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Orthopedics This Week

week in review

05 Orthopedic Heroes of Haiti ♦ The devastating earthquake in Haiti offered the greatest challenge of our lifetime to the orthopedic community of caregivers, professional societies and device companies around the world. How did they respond? Read it here.

11 Bone Cancer: Can the Limb be Spared? ♦ Dr. James Wittig, Chief of Orthopedic Oncology and Sarcoma Surgery at Mount Sinai in New York, knows that most patients with bone and soft tissue sarcomas don't require amputation. Chemotherapy and surgical advances have made the difference.

14 Bruising Biologics Battle Erupts ♦ Last week, CryoLife slammed Medafor against the boards by mailing an open letter to Medafor's shareholders urging them to override management's decision NOT to sell to CryoLife. The gloves are off and CryoLife's Steve Anderson is back in his customary Bad Boy role.

the picture of success

38 Dr. Denis Clohisy ♦ He chairs the AAOS research development committee, has had 22 years of NIH funding, and knows the world of bone cancer. This is Dr. Denis Clohisy, Chair of the Department of Orthopedic Surgery at the University of Minnesota.

breaking news

18 Stryker Finishes Strong in 2009

Treating **Osteoporosis** With Microchips

Brings Stem Cells to **Alphatec**

Shuren **New** Device **Chief at FDA**

Researchers Create **Strongest** Form of **Collagen**

Yielding Sentenced to Prison

TransS1 Lowers Revenue Expectations

For all the news that is Ortho, read on.

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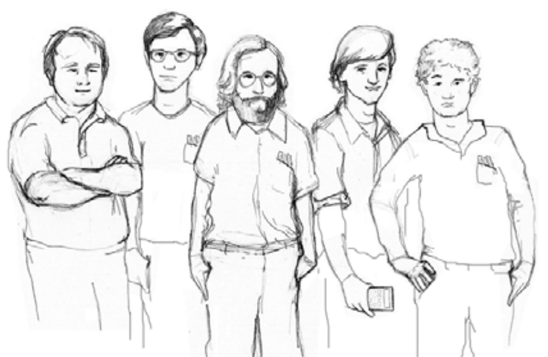

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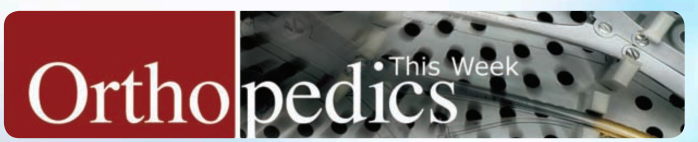
Spine Procedure U.S. Market Reports	Code
Spine Fusion	
Anterior cervical fusion	81.02
Posterior cervical fusion	81.03
Anterior dorsal and dorsolumbar fusion	81.04
Posterior dorsal and dorsolumbar fusion	81.05
Anterior lumbar fusion	81.06
Lateral lumbar fusion	81.07
Posterior lumbar fusion	81.08
Spine 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
Revision 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	83.63
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/ Internal Fixation	79.37

(2004-2008 U.S. Procedure, Sales, Charging and Demographic Data as derived from Medicare AND Private Payer datasets)



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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Orthopedic values took a hit this past week, as did most equities, as the news coming out of both Wall Street and Washington increased concerns over the U.S. economic outlook. The cloud over profit margins and pricing pressures continues. On the bright side, SMA, IART and SYK are bucking the trends.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Integra LifeSciences	15.37%	7.26%	Integra gets another analyst upgrade as RBC capital markets joins JP Morgan with a "Buy."
2	2	Medtronic	31.09	(0.12)	Buys Invatec for $350 million. Doesn't change outlook. Now 2nd cheapest stock in Ortho—after a wholesaler (SMA).
3	5	Stryker	23.50	6.19	Up two spots this week on growing consensus that 2010 will be stronger than 2009 in all respects.
4	4	Symmetry	11.48	13.59	Upgraded by Piper and signs exclusive deal with hot young company—OrthoPediatrics.
5	3	Zimmer	28.10	1.93	Swaps places in the power rankings with SYK due to valuation (higher PSR and PEG).
6	9	Smith & Nephew	22.42	(1.38)	SNN, a leader in wound healing and trauma, was also a leader in the Haiti relief effort. Up three spots.
7	8	Wright Medical	6.61	(5.16)	WMGI will need to report this quarter (expected to be down) to get focus on a 2010 rebound.
8	10	Johnson & Johnson	26.94	(2.06)	Will last year's reorganization create new value? Or is JNJ still too large to grow?
9	6	Exactech	12.61	(10.70)	No news since last October. Buyers need a reason to stay tuned. 2009 numbers expected to be flat.
10	7	CONMED	6.92	(7.70)	Like EXAC and WMGI, CNMD needs to announce 2009 and move into a better 2010.

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Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGBO.OB	$0.30	$1	56.6%
2	Capstone Therapeutics	CAPS	$0.81	$33	22.7%
3	Osteotech	OSTE	$3.57	$64	20.2%
4	Mako Surgical	MAKO	$12.70	$422	18.1%
5	ArthroCare	ARTC	$27.50	$737	16.3%
6	Symmetry Medical	SMA	$9.11	$326	13.6%
7	TiGenix	TIG.BR	$5.88	$145	8.0%
8	Integra LifeSciences	IART	$38.71	$1,100	7.3%
9	Stryker	SYK	$54.04	$21,490	6.2%
10	Synthes	SYST.VX	$138.57	$16,445	5.5%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Exactech	EXAC	$16.69	$214	-10.7%
2	TranS1	TSON	$3.17	$65	-10.2%
3	Orthovita	VITA	$3.43	$262	-9.0%
4	CONMED	CNMD	$21.58	$628	-7.7%
5	RTI Biologics Inc	RTIX	$3.18	$173	-7.3%
6	Alphatec Holdings	ATEC	$4.87	$256	-6.0%
7	Wright Medical	WMGI	$18.00	$695	-5.2%
8	CryoLife	CRY	$6.20	$176	-4.5%
9	Johnson & Johnson	JNJ	$63.20	174,380	-2.1%
10	Smith & Nephew	SNN	$49.92	$8,820	-1.4%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Symmetry Medical	SMA	$9.11	$326	8.98
2	Medtronic	MDT	$43.30	$47,830	13.60
3	Johnson & Johnson	JNJ	$63.20	$174,380	13.87
4	*Average*			*$11,567*	*14.78*
5	Kensey Nash	KNSY	$25.45	$282	14.82

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$49.92	$8,820	80.77
2	Synthes	SYST.VX	$138.57	$16,445	43.09
3	RTI Biologics Inc	RTIX	$3.18	$173	38.96
4	NuVasive	NUVA	$31.56	$1,210	28.89
5	ArthroCare	ARTC	$27.50	$737	24.19

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Orthofix	OFIX	$30.40	$521	0.83
2	CryoLife	CRY	$6.20	$176	0.83
3	Symmetry Medical	SMA	$9.11	$326	1.15
4	Exactech	EXAC	$16.69	$214	1.16
5	Medtronic	MDT	$43.30	$47,830	1.24

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$31.56	$1,210	3.01
2	Zimmer Holdings	ZMH	$60.59	$12,900	1.87
3	Johnson & Johnson	JNJ	$63.20	$174,380	1.83
4	RTI Biologics Inc	RTIX	$3.18	$173	1.71
5	*Average*			*$11,567*	*1.70*

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$3.57	$64	0.70
2	Symmetry Medical	SMA	$9.11	$326	0.83
3	CONMED	CNMD	$21.58	$628	0.94
4	Orthofix	OFIX	$30.40	$521	0.99
5	RTI Biologics Inc	RTIX	$3.18	$173	1.12

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$5.88	$145	202.04
2	Mako Surgical	MAKO	$12.70	$422	15.66
3	Synthes	SYST.VX	$138.57	$16,445	10.05
4	Kensey Nash	KNSY	$25.45	$282	3.53
5	NuVasive	NUVA	$31.56	$1,210	3.49

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Orthopedic Heroes of Haiti

By Walter Eisner

Photo Courtesy: PD-USGOV-MILITARY-NAVY / Wikimedia Commons

Haiti Earthquake/UN Photo/Logan Abassi / Wikimedia Commons

"It looks like an atomic bomb went off in Port-au-Prince," is how philanthropist Hank Asher described what he saw a week after a 7.0 earthquake hit the island nation of Haiti on the western end of Hispaniola. The earthquake created one of the greatest needs for the assistance of the orthopedic community in our lifetimes.

The orthopedic community responded quickly, generously and efficiently. Within hours hundreds of orthopedic surgeons, caregivers and device company employees volunteered to help and rushed to Haiti.

The Catastrophe

The January 12 earthquake has been estimated by various organizations to have killed approximately 200,000 people, with 80,000 already buried in shallow graves and hastily dug trenches.

"We just dump them in," said one relief worker directing trucks with the dead bodies.

But it wasn't the dead who needed help. The earthquake not only destroyed, injured and displaced over three million people, but according to the Pan American Health Organization/World Health Organization, at least eight healthcare facilities, including at least four hospitals, were destroyed or severely damaged in the earthquake.

On Saturday, January 16, CNN reported that Jennifer Furin of Harvard Medical School noted that almost a third of the patients at a makeshift hospital on a United Nations compound near Port-au-Prince's airport would die without surgery. "They will die of infections, they'll die of dead tissue," said Furin.

Hastily erected emergency medical centers almost everywhere were swamped with patients critically injured by the quake. There were dire shortages of surgeons, nurses, medicines, and medical tools.

Crush Syndrome

Doctors said patients were dying of sepsis from untreated wounds. "A large number of those coming here are having to have amputations, since their wounds are so infected,"

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USNS Comfort Arrives in Haiti/Army Knowledge Online (AKO) / Wikimedia Commons

said Brynjulf Ystgaard, a Norwegian surgeon at a Red Cross field hospital.

Edward P. Fink, M.D., was quoted on the American Academy of Orthopaedic Surgeons' (AAOS) Web site, "We are seeing the first wave of patients currently—those individuals who have significant open injuries, crush injuries, and lacerations. The next wave will be individuals with closed fractures who will require treatment; the third wave will be individuals with musculoskeletal complaints without obvious fractures."

Help Arrives

By Wednesday, January 20, the United Nations had brought in seven field hospitals to augment those few Haitian facilities left standing. On that day the USNS *Comfort* hospital ship also arrived.

The *Comfort* was carrying nearly 550 doctors, nurses, corpsmen, technicians and support staff, who were joined by 350 other medical staffers once the ship reached Haiti, according to the U.S. Southern Command. CNN reported that the ship has six operating rooms available and can house up to 1,000 patients.

One hospital left standing was the Adventist University Hospital where an American volunteer, Eli Call told one reporter, "We have 300 to 400 patients waiting to be seen, and if we can't get to them in the next 48 hours, half could die."

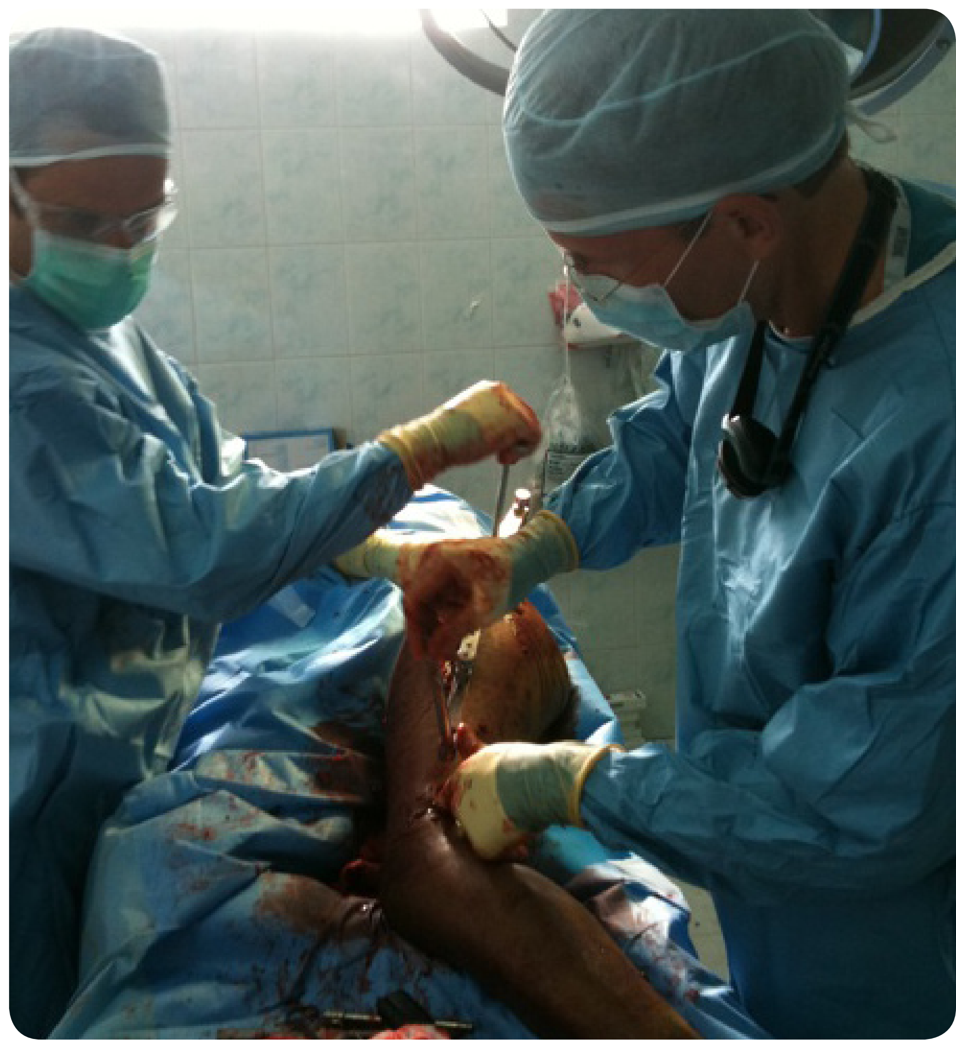
Dr. Scott Nelson, the first orthopaedic surgeon to start work in Haiti following the quake is joined by SIGN's Dr. Lewis Zirkle at Adventist Hospital / SIGN / blogspot.com

As is often the case, the Surgical Implant Generation Network (SIGN) and its founder Lewis Zirkle, M.D., were on the scene within days and began working out of Kings Hospital in Port-au-Prince.

