Bringing the best scientists and clinicians in their fields together for cooperation rather than competition has been a tremendous boon to the innovative process."

3. Consistent progress. "In some ways, after two years the timelines seem less ambitious than they seemed originally. In part, this is because we are meeting our milestones and moving our products through the stages necessary to reach wounded warriors."

4. Realistic selection process. "We make every effort to only move those projects forward that are likely to reach clinical trials within the five-year funding period. This allows us to add funding to the projects that are closer to clinical trials. Our focus is always on getting new and improved therapies into the hands of military physicians and surgeons as quickly as possible. One source of support for projects at early stages of development is our program Center for Military Biomaterials Research (CeMBR), which is also funded by the DoD."

When asked what he is most proud of Kohn of course points to the ability of the group to bring viable treatment options to soldiers. "We are most proud of the number of programs moving rapidly forward to help wounded warriors. The original goal of the AFIRM was to have one product in clinical trials by the end of the five-year funding period. Our Rutgers/Cleveland Clinic Consortium may have as many as five products in trials by then." ◆

The Role of Physician Assistants in Orthopedics

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

Dr. Alpha: I'm thinking about hiring a PA…you know, a physician's assistant, a physician extender, an orthopedic physician's assistant.

Dr. Beta: We have several PAs in our practice. You should know about the terminology though… "physician extender" is not the term used these days…and do you know what they do?

MorgueFile

Dr. Alpha probably does not know what *physician assistants* (PAs) do. If Dr. Beta does in fact know, then he or she is ahead of the game. Orthopedists and others in the field are usually unfamiliar with the role of PAs in orthopedic practices, says Roderick Hooker, Ph.D., PA, who works with the Department of Veterans Affairs in Dallas, Texas.

Dr. Hooker explains, "A major part of the confusion about PAs working in orthopedics surrounds the terminology used by physicians to describe them. There are technicians who call themselves orthopedic PAs (OPAs), and then there are the formally trained PAs who work in an orthopedic setting. While both groups have 'orthopedic' in the title, and each may refer to themselves as 'OPAs,' their training and skill sets are quite different. Individuals trained in orthopedic assistant programs learn technical orthopedic tasks, but are not taught the basic medical sciences that are emphasized by the certified primary care PA programs."

"Furthermore," says Hooker, "OPAs are not eligible to sit for the Physician Assistant National Certification Examination, which is administered by the National Commission on Certification of Physician Assistants. The National Board for Certification of Orthopedic Physician Assistants manages the examination for certifying OPAs. This latter test is not equivalent to the NCCPA's examination, and the organizations are not affiliated."

The fully trained and formally certified PAs, however, can be like gold in an orthopedic practice. Rod Hooker: "NCCPA Certified PAs are involved in patient care at every level, including writing orders and progress notes, writing prescriptions, performing history and physical exams, ordering laboratory and radiographic tests, assisting in surgery, and participating in postoperative care. To a large extent, PAs make it possible for orthopedists to transfer much of their non surgical work, thus giving the surgeon more time for the operating room (OR). But along with cardiovascular surgery and neurosurgery, orthopedic surgery has the lowest ratio (largest number of PAs relative to physicians) amongst the surgical subspecialties, with approximately one PA for every three surgeons."

Those practices that are PA savvy, though, benefit mightily. "In vertically integrated systems such as the VA or Kaiser Permanente, PAs might be managing 90% of closed fracture cases, managing preoperative care, and coordinating discharge planning. Once a patient is stabilized

they need periodic evaluation, which is also something PAs can do."

Caution is warranted, however, says Hooker. "An orthopedist excited by the prospects of bringing on a PA may overestimate the training of the individual and think that he or she is able to do everything. More often, however, the surgeon just doesn't know what PAs do, or doesn't know their range of skills because so little has been published about their role. PAs are also at fault because they have largely not taken the initiative to document their range of skills and roles as they apply to orthopedics."

What we need, states Dr. Hooker, is hard data on what exactly PAs contribute to orthopedic practices. "In my 'funding dreams' I have ample grant money to identify as many practices as possible for conclusive findings (solo with a PA, solo without a PA, large practices with one PA versus those with more PAs than surgeons, etc.). Given the resources, I would look at one year's worth of cases by ICD and CPT codes and identify how productive PAs were in terms of patients seen, cases administered, surgical versus non surgical time, to try to get a sense of the efficiencies of the organization and how the labor is divided. Orthopedic surgeons have 'hit on' a very good thing when it comes to PAs, but it would helpful to be able to reflect that with data."

Hooker notes, "A 2010 paper on orthopedics in Winnipeg documented that with the incorporation of PAs to the orthopedic service surgical cases increased, wait times decreased and annual productivity was substantially enhanced."

"As people are living longer and we are adding more people to the insurance rolls, it becomes imperative that we have trained care providers to help them. Heading into the future we will need more certified physician assistants in orthopedic surgery. The inclusions of teams in any type of care will improve the overall benefit and outcome to the patient."

Dr. Charles Cornell, an orthopedic surgeon at Hospital for Special Surgery (HSS) in New York, knows that if the future is anything like the past, then Dr. Hooker is right on target. "Fifteen years ago there were 15 physician assistants at HSS…now there are 70. PAs are now on the front lines in orthopedics and they can be tremendously helpful in providing services that free up the surgeon."

