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Orthopedics • This Week

week in review

05 Not Your Father's Wound Care ♦ Wound care; it doesn't do your surgery—it makes your surgery better. With nanocrystaline silver dressings, 1,000 miles per hour water jets and negative pressure dressings, Smith & Nephew's Tom Dugan makes a great case that it's not your father's wound care anymore.

09 Carpal Tunnel to IEDs ♦ How one simple device is offering diagnostic promise and stirring up debate about how doctors diagnose and treat everything from repetitive stress syndromes to traumatic brain injuries.

12 Delivering Bad News: *"Don't Tell Me"* ♦ Drs. John Bergfeld and Tim Hosea give details on approaching patients when the news is difficult to deliver and difficult to hear. How? Be prepared to outline a treatment program, have current data, and be positive.

16 Zuckerman to Callaghan ♦ The passage of the Presidency of the American Academy of Orthopaedic Surgeons from Joseph Zuckerman, M.D., to John Callaghan, M.D., mirrors the nation's debate over the future of health care in the U.S. Read what they told *OTW* in New Orleans.

the picture of success

31 Dr. Richard Parker ♦ He is the head team doctor for the Cleveland Cavaliers…he also is an ACL expert. Dr. Richard Parker, Chair of Orthopaedic Surgery at Cleveland Clinic in Ohio, studies the variables involved in ACL injury, as well as recovery after reconstruction.

breaking news

20 R.I.P. **Charité**

MAKO Revenues Up, Losses Down

Tillman Leaves FDA for Microsoft

Stryker Strikes at Mobile Bearing Knees

Exploding Numbers of Adult Stem Cells?

N.M.B.'s Nailing System Approved

Say Ah or Nah? **Bisphosphonates.**

For all the news that is Ortho, read on.

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- Reimbursement rates
- Associated procedures
- Private payer and Medicare data
- Patient demographics
- Regional and State charging data
- Associated diagnoses
- State reimbursement data
- Comorbidities

Spine Procedure U.S. Market Reports	Code
Spine Fusion	
Anterior cervical fusion	81.02
Posterior cervical fusion	81.03
Anterior dorsal and dorsolumbar fusion	81.04
Posterior dorsal and dorsolumbar fusion	81.05
Anterior lumbar fusion	81.06
Lateral lumbar fusion	81.07
Posterior lumbar fusion	81.08
Spine Refusion	
Posterior lumbar refusion	81.38
Other Spine Procedure	
Discectomy	80.51
Decompression	03.09

Large Joint Reconstruction	Code
Total Hip Replacement	81.51
Total Knee Replacement	81.54
Revision of Hip Replacement	81.53
Revsion of Knee Replacement	81.55
Excision of Semilunar Cartilage	80.6
Cruciate Ligament Repair	81.45
Synovectomy of the Knee	80.76
Removal of Implanted Device Tibia/Fibula	78.67
Hemiarthroplasty	81.52
Hip Resurfacing	00.85

Extremity Market Reports	Code
Ankle Fusion	81.11
Triple Arthrodesis	81.12
Subtalar Fusion	81.13
Total Shoulder Replacement	81.80
Partial Shoulder Replacement	81.81
Rotator Cuff Repair	81.63
Total Ankle Replacement	81.56
Open Reduction of Fracture Radius & Ulna w/ Internal Fixation	79.32
Open Reduction of Fracture Humerus w/ Internal Fixation	79.31
Open Reduction of Fracture Tarsals & Metatarsals w/ Fixation	79.37

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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Health care reform bill has passed and is about to be signed by Obama. What does it mean? More patients but not necessarily more money. Insurance rates will probably rise. Medical device profit margins, already under pressure, are more vulnerable. This was a political act, not a business act.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	11.00%	2.58%	Just 1x sales, beating Wall Street's estimates each quarter, building cash, paying off debt.
2	2	Exactech	12.61	9.84	Brigantine (who?) initiates coverage. On balance, EXAC is the 5th least expensive company in orthopedics.
3	3	Integra LifeSciences	15.37	10.03	From a trading standpoint, IART is a very streaky company. Right now, the trend is up. Will fundamentals support?
4	5	Johnson & Johnson	27.1	2.04	JNJ is the new bellwether stock by which Wall Street will measure the affect of health care reform on medical suppliers.
5	7	Alphatec	-0.44	31.53	Up two more spots this week on rising Wall Street expectations for future earnings.
6	6	Medtronic	31.37	2.49	MDT is the other bellwether stock. More units to be sold, but at lower prices under the new health care plan—we expect.
7	4	Stryker	24.71	6.55	MacMillan is becoming the dean of the device industry. His comments on health care reform were very thoughtful.
8	9	Smith & Nephew	19.17	-1.87	New faces in top places at SNN. Could the sleepy SNN be waking up?
9	8	Zimmer	27.71	-1.94	Health care reform, we think, favors larger companies like ZMH which are more efficient and have liquid balance sheets.
10	10	Symmetry	11.48	-1.33	SMA will need to be nimble to prosper in the coming 12-24 months post health care reform.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	NuVasive	NUVA	$45.84	$1,780	53.1%
2	Alphatec Holdings	ATEC	$6.80	$368	31.5%
3	RTI Biologics Inc	RTIX	$4.30	$235	27.2%
4	Regen Biologics	RGBO.PK	$0.30	$3	15.3%
5	Osteotech	OSTE	$4.13	$74	15.0%
6	CONMED	CNMD	$24.85	$725	11.5%
7	Integra LifeSciences	IART	$43.55	$1,240	10.0%
8	Exactech	EXAC	$19.20	$246	9.8%
9	ArthroCare	ARTC	$28.98	$779	8.9%
10	Orthovita	VITA	$4.18	$319	6.9%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TiGenix	TIG.BR	$4.12	$127	-16.6%
2	CryoLife	CRY	$6.63	$189	-5.0%
3	Wright Medical	WMGI	$16.63	$645	-4.5%
4	Zimmer Holdings	ZMH	$56.97	11,550	-1.9%
5	Smith & Nephew	SNN	$50.37	$8,930	-1.9%
6	Symmetry Medical	SMA	$8.88	$318	-1.3%
7	TranS1	TSON	$3.37	$70	-0.6%
8	Mako Surgical	MAKO	$12.89	$428	0.1%
9	Synthes	SYST.VX	$120.46	$14,295	0.8%
10	Capstone Therapeutics	CAPS	$1.10	$45	0.9%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Kensey Nash	KNSY	$22.78	$249	12.93
2	Medtronic	MDT	$44.79	$49,340	13.82
3	Symmetry Medical	SMA	$8.88	$318	13.88
4	Johnson & Johnson	JNJ	$65.11	179,180	14.06
5	Zimmer Holdings	ZMH	$56.97	$11,550	14.16

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$50.37	$8,930	76.86
2	RTI Biologics Inc	RTIX	$4.30	$235	48.67
3	NuVasive	NUVA	$45.84	$1,780	44.06
4	ArthroCare	ARTC	$28.98	$779	26.74
5	CONMED	CNMD	$24.85	$725	24.98

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CryoLife	CRY	$6.63	$189	0.72
2	NuVasive	NUVA	$45.84	$1,780	0.81
3	Integra LifeSciences	IART	$43.55	$1,240	1.04
4	Smith & Nephew	SNN	$50.37	$8,930	1.09
5	Alphatec Holdings	ATEC	$6.80	$368	1.24

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CONMED	CNMD	$24.85	$725	9.95
2	Orthovita	VITA	$4.18	$319	7.18
3	Johnson & Johnson	JNJ	$65.11	179,180	1.93
4	*Average*			*$11,772*	*1.74*
5	RTI Biologics Inc	RTIX	$4.30	$235	1.67

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$4.13	$74	0.77
2	Symmetry Medical	SMA	$8.88	$318	0.86
3	CONMED	CNMD	$24.85	$725	1.03
4	Orthofix	OFIX	$35.36	$606	1.12
5	Wright Medical	WMGI	$16.63	$645	1.32

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$4.12	$127	123.29
2	Mako Surgical	MAKO	$12.89	$428	12.51
3	NuVasive	NUVA	$45.84	$1,780	4.81
4	Synthes	SYST.VX	$120.46	$14,295	4.21
5	Orthovita	VITA	$4.18	$319	3.44

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Orthopedics This Week

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Not Your Father's Wound Care

By Robin Young

The Johnson brothers in the U.S., Smith and his nephew in Britain formed companies in the late 1800's to commercialize the then revolutionary concept of sterile surgical bandages. The corporate progeny of these four entrepreneurs are the only two companies with more than 100 years experience in wound care. In the late 1800s neither the Johnsons nor Smith nor his nephew could have imagined where wound care would wind up 130 years later. Wound care in 2010 is as much about negative pressure wound dressings, nanocrystalline silver dressings, and 1,000 PSI water jets as it is about infection control.

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Wound care; it doesn't do your surgery—it just makes your surgery better.

Shifting Practice of Surgery

When SNN's PR folks called to ask if we'd interview the head of wound care we jumped at it. The practice of orthopedic surgery is shifting, we think, to more risk management and strategies for creating better outcomes using such low-cost, low-risk innovations as wound care.

Tomorrow's orthopedic surgeon is going to have to get BOTH the surgical carpentry right and master the perhaps arcane aspects of wound care. Surgeons who do both well will invariably post-up superior outcome statistics. Time may heal all wounds, but in today's hospital, time is big money so attending to wound care is no trivial matter. For every day a wound goes unhealed, reciprocal costs involving care delivery, medications, and other risk factors (such as infection) increase. Lastly, products and methods used to treat wounds have evolved significantly in recent years, and product price is not an accurate performance gauge.

A recent study "Cost and Cost Effectiveness of Venous and Pressure Ulcer Protocols of Care," makes this point well. Three wound care protocols were tested on about 5,300 patients with chronic ulcers (among the hardest to heal wounds). The "tried-and-true" protocol was saline gauze (1,785 patients). The other two protocols were Comfeel and DuoDerm. The "old standard," lower-priced saline gauze approach was actually a higher cost approach (estimated to be $3.9 million on a 100,000 patient population) than the other, more expensive protocols

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(Comfeel and DuoDerm) when hospital stay, home healthcare, or long-term care costs were considered. The saline gauze protocol was penny wise/pound foolish.

Smith & Nephew's wound care division is the market leader in Europe and the second largest supplier in the United States. Tom Dugan is SNN's new President, North American business. He's excited about wound care. Especially the tough cases—like chronic wounds. In Tom's bag are a group of technologies that, no kidding, are interesting and exciting. We'll highlight just three.

