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Orthopedics This Week

week in review

SAS 10
New Orleans, Louisiana
April 27 - 30, 2010

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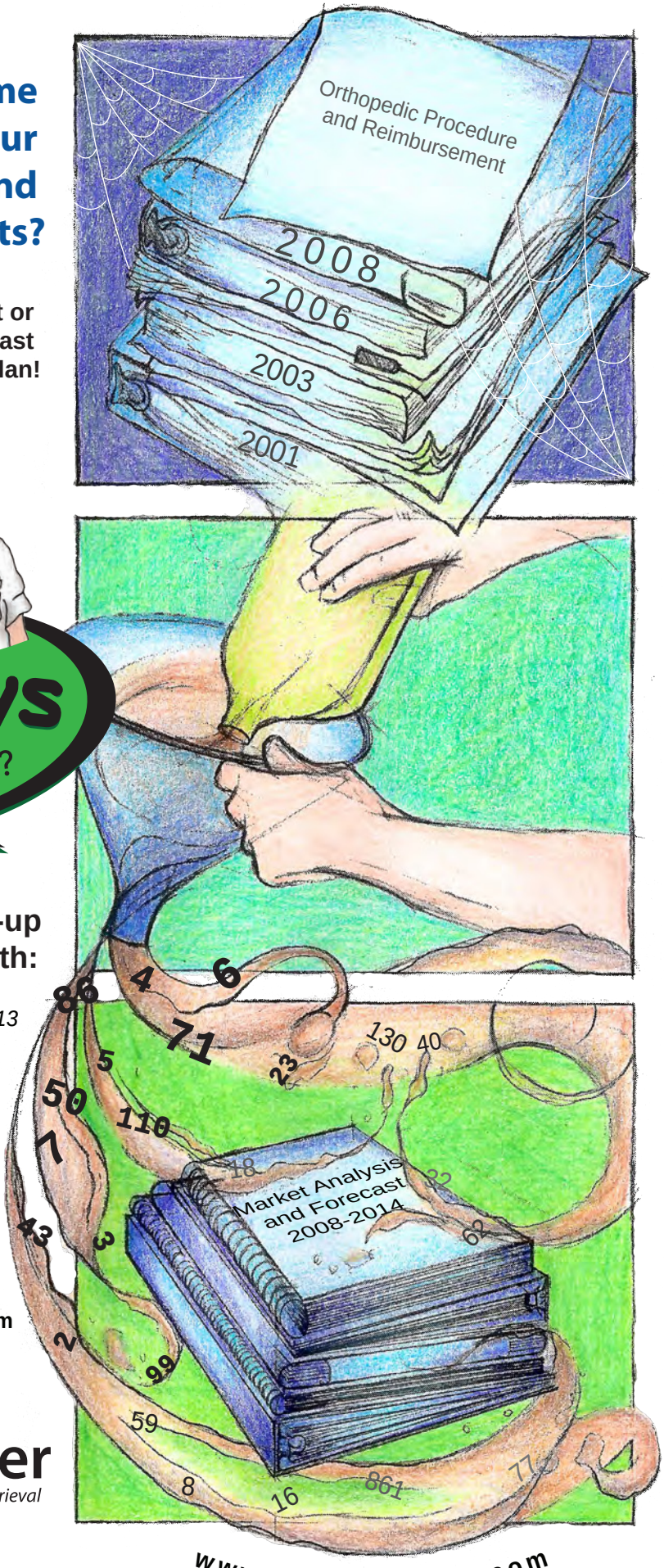

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Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

This Week: Back to the future. Which are the most attractive orthopedic companies today? It's the market leaders—Stryker, Zimmer, DePuy. In an uncertain reimbursement and regulatory environment, these are the ships than can bring surgeons and investors through the increasingly choppy seas. They have the efficiencies, product breadth and cash to ride out the U.S. markets.

Rank	Last Week	Company	TTM Op Margin	30-Day Price Change	Comment
1	3	Stryker	25.88%	(5.33%)	Such an impressive quarter. Large joint recon and hospital equipment led the charge. SYK is the most diversified and cash rich major.
2	NR	Zimmer	27.69	(0.98)	#2 in the Power Rankings this week with solid recon, hip and knee growth, and rising operating margins.
3	8	Johnson & Johnson	27.03	(2.93)	13% year-over-year sales growth at DePuy pushes JNJ up 5 spots this week. If DePuy were independent, it would be #1 or #2.
4	5	Symmetry	10.70	3.63	11% sales growth and, yes this is a real number, 225% operating profit jump. The core business of orthopedics is clearly healthy.
5	6	Exactech	12.72	(8.00)	13% sales growth and three times that in earnings growth—much of it from overseas sales.
6	1	Orthofix	13.51	(16.77)	1Q report was really outstanding, but margins are still roughly half of those at SYK, ZMH or DePuy.
7	2	Integra LifeSciences	14.86	(7.90)	7% sales growth in 1Q led by even stronger growth rate from orthopedic product sales. The real question is, what's the next deal?
8	4	Medtronic	32.01	(7.88)	Spine is kind of quiet. Is this drifting or is it the calm before the resurgence?
9	7	CONMED	8.06	(13.42)	CONMED's 7.5% sales increase was better than expected and signals a recovery in hospital spending.
10	9	Alphatec	(0.28)	(13.95)	We're expecting some transition numbers as Alphatec absorbs Scient'x. Consensus is for a small loss in 1Q.

Robin Young's Orthopedic Universe

Top Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Capstone Therapeutics	CAPS	$0.93	$38	6.9%
2	TranS1	TSON	$3.35	$69	5.0%
3	Symmetry Medical	SMA	$10.86	$389	3.6%
4	Wright Medical	WMGI	$17.65	$663	-0.1%
5	Kensey Nash	KNSY	$22.37	$226	-0.5%
6	Zimmer Holdings	ZMH	$58.50	$11,880	-1.0%
7	Johnson & Johnson	JNJ	$63.31	174,220	-2.9%
8	*Average*			*$11,277*	*-4.5%*
9	Stryker	SYK	$54.12	$21,470	-5.3%
10	Smith & Nephew	SNN	$47.05	$8,310	-6.0%

Worst Performers Last 30 Days

	Company	Symbol	Price	Mkt Cap	30-Day Chg
1	Regen Biologics	RGBO.OB	$0.20	$2	-55.6%
2	Orthovita	VITA	$3.33	$255	-26.3%
3	TiGenix	TIG.BR	$2.79	$86	-24.9%
4	CryoLife	CRY	$5.05	$145	-21.7%
5	Orthofix	OFIX	$31.92	$562	-16.8%
6	Osteotech	OSTE	$3.38	$61	-16.1%
7	RTI Biologics Inc	RTIX	$3.60	$196	-15.1%
8	Alphatec Holdings	ATEC	$5.49	$297	-13.9%
9	CONMED	CNMD	$20.78	$606	-13.4%
10	ArthroCare	ARTC	$27.86	$750	-12.8%

Lowest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Kensey Nash	KNSY	$22.37	$226	12.14
2	Medtronic	MDT	$41.25	$45,440	12.73
3	CryoLife	CRY	$5.05	$145	13.04
4	Johnson & Johnson	JNJ	$63.31	174,220	13.57
5	*Average*			*$11,277*	*13.69*

Highest Price / Earnings Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	P/E
1	Smith & Nephew	SNN	$47.05	$8,310	66.44
2	RTI Biologics Inc	RTIX	$3.60	$196	59.86
3	NuVasive	NUVA	$38.96	$1,520	35.23
4	Symmetry Medical	SMA	$10.86	$389	21.67
5	CONMED	CNMD	$20.78	$606	19.08

Lowest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CryoLife	CRY	$5.05	$145	0.57
2	NuVasive	NUVA	$38.96	$1,520	0.87
3	Smith & Nephew	SNN	$47.05	$8,310	1.00
4	Orthofix	OFIX	$31.92	$562	1.12
5	Integra LifeSciences	IART	$39.98	$1,160	1.16

Highest P/E to Growth Ratio (Earnings Estimates)

	Company	Symbol	Price	Mkt Cap	PEG
1	CONMED	CNMD	$20.78	$606	8.94
2	Alphatec Holdings	ATEC	$5.49	$297	2.73
3	Symmetry Medical	SMA	$10.86	$389	2.12
4	Johnson & Johnson	JNJ	$63.31	174,220	1.86
5	RTI Biologics Inc	RTIX	$3.60	$196	1.73

Lowest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	Osteotech	OSTE	$3.38	$61	0.63
2	CONMED	CNMD	$20.78	$606	0.86
3	Orthofix	OFIX	$31.92	$562	1.01
4	Symmetry Medical	SMA	$10.86	$389	1.06
5	RTI Biologics Inc	RTIX	$3.60	$196	1.21

Highest Price to Sales Ratio (TTM)

	Company	Symbol	Price	Mkt Cap	PSR
1	TiGenix	TIG.BR	$2.79	$86	83.40
2	Mako Surgical	MAKO	$11.96	$402	12.93
3	Synthes	SYST.VX	$109.13	$12,951	3.81
4	NuVasive	NUVA	$38.96	$1,520	3.79
5	Stryker	SYK	$54.12	$21,470	3.10

The Growing Up of SAS

By Walter Eisner

The recently completed meeting of the Society for the Advancement of Spine Surgery (SAS) in New Orleans left many vendors and exhibitors muttering about a "dead" meeting and the lack of spine surgeons visiting their exhibits.