Orthopedic Community Leaps into Action!

The rest of the worldwide orthopedic and surgical community also responded immediately.

Within hours of the quake, Synthes Chairman Hansjörg Wyss, M.D., contacted the Hospital for Special Surgery (HSS) in New York and offered the company's airplane to bring a team of anesthesiologists, nurses and orthopedic trauma surgeons led by David Helfet, M.D., and Dean Lorich, M.D., to Haiti. They were joined by physicians from New York-Presbyterian Hospital. The team left for Haiti on Friday, January 15, and began working round the clock at Hopital de la Communaute Haitienne in Port-au-Prince suburb of Petion-Ville.



Dr. Scott Nelson and Dr. Duane Carlson work simultaneously on a fractured femur case / SIGN / blogspot.com

That team was relieved two days later when a new team from HSS took their place.

"We had to quickly adjust from the high-tech Hospital for Special Surgery environment with the most state-of-the-art radiologic and surgical equipment, to a makeshift hospital where we are trying to save lives and limbs," said Helfet.

That first HSS team to arrive in Haiti included surgeons Helfet, Lorich, Daniel Chan, Devon Jeffcoat, Neil MacIntyer, Anna Miller, Andrew Nevaiser; anesthesiologists Doug Green and Kethy Marie Jules-Elysee; nurse practitioner Patricia Donohue; and, RNs Ronald Perez and Louise Strickland.

Synthes spokesperson Gilgian Eisner told *OTW* that after a long wait for clearance to land on the island, the plane landed in the Dominican Republic and then transferred to Haiti on Saturday morning. Also on board was a large shipment of the company's trauma products that had been requested through the Partners in Health Organization and coordinated with Dr. Helfet.

The plane returned to its home base and loaded up additional 4,500 pounds of product, which it flew back to Haiti on Sunday morning.

One of the first reports coming from the ground came through posts on the *huffingtonpost.com* Web site by Mark Hyman, M.D.

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Haiti earthquake camp/photo by: Agência Brasil / Wikimedia Comons

"Two orthopedic surgeons, my wife and father in-law, started the first amputation without water, electricity, or disinfectant. They used a rusty hacksaw we washed with vodka, lit by camping headlamps in an empty room with a few boxes of supplies we had packed into our plane."

Here Come the Israelis

On the same day the HSS trauma team was on its way to Haiti, two Israeli jets carrying nearly 10 tons of medical equipment, 220 doctors, nurses, medics, police forces, and an elite search and rescue team landed in Haiti.

The Israelis established the field hospital noted earlier that included 40 doctors, 24 nurses, medics, paramedics, x-ray equipment and personnel, a pharmacy, an emergency room, two surgery rooms, an incubation ward, a children's ward, a maternity ward, and more. Their field hospital was capable of treating nearly 500 victims per day and performing initial surgeries.

AAOS Coordination

On the 19th, AAOS was receiving reports that it seemed that finally, the log jam of trying to get medical supplies and personnel into the country was loosening.

"We have received numerous reports that orthopedic aid organizations are on their way to Haiti, and some—such as Operation Walk/Haiti, SIGN, CURE International, and many academic institutions—are already on the ground," wrote the AAOS leadership team of Drs. Joseph Zuckerman, John Callaghan and Daniel Berry.

The Academy coordinated member efforts to facilitate the movement of medical equipment and healthcare personnel to Haiti.

One member, Carlos Lavernia, M.D., reported he had access to a 40,000

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sq. ft. warehouse in Miami, where equipment can be sent and held until arrangements for shipping it into Haiti can be made. Groups that have or are in the process of making arrangements to go to Haiti can also use the warehouse as a holding space.

If your hospital is willing to support this effort, AAOS is asking you to please forward the following information to Haiti@aaos.org :

- Name of hospital
- Number of patients you can accept
- Pediatric or other specialty patients you will accept
- Availability of housing for family members

The Academy deserves special recognition for quickly sounding the alarm to its members to get involved and provided frequent updates and instructions for members to join relief efforts.

NASS and SAS

The North American Spine Society (NASS) issued a statement on January 19 encouraging its members to visit a list of links on its Web site where the members could offer their services or financial contributions.

The International Society for the Advancement of Spine Surgery (SAS) sent *OTW* a statement saying the group believes other organizations are better positioned to help at the moment, but that they were discussing a delayed mission in a couple of months when the emotions and journalists were gone and the need to treat is high

Industry Partners

While surgeons and some of their societies jumped into action, their industry partners responded quickly with calls for equipment, instruments and medical devices.

Sorting Contributions at SIGN / SIGN

This list is hardly exhaustive but the following are some of the contributions made by companies as reported to *OTW*:

Synthes, in addition to the support previously noted, helped restock the USNS Comfort. Due to other needs for the loading cranes, Synthes staff hand-carried everything on board the ship in an effort to save time.

DJO, Inc., donated orthopedic rehabilitation devices including immobilizers and splints for the neck, shoulder, arm, wrist, knee and foot and ankle valued at approximately $200,000. The donation was made to Project HOPE (Health Opportunities for People Everywhere).

Stryker and its employees were contributing up to $250,000 to the Red Cross. Product donations will be made as appropriate. The company's Trauma business donated product with a value of about $200,000, and other divisions will respond to requests as well.

Smith & Nephew is donating more than $2 million in orthopedic implants and surgical instruments. The products will be distributed to trained surgeons by Hope Force International.

Orthopedic surgeons who are trained to use these instruments and who are travelling to Haiti to assist in the relief effort are instructed to contact HFI (hopeforce.org) in the United States at (615) 371-1271 or info@hopeforce.org.

Zimmer was working through its ongoing product donation partner, AmeriCares.

Medtronic donated $1 million through its foundation.

Hanger Orthopedic Group contributed $250,000 in cash and devices, including neck and back braces, limb immobilizers, fracture boots, wrist splints, and cervical collars, to Physicians for Peace and Project HOPE.

DePuy Orthopaedics and Spine contributed a supply of trauma-related orthopedic products and instruments. DePuy's parent, Johnson & Johnson helped to airlift four disaster relief modules into Haiti. Sixty pallets of the company's first aid and consumer hygiene kits were shipped. Antibiotics and pain medications were donated for use in acute care. Specialized medical devices to assist with traumatic limb and body injuries are being provided to qualified surgical teams.

Biomet reported it was contributing money and product to the recovery effort.

NuVasive contacted *OTW* with an offer to make supplies and devices available to efforts already reported in *OTW*.

The Bottleneck Opens

By Friday, January 22, the *Miami Herald* was reporting that after many examples of massive bottlenecks in getting supplies and medical equipment and personnel to victims, "deeply needed aid streamed into Haiti's ravaged capital in quantities that relief agencies said is a clear sign of progress. Roads have been cleared, additional food and water distribution points are available and some new medical clinics were open."

The call for help from Haiti was unprecedented and immediate. For those in the orthopedic community that answered the call, we say you shined brightest in the moment of greatest need.

Crianças do Orfanato Fondation Blessing Hands / Wikimedia

Bone Cancer: Can the Limb be Spared?

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

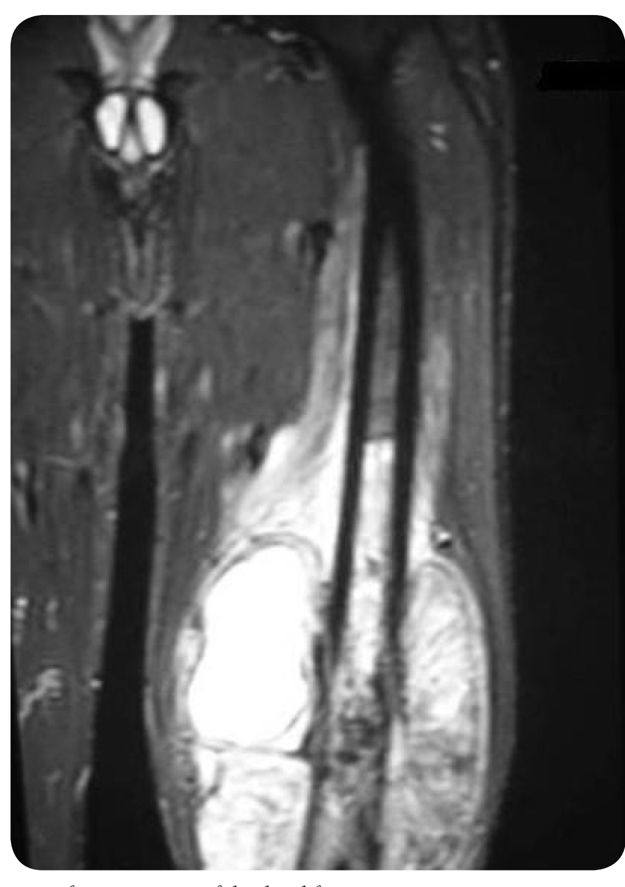
An otherwise healthy patient has been having knee pain for a few months and ends up visiting the local emergency room where she is diagnosed with an osteosarcoma of her lower extremity. She initially sees an old-time general practitioner in the area who discusses the serious potential of requiring an amputation for treatment and refers her to a local surgeon. The patient searches at length and finally finds Dr. James Wittig, and is told that the limb can be spared. It is important to spread the word that nowadays, most patients with sarcomas can safely undergo limb sparing surgery, says Dr. Wittig, Chief of Orthopedic Oncology and Sarcoma Surgery and Associate Professor of Orthopedic Surgery at Mount Sinai Medical Center in New York City.

Avoiding Amputation

Dr. Wittig, one of only approximately 150 orthopedists in the U.S. who handles bone and soft tissue cancers that threaten life and limb, states, "There have been such extraordinary advances in chemotherapy and limb saving surgical techniques that the majority of patients with bone and soft tissue sarcomas can have their extremities salvaged. This is in contrast to our situation pre-1979 where the majority of patients were treated with amputation. We now have a better understanding of the tumor and how sarcomas grow locally, not to mention the improved radiological imaging that enables us to view the tumor with more accuracy. Also making a significant difference are the advances in surgical techniques and prosthetics. With regard to the all-important chemotherapy regimen, for sarcomas it is now given preoperatively and results in a dramatic killing of the tumor—making it easier to remove the tumor without removing as much soft tissue."

Biopsying a tumor carefully, says Dr. Wittig, can determine whether Mr. Jones leaves the hospital with his extremity intact. "The number one reason that unnecessary amputations are performed is that the biopsy is done incorrectly. The patient goes to see a general surgeon or orthopedist, perhaps someone who doesn't have experience in treating these tumors, and undergoes a biopsy. If the biopsy is placed in the wrong position or results in bleeding that contaminates the surrounding tissue, this can preclude a limb sparing surgery."

"Any time physicians encounter a musculoskeletal tumor," continues Dr. Wittig, "it should be biopsied by the surgeon who will perform the limb sparing surgery or by a radiologist under the surgeon's direction. Why? Because it is important that the incision for the biopsy be small, and placed in a position where there is no contamination of the neurovascular structures or important muscles. It needs to be placed longitudinally in line with



MRI of osteosarcoma of the distal femur
Mount Sinai Medical Center

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the planned skin incision that is used to save the extremity. If the incision is placed transversely, the surgeon must remove an enormous piece of skin or other soft tissue because that has been contaminated. This can often preclude a limb sparing surgery and leave no other alternative but an amputation."

Then there are the fortunate patients who select Dr. Wittig for a second opinion.