Nanocrystaline Silver Dressings

Silver's anti-microbial properties have been known for more than a century. Smith & Nephew created Acticoat which delivers to the wound site an Ag+ form of silver, which can be release in a sustained, predictable way. Silver, which can be deactivated by choride or organic matter, must be released in a controlled manner.

SNN uses a nanocrystalline version of silver. Nanocrystalline refers to a production method called physical vapor deposition. This method creates a very porous material—essential to wound healing. Because it is porous, it allows water to permeate the silver more completely. In simple terms, the silver reaches dissolution in water at between 70 and 100 parts per million—reliably, consistently, every time.

Acticoat Absorbent with SILCRYST/Smith & Nephew

What does this mean for the surgeon?

- A silver anti-microbial barrier that is in direct contact with the wound bed
- An ability to kill micro-organisms in as little as two hours
- Broad spectrum activity against over 150 pathogens
- Sustained activity throughout the wear time of the dressing (up to seven days in vitro).

Wound Care at 1,000 Miles per Hour

I saw this once. Tough-guy motorcycle accident victim is sitting on the gurney waiting for the ER nurse to clean up his skin abrasions. She walks in with a scrub brush. He almost passes out.

A key part of wound care is debridement which is the removal of damaged, infected or dead tissues in order to create a healthy bed of tissues for eventual wound healing. But scrub brushes and scalpels are, to put it mildly, crude tools.

Enter Versajet. Versajet uses 1,000 miles per hour water in a safe, hand-held system to debride damaged or dead tissue with very high precision. With Versajet, case managers find that they can reduce the number of debridements, reduce healing time (compared to scalpel or scrub brushes), consume less operating room time, and, of course, lower costs.

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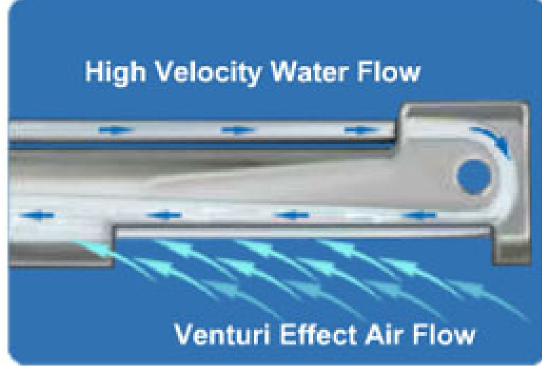
Better debridement means better outcomes. What kinds of outcomes? Better graft and synthetic dressing results (Cubison CS et al., *"Dermal preservation using the VERSAJET Hydrosurgery System for debridement of pediatric burns", Burns, 2006, 32,*



Source: Smith & Nephew

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714-720 and McCardle JE, "VERSAJET hydroscalpel: treatment of diabetic foot ulceration", British Journal of Nursing, 2006, 15, Tissue Viability Supplement).

Negative Pressure

Negative Pressure Wound Therapy (NPWT) seals the wound and prevents premature "bursting" open of a wound along the suture line (called dehiscence). This is a surgical complication that results from poor wound healing. NPWT reduces dehiscence with a gauze or foam filler dressing, a drape and a suction or vacuum source that applies negative pressure to the wound bed with a tube threaded through the dressing. The vacuum can continuous intermittent—depending on the type of wound and the physician's clinical objectives.

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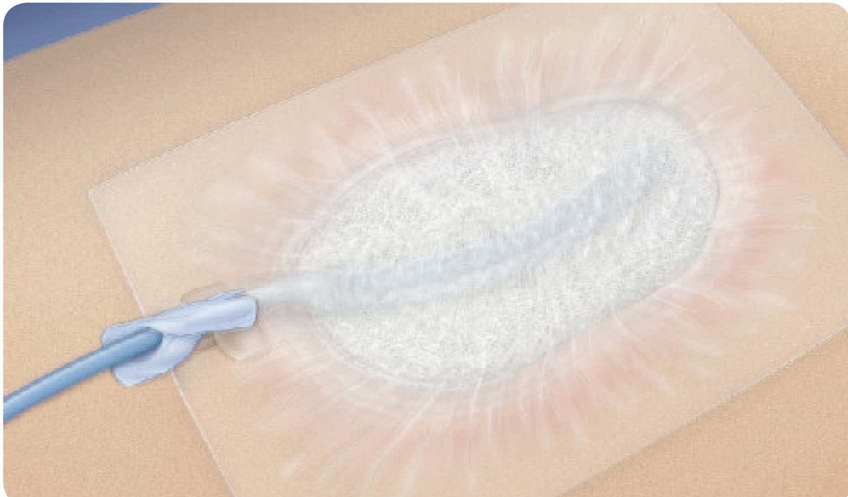
The vacuum pulls and drains excess serous fluids from the wound. In 1995 the Food and Drug Administration approved the first negative pressure system. It was originally marketed as a vacuum assistant closure (VAC) device by its manufacturer, Kinetic Concepts. In medical trials, the VAC device was shown to be as safe as, and more effective than, moist treatment for diabetic ulcers.

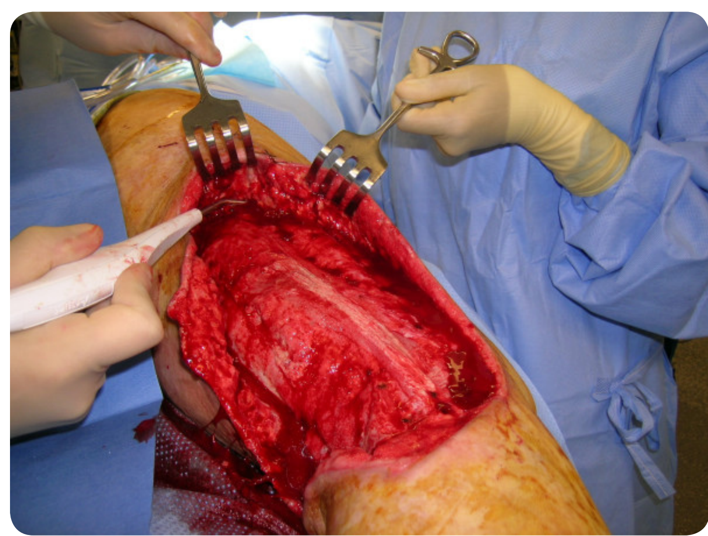


Negative Pressure Wound Therapy/Smith & Nephew

Most experts agree (see Willy C, editor. *The theory and practice of vacuum therapy. Scientific basis, indications for use, case reports, practical advice. Ulm,Germany: Lindqvist book publishing; 2006. 405 p)* that there are five ways that aids the healing process:

- Wound retraction
- Stimulation of granulation tissue formation
- Continuous wound cleansing after adequate primary surgical debridement
- Continuous removal of exudate
- Reduced interstitial edema

Willy, in his book, states that wound retraction under negative pressure brings the edges of the wound closer



together and thereby puts mechanical stress on the tissue. That stress helps to create micro deformations in individual cells. When they are so "deformed" they then stimulate production of cellular messengers which trigger more matrix synthesis and cell proliferation within the wound.

Several studies have noted that NWPT increases the rate of granulation tissue formation. Continuously pulling excess exudate reduces the bacterial burden present in a wound. Interstitial fluid (exudate) that accumulates in a wound may mechanically compress local capillaries and restrict blood flow into the wound. Removal of exudate from a wound may reduce tissue edema and promote blood flow back into the wound area.

In 2007, Smith & Nephew acquired Blue Sky Medical, which had developed its own NPWT system. Roughly a year ago, SNN announced and brought to market the RENASYS EZ and RENASYS GO NPWT systems. RENASYS works with both foam and gauze wound dressings.

Tom Dugan Gauging the Wind

Tom Dugan came to Smith & Nephew after 27 years in health care. Most recently he was SVP of Global Marketing and U.S. Sales at Sonosite. He was President of InverVascular (subsidiary of Datascope Corporation) before that. He also served as Vice President of Marketing for US Surgical Corporation, a division of Tyco Healthcare from 1999 to 2001, with responsibility for their Auto Suture and USS/D&G Suture businesses. From 1996 to 1999, he headed Business Development for US Surgical during a period of substantial corporate activity. Tom started his career at Johnson & Johnson's Critikon division and then continued his career in sales, marketing and international with C.R. Bard and Puritan-Bennett.

Dugan knows he has the chops and the technologies to make every surgery better, every surgeon stronger, every patient a faster healer. As Bob Dylan wrote a long, long time ago, you don't have to be a weatherman to tell which way the wind is blowing. Dugan can feel the winds of health care blowing and they would appear to be blowing in the direction of improved wound care.

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Orthopedics This Week
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Carpal Tunnel to IEDs

By Jacqueline Rupp

IED Simulation/Creative Commons

At first sight, the Time Resolve Force Technology doesn't look like a cutting edge breakthrough. About the size of a roll of quarters the steel cylinder has some wires sticking out and buttons which makes it look like a cross between a fishing lure and a woodwind. But device's creators, Dr. William Paske and his brother Charles who is currently marketing the device through his employment screening company Work Wright Inc. of Helena, Montana, see great potential.

The device, which measures how quickly a person's fingers can press buttons, collects the subsequent data and precisely compares to a base line number, is giving promising and even exciting results. But there's an interesting off shoot that occurred during the testing phase of this diagnostic instrument. It appears from research data collected that the Time Resolve Force Technology actually may be able to diagnose mild traumatic brain injury (MTBI) as well. And this development has sparked the U.S. military's as a tool for physicians serving in combat arenas.

William Paske/Work Wright Inc.

Checking for Carpal Tunnel

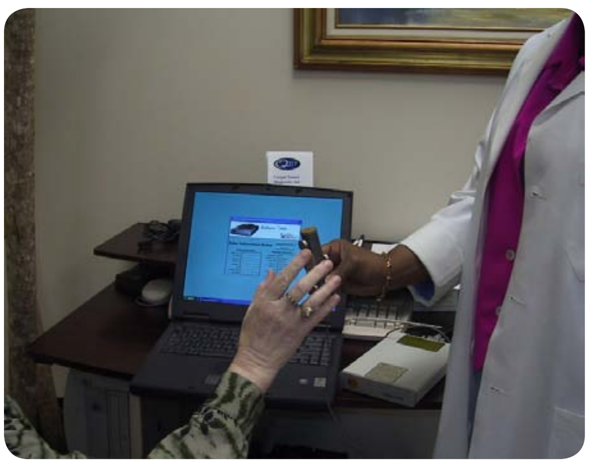
Carpal tunnel syndrome (CTS) is a collection of issues that result in pain and stiffness and may sometimes be caused by repetitive stress on soft tissues. It's also a huge portion of today worker's compensation costs. In fact, accord to Charles Paske, about 60 cents of every dollar in worker's compensation goes to the care of repetitive stress injuries of the upper extremities.

