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Orthopedics This Week

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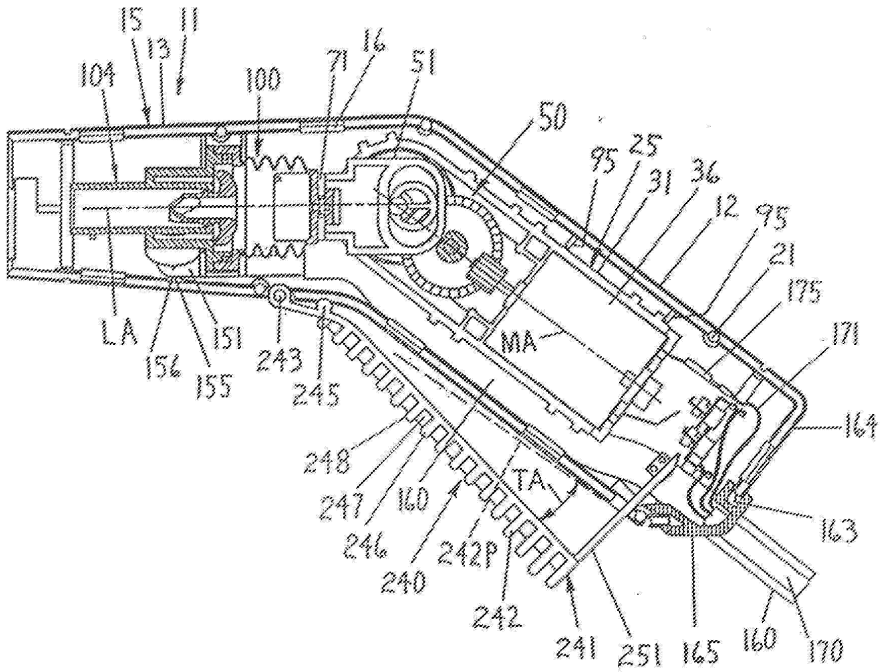
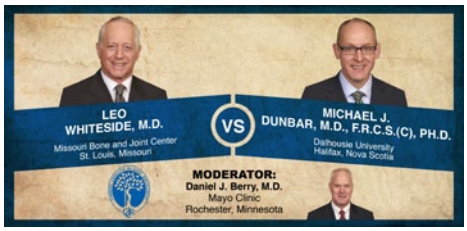
7 DePuy Synthes Spine: Sales Disruption Woes >> No one expected the birth of an orthopedic Superpower to go smoothly. The merger of Synthes and DePuy caused disruption in the spine business as different sales models collided. Some sales reps left. Now the company is suing them. Read it here.

10 CMS Wants More Tender Loving Care? + Simulation or Hands-on Bioskills? + Checklists Cut Death Rates 47% Marketing 101 for Surgeons >> Vanderbilt orthopedic researcher tells why you should care about patient satisfaction. Peter Millett says we need a flight simulator for orthopedic training, and the president of the SRS talks about the new checklist for spine surgery. The president of the AOFAS says it's time for foot and ankle specialists to learn marketing.



13 Whiteside, Dunbar: Six Rounds Over Neutral Alignment >> Leo Whiteside says, "Neutral mechanical alignment is the way to go." Dunbar counters, "But in the future, a patient specific approach to knee implantation strategy is the future of TKA."



BREAKING NEWS

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Steven L. Haddad, M.D. Named **AOFAS President**

For all news that is ortho, read on

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Equity markets had a lousy week last week. How bad was it? It was the worst 5-day stretch for the Dow Jones Industrial Average in over a year. The S&P 500 was down more than 1.5% while the Dow Jones Industrial Average was down nearly 1.8%. Retreat, in other words, was widespread. This is a thin late summer equity market. So, in times like this, what do smart investors look for? Cash flow.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	3	Medtronic	28.78%	(0.90%)	At 13.98x earnings, MDT has THE lowest future PE of any company on the Power Rankings. Valuation is way out of synch with earnings power.
2	6	Globus Medical	28.53	0.00	Another company that has exceptional earnings power is GMED. That gives GMED the financial means to match its entrepreneurial ambitions.
3	5	Integra LifeSciences	11.77	8.92	Piper upgrades IART on news that the FDA has given the firm's Plainsboro facility the green light. Up two spots.
4	2	Zimmer	29.28	(2.62)	Like MDT, ZMH is posting up terrific cash flows yet trades as if it were a blue light special at KMart.
5	8	Smith & Nephew	20.78	1.38	Compared to ZMH and SYK, SNN has had a great month. Why? Low PE plus a 2% dividend yield. Simple.
6	1	Stryker	18.71	(2.02)	Ronda Stryker sells $500k of stock. In this choppy market, small moves like this take on oversized importance.
7	4	Johnson & Johnson	26.68	(0.84)	JNJ announces that it is planning to divest its diagnostics business. Is this the beginning of strategic break up to unlock value?
8	7	Symmetry	7.49	(5.64)	SMA's price to sales is lowest in orthopedics. Investors don't think $1 of SMA sales is as productive as other ortho manufacturers.
9	9	Conmed	10.57	(5.88)	CNMD has not performed well this past month, but neither have most other orthopedic equities.
10	NR	NuVasive	6.30	(12.13)	The OIG issue is WAY overblown. Wall Street analysts agree, NUVA has the potential to grow EPS the fastest.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Integra LifeSciences	IART	$41.40	$1,163	8.92%
2	Tornier N.V.	TRNX	$19.24	$919	8.64%
3	MAKO Surgical	MAKO	$13.89	$653	6.03%
4	Bacterin Intl Holdings	BONE	$0.60	$31	3.47%
5	Smith & Nephew	SNN	$60.84	$10,953	1.38%
6	Globus Medical	GMED	$17.46	$1,621	0.00%
7	Johnson & Johnson	JNJ	$89.37	$251,851	-0.84%
8	Medtronic	MDT	$53.91	$54,310	-0.90%
9	MiMedx Group	MDXG	$5.59	$539	-1.24%
10	Stryker	SYK	$67.97	$25,702	-2.02%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$0.36	$45	-45.26%
2	Orthofix	OFIX	$22.22	$432	-20.59%
3	RTI Biologics Inc	RTIX	$3.45	$194	-18.82%
4	Alphatec Holdings	ATEC	$1.98	$192	-14.29%
5	Wright Medical	WMGI	$24.01	$1,130	-13.73%
6	NuVasive	NUVA	$23.46	$1,045	-12.13%
7	ArthroCare	ARTC	$33.13	$936	-11.35%
8	CryoLife	CRY	$6.75	$186	-9.64%
9	Exactech	EXAC	$19.35	$261	-8.03%
10	Conmed	CNMD	$31.07	$854	-5.88%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$22.22	$432	8.65
2	Zimmer Holdings	ZMH	$79.54	$13,486	12.85
3	Medtronic	MDT	$53.91	$54,310	14.50
4	Smith & Nephew	SNN	$60.84	$10,953	15.02
5	Globus Medical	GMED	$17.46	$1,621	15.48

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$23.46	$1,045	83.79
2	Symmetry Medical	SMA	$8.36	$311	33.44
3	RTI Biologics Inc	RTIX	$3.45	$194	25.13
4	ArthroCare	ARTC	$33.13	$936	22.45
5	Integra LifeSciences	IART	$41.40	$1,163	19.81

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$17.46	$1,621	1.03
2	Orthofix	OFIX	$22.22	$432	1.24
3	Exactech	EXAC	$19.35	$261	1.24
4	Conmed	CNMD	$31.07	$854	1.28
5	Zimmer Holdings	ZMH	$79.54	$13,486	1.40

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$23.46	$1,045	7.32
2	CryoLife	CRY	$6.75	$186	4.82
3	Symmetry Medical	SMA	$8.36	$311	2.79
4	Johnson & Johnson	JNJ	$89.37	$251,851	2.72
5	Medtronic	MDT	$53.91	$54,310	2.18

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$8.36	$311	0.76
2	Bacterin Intl Holdings	BONE	$0.60	$31	0.91
3	Orthofix	OFIX	$22.22	$432	0.93
4	Alphatec Holdings	ATEC	$1.98	$192	0.98
5	RTI Biologics Inc	RTIX	$3.45	$194	1.09

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	$5.59	$539	19.91
2	TiGenix	TIG.BR	$0.36	$45	11.12
3	MAKO Surgical	MAKO	$13.89	$653	6.36
4	Baxano Surgical Inc	BAXS	$1.93	$87	5.99
5	Globus Medical	GMED	$17.46	$1,621	4.20

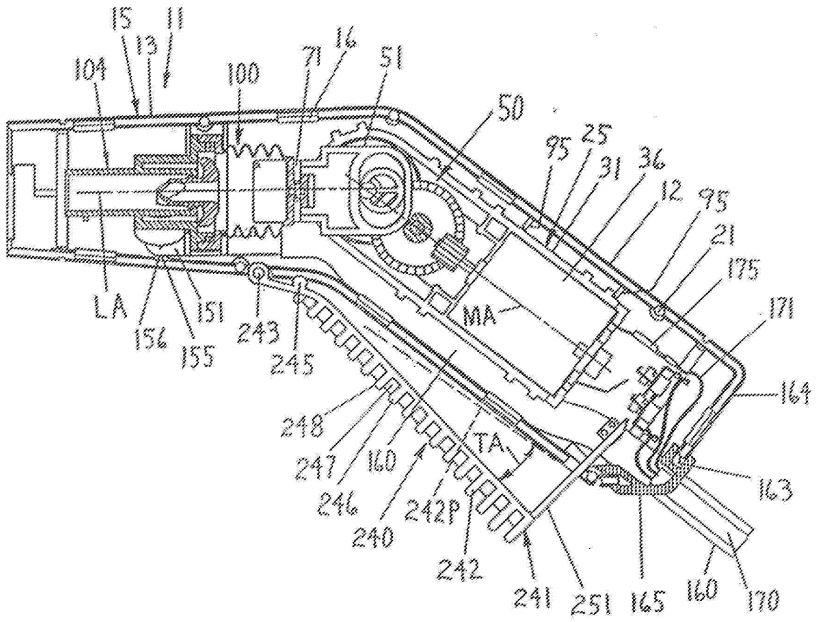
PSR: Aggregate current market capitalization divided by aggregate sales and the calculation excluded the companies for which sales figures are not available.