> *"On many occasions patients come to me after seeing another doctor…someone who has told them, essentially, 'You have sarcoma, and that means you will need an amputation.' Honestly, where they get their information and why they are so steadfast in their opinions puzzles me to say the least."*

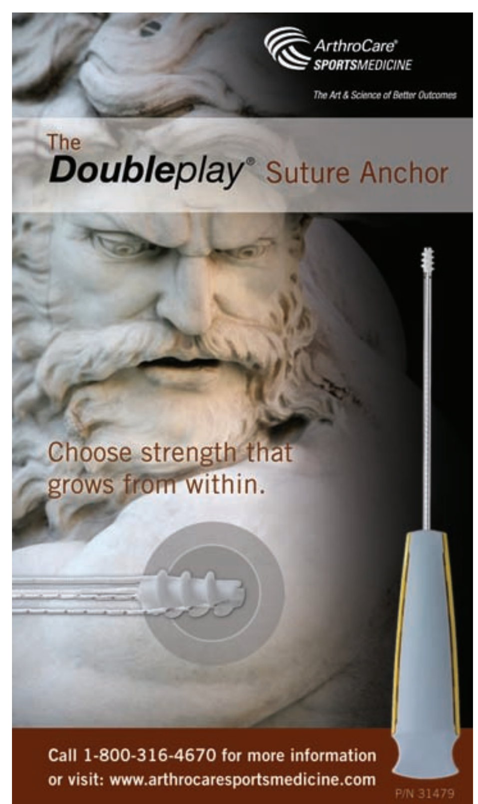
"Where they see something daunting, I often see something straightforward. For example, let's say the tumor is relatively small, would involve a straightforward operation, the bone is not fractured, and the tumor isn't wrapped around the neurovascular structures. In that situation the person would receive three months of chemotherapy, undergo limb salvage surgery, followed by more chemotherapy."

"Or, perhaps it's a large tumor where there is some question if it is pushing up against or involving the neurovascular structures. You can still give that patient preoperative chemotherapy. They will likely have a good response to this, and then during surgery it will be easier to separate the sarcoma from the neurovascular structures and from the normal surrounding tissues. So in the end, there is no need for amputation—you can save the extremity."

Working from Years of Experience

How can Dr. Wittig be so sure? Experience. Volume. "So much depends on the experience level of the surgeon and how much of any type of tumor he or she has treated. If the tumor is wrapped around the neurovascular structures or involving so much soft tissue in the extremity that removal of the tumor would be dangerous, then you can't proceed. I look at a lot of large tumors and say to the patient, 'I think we can get this out safely and save your extremity,' but another surgeon could say, 'This will never come out safely.' It's not only experience and science behind the surgical procedures but also the art and one's own creativity."

In addition to these skills, one must also follow the guidelines, advises Dr. Wittig. "There are specific indications for an amputation. Unless the situation fits this to a 'T,' we should think more critically about how to handle the case. Some things are controversial, naturally. Patients who have sarcomas that develop from the bone rarely fracture in the area of the sarcoma…



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that is a relative contraindication for saving the extremity. When the bone fractures, it bleeds, the theory being that if the fracture has displaced sufficiently and has bled, that the tumor has dispersed into the surrounding soft tissue, thus precluding limb saving surgery.

"In certain instances, however, the extremity can be immobilized—particularly in osteosarcoma and Ewing's sarcoma. If the tumor responds to chemotherapy, meaning more than 90% of it is killed, then the fracture will heal and then you can often safely salvage the extremity without compromising the patient's survival. Much of it depends on the severity and displacement of the fracture and whether you can resect the entire area that was likely contaminated. If the patient responds well to chemotherapy, then the microscopic cells that escaped with the hematoma are often killed, thus making the surgery safer."

Educating Patients and Surgeons

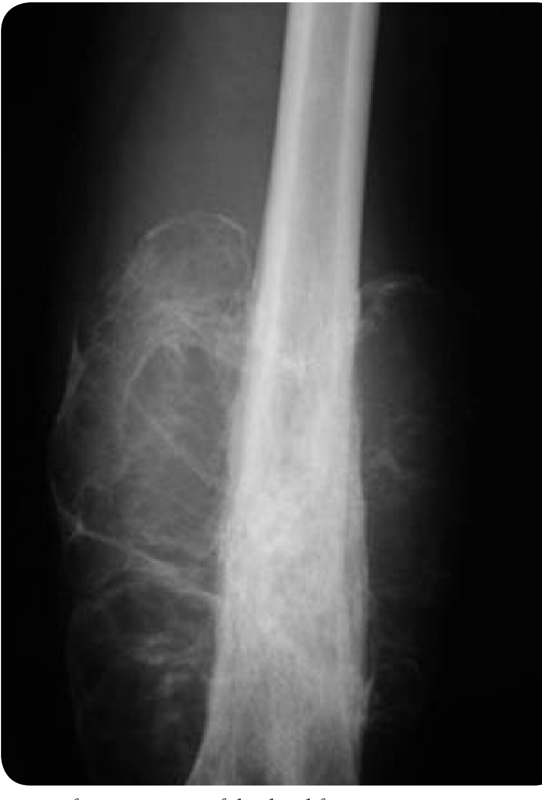
Surgeons must be bold in order to manage the difficult situations they encounter, but they can't walk on water...they must realize when they have reached their limits. "Other surgeons should know that any type of soft tissue, bony mass, or lump should be referred to an orthopedic oncologist. In particular, they should not operate on these lumps or bumps without an MRI. Many times tumors are dismissed as lipomas based on how they feel. Some surgeons may proceed to operate, try to remove the tumor, and contaminate the entire area—meaning that an amputation is now unavoidable."

So a bit of enlightenment for many parties is in order.

> *"Because the majority of people can have limbs salvaged, if someone is being told that an amputation is necessary, they should seek a second opinion. Also, we should educate health care professionals in other fields on how to recognize, diagnose and treat sarcomas since these individuals are the first line of defense for patients with such a tumor. Yes, we have courses on musculoskeletal tumors; however, after medical school, most familiarity comes from working with these very rare types of tumors on a regular basis."*

And yet, there are times when even the most experienced orthopedic oncologist must deliver the news no patient wants to hear. "In the event that the tumor is infected, it may mean that limb sparing surgery is impossible. Some tumors can get infected after inappropriate biopsies or can grow to a large size and fungate through the skin resulting in an infection. In these instances it can be very difficult to eradicate the infection and save the limb at the same time trying to expeditiously save the patients life."

"Or, if the tumor is recurrent, and the patient has already been treated with limb salvage, you might not be able to do the same surgery again. If it is relatively large or in a bad location (involving a muscle that you had to remove that provided the majority of



X-ray of osteosarcoma of the distal femur
Mount Sinai Medical Center

functioning to the extremity), then you might not want to attempt the surgery. Or let's say the patient previously had the tumor removed and the tissue was irradiated. In that case you would have to operate through those irradiated tissues, something that would hold a high risk of complications, and the wound would likely not heal properly. If the tumor recurs so many times, there are likely microscopic cells that are growing back that could not be previously removed…you would have to do an amputation."

Fortunately, says Dr. Wittig, those are rare cases indeed.

Bruising Biologics Battle Erupts

By Robin Young

The gloves have come off in the cold war between Atlanta-based, CryoLife and St. Paul-based Medafor, Inc.
Last week, CryoLife, in effect, slammed Medafor against the boards, when it drafted and then mailed an open letter to the Medafor's shareholders urging them to contact Medafor's management and help CryoLife CEO Anderson force the sale of the company for cash and CryoLife stock.

No doubt about it, CryoLife, the often controversial and, at one time, biologics' industry bad boy (more about that later) has launched a hostile takeover attempt against St. Paul, Minnesota-based Medafor, Inc. Medafor is one of CryoLife's most important suppliers representing, according to public filings, $6 million in revenue (5% of total CryoLife sales). This isn't the first time CryoLife has tried to buy Medafor. But we're getting ahead of the story.

We begin April 2008 when Medafor signed the now notorious distribution agreement with CryoLife. That agreement gave CryoLife exclusive rights to distribute Medafor's MPH biologic hemostat (a material to stop bleeding). Specifically, Medafor granted CryoLife exclusive rights to distribute in the U.S. for cardiac and vascular surgery (excluding U.S. Department of Defense hospitals) and internationally (excluding China and Japan) for cardiac, vascular, and general surgery, other than orthopedic and ear, nose and throat surgery.
So far, so good.

Medafor's MPH, it turned out, was a hit. According to CryoLife's CEO Steve Anderson; "This technology serves as a perfect complement to our BioGlue technology, allowing us to offer surgeons a full range of products to assist them in controlling and preventing bleeding." In about a year, sales of MPH rose to $6 million per year.

MPH is a microporous polysaccharide hemostatic powder which, as CryoLife's customers learned, works very well in cardiac and vascular surgeries. It has a CE Mark (approved in 2003) and FDA ***pre-market approval*** (since September 2006).

The product works. When applied to the surgical site, it quickly dehydrates blood and speeds up the clotting cascade. MPH comes to the surgeon as an easy-to-use, ready-to-use applicator filled with flowable powder. MPH doesn't promote infection and is absorbed within 24 to 48 hours of application at the wound site—which was much better than surgical hemostats which can take 3 to 8 weeks to fully break down. Finally, it's cheap and generates for both CryoLife and Medafor, very good profit margins.

"No" Means "No"

CryoLife's first offer to buy Medafor came seven months after the distribution agreement was signed—November 2008. According to a

shareholder letter which is available on Medafor's Web site, that first offer had no price attached to it.

Medafor said, in effect, thanks but no thanks.
Two months after THAT, CryoLife made its second attempt to buy Medafor. This time CryoLife CEO Steve Anderson put a price on his offer—$25 million in CryoLife stock—which trades on the New York Stock Exchange under the symbol "CRY."

Medafor's answer was, again, "No."

Medafor CEO Gary Shope said about the takeover bid in a shareholder letter shortly after the unsolicited offer came in...$25 million in CryoLife stock is "a significant undervaluation that does not come close to even CryoLife's remaining minimum commitment on its contract with Medafor, which is valued at approximately $40 million."

About two months after Medafor said "no" for the second time, Anderson sued Medafor in U.S. District Court for the Northern District of Georgia alleging breach of contract, fraud, negligent misrepresentations, and violations of the **RICO racketeering statutes.**

RICO statutes were originally developed as a tool to attack organized crime.

In 25 years of covering medical companies, this is the first time we've ever seen a RICO case filed by a buyer against a supplier. In effect, what CryoLife was claiming was that they were stuck in an agreement with a fraudulent racketeering supplier. Not good. In light of those claims, did CryoLife stop or curtail its business activities with this "racketeering" firm? They did not. In fact, CryoLife increased its purchases of MPH from Medafor.

Medafor quickly answered CryoLife's lawsuit (again, all of these court documents are on the Medafor Web site which is www.medaforinc.com) and said, in effect, "BS" in the form of a motion to dismiss the lawsuit. The court agreed with Medafor and the motion to dismiss most of the suit was granted this past December 9th.

Specifically, the court said:

> "For the reasons above, the defendant's 12(b)(6) motion to dismiss the civil RICO claim is GRANTED in part and DENIED in part. To the extent the plaintiff's RICO claim depends on acts directed towards, or harm incurred by, individuals other than itself, the defendant's motion to dismiss is GRANTED. To the extent the plaintiff's claim depends on pre-contractual acts, the defendant's motion to dismiss is GRANTED. The defendant's motion is DENIED with respect to the other parts of the RICO claim. The plaintiff is ORDERED to recast its complaint to sufficiently plead the alleged post-contractual predicate acts within 20 days."

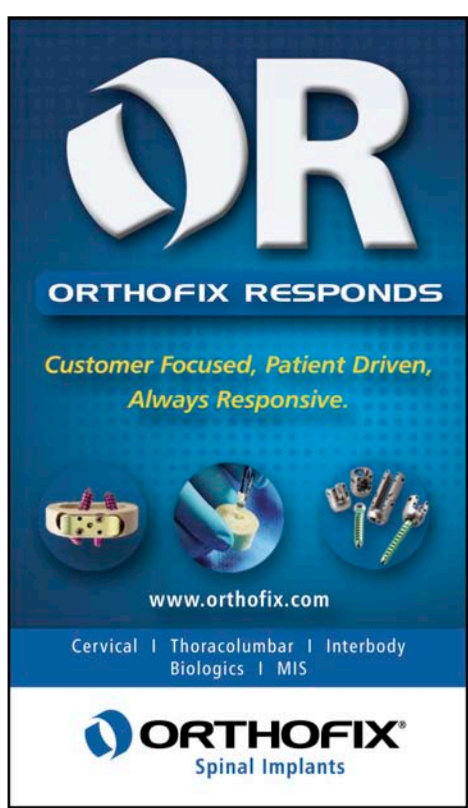
Get Us Out of Here!

One might think that the party claiming all of these dastardly things would be the party trying to get out of the distribution agreement. But that was not the case. It was, rather, the defendant in these lawsuits—the alleged racketeering firm—that finally, formally tried to get out of this clearly dysfunctional distribution relationship.

On September 18, 2009, Medafor sent a letter to CryoLife notifying them of their intention to terminate the relationship on the grounds that CryoLife had tried to get regulatory approval of MPH in Hong Kong—a violation of the agreement.