For his colleagues unfamiliar with the role and skills of a PA, Dr. Cornell states, "PAs complement an orthopedic practice and are highly skilled professionals who, with proper training and experience, can become extremely competent in orthopedic care. I worked with one PA in Queens who was incredibly sophisticated. He had been in the field for 12 years and was superb at doing history and physicals and was an excellent diagnostician. This gentleman was very helpful in the OR, and would prep patients and assist with surgery, including opening and closing wounds. He was my alter ego."

The model of the PA in an orthopedic practice is shifting toward one of independence, says Dr. Cornell. "It is increasingly common to see practices where the PA has their own practice within the group. They do the initial screening and workup on new patients and then refer the person to the appropriate orthopedic surgeon within the practice. This is useful because PAs can

independently generate business for the practice and bill independently for their services (although what is permissible likely varies from state to state)."

And the more time a PA has spent in the classroom *and* in a clinical setting, the more independent he or she will be. "Many PAs are involved in administrative work such as quality assessment projects and personnel management. They can also take call and perform the initial examinations in the ER, order X-rays, make a diagnosis, and then consult with the supervising doctor. On the research front, as long as you provide opportunities for training, then a PA can easily participate in this realm. The star PA at Queen's Hospital helped me establish a database of hip fracture patients, collected the data, and supervised several research students. In essence, PAs have a Masters degree, a year of basic science research, and a clinical year (similar to someone with two years of medical school). This is only a starting point for them, however, as PAs can pursue public health training, attend AAOS courses, participate in journal clubs, etc. As long as someone is trained and motivated to further their knowledge and skills the surgeon should give them as much responsibility as they can handle."

But in doing so, advises Dr. Cornell, try not to step on any toes. "There is a natural conflict between PAs and residents, and in many situations they have not yet worked out how to share responsibility. There are often chain of command issues where the senior residents and experienced PAs must 'feel out' their relationship in order to work well together. I have seen some PAs who don't want to work with residents at all because they don't want to 'answer to' residents. These issues also occur in the operating room, where PAs use their skills to close wounds and assist with surgery. However, because my primary responsibility is to train residents, if a resident enters the OR I must allow the resident to do those tasks instead of the

RRY Publications

PA. To avoid these conflicts, when we have residents scrubbed in on a case we don't have PAs present."

Whether in the OR or in the office, egos and poor communication can be detrimental to patient welfare, warns Dr. Cornell. "One of the biggest things that results in medical errors is poor communication and 'handing off' patients between staff. All members of the team need to establish who is in charge at any given time; residents and PAs must have clearly delineated responsibilities and communicate regularly about what is happening. You never want to get into a situation where people are saying, 'That wasn't *my* patient that was *your* patient.'"

Much of a doctor's ability to work with PAs depends on their mindset. Dr. Cornell: "Some surgeons are not comfortable delegating to non-physicians, something that I think is going to have to change. The resident workforce is limited—at HSS, for example, we have eight residents a year, meaning that there are only 16 fourth and fifth year residents—and that is to help cover 60 cases a day. So at a number of institutions you have PAs doing more work in the OR; traditionalists, however, are uneasy with these lines being crossed."

We should remember that as compared with the profession of medical doctor, the physician assistant profession is a young one…and that means patients as well need time to get comfortable with the role of a PA. Dr. Cornell: "If patients see that a PA works closely with the physician then they feel more comfortable. You should be careful, however, if the patient is not doing well and they are unhappy. In that case, you need to ensure that they see the attending surgeon. A patient with complications who calls to speak to his or her doctor and is put through to the PA each time is not going to be satisfied…and may pursue litigation."

But as they always do, things change. The future is here…and it is physician assistants. ◆

company

Lanx's Oopsie

We reported on June 9 that Colorado-based Lanx, Inc. had "snagged" former Medtronic COO Michael DeMane as its new CEO and Chairman.

Before the rockets red glare of the Fourth of July could be seen, the company issued a new statement:

"Michael DeMane has declined to assume the role of chairman and chief executive officer and will assist the company as a consultant."

Oopsie. We called the company to ask what happened. Our call was not returned.

Premature Announcement

Thomas Lee of *Medcitynews.com* provided some insight into this bizarre event on July 1. Lee reported that, Peter McNerney, a well known venture capitalist and former partner of DeMane's, had told Lee after the first Lanx announcement that he thought the announcement may have been a bit premature.

It sure looked like a done deal. The original announcement quoted DeMane, who said, "Founders Michael Fulton, Jeffrey Thramann and their team have built a company with a responsive, solutions-oriented culture, while maintaining a high level of ethics and integrity. We expect to continue our commitment to those values in our mission to build a world-class spine company over the long-term."

Or these comments from the company that stated that Co-Founder and former CEO Michael Fulton would assume the role of Chief Technology Officer, and would continue to guide the company's innovation and new technology initiatives.

Fulton said at the time, "The Board and I are extremely excited to have an executive of Michael's industry stature accept this leadership role at Lanx. His decision to join our company is a testament to the innovation and dedication to technology that has driven our growth to date."

Jeffery Thramann, Co-Founder and former Chairman, said, "Michael DeMane unquestionably has the ability to lead the organization and will be a catalyst for taking Lanx to the next level of growth and expansion."