Zimmer Zonked for Treble Damages

BY ROBIN YOUNG

Stryker Corporation, which owns about 905 patents, used to share virtually the entire market for orthopedic pulsed lavage devices with Zimmer Holdings, Inc. No longer. A jury ruled in late July that Zimmer willfully infringed Stryker's three pulsed lavage patents and, therefore, must pay for all of Stryker's lost profits—about $73 million—and then treble that number. Add in Stryker's $11 million legal fees, the check to rival Stryker is for $228 million big ones.

Now that Zimmer rolled out the redesigned version of Pulsavac Plus, it's no longer Stryker's legal monopoly.



Source: Stryker's Corporation's Patent Filings

An Orthopedic Spray Gun

A modern, orthopedic pulsed lavage device is a combination spray-gun and suction tube. It's used by surgeons to clean wounds and remove necrotic tissue from wound sites.

Early-model pulsed lavage devices were bulky and required a centralized power source. They had to be wheeled around a hospital, from one room to another. Stryker's innovation was to shrink the size of these boxes to a portable, disposable, battery-powered lavage device that looked like a spray gun on steroids.

It was a disruptive innovation. Zimmer, the only other major supplier of orthopedic pulsed lavage devices, had no answer. Its market share started to melt away and Zimmer's future in the pulsed lavage marketplace became an open question.

So Big Blue fought back. Zimmer's managers hired an independent contractor, with no experience in pulsed lavage devices and asked him, as the jury found in this case, to copy Stryker's product.

Sadly, Zimmer forgot to check with their patent counsel about the risk of infringement and went to work successfully luring customers away from Stryker.

Zimmer Is Sued. Gets Zonked

In 2010, Stryker sued Zimmer saying that Zimmer's Pulsavac Plus was a blatant knock-off of Stryker's patented (No. 6,022,329, No. 7,144,383 and No. 6,179,807) pulse lavage device.

The suit went to a jury in a trial that lasted just two weeks. The verdict came quickly and unequivocally in Stryker's favor. The jury found that Zimmer willfully infringed Stryker's patents.

In reading the case, it is clear that Zimmer's lawyers really had no chance. They fought hard but lost, literally, every argument on claim construction, on disputed claims and finally on all claims at trial. Post-verdict, they were even skunked on every one of their ten post-verdict motions.

Amazingly, even after losing all of those arguments and getting the clear jury verdict, Zimmer kept infringing. Any hospital that wanted to buy a Pulsavac Plus which had just been ruled to be an infringing product, could do so.

Did Zimmer's managers not get the legal memo saying "we lost"?

On May 21, 2013, about four months after the end of the trial and weeks after the parties had wrapped up their third and final round of briefing on post-ver-

dict motions, Zimmer unveiled a redesign of its otherwise infringing Pulsavac Plus.

And asked the court to allow it to sell the new Pulsavac Plus.

U.S. District Court Robert Zonker sidestepped the issue of whether the redesigned Pulsavac Plus was okay to sell or not, but that didn't stop him from rejecting Zimmer's motion.

Zonker zonked Zimmer's motion.

Willful Infringement

At trial, the jury heard testimony that Zimmer all-but instructed its design team to copy Stryker's products. Zimmer's lead engineer, Bill Donizetti, testified that Zimmer had instructed his design team to model the Pulsavac Plus after features of Stryker's products. He went further saying that Stryker's inventions were "pioneering," suggesting they were novel and non-obvious.

Zimmer also admitted at trial that it did not take any actions to stop selling the accused products, even after the court found that Zimmer was infringing several claims of the patents-in-suit.

Permanent Injunction

Stryker asked the court to permanently stop Zimmer from manufacturing and distributing the infringing design of the Pulsavac Plus (but not the current redesigned version). The court ageed.

In Judge Zonker's view, Zimmer's infringement harmed—and continued to harm—Stryker by depriving it of market share and diminishing Stryker's right to exclude others from practicing its patents, all to the direct harm to Stryker.

Lost Market Share

According to court records, Zimmer's sales of the Pulsavac Plus took 15-18% of the market away from Stryker. The judge called it "a textbook example of irreparable harm" and cited lost market share, revenues and brand recognition as a result of Zimmer's infringement.

Furthermore, experts at the trial testified that the orthopedic pulsed lavage market consists, for all practical purposes, of just Stryker and Zimmer.

One of those experts was a Zimmer brand manager who testified that Stryker and Zimmer are the two major competitors in the orthopedic pulsed lavage device market. So, in effect, any Zimmer gain was by definition a Stryker loss.

Zonker ruled: "In this case, there is no doubt that Zimmer's infringement not only cost Stryker market share and deprived it of the exclusive use of proprietary technology, but that it directly benefitted Stryker's only rival in the orthopedic pulsed lavage industry. That is more than enough to establish irreparable injury."

In its defense, Zimmer argued that Stryker delayed seeking injunctive relief—by, for example, not seeking a preliminary injunction at the outset of the lawsuit—which demonstrated that Stryker has not suffered irreparable harm.

Zonker, again, rejected Zimmer's arguments. "To the contrary, an infringer's past successful infringement should not become a sort of de facto license to continue infringing. Infringement does not cease to be a problem just because the patent holder has not pursued a particular remedy."

Going for Game, Set and Match

The jury calculated that Stryker lost about $70 million in profits during the period that Zimmer was selling its Pulsavac Plus. But that only reflected lost profits through November 30, 2012. From December 1, 2012 to February 28, 2013, Zimmer was still selling Pulsavac Plus. So Stryker's damages expert asked the court to increase damages by $2,351,257.66.

Zonker agreed.

And then Stryker asked the judge to TRIPLE the damages.

In order to qualify for treble damages, the facts of a case have to be particularly egregious. And there are some clear guidelines for this. They are called the nine *Read* factors, or questions. Judge Zonker had to ask the following questions and, depending on the answers, could potentially grant Stryker treble damages. Those questions were:

1. Did Zimmer deliberately copy Stryker's ideas or design?
2. Did Zimmer investigate the scope of Stryker's patents and form a good faith belief that they were invalid or not infringed?
3. What was Zimmer's conduct during litigation?
4. What's Zimmer's size and financial condition? Could Zimmer handle treble damages?
5. How close was this case?
6. How long did Zimmer's infringing conduct last?
7. Did Zimmer take any remedial actions?
8. What was Zimmer's motivation for infringing?
9. Did Zimmer try to hide its misconduct?

For example, one of Zimmer's engineers noted that use of gear drives, like the ones ultimately incorporated in the Pulsavac Plus devices, "would be probably copying." Zimmer never checked to see if they were infringing. Zimmer also, according to Judge Zonker, needlessly delayed in producing requested information concerning its application for a patent for the Pulsavac Plus.

This was not a close case. Every major decision—from claim construction through post-verdict motions—went against Zimmer.

Zimmer's infringement lasted more than a decade, from 2000 all the way through part of 2013—a considerable amount of time. The judge noted in his opinion that at no point during those 12-plus years of infringement did Zimmer take any remedial action to stop infringement or mitigate damages.

Motivated by a Desire to Harm

Finally, since Stryker and Zimmer were the only major competitors in the orthopedic pulsed lavage device market, the court ruled that Zimmer's infringement of Stryker's patents could only have been motivated by a desire to harm Stryker.

In his final ruling, Judge Zonker wrote: "Given the one-sidedness of the case and the flagrancy and scope of Zimmer's infringement, the Court concludes that treble damages are appropriate here."

And the judge went on to say, "At bottom, there is simply no good reason *not* to treble the award of supplemental damages here when the Court has determined that treble damages are appropriate for pre-November-30th lost profits."

Zimmer Plans to Appeal

Stryker's attorney, Greg Vogler, of McAndrews Held & Malloy, applauded the ruling saying to *Law360*: "It's a just decision. Stryker came up with a pioneering invention, and Zimmer simply copied it. This is what happens when a company recklessly ignores patent law."

Zimmer is vowing to appeal. Zimmer, with its re-designed version of the Pulsavac Plus, is planning to appeal Judge Zonker's rulings. In a statement the company said: "Zimmer is disappointed with the judge's recent rulings denying our post-trial motions and increasing the damages awarded by the jury earlier this year.

Stryker was represented by Gregory J. Vogler, Sharon A. Hwang, Deborah A. Laughton, Laura M. Personick and Justin J. Paul of McAndrews Held & Malloy Ltd. and by David J. Gass and D. Andrew Portinga of Miller Johnson.

Zimmer was represented by David K. Callahan, Bryan S. Hales, Eric D. Hayes and Michael I. Cohen of Kirkland & Ellis LLP and by Kevin Abraham Rynbrandt of Rynbrandt & Associates.