CryoLife responded by ceasing its sales and marketing activities in Hong Kong and promising to withdraw all unsold product. Both parties then backed off—Medafor took back its notice of termination and CryoLife withdrew its motion for an injunction (to stop Medafor from terminating the distribution agreement).

Then Medafor found another breach (CryoLife was trying to sell product in Spain). This past December Medafor gave CryoLife its second notice of



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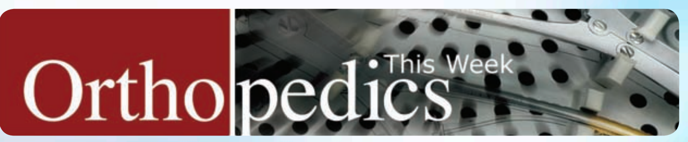

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intent to terminate—this time by January 8, 2010. Also in December, the district court judge dismissed most of the claims in CryoLife's original lawsuit against Medafor. Indeed, the judge even characterized CryoLife's claims as a "shotgun pleading."

The Bear Hug

What was CryoLife to do? Its two unsolicited bids were rejected. Its lawsuit was unraveling. Of course, it could just live with its original distribution agreement. Instead, on January 13, 2010, CryoLife CEO Steve Anderson informed Medafor that his company had bought 1.6 million Medafor shares amounting to $3.2 million and 8% of the company. They also sent a letter to Medafor's board of directors offering to purchase all of Medafor's stock at the same $2 per share price.

Medafor responded by saying they will study the offer.

CryoLife didn't wait. One week later, Anderson sent a letter directly to Medafor's shareholders urging them to pressure management into accepting the $2 per share bid.

It is not clear whether CryoLife and CEO Steve Anderson are really interested in a response from Medafor's management. They've been turned down twice. The lawsuit failed and Medafor has apparently caught Anderson with his hands in the proverbial cookie jar (his attempt to sell MPH in Spain).

Medafor is clearly heading for the door and as fast an exit as possible. But, again, this is Steve Anderson. Anything is possible.

Biologic's Bad Boy

Minnesota gave Steve Anderson some his highest professional experiences and, most assuredly, his lowest. Anderson grew up in Minnesota and, to a large extent, is a product of the early cardiovascular industry there.

Brian Lykins also grew up in Minnesota and, in 2001, was a young 23-year-old man in need of knee surgery. His surgeon, a CryoLife customer, chose to implant one of that company's "fresh" allograft cartilage products. Turns out the allograft was far from "fresh." It had been harvested too long after death of the donor. It had not been tested adequately and was teeming with one of the most deadly of all bacteria—Clostridium Sordelli. Brian Lykens develop a massive infection and died shortly after his surgery.

As is often the case, when bad things happen, some people figure out how to do the right thing and others don't. In the classic 1986 Tylenol contamination case Johnson & Johnson immediately recalled all Tylenol at tremendous cost (more than $1 billion) to the company and would not reintroduce it until it could do so safely. Anderson missed that lesson.

The Centers for Disease Control and Prevention investigated Lykins' death and found 25 cases of serious bacterial infections in people receiving similar operations and identified a single company (CryoLife) as being involved in 14 of those cases. In 2002 the FDA shut down substantial parts of CryoLife's operations saying that the company could not adequately assure patients that its products were safe.

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Dr. Mary Malarkey, director of the division of case management at the FDA's Office of Compliance and Biologics Quality was quoted in *The New York Times* at the time as saying about CryoLife: "We found significant violations from our regulations. What they were doing did not ensure tissue safety. CryoLife's response was, said Malarkey, "inadequate." CryoLife's lawyers at the time said they would file an appeal.

The CDC said that CryoLife's products were involved in 14 cases. The FDA cited more. With just two exceptions, CryoLife did not admit to causing any infections in any tissue recipients. We won't recount the tortured way in which the truth finally emerged but suffice it to say that it required investigations from the Centers for Disease Control and the FDA to fully uncover all of the problems at CryoLife and to ensure that new policies and procedures were in place.

The FDA imposed some of the most severe sanctions ever imposed on a still-operating company. At one point, CryoLife had to lay off nearly a quarter of its employees.

How does this bear on the Medafor situation? CryoLife and its CEO Steve Anderson have an established track record of full-contact business tactics.

Could Anderson and CryoLife have met their match with Medafor? Or will Medafor ultimately succumb to this bad boy's bear hug?

Stay tuned. More is on the way and it will almost certainly be interesting.

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company news

Biomet Narrows Losses

Biomet reported that revenues for the second quarter of 2010 rose 8% to $696 million while losses narrowed to $7.2 million from $39.7 million from the second quarter of 2009.

During a conference call with Wall Street analysts on January 6, company CEO Jeff Binder responded to questions from analysts regarding the slowing of the company's recent gains in market share against its larger rivals.

Binder said it was hard to say how the last quarter stacked up against competitors because Biomet is the first to report revenues. He noted that the company is not satisfied with recent gains and that the company's goal is to reach the same market share levels as Stryker, Zimmer, and DePuy.

Key drivers to continued market share gains will be, "innovation, new products and execution," said Binder.

With less cash and higher debt then competitors, it will be challenging for Biomet, particularly with an expected new device tax, to pay for innovation and acquisitions. On the other hand, its Wall Street owners led by the Blackstone Group have deep pockets. According to Binder the company expects to deal with the device tax through increased sales and cost reductions.

Said Binder, "The Biomet team continued to deliver strong sales growth in orthopaedic reconstructive devices during the second quarter, driven by an 11% growth rate for U.S. knee sales and an increase of 7% for U.S. hip sales. Our extremity reconstructive sales continued to ramp at a rate of 44% in the U.S. during the quarter and we posted double-digit sales growth for our biologics franchise, which is also reported in reconstructive sales. Additional product categories contributing to our second quarter consolidated sales growth were spine hardware, sports medicine, and craniomaxillofacial fixation."

The company reported the following product category results for the second quarter of 2010:

Biomet	2Q10 $ Millions	% Change
Reported Revenues	$696.0	up 8%
Reconstructive	$528.0	up 12%
Knees		up 15%
Hips		up 8%
Extremities		up 29%
Spine	$58.9	up 7%

Source: Biomet

—WE (January 13, 2010)

Biomet Corporate Headquaters

company news

TranS1 Lowers Revenue Expectations

TranS1, Inc.'s revenues for the fourth quarter of 2009 will be lower than the company had previously suggested.

The company announced on January 7 that revenues for the quarter will be approximately $6.2 million to $6.3 million instead of the previously announced guidance of $6.7 million to $7.2 million for the quarter.

Company CEO Rick Randall said in a press release:

> *"Our results this quarter were again impacted by concerns in the marketplace surrounding reimbursement for our AxiaLIF procedure, which we continue to address through increased education and support resources for our current and prospective surgeon users. We must now further advance our efforts to secure definitive resolution with the private payers and CMS [Centers for Medicare and Medicaid Services] as we remain confident in our products, clinical benefits and prospects for future growth as the market for minimally invasive spine surgery continues to expand."*

Trans1's procedure is not the only LIF procedure under scrutiny by payers. NuVasive's XLIF and Medtronic's DLIF

were noted in a recent letter from the North American Spine Society encouraging payers to reimburse the fusion procedure.

TranS1 currently markets two single-level fusion products, the AxiaLIF and the AxiaLIF 360, and a two-level fusion product, the AxiaLIF 2L, in the U.S. and Europe. TranS1 was founded in May 2000 and is headquartered in Wilmington, North Carolina.

Complexity associated with the Category III reimbursement code for the TranS1's AxiaLIF procedure has made it difficult for some surgeons to receive full reimbursement. As a result, some surgeons have limited their use of the technique in their practice, and some have been prevented from adopting the procedure at all.

The company's full fourth quarter results are expected to be released in late February 2010.

—*WE (January 13, 2010)*

AAOS Coordinates Volunteers for Haiti

The American Academy of Orthopaedic Surgeons (AAOS) reports that more than 100 members have contacted the Academy to offer their services on the ground in Haiti. International Department staff are managing all calls and inquiries.

AAOS is working primarily with two organizations that have personnel on the ground and expect to be ready to begin flying volunteers into Haiti by Friday or Saturday of this week. The organizations are International Medical Corps (http://www.imcworldwide.org) and Global Outreach International (http://www.globaloutreach.org).

While many surgeons would like to go immediately to lend their services, these organizations have reminded AAOS they will need multiple volunteers over a prolonged period of time. AAOS staff is sending them daily an updated list of interested volunteers. Those organizations will contact volunteers directly to arrange further details.

To assist the Academy with this process, interested volunteers who have not yet contacted the Academy are asked to please send by email (Haiti@aaos.org) the following information:

- Full name as it appears in your passport
- Citizenship
- Passport Number
- Passport expiration date
- Dates you would be available to travel
- How long you would be able to stay in Haiti (as few as three days is acceptable)
- Main phone number where you can be reached, including over the weekend

company news

Soldiers Aid Haiti Refugees/wikimedia commons

- Email address
- Orthopaedic specialty
- Experience you have had working in earthquakes; please provide a short list of those experiences
- Are you willing to pay your own way to fly to Haiti?
- An abbreviated CV (not more than 3 pages)
- Please indicate if you speak French (if you do not speak French, it will not disqualify you as a volunteer)

The International Department will provide this information to the organizers on your behalf.

The Academy has also provided a list of answers to frequently asked questions about joining rescue efforts in Haiti. Click here to link to the AAOS Web site http://www.aaos.org/news/whatsnew/haiti.asp

—*WE (January 15, 2010)*

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Stryker Finishes Strong in 2009

Stryker Corporation's total revenues for 2009 rose only 0.1%. But as the recession ended, revenues in the fourth quarter rose 6.8%.

Newly installed Chairman of the Board (and still President and CEO), Stephen MacMillan said on January 12:

"It was nice to end the year on a stronger note. We are particularly pleased that in a challenging year, our U.S. orthopedic implant businesses performed well. Additionally, we are feeling better as we enter 2010 that our MedSurg franchises have stabilized and are showing signs of a modest recovery."

Challenging 2009

MacMillan and Stryker employees must be glad to get 2009 behind them after plunging hospital endowments cut into spending, outstanding FDA warning letters, and a biologic product, OP-1, which gave the company both regulatory and legal headaches.

Optimistic for 2010

MacMillan and company are optimistic about 2010. The FDA warning letters are getting resolved, hospitals are spending again and patients are continuing to get their hips, knees, spines, and other orthopedic problems fixed. Maybe its biologic division will even make a comeback.

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company news

In a further sign of optimism for 2010, MacMillan announced that the company expected to increase net sales for the year by 5% to 8% on a constant currency basis as a result of expected growth in shipments of orthopedic implants and medical surgical equipment.

Selling Notes

Taking advantage of low interest rates, the company also announced that it has priced an offering to sell$500 million of senior unsecured notes due 2015 and$500 million of senior unsecured notes due 2020. The 2015 notes will bear interest at 3.00% per year and the 2020 notes will bear interest at 4.375% per year.

The company intends to use the net proceeds from the offering for working capital and other general corporate purposes, including acquisitions, stock repurchases and other business opportunities.

MacMillan and company management will discuss detailed 2009 results on January 26, 2010, with Wall Street analysts. Until then, here is a snapshot of overall financial performance for the fourth quarter and full 2009:

Stryker	4Q09s		2009	
	Sales ($ in millions)	% Change	Net ($ in millions)	% Change
Total	$1,834	up 6.8%	$6,723	up 0.1%
Domestic	$1,159	up 2.7%	$4,317	up 0.8%
International	$676	up 14.6%	$2,406	down 1.2%
Ortho Implants	$1,116	up 9.7%	$4,120	up 3.8%
Med Surg	$719.0	up 2.5%	$2,603	down 5.4%

Source: Stryker Corporation

—WE (January 14, 2010)

AAOS Sends Out Appeal for Haiti

The American Academy of Orthopaedic Surgeons has sent out an appeal for help in responding to the earthquake crisis in Haiti.

AAOS President Joseph Zuckerman, M.D., put out the following statement:

On behalf of the 35,000 members of the American Academy of Orthopaedic Surgeons (AAOS), I send my deepest sympathies and concern to the people affected by yesterday's disaster in Haiti.

A coordinated and ready response to this tragedy has been the Academy's top priority today. Right now, we are collecting information about all medical and emergency relief efforts and fielding calls from many members and health professionals, moving to connect all interested parties with volunteer and donation opportunities. Orthopaedic response efforts are underway to assist with the trauma in Haiti.

Haitian civilians receive assistance in a camp set up by the Brazilian Army

Historically, severe earthquakes cause a high number of orthopaedic traumas. With the staggering number

company news

of reported injuries and deaths in Haiti, we believe the need for any and all volunteer medical support is high and our members are responding in sync with that need. We encourage all interested parties—doctors, nurses and medical staff—to visit www.aaos.org/Haiti, where we will post additional information as it becomes available. The AAOS will provide whatever support we can to assist in the response.

AAOS has set up a Web page to serve as a source for information on orthopaedic relief efforts. Click on this link http://www.aaos.org/news/whatsnew/haiti.asp to assist the AAOS in helping respond to this medical crisis.

