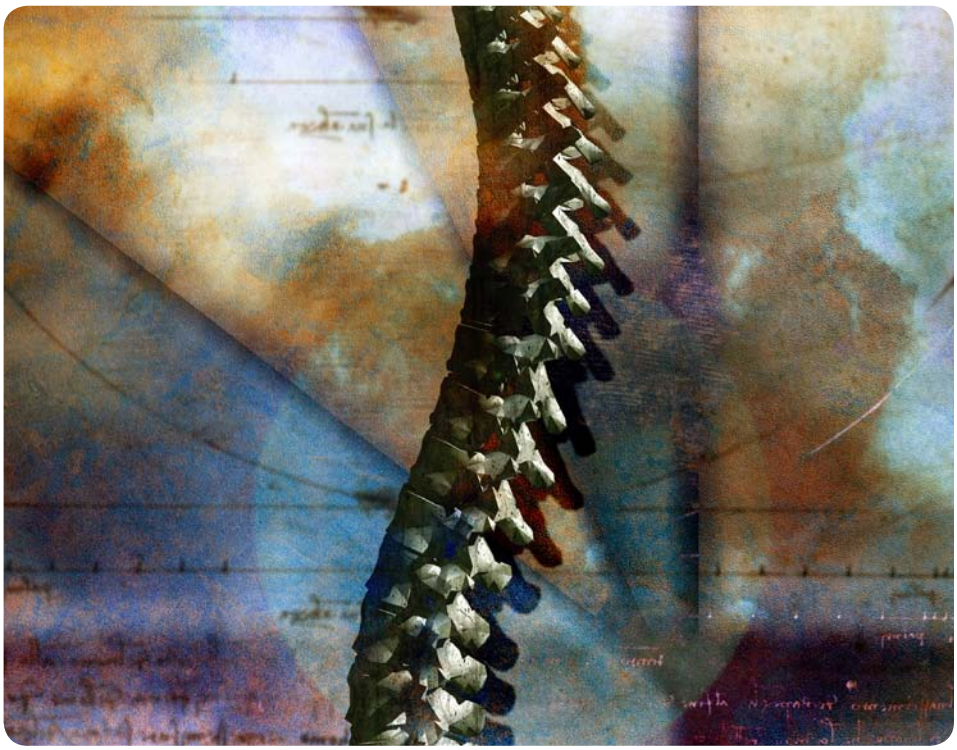
VOLUME 5, ISSUE 27 | SEPTEMBER 1, 2009

Orthopedics This Week

week in review



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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: We will miss August. Six out of ten of the Power Ranking companies rose by double-digit rates. Alphatec, Symmetry and ArthroCare were up more than 25%. Stryker, Medtronic and Zimmer remain at historically low P/E and PEG multiples. And this week we add Smith & Nephew to the Power Rankings.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	2	Stryker	23.28%	5.36%	#1 in the Power Rankings due to historically low P/E and PEG multiples. Quality at bargain prices.
2	1	Orthofix	7.65	15.63	3rd lowest Price-to-Sales ratio; 2nd lowest P/E-to-Growth ratio. AND rising cash flows.
3	3	Medtronic	31.37	11.06	Biologics (InFuse) is still declining. Hardware is stable. But, it's the 2nd cheapest stock in ortho.
4	5	ArthroCare	16.87	29.89	Buyers can't get enough of ARTC. Up 30% in the last month. Up 100% in the last 90 days.
5	4	Integra LifeSciences	12.32	9.77	Consensus Wall Street view is IART to report 13% earnings growth on 2% sales growth—unless Stu buys something.
6	6	Alphatec	-8.51	25.86	It's all about expectations. Consensus view is a 4Q profit. Of course, a 26% sales growth rate doesn't hurt.
7	9	Zimmer	29.31	3.43	Upgraded by the hottest hand in ortho right now—Denhoy at Weisel. Up two spots.
8	8	Symmetry	10.8	30.09	What an amazing stock this has been. Still THE lowest combination of P/E, PSR and PEG in ortho.
9	NR	Smith & Nephew	20.95	10.63	Mr. Smith and his Nephew crack the top ten this week, replacing JNJ. Back to basics in ortho will lift all boats, including SNN.
10	7	CONMED	8.28	1.47	It's all about hospital spending. Good news, arthritis, back pain, and trauma don't follow the business cycle.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	CryoLife	CRY	$7.49	$213	37.4%
2	Symmetry Medical	SMA	$11.24	$403	30.1%
3	ArthroCare	ARTC	$17.60	$386	29.9%
4	Alphatec Holdings	ATEC	$4.77	$250	25.9%
5	Regen Biologics	RGBO.OB	$2.00	$20	25.0%
6	Capstone Therapeutics	CAPS	$0.66	$27	17.9%
7	Wright Medical	WMGI	$16.24	$627	17.0%
8	Synthes	SYST.VX	$110.92	$13,163	17.0%
9	I Flow Corp	IFLO	$8.78	$215	15.7%
10	Orthofix	OFIX	$27.97	$480	15.6%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	TranS1	TSON	$4.80	$99	-26.9%
2	Orthovita	VITA	$4.45	$340	-18.8%
3	Osteotech	OSTE	$4.49	$81	-6.3%
4	Kensey Nash	KNSY	$26.52	$296	-5.7%
5	TiGenix	TIG.BR	$6.24	$152	-2.5%
6	NuVasive	NUVA	$40.39	$1,520	-1.8%
7	Johnson & Johnson	JNJ	$60.29	$166,150	-0.2%
8	Mako Surgical	MAKO	$8.28	$208	0.4%
9	CONMED	CNMD	$17.93	$521	1.5%
10	***Average***			***$10,145***	***3.2%***

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	ArthroCare	ARTC	$17.60	$386	8.51
2	Symmetry Medical	SMA	$11.24	$403	10.25
3	Zimmer Holdings	ZMH	$47.96	$10,280	11.70
4	Medtronic	MDT	$38.67	$43,020	12.86
5	Johnson & Johnson	JNJ	$60.29	$166,150	13.36

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	I Flow Corp	IFLO	$8.78	$215	84.27
2	RTI Biologics Inc	RTIX	$4.80	$261	82.83
3	Smith & Nephew	SNN	$42.87	$7,570	74.98
4	NuVasive	NUVA	$40.39	$1,520	38.91
5	Synthes	SYST.VX	$110.92	$13,163	34.49

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	ArthroCare	ARTC	$17.60	$386	0.34
2	Orthofix	OFIX	$27.97	$480	0.88
3	CryoLife	CRY	$7.49	$213	0.92
4	Symmetry Medical	SMA	$11.24	$403	0.99
5	Exactech	EXAC	$15.14	$194	1.06

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$40.39	$1,520	4.33
2	RTI Biologics Inc	RTIX	$4.80	$261	2.44
3	Johnson & Johnson	JNJ	$60.29	166,150	1.64
4	CONMED	CNMD	$17.93	$521	1.63
5	***Average***			***$10,145***	***1.51***

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	CONMED	CNMD	$17.93	$521	0.77
2	Osteotech	OSTE	$4.49	$81	0.83
3	Orthofix	OFIX	$27.97	$480	0.91
4	Symmetry Medical	SMA	$11.24	$403	0.99
5	ArthroCare	ARTC	$17.60	$386	1.15

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$6.24	$152	344.77
2	Regen Biologics	RGBO.OB	$2.00	$20	12.70
3	Mako Surgical	MAKO	$8.28	$208	9.94
4	Synthes	SYST.VX	$110.92	$13,163	8.05
5	NuVasive	NUVA	$40.39	$1,520	4.93

5 Orthopedics This Week
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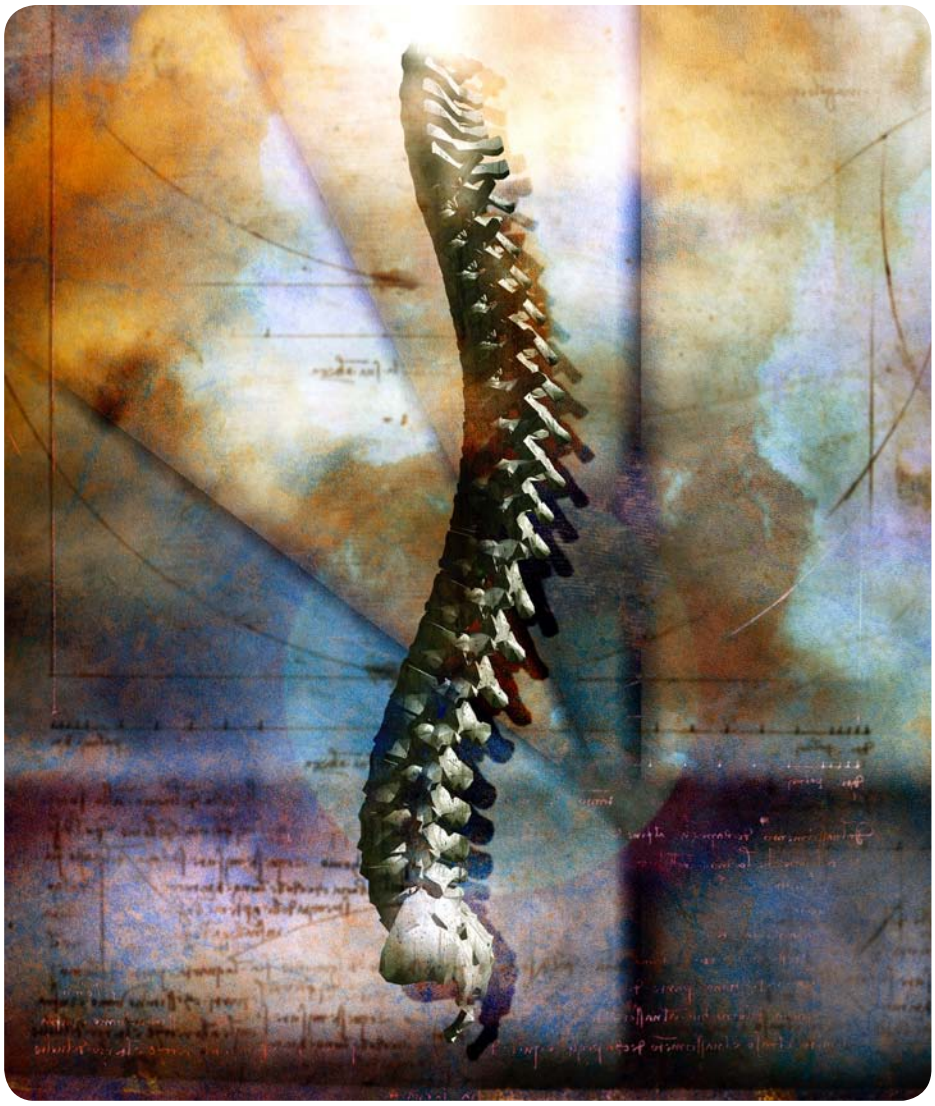
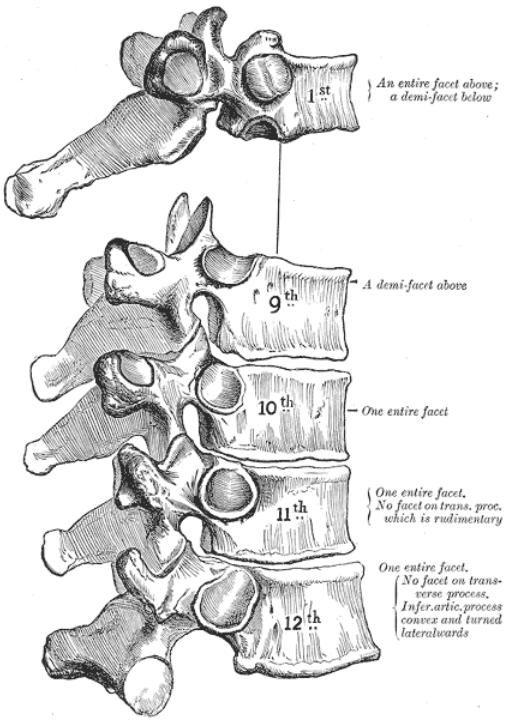
Spinal Motion Preservation: Update and Outlook — (Part 1 of 3)

By Matt Menze, Senior Analyst, PearlDiver Technologies



At the start of the new millennium, the concept of motion preservation technology took the spine industry by storm. While clairvoyants preached the end of the world, pundits in the spine industry proclaimed "the end of fusion." Neither prediction came true.