Charles Paske goes on to say that the current diagnostic procedures for CTS are under-performing. "There is about a 48% rate for CTS diagnosis and that means the current gold standards for diagnosis are grossly inaccurate. That number is just as good as flipping a coin." Paske says the Time Resolve Force Technology device is above 90% accurate.

Based on a pre-existing relationship with the state of Montana, involving the pre-screening of workers for hand problems, the Community Medical Foundation for Patient Safety of Bellaire, Texas, became involved in the testing of the device. Matthew C. Mireles, B.S., M.P.H., Ph.D., President and Chief Executive Officer of the Foundation led the testing of this FDA-approved instrument. "We saw it as a fast non-invasive way to screen people, to say this job might not be optimal for you."

"I figured out a way here to see if the ulnar nerve and the median nerve are communicating properly," explains Bill Paske. "If you hold a Styrofoam

coffee cup in your hand, your hand knows to hold it a certain way. Too much force and you crush the cup, to little pressure and you drop it. It all involves your hand receiving the right sensory feedback. "I measure what that functionality is and that helps to determine CTS."


William Paske/Work Wright Inc.

The device consists of three independent measurements of the index and small fingers and the thumb and checks for small changes in coordination. "We can make some fine measurements; we can see how things change over time," adds Paske. In fact the device collects about 180,000 bits of information every five minutes and tests both hands twice."We take advantage of the hand being tired, that's why we test twice."

Change Doesn't Come Easy

CTS is a very common repetitive stress injury and Mireles says it first began to appear in the 1970s when word processing became a major job function. He says CTS isn't just one affliction but a syndrome that's comprised of many issues, from inflamed nerves to muscular and bone-centered problems around the wrist and through the channel, where constriction and compression can occur. "It was during the 80s and 90s that orthopedists and neurologists began to see a large number of sufferers," states Mireles. "CTS became a cottage industry. Clinical diagnostic tools that are used are often inaccurate, painful and expensive. And today there is going to be a huge resistance to change in that routine."

Charles Paske knows resistance first-hand. Most of the physicians he's approached about the device have not exactly been beating down his door. Said Charles Paske: "We had the device reviewed by several publications and have measured hundreds of people to develop an accurate base line. But for us, it simply comes down to people making more money **not** using our device, so how do you market it then?" Mireles isn't optimistic of acceptance anytime soon, and with so many companies turning it away, it doesn't appear that the device will be available to potential patients for quite some time. "Of course you don't want to just roll a product out, but this one has been tested, for nearly a decade. One surgeon in Houston told me he will not operate on another hand until he uses this device. However there's not a financial incentive for others to feel the same way. I once heard a cardiologist say 'Why would I talk to my patients about diet and exercise?' and I think that's the common feeling about this product."

An Accidental Benefit Takes Center Stage

But remember that interesting aside that showed the Time Resolve Force Technology just might help with the treatment of MTBI? Charles Paske is banking on this unexpected outcome. The Paske brothers never intended for their device to be used to diagnose anything but hand conditions. Then a few patients that Mireles was testing came back with some interesting results. These patients didn't have CTS, but their results were off the base line findings. Paske's research team delved deeper into the medical histories of these outlier patients and learned that each one had at some

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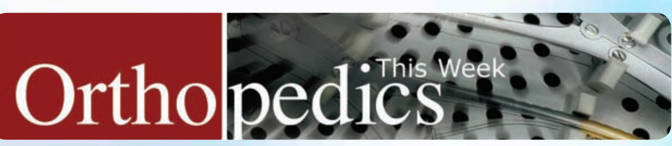

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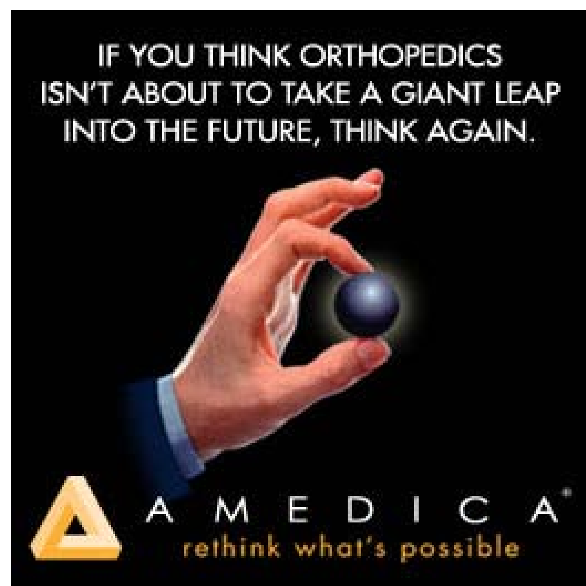
point in the past had suffered a form of brain trauma.

"We captured something very unique in the readings and began to think, 'Maybe TBI can be measured in the hand,'" says Mireles. At this point Charles Paske began to explore the further applications of the device and more testing began. The U.S. military became very interested in the Time Resolve Force Technology, not so much for severe brain trauma, but for the less severe type that often goes undiagnosed, but can have far reaching effects. "There are also going to be other applications, like in car crashes and sports medicine where MTBI is just getting the attention it deserves," continues Mireles. "We can test based on a normal base line and can then form a decision from real data. Right now for these types of injuries it's poorly subjective. A coach will ask you your name or something like that." He adds that the Time Resolve Force Technology fits perfectly into these situations because it's small, more convenient than an MRI and quickly offers a reading. A military application could also promise custom readings where each soldier is tested before going on duty to assess his particular base line, with subsequent readings being made after an injury is sustained.

Beyond the Obvious Benefits

With the connection made between finger reaction time and brain health, the possibilities for the Time Resolve Force Technology are growing rapidly and they could be far reaching. Mireles says that he sees a future beyond MTBI and is in the process of planning an early Alzheimer diagnosis study. "Many people think memory is the first thing to be affected by Alzheimer's, but actually if you ask close family members of a sufferer they will tell you handwriting is usually one of the first signs." The proposed study will follow people in their 40s and test them using the Time Resolve Force Technology to find out when the first signs of Alzheimer's begin, because it could be much sooner than anyone thinks.

It is interesting to note, however that the one condition the Time Resolve Force Technology device was designed for will probably be the last for which it is used. "I think it's going to be a long time before it becomes accepted for repetitive stress injuries," adds Mireles. "It will become more recognized for MBTI because of the military's interest and after that I think people will look at the carpal tunnel diagnosing potential because after all it has been approved by the FDA for that purpose. I just find it amazing that Dr. Paske invented something so simple, quick and accurate and all of things he chose to focus on hand functionality and from that has come so many possibilities."



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Delivering Bad News: *"Don't Tell Me"*

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

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Many orthopedic surgeons select this field because they are *not* dealing with life and death issues...because under most circumstances they won't have to say, "I'm sorry, but we have done everything that we can." That doesn't mean, however, that they never have to deal with human expectations, disappointments—and sometimes worse.

Dr. John Bergfeld, a senior surgeon in the Department of Orthopaedic Surgery at Cleveland Clinic, says, "In one worst case scenario an orthopedist could well have to deliver the news that someone has a tumor. It is vital in those cases to *not* get ahead of yourself in communicating with the patient…always know exactly what it is that you are dealing with. You should not only have all of the information on that patient, but know the current data related to that person's condition. Each tumor has its own outlook. You can't really give the patient a definite scenario. Whatever you do, though, don't walk in the exam room without being prepared to outline a treatment program for the person. This does many things, not the least of which is to give the person a sense of control and hope."

In conveying this information, surgeons should be especially careful in their choice of words. "Many times the patient suspects that something bad is happening to them. The most frequent reaction I get is, 'Are you sure?' You can never be 100% sure, so you should encourage them to get other opinions. Their next question is usually, 'What is the outlook if I go through all of this treatment?' Certain tumors can be cured, while others cannot—you've got to be careful with the use of the word 'cure.' I once had a patient with a synovial sarcoma who was told by a medical oncologist, 'You've survived three years and you are cured.' I called the doctor and took issue with what he had told this person."

Communicating such difficult information is a balancing act, says Dr. Bergfeld. "What the medical oncologist should have said was, 'You have survived three years and that is better than the average patient in this situation.' As you can imagine, he was terribly upset about this conflicting information. Unfortunately, a year and a half later he was dead. The bottom line is that you must tell them the truth while trying to be positive. A good statement is usually, 'We are going to go after this as aggressively as possible.' Most doctors aren't so comfortable with these discussions, however, and can make the mistake of not allowing enough time to talk to the patient. Ideally, you should schedule the patient for the end of the day so that you can give them the attention they need."

From a dawning feeling that something is wrong to the sudden realization that you're waking up in an ER, patients will likely need comfort. Dr. Bergfeld: "In the event of a trauma, say, a motorcycle accident where someone's leg is crushed, the person usually reacts along the lines of, 'This can't happen to me.' Their world is turned upside down because they could be disabled for a couple of years and may have to find another line of work. Before that, however, they must undergo skin grafts and bone grafts. You can assist them emotionally,

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however, if you take a team approach and together outline a program to get them as healthy as possible. If appropriate, you may refer them to counseling and an entity that can provide them with workforce assistance."

On the less dramatic, but still important, front, there are the injured athletes. "Most people I see with this injury never play basketball again." You may be thinking this, but don't say it. Dr. Bergfeld: "Let's say you have a talented athlete who tears his ACL. Only after I have the entire picture do I sit down with the patient and say, 'OK, we know what's going on here.' I focus on being positive but realistic. I will say, 'We have good ways to fix this and there is a 90% chance that you can return to your sport.' You do want them to realize, however, that there are 10% of people who don't make it back to their sport."

In many cases, either in adolescent sports or with those individuals who are on a professional level, treatment is a team event. "Get in the room with the athlete and his or her family member and outline everything, even what you will tell the public. I might say, 'OK Jim, there are eight other people who want to know what's going on with you. This is what I want to tell them.' It may be the trainer, the coach, or the agent who wants to know. Or it could be the media. In the latter situation, I will tell the athlete, 'Here is what I am going to tell the PR guy from the team and you and he can work out what you tell the newspapers.' I will not talk directly with the media. It's important

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that everyone is clear on this sort of thing. I recall an instance in which an orthopedist told a newspaper one thing and the athlete said another. The surgeon said, 'That is the worst injury I have ever seen.' The athlete was understandably shaken as he didn't want people thinking that he would never play again."