Incoming President Thomas Errico, M.D., told *OTW* on May 6 that a gathering of over 650 spine surgeons was not exactly a small meeting. But quite candidly, he acknowledged that the time has come for the society to look for new ways to bring industry and spine surgeons together in a way that highlights new and innovative surgical technologies.

Indeed, SAS reported to *OTW* that meeting attendance fell 8-10% from last years' meeting but that membership increased 15% from the previous year.

Errico's speech to attendees solidified the changes in the focus of the organization that began two years ago under the leadership of former SAS President Karin Büttner-Janz, M.D. The fact that Errico spent the majority of his speech explaining what SAS stands for was a clear indication that the Spine Arthroplasty Society (the original name of the SAS), was now dead.

In its place?

"SAS is now the International Society for the Advancement of Spine Surgery," Errico told the audience in prepared remarks. "We still cover spinal arthroplasty, but we've expanded our scope to all surgical treatments that help spine patients."

"SAS has always been international, but we really want to emphasize how quickly and effectively we are reaching around the globe." There are now chapters in Korea, China, Taiwan,

Thomas Errico, M.D./President, SAS

India, and the Middle East, and starting this June, in Latin America under the leadership of Brazil's Luiz Pimenta, M.D.

"SAS is a society that deals only with innovative spinal technology, from occiput to pelvis, minimally invasive to maximally invasive, young to old, and degenerative to deformity. **So SAS is the place where spine surgeons can discuss the things relevant to us and more importantly our patients,**" continued Errico.

Long live the ISASS er…SAS.

But a nagging question remains. Is there a need for a spine surgeon society when the North American Spine Society (NASS) is experiencing growing membership and influence with payers and regulators?

Errico, a former NASS president explained why surgeons need their own society after NASS made a strategic decision in the late 1990s and early 2000s to expand the organization.

"NASS holds a special place in my heart, they are our friend," said Errico. He said he remembers being the program chair for the annual NASS meeting in New York in the late 90s and reaching a critical mass of 1,800 members. At that point the Society moved out of meetings in hotels and moved into convention centers.

He said he and his fellow NASS board members made the right decision to grow the organization. To accomplish that growth, NASS needed to reach beyond surgeons and include anyone dealing with the spine. That included rehab and pain management specialists, interventional radiologist and others.

"We were incredibly successful because there was a great need," said Errico. He says NASS now has over 5,000 members and is no longer just a society for spine surgeons.

A Surgeon Society Gap

Errico believes there is a gap and a need for an international spine surgical society. "That's the niche we are trying to carve out. We are in the process of an evolution."

How will going global make it possible for SAS to advocate on public policy issues in different countries?

Errico says individual chapters in Korea, China, India, and Latin America will do that themselves while the larger organization will work in the U.S. and Europe.

We asked Errico if there a tension between advocating for surgery and other appropriate spinal care?

"No. It all starts with appropriate care for the patient. History is on the side of innovation that helps patients," he concluded.

"Does that mean every hiccup of an idea someone has is a good idea? No. That's why SAS exists, to discuss those ideas."

The Surgery Bias: Pro and Con

Errico says there is now an incredible amount of level-one clinical evidence. A few years ago spine surgeons were accused of being biased towards surgery without enough available evidence. That evidence now exists, but he believes payers and regulators still have a bias against surgery and

continue to move the bar to approve new devices and pay for them.

"You can't let your bias get in the way of prospective randomized studies."

In an era of comparative effectiveness, Errico believes industry needs to fund societies to study existing technologies for their effectiveness. "I believe we are going to discover that surgery is the more cost-effective route [in many cases]."

"We will need to get rid of some of the existing technology that do not really work."

This is where the tension will lie between various providers of spine care. With every innovation in a limited pool of resources, the existing technology must share the wealth.

As we've heard said in politics, "When the watering hole shrinks, the animals all start to look at other differently."

Will some types of disc replacement be cheaper and better than fusion. "My intuition tells me that's possible, says Errico. "This needs to be discovered without bias by either surgeons or payers."

In his New Orleans speech, Errico said there are many things in spine surgery that remain poorly studied or lack consensus. Comparative effectiveness research could help resolve some of these uncertainties.

"Spine surgery is already far ahead of most other medical specialties in this game, because most of our best research has been comparative all along—we don't really ever waste time and money studying placebos or waitlists in our clinical trials."

Looking at arthroplasty for example, Errico says the early FDA trials were all comparative effectiveness research, because the comparison group—fusion—is an active real-world treatment that is routinely used. And now, he says the ongoing trials of Kineflex and Activ-L are even more purely comparative, because they compare one disc against another. "These studies may shed light more generally for all discs on the relevance of various disc design features."

More research is needed to guide choices, not to eliminate them, added Errico. Increased promotion of research should benefit everyone by reducing uncertainty.

Improved Patient Selection

"We need new research to improve patient selection for some procedures. For example, among patients receiving fusion for degenerative disc disease, are there certain patient factors—age, smoking, Worker's Comp, depression—that reliably predict lack of clinical improvement?

"We also need research to determine if some forms of treatment for a condition are better suited to specific subgroups of patients than others. For example, does kyphoplasty bring greater clinical benefit to certain subsets of vertebral fracture patients, such as the elderly or women, while vertebroplasty is better suited to other subsets of patients? These are questions we need to answer to better match the optimal treatments with the right patients."

Industry/Surgeon Collaboration

In the old model of answering these questions, Errico says a company would come to surgeons and say, "Look, we've got this amazing new Spine-Widget, and we want you to do a study on it. You enroll the patients, we'll provide the widgets; you do the surgeries, we'll fund it." But he acknowledges that the public is getting increasingly skeptical of these arrangements, due to perceived conflicts-of-interest.

A New Model

In the new model, Errico says a university department, private foundation, or professional society such as SAS will develop a portfolio of priority research themes that need

to be addressed. Private donors, including industry, will contribute unrestricted sponsorship to this research program. Researchers will propose specific studies addressing the topics identified, and the foundation, university, or society will select specific studies to receive funding, based on peer review of the proposal merits.

"This model will create a buffer-wall against inappropriate influence while ensuring closer dialogue, and it will make precious data more widely available for the greater good of the entire spine surgery community," predicts Errico.

SAS Grows Up

Errico believes spine surgery is at a historic pivotal moment.

"Many breakthrough technologies are in the pipeline these days, and at the same time government is getting involved in healthcare like never before. We the spine surgery community need to proactively get research out there showing the benefits and value of our best available treatments.

"Medical companies have a crucial role to play in the R&D of the surgical technology we use to help our patients."

He hopes that SAS will be the meeting place and mediator among spine surgeons from around the world and between surgeons and industry partners.

Will they come? Will a new mission and a new, yet undefined revamping of the annual meeting at the Venetian in Las Vegas next year, increase attendance and make exhibitors happy?

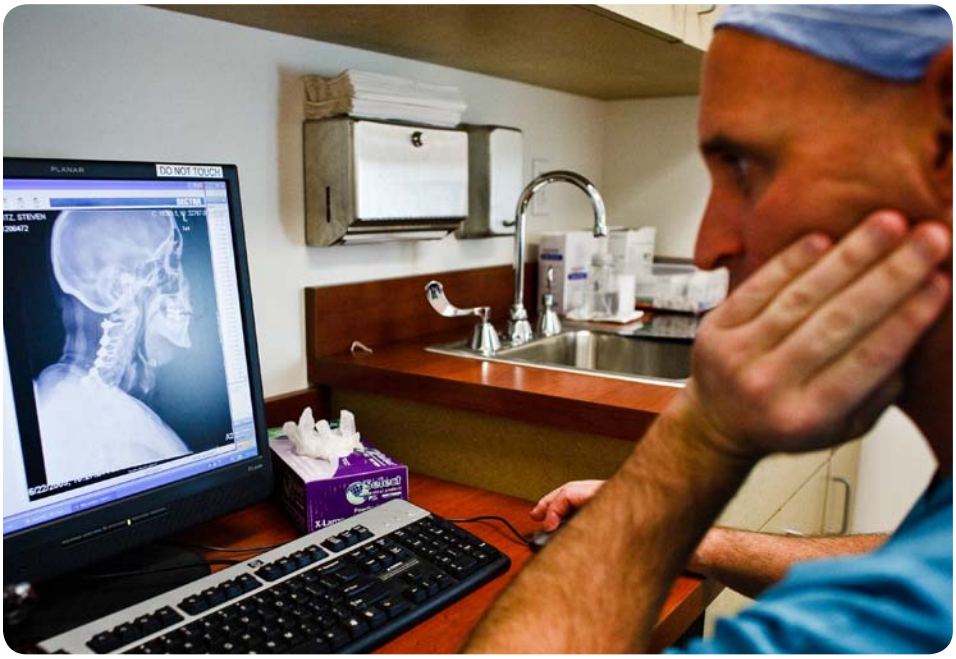
Will the new global SAS live long?

If Tom Errico is right and history is, as he says, on his side, then spine surgeons around the world who want to have their own venue, mission, and society will come and the answers will be yes.

Like a teen-ager inventing their way to adulthood, we'll soon know what SAS looks like all grown up.

Bury My Heart at SAS

By Robin Young



Photographer: Andrew Huth

If a paper falls in the forest, will healthcare providers hear it? Last week a super abundance of Level One clinical papers covering spine technologies and cost data was presented—to a half-empty hall at SAS's annual meeting in New Orleans. So if researchers present high-level comparative effectiveness, MIS and arthroplasty data will the Centers for Medicare and Medicaid Services (CMS) and the private payers notice?