Artificial discs, interspinous process spacers, and dynamic constructs continue to evolve, but to what end? What will become the standard of care? Today we take a sobering look at motion preservation and at posterior pedicle based dynamic stabilization technologies. Based on our conversations with leaders in the field, pedicle screw based dynamic stabilization could be the most logical solution for most surgeons and patients who are seeking to preserve motion while still treating spinal instability and back pain. There is, in



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other words, a middle road between disc arthroplasty and spine fusion—a middle road that ultimately may be more consistently successful for patients and their surgeons.

Introducing Motion to the Spine From the Posterior Approach

Beginning in 2004, with the FDA clearance of the Charité artificial disc, the era of motion preserving technologies implanted from the anterior approach began. Proponents of artificial discs point out that the anterior approach provides superior access to the disc space, which is critical to the success of the surgery. Beyond this, some spine surgeons are familiar with the anterior approach based on experience with cervical spine fusion, where the anterior approach is commonly employed. Indeed, all of the approved lumbar artificial discs and the majority in development are designed to be implanted from the anterior. However, Dr Vijay Goel, Co-Director at the Engineering Center for Orthopaedic Research Excellence at the University of Toledo, related that neurosurgeons tend to be uncomfortable with the anterior approach. He also cited that the literature has shown evidence of facet syndrome in patients who have received a total disc replacement. What about the prospect of introducing motion preservation technologies from the posterior approach?

Based on our analysis, there are few artificial discs designed to be implanted from the posterior. During our conversation with Dr. Avinash Patwardhan, Director of the Musculoskeletal Biomechanics Laboratory at Edward Hines Jr. VA Hospital and Professor of Orthopaedic Surgery at Loyola University Medical Center, we learned that posterior discs have good rationale from a clinical point of view versus an anterior device, but there are still design issues that need to be settled.

This leaves interspinous process spacers as the primary motion preserving technology which is exclusive to the posterior. However, interspinous process spacers such as the X-Stop are primarily indicated to treat spinal stenosis in elderly patients. In addition to being a fairly rigid device (made of PEEK or titanium), interspinous process devices do not address the full range of motion in the spine. According to Dr. Manohar Panjabi, Professor Emeritus Department of Orthopedics and Rehabiliation Yale University School of Medicine, the device allows for flexion, but very little extension, essentially taking away some of the natural motion of the spine.

While total disc replacement and interspinous process spacers will remain an option for the appropriate indications as determined by the surgeon, there remains a potentially better technology when introducing motion to the spine from the posterior approach. Based on our research, pedicle based dynamic stabilization systems may be poised for resurging interest among surgeons as the best technology to introduce motion into the spine from the posterior approach (which is used in 70% of all lumbar spine fusion surgeries), while maintaining spinal stability.

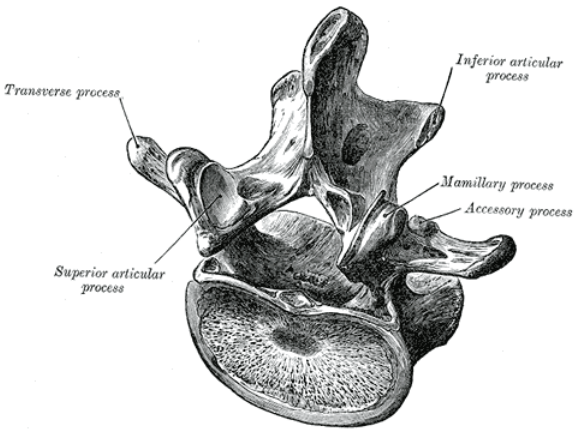
Pedicle Screw Based Dynamic Stabilization Technology as a Solution

Essentially, the goal of spine fusion is to eliminate motion in the spinal segment that is causing the pain by inducing bone growth between two vertebrae. However, based on our conversation with Dr. Panjabi, the theory that increased range of motion leads directly to back pain has largely been discarded, as it has been shown that you can decrease back pain without eliminating motion, and, more importantly, elimination of gross motion by spine fusion does not always take away back pain. However, fusion does have consequences. The elimination of motion by fusion at one level, may cause hyper-mobility at the adjacent segment and accelerate the degenerative cascade. This is called adjacent

segment disease and is one of the key consequences of fusion that motion preservation technologies seek to prevent. Other goals of the technology, besides helping reduce or eliminate back pain, include: controlled motion in the destabilized spine, limiting stress shielding, increasing anterior load sharing, protecting the facet joints, and protecting the musculature.

Players in the Spine Industry Are Taking Notice

Companies in the spine industry are increasingly gravitating toward dynamic stabilization. Perhaps the most well known companies that have dynamic stabilization technologies in their portfolios include Zimmer Spine, Scient'x, and Applied Spine. While these technologies essentially seek to meet the goals mentioned previously, approaches and designs vary by technology. The Dynesys Dynamic Stabilization System, by Zimmer Spine, is held in place by titanium pedicle screws and is considered a tension band device due to the polyethylene cord used in the device. Scient'x markets the Isobar semi-rigid rod system, which utilizes a mobile joint within the rod (dampener) to allow motion. Applied Spine has developed the Stabilimax NZ, which is held in place by pedicle fixation. Motion is driven by dual springs which are utilized in the system though connecting rods. Other devices in development include the DSS by Paradigm Spine and the NFix II now market by Synthes Spine.



Source: Wikimedia Commons

How Much Motion Is Enough?

Given the variability of spine conditions and various stages of degenerative spine disorders, the key question becomes: how much motion is enough?

According to Dr. Goel, it depends. Because "we do not know what magnitude of motion we need to preserve and what should be the shape, NZ (neutral zone) reduction is important and/or the overall range of motion (ROM); axial and lateral bending stabilization may also become essential." So, said Dr. Goel, surgeons should consider five elements in their surgery planning:

What is the grade and characteristic of the patient's degenerative instability? Low grades may be treated with an insterspinous process spacer, while high grades like spondylolisthesis may need fusion.

Motion variations as a function of the individual patient are important, and should be assessed on an individual basis by the surgeon in order to determine if the motion preservation device is appropriate.

1) What type of decompression is needed (laminectomy, facetectomies, etc.)?

2) What is the relationship between disc degeneration, stenosis, and instability?

3) What combination of implants with different stabilizing capabilities may be the best solution?

Device Design and Biomechanical Considerations

Pedicle based dynamic stabilization expands upon traditional, rigid fixation systems by introducing motion. This new paradigm forces bioengineers and surgeons to think differently in evaluating design characteristics, materials, and device testing.

Design Considerations

Dr. Goel suggested several key design considerations:

1) The device should be able to control the motion in the spine.

2) The device should bring the motion back to "normal" (restore the motion) and reduce instability. This also means restoring the center of rotation.

3) It should produce load sharing between the disc and the device so that the disc is unloaded, allowing it to begin to regain its height and be regenerated.

4) Specifications may depend on the application (requirements for the device stiffness will vary). If the goal is to restore stability alone vs. a procedure that creates additional instability such as a discectomy/ laminecomty/facetectomy

5) The device should seek to minimize stress at the bone-screw interface.

In addition, Dr. Patwardhan adds that pedicle-to-pedicle excursion (interpedicular travel) should be monitored as well. Finally, the quality of motion is just as important if not more so than the quantity of motion.

Part 2—Next week, the persistent issue of using pedicle screws as part of motion preservation.

For more articles by this author, please select the following link: **http://www.pearldiverinc.com/pdi/spine.jsp**

Orthopedics This Week

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The Elbow…All Grown Up

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

Like the quiet, cooperative child who receives less attention than her unruly sibling, the generally well functioning elbow may receive less attention than the aching back. But things are shifting for the humerus, ulna, and radius.

Delving into the Elbow

Dr. Ken Yamaguchi, the Sam and Marilyn Fox Distinguished Professor of Orthopaedic Surgery at Washington University School of Medicine in St. Louis, is part of the shift. "Elbow is one of the more exciting areas in orthopedics these days. Until relatively recently there was little known about it because there were fewer people working on elbow innovation as opposed to other body areas. Surgeons had also shied away from the elbow because they weren't sufficiently familiar with the anatomy or procedures available. In the last 20-30 years, there has been strong leadership and mentoring by select people such as Bernard Morrey, Shawn O'Driscoll and Graham King, who produce a lot of research on the elbow…and they have inspired others."

While the elbow used to be the bailiwick of general orthopedic surgeons, says Dr. Yamaguchi, patients are now demanding specialists. Dr. Yamaguchi, who has worked with Arthrex to develop an elbow arthroscopy instrumentation system, says, "There has been an exploding trend toward elbow arthroscopy in recent years. We're learning more and more that many of the surgeries we did with large, open procedures were better performed arthroscopically. One of the areas growing in popularity is the arthroscopic treatment of elbow arthritis, a particular challenge because of the difficult anatomy and the small area that you have to operate in as compared to the knee or shoulder. The nerves and blood vessels are very close to sharp instruments so theoretically it is a more dangerous operation than other arthroscopies."