The case was Stryker Corp. et al. v. Zimmer Inc. et al., case number 1:10-cv-01223, in the U.S. District Court for the Western District of Michigan. ♦

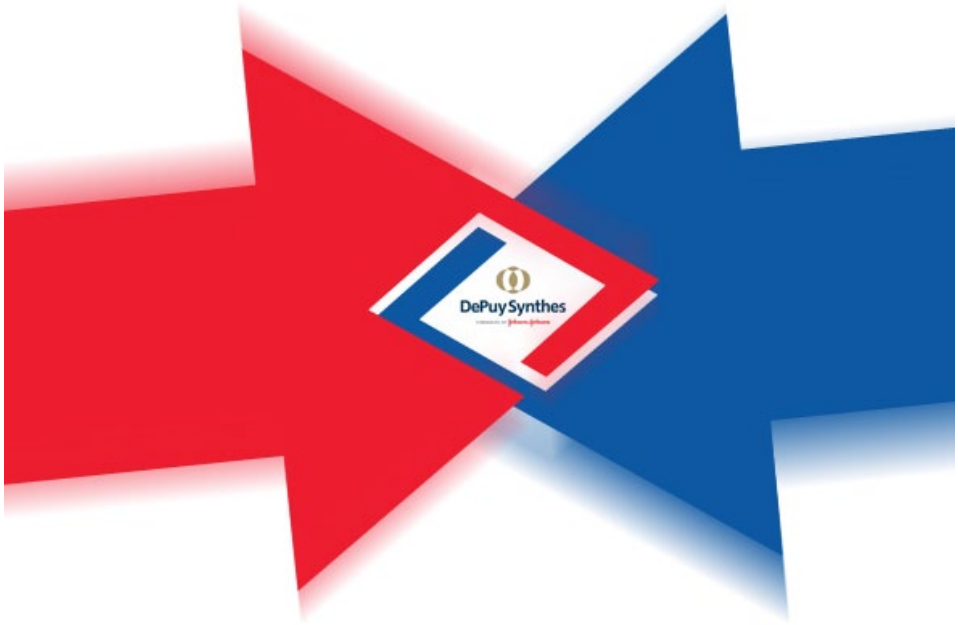
DePuy Synthes Spine: Sales Disruption Woes

BY WALTER EISNER

Michael Jones and Jacob Schools were sales representatives for DePuy Synthes Companies in Eastern Virginia for several years, first as reps working for Quizmo, Inc., a DePuy Synthes sales organization, and then as sales reps employed directly by DePuy Synthes.

At the end of 2012, they resigned from the company and went to work in the same area for a Globus Medical, Inc. distributor named Sky Surgical.

On July 16, 2013, DePuy Synthes sued their former sales reps and their new employer. More on that later.



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Reverberations From DePuy/Synthes Merger

Looking at the numbers for the first half of 2013, it appears that the DePuy Synthes merger may have been more difficult for its spine business than originally expected.

Of the 11 major spine companies, 7 reported rising sales in the second quarter ended June 2013. And of those companies, one stood out with a double-digit rate of growth—it was Globus Medical at 11.5% year-over-year (YOY) sales growth. The next closest was NuVasive, Inc. with 6.9% year-over-year sales growth.

The companies that reported declining year-over-year sales growth were: Biomet, Inc. (down 4.0%), Integra LifeSciences Holding Corporation (down 3.0%), Orthofix International, NV (down 2.0%), TranS1, Inc. (down 13.3%) and DePuy/Synthes (down 2.0%).

In fact, DePuy Synthes is expected by Wall Street's analysts to report a continued drop in sales through 2013. In a recent note to investors, Wells Fargo's Larry Biegelsen forecasted that DePuy/Synthes sales of spinal instrumentation would be down 3% YOY in the second half of this year.

For the whole of this year, Biegelsen expects DePuy Synthes' Spine business to post $1.88 billion in sales. Next year he thinks that the number rises to $1,904 billion, a 1% increase.

The Changing Distribution Model

In his note to investors, Canaccord Genuity analyst Bill Plovanic made a very interesting point about the apparent shift to more direct sales representation. Writing about both NuVasive and Globus Medical quarter, he said: "As the company [NuVasive] grows, we expect it to naturally migrate toward a direct model over time. In that case, margins would expand as sales reps are still compensated the same but NUVA would no longer pay an overhead premium to distributor agents."

Then, about Globus, Plovanic said:"Not surprisingly Globus expanded its representation in the U.S. at a rate of 10-15% in 2011 and 6% in 2012 after a pause in 2010."

"More importantly, management noted recruiting was again very strong, with the company continuing to add high quality reps in the Q2/13. We estimate that Globus has added ~50 reps in the 1H/13, bringing the U.S. total to ~400 reps. Given the disruption in sales caused by the integration of the Synthes and DePuy sales organizations, we expect competitive hiring to continue in earnest for the remainder of 2013." Globus uses both direct sales people and distributors.

Synthes Direct Sales Model Adopted

Putting Synthes and DePuy together forced a choice between the direct sales model and the distributor model. By and large, DePuy choose direct. Which was the Synthes approach. Synthes built the business using a direct sales force model.

But can DePuy make the change?

"We're going to be very thoughtful and deliberate about the way we go about combining our spine units," Alex Gorsky, then vice chairman of the executive committee at Johnson & Johnson (J&J), said in an interview at the time of the merger. "We think that can be done with minimal disruption."

Integrating two behemoth companies is tough as DePuy Synthes' boss Michel Orsinger acknowledged in a June 2013 interview with the Swiss publication, *Finanz und Wirtschaft* (*FuW*), that disruption has occurred in the spine sales division. Orsinger was the former CEO of Synthes before taking over the combined orthopedic and spine business of DePuy Synthes as worldwide chairman, Global Orthopaedics Group.

Orsinger acknowledged that DePuy Synthes has lost spinal implants business customers as well as employees in research and development.

During a quarterly conference call with Wall Street analysts on July 16, 2013, Gorsky, now J&J's chairman and CEO, told analysts that he and his colleagues are really pleased with the way the integration is going.

"Taking on a company the size of Synthes…is no small undertaking. Bringing together (the companies) the way that our teams have, I think, they are really to be commended for it. We have got a multi-phased program in place to bring it together commercially, the entire research and development organization as well as all the supporting functional areas…While we still have work to do in certain areas of the integration, we are making good progress."

Michel Orsinger/Source: Yvon Baumann/Finanz und Wirtschaft

Alex Gorsky/Source: Patti Sapone/The Star-Ledger

Suing Jones and Schools

Indicative of the challenges of moving from a distributor-based sales model to a direct model is the Jones and School lawsuit which provides a small window into a sales force disruption resulting from the $21.3 billion merger between Synthes, Inc. and Johnson & Johnson's DePuy Inc. in 2012.

The lawsuit also highlights the challenges when two separate sales models are combined.

On November 10, 2012, Jones resigned from DePuy Synthes. According to the lawsuit, when the company inquired as to his employment plans post resignation, Jones disclosed that he had received an offer from an unnamed Globus distributor and a direct competitor of DePuy Synthes. Jones further stated that he planned to abide by the terms of his Employee Secrecy Agreement.

Schools followed Jones' resignation with his own on December 20, 2012. When the company inquired as to his employment plans, Schools allegedly told them that he planned to leave the spinal implant business and enter the software development business.

DePuy Synthes Plays Hardball

DePuy Synthes' complaint against the two former reps tries to paint a negative picture.

According to the suit, "Sky Surgical, Jones and Schools have acted willfully, wantonly and in conscious disregard of DePuy Synthes' rights. The actions of Sky Surgical, Jones and Schools already have caused irreparable damage to DePuy Synthes' business. Absent injunctive relief, DePuy Synthes will suffer irreparable harm from the activities of Sky Surgical, Jones and Schools."

Shortly following the resignation of Jones and then Schools, the lawsuit claims certain key surgeons who previously used DePuy Synthes products switched to Globus.

Sentara Norfolk and Sentara Virginia Beach were DePuy Synthes accounts until recently. Now, says the lawsuit, they're using Globus products. Both hospitals were significant DePuy Synthes accounts that had been serviced by Jones and Schools.

The lawsuit also claims that on January 31, 2013, Jones was seen selling Globus products on behalf of Sky Surgical at Mary Immaculate Hospital—another former DePuy Synthes account.

On February 19, 2013, Schools was allegedly working on Sky Surgical's behalf at Sentara CarePlex. On February 20, 2013, Schools allegedly covered a spinal surgery case using Globus products at Mary Immaculate Hospital.

Jones is also accused of soliciting at least one DePuy Synthes employee to join him at Sky Surgical to sell Globus products.

The Non-Compete Agreements

The company claims that Jones and Schools each agreed that, during his employment and for a period of eighteen months following the end of his employment, he would not perform work for a competitor in a position in which he could disadvantage DePuy Synthes or advantage a competitor of DePuy Synthes by the disclosure or use of DePuy Synthes' confidential information to which he had access.

Jones and Schools also allegedly each agreed that for a period of 18 months following the end of their employment, they would not sell competitive products to any of the DePuy Synthes accounts, customers or clients with whom he had contact in the past 12 months.

Relief Demanded

There are four counts in the lawsuit. The first two allege Breach of Contract against both Jones and Schools. The third is against Sky Surgical for Tortious Interference with Contract. The fourth is Statutory Conspiracy in that Sky Surgical, Jones, and Schools conspired with each other to have Jones and Schools breach their fiduciary duties, use and misappropriate confidential information and otherwise violate their Employee Secrecy Agreement.

Finally, DePuy Synthes asks the Court to enjoin Jones and Schools from soliciting any competitive business, working in any sales or management position and in any location in which he could disadvantage DePuy Synthes or advantage Defendant Sky Surgical.

They are also asking no less than $1 million in compensatory damages against Jones and Schools and at least $1 million in compensatory damages against Sky Surgical. In addition, the company wants punitive damages against Sky Surgical in the amount of $350,000 and treble damages under the conspiracy charge after a jury trial.

The Big Picture

If, as Wells Fargo's Biegelsen is forecasting, DePuy Synthes loses approximately $300 million or 20% of its U.S. spine instrumentation because of all the challenges from integrating sales forces, then the sales force disruptions from this merger will have been significant.

