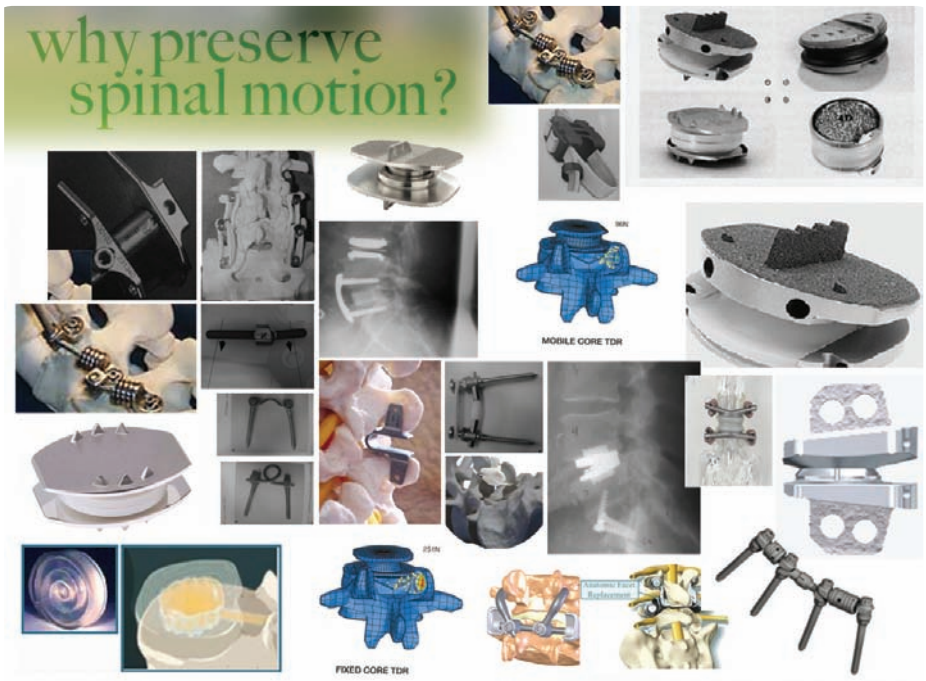
VOLUME 6, ISSUE 12 | APRIL 13, 2010

Orthopedics This Week

week in review



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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
Refusion	
Posterior Lumbar Refusion	81.38
Other Spine Procedures	
Discectomy	80.51
Decompression	03.09

Large Joint Reconstruction Market Reports	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

- *U.S. procedure volumes and forecasts to 2013*
- *Regional and State charging data*
- *Reimbursement rates*
- *Associated diagnoses*
- *Associated procedures*
- *State reimbursement data*
- *Private payer and Medicare data*
- *Comorbidities*
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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Orthovita comes roaring onto the Power Rankings with a dramatic increase in sales and earnings estimates. Consensus of the six analysts who cover VITA is that the firm will grow sales 18% this year to $110 million and that earnings will top $0.02 per share this year and continue increasing to nearly $0.14 next year.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Orthofix	11.00%	7.56%	Everything about OFIX looks positive right now—including a pattern of reporting surprisingly strong cash flows.
2	2	Stryker	24.71	5.07	Analysts raising opinions of SYK to Neutral. ?? No guts, no glory. #2 on our Power Rankings.
3	3	Integra LifeSciences	15.37	2.94	Consensus of all analysts is that IART ended the first quarter with a solid 21% pop in earnings.
4	7	Symmetry	11.48	11.15	SMA is such a streaky stock. The buyers are back and SMA is up 11% on light volume.
5	5	Johnson & Johnson	27.1	1.35	After the re-org how is DePuy doing? Not quite sure, but heard good reports from surgeons this past week.
6	6	Medtronic	31.37	2	Still losing share in spine. Could a turnaround be on the horizon? This is a new Medtronic spine.
7	4	Alphatec	-0.44	20.64	Deyo strikes with a study that says too much spine surgery in elderly patients. If Deyo says it, sadly, CMS and FDA believe it.
8	NR	Orthovita		5.48	Could Tony Koblish's dream for VITA be on the verge of happening? Hang on to your hats, it just might be!
9	9	CONMED	7.73	2.87	Four analysts think sales rose 7.9% in the March quarter. Last year CNMD missed by 21%. It's crunch time.
10	8	Exactech	12.61	-1.36	Downgraded by Baird. Down earnings expected for March quarter.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGBO.PK	$0.67	$7	168.0%
2	Alphatec Holdings	ATEC	$6.37	$345	20.6%
3	ArthroCare	ARTC	$31.79	$856	16.5%
4	Symmetry Medical	SMA	$10.37	$372	11.1%
5	Orthofix	OFIX	$38.14	$668	7.6%
6	Orthovita	VITA	$4.43	$339	5.5%
7	Stryker	SYK	$57.64	$22,940	5.1%
8	Wright Medical	WMGI	$17.88	$693	4.6%
9	RTI Biologics Inc	RTIX	$4.29	$233	4.1%
10	Integra LifeSciences	IART	$43.47	$1,250	2.9%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TiGenix	TIG.BR	$3.66	$113	-27.5%
2	TranS1	TSON	$3.17	$65	-21.7%
3	CryoLife	CRY	$6.11	$174	-12.1%
4	Capstone Therapeutics	CAPS	$0.86	$35	-6.5%
5	Kensey Nash	KNSY	$21.97	$240	-5.1%
6	Mako Surgical	MAKO	$13.00	$437	-3.8%
7	Synthes	SYST.VX	$120.73	14,328	-1.6%
8	Exactech	EXAC	$19.57	$252	-1.4%
9	Smith & Nephew	SNN	$52.04	$9,190	0.1%
10	Zimmer Holdings	ZMH	$59.55	12,080	0.7%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Kensey Nash	KNSY	$21.97	$240	12.47
2	Medtronic	MDT	$45.43	$50,040	14.01
3	Johnson & Johnson	JNJ	$65.14	$179,260	14.07
4	*Average*			*$11,855*	*14.55*
5	Zimmer Holdings	ZMH	$59.55	$12,080	14.80

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$52.04	$9,190	79.41
2	RTI Biologics Inc	RTIX	$4.29	$233	48.55
3	NuVasive	NUVA	$43.61	$1,690	41.92
4	ArthroCare	ARTC	$31.79	$856	29.39
5	CONMED	CNMD	$24.00	$700	24.13

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CryoLife	CRY	$6.11	$174	0.67
2	NuVasive	NUVA	$43.61	$1,690	0.78
3	Integra LifeSciences	IART	$43.47	$1,250	1.03
4	Smith & Nephew	SNN	$52.04	$9,190	1.11
5	Exactech	EXAC	$19.57	$252	1.35

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CONMED	CNMD	$24.00	$700	9.75
2	Orthovita	VITA	$4.43	$339	7.47
3	Johnson & Johnson	JNJ	$65.14	$179,260	1.93
4	Symmetry Medical	SMA	$10.37	$372	1.85
5	*Average*			*$11,855*	*1.76*

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$4.20	$76	0.78
2	CONMED	CNMD	$24.00	$700	1.01
3	Symmetry Medical	SMA	$10.37	$372	1.02
4	Orthofix	OFIX	$38.14	$668	1.23
5	Wright Medical	WMGI	$17.88	$693	1.42

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$3.66	$113	109.61
2	Mako Surgical	MAKO	$13.00	$437	12.96
3	NuVasive	NUVA	$43.61	$1,690	4.58
4	Synthes	SYST.VX	$120.73	$14,328	4.22
5	Regen Biologics	RGBO.PK	$0.67	$7	3.78

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Why Preserve Motion in the Spine?

By Robin Young

Courtesy of the Florida Orthopedic Institute

Simple question, we suppose. But illogical.

Nature imbued every spine with the ability to move. Both natural and unnatural forces (like trauma or spine fusion surgery) conspire to rob the spine of movement. If motion is good enough for nature, why do we ask this particular question?

Actually, asking this question implies that, maybe, motion preservation of the spine might NOT be healthy, beneficial or necessary for the otherwise traumatized or deteriorated spine.

Maybe Mother Nature made a mistake. Could CMS (Centers for Medicare and Medicaid—which has roundly criticized motion preservation), the FDA (which is increasingly adversarial to any motion preservation spinal implant), Deyo (who is one of the leading critics of spine motion preservation) and other critics know better?

At this past week's Preservation of Motion in the Spine meeting at Duck Key, organizer Dr. Antonio Castellvi opened the meeting by asking; Why preserve motion in the spine? Not a single surgeon in the audience laughed or said, are you kidding?

We do live in strange times.

Let's start with a case study. The patient is a young military man who is also a fairly heavy smoker. He began to experience low back pain and right leg pain four years ago. Conservative care did not stop his pain. An MRI showed that he had a right lateral herniated nucleus pulposus at L5-S1.

