VOLUME 6, ISSUE 16 | MAY 18, 2010

Orthopedics This Week

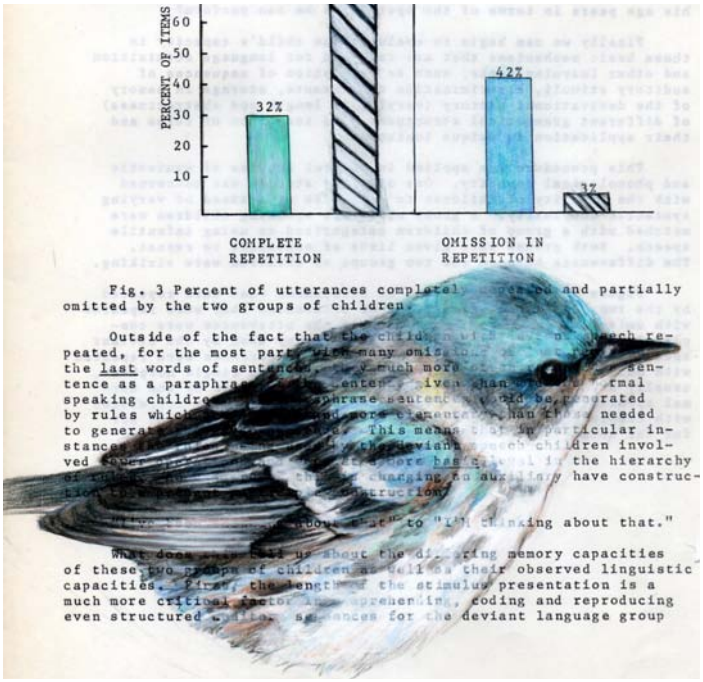
week in review

5 **Beautiful Evidence** ✦ Standards of quality, relevance and integrity in medical research are diminished by audience indifference, PowerPoint presentations and the passive voice. Beautiful evidence is hard won and not often found in today's standard 10-minute flash card presentation. Time for an antidote.

9 **"Where Have All the Women Gone?"** ✦ Half the patients are women, but fewer than 10% are the doctors. What's with the women? Why don't they go into orthopedics? Laura Gehring, President of the Ruth Jackson Orthopedic Society, a women's society within AAOS, is trying to find out.

12 **After Closing: Spine Postop Protocols** ✦ The postoperative phase of surgery is vital to the procedure's success…and begins preoperatively. So say our experts, Dr. Carl Lauryssen, Dr. Stephen Hochschuler, and physical therapist Jason Brewton, who also detail what to tell patients.

15 **A Picture of Costs** ✦ Proviers and manufacturers who want the clearest "picture" of the total economic costs of orthopedic devices and procedures, now have a tool to measure the cost effectiveness of their work. See the presentation from the folks at Zimmer that won a "Best of Category" award at AAOS.



picture of success

30 **Dr. Christopher Bono** ✦ He was accepted into medical school as a senior in high school and has developed a talent for meta analyses. Learn more about Dr. Christopher Bono, Chief of the Orthopedic Spine Service at Brigham and Women's Hospital in Boston.

breaking news

20 Gymnastics an R**x for Bone Strength**

Alphatec's 1Q10: A Good Start

Bone Solutions Inc. Broadens Its Horizons

Only a **Fraction of Fractures** Properly Addressed?

Whistleblower Blown-Out in Michigan

Cartilage **Regeneration** Breakthrough

MAKO's 1Q10 Mixed Bag

For all news that is Ortho, read on.

Can't remember the last time you "tuned up" your procedure and reimbursement reports?

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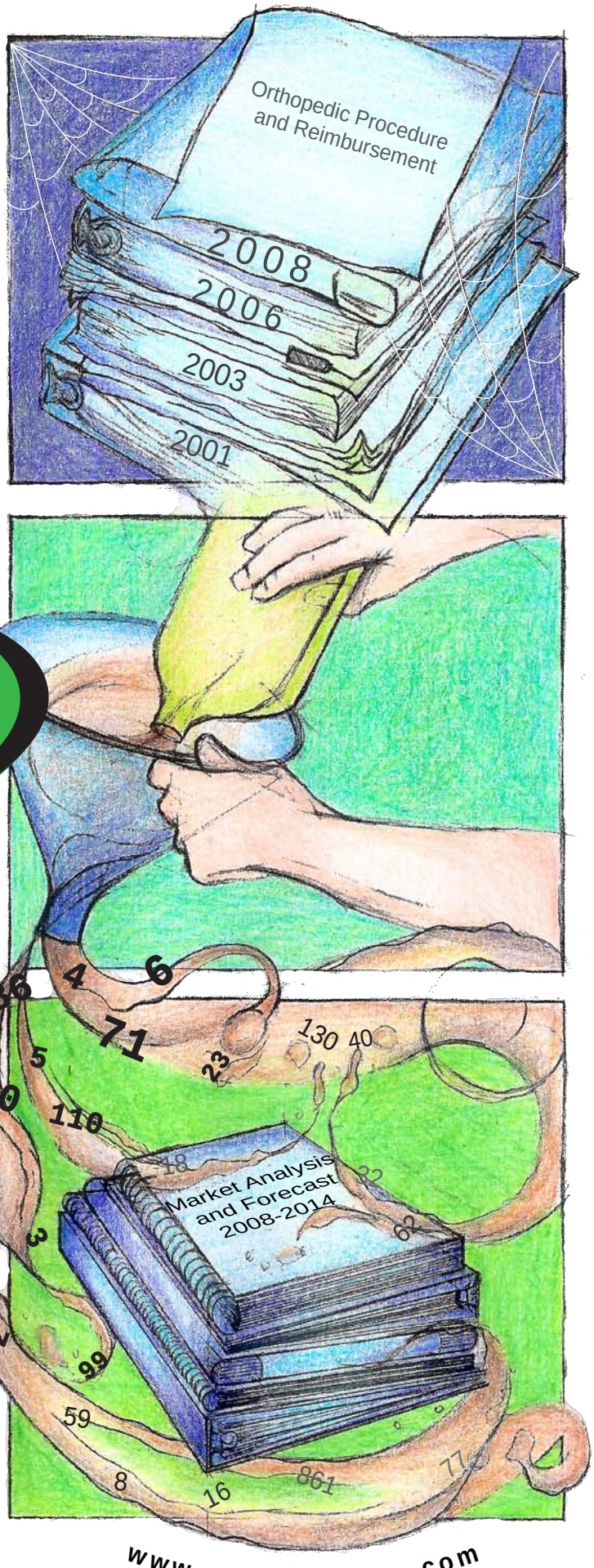

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Orthopedics This Week

VOLUME 6, ISSUE 8 | MAY 18, 2010

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Every bull market has comes face to face with a seemingly relentless string of bad news. Increased government regulations. New taxes. Lower reimbursement. It's called the Wall of Worry. And it usually obscures other facts, like better-than-expected sales and earnings reports and a fundamentally healthy demand for products.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Stryker	24.71%	(2.17%)	Upgraded by Barclays as SYK's expected sales and earnings growth rates move higher.
2	2	Zimmer	27.69	(2.41)	JP Morgan upgrades ZMH to "Overweight." With the 3rd lowest future PE, ZMH is certainly cheap.
3	3	Johnson & Johnson	27.1	(2.32)	JNJ has raised its dividend consistently for more than a decade. Current yield is 3.10%.
4	4	Symmetry	11.48	10.85	Management raised the sales and earnings outlook for 2010. Could the worst be over?
5	5	Exactech	12.61	(5.04)	Management has beaten Street's expectations four quarters in a row. Consensus is for flat earnings this quarter. Yeah, right.
6	7	Integra LifeSciences	15.37	(5.17)	So quiet these days at IART. With a dozen analysts covering, someone must think something.
7	6	Orthofix	11	(10.59)	Investor are having a hard time understanding OFIX. Only six analysts covering. Can't "grok" rising cash flows?
8	8	Medtronic	31.37	(7.26)	According to Wall Street, the current quarter will be the best of the year for MDT.
9	10	Alphatec	-0.44	(2.58)	Wall Street is expecting nothing but profits from here on out. On paper, should work.
10	9	CONMED	7.73	(14.32)	CL King (who?) upgrades CNMD to "Neutral." Frankly, we think CNMD will beat the Street this quarter—again.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Symmetry Medical	SMA	$11.65	$419	10.8%
2	Kensey Nash	KNSY	$23.69	$239	6.3%
3	Mako Surgical	MAKO	$14.24	$481	4.6%
4	Osteotech	OSTE	$4.28	$77	0.9%
5	Stryker	SYK	$56.46	$22,400	-2.2%
6	Johnson & Johnson	JNJ	$63.97	176,040	-2.3%
7	Zimmer Holdings	ZMH	$59.56	$12,080	-2.4%
8	Alphatec Holdings	ATEC	$5.66	$306	-2.6%
9	Capstone Therapeutics	CAPS	$0.87	$35	-3.3%
10	Wright Medical	WMGI	$17.72	$688	-3.6%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGBO.PK	$0.15	$1	-77.3%
2	Orthovita	VITA	$3.38	$260	-25.7%
3	TiGenix	TIG.BR	$2.90	$89	-19.5%
4	RTI Biologics Inc	RTIX	$3.67	$201	-17.3%
5	CONMED	CNMD	$21.33	$622	-14.2%
6	CryoLife	CRY	$5.71	$164	-12.3%
7	TranS1	TSON	$3.18	$66	-10.7%
8	Orthofix	OFIX	$34.02	$599	-10.6%
9	ArthroCare	ARTC	$28.31	$763	-10.2%
10	Smith & Nephew	SNN	$47.55	$8,450	-10.0%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Kensey Nash	KNSY	$23.69	$239	12.86
2	Medtronic	MDT	$42.39	$46,690	13.08
3	Johnson & Johnson	JNJ	$63.97	176,040	13.71
4	*Average*			*$11,497*	*13.95*
5	Zimmer Holdings	ZMH	$59.56	$12,080	14.35

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$47.55	$8,450	67.14
2	RTI Biologics Inc	RTIX	$3.67	$201	61.02
3	NuVasive	NUVA	$41.74	$1,620	37.74
4	Symmetry Medical	SMA	$11.65	$419	23.25
5	CONMED	CNMD	$21.33	$622	19.59

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CryoLife	CRY	$5.71	$164	0.65
2	NuVasive	NUVA	$41.74	$1,620	0.94
3	Smith & Nephew	SNN	$47.55	$8,450	1.05
4	Alphatec Holdings	ATEC	$5.66	$306	1.06
5	Orthofix	OFIX	$34.02	$599	1.17

