VOLUME 5, ISSUE 23 | JULY 28, 2009

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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: Zimmer's hip and knee revenue declines were higher in 2Q than in 1Q. But by reiterating 2009 guidance, management signaled that the business is stabilizing. Still not enough to return to the Power Rankings, but good news, for sure. IART, SYK and ARTC remain #1, 2 & 3, respectively, this week.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	1	Integra LifeSciences	12.35%	18.71%	Organogenesis deal adds new tendon repair product. Consensus is 5% overall sales growth this year, 10% next year.
2	2	Stryker	23.18	(1.49)	Poor MedSurg numbers are no surprise. The issue is the economic rebound in the coming 12 months. Buy low, sell high.
3	3	ArthroCare	16.87	26.98	No financial reports since May 2008. Reverse psychology for Wall Street. No news = good news.
4	4	CONMED	9.80	17.34	Wall Street is expecting sales to decline 15% this quarter. But with ortho's lowest PSR, investors have fully discounted the news.
5	7	Alphatec	(11.34)	23.97	Consensus is for a $30 million quarter, up 26% for the June period. Along with neighbor NUVA, ATEC is gaining market share.
6	5	Medtronic	31.68	4.94	Medtronic's legal angst continues. Pyrrhic victory against Globus. Now NUVA is hammering MDT. Slips in Power Rankings.
7	8	Symmetry	11.05	(3.26)	Quarterly results expected this week. Should be another $100 million quarter. SMA is now officially the cheapest ortho stock.
8	10	Orthofix	8.14	(4.46)	Sweet deal with one of the most talented product design teams in ortho—Stout Medical. Up 2 places this week in the Power Rankings.
9	6	Exactech	13.42	(3.71)	This quarter will likely be flat—say analysts—but full year up 8%. With so much back loaded for the year, waiting and seeing.
10	9	Johnson & Johnson	25.36	10.91	The run has been nice, for sure, but time for reality to intrude. Summer doldrums are here. Anchoring the bottom for now.

Orthopedics This Week

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Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	ArthroCare	ARTC	$13.65	$363	27.0%
2	Alphatec Holdings	ATEC	$3.62	$172	24.0%
3	I Flow Corp	IFLO	$7.42	$181	20.3%
4	Integra LifeSciences	IART	$30.46	$865	18.7%
5	CONMED	CNMD	$17.53	$509	17.3%
6	Osteotech	OSTE	$4.73	$85	12.6%
7	Kensey Nash	KNSY	$27.82	$316	11.6%
8	Johnson & Johnson	JNJ	$61.51	169,490	10.9%
9	Orthovita	VITA	$5.48	$417	10.0%
10	***Average***			***$9,986***	***8.3%***

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGBO.OB	$1.70	$17	-24.4%
2	Capstone Therapeutics	CAPS	$0.64	$26	-9.9%
3	Wright Medical	WMGI	$13.94	$530	-7.3%
4	TiGenix	TIG.BR	$6.12	$149	-4.6%
5	Orthofix	OFIX	$23.58	$403	-4.5%
6	Exactech	EXAC	$14.00	$179	-3.7%
7	Symmetry Medical	SMA	$8.30	$297	-3.3%
8	Mako Surgical	MAKO	$8.68	$217	-2.6%
9	Stryker	SYK	$39.56	$15,720	-1.5%
10	NuVasive	NUVA	$42.00	$1,530	0.2%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Symmetry Medical	SMA	$8.30	$297	7.20
2	ArthroCare	ARTC	$13.65	$363	8.02
3	Zimmer Holdings	ZMH	$44.62	$9,600	10.88
4	Orthofix	OFIX	$23.58	$403	11.61
5	Medtronic	MDT	$35.05	$38,990	11.95

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Osteotech	OSTE	$4.73	$85	152.88
2	I Flow Corp	IFLO	$7.42	$181	77.08
3	Smith & Nephew	SNN	$38.55	$6,810	68.92
4	NuVasive	NUVA	$42.00	$1,530	40.46
5	RTI Biologics Inc	RTIX	$4.45	$241	38.20

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	ArthroCare	ARTC	$13.65	$363	0.32
2	Symmetry Medical	SMA	$8.30	$297	0.73
3	CryoLife	CRY	$5.42	$153	0.81
4	Exactech	EXAC	$14.00	$179	0.84
5	Integra LifeSciences	IART	$30.46	$865	0.92

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	NuVasive	NUVA	$42.00	$1,530	5.19
2	RTI Biologics Inc	RTIX	$4.45	$241	2.02
3	Johnson & Johnson	JNJ	$61.51	$169,490	1.69
4	CONMED	CNMD	$17.53	$509	1.55
5	***Average***			***$9,986***	***1.53***

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Symmetry Medical	SMA	$8.30	$297	0.71
2	CONMED	CNMD	$17.53	$509	0.71
3	Orthofix	OFIX	$23.58	$403	0.78
4	Osteotech	OSTE	$4.73	$85	0.86
5	ArthroCare	ARTC	$13.65	$363	1.08

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$6.12	$149	337.78
2	Mako Surgical	MAKO	$8.68	$217	34.67
3	Regen Biologics	RGBO.OB	$1.70	$17	14.72
4	NuVasive	NUVA	$42.00	$1,530	5.75
5	Orthovita	VITA	$5.48	$417	5.21

Orthopedics This Week

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Medtronic's Sisyphean Legal Battles

By Robin Young

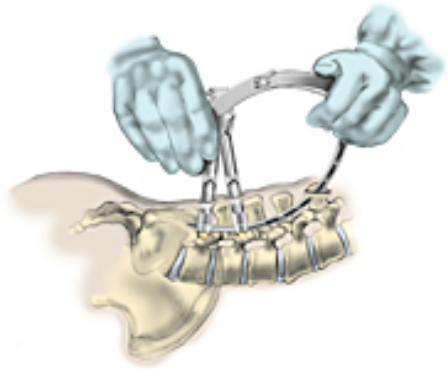
The courtroom is not a warm and fuzzy place for Medtronic. Since its acquisition of Sofamor Danek, Medtronic has had probably more than its share of misery at the bench. Certainly the billion-dollar losses to Gary Michelson for patent infringement are Exhibit A.

But in the last 10 months, a string of courtroom setbacks has Medtronic looking like the subject of some Camus treatise on the futile search for meaning.

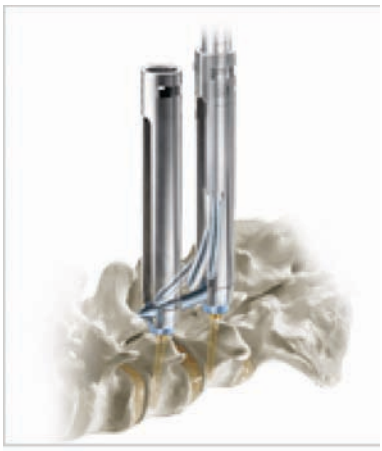
On September 22, 2006, Medtronic filed a lawsuit against Globus Medical alleging that the company had infringed six patents. This past week, the Honorable Norma L. Shapiro of the U.S. District Court (Eastern Pennsylvania) ruled on the final two patents in question—the two having to do with Medtronic's Sextant System, which was invented by Dr. Kevin Foley (Professor of Neurosurgery, University of Tennessee), Michael Sherman (at the time an engineering executive with Sofamor Danek and now partner with MB Ventures Fund), and Jeff Justis (an engineering executive). The other four disputed patents mentioned in the original lawsuit have been settled.

Medtronic was asking the court for three forms of relief:

- An award of $2,866,405 to compensate for Medtronic USA's lost sales of the Sextant System because of the infringement;
- An award of $1,327,866 for statutory royalties on Globus's sales of its Pivot System for which Medtronic USA did not claim lost profits; and
- Entry of a permanent injunction prohibiting Globus from selling the Pivot System.



Medtronic's Sextant System



Globus's Pivot System

The court ruled, however, that Medtronic was NOT entitled to recover damages for infringement. Instead, it ruled that a Medtronic subsidiary (Warsaw Inc.—a legal entity created from the merger of SDGI Holdings and Sofamor Danek Holdings) was the only party entitled to recover for infringement. While Medtronic tried to move the damages, in effect, upstream to the parent, the court said "no."

Judge Shapiro held that the licensing agreements between Warsaw and the other Medtronic subsidiaries FAILED to transfer exclusionary rights that would grant the subsidiaries standing to sue for patent infringement.

Medtronic's Warsaw unit was awarded $2.1 million from Globus (an amount equal to 15% of Globus's gross revenues from the sales of Pivot). But because Warsaw is a manufacturer and not a distributor, the court concluded that Warsaw was unlikely to suffer irreparable harm.

Bottom line: no permanent injunction and no award for Medtronic's lost profits.

Globus has now weathered two major intellectual property lawsuits—one from Synthes and this one from Medtronic. Last quarter, Globus booked $64 million in revenue and appears well on its way to record 2009 annual sales of about $250 million.

Medtronic, on the other hand, has not had very good fortune with its litigation initiatives this past year.

The Search for Meaning in Court

Less than one month ago, DePuy Spine won a whopping $179 million judgment against Medtronic regarding its patent infringement suit over spinal screws. Medtronic has since announced that it plans to appeal. The stipulation was filed June 29, 2009, in the U.S. District Court for the District of Massachusetts.

Then, nine months ago Medtronic was ordered to pay BrainLAB $4.38 million in yet another patent infringement suit. This time it was the District Court of Colorado and the order was for Medtronic to pay attorney fees, costs and expenses to BrainLAB. This was a case of a patent suit brought by Medtronic. The suit was filed in 1998 only to be dismissed by the U.S. District Court in Denver in February 2006. Medtronic appealed the ruling and lost again.

Then there is the December 9, 2008, ruling from the home town court (U.S. District Court in Memphis) ordering Medtronic to pay Synthes the equivalent of lost profits for approximately half of the infringing sales of Medtronic's Maverick disc PLUS a royalty of 18% on the remaining sales. The Memphis court ruled that Medtronic has willfully violated the intellectual property supporting Synthes's ProDisc-L product.

