VOLUME 5, ISSUE 39 | DECEMBER 15, 2009

Orthopedics This Week

week in review

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breaking news

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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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Orthopedics This Week

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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Planning for 2010 is done at virtually every major orthopedic company and the consensus is that margin pressure will intensify in the coming 18 months. Tougher reimbursement. The FDA's burden on small and large companies is rising significantly. If ever there was a time for creative thinking, this is it.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	2	Medtronic	31.09%	8.43%	Last time MDT was #1 was…never. Why now? $4.5 billion in cash and investments; 31% margins and 2nd lowest future P/E.
2	1	Zimmer	28.1	7.3	At nearly $60, ZMH is not quite the cheap ortho stock but momentum remains positive.
3	4	Integra LifeSciences	15.37	7.53	Integra supplies Luxtec headlights? Signs new deal with Premier for Luxtec. Up one notch this week.
4	5	Stryker	23.5	4.02	$750 million stock buyback. Quarterly dividend payments of $0.15 per share. $2.9 billion in cash and investments.
5	3	Smith & Nephew	22.42	7.08	Analysts are expecting sales will grow 2.2% this quarter and then keep rising through 2010 to 7.3%.
6	6	Johnson & Johnson	26.94	7.39	With a 14x future P/E, JNJ has the lowest future P/E of all stocks in the universe.
7	8	Orthofix	10.33	-0.72	Every small cap company lost ground in the past 30 days. Investors want size right now.
8	7	Wright Medical	6.61	-3.91	This quarter may not be pretty in terms of YOY comparisons, but analysts' expectations for the next 12 months are upbeat.
9	10	CONMED	6.92	-3.25	Analysts are forecasting a particularly strong 8.3% rate of sales growth for 1Q10
10	9	Exactech	12.61	-6.18	Keeps getting cheaper and cheaper. Now 3rd least expensive equity among all public orthopedic companies.

Orthopedics This Week

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Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	CryoLife	CRY	$6.41	$182	14.5%
2	ArthroCare	ARTC	$21.90	$587	12.3%
3	Mako Surgical	MAKO	$10.27	$341	10.4%
4	Medtronic	MDT	$43.48	$48,120	8.4%
5	Integra LifeSciences	IART	$34.29	$977	7.5%
6	Johnson & Johnson	JNJ	$64.85	$178,930	7.4%
7	Zimmer Holdings	ZMH	$59.36	$12,640	7.3%
8	Smith & Nephew	SNN	$50.24	$8,870	7.1%
9	***Average***			***$11,651***	***6.7%***
10	Stryker	SYK	$51.26	$20,390	4.0%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGBOE.OB	$0.21	$2	-48.8%
2	NuVasive	NUVA	$28.58	$1,090	-27.8%
3	Osteotech	OSTE	$2.75	$50	-16.9%
4	TiGenix	TIG.BR	$5.57	$137	-13.2%
5	RTI Biologics Inc	RTIX	$3.55	$193	-10.1%
6	TranS1	TSON	$3.58	$74	-9.4%
7	Orthovita	VITA	$3.62	$277	-9.0%
8	Kensey Nash	KNSY	$22.96	$255	-8.2%
9	Exactech	EXAC	$16.84	$216	-6.2%
10	Symmetry Medical	SMA	$7.59	$272	-4.9%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Symmetry Medical	SMA	$7.59	$272	7.48
2	ArthroCare	ARTC	$21.90	$587	12.96
3	Kensey Nash	KNSY	$22.96	$255	13.37
4	Medtronic	MDT	$43.48	$48,120	13.65
5	Johnson & Johnson	JNJ	$64.85	178,930	14.23

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$50.24	$8,870	81.28
2	RTI Biologics Inc	RTIX	$3.55	$193	43.49
3	Synthes	SYST.VX	$131.30	$15,581	40.82
4	NuVasive	NUVA	$28.58	$1,090	26.16
5	CONMED	CNMD	$21.14	$615	21.94

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	ArthroCare	ARTC	$21.90	$587	0.52
2	Orthofix	OFIX	$30.29	$519	0.83
3	CryoLife	CRY	$6.41	$182	0.83
4	Symmetry Medical	SMA	$7.59	$272	1.01
5	Exactech	EXAC	$16.84	$216	1.10

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$28.58	$1,090	2.75
2	Johnson & Johnson	JNJ	$64.85	$178,930	1.91
3	RTI Biologics Inc	RTIX	$3.55	$193	1.89
4	Zimmer Holdings	ZMH	$59.36	$12,640	1.83
5	***Average***			***$11,651***	***1.74***

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$2.75	$50	0.52
2	Symmetry Medical	SMA	$7.59	$272	0.72
3	Conmed	CNMD	$21.14	$615	0.89
4	Orthofix	OFIX	$30.29	$519	0.97
5	Regen Biologics	RGBOE.OB	$0.21	$2	1.17

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$5.57	$137	191.25
2	Mako Surgical	MAKO	$10.27	$341	12.65
3	Synthes	SYST.VX	$131.30	$15,581	9.52
4	NuVasive	NUVA	$28.58	$1,090	3.26
5	Medtronic	MDT	$43.48	$48,120	3.18

Dr. Wardak, Innovation and the Taliban

By Walter Eisner

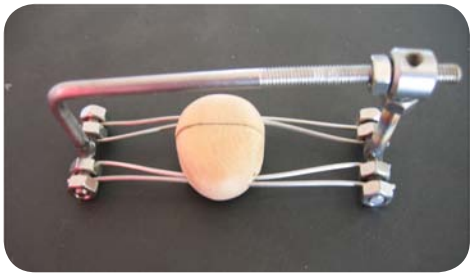
If you think it's tough to develop a new orthopedic device under the FDA. Try developing one under the former rulers of Afghanistan, the Taliban.

That's what Lt. Colonel Mohammad Wardak, M.D., did back at the turn of the century in 1999. Dr. Wardak was and continues to be the Chief of Orthopedic Trauma at the National Military Hospital in Kabul, Afghanistan.

Innovation Under the Taliban

By 1999, the Soviets had long ago slunk back to Moscow to disintegrate and the Taliban, then in power in Kabul, was engaged in a civil war with the Northern Alliance.

Under those conditions, Dr. Wardak developed the Afghan External Fixation device for the knee and elbow.



The Afghan External Fixation Device/Wardak

Necessity being the mother of invention, Dr. Wardak told us that while there were many fixation devices in orthopedics for long bone,

> "There were no devices for the knee and elbow. We thought about this and decided to make a small fixation device made from other external fixation devices."

It was not easy. Dr. Wardak said there was nothing in the international literature or books for this type of device and his facility didn't have the tools and instruments necessary to develop a new device. "It was very difficult having nothing and trying to do research. Finding X-rays, taking pictures and keeping them was not allowed. There was a lack of instruments. Many things are necessary in orthopedics."

And then there was the Taliban. "The regime didn't care much for officers," said Dr. Wardak. He had to take pictures secretly and hide them. The Taliban didn't allow photographs of people. There were no digital cameras. "I convinced my young patient, fixed with the device, to go with me to a hidden place where I could take the first pictures of a patient fixed by the device. Actually as they [the Taliban]

were not physicians, the science or research was neither important nor interesting for them."

Still, the consequences of getting caught with photos of humans was to have the camera smashed. Sometimes there were beatings.

Production

To make the device, Dr. Wardak cannibalized parts from a Russian orthopedic device and got other parts from a local bicycle shop.

Bicycle shop parts maker/Wardak

"Yeah, I ordered parts from a bicycle shop. He made the parts for me for about $2-$3. The original metal was not very good so the device was only good for one patient and I had to put in more orders."

Dr. Wardak says his device's unique mechanism causes compression of the fracture site through the tensioning of all wires at the same time with simple turns of one nut.

Patient Results

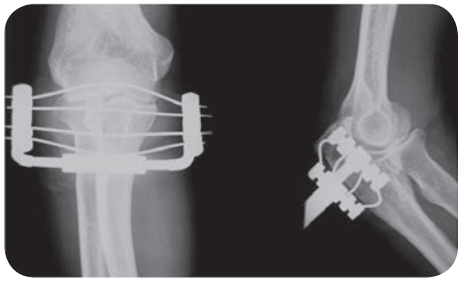
"We tried it on a patient, it worked well and slowly over a few years we changed it and now it's a good device"

"Now I have more than 200 cases of the Afghan device with excellent results. Most orthopedic surgeons in our country are using this device and the old methods are all abandoned here in Afghanistan."

Afghan Device Patient/Wardak

"All of the fractures healed with full recovery in four to six weeks, the mean time of healing or fixation was 34 days with no subsequent surgery or retained hardware. One hundred seventeen patients regained excellent motion and the mean knee score of 98 points. Seven cases had poor motion with less than 0-90 degrees of motion with a mean knee score of 85 points. However, four had contracture antecedent to our treatment. Other complications included: two wire site infections, nine wire site reactions and three cases had temporary synovial fluid leakage. One case of patella osteomeylitis."