This was probably the best SAS meeting as measured by the quality of the podium presentations and overall program (thank you Todd Albert and Jeff Goldstein). As a scientific society, SAS solicited, organized and delivered relevant and rigorous data to spine surgeons. As a surgeon society could SAS be winning the battle but losing the overall war?

U.S. surgeons may agree that good scientific evidence exists for arthroplasty or MIS or biologic treatments and that the benefits of these FDA approved technologies substantially outweighs the potential risks. If no payer reimburses it, however, then discussing these technologies with eligible patients is an exercise in either futility or altruism.

It is a testament to the commitment of spine surgeons to improving patient outcome that 650 attended to hear these podium presentations—despite payment issues.

The data (see below) is clearly pointing to improved outcomes with motion preserving implants and MIS procedures. SAS made a concerted effort this year to attack the issue of Level One data for cervical disc arthroplasty, lumbar disc arthroplasty, MIS, biologics and other new technologies and procedures for treating spine disease. They succeeded to an impressive extent.

Ranking the Quality of Evidence

Probably the most widely used system of ranking the quality of clinical evidence is the U.S. Preventative Services Task Force ranking. Here is that ranking:

- Level I: Evidence obtained from at least one properly designed randomized controlled trial.
- Level II-1: Evidence obtained from well-designed controlled trials without randomization.
- Level II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- Level II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled trials might also be regarded as this type of evidence.
- Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

What SAS Presented

In a quick-read and summary form, here is are some of the clinical study highlights CMS, FDA, United Healthcare, the Blues, Aetna and Cigna may have missed.

Study Title	Level of Evidence	# of Patients	Conclusions
Abstract: 132: Lumbar Disc Arthroplasty versus Anterior Lumbar Interbody Fusion: Five-year Outcomes for Patients in the Maverick Disc IDE Study *M.F. Gornet1, J.K. Burkus2, R.F. Dryer3, J.H. Peloza4*	Prospective, Randomized (2:1), controlled, 31 centers. **5-year follow up.**	577	**Conclusions:** Consistent with the two-year IDE study outcomes, treatment of single-level lumbar degenerative disease with the MAVERICK Disc resulted in outstanding clinical outcomes at five years after surgery, including Oswestry and SF-36 PCS, resulting in improved physical function, reduced pain, and greater patient satisfaction.
Abstract: 90: 5-year Results of the Prospective, Randomized, Multicenter FDA Investigational Device Exemption Study of the ProDisc-L Total Disc Replacement versus Circumferential Fusion for the Treatment of 2-level Degenerative Disc Disease *R. Delamarter1, J.E. Zigler2, R.A. Balderston3, J.M. Spivak4, R.J. Linovitz5, J.F. Zucherman6, J.J. Yue7, T.T. Haider8, S.H. Kitchel9, F.P. Cammisa10, G.O. Danielson, III11, D. Geiger12, R. Watkins13, H. Yuan14, J.E. Sherman15, H.N. Herkowitz16, M.A. Kropf1, J.A. Goldstein4*	Prospective, randomized (2:1), 16 centers, **5-year follow up.**	237	**Conclusions:** The data shows that significant clinical improvement was achieved and maintained in the ProDisc-L patients out to 60 months; in properly chosen patients, ProDisc-L has been shown to be superior to circumferential fusion at two levels by multiple clinical outcomes.

Study Title	Level of Evidence	# of Patients	Conclusions
Abstract: 219: Preliminary Observations from a Prospective, Multi-center, Randomized, Controlled Clinical Trial Evaluating Anular Repair after Lumbar Discectomy *A. Bailey1, G. Amundson1, S. Blumenthal2, M. Chedid3, R. Guyer2, J.S. Gerdes4, J. Messer5, S.L. Griffith5*	Prospective, randomized (2:1), 34 sites, **2.5-year follow up**	**750**	**Results:** Similar clinical outcomes were noted in the two groups with similar occurrence rates of adverse events. Based on current data available, there was a trend toward a 1.75 times greater risk over time of re-herniation in the control group requiring a second surgery and an overall 57% reduction in the risk of re-herniation with the device. As the number of enrolled patients per surgeon increased, the beneficial treatment effect of annular repair to reduce reoperation due to recurrent herniation increased.
Abstract: 106: 5-year Results of the Prospective, Randomized, Multicenter FDA Investigational Device Exemption ProDisc-C Clinical Trial *R.Delamarter1, D. Murrey2, M. Janssen3, J.A. Goldstein4, J. Zigler5, B.K.-B. Tay6, B. Darden II2*	Prospective, randomized (1:1), 21 sites **2-year follow up**	**236**	**Results:** NDI, VAS and SF-36 scores of ProDisc-C patients improved more than those of ACDF patients at five years, though not significantly. There was a greater difference in VAS satisfaction improvement in ProDisc-C compared to ACDF patients was seen. At 24 months, 84.4% of ProDisc-C patients achieved ≥4 degrees of motion or maintained functional motion (relative to baseline) at the operated level, remaining consistent to 60 months. Within 60 months, the number of secondary surgeries differed significantly; 0.2% of ProDisc-C compared to 8.8% of ACDF patients ($P = 0.006$) needed a re-operation, revision, or supplemental fixation.

Study Title	Level of Evidence	# of Patients	Conclusions
Abstract: 74: Prospective, Randomized Study Comparing Cervical Total Disc Replacement to Anterior Cervical Fusion: *C. Lauryssen1, D. Coric2, R.D. Guyer3, C. Gordon4, P. Nunley5, C. Carmody6, T.A. Dimmig7, W. Taylor8, R. Buckley9, J. Donner10, J. Rhee11, P.C. Gerszten12, P.J. Tortolani13, J. Rappaport14, R.Q. Knight15, G. Dix16, K.T. Foley17, F.D. Bitan18, R. Bains19, H.N. Herkowitz*	Prospective, randomized (1:1), 21 sites **2-year follow up**	**269**	**Results:** Mean blood loss, operative time, and length of hospital stay were not significantly different in the two surgical groups and hospital stays averaged approximately two days in both groups. The mean NDI scores improved significantly in both groups by six-week follow-up and remained improved throughout 24-month follow-up. There were no significant differences between groups at any visit. The VAS pan scores followed a similar pattern, improving significantly in both groups with no significant differences between groups.
Abstract: 107: Prospective, Controlled Results of Patients Treated with Expanded Indications for ProDisc-C *M.E. Janssen1, R. Delamarter2*	Prospective, randomized, 14 sites, 1 level TDR adjacent to fusion, 2 level TDR and 3 level TDR **2-year follow up**	**55**	**Results:** NDI and SF-36 scores were significantly less compared to pre-surgery scores at all follow-up visits for all indications. Overall neurological success was achieved by about 90% of patients at all time points. VAS neck pain intensity and frequency as well as VAS arm pain intensity and frequency were statistically lower at all follow-up time points compared to pre-operative levels for all indication treatments. Radiological evaluation showed no evidence of device migration, device subsidence, or decrease in disc height. Results show that at 24 months post-operatively, greater than 80% of ProDisc-C patients achieved ≥ 4 degrees of motion or maintained motion relative to pre-operative baseline at each operated level. 82% of patients at each time point responded "yes" to having the same surgery again.

Study Title	Level of Evidence	# of Patients	Conclusions
Abstract: 352: SECURE-C Cervical Artificial Disc IDE: Two Year Clinical Outcomes *J. McConnell1, J. Marzluff2, J. Highsmith2, C.R. Tomaras3, T.J. Morrison3, I. Volcan4, A. Goodrich4, P. Asdourian*	Prospective, randomized (1:1), 5 sites **2-year follow up**	**188**	**Results summary:** 188 patients were treated at five sites: 108 patients received the investigational SECURE-C device and 80 received the control ACDF. 143 patients reached two-year follow-up: SECURE-C patients demonstrated significant improvement in average NDI from 51.9 preoperatively to 10.6 at two years, as compared to control patients improving from 54.5 pre-op to 14.9 at two years. Both groups also demonstrated statistically significant improvement in VAS neck and arm pain at two years compared to preoperative values. Differences between NDI and VAS outcomes for SECURE-C and ACDF treatment groups are not statistically significant. At 24-months post-op, patient satisfaction was 92% for the SECURE-C group and 86% for the ACDF group.
Abstract: 504: Cost-effectiveness of Lumbar Total Disc Replacement versus Lumbar Fusion *A. Tuschel1, M. Meissl1, M. Ogon1*	**Methods:** Model treatment and associated direct costs (surgery, inpatient stays, outpatient visits, GP and orthopaedic consultations, x-ray, medication, rehabilitation and physiotherapy) over a 18-months time horizon. Outcomes measured by ODI and SF-36 at one-year follow-up and costs. Costs were derived from standard Austrian price lists and from hospital's cost unit accounting.	**Results:** Disc arthroplasty patients had outcome-scores at 1.5-year follow-up comparable to fusion but had lower costs than lumbar fusion: Costs per improved ODI-point were €954 in the fusion group and €645 in patients treated with lumbar disc arthroplasty. Costs for one gained SF36-point were €1645 after fusion and €954 after disc arthroplasty.	