Nostalgic for the Pedicle Screw Litigation Days?

There was a time, not so long ago, when Philadelphia lawyers cowered before the pit bull known as Sofamor Danek and, more specifically, its leader—Ron Pickard. In the mid-1990s all manufacturers of stainless steel bone screws for internal fixation of the spine were hit with literally thousands of lawsuits. When the pedicle screw lawsuits hit, these implants had been used in more than 30,000 surgeries and had become the standard of care for certain fusions. As of December 17, 1993, there were no pedicle screw lawsuits against Sofamor Danek.

That December night the ABC Television Network broadcast a "20/20" program entitled, *"The Secret of the Bone Screw."* The next day an avalanche of lawsuits started. Not only were the major manufacturers

U.S. District Court, Eastern District of Pennsylvania

sued (like Acromed and Sofamor Danek), but also so were more than 200 physicians, hospitals and even the North American Spine Society (NASS), the American Academy of Neurologic Surgeons (AANS) and other surgeon societies.

The thousands of lawsuits claimed that the manufacturers illegally marketed their bone screw products.

In less than a year, with Pickard and his executives like Alex Lukianov in the lead, all the federal lawsuits were consolidated for pretrial purposes and transferred to the United States District Court for the Eastern District of Pennsylvania under the supervision of the Hon. Louis C. Bechtle.

The Philadelphia lawyers thought they had the hicks from Memphis on the run, particularly since the cases were being heard in Philadelphia. Little did they know that Ron, et al. had them surrounded.

Under focused attack from Sofamor Danek, the plaintiffs' cases began to unravel. The judge failed to certify the cases as a class. Not one expert was found who would say that the screws were poorly made or flawed.

As rulings piled up against the plaintiffs, the lawyers switched tactics and, in addition to suing surgeons and their societies, began advertising for clients. "If you have had back surgery, call 1-800...." was a typical advertisement. They then expanded the claims against Sofamor Danek (breach of warranty, strict liability, negligence, and misrepresentation). All of those attempts ultimately failed.

Over the course of the ensuing five years Sofamor Danek won more than 6,000 cases.

What's Next

In the late 1990s, the FDA recommended down-classifying bone screws for surgery in the pedicle.

Ironically, not only was last week's ruling in the Medtronic v. Globus case also from the legendary U.S. District Court in Philadelphia—the location of Sofamor Danek's greatest victories—but next up is the patent litigation fight against Alex Lukianov and his company NuVasive. Lukianov was part of Ron Pickard's inner circle during the pedicle screw fights. Now his old firm is suing him.

Like Sisyphus, the figure of Greek mythology, the Medtronic legal team will throw themselves into the task of pushing their legal arguments up a mountain. This time it is Alex Lukianov (CEO of NuVasive) pushing on the other side. How can Medtronic's lawyers be feeling? As Camus himself said at the end of his essay on Sisyphus, "The struggle itself...is enough to fill a man's heart. One must imagine Sisyphus happy."

Orthopedics This Week

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AAOS Through the Eyes of Residents: Part Two

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

Last week we heard residents give their impressions on the logistics and educational programs of the 2009 AAOS Conference. We continue this week with their thoughts on the buzz and breadth of the exhibit floor, and on their contact with senior surgeons. They also had a few suggestions for next year's meeting, as well as for future resident attendees.

Industry Exhibits

There are several high-wire acts in Las Vegas, one of which took place on the floor of the Sands Expo this past February. Balancing the need to work with industry with the need to be free of even the hint of impropriety is a professional performance that residents are just beginning to learn. And this year, say some residents, the industry folks were displaying not just new products, but a new attitude.

Dr. Waldron explains, "I had been told that during past meetings it was customary for sales reps to take residents out at the end of the day. Things were very different in 2009, however; I even got an email from a rep saying that his company had instituted a new rule that they couldn't even speak to doctors after 5PM. When I did interact with the industry people at the booths they were quite nice and helpful. There were a number of companies I had never heard of, so it was a good chance to expand my knowledge in this area. Generally speaking, I think the onus is on the surgeon to not get sucked into something just because you like the sales rep. The bottom line is that we must choose a product based on its merit."

One resident thought that the only thing missing was a Tilt-A-Whirl. Dr. Labson: "It was such an amusement park atmosphere with all of the glitz and noise. You could tell who had the most money to spend. I interacted with people from the large companies, but what struck me was that there were so many smaller companies I had never heard of. It was nice to learn about them."

One resident said there was a bit of cloak and dagger amidst the screws and fixators. Dr. Upasani: "The reps were less aggressive this year, even waiting to be approached by doctors. I actually heard that there were undercover agents in the exhibit hall monitoring reps and their interactions with surgeons."

Dr. Van Sice noted, "The industry presence surpassed my expectations and was a bit overwhelming. Unfortunately, where I work we are contractually limited to two companies, so it's a bit frustrating to see all that's available, but not be able to use it. As for mixing with the

industry folks, my resident colleagues and I were well aware of the fine line that must be walked and did not socialize with the sales reps. But the fact is that industry *is* a big part of the meeting and the field, so that must be taken into account. I'm still trying to determine where I stand on this issue."

"I didn't feel that anyone was inappropriately pushing anything," said Dr. Strebe. "The company representatives were helpful and took the time to explain their products. And I never felt treated differently because I am a woman."

On the other hand, Dr. Siemionow's experience was not as positive. "There were times when company representatives were not as welcoming as they could have been. I look very young, so perhaps this affected their decision about whether or not to interact with me. It was a bit like going to an expensive boutique and being ignored by the salesperson."

And here's that "O" word again. Dr. Ali: "The expo booths were overwhelming. Also, it wasn't obvious to me how things were organized. I spent a fair amount of time wandering around and would have preferred it if things were more clearly laid out."

Generally speaking, the industry exhibits did not occupy much of the residents' time while at the 2009 meeting. Perhaps this is because, as Dr. Harris said, "The exhibit area is not very helpful because I am not in practice yet. Aside from the fact that it's so overwhelming, many of the products featured there don't relate to what I do on an everyday basis."

Contact With Senior Surgeons

Residents perusing the program not only focused on the topics available, but on who was delivering the information. While they were pleased to see so many orthopedic dignitaries on hand, some residents had difficulty getting access to the surgeons. Some just wanted to ask questions of the orthopedic veterans, while others sought to explore the possibility of a fellowship. In the end, most residents relied on friends and colleagues to help them make new connections.

Dr. Kuntz sums up the process by which many residents met seasoned surgeons: "Most of my contact with surgeons was because one of my faculty members introduced me around. Overall, I felt like I had enough time to speak to surgeons at the meeting."

Dr. Labson felt the hint of a pecking order at play. "My colleagues and I traveled around the meeting with a gaggle from UC Davis, so I met surgeons through these people. In general, I was not able to interact with the presenters because they were inundated by other people. We residents were essentially beat out by the attendings."

The folks from Ohio also moved en masse. Dr. Siemionow: "I traveled around with a large pack from the Cleveland Clinic and was basically able to meet new surgeons because someone I was with bumped into someone they knew."

Drs. Upasani and Harris found little difficulty interacting with surgeons after the educational sessions. Dr. Upasani adds: "I met surgeons after the lectures, as well as at our UCSD reunion party."

For Dr. Shanti, however, things could have been better. "I didn't have enough interaction with surgeons because I felt like I couldn't stay after the lectures…I had to run to catch the next presentation. A couple of my resident colleagues told me that they attended seminars where the speakers didn't even remain for Q&A."

Advice for Future Resident Attendees

Most of the residents interviewed acknowledged that being prepared is the best way to approach the AAOS annual meeting. They had other suggestions as well for those who will attend these meetings in the future. The bottom line, however, is that there is no one entity telling you how to

prepare. You must do your own due diligence and strategic planning.

Dr. Kuntz recommends, "Have a game plan! When you get the final program at registration, sit down and look at each day's offerings and strategize."

On the focus issue, Dr. Waldron concurs with many residents: "Before you arrive, or soon after, decide why you are there. It is easy to get distracted by any number of things, including the location of the meeting. Have a plan."

Sounding a similar note, Dr. Strebe says, "Residents should attend the day-long symposium that is designed for us, especially the fourth and fifth years who need to devote time to issues in our careers that we don't normally consider."

In addition to this, says Dr. Labson, reach out to others who have gone before. "Ask attendings about what to expect at the meeting and how you should navigate through all the various activities."

With so many concurrent sessions, says Dr. Upasani, trying to do too much is the kiss of death to a good meeting experience. "As a second year it was particularly hard to focus. This early in my residency I felt like I wanted to attend a bunch of different sessions in a variety of different subspecialities and it was difficult to organize my days to make it all work out. I really should have spent more time before the meeting selecting the sessions that were most important to me."

Dr. Ali adds, "Go over the schedule thoroughly and only attend those things that will be most relevant to your practice. I would also recommend that you try to interact with as many people as possible in your area of interest."

Dr. Shanti not only learned lessons about pre-registration, but decided that it was face time with surgeons that is the most beneficial. "I found the AAOS website to be a little difficult to navigate. I tried signing up for courses online prior to the meeting, but gave up because it was so confusing. Later I realized that you don't have to sign up on the site. Also, based on my experience this year, I would recommend that residents focus on getting to know surgeons instead of attending as many talks as possible."

If You Were in Charge…

The good news is that when asked if they were given the responsibility for improving the AAOS meeting experience for all residents, most folks interviewed felt that there was not a lot of room for improvement. The other good news is that they had some interesting ideas.

A popular cry from the residents was, "more residents." Dr. Kuntz: "I'd like to see more of my fellow residents in attendance. I think the issue is home hospital coverage; there are no barriers from the Academy."

Dr. Van Sice agreed about coverage issues, adding, "I want more residents there, but I know that the programs are sometimes limited by the amount of funding."

