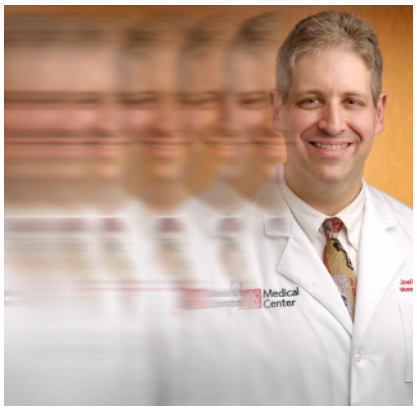
VOLUME 7, ISSUE 17 | MAY 24, 2011

Orthopedics This Week

week in review

4 **Ankle Surgery Biologics Drama at FDA Panel** ◆ Biologics for ankle fusion got a shot in the arm when the FDA's Orthopedic Panel voted to recommend approval for BioMimetic's Augment. It wasn't pretty. It was dramatic, close and contentious. We were there when CEO Lynch made his "Hail Mary" pitch.

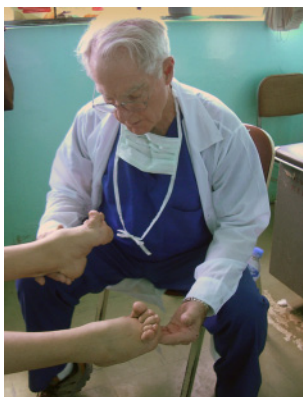
8 **The Restless Orthopedic Surgeon** ◆ Creativity and orthopedic surgery are usually incompatible concepts – except in oncology. There we find a restless class of surgeons who scramble onto the surgical high wire and perform remarkable feats of anatomical reconstruction.



13 **Scalpel…Now or Later?** ◆ What does the latest evidence-based literature say regarding the surgical timing of injured extremities? Are there guidelines for acute versus staged care? What if there are pulmonary problems or a chest injury…read on.

picture of success

27 **Dr. Taylor Smith** ◆ Dr. Taylor Smith, winner of the 2011 Humanitarian Award from AAOS, has worked with Chinese refugees in Hong Kong, contributed first hand to musculoskeletal care in Fiji, and has made a number of trips to Haiti since the earthquake.



breaking news

17 Biotech Firms **Histogenics** and **ProChon Merge**

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Anesthetic Change Boon for Patients

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U.S. Senate **Looking at PODs**

Quick to Dough PMMA From **Medtronic**

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Macro factors such as regulatory, reimbursement and the general economic funk (high unemployment rates and budget cuts at state and federal levels) create conditions for low sales growth rates, but building pent-up demand. Low single-digit sales growth generally is the new normal.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Alphatec	1.11	13.55%	According to Wall Street's analysts, ATEC is expected to have the highest rate of earnings growth of any orthopedic stock in 2011.
2	2	Orthofix	14.49	17.19	With the lowest P/E to growth ratio and the 3rd lowest future P/E, OFIX still best value.
3	3	NuVasive	6.69	11.73	NUVA is now the bellwether spine surgery implant supplier. It will pull up the industry.
4	4	Zimmer	26.64	10.01	The key to ZMH is that operating margin. It forms the basis for investor interest. Any investor.
5	5	Johnson & Johnson	26.33%	2.02	Now comes the long, slow process of merging two armies—Synthes and DePuy.
6	7	Stryker	25.61	2.34	Valuation is actually pretty attractive at these levels—8th best in ortho.
7	8	Medtronic	31.23	8.58	New CEO should give MDT a sense of direction and renewed purpose.
8	6	Integra LifeSciences	15.18	3.76	IART's collection of small to mid-sized companies a strategic conundrum in a period of health care reform.
9	9	Smith & Nephew	23.22	2.54	Is wound care the new hot product category? Biohealing's sale to Shire colors SNN.
10	10	Symmetry	8.08	(3.50)	2nd best PSR and very low P/E to growth rate is the only reason SMA makes the Power Rankings.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Orthovita	VITA	$3.83	$295	76.50%
2	Tornier N.V.	TRNX	$26.98	$1,053	34.90%
3	Mako Surgical	MAKO	$31.98	$1,310	21.14%
4	Orthofix	OFIX	$39.00	$704	17.19%
5	Alphatec Holdings	ATEC	$3.52	$314	13.55%
6	NuVasive	NUVA	$30.85	$1,224	11.73%
7	Zimmer Holdings	ZMH	$67.70	$12,996	10.01%
8	Stryker	SYK	$63.42	$24,607	8.58%
9	Medtronic	MDT	$42.21	$45,138	3.76%
10	*ConMed*	*CNMD*	*$28.82*	*$816*	*3.56%*

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TranS1	TSON	$4.25	$89	-20.56%
2	TiGenix	TIG.BR	$1.65	$51	-8.00%
3	Symmetry Medical	SMA	$9.64	$351	-3.50%
4	CryoLife	CRY	$5.30	$148	-3.11%
5	ArthroCare	ARTC	$33.25	$908	-2.72%
6	Wright Medical	WMGI	$15.40	$601	-2.28%
7	Kensey Nash	KNSY	$24.50	$209	0.45%
8	Exactech	EXAC	$17.77	$232	0.97%
9	RTI Biologics Inc	RTIX	$2.84	$157	1.07%
10	Bacterin Intl Holdings	BONE	$3.35	$128	1.52%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Medtronic	MDT	$42.21	$45,138	12.79
2	Johnson & Johnson	JNJ	$65.69	180,066	13.63
3	Kensey Nash	KNSY	$24.50	$209	13.92
4	CryoLife	CRY	$5.30	$148	14.32
5	Zimmer Holdings	ZMH	$67.70	$12,996	14.94

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	NuVasive	NUVA	$30.85	$1,224	36.73
2	ArthroCare	ARTC	$33.25	$908	27.94
3	Wright Medical	WMGI	$15.40	$601	23.69
4	Synthes	SYST.VX	$169.72	$20,159	22.19
5	ConMed	CNMD	$28.82	$816	22.00

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Orthofix	OFIX	$39.00	$704	0.87
2	Kensey Nash	KNSY	$24.50	$209	0.98
3	Exactech	EXAC	$17.77	$232	1.13
4	NuVasive	NUVA	$30.85	$1,224	1.15
5	Symmetry Medical	SMA	$9.64	$351	1.38

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	Alphatec Holdings	ATEC	$3.52	$314	4.46
2	CryoLife	CRY	$5.30	$148	2.86
3	ConMed	CNMD	$28.82	$816	2.43
4	Johnson & Johnson	JNJ	$65.69	180,066	2.06
5	Integra LifeSciences	IART	$51.01	$1,457	1.81

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	RTI Biologics Inc	RTIX	$2.84	$157	0.94
2	Symmetry Medical	SMA	$9.64	$351	0.97
3	ConMed	CNMD	$28.82	$816	1.14
4	Wright Medical	WMGI	$15.40	$601	1.16
5	Exactech	EXAC	$17.77	$232	1.22

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Mako Surgical	MAKO	$31.98	$1,310	29.57
2	TiGenix	TIG.BR	$1.65	$51	21.35
3	Synthes	SYST.VX	$169.72	$20,159	5.47
4	Tornier N.V.	TRNX	$26.98	$1,053	4.63
5	TranS1	TSON	$4.25	$89	3.40

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

Ankle Surgery Biologics Drama at FDA Panel

By Walter Eisner

Photo manipulation by RRY/ Walter Eisner

Sam Lynch, founder, president and CEO of BioMimetic Therapeutics, Inc., had heard enough.

Lynch, D.M.D., D.M.Sc., had been in the audience all day on May 12 as FDA staffers and some members of the FDA Orthopedic and Rehabilitation Devices Panel tried to rip apart his company's Augment Bone Graft clinical study.

Augment is designed to be used by orthopedic surgeons during ankle surgery, specifically hindfoot and ankle fusion procedures, as a replacement for autograft bone harvesting. BioMimetic is seeking a premarket application (PMA) approval.

More on the specifics of Augment and the clinical study later.

Trial Questioned

"The trial has no meaning," said Brent Blumenstein, Ph.D., a statistical consultant and long serving member of the Panel. Lynch had also listened to the FDA point out the risk for "potential" for cancer formation in patients receiving Augment based on a Black Box warning for a Johnson & Johnson product called Regranex. Augment contains the same PDGF molecule as Regranex. Regranex is FDA approved for use as a foot ulcer treatment. In addition, Lynch's team had to spend the day responding to questions about the way adverse events were defined and reported in the study, shifting primary study endpoints, the appropriateness of CT scans and the effectiveness of bone grafting itself.

Lynch's "Hail Mary"

The panel was about to vote when Lynch made an unscheduled and impassionate presentation to the panel.

"Please," he pleaded, "judge our product by our clinical evidence, not some other product." Lynch told the panelists that the company's recombinant human

Sam Lynch, D.M.D., D.M.Sc./BioMimetic

platelet-derived growth factor (rh-PDGF) had been in clinical use for over five years, in 250,000 patients as a dental product (sold under the brand name GEM 21S). Furthermore, Lynch pointed out, 600 patients in the U.S., Canada and Europe had already been treated with Augment and ***not one*** significant adverse event was ever reported.

Lynch felt compelled to speak directly to the panel to address items brought up during the meeting. As the leader of the team and given how the day had gone, Lynch thought it was his responsibility to make the final argument, and if necessary, "take the bullet" if the panel voted against approval. Considering how the day had gone, that outcome would not have been surprising.

Biologic FDA Woes

The FDA has not been a friendly place for biologic products intended for surgery. Recently the agency denied Medtronic's application to have its bone morphogenic protein product, Amplify, approved for spine fusion surgery and before that the FDA panel failed to recommend Stryker's bone morphogenic protein, OP-1, also for spine surgery.

The financial markets, in anticipation of yet another panel biologics rejection, had sold BioMimetic's stock off – driving it down to 40% to $8.00 from $14.00 –

when word of the FDA's concerns with the company's PMA was made public.

It was under those circumstances that Dr. Sam Lynch stood up and made his speech at the end of a brutal day in front of the panel.