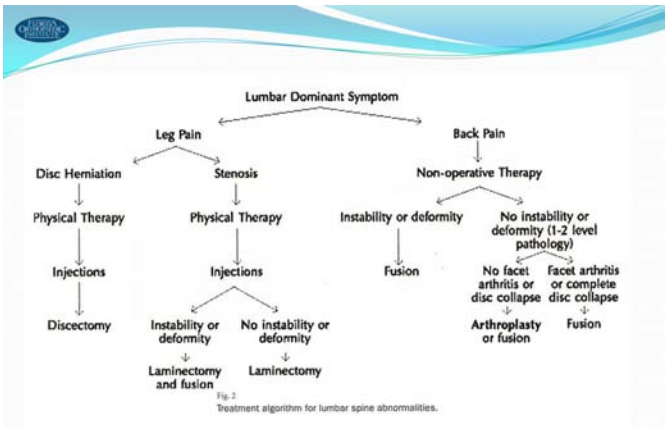
Dr. Castellvi put up some of the X-rays for this case and told the assembled surgeons that he performed a laminotomy on this patient after conservative care failed (about seven months later). Leg pain and weakness went away.

A year and a half later the patient returned complaining of new and excruciating low back pain. Unlike the first time he crossed Castellvi's threshold, this time the pathology was at three levels. Pain generators now were at the disc level AND down the leg. Dr. Castellvi slapped up more MRI and CT scans. "Now this patient was

suffering from three level discogenic and concordant pain. Do we do a three level fusion?" he asked his surgeon audience. The answer came back quickly—"No!"

Ok, what do the experts say?

Here is a table from the JBJS (*Journal of Bone and Joint Surgery*) which could be considered a road map for most spine surgeons.



Courtesy of the Florida Orthopedic Institute

Notice that the chart splits into two sections: Leg Pain and Back Pain. This patient has both. None of the resulting decision branches addresses three-level deterioration. The closest paradigm we see is under back pain where the chart, in parenthesis, says 1-2 level.

This patient has already been treated with laminectomy. What now? This may be uncharted territory, but it is by no means unfamiliar to busy spine surgeons. Should surgeons do a two-level fusion and then top off the third level? Should surgeons do the exceedingly difficult and biomechanically risky three-level fusion surgery?

Leaving his audience to ponder the conundrum, Castellvi pulled his discussion back to the biologic basics. The spine holds the body erect and 80% of the daily pounding is absorbed by those 22 spongy shock absorbers known as the nucleus pulposus.When the system begins to break down, it usually starts in the nucleus.

Surgeons know the nucleus is breaking down when it changes shape, loses fluid, shrinks and gets less spongy. Then the nucleus starts to shift out of alignment. When the nucleus is out of alignment, the other connected structures (vertebrae, facet joints, adjacent levels) also shift.

When any segment of the spine begins to move out of alignment the spine's ability to carry the body's load also changes. In the healthy spine, loads are carried well when they, essentially, line up from top to bottom. It's like a beautifully curved plumb line for the body. Not only is that center line critical for healthy load bearing, but it also forms a center of rotation for the spine.

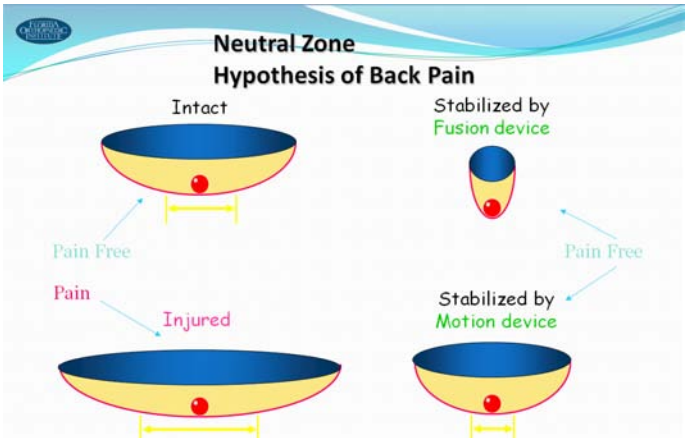
Oh yes, the spine must rotate. And flex. And extend.

When everything lines up along the center of rotation, then loads are absorbed and transferred around the spine brilliantly. The spine is, if nothing else, a masterpiece of engineering. Degeneration of the nucleus changes the spine's ecology and starts to transfer loads in directions that move the center of rotation out of alignment—nerves are impinged and the body's warning system (pain) kicks in with a vengeance.

Spine fusion works because it puts the spine back into alignment and removes the pain generator. However, it does reduce the spine's ability to rotate, flex and extend. In some segments, like L5-S1, that's not such a big deal. In the cervical spine (neck) it's a bigger deal.

A helpful way to visualize the importance of the center of rotation to spine health is the following graphic that shows the relationship of the spine's neutral zone to back pain.

The neutral zone is nature's sweet spot where the spine is lined up and is handling its load bearing job well. Think of the neutral zone as a ball in a bowl. When the spine is healthy, the neutral zone's ball sits at the bottom of a soup bowl and can move within



Courtesy of the Florida Orthopedic Institute

a narrow range as the spine rotates or flexes and extends. That's a health, pain free spine.

When the nucleus begins to wear out, the vertebrae and other structures shift out of that healthy curved plumb line which stretches our imaginary bowl out and the center of rotation starts to swing too far out like, in effect, a marble in a shallow salad bowl. The result is pain.

What does fusion do to our imaginary bowl? It turns it into, essentially, a shot glass which stops the neutral zone from moving. Yes, the patient may be pain free, but rotation, flexion and extension are almost eliminated at that segment.

If it were possible to introduce some amount of motion with stabilization, then the spine could return to its proper alignment but still allow for a center of rotation to move within a narrow range.

Fusion alone has two big concerns for surgeons. First, fusion concentrates the load bearing of the spine and, since fused segments can't move they can't transfer the loads in a healthy way. What happens next? The sections of the spine that are now absorbing new loads begin to also change—sometimes painfully. In some patients, it begins a new cycle of deterioration.

Many studies have been conducted to measure the amount of new pressures that are created by fusion. They all show that intradiscal pressures increase at the levels adjacent to the fusion—on average by about 45%. And those pressure changes have a global effect on the entire spine.

Over the last two decades spine surgeons have become expert at figuring out how to use fusion to minimize these problems providing the disease is at one level and the spine is otherwise healthy. Even two-level fusions are routinely managed well—assuming an otherwise healthy, non-smoking, non-osteoporotic, non-diabetic, or non-obese patient.

Ok, fine. But we have a young smoker with a three-level deterioration and leg pain and disc pain. Again, when Castellvi asked his audience if they would fuse three levels, the surgeons said "no".

Again, three-level spine deterioration is not uncommon. As far back as the mid-20th century, researchers were pondering treatments for these patients. Ulf Fernstrom offered his suggestions in a 1966 paper titled "Arthroplasty with


Courtesy of the Florida Orthopedic Institute

intra-corporeal endoprosthesis in the herniated disc and painful degenerative disc" *Acta Scandanavia (supplement) 1966.* He proposed the very simple idea of implanting a metal ball in the disc space, like a marble in the bowl. Here is an X-ray of implanted Fernstrom balls.

One hundred and ninety-one Fernstrom balls were implanted in 105 patients between 1962 and 1964 (including President John F. Kennedy). Only one ball displaced backwards, hit a nerve root causing temporary palsy which cleared upon removal of the ball. These are phenomenal results.

On the strength of these outcomes and, again, understanding that the spine is suppose to rotate, flex and

extend in order to carry the body well, more than 60 motion preserving implants were invented in the ensuing thirty years to 1994.

1994. Sixteen years ago. And how many motion-preserving devices are both approved in the U.S. and paid for by reimbursing agencies today? Three motion preserving implants—at best.

Outside the U.S. surgeons are now on the fourth and fifth generation of motion preserving implants and the range of choices is far beyond any available in the U.S. Here is a picture of some of the motion preservation devices that are facing a decidedly uncertain future at the hands of an adversarial FDA and CMS.

What happened to the young military veteran with three-level disease and both discogenic and leg pain? He went to Germany for treatment.

In this country CMS has repeatedly denied reimbursement for motion preserving devices. In both its written and oral commentary to the industry CMS has denigrated the value of motion preservation in the spine. The FDA, which has approved a handful of motion preserving implants, is by its own admission a "broken system."

So spine surgeons ask the illogical question with a straight face and, since they do truly care about patient outcomes, a heavy heart: Why preserve motion in the spine?

Courtesy of the Florida Orthopedic Institute

Deadeye Deyo Takes Aim

By Walter Eisner

Photographer: Andrew Huth

There was a spring-time "Deyo" sighting in the *Journal of the American Medical Association* (JAMA) the first full week of April.

Richard Deyo, M.D., MPH, either the devil or angel of the spine community, published a study that found that older

Richard Deyo, M.D., MPH

patients are getting more "complex" spine surgeries and are experiencing greater complications. Deyo is consistent in his assertions that, when it comes to the spine, we operate too quickly on patients and put them at higher risks and waste money.

Deyo's study, *"Trends, Major Medical Complications, and Charges Associated With Surgery for Lumbar Spinal Stenosis in Older Adults, JAMA 2010; 303: 1259-65),* as usual, garnered wide attention.