Could the overall pricing pressures in spine be pushing companies, as Plovanic wrote in his NuVasive note, to a more direct model? If so, then such lawsuits as this one won't be the first, nor will it probably be the last.

DePuy's choice to go direct has been disruptive. But, after all, Superpowers are usually born from great disruption and trauma. ♦

CMS Wants More Tender Loving Care? + Simulation or Hands-on Bioskills? + Checklists Cut Death Rates 47% Marketing 101 for Surgeons

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

CMS Wants More Tender Loving Care? It's really not that hard, says a seasoned orthopedic researcher. To make patients happier—and to help ensure that you get the appropriate reimbursement—all that is required is a bit more TLC. Brent Morris, M.D. is with the Vanderbilt Orthopaedic Institute Center for Health Policy. Dr. Morris and his colleagues recently examined the issue of patient satisfaction as related to trauma patients. He tells *OTW*:

> "Making patients happy may sound like the fluff side of medicine but it is being emphasized more and more. We have to do more to improve patient satisfaction. More than ever, CMS [Centers for Medicare and Medicaid Services] is trying to adequately define and measure quality of care…patient satisfaction is a huge part of that. In fact, CMS is making incentive payments to acute care hospitals based, in part, on the results of patient satisfaction surveys completed by patients after they are discharged.
>
> One study showed that 90% of medical inpatients were not able to name the treating physician upon discharge. It was even more challenging for orthopedic patients who are admitted via the emergency department (ED); past research has shown that individuals admitted through the ED are less able to identify their treating physicians. My team and I decided to measure patient satisfaction amongst trauma patients, i.e. those individuals meeting doctors on one of the worst days of their lives. The care is acute and unplanned.
>
> Our most encouraging finding is that even simple interventions can improve the patient's feelings about his or her medical experience. We distributed biosketch cards to orthopedic trauma patients in order to improve patient recognition of the attending surgeon. Our early results show improved physician recognition and increased patient satisfaction scores, even in this challenging population. Some things other than biosketch cards that can help improve patient satisfaction include basics ways to improve patient-physician communication. Physicians being empathetic and acknowledging the difficulty of the patient's situation, the doctor refraining from interrupting the patient when obtaining a history, and appropriately setting patient expectations for the goals of surgery can all help to improve patient-physician communication and ultimately improve patient satisfaction.
>
> Going forward we need better data to evaluate patient satisfaction so that we better stratify and standardize our results. We know that patient satisfaction varies based on the type of surgery required for the patient. Variables such as pain control and depression also affect outcomes and patient satisfaction, so we must control for these variables. Ultimately, it is hard to use a 'one size fits all' approach to measure patient satisfaction, and we need to tailor our outcome measures and interpret results accordingly."

Photography by Andrew Huth/RRY Publications LLC.

Simulation or Hands-on Bioskills?

"All hands on deck!" is the latest cry for those in training. Peter J. Millett, M.D., M.Sc., Director of Shoulder Surgery at The Steadman Clinic in Vail, Colorado, says that there is an increasing emphasis on hands-on training in orthopedics. He tells *OTW*:

> "The power of hands-on surgical training is undeniable. Industry has recognized this and now several major manufacturers offer fellowship courses that are focused on lab experience. As part of our fellowship training program, we have a bioskills lab that is incorporated into the academic curriculum. It's like a flight simulator for pilots. You create potentially real surgical scenarios where it's acceptable for the trainee to be less than perfect so they can practice, improve, and learn from their mistakes. In a bioskills lab the trainee receives tactile feedback and can take as long as they need (not something we can always do in real life).
>
> Perhaps the most challenging aspect of this is that we must determine how exactly to measure surgical performance. Testing one's surgical skills would have to evaluate the ability to perform major steps in a procedure correctly and to do the surgery in a technically proficient manner. Moreover, we would of course have to do this for many surgeries. For example, in arthroscopic shoulder surgery, trainees would learn basic procedures like diagnostic arthroscopic evaluation of the shoulder, rotator cuff repair, shoulder instability procedures, and a Bankart tear repair. One of the challenges of measuring performance is determining how exactly can we say that a given repair is satisfactory?
>
> It seems incredible, but we still don't have a method to evaluate a core set of surgical skills that residents and fellows should acquire during their training. There is no checklist of what people have accomplished… it's just, 'oh, well look at the calendar, your year is up. What cases did you do? Good luck.' We need a more objective method to measure surgical skills and better methods for teaching surgeons these important skills. The credentialing bodies are trying to make headway in defining these things, but we still have a long way to go. And it's not just orthopedic surgery; other surgical specialties haven't figured any of this out either."

Checklists Cut Death Rates 47%

When WHO tested the surgical checklists at eight hospitals from around the world, says Kamal Ibrahim, M.D., president of the Scoliosis Research Society (SRS), their death rate decreased by 47%. Kamal Ibrahim is clinical professor of Orthopedics and former chief of division of Pediatric Orthopedic & Scoliosis Surgery at Loyola University in Chicago. He tells *OTW*:

> "When I began my tenure as president of the SRS last September I decided to focused on the issue of safety in the OR. We began discussing this topic with other societies, building on initiatives that have been underway in different areas of surgery over the last ten years. In 2004 the World Health Organization [WHO] determined that there were seven million people injured during surgery globally, and one million deaths.
>
> They compiled a surgical checklist that was published in 2010; this list covered things the staff should do before anesthesia, before the operation, and afterwards. Is this the correct patient, have the antibiotics been given, does everyone in the room know what needs to be done. They then tested that checklist in eight hospitals around the world—including the U.S. and UK—and got very impressive results; the death rate decreased by 47%, the infection rate decreased by 50%, and the reoperation rate decreased by 25%. Largely as a result of this work, checklists are now mandatory in England.
>
> Just this year a Harvard study found that only 25% of American hospitals use checklists. It became clear to me that the push for increased awareness was going to have to come from surgeons and hospitals. So I put together a task force of SRS members to study the topic of checklists; then we set out to create a checklist specifically for spine surgery. We will debut the checklist in Lyon this September at SRS annual meeting. Surgeons can use this upcoming checklist when doing deformity surgery. This is meant to help them be aware of changes in neuromonitoring and to follow well-organized steps of management to elevate the neurological problem (is the patient's blood pressure stable, did the room temperature change, etc. all the way to the wake up test). The SRS will advise its members to use this checklist going forward. I just presented this checklist at a recent spine societies meeting organized by North American Spine Society and it generated quite a lot of interest from the other societies. When I presented the checklist at the recent International Meeting on Advanced Spine Techniques 'IMAST' in Vancouver there was significant interest, to the point where people from around the world approached me and asked me for my slides. I'm so pleased to be a part of this process as it becomes an increasingly standard part of our quality control efforts."

Marketing 101 for Surgeons Surgical skills aside, brand awareness may be the most important tool a medical specialty society has when it comes to reaching potential patients. Steven L. Haddad, M.D., the newly elected president of the American Orthopaedic Foot & Ankle Society (AOFAS), told *OTW* that a major focus for the AOFAS today is public education and outreach.

"The public often doesn't understand that our training as orthopedic surgeons differentiates our members from other non-M.D./DO practitioners who treat foot problems," said Dr. Haddad, who also serves on the faculty of the Illinois Bone and Joint Institute. "There is no doubt that AOFAS members are the most qualified to treat both common and complex foot and ankle problems.

"One issue facing AOFAS members, particularly those who are younger, is hardened referral patterns within their communities and increasingly within hospital systems. Many physicians, and even many of our own orthopedic colleagues, refer patients with foot problems to non-M.D./DO practitioners," said Dr. Haddad. "They do not really understand the value that our comprehensive training as orthopedic surgeons brings to treating both common and complex foot and ankle problems. Our goal is to increase awareness of the value we bring in delivering safe, cost-effective care to patients."

"One way to raise that awareness is through better marketing. The AOFAS is using social media to reach out and educate the public on the reconstructive foot care our members provide, the sports injuries and trauma they treat, and new technology available that allows patients to maintain mobility and improve their quality of life," said Dr. Haddad. "We must also help internists and family physicians understand that referring patients to a non-orthopedic practitioner may be easier but the quality may not be the same. This educational process is truly a call to arms for our younger colleagues."

"Fortunately, increased interest in the AOFAS and its mission is helping build the orthopedic foot and ankle brand. The AOFAS membership is steadily growing, and we now have more than 2,000 members," said Dr. Haddad. "Over the past few years, there has been an increase in applications for our foot and ankle fellowship programs and an increase in the number of young members."

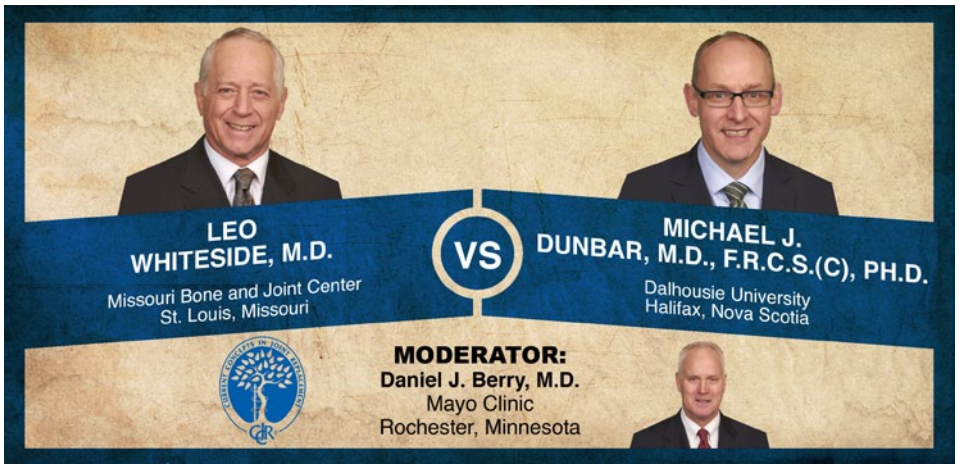
"We have also seen a significant increase in attendance at our annual meetings, as well as growth in the number of manuscripts submitted for our *Foot & Ankle International* journal," he added. "These are all good signs for our organization, and coupled with new technology available for treating foot and ankle problems, the future is bright for the AOFAS." ♦

Whiteside, Dunbar: Six Rounds Over Neutral Alignment

BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

Leo Whiteside says, "Neutral mechanical alignment is the way to go." Dunbar counters, "But in the future, a patient specific approach to knee implantation strategy is the future of TKA [total knee arthroplasty]."