There are a maximum of opportunities in this minimally invasive realm, says Dr. Yamaguchi. "Most patients with elbow degenerative arthritis are not so bad that they need a joint replacement, but they're not in good enough shape that no treatment is warranted. There are two growing areas of opportunity in elbow

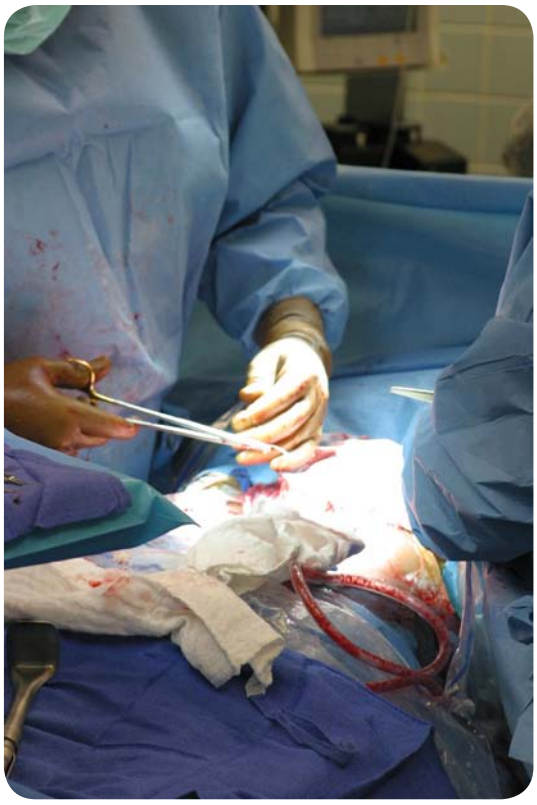
arthroscopy, one being to continue to develop and refine new techniques for existing indications of open surgery. The other, bigger opportunity is to disseminate information about elbow arthroscopy such that more people feel comfortable doing the procedure. More and more fellowships are giving trainees the opportunity to learn under the guidance of elbow athroscopists; AAOS has increasingly stepped up to the plate by offering related instructional courses. But those are only a start because elbow arthroscopy is not something that is easily aced by going to one or two courses."

Dr. Yamaguchi, co-developer of The Tornier Latitude Total Elbow, notes, "The type of elbow arthritis we will need to treat in the future has changed. In the past, elbow joint replacements were commonly done for rheumatoid arthritis (RA) but that type of indication is far less common because the medications for RA are so effective. In contrast to RA, and just like all other joint replacement surgeries, the need for elbow replacement for degenerative arthritis will likely increase because the population is aging. These types of patients may require prostheses that have different attributes than the prosthetics that were effective for RA patients. The difference between degenerative arthritis and rheumatoid arthritis is that people with RA have low activity expectations because the disease affects many joints. Those young patients with degenerative arthritis, however, tend to be healthy overall and want to lead an active lifestyle. These more active people may require a more durable prosthesis than currently available."

From the elbow rotation required in a curve ball to the rapid elbow extension in an overhead throw, there are any number of sports-related injuries that befall the elbow. Dr. Yamaguchi: "We now have more sophisticated treatments for the elbow that is injured in overhead throwing. We are learning about how to do ligament reconstructions with a 'less is more' approach. This involves smaller incisions, dissecting less and putting in ligament replacement or reconstructing grafts that replace the original ligament. The effect of this work is that players are getting back to the field, court, etc., faster."

The Father of Elbow Treatments

If the elbow had a father, some say it would be Dr. Bernard Morrey, an orthopedic surgeon at Mayo Clinic in Minnesota. The creator of the first linked semi constrained artificial total elbow, Dr. Morrey continues to contribute to, and observe, the field: "At present the most exciting work coming out of our lab is the



investigation into how host variation (genetic differences) may help explain why some patients react aggressively to trauma around the elbow. Some experience stiffness from minor injuries, while for others it takes a major trauma. We are in the preliminary stages now, and are developing animal models. Our hypothesis is that there will be genetic variations that explain the different levels of joint stiffness in elbow patients."

Dr. Morrey, the co-developer of an external fixation system for traumatic elbow injury, continues, "Our clinical experience has shown that there is a wide range of ways that people react to the same surgery or the same injury. You can have 10 fractured elbows and get very different outcomes even though the treatments are all the same. It seems that different motion patterns also have something to do with the outcomes. If our hypotheses are true then we could potentially screen patients at risk for developing more extensive contractures. In the event that the animal models and experiments are successful, after we figure out who may be at risk, pharmacological solutions can be developed to prevent stiffness—or to treat the stiffness with medications rather than surgery. Other investigators are looking at biochemical and biological changes in stiff joints, but overall there is not a lot of research being done in this area."

Dr. Morrey is pleased to see that a procedure popular for hips, knees, and other areas is increasingly being used to help those with elbow issues. "The use of arthroscopy is finally accepted as having value for a broad spectrum of elbow pathology, a change that has come about in the last 10 years. To a certain extent we are still getting a feel for the appropriate indications and the techniques that can be brought to bear on the elbow. The utility of arthroscopy in treating elbow problems is one of the great clinical changes in recent years, a change that will likely continue and flourish, especially with the increasing documentation of outcomes."

When asked what his non-elbow colleagues might not know about treating the humerus, radia, and ulna, Dr. Morrey says, "In general there is a lack of awareness of the progress that has been made in total elbow work. The perception is that elbow joint replacement is not successful, something that is patently untrue. We now have much better designs and techniques than we did 20 years ago. At Mayo over the last 25 years we have found that linked implants (where a mechanism mechanically locks two components together), is more successful than an unlinked implant. Because of that we feel that replacement is a viable concept. In the last decade orthopedic manufacturers have determined that they want an artificial elbow as part of their offerings…all of the major manufacturers have one in their toolboxes."

As for what he would like to happen in the elbow realm going forward, Dr. Morrey states, "My number one goal would be that orthopedists step back and focus on better management of acute elbow fractures. We have evidence showing that when we try to salvage or revive an injured elbow, the outcome of the initial treatment, if done right, is always better than the outcome of the reconstruction. Secondly, I would like to see an enhanced awareness of the indications and outcomes for interventions by the orthopedic community. And finally, I would hope that more orthopedic surgeons could understand and possess the competence to execute these treatments."

Take note, medical students. An old field is new again.

Extremity Product Sales Defy Odds

By Dev Joshi, PearlDiver Extremities Analyst

Hold on to those fingers and toes! Despite the economic slowdown, you'll still need two hands and maybe one foot to count the double-digit growth rate in the extremities repair and device market. With companies hitting 15% to 20% growth rates in annual product sales prior to the fourth quarter of 2008 (4Q08), even the current economic storm couldn't stop a sustained double-digit growth percentage throughout the first half of 2009. This market has apparently found a break in the clouds and a ray of sun to beat the odds and hold on to strong growth.

Extremities device sales have been rising steeply over the past decade (the market grew by more than 110% between 2005 and 2008), and we expect that total sales will surpass the $1 billion mark this year. Outside observers wondered if soft sales in the hip and knee device sectors would drag down extremity device sales as well, but shoulder, foot and ankle implant sales remained strong and remain some of the fastest growing sectors in orthopedics. For those larger companies with diversified product lines, the extremity sector even helped stabilize losses in hip and knee device sales.

Extremity product sales for 2Q09 totaled $241 million worldwide and grew at the rate of 11.6% year-over-year (YOY). Growth rate winners this quarter were Biomet, Inc., Wright Medical, Inc. and Exactech, Inc., three companies that posted strong double-digit growth for the quarter. Zimmer

Table 1: Worldwide Extremity Product Earnings (in millions) by Company (2009-2012E)

Extremities	2009E							
Market	1Q09	2Q09	3Q09E	4Q09E	2009E	2010E	2011E	2012E
DePuy	$65.6	$50.4	$55.1	$63.3	$234.4	$260.0	$293.1	$326.2
Tornier	$39.2	$35.3	$37.8	$44.0	$156.3	$180.0	$206.5	$235.0
Zimmer	$33.3	$33.7	$30.3	$32.8	$130.1	$139.8	$151.8	$166.0
Wright Medical	$25.9	$25.6	$25.4	$29.1	$106.0	$128.2	$153.8	$182.0
Biomet	$20.3	$22.9	$20.2	$21.0	$84.4	$98.2	$116.6	$132.7
ArthroCare	$16.2	$17.3	$17.0	$18.0	$68.5	$78.7	$87.0	$94.5
Ascension Orthopedics	$6.1	$5.5	$5.8	$6.8	$24.2	$31.0	$40.8	$50.6
Exactech	$5.8	$5.1	$5.7	$6.8	$23.4	$31.2	$43.5	$54.4
Stryker	$5.8	$4.8	$5.4	$6.4	$22.4	$24.8	$26.7	$28.9
Others	$45.2	$40.4	$42.8	$50.0	$178.4	$202.8	$236.0	$264.3
Total	$263.4	$241.0	$245.5	$278.2	$1,028.1	$1,174.7	$1,355.8	$1,534.6
YoY Growth	11.8%	11.6%	11.8%	12.3%	11.9%	14.3%	15.4%	13.2%

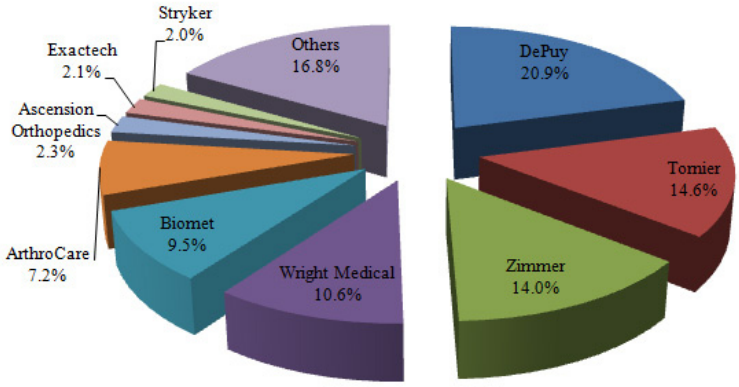
Source: SEC filings, PearlDiver estimates and press releases. ArthroCare has not reported sales since 1Q08. Stryker sales represent just their shoulder sales. Ascension and Tornier represent estimates.

Holdings, Inc. also rebounded after two quarters of low growth rates.

Manufacturers blame a decline in the number of procedures performed as the primary reason for the lower growth rates in 2009 as compared to 2008. Company officials reported flat pricing and believed it had no significant impact on sales. Innovative new technologies such as the second-generation reverse shoulder arthroplasty and the continued success of the total ankle replacement devices contributed to the growth of the extremity product market. Domestic growth in particular sustained the market while international growth was minimal due to fluctuations in foreign exchange rates. Table 2 illustrates the growth rate for each company's extremity sales for the first two quarters of 2009 and estimates for the third and fourth quarter of the year.

DePuy continues to lead the worldwide extremity product market with the largest slice of market share for 2Q09. Tornier, Inc., a privately held company now based in Minnesota, is number 2, followed by Zimmer, Wright Medical and Biomet as numbers 3, 4 and 5 respectively. Chart 1 illustrates the market share by company for 2Q09.

Chart 1: 2Q09 Extremity Product Market Share



Source: Company's SEC filings and press releases

Biomet, Inc.

Privately held Biomet, had a highly successful quarter. In their second quarter of 2009 (ending May 31), total extremity product sales were $22.9 million, representing an 18% YOY worldwide growth rate, compared to 2Q08. Extremity sales were led by a 28% growth in the domestic market. With the end of 2Q09, Biomet now holds a 9.5% market share, an increase from 7.8% from 1Q09.