Dr. Wardak and patient/ Wardak



Beyond Afghanistan

After seeing the success of the device in his own country, Dr. Wardak began thinking about getting his device beyond Afghanistan.

"One of our Afghans came from Germany and he took my abstract to an international conference in Baden-Baden, Germany in 2004. I represented the device there.

Then I went to the U.S. for a military conference and did a presentation of the device. In 2006 I went to the Brooke Army Medical Center (BAMC) and was helped a lot to write the research paper by Roman Hayda M.D. We then applied for a U.S. patent."

Gold Plated Afghan Device

BAMC Orthopedic Department 2006/Dr. Wardak in center

"I was in training in BAMC San Antonio where I met Kevin Walker, a very kind and smart rep from Smith & Nephew. He arranged my meeting with Randy Wilkinson, the company's National Director of Military/VA sales." Wilkinson took the device to the company. Dr. Wardak said the company then decided to try and manufacture it. Smith & Nephew submitted the device to the FDA for clearance. Dr. Wardak hopes to hear soon if the FDA will allow the device to enter the market in the U.S.

We spoke to Smith & Nephew. The company told us that they would not make any comments about the device while any regulatory processes were underway.

The possibility of having a new medical device named after Afghanistan has made Dr. Wardak very popular with Afghan politicians.

"It was unbelievable for me when Randy [Wilkinson] came last year [2008] to Afghanistan and brought a gold-plated Afghan device with him to Kabul and presented it to our Secretary of Defense and then he gave it to me."

"Mr. Kanony the leader of the Afghan Parliament gave a speech offering us (me and my teacher Dr. Siawsh) the appreciation letter from Parliament. He said, 'Dear Parliament members of Afghanistan. Every day we discuss our problems and try to find solutions. But today I have good news for you. One of our young physicians made a device by the name of Afghan Device, which will one day be available in the world medical market for treating patients.'"

Dr. Wardak says people in his nation are very hopeful in their future, but he has no desire to be involved in politics.

"I like my doctor job. When I was in military school they accepted me for medical college. I like my job very much and enjoy working for those people who have nothing."

What he likes best about his experience in trying to get his device to patients outside of Afghanistan is that the word "Afghan" will be the name on the device. "It's the first orthopedic invention from our country."

Taliban to FDA

Another plus of dealing with a western manufacturer is that there will be adequate financing for good marketing and, says Dr. Wardak, "perhaps even some money for the inventor." What might the inventor do with the money? "Improve the quality of our hospital," said Dr. Wardak.

While the FDA has not yet granted clearance for the Afghan device, the Afghan's and Dr. Wardak's hopes are riding on Smith & Nephew to wind their way through the FDA. Dr. Wardak got it through the Taliban. It would be a shame if Smith & Nephew couldn't get it past the FDA.

When we met Dr. Wardak for the first time at a SOMOS (Society of Military Orthopaedic Surgeons) meeting in Las Vegas in 2008, he had just arrived from Kabul. We wondered what his impressions were of leaving the behind the sands and culture of Kabul for the sands and culture of Las Vegas.

"Working hard is the key of success and there is no difference between these sands." Then he added with

a grin, "But I found great differences in other things."

To watch a three and a half minute video about Dr. Wardak and his device produced by the NATO Network, click here: http://www.liveleak.com/view?i=729_1237815472

Triumph of Inspiration

At a time when the disruption of industry/surgeon relationships and a dysfunctional FDA seem to be stifling innovation, Dr. Wardak's story sends a powerful message of inspiration to any physicians looking for a better way to serve their patients.

Thank you!/Wardak

POSTSCRIPT

Dr. Wardak informed us, as we were going to press, that Smith & Nephew had just contacted him to let him know the FDA has cleared his device. We'll provide details when Smith & Nephew makes an official announcement.

Orthopedics This Week

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Street Smarts for the Orthopedic Surgeon

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

As a doctor, you've taken the pulse of many a patient. But have you taken the pulse of "the street?" Dr. Robert Schultz, an orthopedist and author of the book, "Street Smarts for the Practicing Physician and Surgeon," thinks that some orthopedists haven't yet had that chance.

Dr. Schultz: "While you cannot give someone an experience, learning from the experiences of others can help you prepare for unusual situations, grow your practice, and know that you are not alone. This is particularly important for young surgeons just emerging from training."

The Fundamentals

One of the fundamental street smarts is to set your mind to "positive," says Dr. Schultz. But don't set your watch when you're with patients. "You must have an attitude of positivity and patience….and you should learn to expect the inevitable. Seeing a doctor often represents a detour in a patient's daily life, and most likely they are not excited to be going to the appointment. This means that they might not be in the best, most accommodating mood. You, however, must maintain your composure and act in a professional manner. Surgeons coming out of training have learned how to develop a treatment plan and how to operate, but have not been exposed to dealing with people over the long term because they rotate through different services. Thus, they never get a sense of what it means to have long-term follow up with patients."

"Once you are in practice, however, you get to know people over many years," states Dr. Schultz. "This can give patients the feeling that you understand who they are and are looking out for them long-term instead of being like a robot who comes up with answers but can't relate to patients as individuals. Take two restaurants: at establishment A the owner comes to your table, asks how you are doing, provides complimentary appetizers, etc. The food is just average, however. Over at restaurant B the food is superb, but there is no personal touch. Restaurant A is consistently more successful than the other establishment.

"The point is that you can be highly skilled as a doctor, but if you don't have an attitude and self presentation that gives people a sense of safety and belonging, then things aren't going to go well. This includes things such as dressing professionally, not getting upset with staff, listening intently, etc."

The personalities of the people doctors treat vary more than the conditions they have. And because there is such interplay between the two, it is more than a little helpful to learn some people skills. Dr. Schultz: "Whatever you do, don't be self absorbed or aloof. That will eventually kill your practice. Solicit patients' opinions, both in conversation and through evaluation forms."

"In our waiting room there is a TV screen that not only displays information on orthopedic problems, but provides details on the practice. When the patients complete the post-visit questionnaire, they are asked if they watched the TV program, and if so, what they found to be most helpful. The questionnaire also has questions such as, 'Do you now understand your disease?' and 'When the doctor used terms to describe your disease, was it understandable or did you have to go on the internet to learn more?' and, 'Did you feel that the staff was concerned about you?' and so on. Our practice set up a cybercafé where people can get a pastry and/or coffee, and use a credit card to go online and entertain themselves while they wait."

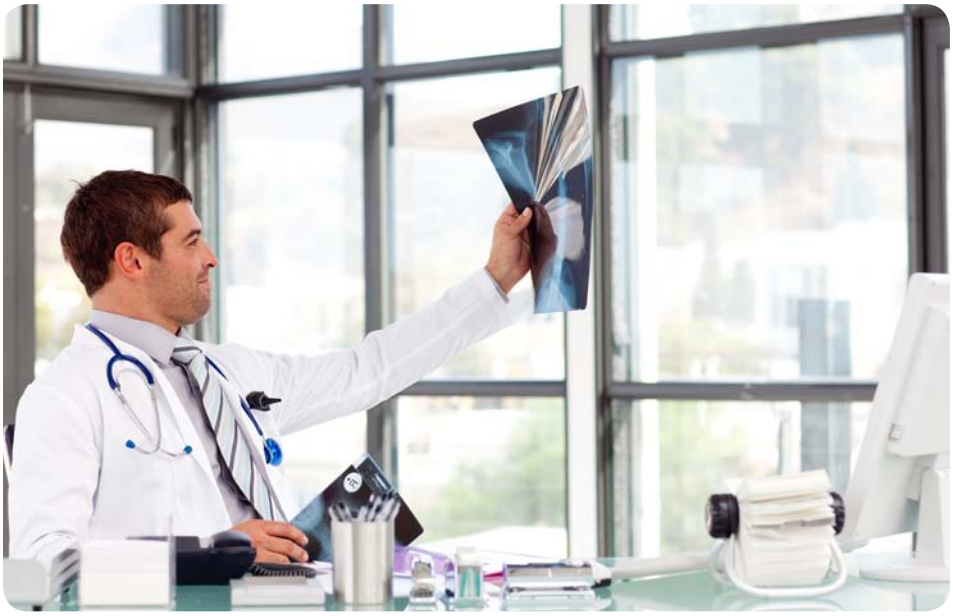
Problem Patients

But what if the person just wants to hang out at the front desk, ask a litany

of questions of the staff, demand to see the doctor right away, etc? This is someone you may want to point towards the door. "There are patients who can end up dragging you and your practice down," says Dr. Schultz.