Study Title	Level of Evidence	Conclusions
Abstract: 56: Cost Comparison of Total Disc Replacement vs. Fusion in Patients with Insurance Denial for Disc Replacement *D.D. Ohnmeiss1, C.S. Hume1, R.D. Guyer2, J.E. Zigler2, S.L. Blumentha*	**Methods:** Eight TDR who were denied insurance coverage and had fusion. These were matched with 8 patients who received TDR re level(s) operated (exact match), date of surgery (< 25 days between matched procedures), and all at performed at the same hospital. Both groups had five single-level cases and three two-level cases. Seven fusions were combined anterior/posterior procedures. Cost data included total billed and total actually received. Costs were further subclassified and compared by category.	**Results summary:** The total cost billed as well as the categories of hospital room, pharmacy, sterile supplies, operating room, and anesthesia costs were significantly greater for fusion compared to TDR (P< 0.05). There were trends for the total actually paid, intravenous supplies and implants and related supplies to be greater in the fusion group. The only cost significantly greater in the TDR group compared to fusion was radiology services. Costs were similar in the two surgery groups for nonsterile supplies and recovery room. Both the total amount billed and amount actually paid for fusion were approximately 50% greater than TDR.

There were approximately another 200 studies presented including many, many more Level One studies. Please contact SAS for a copy of the meeting abstract book.

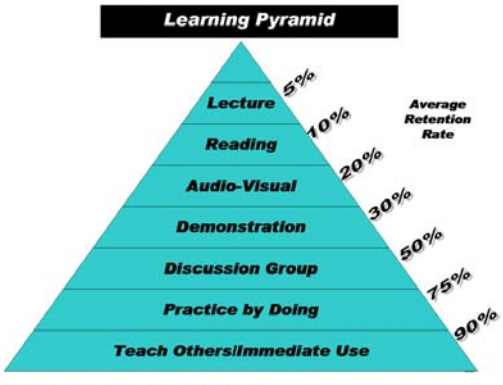
Circle the Chairs: Case Based Learning

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

The topic is sufficiently captivating and the presenter is an acknowledged expert… and yet your eyes begin to close and the heads nodding in the room are not because their owners are expressing agreement. What is happening? The presenter has formulated the learning experience in a way that doesn't encourage participation, says Dr. Jesse Jupiter, a renowned hand surgeon and educator at Massachusetts General Hospital in Boston.

Dr. Jupiter, a student of the educational process, spent years mastering the elements involved in teaching. He states, "We are increasingly recognizing that busy professionals learn differently than college or high school students. It has also become clear to us that to provide excellent continuing medical education (CME) we must not only deliver information, but deliver it in formats that are better received and understood. And according to published research, the lecture format is the least effective form of communication as far as the retention of information."

The wave of the future, says Dr. Jupiter, is the somewhat old fashioned "Case Based Learning." "This is education that occurs in either small or large groups and during which there is a great deal of learner participation. Case based learning has been shown by those who study such matters to have excellent results.



National Training Laboratories, Bethel, Maine

In a sense, this approach takes much of the randomness out of education. In the past CME courses were coffee clubs where there was no real means of assessing how information was delivered or received. That is changing. Pressure is growing from several parties, including state medical societies, to document how information is given and what the outcomes from that education are."

You might characterize this "new" educational modality as one that creates an actual connection between the giver of information and the receiver of information—which, in turn, forms a greater bond between the learner and the topic at hand. Dr. Jupiter says, "Teaching and learning are two different things. You can seem to be a good teacher by giving a well illustrated lecture complete with witticisms, but the learner has to put in some effort in order to benefit. Small group discussions involving cases are very successful at delivering information because they require the learner to join in and they also bring to the learner information they can relate to."

The former head of the international education board for the AO Foundation, Dr. Jupiter notes, "Let me first say that while these events may appear to be freeform, they actually involve a lot of organization. Those who taught me, and who I believe do these events best, are from the AO Foundation. Working alongside professional educators I looked at every aspect of instruction including, for example, the learning

Dr. Jesse Jupiter

environment. In a traditional lecture the lights are typically lowered, encouraging fatigue, and there is little to no means of addressing people's questions. One thing we have found to be effective is to arrange participants in a horseshoe so that they can have continuous eye contact with the leader and with each other (encouraging active participation)."

Elaborating on the strategy, Dr. Jupiter says, "Sometimes one or two people try to dominate the group. The last thing you want to do is embarrass them; you can, however, seat someone like this to your left so that you are no longer making eye contact with him (and he will feel less inclined to have constant input). With regard to the session's structure, the cases must be in a format such that the topic and how you want to handle it are worked out ahead of time. Specifically, you should establish the needs of the participants and then identify your learning objectives."

Whether it's a torn ACL or meniscal injury, Dr. Jupiter makes good use of the much abused knee to illustrate his lessons. Dr. Jupiter: "First, determine your objectives in terms of what information the participants need or want to learn (of course this varies depending on whether these are medical students or established surgeons). Then you design the course based on a particular case, the format of which is an introduction with visuals, followed by treatment options. You finish up with what was actually done in that case. For comparison purposes you could take a different case, show complications and have a discussion with regard to why the knee didn't heal properly. Again, preparation is required…as the leader I would have had to prepare all of this in advance. And ideally you would want the participants to have read related articles beforehand—you don't want them to be passive learners. You wind up the session with an evaluation, one which includes a summary of the key learning points and conclusion regarding the treatment and outcome of the specific case."

Ah, they make a beautiful couple… theory and practice, that is. "Whether you're 'just' doing a case based presentation or you're holding a full event with a cadaver lab, the beauty of the structure is that learners can integrate what they learn in books with what they learn in practice. This makes for a more engaged learner who, as a result, retains more information. Such an approach is increasingly important given that we are finding that young people don't often attend lectures because they are available on the internet. They will, however, go to case discussions because they are stimulating and because the format allows them to clarify learning points. 'This is what I thought I understood…is this correct?' Contrast this with a lecture environment, which is diffuse and does not promote an open exchange of ideas. In a lecture there is no chance to say, 'You know, I read such-and-such article and I don't think the data was sufficient.'"

In the event of a large group, states Dr. Jupiter, there are also ways to encourage active participation. "In a bigger gathering, ask that people move up to the front of the room (otherwise you lose the ability to have eye contact). Get people involved by reviewing a case and asking what their experience has been with similar cases.

Early on during the session ask, 'Can I get a show of hands as to how many of you have found problems with this?' Doing that will allow you to get a sense of what type of audience you have."

Emphasizing the dynamism involved in case based learning, Dr. Jupiter notes, "During the course you can ask the participants what they thought they knew well and didn't know before they came. Then after the course you will have a more objective way of understanding the program. You can change the direction of the discussions and even cases based on the response of the participants."

Although enthusiasm abounds for case based learning, there are some whose personality issues prevent them from jumping on board. "One type of individual who may not like such an environment is the expert him or herself. He is asked to participate and is set to give a lecture that shows off his skills; he doesn't want to prepare much because he already has his lecture. If he is told, 'I want you to come for two days, but there will be no lecture,' then he's just another guy. Also, let's say this is a case based event with a panel and Dr. X is asked to sit on the panel. He is now in a position where he will be asked questions, something he may not be comfortable with."

An interested—and varied—demographic that at times requires special forethought are those clinicians who arrive for training from outside the U.S. "There can be language issues when you have participants from other countries. This can be overcome in many instances by not only speaking slowly but identifying those in the group who can help as interpreters. Also, in some parts of the world you encounter deferential behavior to one's older colleagues. This means that if you call on a younger colleague who is seated next to a senior person in his department the last thing he wants to do is say the wrong answer. To help with this issue, I recommend a pre-course seminar on cultural customs that is geared toward the faculty. I have seen a bit of a shift in Asian cultures, however, with younger students appearing more headstrong these days."

The active exchange of ideas, an increased focus on evidence, and an audience that doesn't appear anesthetized are all the clear benefits of using the case based learning methodologies. Dr. Jupiter: "The case based environment is pivotal in helping learners think more deeply and integrate practice and knowledge. Continuous learning is one of the things that my colleagues and I enjoy most about orthopedics. Why not have a learning experience that is as dynamic and memorable as possible?"

Why not indeed! For more information, Dr. Jupiter may be reached at jjupiter1@partners.org.

Zimmer Opens Trabecular Training Gem in NJ

By Jacqueline Rupp

Ribbon Cutting/Zimmer Holdings, Inc.

Nine blue suits squinted in the spring sun and, no doubt, wished they could pull out the Dockers this past April 23, 2010, in northern New Jersey. But to honor this important milestone in the continuing development of orthopedic biomaterials, the senior executives from Zimmer, accompanied by every employee of the new state-of-the-art training facility AND the mayor and members of Parsippany's city council wore their Sunday best and big, big smiles. The Trabecular Metal dream, one of the most ambitious and promising in orthopedics, was taking a huge step forward.

It was a truly beautiful day for a ribbon cutting. The sun warmed the cool breezes. The crocus and irises were just showing off their full array of colors. Was it fung shei or just Mother Nature? Whatever it was, the beauty of the day somehow affected the speeches and even inside the facility, it was as if the sun was shining on the future of Zimmer and Trabecular Metal.

Trabecular Metal

The history of orthopedic implants is the tale of many innovative surgeons and engineers. It is also the history of biomaterials. The great John Charnley, for example, might never had solved the problem of an articulating hip implant had his assistant not chased down the polymer salesman (after Sir John kicked him out of the lab!) to get his material tested as an implant. After approximately 300 consecutive implant failures (in humans), Sir John Charnley had a polymer material for his acetabular cup. The rest is orthopedic history, of course.