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CONMED	CNMD	$21.33	$622	8.82
2	Symmetry Medical	SMA	$11.65	$419	2.20
3	Johnson & Johnson	JNJ	$63.97	176,040	1.88
4	RTI Biologics Inc	RTIX	$3.67	$201	1.76
5	Average			$11,497	1.70

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$4.28	$77	0.80
2	CONMED	CNMD	$21.33	$622	0.90
3	Orthofix	OFIX	$34.02	$599	1.10
4	Symmetry Medical	SMA	$11.65	$419	1.16
5	RTI Biologics Inc	RTIX	$3.67	$201	1.32

Highest Price to Sales Ratio (TTM)

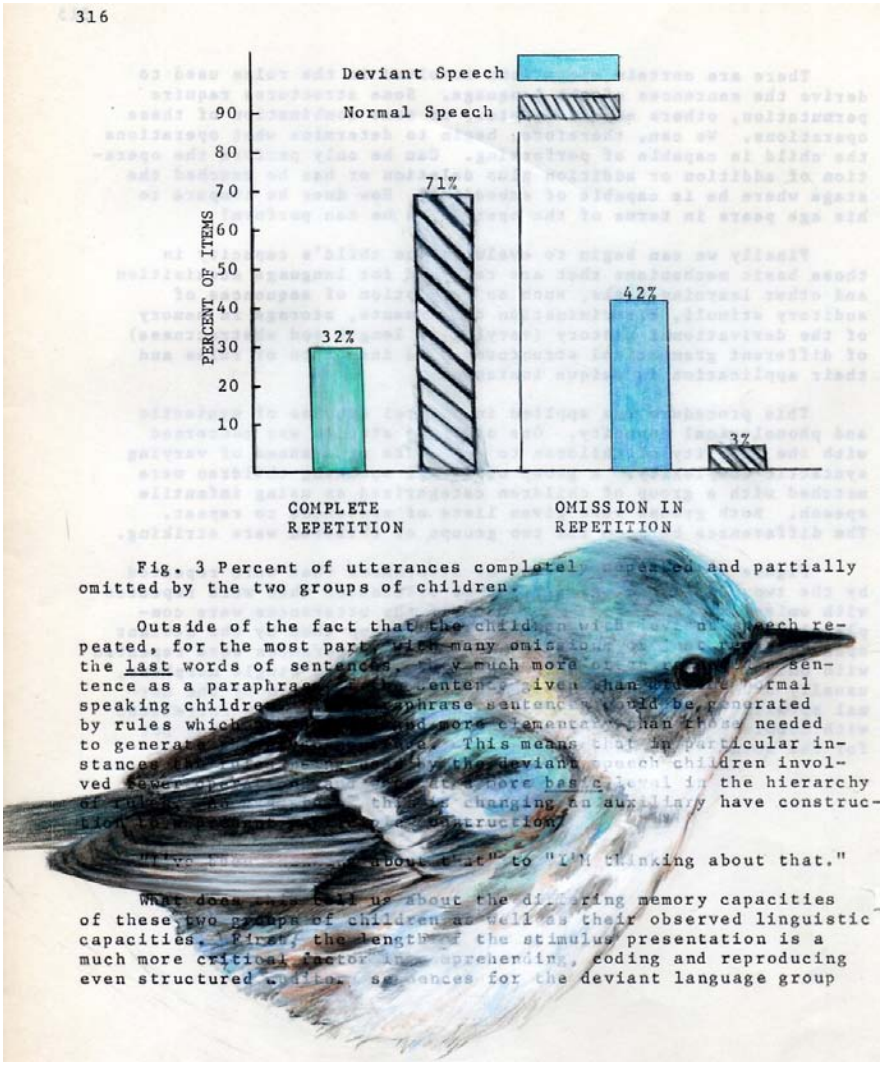
	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$2.90	$89	86.65
2	Mako Surgical	MAKO	$14.24	$481	12.75
3	NuVasive	NUVA	$41.74	$1,620	4.16
4	Synthes	SYST.VX	$115.06	$13,655	4.02
5	Stryker	SYK	$56.46	$22,400	3.29

Orthopedics This Week

VOLUME 6, ISSUE 8 | MAY 18, 2010

Beautiful Evidence

By Robin Young



Artist: Paula Swisher

With special thanks to Dr. Edward Tufte and his many books on this subject.

Another article lands on my desk for editing. I hold my pen like a sword, poised to pierce every passive sentence I spot. I hate passive sentences. Passive sentences are *effects without causes*. In a passive sentence there is no actor. We don't know who made the plan, *who* did not follow up, *who* performed the surgery. It's immaculate conception! A depressingly large percentage of writers think that a passive voice conveys a tone of authority. It doesn't. Writers who use the passive voice, whether they realize it or not, are avoiding responsibility by describing an effect without a cause or actor.

No doubt, the preceeding lecture sounds uncomfortably familiar to a fair number of former freshman English students. But it should also ring a bell among surgeons because there also exists a passive voice in clinical studies and statistical reasoning.

I suppose I attend roughly a six or seven surgeon society meetings a year. I spot the passive voice in *many, maybe* most podium presentations. Perhaps I'm attending the wrong meetings. At any rate, some years back, I took a famous surgeon to task on these very pages for his anti-causal, jumble of effects without causes presentation. He

may not have appreciated the criticsm but perhaps his next talk was sharper.

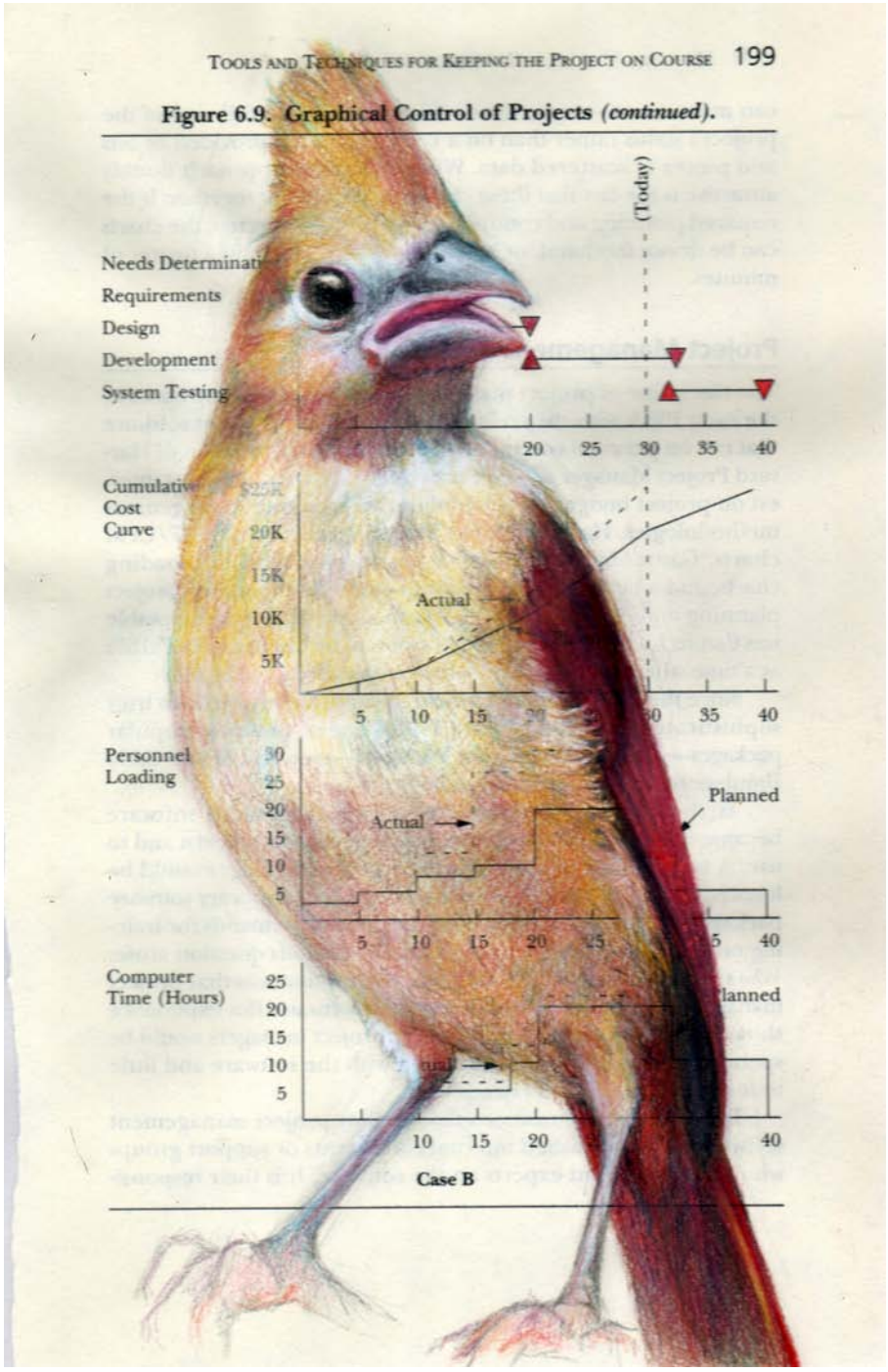
Audiences need to spot causality-from-nowhere in podium presentations. And then stand at the microphone and ask questions about causality. "So Dr. Famous, you gave data about x, y and z but you did not describe the cause associated with this effect. What did we *learn* that is relevant to my practice or this particular disease state?"

I can easily recall PowerPoint presentations where the presenting physician shoveled loads of information at the audience but had no ideas. Many times we hear the passive voice (no actor, no person doing or not doing something) in verbal reasoning and then sit back as the speaker uses techniques like data mining, factor analysis or multi-dimensional scaling to reduce data to digestible bites and never mentions a cause or causal model.

The lesson for speakers and audiences is to remember that data crunching is the means to a goal, which is evidence about a causal process. When researchers at the podium do that, then their talk becomes one of those great and too rare moments of clarification, insight and, yes, beauty.

Dr. Famous and Substituting Enthusiasm for Evidence

A very important Boston surgeon visiting the University of Arizona's medical school a few years back gave a great treatise on a large number of patients who had undergone successful heart valve surgery. At the end of the lecture, a young student at the back of the room timidly asked, "Do you have any controls?" Well, the great surgeon drew himself to his full height, hit the desk, and said, "Do you mean did I not operate on half of the patients?" The hall grew very quiet then. The voice at the back of the room very hesitantly replied, "Yes, that's what I had in mind." Then the visitor's fist really came down as he thundered, "Of course not. That would have doomed half of them to their death." The room was quiet and one could scarcely hear the small voice ask, "Which half?"



Artist: Paula Swisher

(Paraphrased from a story told by Dr. E.E. Peakcock, Jr., University of Arizona College of Medicine; as quoted in *Medical World News* (September 1, 1971), p. 45.)