"They tend to seek out a lot of attention, are looking for certain feedback from others, and need to feel that their illness is the most important thing in the world for the doctor. They indeed may have a real illness—or they could be embellishing a minor problem. If you tell such a patient that he has tendonitis and that he need only change his lifestyle and take medication for awhile, this person will continue to make office visits and give the staff a hard time. The staff only has a certain amount of time for each patient, of course, but the person feels insulted. There comes a point where you say to yourself, 'I don't want to treat this person anymore.'"

"Those doctors just out of training may not realize that it's possible to remove someone from their practice," notes Dr. Schultz. "While ethically or legally you cannot just abandon the patient, there is no law saying that you must treat everyone. There is a process to follow, however. First you must send a letter to the patient explaining that you don't feel that you can adequately treat them and give them the names of three doctors they could see. Tell them that they can continue to see you until they have found another physician (the length of time you have to give them for this varies depending on the state). And the letter should come from you and be signed by you. If your staff writes the letter,



then the patient will just say, 'I want to speak to the doctor.' This process leads to appropriately ending the doctor/patient relationship."

Ideally, however, you will be sufficiently tuned in to who might be a problem *before* he or she is a problem. "There are lots of little yellow and red flags that crop up with folks like this. Perhaps they are full of praise for you ('I have heard you're the best'), they disparage their former physician ('Dr. Jones down the street is awful, and his staff is really bad'), start calling you by your first name, bringing you birthday cards, etc. This person is setting you up for some bizarre interactions that can lead to lot of angst for you and your staff, who by the way, begins to complain about the person. And it is usually the case that this type of patient showers the physician with praise while complaining about the staff."

"If you recognize these behaviors early you can nip it in the bud. Instead of responding when they praise you, say nothing; be businesslike and do not give them extra time. I'm not saying to be cold, but you must distance yourself from such people. In most cases the patient will get turned off and leave the practice."

Marketing (Not Advertising)

The fact is, however, that these people *will* walk in the door. Especially since so many doctors are trying to grow their practices, and are using the powerful bullhorn of advertising. But don't call it advertising, says Dr. Schultz…it's marketing. "Marketing is a vital aspect of building a successful practice these days. But it has to be approached with caution. AAOS has provided clear guidelines on this topic whereby if a surgeon steps outside them it is unethical. You cannot make any outrageous claims, for example, saying you are world renown when you are not. But a marketing strategy is helpful, and can be altered based on what you learn from your patients. For example, you can survey patients and ask, 'Does the fact that your doctor is on TV make you feel proud or embarrassed?'"

Dr. Schultz continues, "Part of your strategy could involve giving talks to the community, including workers compensation groups, for example. When you do these events, however, make sure that you promote the practice instead of yourself. One way to do this is to bring business cards that only have the practice name on them. Also, you have to get the pulse of the community you're serving. Marketing your prowess in joint replacement surgery to a neighborhood or group of young people loses the audience and gets you nowhere."

Of course, you will want to ensure this is a practice that you want to promote. If things aren't going well, says Dr. Schultz, the seeds of your discontent may be found in your personal history book. "Avoiding divorce starts with choosing the right marriage partner. Know who you are and what you want your role in a partnership to be: entrepreneurial or simply a 9-5er. Make sure the partners are who you think they are by going into the OR or playing a round of golf with each of them. People under stress reveal their true colors."

The underlying message? Prepare, assess things along the way, maintain a sense of professionalism whether you're in front of a patient or a television camera, and display a genuine concern for those you treat.

Remote Control Scoliosis Surgery

By Robin Young

The idea of adjusting implants by remote control has been knocking around orthopedics for many years. Point the remote controller at the patient, press a button, gears whirl and a metal contraption begins to grow in the body. Hopefully the FCC has a special frequency bandwidth available. How awful would it be if a garage door opener triggered the device, or a cell phone? Bummer!

No patient wants to sign up for a series of surgeries. And most surgeons dread having to explain to the parents of a nine-year-old child that he or she will need numerous surgeries over several years. Unfortunately, this is precisely the situation with many children who are diagnosed as having severe scoliosis.

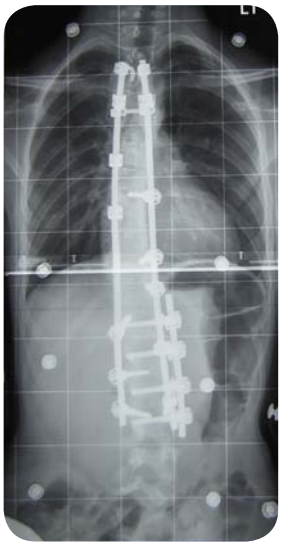
Today's Growing Rod Approach

Most surgeons who are contemplating deformity correction surgery on a child are thinking about techniques that would allow the spine to grow even as the deformity is being corrected. This growing rod approach is accomplished in several steps and, therefore, several surgeries. The initial surgery puts an internal bracing system in the spine and that can usually correct the deformity by about 50%. Then the child must return every six months to have the rods "lengthened" approximately one centimeter to keep up with the child's growth. While this is an outpatient procedure it still requires a small incision and most children wear a brace to protect the instrumentation.

This approach, while helping to preserve the ability of the spine to grow, also has a high complication rate.

Among the strategies to avoid difficult and prolonged surgery is better diagnosis. One such technology which is showing substantial success in identifying accurately which children will require corrective surgery and which will not is the ScoliScore from Axial Biotech and JNJ's DePuy division. ScoliScore is a predictive screening system for children which can reduce the chance of mistakenly diagnosing the kind of spinal deformity that requires surgery.

But for those children who do require surgical intervention and metal instrumentation, the idea of implants that grow as the bones grow and without additional surgery is extremely attractive.



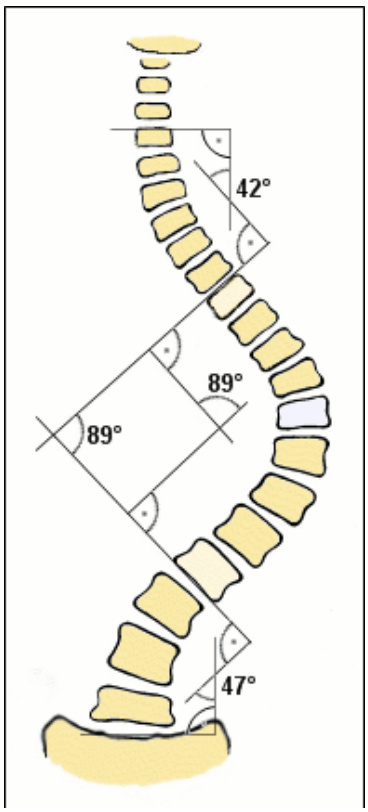
Anterior-posterior X-ray of a case of adolescent idiopathic scoliosis post-fusion/commons. wikimedia.org

Chiba University Remote Control System

In 1998, researchers from Chiba University's Department of Orthopaedic Surgery (Takaso, Moriya, Kitahara, Minami, Takahashi, Isobe, Yamagata, Otsuka, Nakata, and Inoue) in Japan described an innovative system that would stretch and apply corrective pressure to structural deformities of the spine repeatedly and non-surgically. The researchers built the device and then tested it on five beagle dogs with induced scoliotic deformities.

The device, incidentally, was an expandable rod system with a built-in motor and wireless signal receiver. It had four parts to it—an outer cylinder with a rod, a small motor with a gear head, an inner gear and, finally, an expandable rod. The hooks were attached to the rod with conical sleeves.

advertisement



Cobb angle measurement in scoliosis/ commons.wikimedia.org

The rods and hooks were made of stainless steel. The implanted receiver box was made of die cast alloy and was connected to the implant with a lead wire covered with silicon. The motor with the gear head (also implanted) used a 13 mm diameter coreless direct current (DC) motor (manufactured by Maxon DC motor; Interelectric AG, Brünigstrasse, Sachseln, Switzerland).

Here is what the Chiba University researchers noticed when they turned on their tiny, implanted motor.

The signal from the controller started the implanted motor and began to change the shape of the metal rods which in turn induced a maximum distraction force of 194 N. That level of force was sufficient to correct up to ***1 cm of deformity.*** The animals were awake and the correction was non-surgical.

The same 1 cm correction was then repeated at 6, 9, and 12 weeks after the operation. The average initial Cobb's angle of induced scoliotic deformity was 25. After using the remote controller, the researchers were able to change Cobb's angle to 20, then 18, 15 and finally 3. It took roughly 12 weeks to work down to a Cobb angle of 3.

Generally, a Cobb angle of 10 is regarded as the minimum angulation to define scoliosis. The "Cobb angle" is one of the most commonly used methods for quantifying spinal deformity.

Every correction that the researchers induced using their remote controller was performed *without a single incision* apart from the original surgery and there were no apparent complications from using the controller.