With regard to getting and staying involved in the Academy, Dr. Van Sice noted, "AAOS has a resident liaison program whereby each orthopedic department designates one resident to be the point of contact for their program. The liaison meeting at AAOS was basically a slideshow lecture to indicate what the Academy can do for residents, a la, 'Welcome, these are your contacts, stay in touch.' It is easy for residents to attend and *say* they're going to be involved. I think it would be helpful if at the end of this session each resident wrote down goals for their program. For example, have a resident in their program apply for a committee position, or arrange for a guest lecturer to visit their program."

Practicality was the order of the day for Dr. Waldron, who said he would like to see more presentations geared toward helping residents prepare for their careers. "I also think it would be useful to learn about any programs that the Academy offers to residents to help them find the right job. Additionally, any specialty-specific presentations about career planning would be particularly helpful, since the types of jobs available differ greatly amongst specialties."

If in charge, Drs. Ali and Strebe would plan social events that would enable residents to interact in a relaxed atmosphere. Dr. Ali: "I would hold one or two resident cocktail receptions or coffee hours at times that don't conflict with anything else." Dr. Strebe added, "A residents-only reception would go a long way toward making us feel welcome and included in the meeting."

Dr. Ali also indicated that he would like to have a business education/practice management seminar that doesn't conflict with anything else, adding, "I found the instructional course lectures to be a bit too expensive. Perhaps the Academy could arrange it so that residents attend one or two at no charge."

If given the chance, Dr. Harris is ready to roll up his sleeves. "I'd like to see more resident specific courses during the week, especially those that involve hands-on activities. We could work with sawbones, other equipment, and do hands-on demonstrations with new implants. Labs and didactic sessions would also be great learning opportunities."

A bit of on-site mentoring would enhance the meeting experience, said Dr. Labson. "It would be great if it could be arranged for senior residents to attend different events with attending level surgeons. For the junior residents perhaps there could be one or two sessions directed more toward basic orthopedic topics."

Drs. Upasani and Siemionow would like to see more pre-meeting coordination. Dr. Siemionow specifies, "The resident-specific events should be better advertised. I'm definitely part of the AAOS email chain and I don't recall too many notifications, if any, about resident events. It also wasn't clear if these activities were things the program coordinators were supposed to know about/help us with."

He continues, "Last year the North American Spine Society held a fellows dinner which was led by a surgeon who had just completed his program. He gave an informative presentation about his first year in practice. On hand were a number of fellowship program directors from across the U.S.; it was a super opportunity to get to know them. There's no reason why we couldn't have a residents dinner at AAOS with a similar program/agenda."

Dr. Upasani adds, "I really enjoyed the residents forum organized by Clinical Orthopaedics and Related Research and feel that more sessions to allow informal interactions between the residents and senior surgeons would be useful."

Wrap Up

On the whole, those residents interviewed felt welcome and generally well-integrated into the 2009 meeting of the American Academy of Orthopaedic Surgeons. Because the majority of the residents had scheduling/organizational challenges, however, perhaps a more formalized system could be instituted to address these issues. (For example, enhanced communication between AAOS and residency coordinators.) Additionally, it may be worth exploring the extent to which residents benefit from the industry exhibits. There may be a lack of clarity as far as how this part of the conference impacts residents, especially at this point in their careers. Lastly, as it is now, the process of resident/surgeon interaction seems somewhat random and at times, harried. Thus, it is likely that residents would gain from having specific time set aside to meet with senior surgeons.

Congratulations to the Academy for its continued efforts to meet the needs of future orthopedists. After all, now a resident…later, a President.

Jeff Wang Under Attack

Walter Eisner

Last week, the University of California–Los Angeles announced that it had removed Jeffrey Wang, M.D., as co-executive director of the UCLA Comprehensive Spine Center. The University is investigating whether Dr. Wang's research was affected by payments he received from spine device companies. Wang will remain on the school's faculty while the investigation is being conducted.

Jeffrey Wang, M.D.

UCLA

From our perspective, it appears as though UCLA has thrown one of its own research and surgery stars under the bus.

The genesis of last week's surprising announcements could arguably be traced back to May 2009, when Senator Charles Grassley sent a letter to the Chancellor of UCLA stating that Dr. Wang "consistently checked no" on university forms when asked whether he had received income of $500 or more from companies funding his clinical research. California requires that state university researchers disclose all financial ties to nongovernmental entities funding their work.

UCLA has alleged that Dr. Wang did not disclose financial interests in connection with the following research projects:

- DePuy Spine, which paid Dr. Wang $125,900 in royalty and consulting payments from 2002 through 2008;
- Facet Solutions Inc., a company in which Dr. Wang acquired options for 18,000 shares in 2004;
- Paradigm Spine, an entity related to another company in which Dr. Wang received options for 20,000 shares;
- FzioMed, which paid Dr. Wang $144,000 from 2002 through 2008; and
- Medtronic Inc., which paid Dr. Wang $275,000 in royalty and consulting payments from 2003 through 2008.

According to the school, Dr. Wang did report some, but not all, payments from Medtronic.

Employment Contract Enforcement

Dr. Wang is a NASS (North American Spine Society) board member and chair of the Society's CME Committee. NASS has the profession's strictest disclosure policy, and we have personally heard Dr. Wang present from the NASS podium and disclose his financial relationships with companies.

We note that Dr. Wang had made disclosures to NASS and as part of his published papers and in those venues he had disclosed his financial relationships with the firms listed above.

Orthopedics This Week asked a representative of UCLA, Ms. Roxanne Yamaguchi Moster (Director of UCLA Health Sciences Media Relations), about Dr. Wang's other disclosures as well as the sense that UCLA is losing talented surgeons due to confusing and obfuscatory employment policies. She did not answer our inquiries directly but, instead, offered the following statement:

NASS NORTH AMERICAN SPINE SOCIETY

"The University regrets that a pattern of non-disclosure could have persisted without our knowledge," in the case of Dr. Wang. She went on to say that UCLA was committed to examining the institution's processes to determine "how, as an institution, we will prevent

similar problems in the future. Our internal investigation will be thorough and is proceeding with deliberate speed."

Star Chamber

Moster's statement said that an independent committee has been appointed and is charged with reviewing "whether any of the potential conflicts-of-interests identified have in any way affected the research performed and if there are any mitigating actions needed to ensure the integrity of the research results."

OTW has requested the names of the committee members but was informed that the committee is an internal advisory group and UCLA does not release names of such committee members.

As an aside, we did find it curious that the institution declined to name its committee members as the institution's stated policy is: "UCLA understands that conflict-of-interest policies that provide the highest level of transparency and accountability are critically important to UCLA and all other academic medical centers." We believe that investigations of conflicts-of-interest also require the highest level of transparency and accountability.

Moster stated that UCLA has seen no indication of research misconduct as defined by federal regulation, only a failure by Dr. Wang to make timely reports of financial interests. She said they were evaluating an appropriate action against him in connection with those omissions.

The University of California has sent a complete copy of UCLA's response to Senator Grassley to the California Fair Political Practices Commission, the body which oversees conflicts-of-interest matters in California.

In addition to these actions, UCLA's David Geffen School of Medicine has developed and implemented a new faculty disclosure process that supplements the annual disclosure of outside activities. This procedure is now part of the School of Medicine's salary negotiations process. Moster's statement also said the school is reviewing policies and procedures to "identify

appropriate enhancements that will better support management of conflicts-of interest."

If Senator Grassley had not requested documents from UCLA about its surgeon salary agreements, it's doubtful that we'd be seeing this played out in public.

Show Me the Money

Money and medicine are a volatile mix. In New Jersey, the efforts to separate orthopedic manufacturers from their surgeon inventors and advisors resulted in a $311 million fine levied against the major orthopedic implant manufacturers. Since then, we've learned that more than $50 million of those dollars went to affiliated friends and colleagues of the lead prosecutor. We've also calculated that roughly $200 million of the settlement amount came directly out of surgeon's pockets.

Given the recent history of attacks on the relationships between surgeons and manufacturers, we are skeptical about UCLA's positioning in this case—particularly with the backdrop of California's financial meltdown. For example, did UCLA attempt to receive any of these research and other funds for itself? What are the rules for UCLA scientists and researchers with regard to studies and intellectual property? What are the UCLA policies with regard to surgeon research and consulting fees?

Policies regarding surgeon consulting practices are available online from NASS, SAS (Spine Arthroplasty Society), AANS (American Academy of Neurologic Surgeons), and AdvaMed. We could not find any such policies for UCLA online, nor were they provided to *OTW* by the University.

Furthermore, if a researcher discloses his or her financial ties through the surgeon societies and if that information is public (as in available online), then has the researcher adequately disclosed?

Robin Young, publisher of *Orthopedics This Week* and a frequent podium speaker at spine surgeon meetings, had a strong reaction to the UCLA action and statement.

Said Young; "UCLA bears culpability in this matter. We know from our own research that Dr. Wang had disclosed his financial ties in other venues, most notably at the North American Spine Society. Furthermore, UCLA itself suffers from a lack of transparency, which undermines the legitimacy of their actions. Finally, we believe strongly that many of the problems attributed to Dr. Wang are quite likely the result of institutional mismanagement and confiscatory rules that affect not only research dollars coming into UCLA but also legitimate consulting contracts coming to its best and brightest researchers."

2009 Orthopedics This Week Spine technology Awards

Deadline approaching for awards submissions!

Submit your spine technology by August 15, 2009

Remember, it costs you nothing to enter your new spine technology or product, and there are no limits to the number of submissions by any company.

All submissions will be voted on at the Spine Technology Awards Banquet on November 9, 2009, in San Francisco, by attending spine surgeons.

These awards are the first of their kind and are designed to honor the best spine products, engineering teams and inventors of 2009.