Tongues wagged throughout the industry as speculation ran rampant that DeMane discovered new things upon digging into the company or that previous non-compete agreements with Medtronic forced him to reconsider.

None of those seem plausible. Perhaps Lanx just jumped the gun. Since neither Lanx nor DeMane are talking, speculation will continue.

What is known is that this bizarre episode has given the company, which touts its high level of ethics and integrity, some credibility problems with its next public announcement.

—WE (July 16, 2010) ◆

Alphatec Rebounds After FDA Scolding

Finger Pointing/Wikimedia Commons

The warning was clear and it was definite. The FDA sent a warning letter on June 21 to Alphatec Spine, Inc., the subsidiary of Alphatec Holdings, Inc. This action came after Alphatec's response letter to the FDA's Form 483 "List of Investigational Observations" didn't quite cut it with the FDA. The original Form 483 was brought on after an inspection of Alphatec's Carlsbad, California, manufacturing facilities.

In this inspection, which ran from January 20 to February 11, 2010, the FDA found the company insufficient with its internal procedures for design controls, complaint handling, and medical device reporting.

Although the warning letter sounds imposing, it doesn't necessarily impede Alphatec's production, since no restrictions on production or shipment have been imposed and the company is free to continue with its sales and marketing. No recalls have been issued either. Instead, Alphatec is working with the FDA to rectify the problems found during the inspection.

But until that resolution is achieved, Alphatec is going to be open to restric-

tions, something which could impact the company's productivity and even affect Alphatec Holdings. And for now the company has to be content with waiting to hear if what they are doing is enough to satisfy the FDA or if the FDA will take action beyond just a written scolding.

Even though that sounds pessimistic, some analysts aren't concerned. Raj Denhoy, managing director at Jeffries & Company Inc. says that the warning letter shouldn't affect the good prospect for the company as a whole. In Denhoy's note on the subject, which is subtitled "Impact Likely to be Minimal," he points out that the "warning letter focused on control and procedures—not product defects." He adds, "Alphatec has assembled both a product pipeline with some of the more interesting offerings in spine as well as a vast and largely underutilized worldwide sales network. The marrying of the two should generate significant outperformance at Alphatec over the coming years."

—JR July 14, 2010

Biomet Job Expansion Reported

According to Kosciusko County officials in Warsaw, Indiana, Biomet plans on creating 280 new jobs that will pay an average of $50,000 a year following a $26 million expansion in the community.

This would be a nice change from previous company statements that stated that the new device tax in the health care bill could cause employee layoffs in the device industry.

According to the *Fort Wayne Journal Gazette*, the company requested "economic development status" for part of its campus in Warsaw. Such designation is the first step in getting the local taxing authorities to abate taxes on an expansion project.

Kosciusko Council President Harold Jones told the Gazette that the council approved the new designation and expects a Biomet representative to attend its August 12 meeting to formally ask for the abatement, which, he said is sure to be approved.

Jones said Biomet's project has four components—manufacturing, distribution, technology and research and development. The plan is to renovate existing property and add new equipment. The jobs will be added over a two-year period and pay more than $50,000 a year on average.

"It's just one of those success stories that everybody would like to have," Jones added.

Biomet Responds

However, Bill Kolter, Biomet's Corporate Vice-President Government Affairs, Public Affairs, and Corporate Communication, said nothing is final yet and the company has simply asked for support from the county.

Kolter told *OTW* that the company is seeking a tax abatement in Kosciusko County as well as support from the Indiana Economic Development Corporation (IEDC) related to proposed expansion of its Warsaw campus.

He added, "Biomet was founded in Indiana and seeks to expand its capabilities in the state. Included in the proposal is a multi-year plan for expansion of manufacturing and non-manufacturing employment as well as related capital expenditures. One of the factors that will impact the company's ability to move forward with its plan as proposed is the response to its requests from IEDC and the Kosciusko County Council. The company is in the process of requesting support, and cannot predict the outcome of the reviews of the company's requests."