Biomet, which rolled out its second-generation reverse shoulder prosthesis device in May 2009, expects this product to have an impact on third quarter earnings. The products that led to its high growth rate this quarter were the Copeland Humeral Resurfacing Head, the Comprehensive Primary Shoulder Device and the Total Evolutive Shoulder System.

Biomet has gained a strong position in the upper extremity product market, and we expect it to have high double-digit growth in the third quarter. We estimate that Biomet will report 15.4% YOY growth from sales of $20.2 million. The reverse shoulder device is gathering strong reviews and will be a key contributor to high growth.

Wright Medical Technologies, Inc.

Even though upper extremity products represent almost three quarters of the total extremity product market, Wright Medical found high sales growth by targeting the lower extremities. The company is now the top selling manufacturer in the lower extremity division. However, Wright Medical has not written off upper extremity products completely; the company also has a shoulder system (Olympia) in the market. The company's extremity division represents 21.6% of its net sales worldwide, an increase from 2Q08 of 18.5%.

Table 2: Extremity Companies Growth Rate (1Q09 – 4Q09E)

Companies	1Q09	2Q09	3Q09E	4Q09E
Ascension Orthopedics	36.6%	34.1%	34.9%	28.3%
Exactech	56.8%	30.8%	35.7%	36.0%
Biomet	12.8%	18.0%	15.4%	15.4%
Wright Medical	26.3%	16.9%	17.1%	17.3%
Tornier	11.2%	10.7%	11.5%	11.6%
Others	12.7%	10.4%	10.3%	10.6%
DePuy	7.5%	9.6%	10.2%	11.1%
Zimmer	4.1%	8.7%	8.2%	9.3%
ArthroCare	6.6%	6.8%	6.9%	7.8%
Stryker	7.4%	-4.0%	1.9%	3.2%
Total	11.8%	11.6%	11.8%	12.3%

Source: Company's SEC filings and PearlDiver estimates

For 2Q09, Wright Medical reported a growth of 17%, taking in $25.6 million in extremity product sales. While that growth is lower than the company's last six or seven quarters, it is still phenomenal for the lower extremity region, making Wright Medical the number 1 lower extremity manufacturer ahead of DePuy and Tornier.

Wright Medical drove its domestic sales up by 24% with the help of products like INBONE, CHARLOTTE Foot and Ankle system, DARCO plating systems, and the RAYHACK Osteotomy System acquired in September 2008. International sales decreased by 8% from 2Q08 which brought down the overall sales increase. Wright Medical's extremity sales now represent 10.6% of the total extremity product market worldwide up from 9.8% at the end of 2008. Taking into account the slight decline in growth over the last two quarters, we estimate the 3Q09 will bring Wright Medical total sales of $25.4 million with a growth rate of around 17% annually.

Exactech, Inc.

Exactech' shoulder division has experienced a great run over the past two years. Even though this quarter saw a slight decline, the growth was still exceptional. For 2Q09 Exactech reported a growth of 31% in its shoulder division. This represented a drop as the company had been reporting a higher than 50% growth rate each quarter for the past two years. According to management, the reason for the decline was a slow start at the beginning of the quarter. Sales picked up as the quarter progressed reaching $5.1 million.

For the first half of 2009, sales of Exactech's extremity products were up by 42% to $10.9 million compared to $7.6 million for the same period in 2008. This was due to the continued success of the Equinoxe Shoulder system. We estimate that the shoulder division will grow in the neighborhood of 35%, bringing in $5.7 million in sales. Extremity product sales for 2Q09 represent 11.7% of Exactech's total sales compared to 9% of the total sales for 2Q08.

Exactech now holds 2.1% of the total extremity market share worldwide, which is an increase from 1.8% in 2Q08. Its new products such as the Fracture Plate and Fracture Platform, which are being launched late in the third quarter, will likely boost sales in 2009 and 2010. We estimate that Exactech will close its sales for 2009 at $23.4 million with a 40% annual growth.

DePuy Orthopaedics, Inc.

For 2Q09, Johnson & Johnson's DePuy, the leading extremity product company worldwide, reported close to 10% YOY growth, down from the prior period of 12.2% growth. This was slightly higher than our prior forecast of 7.5% due to the company's strong growth ($50.4 million) in shoulder product shipments. Domestic extremity product sales represented the majority of sales for the second quarter.

DePuy' share of the extremity product market for 2Q09 is, we estimate, now 20.9%, slightly down from 21.3% in 2Q08. The shoulder market, which represents close to 80% of DePuy's total sales, is the driving force behind the company's growth. However, DePuy's loss in market share is due in part to the stiff competition from Wright Medical and Tornier in the foot and ankle division. For 3Q09 we estimate DePuy's extremity sales will continue to grow at a low double-digit rate of 10.2% buoyed by a strong shoulder device market. For the year 2009 we estimate a solid 10% growth with annual total sales of $234.4 million.

DePuy still reigns as the shoulder division leader with more than $200 million in extremity product sales annually, but it's not easy to stay king of the mountain forever. Wright Medical is giving DePuy strong competition within the lower extremity division while Biomet and Tornier are doing the same in the shoulder market.

Zimmer Holdings, Inc.

After two dismal previous quarters, Zimmer bounced back to life in 2Q09. Extremity product sales grew by almost 9% resulting in total sales of $33.5 million. The fourth quarter of 2008 and the first quarter of 2009 experienced only 3% and 4% YOY growth, respectively. The company's extremity product sales now represent 3.3% of its total sales which is an increase from 2.9% in 2Q08.

Zimmer's domestic sales for the quarter represented 76.6% of its total extremity product sales with a growth of 19% YOY. The Bigliani/Flatow Shoulder Solution and the Zimmer Trabecular Metal Reverse Shoulder System led its extremity product sales in the U.S. while international growth suffered a decline due to changes in foreign exchange rates. Europe, which represents 17.8 % of Zimmer's extremity product sales, reported a 19% decline from the second quarter of the prior year. Asia-Pacific, which represents 5.6% of Zimmer's total extremity product market, reported a 7% decline as compared to 2Q08.

Extremity products were the second best performing market for Zimmer behind spine products, which represented an 18% annual growth due to the acquisition of Abbot Spine in 4Q08. For 3Q09 we estimate that Zimmer will retain consistent growth as it did in this quarter at 8% YOY, bringing in $30.3 million in extremity product sales.

Other Extremity Companies

We estimate **Tornier**, the second largest extremity product manufacturer, to have $141 million in extremity sales for the year 2008. We estimate that Tornier will report around $156 million in total extremity sales for 2009, a consistent 11% annual growth rate and continued stiff competition for DePuy. Tornier's lead products are the Aequalis Shoulder System and the NexFix MTP Fusion System.

Integra LifeSciences Holding Corporation is another good performer in the extremity product market posting double-digit growth, according to management. We estimate that Integra LifeSciences

annual extremity product sales for 2009 will be in the range of $70 million to $75 million. **Stryker Corporation**, which does not play a significant role in extremity, reported an estimated 4% decline in its quarterly shoulder division sales. **Small Bone Innovation, Inc. (SBi)**, **Arthrex Inc.**, **Orthofix International N.V.** and **Acumed LLC** are other established extremity companies that represent an estimated 10% to 12% of the total extremity market.

We expect third quarter to be consistent with the first and second quarter earnings. Extremity product manufacturers still make up a small, growing market compared to the hip, knee and spine product markets. Joint replacement and reconstruction procedures for extremities are still increasing due to a low base, and prices remain steady compared to other orthopedic markets where procedure volumes and prices are dropping. There is still demand for more procedures and devices, and with innovative products being introduced every quarter, the extremity product market has what it takes to beat the odds.

For other articles by this author, please select the following link: http://www.pearldiverinc.com/pdi/ext.jsp

ANNOUNCEMENT: Our new Claim

Our group is engaged in an ongoing process of internationalization: today we have an active presence in 14 countries in 3 continents and, thanks to our extensive sales network, the Lima brand Lima Corporate is known all round the world.

This developing situation led us to rethink our corporate identity; the master brand is the first concrete expression of this important process. Our logo certainly represents our dynamism but at the same time communicates the notion of globalism which characterizes Lima today. But it has to be said that our group now goes way beyond that. Lima is a multifaceted enterprise: Lima is orthopaedics, passion, innovation and movement. The logo alone is unable to express all of this and so we have been trying to find the right claim to encompass the group's current entrepreneurial vision. And now we want to let you know that we have found it:

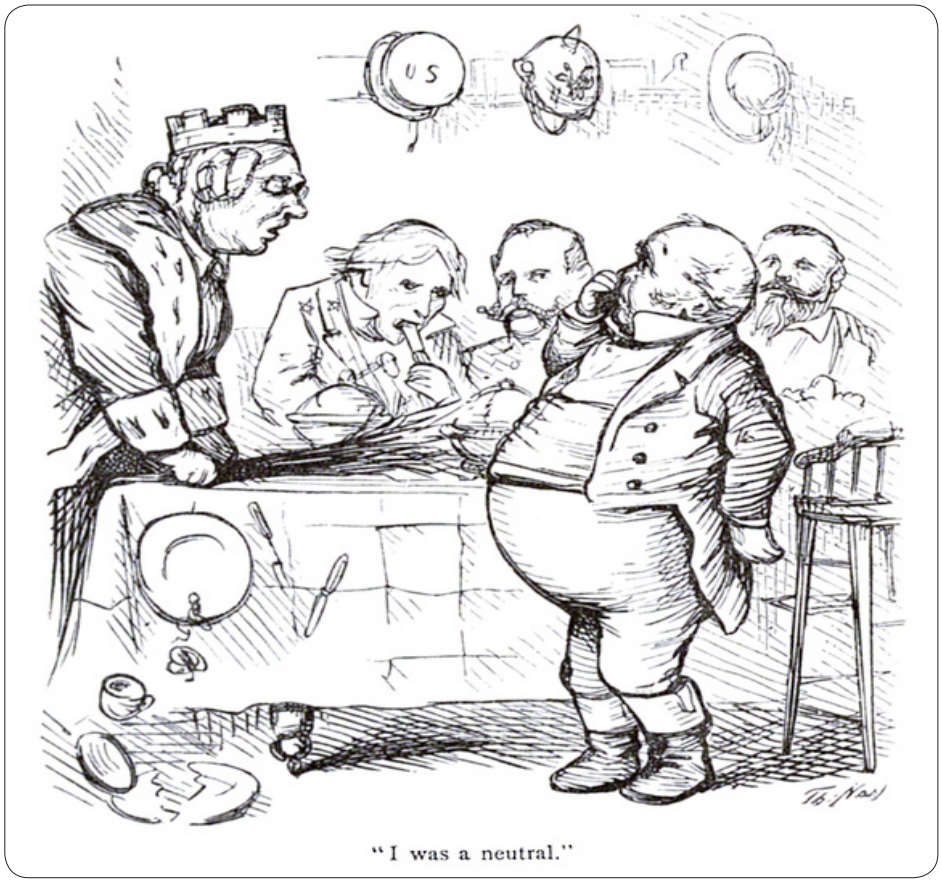
Orthopaedic motion

Orthopaedic Emotion acts as a reminder of the market sector (orthopaedic) within which Lima operates with passion and which is in continual evolution; Orthopaedic Emotion is the trust which we place in technological innovation and with which we will approach all future challenges.
In a play on words/graphics **motion**, stands both for Movement and Emotion. Lima is movement and is in the movement of those people all over the world who have regained mobility thanks to our implants; Lima is emotion and is part of that emotion people feel when they recover the proper use of their joints.