Authors included: Deyo; Sohail K. Mirza, M.D., MPH; Brook I. Martin, MPH; William Kreuter, MPA; David C. Goodman, M.D., M.S.; and, Jeffrey G. Jarvik, M.D.

Innovation, Safety and Motivations

The study was about data. But the real attention was focused on Deyo's conclusions. While the study notes "it is unclear why more complex operations are increasing," Deyo speculated that the increase in such complex surgeries can be partly attributed to good marketing, ego, and financial incentives.

The leaders of the North American Spine Society (NASS) read the study with great interest.

This could have been another confrontation between forces of innovation (surgeons) and the forces of safety (academicians). This dynamic is played out at every FDA orthopedic panel meeting and underlies the internal tension of the 510(k) program between getting treatments to patients as fast as possible, but braking for safety.

Not far from Deyo in Portland, Oregon, Ray Baker, M.D., the President of NASS, was in Seattle, Washington, drafting a response. Over the next couple of days, Baker and his Executive Committee came up with an eight-point response. Baker spoke with *OTW* on April 7.

Regarding the motivations of surgeons, Baker said, "Association is not causation. Deyo's study points to the need for comparative effectiveness, to help determine what is effective," [and ultimately reimbursed].

NASS is gaining credibility with payers as a source of medical opinion to justify coverage and payment decisions. The recent reversal by several insurance carriers over XLIF coverage showed the role that NASS can play in promoting innovation.

Baker told us that, overall, NASS agrees with the evidence in Deyo's study, but questions the conclusions about financial motivations because the study wasn't designed to answer those questions.

The Deyo Study

Deyo has become almost legendary as an academic gadfly who is trying to save the spine establishment from itself.

In an interview with *OTW* four years ago, the kindly and calm Deyo said that he can understand why some see him as the devil and a tiny few see him as an angel. He says following the best evidence is in the best long-term financial interest of the spine community and best health interest of patients.

Ray Baker, M.D.

Deyo's team performed a retrospective cohort analysis of Medicare claims data for patients ages 65 and older with a primary diagnosis of lumbar spinal stenosis (98.2%) or spondylogenic compression of the lumbar spinal cord.

Their goal was to better define trends in the use of various surgical procedures for lumbar stenosis; see how complications vary as a function of age, comorbid conditions, previous surgery, and complexity of the surgical procedure; and identify health care use associated with stenosis surgery.

Patients were divided into three groups according to the type of surgery they received—decompression alone, simple fusion of one or two disk levels using a single surgical approach, or complex fusion of more than two disk levels.

They discovered that over a six-year period, the rate of complex procedures to treat spinal stenosis increased 15-fold, while overall procedure rates actually declined. The decline was from 137.4 procedures per 100,000 beneficiaries in 2002 to 135.5 in 2007. The rate for complex procedures during that period went from 1.3 to 19.9 procedures per 100,000 beneficiaries.

Increased Complications

Not surprisingly, they found that as complex procedures increase, so have the complications.

According to the study, "life threatening complications increased with increasing surgical invasiveness, from 2.3% among patients having decompression alone to 5.6% among those having complex fusions."

Deyo said the evidence generally does not show that complex operations are much more effective, if at all, and absent data showing clear superiority for more complex operations, surgeons and patients might want to identify the

least invasive type of surgery that will yield good pain relief and functional outcomes.

The study noted, "This contrasts with a competing theory that surgeons should correct every anatomic abnormality, hoping to avoid future symptoms."

It wasn't just about safety. Mean hospital charges were likewise higher for the complex procedures ($80,888 versus $23,724).

The Deyo study acknowledged its limitations, including:

- The possibility of miscoding of diagnoses and procedures in claims data
- Incomplete information on use of implants
- The possibility that complications are not consistently recorded
- The lack of information on severity or extent of anatomic changes, patient symptoms, or functional status
- The use of hospital charges, rather than actual resource costs or reimbursements

The study was supported in part by grants from the National Institute of Arthritis and Musculoskeletal and Skin Diseases, the National Institute on Aging, and the National Center for Research Resources.

NASS Responds

The NASS leadership team responded.

First, they noted the *JAMA* study "is in general agreement with the recommendations of the NASS Clinical Guidelines on Spinal Stenosis published in *The Spine Journal* in 2008, which took an enormous amount of time and effort to develop."

Those guidelines say:

- "...decompressive surgery alone is effective approximately 80% of the time"
- "...there is no evidence to support the addition of fusion" [in the absence of spondylolisthesis or instability]
- "...decompression with fusion results in better outcomes than decompression alone" [with spondylolisthesis]
- "...decompression with fusion provides better outcomes than decompression alone at greater than 2-year follow-up" [with instability]
- "...The addition of instrumentation...increases the radiographic fusion rate, but not necessarily the clinical outcomes" [with spondylolisthesis]

Registry

Second, NASS supports a spine registry to "gather data on the best treatment options" because leadership agrees that "for patients with more complex combinations of pathology the evidence is less clear and that more

complex surgery is associated with more complications."

Rising Demand

Third, NASS agrees with Deyo that "there are likely multiple factors" that have led to an increase in complex fusion rates.

Those factors include:

- "Improved surgical and [other] techniques...have made more complex surgeries feasible in sicker, older, or more complex patients"
- "Patient demands...altruism can lead to seemingly irrational behavior when a physician has a patient sitting in front of him or her and there is a lack of alternative treatments"
- "Hope that newer technologies yield superior...benefits."
- "Continued perception that solid fusion is correlated with a better outcome, despite a lack of clear scientific evidence"

Fourth, citing NASS' most emphatic disagreement with Deyo, the group wrote, "while contributing factors...the effect of financial incentives...opinion leaders, and device marketing has on complex surgery rates is unknown." Baker emphasizes in the letter that his membership "chooses the treatment option that they honestly feel will yield the best outcome."

Value Assessments

Fifth, NASS will continue to educate its members. "It takes time to change established behavior and change long-held perceptions." The letter also noted that NASS is beginning to incorporate value assessments into its recommendations, "although the science is still lacking in most fields of medicine."

Limited Date for Analysis

Sixth, "There are limitations of the dataset which limit analysis: the lack of consistent methodology and terminology for coding (CPT and ICD), absence of standardized diagnostic category assignment, technique and technical variation that are totally opaque in this analysis really hamper any scientific arrival at causality," stated the letter.

Baker offered that NASS is participating in a multi-stakeholder conference in July to "look at ways of classifying diagnoses and quantifying outcomes. AHRQ, NIH, CMS, and others will be at the conference."

More Funding

Seventh, lack of funding for research. "There is very little federal funding for clinical trials or basic research into the biology of spinal disorders...funding, by default, usually comes from industry." The letter specifically notes the lack of funding from NIH.

The letter points to the "significant impact" made by the well funded, $15 million SPORT study—the largest grant ever for spine care. "This level of funding pales next to the dollars going

Photographer: Andrew Huth

to investigate innumerable health problems of much smaller societal concern."

Grave Concerns

Eighth. NASS is "gravely concerned about overutilization of precious resources that may in fact be injurious to patients." However, Baker and colleagues are equally concerned that decisions over access for patients may be based on "very coarse" datasets and questions designed, not for therapeutic outcomes, but for expenditure outcomes.

All in all, the study, admittedly, did not offer any surprising findings. What was noteworthy was the tenor and speed of the NASS response to find common ground with Deyo.

Must be something in the water in the Great Northwest.

Testing Today's and Tomorrow's Surgeon

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

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Even when orthopedists emerge from fellowship, they are still in training. Actually, some say the most rewarding aspect of being an orthopedist is the vast amount of learning opportunities in the field. They get accustomed to being lifelong learners in part because of the Orthopaedic In-Training Examination (OITE), a carefully formulated and validated test taken annually by residents around the globe.

Dr. Lawrence Marsh, Chair of the American Academy of Orthopaedic Surgeons (AAOS) Evaluation Committee, gives a history lesson: "The OITE was the first of its kind—namely an annual test in a specialty—and was first administered in 1963. The ability to have an exam that documents and guides the process of learning during graduate training was increasingly seen as important to the field. This effort was led by a predecessor of the evaluation committee under the auspices of AAOS."

So what happens behind the scenes to bring this exam, which encompasses 12 orthopedic knowledge domains and 275 questions, to fruition? Dr. Marsh notes,

> *"There are 32 committee members, all of whom sub specialize and thus develop content in their areas of expertise. Other areas include rehabilitation, medically related issues, and professionalism. Each member proceeds to develop questions based on their interest, the literature, and activities they observe in their practices."*

They don't go to an island or make anyone stand up and sing…but they do stay in a big room for two days. Dr. Marsh states, "The questions are then submitted to the evaluation committee where they undergo an extensive review. Afterwards, they are sent back to the committee members who take this preliminary test and comment on all of the questions. Their feedback is compiled into a book and distributed to all of the question writers; then we hold a field test meeting—a full day event where committee members use the field test book and have interactive discussions, thus allowing the questions to be brought to their final form. Each question is then ranked for quality and importance, and is delivered to the committee chair. They usually provide me with a surfeit of


Photographer: Andrew Huth

questions in the event that one or two questions are going to be unusable."