Safe, Effective and Beneficial

The final vote was 12-6 in favor of approving Augment as a safe treatment for ankle surgery. The panel members spoke publicly about their votes. Panelists and clinicians Glenn Johnson, M.D., and Sam Nasser, M.D., Ph.D, both said they were swayed by Lynch's summation and were openly critical of the FDA for not presenting the safety record of the company's dental product. When the panel was discussing adverse reaction definitions, Nassar said he thought the agency came in to the meeting with an agenda. Mark Malkerson, the agency's representative on the panel, gamely told the panel that the agency would endeaver to do better in the future.

The panel went on to vote 10-8 that Augment for ankle fusion surgery was effective and, finally, voted 10-8 that this PDGF biologic product when used by surgeons in hindfoot and ankle surgery, delivered benefits that outweighed the risks.

A contentious and long day had come dramatically to an end.

Lynch and the BioMimetic's team had swayed a particularly large panel with 18 voting and three non-voting members.

Panel Deliberations

As is customary, the day of the FDA Panel meeting began with a presentation by the company and was followed by a full bore attack by the FDA. In fairness, the FDA staff is required to play "devil's advocate" and give panel members reasons to find shortcomings with the company's PMA and clinical trial data. The panel is made up of clinicians, academicians and statisticians who are charged with reading and considering the voluminous materials, testimony and then to openly debate the merits of the application and criticisms.

Walter Eisner

In our experience with panels, statisticians almost always find enough faults with the applicant's clinical trials to deem the study "meaningless." It's usually left to the clinicians who have the responsibility of treating patients, to provide the "real" world perspective for the FDA.

And so it was with Augment.

The Challenge

Ironically, it was a clinician, William Rohr, M.D., an orthopedic surgeon from California who took the panel on an early tangent over the effectiveness of bone graft in general. BioMimetic set out to prove that Augment was not inferior to autologous bone graft in promoting fusion. Its primary benefit is that the use of the product spared patients from undergoing a second ankle surgery to harvest bone.

In Rohr's view, Augment was being recommended by BioMimetic for a questionable procedure (bone graft fusion), which could open up new potential risks (cancer) for little or no benefit (bone graft harvest site pain).

It was left to the other surgeons on the panel to forcefully argue that while using bone graft to promote fusion in the ankle was not a preferred choice, for patients with various comorbities such as diabetes, obesity and aging bones, using bone grafts was the gold standard. Several panelists even argued that the absence of pain by not having a second operation to harvest their graft was irrelevent.

Due to the relatively low number of ankle surgery patients in the study (434), the dropping of 37 patients for major protocol violations or not treated at all, caused the statisticians to declare the study underpowered. Again, the clinicians spoke up and said they

found the reasons for excluding the 37 patients as reasonable.

Clinical Trial

BioMimetic's clinical trial for using Augment in ankle surgery was approved by the FDA in 2007. The company enrolled 434 patients for treatment in a Pivotal Randomized Controlled Trial (RCT) at 37 centers in the U.S. and Canada. It was the largest RCT ever for the foot and ankle. The company's PMA was accepted for review by the FDA in 2010.

The primary endpoint was the percent of patients whose ankles successfully fused at six months (a 50% osseous bridging via CT). Secondary endpoints were clinical, functional, radiologic, quality of life, and safety outcomes.

The data was not perfect. While six-month data showed that Augment was non-inferior to autografts, Augment failed to show non-inferiority at the 36-week and 52-week follow-up points. The results were close and hurt by the unavailability of some patients for follow-up. The long term follow-up points caused the spine surgeon on the panel, Raj Rao, M.D., to comment that biologics may not stay as robust over time and degradation of the bone quality is possible.

Augment Bone Graft

Augment is a blend of calcium phosphate (beta-TCP), bovine collagen and human platelet derived growth factor. Augment's beta tri-calcium phosphate is the scaffold upon which bone is expected to grow after surgery. The human platelet derived growth factor (rhPDGF-BB) is the signaling protein that triggers new bone growth in the ankle. The conclusion of the study was that the matrix plus the biologic accelerated fracture healing and enhanced joint fusion with no evidence of ectopic bone formation (a plus over Infuse) and no evidence of toxicity.

Augment's PDGF is created using recombinant DNA technology which is more than two decades old and has been used by spine surgeons and other physicians in hundreds of thousands of patients globally.

Platelet-Derived Growth Factor (PDGF) is a naturally occurring protein and one of the primary growth factors released when platelets activate and degranulate in response to injury. PDGF is responsible for triggering a number of cellular events critical to bone growth and healing.

Treatment for Arthritis, Ankle Pain or Fracture

Surgeons often recommend a fusion of the foot or ankle when a patient presents with debilitating end stage arthritis of the ankle, hindfoot and midfoot. For patients with diabetes or osteoporosis or fracture, there is a high risk that the bones following surgery will not heal completely. That is known as a non-union. Typically, surgeons have relied on a second ankle surgery, an autograft procedure to harvest chips of healthy bone, to then implant into the surgery site and, hopefully, improve healing. Often surgeons harvest this bone from the patient's hip, tibia or heel. When that happened, patients can experience a number of post surgery complications and, according to the eight published studies, 27% will complain of chronic donor site pain.

BioMimetic's success with GEM 21S, indicated for periodontal bone defects and gum tissue recession, and approved by the FDA in 2005, gave the company confidence the material could be used for other orthopedic indications.

If approved by the FDA, Augment Bone Graft would be the first, new recombinant protein technology for orthopedics introduced to the market in nearly a decade and the first and only cost effective fully synthetic bone growth factor replacement for autograft with Level 1 data supporting its safety and efficacy.

Since we started with Dr. Lynch, we'll let him finish.

"Many years ago, my colleagues and I first imagined the possibilities of using PDGF as a broad multi-factorial stimulator of musculoskeletal tissue repair. It is exciting to see that our hypothesis culminated today with a favorable advisory panel recommendation."

Lynch should thank the clinicians. ◆

The Restless Orthopedic Surgeon

By Biloine Young

"One of the things about orthopedic oncology is that every patient is different. If you do total joint replacements you take care of the same problem, with only a little different flavor. If you do sports medicine you take care of the same problems, with slightly different flavors, in each person. But in oncology you work with people from the very young to the very old and everyone in between. The youngest patient I have taken care of was a couple of months old. The oldest was in his high 90's." — Dr. Joel Mayerson, Associate Professor of Orthopaedics; Director, Division of Musculoskeletal Oncology; Ohio State University Medical Center.

Dr. Joel Mayerson

Creativity and orthopedic surgery are usually incompatible concepts—except in oncology where the ability to think creatively in five dimensions (3D spatially + biomechanically + biologically) has forged a restless class of surgeons who scramble onto the surgical high wire and perform remarkable feats of anatomical reconstruction. Formulary? Text books? These guys don't need no stinkin' formulary.

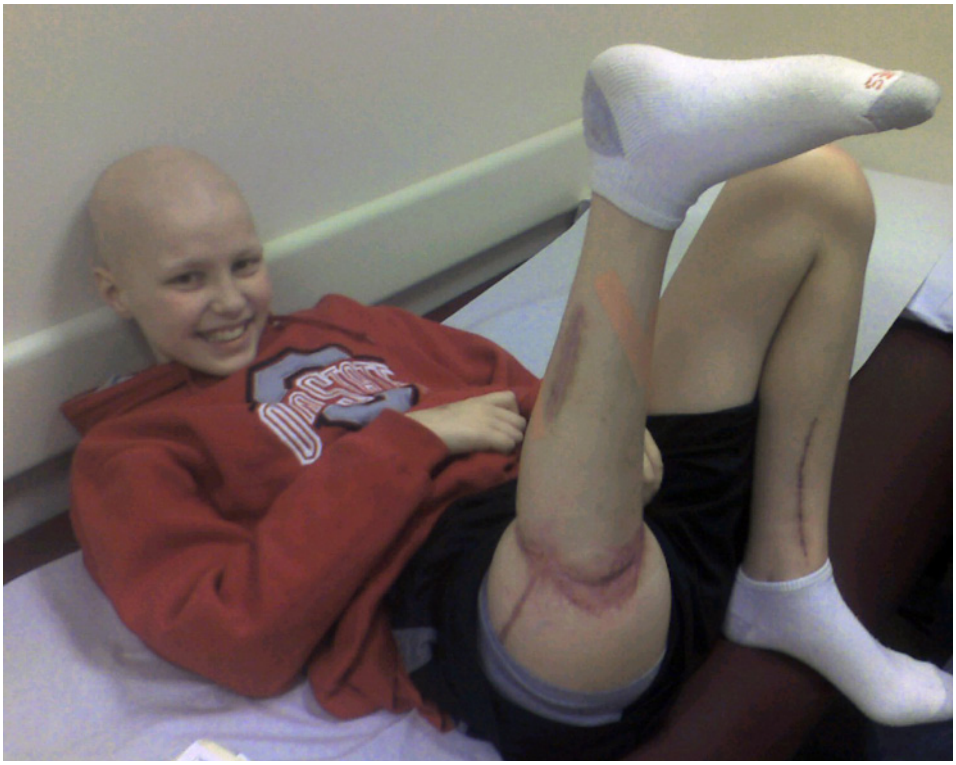
Mayerson, whose surgical legerdemain *OTW* has featured a couple of times, is the orthopedic oncologist who reinforced his patient's pelvis with bones from his amputated leg. Where do these restless orthopedic surgeons come from?

In Mayerson's case, the industrial rust belt town of Lima, Ohio, a pharmacist father and stay-at-home mom. His first distinction in life came from becoming one of the 2% of Boy Scouts to attain the rank of Eagle. "In scouting I got to do outdoor activities that I never would have done otherwise," he said. "My parents were not outdoor type people. With scouting I got to do camping and activities that they would not have gotten me involved in."

On his lengthy list of professional and academic awards, Mayerson's Eagle Scout rating tops the list. He credits scouting with teaching him how to be a leader and a member of a team. "Being part of a team is another part of being a good surgeon," he says. "Learning how to be the captain of a team was developed in me during those early years in scouting."