Lima Corporate today represents all of this: emotion in movement in orthopaedics.

AAOS Chastises Obama

By Walter Eisner



John Bull Chastised by Dame Europa (1871) Thomas Nast

This is a story about Joe, the orthopedic surgeon, and Barack, the leader of the free world.

Joe Zuckerman, M.D., and Barack Obama, J.D., are the respective presidents of their organizations, the American Academy of Orthopaedic Surgeons and the nation of the United States of America.

During recent rebellious town hall meetings about healthcare reform, President Obama urged all parties to stick to the facts and avoid overheated hyperbole. But then the president made some inaccurate statements about orthopedic surgeons that did not go over well with Dr. Zuckerman and the AAOS.

Joseph Zuckerman, M.D.

A Presidential Gaffe

First the president made a remark about surgeons taking out tonsils because it was more lucrative than preventive care.

Then came a comment about amputations, and the AAOS officially entered the fray over healthcare reform.

At a town hall meeting on August 11, President Obama was answering a question from a nurse practitioner about controlling healthcare costs.

"One of the things we can do is to reimburse doctors who are providing preventive care and not just the surgeon who provides care after somebody is sick."

Obama knew he was wading into trouble because he immediately added:

"Nothing against surgeons…I don't want to be getting a bunch of letters from surgeons now. I'm not dissing surgeons here." – President Obama

Barack Obama, J.D.

Then he continued, "All I'm saying is let's take the example of something like diabetes, a disease that's skyrocketing, partly because of obesity, partly because it's not treated as effectively as it could be. Right now if a family care physician works with his or her patient to help them lose weight, modify diet, monitors whether they're taking their medications in a timely fashion, they might get reimbursed a pittance.

"But if that same diabetic ends up getting their foot amputated, that's $30,000, $40,000, $50,000—immediately the surgeon is reimbursed. Well, why not make sure that we're also reimbursing the care that prevents the amputation, right? That will save us money."
– President Obama

Whoops.

Up to that point in the healthcare reform debate, Dr. Zuckerman had kept the Academy's powder dry and worked with fellow medical societies through an alliance of specialty groups.

The president may not have wanted any letters, but he got his facts wrong and the challenge to surgeons had been issued. Dr. Zuckerman and the AAOS fired back swiftly.

Surgeon Response

In an August 13 letter to the president, the surgeons made their points:

- The Academy was "profoundly disappointed" with the president's comments.

Bradley C. Bower/Associated Press

- The president was "blurring the realities" of physician reimbursements.
- It was a "mischaracterization" to suggest that physicians are reimbursed immediately.
- The president was urged to "disengage from hyperbole."
- The most expedient way to accomplish healthcare reform is to ensure that the debate is based in fact and reflects the value of the services that all physicians, including orthopaedic surgeons, provide.

"Surgeons are neither reimbursed by Medicare, nor any provider for that matter, for foot amputations at rates anywhere close to $50,000, $40,000 or even $30,000. Medicare reimbursements to physicians for foot amputations range from approximately $700 to $1,200, which includes the follow-up care the surgeon provides to the patient up to 90 days after the operation," stated the letter in correcting the president's amputation remarks.

"We implore [the president] to disengage from hyperbole and acknowledge that healthcare delivery can only be improved by recognizing that health care is a system in which orthopaedic surgeons play a crucial role. With $849 billion of our national economy impacted by musculoskeletal conditions, orthopaedic surgeons provide care that improves lives and puts people back to work."

Chastising a President

In comments to *Orthopedics This Week* late on Sunday night, August 23, Dr. Zuckerman (who was seeing 35 patients the next day) said that the amputation comment presented itself as an opportunity to speak up

for members of the Academy. He hoped the AAOS letter would be a first step in having some dialog with policymakers and requested a meeting with the White House.

Earlier this year members of the Academy met privately with a group from the Obama administration that included Ezekiel Emanuel, M.D., brother to White House Chief of Staff, Rahm Emanuel. But since that time no other meaningful dialog has occurred between the AAOS and senior administration officials.

Dr. Ezekiel Emanuel is Special Advisor for Health Policy to Peter Orszag, the Director of the Office of Management and Budget.

A Complicated United Surgeon Front

As an individual society, the Academy has not had a seat at the main table of the healthcare reform debate. The Academy has not endorsed any of the various proposals that have come from the White House or passed congressional committees in the House.

The American Medical Association and the American College of Surgeons have each endorsed reform proposals in some form. This leaves the AAOS with a problem if it wants a united surgeon/physician front on healthcare reform. The College of Surgeons' position presents "a little complication" for the AAOS, said Zuckerman.

"We know the AMA took the position they did to have a place at the table. The Academy took a different approach." The Academy believes that the real action in Washington will not start until September and chose to keep its powder dry until then.

The Academy's Position

"The Academy and I represent orthopedic surgeons," said Dr. Zuckerman. He said the president had simply gotten his facts wrong, thereby offering surgeons an opportunity to educate the president, legislators and the public about the contributions orthopedic surgeons make in keeping the nation healthy and working.

Peter Mandell, M.D., AAOS' Advocacy Chair, provided us with the organization's position statement regarding healthcare reform.

The current health insurance and healthcare delivery system is not sustainable and the Academy believes some of the factors leading to increased and inefficient healthcare spending include:

- High administrative costs.
- A broken liability system.
- An increased prevalence of chronic disease.
- A shift in costs from the uninsured to the insured.
- A predominant third-party payer system.
- Unnecessary patient care.

The position papers states that the Academy believes that the demand upon physicians, providers, and payers "is infinite," but can be contained through incremental changes to the system. For example, altering the

allocation of federal and state resources or increasing the portability and availability of healthcare coverage can increase the number of individuals with health insurance.

As healthcare reforms are considered, the Academy believes policymakers should:

- Make certain that patients are empowered to control and decide how their own healthcare dollars are spent.
- Ensure unencumbered access to specialty care.
- Make healthcare coverage more affordable.
- Improve the quality of care.
- Extend both coverage and access for the uninsured and under-insured.
- Avoid establishing new unsustainable programs.

Opposes Single-Payer

While the Academy believes that expanding healthcare coverage and access should be implemented through a public-private partnership, it strongly opposes proposals that create a federal healthcare authority or move healthcare further in the direction of a single-payer healthcare system.

To ensure portability and continuity of care, the Academy believes that a newly reformed healthcare system should allow individuals or employers to "assert social responsibility" when purchasing additional services or insurance as part of a structured or packaged offer. Open market approaches similar to the Federal Employees Health Benefits Program (FEHBP) are cited as an example.

The Academy supports providing physicians with tax initiatives to defray the cost of uncompensated care. It also thinks that federal and state governments should provide adequate long-term sustainable funding for existing government healthcare programs.

Reigning in Insurance Companies

The Academy also believes that administrative expenses in private healthcare plans should more closely mirror those of public programs, ensuring that a more significant portion of spending is dedicated to medical care.

The Academy's position statement concludes:

"As we approach the great public debate on healthcare reform in America, the AAOS believes preservation of the autonomy of the physician-patient relationship to be of the highest priority."

The entire position statement of the AAOS can be read here: http://www.aaos.org/about/papers/position/1176.asp

Librarything.com

The End Game

But back to Joe and Barack.

Healthcare reform has emerged as one of the most urgent and debated political subjects in decades. Now that the Academy has entered the fray, its strategy of keeping its powder dry will be tested.

Whether or not a reform package actually gets passed this year is still unknown. But perhaps in the final hours of the debate, Barack will need Joe to tip a vote or two in Congress. Dry power could be a valuable commodity in the end game.

company news

HydroCision's 43% Quarter

HydroCision's revenues increased 43% in the second quarter of 2009.

Doug Daniels, the company's CEO, told *OTW* he attributes the increase to continued surgeon education and the highlighting of positive results from clinical studies.

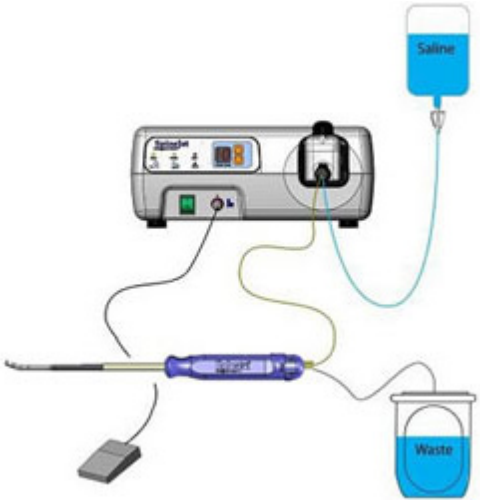
One such study was presented by Larry Khoo, M.D., at a recent Western Orthopedic Society meeting.

Khoo's study, "The Impact of Hydrosurgical Instruments and BMP on Minimally Invasive Lumbar Fusion Outcomes," concluded that "MITLIF using hydrosurgical tools reduces postoperative complications compared to conventional methods while producing a similar fusion rate to that of BMP."

Daniels believes that the company's fluidjet products demonstrate "medico-economic benefits" to the health care system and is helping drive sales.

Fluidjets cut like a "smart" scalpel, says Daniels, and provide surgeons with a tool to hold, cut and remove unwanted soft tissue and minimize damage to surrounding healthy tissue. In fact, the fluidjet delivers more power to a point than a laser, Daniels told us.

HydroCision has released multiple products for two spinal applications. One application is for spinal fusion



preparation and the other is for minimally invasive discectomy.

"Both platforms demonstrated strong year-over-year growth in the second quarter," Daniels commented. "We are pleased with the growth of our SpineJet franchise."

The company also announced that it will be introducing two new products in the near future.

One product, to be launched in September, is called EndoResector. It is designed to fit through the working channel of the vast majority of endoscopes for endoscopic discectomy.

In a sign that HydroCision's revenues are accelerating, Daniels noted that trailing quarter product sales increased by 21%.

If HydroCision convinces payers that their product offers the medico-economic benefits and saves them money, they may fare well in a world of comparative effectiveness.

—*WE (August 25, 2009)*

Uneventful Medtronic 1Q10

Medtronic reported an uneventful 7% increase in spine and biologics revenues in the first quarter of 2010.

While its reported core spine business revenues increased by 9%, the biologics business declined by 1%. Total revenue was $915 million.

Chairman and CEO Bill Hawkins told analysts during a quarter conference call on August 25 that the company was "working to invigorate...and reestablish innovate leadership" in spine and biologics. He noted increased investments in BMP and a "vigorous" defense of its intellectual property, including kyphoplasty.