"If we slow down a little then we can act as doctors are supposed to act…with compassion. Some people need more reassurance than others. Tell patients that they should feel comfortable asking for more information. Have them go home and talk to their family members and let them know that they will probably have more questions later. Offer to talk to others such as parents who may be involved in and concerned about their situation. Yes, it's hard to imagine having time for all of this, but we must make the time. If you have 15 patients scheduled between 8 and 11 and you know this patient is going to take an hour and make you run behind all day…and on top of that you've got surgery, it's difficult. But no one said we'd have an easy job. If we're lucky, what we have is a meaningful job."

Tim Hosea, an orthopedic surgeon and partner with University Orthopedic Associates, LLC in New Brunswick and Princeton, New Jersey, also approaches difficult situations with caution. This sports medicine specialist says, "You should be careful to deliver the message at a level the patient can understand, without using esoteric medical terminology that may confuse the person. At the same time you don't want to be patronizing or present an arrogant front—just maintain a calm, professional manner. And as my colleague noted, don't deliver bad news until you are certain…otherwise the patient gets upset for no reason. If you suspect a problem, do a workup or refer the person if necessary."

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Knowing that participating in sports represents a significant part of a young person's life, Dr. Hosea always tries to stay positive. "Attempt to keep their thoughts focused on the half full part of the glass by engaging them in thoughts of the future. You can say for example, 'Yes, you will miss the next game, but you should be ready to play in the next event.' Get them involved in developing a treatment plan—that way they will be less likely to wallow in their current situation."

And to give the patient and his family time to acclimate to the new situation, Dr. Hosea states, "Let's say you do an initial evaluation on an athlete with a bad knee. It is good practice to give the person a range of possible diagnoses, saying, 'We're not sure yet. We may have to examine you under anesthesia.' If you ask them to return in a week it gives the family and patient a chance to get used to the new scenario, process it, and understand the options."

One thing you can't do? Delegate. Dr. Hosea: "Even though it's not fun to deliver bad news, it is never appropriate to duck the conversation. At no time should you leave this responsibility to your nurse or physicians assistant. You must sit down face to face with the person and take the time necessary to work through their concerns. In the end, this is what 'doctoring' is all about."

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Zuckerman to Callaghan

By Walter Eisner

Photo by Walter Eisner

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We heard more than once that the recent meeting of the American Academy of Orthopaedic Surgeons (AAOS) in New Orleans had nothing dramatic to offer. We heard complaints that no new blockbuster scientific advances or groundbreaking devices were announced or introduced.

Those looking for the trees would have missed the forest.

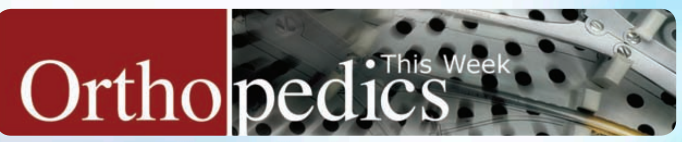
A Pivotal Moment for Orthopedics

This year's meeting of the AAOS and the passage of leadership from departing President Joseph Zuckerman of New York to the new President, John Callaghan of Iowa, comes at a pivotal moment for orthopedics as a national health care debate rages, a national device registry is on the cusp of creation, and new standards of proof for coverage and reimbursement loom on the horizon with the arrival of comparative effectiveness.

The passage of leadership melds Zuckerman's nimble handling of the Academy's engagement in the health care debate with Callaghan's hope for a steady focus on quality and research.

In an exclusive interview with *OTW* on March 9, Drs. Zuckerman and Callaghan stressed that a change in presidents does not change the current mission or path of the Academy. "We're all playing from the same sheet of music," said Callaghan.

Departing AAOS President Joseph Zuckerman, M.D.



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Balancing Interests

As stakeholders in the health care debate seek to protect their own interests, Zuckerman said physicians have to balance their own interests with the concept that the commodities physicians deal with are human beings with orthopedic problems.

"It's not like those other [stakeholders]. We always have to find the balance between the two [interests of patients and physicians]. That's why the health care issues, government regulations, the restriction on things, practice difficulties, all become important because they interfere or complicate the ability of orthopedic surgeons to provide the care that we want to provide for our patients in a manner in which we feel it should be provided."

"Physicians are no different than any other profession or field," said Callaghan. If physicians can do something better or more cost effective, he feels physicians are then truly helping the [healthcare] system by getting people through in a better and sometime, safer way.

Incoming AAOS President John Callaghan, M.D.

Focus on Quality

Callaghan will be focusing on the quality movement during his term. "For us [AAOS] that means we want to make sure that we understand what the important quality issues are and that there are appropriate quality measurements. Then we want to help our members and our patients understand what those measurements are and to help our members take better care of the patients." And, continued Callaghan, to do it in a more cost effective and efficient manner.

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"We think that is all part of the quality movement, but we are a little bit concerned that some in government may not have their eye on the right target. We want to try to help them redefine that," said Callaghan

Zuckerman's focus, before having to pile deep into the health care debate and marshal the Academy's resources on the Haitian orthopedic catastrophe, was on practice management.

"Why is practice management important?" asks Zuckerman, "Because you have to run a business efficiently. There are ways that you can do things that make it run more efficiently and decrease your overhead. At the same time, government regulations are adding more overhead like requirements for electronic medical record or other things. So, you know, it is harder to actually do that.

"So as an organization, we're trying to provide our members with help in that area. At the same time, if health care reform goes through, there will be many more patients that we are going to have to be taking care of. If the plan is to ensure another 30 million Americans with more ready access to care, they will have to be taken care of. They're going to require more care.

"So when John [Callaghan] talks about the ability to do things effectively over large populations of patients, consistently and effectively, that's important. We also need to take a closer look at what we do, how we do it and what works regarding comparative effectiveness."

Callaghan asked, "With the numbers Joe [Zuckerman] noted, there are going be 3.6 million total joints that

will need to be done. Who is going to do it? We are not training enough people because they do not want to go into this because they are concerned about reimbursement."

Callaghan's Passions: Quality and Research

Callaghan is ready to integrate his life long passions of research and quality into his term. He told attendees during his inauguration speech that the Academy went through a restructuring process six years ago and the Council on Research was changed to the Council on Research, Quality Assessment, and Technology.

He noted the Obama administration's call for comparative effectiveness initiatives and its injection of $1.1 billion dollars into NIH funding. "With the stimulus package, quality has come front and center," said Callaghan.

American Joint Replacement Registry Project

On another front, Callaghan told his colleagues that the Academy, through the American Joint Replacement Registry Project team led by David Lewallen, M.D., has made headway in making an independent voluntary non-regulatory hip and knee replacement registry a reality in the U.S.

"It will dwarf all the other registries in the world with the potential for 750,000 entries in the first year," said Callaghan.

Callaghan said this model for a registry, as demonstrated in countries throughout the world, has been shown to markedly improve the quality of care by behavior.

"Although it has taken us over nine years, I am convinced that this registry will come to fruition. We intend for it to represent a jewel for all of medicine to see the seriousness of our orthopaedic profession."

Implants of Interest

Henrik Malchau, M.D., one of the fathers of the Swedish registry and architects of the U.S. registry, said survivorship information gained from revision surgeries will identify "Implants of Interest."

CIGNA's Medical Director, David Mino, M.D., another architect of the U.S. registry told an audience that CIGNA will not use information from the registry to make coverage or payments decisions.

Some in the audience found that hard to believe.

Health Care Town Hall Meeting

The Academy offered its own version of a health care Town Hall Meeting presided over by President Zuckerman. The evidence of the important role advocacy took this past year at the Academy was noted in that the Academy's number of full-time equivalent employees went from 2.5 employees to 15. The Academy opposed the reform package proposed by Congress.

It was clear from Zuckerman's review of Academy advocacy efforts during the year that a schism developed between the traditional voice of physicians—the American Medical Association—and the surgeon societies.

Zuckerman didn't sugarcoat problems with the AMA over its support of the President's health care plan. "Many of us have been disappointed in the AMA," said Zuckerman. But he cautioned about a fragmentation of the physician voice, citing a "Divided We Fall" theme. "There has to be some cohesiveness to succeed," said Zuckerman.

AMA Schism

The schism with the AMA is particularly tricky for specialty societies because the AMA houses the AMA/Specialty Society Relative Value Scale Update Committee (RUC). The RUC makes annual recommendations regarding new and revised physician services to CMS (Center for Medicare and Medicaid Services). This proprietary tool makes the AMA a little like the Catholic Church before Luther spawned the Reformation.

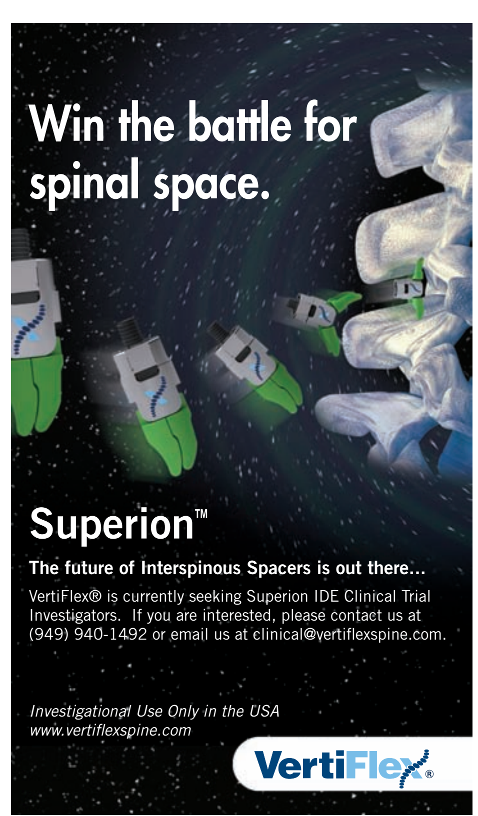
Perhaps nothing highlighted the role Zuckerman and the Academy played in the health care debate more than Zuckerman's highly publicized spat with President Obama over comments the President made about surgeons quick with the scalpel. After the spat, Zuckerman was invited to a meeting at the White House with senior administration officials.