—WE (July 13, 2010) ◆

Kosciusko County Courthouse, Warsaw, Indiana/Wikimedia

large joint

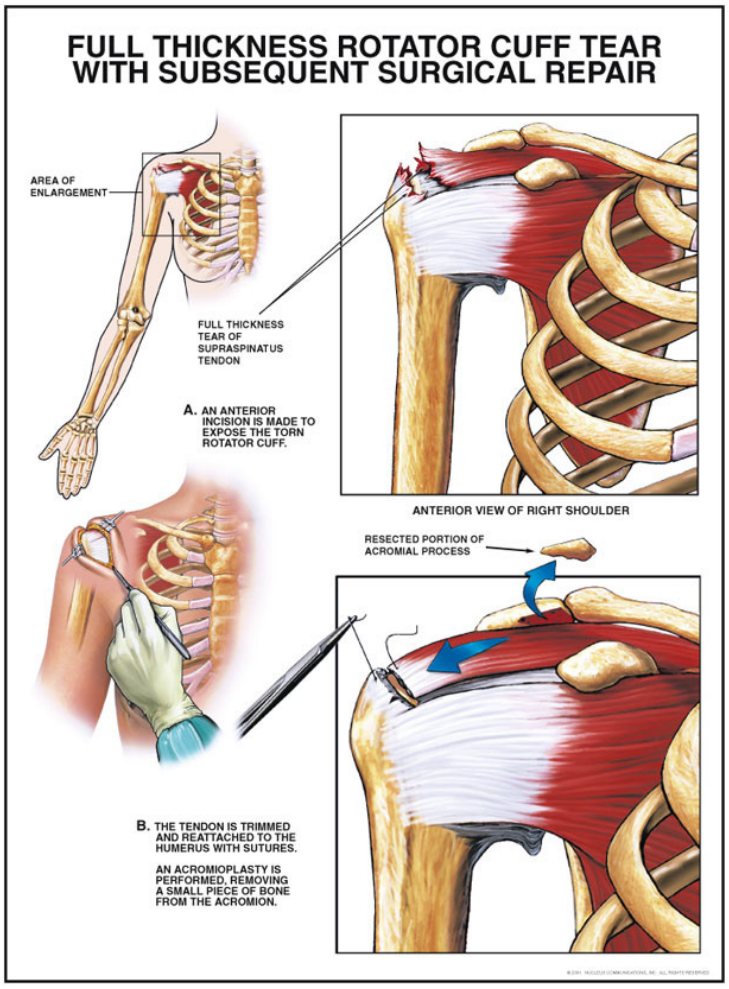
Rotator Cuff: To the OR or Not?

What to do and when to do it… those are the questions. A new comparative effectiveness report published by U.S. Department of Health and Human Services' Agency for Healthcare Research and Quality (AHRQ) finds that when treating rotator cuff injuries, it is unclear whether surgical or nonsurgical treatments are best.

The report, prepared for AHRQ by the University of Alberta Evidence-based Practice Center, notes that all treatments, either surgical or nonsurgical, result in improvement, but that there are few differences between interventions. There was no evidence indicating ideal timing of surgery.

Most older patients with a rotator cuff tear are first treated with up to three months of nonsurgical treatment. If this is unsuccessful, then the rotator cuff may be repaired surgically, after which time the patient undergoes rehabilitation. Some doctors indicate that earlier surgery results in less pain and better use of the shoulder, leading to an earlier return to work and decreased costs; so, patients often must decide between surgery and waiting for nonoperative treatments to work. Researchers, however, found little evidence that earlier surgery benefits patients.

Commenting to *OTW* was Jean Slutsky, PA, MSPH, Director of the Center for Outcomes and Evidence at the Agency for Healthcare Research and Quality. Slutsky noted, "We were most surprised to learn that even with rotator cuff tear surgery being so common, we still don't know the ideal time to pursue it. This is surprising because rotator cuff tears are so common in older adults. More than half of patients over the age of 60 have a partial or complete tear in their shoulder. It's a common injury and we have many good tools to treat it—but we don't know the best way to use those tools."



Rotator cuff tear surgical repair procedure/Wikimedia Commons

She also told *OTW,* "The essential question that we now need to answer is when is the optimal time to forego nonoperative treatments and pursue surgery. As with all surgeries, rotator cuff tear surgery is an invasive procedure. Some patients, particularly older patients or those who are in poor health, may not be good candidates for an operation. Therefore, it's important that patients with a rotator cuff tear talk with their doctor about their options and determine the best course of treatment for them."

—EH (July 16, 2010) ◆

Search Results a Mixed Bag

When patients search the web for orthopedics information, what do they find? Is it accurate information, speculation or advertising? Two studies are offering insight into just what patients are finding online.

The Internet has become the go-to spot for answers when there is a question. And when potential patients are looking for answers on everything from why their joints hurt to which joint replacement surgery is best, they go to a search engine and begin their hunt for information. And this is a critical moment in a patient's health. The search engine results they initially obtain can set the tone for the treatment they seek.

So what are they finding online? Well it's good and bad. Orthopedists at the Carolinas Medical Center took to the web to see just what their patients were finding. Logging on to two of the most popular search engines, Google and Yahoo!, the physicians searched for information on the top ten most common orthopedic conditions. The top ten results the doctors ended up with were then analyzed for three qualities:

- completeness
- correctness
- clarity

Since 75% of U.S. residents have Internet access and about half of them use the Internet to get their health information, determining what these cyber surfers are finding is critical to patient care.

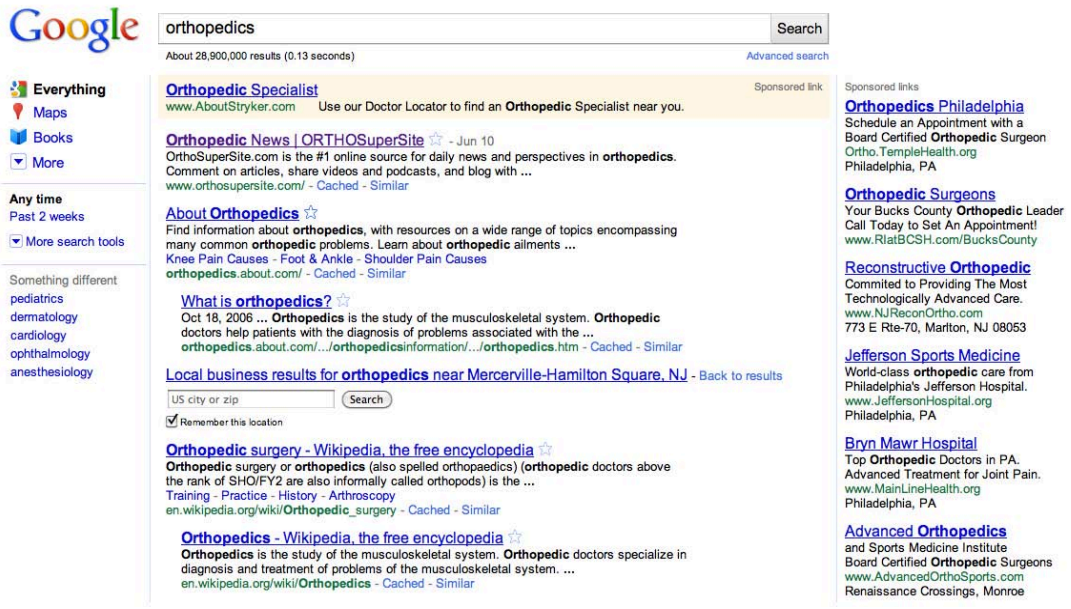
So here's the good news!