From a young age Mayerson wanted to be a doctor. "I enjoyed science and I wanted to help people. Medicine was a good way to mesh the two together. My parents tell me that I wanted to be a doctor from the time I was in elementary school." An offensive tackle on his high school football team ("I was a big guy," he says), as well as a runner and a wrestler, he wanted to become a sports medicine doctor and take care of athletic teams.

Mayerson graduated from the University of Toledo in 1990, summa cum laude in biology, and received his M.D. degree from John's Hopkins in 1994. His course was set when, as a fourth year medical student on an elective rotation he was, totally by accident, assigned to



Rotationplasty/Source: Dr. Joe Mayerson

work with Dr. Frank Frassica , chair of the orthopedic oncology service. "From that day," Mayerson says, "I fell in love with orthopedic oncology."

Mayerson continued. "Everyone who has a tumor, has it in a different location in the body. Some people have it in their bones, some people have it in their muscles, sometime the tumor starts in that area, and sometimes it starts in another place and spreads to their bones and muscles. Every patient is different, every problem is different. When I graduated from my fellowship I had done over 500 oncology cases and several hundred as a resident. I thought I was really well trained and there was not a whole lot more that I was going to see.

"I was pretty naïve. I have been in practice now for 11 years and I still see new stuff every day. That is one of the reasons I love my job—it is different all of the time. I would have a hard job doing the same thing over and over again. With this career I do not have to."

Mayerson finds that anatomy is pretty much all the same. "The important part of oncology is not only anatomy. You have to work at the six cardinal directions, figuring out where you can get around the tumor, make sure you can remove it with appropriate margins, top and bottom, left side and right side, front and back. And we have to look at the imaging, know where the pitfalls are and how we are going to get around them."

The reconstructive side, he says, should be decided by the patient's expectations and what they want to do in their life. "You have to get to know the patient," he says. "People have different reconstructive needs and varying levels of desires in life. Somebody who is 80 years old has different needs to ambulate and get around in life than if they were 15.

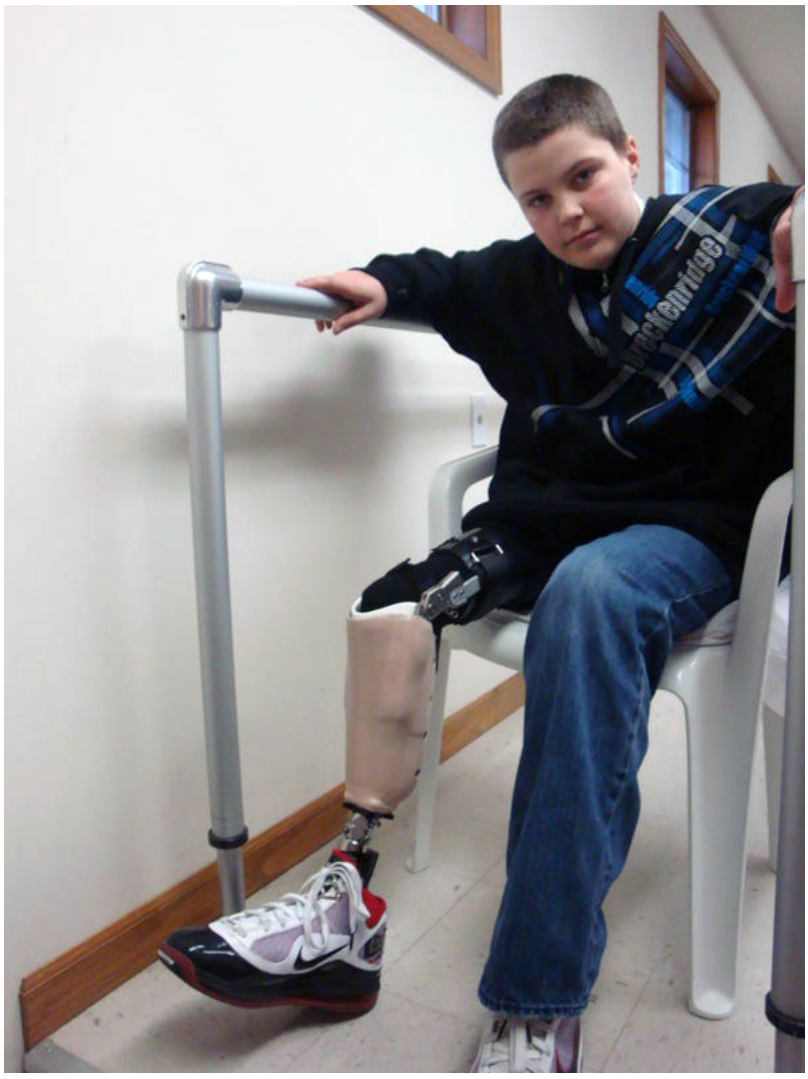
A recent patient was a ten-year-old fourth grader who, when he broke his femur, doctors discovered that he had a softball size malignant tumor just above his knee. The standard of care in the United States would have been to fill the void with a cadaver bone and a metal knee.

In talking with his patient, Mayerson discovered that what his young patient wanted most to do in life was play baseball. "That was his goal and all that he wanted. He wanted to be a major league baseball player." The most important consideration was the boy's activity level now and into the future. Mayerson knew that with a cadaver bone or a metal bone in his leg the boy would not be able to play sports. The cadaver

bone is fragile and the metal and plastic parts wear out—usually between 10 and 15 years. "Like the transmission on your car," Mayerson notes, "they have a certain number of miles in them and then they wear out and you have to do a revision and fix it. Every time you fix it, it gets harder. After a while you run out of opportunities to redo it."

Taking into consideration the patient's young age and his fervent desire to play baseball, Mayerson performed a rare procedure, called rotationplasty, in which the leg is amputated, turned around, and the foot is attached to where the knee joint used to be. The foot's heel is in front with the toes pointed back so that the ankle joint functions as a knee joint. The surgery was a success and the boy is playing baseball.

In another rare surgery Mayerson implanted a device called the Repiphysis, by Wright Medical Technology, in the arm of a five-year-old girl with cancer. Mayerson removed most of the cancerous upper arm bone to treat the cancer and filled the gap with donated living bone and the high-tech implant that could be lengthened as the girl grew. Since the implant had not yet been approved by the FDA, he had to get a "compassionate use" approval before he could proceed with the surgery. The implant consisted of a hollow titanium tube inside a plastic tube housing a compressed steel spring. When warmed by heat, generated by an electromagnetic field, the device lengthens. "Because of this device, Elizabeth was able to keep her arm, which will help her lead a normal healthy life," said Mayerson.



Source: Dr. Joe Mayerson

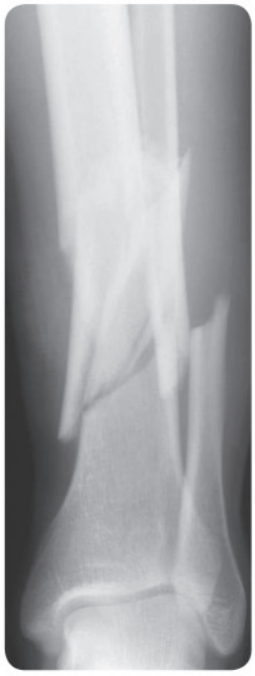
In the first surgery of its kind performed in the United States (or, perhaps anywhere) Mayerson and his team removed the left leg, hip and part of the pelvis of a cancer patient and used the healthy bone, blood vessels and muscles from the amputated leg to rebuildthe hip and pelvis so it would be strong enough to support a prosthetic leg.

The surgery was performed by the entire sarcoma surgery team that Mayerson had put together and heads. Working together in the operating theater was a surgical oncologist to make sure that the bowel and blood vessels were moved out of the way; there was a neurosurgeon to do the spine part of the surgery; there was a plastic surgeon who was able to dissect out small blood vessels so they could save the parts that were not being amputated and could be used in the reconstruction and an anesthetist who could deal with major blood loss.

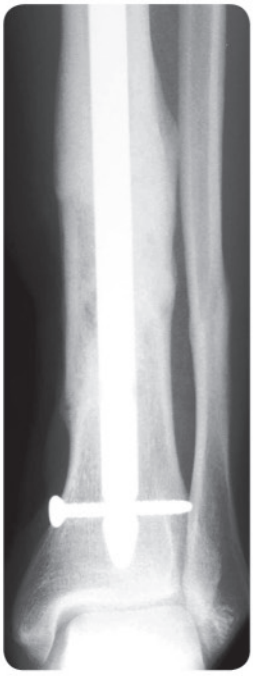
"As a team, we all sat down for seven to eight hours in advance and went through each step of the surgery," said Mayerson. " The first day the patient had surgery for twelve hours—with two shifts of doctors. The second surgery lasted for 25 hours with three or four shifts of people." Mayerson esti-

Medtronic

Acute open tibial fractures present many challenges



Pre-Op



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* BMP-2 Evaluation in Surgery for Tibial Trauma (BESTT). Govender et al. Journal of Bone and Joint Surgery 84A:2123-34, 2002.

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INFUSE® Bone Graft has not been tested in pregnant women to determine if it could pose harm to a developing fetus, nor has it been studied in nursing mothers. Women of childbearing potential should not be treated with INFUSE® Bone Graft immediately prior to or during pregnancy, and should be advised not to become pregnant for one year following treatment. They should be warned of potential risks and should discuss other possible treatments with their doctor.

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mates that, altogether, counting nurses, technicians and staff in the blood bank, from 400 to 500 people were involved in this surgery.

Mayerson says, "One of the things we have worked very hard to do is develop a multi-disciplinary team. There are very few centers in the country that have an entire team that is able to do these things. Our goal is to continue to build the program and let people who have terrible problems know that there are various ways to take tumors out. Other places may not have the team and so they tell their patients that their tumors are not removable and that they cannot help them. We want these people to know that this institution is a place that may be able to help them."

Does Mayerson and his team celebrate their successes? "Absolutely," he said. "We are always a little bit anxious when the surgery is done because there are a whole host of complications that can occur. Our celebration may not be that day. But when Mr. P (the pelvis reconstruction patient) left the hospital in three weeks, off pain medication, we celebrated. It was one of the most amazing things I have ever seen."