"We met in the Treaty Room in a building near the White House," said Zuckerman. "I thought maybe we could get a casino deal out of the whole thing to pay for the costs of the health care bill," joked Zuckerman. His humor will be missed.

One courtly elderly physician from Kentucky asked his leadership panel what the official position of the Academy was on universal access to health care for all citizens. "You mean socialized medicine?" responded Peter J. Mandell, M.D., chair of the Council on Advocacy. That answer did not seem to go over well with some attendees as they admonished their leadership that they can't lose sight of the fact that they are patient advocates and not businessmen.

Zuckerman noted that the Academy did not have a detailed plan for universal access.

Joseph Zuckerman gave the Academy a clear and powerful (and often irreverent) voice as the nation went through a very loud public debate over access to health care. With the shouting out of the way, John Callaghan sets a course to makes sure that clear quality standards will define how that access will be served by physicians and paid for by government and private payers.



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company news

MAKO Revenues Up, Losses Down

MAKO Surgical Corp continued to increase the number of RIO robotic arm interactive surgical platforms and knee implants sold and minimally invasive orthopedic knee resurfacing procedures performed during the fourth quarter of 2009.

During the quarter, the company sold seven more systems, bringing the total systems in use to 36. The number of procedures performed increased by 181% from the fourth quarter of 2008, to 561. Since June 2006, 2,384 procedures have been performed.

The quarter also had the company sell its second unit to an existing site and saw monthly utilization per unit jump to six procedures per month from four procedures in 2008.

Revenues Growing, Losses Shrinking, Cash Rising

Fourth quarter revenues increased to $8.9, up from $1 million from the fourth quarter in 2008.

Dr. Ferré and the RIO

Losses narrowed as operating expenses increased to $13.8 million from $10.9 in the fourth quarter of 2008. Not bad when one considers revenues increased by $7.9 million and expenses only increasing by $2.9 million. At the end of the year, MAKO had $71.2 million in cash on hand, up from $63.6 in hand at the end of 2008.

The company also held two clinical education sessions during the quarter with prospective surgeon users and submitted two manuscripts to peer-reviewed journals.

Maurice R. Ferre, M.D., President and CEO of MAKO said on March 8:

> "The addition of seven new commercial sites, including for the first time, a sale of a second RIO system to an existing MAKOplasty site, and the 561 MAKOplasty procedures performed in the fourth quarter represent an increase of the adoption trends that we experienced in the first three quarters of 2009."

For all of 2009, revenues were $34.2 million, compared to $2.9 million in 2008. Losses for 2009 were $34 million compared to $37.6 million in 2008.

With revenues increasing, losses shrinking, more cash on hand and repeat customers, things look like they're moving in the right direction for MAKO.

—WE (March 17, 2010)

legal & regulatory

Wright Cleared by SEC

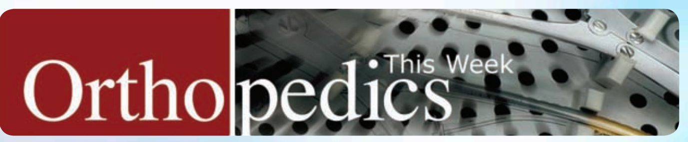
Wright Medical is in the clear with the Securities and Exchange Commission (SEC) regarding foreign sales practices.

According to an SEC document made public March 9, the company said it was advised by the SEC's Division of Enforcement "that this investigation has been completed as to [Wright] and that the Division of Enforcement does not intend to recommend any enforcement action by the Commission against [Wright]."

The SEC has been conducting an informal investigation of numerous medical device companies over potential violations of the Foreign Corrupt Practices Act. The Act is the international version of domestic Justice Department investigations of medical device company and surgeon relationships.

Industry Investigation

Other companies that had been subpoenaed in the informal investigation included Medtronic, Smith & Nephew, Stryker, and



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legal & regulatory

Zimmer. The SEC document only related to Wright.

In its 2008 annual report, Medtronic officials said the investigation's scope reached to "an unspecified number of foreign countries, including Greece, Poland and Germany."

Smith & Nephew's 2007 annual report said the SEC also wanted information related to its sales operations in Greece, Poland, and Germany, especially the Plus Orthopaedics business it acquired in 2007. The company took a heavy loss as it put to bed the Greek mess acquired from Plus.

In 2007, Stryker disclosed that the SEC made an informal inquiry regarding "possible violations of the Foreign Corrupt Practices Act in connection with the sale of medical devices in certain foreign countries. Subsequently, in 2008, the company received a subpoena from the U.S. Department of Justice, Criminal Division, requesting certain documents for the period since January 1, 2000 in connection with the U.S. SEC inquiry."

The *Kalamazoo Gazette* reported on March 10 that there was no word from Stryker regarding the end of the investigation.

Memphis' commercialappeal.com Web site reported on March 9 that a Medtronic official said the company had no comment on the matter. A Smith & Nephew spokesman said the company had not been notified that its investigation had ended.

Beginning of the End?

Whether or not the deferred prosecution settlements in the U.S. with the major orthopedic device companies and the ending of the SEC's investigation of Wright signals the beginning of the end of scrutinizing industry/surgeon relationships is hard to tell. Prosecutors haven't rested and got the scalp of an orthopedic surgeon from Florida earlier this month. The Brits recently announced the investigating a former DePuy executive, so there is likely more to come.

—WE (March 18, 2010)

biologics

Exploding Numbers of Adult Stem Cells?

New study grows an abundant amount of hardy adult stem cells thanks to one key type of blood vessel cell.

Growing adult stem cells hasn't been a problem for many research groups, however keeping them alive long enough to see any benefits from their existence has always been a sticking point. Now, scientists at the Ansary Stem Cell Institute at Weill Cornell are unveiling exciting findings that offer promising evidence to back up the importance of the endothelial cells in building and sustaining adult stem cells.

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Endothelial cells, that is, the cells that make up the inner linings of blood vessels may be the key to creating a bounty of viable adult stem cells.

So what's so special about endothelial cells? It turns out it has a lot to do with the nature of these cells and their proximity to adult stem cells in the body. So, senior author of the study, Dr. Shahin Rafii, Arthur B. Belfer Professor in Genetic Medicine and co-director of the Ansary Stem Cell Institute and his team imagined that these endothelial cells might help in nurturing adult stem cells in the body.

The group, using a mouse model, grew adult stem cells for several weeks and not only did the cells stay alive, but they grew in numbers to actually 400 times the original amount. Tumor growth is always a concern, but this study showed that after a year, there were zero indications of any type of abnormal growth.

This study, which appears in the journal *Cell Stem Cell*, comes on the

biologics

heels of Dr. Rafii's past work which originally showed endothelial cells to be more than just delivery men for vital nutrients. In that study, the team demonstrated that these special cells aid in the growth of new stem cells.

Up to now, one hurdle has been that adult organs have few stem cells, nowhere near the number needed for regeneration. Rafii points out previous attempts at culturing stem cells used serums and genetically manipulated cells, but by using endothelial cells, these extra measures weren't necessary.

The high-maintenance factor of endothelial cells had to be considered. These cells die quickly if they don't have the right "food" substances. By using genetically engineered endothelial cells that remain in a fixed survival state (an advancement pioneered by Rafii in 2008) the team was able to use these cells over long periods of time without constant tending.

"The endothelial cells act as feeder cells," explains Rafii. "This knowledge can aid in all aspects of therapeutic treatments because people right now can't get the quantity of adult stem cells they need and this study promises to provide huge amounts of stem cells."

"The sky is the limit!" says Rafii. "How do stem cells decide to go ahead and reproduce themselves? Endothelial cells can help us answer this question," adds Rafii. "Right now we have no clue, no one does, so little is actually known, but endothelial cells can help us."

And Rafii adds this will create significant impact in the orthopedic field. "We are actually working closely with a very prestigious group of orthopedic surgeons because this technology can have such important contributions to bone formation and bone regeneration."

—JR (March 16, 2010)

extremities

KO'd Bone Forces Doctors to Get Creative

A violent motorcycle crash leaves the driver without a critical piece of bone. What's more interesting is the solution doctors at University of Arkansas for Medical Science (UAMS) came up with to save the injured limb.

Motorcycle accidents can often present challenging injuries for doctors. But in 2008, doctors at the University of Arkansas for Medical Science were presented with a seriously strange problem. College student Michael Jevicky came in with three significant injuries, including a broken hip and a severed ulnar nerve sustained during a collision at an intersection.

But he also suffered a more unusual injury. "Five inches of the humerous bone in his upper right arm, had actually separated and come out of his body, says Dr. Ashfaq Hasan, Associate Professor of Orthopedics at UAMS who treated Jevicky. "So this was a very unique case. Three or four

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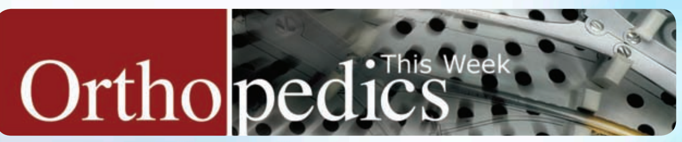

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extremities

days after the accident, we went in to do micro-surgical repair [on the ulnar nerve] and then were faced with the challenge of what to do for the limb." Dr. Hasan explains that the piece of bone that had popped out through a small laceration was contaminated in the crash and couldn't be reattached and a replacement bone had to be vascularized, otherwise the reconstruction wouldn't work.

Doctors at UAMS were left searching for a solution to this peculiar injury. After all, the bone needed to be repaired or Jevicky might lose his arm or in the least the function of the limb. Plastic surgeon Dr. James Yeun joined the team and the pair determined that a portion of the fibula would reconstruct the humerous.

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"Because of the missing segment the only way we could solve it was to provide bone that had vascularization," says Dr. Yeun. "In other words we needed a bone that had circulation. The fibula is a workhorse for us; we've done plenty with it for shoulder, head and jaw surgeries."

Dr. Yeun harvested the bone and blood vessels and because clotting was a worry, used a Doppler Laser to measure blood flow. "We took a piece of skin," explains Yeun, "and attached it to the bone and out onto the exterior. I used the Doppler to measures blood flow on this piece of skin. Otherwise, because the area of concern was internal, we wouldn't be able to see what was going on. This was done for around five days after."

Today, Dr. Hasan says that his patient is back to essentially full activity and the team will be writing this experience up so that other doctors can replicate it for repair of bone loss in the arm from infection or trauma.

—JR (March 16, 2010)

large joints

Stryker Strikes at Mobile Bearing Knees

Mobile bearing knees offer no clinical advantage over fixed bearing knees.