Entries are being accepted in eight categories:

- Device Technologies for Cervical Care
- Lumbar Care
- Motion Preservation of the Spine
- Minimally Invasive Care
- Biomaterials
- Diagnostics and Imaging
- Pain Management
- Regenerative Technologies

Each company or individual that submits products for evaluation will receive a corporate award from *Orthopedics This Week* at the podium during the awards ceremony on November 9 in San Francisco.

The 24 finalists and the first place, second place and third place **awards in each category will be determined by two separate real-time surgeon votes at the November 9 event.** The engineers/inventors for the top three products in each of the eight categories will be invited to the podium to describe their invention to the assembled surgeons before the final ranking vote is taken. The top three products in each category will receive crystal awards at the ceremony. Those receiving awards need not be present to win.

Enter today—your technology could be judged a winner by spine surgeons!

Click here to print an entry form and obtain more information, or contact Tom Bishow at tom@ryortho.com or Lisa Carpenter at lisa@ryortho.com.

RY Publications

Amniotic Tissue: Making Waves, Fixing Smiles

By Daniel Knowlton

Regenerative medicine: it's a hot spot of research and development in almost every medical field. In medicine, finding ways to help the body heal itself is continuously aiding or, in some cases, replacing implants and devices made of metal and plastic. To find one of the best healers in the human body for dentistry, Robert Tofe, president of Snoasis Medical, looked back to one of the first tissues of life, to find a source for his regenerative product line; the placenta. As it turns out, this often discarded tissue has the potential to protect and heal the body long after its time spent protecting a baby during pregnancy.

Mr. Tofe is leading the way in developing uses for this technology. He's using amnion tissue, the inner most lining of the placental sac, to heal tissue in the oral cavity, called mucosal tissue. "What makes amnion so special?" asks Mr. Tofe. "The basement membrane, the part cells travel on, closely mimics the basement membrane of oral mucosal tissue. It has a high concentration of laminin-5, which is found in the basement membrane of both of these types of tissue; laminin-5 is the primary cellular adhesion factor for gingival epithelial cells."

Mr. Tofe, however, is not the first to discover the healing properties of amnion. The first recorded clinical use of amnion tissue was in the early 1900s, when physicians began using it on patients with burns or ulcerated skin conditions. Fast forward to 2009, and we finally have the research and scientific know-how to develop widely available amnion tissue based medical products.

Probably the first "aha' moment for clinicians occurred early on when, as was published in the American Journal of Surgical Research in the 1930's, human amnion membrane was found to be transplantable from one person to another, without fear of the host rejecting the transplant. "One really exciting aspect of amnion," explains Mr. Tofe "is that it is immunoprivleged. Placental tissue, including amnion, does not exhibit a class II antigen. For example, if you took a piece of my tissue and transplanted it into your body, it would exhibit an immune response and possibly graft rejection. With amnion, you don't get that. The placenta serves as a barrier that protects the baby from the mother during its term in the womb."

"In fact, since the first recorded publication of its use in 1910, I've never seen mention of an immune response to amnion tissue - fresh, frozen or processed."

Fixing Smiles

So what does Robert Tofe use this wonder tissue to treat? Gingival recession. This condition occurs when the gums recede; exposing a tooth's root, causing sensitivity and pain. "There are basically only two treatments," says Mr. Tofe. "Dental surgeons can harvest a piece of tissue from the roof of the mouth, known as the palate; however, this is not very

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1. Data on file at DePuy Orthopaedics, Inc.

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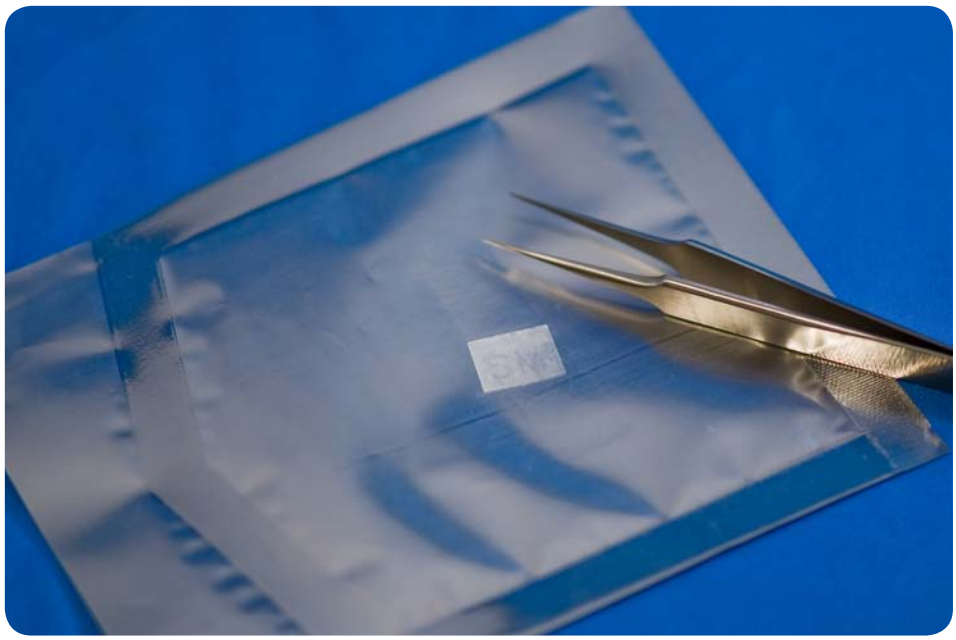


BioCover allograft

fun for the patient. In those cases, the surgeon has to make an incision to expose the tooth's root and then use that piece of the patient's palate to suture over the defect. But, wait, there's still more. The surgeon must then bring the original flap of tissue back over the wound site and suture that in place."

So the surgeon has to create a new wound, suture twice and worry about all the extra pain and infection potential. Before Tofe and Snoasis, the dental surgeon's only alternative to the cut twice and suture twice approach was to use donated (from cadavers) allograft dermis tissue.

"Cadaveric tissues are difficult to use," says Mr. Tofe. "Among the reported problems with cadaveric skin is that early healing associated with its use is often less than ideal. Specifically, physicians have reported that cadaveric skin can be discolored, have a foul smell and if the membrane becomes exposed, it can get infected. The use of dermis tissue does not eliminate all of the pain. Once placed, patient's gum tissue is stretched over this bulky material and sutured into place, causing discomfort and local trauma."

Now comes a third option from Snoasis and Robert Tofe. BioCover is the product's brand name and it is processed, dehydrated allograft of amnion tissue for use in treating gingival recession. "Our material is very thin, which is actually better suited than allograft dermis (much thicker) for oral surgery," says Mr. Tofe. "Surgeons can put BioCover onto the surgical site dry. The natural moisture in the wound allows the amnion membrane to self adhere to the exposed root surface and proximal bone."

"The clinician does not need sutures to secure BioCover in place which actually eliminates the most technical step of the surgery. I've heard so many doctors say, 'Oh, it's so easy!' and it can reduce surgery time by 50% to 80%."

The tissue donations, which eventually turn into sealed packages of BioCover, originate from a completely different kind of operation. "We get our amnion tissue from consenting mothers who undergo elective cesarean section surgery," says Mr. Tofe. "A procurement agency retrieves the tissue and delivers it to processing, where it is cleaned, dried, fused, embossed and terminally sterilized." Snoasis embosses each BioCover product with the company initials, SM, in order to help clinicians identify the basement side of the allograft. "Another benefit," adds Mr. Tofe, "is that BioCover is stored at room temperature and has a five-year shelf life."

Although Snoasis has only been selling BioCover for seven weeks, this short amount of time has been long enough to see patient's sporting pain-free smiles. "The early healing is phenomenal. Patients usually take ibuprofen for 24 hours, and after that they're fine. They can return to their lives. They can't brush that spot for two weeks, obviously, but they aren't in pain. It hurts to harvest palatal tissue. With our product, the clinician simply makes the incisions, covers the defect with BioCover, and closes it."

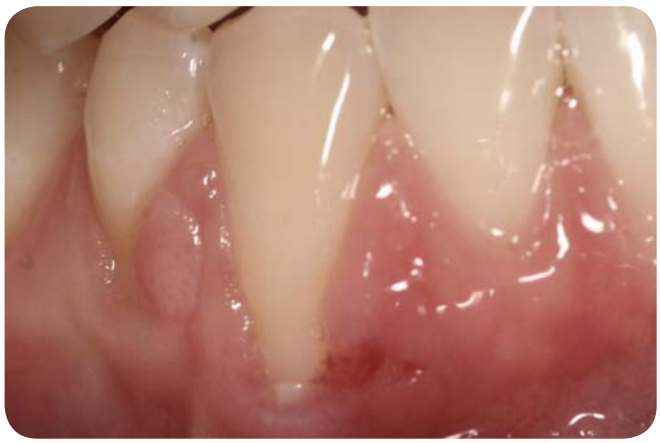
The Road to Commercialization

The product and the procedure may seem simple and straightforward, but the path Robert Tofe took to start Snoasis and develop BioCover had its share of twists and turns. He began building the company in February,

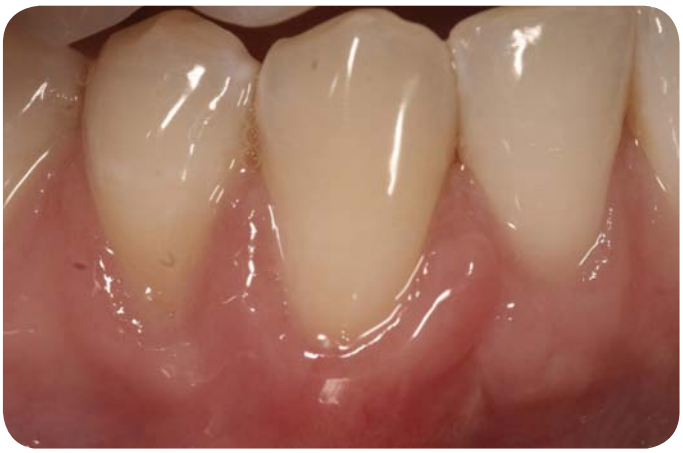
2007, by investing a good deal of his time and money. Mr. Tofe took it upon himself to begin research of the placenta by looking online. "I've done a lot with Google," he says. Robert's father, Andrew Tofe, Ph.D., a man who found both CeraMed and CeraPedics, called Surgical Biologics, through a Google search. "They had actually started down the path of amnion research in the dental field. They were about three or four months ahead of me, and they already had prototypes. At first, it seemed like I had a competitor."