This week's Orthopaedic Crossfire® debate is "Straight and Balanced: Gimme That Old Time Religion." For the proposition is Leo Whiteside, M.D. of the Missouri Bone and Joint Center in St. Louis; against the proposition is Michael J. Dunbar, M.D., F.R.C.S.(C), Ph.D. from Dalhousie University in Halifax, Nova Scotia. Moderating is Daniel J. Berry, M.D. from Mayo Clinic in Minnesota.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Whiteside: "The knee is so complex that nobody really understands it…just like the universe. Religion is often used to describe how it works, and people's opinions on total knee replacement begin to sound like religion."

"I speak to God a lot, sometimes loudly in the OR. The road to salvation is straight and narrow and you get there one step at a time. Excellence is expected…but not perfection."

"This is how a good knee should work: as the hip and knee flex, the tibia stays in the AP axis and it rotates around the epicondylar axis. As you flex the knee you can see up the tibia, down through the AP axis of the femur and right to the femoral head. A good knee is a little looser laterally than medially in extension; in flexion it's a bit looser than in extension and looser laterally than medially."

"The way to do this is bone landmarks aligned separately in flexion and extension with tight ligaments released based on function. Then you cut by the prevalgus angle of the femur, perpendicular to tibia. The AP axis of the femur is your alignment landmark on the femur, on the bone, in the knee. Stay on the bone and out of trouble. For matched resection, resect the thickness of the implant from the intact surface and that gives you a knee that is balanced in flexion and extension."

"Let's look at a varus knee. You find a reliable landmark such as the AP axis. Down the center of the canal we make a hole with the reamer and ream down the cement center of the tibia as well. And you must aspirate the medullary canal of the femur. Then the intramedullary rod is inserted. The AP axis marks the femur in flexion; the intramedullary rod is inserted into the tibia down to the ankle. You make cuts based on the medullary canal, and you correct the deformity. Then, osteophytes are removed, the tight ligaments are released, and you stabilize it with a thicker polyethylene."

"It's similar with a valgus knee. The tibia is outside the AP plane; you're going to put it in the AP plane by following the AP axis. When you hold the leg straight, the AP axis is perpendicular to the floor. That is going to correct the deformity on the femoral side. You put the medullary rod in and cut based on the intact surface—even if there is a defect left on the lateral side. Then apply the cutting guides, which are aligned relative to the AP axis. Then you finish your cuts, correcting deformity on the femur based on the AP axis of the femur; you put the intermedullary rod on the tibia."

"Now it's loose medially in flexion and tight laterally. And we have a complex series of ligaments to deal with. You do a gradual release from front to back for flexion on the epicondyles, which creates partial correction. And finally the epicondylar release. The posterior/iliotibial band gives a knee that is correct in flexion and extension."

"Rule number two is that the road to hell is paved with good intentions… and I mean tensioners, constitutional varus, magic instruments that eliminate ligament balancing, navigation, bogus Internet advertising, and taking money for doing nothing. Then God Almighty will show up at your office in the person of plaintiff's attorneys, angry patients, and the Department of Justice."

Dr. Dunbar: "Bless me, Father Leo, I have sinned. I no longer follow the tenets of the gospel that has been laid out. While a neutral mechanical axis is still the gold standard until proven otherwise, it won't be the gold standard for all patients in the future."

"Why do we stick to a neutral mechanical axis? The most widely quoted paper in recent literature is the 1991 paper from the UK with 115 Denham knees followed up from 1976-1981 and using an intramedullary alignment. The participants were mainly female and about half of them were rheumatoid patients. They found that if you left the knees in neutral only about 2.5% of them failed; if they were more than 3 degrees of valgus then 12.5% failed. If they were greater than 3 degree of varus then 33% failed."

"The prosthesis used in that study is obviously not what we are using today. This had a 7 degree fixed valgus angle on the femoral component. The process was to drop the intramedullary rod in while you cemented the tibial component and then shave it with a pair of shears."

"The most important argument as to why we need to consider an alternative to neutral mechanical alignment is the fact that around the world the number of patients dissatisfied with their knee replacement is 18% (the UK, Sweden, and Canada). It goes back to the basic epidemiology we learned in grade school about frequency distributions in populations. So as we take the straight and balanced approach we are covering the majority of the curve, but missing the tails—those who are never in neutral mechanical alignment, and who don't like being in neutral mechanical alignment."

"An important paper by Johan Bellemans, M.D., Ph.D. et al, spoke to this. They studied 500 healthy individuals in their twenties, and they looked at them with long length standing films. It turned out that on average, the alignment of this group is 1.3 degrees varus. Broken down by gender, 1.9 degrees varus for males and 0.8 degrees of varus for females. A full 32% of the males were greater than three degrees of varus; 17% of women were greater than three degrees of varus."

"Despite this, we stick to the tenets of St. Leo and decide that even though only 2-3% of the population has a tibia that's neutral to the floor, we must do a

neutral cut on the tibia. And once you do that you must make a compensatory gap in extension where you take asymmetrical cuts. More importantly, in flexion we have to go through machinations to rotate this femoral component in a position it wasn't meant to be in so that we can balance this flexion/extension gap. Perhaps if you don't follow this tenet, and you do put the components where they perhaps should be in other than Leo's alignment, then you may not have to do these releases."

"In 2011 at this conference Adolph Lombardi said, 'Although technology has improved surgical precision, it has not eliminated the human factor, and aiming for neutral provides the safest margin for error. The foremost objective of TKA is a durable and well-functioning joint, not necessarily one that replicates normal or the patient's native condition.' This is what patients are complaining about. They say their knee doesn't feel normal and we told them, 'Too bad because you're in neutral mechanical alignment and your X-rays look good.'"

"The renaissance is a 3D perspective. There are different morphological variations of femurs that we're operating on daily, and we don't compensate for this as we approach. Another blasphemous tool that I'm keen on is navigation, which shows us that patterns of alignment through range of motion (ROM) are important. Normally, when we approach a varus knee we think that it's varus through ROM, but after looking at thousands of these we know that some patients start in varus and by the time you flex them they're into valgus."

"Lastly, there are two different kinds of outcomes. In the St. Leo tenet you take an unstraight knee and after your cuts they are straight. But there's a compelling example of other types of patients who have this sinusoidal morphology…and after you've operated on them, wittingly or unwittingly, all you've done is shift their curve. They have kept the same morphology. In the end, a patient specific approach to knee implantation strategy is the future of TKA."

Moderator Berry: "Is this just an esoteric argument or are we just not good enough to measure it yet?"

Dr. Whiteside: "The study from Merrill Ritter's group shows that a knee that is significantly out of alignment does much worse than those within a reasonable level. Sometimes five degrees

of mechanical axis of varus is not easy to detect by eye. The Mayo Clinic study suggests that three degrees of varus or valgus mechanical axis malalignment is alright. I agree, but remember that three degrees is 1.5 on the femur, 1.5 on the tibia. If you can get more accurate than that you're better than I am."

Dr. Dunbar: "It's not an esoteric question at all. The renaissance is all these tools (4D assessment, gait analysis, etc.). Merrill Ritter's paper looked at short, 2D films—a 110 year old technology."

Moderator Berry: "So Mike, you think that eventually we'll be able to do better and we will be able to individualize optimal implant position, balancing, and alignment? Is it also fair to say that right now we don't know how?"

Dr. Dunbar: "Yes, that's why I started my talk by saying that neutral mechanical axis is the gold standard."

Dr. Whiteside: "I love you computer/navigation guys and I can't wait for you to come up with something that we can use."

Dr. Dunbar: "I don't know what to do with the data, but it is compelling that there are differences between the patients. I imagine that pilots had this argument 25 years ago: 'There's no way that computer is flying my plane!' But no pilot would be allowed to take off if the computers weren't working. Not because the pilot can't fly the plane, but because the margin of error goes down and outcomes improve."

Moderator Berry: "Everybody's emphasized the importance of proper femoral rotational alignment. Leo, when you're doing the AP axis of the femur; are there any ways you can get fooled?"

Dr. Whiteside: "By trying to use deformed anatomy to adjust your line. Center the intercondylar notch posteriorly and if you have to, remove the osteophytes. The deepest part of the patellar groove just above the intercondylar notch…use that as a basis to make your line further anteriorly and ignore any deformity in the patellar groove."

Moderator Berry: "If the patella has eroded the trochlea does it mess it up?"

Dr. Whiteside: "It does not because that deepest part of the groove is still there."

Moderator Berry: "Mike, how do you set your femoral rotation?"

Dr. Dunbar: "I do it off the navigation and trying to get equal resections posteriorly off the femoral condyle."

Moderator Berry: "Thank you both." ♦

Please visit www.CCJR.com to register for the 2013 CCJR Winter Meeting, December 11–14 in Orlando, Florida.

"You may now view content from the CCJR Meetings on the CCJR Mobile™ App. Please scan the QR code to download the CCJR Mobile App to your Android or iOS mobile device, or visit www.ccjrmobile.com."