One surgeon who is accustomed to the questioning of his questions is Dr. John Richmond, Professor of Orthopaedic Surgery at Tufts University School of Medicine. "If I write a question it is almost always rewritten because it may not be worded just right. Or there may be an issue of the illustration or MRI not showing what you want to depict."

Examples of questions that won't win any beauty contests? Dr. Richmond: "A bad question can be one that is too contrived. For example, 'When is a double bundle ACL indicated?' There are no clear indications for these procedures. Also, you can't put the focus on the negative, i.e., 'Which of the following are not appropriate treatments for XYZ.' We want the focus to be on what you ***should*** do."

To clarify things for those charged with testing future generations of doctors, the committee is providing more pointed guidance. Dr. Marsh: "We are compiling an instruction manual to help committee members understand what AAOS thinks is the appropriate way of writing multiple choice questions. When someone starts a term on the committee they usually write the first few items in a style that is not appropriate for the test (true or false questions, multiple correct answers, etc.)"

The OITE spans three levels of sophistication in an attempt to ensure that residents are not only memorizing, but also learning how to integrate knowledge in a useful manner. Dr. Marsh states, "Questions that meet the above parameters can still be unsatisfactory based on content. A question like, 'What is the bone between the hip and the knee?' is just too easy to be educational. There are three levels of questions: taxonomy one, where we ask for a fact; taxonomy two, where questions require an interpretation; taxonomy three, where the questions are aimed at problem solving, i.e., 'Given the imaging, which management strategy would you recommend?'"

The last committee members to leave the field test are likely those struggling with taxonomy three. Dr. Marsh explains, "While we prefer that a reasonable percentage of the test be taxonomy three questions, these items are the ones that can stir up controversy. For example, you have an Xray of a 62-year-old woman who has fractured her right hand. The question writer says, 'I would manage her with an open reduction and fixation and I

can write two different nonoperative distracters that are wrong and two operative strategies that are wrong.' But when someone from another practice looks at it he or she may say, 'I may not have operated on that case.' In the field test process they sit as a group and modify it to the point where everyone can agree… for example, someone may say, 'If you made her a 25-year-old then I would definitely operate.'"

Despite these painstaking efforts, there are calls and emails from perturbed test takers. Dr. Marsh: "Some of the most frequent complaints are that the quality of the images is poor and that we ask obscure questions. We go through a detailed process using statistical methods to assess how the questions perform. Later, we review the questions that didn't perform well and decide whether to exclude them."

Dr. Richmond adds, "In any given year the residents complain that there is too much basic science. And what is relevant or interesting for one specialty area could make someone in another area yawn. 'Gee, there are no questions on knee ligament injuries but six questions on hand anatomy. I'm in sports medicine so I don't need these questions.'"

When you create something you run the risk of having it used for unintended purposes. This, says Dr. Marsh, is a real possibility with the OITE.

> *"There is more than a little bit of disagreement regarding the purpose of the exam. The perspective from AAOS and the evaluation committee is that it is an educational tool…essentially a metric for individual residents to identify their strengths and weaknesses. It also can serve to motivate residents, as well as allow for the monitoring of their progress. Another important use of the OITE is as a tool for the programs to assess their educational program (based on their residents' performance on this exam)."*

He continues,

> *"There is the potential that the exam would be used as a metric of an individual resident's success. For example, this may be a factor in deciding whether someone should be awarded a competitive fellowship or not. At times it is also used by programs to advertise their strengths. Those people who feel that using the exam in these ways is important want AAOS to exert more influence on how the exam is taken."*

Speaking of control, to what degree is AAOS able to insist that the test be taken in the manner it deems appropriate? Dr. Marsh notes, "The Academy has guidelines, including that it should be proctored, be given at a defined time, and that the proctor not allow it to be an open book exam. While AAOS can recommend those things, they can't control them. But those who feel that control of this exam is important are concerned that it's unfair that another program (which may allow open book, for example), would achieve scores that give the impression of being better than theirs."

Perhaps most exciting, says Dr. Marsh, is that the exam continues marching into the future…via computer. "I am proud to say that as of fall 2009 orthopedics is the first graduate medical education specialty to produce an electronic in-training exam. In one year, we did several pilot tests and converted residents in over 200 programs around the world to an electronic format on DVD-ROM… that's 4,300 residents. The testing environments ranged from controlled medical school computer labs to rented laptops."

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And that variability can inject new questions into the process. Dr. Marsh notes, "Of course we asked, 'What prevents residents from searching the Internet or looking at notes on their desktop?' The answer was to build in a feature such that if residents left the exam environment then the program crashed. Although successful, the shutdown feature was overly sensitive, leading to excessive shutdowns for several residents. Proctors were given a code that allowed them to restart the program. We found that there were a small number of legitimate, computer-related issues that resulted in the shutdown of several residents' exams…meaning that their answer files were lost."

Overall, says Dr. Marsh, the residents have been positive about this transition. "In future OITE exams we will use videos to make the testing experience more real, especially when it comes to arthroscopy and operative approaches. Also, now that the imaging studies are in an electronic format, MRI and CT questions will be presented such that residents can scroll through multi-slice images. This makes the experience more similar to clinic. We are continuing to solicit feedback from residents and plan ongoing assessments of these new formats."

The Pursuit of Height

By Jacqueline Rupp

Wikimedia Commons

Tall, dark and handsome…a leggy blonde…supermodel stature…there's no denying that physical attractiveness is linked in today's culture in many ways to a person's height. If being tall wasn't desirable, why would women perch themselves on high heels to gain an inch or two? Up until several decades ago though, the only way to grow taller was through artificial means like heels. But that all changed with the advent of the limb lengthening procedure that was discovered almost by accident. The procedure has helped thousands of individuals with severe leg and arm deformities. However there is also the cosmetic application. And some argue that this not only shows the extreme lengths some will go to for the pursuit of perfection but also the field of orthopedics moving into a strange new world. However, ask a man who began the procedure at five-foot four-inches how life has changed by growing three inches and the procedure begins to seem a lot less vain.

A Tall History

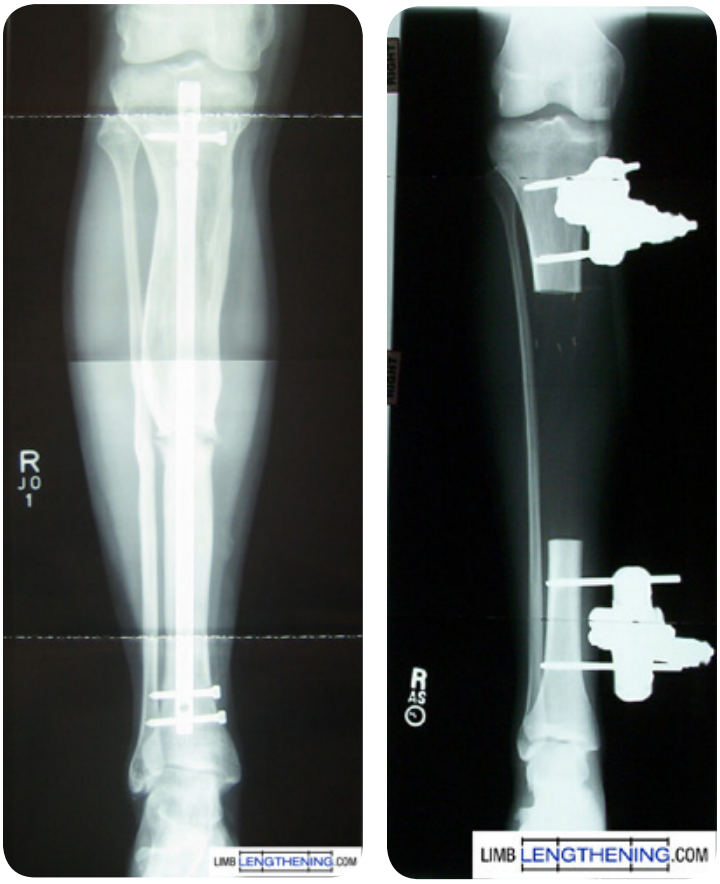
Limb lengthening is not at all a new procedure and is for that matter relatively low-tech. The procedure was developed about half a century ago in Kurgan, Russia, where Gavriil Ilizarov was trying out methods for healing leg fractures of World War II veterans whose injuries had not healed properly. Dr. Ilizarov knew that compressive forces could stimulate bone healing in a fracture so he invented an external fixation frame that could be mounted around the injured leg to compress the bone. Patients were then instructed to turn the attached rods to keep the compression level up as the bone grew properly together. But an interesting side effect of the project occurred. One patient turned the rods the wrong way. That of course caused distraction of the bone, further separating the fracture. But Ilizarov saw something interesting in the patient's error: new bone was forming in the expanding gap. From that first patient mistake, research began to determine whether limb lengthening was possible and whether it was indeed safe. There had been other methods used in the past from the beginning of the 20th century to create bone distraction, but Ilizarov was the first to identify the factors needed for bone and soft tissue regeneration and used better scientific methods than past doctors.