These two budding companies, however, met face-to-face and eventually decided to combine forces. In November 2007, "we agreed in principal to work with one another," says Mr. Tofe. "Then it took us to July of 2008 to complete the deal. It was a long negotiation, but now we have a wonderful arrangement. Snoasis owns the exclusive dental rights to their intellectual property and all current and future products. Surgical Biologics, including improvements originating from Snoasis, owns the exclusive rights for all non-dental applications. I think this arrangement enables a high level of cooperation. Surgical Biologics is a phenomenal partner."

It did, however, take some convincing on Mr. Tofe's part to bring the two companies together. "I knew this was going to work. I remember thinking that this could be huge. Surgical Biologics wanted to find a big corporate partner, and I told them that if they go with Snoasis, we would out perform any of the large dental implant companies." Why? "The



Gingival recession, prior to treatment.



Gingival recession, after treatment with the BioCover allograft.

larger companies focus on implants and as history has showed over and over again, they do a poor job at marketing hardware and regenerative products."

It also helps that, despite being at the young age of 34, Mr. Tofe has had many years of experience in the field. "I spent a number of years in dentistry. My dad founded CeraMed, a dental bone substitutes in the late 1980s; I started working there when I was 15. I stayed all the way until I was 26, but when my dad started CeraPedics, an orthopedic bone substitutes company in 2002, I jumped ship and became his fourth employee. That was a hell of a ride." However, after CeraPedics secured a $14.5 million of venture capital, Mr. Tofe decided to use what he had learned over the years and created his own company. "I've got four employees, and this is all really new. Periodontists are the scientists of the dental community, so they are skeptical. But I never worry. Snoasis has an incredible products and I'm excited to share my love for our amnion based tissue products with others."

To ensure the safety associated with the use of this product, BioCover is procured and processed according to standards established by the United States Food and Drug Administration (FDA) and The American Association of Tissue Banks (AATB). An additional assurance of safety is achieved by terminally sterilizing each membrane.

The Future of Amniotic Tissue

Mr. Tofe hopes that the benefits of this novel allograft from living donors, reduced surgery time, improved patient outcomes, and an affordable price tag, may be just enough to convince the skeptics.

"In dentistry, a product has to work. It has to be easy to use, and it has to be economical; there is very little third party reimbursement. BioCover delivers on all counts."

Mr. Tofe has certainly set himself up to achieve his simple goal of "building the number one dental regenerative products company."

As for the future of this technology, amnion tissue has many potential uses across the field of medicine. Mr. Tofe has two other amniotic tissue products currently in clinical trials: another product to treat gingival recession and a membrane barrier for guided bone and guided tissue regeneration. "I believe this technology has tremendous potential wherever there is mucosal tissue" says Mr. Tofe. But for now, Robert Tofe is content to use the placenta as basis for helping dental professionals improve outcomes. "I don't have to take the world. I'll just take dentistry."

company news

NY Hospital Queens: New Ortho Center

George F. Heinrich, M.D, Chairman, board of trustees, Jeffrey Rosen, M.D., Chairman, department of orthopaedics and rehabilitation, Assemblywoman Grace Meng, William Gibbs, M.D., Medical Director, physical medicine and rehabilitation, and Stephen S. Mills, President and CEO.

With the snap of a ribbon, aching Queens-ers have a new place to seek help. New York Hospital Queens has just opened of its new 7,200-square-foot Center for Orthopaedics and Rehabilitation Medicine in Fresh Meadows. All manner of musculoskeletal help is available, including orthopedics, physiatry and rehabilitation. The new patient care center houses the practices of three board certified orthopaedic surgeons, a digital x-ray machine, a full range of physical therapy services and occupational therapy services.

Commenting to *OTW* was Jeffrey Rosen, M.D., Chairman, Orthopaedics and Rehabilitation, who noted, "The department of Orthopaedics and Rehabilitation in New York Hospital Queens is expanding its ability to deliver the highest quality of care to the community in Queens—the most ethnically diverse county in the country. Our area population is aging rapidly and the need and demand for joint replacement is increasing as well. To meet our growing demands, we have hired new clinical leadership in orthopaedics and rehabilitation medicine. We have welcomed two full-time fellowship trained orthopaedic surgeons to our staff—one is fluent in Chinese, and one is fluent in Russian."

He also said, "This center is a state of the art medical facility with electronic medical records, a digital x-ray machine that is accessible from the hospital, new physical therapy equipment and new office space for the expanding faculty. With the growth of our orthopaedic surgeon base, we will deliver care to the community for all aspects of musculoskeletal medicine, including the latest non surgical treatment alternatives. Our expertise in surgical orthopaedic solutions will include sports medicine; ligament and tendon repairs/ reconstructions; joint replacement; joint preservation; fracture care; and computer/robotic surgery. We are also expanding our occupational therapy, vestibular therapy and lymphadema therapy programs."

Concerning the challenges and/or milestones of getting the center up and running, Dr. Rosen told *OTW*, "The main challenge has been budgetary in these difficult economic times. However, New York Hospital Queens has shown great commitment to this community by moving forward with this center. Additionally, developing completely paperless electronic medical records is a large investment that takes a great deal of effort and time to build. In the end, this will enhance the care for all patients and be a model for the community to follow."

—EH (July 21, 2009)

ConforMIS Garners $50 Million

It's "iTotally" wonderful… Celebrating its largest round of funding yet, ConforMIS, maker of the iDuo and iTotal knee products, has raised a glass in honor of its recent $50 million from private-equity and sovereign-wealth funds in the U.S., Asia, Europe, and the Middle East.

"With this round of funding, we believe we are well positioned to continue investing in our breakthrough, patient-specific orthopedic implant technologies. Our technology platforms provide

company news

With ConforMIS' $50 million round of funding, the company is positioned to continue to invest in its personalized orthopedic implant technology platforms, which provide a scalable approach to the patient-specific design and manufacture of the company's line of implants, as well as the accompanying single-use iJig instrumentation®."

a scalable approach to the patient-specific design and manufacture of not just the instruments, but the actual implants as well," said Dr. Philipp Lang in the news release. The CEO and Chairman of the Board of ConforMIS, Dr. Lang added, "With our personalized approach to both the implants and instruments, we think the potential for product and business model innovation is substantial."

As for the business model innovation, Dr. Lang commented to *OTW,* "With ConforMIS' technology all components of the system are made for one-time use. This patient-specific approach to orthopedics creates significant opportunities for business model innovation, by introducing manufacturing technologies that have previously not been used in orthopedic manufacturing and creating a just-in-time (JIT) delivery system to the hospital. Through manufacturing redesign, we are able to employ rapid prototyping technologies that are ideally suited for cost-effective small run production of implants and instruments. This radically reduces the inventory and capital requirements to run the business, while also creating opportunities to introduce product improvements more quickly. Finally, the JIT approach creates efficiencies in the delivery and management of the system that benefit the hospitals as well."

Specializing in personalized resurfacing implants and instruments for the routine treatment of knee osteoarthritis, ConforMIS indicates that its implants are a less-invasive alternative to traditional total knee replacement, which uses off-the-shelf components that may require significant removal of healthy tissue during the procedure.

ConforMIS, which has just received CE Mark certification for its iDuo bicompartmental knee resurfacing system, has more than 250 patents and patent applications, including several foundational patents awarded this year. The company had previously received CE Mark for its iForma implant and its iUni unicompartmental knee resurfacing system. All devices have been cleared by the FDA marketing in the U.S.

Regarding how the funds will be divided amongst company projects/goals, Dr. Lang told *OTW,* "This funding enables us to pursue three key priorities in our business plan. First, we will continue building our commercial presence, including expanding our U.S. sales force and our presence outside the U.S. Second, this funding allows us to invest in our manufacturing platforms to support volume growth and the incorporation of new technologies to reduce cost and lead time. Finally, these funds will support the successful product launch of the iTotal platform."

—EH (July 21, 2009)

Stryker 2Q09: Controlling the Controllables

It wasn't exactly Donald Rumfeld's "known unknowns," but Stryker chief Stephen MacMillan described the company's first half performance of 2009 by saying the company "controlled the controllables."

With that, MacMillan explained that while reported revenues for the second quarter were down 4.6% to $1.634 billion, cost-cutting measures begun when the economy began to tank last year allowed Stryker to

company news

keep churning out a decent bottom line of $0.73 per share in earnings, topping consensus by a penny.

Hips, Knees and Spine

Stryker	2Q09	U.S.
Reported Revenues	down 4.6%	down 0.5%
Ortho Implants	down 0.2%	up 9.1%
Hips	down 2%	up 9%
Knees	unchanged	up 11%
Spine	up 9%	up 14%
MedSurg	down 11%	down 11%

Source: Stryker company records

As also reported so far by competitors (Biomet, DePuy), the U.S. markets performed well above overseas business as the strengthening dollar hurt revenues. Additionally, as also reported by competitors, the company's spine business grew at the strongest pace. Stryker's medical surgical equipment business was deeply impacted by slower capital purchases by U.S. hospitals.

Domestically the strength in hips for the quarter came from the Trident (especially TriTanium Cups) and X3 product lines. For knees, sales were strong in the Triathlon lines.

Domestic spine was led by its thoracolumbar products. Bill Plovanic, senior analyst with Canaccord Adams, said that though Stryker remains a smaller player in the spine market, the company appears well positioned to take market share from the larger players with its spinal implant products.

The company reported that it had pared back on sales force expansion. Plovanic said this was in contrast with 2008, which experienced the hip recall, increased spending toward the quality assurance initiatives, and higher expenses associated with compliance activities resulting from the Department of Justice investigation into physician consulting agreements.