COMPANY

Australian Hazard Alert for Stryker Spine Plate

Stryker Australia and Australia's regulatory agency, the Therapeutic Goods Administration (TGA), issued a hazard alert regarding the company's Oasys Midline Occipital Plate in July.

An Oasys Midline Occipital Plate is a part of the Oasys System, which is used in spinal surgery to promote fusion and provide stabilization at the junction between the occipital bone and the vertebrae in the cervical and thoracic spine.

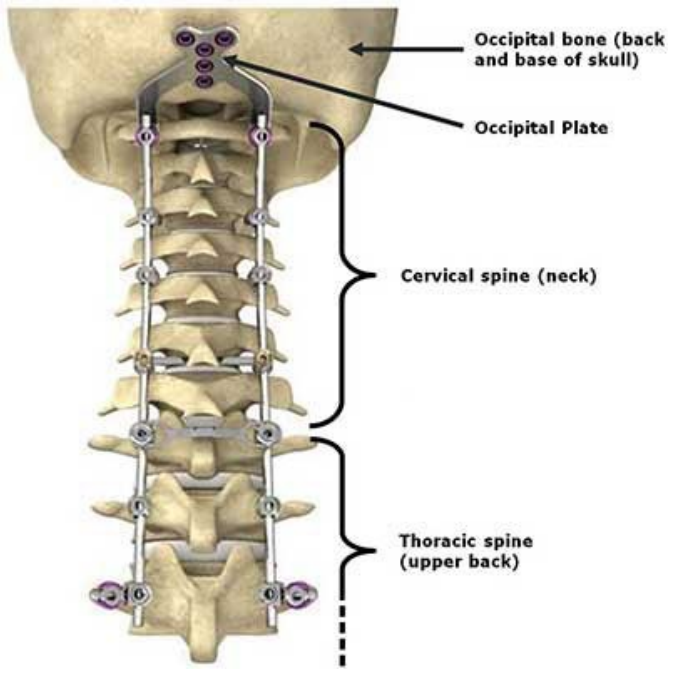
Post-Operative Pin Fracture

Stryker received reports from the field in the U.S. and Belgium indicating post-operative fracture of the pin that connects the tulip head to the plate body, either as a result of an excess acute load or excess repetitive load (fatigue fracture). This can lead to destabilization of the plate and revision surgery may be required.

The root cause of the problem is not yet known and the manufacturer is continuing to investigate reported cases from the USA and Belgium. At the time of this hazard alert, no cases of this problem had been reported in Australia.

Stryker Australia has contacted surgeons who have implanted an Oasys Midline Occipital Plate, providing further information regarding this recall and advice on how to treat affected patients.

To minimize risk to patients, Stryker Australia has removed this device from the market until the definitive root cause is identified.



tga.gov/Oasys Midline Plate

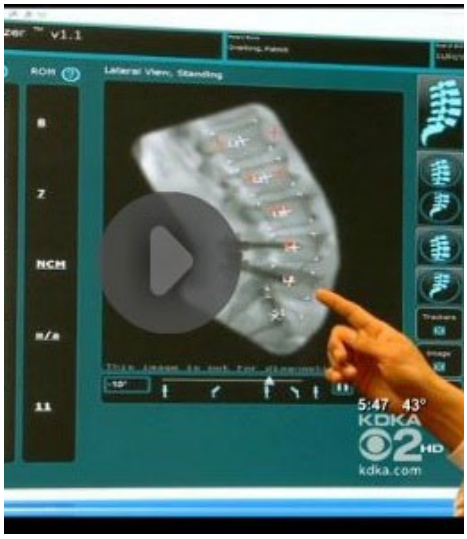
If a surgeon has already implanted one of the plates, he or she is advised to continue undertaking routine clinical and radiographic post-operative evaluation of patients.

For more information, click here: http://www.tga.gov.au/safety/alerts-device-oasys-midline-plate-130722.htm#consumers

—WE (August 16, 2013)

Ortho Kinematics System Cleared for Cervical

The FDA has given Austin, Texas-based Ortho Kinematics, Inc. clearance to expand the company's VMA (Vertebral Motion Analysis) system beyond the lumbar spine to the cervical spine. This may be good news for surgeons needing evidence with insurance payers.



Ortho Kinematics, Inc./VMA System

Ortho Kinematics is a diagnostic company focused on spine imaging informatics.

The VMA system is a new diagnostic technology that, according to the company, is an alternative to a test that has been routinely prescribed for the assessment of spinal instability for over 70 years. The company says the current method of detecting spinal dysfunction, static end-range bending X-rays, is outdated. Spinal instability can result in severe back and neck pain, and is the number one diagnosis driving the 500,000+ spine fusion surgeries performed in the U.S. each year.

The VMA is a noninvasive painless test that uses fluoroscopy to capture X-ray videos of patient's spine in motion. These videos are then used to produce measurements of the movement between the bones in the spine.

Evidence for Payers

David Lee, M.D., a spine surgeon user of the VMA lumbar system, said, "I have seen for myself cases where the VMA has been the only test capable of providing the evidence demanded by insurance companies to approve coverage for lumbar surgery. With the new cervical system, I can now offer this valuable option to my neck pain patients as well."

This technology standardizes and automates each of its basic steps:

1. Patient bending utilizes patented Motion Normalizer devices, which provide powered passive trunk bending in either a standing or lying down configuration.
2. Image acquisition with hundreds of fluoro-images of the spine are captured at standardized trunk bending angles.
3. Image analysis image recognition software locates the vertebrae on each frame. The Intervertebral Angle (IVA) is plotted as a function of the degree of trunk bending, creating a plot for each vertebral level.

VMA testing is now available at a select set of leading spine surgery centers. A large scale national roll-out is scheduled for early 2014.

—WE (August 16, 2013)

New Patent for Soft Tissue Regeneration

Soft Tissue Regeneration, Inc. (STR) has announced that it was issued a U.S. patent related to the L-C Ligament, a device for soft tissue regeneration of the anterior cruciate ligament (ACL) of the knee. The device was invented by Cato T. Laurencin, M.D., Ph.D., and is a bioresorbable scaffold that is designed to regenerate knee ligament tissue after ACL reconstruction surgery.

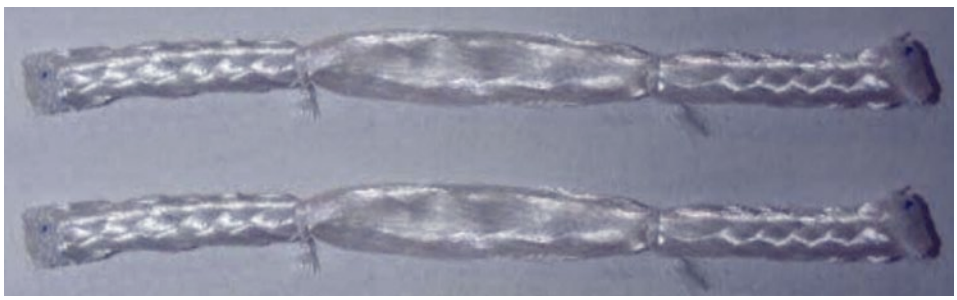
The patented technology uses a clinically proven degradable polymer called poly(L) lactide acid (PLLA) to address known risks and morbidity associated with allograft and autograft tissues. The technology requires no harvesting of the patient's tendon, which eliminates the risks associated with the harvest site. The L-C Ligament encourages the regeneration of the patient's own ligament tissue. To date, results from large-scale animal testing at one year and longer have demonstrated that the L-C Ligament can successfully regenerate a native ligament intra-articularly.

The L-C Ligament is an investigational device and is not available for use or sale in the European Union or the United States. It is only available as part of the clinical trial.

STR President and CEO Joseph Reilly told *OTW*, "We have completed all animal studies needed to justify our recent 'first in man' surgery on June 18 as part of a 15 patient safety study being conducted in Europe. However, we currently have eleven (11) sheep that were implanted with the L-C Ligament as part of a long term animal study. Three (3) of these sheep were implanted 3 years and 3 months ago and eight (8) of the sheep were implanted 2 years and 2 months ago. All of these sheep are doing fine and have ambulated normally since the day of their surgery. We are developing a program to bring some of these sheep out for as long as 5 years. It should also be noted that with almost 90 sheep that were implanted with the L-C Ligament, not one ever failed in vivo."

Asked about having a patent, but not being able to sell the device in the U.S., Reilly stated, "In July of 2013, we submitted a Pre-Submission filing to the FDA to begin the process of obtaining IDE [investigational device exemption] approval to begin a clinical trial in the USA. After receiving 12 month data from our EU safety study in late 2014, we expect to file that information with the FDA and to receive IDE approval in 2015. Then we will begin a clinical trial in the USA that would allow Soft Tissue Regeneration to eventually obtain pre market approval (PMA) to market the L-C Ligament in the USA."

—EH (August 15, 2013)



Soft Tissue Regeneration

LEGAL

Civil Battery Alleged Involving Blackstone Payments

Harvey Thomas, M.D., a neurosurgeon in Prescott, Arizona, is being sued for civil battery by a former patient for putting in an implant without disclosing that he was taking money from Blackstone Medical Inc.

John Sherman, the patient, claims that Thomas failed to tell Sherman that he had a deal with Blackstone before performing surgery on his neck and back.

Morguefile and southernfried

Civil Battery

Findlaw.com states: "Battery is the intentional touching of, or application of force to, the body of another person in a harmful or offensive manner (and without consent).... A battery is an intentional tort, as opposed to an act resulting from negligence. The elements to establish the tort of battery are the same as for criminal battery, excepting that criminal intent need not be present."