Nonprofits are doing a great job at supplying user-friendly and accurate information. These sites can generally be spotted by their ".org" ending and include spots like the American Academy of Orthopedic Surgeons' site "Your Orthopedic Connection," The American Academy of Pediatrics and American Academy of Family Physicians. Academic sites are good too, as are commercial sites such as WebMD.

Commercial sites that promote a specific product don't fare nearly as well. These sites make up about 2 in 10 of the health sites out there and sell health care products such as pharmaceuticals and medical devices. But they can't seem to separate the information from the marketing and focus more on promoting the benefits of their products rather than supplying well-rounded insight.

Another concern that is springing up online in the health care community is the growth of sites promoting stem cell therapies.

A study published in Cell Stem Cell by researchers at Stanford University found that there can be a real danger to curious patients looking for the latest in cutting edge technology. The research-



Google Screenshot

ers used search engines for results of queries for stem cell therapies and came up with hundreds of companies promoting the therapy for a whole host of conditions. The danger lies in that many of these search results were actually from practices located in countries with questionable health care regulation. While touting the miraculous benefits of their treatments, many of these sites ignored all safety concerns and provided little concrete substantiation for their claims. In fact, many a site out right lied about affiliation with trusted stem cell organizations.

To counteract this bad behavior the International Society for Stem Cell Research created A Closer Look at Stem Cells to help patients wade through the scams and these modern-day medical hawkers.

—JR (July 7, 2010) ◆

Middle-Aged Options for Knee OA

Keep on truckin' (or running or playing rugby)…Middle-aged men and women with osteoarthritis (OA) of the knee have more options than ever — operative and non-operative—for treatments that may allow them to remain active in the sports they love, according to a review published in the July 2010 issue of the *Journal of the American Academy of Orthopaedic Surgeons*.

"There is an increasing trend in the United States of people who want to stay active in sports and recreational activities after the age of 40. These patients are not content with being told to stop what they love doing," said lead author Brian Feeley, M.D., assistant professor of orthopaedic surgery, University of California, San Francisco, in the news release. "As a result, orthopaedic surgeons and other physicians need to come up with different treatment strategies, including non-operative treatments or even cartilage restoration procedures, to address pain and functionality and to help keep patients as active as possible."

"In a vast majority of cases, the onset of arthritis is a slow, degenerative process and therefore there is rarely a need to rush to surgery," he added. "Depending on the symptoms and activity level, many patients can be managed well with non-operative treatment strategies, whereas others truly benefit from surgical procedures. For each patient, it is important to tailor treatment to their symptoms and activity level, and to look for a healthcare provider who is willing to work with them over time to keep their knee as healthy as possible."

Dr. Feeley noted that bracing, hyaluronic acid, activity modification or anti-inflammatory medication might be used initially, to see if the symptoms resolve or if there is a chance of avoiding surgery. While acupuncture, glucosamine and chondroitin may be used, Dr. Feeley stated that there is no strong clinical evidence supporting the efficacy of these treatments.

Regarding non-operative treatments, Dr. Feeley told *OTW*, "The most important aspect of non-operative treatments is to talk with the patients and match the goals of the patients with the non-operative treatment modality that will best restore their activity level. There are no great new updates in what is available but better recognition of the arthritis early with high resolution MRI tends to help with early management. With better early management, we can decrease symptoms of arthritis more predictably."

Dr. Feeley also commented to *OTW*, "Cartilage restoration is very promising in the younger population. Many of the recent scientific advances in orthopaedic surgery are in cartilage restoration

Wikimedia Commons

procedures. The newest technology is in using scaffolds to patch smaller cartilage defects. These scaffolds are very promising in early clinical trials."

—EH (July 14, 2010) ◆

biologics

Amniotic Tissue Repairs Cartilage

Up until now the amniotic membrane has been just discarded after a birth, but now it is actually showing great promise in repairing articular cartilage.

Human amniotic membrane (HAM), the tissue that composes the amniotic sac, has for several years been developed and marketed for its therapeutic applications, from eye surgery to burn care. Now cryogenically preserved HAM is being examined as a means to repair damaged articular cartilage.

This is particularly important cartilage is not a self-healing tissue.