Orthopedic volunteers and supplies urgently needed. On Tuesday, January 12, a magnitude 7.0 earthquake occurred just outside of the Haitian capital city of Port-au-Prince. Early reports state that much of the capital has been leveled—including many of the hospitals—and the death toll is expected to run into the thousands. According to medical personnel on the scene, many survivors have sustained traumatic orthopaedic injuries. The need is great for supplies and assistance from orthopaedic surgeons, nurses during this disaster.

—WE (January 13, 2010)

Parcell Brings Stem Cells to Alphatec

Alphatec Holdings, Inc. recently announced that it has entered into an exclusive distribution agreement with Parcell Spine, LLC. The agreement gives Alphatec Spine, Inc. the exclusive global rights to distribute Parcell's proprietary adult stem cells.

Alphatec has found success, and plenty of room for growth, within the company's niche of treating the aging spine, and company officials hope that they can improve fusion rates and other spinal treatments by adding biologic stem cell solutions. Parcell officials call their proprietary stem cell the ELA stem cell because it is an "embryonic-like" adult stem cell. According to Alphatec's recent press release, Parcell's method for obtaining the donated ELA stem cells can "yield up to six hundred times more cells than a similar volume of mesenchymal stem cells harvested from bone marrow." The cells come from tissue which is usually discarded as medical waste.

In the recent press release, Alphatec's President and CEO Dirk Kuyper says, "The addition of an osteoprogenitor stem cell will provide Alphatec with an excellent position in the growing market of stem cell therapies for treating disorders of the spine, and will be a strong complement to the other innovative technologies in our core fusion and aging spine portfolios."

Pamela Layton, CEO of Parcell Spine, also says that the new agreement is just what the company was looking for: "We believe that our supply and distribution agreement with Alphatec is an important strategic milestone for the Spine Division of Parcell Laboratories. It is consistent with our objective of partnering with best-of-breed companies that are positioned to fill the gap in the large orthobiologics arena."

Mr. Kuyper expects that Alphatec will release an ELA stem cell product in the second half of this year and then gain substantial revenue from the product in 2011.

—DK (January 18, 2010)

Alphatec logo/Alphatec Holdings, Inc. & Mesenchymal Stem Cell/Wikimedia Commons

legal & regulatory

Yielding Sentenced to Prison

The saga of the Yieldings of Arkansas has drawn to a close with the announcement on January 7 that Geffrey Yielding will spend over six years in prison and pay almost $1 million in restitution for violating the healthcare anti-kickback statute and falsifying documents in an effort to conceal his crime.

Kickbacks

As a physician's assistant for North Little Rock neurosurgeon, Dr. Richard Jordan, Yielding was able to dictate what products were ordered for use in surgeries performed by Dr. Jordan at the Baptist Health Medical Center—North Little Rock (NLR) in 2003 and 2004. Yielding ran the orders through his now deceased wife, Kelley Yielding's company, ANI (Advanced Neurophysiology, Inc.). ANI represented Orthofix bone growth stimulators and Osteotech allograph bone. The couple pocketed $380,000 in commissions during the time of the scheme.

Wikimedia.commons

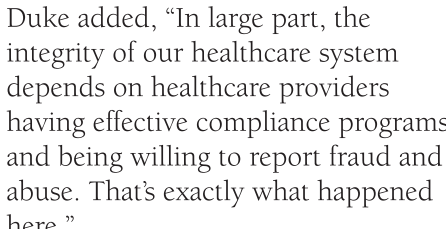
Bribery

Geffrey Yielding also bribed Jordan Wall, a charge nurse at NLR to order excessive amounts of the products for which Kelley Yielding received commissions. When Wall was terminated by the hospital, Geffrey Yielding created a fraudulent promissory note in an effort to disguise the bribes as a loan. Wall subsequently pled guilty to making a false statement to a federal agent and was sentenced to a term of probation and a fine. Wall testified against Yielding during the April 2009 trial.

Hospital Self-Disclosed

According to Jane Duke, United States Attorney for the Eastern District of Arkansas, the case came to the attention of the FBI when Baptist NLR self-disclosed to the FBI that it suspected criminal activity by one of its employees.

"Based on this information, federal investigators were able to confirm that this employee, a charge nurse, had accepted over $50,000 in bribes from the Yieldings over a two-year period."



Duke added, "In large part, the integrity of our healthcare system depends on healthcare providers having effective compliance programs and being willing to report fraud and abuse. That's exactly what happened here."

United States District Judge Brian S. Miller imposed sentencing enhancements against Yielding for both obstructing justice and for his aggravating role as a leader or organizer of the criminal activity. Yielding's obstruction of justice occurred in December 2004 when he aided and abetted Wall in falsifying the promissory note referenced above.

Restitution

As a part of Yielding's sentence, he is ordered to make restitution in the amount of $944,995.84 to Baptist NLR; Travelers Insurance; Medicare; Medicaid; and TriCare for each of their respective losses.

He is currently scheduled to self-report to the Federal Bureau of Prisons by March 8, 2010, at 2:00 p.m.

Kelley Yielding died while driving through a fast food restaurant the day before she was to testify before a grand jury investigating charges against one of her customers, Arkansas neurosurgeon Dr. Patrick Chan. Chan was sentenced in April 2008 after admitting to demanding and receiving kickbacks for using specific spinal devices.

—WE (January 11, 2010)

legal & regulatory

Shuren New Device Chief at FDA

Jeffrey Shuren, M.D., J.D., has been named the permanent head of the device division at the Food and Drug Administration.

FDA spokesperson Mary Long told OTW that Shuren's appointment was announced by FDA Commissioner Margaret Hamburg, M.D., at a CDRH (Center for Devices and Radiological Health) all-staff meeting on January 20.

Shuren had been the acting head of the CDRH since Daniel Schultz, M.D., resigned "by mutual agreement" with Commissioner Hamburg last August.

Since taking over the division, Shuren has led an initiative to review the agency's 510(k) pre-marketing program and hired the Institute of Medicine to study possible changes to the program.

The 510(k) program had become a divisive issue within the agency, with some agency scientists complaining that top managers had put pressure on them to clear devices. It got ugly when Congress got involved and device companies got caught in the middle of the bureaucratic infighting.

Last September it was widely reported that Shuren was actively lobbying to become the permanent director of the CDRH. He announced six immediate priorities for the center, including reviewing the 510(k) pre-market notification program,

Jeffrey Shuren, M.D., J.D.,/Director of CDRH

learning how the FDA can adapt to changing technology while providing a predictable regulatory pathway, and establishing clear procedures for resolving differences of opinion within the center.

Payment and Regulatory Experience

Shuren brings an interesting mix of regulatory and payment coverage experience to the job.

Before taking over the devices division, Shuren was the FDA's Associate Commissioner for Policy and Planning and directed the Agency's Office of Policy and Office of Planning. Shuren received his medical doctorate degree from Northwestern University and his juris doctorate degree from the University of Michigan. He is board certified in neurology, and served as an Assistant Professor of Neurology at the University of Cincinnati.

In 1998, Shuren joined the FDA as a medical officer in the Office of Policy. In 2001, he became the Director of the Division of Items and Devices in the Coverage and Analysis Group at Centers for Medicare and Medicaid Services. He returned to the FDA as the Assistant Commissioner for Policy in 2003.

We hope to provide our readers an in-depth interview with the new director in the near future.

—*WE (January 20, 2010)* of

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extremities

Extremity Medical: Trapezium Device Cleared

An American and European thumbs up…Extremity Medical, LLC has announced that it has received FDA clearance for the TrapEZX Anatomic Trapezium Prosthesis. In other good news, it has received CE Mark for the product and is initiating limited release in selected centers in U.S. and Europe.

Extremity Medical: Trapezium Device Cleared

According to Extremity Medical, the TrapEZX Prosthesis is the first completely anatomic trapezium bone replacement available in the world. The device is intended to treat degenerative and post traumatic disabilities of the thumb basal joint. The implant design and surgical technique were developed in close collaboration with Amy Ladd, M.D., Professor and Chief, Robert A. Chase Hand & Upper Extremity Limb Center, Stanford University Medical School, Arnold Peter Weiss, M.D., Professor of Orthopedics, Alpert Medical School of Brown University, and John Faillace, M.D., FAAOS, Hand and Orthopedic Surgery, Waco, Texas. Contributing on the biomechanics end of things was Professor J.J. Trey Crisco, Ph.D., Director Bioengineering Laboratory, Department of Orthopaedics, Alpert Medical School of Brown University.

The company emphasizes that the TrapEZX Trapezium Replacement is the first of its kind that is anatomic and incorporates a window designed to offer the potential of hematoma encapsulation for long-term stability. In the news release, Dr. Ladd commented, "Extremity Medical has delivered the first anatomic trapezium prosthesis which restores the natural architecture and biomechanics of the basal thumb joint." Dr. Weiss added, "The simple, single-piece design allows for a rapid procedure, requiring only trapeziectomy using standard technique, provisional fixation with a suture anchor and standard capsular closure. This device gives the hand surgeon a new option with the potential to restore grip and pinch strength following debilitating osteoarthritis of the CMC joint."

Commenting to *OTW* was Scott Hunter, Vice President, U.S. Sales & Marketing, who noted, "TrapEZX will be launched to select centers in the U.S. and Europe initially to evaluate surgical technique and early clinical results. A broader launch of the product will commence in Q2 2010."

He added, "The TrapEZX was designed in collaboration with Drs. Weiss, Ladd, Fallaice and Crisco. Dr. Crisco heads up the Bioengineering lab at Brown University and has a broad knowledge of the kinematics of the wrist and thumb. Drs. Weiss and Ladd have also done a lot of work in studying the anatomy and kinematics of the CMC joint. Our goal in designing the TrapEZX was to create an implant that was anatomic to try to duplicate normal motion and kinematics of the CMC joint."

Dr. Weiss told *OTW*, "The development of the TrapEZX implant was a very collaborative process that examined the basic kinematics of the trapezium, wear patterns of arthritis, contour issues of implant/bone contact and tried to develop a structural implant that would prevent subsidence of the thumb metacarpal with time, so often a problem with current soft tissue reconstructive procedures. TrapEZX has enough 'open space' to allow soft tissue ingrowth through the implant which will provide substantial mechanical support and a relatively anatomic contour to minimize joint contact stresses. Stability trials in cadaveric specimens were extremely encouraging and we anticipate that the early clinical results should mirror these findings."

—EH (January 19, 2010)

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Orthopedics This Week
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large joints

Running Shoes Damage Knees, Hips, Ankles?

Those who lace up and drag themselves out into the cold at 5am might want to reconsider what's on their feet…a new study published in the December 2009 issue of *PM&R*: The journal of injury, function and rehabilitation, has found that running shoes exerted more stress on hip, knee, and ankle joints compared to running barefoot or walking in high-heeled shoes.

A total of 68 healthy young adult runners (37 women), who run in typical running shoes, were selected from the general population. None had any history of musculoskeletal injury and each ran at least 15 miles per week. Each athlete was provided with a running shoe that was selected for its neutral classification and design characteristics that are typical of most running footwear. Using a treadmill and a motion analysis system, each subject was observed running barefoot and with shoes. The researchers found increased joint torques at the hip, knee and ankle with running shoes compared with running barefoot. Disproportionately large increases were observed in the hip internal rotation torque and in the knee flexion and knee varus torques. An average 54% increase in the hip internal rotation torque, a 36% increase in knee flexion torque, and a 38% increase in knee varus torque were measured when running in running shoes compared with barefoot.

The authors say that these findings are confirmation that while the typical construction of modern-day running shoes provides good support and protection of the foot, one negative effect is the increased stress on each of the three lower extremity joints. These increases are likely caused in large part by an elevated heel and increased material under the medial arch, both characteristic of today's running shoes.

Runners at the Panathenaic games, ca. 530 BC. / Wikimedia Commons

Writing in the article, lead author D. Casey Kerrigan, M.D., JKM Technologies LLC, Charlottesville, Virginia, and co-investigators state, "Remarkably, the effect of running shoes on knee joint torques during running (36%-38% increase) that the authors observed here is even greater than the effect that was reported earlier of high-heeled shoes during walking (20%-26% increase). Considering that lower extremity joint loading is of a significantly greater magnitude during running than is experienced during walking, the current findings indeed represent substantial biomechanical changes."

When asked what led her to undertake this research, Dr. Kerrigan told *OTW*, "I have been studying gait (walking and running) for 20 years, first at Harvard Medical School, where I also received my medical degree and then at the University of Virginia where I was most recently professor and chair of the department of physical medicine and rehabilitation. This most recent study on running shoes was one of several where my team has studied the effects of different types of footwear and footwear modifications on a number of biomechanic parameters including joint torques. I have been particularly interested in the external knee flexor and knee varus torques since those torques correspond to greater pressures in the areas of the knee most prone to osteoarthritis. As a physical medicine and rehabilitation

physician I am acutely aware how debilitating knee osteoarthritis is."