In 1966, Drs. Grace, Muench and Chalmers (some of the most prolific proponents of evidence-based medicine) published a meta analysis of 53 published papers evaluating portcaval shunts for esophageal surgery ("The Present Status of Shunts for Portal Hypertension in Chirrhosis" Gastroenterology 1966, 684-691). The investigators rated each study according to its level of enthusiasm of the findings for the surgery and cross referenced that against the quality of the research design.

The researchers defined quality of research design as the level of random assignment of patients to treatment or control. Poor quality studies did not compare the treatment group with any proper control. The better quality research designs were those which assigned patients randomly to the treatment or the control group.

Of the 53 published studies, 6 were randon control treatment (RCT) and 47 were not. None of the RCT studies were enthusiastic about the surgical intervention. Not so for the 47 studies lacking valid controls. Thirty-four of those studies expressed marked enthusiasm for the surgery. Or put another way, 72% (34 of 47) of the non-randomized studies endorsed a surgical procedure that the gold standard studies did not.

If nothing else, this offers strong support for more meta-analysis and, again, pulling the medical reality—the cause, in other words—out of the descriptive statistics that pass for data.

One last point here: how often is the first published study testing a new technology the study that provides the strongest evidence that will ever be found for that treatment? (I'm thinking about you BAK).

That tendency (noted in the paragraph above) is why we were so impressed with the SAS meeting two weeks ago. The organizers of the program made a special effort to organize more than the usual number of Level One (highest level of RCT studies) studies and there were several long-term (up to five years) RCT follow-up studies with high numbers (500 to 800) of patient participants regarding motion preservation implants. The strong message of those eighth, ninth and even tenth study of motion preservation is that these new surgeries are ***evidence-based improvements*** over fusion surgery for many patients.

Bullet Points, PowerPoints and Points of View

Let's talk about your treatment. And use sentences with subjects, verbs, predicates and nouns and employ the time-tested technique of combining information sequentially to form paragraphs with compete thoughts.

Or, alternatively, we can use a PowerPoint presentation to talk about your treatment.

Which approach encourages a thoughtful exchange of information and a mutual interplay between speaker and audience? Which approach amounts to a sales pitch with bullet points?

Microsoft's PowerPoint is the fast food of information. To quote Dr. Edward Tufte, Profesor Emeritus at Yale University where he teaches courses in statistical evidence, analytical design and political economy, "PowerPoint comes with a big attitude. It forces presenters to have ***points***, some points, any points. Audiences, therefore, endure a relentless sequentiality, one damn slide after another. Information stacked in time makes it difficult to understand context and evaluate relationships. Visual reasoning usually works more effectively when the relevant evidence is shown adjacent in space within our eyespan. This is especially the case for statistical data, where the fundamantal analytical task is to make comparisons." (From "Beautiful Evidence" by Edward Tufte, 2006, Graphics Press LLC, pp: 158-159).

In order to, in effect, overcome the "attitude" of PowerPoint, speakers must have strong content, self-awareness and an analytical style that neutralizes or avoids the PowerPoint style. Otherwise, the danger with PowerPoint is that by reducing information to five to seven bullet points per slide, statistical reasoning becomes almost impossible and verbal and spatial thinking is perhaps fatally weakened.

To quote Dr. Tufte again, PowerPoint sets up "a dominance relationship between speaker and audience, as the speaker makes power points with hierarchical presenatation bullets to passive followers." In a typical PowerPoint slide, the lack of space for words pushes presenters to create imprecise statements or slogans if not outright clichés.

What's a good antidote for the ubiquitous PowerPoint presentation? A paper handout. Within the slides themselves, try to provide content-rich graphics and a clear context for data with comparisons offered. The key, I think, is to create the conditions in a meeting for several modes of learning and interplay between speaker and audience.

Fair Enough, What's the Point?

When it comes to medical technologies, evidence is the best way we know of for answering complex questions involving biology, patient, surgeon, and product variabilities and interactions. But the manner in which presenters are delivering these 10 or 15 minute flash cards of information is not delivering, in fact, beautiful evidence. Presenting physicians and their audiences, together, need to re-commit to linking effects to causality and to raising the quality, relevance and integrity of podium presentations across the board.

In short, ruthlessly cut out those passive sentences and bullet point evasions. Because, in fact, there are some veryworthy technologies, procedures and patients who would benefit. ✦

"Where Have All the Women Gone?"

By Billie Young

Women make up more than 50% of the population, comprise half of all students in medical school and are 30% of the gowned and masked individuals practicing general surgery. However, if you are looking for women in orthopedics you have to search hard to find them. Until a few years ago, barely 3% of female surgeons went into orthopedics. While that number is now a bit south of 10%, orthopedics still has the lowest number of women of any sub-specialty.

What is going on here? That is something that orthopedic surgeon and President of the Ruth Jackson Orthopedic Association (RJOA), Dr. Laura Gehrig, would like to know. "Historically, there were very few women in any kind of surgeon specialty," she said. "As time passed women gained ground in medicine in general, but they just have not broken into ortho." The Association is trying to figure out why. Are women being discouraged—told that they do not have the necessary upper-body strength, or lack aptitude because they may not have played with tools or built models as children?

Gehrig calls such reasons myths saying that she knows many women who are accomplished total joint surgeons. "Part of the problem is they fear they cannot have a family and home life—that orthopedics is more demanding than other specialties." While insisting that that, too, is a myth, she admits that orthopedic residencies can be a lot of work and noted that the most common injury presented to emergency rooms is a musculoskeletal injury for which an orthopedist is called.

Inspired by her work with polio patients, Ruth Jackson, the namesake of the organization, became the first practicing woman orthopedist in the U.S. She graduated from the University of Iowa in 1932 and opened her office in Dallas, Texas. When the American Academy of Orthopedic Surgeons (AAOS) was founded a year later it invited all orthopedists to join—except Dr. Jackson. Undaunted, she passed the Board Exam in 1937 and became the first woman to be certified by the American Board of Orthopedic Surgeons and, subsequently, the first woman admitted to the AAOS.

The Association that now bears Jackson's name was founded in 1983 and is a separate society within the AAOS. It focuses on the body of health knowledge that affects woman, musculoskeletal issues for women, and encourages women in medical schools to apply for orthopedic residency programs. The founding women doctors, besides Jackson, were Liebe S. Dia-

Dr. Laura Gehrig

tive Americans have sturdier bones than do Whites and Asians. "If an African-American male comes in at the age of 60 with a broken hip, something else is really going on," she says.

Gehrig went to medical school at the age of 32, after marriage and with four children. She earned her undergraduate degree from the University of Saskatchewan in Saskatoon and her M.D. from Louisiana State University in Shreveport. She believes that her interest in orthopedics came about because of her father's talents as a mechanic and her participation in sports.

"My father fixed everything around the house and I was with him while I was growing up. Then I played all kinds of sports—baseball, soccer, basketball, volleyball. I was third baseman on a baseball team for 14 years, until I was 22." She also had an interest in basic science and was fascinated by metabolism, by the fact that bones can heal without leaving scars.

Her desire to "fix things" is reflected in what Gehrig most enjoys about orthopedics—dealing with trauma. "It is a matter of helping people get back to normal, of healing them. It is mostly the ordinary, hard-working people who are just doing their jobs when an accident happens who are most grateful for the help you can give them." She recounted a recent accident in which a young man was brought

mond and Mary L. Morden, of Baltimore; Sandra Thompson of Boston; Jacqueline Perry of Downey, California and Mary Ann Shannon, Minneapolis. The association now has just under 600 members.

Gehrig points out that a doctor's approach to an orthopedic woman patient should be different from that to a man. "Men have stronger bones than women," she notes. "If a 60-year-old man comes in with a hip fracture from a fall from no greater than a standing height, I look for something else going on. Is he a smoker? Does he have COPD? Is he on steroids? If a woman comes to me with a hip fracture from a standing height I think more of osteoporosis based on estrogen withdrawal."

Gehrig also notes differences based on ethnicity. African-Americans and Na-

into the emergency room with an open femur fracture and a severe knee injury from a truck having fallen on him. Gehrig cancelled her clinic for the day and took him immediately into surgery. When, eight and a half hours later, she emerged from the operating room to meet with the young man's parents, they were so grateful for her work that the boy's mother asked if she could hug her.

Gehrig's other area of interest is osteoporosis and she works at prevention—getting her young patients to take calcium and vitamin D. She has found that a high percentage of girls between the ages of 8 and 13 are so deficient in those minerals that, if not corrected, they will begin to experience bone loss by the time they are in their 30's.

Gehrig is aware that mentoring of individuals has been significant in helping women enter and become successful in the field of orthopedics. During her year as President of the Ruth Jackson Orthopedic Association she wants to collect and publish the stories of the mentors, men and women, who have helped develop this generation of surgeons. "I want to pay tribute to them," she says.

And lay the foundation for more women in orthopedics.

For more information about the Ruth Jackson Orthopedic Society go to www.rjos.org. ✦

After Closing: Spine Postop Protocols

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

Jason Brewton, Director of Physical Therapy, Texas Back Institute, instructing a patient on a lumbar stabilization exercise

Open, operate, close. But "closed" doesn't mean "finished." While the rehabilitation phase of treatment involves less work for the doctor and more for the patient, the surgeon must stay involved and guide the process.

Dr. Carl Lauryssen, a neurosurgeon and Director of research and education at the Olympia Medical Center in Los Angeles, states, "Many surgeons think that once they are done in the operating room, then their work is complete. The postoperative phase is vital to the success of the surgery, and actually begins preoperatively."

Part of the surgeon's mission, says Dr. Lauryssen, is putting the brakes on a runaway mindset. "You must prepare patients so that they have reasonable expectations of the surgery, including the vital issue of pain levels. Additionally, the closer patients are to their ideal body weight the less the surgeon will have to wade through operative adiposity—postoperative rehab will also be less onerous for the patient. We live in a fast food/immediate satisfaction society and patients tend to apply that mentality to surgery. Surgeons must explain to patients that their behavior affects the outcome, meaning that we must talk to them about nutrition, refraining from smoking, realistic expectations, etc. It always amazes me how we can perform the identical surgical procedure for a given pathology, with stellar results on one side of the spectrum, and slug results on the other!"

Taking microdiscectomy and lumbar spinal stenosis as examples, Dr. Lauryssen states, "Assuming that all went well, the person can go home the same day or the next. Discharge planning should be thorough at the preop clinic visit, with the surgeon and patient discussing the post operative risks. For patients, red flags include fever, pus, and redness around the incision, all of which are more likely to occur during two weeks postop. Constipation is also a problem for many patients, and the surgeon should start the patient on medication immediately after surgery."