Over time, Ilizarov and his team performed literally thousands of limb lengthening procedures. The Western world only discovered his work when Italian surgeons took up the procedure in the 1980s. Interest in limb lengthening grew and the device and mechanics improved and by 1988 the first limb lengthening procedure was performed in the U.S.

The Mechanics of Growth

Most limb lengthening techniques aren't done for cosmetic reasons. In fact there is a multiple set of issues the process can resolve, including the replacement of missing bone and the lengthening and/or straightening of deformed bone segments. "Ninety-five percent of what we do is reconstructive for deformity and discrepancy and limb salvage," says Dr. S. Robert Rozbruch, director of the Institute for Limb Lengthening & Complex Reconstruction at Weill Cornell Medical College's Hospital for Special Surgery in New York City. These could be caused by birth defects, diseases or injuries and doctors can perform the procedure on both children and adults. One of the biggest reasons for limb lengthening is to correct an unequal limb which, if left untreated, can cause complications such as arthritis. Although today there are several slightly different methods, they all follow the principle of distraction osteogenesis.

Distraction osteogenesis is a shining example of the fundamental biologic fact that bone regenerates. Rozbruch explains the procedure used at his institute, "We cut the bone and pull the ends apart very slowly at 1mm per day (one inch per month). Bone has the ability to regenerate. We have innovated new hybrid techniques where we use the external fixation for the lengthening phase and



X-ray images of limb lengthening devices / Institute for Limb Lengthening & Complex Reconstruction

then substitute internal fixation to support the new bone. In this way we can limit the time needed in an external fixator to one month per inch of lengthening." At the Institute, Rozbruch uses a variety of techniques, including monolateral and circular external fixation devices for the correction of angular deformities and limb length discrepancies.

Some of the risks from the procedure include bone infection, injury to nerves and blood vessels, poor bone healing, avascular necrosis of the femoral head, chondrolysis and complications from the hardware used, including infection of the pins or wires that go through the bone. "Yes of course there are risks," adds Rozbruch, "but in experienced hands they are minimal like other surgery. We have had excellent physical and emotional outcomes."

The regenerated bone is normal bone and is no weaker or prone to wear than any other bone. The muscles, nerves and blood vessels grow in response to the osteogenesis just as they would during a growth spurt. And although the procedure takes several months to complete, all of which during the patient must wear a cylindrical metal device around a leg, the patient can go about a somewhat normal life and can still retain mobility.

Candidates for New Height

(Before and after photos of double level osteotomy of tibia for lengthening and deformity correction/ Institute for Limb Lengthening & Complex Reconstruction)

Aside from the patients with medical conditions that demand a treatment such as this, there is a class of patients who seek limb lengthening for quality of life issues. Those suffering from dwarfism for instance are prime candidates. The Little People Association of America at one time came out against limb lengthening, but today has developed a position summary that presents the risks and guidelines for patients considering the procedure. In the statement however the organization does state, "There are no established medical indications for symmetric extended limb lengthening." The Institute for Limb Lengthening & Complex Reconstruction has been able to give dwarf patients nearly one foot of growth in the legs and five inches in the arms, something that allows these patients to function more independently. Just imagine for the first time being able to reach the gas pedal of your car!

However it is not only people that have a height condition that are

Before and after photos of double level osteotomy of tibia for lengthening and deformity correction/ Institute for Limb Lengthening & Complex Reconstruction

seeking the procedure. Men and women who are above five-feet are also looking to limb lengthening to offer a way to be head and shoulders with their peers. Rozbuch explains the guidelines he follows. "We will perform limb lengthening on below normal stature patients and anyone less than five-foot five-inches tall for a man who has psychological dysphoria related to this. We have patients undergo a thorough psych evaluation to determine if they are a suitable candidate." The procedure appears to be particularly popular with men, who see the promise of an extra few inches of leg to be beneficial to all aspects of their life, from sports and social interactions to landing a better job. Rozbruch sees an expanding field in limb lengthening. "As we further improve our techniques, it will become more popular."

The Height of Ethics

There has been no shortage of controversy surrounding the subject, beginning with its introduction into the U.S. Lately the topic has become a popular debate issue on network news, with critics holding it up as a symbol of society's increasing efforts at perfectionism and obsession with attractive appearances. Besides what the need for height says about us as a society, the procedure is also turning a new page for the orthopedics community, who are in the position now of offering a procedure for purely cosmetic purposes. It raises many questions then about the role of the orthopedic surgeon and the relationship between doctor and patient in the decision making process.

Dr. James Capozzi is a member of the American Academy of Orthopaedic Surgeons ethics committee and a board certified orthopedic surgeon, specializing in joint replacement surgery. He says this procedure raises interesting questions and should give doctors time to think about their own medical values and how they balance these against those of their patients. "We have to be careful not to impose our values and our priorities," explains Capozzi. "Our ethical obligation is to convey information about a procedure or a condition to the patient so that they can make an informed decision. The patient makes the decision. The doctor can decide whether they want to perform the procedure, since just because the patient is requesting something doesn't mean you need to go along with it."

He adds that limb lengthening presents debate because the motivations can be objective and interpreted differently by each person. He asks who determines what height constitutes a cosmetic procedure rather than a medical one and how does one person's perception's affect the care of another. He suggests the orthopedic community look to the plastic surgery field for some answers. "They run the gamut in terms of procedures, from medically necessary treatments to purely cosmetic ones. They have done the work to explore this issue and I think we can gain a lot from their experience and examine the spirit of their guidelines to determine the best approach to an open dialogue on the subject within the field of orthopedics. As orthopedists we are essentially about quality of life procedures, so the groundwork has already been laid for this type of procedure."

company

TranS1 Opens New HQ

TranS1, Inc. opened its new corporate headquarters on March 30 in Wilmington, North Carolina.

One of the state's U.S. Senators, Republican Richard Burr, was on hand to cut the ribbon.

The new quarters, located at 301 Government Center Drive, occupy 32,000 square feet of research and development, training, marketing, regulatory, and customer service activities.

Senator Burr and Wilmington Mayor Bill Saffo both participated in the ribbon-cutting ceremony. According to a company press release, Senator Burr addressed the media and TranS1 employees on the status of health care reform and the importance of cutting-edge companies like TranS1 to both the local and state economy. Senator Burr expressed his vision that TranS1 will be an important component of a technology corridor along I40 linking the southeastern coast of North Carolina to the Raleigh-Durham area.

Senator Richard Burr and CEO Rick Randall Cut Ribbon / TranS1

Company CEO Rick Randall praised Senator Burr for his strong support of the medical device industry, specifically his opposition to last year's proposed $40 billion tax on medical device companies that has been cut in half. Randall said the original proposed tax would have impeded innovation, medical device entrepreneurship and the future availability of innovative medical technologies that benefit patients.

TranS1 currently markets the AxiaLIF portfolio of products for single and multilevel lumbar fusion and the Vectre and Avatar posterior fixation systems for lumbar fixation supplemental to AxiaLIF fusion. The company, which was founded in 2000, has experienced reimbursement challenges for its device. Opening a new headquarters looks like a sign that the company is confident of resolving those issues.

—WE (April 7, 2010)

company

Physician-Owned Distributorship Lowers Prices

Inland Spine and Orthopedics is lowering the prices of implants it sells to three contracted hospitals in the Redlands, California, area.

Inland is the first physician-owned distribution company set up by Alliance Surgical Distributors. An article in *Orthopedics This Week* on February 8 about the legal and business ramifications of physician-owned distributorships, set off a firestorm of anonymous posts on the spineblogger.blogspot.com Web site.

John Steinmann, D.O., Founder and CEO of Alliance, stated in an April 7 press release:

> "In light of our continued success as well as the current economic environment we felt it our responsibility to find a way to reduce our prices so our hospitals can remain competitive and profitable in 2010. Hospitals find they are losing money on some orthopedic services and no other model has demonstrated such profound effects in reducing healthcare costs associated with orthopedic implants."

The announcement stated that price reductions are traditionally unprecedented in an industry where the costs of orthopedic implants, "typically increase 13% annually."

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According to a scientific exhibit presented at the 2009 American Academy of Orthopaedic Surgeons (AAOS) annual meeting, Inland Spine and Orthopedics' prices were already well below the nearest contracted price.

The AAOS exhibit followed the total cost of implants sold by the surgeon-owned distributorship during a two-year study period. That total cost was $2,058,217. According to the study, the total cost of purchasing the equivalent implants using the hospitals average contract price during the study period would have been $3,099,192. Hospital savings resulting from purchasing implants from Inland was $1,040,974, representing a 34% savings.

The company attributed the current price reductions to surgeons implementing "much needed efficiencies." The specific price reductions were not noted in the announcement.

The firestorm on the anonymous blog site was fueled by self-described device sales reps who feared their livelihood was threatened by distribution companies owned by their current customer surgeons.

Question over the legality of such distributorships have been answered for now by a California Attorney General opinion siding with the physicians.

—WE (April 8, 2010)

extremities

Girls Benefit From ACL Injury Prevention

For over a decade research has shown an increased risk for anterior cruciate ligament (ACL) injuries amongst girls who play sports. Now evidence is mounting to show the beneficial effects of preventative training.