This if the first time we've seen this tort claim used by a patient against their surgeon involving the failure to disclose financial ties to a manufacturer.

Alleged Kickbacks

According to an August 14, 2013 story in *Courthouse News Service*, "Between approximately 2000 and 2006 defendant Thomas was in a financial scheme with one or more of the Blackstone defendants where defendant Thomas received financial incentives to install Blackstone Medical devices," Sherman claims in the lawsuit. "During the relevant timeframe, defendant Thomas exclusively used Blackstone medical devices."

The Justice Department announced a $30 million settlement in 2012 with Orthofix International, N.V. (which had purchased Blackstone), over allegations that Blackstone, before being acquired by Orthofix, paid surgeons to use their devices.

"These alleged kickbacks took a number of forms, including sham consulting agreements, sham royalty arrangements, sham research grants, travel and entertainment," the Department of Justice said in a statement in 2012.

Tainted Consent

Courthouse News reports that Sherman claims his surgeries constituted battery because he would not have had them if he'd known about Thomas' deal with Blackstone. "Plaintiff would not have consented to a procedure such as the neck and back procedures performed by defendant Harvey Thomas, M.D. if informed that the surgeon had a financial incentive that impaired his ability to make a reasoned and proper medical decision," the complaint states.

"Defendant Harvey Thomas, M.D. committed battery when he performed a surgery while receiving financial incentives from the device's manufacturer."

Sherman also claims that Blackstone engaged in a civil conspiracy to commit battery. "Blackstone Medical Inc. enticed Dr. Thomas to use its equipment, exclusively, through a financial arrangement that impaired Dr. Thomas's independent medical judgment," the lawsuit states.

Sherman is seeking punitive damages and costs from Thomas, Orthofix International and Orthofix Spinal Implants in Pima County Court.

—WE (August 14, 2013)

DePuy Recalls Femur Component

On August 1, 2013, the FDA posted a Class 1 device recall notice for a DePuy Orthopaedics, Inc. femur device component. A Class I recall is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

LPS Lower Extremity Dovetail Intercalary Component

The agency and the company have notified healthcare professionals of the recall of the LPS Lower Extremity Dovetail Intercalary Component due to the potential for fracture of the female component, at the dovetail, when exposed to normal physiologic loads while walking.

This fracture may also lead to additional pain, infection, loss of function, loss of limb, neurovascular injury or need for revision surgery. Patients greater than 200 pounds and/or those with high levels of activity are at higher risk of fracture.

The LPS Lower Extremity Dovetail Intercalary Component is intended for replacement of the mid-shaft portion of the femur, top (proximal), bottom (distal) and/or total femur, and top (proximal) tibia, especially in cases that require extensive resection (i.e., tumors, trauma, infections, etc.).

DePuy issued an Urgent Medical Device Recall on July 11, 2013, alerting distributors, hospitals and surgeons of the problem, asking them to immediately stop distributing or using the recalled lots. These products were manufactured and distributed from February 2007 through May 2013.

The company is providing a patient letter template to assist surgeons with notifying and discussing the risks of the implant fracture and the method for detecting implant failure with their patients. DePuy is not recommending revision or additional follow up in the absence of symptoms of patients with this implanted device.

Surgeon Options

If a patient presents with a fractured LPS Lower Extremity Dovetail Intercalary Component with well-fixed proximal and distal stems and the surgeon determines that replacing the LPS Lower Extremity Dovetail Intercalary Component is the best treatment option, DePuy will make the LPS Lower Extremity Dovetail Intercalary Component available. If the LPS Lower Extremity Dovetail Intercalary Component has fractured and the surgeon determines that the replacement LPS Lower Extremity Dovetail Intercalary Component is not the best treatment option for a patient, other commercially available products should be considered.

Questions should be directed to Kim Earle, DePuy's Recall Coordinator at 574-371-4917, Monday through Friday from 8 am to 5 pm Eastern Time.

Read the complete FDA recall notice, linked below, for further recommendations and a list of affected product codes and lot numbers. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm363452.htm

—WE (August 12, 2013)

fda.gov

LARGE JOINTS

Extra Washing Cuts Surgical Site Infections

A simple program is cutting surgical site infections by a dramatic percentage, according to orthopaedic traumatologist and joint reconstruction doctor Brian Tonne, M.D., at the University of Tennessee Medical Center. Before undergoing a hip or knee replacement patients take an infection-prevention class called "project joints."

Patients' noses are swabbed to check for the presence of staph bacteria and three days before their surgery doctors

Wikimedia Commons and Siva301in

instruct prospective patients to wash with a special anti-bacterial, anti-septic soap. They tell them to spend three minutes scrubbing their affected limb. As an added precaution, doctors use clippers at the surgical site instead of razors.

The University of Tennessee Medical Center's infection rate for knee and hip replacements was almost 2% before project joints. Now, "it has dropped to approximately 0.5%," Tonne said.

The "project joints" procedure is currently in use in hospitals in eight states and is expanding to facilities in five more, according to Tonne.

He indicated that the program is only being used for patients getting hip and knee replacements, but he believes it should be used in conjunction with other joint replacements and orthopedic procedures. He notes that every year 300,000 Americans get surgical site infections—the most common healthcare associated infection in the U.S.

—BY (August 15, 2013)

BIOLOGICS

Versatile Stem Cells Found in Urine

Stem cells, it seems, are everywhere. Researchers at Wake Forest Baptist Medical Center's Institute for Regenerative Medicine have not only identified stem cells in urine but, for the first time, have directed them to become multiple cell types. They have found that urine-derived cells have the potential to form bone, cartilage, fat, skeletal muscle, nerve and endothelial cells.

The researchers obtained urine samples from 17 healthy individuals ranging in age from 5 to 75 years and evaluated the cells' ability to become multiple cell types. They found that the cells differentiated into the three tissue layers (endoderm, ectoderm and mesoderm) and into specific cell types.

Wikimedia Commons and Markhamilton

The researchers then placed the cells that had differentiated into smooth muscle and urothelial cells onto scaffolds made of pig intestine. When implanted in mice for one month, the cells formed multi-layer, tissue-like structures.

"These stem cells represent virtually a limitless supply of autologous cells for treating not only urology-related conditions such as kidney disease and urinary incontinence, but they could be used in other fields as well," said Yuanyuan Zhang, M.D., Ph.D., one of the researchers.

They published their findings in the journal *Stem Cells*.

The urine-derived stem cells have markers of mesenchymal cells, which are adult stem cells from connective tissue such as bone marrow and markers for pericytes, a subset of mesenchymal cells found in small blood vessels.

Zhang noted that with this scientific breakthrough, the harvesting of stem cells for therapy may one day be as simple as asking patients for a urine sample.

—BY (August 14, 2013)

RTI Surgical Implants First Cell-Based Bone Graft

RTI Surgical Inc, a surgical implant company that provides surgeons with biologic, metal and synthetic implants, has successfully completed the first human implantation of the company's map3 Cellular Allogeneic Bone Graft implant.

Franco E. Vigna, M.D., M.P.H., a board-certified orthopedic surgeon with Spine Surgery of Buffalo, New York and a fellow with the American Academy of Orthopaedic Surgeons, performed the first implantation during a spinal surgery in New York. He used the implant's chips allograft configuration, one of two configurations that the firm plans to make available.

"I am excited to have map3 as an option for my patients because of its specific osteogenic and angiogenic properties," said Vigna. "The future of spine surgery is biologics. We can place the best metal implants but if the bony fusion does not take place, those implants will loosen and the fusion will fail. Having top quality natural biologics along with excellent metal implants gives physicians and patients the best of both worlds."

Courtesy of RTI Surgical Inc.

According to company officials map3 cellular allogeneic bone graft is a natural and safe alternative to autograft. They claim that map3 provides a streamlined approach to bone grafting and supplies the three elements necessary for bone repair—osteogenesis, osteoinduction and osteoconduction—in a single allograft. Map3 incorporates multipotent adult progenitor cell-based technology with stem cells isolated from the same donor as the other bone material.

The MAPC technology, which the firm licensed from Athersys, Inc. for this orthopedic application, represents what company officials claim to be a distinctive type of stem cell with recognized angiogenic and immuno-modulatory properties. Once launched, they say that map3 will be available in multiple configurations and sizes, providing bone grafting options for various bone repair, reconstruction and fusion procedures. They anticipate a market release of the implant later this year.

"We are thrilled to reach this milestone for map3," said Brian K. Hutchison, RTI president and CEO. "The MAPC-based technology offers the greatest potential to create high quality, innovative implants for our surgeons and their patients." RTI is headquartered in Alachua, Fla., and has four manufacturing facilities throughout the U.S. and Europe

—BY (August 15, 2013)

EXTREMITIES

Occupational Injury Amongst Orthopedic Surgeons

Manish Sethi, M.D., assistant professor of orthopedics and rehabilitation at Vanderbilt University Medical Center, is enlightening his colleagues about the injuries that can occur in the OR. He and his team set out to determine the prevalence and types of injuries that orthopedic surgeons sustained in the workplace.

Wikimedia Commons/U.S. Navy photo by Photographer's Mate Airman Sarah E. Ard

Dr. Sethi and his co-authors developed and distributed electronic surveys to every orthopedic surgeon in Tennessee—495 individuals. A total of 140 surveys were returned, with representation from all orthopedic subspecialties. Sixty-one (44%) of the respondents reported sustaining one or more injuries at the workplace. A significant association was found between years performing surgery and prevalence of injury, with surgeons working between 21 and 30 years reporting the most injuries.

Fourteen (10%) of the surgeons reported missing work as a result of an occupa-

tional injury, most of which were result of injuries to the hand and the back. Five (4%) missed at least three weeks of work. Twenty-three surgeons (37% of injured respondents) reported that no institutional resources were available to support their recovery from the injury.