And if Mr. Jones does have to eat hospital food one more night? "The reason someone stays one day versus two is pain. If the patient has been working with a pain specialist and is on significant narcotics before surgery then their stay is usually longer. It is also harder to control that person's pain post operatively, so we try to get these patients to reduce their pain meds preoperatively."

You may have 18 people in the waiting room, but don't skimp on preop time with the patient. "Patients should know that it is normal to have swelling in the incision region, and that it could resemble a golf ball cut in half. If there is no redness or swelling, they are fine. If they see a reddened area surrounding the operative site, they should take a permanent maker, circle it, and then assess it the next day. If the redness increased in area then they should see the doctor immediately."Also ensure that patients understand the nuances of postop physical sensations, recommends Dr. Lauryssen. "It is normal for

specific preop pain to be significantly reduced after surgery, but there is a memory to the pain and some patients feel it come and go for the first few weeks. And if patients had numbness before surgery then they expect it to be gone afterwards. The fact is that numbness may last forever and can even be a little worse postop. On the activity front, if the patient sits or stands too long then a mild version of these symptoms can return."

Resistance to doctor's suggestions—bad. Resistance in the physical therapy (PT) realm—good. Dr. Lauryssen: "At six weeks postop I send patients to PT, where they start with isometric exercises and gentle range of motion movements. A good physical therapist understands the healing that is underway and that if he or she is too aggressive that the sutures—or a muscle—will tear."

"At three months I release patients to unrestricted activity. Before that there is a logical progression of appointments and activity. Clinically, it is useless to see them in the first week; it is also difficult for them to get into a car. In the second week they are somewhat irritated and realizing that the surgery may not have done what they had expected. I see them in the third week… they are normally over the worst, and are happy to see me! Also, I don't let them lift anything heavier than 10 pounds, for the first three weeks."

Dr. Lauryssen covers the details with the patients…but not the incision. "I was trained to cover incisions and make them water tight. I now think they need to be aired; Dermabond is great. I recommend a 'sailor's shower'—they get in the shower, wet the body and then turn the water off. They soap up (avoiding the incision), and then wash their hair, rinse off, and they are done. There is no direct stream of water on the incision. They emerge and put on loose fitting clothing…no bandage."

After all this, they may need a nap. But then they recall Dr. Lauryssen's advice. "I allow patients to sleep however they feel comfortable, and make sure they know that medication, surgery, and anesthesia are going to alter their sleep for awhile. Sleeping pills aren't the answer because that will just exacerbate the problem. And no napping as they need to get back to their regular schedule. Managing pain is the most common problem patients have after surgery. Pain meds need to be taken on a regular schedule for the first two weeks, even setting the alarm to wake them at night to stay ahead of the pain curve."

"They should avoid significant bending, twisting, and lifting until the three-week visit. At that time I increase their weight limit to 20 pounds and allow them 50% range of motion. Most important is that patients avoid the combination of bending and twisting."

To drive this, and other points home, Dr. Lauryssen makes use of the website, www.graphicsurgery.com. "This uses 3D animations without the blood and gore to educate patients about their surgery, document their viewing. It also helps to reduce liability exposure as an informed consent tool." Dr. Stephen Hochschuler, Chairman and Co-Founder of Texas Back Institute, is so committed to the preop part of postop that he gently corrals patients into a class of sorts. Dr. Hochschuler: "I tell patients that most surgeries I perform aren't emergencies and that they could likely live with their situation. Now if someone is at an '8' on the pain scale they will probably need surgery—but I will never tell that person that he or she will be at a '0' postoperatively."

"Twenty years ago we began filming educational videos in English and Spanish that included surgical indications and potential complications. Patients sat down with a nurse and an anatomic model, watched the video, and signed a document indicating that they saw the film and had their questions answered. Now we have interactive CDroms that include questions at the end. If patients answer incorrectly they must return to that part of the CD. We also send our patients

to a website I helped develop—www.spine-health.com—which contains interactive depictions of the surgery."

The prescription pad is underused in the postop realm, says Dr. Hochschuler. "While most doctors send patients to PT, rarely do they write a specific prescription. Rehabilitation is a team approach, and orthopedists should reach into the physical therapy world and specify the exercises that will result in the best healing process. I prescribe aerobic conditions, spine stabilization, and core strengthening. I also order kinetic chain (core stabilization) exercises, something that nine out of ten spine surgeons don't order. All of this must be patient-specific… therapy is not therapy is not therapy."

No one knows that better than an experienced physical therapist. Jason Brewton, Director of Physical Therapy for Texas Back Institute, states, "PT is quite effective, and most patients are committed to post surgical physical therapy. Those who don't engage in therapy and need future surgical revision always lament that they didn't stick with PT the first time."

Breaking down the process, Brewton states, "The first phase involves calming the tissues, reducing swelling, and protecting the surgical repair through the use of isometrics. This is followed by the initiation of supervised PT (stabilization, restoration of flexibility, and proper body mechanics). The third phase involves restoring recreational activities, return to work, and restoration of functional capacity."

"With fusions we have to aggressively protect the graft and promote fusion, meaning that we limit range of motion (ROM) exercises for about three months. (This also lets the tissues calm down.) The doctors want to see radiographically that the fusion is taking well before they start ROM exercises in the immediate surgical region."

The physical therapist also dons the mother hen hat with regard to discectomies and laminectomies, says Brewton. "For these patients, we must limit flexion and extension to protect the surgical site for the first three weeks, and limit rotation for six weeks. When the surgeon has removed the lamina or a portion of the disc we want to reduce stress to the healing structures."

Other surgeries—such as total disc replacement—are less restrictive. "There are no ROM restrictions except for in the extension plane because we could possibly dislocate the prosthesis. In general, we don't allow any extension for the first six to eight weeks depending on how the patient is healing."

To orthopedists who might overlook the power of physical therapy, Brewton states, "Patients are only going to value the rehab process as much as the doctors do. If surgeons don't spend time discussing why it's important to engage in PT then patients aren't going to do it thoroughly. We have had patients who had surgery elsewhere and the doctor put no importance on rehab…the patient was given a list of exercises, but was essentially hung out to dry and had a poor post surgical outcome."

How to define surgical success is a growing area of interest in the field of orthopedics. All told, surgeries s tand a better chance of being labeled a success if the physicians take an assertive attitude toward postoperative rehabilitation. ✦

A Picture of Costs

By Walter Eisner

Photographer/Wikimedia commons

Do we really understand the economic value of the orthopedic surgeon compared to, for example, the hospital, or device or alternative treatments or procedures?

What percentage of the total patient cost for a disease condition is attributable to rehab therapies, pharmaceutical treatments, the surgeon, the hospital or other variables?

Limited data is available. Few studies have tackled the multi-variable total "economic cost" of total joint arthroplasty (TJA) surgeries.

Many obstacles prevent researchers from performing such costs studies. Those obstacles include opaque cost and pricing policies at the hospital level, confidential purchase contracts between device manufacturers and hospitals, and antitrust prohibitions against physicians talking to each other about pricing or sharing information for collective bargaining.

Because of limited data, surgeons have had a difficult time negotiating effectively with hospitals about the allocation of resources for orthopedic investments and payments.

In an era where the overall rise in healthcare costs, an overly committed public purse, and newer technologies are trying to claim a share of available healthcare dollars, surgeons are under increasing financial stress to prove the cost effectiveness of their work.

Total Cost of Total Joint Replacement Surgery

Understanding the total cost of treating orthopedic patients throughout all the stages of the disease process and then correctly measuring orthopedic specific related treatment costs is vitally important to device manufacturers as they develop and introduce new products into the market.

Zimmer's Global Market Access Group, led by the group's Director, Ryan Graver presented a paper at the recent AAOS (American Academy of Orthopaedic Surgeons) meeting in New Orleans titled "Cost of Illness Models for Primary TKA and THA Procedures in the United States." It was the first comprehensive analysis of the total costs of total joint replacement drawn from both Medicare and commercial payer data. The presentation was selected as Best in Category by the AAOS committee for Practice Management and Rehabilitation.

Ryan Graver/Zimmer

Few studies have comprehensively investigated the direct cost of both orthopedic and non orthopedic associated care, longitudinally, for both Medicare and commercial insurance patients.

High Surgeon Interest at AAOS

Graver said the presentation garnered a good deal of attention at AAOS and received positive feedback from surgeons. "This type of information—showing how much potential revenue is generated over time by knee and hip procedures—had not previously been published. Most surgeons expressed surprise at the total levels of revenue generated by total joint arthroplasty procedures and were excited to discuss with their hospital administration the potential value that these orthopedic procedures can generate for a health system."

Hospital Opaqueness

Hospitals have reported conflicting information about the economic value of orthopedic procedures to their institutions.

In a 2008 article in JBJS, it was reported that, "many hospitals now have a problem generating a profit on primary total joint arthroplasties." Average Medicare payments to hospitals for total joint replacements between 1991 and 2007 increased 24%, while physician payments declined by 39%.

However in a 2008 paper published by The Advisory Board reported that the average profit per case for a total hip and knee replacement was $4,131 with a 36% contribution margin.

No wonder surgeons attending the presentation were excited to go back and talk to their hospital administrators.

Model of Costs

Graver told OTW that the study established a model of total direct economic costs by analyzing the consumption and cost of all care involved in total joint arthroplasty procedures, including pre- and post-operative care. He defined "economic costs" as the dollars exchanged for goods or services, with reimbursement amounts utilized to approximate costs.

"It is widely acknowledged that TJA is highly cost-effective, and we believe this study will help to clarify the specific procedure related costs incurred by the two largest payer categories, Medicare and Commercial. Additionally, it will provide a platform for future studies on the effect that new interventions have on costs. For example, as new techniques are refined or as new implants are adopted, this model will provide a useful benchmark to evaluate the economic impact of advancements," said Graver. Graver said stakeholders are best served by developing a clear understanding of the incremental costs incurred in TJA care. Graver added, "It is extremely difficult for hospitals to track individual patients across service lines. Our analysis offers hospitals greater insight into the total economic

consumption, and the revenue potential, that each patient may represent."

Analyzing Medicare and Commecial Claims

One of the benefits of this analysis was that the researchers were able to analyze Medicare and commercial claims of patients longitudinally. They said much of the published clinical literature references economic-related information for the Medicare population only, as this information is readily available. By including both Medicare and Commercial data, the researchers were able to understand the difference in reimbursement levels between these two patient populations.

The research found that Medicare pays less than commercial payers for a similar set of services. This finding was not surprising to the authors given that commercial payers negotiate contracts with providers, and Medicare reimburses at an established level that is intended to approximate costs to the provider.