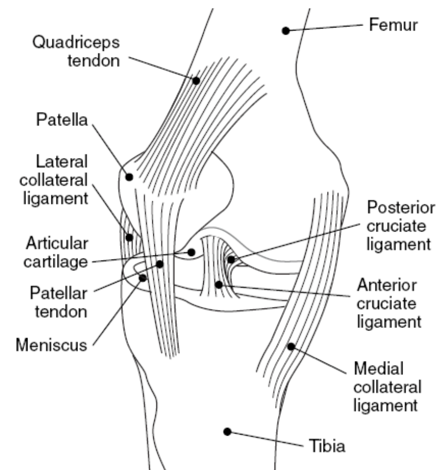
Concerning her future work, Dr. Kerrigan commented to *OTW*, "The laboratory that I founded at the University of Virginia plans to continue to study the biomechanic effects of different types of footwear. I, however, have decided to leave the University to pursue what I believe to be the solution to these collective research findings—develop an entirely different footwear design that reduces rather than increases these joint torques. I have patented that design which is owned by JKM Technologies, LLC, of which, I am chairman."

When asked about the conundrum of running shoe design, Dr. Kerrigan told *OTW*, "We have evolved to walk and run on compliant surfaces, not the hard surfaces we typically encounter now. Thus, the scientific foundation for providing compliance in a running shoe is sound, based on Thomas McMahon, Ph.D.'s work at Harvard University in the '70s and '80s showing that adding a compliant surface to an otherwise hard surface reduces injury. However, no athletic shoe to date has actually been demonstrated to provide the amount of compliance that McMahon used in his work. Athletic shoes need to be completely re-designed so as to provide true, effective, and measurable compliance while simultaneously reducing peak joint torques and forces. The only solution I can think of to do that is the design I have now patented (CDCSuspension.com). It is comprised of flexible cantilevers running the length of the sole of the shoe (think of a U on its side with the vertex on the lateral side of the foot). This design uniquely works in harmony with foot motion (rather than against it) to provide compliance at the precise time resulting in a reduction rather than an increase in these torques."

—*EH (January 12, 2010)*

Self-Management: Enough to Treat Early OA?

Deep knee bends and champagne all around…for there is a good bit of news for those suffering with knee osteoarthritis (OA). Researchers participating in the Multidimensional Intervention for Early Osteoarthritis of the Knee (Knee Study) determined that physically inactive, middle-aged people with symptomatic OA benefitted equally from strength training regimens, self-management programs, or a combination of the two.



Medial View of the Knee/Wikimedia Commons

"We hypothesized that combining the two treatments might enhance the outcomes," said Patrick McKnight, lead author of the Knee Study, in the news release.

The 24-month Knee Study, conducted at the University of Arizona Arthritis Center in Tucson, was an unblinded, randomized intervention trial to compare the effects of strength training programs, self-management programs, and a combination of both. The 273 study participants were between 35 and 65 years of age, reported pain and disability due to knee pain on most days in one or both knees for a period of no more than five years, and had Kellgren/Lawrence classification grade 2 radiographic evidence of knee OA in one or both knees.

Participants were randomly assigned to one of three treatment groups. The strength training group engaged in a nine-month initial phase designed to improve the core areas of stretching and balance, range of motion and flexibility, and isotonic muscle strength. The second, 15-month phase of this group concentrated on developing independent, long-term exercise habits. The second study group participated in a two-phase self-management program designed to educate participants and provide one-on-one treatment advice. The combined group participated in both the complete strength training and self-management programs. A total of 201 out of 273 participants completed the two-year trial, with the self-management group achieving the highest compliance rates.

large joints

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While the researchers set out to demonstrate that a combination of OA treatment programs would prove most effective, the study failed to uncover significant differences in results among the three groups. All three groups demonstrated improvements in physical function tests and decreased self-reported pain and disability.

"The logic behind the combined treatment was that the different factors addressed in physical and psychological treatments might produce an additive effect if administered together," said Dr. McKnight in the news release. "These results suggest otherwise. Instead, the comparison of the three treatment arms showed no difference, suggesting similar benefits for all three over a two-year period."

When asked what led him to undertake the research, Dr. McKnight told *OTW*, "My colleagues and I were interested in additive effects—particularly those involving two known effective treatments for osteoarthritis. We wondered whether a combined treatment that had both behavioral (exercise) and cognitive (self-management) components would lead to more lasting effects over reasonably long period post intervention compared to each individual treatment. Those questions lead us to design a study focusing on a relatively high base-rate problem of osteoarthritis."

He also commented to *OTW*, "We had many surprising findings but I think the most intriguing was the finding that the combined treatment did not outperform each individual treatment. Null findings are not always terribly informative, but we planned our study with the potential for no difference findings. Specifically, we had more than adequate statistical power to detect a difference among the three groups and our treatment oversight ensured high levels of participant compliance with each treatment. We were impressed by our participants' willingness to engage in these treatments in spite of the fact that they were all sedentary individuals with little to no history of exercise participation and they all reported recent knee pain. So we learned that sedentary people with knee pain will comply with exercise at the same rate as they would comply with a cognitive (i.e., non-exercise) treatment."

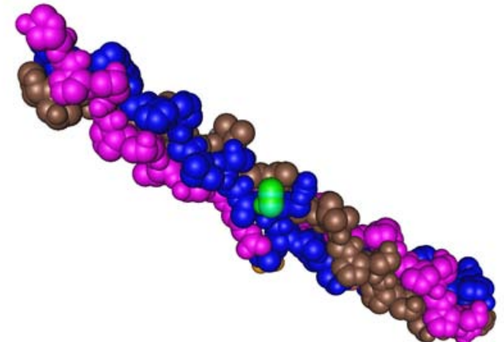
The full study may be found in the January 2010 issue of *Arthritis Care & Research*, a journal published by Wiley-Blackwell on behalf of the American College of Rheumatology.

—EH (January 13, 2010)

Researchers Create Strongest Form of Collagen

Mother nature…improved. A team of University of Wisconsin-Madison researchers has created the strongest form of collagen known to science, a stable alternative to human collagen that could one day be used to treat arthritis and other conditions that result from collagen defects. "It's by far the most stable collagen ever made," says Dr. Ron Raines in the news release. Dr. Raines, a University of Wisconsin-Madison professor of chemistry and biochemistry, led the study, which was published in the January 12 issue of the Proceedings of the National Academy of Sciences.

In 2006, Raines' team figured out how to make human collagen in the lab, creating collagen molecules longer than any found in nature.



Collagen Triple Helix/Wikimedia Commons

Now, using funds from the NIH [National Institutes of Health], the researchers have creating a form of super-strong collagen that may one day help millions.

Regarding when this collagen might be available to help those with arthritis and other conditions, Dr. Raines told *OTW*, "The application of our hyper-stable collagen to arthritis will take time, as its delivery to arthritic tissue is difficult. We are already, however, at a preclinical stage in the use of the technology to heal wounds."

To make the new form of collagen, Raines' team substituted two-thirds of the protein's regular amino acids with less-flexible versions that stiffened the overall structure of the protein and helped it hold its form. "The breakthrough of this approach was the use of rigid analogues that have shapes similar to [the shapes the natural amino acids take] in the folded, functional form of the protein," explained Raines in the news release.

The resulting collagen holds together at temperatures far above what it takes for natural collagen to fall apart. And although it's built largely from amino acids that aren't found in nature, X-ray crystallography confirms that the three-dimensional structure of the lab-made collagen is indistinguishable from that of natural collagen, according to UW-Madison bacteriologist Katrina Forest, a co-author of the study.

As for what he would like orthopedists to know about this work, Dr. Raines commented to *OTW*, "Over the last decade, we have achieved an understanding of collagen structure and stability that is extremely thorough, going all the way to a quantum mechanical level. That understanding led to the rational design of hyper-stable collagen. Our goal now is to use our hyper-stable collagen to empower orthopedists with new modalities for their patients."

When asked where they go from here, Dr. Raines told *OTW*, "Our hyper-stable collagen is a triple helix. Natural collagen is made of fibers, which are bundles of triple helices. We are now working to make collagen fibers that are like nature's, but stronger and longer. In the short term, we are using our existing hyper-stable triple helices to heal wounds. You will see fresh approaches from us on re-engineering wound beds within the next year or so."

—EH (January 20, 2010)

MSC Health in Sub Saharan Africa

From the veld to the Sahel, what is the state of musculoskeletal (MSC) health in sub-Saharan Africa? Specifically, what about those MSC conditions not attributable to injury? Researchers from the University of Cape Town set out to determine the prevalence of MSC conditions and the functional implications in a sample of people attending community health centers in Cape Town, South Africa.

The cross-sectional research was undertaken by Professor Jennifer Jelsma, Head of the Division of Physiotherapy in the School of Health and Rehabilitation Sciences at the University of Cape Town, as well as Romy Parker, Senior Lecturer in the Division of Physiotherapy in the School of Health and Rehabilitation Sciences at the University of Cape Town.

The descriptive study, partially funded by the South African Arthritis Association, was conducted in clinics in two resource-poor communities. Phase I consisted of screening for MSC not due to injury in the past three months. Those who screened positive for peripheral or spinal joint pain went on to complete Phase II, which included the Stanford Health Assessment Questionnaire.

A total of 1,005 people were screened in Phase I. Of these, 362 (36%)

Africa NASA-Satellite/

large joints

reported MSC not due to injury in the past three months. Those with MSC had higher rates of co-morbidities in every category than those without. The mean Disability Index for those with MSC was mild to moderate, and moderate to severe in those aged over 55 years.

Although the sample may not be representative of the general community, the prevalence is considerably greater than those reported elsewhere even when the population of the catchment area is used as a denominator, say the researchers. They also note that any new determination of burden of disease due to MSC should acknowledge that these disorders may be more prevalent in developing countries than previously estimated.

Co-author Romy Parker told *OTW*, "We were surprised that over one-third of people attending the community health clinic had musculoskeletal pain which was not due to trauma or injury. This figure is very high and when we looked at the figures relative to the size of the community, the prevalence was 362/100 000 which was over twice the estimated BoD (burden of disease) prevalence rate for Sub-Saharan Africa. We would like to conduct a community-based survey in order to explore whether the figures we obtained in those attending the clinic are reflected across the community."

When asked what might be helpful/ interesting for American orthopedists to know about their work, Parker said to *OTW*, "The majority of people presenting to this clinic with musculoskeletal pain had co-morbidities relating to age and life-style. The most common co-morbidities were hypertension, diabetes and heart conditions. Management of these patients needs to be comprehensive including appropriate medication, exercise and advice which is appropriate for all their conditions."

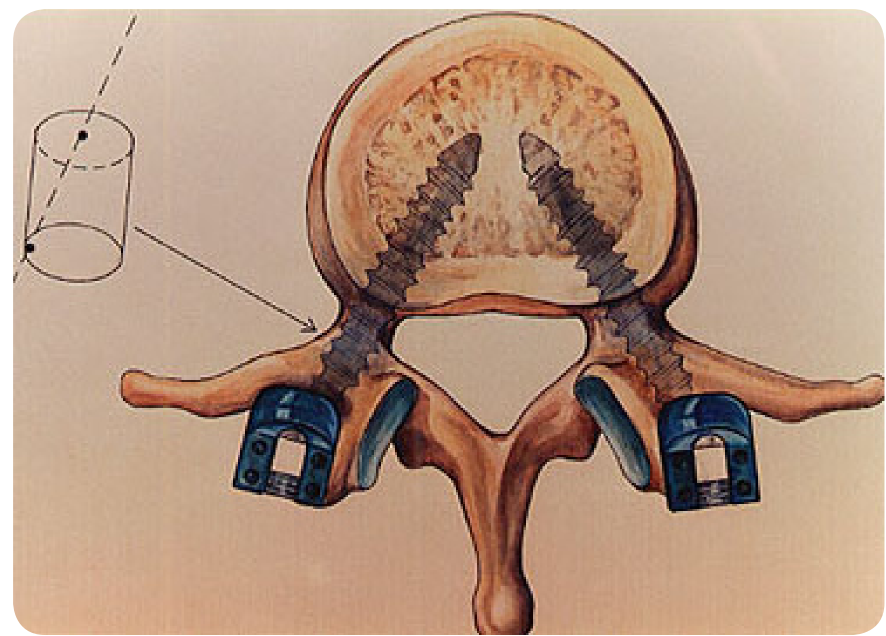
—*EH (January 21, 2010)*

spine

10,000th Case for PediGuard

Listen up…it's your pedicle talking…SpineGuard has announced that the 10,000th case has been performed using PediGuard, a device for safer pedicle screw placement in spine surgery—one that offers auditory feedback to enhance screw placement.

"PediGuard will probably become a standard tool in any spine surgery requiring instrumentation," said Randal Betz, M.D., Chief of Staff, Shriners Hospitals for Children, Philadelphia, in the news release. "Anything we can do to help us get a safer screw insertion is certainly worthwhile, given that published rates of pedicle screw misplacements are as high as 20%. PediGuard makes spine surgery safer for surgeons also. Fluoroscopy (a type of X-ray) is an imaging technique commonly used by physicians to obtain real-time images of the spine during surgery. While the exposure to a patient during one surgery is minimal, spine surgeons may perform 140 or more cases per year. Studies are showing that the use of PediGuard reduces fluoroscopy time by one-third in some surgeons'



Pedicle with screws / Medscape.com

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spine

cases. Less use of fluoroscopy per case means significantly less accumulated radiation exposure over the course of a typical year's worth of cases."