"ACL injuries have developed into a chronic problem, particularly in female athletes, and often stem from sudden overuse compounded by improper training," explains Ori Gorfine, General Manager of Balance Gym Kalorama in Washington, D.C.

extremities

Girls Playing Soccer / Wikimedia Commons

In fact over the past decade a strong case has been made to show why physiologically girls are at a greater risk of ACL injury. Primarily it has to do with the boys and girls playing the same sports, but not having the same bodies. Girls, it has been shown, have thinner ACLs and this combined with their pelvises being wider creates an angle which puts more stress on the anterior cruciate ligament.

Traditional workout exercises have done little to prevent these injuries, but now there appears to be an emerging solution. "Sitting on a machine and working out your quads, glutes and hamstrings does not effectively develop the stabilizing muscles that protect your joints and ligaments from the abuse taken on the field or court or even throughout our lives," says Gorfine.

Balance Gym has instead recently created an ACL injury prevention class that focuses on developing stability through full body movements. Gorfine says moves like squats, lunges and deadlifts are what girls need to focus on. The gym's program also has plyometrics and agility training as well. "We use bands, kettlebells, sandbags, speed ladders, ropes and a plethora of other tools to make workouts challenging and fun." Gorfine says that by working on these functional movements that mirror the movements girls will encounter on the sports field, it can train the body to endure the stress of play.

But it's not just Balance Gym that is implementing an ACL injury prevention program. The Santa Monica Orthopaedic and Sports Medicine Research Foundation began the The Santa Monica ACL Prevention Project which in turned has now developed the PEP (Prevent Injury and Enhance Performance) Program. PEP focuses on warm-up, stretching, strengthening, plyometrics, and sport specific agilities, while also emphasizing form, soft landings and minimizing side-to-side movements. The guidelines for this program include completing the workout three times a week and before games.

"Functional training has long been the workout of choice for athletes and has quickly become popular with those just looking to get fit," adds Gorfine. "The benefits of stability and functional training are becoming increasingly evident, and so their application will continue to broaden."

He notes the case of one young teen, Corinne, who had torn her ACL playing soccer. "She came in before her surgery and we worked on her stability and development. Building joint and ligament stability is possible anytime, before a surgery, while injured, and after. Within a year of having her ACL repaired, Corinne was back on the field. Since then, she has been injury free and has thrived playing soccer, hockey, and lacrosse." Gorfine adds that Corinne's knee is stronger than it has ever been, and that her

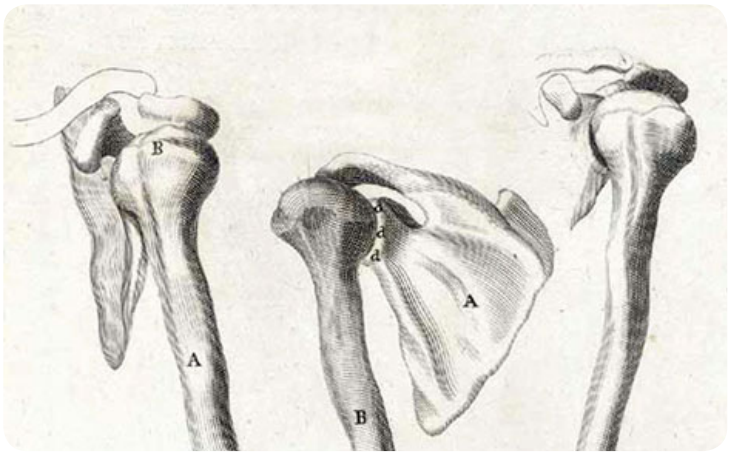
extremities

quick recovery and subsequent field performance motivated many of her friends and teammates to join the gym's preventative training program.

—JR (April 7, 2010)

large joints

Forteo and Rotator Cuff Healing



Shoulder – 3 Views – Etching

When good is not good enough, call in the HSS researchers…investigators from Hospital for Special Surgery (HSS) have recently announced the results from a study on rotator cuff tears and Forteo, a drug approved for osteoporosis. Rotator cuff surgery does not always result in a full recovery of function due to poor healing. The HSS team found that Forteo may speed healing and improve patient outcomes.

"According to a previous study, only 69% of rotator cuff repairs were completely healed when evaluated two years after the surgery," said Scott Rodeo, M.D., in the news release. Dr. Rodeo, Co-Chief of the Sports Medicine and Shoulder Service at Hospital for Special Surgery and senior author on the study, added, "Although not all of the patients with failed rotator cuff tendon healing had poor clinical outcomes, we wanted to look for ways to further improve patient outcomes."

Dr. Rodeo told *OTW*, "Forteo was chosen because it has a positive effect on new bone formation. Since rotator cuff tendon healing to bone involves new bone formation, the rationale is that a factor that improves bone ingrowth could have a positive effect on cuff tendon-to-bone healing."

"The healing process occurs from both the bone and the tendon, which is made up of collagen," said Carolyn Hettrich, M.D., MPH, in the news release. Dr. Hettrich, a fifth-year resident in orthopedic surgery at Hospital for Special Surgery and lead author, added, "We knew the drug Forteo is osteogenic and can stimulate bone growth, but we found reports in the literature that it is also chondrogenic, so it can promote cartilage formation as well."

Using a rat model, they performed the surgery and then gave some rats Forteo injections in amounts comparable to human doses.

Two weeks post surgery, the repair was not as strong in the rats who received the Forteo; at weeks four through eight, the tendon to bone interface in those rats was more like normal tissue. Not only had the Forteo rats produced more bone and cartilage cells, but the organization of the tissue was better and more closely resembled normal tissue. The tendon was also significantly stiffer, a sign of proper healing, at eight weeks.

"The results are positive, but now we want to understand why at week two the tendon wasn't healing as well," added Dr. Hettrich. "Our next experiments will look to pinpoint these causes and determine the optimum delivery time of the drug after surgery."

Regarding why the two-week healing wasn't as successful, Dr. Rodeo told *OTW*, "It is possible that the newly formed bone was not well-integrated with the tendon graft. Also, an alteration in the balance of osteoclastic resorption versus osteoblastic bone formation may also have adversely affected the mechanical properties of the healing attachment site. Lastly, increased/excessive angiogenesis (new blood vessel formation) may have an adverse effect in the early healing period."

—EH (April 6, 2010)

large joints

Guidelines, Exam for Musculoskeletal Ultrasound

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Creating "ultraprofessionals" in ultrasound…The American Institute of Ultrasound in Medicine (AIUM) has announced that four professional societies—The American Academy of Physical Medicine and Rehabilitation, American Medical Society for Sports Medicine, American Podiatric Medical Association, and Musculoskeletal Ultrasound Society—have endorsed the recent AIUM Training Guidelines for the Performance of Musculoskeletal Ultrasound Examinations.

"When multiple societies can come together to develop and agree on training guidelines, it lays a solid framework for the area to grow and initiates high-quality patient care," said AIUM President Harvey L. Nisenbaum, M.D., in the news release. With numerous specialists performing musculoskeletal ultrasound exams, the development of a comprehensive training guideline has always presented a challenge in the field.

"A guideline like this ensures a balance that allows all qualified practitioners to adopt the technology," added Levon Nazarian, M.D., who began collaborating on the issue across societies on behalf of the AIUM in 2008.

Additionally, the Board of Directors of the American Registry for Diagnostic Medical Sonography (ARDMS) has announced to the AIUM that it has approved the development of a credentialing examination in musculoskeletal ultrasound.

"The development process is underway for a musculoskeletal sonography credentialing examination that will test in a broad range of practice areas," said Patty Prince, RDMS, RVT, Chair of the ARDMS Board of Directors, in the news release. "International experts will be appointed to the examination-development task force and, as the process proceeds, ARDMS will be sharing more specifics with the sonography community."

Commenting to *OTW* on the development of the examination was Dale R. Cyr, MBA, CAE. Cyr, the Chief Executive Officer and Executive Director of ARDMS, noted, "The ARDMS is presently receiving nominations of musculoskeletal (MSK) sonography professionals, across multiple clinical disciplines, for appointment to the ARDMS MSK Exam Development Task Force (EDTF). Once the EDTF is in place and begins test development a preliminary timeline for the examination to go live would be approximately 24 months."

Cyr also told *OTW*, "MSK sonography offers ARDMS unique opportunities and challenges in building and delivering a credentialing examination given the spectrum of medical professionals and clinical practices that perform MSK sonography. Given this spectrum of practice special care will be taken in determining examination prerequisites and the actual content that will be tested."

—EH (April 8, 2010)

large joints

Obesity, Hips, Knees and Canadians

"Bulging waistlines lead to surge in hip, knee replacements," announced a recent headline in the *Vancouver Sun*.

The headline referred to a study released on April 6 by the Canadian Institute for Health Information which found a 101% increase in the number of hip and knee replacement surgeries in Canada over the past decade. The rise is attributed to an aging population, increasing demand and bulging waistlines. Overweight and obese patients in all age groups represented the highest proportion of recipients for both joint replacement surgeries, stated the article. The study also revealed that although heavier patients accounted for most surgeries, the higher a patient's body mass index, the longer they waited for surgery.

http://ivyleagueinsecurities.com

The bias was partially attributed to the fact that "fast track" joint replacement surgeries tend to cater to patients who pose less chance of complications, said the Co-Chair of the Canadian Joint Replacement Registry, Dr. Michael Dunbar.