The Study

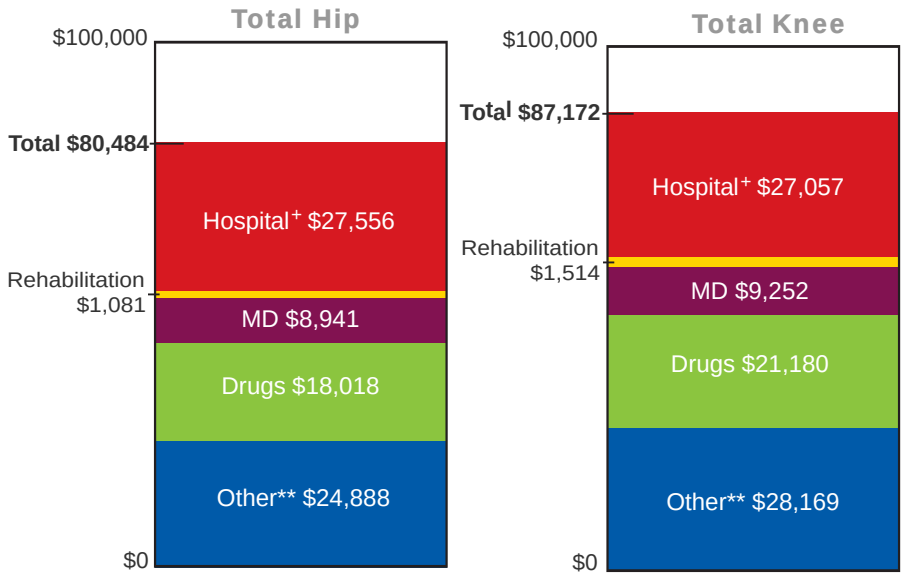
Graver's group looked at 93,717 patient records of primary total hip and knee arthroplasty procedures from January 1, 2003 to December 21, 2006.

The date endpoints were segmented into orthopedic-related vs. non-orthopedic related care for both inpatient and outpatient claims. Cost variables analyzed included: hospital access, in-patient hospital stay, orthopedic procedures, medications, outpatient drug utilization, specialty provider's visits and contacts with medical specialty in the three-year pre-surgery or three-year post surgery period.

Combined Medicare and Commercial Direct Costs

Figure One shows that during the entire study period, the total inpatient hospitalization cost were approximately the same for hip and knee procedures, with physician costs slightly higher for knee procedures than for hips.

Combined Medicare & Commercial Direct Costs During Study Period



+ Implant related costs included in Hospital costs for both THA & TKA.
*** Other costs include all medical expenses reimbursed by insurance not categorized in Figure 1, including but not limited to; x-ray, MRI, chiropractic care, etc.*

TABLE 1: Mean Cost

	3rd-Year Pre Procedure[A]	2nd-Year Pre Procedure[A]	1st-Year Pre Procedure[A]	1st-Year Post Procedure[B]	2nd-Year Post Procedure[B]	3rd-Year Post Procedure[B]	Total
Commercial							
Total Hip Cohort							
All Causes	$8,762	$10,076	$11,475	$37,445	$11,980	$11,307	$91,046
Orthopedic Related	$2,461	$3,016	$3,959	$29,121	$4,172	$3,326	$46,055
Total Knee Cohort							
All Causes	$10,443	$11,433	$12,412	$40,164	$14,336	$13,530	$102,317
Orthopedic Related	$3,218	$3,810	$4,222	$30,132	$5,030	$4,324	$50,736
Medicare							
Total Hip Cohort							
All Causes	$8,135	$9,153	$10,935	$26,550	$11,459	$11,377	$77,609
Orthopedic Related	$1,955	$2,264	$2,856	$17,739	$2,685	$2,285	$29,785
Total Knee Cohort							
All Causes	$9,579	$9,834	$10,696	$27,206	$12,410	$12,084	$81,808
Orthopedic Related	$2,164	$2,446	$2,611	$18,324	$3,047	2645	$31,237

[A] *Includes costs of services rendered prior to the index procedure, for any medical reason.*
[B] *Includes costs for services rendered following and including the index procedure, for any medical reason.*
Source: The Total "Economic Cost" of Primary Total Joint Replacement Surgery in the United States; Ryan M. Graver, MPH; Lisa Da Deppo, PharmD, MPH, MSc; Erik M. Harris, MHA; Shamiram R. Feinglass, MD, MPH

Mean Costs

Table 1 shows the mean costs broken down by commercial and Medicare payers. Orthopedic related costs for both hips and knees were proportionally higher relative to total costs for Commercial payers than Medicare.

The Manufacturer's View

Cheryl Blanchard, Ph.D., Zimmer's Senior Vice President and Chief Scientific Officer, said the company is committed to helping guide its customers through an increasingly expansive and intricate market by providing comprehensive data describing the costs and benefits of orthopedic surgery.

As a manufacturer, Blanchard said:

"We are conscious of the financial pressures faced by healthcare providers, and are eager to provide information that demonstrates the value proposition of our technologies. This research gave Zimmer the information necessary to understand how technologies fit into the overall cost of care. This guides the development of value dossiers that outline the impact of our technologies in the context of the lifetime costs of care for specific patient populations.

"It will also provide a baseline from which to compare the cost benefit of new technologies as they launch. We seek to understand how, by providing appropriately patient-matched technologies, our products can impact costs. For example, future research will examine specific costs such as medication and rehabilitation service-utilization.

"These specific costs can then be tracked in relation to the use of specific implants for specific patient populations, allowing providers to identify potential opportunities to positively impact cost and healthcare utilization. They can also be used to show the benefit of new technologies as they are commercialized."

As competition for healthcare dollars takes on a new urgency with the introduction of comparative effectiveness and a new CMS (Centers for Medicare and Medicaid Services) advisory panel to control costs, providers who have the clearest picture of the cost-effectiveness of their devices and procedures will have a big advantage. This snapshot of total economic costs of total joint replacement is a good start to that clear picture. ✦

company news

Alphatec's 1Q10: A Good Start

After completing the acquisition of Scient'x in late March, Alphatec reported a 25.6% increase in revenue for the first quarter of 2010.

Combined revenue was $38.4 million with a net loss of $4.7 million. U.S. sales were up 19% to $28.4 million, and European sales rose to $3.9 million from $1 million. The company also raised $42.5 million in an equity offering in April. This was technically not a first quarter event, but was discussed by the company during a quarterly conference call with Wall Street Analysts on May 10.

11th Consecutive Quarter of Record Revenue

Dirk Kuyper, company President and CEO, said this was the company's 11th consecutive quarter of record revenue and strong year-over-year growth.

"With the closing of the Scient'x acquisition and the completion of the equity follow-on offering, Alphatec Spine has become a leading pure-play spine company that is truly global, with scale to address the spine market in the U.S., Asia, Europe and Latin America," said Kuyper.

Continued Kuyper, "We are particularly pleased with our ability to demonstrate operating leverage, as evidenced by adjusted EBITDA of more than $5.0 million reported in the first quarter of 2010. We look forward to leveraging our broad-based international distribution network to drive long-termgrowth and profitability."

Wikimedia

Scient'x Integration

"Lastly," concluded Kuyper, "I am pleased with the progress we have made with the U.S. integration of Scient'x into Alphatec Spine. As of April 30th, Scient'x's U.S. operations have been consolidated into Alphatec Spine, and we remain on track to realize at least $5 million of savings by eliminating redundancies in Scient'x's operating expenses."

Alphatec, according to the company, is now the third largest independent spinal implant company in the world, reaching over 50 countries.

OsseoFix and OsseoScrew Updates

Kuyper highlighted two product developments during the first quarter.

First, as of March 31, 2010, over 900 patients have been treated in the EU with the company's OsseoFix Spinal Fracture Reduction System, a minimally invasive device that stabilizes the vertebral body following a vertebral compression fracture.
Second, OsseoScrew, the company's proprietary expandable pedicle screw system, designed for use in patients that require additional fixation, was approved and launched in the EU in the first quarter 2010.

The company reaffirmed full-year 2010 financial guidance and anticipates pro forma combined revenue of $220 million to $225 million for the year.

A Good Start

Jefferies analyst Raj Denhoy stated new products introduced last year "set the stage for higher domestic growth and rep productivity in 2010. He also noted that the company acknowledged that new questions have been raised by the FDA over the company's 510(k) clearance request for Solus and now aims for a launch in the third quarter. FDA has already requested additional clinical data for OsseoFix and OsseoScrew and Alphatec will be meeting with the agency over the next few weeks to define expectations and will provide additional clarity on the timelines soon.

All that said, Denhoy stated it was a good start to 2010, with Scient'x benefits still to come.

—WE (May 11, 2010) ✦

company news

MAKO's 1Q10 Mixed Bag

For MAKO Surgical, getting to profitability is all about installing new RIO systems and increasing the utilization rate for those systems.

The first quarter of 2010 was a mixed bag of success for the company on that journey. During the quarter, the company installed four new systems and saw 731 MAKOplasty procedures performed (up 176%). This brings their total number of installed units to 40 and brought the utilization rate of procedures per system from 4.9 to 6.6 over the previous year's first quarter.

Total revenue for the quarter rose 94% and reached $7.2 million.

Strong Procedure Volume/Modest System Sales

Wells Fargo analyst Mike Matson notes that the strong growth in procedures may not make up for the shortfall in new systems installed. Matson had expected to see six new systems installed for the quarter. Due to the slower growth of installations, Matson lowered his 2010 and 2011 revenue estimates from $44.5 million to $41.3 million and $78.4 million to $75.3 million, respectively.

The company reiterated its 2010 guidance for 30 to 37 systems installed and 3,400 to 3,700 procedures performed.

Here Come Hips

Company Founder and CEO Maurice Ferré was happy to announce to analysts that the company was investing heavily in research and development and building clinical evidence for the effectiveness of the system and procedures.

Rio System/MAKO Surgical

A significant increase in R&D spending from the first quarter of 2009 from $.8 million to $3.3 million in the first quarter of 2010 was primarily attributed to the ongoing development of its total hip arthroplasty system and future products for hip procedures.

510(k) Clearance

Ferré also announced that the company had received a third 510(k) marketing clearance from the FDA for that development.

"As you recall," said Ferré, "our prior clearance was limited to utilizing the RIO to place an acetabular cup. The recent clearance is expanded to increase the placement of the femoral stem, which means that our RIO system is cleared to address all components of the total hip arthroplasty. We believe this clearance enables us to remain on plan to begin clinical procedures through our surgeon-preference evaluation process by the end of 2010 as part of our ongoing development process."