Wells Fargo analyst Larry Biegelsen said Medtronic's spine sales beat their estimate by $37 million. "Adjusting for currency and the impact of the extra selling week in the quarter, the spine business grew about 3% which is in-line with recent trends. Core spine was relatively strong whereas InFuse was somewhat weak."

Medtronic	1Q10 Millions	1Q09 Millions	% Change
Spine	$915	$859	Up 7%
Core (includes Kyphon)	$696	$638	Up 9%
Biologics (Includes MBP)	$219	$221	Down 1%

company news

Medtronic Headquarters courtesy Wikimedia

Hawkins told analyst the spine market is robust and procedures are up for the quarter.

Without mentioning any particular physician or product, Hawkins went head-on at recent publicity regarding physicians/industry relationships.

Hawkins said, "Appropriate relationships are vital," and the company still believes in "Bedside-to-Bench-to-Bedside," because "physicians are the best innovators."

"There is much work to be done on this topic."

Medtronic recently named D. Cameron Findlay as senior vice president, general counsel and corporate secretary. Findlay will reportedly oversee an initiative focused on the development of new standards for clarity and transparency in the company's relationship with physicians. Hawkins also noted the recent vertebroplasty study from the *NEJM* and reminded analysts that the study was not about kyphoplasty. He pointed to the company's own FREE study which compared kyphoplasty favorably to non surgical treatments.

Medtronic is in the middle of a lot of storms. An uneventful quarter beat expectations.

—WE (August 26, 2009)

U.S. Spine's Busy August

It's been a busy August at US Spine. First the company was awarded the first patent for its Facet Fixation System and then it launched a new spine system.

Commercialization of the facet fixation system began in 2008 and features US Spine's Facet Gun and Facet Bolt devices.

The gun is designed to allow surgeons to lock the facet joint in two steps via a gun-shaped delivery system. According to the company, the bolt, a locking facet implant, provides the same stiffness and strength as conventional stabilization and fusion devices.

The company says the benefits of their system are that a surgeon can lock a spinal motion segment in just minutes rather than the hours required from traditional stabilization methods.

Company Founder Doris Blake and Paul Sendro, the company's new Executive Vice President, were understandably upbeat about the issuance of the patent. Blake said the company will now move closer to reaching a broader field of surgeons while Sendro said this was only the first of several patents related to the system.

The Patent and Trademark Office assigned patent number 7,563,275 to the Facet Fixation System.

Preference 2 Complex Spine System Launched

The company's gun and bolt weren't the only things making news in August.

A few days after announcing the facet patent, the company

company news

announced the full national launch of its Preference 2 Complex Spine System.

Sendro said he knows the company is primarily known for the gun and bolt system. But he says the rollout of the new spine system allows the company to make an impact within the deformity, trauma, and tumor market.

The new system is a hook, rod, and pedicle screw system with several implant options allowing multiple correction techniques and comprehensive instrumentation designed specifically to treat complex spinal pathologies. "The system provides spine surgeons with a specialized solution to correct complex spinal pathologies such as scoliosis, kyphosis, trauma, and tumors," a company announcement stated on August 25.

Now let's see what they can do in September.

—WE (August 27, 2009)

legal & regulatory

Polly Leaves AAOS Board

David Polly, M.D., has resigned from the American Academy of Orthopaedic Surgeon's Board of Directors.

In a letter on August 19 to Academy President Joe Zuckerman, M.D., Polly said media attention on his consulting activities has "become an unnecessary distraction" to the society.

David Polly, M.D.

In response, Dr. Zuckerman said "when those relationships come under scrutiny, as Dr. Polly's have, we agree with him that this creates an unnecessary distraction from (the Academy's) mission."

Heisenberg's first law of physics has now come to orthopedics. The simple act of observing something, changes it.

No one has accused Dr. Polly of anything improper. Senator Grassley has accused the University of Minnesota of an inadequate conflict-of-interest policy and has been a thorn in Medtronic's side for some time now.

We can understand the University of Minnesota and Medtronic, Dr. Polly's collaborative partners, responding to pressures from Senator Grassley. But we would expect Dr. Polly's Academy colleagues to stand with one of their own. Accepting this resignation because of an "unnecessary distraction" is a precedent the Academy may come to regret.

Dr. Zuckerman told us this was not about the Academy "standing-shoulder-to-shoulder" with one of its own. "We're volunteers," said Zuckerman. He said individual members have to make their own decisions about their role in the organization. "Dr. Polly felt he needed to resign and we accepted his decision."

Joseph Zuckerman, M.D.

This goes beyond "innocent-till-proven-guilty" territory and enters a "through-the-looking glass" world. A world where reputations, careers and, most importantly, scientific progress may be stymied by a simple act of public scrutiny over a surgeon's consulting relationships.

Wrote Dr. Polly to the AAOS president:

legal & regulatory

"I look forward to the day when the rules for consulting are clearly defined, for without clear rules, there are only varying individual opinions of right and wrong."

We agree. This is too important to leave to individual opinions. We hope Senator Grassley gets his Sunshine Act passed soon so that clear, consistent and unambiguous rules about physician/industry relationships can be uniformly established. Hopefully then the simple act of observation won't undermine a system that has produced great scientific advancements for patients with musculoskeletal conditions.

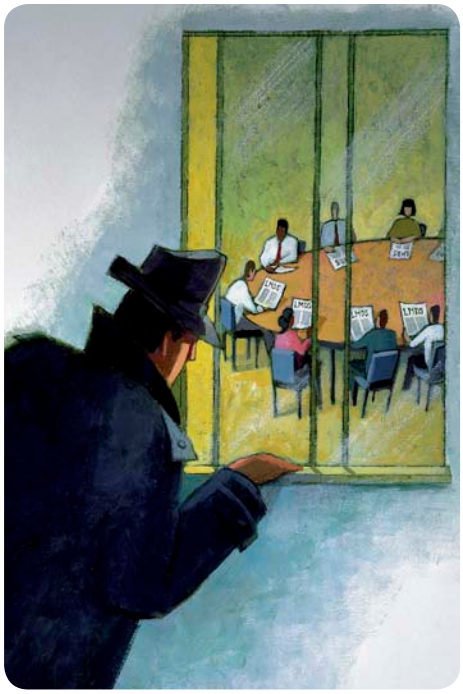
—WE (August 25, 2009)

GPOs: The Next Target

Do group purchasing organization (GPO) contract negotiations inflate health care costs for taxpayers?

No one knows for sure because in many instances the GPOs select preferred manufacturers and the negotiated prices are kept confidential by requirements in the contracts.

Now, three U.S. senators are demanding that seven of the largest GPOs hand over their contracts and other detailed information about their business practices. The three senators, Democrats Herb Kohl and Bill Nelson and, yes, Republican Chuck Grassley sent letters to the GPOs on August 11 demanding the information.



The New York Times reported on August 13 that for years there have been complaints that the buying process is opaque and unfair. The purchasing companies' operating expenses are usually paid by the manufacturers sitting across the bargaining table, leaving them open to accusations of steering huge blocks of institutional business to the vendors willing to pay the most.

The group purchasing organizations deny this, according to the story, and say they award contracts on the merits and help hospitals get good deals, saving the government money.

Responding on the Health Care Renewal Blog on August 17, Curtis Rooney, President of the Health Industry Group Purchasing Association writes:

"Unfortunately, the story in the [New York Times] resurrects old claims against the health care group purchasing industry and suggests that new congressional interest will force much needed change. The fact of the matter is that our industry is one of the most transparent, ethical and efficient in the health care arena."

Safe Harbor From Stark

Normally, Medicare's law against kickbacks, the Stark Act, would bar vendors from paying the companies that award them contracts, but Congress granted the industry a special "safe harbor" many years ago, in the belief that volume purchasing saved money. The Times article says the senators seem to want to test that belief and perhaps change or abolish the safe harbor, something that would turn the industry on its head.

The senate inquiry, according to the story, suggests they want to know whether vendors are using the contracting companies to quietly channel money and in-kind donations to hospitals, building brand loyalty at taxpayer expense.

Any such contributions could be problematic if the hospitals failed to deduct them when submitting their cost reports to Medicare. In that case, the hospitals could get too much money from Medicare.

Only one of the companies, MedAssets, of Alpharetta, Georgia., is publicly traded. The others are

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Premier, of Charlotte, North Carolina; Novation, of Irving, Texas; Consorta, of Schaumberg, Illinois.; Broadlane, of Dallas; Amerinet, of St. Louis; and the HealthTrust Purchasing Group, of Brentwood, Tennessee.

We've seen this movie before. Senators demand information and soon we'll see that information leaked to The New York Times and The Wall Street Journal. If that happens, we may soon see detailed pricing of medical devices publicly disclosed.

The senators have given the GPOs until September 8 to send in their information.

—WE (August 28, 2009)

extremities

Wright Foot Forward: CORETRAK

In the know on healing outside the body…Wright Medical Group, Inc. is announcing the launch of its patent pending CORETRAK Articulating External Fixator, designed for challenging fixation cases of the foot, such as those involving diabetic patients.

Make things easier for surgeons, patients, and hospital staff… that was Wright's goal when it set out to develop CORETRAK. The new product is minimally invasive and, says the company, respects the body's natural ability to heal, something particularly

important for diabetics who are already at a high risk for surgical complications.

Robert D. Santrock, M.D., of Midlands Orthopedics in Columbia, South Carolina, specializes in the care and treatment of the diabetic foot and its associated complications. Dr. Santrock said in the news release, "The new articulating CORETRAK fixator will take external fixation to a new level with its low profile, patient-friendly design and adaptability to multiple conditions in the foot." His associate William C. James, III, M.D., noted, "External fixation is particularly useful for the diabetic foot due to its ability to stabilize bones while avoiding areas with open wounds and/or infection. I find it a useful tool for reconstructing the foot in a high risk patient."

Bradley M. Lamm, D.P.M., Head of Foot and Ankle Surgery, International Center for Limb Lengthening of the Rubin Institute for Advanced Orthopedics at Sinai Hospital in Baltimore, Maryland, further added, "I am looking forward to this new technology for the treatment of arthritis in the big toe joint. The CORETRAK articulating fixator has specific design features to address pain and stiffness in the toe joint and may save a patient from a joint replacement or fusion."

No need to sterilize on the receiving end as the CORETRAK Articulating Fixator is delivered in a sterile packaged procedure kit. The kits may also be useful for military and emergency operations where time is critical. The new CORETRAK fixator will be made available immediately in the U.S. through Wright's specialized foot and ankle sales force, and in select countries outside the U.S. through its direct and distributor-based sales representatives.