In the half century since Sir John, biomaterials have continued to advance and in some cases revolutionize patient care. One of the potentially most revolutionary biomaterials since high molecular weight polyethylene is Trabecular Metal.

Imagine, for example, a sponge-like metal foam that can either coat an implant or even ***be*** the implant. Now imagine further that the foam, spongy material uses tantalum, one of the most biocompatible metals known to man, and that engineers can tailor the tantalum material to match the mechanical aspects and load-bearing functions of real bone!

That is the dramatic vision that a little New Jersey (yes, also in Parsippany) start-up company named Implex had for its new biomaterial called Trabecular Metal. Of all the major

orthopedic manufacturers, only Zimmer shared that vision and like Sir John's assistant chasing down the plastic's salesman, Zimmer's business development execs chased down Implex and convinced legendary skinflint Ray Elliot (Zimmer's CEO in 2003) to buy Implex.

Looking back today, that deal looks as beautiful and sunny as the day the Trabecular training center opened in Jersey. But at the time, many of the orthopedic industry's Old Guard thought of Trabecular Metal as little more substantial than a passing cirrocumulus cloud.

The cellular structure of Trabecular Metal is remarkably similar to that of Trabecular bone—the same kind of bone found in the joints of the body and replaced by joint implants. Among the unique characteristics of Trabecular Metal is that it can approximate the physical and mechanical properties of bone more closely than other prosthetic materials.

Trabecular Metal has a high strength-to-weight ratio and low elasticity which delivers to the patient the kind of physiological loading that encourages living bone to grow into the porous structure. Trabecular Metal forms a stronger bond with living bone than with other synthetic porous materials. Bottom line, strong bonds mean longer implant life.

Zimmer's First OWI Training Facility

Zimmer, the world's largest supplier of large joint implants (according to PearlDiver estimates, Zimmer holds a 25% market share followed by DePuy

Zimmer Dental Trainling Lab

at 22%), already had an East Coast presence with its Trabecular Metal manufacturing facility in Parsippany. So the move to New Jersey was almost logical. Still, it is Zimmer's first training facility outside of Warsaw and, according to Richard Stairs, Zimmer's SVP of Global Operations and Logistics, about time.

"With its proximity to New York City, it really will be a global destination," said Mr. Stairs. The facility is just 20 minutes (by car) outside of NYC and another hour or so from Philadelphia. So surgeons up and down the East Coast will be able to receive hands-on training in the 113,000 square foot facility (which includes, by the way, a 15,000 square foot BioSkills lab).

Inside Look at the Classrooms

The training center is set up in two parts. Part one is a state-of-the-art dental facility that offers training in both surgery and prosthetics. "The biggest benefit here is our accelerated learning where clinicians get the chance to work on simulated patient models in a two-day course that would take six months with a patient," says Michael Collins, Vice President of Research and Development for Zimmer Dental.

The second part of the training facility is the BioSkills center which focuses on orthopedic procedures and the implementation of the Trabecular Metal in surgery. Here, physicians have the opportunity to work in cadaveric-based training in a space designed to mimic every feature of a typical operating room. Audrey Beckman, Senior Vice President, Zimmer Institute and Grants Office, explained that the training sessions themselves are designed to maximize the physician's educational experience. "Each surgeon gets to perform at four levels of exposure, first they listen

and watch in the lecture room, but it is much more about the hands-on experience and this is where the surgeons have the chance to watch and learn from each other while having the chance to work on procedures themselves. I think this type of sharing of ideas and techniques makes the facility's educational possibilities limitless."

Beckman adds that there is a uniquely low ratio of physicians to lecturers. Expense was not spared when it came to the technological features of the room. "We've installed a high definition camera system with 1080-pixel monitors that allow for better identification of different tissue. This is essential for physicians because when we are talking hip, knee, and shoulder revisions, because of soft tissue, we really need that fine definition for orthopedic surgeries such as these." Beckman adds that these surgeries can then be broadcast over the intranet and possibly the Internet. "For the physicians, this is all about learning how to minimize damage and enhance their performance during surgery. By having the opportunity to use anatomic tissue, the physicians can really fine-tune their skills on a model that is the closet they can come to an actual patient."

Ok, one more item. Stepping into the spanking new training center is like walking into a posh hotel complete with rich colors of tans, blues, and metallic in a subdued, modern even hip environment. The furniture is sleek and comfortable (we sat in all the chairs, fell asleep once). Lighting is toned down and there's a spacious feel to each room.

Keeping Things Compliant

Zimmer, which has taken an industry lead in ensuring surgeon and company compliance, took special care to

put proper compliance mechanisms in place to make the center fully transparent to all regulatory agencies and that there were no "red flags". As we all know, surgeon and company compliance with all industry and federal regulations can be challenging. But Zimmer has made a very public corporate priority to building a safe regulatory environment for surgeons.

"The biggest concept was the creation of a firewall that literally divided the company into two sections," says Zimmer Institute Director of Medical Education Mark Serafino. "Sales and marketing are on the commercial side and on the corporate side is anything to do with the institute, consultants and contracts. Separating the commercial from the corporate was key." But aside from this main distinction, the training institute itself also has safeguards in place. "The institute handles the process of selecting and hiring consultants, which is important because these are people we are paying and they could very well be someone who is also buying the product. So the corporate side handles all of the selection of the faculty members and we manage their contracts and the payment process."

According to Serafino, Zimmer moved away from faculty developed training content to a model where the institute itself developed course content with the faculty. "By controlling content, we ensure that it is consistent. The FDA of course requires safe and effective training which gives us our basis for offering training. Although we pay for attendees' minimal expenses, we set up the training site at a non-resort location (Parsippany, New Jersey? Not a resort?). We make sure that anything we provide is modest and we keep to a strict timing schedule." Serafino told *OTW* that there's no time for recreation on these training trips and each surgeon spends six or seven hours in training, with only brief breaks for meals.

A Great Environment for Surgeons

Ajey Atre, General Manager of the Trabecular Metal Technology Facility sums up the new training center as "a state-of-the-art-facility that uses state-of-the-art-material." He says he looks forward to seeing it become a hub of education and innovation on the East Coast and potentially the world.

"This is a great environment for surgeons to learn from each other," adds Beckman. "That's so important in the field of orthopedics, where technique is so important and can be so individualized, that dialogue and interaction is so essential."

As we said, it was a great day in Parsippany, New Jersey. Almost resort-like...Almost.

company

Synthes 1Q10: Cautiously Optimistic

Synthes reported first quarter revenues of $911.7 million on April 29. This was a 13% increase on a reported basis over the previous year's first quarter.

The company does not provide product categories, but offered sales results by geographic segments.

Corporate headquarters, West Chester, PA, USA / Synthes

North America: Slow Spine

In spite of "sustained pricing pressures and inventory reduction efforts" by hospitals in North America, company President and CEO Michel Orsinger, said the company experienced "encouraging" sales growth for the region.

Orsinger reported that growth in trauma was solid and supported by targeted sales initiatives and market acceptance of new products, specifically for the distal radius, fibula and clavicle. "The growth momentum was somewhat offset by a slowdown in spine's performance, resulting from pricing pressure and delays in new product launches," noted Orsinger.

Europe: Winter Fractures

In Europe, Orsinger said the company experienced double-digit growth across all product groups. He noted a higher number of winter weather-related fractures as contributing factors to that growth. The company also continued to expand its sales force, introduced new products and offered more educational initiatives.

Outlook: Cautious

While the company was encouraged by the first quarter, the press release announcing the financial results stated that the company remains "cautious" about the remainder of the year. "The challenging and dynamic market environment, which is increasingly difficult to predict, is not expected to change in the short-term."

The tone of Synthes' announcement was decidedly more cautious then the optimistic outlook presented by their American competitors over the last few weeks.

Here are the regional unaudited numbers reported by Synthes:

—WE (May 4, 2010)

First Quarter 2010 (January - March)				
Consolidated Net Sales (US$ in millions)	**2010**	**2009**	**% Change (in US$)**	**% Change (in local currency)***
North America	533.1	500.2	6.6%	6.0%
Europe	226.1	185.7	21.7%	13.3%
Asia Pacific	100.2	77.9	28.7%	16.8%
Rest of World	52.3	41.2	27.0%	7.6%
Total	911.7	805.0	13.3%	8.8%

**Local currency: 2010 results translated at 2009 foreign exchange rates. Source: Synthes*

company

Trans1 1Q10: Bottoming Out?

Trans1 reported on May 4 that revenue increased for the first quarter of 2010. The $6.7 million in revenue was the first increase in three quarters, but was a 23% decline from the first quarter of 2009.

That news was enough to get Mike Matson, Senior Analyst of Wells Fargo, to raise his revenue projection from $24.9 million to $26.7 million for the remainder of the year. He wrote that he believes sales have bottomed out for the company as core users of the AxiaLIF procedure remain committed and other customers may return.

AxiaLIF

TranS1 has developed a proprietary approach to lumbar surgical procedures in which the spine is accessed through an axial trans-sacral approach (AxiaLIF) that is percutaneous, minimally disruptive to the surrounding anatomy, and has outpatient potential for both fusion and, in the future, arthroplasty approaches. The company sells the implants and instruments that enable the AxiaLIF procedure.

Reimbursement Headwinds

What the company has been challenged with is reimbursement. Procedure codes for reimbursement are different from standard fusion codes due to the approach to the spine and perceived risks.