Indeed, chronicling the surgical artfulness of not only Dr. Mayerson, but also his team and other orthopedic oncologists are some of the most amazing stories we cover in *OTW.* ◆

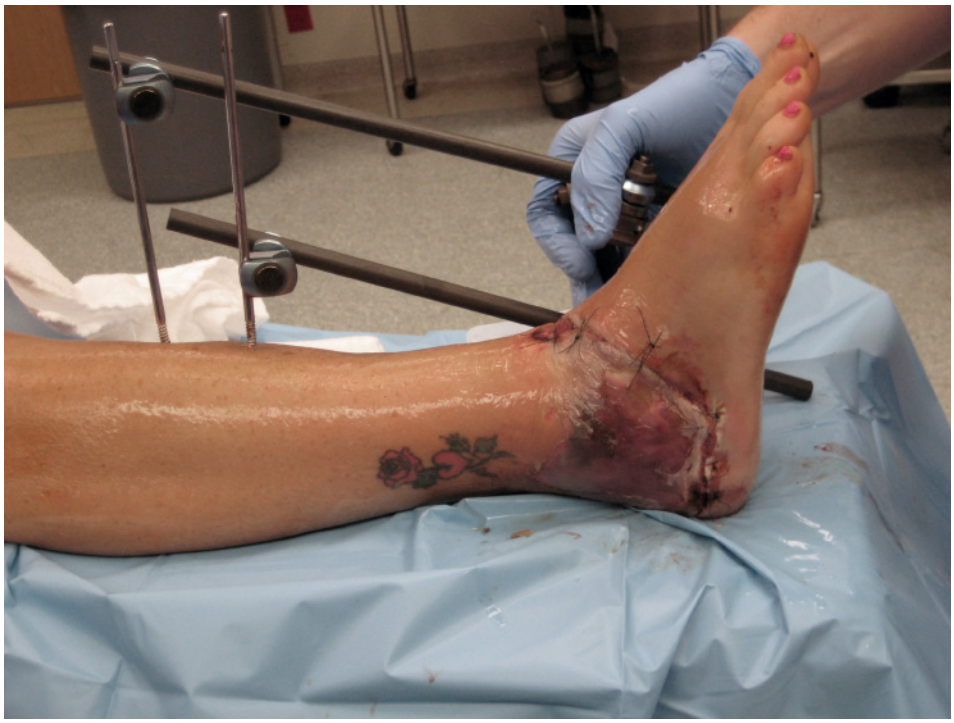
Scalpel…Now or Later?

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

It's 2am and a patient rolls into the ER with several fractures. What should be addressed acutely? What if you suspect a bleeding problem? What are the issues associated with waiting? Along with Drs. Mark Lee, Yvonne Murtha, and Philip Wolinsky, Dr. Brett Crist, Co-Chief of Orthopaedic Trauma at the University of Missouri, reviewed the latest evidence-based literature regarding the surgical timing of injured extremities. The researchers then presented their findings at the 2011 meeting of the American Academy of Orthopaedic Surgeons.

Dr. Crist states, "For several years there has been a debate over the merits of early total care versus staged injury management. Fortunately, there is a lot of good work in the literature to help us identify patients who would benefit from what we call damage control orthopedics, i.e., the staged approach."

Going in and fixing everything during one, long surgery, says Dr. Crist, is just not appropriate for every patient. But there are few hard and fast rules for surgeons to follow. Dr. Crist: "The key is to try to identify the patients who would be harmed by early total care. Several years ago Dr. Hans-Christoph Pape worked with colleagues in Germany to establish guidelines for acute versus staged care. Their research determined several situations in which a patient should receive staged treatment: if there are bleeding problems, if someone is under-resuscitated, if they are hypothermic, have a significant chest injury, or if they have multisystem injuries. Of their study subjects, those who had all these or two out of three of these were at high risk for the 'second hit phenomena' where the inflammatory response causes significant problems potentially leading to multisystem organ failure. "



Source: Dr. Crist

Black and white…easy to identify. Other colors…not so much. "There are extremes at each end of the spectrum, with, for example, an isolated femur fracture identifiable as something that can be fixed acutely. Then there are patients with head, chest, extremity, and abdominal injuries who clearly cannot and should not receive total acute care. It's the ones in the gray zone that can be challenging to identify. We can fall back on the literature, however, for guidance. For example, most studies have shown that fixing high energy pilon fractures acutely leads to an increased risk of infection and wound problems. Due to literature in the late 1990s showing decreased risk of infection and wound problems with the staged approach, today these injuries undergo staged management at most centers."

A large swath of the gray zone, states Dr. Crist, involves those patients with multiple orthopedic injuries. "Let's say that someone comes in with a fractured femur and tibia, and is awake and alert, but has a pulmonary injury that is evolving. The decision making process would be to determine if this patient is adequately resuscitated and how extensive his pulmonary injury is.

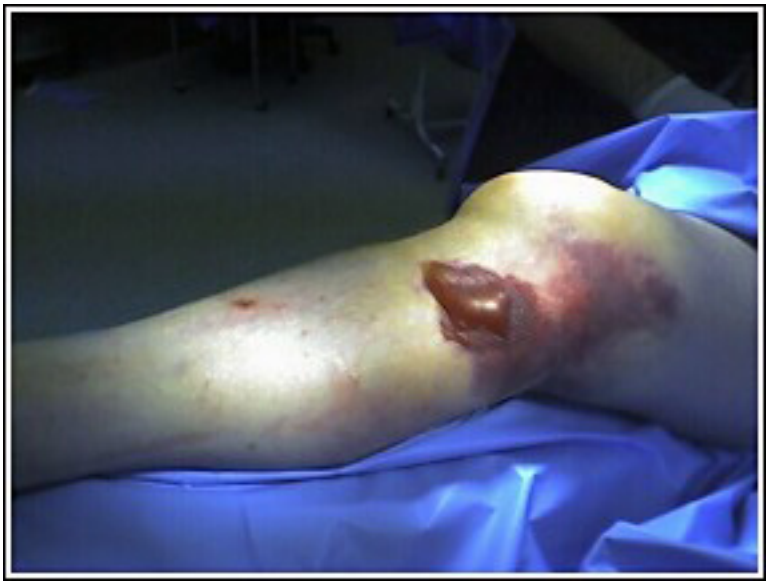
"Let's say that someone comes in with a fractured femur and tibia, and is awake and alert, but has a pulmonary injury that is evolving. The decision making process would be to determine if this patient is adequately resuscitated and how extensive his pulmonary injury is. Using the Hanover Criteria—the aforementioned work from Dr. Pape and his colleagues—is helpful. In addition, one should also look at lactate levels, urine output, fluid and blood requirements."

Using the Hanover Criteria—the aforementioned work from Dr. Pape and his colleagues—is helpful. In addition, one should also look at lactate levels, urine output, fluid and blood requirements. This is mainly determined by allowing a complete evaluation by the general surgeons and orthopedists before rushing to the OR from the ER to nail the long bone fractures. Problems can be avoided by making sure that the patient is not trending toward having pulmonary problems that might be worsened by a prolonged orthopedic surgery. So to avoid problems, adequate evaluation with published guidelines should be used and insure adequate fluid resuscitation."

So when do you stand up and pay very close attention? Dr. Crist states, "The literature shows us that the treatment of joint dislocations should not be delayed because this may result in avascular necrosis or neurovascular compromise. Studies show that hip dislocations should be treated in less than 12 hours and others indicate that less than 24 hours can help avoid an increased risk of avascular necrosis. The barrier to such acute treatment is typically being able to reach a facility that has the appropriate abilities to manage these injuries (most likely an issue in a rural area)."

But, says Dr. Crist, the literature needs more work. "Dislocations are either urgent or emergent, depending on the joint. While we have good data for the hip, unfortunately, the literature is not as good when it comes to other joints."

And if you see blood vessels in distress, advises Dr. Crist, get moving. "The literature has concluded that a patient with vascular issues is indeed emergent



Source: Dr. Crist

"As a subspecialty we are leaning more towards staging things. The downside of a staged approach is that there is a longer hospital stay and more exposure to anesthesia. The downside of treating too acutely is that the patient may need additional surgery later, may be on a ventilator too long, or may develop a bodywide infection."

given the risk of significant blood loss, as well as limb loss. In this case, the liberal use of a tourniquet is appropriate, while clamping off the blood vessels would be done as a last resort. A tourniquet should only be on a couple of hours…otherwise ischemia will kick in. The literature says that these situations need to be addressed within six hours; the problem is that if you're dealing with a large main artery there is no way that someone is going to last six hours."

Things are also unequivocal when the nerves, blood vessels, and muscles are being compressed and starved of oxygen. "Compartment syndrome is a true emergency, and needs to be fully addressed in an acute fashion. Researchers reviewed insurance claims and litigation for compartment syndrome at Massachusetts General Hospital claims over a period of 20 years. The situations that resulted in the highest payouts/awards against the physicians were those where there was a delay in treatment (a delay in seeing the patient or a delay getting to the OR)."

Dr. Crist says that the review process helped them challenge what is considered to be dogma. "For example, take the urgency of fixing femoral neck fractures in young people. The general thinking has been that they should be done in the middle of the night if that is when the patient arrives. But with an increasing number of trauma rooms available, a recent survey of OTA [Orthopaedic Trauma Association] members revealed that if someone comes in at midnight or later then a significant number of traumatologists are starting to put them on as a first case the next morning due to resource availability."

"When we examined literature from other countries we found that there are instances of people showing up a cou-


Source: Dr. Crist

ple of months after their injuries and they still didn't have avascular necrosis. It appears to boil down to fracture patterns and surgical technique—if you get an anatomical reduction and use internal fixation then chances are that the patient will fare better (risk of avascular necrosis and nonunion) than those who had malreductions. Patients with significant displacement and comminution tend to do worse. In summary, the literature indicates that you should treat femoral neck fractures as soon as you feel you can do them *well*. If that is 3am and you have the team and the resources, then do it."