Mix and Pricing

Stryker executives, on the quarterly call with analysts on July 21, said that second quarter overall prices were flat but benefited from positive mix. They noted that domestic recon prices declined by the low single digits though this was mostly offset by modest trauma and spine price increases.

Mike Matson, senior analyst for Wells Fargo Securities noted that management reiterated its first quarter comment that its domestic recon pricing has seen slightly negative pricing for the past five years. Matson thinks that this may have been due to the backslide the company saw with its ceramic hip sales which created a negative mix shift starting in 2004 and may not be representative of the broader market where he thinks domestic pricing was positive during this timeframe. He believes the ceramic hip mix shift has run its course and there may be other factors contributing to recent price declines.

The company lowered its 2009 constant currency revenue growth target to 1% – 3% from 2% – 5%.

—WE (July 23, 2009)

2Q09: Zimmer Steadies

Ever since Ray Elliott left Zimmer through the front door and John Ashcroft came in the back door to monitor the company's physician consulting agreements, the story of Zimmer has been about market share.

Market Share, Market Share, Market Share

So when Zimmer's CEO Dave Dvorak reported Zimmer's 2009 second quarter revenues on July 23 in a quarterly conference call with analysts, all ears were focused on comments about regaining lost market share.

Reported revenues for the quarter declined 5.5% to $1.02 billion.

Said Dvorak, "Our second quarter results provide further evidence that we are successfully stabilizing our business and making progress toward restoring positive momentum. We

company news

achieved sequential improvement in revenue on a day-rate basis for the quarter in six of our seven product categories, including knees and hips. We are once again reaffirming our 2009 sales and earnings guidance."

Surgeon Training

As Zimmer put in place one of the industry's toughest compliance programs, the company was criticized for losing important surgeon customers. To regain those customers, Dvorak said that the company was making "significant progress in the area of professional education through the launch of the new Zimmer Institute. He said the company has made substantial investments to develop a highly interactive education model that he believe sets new standards for the industry.

Officially launched on July 1, the Institute is focusing on individual surgeon needs. During 2009, Zimmer expects to train approximately 20,000 medical and dental professionals worldwide.

When analysts asked if surgeon training would be enough to pick up market share, Dvorak replied, "That's going to be dependent on a lot of things. In addition to training and education, some of these new product approvals being cleared within the U.S. market in the ramp-up time. So, I think the important thing for us is stabilization in the first instance, and then doing all the things that are necessary to get back into the share gain mode in the future, and that's really our objective for the year, as we exit 2009, and enter 2010 with everything coming together, we'd expect to be in that kind of a position."

Analysts pushed further in asking exactly what incremental share the company lost or gained in hips and knees since the end of 2008

CFO Jim Crines answered that the company felt that it had lost about 2 points of share in hips and 1.5 points in knees when comparing the fourth quarter of 2008 to the fourth quarter of 2007. In looking at competitors that have reported so far this quarter, Crines said he doesn't believe they have lost any incremental share in either hips or knees in the first half of this year.

Now for the second quarter numbers:

Zimmer	2Q09	U.S.
Reported Revenues	down 5.5%	down 1%
Reconstructive	down 7%	down 2%
Hips	down 10%	down 4%
Knees	down 6%	down 3%
Spine	up 18%	no data

Source: Zimmer company records

Knees

Dvorak said the knee portfolio continues to benefit from the use of Trabecular Metal Technology. He was pleased with a study in the July *Journal of Bone and Joint Surgery* that indicates the trabecular metal tibial is an effective alternative to standard cemented tibials.

Hips

The hip results reflected the impact of market share losses, which the company believes have stopped in certain product gaps which are been addressed.

"Our hip portfolio continues to benefit from a very strong portfolio of stems. The Zimmer M/L Taper Hip Prosthesis family of stems is growing at nearly five times the market procedure rate. In addition, the Fitmore Hip Stem is the most frequently requested component for femoral insertion during our MIS surgical skills training events," said Dvorak.

Spine

Dvorak said spine growth was being driven by the Abbott Spine acquisition which was completed during the fourth quarter of 2008 and contributed $20 million of incremental spine sales in the quarter. The Zimmer Legacy Spine business was negatively impacted by competitive pressures and ongoing reimbursement challenges.

The story from this call was that Zimmer has stabilized, surgeon

company news

training is resuming and new products are in the pipeline that will get their salespeople excited and aggressive.

Ray Elliott is probably watching Zimmer's $1 per share earnings from Boston with some nostalgia and may wonder how that would fit with his new company's struggling earnings challenge.

—WE (July 23, 2009)

NuVasive Revenues Up 54%

Reporting a 54% increase in 2Q09 revenues from the previous year's second quarter, NuVasive CEO Alex Lukianov told analysts during a July 23 conference call that, "We are determined to become the #4 global spine company." He also reiterated the company's goal to reach $500 million in revenues in the next year and then "onward and upward" to $1 billion in sales.

NuVasive 2Q09: Onward and Upward

On the way to that goal, NuVasive reported 2009 second quarter revenues of $88.5 million, up from $54 million;$1 million from the same quarter in 2008. The company also upped their 2009 financial guidance by $5 million from the previously announced range of $355 million to $360 million.

PearlDiver Senior Analyst Matt Menze told *OTW* that management emphasized that revenue growth was not only being driven by their MIS (minimally invasive surgery) portfolio, but by taking market share. He estimates that NuVasive's market share has doubled from 2007-2009, rising from 2.1% to 4.2% of the $8.9 billion dollar worldwide spine and related biologics market.

"There is still substantial opportunity for further share gains," noted Menze. "By advancing its technology to treat complex disorders such as deformity and spinal instability and by building out its cervical portfolio, the sales force should be able to get deeper penetration into existing accounts while attracting additional surgeons focusing on specialty areas of the spine. By strategically acquiring cutting edge technologies in high growth areas in spine, such as the PCM cervical disc and biologics such as Osteocel, strong revenue growth should continue moving forward."

For NuVasive it's all about market share, new products and growing its sales force.

Lukianov told analysts that by the end of 2009, the company expects to have 250 sales reps and is launching new offices in Europe and a mini-NuVasive in the New York/New Jersey area to serve East Coast and European surgeons.

The company is planning to introduce a new fixation system for adult scoliosis and a vertebral body replacement for trauma and tumor use. Lukianov also told analysts that the company plans to launch a new low-profile pedicle screw system, further improvements to MaXcess for thoracic use, and a new lateral plate. He also said the company expects to apply for a PMA for their PCM cervical disc in the first quarter of 2010.

Lukianov believes NuVasive's Osteocel sales will reach $45 million – $50 million by the end of the year. It also has two Osteocel trials underway for the lumbar and cervical spine

company news

and expects those to be completed by late 2010. He anticipates that with successful trials, the company's biologics business can hit $100 million in the next few years.

But the former Sofamor Danek executive saved his most passionate remarks for a report on the ongoing patent litigation with his former company, now owned by Medtronic. He told analysts that while the lawsuit is in its early stages, Medtronic has already blinked by withdrawing 3 of the 12 claims in its suit. He also told analysts that NuVasive has filed a countersuit against Medtronic.

"We will not seek a settlement, we'll fight this all the way," said Lukianov.

Read more about Lukianov's experience with lawsuit involving Sofamor Danek in this week's feature by our publisher Robin Young.

Finally, Lukianov told analysts that he is not worried about discussions in Washington, D.C., about health care reform and comparative effectiveness. "The marketplace will reward those that are most cost-effective," said Lukianov. In light of a new focus on cost-effectiveness, Lukianov said the company was currently conducting cost-effectiveness analysis on their devices and procedures. He was clearly feeling confident.

Onward to number 4.

—WE (July 24, 2009)

legal & regulatory

Synthes Execs Settle With DA

On July 20, Mike Huggins and John Walsh agreed to plead guilty to a misdemeanor charge of shipping a misbranded medical device, the Norian XR across state lines.

Huggins accepted responsibility for what occurred on his watch, according to a statement released by his attorney. He added that he did not do anything knowingly or intentionally wrong.

We reported last month that Synthes and four executives of the company had been indicted by a grand jury in Philadelphia for conducting an unauthorized trial for a bone cement.

Huggins was president and chief operating officer of Synthes' spine division from late 1994 to January 2008 and Walsh has served as director of regulatory and clinical affairs in the same division since August 2003.

They each face a $100,000 fine and a year in prison when they are sentenced October 22. Huggins and Walsh have reportedly agreed to the fine.

The Philadelphia Daily News reported on July 21 that the two other individual defendants, Richard E. Bohner and Thomas Higgins, also are expected to plead guilty to the same charge.

The original indictment alleged that an unnamed senior Synthes executive ordered Norian to be "test marketed" by training about 50 spine surgeons to use Norian XR to treat fractures in the vertebrae.

On July 21, *The Philadelphia Inquirer* reported that the plea agreements included Huggins' acknowledgment that he was aware of, and involved in, the process of approving the test marketing of Norian SRS and Norian XR.

Walsh's plea agreement stated that he approved the continued promotion of Norian XR for spinal surgery even after three elderly patients died on operating tables. No link has ever been demonstrated between the use of the product and the patient deaths.

legal & regulatory

Synthes has vowed to vigorously defend itself.

—*WE (July 21, 2009)*

large joints

New Report: Obesity and Knee OA

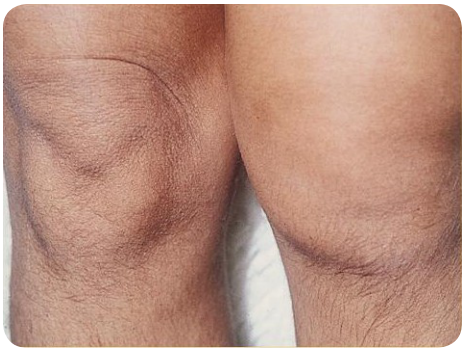
Lose pounds and gain a bit of confidence that you won't be a statistic…The UK-based Arthritis Research Campaign has just released a report indicating that obese individuals are four times as likely to develop osteoarthritis (OA) of the knee as they are to develop high blood pressure or type-2 diabetes.