MAGEC

We were reminded of this intriguing 10-year-old Japanese study when we saw the news that Ellipse Technologies (Irvine, California) had presented data

regarding their remote control system for spine patients at last week's 3rd International Congress on Early Onset Scoliosis and Growing Spine Meeting in Istanbul.

Dr. Gregory Mundis of the San Diego Center for Spinal Disorders, La Jolla, California, presented Ellipse's data. His paper was titled "Innovation in Growing Rod Technique; Study of Safety and Efficacy of Remotely Expandable Rod in Animal Model". Co-authors were Behrooz Akbarnia, M.D., Pooria Salari, M.D., and Burt Yaszay, M.D.

Ellipse's system is called the Magnetic Expansion Control system or MAGEC. The system also uses a remote controller to distract the spine.

During a series of routine outpatient visits, Dr. Mundis and his fellow physicians dynamically adjusted the implanted instrumentation with, according to Dr. Mundis, accurate and controlled distraction. The researchers used a remote controller to activate an expandable rod in the patient.

In a press release from Ellipse, the study's principal investigator Dr. Akbarnia said, "Ellipse has developed a truly remarkable technology that will dramatically advance the treatment of spinal deformity, and significantly improve the otherwise traumatic experience these young children currently endure with multiple surgeries. The MAGEC device has exceeded my expectations for what I had hoped to someday witness during my clinical research career."

MAGEC for Europeans

In November, Ellipse received the CE Mark (Conformité Européenne) for its MAGEC technology which means that it is now available to several thousand of OUS spine surgeons for the treatment of spinal deformity. Ellipse has filed numerous patent applications for the use of the MAGEC Technology for a broad range of clinical applications.

But clearly, its first indications are for spinal and orthopedic trauma applications.

MAGEC's technology is based on using a nitinol wire spring as a form of a motor. Nitinol is an interesting composite metal that can change shape when energy is applied to it. The expandable wire is wrapped around the spine rods and when magnetic force is delivered using the remote controller, the rods move. Specifically, they slide using a pair of sleeves at the opposing ends so they can, in effect, "grow."

The key is that this new technology is capable of non-invasively adjusting implants within the human body from outside the body via remote control. With this, a physician can dynamically adjust the implanted spine rods as an outpatient activity.

Ellipse Technologies, Inc. is based in Irvine, California, and among its financial backers is the $1.3 billion Japan Asia Investment Co. (JAIC) which is one of the premier venture capital and private equity firms in the world and is listed on the Tokyo Stock Exchange. One, among the many, objectives of JAIC is to promote U.S.-Japan cross-border business models and which could bring U.S. technologies to Japan.

Unfortunately, Ellipse is a difficult company to reach and the paper was unavailable to read. We trust it will find its way into PubMed or PearlDiver's database soon. Still, based on a reading of Ellipse's patents and the history of attempts to create this kind of expandable implant, the news is encouraging. Since it is now available outside the U.S. and since the paper was presented at the International meeting, we expect to be hearing much more about this remote control adjustment device in the future.

Healing Paralysis Through Social Change

By Daniel Knowlton

Chris Waddell/Mike Stoner

On September 30, 2009, just two days after his 41st birthday, Chris Waddell reached the summit of Mt. Kilamanjaro. And he did it without ever using his legs. Now, this Paralympic athlete aims to heal and inspire others through the story of his ascent and through his foundation, One-Revolution. With an orthopedist on his climbing team and a venture capitalist in biotechnology as the President of One-Revolution, Waddell hopes to combine science with social change. We may not have the technology to "cure" paralysis due to spinal injuries, but as Waddell points out, there is still plenty of work we can do to help improve life for those in wheelchairs.

"How do average people achieve extraordinary things?" asks Waddell. "I think I was able to do that on the mountain, and hopefully that flips the paradigm on its head and forces people to look at limitations in a different way. I, as an average guy, climbed the tallest mountain in Africa. Hopefully that forces people to look at what it means to be in a wheelchair a little differently. We're not limited by nearly as much as people want to assume."

Chris Waddell has lived his life above and beyond his limitations. In a skiing accident during college, he fractured his T-10 and T-11 vertebrae leaving him paralyzed from the waist down. "I just wanted to get better," says Waddell. "The alternative was feeling like life was over at 20 years old. That wasn't really appealing to me." It wasn't long before Waddell headed back to the slopes, eventually winning 12 medals as a Paralympic skier.

Ascending to New Heights

Going downhill on a monoski requires plenty of skill, but climbing up Mt. Kilamanjaro was a whole different challenge. Waddell completed the climb with the help of a specially designed four-wheel hand cycle. He affectionately calls this vehicle "Bomba," which means "cooler than cool" in Swahili slang.

Some climbers call Mt. Kilamanjaro a "walkable" mountain, but, as Waddell points out, "'Walkable' for me is significantly more challenging than it is for you. The mountain is severely uphill—you gain 13,000 feet from the base to the summit, in about 25 miles. And it took a lot of technical moves for me to get up and over rocks that you would just step over."

Chris Waddell/Mike Stoner

"Personally, I'm almost in awe of what I did in terms of the bulk of work that I was able to do: nine hours a day of pedaling uphill. It's not something that I want to do tomorrow, but it's nice to know that I have the ability to do that. And I think the message applies to just about everyone, not just specifically to me as someone with a disability: how do we achieve something that we think is impossible?"

In answer to his question, it took friends' support, careful planning, and a feat of engineering to make the impossible possible. Dave Penney,

Chris Waddell/Mike Stoner

who had been a bike mechanic during the birth of mountain bikes, helped Waddell modify his hand cycle from an original three-wheeled vehicle designed by One-Off Titanium, Inc. "It is so fulfilling to be able to go a lot of places that you couldn't go otherwise," says Waddell. "The idea of going into production with this vehicle and opening up a whole new world to people is really appealing." As part of his current work with his foundation, Waddell and his team are in discussion with a lobbyist in Washington, DC, about possibly obtaining government appropriations for producing more of these hand cycles. Waddell explains that especially with disabled veterans coming home from Iraq and Afghanistan, there are so many people who could benefit from this kind of vehicle and support.

The One-Revolution foundation is still working on a hand cycle model for developing countries, but the team has already helped in other ways. "We've donated wheelchairs and cycles to people in Tanzania, and now we're making a feature-length documentary film on our work and the climb. We're looking to create social change. We're trying to effectively leverage what we've done on the mountain to move forward."

Bringing Focus to the Foundation

If Chris Waddell is the face and the voice of One-Revolution, his long-time friend Bob More is the engine that keeps the foundation on track. "The good part is that there is a lot of opportunity to make a difference," says More. "The bad part is also that there is a lot of opportunity to make a difference. There are so many problems out there...you have to just take one thing at a time."

Bob More first met Chris Waddell in college when their ski and soccer teams brought them into the same fraternities. Then, about ten years ago, they reconnected when they discovered they were almost neighbors in Parks View, Utah. Now More travels back and forth between Utah and California where he works for Frazier Health Care as a venture capitalist in biotechnology.

When Waddell asked More to be the President of One-Revolution, More couldn't refuse. "I decided to take the position because I'm a big believer in Chris and what Chris is doing. I love working in the medical community, and helping to treat people is very meaningful for me. My biggest role at One-Revolution is helping to provide focus. I make sure that we're focused on accomplishing things, not trying to do too much, and doing one thing at a time. And I try to make sure that what we do, we do it well."

And on what, exactly, is Bob More focused? "With spinal surgery," he says, "we haven't cracked the code as far as reconnecting nerve tissue, but there are a lot of ancillary devices that I think make life better for every type of patient. However, I don't think the infrastructure is built to commercialize and deliver technology from the lab to the end user particularly well. It's a long, difficult process. There are two levers you can push on. You can push on the technology, and there is a lot of great funding going into research to develop new products. But there is also the dissemination of that technology, and you can make a huge difference there. For example, the access that people have in Africa to technology is antiquated at best."

Social Change Abroad and at Home

Both More and Waddell hope the climb up Mt. Kilimanjaro and their documentary film will help bring attention to the need for greater technological access in the developing world. They also hope to change the perceptions that wheelchair-bound people are bound by countless limitations. And for Waddell, this isn't a challenge that only exists in the developing world.

"Some of what we're looking at," says Waddell, "is the assumption that everything is fine here in the U.S., that we have a positive American sensibility and a variety of options open to us. But I think that some of the perceptions still exist, and the perceptions are that paralyzed people have limited to no ability. And I think those perceptions are things that people in Tanzania are sometimes more receptive to changing than people in the U.S."

"We're all bound by our limitations," concludes Waddell. "But most of those limitations are the way in which we chose to see them."

company news

SurgiTrace Releases Tracking System

It's 10:00…do you know where your hip implant is? SurgiTrace, LLC does. The company has just released its "new" E1100 medical device long range tracking system—TRAXMD—a real time software system based on global integrated positioning and triangulation.