"The promise of mobile bearing knee systems are [sic] not fulfilled," said Patrick Treacy, Stryker's knee boss, at the recent AAOS meeting in New Orleans.

As evidence, Treacy cited a recent Stryker FDA-monitored investigational device exemption (IDE) study which found, "no statistical difference in clinical outcomes between its mobile bearing and traditional fixed bearing knee systems." *(Comparable Clinical Outcomes in a Randomized Clinical Trial of a Fixed Versus Mobile Bearing Posterior Stabilized Cemented Tricompartmental Knee Prosthesis. Ormonde Mahoney, MD; Tracy Kinsey, MSPH. Accepted for presentation at the Symposium on Mobile Bearing Total Knee Replacement Devices, ASTM Meeting, St. Louis, MO, May 18, 2010)*

Not surprisingly, the company said it was very happy with its fixed bearing Triathlon knee.

The company said laboratory tests demonstrate that its Triathlon knee, "shows a 97% reduction in total polyethylene volume loss compared with competitive mobile bearing knee systems," and, "offers the lowest risk of revision on the National Joint Registry for England and Wales, a risk of revision over four times lower than the best performing mobile bearing knees."

Treacy said that because mobile bearing knees in general offer, "no clinical advantages, carry an increased cost to their fixed bearing counterpart and result in a higher rate of revision

large joints

Stryker's Triathlon PS Knee System/Stryker

surgery than fixed bearing knees," Stryker has decided not to offer a mobile bearing knee system in the U.S.

What might this mean for Stryker's market share for knees?

PearlDiver Senior Analyst, Scott Ellison, told *OTW* that if the revision figures have had an impact in previous years then this could affect Stryker positively. According to PearlDiver figures from 1Q2008 to 4Q2009, Ellison says Stryker's market share in knees grew from 18.3% to 19.0%.

Added Ellison, "Other factors also helped their market share so it is difficult to view the true impact, but further data released will help to reinforce the success of the fixed bearing implant. This is a clear positive for their market position."

We note Stryker's reliance on foreign device registries for marketing purposes. Some of Stryker's competitors involved in establishing an American registry have shied away from encouraging the use of data from registries for such purposes.

—WE (March 16, 2010)

SNN Launches Shoulder Suture

You might want to throw your other **anchors away**…Smith & Nephew's Endoscopy Division has just rolled out the red carpet on its new TWINFIX Ultra PK Suture Anchor, a new anchor to address wide variation in bone density and tissue quality for rotator cuff repair in the shoulder.

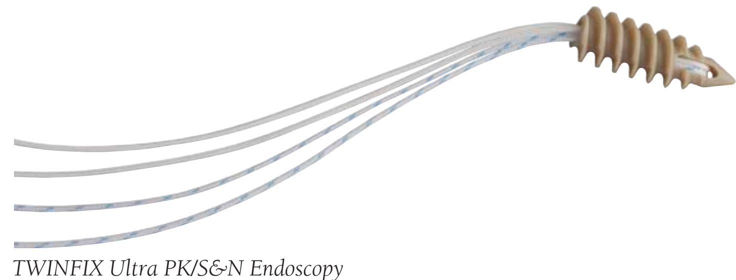
Smith & Nephew is highlighting that the new anchor, which is available in sizes ranging from 4.5 mm to 6.5 mm, incorporates a fully threaded design that makes it easier to insert and provides for exceptional fixation strength. According to the company's internal bench testing, the average fixation strength of the TWINFIX Ultra PK Suture Anchor is superior when compared against two leading competitive anchors.

"The thread count, or pitch, of the anchor is tighter than most anchors which gives it more grip in the bone," said Robert McLaughlin, M.D., Coastal Orthopedics, Beverly Hospital, Beverly, Massachusetts, in the news release. "It's also easy to use. I can insert and disengage the inserter easily with one hand—a feature you don't find in most anchors."

Joe Metzger, Vice President of Corporate Communications for Smith & Nephew Endoscopy, told *OTW*, "Both thread count and depth of the thread matter in fixation strength. It's not a fact that others don't have this, but it's our twin-thread design that provides both speed of insertion and strength. During the development process it's important that the final design consider/contain both these characteristics."

The anchor is molded from Invibio's PEEK, a polymer whose strength, stiffness and biocompatibility are similar to those of cortical bone. It also incorporates Smith & Nephew's ULTRABRAID Suture, which is made of a polyethylene fiber with a unique, proprietary braid configuration. The company indicates that it slides through tissue and anchors easily, resists fraying and creates a stronger knot than traditional suture.

"As a customer-led organization it's vitally important that we obtain voice-of-customer when it comes to product


TWINFIX Ultra PK/S&N Endoscopy

features and benefits," stated Alain Tranchemontagne, Senior Vice President, Global Marketing, Smith & Nephew Endoscopy, in the news release. "The fully threaded design we incorporated into the TWINFIX Ultra PK Suture Anchor is a direct result of that feedback."

Joe Metzger also commented to *OTW*, "Voice-of-customer was obtained through a number of means but mainly through a bioskills labs where we worked with surgeons on a number of iterations. Their clinical feedback led to changes that helped with speed of insertion."

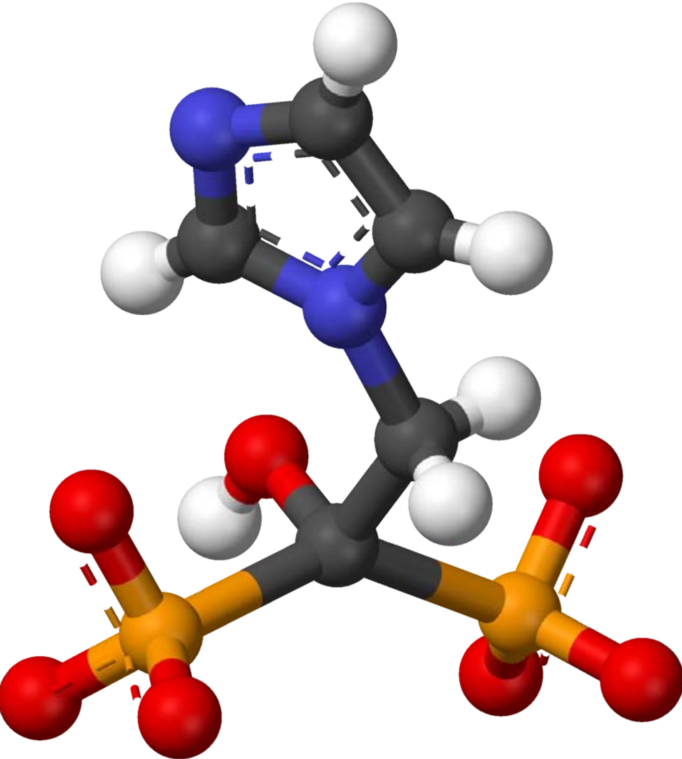
—EH (March 17, 2010)

Say Ah or Nah? Bisphosphonates

Patients taking oral bisphosphonates may feel like they're in an ortho-purgatory these days…recent reports of individuals on this medication experiencing femur fractures have raised a yellow flag.

Researchers from Hospital for Special Surgery (HSS) and Columbia University Medical Center have found that long-term suppression of bone remodeling by bisphosphonates may alter the material properties of bone, affecting the bone's mechanical integrity and potentially contributing to the risk of atypical fractures.

"Although bisphosphonates have demonstrated an improvement in bone quantity, little if anything is known about the effects of these drugs on bone quality," said Brian Gladnick, BS, of HSS, in the news release.



Zolendronate/Wikimedia Commons

"In the early treatment period, patients using bisphosphonates experienced improvements in all parameters, including decreased buckling ratio and increased cross-sectional area," said Melvin Rosenwasser, M.D., in the news release. Dr. Rosenwasser, an orthopaedic surgeon at Columbia University Medical Center, added, "However, after four years of use, these trends reversed, revealing an association between prolonged therapy and declining cortical bone structural integrity."

Scientists at both institutions hinted that at issue may be the fact that bisphosphonates suppress the body's natural process of remodeling bone.

Commenting to *OTW* was Kenneth A. Egol, M.D., professor and vice chair, Department of Orthopaedic Surgery, Hospital for Joint Diseases at NYU Langone Medical Center, who noted, "Bisphosphonates are proven very beneficial in treating women with osteoporosis. At the Hospital for Joint Diseases at NYU Langone Medical, we have seen an increase over the last 12 months in female patients presenting with unusual fracturing and some traumatic breaks of the femoral bone—particularly in women that have been taking bisphosphonate for longer than five years. We are working with colleagues across the medical community to further evaluate these cases, but it is very important that physicians tell their osteoporotic patients that there is no conclusive data connecting the two at this time but that they should always ask about use of long-term medication—particularly if they are experiencing unexplained pain in their hips or legs."

Lisa Cannada, associate professor of orthopaedic traumatology at Saint

large joints

Louis University School of Medicine told *OTW,* "We are seeing new studies on the issues related to long-term use of bisphosphonates; there is another study comparing the bone of bisphosphonate users who took calcium and vitamin D. What we do know for sure is that bisphosphonates are useful in preventing fragility fractures in post menopausal women for a short time period—i.e., 4-5 years. After that it becomes too much of a good thing and there is virtually no bone turnover."

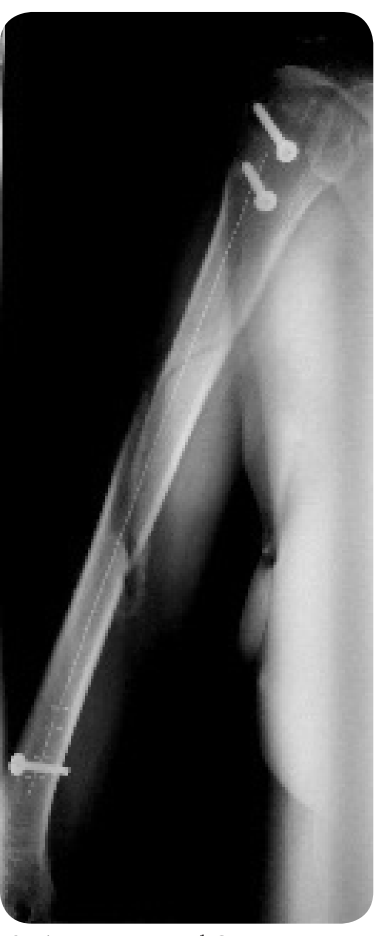
When asked how she would approach research in this area, Dr. Cannada told *OTW,* "I would study effective osteoporosis treatments after the four-year period, with a special focus on the effectiveness of calcium and Vitamin D after the four-year mark."