There is an upside, however, according to Professor Alan Silman, medical director of the Arthritis Research Campaign. "Research shows that losing weight, however modest, when combined with exercise, is a panacea at every stage," said Professor Silman in the news release. "Achieving a healthy weight reduces the risk of developing the disease in the first place, relieves existing symptoms and helps to prevent further deterioration. And weight loss and exercise has been shown to achieve the same level of symptom relief as joint replacement surgery."

With an eye toward recent research, the Arthritis Research Campaign is expressing concern that the true impact of obesity in the development of knee OA has only just become clear. They cite a study which found that at the most extreme, very obese people with a body mass index (BMI) of 36 or more have a 14-fold higher risk of knee osteoarthritis compared to those in the healthy BMI range.

"There are two major risk factors for developing osteoarthritis—aging and obesity—and as both these factors are on the rise in the UK, it's an obvious prediction to make that the outcome could be a massive cost to the health service," he added.

As indicated in the news release, not only are joint replacements are more likely to fail *earlier* in obese patients, but the heavier the patients the less likely it is that surgery will result in symptom improvement. Also noted was that very obese women are 19 times more likely to need knee replacement and four times more likely to need hip replacement surgery compared to women of a healthy weight. Several recent studies have shown that even modest weight loss and exercise can help to reduce not only pain but also mobility and the ability to perform everyday activities.



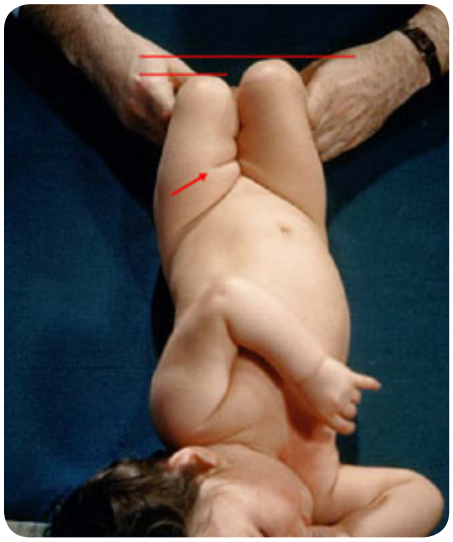
—*EH (July 22, 2009)*

Little Hips, Big Problems

Developmental hip dysplasia, the most common congenital defect in newborns, received some focused efforts lately from a group of researchers from Boston. Their work on this condition, which involves a shallow, unstable, or dislocated hip joint, was published in the July 2009 issue of *The Journal of Bone and Joint Surgery (JBJS)*. The conclusion? Screening all infants for hip dysplasia can significantly decrease their chance of developing early arthritis.

"This study systematically evaluated what we know about hip dysplasia to determine the best screening strategy for newborns," said study author Susan Mahan, M.D., in the news release. Dr. Mahan, a Pediatric

large joints



Orthopaedic Surgeon with Children's Hospital in Boston and instructor in orthopaedic surgery at Harvard Medical School, added, "Our study confirms that pediatricians need to continue their current screening strategies for hip dysplasia. However, our findings refute a recent report from the United States Preventive Services Task Force that was unable to recommend screening strategies."

While the condition is often difficult to detect until adolescence, parents and caregivers are encouraged to be on the lookout for early symptoms such as legs that are asymmetrical during diaper change or a limp or waddle when the child begins to walk. Dr. Mahan and her colleagues analyzed data from more than 70 research studies and clinical trials dating back to 1939, and compared long-term outcomes in the following screening strategies:

- Ultrasound screening for hip dysplasia for all newborns
- Physical exam by a pediatrician for all newborns with ultrasound screening used selectively only for infants with risk factors
- No screening for any newborn

"We found that the best chance for avoiding early arthritis of the hip as a young adult occurs when you screen all babies with a physical clinical exam and utilize ultrasound for those who have risk factors," said Dr. Mahan in the news release. Those risk factors include a family history of hip dysplasia, an infant delivered breech at birth, or positive physical exam.

"We are trying to catch the cases that do not get better on their own," added Dr. Mahan. "The younger the child, the easier the condition is to treat. And, with early treatment, it is more likely that long-term complications may be avoided."

Regarding the details of the study, Dr. Mahan told *OTW,* "We utilized decision analysis techniques to help determine the best technique for screening for hip dysplasia. We tried to determine, of the following screening strategies, what was the best way to limit early hip arthritis:

(1) screening of all newborns with physical exam and hip ultrasound
(2) screening of all newborns with physical exam and utilizing ultrasound for newborns considered at high risk for hip dysplasia (family history or breech presentation at delivery) or with a positive physical exam
(3) no screening

We found that the best method to limit early hip arthritis was screening of all newborns with physical exam and utilizing ultrasound for those with risk factors or positive physical exam. This supports the current recommendations of the American Academy of Pediatrics but refutes the recent findings of the United States Preventive Services Task Force which could not recommend screening for hip dysplasia. No new patients or participants were utilized in the study and instead we used the best available data from previously published studies."

As for publicizing their findings, Dr. Mahan told *OTW,* "The AAOS has put out a press release which has been picked by various sources, including orthopaedic, pediatric and popular press literature."

—EH (July 23, 2009)

spine

FDA Clears LDR's ROI-C

Take a deep breath and swallow easily, the FDA has cleared LDR's ROI-C cervical cage.

The company said on July 20 that its cage, when combined with its Vertebridge plating technology reduces the need for thick cervical plates that may contribute to dysphagia, or difficulty in swallowing.

This stand-alone construct for fusion in the cervical spine offers a zero profile option for the 44,000+ anterior

spine

LDR's ROI-C Cervical Cage

cervical discectomy and fusion implantations projected for the U.S. by 2010, said the company.

The self-guided, curved plating is delivered in the plane of the disc through a direct anterior approach. The company believes surgery can be achieved with less exposure than may be required to implant a traditional cervical plate or even contemporary stand-alone systems with screws that must be inserted at oblique angles.

Christophe Lavigne, CEO of LDR, believes the entry of the cage into the U.S. market represents a huge step for the company in providing solutions for varied spinal pathologies. "The product builds on the success we've had with the MC+ device and Vertebridge plating to provide surgeons with yet another innovative and reliable solution."

Gregory A. Hoffman, M.D., of Orthopaedics Northeast, Fort Wayne, Indiana, and Paul Henry Cho, M.D., of The Center for Neurological Disorders, Fort Worth, Texas, were the first to implant the ROI-C in the United States. Dr. Cho said he was impressed with the speed and ease of plate insertion. Dr. Hoffman noted the "great bone-implant contact and primary stability with immediate loading."

According to the company, LDR's MC+ has been successfully used in more than 5,000 cases worldwide since 2002. The ROI-C evolved from the MC+ and has the same domed surface to match the shape of the endplate, without requiring removal of structural vertebral bone. The chief technological advancement of the ROI-C is the integration of the Vertebridge plating technology.

Clinical evaluation of the ROI-C began in France in April 2009 with over 350 cases completed worldwide prior to its market introduction as a cervical cage in the United States.

—WE (July 21, 2009)

trauma

Sexual Healing by IntimateRider

Here's something that could really enable the disabled. When patients undergo hip or knee joint replacement surgeries, they might imagine their rehabilitation process as physical therapy in a clinical setting. But what about the rehabilitation that happens in the bedroom?

Any injury or surgery that affects an adult patient's physical mobility may also hinder that patient's sexual ability. Resuming normal sexual activity with one's partner after surgery can be a difficult, frustrating and even embarrassing process, but it's an important part of healing and rehabilitation. And the IntimateRider from HealthPostures is here to help.

Designed by a quadriplegic patient with limited arm movement and no trunk or leg muscle control, the IntimateRider is a low seat on a gliding frame which helps restore normal sexual mobility. Although this specialized love seat seems to be designed for men, women can also benefit from using the IntimateRider. The seat is very stable, requires little effort to move, and allows most wheelchair-bound patients to transfer to the IntimateRider on their own. HealthPostures even designed a companion product, called the RiderMate, which is a simple cot on which your partner can lie at the same height as the IntimateRider. The company sells their products in the U.S. through their web site and has several international distributers around the globe.

According to a recent HealthPostures press release, U.S. patients undergo 300,000 total knee replacement surgeries and 190,000 hip replacement surgeries every year. Returning to a normal, active sex life can be quite a challenge during the initial healing process. And for patients with serious spinal injuries and those who require

trauma

a wheelchair, regaining confidence in one's sexuality can sometimes seem impossible. Yet there are plenty of testimonials from patients who found that the IntimateRider helped them get back to a sexually active lifestyle.

One such patient, featured on the IntimateRider web site, says, "I want to be as much a part of this sexual experience as [my partner] is," and the IntimateRider allows this patient "to do natural things as opposed to just lying on my back." He goes on to say that this love seat has "given us back that confidence, that determination, that real intimate feeling of being a couple as opposed to just two people going through the motions."

Sometimes it's easy to forget that a patient's rehabilitation includes not just their physical body, but their mental and sexual health as well. Fortunately, the IntimateRider is the sort of product that reminds patients and their partners, as one testimonial says, that "it's still okay to get wild and crazy."

—DK (July 24, 2009)

The Picture of Success: Dr. James Wittig

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

"We are insane," says Dr. Tracy Watson of himself and his fellow traumatologists. Dr. Watson, a Professor of Orthopaedic Surgery at St. Louis University in Missouri, explains, "My non-trauma colleagues don't understand why we trauma folks do what we do or why we think it is so 'cool.' On paper it doesn't look like a great sell: crazy hours and the inability to make concrete plans in one's personal life. But for me, there's nothing quite as intellectually stimulating as an open tibia…I still get an adrenaline rush. If someone told me I had to do knee scopes and look at a TV monitor all day I think I would find an 'out.' Thank God people like different things."