The report also found that knee replacement is increasing at a much higher rate than hip surgery. Dunbar says this trend can be linked to the increasing body mass of many Canadians and knee joints are less forgiving to increased body mass than hip joints. According to the Canadian registry, 87% of patients who get knee surgery are obese or overweight.

Dunbar added that the trends are indicative of what society and doctors will be dealing with as the population gets older and heavier and that weight problems will end up consuming a significant amount of resources.

"We should be putting efforts into children now, to make sure they don't become obese. That's preventive medicine for their joint health," concluded Dunbar.

—*WE (April 8, 2010)*

Flip Flops, Sneakers and Knees

Don your "Margaritaville" attire…a new study by researchers from Rush University Medical Center has found that flip-flops and sneakers with flexible soles are easier on the knees than clogs or even special walking shoes. Why care? Because loading on the knee joints is a key factor in the development of osteoarthritis (OA).

The study, which included gait analysis on 31 patients with OA symptoms, was published online in the journal Arthritis Care & Research. Gait was analyzed while patients walked barefoot and with four shoe

large joints

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types: Dansko clogs, Brooks Addiction stability shoes, Puma H-Street shoes, a flat athletic shoe with flexible soles; and flip-flops.

"Traditionally, footwear has been engineered to provide maximum support and comfort for the foot, with little attention paid to the biomechanical effects on the rest of the leg," said Dr. Najia Shakoor, in the news release. Dr. Shakoor, a rheumatologist at Rush and the primary author of the study, added, "But the shoes we wear have a substantial impact on the load on the knee joints, particularly when we walk."

For the clogs and stability shoes, the loads on the knee joints were up to 15% greater than with the flat walking shoes, flip-flops or barefoot walking. Knee loading was roughly the same whether the subject wore flips-flops or walked barefoot.

"Heel height is one factor, and may explain why the stability shoes and clogs in our study, both of which had higher heels, produced greater knee loads," Dr. Shakoor added.

She continued, "Stiffness is also a factor. We've shown in earlier studies that barefoot walking is associated with lower knee loads than walking with conventional footwear. It may be that the flexible movement of the bare foot is mechanically advantageous. The natural flex of the foot when it contacts the ground probably attenuates the impact on the joint, compared to the artificial 'stomping' movement created by a stiff-soled shoe."

In the news release, Dr. Shakoor cautioned, "For the elderly and infirm individuals, flip-flops could contribute to falls because of their loose-fitting design. Factors like these need to be taken into account."

When asked what recommendations orthopedists should give their OA patients, Dr. Shakoor told *OTW*, "Based on this study we can't really make any definitive clinical recommendations until longer term studies are performed. However, we can say that the type of shoes people wear can affect their knees and that it is possible that flat, flexible footwear may be beneficial in terms of knee loading."

As for their future work in the area, Dr. Shakoor told *OTW*, "We are currently conducting a large randomized controlled trial to evaluate the effects of footwear on knee joint loading and pain in those with knee osteoarthritis. This study's results

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large joints

will hopefully allow us to make more definitive recommendations regarding footwear to our patients."

—EH (April 8, 2010)

Knee OA and Leg Length

Need a lift? If your legs aren't the same length, maybe so. A new study has found that osteoarthritis (OA) of the knee is linked to having one leg that is longer than the other. Whether or not leg length differential is a direct cause of OA is not clear, but the findings open the door for preventive measures before the onset of the chronic and painful condition.

Developing early strategies for treatment may be possible, says Derek Cooke, Queen's University adjunct professor and a co-author of the study.

"Most pediatricians adopt a 'wait and see' attitude for children with limb misalignment when they're growing," said Dr. Cooke in the news release. "If we can spot factors creating changes in alignment early in bone development, theoretically we could stop or slow down the progression of osteoarthritis."

When asked about the prospects for learning how to spot these factors, Dr. Cooke told *OTW*, "We know alignment factors are linked to progression, especially varus or bow legged alignment. Varus may be a risk factor but likely not alone because not all varus limbs get knee arthritis. So other factors working in combination are involved. Since arthritis is linked to aging the earlier we can identify what these factors are the better the chance to slow or possibly prevent arthritis."

Researchers studied X-ray images from more than 3,000 adults aged 50 to 79 who either had knee pain or risk factors for knee osteoarthritis as a part of the Multi Centre Osteoarthritis Study (MOST). Subjects were reassessed after a 30-month period and the researchers found that osteoarthritic changes in the knee were most significant in individuals with pronounced (more than 1 cm) leg length inequality, the shorter leg being most affected.

Patient with hemihyperplasia/ Heilstedt HA/ Wikimedia Commons

As indicated in the news release, leg length inequality is difficult to detect. A small leg length differential—1 cm or less—can be corrected with a shoe insert, while a more significant one can be corrected with surgery. But because the condition often goes undiagnosed, many people don't realize they have a leg length differential until they're diagnosed with osteoarthritis.

William F. Harvey, M.D., from Boston University, currently at Tufts Medical Center, was the lead author on the paper.

Dr. Harvey told *OTW*, "I think the take home message for orthopedists is that a) leg length inequality is very common and is likely to predispose someone to new and worsening knee OA; and b) that correction of a leg length inequality may represent a relatively inexpensive treatment or prevention strategy for knee OA. Interventions such as shoe lifts require further studies to determine efficacy, and in particular how much correction might be helpful."

—EH (April 9, 2010)

people

MAKO Adds Senior VPs

MAKO Surgical Corp. has filled two newly created senior vice president slots.

The company announced on March 29 that Richard Leparmentier has been made Senior Vice President of Engineering. Leparmentier will assume responsibility for the company's research and development activities, which used to be overseen by company Co-Founder, and current Chief Visionary Officer, Rony Abovitz.

The company also announced that James E. Keller is the new Senior Vice President of Regulatory Affairs and Quality Assurance.

Research and development, quality assurance and regulatory compliance are obviously important priorities for the company as President and CEO Maurice R. Ferré, M.D., said the company was positioning itself for future growth.

Richard Leparmentier and James Keller / MAKO Surgical Corp.

Ferré praised Abovitz's "visionary and strategic talents which have significantly contributed to our success to date."

Leparmentier was U.S. VP of Design and Engineering for ASML, a Dutch lithography equipment company, for the last three years. He gained his business experience at GE Healthcare from 1995 to 2006. At GE he was VP of OEC-Surgery Engineering, Engineering Manager in China, and Lead System Designer for radiographic products in Buc, France.

His engineering degree in biology and micromechanics was earned from Ecole Politechnique in France.

Keller has held senior regulatory affairs and quality assurance positions with numerous companies, including, E.I. Du Pont de Nemours, Medtronic's spine and biologics division, Mallinckrodt, Light Sciences Corporation and, most recently, Medicis Pharmaceutical Corp. and F. Dohmen Company.

Keller earned a B.S. in microbiology from Clemson University and an M.B.A. from John M. Olin School of Business, Washington University.

MAKO makes and sells a robotic-arm interactive orthopedic system and implants for minimally invasive orthopedic knee procedures. The system is a surgeon-interactive tactile surgical platform that incorporates a robotic arm and patient-specific visualization technology and prepares the knee joint for the insertion and alignment of its resurfacing implants through a minimal incision.

We watched a knee surgeon from Taos, New Mexico, try the system at MAKO's booth at AAOS. He looked like he was having fun.

MAKO has an intellectual property portfolio of more than 250 licensed or owned patents and patent applications relating to the areas of robotics, haptics, computer assisted surgery and implants.

—WE (April 6, 2010)

spine

K2M's Serengeti Wins Another Award

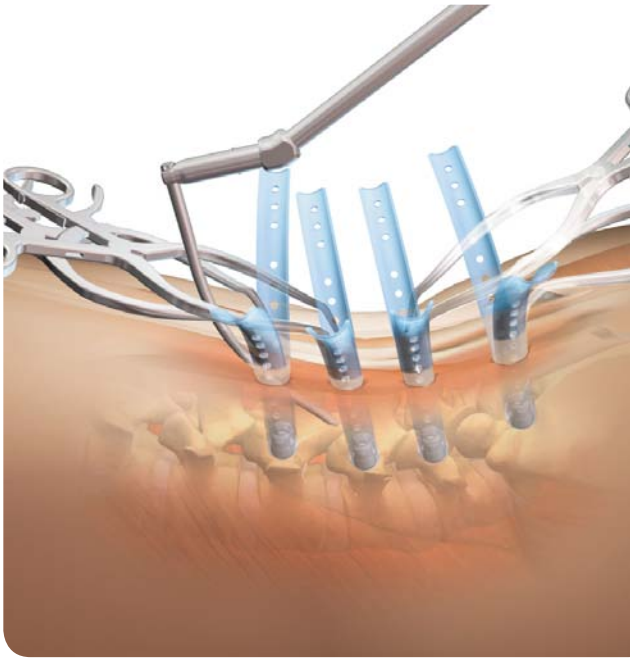
After winning one of *Orthopedic This Week's* "Best Spine Technologies of 2009" awards last fall, K2M has now also received a 2010 Medical Design Excellence Award (MDEA) for its Serengeti Minimally Invasive Retractor System.