"As a PediGuard user for over eight years, I have enjoyed using this device for pedicle screw insertion," added André Kaelin, M.D., Chief, Department of Paediatric Orthopaedics, Children's Hospital, Geneva, Switzerland. "After training and a brief learning curve, you add a third sense—the auditory—as an additional help for pedicle preparation. With time, the sound frequency and tone becomes a preeminent part of your technique. For a University Hospital, PediGuard is an invaluable teaching tool: you can assist your residents and ensure safe control of their actions."

Pierre Jérôme, CEO of SpineGuard, told *OTW*, "Each change in electrical conductivity leads to an immediate change of sound pitch and cadence, thus guiding the surgeon through the pedicle while drilling. When going into the cancellous bone the surgeon will hear a medium pitch, medium cadence. Into the cortical bone the surgeon will hear a low pitch, low cadence. If a breach occurs, the surgeon will be alerted by a high pitch high cadence. By guiding the surgeon through the pedicle, the PediGuard makes safer pedicle screw placement by alerting the surgeon prior to full breach, allowing for redirection of instrument in real time and reducing X-ray exposure."

According to the company, PediGuard is the first and only handheld, wireless device that can detect possible vertebral cortex perforation during pedicle preparation for screw placement. The PediGuard technology is based on electrical conductivity, which enables discrimination of cortical bone, cancellous bone and soft tissues.

Regarding the company's future plans, Jérôme commented to *OTW,* "2009 was for SpineGuard primarily about putting the business fundamentals in place and transferring the PediGuard technology from SpineVision—remember that the company got off the ground on April 7th after eight months of fund raising, negotiation and foundation. In 2010, our three main operational objectives are to increase market adoption, initiate new clinical studies and drive innovation. All those are geared towards the accomplishment of our vision: establish the PediGuard technology as a standard of care in spinal screw placement."

"To increase market adoption, we are expanding our commercial network, we are investing in the training of our sales forces and we are fostering surgeon-to-surgeon exchange thru case review forums. The fact that we are totally dedicated to PediGuard and our mission of making spine surgery safer allows us to partner with high performing distributors regardless of the spinal screw brand they commercialize," added Jérôme.

He continued, "PediGuard clinical efficacy has already been clearly demonstrated in several peer reviewed journal publications, multiple abstracts and posters as well as through the 10,000 cases already performed. However, we wish to continue to invest in clinical studies to further establish its superiority over other modalities i.e., manual techniques, fluoroscopy, navigation, EMG and to highlight its cost effectiveness. Not to mention that clinical studies on Pediguard cost much less time and money than traditional clinical studies in spinal surgery because you can measure its accuracy at the time of the case (no need to follow-up patients) and there are least four screws placed on every patient."

Jérôme also told *OTW*, "With SpineGuard and our full focus on PediGuard, we have identified more than 40 potential technology developments. We are now in the process of precisely defining, qualifying and calibrating those R&D projects, all derived from the PediGuard technology platform. Our product is unique, our IP is strong but we want to develop it further and remain ahead of the game in making spine surgery safer. At the end of January, we will be holding our first SAB (Scientific Advisory Board) meeting with the objective to prioritize our clinical and R&D pipeline. This will be a very important step forward for us."

—EH (January 11, 2010)

trauma

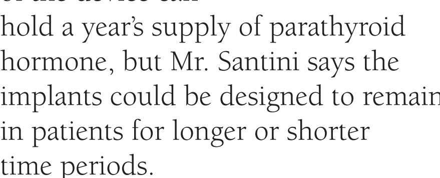
Treating Osteoporosis With Microchips

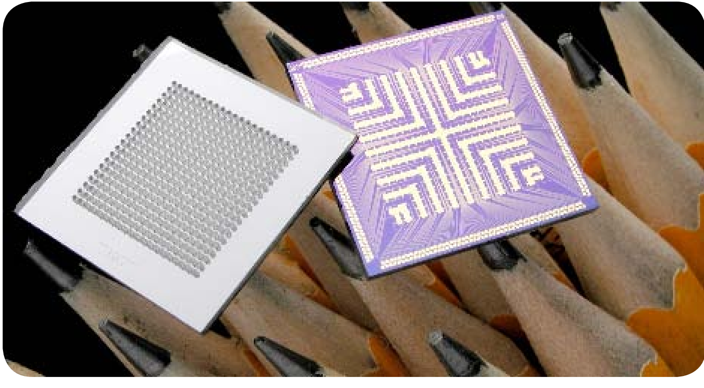
Microchip implants which automatically deliver daily doses of osteoporosis medicine: science fiction or the new reality in 2010? It isn't yet commercially available, but if you ask anyone at MicroCHIPS, Inc., the technology does indeed exist. The company recently announced that it has secured $16.5 million in equity financing and is working toward the first clinical studies of the safety and efficacy of treating osteoporosis with microchip implants.

High-Tech Drug Therapy

"It looks very much like a pacemaker or a defibralator," says MicroCHIPS President and CEO, John Santini. Inside a titanium case, the drug, an anabolic bone building agent called parathyroid hormone, sits in a micro reservoir array in a microchip. The electronic device releases the medication on demand or at pre-programmed intervals. The company is also developing a device to help treat diabetes which can monitor glucose levels in the blood and send data to a mobile device.

Some patients may not like the idea of getting an electronic implant, but for many, it would be a nice alternative to daily injections of medicine. Physicians can implant the microchip device subcutaneously, most likely in the patient's abdominal area, with a minimally invasive procedure which takes about 20 to 30 minutes and requires only local anesthetic. The physician then turns on the device wirelessly, and a pre-installed program begins to deliver medicine on a daily basis. Current models of the device can hold a year's supply of parathyroid hormone, but Mr. Santini says the implants could be designed to remain in patients for longer or shorter time periods.





Dana Lipp Imaging / Provided courtesy of MicroCHIPS

Ensuring 100% Compliance

MicroCHIPS isn't the only company creating alternatives to injectable osteoporosis drugs. For example, Emisphere Technologies, Inc. is developing oral forms of these medicines, and TransPharma Medical Ltd. is working on transdermal drug delivery with patches patients can place on their skin.

However, according to Mr. Santini, needles aren't the only problem with current osteoporosis drug therapy. "One of the issues with this particular treatment is very poor compliance. Within a year, there are only about 20% to 50% of patients still taking that drug. The fact that this is a daily medication plays a significant role in whether or not people stay on it, and any daily medication has poor compliance. Blood pressure medication is a particularly good example because you don't feel sick, and if you don't feel sick, even though you know it's good for you, you don't take the medication. Osteoporosis is one of those diseases—until you fracture a bone or until you have disability caused by the osteoporosis, you don't feel sick. In our case, however, once you have the implant, you don't think about it until the year is up."

Researchers at MicroCHIPS have completed pre-clinical studies and hope to begin the first clinical study within the next year or so. As far as the cost of the implant, Mr. Santini says, "we are going to be very competitive with the therapies that are already out there." In the midst of the current health care debate, no one can predict whether or not insurance companies would provide reimbursement for this kind of device, but Mr. Santini remains hopeful. "Part of the philosophy behind healthcare reform is to ensure that people are getting the right therapy at the right time. Our view is that ensuring 100% compliance is going to be better not only for the patient but for the health care system as well."

—DK (January 15, 2010)

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trauma

Work Time Lost After Trauma

No walkabouts if your leg's broken…so that can't be the reason that Mr. X is still off work. Australian researchers have set about studying what factors might give clues as to the duration of time away from work following acute orthopedic non life threatening trauma. Their findings? That a number of injury-related and psycho social issues affect how long someone is off work following orthopedic injury…and that some of these things can be modified.

The six-month study involved 168 patients ranging in age from 18 to 64, all of whom worked prior to the injury and sustained a range of acute unintentional orthopedic injuries resulting in hospitalization. In this prospective cohort study, conducted at four hospitals in Victoria, Australia, researchers gathered baseline data via survey and medical record review. The study achieved 89% follow-up.

A full 68% of participants returned to work during the study. Multivariate Cox proportional hazards regression analysis identified that blue collar work, negative pain attitudes with respect to work, high initial pain intensity, injury severity, older age, initial need for surgery, the presence of co-morbid health conditions at study entry and an orthopedic injury to more than one region were associated with extended duration away from work following the injury. Participants in receipt of compensation who reported high social functioning at two weeks were 2.58 times more likely to have returned to work than similar participants reporting low social functioning. When only those who had returned to work were considered, the participant reported reason for return to work "to fill the day" was a significant predictor of earlier RTW [return to work] whereas "financial security" and "because they felt able to" did not achieve significance.

Some of these predictors may be modified with the proper assistance, say the researchers. Further consideration of the reasons provided by participants for returning to work may provide important opportunities for social marketing approaches designed to alleviate the financial and social burden associated with work disability.

Providing background to *OTW* was Fiona Clay, a Ph.D. student at Monash University, who noted, "Acute orthopaedic trauma is a common reason for hospitalization and is often associated with ongoing pain and disability. To date there has been little research examining person-specific factors associated with the duration of time away from work following acute trauma. Although a number of studies have considered work disability in the context of multiple injuries or

in relation to specific acute injuries there has been little research that has examined the determinants of return to work following non life threatening acute orthopaedic trauma. These injuries comprise the majority of traumatic injuries. While they are less serious with respect to the threat to life, it is not known whether they are less serious with respect to long-term disability. There is current uncertainty about who is at risk of work disability and a need to better manage the socioeconomic costs associated with ongoing work disability."

She also told *OTW*, "We were surprised at the extent of ongoing pain and work disability in the study cohort. Thirty-two percent of the cohort remained off work at the end of the six-month study. More than fifty percent of the sample reported the presence of persisting pain six months post injury. The results highlight the need for additional research into long term outcomes following non life threatening acute orthopaedic injuries."

As for future work in this area, Clay told *OTW*, "Additional work has been carried out to understand the prevalence of persistent pain and identify early predictors of pain and pain related work disability in this injury sample. Future work will examine the role of recovery expectations and what the injured workers indicated would assist their recovery."

The work was carried out at the Monash University Accident Research Centre. The study was funded by the Transport Accident Commission (TAC) and the Monash Postgraduate Students Fund.

—EH (January 18, 2010)

Ortho Community Races to Haiti

News continues to trickle in about the earthquake in Haiti and efforts by orthopedics surgeons, nurses, hospitals, medical societies, and other providers to respond to what is looking like the worst orthopedic catastrophe in recent memory. Unlike tsunamis, floods and other natural disasters, earthquakes break bones and break the medical infrastructure which is needed to respond to tens of thousands of traumatic injuries. The need for surgeons and orthopedic health care providers is the greatest in such circumstance.

Barth Green, M.D.

We will continue to keep our readers updated on the latest efforts by the orthopedic community to save Haitians.

HSS Ortho team prepares to depart for Haiti/photo courtesy of HSS

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trauma

While the American Academy of Orthopaedic Surgeons has coordinated volunteer efforts of its members with rescue organizations, reports are coming in of other efforts to help.

One such effort is by the Hospital for Special Surgery (HSS) in New York. Last Friday anesthesiologists, nurses and orthopedic surgeons left for Haiti on Friday to join other medical teams in this humanitarian effort. A hospital spokesperson has promised to update our readers as the team is able to report on their efforts.

In another effort, the *Miami Herald* reports that one of the first surgeons to get into Haiti after the earthquake was Barth Green, M.D., a University of Miami neurosurgeon and co-founder of Project Medishare for Haiti in 1994 Medishare runs clinics and training programs in several Haitian cities, in partnership with the Ministry of Health.

The *Herald* reports that Green is helping coordinate international medical relief, and will oversee a new field hospital rising on vacant land in the northwest corner of Port-au-Prince's international airport in two tents arranged with the help of retired Miami Heat star Alonzo Mourning.

One will house about 100 medical staff; the other 300 patients and two operating rooms. It is expected that patients will start moving in Monday, January 18.

A University of Miami spokesperson told the Herald that all the medication and equipment, such as sonogram and X-ray machines, have been donated, as have the corporate jets flying doctors and supplies in and out of the island.

—*WE (January 18, 2010)*

Contribute to Orthopedic Caregivers

After reading about the Hospital for Special Surgery's orthopedic team's efforts in Haiti, some device companies contacted *Orthopedics This Week* to offer their support.

We've set up a link for orthopedic and spine device companies to offer supplies, implants or cash to orthopedic caregivers rushing to Haiti.

trauma

Please click on the link to the organization your company would like to contact to offer assistance.

Orthopedics This Week is interested in hearing about your company's participation and contributions to the orthopedic relief efforts in Haiti. Please email us at walter@ryortho.com with your stories and information of your involvement. We'll share those with our readers.