A Rural Upbringing

While now exposed to the wider world, Dr. Watson grew up in a remote region with a strong culture all its own. "I was raised in Worland, Wyoming, a mountain area where fishing, hunting, and skiing were regular activities. My college-educated grandparents had homesteaded there as little children in the late 1800s and my parents stayed on because of the lifestyle. My dad, who flew C-47's and B-17's with the Army Air Corps in WWII, earned his business degree after WWII and then moved to Los Angeles to help manage LAX. My mom, an accomplished pianist who graduated from the Oberlin College Conservatory of Music, was also from Wyoming. She and my father grew fatigued by the lifestyle in L.A. after awhile and fled back to Wyoming."

Musing about the effect of his upbringing, Dr. Watson notes, "If I had grown up in a city I would probably be less interested in the welfare of the type of people in the rural area of my youth, namely, hardworking ranchers and farmers. These people are worthy of our respect as they work extraordinarily hard, don't rely on pain medications, and go without disability. It is a culture of extreme self-reliance."

Introduced to medicine by his aunt, a nurse, Tracy Watson says, "She worked in a rural hospital that served 18,000 people. A gregarious individual, she enthusiastically hauled things such as a jarful of tonsils and old stethoscopes home for me to examine. Her encouraging manner helped facilitate my interest in pursuing a medical career."

Medical Training in the "Big City" and Beyond

After graduating from the University of Wyoming with a degree in Zoology and Physiology, Tracy Watson entered Creighton University School of Medicine in Omaha, Nebraska. He laughs, "This was the big city where I was exposed to students from both the east and west coasts. With the former being very 'in your face' and the latter more interested in 'sun and fun,' I learned quite a lot about human nature…and made great friends. On the academic front it was news to me just how much information I was expected to process in medical school—and that I couldn't just do it the night before an exam. I wanted to walk away the first semester, but my dad said, 'At least finish one year. Then, if the content is not to your liking, you may leave.'"

Having found his medical stride, *Dr.* Tracy Watson undertook a general surgery internship in 1981 at the Cleveland Clinic Foundation and then stayed on for an orthopedic surgery residency. "I was seeking a different environment and lifestyle and was pleased to learn that I was accepted to this program, my top choice. The winters were pretty vigorous, however. At least in Wyoming it would snow three days, then the sky would open into a bright blue panorama. In contrast, Cleveland weather can

be extremely gray and dreary. The primary bright spot was that I met my wife while there."

Hunkered down inside, however, Dr. Watson found several rays of sunshine. "The eminent Dr. Bernie Stulberg, a total joint surgeon, inspired me to learn the ins-and-outs of research. He taught me how to plan a project and write it up properly. And he conveyed how important it was to ensure that the research addressed a question that interests you. My path also crossed with that of Dr. John Bergfeld, the chief of the sports medicine service, who served as a role model for how to interact with patients. He had an engaging bedside manner and knew the value of comporting oneself and dressing in an appropriate, professional manner. There was also Dr. Art Steffe, a renaissance surgeon who thoroughly enjoyed the residents and was instrumental in my pursuit of internal fixation and subsequent implant design. Regarding the program itself, I got a great feel for many areas of orthopedics. I felt very comfortable coming out of there knowing that I could operate well and figure things out along the way if I had to."

One of the things he figured out was that trauma was his bailiwick. "In 1986 I headed to the University of Texas Health Science Center/Parkland Hospital in Dallas, Texas for an orthopedic traumatology fellowship, one of only three or four such programs in existence at the time. The chief of the orthopedic trauma service was Dr. Ken Johnson, a no nonsense surgeon who insisted that we achieve perfection on each case. It was during this time that I felt drawn in by the variety inherent in trauma work. I could see that every fracture was different, as opposed to total hips, which can become somewhat routine."

He then connected with Europeans for advanced training, on, among other things, the ability to handle soft tissues with Swiss precision. "I had two AO Foundation fellowships, the first involving five months in St. Gallen, Switzerland with Professor Fredrick Mageral where I learned techniques for soft tissue handling. Also emphasized there was detailed preoperative planning. Following this I went to Munich for five months to work with Dr. Berndt Claudi, who taught me the challenge of dealing with a high volume of blunt trauma patients."

Dr. Watson further expanded his mind by learning to extend bones. "In 1987 I returned to the U.S. and began working at the Cleveland Clinic. During my European fellowship, I snuck away to France to learn the Ilizarov technique for bone lengthening from Professor Jean Marie Hardy. He was doing amazing things in bone transportation and limb lengthening, both rare at the time. The company that had been supplying him with frames gave me a set, but upon my return to the U.S., customs was having none of it because the product was from a foreign manufacturer. I ended up getting the equipment via French Canada."

Flying around the world to learn this technique, says Dr. Watson, also meant flying by the seat of his pants. "There was no formal instruction available on how to perform this technique…and not much written on it either. In 1987 Professor Ilizarov came to the U.S. for the first time and delivered a lecture in New York. In attendance was a 'Whos Who' of orthopedics, with the majority of participants being department chairs. And then there was me, who only received an invitation because of my interest level. Most lectures were in Russian and unfortunately they had a bad interpreter. It was a three day symposium…by the final day there was hardly anyone left in the audience."

Most would only venture to Siberia as the result of a banging gavel. Dr. Watson, however, was eager to go. "As a company in the U.S. started providing materials to do these cases, a small, but increasing number of orthopedists stepped up and got interested. A self taught bunch, we would send Xrays around to consult with one another. The crowning moment was when we stepped on the plane that would take us to learn from Ilizarov in Siberia. For over two weeks we worked in his 1500 bed hospital using only external fixators. He also had an enormous animal research facility with 400-500 Ph.D.'s—all of this in the middle of nowhere. Today, the Ilizarov technique is still used for some difficult problems. The technology has been refined and Americanized to include fancy technical aspects, but the basic idea of distracting bone and lengthening limbs remains the same."

Looking for Trauma

Returning briefly to the Cleveland Clinic, Dr. Watson soon realized that he needed more trauma. "In 1991 I left for the Henry Ford Hospital in

Detroit, where I knew I would find a substantial amount of trauma. Here I worked with Dr. Roy Moed and we built a large trauma service and began a legacy of publications. After 14 years and the addition of talented staff, the institution changed and Dr. Moed was recruited as Chair to St. Louis University. I followed suit."

Commenting on how his specialty has fluctuated throughout the years, Dr. Watson notes, "Traumatology is different now than when I first started. It used to be that an institution would hire one person and work him or her into the ground. In an academic facility you are expected to publish and obtain grants, but if you are the only trauma surgeon you're in the OR all the time…not in the lab or sitting behind a desk. So you come up for review and the Chair says, 'But you didn't publish.' And you exclaim, 'But I did 2000 cases!' This is usually an unacceptable answer, however. Such a situation sends most burned out traumatologists fleeing the hospital and into private practice."

His mentor, however, saw possibilities amidst the morass. "When I joined Dr. Moed in 1991 he had an idea that we start an orthopedic trauma service with a core number of individuals who could share the load, take care of a high volume of patients, and yet have time for the academic pursuits of research and publishing. He convinced Henry Ford Hospital to establish this type of orthopedic traumatology service….separate from the rest of the orthopedic department. This would mean that the remaining faculty in the orthopedic department could do more elective surgeries and not be burdened with the trauma cases. When there is only one trauma person, the elective

surgeons by default have to do trauma cases as well and are not able to build a viable elective practice. This new model also meant that you could have a life—only if it was just a little control over your schedule."

Research and Politics

Part of his life away from the OR involves investigating orthobiologics and bone graft substitutes. Dr. Watson: "Engaging in this work is letting me know how much we need to learn about autoengineering. We thought that if you take simple bone marrow, process it, and inject it into a nonunion then the bone would heal, but it didn't work. We have to do more than just aspirate the marrow and inject it into the fracture site. This might involve expanding the cells in tissue cultures or processing them in a different manner."

Another way of contributing to the field is by holding up a mirror to oneself and others. "I serve on the hospital's Trauma Peer-Review Committee, where we sit down monthly to review the trauma cases on the orthopedic and trauma general surgery services. We analyze complications and less than favorable outcomes on approximately two or three cases a month. It's definitely challenging to be critical of oneself and one's peers. You're also doing a bit of tiptoeing around very strong surgeon personalities…..because we are all working towards process improvement and a better functional outcome for the patient. In this process we sometimes have to 'educate' our colleagues that there may be a better way to accomplish those goals."

He thought trauma was a jungle… then he got into politics. Dr. Watson: "I have just completed my term as President of the Orthopaedic Trauma Association. This apolitical orthopedist got his wake up call, and I realized that I had to learn to think in a much different manner. The volume of work was also a challenge. I learned that while I'm a typical traumatologist in that I procrastinate, I had to rectify that tendency. (We tend to put things off because we're used to just dealing with whatever emergencies roll in the door.) I recently advised the incoming President, Dr. Dave Templeman, to invest in a Blackberry. 'Look,' I said, 'the last thing you want is to get home at 8pm and find 20 emails that ***must*** be answered before you go to sleep."

To unplug from the e-world, Dr. Watson and his family head to the open skies of Tensleep Wyoming. "I have a little ranchette out there of about 90 acres at the base of the Bighorn mountains. We go fly fishing, visit my mom, drive in the wide open spaces (in my 4 wheel drive truck)… and leave the Blackberry behind."

"Much of my success," states Dr. Watson, "can be attributed to my pragmatic, accomplished wife. She is a nurse and was often in charge of a surgical trauma ICU for many years when we were in Cleveland. So she understands what it is that I do for all those hours, and often gives me great patient advice! I have been very fortunate that she can function independently with regard to her interests outside of my work (and not rely on me to be the sole source of entertainment)."

Dr. Tracy Watson—lengthening limbs and strengthening lives.

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