Source: SurgiTrace

Regarding how TRAXMD shortens the period-end close cycle, Bob Salvat, CEO of SurgiTrace told *OTW,* "Introducing the automatic transference of real-time information makes response time more accurate and faster. Lag times in manual data transference allow for variables to be affected, especially where humans are involved. Due to a hospital's unwillingness and inability to manage mass quantities of inventory, this becomes an outsourced or 'just-in-time' solution. Many are not aware that manufacturers typically ship in their products a day or two before surgery. This is usually done by courier and is only tracked by the online tools they provide. Let's say a $300,000 implant tray and instruments are being shipped to a hospital across the nation by next day air. They are scheduled to arrive 24 hours before surgery and there is a 12-hour snow layover in Chicago. The manufacturer isn't notified, neither is the field rep or the hospital, unless a specific inquiry is made and by that time it is usually too late. Perhaps the airport is hours away from the hospital. And what if the courier brings only four out of the five trays that are needed for the case? These and more can create timing problems for the OR."

This, Salvat said to *OTW,* should not happen in our high tech era. "This method has been used for many years and with the availability of today's technology it is a shame. Patients' lives are at risk and costly OR time is wasted. Relationships between the manufacturer, the surgeon, and the hospital are strained and sometimes ruined. Mistakes like these are costly and in the end we all pay."

SurgiTrace uses a geofence tool—a virtual perimeter on a geographic area using a location-based service. This means that when medical equipment fitted with an enabled tracking device enters or exits an area, a notification is generated and can be sent to an end user's mobile telephone or email. It allows manufacturers to draw zones around any area of interest including distribution points in their supply chain.

Detailing how TRAXMD puts the mind at ease, Salvat commented to *OTW,* "The SurgiTrace tracking solution combined with the TRAXMD system will help to eliminate logistics errors by catching them faster. It will help to reduce shipping costs by giving the manufacturer confidence that the information related to the asset is complete and not conflicted with the potential of human error. Representatives in the field can perform services more efficiently without having to worry about a container or asset that is lost and not ready for their next case. Surgeons can arrive at the OR knowing that all of their tools are present and ready to go. Hospitals can feel at ease knowing that the constant flux of implants, instruments, and medical equipment coming through their doors is being constantly monitored, in turn reducing their liability."

Regarding product adoption, Salvat told *OTW,* "SurgiTrace has received consistently positive feedback, but I realize we are all creatures of habit. SurgiTrace pioneers a new market niche in real-time long-range tracking very similar to the early generation cell phones that exploded onto the market in the '90s. A similar evolution can be expected of the long-range tracking market for medical devices pioneered by SurgiTrace, but the only difference is that the technology is already here. It's affordable, and waiting to be harnessed by all."

Salvat also told *OTW,* "Currently the FDA is pushing for the adoption of a universal solution in what they are calling the UDI program (Unique Device Identification). In fact, by 2012 the question of adopting a method of tracking medical device usage similar to the SurgiTrace product offering may not be a question at all but instead a necessity."

company news

Regarding a learning curve and training, Salvat commented to *OTW,* "Our three primary objectives are to be efficient, effective, and easy-to-use. Our research revealed that anything more intuitive beyond what is needed is a data migration nightmare. During the implementation process a SurgiTrace team will travel to a new user's facility, assist in retrofitting the tracking systems, load their data into the system, and cover all aspects of learning the system. Then the user can log-in and begin locating their assets by simply choosing an asset's ID number. Or, the user may choose an inventory distribution point such as a hospital or distributor's office in order to obtain the location of all containers in that region. The automated reporting provides location data for each asset several times daily based on a schedule set by the manufacturer's preference. This information is then streamed to the backend system, such as Oracle or an SAP-based system, so the manufacturer knows at all times what is in the field versus what is in their inventory store house."

He also told *OTW,* "Future system enhancements are in their final phases of development, and will give even more precise information of a medical container or asset's location and the status of its contents. These enhancements along with others will aim to complete the entire lifecycle of every single product that leaves the manufacturer's warehouse from their initial shipping point to billing and lastly reimbursement. SurgiTrace is determined to close the gap between technology and medical inventory logistics management in an effort to maximize a device manufacturer's profits and service, streamline reimbursement efficiencies, and more importantly to recognize the true potential of patient safety."

—EH (December 8, 2009)

Stryker Gives Back

When a company earns lots of money, it can, among various options, reinvest the cash in research and development, buy new technologies through acquisitions, buy back public shares or return some of the earnings to the company's owners, the shareholders.

Stryker, which has been famous for 20% earnings growth year after year, with a slight dip this year, took all four options in 2009.

First, the company announced the $525 million acquisition of medical device reprocessor Ascent Healthcare Solutions on November 30. Then the company's Board of Directors authorized a $750 million share repurchase program and a $0.15 per share quarterly dividend on December 3.

We know the company didn't forget about reinvesting in research and development this year. Stryker has spent hundreds of millions over the past couple of years in retooling its quality control and compliance programs after some FDA issues.

Leaders of orthopedic companies rich in cash don't seem too fazed by the expected medical device tax being proposed during the health care debate in Congress.

"We continue to be pleased with our strong financial position," commented Stephen MacMillan, President and Chief Executive Officer in a company press release. "The actions of our Board of Directors today again

Stryker Board of Directors/Stryker Corporation

company news

demonstrate that we have the strength to continue to pursue investments in our business while returning significant capital to our shareholders through share repurchases and dividends."

According to finance.yahoo.com, Stryker has $2.93 billion in cash on its balance sheet.

—*WE (December 9, 2009)*

Clearance for Captiva's Pivotec

Captiva Spine, Inc. reported on December 4 that the company received 510(k) clearance from the FDA for Pivotec, its interbody system.

By definition, a 510(k) cleared device is "like" previous devices. What's unique about the Pivotec?

"The secret [of the Pivotec]," says Dale Mitchell, president and founder of the company, "resides in our proprietary inserter that allows the cage to safely and accurately pivot without disengaging from the instrument, eliminating multiple passes with additional tamps and pushers."

Mitchell added that the system was designed to address the challenge of controlling cage insertion and manipulation during surgery.

company news

Captiva's Pivotec/Captiva Spine

The company hopes the market will quickly decide that their system becomes the "solution of choice" for standard TLIF (transforaminal lumbar interbody fusion) procedures.

The product was introduced at the annual North American Spine Society (NASS) meeting recently held in San Francisco.

Captiva is a privately held company founded in 2007 and is located in Jupiter, Florida.

—WE (December 8, 2009)

AxioMed Spine Raises $6.4 Million

Cleveland-based AxioMed Spine has raised another $6.4 million to continue to develop its Freedom lumbar and cervical disc replacements.

Patrick McBrayer (RIGHT), president and CEO, AxioMed Spine Corp.

AxioMed Spine HQ and CEO Patrick McBrayer/siteselection.com

The company says its artificial discs are based on a viscoelastic prosthetic technology. The technology uses a patented polymer, under an exclusive license to the compay, that provides for "three-dimensional motion that biomechanical testing has shown functions within the natural biomechanics of the spine."

This latest funding comes after having already raised $34 million in venture capital from such firms as CID Equity Partners, EarlyStage Partners, Investor Growth Capital Limited, Primus Capital, Memphis Biomed Ventures, Reservoir Venture Partners and Thomas, McNerney & Partners.

The company won the CE Mark this past May and has introduced its devices in Germany, Switzerland and the United Kingdom.

Patrick McBrayer, company president and CEO, is quoted on medcitynews.com to say that the additional capital will also be used to expand its operations by adding 15 people to its workforce. It will add those employees when the company completes the remainder of a Series C round of $18.5 million.

—WE (December 11, 2009)

biologics

Fixing Bones With Metallic Glass

Doesn't sound like these two should be too close to one another…bone and glass, that is. But researchers from ETH Zurich, a Swiss science and technology university, have produced a biocompatible magnesium-zinc-calcium alloy in the form of a metallic glass—one that overcomes a major hindrance.

The bioabsorbable metals normally used for implants dissolve in the

biologics

body over time. Implants made with magnesium-based alloys, while promising, say the researchers, have a major drawback: when they dissolve they produce hydrogen (H2), which can be harmful. Gas bubbles develop around the magnesium implants, something that hinders bone growth and thus the healing process, and may cause infection.

Materials researchers working with Jörg Löffler, Professor of Metal Physics and Technology at ETH Zurich, have now eliminated these side-effects. Their new biocompatible magnesium-zinc-calcium alloy in the form of a metallic glass shows significantly more favorable degradation behavior. Metallic glasses are produced by rapid cooling of the molten material. The speed of the cooling process prevents the atoms from adopting the crystal structure found in traditional metals.