"With regard to talus fractures," says Dr. Crist, "they have traditionally been thought of as an emergency where you need to immediately reduce the joint and fix it anatomically. The problem, however, is that the soft tissues will often swell and you could have potential difficulties with wound closure or later wound breakdown. We found two studies that looked at risk of avascular necrosis; they concluded that the timing of the repair wasn't the main factor…it was fracture type. Open fractures had a higher rate of avascular necrosis and nonunion. In these cases, one should debride the open fracture and stabilize it with external fixation or a splint—and only address it definitively when the soft tissues allow. Closed fractures should be immediately reduced and undergo definitive fixation when the soft tissues allow as well."

As for what might prevent an orthopedist from making the best decision as far as what is an emergency and what can wait, Dr. Crist says, "Orthopedic surgeons who find themselves struggling with these situations often have resource issues such as OR access or adequate ancillary support. Something else that can be an problem is the surgeon's expertise or comfort level with treating things such as a complex talus or femoral neck fracture."

Ethics…can't live without 'em…but it's hard to get the full picture because we must abide by them. "We would ideally have better literature going forward. But you cannot do a prospective double blind trial on an injury that is rare, and then intentionally delay care to see if it makes a difference when the dogma states you should address it as soon as possible."

So perhaps this is why orthopedic surgeons are holding back a bit on the scalpel. Dr. Crist: "As a subspecialty we are leaning more towards staging things. The downside of a staged approach is that there is a longer hospital stay and more exposure to anesthesia. The downside of treating too acutely is that the patient may need additional surgery later, may be on a ventilator too long, or may develop a bodywide infection."

When in doubt, advises Dr. Crist…stage those injuries that can be staged. ◆

company

Stryker Snaps Up Orthovita for $316 Million

Stryker Corporation announced today that it is buying Orthovita, Inc. for around $316 million in cash, or $3.85 per share.

Joanne Wuensch, BMO Capital Market analyst, notes that this is Stryker's fourth acquisition in the last 12 months and further reshapes the company's orthobiologics franchise, (after selling off OP-1 in February). It certainly looks like Stryker continues to put the snake-bitten OP-1 era in the rearview mirror and replaces it with more basic synthetic bone cement and surgical products.

Orthovita is a manufacturer of synthetic bone grafts, vertebral augmentation, and hemostasis products.

Stryker's CPCEO (Chairman, President, CEO) Stephen McMillan said, "With this acquisition we are meaningfully expanding our orthobiologics product portfolio and strengthening our competitive position in key segments of the Spine, Orthopaedics and Biosurgery markets...We believe the collective talent of our sizable sales forces across multiple franchises positions us to build on Orthovita's success and accelerate sales growth."

Tony Koblish, Orthovita's president and CEO said, "This transaction delivers significant value to our shareholders and allows us to combine our portfolio of orthobiologic and biosurgery products as well as our novel and unique proprietary biomaterials pipeline with Stryker's industry-leading sales and marketing teams.

Orthovita's orthobiologic platform offers products for the fusion, regeneration and fixation of human bone. Its biosurgery platform offers products for controlling intra-operative bleeding. Current fusion and regeneration products are based on the Vitoss Bone Graft Substitute technology and address the non-structural bone graft market with synthetic, bioactive alternatives to patient- and cadaver-derived bone tissue. Cortoss Bone Augmentation Material, an injectable, polymer composite that mimics the mechanical properties of weight-bearing human cortical bone, provides the basis for the company's fixation portfolio. The hemostasis portfolio includes Vitagel Surgical Hemostat, a proprietary, collagen-based matrix that controls bleeding and facilitates healing, and Vitasure Absorbable Hemostat, a plant-based product.

With 2010 revenue of $95 million and expected 2011 revenue of $99 million (based on consensus estimates), Stryker is paying 3.3x Orthovita's 2010 sales, which, says Mizuho Securities analyst Mike Matson, is above Orthovita's small-cap orthopedic peers that are trading at 1.6x 2010 sales, an 80% premium to Orthovita's stock price 30 days ago.

The stock started moving up early April and jumped from around $2.30 per share to over $2.80 per share with the May 5 announcement that Noridian Administrative Services, LLC published a Part B Future Local Coverage Determination (LCD) revisions providing for continued reimbursement of physician fees for vertebroplasty and vertebral augmentation procedures related to vertebral compression fractures. Cortoss Bone Augmentation Material, approved and launched in the U.S. in 2009, is indicated for use in vertebroplasty and vertebral augmentation.

Matson pointed out that Orthovita's revenue growth had slowed from over 25% in early 2009 to the low single-digits. He thinks Orthovita's main problems were its lack of scale and product breadth and sales should be significantly higher in the hands of Stryker's numerous sales forces. Matson also noted that with the biologics market becoming increasingly price sensitive, he thinks that lower-cost synthetic products such as Vitoss are positioned to gain market share from higher cost alternatives.

—WE (May 16, 2011)

Stryker / Orthovita

legal

More Hip Surgery in Rural America

So much for popular wisdom. The assumption that rural areas in the United States lack medical care was dealt a blow by a study of almost 46 million Medicare patients conducted by researchers at Texas Tech University Health Sciences Center in El Paso, Texas. Published May 2011 in the *Archives of Surgery*, researchers found that older residents in rural areas are *more* likely to undergo any of nine common surgeries—including back surgery and hip and knee replacements—than are residents of cities.

The researchers used ZIP codes and a government classification system that ranks regions on a 10-point scale, 1 being the most urban and 10 being the most rural. They compared surgery rates among residents in regions 7-10 (most rural) with residents in regions 1-3 (most urban). According to the study results, rural residents were 20% more likely to undergo heart valve replacement and 15% more likely to undergo knee or hip replacement.

The study was conducted in 2006 and left many questions unanswered. For example, the study does not indicate where rural residents suffering from hip or knee arthritis or debilitating back pain went for their surgery, how quickly they recovered, or whether rural residents were in worse overall health than their urban counterparts. The study did reveal that rural residents underwent both emergency surgery and elective surgery more frequently than did city dwellers.

The authors of the study say their findings could mean that rural residents are sicker, getting treatment they don't need, or are more likely to delay treatment until they worsen and require spine or hip surgery. "When I first saw the result, I looked at it and said maybe I got it backwards," said lead author Dr. Mark Francis, a researcher at Texas Tech University Health Sciences Center in El Paso. Though the cases are five years old, Francis believes the results likely reflect current practice as he had found similar trends going back to the 1990s. He said it's unlikely the recession had much impact because these patients are covered by Medicare.

—BY (May 20, 2011)

Source: Jvoll/Wikimedia Commons

FDA "522s" Metal-on-Metal Hips

The FDA was very visible at the February 2011 AAOS (American Academy of Orthopaedic Surgeons) annual meeting and telegraphed that the agency was going to take a closer look at metal-on-metal (MoM) hips. On May 6, the agency sent out letters ordering 21 makers of the hips to submit plans within 30 days for conducting post-market studies on patients who have received the device. The agency wants to know whether or not the implants are shedding high levels of metallic debris into patients.

In the "522" letter the agency outlined four major areas for the study:

1. Adverse events observed
2. Levels of serum and whole blood levels of chromium
3. Patient selection criteria associated with higher metal concentrations
4. Modes and causes of failure

Photo manipulation by RRY Publications LLC/Wikimedia Commons

MoM hips, in which the ball-and-socket components are made from metals like cobalt and chromium, used to account for almost one-third of the estimated 250,000 hip replacements performed in the U.S. annually.

However, over the last two years as reports surfaced that the implants were prone to early failure and that some patients had developed serious health problems related to particles of metallic debris, their use has declined.

In March we wrote that the British Orthopaedic Association reported that DePuy's ASR implant might fail in up to one-half of the patients who received the device within six years after implantation. DePuy pulled the device from the market last year. Other major producers of the hip implants include Zimmer, Stryker, Biomet and Wright Medical.

Among other things, the FDA is recommending a cross-sectional study design which captures patients with or without revision to their original MoM THR (total hip replacement) at time periods between initial implant and eight years after implantation.

Biomet responded to an *OTW* inquiry with a written statement that the company was "supportive" of the FDA request. Biomet has collected clinical data on approximately 23,000 hips and noted that, "Careful review of currently available evidence indicate that our products are safe and effective."

The list of companies receiving the FDA 522 letter included:

- Advanced Bioresearch Association
- American Ortomed Corp.
- Biomet
- C.R. Bard Inc.
- Downs Surgical Ltd.
- Encore Medical
- Endomedics Inc.
- Implantology Corp.
- Johnson & Johnson (DePuy)
- Joint Medical Products Corp.
- Link America Inc.
- Med-Tek Corp./Synergy Orthopaedics Intl. Inc.
- Orthopaedic Device Corp.
- Orthopedic Manufacturing Co.
- Osteo Technology, Inc.
- Pfizer Inc.
- Stryker Howmedica Osteonics
- Techmedic Inc.
- Turnkey Intergration USA Inc.
- Wright Medical Technology
- Zimmer

—WE (May 18, 2011)

U.S. Senate Looking at PODs

Orthopedics This Week has learned that the United State Senate Special Committee on Aging and the Senate Finance Committee are taking a renewed look at Physician-Owned Distributorships (PODs).

We've also learned that some letters of inquiry went out to a half a dozen such distributorships some time ago. The Committees are now renewing a review in a bipartisan manner. Sources in the Senate tell us they would like the HHS OIG (Department of Health and Human Services/Office of Investigator General) to provide regulatory clarification to what is a rather muddled picture concerning what these proliferating entities may or may not be doing.

John Steinmann, D.O., the founder of one of the first PODs in the industry, Inland Spine and Orthopedics in California, told *OTW* that he would like the opportunity to testify before the committees to tell his distributorship story and paint the model in a fair light. Steinmann and his colleagues at AASD, the trade association formed by PODs, want to encourage policymakers in Washington to find favor with the model, provided appropriate safeguards are in place.

—WE (May 16, 2011)

Morguefile

biologics

Bone Marrow Signaling Secrets Revealed

Researchers have long been aware that cells in bone marrow play a role in the healing of wounds on the skin. What had not been understood is which specific bone marrow cells are involved, what starts the healing process and how the appropriate cells are lured to the affected skin. Now, researchers at King's College, London, and Osaka University in Japan believe they have answered those questions.