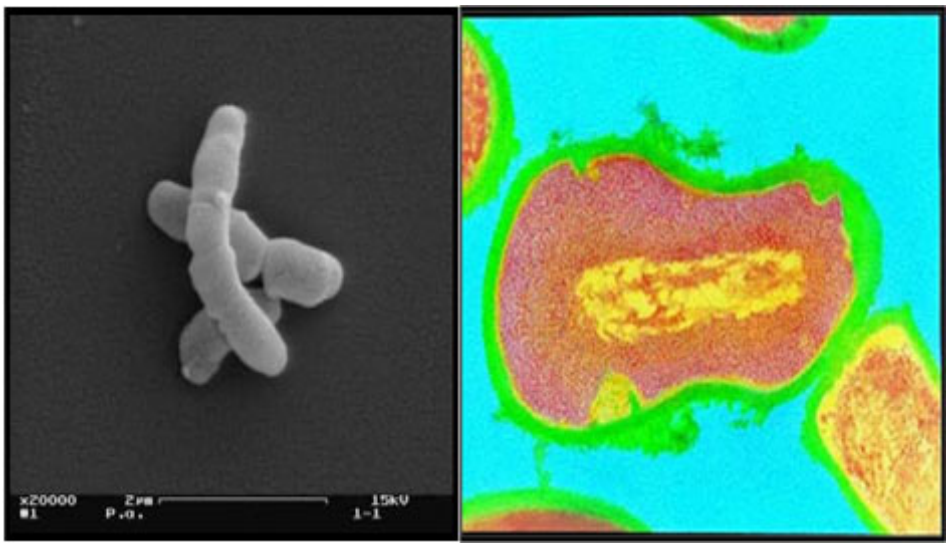
The company was contacted for comment, but wished to add no further information.

—EH (August 25, 2009)

Eliminating Bacteria Before Shoulder Surgery

Choose your preop wipes carefully, say recent data published in *The Journal of Bone and Joint Surgery.* Researchers led by Dr. Matthew D. Saltzman, Assistant Professor at Northwestern University, have found that ChoraPrep is more

extremities



efficacious than both DuraPrep and betadine at eliminating bacteria from the shoulder.

In a randomized, prospective study, 150 patients undergoing shoulder surgery were evaluated after being prepared with ChloraPrep, iodine or DuraPrep. The findings show that use of the preoperative skin preparation ChloraPrep (a CareFusion product) is significantly more effective than both DuraPrep and povidone-iodine at eliminating overall bacteria from the shoulder region. After antisepsis with ChloraPrep (2% chlorhexidine gluconate and 70% isopropyl alcohol), only 7% of skin cultures tested positive for bacteria compared to 19% for DuraPrep (0.7% iodophor and 74% isopropyl alcohol) and 31% for povidone-iodine (0.75% iodine scrub and 1% paint).

"While the presence of bacteria on the skin doesn't automatically lead to an infection, significantly reducing bacteria on a patient's skin is a key component of reducing the overall risk of infection," said Dr. in the news release. "In terms of bacterial reduction, these study results suggest that ChloraPrep may better protect patients than DuraPrep or iodine."

"Surgical site infections pose a major health threat to patients, and are costly for the health care system," said Cindi Crosby in the news release. Crosby, VP of Global Medical Affairs, Infection Prevention, with CareFusion, added, "This study adds to the growing clinical body of evidence that supports use of ChloraPrep for skin prepping prior to surgery."

According to the news release, the efficacy and safety of ChloraPrep are supported by more than 35 clinical studies and recommendations by 17 internationally recognized organizations or guidelines, including 10 that specifically recommend 2% chlorhexidine gluconate (a key ingredient in ChloraPrep).

Dr. Saltzman told *OTW*, "Many recent studies have identified *Propionibacterium acnes* as a major cause of infection following shoulder surgery. We wanted to determine the most common organisms present around the shoulder prior to surgical skin preparation and secondarily to determine which of several currently available surgical preparation solutions is most effective at eliminating bacteria from the shoulder. Our study clearly showed that ChoraPrep is more efficacious than both DuraPrep and betadine at eliminating overall bacteria from the shoulder."

He added, "We are currently conducting a study looking at the effect of using chlorhexadine wash the day before shoulder surgery on bacterial counts at the time of surgery."

Funding of this study was provided as an unrestricted educational grant by CareFusion, manufacturer of ChloraPrep. This funding was used exclusively for microbiology expenses, and the company was not involved with the organization or analysis of the data.

—EH (Aug 27, 2009)

spine

Cervical Spine Surgery Helps Headaches

Problems with C1-C7? New research shows that one of those problems—post surgery—may not be headaches.

spine

A study published in the August 2009 issue of *The Journal of Bone and Joint Surgery* (JBJS) reveals that two years after anterior neck operations, patients who have arthroplasty or spine fusion should experience a significant improvement in their headache symptoms.

In the news release, lead author, Joseph Riina, M.D., of Orthopaedics Indianapolis, stated, "This is not a 'cure' for all headaches. But, if you have headaches associated with neck pain and dysfunction, surgery for the neck problem can significantly improve the related headaches. And, anytime overall quality of life can be improved with surgical treatment, that is something to note."
Researchers set out to determine the prevalence of headaches in patients with cervical radiculopathy (shooting pain in the arm) or myelopathy (spinal cord dysfunction). They also sought to assess the effectiveness of anterior cervical surgery in relieving headache symptoms associated with the cervical disease.

None of the participants underwent the operation for treatment of their headaches; headaches were not their only complaint. Individuals with migraine headaches were not included in the study.

The authors indicate that there still is a lack of knowledge regarding the exact anatomical structures that cause headaches, which could be caused by the disc, joints, muscles or some combination of those. They found no significant difference was reported in headache severity between the arthroplasty and arthodesis groups. The study participants (51.6% of whom were male) ranged in age from 25 to 78. The results were as follows:

Prior to surgery: 86.4% reported headaches; 34.1% reported mild headaches (a 1 or 2 rating on the scale); 52.1% reported severe headaches (a 3, 4 or 5 on the scale). Two years after surgery: Of the 803 patients responding, 65.1% reported headaches; 34.9% reported no headaches; 46.7% reported mild headaches; 18.4% reported severe headaches.

"This is the largest study that we know of, in which incidence and improvement of headaches has been studied related to anterior spine

spine

surgery. I think we answered a big question: Can patients have less neck pain and fewer headaches after this kind of surgery? And, the answer is yes," added Riina. "We evaluated more than 1000 patients, using the Neck Disability Index questionnaire before surgery and at five increments after surgery, the latest was 24 months post surgery and the evidence suggests that there can be significant improvements in headache pain."

Co-author Dr. Paul Anderson, Professor in the Department of Orthopedics and Rehabilitation at the University of Wisconsin, told *OTW*, "Hopefully the article will raise this issue so that the surgeons have a factual basis on how to counsel patients about headaches. This is in print and we have presented at several national meetings."

Regarding how orthopedists might use this information, Dr. Anderson told *OTW,* "The doctor can confidently inform patients with radiculopathy who are being treated surgically, that if they have associated headaches that they have about an 85% chance of resolution."

—EH (August 24, 2009)

SpineMark, NeuStrategy: Spine COE Survey

Back pain can be random… but treating the spine doesn't have to be. To that end, Chicago-based NeuStrategy, Inc., and SpineMark Corporation of San Diego, have undertaken an effort to standardize best practices in spine care. In fact, they are announcing the results of the nation's first-ever Spine Center of Excellence (COE) Survey. Researchers looked at the critical infrastructure of 99 spine care programs across 35 U.S. states and 3 international locations, and have made the results available to participating hospitals and practices so that they might compare their program strengths, identify gaps, and plan for improved delivery of spine care.

"While the cost of diagnosing and treating back and neck problems continues to rise, many patient care delivery systems are failing to show improved patient outcomes," explained Kevin Dunne, NeuStrategy Partner, in the news release.

NeuStrategy and SpineMark worked with industry experts to identify the critical infrastructure components of spine centers. Participants took a web-based survey in the winter of 2008, and have received a customized report card detailing how their services compare to others across the country.

"The Spine COE Survey is the first step toward standardizing measures to define spine centers of excellence. Hospitals today must define themselves by programs that improve the quality of care and the services provided," explained Marcy Rogers, President and CEO of SpineMark, in the news release. "The results of the survey prove that there is room for improvement in spine care. We have created a comprehensive care model that aligns the interests of patients, physicians, and facilities to offer quality-based care with measurable results."

Regarding the room for improvement in spine care, Rogers told *OTW*, "Success for a patient receiving spine care happens when all the parties providing that care are working together through the use of a comprehensive team. Pulling together a collaborative effort has been out of reach for many practices or facilities because of the independence of the parties or entities and the fragmentation associated with a practice or departmental versus team approach to care. A center of excellence requires a proactive approach, namely looking at, planning for, and being accountable for the entire patient experience by all those

spine

who provide it—and committing to transparency, accountability through outcomes and continuous quality improvement to drive the process!"

Participating hospitals fall into two categories: emerging (EP) versus comprehensive programs (CP). In addition to exhibiting an interdisciplinary team in a focused environment, hospitals with an emphasis on tracking performance and quality achieve the highest ratings. "Back problems increase with age, so U.S. hospitals face a double-edged sword," continued Dunne. "The aging population will continue to drive up demand for expensive, new diagnostic and treatment technologies at a time when greater scrutiny is being placed on outcomes. Only spine centers that streamline access to care and provide excellent outcomes at a reasonable cost will be able to successfully reconcile these two conflicting interests."

Rogers also told *OTW*, "Today's spine patient is more informed than ever before and is actively seeking the latest advances in spine care. As a result, facilities must respond by building research programs as an adjunct to their normal care delivery to support these advances. Effective, comprehensive spine programs must rely on research not just to educate and advance spine care, but to establish program leadership and brand identity."

As for how some facilities are getting it right, Rogers told *OTW*, "In the past, quality was based on reputation alone. Today and in the future, quality for a spine center means you first have a set of clinical pathways that help guide decisions in conjunction with physician judgment. Yet tracking outcomes is only part of the story, most organizations focus on getting the data, what about USING the data? How do we SHARE the data, and use it to continuously improve the way care is delivered. Organizations may actively collect data but the analysis, dissemination and utilization of that data relative to short- and long-term models remains a work in process."

—EH (Aug 28, 2009)

trauma

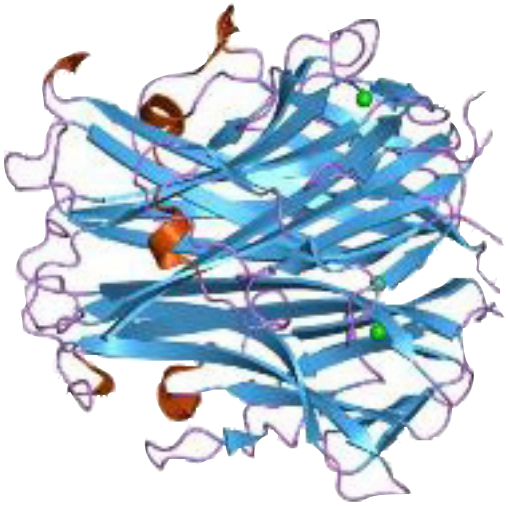
Study: New Role of Immune System in Bone Loss

HDL is related to LDL is related to bone…but how? Researchers from the University of California, Los Angeles (UCLA) have uncovered the relationship between high cholesterol and osteoporosis and identified a new way that the body's immune cells play a role in bone loss. The work, published August 20 in the journal Clinical Immunology, may result in novel immune-based treatments for osteoporosis.