The findings by Institute of Biomedical Research of La Coruña, Spain, and published in *Cell and Tissue Banking* suggest that the frozen preserved membrane can work as the perfect scaffold for tissue growth scaffold for growing the elusive chondrocytes cells, the only cells that make up cartilage. Some of the membranes key benefits are that it not only offers a consistent scaffold surface, but also is able to fit into the gaps and fill open spaces.

HAM itself is a natural choice for research because it is so user-friendly according to two studies ("The amniotic membrane in ophthalmology" in a 2004 issue of *Survey of Ophthalmology* and an older study, "Amniotic membrane transplantation" from 1999 found in the *British Journal of Ophthalmology*).

Here are some of its top selling points that came out of these published studies, that illustrate everything HAM is:

- Anti-microbial
- Anti-angiogenic
- Anti-tumor
- Anti-inflammatory
- Pain reducer
- Does not produce a immune response

Pregnant Woman/Wikimedia Commons

Beginning with the amniotic membrane, the team was able to actually harvest chondrocytes in just under a month's time, which were then used in 44 cases of arthritic cartilage. The patients were then assessed at several weeks later. It was shown to integrate well with the patients' own cartilage. In fact, the implanted chondrocytes actually were shown to have a greater cellular density than the native cartilage.

But there are some downsides to this therapy. It can only benefit patients still have some healthy cartilage cells and does inflict further damage upon the joint itself. Still the therapy may be the direction osteoarthritis therapies are headed in, with regeneration appearing to show more promise than surgeries or medications.

—JR July 15, 2010 ◆

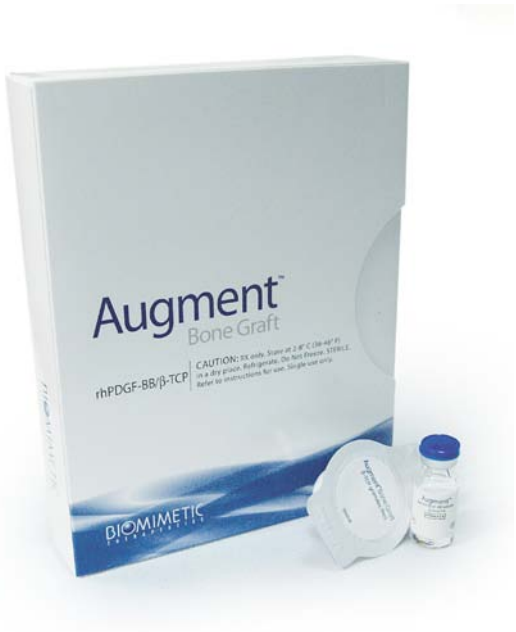
Positive Results for Augment

Less pain, less time in the OR…tell me more! BioMimetic Therapeutics is announcing the final, one-year results of its North American Pivotal Study comparing Augment Bone Graft to autograft in foot and ankle fusion. The trial had already met its pre-specified primary endpoint of non-inferiority of Augment to autograft at six months, and the company's Premarket Approval (PMA) application for Augment was recently accepted by the FDA.

Out of 16 secondary endpoint measures at the 52-week time point, 15 were statistically significant for non-inferiority. Augment compared favorably to autograft with healing rates of 87.8% and 88.3%, and a therapeutic failure rate of 7.3% and 8.0%, respectively. The Augment treatment group had fewer complications and infections compared to autograft.

They also have results of the European Union Augment foot and ankle fusion study, which found a 7% revision rate, (consistent with the therapeutic failure rate observed in the U.S. pivotal trial for Augment and autograft and Canadian registration trial, and a safety profile that was consistent with all other studies of Augment to date).

When asked about getting surgeons to "convert" from autograft, Steven Hirsch, COO and EVP of Orthopedics for BioMimetic told *OTW*, "It is always challenging to change surgeon habits away from a standard of care treatment. But comprehensive studies such as ours do not come along very often, and we feel that surgeons will pay attention to the relative safety benefits of Augment, the time



BioMimetic Therapeutics

saved in the OR and the reduction of patient pain, as well as the elimination of the risk for complications related to the graft site harvest. We believe that surgeons will try Augment on some challenging cases to begin with and, as they get comfortable with it, will tend to use it more routinely. Some surgeons have said that they would give the patient the option, in which case, I like our chances—especially considering all the complications surrounding the harvest of autograft when compared to Augment, which is an off-the-shelf product."

He also commented to *OTW*, "We are awaiting the FDA Orthopedic Advisory Panel, which we expect to be in late 2010 or early 2011. This panel, which will mainly consist of orthopedists, including foot and ankle surgeons, will advise the FDA on whether they believe Augment is safe and effective. The FDA is not bound by the determination of the panel. However, if the panel concludes that the product is safe and effective, we would hope that the FDA would move quickly to grant final approval to market Augment."

—EH (July 15, 2010) ◆

extremities

Do We Need Flawless Feet?

Will feet become the next target of scrutiny and modification for those seeking the perfect body?

The American Orthopaedic Foot and Ankle Society (AOFAS) recently warned against the unnecessary dangers of cosmetic foot surgery. Who knew people were even willing to go under the knife in the pursuit of podiatric perfection?