Thanks for your support.

—WE (January 19, 2010)

Organization	Link
American Red Cross	http://www.redcross.org
Clinton Bush Haiti Fund	http://clintonbushhaitifund.org/
Center for International Disaster Information	http://www.cidi.org/reg_off.htm
Catholic Relief Fund	http://www.crs.org
Doctors Without Borders	http://doctorswithoutborders.org
Global Outreach International	http://www.globaloutreach.org
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Mercy Ships	http://www.mercyships.org
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Project Hope	http://www.projecthope.org
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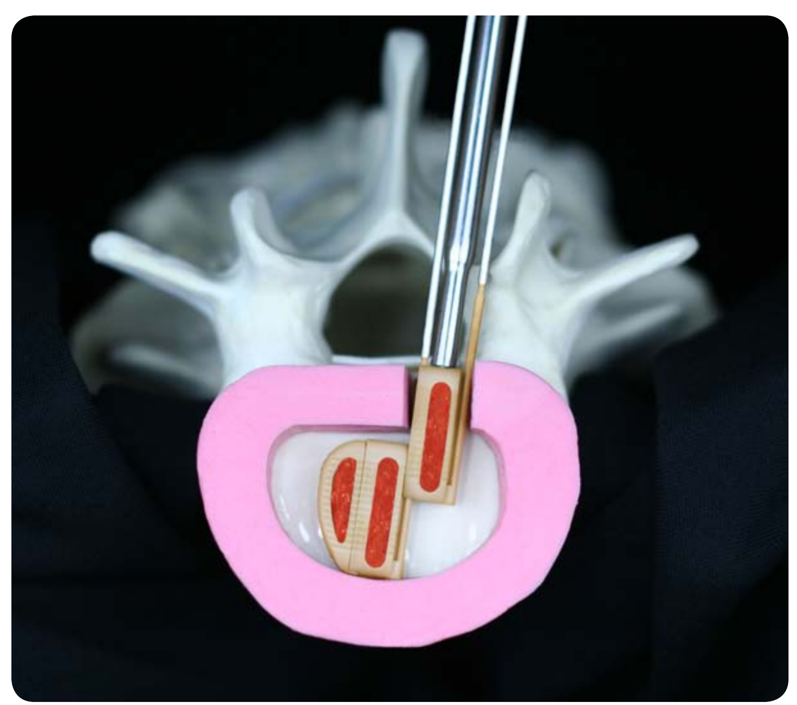
500th Surgery for InterFuse



An eight-year-old wonders, "How did they get that ship in the bottle?" A 40-year-old orthopedist says, "Ah, this is how you assemble a big implant *inside* a patient." And now, Vertebral Technologies, Inc. (VTI), is announcing the implantation of the 500th InterFuse Device. The procedure was performed using VTI's patented Intraoperative Assembly technology, which allows surgeons to assemble a large implant through a minimally invasive surgical approach. The Unilateral Posterior Lumbar Interbody Fusion (UPLIF) procedure uses a single posterior incision to access the disc, reducing tissue dissection and nerve root retraction while preserving the facet joints.

Gregory D. Carlson, M.D., of Orthopaedic Specialty Institute of Orange County in Orange, California, said in the news release, "The InterFuse Interbody Fusion System allows me to treat patients using a minimally invasive posterior surgical approach to the spine and implant a larger fusion device than is possible with other systems. This combination offers my patients better fusion outcomes while significantly reducing post-operative pain."

Jeffrey Felt, M.D., Chief Executive Officer of VTI, added, "Achievement of this milestone less than 16 months after introduction demonstrates the rapid adoption of the Interfuse Interbody Fusion System and validates our Intraoperative Assembly approach to implanting large devices through minimal access surgery. VTI continues to develop this concept for surgical approaches using both fusion and non-fusion devices, particularly the InterCushion Disc Nucleus Replacement Device."

As indicated by the company, it has pioneered intraoperative assembly technology which enables spine surgeons to implant large, customized devices in the intervertebral disc space. This technology platform is being adapted for a number of spinal implant applications. VTI's first two products are the InterFuse Interbody Fusion System, which has been available for sale in the U.S. since 2008 and the InterCushion Disc Nucleus Replacement, which will begin human clinical testing in 2010.

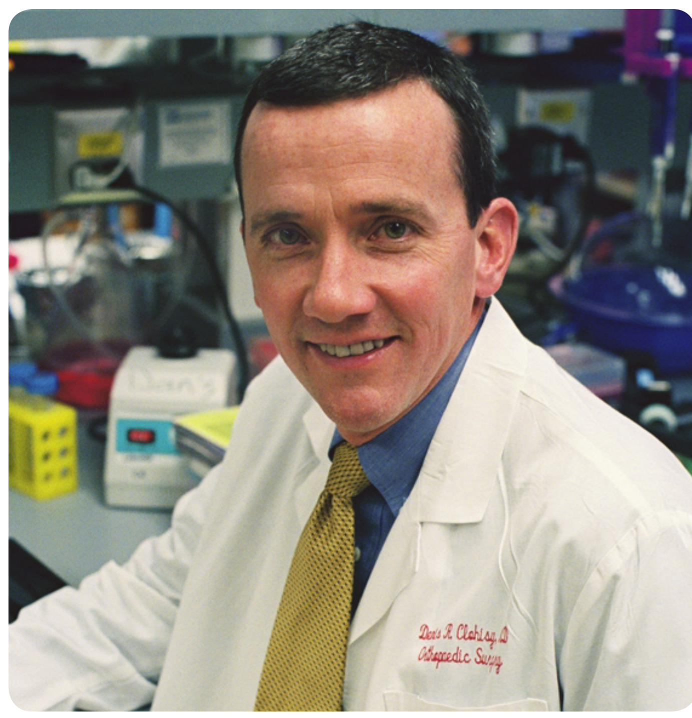
Regarding the commercial distribution, Tim Kelly, Vice President of Sales, told *OTW*, "VTI completed the pilot phase of the InterFuse launch in 2009 and is poised for broad market introduction in 2010. VTI has established a network of independent distributors and is currently expanding into new geographic markets on a weekly basis. The unique nature of the InterFuse allows these distributors to add a clearly differentiated product to their portfolio."

When asked about future milestones, Dr. Felt commented to *OTW*, "In 2010, we will continue to expand distribution in the U.S. and to grow sales of the InterFuse Interbody Fusion System. Commercial distribution is progressing, supported by new marketing materials including website, teaching models, and presentation of outstanding clinical effectiveness data at CNS and the upcoming AANS/CNS Joint Section on Disorders of the Spine."

—EH (January 15, 2010)

The Picture of Success: Dr. Denis Clohisy

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



Being one of ten children, he had to learn to focus. Fortunately for those suffering from bone cancer, Dr. Denis Clohisy, Chair of the Department of Orthopedic Surgery at the University of Minnesota, has brought his pinpoint vision and insight to the lab.

Born in Evanston, Illinois, Dr. Clohisy is philosophical about his upbringing. "Being one of ten kids was a wonderful experience, and I think, has helped me better understand the variety of personalities, talents and dreams that are out there. As for my parents, they just expected that we do our best."

Denis Clohisy took this expectation and, well, magnified it. "In high school I developed a fondness for chemistry, then went on to major in that field at Knox College in Galesburg, Illinois. I was able to do an independent study using the electron microscope and was fascinated because it could take you down into the cells…it was like driving around in the cell. That's when I realized I wanted to both pursue a career in research—and be a doctor."

Training for the Lab and the Hospital

Setting his sights high, the modest Dr. Clohisy says he then bumped up against a few people higher up on the intellectual mountain.

> *"I attended Northwestern for medical school, in part because I already had a connection there—during college I was a research fellow at Northwestern through the American Heart Association. One of the main things medical school taught me? That there are a lot of people out there who are smarter than I am… a good life lesson."*

But he was certainly savvy enough to negotiate for what he wanted. "In 1983 I began an orthopedic residency at the University of Minnesota—this is after ensuring that they would give me enough time to explore research opportunities inherent in orthopedics. In all, the program took seven years because I spent two years doing full time research at Washington University in St. Louis. While there I worked with a world expert in bone disease, Dr. Steve Teitlebaum, who taught me that I should always have a vision of achieving something great. Also critical to my professional life was Dr. Zvi Bar-Shavit, an Israeli scientist who taught me how to conduct top notch research, imparting the helpful wisdom that a researcher should focus his efforts on one thing and do it exceptionally well. Then there was Dr. David Lacey, who possessed a unique talent and enthusiasm for applying science to medicine."

Returning to Minnesota for three years, Dr. Clohisy then made a strategic decision. "I knew that in order to do the research I wanted to do, I would have to be at a major medical center. I knew I would have that freedom within the world of orthopedic oncology because most of this work occurs at such institutions. There was also the dawning realization that I really liked taking care of pediatric oncology patients."

The wisdom of other prominent orthopedists also helped him find his path. "In 1990 I began a fellowship at Harvard in musculoskeletal oncology, something which held a significant amount of responsibility. Fellows oversaw the clinical program, including the residents, patients, surgical scheduling, ordering implants, etc. The preeminent academic surgeon, Dr. Henry Mankin, guided me through much of this. His love

of orthopedics and medicine was impressive, as was his tendency to ask 'the why's' of orthopedics. Dr. Dempsey Springfield taught his clinical mastery by example, and Dr. Mark Gephart gave me a wonderful experience in dealing with children who had cancer. In particular, he set a helpful example of how to work with families."

Researching Cancer and its Treatment

Looking back over 22 years of continuous NIH funding, Dr. Clohisy reflects, "Early on we discovered that osteoclasts destroy bone at the sites of the tumor, in contrast to the long-held belief that tumors ate at bone. While we weren't the only ones pursuing this line of research, I am proud to say that our work helped change things such that we now treat osteoclasts in addition to treating the cancer."

But ultimately, of course, they are treating a human being who has bone cancer pain. And, says Dr. Clohisy, if they can determine the exact mechanism of pain, then they can better treat those tormented by this condition. "One part of the pain is caused by the osteoclasts stimulating the nerves. Other pain is caused by weakening of the bone. I collaborated with Dr. Patrick Mantyh, a neuroscientist, on this work. I understand bone cancer and he understands pain and neuroscience, so it was a good fit. Working with Dr. Mantyh was a once in a lifetime opportunity and an adventure. We formed a great team, which was driven primarily by his energy and wonderful commitment to discovery. It was a rare thrill to be the first group to discover many of the ways that bone cancer causes pain."

The American Academy of Orthopaedic Surgeons (AAOS) chose Dr. Clohisy to Chair the research development committee. Dr. Clohisy, who has a particular interest in the development of orthopedic clinician scientists, notes, "The greatest thing about this role is working with people on the committee. The variety of talents comes from the Orthopaedic Research Society, the Orthopaedic Research and Education Foundation, AAOS Leadership Fellows, etc. We also have resident representative from AAOS who work on the clinician scientist development program, attend NIH discussions, and meet congressional leaders."

Advice for Aspiring Clinician Scientists

In terms of what residents need to become clinician scientists, Dr. Clohisy states, "There are a couple of obstacles to this, the most significant being the debt that many residents have from educational loans. This is an especially heavy burden because clinician scientists have lower salaries and don't enter the workforce until later because of the extra time required for scientific training. In addition, for the past five or six years, there has been an increasingly competitive funding environment at NIH. There has been a bit of relief from the stimulus package, however. Another issue is that residents often have limited training in grant writing.

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That is being corrected to a certain extent as we now have grant writing training programs through the Bone and Joint Decade, as well as several programs through the specialty societies."

Then there are the cultural issues: 1) lab versus OR; and 2) How does young Dr. Smith advocate for her superiors to understand the importance of lab time? An adamant Dr. Clohisy says,

> ***"Residents must have protected time to do their research. Most of these young surgeons are understandably excited about their surgical skills, and that tends to draw them away from using the protected time for lab work. Also, the orthopedic leadership in the departments may not fully understand the protected time needs that they have. This is not always part of the institutional culture, particularly in the surgical disciplines. But how else will our field advance?"***

In this time of shoestring funding, it is especially important to drive home the importance of research. Dr. Clohisy reports: "With the support of AAOS, we go to 'The Hill' to deliver our message. Patient advocates and physicians hold 'Capitol Hill' days in which we advocate for research funding. There is also an educational program for the patients, physicians and scientists, followed by a dinner with a speaker who discusses the need for musculoskeletal research. The next day the patients go to Capitol Hill where they are divided into geographic districts—then they go see their congressional representatives from their districts. Everyone makes important contacts and follows up with their representatives later on reporting the status of musculoskeletal research."

When he comes down from the hill and the lab, Dr. Clohisy meets a bevy of children—not ten, mind you, but a few. "My overall happiness is a reflection of my family. They are highly supportive of my work needs and my responsibilities. I have three children, two boys and a girl—all teenagers. I get involved in their sports, and watch my daughter dance—her passion. When we get away as a family, I make sure it is to anyplace warmer than Minnesota and usually go fishing."

Dr. Denis Clohisy…asking "why" and searching for answers.

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