Providing details, Professor Löffler told *OTW,* "We have produced a magnesium-based alloy in the form of a metallic glass. Thanks to this procedure we can add much more zinc to magnesium than is possible with conventional alloys. By adding more than 28% of zinc atoms to the alloy, a zinc- and oxygen-rich passivating layer forms on the metal's surface, which fundamentally alters the corrosion behavior of the material. By varying the zinc content in this range we can tune the degradation behavior of our alloy."

Professor Löffler also commented to *OTW,* "We have performed animal studies (in various tissues of domestic pigs), where the MgZnCa glass was found to be fully biocompatible and the surrounding tissue free of hydrogen bubbles. We intend to run clinical trials on a few patients in the future to make sure that all requirements of a bone implant material are fulfilled."

Arc melter in which a plasma of up to 3000°C is produced between a tungsten tip (center) and a water-cooled copper plate/ETH Zurich

The research has been published in the online version of *Nature Materials.*

—EH (December 7, 2009)

extremities

The Problem With Ankles

Travails of the talus…A new review article published in the December issue of *The Journal of American Academy* of Orthopaedic Surgeons shows that a detailed description of ankle injuries, recognition of subtle diagnostic imaging clues, and a targeted physical exam can help avoid long-term injuries and disabilities that may occur as a result of these uncommon fractures.

Apparently, it's a bit of hide and seek when it comes to the ankle. The researchers indicate that ankle injuries are often in areas that are hard to visualize with imaging, and that these injuries are the most frequently misdiagnosed of all foot fractures. Delayed diagnosis can have serious consequences, sometimes leading to permanent disability.

"The talus is a very important bone in the ankle," said study co-author Joseph Kou, M.D., in the news release. An attending surgeon at Muir Orthopaedic Specialists in Walnut Creek, California, Dr. Kou added, "Injury to the talus and its surrounding structures will significantly affect the function of the

extremities

foot and ankle and can lead to long-term disability if not treated properly."

With regard to the subtle radiographic hints, Dr. Kou told *OTW,* "Look for clues such as joint space asymmetry and double density signs. If in doubt, contralateral views, stress views, and CT scans are very helpful."

The authors indicate that foot and ankle injuries involving the talus (or peritalar region) often occur as a result of car accidents or other high-impact trauma, and can also occur as a result of low-impact events, such as twists and falls. When treatment of these injuries is significantly delayed, permanent disability can occur, and surgical intervention may be necessary to restore function.

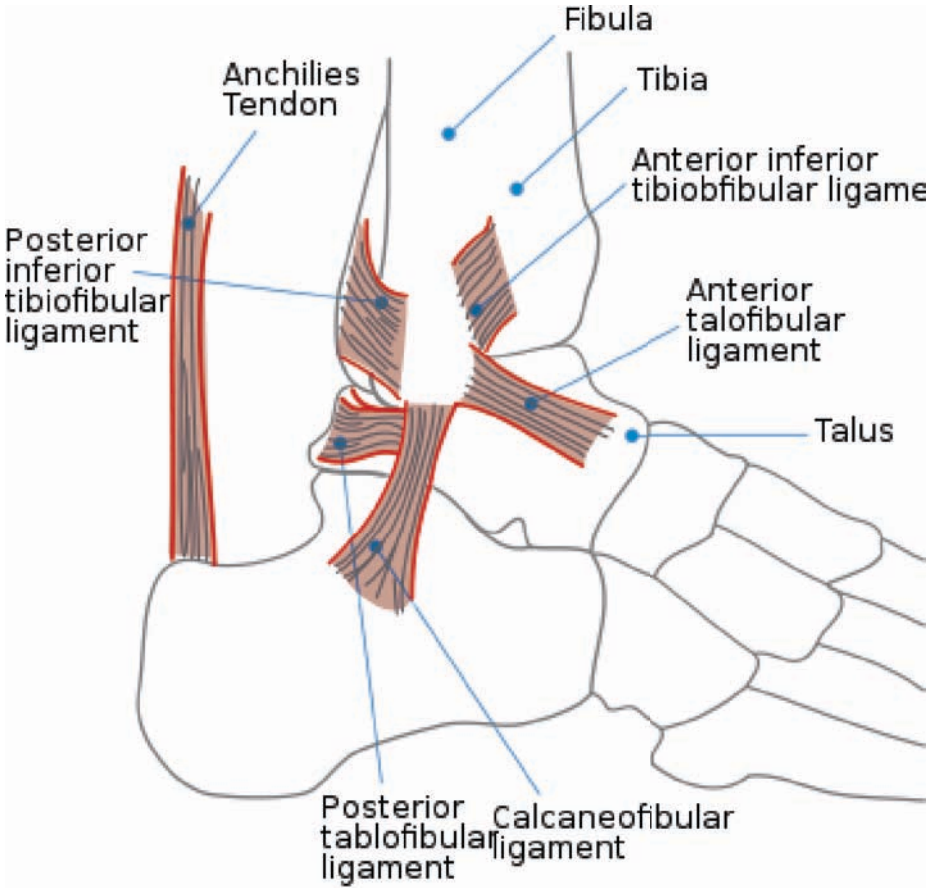
The researchers encourage patient participation in the diagnosis process, and state that patients should give their physician a complete and accurate description of how the injury occurred, and should identify the area of the foot and ankle where the pain is most severe. Men and women who suffer an ankle injury should inform their physician about unusual or persistent symptoms, including, persistent pain that is not improving, the inability to bear weight, and severe swelling, bruising, and blistering of the skin.

As for what patients tend to leave out of their description of the problem, Dr. Kou told *OTW,* "It is very important for patients to show the physician where the point of maximum pain is to localize the area of injury. Occasionally, patients will complain only of diffuse pain and not specify precise locations, which can make proper diagnosis difficult."

"The foot has complex three-dimensional anatomy that can be difficult to fully assess on conventional two-dimensional radiographs, such as X-ray," Dr. Kou noted in the news release. "Also, while most foot and ankle injuries involve innocuous sprains, a small percentage of these injuries are significant. The rarity of these injuries results in frequent misdiagnosis."

"A delay in diagnosis can adversely affect the long-term outcome of the injury," Dr Kou stated in the news release. "Better knowledge and awareness of the existence of these talus injuries throughout the orthopaedic community will decrease the incidence of missed diagnosis, and significantly improve patient outcomes."

—EH (December 9, 2009)



The Ankle/Wikimedia Commons

extremities

LifeHand: Prosthesis Controlled by Thoughts

LifeHand/Università Campus Bio-Medico di Roma

Talk about the power of positive thinking…Italian researchers from Università Campus Bio-Medico di Roma and Scuola Superiore Sant'Anna di Pisa have developed a prosthetic hand that can be controlled by one's thoughts. Pierpaolo Petruzziello, a 26-year-old who previously underwent an amputation of the left upper limb after a car accident, was the first to test the amazing new device.

Leading the team was Paolo Maria Rossini, a professor of neurology, who told *OTW,* "We were surprised to learn that by using several recording electrodes in the nerves of the stump and by combining processing of signals from nerves and brain it is possible to control online several different movements of the robotic hand including those of individual fingers. Moreover, we were surprised to see that by training with the robotic hand and by regaining the perception of a body scheme progressively involving again the amputated limb/hand, the subject was getting progressively free of the distressing symptoms linked to the 'phantom limb syndrome.'"

The project, funded by the EU to the tune of €2 million (euros), involved implanting electrodes in Petruzziello's median and ulnar arm nerves, and resulted in his being able to feel sensations in the prosthesis, and move the artificial hand solely via cerebral impulses. He successfully performed three movements: thumb-forefinger opposition, fist clasp, little finger movement.

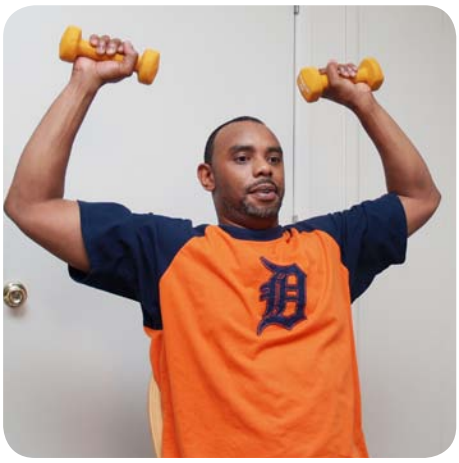
Regarding what the researchers will undertake next, Professor Rossini commented to *OTW,* "1) Improving the sensory part of the experiment by connecting robotic hand sensors to the intrafascicular electrodes and dispatching to the subjects an appropriate sensory feedback while moving the robotic hand and while touching objects with the robotic fingers; 2) miniaturizing the signal processor in a microchip able to be inserted in a subcutaneous pouch; 3) making the hand suitable for direct application to the stump."