Expanding Clinical Data

The company also continues to gather clinical data with 15 manuscripts, 40 abstracts, 5 book chapters and 39 ongoing studies underway. Additionally, a series of white papers has been created to show the economic impact of MAKOplasty. One of these that management highlighted on the call showed that a surgeon who adopted MAKOplasty saw a 98% increase in his knee arthroplasty procedures.

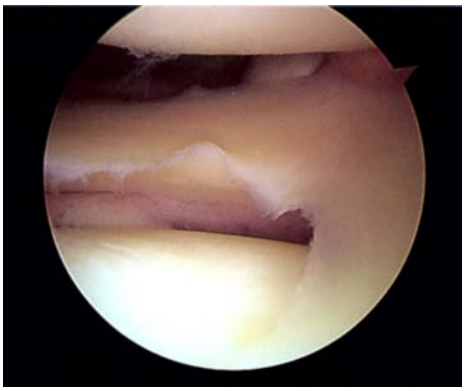
The next quarter's results will be watched for an increase in RIO system sales. As Matson wrote his investors, MAKO's ramp has steepened as the company will need to sell six units to stay on track.

—WE (May 11, 2010) ✦

biologics

ISTO's Cartilage Regeneration Breakthrough

ISTO Technologies has been in search of one of the Holy Grails of orthopedics. The regeneration of cartilage.



Wikimedia

An entire industry of joint replacements has evolved on the premise that when cartilage, the natural shock absorber in joints, is damaged or diseased, it will never heal and joints need to be replaced.

No Fear of Rejection

ISTO of St. Louis announced recently that it is publishing its first peer-review paper demonstrating that cells harvested from the cartilage of deceased juveniles may be transplanted, without the fear of rejection, to older patients. The allogeneic cells from juvenile donors have greater potential to restore articular cartilage than adult cells. The removal of fear of rejection may, one day, be deemed as important as Osiris' discovery that cells can be harvested from the bone marrow of cadavers and transplanted into bone to promote bone growth.

The paper, *"The Potential of Human Allogeneic Juvenile Chondrocytes for Restoration of Articular Cartilage,"* is scheduled to appear in the July 2010 edition of The American Journal of Sports Medicine.

More to Come

Mitchell Seyedin, PhD, President and CEO of ISTO said, "Our scalable technology for growing juvenile chondrocytes offers a platform that potentially addresses medical needs in a number of clinical applications."

The Paper

The authors hypothesized that juvenile chondrocytes would show stronger and more stable chondrogenic activity than adult cells in vitro and that juvenile cells pose little risk of immunologic incompatibility in adult hosts.

Cartilage samples were from juveniles under 13-years-old and adults over 13-years-old. The chondrogenic activity of freshly isolated human articular chondrocytes and of expanded cells after monolayer culture was measured by proteoglycan assay, gene expression analysis, and histology. Lymphocyte proliferation assays were used to assess immunogenic activity.

The results showed that "proteoglycan content in neocartilage produced by juvenile chondrocytes was 100-fold higher than in neocartilage produced by adult cells. Collagen type II and type IX mRNA in fresh juvenile chondrocytes were 100- and 700-fold higher, respectively, than in adult chondrocytes. The distributions of collagens II and IX were similar in native juvenile cartilage and in neocartilage made by juvenile cells. Juvenile cells grew significantly faster in monolayer cultures than adult cells ($P = .002$) and proteoglycan levels produced in agarose culture was significantly higher in juvenile cells than in adult cells after multiple passages ($P < .001$). Juvenile chondrocytes did not stimulate lymphocyte proliferation."

These results of the study document a dramatic age-related decline in human chondrocyte chondrogenic potential and show that allogeneic juvenile chondrocytes do not stimulate an immunologic response in vivo.

Zimmer and ISTO entered into a co-development agreement in 2002 granting Zimmer exclusive worldwide commercial distribution rights to some of ISTO's technology.

—WE (May 14, 2010) ✦

biologics

Cerasorb: One Millionth Bottle!

The product was synthetic, but the excitement was real…the employees of curasan AG celebrated recently when the one millionth bottle of its synthetic bone substitute—Cerasorb—was produced. While Cerasorb is used in orthopedics and traumatology, the batch containing this special bottle was part of an order placed by Riemser Arzneimittel AG, which has been selling Cerasorb in the dental market since mid-2008.

Dr. Fabian Peters, Technical Director at curasan AG, handed over both the 1,000,000th and the 1,000,001st unit, to Hans Dieter Rössler, CEO of curasan AG and Dr. Michael Mehler, CEO of Riemser Arzneimittel AG.

"This represents to us yet another milestone in this product's 12-year success story. We estimate that more than 800,000 patients worldwide have been treated with the one million units sold to date," explained Rössler in the news release.

Dr. Mehler added: "We at Riemser Arzneimittel AG are pleased to have contributed towards the reaching of this magical number with our sales activities. Our customers in the dentistry market appreciate the value of a safe and proven product such as Cerasorb."

Rössler told *OTW*, "This milestone provides clear evidence of the acceptance and success of Cerasorb. Every user who sets value on a safe and proven bone regeneration material gets the right product with Cerasorb. Cerasorb has been successfully used in the entire skeletal system for more than 12 years. In addition to morsels, we offer special product versions for applications in orthopaedic surgery."

Regarding the company's next steps in the orthopedics community, Rössler commented to *OTW*, "A few months ago, we founded our new subsidiary in the U.S. for the orthopedic community. Presently, we have started to develop a distribution network consisting of independent sales agents."

—EH (May 10, 2010) ✦

large joints

More Data Needed on Naproxcinod

Hallux Varus with Osteoarthritis / Al Kaissi et al

A new review says that orthopedic surgeons can have significant impact on identifying patients suffering from osteoporosis and initiating a dialogue with first-time fracture suffers that can lead patients to much needed treatment for the disease.

Attention orthopedic surgeons! You have the chance to make a significant impact in the lives of millions of women, and we aren't talking about in the operating room. That is the message being sent from a recent review that found women who are treated for fractures are generally also suffering from osteoporosis, yet these are the same women that aren't receiving any treatment. And since this can equate to subsequent fractures resulting in a greater chance of morbidity, it's becoming more and more apparent that orthopedists are on the front line for spotting and alerting patients to their risk factors, before they suffer life-altering injuries.
The sobering statistics and call to action comes from a review being published in the May 2010 *Journal of the American Academy of Orthopedic Surgeons*. Dr. Evan F. Ekman, president of the Southern Orthopaedic Sports Medicine and medical director of the Palmetto Health Alliance/Parkridge Surgery Center in Columbia, South Carolina led the review which examined existing statistics and literature to look for patterns in the treatment women were receiving. According to the review, 50% of women in the U.S. will at some time suffer a fracture that can be attributed to osteoporosis.

But the review also reveals a gap in preventative care, as only a fraction (less than 10%) of these women received any type of follow-up care or information for their possible osteoporosis, even though these initial fracture injuries indicated a significant risk for the disease. "It becomes somewhat apparent orthopedic surgeons aren't doing quite as well as we should in making sure people get the care that they need," says Ekman.

And because injuries like hip fractures carry a high mortality rate (between 15 to 33% according to Ekman), a change in the way physicians approach an initial fracture can be a lifesaver. "The motivation for this review was because of the morbidity associated with hip fractures and, in a broader, sense osteoporosis," explains Ekman.

But there is good news as Ekman points out, that when patients did receive information about osteoporosis post-op their outcomes improved. "So much has changed in just a few decades in terms of osteoporosis treatment. When I was a resident the most we could tell patients was to exercise and have good nutrition to prevent bone loss. Now there are a full range of options and an entire class of medications."

Ekman wants to inspire every orthopedic doctor to realize they are at the front lines for change. "We can get these patients involved in care! If we see a hip fracture the patient is probably osteoporotic and we can order a bone density test. You can either diagnose or get them in the hands of someone who will treat them. My goal is to draw attention that with every single one of these patients with a hip fracture we have a tremendous opportunity to positively affect their bone health and can take proactive measures to really help these patients."

—JR (May 10, 2010) ✦

large joints

Exercise to Stave Off Osteoporosis

Hit the treadmill…years before osteoporosis hits you. Researchers from the Medical College of Georgia have found that bone density starts to decline years before estrogen levels drop.

Dr. Joseph Cannon, Kellet Chair in Allied Health Sciences and principal investigator of the National Institute of Aging-funded study, has learned that it is during these years that levels of follicle-stimulating hormone (FSH), released by the pituitary gland to help regulate ovarian function, actually increase. Dr. Cannon theorizes that

Dr. Joseph Cannon--Phil Jones/Medical College of Georgia

higher levels of FSH decrease bone mineral density by increasing cytokines (regulatory proteins produced by white blood cells). One cytokine in particular, interleukin-1, signals certain cells to transform into osteoclasts, which break down and resorb bone.

"We hypothesize that the higher levels of FSH decrease bone mineral density by influencing the production of cytokines," said Dr. Cannon in the news release.

The team measured FSH and bone mineral density in 36 women between the ages of 20 to 50, and then correlated higher FSH levels with lower bone mineral density. When they incubated FSH with white blood cells isolated from the women, it stimulated production of interleukin-1. They also found that higher circulating levels of IL-1 correlated with lower bone mineral density, if the levels of interleukin-1 inhibitory factors were taken into account. Additionally, they found that study participants who exercised more than 180 minutes a week retained greater bone density. Dr. Cannon told *OTW*, "The association between physical activity and interleukin-1 receptor expression was unexpected."

"Our work provides more evidence that physical activity is important for maintaining bone density. It's a case of 'use it or lose it,'" Dr. Cannon said in the news release, citing his team's findings that exercise seemed to promote inhibitory factors that help keep interleukin-1 and bone breakdown under control. Going forward the team will determine how exercise influences the expression of interleukin-1 inhibitory factors.

Regarding how exercise influences the expression of interleukin-1 inhibitory factors, Dr. Cannon told *OTW,* "It is not clear why habitual physical activity would reduce expression of the signal-transducing type I interleukin-1 receptor and increase expression of the "decoy" type II receptor. Right now, I am trying to learn all that I can about the mechanisms that control the expression of these receptors in the context of infection and inflammation."

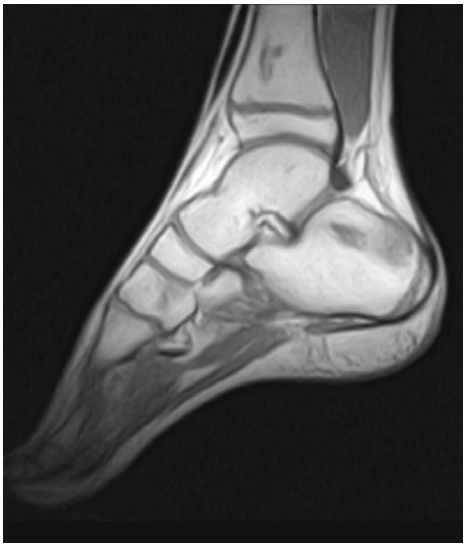
—EH (May 13, 2010) ✦

large joints

New Treatment for Osteonecrosis?