—EH (March 18, 2010)

N.M.B.'s Nailing System Approved

Excellence can sometimes be hard to nail down...for N.M.B. Medical Applications Ltd., however, they may have hit that nail on the head. The company is announcing that its QUANTUM Humeral Composite Nailing System, CE-approved in 2009, is now approved by the FDA.

The QUANTUM is an intramedullary interlocking nail made of ENDOLIGN, a product from Invibio Biomaterial Solutions. ENDOLIGN is an inherently pure and inert composite of continuous carbon fibers in a PEEK-OPTIMA polymer matrix, and enables patient/surgeon benefits that can advance the treatment of long bone fractures. According to the company, regulatory clearance was supported by biocompatibility data, Master File and other biomaterial and technical expertise provided by Invibio.



QUANTUM Humeral Composite Nailing System/N.M.B. Medical Applications Ltd.

A company spokesperson elaborated on "Master File," telling *OTW,* "This refers to Master Files for Devices (MAFs). These are confidential data and information that provided to the FDA by third parties (e.g., material suppliers) whose products are used in a device submitted for FDA approval. This information is kept on file with the FDA for reference during device evaluations. The type and extent of data varies greatly between companies and products, so not all implantable material suppliers will have the same level of information to support FDA submissions."

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According to Elad Einav, N.M.B. Project Manager, Invibio's advanced biomaterial gives the QUANTUM Composite Nail more highly tailored elasticity, higher fatigue strength, and MRI-compatibility, which is helpful in the MRI fracture follow-up. In addition, the nail's radiolucent properties enable fluoroscopic and CT visualization of the bone fracture site during implantation as well as during follow-up. PEEK-OPTIMA's proven, 10-year+ clinical history of safety as a raw material for implantable devices is another major advantage.

large joints

Other highlights of the QUANTUM include longitudinal marking for easy insertion, positioning and follow-up. Radiopaque markers over the distal interlocking holes enable easier drill trajectory adjustment. A propriety disposable radiolucent drill drive is also available. The company also notes that the mechanical properties of the QUANTUM can be tailored to meet a wide range of needs.

"The QUANTUM Nail is the first nail designed to treat long bone fractures that allows the surgeons to clearly see the fracture site and surrounding structures," Mr. Einav added in the news release. "This is especially important in cancer cases where it is critical that the bone structures and soft tissue are visible in follow-up."

Invibio President Michael Callahan told *OTW*, "The first FDA approval for a humeral nail made with Invibio's ENDOLIGN composite is more than just another noteworthy first for the company—the broader impact will be felt in terms of optimizing patient outcomes, extending surgeon options and advancing surgical techniques. Additionally, it indicates that even in this tough regulatory environment, the introduction of new technology is still possible."

—EH (March 17, 2010)

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Boskey Wins Shands Award

With a bow towards biology, the Orthopaedic Research Society and the American Orthopaedic Association have just presented Adele L. Boskey, Ph.D., the Starr Chair in Mineralized Tissue Research at Hospital for Special Surgery in New York, with the Alfred R. Shands, M.D. Jr. Award. Dr. Boskey, Director of the Mineralized Tissue Laboratory at HSS, is known for her work in biomineralization and osteoporosis.

"I can't think of a more deserving recipient," said Regis J. O'Keefe, M.D., Ph.D., President of the Orthopaedic Research Society, in the news release. "I am pleased and honored to have a part in this recognition of Dr. Boskey's distinguished work."

Adele L. Boskey, Ph.D.

Dr. Boskey told *OTW*, "It is a great honor to have been chosen as the 2010 Shands' Award winner for my achievements in orthopaedic research, to be the second woman chosen for this prestigious award, and to be counted among the orthopaedic research leaders who have changed the face of orthopaedic surgery today. I hope that my continuing mentoring and research activities will continue to have a sustained impact."

Dr. Boskey the Program Director of the Musculoskeletal Integrity Program at Hospital for Special Surgery, and was the first female President of the Orthopaedic Research Society. Her mentoring of other women researchers was recognized in 2008 with an award from the Orthopaedic Research Society Women's Leadership Forum.

people

Dr. Boskey's research focuses on bone quality, which takes into account the bone matrix and the mineral of bone. While most are using bone density to identify osteoporosis and the possibility of fractures, Dr. Boskey believes that measuring bone quality promises greater accuracy and could significantly decrease the number of patients that are at high risk for fracture because the quality, not quantity, of their bones puts them in danger.

Dr. Boskey is using infrared spectroscopy to approach the quality of bone when biopsies are available. Her laboratory, the Musculoskeletal Repair and Regeneration Core Center at Hospital for Special Surgery, which is one of only five national core centers funded by the National Institute of Arthritis and Musculoskeletal and Skin Diseases, is using this to understand how mineral size and content are tied into osteoporosis and fracture risk.

"Biology will become more important in the study and treatment of orthopaedic disease in the future," stated Dr. Boskey in the news release. In the case of arthroscopy she stated, "I foresee less of an emphasis on metals and devices and more on understanding the biology that leads to the need for a total joint or revision."

Elaborating on her work, Dr. Boskey told *OTW,* "My current research continues to focus on the extracellular matrix proteins that regulate the way bone and tooth mineral develops, on the role of collagen in controlling bone formation, and on understanding how current therapeutics modify bone quality."

—EH (March 15, 2010)

Tillman Leaves FDA for Microsoft

Another senior FDA official involved in the botched ReGen Biologics clearance process has left the FDA.

Donna-Bea Tillman, Ph.D., issued an email to her colleagues at the device division at the FDA on March 1 that said she was joining the Washington office of Microsoft Corp. Dr. Tillman has been with the FDA's Center for Devices and Radiological Health since 1994.

In the email, Tillman, who has a doctorate in biomedical engineering from Johns Hopkins University, said she was interested in the potential for health IT to "reduce the skyrocketing cost of health care."

She added, "One thing that gives me comfort is the knowledge that you all will continue to do the same great work that you have always done, so that the next time I am in need of a medical device, I can be confident in its safety and effectiveness."

She was at odds with some FDA staffers over the agency's decision to decide that ReGen's Collagen Scaffold had a predicate device and could therefore enter the market through the 510(k) clearance process instead of the more expensive PMA (premarket approval) process.

Dr. Tillman will become part of Microsoft's development efforts in medical information technology

Dr. Donna-Bea Tillman/picasaweb.google.com

people

systems and expand the profile of the company's health group in Washington. She said she would not personally lobby on behalf of the company.

A September 2009 internal FDA report on the ReGen clearance process said the decision-making process by Tillman, the ODE director, "may have been affected by her sense of professional loyalty." The report added, "The ODE director felt a duty to back the center director who by then had decided in favor of granting approval under the abbreviated process."

The director of the device division, Dan Schultz, M.D., resigned last August, before the release of the ReGen report. Dr. Schultz joined Greenleaf Health in January 2010.

Dr. Tillman said her departure was not related to the ReGen issue.

The FDA's orthopedic panel is meeting at the end of March to take another look at ReGen's device.

—WE (March 15, 2010)

spine

R.I.P. Charité

DePuy Spine made it public this week. It has stopped production of the Charité artificial disc invented by Karin Büttner-Janz, M.D., Ph.D.

Debbie Williams, DePuy Spine's Director of Communications confirmed in a March 18 email to *OTW* that the Charité disc was no longer in production. The Charité has been replaced by the In Motion artificial disc. Williams told OTW that the In Motion disc retains the Charité's essential features and incorporates several minor modifications designed to facilitate insertion.

The In Motion disc was first introduced in December, 2007. Williams added that DePuy Spine has not initiated any field action regarding the Charité disc.

"The In Motion disc builds on the essential sliding core design of the Charité," said Williams. She noted that the company has been working with customers since 2007 to phase in the new disc.

Legendary Status

The Charité disc will be remembered as having attained legendary status because its creation opened the door to further attempts to preserve motion of the spine through the total replacement of diseased lumbar and cervical discs.

DePuy Spine

The device had a lengthy road from its creation behind the Iron Curtain in East Berlin at the CHARITÉ University Hospital in the mid-1980s by the former Olympic gymnastic champion. Further refinements to the design were incorporated at Waldemar Link GmbH, a leading European based medical device manufacturer.

DePuy Spine acquired the Link Spine Group in 2003 and gained exclusive worldwide rights to the disc. The FDA approved the device in October of 2004 after extensive review of the two year U.S. clinical trial results. In addition to these studies, total disc replacement with the device was performed in Europe for over 17 years.

Since the FDA approved the artificial disc, more than 5,000 patients received the implant. But opponents such as Charles Rosen, M.D., criticized its design as well as the methods used to approve it. Numerous lawsuits were filed and are still pending. The device also prompted CMS (Centers for Medicare and Medicaid Services) to issue a non-coverage decision for all lumbar total disc devices for patients over 60.

The Charité may not have been perfect, but like Orville and Wilbur's airplane, it defined a "before and after" moment in scientific history.

—WE (March 19, 2010)

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trauma

Integra LifeSciences Lets Doctors Get Flexible With New Bone Filler

Integra LifeSciences launches new Moldable Morsels. Part of their Mozaik product line, this synthetic bone void filler gives surgeons a greater range of grafting options.

It's always nice to have your voice heard. And when Integra LifeSciences' Orthobiologics team listened to what surgeons were saying they needed from a synthetic bone void filler, those discussions led to the launch of Integra Mozaik Moldable Morsels. This product's standout benefits include enhanced composite grafting and optimized compression resistance.

Robert Seth, Director of Marketing at Integra Orthobiologics says the launch of Moldable Morsels rounds out Integra's Mozaik product line.