Company CEO Rick Randall acknowledged to OTW on May 5 that reimbursement has been challenging but the company is working with payers, surgeons and medical societies to educate them about proper coding. He also believes limited product releases later in the year will lessen the headwinds caused by the reimbursement challenges.

These products include the AxiaLIF 2L+, Avatar and Vectre product lines. Randall says these products have all gone well and he is encouraged by surgeon feedback.

Clinical Data

Making headway with customers, payers and medical societies is going to require clinical data.

Matson noted that AxiaLIF clinical data was presented at the recent SAS (Spine Arthroplasty Society) meeting and is being published in two upcoming journals. Four podium presentations and eight posters on the AxiaLIF were presented at SAS.

According to Matson, data was presented from a retrospective, multi-center study of 154 AxiaLIF patients that showed a 90% fusion rate at two years. Additionally, Trans1 noted that a study was published in a peer reviewed journal which showed 100% fusion rates at one year for AxiaLIF in deformity procedures. And an additional paper on the AxiaLIF has been accepted for publication.

Road to Recovery

There are some similarities to the NuVasive XLIF reimbursement experience. One industry insider told us that while Trans1 caught the flu, NuVasive caught a cold.

Compelling clinical data, surgeon acceptance and easing medical society concerns over perceived risk will be the chicken soup Trans1 needs to get over the reimbursement flu.

—WE (May 5, 2010)

company

Wright's "Settled" First Quarter

Wright Medical Group announced on May 4 that the company expects to settle an ongoing Department of Justice investigation for $8 million and, that on a reported basis, revenue rose 9% to $131.2 million in the first quarter of 2010. The revenue number beat analyst expectations. The company expects full year revenue to reach $515 million to $530 million.

First quarter 2010 Wright revenue growth on a reported basis:

- Knees 6.7%
- Hips 10.4%
- Extremities 16%
- Biologics .1%

According to Joanne Wuensch of BMO Capital, it appears that Wright is holding its own in the hip market but may be losing some market share in knees.

Metal-on-Metal Impact

Wells Fargo analyst Mike Matson said hip growth did not appear to be materially impacted by metal-on-metal pseudo-tumor issues. He noted that Wright's U.S. hip average selling prices increased despite a contraction of market penetration of metal-on-metal hips from 58% in the first quarter of 2009 to 50% in the first quarter of 2010.

Wright management noted a U.S. IDE study for the company's Conserve

Creative Commons

Plus following 1,300 patients with an average follow-up of approximately seven years and zero reported pseudo-tumors may prove to be a competitive advantage. In the immediate future, Wuensch says it is fair to say that the negative publicity may have adverse effects.

New Knee, Reps and Biologics

Wright also announced plans to launch a new posterior stabilized knee system called Evolution. This is a medial-pivot knee built on the design of Wright's Advance knee.

"We think this is a very significant launch with potential to push Wright's knee growth into double digits in 2011," said Matson.

Matson also predicted that extremities sales should improve over the next few quarters as the company added 20 foot and ankle sales reps in the first quarter. This brings the total sales force to approximately 150 reps.

JMP Research reported in an investor note that biologics sales continued to suffer from pressure on the company's DBM (demineralized bone matrix) business as customers continue to use cheaper alternatives to Allomatrix. The note continued that management expects improved growth in biologics on the launch of Pro-Stim bone graft substitute.

—WE (May 6, 2010)

S&N 1Q10: Mojo Returns

With better-than-expected results, Smith & Nephew announced a first quarter 2010 reported revenue increase of 15% to $995 million.

company

The company's orthopedics sales grew 11% during the quarter with hip and knee sales reporting increases of 12% and 14%, respectively.

First Quarter 2010 Reported Revenue Percentage Increases

Total Revenues:	**15%**
Orthopedics	11%
Hips	12%
Knees	14%
Trauma	3%
Endoscopy	21%
Wound Therapy	20%

Company CEO Dave Illingworth said the growth in knees was driven by Legion Revision Knee and Genesis Total Knee systems and an FDA approval during the quarter for a 30-year wear claim for the Legion Ox and XLPE.

The R3 Acetabular Cup and Anthology Stem Systems drove hip sales.

BMO Capital's Joanne Wuensch wrote to her investors that, "there appears to be increasing momentum" in Smith & Nephew's business.

Hip Resurfacing Weakness

While noting some weakening in the company's Birmingham Hip Resurfacing product, the company touted the benefits of the product, emphasizing clinical data from the Australian Registry. Wuensch added that the company did not break out the overall growth rate caused by the decline in BHR sales. Company officials did say there was a "bracket around year-on-year movement" in the U.S. that was continuing to decline.

RRY Publications

Illingworth reported that the company's China manufacturing plant began to make a "substantial" contribution during the quarter. The company is also consolidating its Memphis, Tennessee, orthopedic business and opening an orthopedics manufacturing facility in Beijing this May.

In addition to an 11% reported revenue growth in its orthopedic business, the company also reported revenue growth of 21% and 20%, respectively, in its Endoscopy and Advanced Wound Therapy business.

The Endoscopy growth was largely driven by sports medicine products. The company also announced major launches at AAOS (American Acadamy of Orthopaedic Surgeons) of the Twin Fix Ultra PK Suture and the Bioraptor Knotless Suture Anchor systems.

company

Looking forward into the rest of 2010, company officials commented they expected their hip and knee sales to return to market rate growth.

—*WE (May 7, 2010)*

biologics

Printing Out Wound Healing

Printing out a letter on a standard inkjet printer is as simple as a few mouse clicks. Now, thanks to technology developed by a research team at Wake Forest, skin wounds might be treated just as easily.

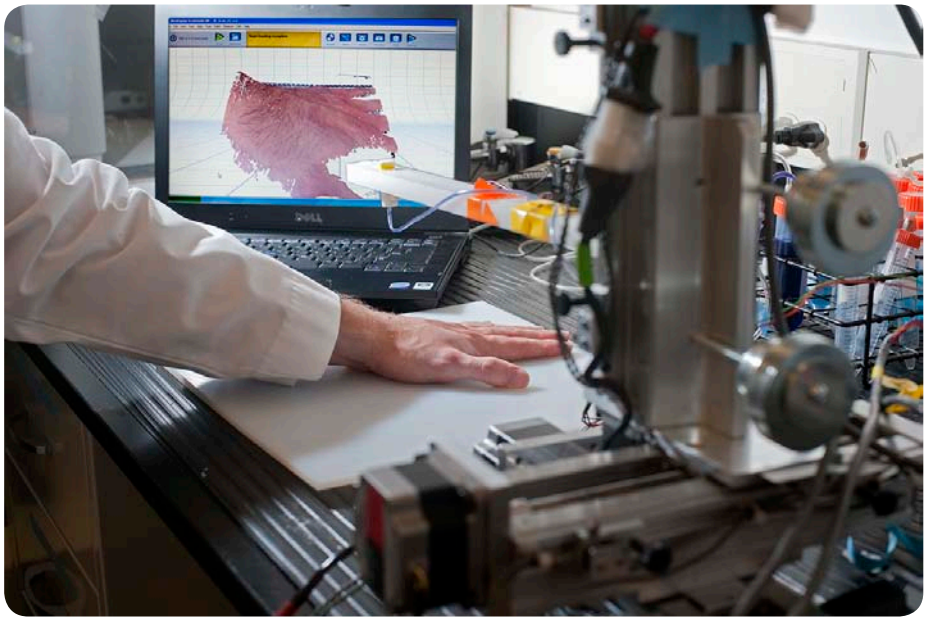
Wound care can pose anything but a quick and simple treatment. But now researchers at Wake Forest are offering a promising new possibility for "bioprinting" using simple ink jet technology, the same kind that's probably sitting on your desktop right now.

Anthony Atala, director of the Wake Forest Institute for Regenerative Medicine, says bioprinting is an adaptation of various printing techniques and for one technique an inkjet printer is used.

> *"But, instead of using ink in the cartridge to print on paper, we use cells to print tissues and organs in a three-dimensional shape."*

In fact much of the same technology is used for this biological print out as with most home office print jobs. A program like PowerPoint for instance is used to "draw" the organ or tissue that will be printed. "The appropriate cells are placed in reservoirs—very similar to ink being stored in a cartridge. In the current project to print skin cells on burn wounds, a laser scans the wound to determine the size and depth, creating a "map" of the wound." The computer then controls which cells are released much like it would different colors when printing a picture.

> ***The concept of "printing" out tissue isn't a new one. Atala says that although the concept and various designs have been around for a while, the science is just catching up with computer technology. Advancements in stem cell technology are key to the success of this latest bioprinting device and its applications.***



(Bioprinting/Wake Forest Institute for Regenerative Medicine and Dept. of Urology)

"Bioprinting would build skin in place, rather than having to surgically move skin from one part of the body to another." For a burn injury for instance, the tissue "ink" is composed of harvested skin cells, stem cells, and nutrients. The layer of fibroblast skin cells are first sprayed on to act as a substrate, with a layer of keratinocyte cells being added for protection followed by the stem cells which can expedite healing.

Besides being a method that can speed healing, bioprinting is also showing promise for its mobile uses. In fact the Armed Forces are looking into the device to treat wounds on the battlefield. "The goal of the project is to develop a treatment that can quickly cover and stabilize a wound,"

biologics

adds Atala. "Research has shown that the longer it takes to cover a wound with skin, the higher the risk of infection, complications, and death."