Working with mice, some of which had skin grafts and some did not, they discovered that certain specific bone marrow-derived cells migrated to the skin graft to heal the skin much more quickly than did others. They found that very few bone marrow cells traveled to the un-grafted wound sites and those that did contributed little to the repair of the skin. The researchers found that one in every 450 bone marrow cells appears to have the capacity to transform into skin cells.

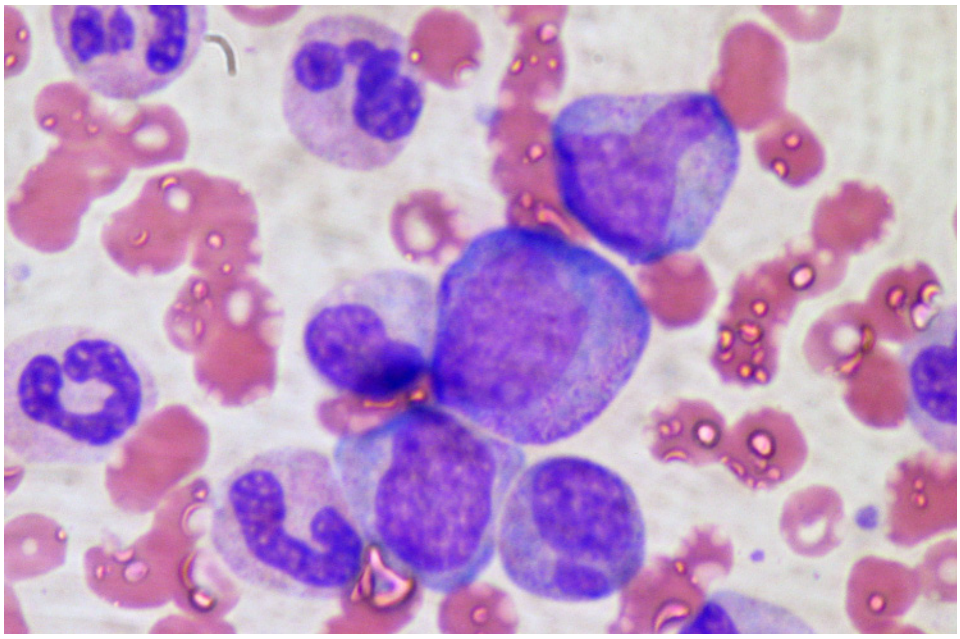
"This work is tremendously exciting for the field of regenerative medicine," said Professor John McGrath, head of the genetic skin disease group at King's. "The key achievement has been to find out which bone marrow cells can transform into skin cells and repair and maintain the skin as healthy tissue, and to learn how the process happens."

The researchers also discovered that, when injured, skin releases a distress hormone called HMGB1 which mobilizes cells from bone marrow and directs them to where they're needed. Mice with skin grafts had high levels of HMGB1 in their blood.

"Understanding how the protein HMGB1 works as a distress signal to summon these particular bone marrow cells is expected to have significant implications for clinical medicine, and could potentially revolutionize the management of wound healing," McGrath said.

McGrath hopes to harness the key parts of HMGB1 to create a drug treatment that can augment tissue repair. The developed treatment will be tested in animal models within a year and enter clinical trials shortly afterwards.

—BY (May 20, 2011)



Source: bobjgalindo/Wikimedia Commons

Biotech Firms Histogenics and ProChon Merge

In a stock-for-stock exchange—the dollar value of which has not been released—Waltham, Massachusetts-based Histogenics Corporation acquired ProChon Biotech Ltd., a privately held biotechnology company

Histogenics Corporation

originally founded in Israel. Histogenic's new management team will be led by Patrick O'Donnell, former CEO of ProChon. O'Donnell will also serve on the Board of Directors.

Histogenics develops and manufactures products to improve the body's ability to regenerate healthy cartilage, improve joint function and prevent degenerative disease. Formed in 2000, the company is developing new treatments for sports injuries and other orthopedic conditions where demand is growing for

long-term alternatives to joint replacement. Histogenics has successfully completed Phase I and Phase II clinical trials in which the NeoCart autologous tissue implant's effectiveness is compared to that of standard microfracture surgery.

ProChon's research has been focused on modulating the fibroblast growth factor system in humans (an innovative pathway to tissue growth) which have allowed ProChon to create innovative and, the company hopes, more effective solutions for tissue regeneration. Specifically, ProChon's technologies allow for the combination of cell regeneration technologies with proprietary growth factors and biocompatible scaffolds. As a result, ProChon's technologies can potentially deliver to patients the ability to restore injured or chronically damaged tissues to a more normal state. ProChon has an extensive patent estate with issued patents from the United States, Europe, Israel and Australia.

"This acquisition positions the new Histogenics as a leading regenerative medicine company with products in the clinic, with solid intellectual property, and with experienced commercial and technical management," O'Donnell said. "Merging these two companies will have a significant positive impact on the adoption of regenerative medicine, beginning with cartilage regeneration. We will leverage each company's distinctive capabilities to develop a broad regenerative medicine pipeline that will address surgical applications in orthopedics, vascular, and neurosurgery."

O'Donnell indicated that the company has positive Phase II clinical data on its NeoCart autologous cartilage regeneration technology. Other promising clinical data is on products that augment cartilage repair in microfracture procedures and in soft-tissue regeneration based on a combination of proprietary growth factor, stem cell, scaffold, and bioadhesive technologies. The initial focus of the company will be to complete the NeoCart Phase III clinical study.

Histogenics is privately held. Investors include Altima Partners, Boston Millennia Partners, Foundation Medical Partners, Stryker Corporation, Inflection Point Partners and Takagi Sangyo. Boston Equity Advisors, LLC served as the investment bank and was responsible for identifying and arranging the transaction.

—BY (May 18, 2011)

Terumo Buys Harvest Technologies

Terumo Americas Holding, Inc. is acquiring Harvest Technologies Corporation, an innovative biotechnology company that invented the technology that allows physicians to derive highly concentrated autologous adult stem cells from their patients in 15 minutes. Terumo Americas Holding, Inc. is the U.S. subsidiary of Japan's Terumo Corporation, one of the world's leading medical device manufacturers with $3.4 billion in sales and operations in more than 160 nations.

Harvest Technologies Corporation developed two medical device therapies that show promise in optimizing the body's natural healing process. The first is the *SmartPReP®2* APC+ system which allows physicians to rapidly prepare highly concentrated, autologous platelet rich plasma (PRP) enriched with growth factors to naturally stimulate the body's healing process for bone and soft tissue wounds. The second is the *SmartPReP 2 BMAC* technology platform, a point-of-care device that requires just 15 minutes to process and concentrate adult stem cells from a small aspirate of autologous bone marrow. (Other concentration techniques require hours, or in some cases days, to prepare.) Both applications have shown promising results in the treatment of cardiovascular and peripheral artery disease.

SmartPReP 2 BMAC is considered a breakthrough technology. The concentrate produced by this system has been documented to generate more total nucleated cells with enhanced viability that affect a desired outcome in animal

Image manipulation RRY Publications LLC/Terumo/Harvest/morgueFile.com

models compared to concentrations obtained by using the more common laboratory methods. The system is easy to implement and requires half the amount of aspirate of bone marrow from the patient.

Harvest Technologies Corporation is focusing its initial commercialization efforts in Europe to support clinical research for the treatment of end-stage critical limb ischemia (CLI), a result of peripheral artery disease, which often leads to lower-limb amputation and increased patient morbidity and mortality rates. The company is also conducting a 42-patient pilot, randomized, controlled, safety cardiac study of its BMAC system in three U.S. medical centers. The BMAC product is injected into the patient's heart muscle during bypass surgery to study its safety and effectiveness in this patient population. Previous studies have shown clinical promise.

Per the May 11 press release: "Harvest Technologies Corporation is at the technological forefront of developing point-of-care systems that allow physicians to apply non-surgical approaches for difficult-to-treat diseases such as CLI," said Gary Tureski, President and CEO of Harvest Technologies Corporation. "Terumo Corporation has long been a global leader in medical device technology to treat vascular and peripheral disease. We are excited about the expanded opportunities this partnership will provide to both companies and look forward to advancing the standard of care for patients worldwide who suffer from these debilitating diseases."

—BY (May 17, 2011)

large joints

Zimmer Launches Cavity Fillers for Knee Revisions

A new range of trabecular material augment shapes and cones in knee revision surgeries was launched by Zimmer Holdings, Inc., on May 17.

Jeffery McCaulley, the president of Zimmer Reconstructive, said these new anatomic sizing options allows surgeons to put in implants and fill defects in all kinds of knee revision cases with the NexGen Knee system.

The new augments are, "designed to fill these defects, provide a structural foundation to the existing bone and help support revision knee implants," according to a company statement. Surgeons are often faced with a range of small to large cavitary defects.

According to the company, "Trabecular Metal Tibial and Femoral Cone Augments have the potential to provide reliable structural replacement of bone and stable fixation for femoral and tibial articulating components in even the most challenging knee revision cases. Designed to treat deficiencies in the knee independent of the final implant position, the tapered shape of the augments fits the patient's anatomy without dictating implant alignment."

The augments are made from Zimmer's trabecular metal material, "a highly porous biomaterial that resembles the structure, function and physiology of trabecular bone." The company says, "No other porous metal material is supported by the amount of peer-reviewed, published clinical data of Trabecular Metal Technology and its history of clinical success in orthopaedic applications. This novel material supports bone formation, enabling biologic fixation and a stiffness similar to cancellous bone. The elasticity of Trabecular Metal Technol-

Zimmer Augments/Zimmer Holdings, Inc.

ogy provides more normal physiological loading which has the potential to decrease stress shielding and improve long-term implant fixation."

More than three million NexGen Knees have been implanted worldwide, according to the company, with more than 1.45 million implanted in the U.S. since the system's introduction in 1994. The company claims that each year, nearly 1 in every 4 knee replacements in the U.S. uses a NexGen product.

That's going to be a lot of cones and augments.

—WE (May 20, 2011)

Paper Triumphs In Patient Ed

Patients are not very good at absorbing or remembering information about the joint replacement surgeries they are about to undergo. In an attempt to prepare their patients, doctors have used a simple printed handout, had nurses explain the procedure, and shown patients explanatory videos. So which method is the most effective in helping patients grasp the risks and benefits of the surgery before they undergo it?