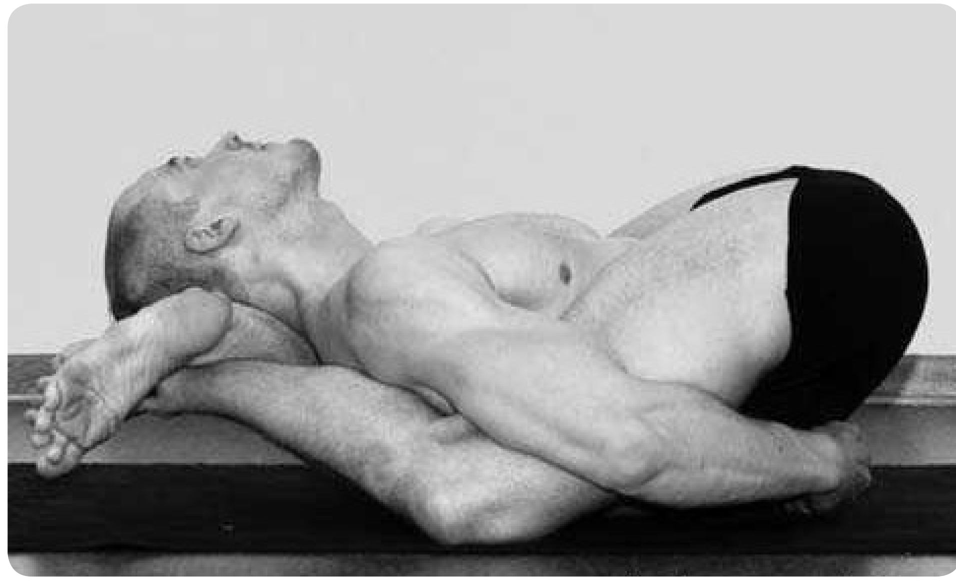
"What's exciting about Moldable Morsels is that we're evolving the Mozaik product line."

"We used the feedback from surgeons and listened to what they were asking for. The Moldable Morsels provides better handling in a different format and is designed in an easy to mix packaging to make composite grafting easier."

"The reason we have so many different products," adds Seth, "is because surgeons have different preferences and our goal at Orthobiologics is to accommodate that diverse spectrum of preferences.

Moldable Morsels uses a pure type 1 collagen that utilizes the same patented collagen technology that is employed in other Integra products, like DuraGen.

"Integra has had 20 years of experience with collagen," explains Seth. "Our collagen has been implanted in 10 million people and used in everything from burn treatments to neurosurgery. The collagen technology is a beautiful fabric and it was only natural to extend that to bone regeneration and the latest launch gives us another way to deliver that technology while taking into account the personal preferences of surgeons."



Yoga Nidrasana/Creative Commons

Beside the robust handling and large compression benefits, Moldable Morsels also features a pure tricalcium phosphate composition, which makes it easily reabsorbed and replaced by natural bone. "This is very important, because when you implant you want it to be replaced by natural body tissue, and this implant is efficiently reabsorbed and replaced by natural bone," says Seth.

Seth adds that the new Moldable Morsels will offer surgeons many applications, in a new, easy-to-use design. The packaging makes mixing composite grafts easier and the new product is also simpler to hydrate. The spine market in particular should take note of the launch as the Moldable Morsels can work particularly well in small spaces. However, Seth points out that the applications are nearly limitless.

The real beauty of this product is its incredible versatility; the Moldable Morsels can be used for so many different treatments, surgeons of all types should find it extremely useful.

—JR (March 17, 2010)

The Picture of Success: Dr. Richard Parker

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

Dr. Richard Parker, Chair of Orthopaedic Surgery at Cleveland Clinic in Ohio, learned the art of diplomacy in a crowded Buick. Raised in Youngstown, Ohio, Dr. Parker says, "My father owned a dry cleaning business and both he and my mother drove home the point that my two siblings and I needed to work hard and be responsible. My father put his customers first, something that is not lost on me as I go about my workday trying to put patients first. As the middle child I was the peacekeeper in the family. There were many trips in the family car where I had to sit between my older brother and younger sister in order to keep them from hurting each other. This early lesson in peacemaking goes a long way toward helping me negotiate interactions with residents, fellows, and peers."

While somewhat motivated by the shock factor in science, Richard Parker came to see that there were real life possibilities for his interests. "The most fun part of my science education was a project my freshman year when I dissected an earthworm and examined the six aortic arches. (I enjoyed the fact that it freaked out the English teacher, who promptly fled the room.) Overall, however, I spent more time on athletics than on my studies. When I had an injury, and went to a well respected podiatrist in Youngstown, something clicked and I found myself interested in his work. As I moved into my college years I realized that if I studied I would do well—and that the medical field held infinite possibilities and frontiers."

After graduating from Walsh College in Canton, Ohio, Dr. Parker took his emerging interest in medicine to Ohio State University's College of Medicine in 1981. "I was a little concerned about measuring up because I had attended from a small school (85 people in my graduating class) but Walsh had prepared me very well. The combination of a good college foundation and the fact that I was raised in a family with an incredible work ethic meant that I could complete medical school in three years."

A young Dr. Parker's philosophy was taking shape along the way. In part, he felt, "What is the point of your days if you are not able to live as you wish?" Dr. Parker: "I was leaning towards cardiology, but after an orthopedic rotation that went by the wayside. The visual side of things in orthopedics—the anatomy—along with the engineering that was required, was very alluring. I saw that orthopedists could vastly improve quality of life, something as important if not more important than saving lives."

Since so much of his youth had been spent on the athletic field, Dr. Parker was naturally intrigued by how knee twists caused injuries and what happens when ankle ligaments are overstretched. "While in medical school I was given the opportunity to be student doctor for the school's athletic department. I was assigned to hockey and it amazed me to see how accepting athletes were and that they called me 'doc' from the outset."

An internship then narrowed his focus. "In 1982 I did six months of surgery and six months of internal medicine at The Mount Sinai Medical Center (now closed) in Cleveland. This experience solidified my desire to pursue orthopedics...I didn't like that, with regards to chronic diseases, we are only able to temporize and not influence them in a more permanent and positive manner."

Remaining at Mount Sinai for his residency, Dr. Parker learned the importance of avoiding the random approach to treatment. "The Chair was Dr. Avrum Froimson, a superb doctor who insisted upon an extraordinary attention to detail. 'Do step A correctly,

then move to step B, then C…no skipping B.' Dr. Malcolm Brahms, the former Cleveland Browns team orthopedist, also influenced me in the caring way that he worked with patients, and on more specific situations such as how to behave in a training room."

He already knew how to behave in an OR—talk. "In 1986 I began a sports medicine fellowship at Orthopaedic Specialty Hospital in Salt Lake City, where I was able to train with two of the most innovative, respected sports medicine surgeons in the country. Dr. Tom Rosenberg taught me how to be an arthroscopic surgeon, emphasizing attention to detail and the importance of doing things in a methodical fashion. At the same time he stressed innovation, something which allowed me to develop new ways of doing things. It was a really stimulating environment as there were always engineers and industry people who were picking his brain during surgery."

"Also showing me the arthroscopy ropes was Dr. Lonnie Paulos, who taught me the importance of engineering and biomechanical research. He showed me the pitfalls of not carefully reading the literature—he also made sure I understood how to synthesize it. I got to learn as he performed innovative arthroscopically guided procedures that were not yet being done in Cleveland."

Returning to Mt. Sinai in 1987, Dr. Parker was charged with building the department's sports medicine program. "Although things came together pretty well, I wanted to care for athletes beyond high school and could see that this was probably not a possibility

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at Mt. Sinai. In 1992 I learned that Cleveland Clinic was adding another surgeon and after a long interview process I joined their staff the next year."

The early lessons in statesmanship would serve Dr. Parker well in his next roles.

"I soon became fellowship director for sports medicine and then was later named Education Director of Sports Health for Cleveland Clinic Sports Health. This meant that I had responsibility for the orthopedic sports medicine fellowship, the primary care sports fellowship and some of allied health programs. I came to see the importance of understanding that each of these disciplines historically have a different way of approaching their educational experiences, including, for example, how much case based learning is involved."

More and more, the young man who once wondered if he would "measure up" had his answer. "In 1997 I had my first break as a head team doctor at a professional level. I had been working as the team physician for the local all boys' high school when I was approached to be the team doctor for the new Women's National Basketball Association franchise, the Cleveland Rockers. I held that position for the five years they were in existence and because of that experience, in 2000, I was asked by Dr. John Bergfeld of

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Cleveland Clinic and the Cleveland Cavaliers to be the head team doctor. The adrenaline rush for me being on the sidelines is as thrilling today as it was then."

"The Cleveland Cavaliers basketball team has improved its record from 17 wins in 2004 to 66 wins in 2009…I had much to do with that of course… me and a certain gentleman named Lebron James. While the medical staff is there to maximize the athletes' potential and help them have a long career, the reality is that when the team is losing the team doctor is faced with a situation where injuries that might otherwise have been considered to be trivial can be magnified. The bumps and bruises hurt more, and the depth of a team's talent may not be as great and, as a result, players may not be able to take off as much time to heal."

Dr. Parker's mentors would be pleased to find that their former trainee has found his own creative spark. "I have been able to participate in the development of several arthroscopic, as well as open, techniques related to posterior cruciate ligament reconstruction, all of which involve an inlay technique. Another topic of interest for me is knee meniscal cartilage transplantation, an area in which I have developed techniques and guides which provide surgeons easier access of fixation points."

In 2005 Dr. Parker became Professor of Surgery at the Cleveland Clinic Lerner College of Medicine. "Three years later Cleveland Clinic changed to the institute model and so the orthopedics and rheumatology departments joined to form the Orthopaedic and Rheumatology Institute. After a national and international search in December 2009 I was chosen to be the Chair of the department of orthopedic surgery."

Dr. Parker would then focus his experience and dynamism and enact a higher level of personal efficiency. "Becoming Chair meant going from 90% clinical care to 40%; this demanded that I refocus my efforts in order to be as clinically efficient as possible. In preparation for this I stopped performing shoulder surgery two years ago and began focusing on the knee. Since then I have narrowed my focus to knee problems as they relate to sports and arthritis in patients who are under my ongoing care."

Dr. Parker informs his clinical work with a devotion to systematically studying ACL injuries. "We are involved in the Multicenter Orthopaedic Outcomes Network, a group of eight medical centers including around the country that have come together to investigate the variables associated with ACL injury, as well as those affecting recovery after reconstruction. This is a longitudinal cohort that has resulted in numerous observations which are helping us give our patients appropriate prognoses."

Some of that advice makes in onto the court. "My passion is being the Head Team Physician for the Cleveland Cavaliers. It's really the merger of work and hobby. I reserve much of my energy for my family—my wife of 30 years, Jana, and our two children; Aric who is 21 years old and is enrolled at school in Boulder, Colorado, where he studies Eastern Religion and Jaclyn who is 19 years old and is in college here in Cleveland. I do indulge in the typical doctor sport of golf, and I also enjoy the adventure involved in traveling."

Dr. Richard Parker…dedicated to ensuring that people can live as they wish.

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