—JR (May 5, 2010)

large joints

Metal-on-Metal Hip Replacement News

The Medicines and Healthcare products Regulatory Agency (MHRA) of Great Britain recently put out an alert regarding metal-on-metal hip replacements. The review however doesn't raise any urgent alarms, assuring patients that the majority of those implanted with metal hip replacements are considered at low risk of developing serious problems.

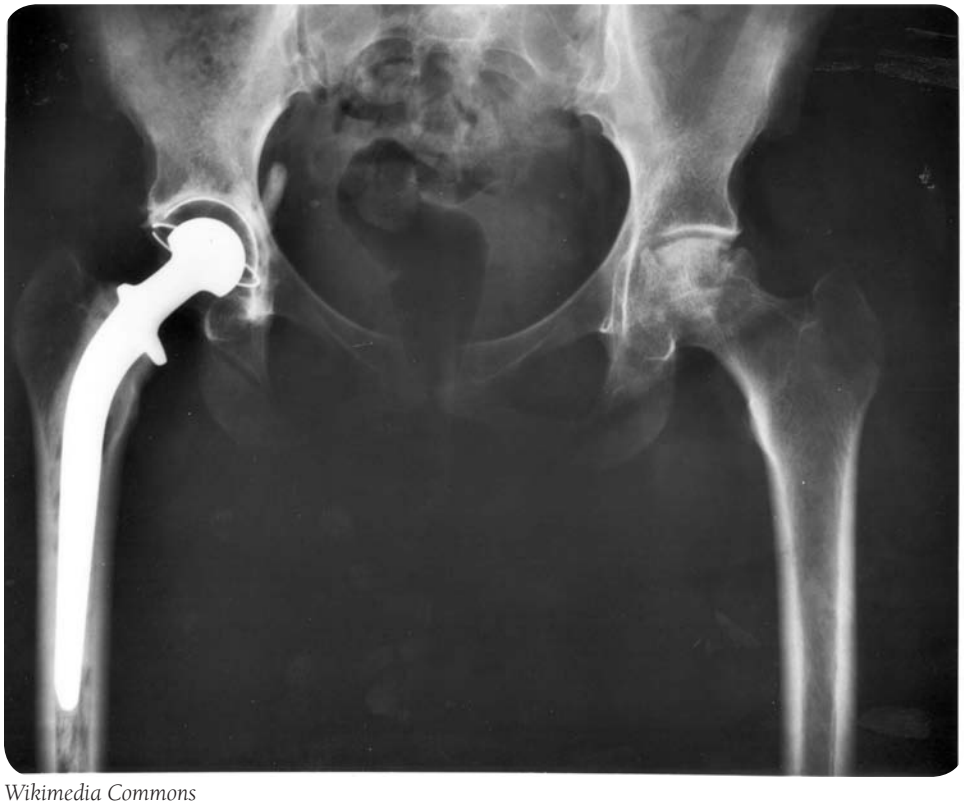
In a statement regarding the release, the MHRA says, "We are aware of the association between metal-on-metal articulation hip replacement and soft tissue injury. We established a Joint Working Group to study this further and to produce advice and guidance for the Health Services based on the results."

The MHRA issued the medical device alert to healthcare professionals because a small portion of patients with metal-on-metal devices are at risk for developing progressive soft tissue reactions that comes from the wear debris caused by the hip's movement. Soft tissue necrosis or non-cancerous tumor growth can result from the debris.

That is why the agency is now reviewing the cases of patients with this type of hip replacement and a blood test may be given to those at risk to check for high levels of metal compound. Some patients may even require a subsequent hip replacement. It is believed that an early revision of hip replacements that have performed poorly should offer up a better outcome for these patients. With 13% of female patients suffering from these reactions, women appear to be at particularly a greater risk.

Scott Ellison, PearlDiver Senior Analyst for Large Joints says this is not a new issue. "There seems to be a lot of talk lately about the metal-on-metal implants since *The New York Times* article on March 4, but this issue isn't a new one. Back in December of 2008 at Current Concepts in Joint Replacement, they were discussing the effects of large metal particles on tissue and resulting pseudotumors, progressive osteolysis, and unremitting pain."

Ellison says that Thomas P. Schmalzried, M.D., of the Joint Replacement Institute noted during this presentation that the risk of cancer associated with a metal-on-metal bearing is no greater than that associated with a metal-on-poly bearing.



Wikimedia Commons

large joints

On the industry front Ellison says that Stryker has the least investment in the market, with their only metal-on-metal product being the Cormet hip resurfacing system. "According to a release from Wells Fargo Securities—as a percentage of sales, Wright [Medical] has the most exposure with an estimated 50% of hip sales from metal-on-metal," adds Ellison.

—JR (May 1, 2010)

Not All Knees Are the Same

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Using the members from the Osteoarthritis Initiative (OAI) cohort, a research team from the Feinberg School of Medicine at Northwestern University examined the frequency of varus (bow-legged) and valgus (knock-kneed) thrust in the group and differences between two racial groups: African-Americans and Caucasians. Just over 3,500 patients were evaluated, including approximately 600 African-Americans and 3,000 Caucasians. These participants were split into two other groups, those with osteoarthritis (OA) in one or both knees and those without.

Because there has been past research to support a link between varus thrust and an increased risk for knee osteoarthritis progression, this subsequent study has significance beyond just demographic statistics. Varus thrust can be seen in someone's walking pattern and involves the development or worsening of a varus or bow-legged malalignment while the leg is taking on weight.

The results of the study appear in the May issue of *Arthritis & Rheumatism* and show an interesting difference between the races. Healthy gait does not reveal a thrust in either the varus or the valgus direction. The evaluation of the cohort revealed that African-Americans in general had more valgus thrust in their gait than did Caucasians, while Caucasians more often had varus thrust than did African-Americans. All together, a varus thrust was found in close to 37% of individuals with knee OA and 32% without, while valgus thrust was found in 9% of persons with knee OA and 7% whose knees were OA-free.

In statistical analyses adjusting for other factors, African-Americans were significantly less likely to have a varus thrust and more likely to have a valgus thrust.

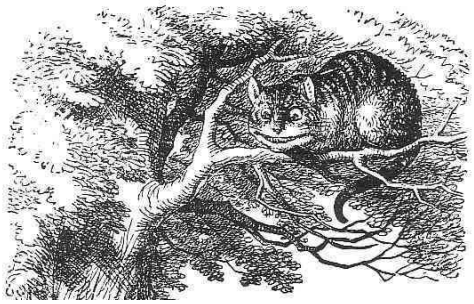
The principal investigator of the study, Dr. Leena Sharma, Professor, Division of Rheumatology at the Feinberg School of Medicine at Northwestern University in Chicago says the study illustrates that knee OA may have a different natural history in Caucasians and African-Americans. "It showed that African-Americans were more likely to have a valgus thrust during gait than Caucasians in the study and that Caucasians were more likely to have a varus thrust. What is particularly interesting about this is that a previous study had suggested that African-Americans more often had narrowing of the lateral (outer) compartment of the knee. Valgus thrust is a risk factor that might help to explain this."

—JR (May 7, 2010)

reimbursement

Happy Ortho CMS Payment Update

America's 3,500 acute care hospitals that provide services to Medicare beneficiaries will see their overall payments from the government drop by $142 million in 2011.



Drawn by John Tenniel, 1866 / Wikimedia Commons

However, their payments for orthopedic services will continue to see modest rate increases.

That's the news from the Centers for Medicaid and Medicare Services (CMS) on April 19, as they announced their annual update to the Inpatient Prospective Payment System (IPPS). Hospitals are not happy about the negative update and have until June 18 to comment to CMS. CMS will issue their final rule August 1.

Good for Orthopedics

Wall Street analysts were quick to proclaim the good news for orthopedic device manufacturers.

"The proposal seems slightly more positive than one might have feared during a period complicated by healthcare reform and budgetary pressures, and should be a modest positive for cardio and ortho players," Leerink Swann analyst Rick Wise said in a research report.

Analysts at Piper Jaffray reportedly said:

> "We recognize that most of our companies are one step removed from Medicare, but if hospitals are seeing higher rates for specific procedures, they may not exert additional pricing pressure on their suppliers."

Specific orthopedic procedure updates include:

- Spinal Fusion up 3.7%
- Kyphoplasty/Vertebroplasty up 7%
- Non Fusion up 3%
- Hips, Knees and Lower Extremities up 1-3%
- Shoulder up 5%
- Trauma up 5%

The proposed rule does not take into account new health reform law provisions and may cause some adjustments.

The proposed rule is on display at the Federal Register, and can be found under Special Filings at: www.archives.gov/federal-register/public-inspection/index.html.

—WE (May 4, 2010)

spine

Ray Elliott Sighting in Spine

Oh, oh...don't look now, but there's been a Ray Elliott sighting in the spine market. The former Zimmer boss wants to correct failed spine surgeries.

Elliot's new company, besieged Boston Scientific, announced on May 3 that the company has started enrollment in the Evidence clinical trial that's comparing spinal cord stimulation (SCS) for patients whose first back surgeries failed.

The company is enrolling the first of 132 patients at 20 sites worldwide in a clinical trial comparing its Precision Plus Spinal Cord stimulator with revision surgery to treat patients whose first back surgeries failed. The first patient was enrolled by Joseph Buwembo, M.D., and Krishna 0Kumar, M.D., F.R.C.S.C., at Regina General Hospital in Regina, Saskatchewan, Canada.