The authors believe that their study is the first of its kind to demonstrate that many orthopedic surgeons sustain occupational injuries during their careers. The volume of work missed suggests that occupational injury has economic implications for the health care system and providers.

Dr. Sethi told *OTW*, "I was surprised to learn that most hospitals really don't have programs to help physicians injured on the job. I think it would be reasonable if institutions could help surgeons through counseling and basic support."

Asked why he thought that reporting the injuries to the institution was so low, Dr. Sethi stated, "I think it is because most surgeons feel there is nowhere to report them."

There was a finding that 38% of the injured surgeons said that this type of pain had at least a minimal impact on their operating room performance. Asked if we know what kind of impact this had, i.e., the surgeon slowed down/changed positions, etc., Dr. Sethi told *OTW*, "We did not ask this question but it is up to the professional judgment of the physician as to whether he or she feels they can do a case safely. I can't speak for everyone but the surgeons I know would never put a patient at risk or in harms way."

—EH (August 15, 2013)

Integra's Titan (Reverse Shoulder) Lifts Off

The folks at Integra LifeSciences Holding Corporation are celebrating. The FDA has granted a 510(k) clearance for its Titan Reverse Shoulder System. The company plans to begin a limited market release of the system in the U.S. in the third quarter of 2013 and, upon CE Mark clearance in Europe, initiate a full global commercial launch.

Integra officials explain that the Reverse Shoulder System is built on a platform stem, which simplifies the conversion of a primary total shoulder, or hemi for fracture, to a reverse shoulder, without the need to remove a stem that is well-fixed in the patient's bone. The system offers fully interchangeable components, allowing all primary, reverse, and fracture humeral bodies to be used with either the press-fit or cemented platform stems.

Analysts anticipate that the global shoulder replacement market will reach nearly $865 million in 2014 and $1.3 billion by 2017. With the addition of the Titan Reverse Shoulder System that addresses both the press-fit and cemented reverse shoulder market, Integra believes that it is well positioned to gain a key foothold in this rapidly growing market.

—BY (August 15, 2013)

Wikimedia Commons and Reuben Barton

Dr. Peña Forges New Ground in Ankle Surgery

Orthopedic Surgeon Fernando Peña, M.D., an assistant professor in the Department of Orthopedic Surgery at the University of Minnesota and a practicing ankle surgeon, could not sleep one night and instead lay in bed debating what to do about one of his young patients. The young woman had arthritis in her ankle and was in a great deal of pain.

Courtesy of University of Minnesota and Tria Orthopedics

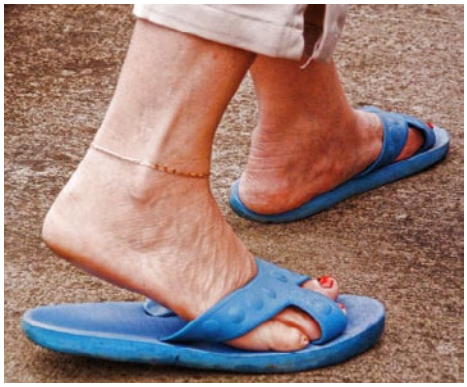
If Peña fused the bones in the patient's ankle all motion in the joint would be gone. If he installed an artificial joint, as is done with hips and knees, the joint would last a maximum of ten years. (Peña compares artificial joints in the ankle to tires on a car. With use they wear out.) A second replacement joint would last only five years—due to scaring and changes in the bone. A third joint, if one were to be installed, he said, would have a life of only two and a half years.

Peña and his patient, decided on a totally different approach. Peña cut off the arthritic end of the bone in the bottom half of the ankle joint (called the talus), removing the dome of the bone. Then he made an identical cut on the bone of a teen-aged cadaver and fixed that piece of bone, with screws, to the talus of his patient. Within six weeks the transplant had fused into the patient's ankle and Peña reported that healthy bone and healthy cartilage extended across the joint.

That was four years ago and the first time that Peña performed this surgery. The patient was a 17-year-old girl who, to treat her leukemia, had been treated with steroids. The steroids had effectively killed the bones in her ankles. When she first appeared in Peña's clinic she was a wheel chair bound 16 year old. It's a much different story today. After performing his unique operation of attaching cadaver bone from a youthful donor to the ends of her talus, she was able to leave her wheelchair behind. Today the young woman is finishing college, walking and has had a healthy baby. "She is doing perfectly fine," said Peña.

To date, Peña has performed this surgery on approximately 20 patients and is following up on all of them. "I am not the only guy doing it," he says. He believes that there may be three other surgeons in the U.S. who are performing similar but not exactly the same ankle procedure as he is. He compares the situation to occasions where three individuals, contestants for major prizes, will be found to have simultaneously come up with the same idea.

Peña has found the talus to be a common site of arthritis. He says that 80% to 90% of arthritis is found to be there with only 10% to 15% located on the



upper surface of the joint, which is the lower end of the tibia. While he believes his approach has a great deal of potential, he also notes that "a problem is that, to be successful in the surgery, patients cannot have arthritis on the upper surface of the ankle. Only on the bottom. If they have it on both sides it is bi-polar disease and for this we need to truly fuse the ankle."

Peña is skeptical about ankle replacements saying that "it is extremely difficult to make them work." He claims that "the data on ankle replacements is debatable because the results that the ankle designers have accomplished have not been reproduced by other surgeons." He says ankle replacements "are a solution but not a good solution. We are still in diapers compared to where the science is on the replacement of ankle is concerned compared to hips and knees." Hips and knees, he says, have been done for 50 years. "We have been doing ankles for ten years," he said.

Peña says that he went into ankle surgery because "it is a humongous black box—people do not understand ankles well. There is so much potential for learning and innovation. The difference between ankles and knees is that ankles are very forgiving. They can look horribly bad and still work quite well. While a knee can look so-so and still hurt like the dickens. Foot and ankle has not been researched as much as shoulders and knees."

Peña was born in Brazil and moved with his family to Spain where he grew up and attended medical school. Since his teen years he wanted to be an orthopedic surgeon. Disillusioned by the attitudes of physicians in the socialized medicine system of Spain Peña, at the age of 24 and speaking little English, came to Minneapolis where he had one contact, a friend of his father's who was the head of radiology at the University of Minnesota medical school.

Peña learned English, went back to Madrid to finish his sixth year of medical school and returned to Minnesota where he passed his board examinations, was admitted to the residency program of the University of Minnesota and became the first foreign student to graduate from the orthopedics department. Study in Canada, Norway and London completed his preparation for joining his alma mater, the orthopedics department of the University of Minnesota in 2003.

Ankles are the only joint surgery that Peña does and, in his mind, there is beauty in the fact that foot and ankle have not been well researched and explored. He says that knees were the joints of the 1990s; shoulders were the joints of the 2000s. He believes that ankles and elbows may be next. He notes that he has very satisfied patients. "They were once miserable and we made them happy by enabling them to do just plain walking," he said. Patients have said to Peña, "I would like to walk again, free of pain." He finds that to be "in this country a pretty basic, very humble request."

—BY (August 14, 2013)

PEOPLE

Steven L. Haddad, M.D. Named AOFAS President

Steven L. Haddad, M.D., senior attending physician with Illinois Bone & Joint Institute (IBJI) in Glenview, Illinois, is the new president of the American Orthopaedic Foot & Ankle Society (AOFAS). In addition, Haddad will serve on the Board of Directors of the Orthopaedic Foot & Ankle Outreach & Education Fund.

Haddad is a board-certified orthopedic surgeon who specializes in ankle replacement surgery, complex ankle reconstruction, foot and ankle deformity correction, and ankle arthritis management. He is also an educator and researcher, and has served as Principal Investigator in an FDA protocol and in numerous clinical and basic science research studies. He also works in product development, working with engineers to create two total ankle prostheses, and individually developing orthopedic hardware technology to stabilize bones throughout the body.

Haddad has served in leadership positions and as faculty member and course developer for AOFAS and the American Academy of Orthopaedic Surgeons. He has edited or co-edited 8 books and journals and authored or co-authored

Steven L. Haddad, M.D.

more than 50 journal articles and book chapters. He has given hundreds of scholarly presentations worldwide, including in Australia, South America, South Africa and throughout North America and Europe.

Haddad received his bachelor's degree in Honors Biology from the University of Michigan in 1985. He entered the Johns Hopkins University where he earned his doctorate in medicine. Haddad completed his orthopedic surgery residency at Georgetown University and a fellowship in foot and ankle surgery at Union Memorial Hospital in Baltimore.

He has served as faculty at both Northwestern University Medical School and University of Chicago Pritzker School of Medicine and received numerous awards and academic honors including the Roger A. Mann award from AOFAS and the James K. Stack Resident Teaching Award from Northwestern.

Dr. Haddad told *OTW*, "In the year 2013-2014, under my presidency, we have a number of major initiatives to accomplish. It is my goal work with our board of directors to make the AOFAS the premier provider of foot and ankle care in the lower extremities in the United States. This will require simultaneous education of other health care providers of the lower extremity so that all patients benefit from better care. Expanding physician education supported by outcomes research will provide validated methods for surgeons to learn how to treat both simple and complex problems. In fact, we will oversee the largest foot and ankle meeting held worldwide, with the joint meeting of the AOFAS and International Foot and Ankle Society in 2014 in Chicago. Finally, it is my goal to work to build the infrastructure of the organization, beginning with the purchase of a new Association Management System to revamp our aging computer network. This system will provide deeper integration with our website, bring e-marketing and social media collaboration, and revenue opportunities through a physician resource center that will strengthen our organization financially. Thus, this will be a strong year of both creation of new policies and refining older ones to allow the AOFAS to rise even further at the forefront of medical specialty societies."

—EH (August 12, 2013)

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