Cosmetic foot surgery encompasses a host of procedures that make the feet look more like a supposed "perfect foot" archetype. These operations can and do include:

- Shortening of the second toe
- Toe Tuck - that is the thinning of the little toe
- Narrowing of the foot
- Foot facelift - a combination of the above procedures

One of the main motivating factors for surgery is the desire (mainly by women!) to fit into stylish shoes. Yes, we're talking high heels, which fit better with narrower feet and shorter, uniform toes. These cosmetic procedures therefore shouldn't be confused with orthopedic reconstructive surgery, that generally has a goal to relieve pain and/or improve function.

A quick Internet search engine scan reveals that indeed many practices are offering such cosmetic services, many times right alongside common podiatric surgeries. Combining reconstructive benefits with cosmetic surgery procedures also seems to be a trend.

But according to the Society, so-called foot facelifts carry their own set of dangers. Infection, pain, scarring and nerve damage are just some of the risk factors for these elective cosmetic procedures. But there may also be greater risks to function and that's why the AOFAS has made the blanket statement to say that "No surgery should be performed for the sake of appearance to a foot that is functioning well and is not in pain."

With flip flop and sandal-wearing in full swing this summer season, the Society's statement seems perfectly timed. Like the issue of cosmetic limb lengthening, this is another time when orthopedics and cosmetic medicine have intermingled with interesting…and controversial effects.

—JR July 15, 2010 ◆

Feet in Garden/Creative Commons

reimbursement

BMP Evidence on MEDCAC Agenda

While the FDA figures out whether or not to approve a new BMP (bone morphogenic proteins) from Medtronic, (Amplify rhBMP-2 Matrix) later this month, Medicare will be meeting on September 22 to determine if there is enough evidence to decide if the agency should continue to pay for any BMPs.

The Centers for Medicare and Medicaid Services (CMS) has called the September meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) to consider the currently available evidence regarding the clinical benefits and harms of on-label and off-label use of BMPs.

Infuse and OP-1

More than 20 BMPs, including Medtronic's Infuse and Stryker's OP-1, have been identified. But only BMPs -2, -4, -6 and -7, according to CMS have been shown to have significant osteogenic properties. The main physiologic role of BMP is to promote differentiation of mesenchymal cells into chrondrocytes and osteoblasts, to promote differentiation of osteoprogenitors into osteoblasts, and to influence skeletal pattern formation. Human BMPs are now produced using recombinant DNA technology.

Currently, two recombinant BMPs have some form of FDA approval and are commercially available in the United States: rhBMP-2 (Infuse) and rhBMP-7 (OP-1). The on-label and off -label use of BMPs has rapidly grown since becoming clinically available in 2001.

Wikimedia Commons

There are reports stating that up to 85% of BMP use is for off-label indications, mostly in the spine. There have also been a number of reports of adverse events associated with the use of BMPs.

Off-Label Controversies

The off-label use of BMPs has been highly controversial and has resulted in prosecutions and guilty pleas by former Stryker sales reps who admitted to promoting the off-label use of OP-1. Medtronic's Infuse has had its own share of controversy with consulting spine surgeons accused of cooking research papers and harming patients with off-label use.

This should be the most interesting and watched MEDCAC meeting for orthopedics since the Committee met in 2006 to consider the evidence for fusion in treating lumbar disc disease.

Those interested in attending can register at: http://www.cms.gov/apps/events/event.asp?id=602&Kw=&Mh=NoMonth&cboOrder=date&Yr=NoYear&type=2

—WE (July 15, 2010) ◆

THE PICTURE OF SUCCESS

Dr. Robert B. Anderson

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

Dr. Robert B. Anderson

Dr. Robert Anderson, an orthopedic foot and ankle specialist at Ortho Carolina in Charlotte, North Carolina, and the head of the National Football League's Foot and Ankle Subcommittee within the Injury and Safety Panel, loves nothing more than unraveling the complexities of "turf toe" or ankle reconstruction and getting athletes back to the joy of playing or, on a "regular" day, helping the average citizen walk without pain for the first time in years.

Born in Milwaukee, Wisconsin, Robert Anderson grew up under the tutelage of parents who knew the value of a textbook. "I am from a conservative, middle-class family; my parents were enormous supporters of public education, and made significant sacrifices to ensure that my three sisters and I got through school. When it came time for college, I wanted nothing more than warmer climes. As my parents and I drove south for campus visits at Tulane and Louisiana State University, I saw a sign that read, 'University of Mississippi turn left.' On a whim we took that exit and once I saw the beautiful campus and, frankly, the attractive women, I had made up my mind."

While Robert Anderson had the usual spate of sports injuries that so often come with being an orthopedist, he also had an early experience that solidified his determination to pursue a career in this field. "On several occasions in high school I was treated by an orthopedist; over time I grew fond of the role of doctor, and began to see how great it would be to be able to make someone feel better. In a stroke of luck, during my junior year of college I was asked to work with an orthopedist who was the doctor for the University of Mississippi athletic teams. Putting on casts, removing stitches, etc.…all of that gave me a window into the world of orthopedic surgery. It was a window I was certain that I wanted to go through."

In 1979 Robert Anderson dusted off his winter coat and headed home. "I matriculated at the Medical College of Wisconsin in Milwaukee and lived at home for two years to save money. I knew that being admitted to an orthopedic residency was going to be competitive, so I put my nose to the grindstone. When I came up for air, however, I played a bit. I helped start an annual party called the 'Cadaver Ball' which involved staging an anatomy suite at a local barroom. It was extremely popular and continued for several years."