As for how others might eventually take advantage of this work, Professor Rossini told *OTW,* "All the above steps can be completed three to five years from now, provided the needed research funds are obtained by the EU and other funding institutions."

—EH (December 11, 2009)

New Study: Reconstructing Shoulders

How do you treat a patient who suffers from recurrent shoulder dislocations? In some cases, soft tissue repair may not be enough. A new study from the University of Michigan shows that reconstructing the shoulder joint with cadaver bone and cartilage can be an effective treatment that could help patients avoid revision surgery.



Arthur Goldman/University of Michigan Health System

extremities

Physicians commonly treat unstable shoulder joints by repairing the soft tissue. In many cases, tightening the ligaments that hold the joint in place is enough to stop the shoulder from dislocating. This image shows an X-ray comparison between a stable shoulder joint and a dislocated shoulder. Each time the shoulder dislocates, the cup of the shoulder socket (the glenoid) can chip bone fragments away from the ball of the arm bone (the humeral head). Even small defects can make the joint unstable and lead to failure of soft tissue repairs.

The Study

Dr. Jon Sekiya, surgeon and associate professor in the Department of Orthopaedic Surgery at the University of Michigan, specializes in shoulder repairs that succeed where standard procedures fail. With the help of the study's co-authors from the Musculoskeletal Research Center, Department of Bioengineering, at the University of Pittsburgh, Dr. Sekiya studied cadaver joints in order to find a more effective treatment for dislocated shoulders.

With a robotic testing system, the researchers applied force at different angles to shoulder joints with bone defects of various sizes.

According to the study, "Defects as small as 12.5% of the humeral head have biomechanical consequences that may affect joint stability. In addition, shoulders with large osteoarticular defects (37.5% or 50.0%) may benefit from osteoarticular allograft transplantation to restore shoulder stability." The team published its results in *The American Journal of Sports Medicine* ("Hill-Sachs Defects and Repair Using Osteoarticular Allograft Transplantation").

In the recent press release from the University of Michigan ("New shoulder repair technique effective when standard procedures are not" December 7, 2009), Dr. Sekiya highlights the success of some patients who received treatment with a cadaver bone allograft. Arthur Goldman, for example, feels fully recovered eight months after his cadaver bone transplant surgery to treat his shoulder fracture.

Good/Bad Shoulder/University of Michigan Health System

extremities

Reconstructing the Shoulder

For patients with serious enough bone defects in the shoulder joint, surgeons can use cadaver bone to repair both the glenoid and the humeral head. First, doctors match the cadaver tissue to the patient's shoulder using X-rays. Then, the surgeons shape the tissue to the patient's bones during the operation. Some patients may worry about rejecting the donated bone, but, according to Dr. Sekiya, "cadaver bone and cartilage doesn't reject like organs such as the liver, heart, and kidneys because cadaver bone is less immunogenic. It is not a significant issue clinically."

Even though this allograft may seem like an expensive option, in the long run, it could save patients money and pain. Dr. Sekiya told *OTW,* "The problem with synthetic implants or devices is that they are akin to starting down the path to a total joint replacement—in effect, they are a partial joint replacement. This treatment is biologic—it actually heals to the patient and becomes part of the patient as it integrates and heals. Metal never "heals." In terms of cost, this procedure is expensive not unlike shoulder replacement devices, but if you consider avoiding revision surgery (sometimes 2 or 3 or 4 surgeries), then you can save much in terms of real dollars. If you talk about saving personal costs, that can't be measured."

—DK (December 11, 2009)

people

Tillman, Williams, Join Millstone-Memphis

Elvis may have left the building…but two new stars are in town. Millstone Medical Outsourcing, which provides advanced inspection and other services to orthopedic companies, has announced that it has recently appointed two experienced professionals to its leadership lineup in Memphis, Tennessee. Jonathan Tillman, who formerly led sales from the Fall River, Massachusetts, headquarters, recently relocated to Memphis to lead the sales and relationship development effort for Millstone Memphis and provide management of operations and program development. Tom Williams was a program manager in Fall River and will now be responsible for day-to-day operations in Memphis. As indicated by Millstone, both appointees bring a client-centric approach to management and will enable the company to provide enhanced service to customers and expand services in Memphis.

"We are expecting significant growth in volume, customer base, and service offerings at our Memphis location over the next two years," said Christopher Ramsden, CEO, in the news release. "Jonathan and Tom were transferred to Memphis to lead the facility through this growth phase. Both offer experience in program development, process improvement, and client interaction that will enable Millstone to maintain and advance current and future Memphis service offerings."

Jonathan Tillman, VP of Sales, joined Millstone Medical in 2002. He has been responsible for developing and implementing strategies to expand the

Jonathan Tillman and Tom Williams/Millstone Medical

people

company's customer base. In doing so, Tillman helped customers develop packaging and post-manufacturing programs, provided program management oversight, and helped envision and launch the Memphis facility.

Regarding his first steps in the program development arena, Tillman told *OTW,* "Our focus will be on the improvement of current processes. Meanwhile, we will continue to identify and communicate additional enhancement opportunities. The overall goal is to make the current processes more efficient and create an environment where process improvement comes from the operators to the managers. Longer term we plan to replicate all the packaging capabilities we currently provide our clients through our Fall River, Massachusetts, facility."

As for relationship development, Tillman commented to *OTW,* "Memphis has become a hot bed for medical device companies. Our close proximity to clients and the ability to conduct onsite meetings at a moment's notice allows us to understand our clients' needs better and provide superior service. I look forward to developing stronger partnerships with our existing clients located in Memphis, and I am confident that our accessibility will be a deciding factor for new clients."

Tom Williams, who began as a program manager for Millstone Medical in 2008, was the liaison between Millstone and clients and wrote client-specific processes and procedures. Prior to joining Millstone, Williams was regional director for Challenger Sports Corp where he was responsible for sales and account management as well as budgeting and staff hiring, training, and management. His was previously a civil servant with the Cardiff Crown Court in Cardiff, UK, where he served as the liaison with Barristers' Chambers. In his new position, Williams will be responsible for daily operations, including loaner kit processing and distribution services. He will also manage staffing and process improvement duties.

Commenting on how he will bring a "client-centric" approach to the company, Williams told *OTW,* "One of the benefits of Millstone's client-centric approach is the ability to pass along the efficiencies we develop through process improvement to our clients. Through open dialogue and partnership building, we enhance our understanding of our clients' goals and focuses. Then we increase operator understanding of client product and end use. The result is a highly efficient and effective process that provides a real return for our clients."

—EH (December 11, 2009)

spine

Applied Spine's Articulating Patent

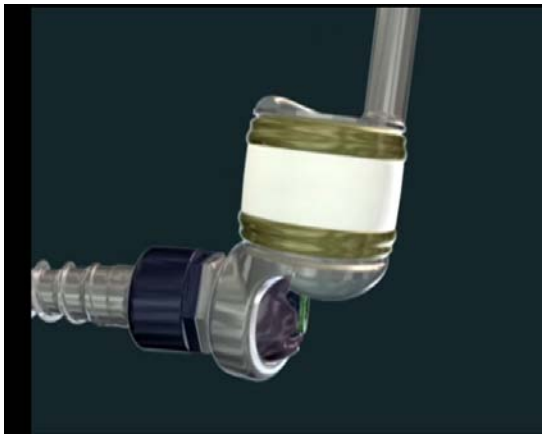
Applied Spine Technologies announced recently that the U.S. Patent Office had issued the company a new patent (No. 7,615,068) titled "Mounting mechanism for pedicle screws and related assemblies."

With all due respect we contacted Applied Spine and asked them if the world really needed another pedicle screw and what was special about this one.

Turns out, we're glad we asked. This is a unique pedicle screw.

Company CEO Craig Corrance explained that from the neck on down, most pedicle screws are the same and the rods and screws in

spine



Articulating Pedicle Screw/Applied Spine

stabilization devices are fixed. This pedicle screw has an articulating head and is designed to work with Applied's dynamic stabilization device. The design allows movement at the intersection where the screw head and dynamic rod meet.

Or as Bruce Robie, Ph.D., company VP of Research and Development said, "The two key elements of an optimal dynamic stabilization device are a connector that can change length, and a mechanism that permits dynamic angulation between the connector and the pedicle screws, as the patient bends."

Corrance concluded, "In conjunction with our previously issued intellectual property, this new patent offers us protection within critical elements of dynamic stabilization devices, particularly dynamic angulation. Interestingly, other devices that lack dynamic angulation capabilities have reported clinical failures. We believe, therefore, that our new patent significantly enhances the company's IP portfolio."

—WE (December 7, 2009)

The Picture of Success: Dr. Alan Hilibrand

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

The old cliché says that engineering types are not gregarious people, but Dr. Alan Hilibrand, a spine specialist at The Rothman Institute at Thomas Jefferson University in Philadelphia, certainly doesn't fit that mold.