As Dr. James H. Lubowitz, who heads the Taos Orthopaedic Institute in Taos, New Mexico, noted, an artificial knee does not work the same as a normal knee. "It is metal and plastic and bone cement. Patients expecting 'normal' may be disappointed, thus emphasizing the importance of preoperative patient education."

In an attempt to determine the best means of communication, researchers divided 151 patients about to have a total knee replacement at the Minneapolis Veterans Affairs Medical Center into three groups. One group filled out a computer-based informed consent form called iMedConsent and received a printed handout about the risks and benefits of the surgery. The second group received the hand-out and also watched a video. A nurse spoke with the third group after they had received both the handout and seen the video.

The patients later filled out three multiple choice questionnaires that asked them about their surgery. They filled out the first at the time they consented to it. They filled out the second on the morning of the surgery and completed the third about six weeks later.

Overall, the patients scored 75% to 80% correct answers on knowledge about the procedure, and there was no difference among the three groups. "We expected that the more intense education (printed hand out plus video plus nurse) would yield higher scores," said Dr. Terence Gioe of the Minneapolis Veterans Affairs Medical Center, who led the work. "We may be able to do more with simple handouts that patients can review and refer back to after the initial consultation."

Lubowitz remains ambivalent. "I would not say that video aids or nurse educa-

Source: Wikimedia and U.S. Navy

tion are unnecessary, nor would I insist that they are necessary," he said. "In non-VA, high-volume practices, or settings where orthopedic resident 'training knees' (to show to patients) are not available, the use of video or nurse educators could be extremely valuable." The findings appear in the *Journal Arthritis Care and Research.*

—BY (May 17, 2011)

Anesthetic Change Boon for Patients

Photo by Andrew Huth for RRY Publications LLC

Barry Oldham, a 68-year-old grandfather, was doing leg raises 20 minutes after leaving the operating room where he had had his right knee joint replaced. A few hours later he was walking around his room on crutches. In. 48 hours he was home. What was going on? Oldham was participating in a new approach to knee joint replacement surgery known as "rapid rehabilitation."

The usual procedure was for a doctor to administer nerve blocks (injections of local anesthetic at the top of the leg) followed by a general anesthetic. With this procedure the patient is pain free following surgery but he cannot move his leg muscles until the effects of the drugs wear off—usually in 36 hours. Many patients feel nauseous for a time afterwards and—being immobile for so long—are at risk of developing deep vein thrombosis.

With rapid rehabilitation neither a general anesthetic nor nerve blocks are used. Instead, in a technique called local infiltration anesthesia developed in Sydney, Australia, a large dose of anesthetic solution is injected directly into the tissue surrounding the knee joint before, during and at the end of surgery. Patients are also given mild sedation and a spinal anesthesia, similar to an epidural, which wears off in a couple of hours, enabling them to start moving their legs.

Tony Smith, who is based at Robert Jones and Agnes Hunt Orthopaedic Hospital in Oswestry, Shropshire, England, explains: "While the anesthetist takes care of the patient's sedation, I inject the anesthetic solution. The same day as their op, they're encouraged to get up and walk around their beds and do weight-bearing exercises. It's really good for their mental well-being to get mobile the same day as their surgery. We always explain that they'll be up and dressed the day after surgery."

Oldham described his experience. "I had the op on the Friday evening and the next morning I was up and shaving. By 11am I was on crutches walking around the ward. I passed the beds of men who had conventional knee surgery and got chatting. They couldn't believe I had my op the previous night. This made me realize how lucky I was to have been on the rapid recovery program."

Twelve days following his surgery, Oldham dumped his crutches and was driving his car. On the 17th day he walked a mile to a favorite tea room and back. With conventional knee surgery, patients are on crutches for four to six weeks. Surgeons in the UK perform about 70,000 knee replacement procedures annually.

—BY (May 15, 2011)

people

Ishrak Named Medtronic Leader

During a time of industry consolidation, Medtronic, Inc. finally has a new CEO and chairman.

The company announced on May 11 that Omar Ishrak, Ph.D., will take over for departing Chairman and CEO Bill Hawkins on June 13. Hawkins announced his retirement at the end of last year and the search for his replacement took longer than expected, sparking rumors of some disagreement among board members.

Omar Ishrak, Ph.D./Medtronic, Inc.

GE Track Record

Ishrak is leaving as president and CEO of GE Healthcare Systems, a $12 billion division of GE Healthcare supported by approximately 20,000 employees in 120 countries. Ishrak was also a senior vice president of GE Corporation and a member of the GE Corporate Executive Council.

A Medtronic statement said Ishrak brings, "exceptional experience and a strong track record to Medtronic. During his 16-year tenure at GE Healthcare, he consistently drove top and bottom line growth in a number of leadership positions. He also helped to transform the way in which GE Healthcare innovates, manufactures and sells products, particularly in emerging markets. Under his guidance, the Clinical Systems Division almost doubled in revenues to approximately $5 billion from 2004 to 2009. In addition, he transformed GE Healthcare's Ultrasound business, growing revenues from $400 million in 1998 to $1.8 billion in 2010."

Before joining GE Healthcare in 1995, the company said Ishrak spent more than 13 years in senior technology development and business management roles at Philips Ultrasound, Diasonics Inc. and Elbit Ultrasound Group. He earned a Bachelor of Science degree and Ph.D. in electrical engineering from the University of London, King's College. Ishrak is a member of the board at The Blood Center of Wisconsin and is on the Health Leadership Council of the Save the Children Foundation.

Industry Consolidation

Medtronic is the largest medical device manufacturer in the world and controls well over 40% of the spine market. The company does not compete in the rest of the orthopedic market. Ishrak is joining Medtronic just as a major competitor in spine, Johnson & Johnson, is taking over Synthes. Johnson & Johnson's worldwide chairman of the company's Medical Devices and Diagnostics Group is another GE Healthcare System alumnus, Michael Mahoney.

Will Ishrak follow Mahoney's example and move to further consolidate the orthopedic industry by looking to add a major hip and knee maker to Medtronic's portfolio? We'll ask him after he warms up his new chair.

—*WE (May 18, 2011)*

spine

Quick to Dough PMMA From Medtronic

Medtronic, Inc.'s latest offering for the treatment of spinal fractures with minimally invasive Kyphon balloon kyphoplasty, is the mouthful "polymethylethacrylate (PMMA)," a new version that is "quick-to-dough." Labeled Kyphon Xpede, the PMMA reaches a doughy state more than twice as fast as its predecessors, Lyphone HV-R Bone Cement and Kyphon ActivOs10 Bone Cement. According to Medtronic, the new cement helps streamline the Kyphon balloon kyphoplasty procedure, while providing sufficient time for careful surgical introduction and controlled delivery.

Alex DiNello, general manager and vice president of the Kyphon Products Division, said, "Xpede Bone Cement provides all of the handling characteristics that physicians have grown to expect from the Kyphon Products Division, which pioneered balloon kyphoplasty. These include a long working time and radiopacity for easy visualization during minimally invasive and image guided procedures."


Wikimedia Commons

Medtronic estimates that since it began marketing this treatment in 2000, an estimated 900,000 fractures have been treated worldwide with Kyphon balloon kyphoplasty by approximately 14,000 trained spine specialists.

I find that Xpede Bone Cement streamlines the balloon kyphoplasty procedure," said Dr. Wade Wong, professor of clinical radiology and anesthesiology at the University of California, San Diego and chief of neurointerventional spine. "It is quick to dough, has a long working time which provides me with increased control and ease of handling."

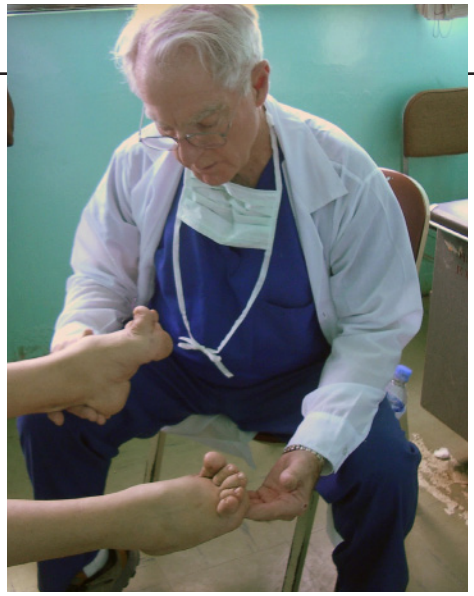
Xpede Bone Cement expands Medtronic's portfolio of bone cements for treatment of patients with vertebral compression fractures caused by osteoporosis or cancer. The company expects Xpede Bone Cement to be available in Europe in the near future.

—*BY (May 18, 2011)*

THE PICTURE OF SUCCESS

Dr. Taylor Smith

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

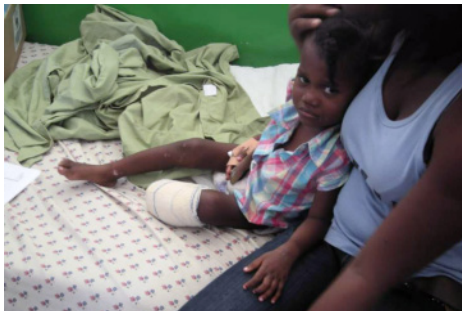


Dr. Taylor Smith

He has treated refugees with tuberculosis and received patients by oxcart. Dr. Taylor Smith, winner of the 2011 Humanitarian Award from the American Academy of Orthopaedic Surgeons (AAOS), has devoted much of his life to serving those in greatest need…even though, says Dr. Smith, it can break your heart.

The founder of the orthopedic division of Operation Rainbow, Dr. Smith says, "There is so much need that I just can't feel fulfilled if all I do is treat patients with 'regular' aches and pains. If a patient is complaining of shoulder pain after a round of tennis, I may find that my mind wanders to the young boy I treated recently in Haiti who had to have his leg cut off."