The trial will examine treatment response rates (leg pain relief with no request for the alternative therapy) at 6 and 24 months. Successful patient response is defined as having greater than or equal to 50% relief of pain in the lower extremities compared to pain levels prior to the intervention.

Spinal Cord Stimulation

The Precision Plus system is designed to pass electrical signals along the

spine

Ray Elliott, Boston Scientific CEO

spinal cord to the brain, masking pain signals by fooling the brain into perceiving them as pleasurable. It's aimed at patients with chronic pain in the torso or limbs who haven't had any luck treating the symptoms with physical therapy, drugs or surgery. It was adapted from Boston Scientific's work with cochlear implant technology, according to a Frost & Sullivan report analyzing the neurostimulation market.

"The standard approach to patients who continue to have persistent back and leg pain after lumbosacral spine surgery has been to look for another surgical treatment," said Richard B. North, M.D., neurosurgeon at The Sandra and Malcolm Berman Brain and Spine Institute in Baltimore, and principal investigator of the trial. "Following the positive, single-center trial we conducted at Johns Hopkins, the Evidence multi-center trial will provide important data on the comparative effectiveness of SCS versus surgical spine reoperation in the management of chronic pain in FBSS (failed back surgery syndrome) patients."

"Ultimately, this study may provide support to shift SCS earlier in the treatment paradigm for patients who suffer chronic pain resulting from FBSS," said Dr. Kumar. "[The trial] may also demonstrate the cost effectiveness of SCS compared to reoperation."

Elliott, the recently appointed CEO of Boston Scientific, has had his hands full with a one-month halt of ICD shipments due to FDA problems. He must be longing for the heady days in Orthoville.

We're keeping watch.

—WE (May 4, 2010)

The Picture of Success: William M. Mihalko, M.D., Ph.D.

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

A father of five, Chief Science Officer at the InMotion Orthopaedic Research Center, and Associate Professor at the Campbell Clinic, University of Tennessee Health Science Center, Bill Mihalko has little time for what doesn't balance. Perhaps he learned to understand the interplay of many moving parts from his father.

"I was born in Jamestown, NY and moved up and down the east coast while growing up. My dad had been born in a coal mining town in Pennsylvania and he grew up without indoor plumbing. As soon as he graduated from high school my dad immediately moved out of the house and found a job in Jamestown where he met my mom. He worked in a steel forge shop by day and earned his business degree at night which eventually landed him a job as VP of Manufacturing in Buffalo, NY."

Visits to the nexus of healthcare activity—his local hospital—left William Mihalko wanting to know more about medicine. "My mother was (and still is) a nurse and she worked at a nearby hospital. I recall the exciting times when we would all pile into the car to go pick her up at the hospital. It was obvious that she worked in a stimulating environment, and I could see that medicine was something very special and that not everybody was cut out for it."

He had started asking "why" during his visits to the hospital. Bill Mihalko decided that his next step would lead him closer to the world of research… and more "whys." "I developed a strong interest in using engineering principles to further medicine and enrolled in an interdisciplinary engineering program at the University of Rochester. I had completed all of my premed requirements but even after I graduated I was still uncertain about making a lifetime commitment to medicine. My fallback plan was to attend a masters program which was associated with a medical school in order to get more exposure and help me determine if medicine was 'it.'"

In 1987 Bill Mihalko began a masters in biomedical engineering at the Medical College of Virginia (MCV), and soon had the MCV M.D./Ph.D. program in his sights. "Along the way, I always had orthopedics in the back of my mind. I had torn my ACL in high school and ended up under the care of the famed Dr. Ken DeHaven at the University of Rochester. I took part in the ACL deficiency studies in his gait lab which further sparked my interest in engineering and orthopedics. The more I thought about this while walking the halls of MCV, the more I felt that orthopedics was my future. I began participating in orthopedic grand rounds and after the first year of my masters I was completely sold on the field."

Not content to "just" pursue an M.D., Bill Mihalko had the interest, confidence, and patience to earn a Ph.D. at the same time. "Dr. John Cardea was the chair of orthopedics and he sat on my masters thesis committee. He was terrifically supportive of the combined degree pathway and toward the end of the program he assured me that I would have a spot in his residency. Bill Krause, Ph.D. and Dr. Wilhelm Zuelzer were my research mentors and they opened my eyes to the rigors—and wonders—of research. I spent six years in the orthopedic biomechanics lab where I got to watch as investigations and answers were produced to many questions in orthopedics."

Love and duty then came calling. "I did my internship year at MCV, but both of my parents soon became ill. Dr. Cardea graciously helped me transfer to SUNY Buffalo, where by chance I met Ken Krackow. He had ideas that he wanted to pursue in the lab…and I had the expertise. SUNY Buffalo did not have an immediate opening in their residency program,

so I did a research fellowship with Ken. It was a prolific year as I ended up generating ten publications with Ken on soft tissue balancing and the effects of different techniques. During this research year I married the love of my life and fell in love with adult reconstructive surgery."

Then it was the balancing of the knee that concerned Dr. Mihalko. "During residency I continued work that I had done in my research year, which involved a system I created to measure the kinematics of the knee. Ken could see the potential in this, and said, 'We need to get this into the OR to help align the knee during surgery.' It was an electromagnetic system, however, and had some issues. So I found a company in Ontario, Canada, just across the border that made infrared tracking systems; Ken purchased it and much of my work transferred to the infrared system. In 1997 I participated in the first computer-assisted total knee replacement in the U.S."

One look at a very special machine and it was love. "For fellowship I was torn between the Anderson Orthopaedic Clinic in Northern Virginia with Charlie and Jerry Engh or the Missouri Bone and Joint Center with Leo Whiteside. Once I visited the latter site, however, it was settled. Dr. Whiteside was extremely entrepreneurial, held multiple patents, and had the most unbelievable biomechanics lab. His advanced knee testing machine blew me away. I could immediately see that I could do the kinematic work that I was doing in Buffalo but to a more precise standard. (He ended up donating the knee machine to my lab years later.) Dr. Whiteside taught me to balance research and practice. (Most people I knew in academics did clinical research but weren't going to the lab to perform basic science research.) Dr. Whiteside cautioned me against the temptation to 'book one more case,'

and emphasized the importance of protected time for research."

Choosing to be close to home, in 2000 Dr. Mihalko accepted a position at a private practice in Syracuse, New York. "This group was willing to give me at least half a day per week to do research at Syracuse University. I spent a lot of time at the school and became an adjunct professor in the department of neuroscience and bioengineering. My own research wasn't exactly on fire at the time because while Syracuse had a lot of equipment, getting time on those machines was hard as a 'lowly' adjunct professor. I was only there one year when the University of Buffalo called and asked me to be Director of Orthopaedic Research. It was a smaller program, but it was home."

But even home can be lonely sometimes. "I really could have used a senior research mentor there because I was literally the only one performing basic science research in the department. I had to wade through grant applications and funding issues solo. I was also Director of the Center for Advanced Technology at Buffalo, and had a substantial state grant to run the center. The purpose of the facility was to spawn new small business opportunities from joint ventures between the university and companies in the university's incubator. Although this position distracted me in many ways it gave me experience as an administrator at an early point in my career, something which has been valuable."

With no one to turn to and say, "Wow. We just discovered something amazing," Dr. Mihalko was a bit disheartened. "In 2006 I left Buffalo in part because I didn't have any research collaborators or mentors. I found my research home at the University of Virginia where Dr. Cato Laurencin was Chair at the time. He was heavily funded by the NIH and had an extensive biomedical engineering lab. While there I began collaborating with a Ph.D. colleague, Yusuf Khan, and looking at the mechanical aspects of the incorporation of a bone healing scaffold. We put rats on a mechanical testing and simulation machine and cycled the load across the scaffold on the tibia. About that time Cato announced that he was leaving. Shortly thereafter Dr. Jim Beaty here at the Campbell Clinic called and asked me to join their practice. They were starting an independent orthopedic research center and wanted me to come and be one of the directors. This was a plum opportunity and I accepted immediately."

Now happily ensconced in his advanced laboratory, Dr. Mihalko spends his protected research time on two lines of inquiry, both of which are related to total knee arthroplasty outcomes. "We have a new retrieval program that was established with the Medical Education and Research Institute in Memphis. We learned that of their 1,000 cadaver donations a year between 200 and 300 have well functioning total knees in place. Using our knee testing machine and knee simulator we are analyzing the kinematic patterns, soft tissue balancing, wear scars and surgical techniques that are associated with total knees that have functioned well over time. We map out the wear patterns and determine how much wear has occurred over the years that the implant has been in use. Then we plug the parameters into a 3D model and try to predict wear pattern. We also take a 3D CT scan of the lower extremities, along with the implant information from the mechanical testing and plug it into a 3D dynamic computer model. Our goal is to get the model to come up with the same wear patterns as the retrieval specimens."

"In addition, we are using interoperative data from computer-assisted knee surgery, taking the kinematics that I record in the OR, along with the position of the implants and anatomic registration data, to help validate the model. We recently began using a local gait lab and are taking postop patients there to see if the model can predict gait patterns as well."

As much as he likes predictability, Dr. Mihalko knows that there is no predictive model for one's family. "My wife and I have decided that at this point in life it's all about balance. Between being a dad to five children, and trying to keep my clinical and research career as a top priority, it is difficult to say the least. My wife, a speech pathologist, has been unbelievably supportive. She has packed up the family and moved countless times and I am truly in her debt."

Dr. William Mihalko…testing, re-testing, and then balancing—it's about knees but also about life.

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