The Serengeti system features a flexible polymer retractor which is captured under the head of a cannulated screw and placed with the screw for secure, spine-based retraction. The company says the retractor provides simplified access to the hard to reach L5 – S1 levels, as well as rod introduction for multi-level complex posterior instrumentation procedures.

On April 8, K2M's President and CEO Eric Major said in a press release:

> "This achievement reflects K2M's continued commitment to innovation and our ongoing goal to provide surgeons with new technologies to enhance patient care. We strive to develop more efficient approaches to address spinal surgery through very small incisions."

The company's Chief Medical Office, Chairman and Co-Founder, John Kostuik, M.D., is the former Chief of Spine Surgery at The Johns Hopkins University School of Medicine. The portfolio of the company's products includes: spinal stabilization systems, minimally invasive systems, motion preservation, annular repair, and nucleus replacement.



Serengeti Retractor System / K2M

The MDEA entries are evaluated on their design and engineering features, use of materials, user-related functions, enhance benefits to the patient, and the ability of the product development team to overcome design and engineering challenges.

The review was performed by a panel of third-party jurors with expertise in biomedical engineering, human factors, industrial design, medicine, and diagnostics.

—WE (April 8, 2010)

The Picture of Success: Dr. Robert Stanton

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

"'Oops' is not a word we use in the operating room."

A young Dr. Robert Stanton, now a veteran sports medicine specialist at Orthopedic Specialty Group Specialists of Connecticut, heard these words years ago from a glowering senior surgeon. More on that later.

Dr. Stanton could have been surrounded by terms such as "id" and "constricted affect" from an early age…but his psychiatrist father was ***healthy***. "I grew up in Great Neck, Long Island, where my dad worked as a psychiatrist—probably the only normal psychiatrist I knew. He didn't bring his practice out of the office. I think he could see that his colleagues who did bring their work home were a bit odd and did their children a disservice. My mom was a housewife who spent much of her time volunteering. She was also a semiprofessional musician with perfect pitch who actually tuned our Steinway grand piano by ear."

The family zeitgeist was that the firstborn should become the next doctor. Robert Stanton would make a brief detour, however. "While enrolled at Williams College in Massachusetts, I applied to the Woodrow Wilson School of International Affairs. Fancying myself the next Henry Kissinger, I envisioned my life as one of international diplomacy. Yet I had always planned on being a physician. Having had a number of relatively minor sports injuries, and enjoying the orthopedist that my father took me to, ultimately pointed me back to medical school."

The bright lights of the big city—and of the operating room—then shone on Robert Stanton.

"After completing Columbia Medical School in 1972, I did two years of general surgery at Columbia Presbyterian Medical Center. It was here at Presbyterian Hospital that a crusty senior general surgeon made my heart stop briefly. I was doing the stitches, made a mistake, and said 'oops.' He paused for a seeming eternity and glared at me, saying, 'Oops is not a word we use in the OR.'"

Dr. Stanton adds, "While in medical school, I was able to keep my interest in international affairs alive. I received an Edward John Noble fellowship from Williams, and spent one year in the School of International Affairs at Columbia."

On the medical side of things, however, Dr. Stanton found the softer side of surgery in a mentor by the name of Ken Ford. "I have tried to emulate the demeanor of Dr. Ford, a general surgeon at Columbia. He had a superb way of interacting with patients and always encouraged students to ask questions. He seemed to genuinely enjoy helping us find answers and made himself readily available to trainees."

His preliminary questions answered, Dr. Stanton then headed to Yale to dig deeper into musculoskeletal mysteries. "Dr. Fred Southwick, the son of Yale's first chair of orthopedics, Dr. Wayne Southwick, was my medical school roommate and teammate on the Old Blue Rugby Club. Dr.

Southwick conducted my residency interview at the Southwick fishing camp—when Wayne was cutting Fred's hair. Dr. Southwick is a true gentleman with great common sense. He was constantly available to help and he made you think on your feet, which challenged me to always be prepared—I still talk with him on rounds at Yale."

Much of what Dr. Stanton learned at Yale emanated from someone who never held a drill or a reamer.

> *"Bill Dayton was the head athletic trainer at Yale for 30 years; he also worked with Olympic athletes. Bill was so skilled that he was given a formal appointment in the department of orthopedics. He taught me things that you don't find in textbooks. 'Just sit with the kids, talk to them, and look at what they're doing as far as how they are moving. Go to the training rooms and observe them,' he would say. 'If they know you and trust you, they will confide in you,' he said. For example, one of my colleagues who works with a girls' basketball team recently had a situation where a player was having a problem with plantar fasciitis. Her father decided that he didn't want her to tell the doctor because he would only tell her not to play. The athlete was the one who confided in the doctor."*

Bidding Yale farewell in 1977, Dr. Stanton had his skis pointed northward. "I am an avid skier and wanted to settle in northern Vermont. My wife didn't want to be so far north, however, so we compromised and went to southern Connecticut. I took a job there with someone trained at Yale, had a solo practice for a couple of years, and then got involved with building the practice I manage now."

Why private practice? Like the vast majority of orthopedists, Dr. Stanton made his decisions in part based on those he came into contact with. "Yale only had a small academic department at the time. This, coupled with the fact that most of those who influenced my career were in private practice, meant that I headed in the same direction."

In a world where more and more orthopedists are going to work for hospitals, Dr. Stanton has managed to construct an effective practice model. "By the early 1990s we had five physicians and I was managing partner. We could see that things were changing, and that the right strategy was one of growth. My partners and I made a conscious decision to expand the scope of the practice and offer comprehensive musculoskeletal care. There was no grand scientific plan behind this, but it was evident that the only way to succeed—indeed, to survive—was to be large enough to negotiate with insurers. Now we are 17 doctors strong."

Although their patients may not have to go far for other services, the practice still can't write its own ticket in one area. "We have a pharmacy, physical therapy department, and an ambulatory surgery center, among

other things. The one area that we're still struggling with is getting an in-house MRI machine…the radiology lobby is a strong player in this state. We still have a couple of options, however."

He adds:

> *"Some theorize that if a physician owns a piece of equipment, he will overutilize it...I disagree. Ethical physicians order only those tests and procedures that are medically necessary. I spend more time talking people out of tests than ordering them. Ultimately, patients benefit from having all services in one location."*

So that private practitioners don't go the way of the dinosaur, Dr. Stanton recommends, "Orthopedists must think of it as a business, although that can seem at odds with how we are trained to think of taking care of patients. One of our Yale residents, who holds an MBA, gave a talk on this issue recently and said that things having to do with the hand and brain are not financially rewarded as well anymore. What is rewarded is providing comprehensive care and utilizing ancillary services appropriately."

Innovation good, reinvention of the wheel bad, says Dr. Stanton. "In setting out to add ancillary services private practitioners should do their due diligence. This involves hiring a consultant and then examining what other practices have done. Don't waste time trying to find your way through the maze when others have already done so. There will be substantial issues, including dealing with government regulators."

Dr. Stanton, who this year will assume the presidency of the American Orthopaedic Society for Sports Medicine, steers the health of athletes young and old.

> *"I serve as Team Physician for all of Fairfield Universities' athletic teams, and have learned some important lessons along the way. The key to being a successful sports medicine physician is availability. Some young people out of fellowship come into a new town expecting to be the next Jimmy Andrews (the famed sports medicine specialist). Formulating such a career takes years, however—years of making yourself available at inconvenient hours. You have to go to local high schools, junior highs, etc. and offer your assistance. You can't have an attitude of, 'I am superbly trained… bring me your people.' Instead, you had better get accustomed to standing on freezing race hills."*

Fortunately for Dr. Stanton—and his wife—he cultivated that talent years ago. "Nearly forty years ago I met my wife Debby while on ski patrol in Vermont. It was love at first sight. She is a competitive rider and a master gardener. Our son, Jim, is married to Christina; they have a 16-month-old son, Jack, and another child due in early summer. It's fantastic to be a grandfather, and we're so pleased that they live nearby."

"As for my pastimes, although I'm an avid skier, I could not make our national ski team as a competitor. I have been a physician for the U.S. ski team for the past 30 years, however. While working at the 1980 Olympics in Lake Placid I met Richard Steadman, who asked me to join the team's medical pool. Travelling with the Olympic athletes all over the world has been a unique and very rewarding experience. Many have become lifelong friends."

"I also play competitive polo, and maintain a string of polo ponies. It sounds crazy for an adult, but it is amazing to play a sport that involves both high level aerobic activity plus hand-eye coordination—and then also to have to ride a horse. The bonus is that I have a group of horses with whom I can have some serious conversations. As long as a carrot is involved, they tend to agree with me."

Dr. Robert Stanton…private practice for a healthier public.

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