"We've known that osteoporosis patients have higher cholesterol levels, more severe clogging of the heart arteries and increased risk of stroke. We also knew that drugs that lower cholesterol reduce bone fractures too," said Rita Effros, Professor of Pathology at the David Geffen School of Medicine at UCLA, in the news release. "What we didn't understand was why."

Dr. Effros set out with the thought that oxidation might be the issue, i.e., cell and tissue damage resulting from exposure of the fatty acids in cholesterol to free radical molecules. Focusing on low-density lipoprotein (LDL), the so-called "bad" cholesterol, she and her team examined how high levels of oxidized LDL affect bone and whether a type of immune cell called a T cell plays a role in the process.

trauma



Blood samples from healthy volunteers were used to isolate the participants' T cells and culture them in a dish. Half of the T cells were combined with normal LDL; the rest were combined with oxidized LDL. The scientists stimulated half of the T cells to mimic an immune response, but did nothing to the other half. According to the researchers, the T cells exposed to oxidized LDL displayed a striking response.

"Lo and behold, both the resting and the activated T cells started churning out a chemical that stimulates cells whose sole purpose is to destroy bone," Dr. Effros said in the news release. Called RANKL, the chemical is involved in immune response and bone physiology.

Delving deeper, the investigators repeated the experiment in a mouse model. Half the animals were fed a high-fat diet starting at one month of age, while the control group ate a normal diet. At 11 months, the mice on the high-fat diet showed elevated cholesterol and thinner bones.

Testing the T cells of the mice on the high-fat diet, the team discovered that the cells acted differently than those of the mice on the normal diet. The T cells switched on the gene that produces RANKL. The chemical also appeared in the animals' bloodstream, suggesting that the cellular activity contributed to their bone loss.

"It's normal for our T cells to produce small amounts of RANKL during an immune response," Dr. Effros said in the news release. "But when RANKL is manufactured for long periods or at the wrong time, it results in excessive bone damage."

"That's exactly what happened to the mice on the high-fat diet," she added. "The animals' high cholesterol increased their levels of oxidized LDL, which told the T cells to keep generating RANKL. This discovery revealed to us how the immune system might play an entirely new role in bone loss."

The team plans to go forward and explore methods to control T cell response to oxidized LDL, the goal being to develop immune-based approaches to prevent or slow bone loss.

When asked what orthopedists might tell their patients about this work, Dr. Effros told *OTW*, "Keeping your cholesterol levels within the normal range may not only be good for your heart, but also for your bones."

—EH (Aug 27, 2009)

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The Picture of Success: Dr. Timothy Hosea

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

His dad feared he might end up a rowing bum. Instead, Dr. Tim Hosea, an orthopedic surgeon with the St. Peter's University Hospital in New Brunswick, New Jersey, grew up, grew in experience, and became the team doctor for the U.S. Olympic Rowing Team.

Paddling His Way through Life

Raised in Grosse Pointe, Michigan alongside his three brothers, Tim Hosea learned about self discipline at an early age. "Our dad was an executive for General Motors and our mom, coming from a family of all daughters, learned to feed and control the rambunctiousness of four boys. As members of an Irish German family, my siblings and I were expected to work hard and pull our own weight. There were a number of engineers in our family, so I decided to see if I was up to that challenge. I went to the U.S. Naval Academy to fly jets, but soon found out that I was too large physically to be comfortable in a jet." However, he discovered that his physicality fit well in a different kind of seat: a rowing shell.

With his jet pilot odyssey altered, Tim Hosea transferred to Harvard in his sophomore year of college. "Although I did take premed courses at Harvard, I majored in English because I knew I would have enough science later, and thought that I might as well read 'the great books' while I could. Taking this unusual path has resulted in developing a wide variety of interests and improved my ability to interact with patients and discuss any number of subjects with them."

And if the patients didn't want to discuss Shakespeare, Dr. Hosea could always talk to them about crew. "I continued rowing at Harvard, but after awhile injured my back. I was so lucky to meet and be treated by Dr. Arthur Boland, someone who has been my mentor ever since. A wonderful, compassionate human being, Dr. Boland was a stellar athlete. I knew instantly that this was someone I wanted to emulate."

This also came as a great relief to Tim Hosea's father. "My dad was really concerned that I would end up as a 'rowing bum,' and was so thrilled when I applied to medical school."

Medical Training

Taking up the medical mantle, Tim Hosea began his studies at the University of Cincinnati College of Medicine in 1975. "The admissions director was an Ivy League veteran with the attitude that if we jocks would just channel our athletic energies into medicine then we would be excellent doctors. There were 192 of us, with about 100 from Ohio and the others from Ivy League or Division I athletic programs. While there, I did a rotation at Harvard, during which time Art Boland let me housesit. Spending time at the Harvard affiliate, the Peter Bent Brigham Hospital (now known as the Brigham and Women's Hospital), exposed me to top quality professionalism and a terrific bunch of people."

At Cincinnati, he spent two years working with Dr. Frank Noyes, getting "under the skin" and "behind the scenes" of orthopedic research, things which would give him a more sophisticated understanding of his chosen profession. "After finishing medical school in 1978 I went to Peter Bent Brigham Hospital for two years of general surgery. We didn't do much in the way of orthopedics, but we certainly learned how to take care of patients."

"Today's orthopedic residents do not receive the depth of experience in general surgery and the related specialties, but rather concentrate on the aspects of medicine related to orthopedics. Although they say that there is not enough time in a training program for this in depth experience in patient care, I think it is important to have a working knowledge of your patients' medical issues because there is a chance they will influence your decisions and the results of your work.

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Open Reduction of Fracture Tarsals & Metatarsals w/ Internal Fixation	79.37

You should not simply get a consult, but should know something about the pathophysiology of the person's condition."

In 1980, Dr. Hosea entered the combined Harvard Orthopedic Residency Program. "I did my orthopedic residency at Harvard, and was pleased to find that it was a truly well rounded program. We were able to work closely with the best and the brightest of all the Harvard hospitals, and learn a variety of approaches to orthopedic problems. Boston itself was unusual in the collegiality among attendings, something that didn't seem to be present in other cities. We had heard lots of negative stories coming out of other cities, so we were really happy to have a great atmosphere in which to work."

Advice from His Mentors

That atmosphere included savvy senior surgeons. "Dr. Drennan Lowell, a joint replacement specialist at Brigham, was one of the innovators in hip replacement. He displayed meticulous attention to detail as he worked on evolving the techniques. Dr. Bert Zarins of Mass General taught me how to focus and how to approach patients. Interestingly, he said that we should treat each patient as if he or she were a member of the carriage trade, i.e., treat them all as if they were the President."

Undertaking a fellowship with Dr. Art Boland, Dr. Hosea would watch a master of common sense and patient care at work. "Dr. Boland always displayed great surgical judgment and technical skills. One of the most important things I learned from him was that when patients have a non life threatening issue and they can't make up their minds about what to do, you should say to them, 'Is this a nuisance or disability?' That inevitably helps focus their thought process."

Dr. Hosea also learned how to tackle decision making on the field. "I worked alongside Dr. Boland as he cared for the Harvard athletic teams. It was a real eye opener to see the interactions between the doctors, the athletic trainer, and the coaching staff. The trainers were often on the firing line and our job as physicians was to ensure that we backed them up and gave them as much information as possible."

To those who might consider such work, Dr. Hosea, now the doctor for the U.S. Olympic Rowing Team, says, "Working with teams requires a different skill set. You must interact appropriately with coaches whose agendas are often different than your own. But as the coaches develop confidence in your skills, you can establish a comfortable working relationship with them. The athletic trainers are often stuck in the middle and require a supportive medical staff to make their job easier and enable the medical team to provide the best care for the athletes."

Finishing up his fellowship in 1985, Dr. Hosea headed to New Jersey. "My wife is from Princeton and I was lucky to be able to join a practice there and take care of intercollegiate athletes. Our practice had an established orthopedic residency affiliated with UMDNJ-Robert Wood Johnson Medical School. This provided me with the opportunity to teach and try to be the example my mentors were to me for the next generation of orthopedic surgeons."

Research, Education and Gold Medals

"Working with industry" usually means being with people who know something about tibial plates or pedicle screws. For Dr. Hosea, however, it meant joining forces with "Detroit." "My research into the biomechanics of the back, work that I had begun as a resident, led to consulting with General Motors on the design of car seats. We determined that there is only a limited range of motion that a car seat and lumbar support needs to cover to have the least amount of spinal load. Interestingly, you don't need an extreme amount of lumbar support."

Dr. Hosea also imparts knowledge in the educational realm. "I teach residents, something I find to be very rewarding. Today's residents are as motivated as we were, but because of their training programs, they are more focused on the orthopedic aspect of the patient instead of the whole patient. With regard to decision making, we have noticed that they lacked exposure to outpatient experiences and the thought processes of the orthopedists, so we have started providing them with more outpatient experiences."

On the research front, Dr. Hosea is involved in helping rowers work with their oars and work out their back problems. "We are seeing more

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and more adolescent and young adult rowers with disc disease. My colleagues and I are documenting this and working the patients up aggressively with MRI's and X-rays. We have an IRB approval and are in the process of collecting data. To alleviate their pain, we advise the patients to work on their core strength and crosstrain so they don't aggravate their injuries. We also tell them how to appropriately use the ergometer rowing machine, and how much resistance to use. The good news is that we can reassure these young athletes that even though rowers have more back problems amongst the intercollegiate population, this reverses later in life. We think this is because rowers tend to stay in shape, refrain from smoking, etc."

In 2000 Dr. Hosea was called upon to not only look after rowers on the international stage, but cyclists, equestrians, and a host of others. "I served as a physician for the 2000 Olympics in Australia, an exhilarating, yet exhausting experience. During the six weeks I was gone, I took care of rowers, canoe-kayakers, and cyclists. One of our rowing athletes had a lumbar disc problem a week before the Olympics began, and I had to call a hospital in Yamba, Australia, the site of our training camp, and ask for the labor and delivery nurse who gave the best epidural at her hospital. He got it…and he medaled."

To those who may be working with Olympic athletes for the first time, Dr. Hosea advises, "*Any* complaint is a major issue for them and should be taken seriously. The Olympic games are what these athletes have been working toward all of their lives… nothing they mention should be denigrated."

And his most interesting day at work? "We recently had a situation where a female athlete was in pain and had a history of medical problems. Our medical doctor thought she shouldn't play, but she was adamant; the coach sided with the player. So I went to the President of the club and he stepped up and said that she could not play. Such a decision is best left to the medical staff…fortunately the President supported us."

For support on the home front, Dr. Hosea turns to his wife and three daughters. "I have been married to the same dynamic wife for 34 years. We live on a farm and she is the one who keeps it running. We had a particularly exciting event a couple of months ago when I delivered my first foal. My daughter and I happened to be around when the horse started labor, so we helped her out."

Dr. Tim Hosea…delivering whatever is necessary to get the job done.

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