The son of an orthopedic surgeon, and the grandson of a general practitioner, Dr. Smith has long been witness to the daily challenges of living of those who suffer. He says, "My dad was the chief of surgery at Shriners' Hospital in Houston, while my grandfather treated



Source: Dr. Taylor Smith

patients in insane asylums and worked on Indian reservations. I was greatly influenced by them both…and I never thought of becoming anything other than an orthopedic surgeon."

Now Clinical Professor of Orthopaedic Surgery at the University of California in San Francisco, Dr. Smith had the early advantage of being prepared for the lifestyle of an orthopedist. "My dad, the team physician for the Rice University football team, took me along to games, where I had a great chance to learn about the injuries and how they were handled. I grew accustomed to the family 'rhythm' of my dad's long hours, calls in the middle of the night, and time away of family. My mom was a teacher…I fought her on certain things all the way through high school. In the end, however, I didn't want to disappoint my parents—so I settled down and got to studying."

Book learning has its place…but, as Taylor Smith soon discovered, life has other lessons. "While doing my internship at Hermann Hospital in Houston, I was drafted. It was a sensitive time, namely, the Cuban missile crisis. The advice I got was, 'If you don't sign up for the Air Force or the Navy then you're going to receive a letter welcoming you into the Army.' I opted for the Air Force, went through their flight surgeon program, and went to the Philippines with only one year of orthopedic training. I was soon reclassified (left the flight sur-

"If a patient is complaining of shoulder pain after a round of tennis, I may find that my mind wanders to the young boy I treated recently in Haiti who had to have his leg cut off."

geon program) and joined the orthopedic department."

There were planeloads of patients at Clark Air Base in the Philippines, says Dr. Smith, but not a lot of surgeon egos. "We got all of the air evacuations from Vietnam, and would receive an average of eight planeloads of injured a night. I spent over two years training with a superb orthopedist named Dr. Ralph Peterson, who not only taught me how to operate expeditiously, but how to avoid any hint of the prima donna. You just could not demand or expect things that weren't available. This time was valuable in many ways, and when I did complete my residency I had more experience than most of my peers. That meant that at an early stage in my career I enjoyed more responsibility."

While Dr. Smith was in the Philippines he took time out to travel to Hong Kong and study with a spine master. Politically, it was the time of the Cultural Revolution in China—clinically, it was a revolutionary time for those who walked for the first time. "I briefly rounded with Dr. Arthur Hodgson, a guru who was famous for using an anterior approach for tuberculosis and scoliosis. When I asked if I could return to study with him, he invited me to be one of his first fellows. We treated a flood of refugees coming in from China, many of whom had a partial or total paralysis. When we did an anterior approach to the spine, lo and behold these patients were walking.

Dr. Smith, staff and patient in Ecador

No one had ever seen this before Dr. Hodgson put it on the map."

Dr. Smith's life course was forever altered by what he experienced in Asia those early years. "This was a turning point for me…from then on my eyes were open as to the value of international work. I was inspired to see how well the local medical personnel could do with the little they had—and they were treating serious conditions such as polio and chronic infections."

After his fellowship in Hong Kong, Dr. Smith found a place for himself in academia…then he had to share a place in the sun with his dad. "I accepted a position as the chief of orthopedics at County Hospital in Oakland, California. It was a different kind of drama/trauma that I encountered there, as this was the era of the Black Panthers and the Symbionese Liberation Army. I was later asked to come to the University of Texas in Houston—the program started by my father—to head up the orthopedics department. It was very humbling to work alongside my dad; his were big shoes to fill. I was the first full time professor of orthopedics there, so I established the department and then after seven years returned to California to join a private practice."

Although his Houston years involved budgets and staff meetings, Dr. Smith did make time for aiding others abroad. "I was sent to Taiwan by the U.S. State Department to do spine surgery; while

"Working abroad is a wonderful way to expand your—and your family's—horizons. Many people feel trapped in a routine where they are taking call, paying the mortgage, etc."

there I met several Australian doctors who had done orthopedic work in Fiji and they asked me to join them on their next trip. The difference between the two locales was striking. Whereas Taiwan was well advanced in orthopedic care, musculoskeletal care in Fiji was adrift because of politics. The government (largely comprised of native Fijians) had passed a law saying that native Indians could not work in the government. Given that all of the doctors were Indians, this left the patients at a real loss."

"Because of my experience treating polio patients, my colleague in Houston asked me to accompany him to work in China on an Operation Rainbow project. We made four trips, but could see that it was really too far and too expensive to continue. We decided to focus on Central and South America after that; in 2010 Operation Rainbow took 13 trips to Haiti and Latin America."

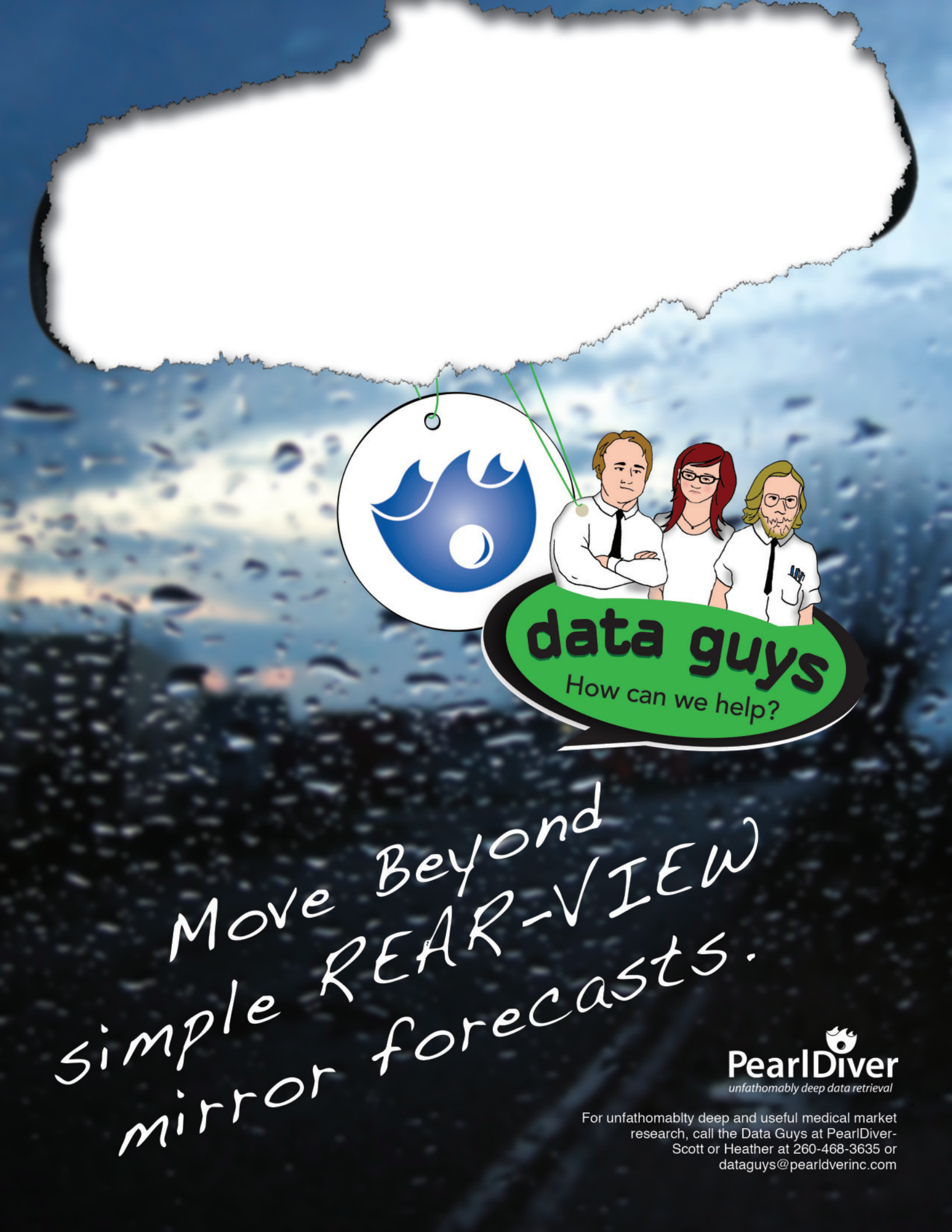
Dr. Smith says that his secret of success is pretty simple…he loves his work. And he has found it especially rewarding to contribute to Haiti's efforts to care for its orthopedic patients. "Two weeks after the earthquake I was in Haiti leading a team put together by Sutter Health, a large California medical plan. We went to a small hospital north of Port au Prince in the town of St. Marc. Along with the team from Mass General, we worked as a well oiled machine and performed a lot of surgeries. Over the next few months we were also able to get a substantial amount of equipment transferred down there."

Never a prima donna, Dr. Smith states, "We don't count on having regular electricity or water, and in fact have gotten used to operating without it. I concentrate on keeping the team small, usually including three orthopedists, a senior resident, a pediatric orthopedic surgeon, two anesthetists, an anesthesia tech and four nurses. Because the island lost a third of its orthopedic surgeons there is much that must be done in the way of rebuilding their infrastructure. To that end we do some teaching when we are there; it is usually one on one, with our anesthesia people working directly with their anesthesia people, etc. My dream is that we could make St. Marc's a center of excellence and other hospitals in Haiti could emulate this work."

The exuberant Dr. Smith is also practical. He says, "Working abroad is a wonderful way to expand your—and your family's—horizons. Many people feel trapped in a routine where they are taking call, paying the mortgage, etc. We get a lot of inquiries from orthopedists who want to work abroad. More often than not, it doesn't work out. So our strategy is to find good people and keep asking them to return."

Reflecting on the intersection of his work and personal lives, Dr. Smith notes, "It was a great sacrifice not being able to spend a lot of time with my family. The upside is that we got to travel together to fascinating places—we spent three months in Taiwan, and a total of two months in Fiji. Instead of being involved with Little League they came to the OR when I was traveling and learned quite a lot from watching the procedures. Other than my practice, my children are my biggest accomplishment. It has been wonderful to have my son go into orthopedics, and have my daughter become a nurse. I have three other children who are still in school."

Dr. Taylor Smith has the last word: "I am amazed that people compliment me on my work. Frankly, I'm embarrassed…I just direct traffic." ◆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