"My early years were spent in southern New Jersey, where I heard stories of my dad's work as an electrical engineer and tales of my mom's days as a pharmacist. I was always interested in how the human body works."

While homemade engineering projects such as making toilet paper roll telescopes won't throw open the doors to MIT, having superb grades and talent will. "I entered the MIT undergraduate program in 1982 and decided to major in biology. Since MIT focused on engineering, my course load was heavy on math and science. I think this gave me a deeper appreciation for the role of engineering in orthopedics."

Orthopedic Training

Entering Yale School of Medicine in 1986, Alan Hilibrand became class president and got a bird's eye view of different specialties... but he didn't need to look far. "I was very impressed by the enthusiasm displayed by the orthopedists at Yale. It is one thing to say, 'Pursuing XYZ field makes sense to me,' and another to say, 'These are the kind of people I want to spend my time with.' I was sold on orthopedics."

Then, being considerate and a bit gallant, he followed the ambitions of his future wife. "She was applying to law schools, so I applied for residency programs in areas that had top notch law programs. Although I initially applied to The University of Michigan because of their great law school, I ended up loving the residency program and went on to match there in orthopedics. At Michigan there was a strong focus on residency education and on faculty taking individual responsibility for residents. They really emphasized training residents rather than having them just be of service to the attendings. One of the nice things was that there were no fellows—meaning that residents covered all of the operations."

While at Michigan Dr. Hilibrand's mentor helped him find the calm in the middle of the residency storm. "Dr. Robert Hensinger, who was President of AAOS during that time, was a very influential person during that phase of my training. He always had an interest in talking with residents about issues that we faced as doctors, and also had a good sense of where orthopedics was headed. I had my mind set on academic orthopedics and Dr. Hensinger was able to provide me with a lot of support as I started out. He remains a mentor to this day."

Also leading Dr. Hilibrand through the training vortex was that master of spine, Dr. Henry Bohlman. "I did my fellowship at Case Western, where my 'apprenticeship' under Dr. Bohlman greatly expanded my understanding of spinal and neuroanatomy. He taught his fellows in a way that enabled them to work with new technologies and procedures that they had never performed during their training. As a result, they obtained detailed, 'hands-on' knowledge of spinal anatomy and physiology. After my year with Dr. Bohlman and his partners at Case Western, I felt that I could work my way around the spine with complete ease."

Dr. Hilibrand then headed for a southern nerve center of spine. "I joined the faculty at Vanderbilt University in 1996 under the guidance of the Chair, Dr. Dan Spangler. Dan was the perfect person to help a junior partner, as he took a lot of time to provide me with academic and emotional support for all the things

we go through when starting a spine practice. Spine is higher risk than a lot of things in orthopedics, and those starting out need to be supported."

Although Dr. Hilibrand found a comfortable home and good friends in the orthopedic surgery department at Vanderbilt, he found that it wasn't long before the Medical Center administration began to tighten its control while failing to meet its commitments to the department. "In the fall of 1998 I left Vanderbilt and returned to the familiar landscape of Philadelphia. The two spine surgeons I knew, Drs. Alex Vaccaro and Todd Albert, both of the Rothman Institute, were so productive academically that I thought, 'These are the kind of people I want to work with.' It was clear to me that they were ***the*** group for spine in Philadelphia, and I had confidence in Dr. Richard Rothman that no matter what changes came along in medicine, he and his practice would always end up on top. And I have never been disappointed."

Pioneering Studies and Research

Dr. Hilibrand soon delved into a major national research project… and became known for being the third highest enroller of patients. "I was fortunate to find myself working on the Spine Patient Outcome Research Trial (S.P.O.R.T.) study, an effort undertaken at 13 institutions around the U.S. to examine the top three back conditions that lead to surgery. This solid clinical research, done in a prospective manner, stands as an important contemporary example of comparative effectiveness research. The enrollment process was interesting, although not perfect. While it was clear to all of the investigators that we wanted people to randomize, we were willing to take people who wanted to choose their own treatment. The goal, however, was to have them allow us to randomize them."

He continues, "One weakness of the S.P.O.R.T. study was that although people were randomized they had the opportunity to cross into the other group. If, for example, someone was in the nonsurgical group and did not improve, you could not deny them surgery. We would say to participants, 'We'd like you to allow us to assign you to a group. In the end, if you are assigned to nonsurgical treatment and you do not improve, we will never deny you the opportunity to 'cross over' into the surgical group and have an operation if necessary.'"

Elaborating on the value of the seven year study, Dr. Hilibrand notes, "The S.P.O.R.T. study provides solid evidence of the very significant benefit of surgery in terms of patients' improvement in physical function, reduction in pain and reduction in disability when compared with continued nonoperative treatment. Perhaps more important in this era of healthcare reform, we have now been able to show the cost effectiveness of these surgical treatments. For example, using the outcomes from S.P.O.R.T., we have been able to measure the ***value*** of the patient's improvement in their quality of life and assign a dollar value to that. Many of the treatments have a quality-adjusted life year (QALY) cost of $50,000 or less at the four year follow-up. This means that surgical management of a herniated disc or spinal stenosis has at least as much value as the medical management of cardiac disease."

Dr. Hilibrand adds, "Overall, one of the most fascinating things about the S.P.O.R.T. study is not only all of the data available to be 'mined,' but the infrastructure that was put in place at Dartmouth by Dr. James Weinstein, the Principal Investigator of S.P.O.R.T. As a result, this data continues to be collected. We plan to take it out to 10 years."

In his other research, Dr. Hilibrand investigated whether solving one spine problem creates another. "As a resident, I loved the concept of using survivorship analysis to assess the durability of hip and knee implants. Back in the '90s people were beginning to do these analyses, but no one had applied the concept to spine. In 1995 I began to examine the

durability of cervical spine surgery by reviewing the long-term outcomes of hundreds of Dr. Bohlman's patients. I created a database of all his cervical spine operations from 1973 to 1992 and then went through all of his patient charts and looked at people who had operations and whether they developed problems in adjacent levels after fusion.

"We found that the operations were 'durable;' however, a small but consistent number of patients, approximately 3% per year, developed symptoms related to degeneration at adjacent levels. I published a paper on this topic in 1999, and for the first two or three years afterwards it was rather well hidden in the *Journal of Bone and Joint Surgery*. Then, when surgeons began studying the potential of lumbar and cervical disc arthroplasty, the subject became more popular, and I learned that a lot of people were dusting off my article."

"Regarding my biomechanical work," adds Dr. Hilibrand, "my team and I looked at the entire cervical spine, including the upper cervical spine, to consider the mechanics of fusion and changes in motion in the cervical spine. Surprisingly, our team determined that the motion eliminated at a fused level is not transferred to the adjacent levels. Rather, it is transferred to the upper cervical spine and the base of the skull. I also designed a study where we measured the range of motion of all patients who had cervical spine fusions. We were fortunate to collaborate with Dr. Sorin Siegler at Drexel University's biomechanics lab, who had developed a very sophisticated testing apparatus that could be used to evaluate motion without constraints. We found that patients' motion was greater after surgery than before the fusion, something that went against conventional wisdom."

Advice for Life and Medicine

No matter what topic of research you select, says Dr. Hilibrand, think outside the lab. "Unfortunately some young doctors who want to do research tend to look around for an attending who is doing interesting work. Their starting point should instead be, 'What in orthopedic surgery interests me?' and then come up with their own hypotheses and ways of testing them. That is how you think outside the box…and that is how orthopedic advances occur."

A member of the AAOS Leadership Fellows Program in 2005-06, Dr. Hilibrand furthered his involvement with the organization by taking up the post of Vice Chair of the Communications Cabinet in 2006. The following year, Dr. Hilibrand was chosen as one of five orthopedic surgeons to represent the United States and the American Orthopaedic Association as an ABC traveling fellow. "It was a tremendous opportunity to meet orthopedists around the world and learn about the practice of spinal surgery under different healthcare systems. Those six weeks traveling literally around the globe truly was a transformative experience."

Although he limits his practice to orthopedic spine surgery, Dr. Hilibrand also believes that all orthopedists must be united to have a stronger voice. "People have a great deal of loyalty to their subspecialties, and in spine there are orthopedic surgeons, neurosurgeons, etc. In the end, however, our focus of advocacy—our voice—should be through AAOS."

And when he slows down? He speeds up. "For nearly 20 years I have been happily married to my wife, an attorney, with whom I share two wonderful children. My avocation to which I have committed a great deal of personal time for the past 25 years is middle to long-distance running (races and marathons) which, during my academic travels, provides a great opportunity to see the sights in cities around the world and stay physically fit at the same time."

Dr. Alan Hilibrand…with whom excellence is academic.

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