For those whose bones lack blood, there is a bit of good news. Researchers at Mount Sinai School of Medicine may have found a new treatment for osteonecrosis, (the death of bone tissue), in people who are treated with steroids. There are currently no treatment options for people with this debilitating disease.

Glucocorticoids are steroids that can cause bone loss, and can eventually cause severe osteoporosis and fracture, as well as osteonecrosis. The Mount Sinai team, led by Mone Zaidi, M.D., Ph.D., FRCP, Professor of Medicine and Physiology and Director of The Mount Sinai Bone Program at Mount Sinai School of Medicine, discovered that injecting the naturally-produced hormone adrenocorticotropic



MRI of child with Leukemia/Wikimedia Commons

hormone (ACTH) in rabbits with osteonecrosis caused by treatment with glucocorticoids significantly reduced bone death in the hip.

"Osteonecrosis is a very painful condition that has the potential to affect hundreds of thousands of Americans who are treated with steroids, with no treatment option until now except hip replacement," said Dr. Zaidi in the news release. "Our research is the first to show the therapeutic benefit of ACTH in experimental osteonecrosis, providing the first treatment option for these patients."

As indicated in the news release, glucocorticoids cause reduced blood flow to bone cells in the hip, resulting in cell death, and ACTH reduces these devastating side effects. However, research indicates that osteonecrosis is not significant in people in which steroid levels are high in the blood. Dr. Zaidi's team knew that these tumors produce excess ACTH, and this spurred the team to evaluate the ACTH's potential therapeutic effect.

The researchers injected one group of rabbits with depomedrol, (a steroid), and another group with depomedrol plus ACTH. Osteonecrosis was dramatically reduced in the rabbits treated with ACTH. Dr. Zaidi's team found that ACTH stimulates the vascular endothelial growth factor (VEGF), a protein that signals for the growth of new blood vessels. The stimulation of VEGF results in increased blood flow to the bone cells, preventing cell death.

Dr. Zaidi told *OTW*, "What has surprised us most during the course of this and other previous studies is that no one, including ourselves and our collaborators, ever tested something as simple as this—whether reciprocal changes in pituitary hormones, in this case lowering of ACTH when steroids are given, could contribute to disease pathogenesis that was traditionally attributed solely to steroid hormones."

As for his future work, Dr. Zaidi commented to *OTW,* "Considering that a form of ACTH is available for the testing of adrenal insufficiency in humans, we could easily undertake carefully controlled clinical studies to evaluate the effect of ACTH in preventing osteonecrosis in humans, and perhaps later, even steroid-induced osteoporosis and fracture."

The research is published in the April 27 issue of *Proceedings of the National Academy of Sciences.*

—EH (May 11, 2010) ✦

large joints

Gymnastics-An Rx for Bone Strength?

Weight-bearing exercise has been shown to build bone strength, but a new study shows rhythmic gymnastics may also be beneficial in preventing osteoporosis.

Those somersaults, roundoffs and cartwheels that young gymnasts effortlessly execute might be doing more than making the rest of us shake our heads in disbelief. These feats of flexibility and power might actually be protecting these girls from osteoporosis later in life. A recent study in Greece shows adolescent girls gaining bone strength, apparently thanks to studying gymnastics for several years. An important part of this study is not only means for these young gymnasts, but what it could mean for the rest of us as well.

The study conducted in Greece by the University of Athens in Greece explores the bone-building benefits of long-term training in gymnastics. The researchers looked at a group of 49 adolescent girls between 9 and 13 years of age—26 of the girls studied gymnastics, while 23 only participated in general physical education. The girls who studied gymnastics for at least two years exhibited several key signs of strengthened bones: greater bone density, bone mineral content and a thicker outer bone shell.

The study, to be published in The Endocrine Society's *Journal of Clinical Endocrinology and Metabolism* (JCEM) is the first to look at the benefits to bone of rhythmic gymnastics. Previous

Rhythmic gymnastics/Wikimedia Commons

studies have focused more on weight-bearing exercise.

"Our study provides information about the effect of intensive rhythmic gymnastics on vBMD [volumetric bone mineral density] and geometry assessed by pQCT [peripheral quantitative computed tomography] at the tibia in premenarcheal athletes and controls," explains Dr. Symeon Tournis, lead author of the study. "We found significant positive effects on bone mineral and bone area and geometry in athletes. Furthermore years of training seem to have positive association with a positive response of bone geometry. Thus it seems that elite training exerts positive effects on the skeleton. It remains to be determined whether these positive effects could be maintained and possibly reduce the risk of osteoporosis later in life."

—JR (May 10, 2010) ✦

large joints

Only a Fraction of Fractures Properly Addressed?

A new review says that orthopedic surgeons can have significant impact on identifying patients suffering from osteoporosis and initiating a dialogue with first-time fracture suffers that can lead patients to much needed treatment for the disease.

Attention orthopedic surgeons! You have the chance to make a significant impact in the lives of millions of women, and we aren't talking about in the operating room. That is the message being sent from a recent review that found women who are treated for fractures are generally also suffering from osteoporosis, yet these are the same women that aren't receiving any treatment. And since this can equate to subsequent fractures resulting in a greater chance of morbidity, it's becoming more and more apparent that orthopedists are on the front line for spotting and alerting patients to their risk factors, before they suffer life-altering injuries.

The sobering statistics and call to action comes from a review being published in the May 2010 *Journal of the American Academy of Orthopedic Surgeons*. Dr. Evan F. Ekman, president of the Southern Orthopaedic Sports Medicine and medical director of the Palmetto Health Alliance/Parkridge Surgery Center in Columbia, South Carolina led the review which examined existing statistics and literature to look for patterns in the treatment women were receiving. According to the review, 50% of women in the U.S. will at some time suffer a fracture that can be attributed to osteoporosis. But the review also reveals a gap in preventative care, as only a fraction (less than 10%) of these women received any type of follow-up care or information for their possible osteoporosis, even though these initial fracture injuries indicated a significant risk for the disease. "It becomes somewhat apparent orthopedic surgeons aren't doing quite as well as we should in making sure people get the care that they need," says Ekman.

(Hips/Creative Commons)

And because injuries like hip fractures carry a high mortality rate (between 15 to 33% according to Ekman), a change in the way physicians approach an initial fracture can be a lifesaver. "The motivation for this review was because of the morbidity associated with hip fractures and, in a broader, sense osteoporosis," explains Ekman.

But there is good news as Ekman points out, that when patients did receive information about osteoporosis post-op their outcomes improved. "So much has changed in just a few decades in terms of osteoporosis treatment. When I was a resident the most we could tell patients was to exercise and have good nutrition to prevent bone loss. Now there are a full range of options and an entire class of medications."

Ekman wants to inspire every orthopedic doctor to realize they are at the front lines for change. "We can get these

patients involved in care! If we see a hip fracture the patient is probably osteoporotic and we can order a bone density test. You can either diagnose or get them in the hands of someone who will treat them. My goal is to draw attention that with every single one of these patients with a hip fracture we have a tremendous opportunity to positively affect their bone health and can take proactive measures to really help these patients."

—JR (May 10, 2010) ✦

legal & regulatory

Stryker Whistleblower Blown-Out in Michigan

A whistleblower lawsuit filed against Stryker by a sales rep for a Zimmer distributor in Florida has been dismissed by a federal judge in Michigan.

Robert Lauricica, a sales rep for Ft. Lauderdale-based Zimmer Deptula, a distributor for Zimmer Holdings, claimed that a competing sales rep from Stryker paid Dr. Hari Parvataneni, an orthopedic surgeon at the University of Miami's Jackson Memorial Hospital, a kickback to use Stryker products.

According to court documents, Lauricica claimed that he sold about $100,000 worth of Zimmer products to Parvataneni. When Lauricica checked back with Parvataneni a few weeks later, the doctor hadn't used any of the Zimmer devices.

Lauricica claims Parvataneni told him that a Stryker rep had taken him to dinner and offered to fund the training of Parvataneni's residents and research in return for using Stryker products. Lauricica then filed a qui tam lawsuit alleging a kickbacks scheme "under which Dr. Parvataneni agreed to use Stryker's medical devices for implantation into Medicare patients in exchange for Stryker's agreement to fund the training of Dr. Parvataneni's residents and various research projects," according to court documents.

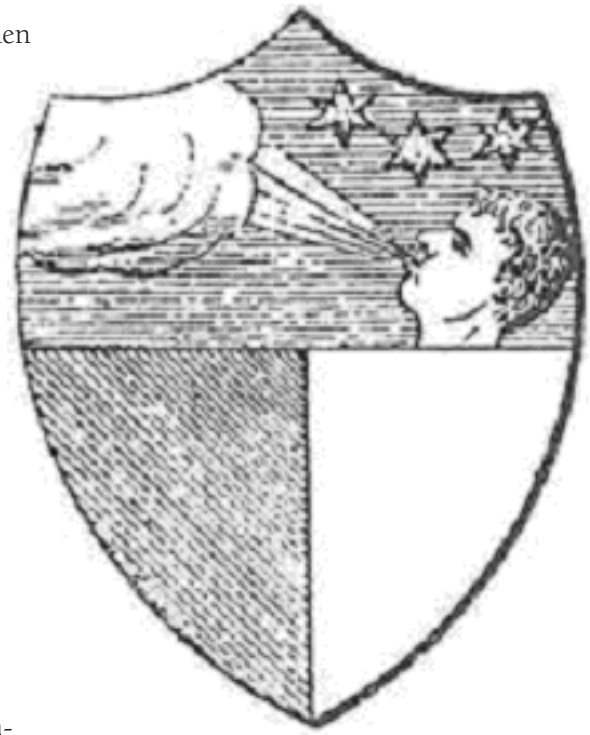
Judge Robert Jonker of the U.S. District Court for Western Michigan ruled on May 3 that Lauricica and the U.S. government failed to prove their contention that Stryker sales reps initiated a kickbacks scheme.

Jonker ruled that the suit failed to provide enough specifics about the alleged scheme to prove its accusations, because it does not supply any times or places when the alleged kickbacks occurred and doesn't allege any specific injury from the supposed fraud.