But it was not for his party planning skills that he was admitted to residency. "During medical school I did an orthopedic rotation in Columbia, South Carolina. There was a significant buzz about Carolinas Medical Center (formerly Charlotte Memorial Hospital) in Charlotte, North Carolina, being a well-kept secret, and many people encouraged me to take a look at their program. I did an early interview there,

"Under Dr. Gould's direction, I learned how to innovate and borrow technology from other areas in orthopedics."

was accepted, and began my residency in 1983."

The Peyton Manning's of today can thank Dr. Anderson's father figure for steering him in the direction of the metatarsals. "The person who gets the most credit for guiding my career is Dr. Basil Boyd, who was a charter member of the American Orthopaedic Foot and Ankle Society and a gifted sports and spine surgeon. He 'looked around the curve' and encouraged me to consider foot and ankle because he could see that it was an area ripe for growth. Indeed, in the mid '80s there were only three foot and ankle fellowships in the entire country…now there are 45. He convinced me that there were a lot of people who had complicated foot and ankle problems and who were going untreated. Another talented sports medicine specialist, Dr. Angus McBride, suggested that I focus on the sports aspects of foot and ankle because no one had taken the lead in this area."

Ready to learn how to lead, Dr. Anderson found that this meant harnessing one's ingenuity in an era of "one-offsmanship." "When I interviewed at the Medical College of Wisconsin, Dr. John Gould, the fellowship director, offered me a position on the spot. In addition to writing several papers and book chapters, I discovered that there was a real paucity of equipment for the foot and ankle. Under Dr. Gould's direction, I learned how to innovate and borrow technology from other areas in orthopedics. For example, in reconstructing the ankle we had to use rods meant for the femur. While other orthopedic specialties were using screws and plates, we were often relegated to using multiple pins for lack of other options."

Armed with dexterity, Dr. Anderson returned to North Carolina, took his place amongst the "firsts," and used his talents to help heal old wounds. "I came back to Charlotte and started the Foot and Ankle Center at the Miller Orthopaedic Clinic with my former mentor, Dr. Boyd. It was pretty heady to be the first fellowship-trained foot and ankle surgeon in the southeast; I was hailed as a guru, but was only a year out of fellowship. It was very exciting when we were asked to revise a number of failed procedures for polio surgeries done in the 1950s and '60s. My colleagues and I also saw a lot of Charcot disease, a diabetic nerve condition that affects the foot and ankle. This condition has its hotbed of genetics here in the Charlotte area. It is a deformity that progresses over time, so we were trying multiple procedures to keep these people ambulating as best as possible."

In the early '90s a prominent football player with a problem helped launch Dr. Anderson (and his colleagues) into the world of high-level sports. "In 1992, a time when foot and ankle sports medicine was taking off, a Green Bay Packer with a recalcitrant foot problem reached out to us for help. There was little in the literature about his condition; he did well under our care, however, and made us 'look good.' It was word of mouth that led us to where we are now—we see the vast majority of foot and ankle injuries in the NFL and NBA and are the team physicians for the Carolina Panthers."

Dr. Anderson has learned that to provide excellent care, one must break out of the OR and go to the podium. "Working with these athletes is exciting, but the problems are complicated and the rehab issues are complex. Because my

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colleagues and I have found that many types of foot and ankle injuries are misdiagnosed or under diagnosed, we have dedicated ourselves to educating trainers and physical therapists. I spend much of my time traveling to NFL and college teams and in fact have just returned from Duke University where I lectured on turf toe injuries, a particularly interesting condition because it was originally believed to occur only on Astroturf. The media has publicized it as being just a sprain, but we now know that it's a complicated ligament injury that if untreated can result in severe arthritis and loss of one's career."

In 2005 Dr. Anderson received a nod from the NFL Commissioner and became the head the organization's committee to evaluate foot and ankle injuries. "It is terrific to be a part of the NFL's research projects as we seek to understand why foot and ankle injuries are increasing in number, what the mechanisms of injury are and how we can best prevent the players from being wounded. It may be the field surface, the shoes, the cleat patterns, and/or the size and speed of these players. We have teamed up with Nike, Reebok and other shoe companies to work on these issues, and the NFL has just hired the University of Virginia biomechanics lab to be a part of this multimillion dollar injury prevention project."

While all of this may sound dazzling, says Dr. Anderson, traditionally, foot and ankle has missed the boat in the glamour department. "Most people think foot and ankle specialists spend our days trimming toenails and handling diabetic feet. They don't see the wonderful opportunities we have to repair and reconstruct feet and ankles, and to keep patients walking with as little pain as possible. They don't know about the young person with the horrible deformity in small-town Georgia who had a new reconstructive technique done and is able to walk for the first time in 10 years. Future surgeons are warming to the field, however… recently there were 383 advertised jobs in foot and ankle, one of highest number of posted jobs in orthopedics."

On the home front, work continues, says Dr. Anderson. "My wife of 30 years puts up with the fact that work is my hobby. Our children are grown and have gone on to successful careers (one has worked for the St. Louis Rams and the other has worked for the Carolina Panthers). Nowadays my relaxation is cutting the lawn and playing golf."

Dr. Robert Anderson…helping others put their healthiest feet and ankles forward. ◆

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