"The skeletal factual allegations in the complaint do not 'raise a reasonable expectation that discovery will reveal evidence of illegal [conduct],'" the judge wrote. "On the contrary, the conduct Mr. Lauricica describes in his affidavit—the basis of all of his allegations—is neutral on its face and could just as easily support an inference of legality as of illegality. A medical device company's funding of research and training is not per se illegal. Legality depends on whether the funding was bona fide and in compliance with applicable rules and regulations or whether the funding was simply a cleverly disguised cover for a flat-out bribe or kickback. Nothing in Plaintiff's allegations make the inference of illegal intent and conduct any more plausible than the inference of legal intent and conduct."

Jonker gave Lauricica and the U.S. government 21 days from the date of his decision to amend their complaint to address its deficiencies.

—WE (May 14, 2010) ✦



Araldiz Manno, 1907/Wikimedia Commons

spine

Bone Solutions Inc. Broadens Its Horizons

Four new filings with the FDA mean Bone Solutions Inc. is going full steam ahead with its plans to promote its OsteoCrete bone void filler to more diverse markets.

Nearly a year to the date that Bone Solutions Inc. (BSI) received its initial FDA certification for OsteoCrete, the company is now moving ahead and filing for greater applications in a move that positions the product strategically toward future partnerships. Last May BSI was granted certification for OsteoCare as a bone void filler, which enables it to be marketed for applications in musculoskeletal structure, trauma, bone grafting, and other related surgeries.

This new move, filing for 510(k) clearance certification involves these new applications: maxillofacial, bone anchoring, cranial, and finally non-load-bearing spine applications. Subsequent studies since the initial certification make BSI's management confident that these new applications will proceed smoothly. BSI President Tom Lally, says the company will also pursue CE Mark certification for EU sales.

"This broad strategy for our unique compound, OsteoCrete—which is resorbable, osteoconductive, and injectable, has high strength, provides physician-friendly flexibility as to handling and setting time, and is designed to set in a wet environment—has major competitive advantages over existing bone graft substitutes on the market today, including lower cost," explains Dr. Tony Copp, EVP and COO at BSI.

Horizon painting/Creative Commons

But Copp points out that the company is looking for applications beyond just bone graft substitutes. "Given recent orthopedic industry transactions such as Baxter International's acquisition of ApaTech, we feel now is the perfect time for BSI to be exploring potential strategic partnerships. We certainly believe we can be competitive with the ApaTech product."

In other OsteoCrete news, BSI, working with Rush Craniofacial Center in Chicago, is developing preformed implants using the OsteoCrete technology. With CT scan data the plan is to create 3D images of the implant site and configure a mold that could be filled with OsteoCrete. Lally says this would create the first anatomically correct personalized implant.

OsteoCrete, the biocompatible magnesium-based bone void filler, is used to fill gaps in the skeletal system. The filler can be both injected and moldable and is indicated for voids that are not part of the stability of the tissue. OsteoCrete benefits include its resorbability and composition that is replaced by bone during healing. BSI holds a U.S. patent for the technology, however four additional patents have now also been filed.

The FDA applications appear to fall right in line with BSI's current mission to "establish its magnesium-based OsteoCrete platform as the 'one stop bone-, tendon- and ligament-injectable, biodegradable adhesive technology' for surgeries at hospitals, clinics and other private surgical centers within the orthopedic industry." Using the *magnesium*-based platform, BSI believes this technology will mark the first time in orthopedic medical history where a platform is designed to attach bone to bone and ligaments/tendons to bone.

—JR (May 8, 2010) ✦

THE PICTURE OF SUCCESS

Dr. Christopher Bono

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

Dr. Christopher Bono

While many high school seniors are worrying about the prom, Dr. Christopher Bono, Chief of the Orthopedic Spine Service at Brigham and Women's Hospital in Boston, was preparing for a career in medicine. This native Brooklyn boy was accepted into medical school in his senior year of high school. Of his early family life, Dr. Bono says, "My dad was born in the U.S., but my mom was born in Sicily. Our roots here in the States are in a densely Italian American neighborhood where street festivals and celebrating saints' days were the norm."

The Bono household frowned on an excess of merriment, however. There were other, more academic, matters at hand. "My dad taught high school math and my mom was a secretary; both emphasized education. But it was my grandfather whose life really influenced me in that regard. In Italy he had been an air traffic controller, but once he came to the U.S. the only job he could find that paid well was that of a longshoreman. It was quite an adjustment for him…at the age of 36 he had never done manual labor. He was tireless in his efforts to convince me that I needed to excel in school, something that wasn't very common in my neighborhood. I listened to him, and decided to pursue my interest in science and math."

The measuring, cutting, and hammering that ran in the family veins would also help. "Many of my dad's family members were carpetlayers and my paternal uncle was a master carpenter. One day when I was 15 I was watching PBS when a show on knee replacement came on. 'I can do that. We have the tools in our garage,' I said a bit arrogantly. My future flashed before me and I began to think seriously about medicine as a career. I was a babe in the medical woods, though, because at that time I didn't even know there were different kinds of surgeons."

Now about that early, early acceptance into medical school. "I got the chance to participate in a special New York City initiative, the 'Brooklyn College Downstate Seven Year program.' It consisted of three years of college, followed by four years of medical school at Downstate. After entering medical school I came to find that I wasn't a good candidate because of my grades. I persisted, however, and turned to Dr. Paul Tornetta, then a first year attending at Downstate. A few seconds of his time—and his belief in me—would alter the course of my life. In desperation I meekly went into his office one day and said, 'Do you think I can get into an orthopedic residency?' His reply was short, but confident: 'Do a research project with me and work hard on your rotations and you will get in.' Thank you, Dr. Tornetta."

Full of zeal for orthopedics, Christopher Bono began working with his new mentor and set about applying to residency programs. "Things clicked at the University of Medicine and Dentistry of New Jersey [UMDNJ] and I began there in 1996. I had an absolutely great time in orthopedics and was really pleased to find that the surgeries felt very natural. I can honestly say that from an early point I felt as comfortable doing an operation as I was doing almost anything else in life. While I had struggled through the first two years of medical school—in part because I was not interested in electrolytes and the like—I couldn't stop reading about orthopedics."

"Dr. Fred Behrens, the Chair at the time, was my most significant mentor. He was a rock of a man, and inspired me to be a thorough researcher, a

dedicated orthopedic surgeon, and a balanced person. When he saw me working so hard as a resident and taking my vacations in the lab, he cautioned me to 'smell the roses.' My research during this time ended up being one of the most significant of my career, namely, a meta analysis of lumbar fusion outcomes. Despite meta analyses being unpopular at the time, along with the fact that I had no statistical training, the work was well received by several societies."

Then a prior meeting opened a door that was nearly closed. "I had met Dr. Steve Garfin in my second year of residency, at which time he asked me to call him when I was ready to look for fellowships. When I finished UMDNJ in 2001 in fact he had stopped taking fellows into his program. He took me anyway; the year was nonstop work, as modeled by the incredibly energetic Dr. Garfin. He absolutely loves spine surgery and is a supremely compassionate human being. In the middle of the fellowship I was vacillating about spine surgery; 9/11 had hit that year and I was worried about my family. I told Dr. Garfin that I needed a week off, something unheard of. He allowed me to take this break; I spent time with my family and then came back refreshed and ready to fully dedicate myself to spine."

Then Dr. Bono found out that confidence, a good team, and perhaps a textbook in the OR can take you a long way. "Drs. Paul Tornetta and Tom Einhorn, both at Boston University (BU), convinced me to join their team. While I wouldn't trade the experience for anything, in retrospect it was a difficult place to start a career. I was a young spine surgeon without any other fellowship trained spine surgeons on staff. I took an outrageous amount of call, something necessary in part because BU was an indigent hospital and was the 'last stop' for many patients. While I was well prepared from my fellowship, it was still challenging to figure out how to handle the complications and indications, especially if it was a type of case that I had not done before."

> "For example, we had a patient with a tumor, something I hadn't encountered much in my fellowship. There was a resident and an approach surgeon, the latter of whom was unsure about how to do a thoracic exposure for spine. He was actually reading an approach textbook in the OR before the operation. It all comes down to having confidence but not overconfidence; you should always ask yourself, 'Am I seeing what I think I'm seeing?'"

Wanting more company and less call, Dr. Bono left Boston University in 2006. "Brigham and Women's Hospital had been recruiting me, and I was really pleased because at BU there was little room for spine collaboration. I was an island. At Brigham I was made Chief just four years out of fellowship, and had a research coordinator and a physician's assistant. I also had the opportunity to collaborate with Massachusetts General researchers on spine projects and a spine fellowship."

While he makes no claims to be a psychiatrist, Dr. Bono is savvy enough to realize that knowing what's going on inside a patient's head affects what he does—or doesn't do—in the office and in the OR. "I am very proud of my current project, which involves looking at the influence of pain on patients' decision making with regard to spine surgery. We surveyed 150 patients who had no previous spine surgeries and tried to determine the threshold of how much pain they had versus what compromises they would be willing to accept. We found that those in more pain accepted more risk and less favorable outcomes. Interestingly, higher educated women are less risk tolerant compared to higher educated men. Also, whites were found to be more risk tolerant than nonwhites. Going forward we will look at whether this new survey instrument was predictive of a patient's decision to have surgery or not."

Dr. Bono, known as a critical reviewer of the literature, is the Deputy Editor for orthopedics for The Spine Journal. Dr. Bono: "Another interesting study I have done is a meta analysis looking at 20 years of lumbar fusion

outcomes. We compared instrumented to noninstrumented fusion and without knowing it, found things that were predictive of what was going to happen. The outcomes of lumbar fusion in the literature are actually not improving, despite all of our new gadgets and hardware. Also, we found that the degenerative diagnosis influenced outcomes. There are prospective studies showing that if there is a lumbar fusion done for degenerative stenosis versus lower back pain then the outcomes are different. Based on our study, as well as others, the government has picked up on different diagnoses resulting in different outcomes. They have in fact used this information to help guide what procedures will continue to be covered and which may potentially not be covered in the future."

Dr. Bono knows that the best use of data is to get it off the pages and into action. As a board member of the North American Spine Society (NASS), and Chair of its Committee on Professional, Economics and Regulatory Affairs, Dr. Bono is a direct liaison between insurers and NASS. "We review policy changes from insurers, something made easier now by the fact that the insurers are listening to us more. In the last five years NASS has gained a significant amount of credibility; in the past, if a payor asked about a procedure the NASS response was always, 'Pay more.' Outcomes were never mentioned. Now, when we respond to policies, we use the best available evidence to support a reasonable rationale."

He may just take the same approach on the home front. "I often like to take my wife and three children to society meetings. Of course, the children want me to lay out for them the activities that are available beyond dad's lecture and cadaver events. When not roaming to conferences, we see my parents, who live in New Jersey. Just spending time together as a family is fantastic…and I squeeze in time at the gym when I can."

Dr. Christopher Bono…
fusing science and the art of life. ✦

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