

# Orthopedics This Week

## week in review

### 4 **SNN and BMET Stand Out in Robust First Quarter** ♦

Ortho sales tanked in the aftermath of The Great Recession. But 2012 is a new year. First Quarter sales reports from the “big five” were generally better than expected. Who won the sales competition for hips, knees and extremities for the quarter? Read it here.

### 10 **Smith & Nephew's Bold Spin Off** ♦

Smith & Nephew's deal with Essex Woodlands to spin off its clinical therapies business into a new company, called Bioventus, raises the specter of a well-capitalized, nimble and aggressive biologic/injectables challenge to the metal and plastic implant business. Is SNN trying to obsolete itself? Well, better them than someone else. Here's what's happening.

### 14 **Pagnano V. Berend on TKA Malalignment** ♦

Mark Pagnano: “There are few issues with regards to malalignment in TKA because, frankly, it's irrelevant to long term outcomes. Michael Berend: “We know that there are many factors regarding long term survivability. Alignment is the most important.”

### 17 **On (and Off) the Record** ♦

New Certification Requirements...Breakthrough Approach to Stimulate Bone Formation and Repair...Preventing Joint Replacement Surgery...First-of-Its-Kind Global Trauma Database Effort Launched...and more.



## breaking news

**21** **New Growing Rods: No Repeat Surgery**  
Sunshine Postponed Until 2013

**War's Lessons** Make All the Difference for One Patient

**New ACL Surgery** Hits 1000 Cases

**Autograft Trumps Allograft** in ACL Study

**MAKO's Quarter Disappoints**

**Bacterin International** Signs Up Third GPO

**MAKO Surgical** Sued in Florida

**For all news that is ortho, read on.**

# Orthopedic Power Rankings

## Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

**THIS WEEK:** NuVasive's phenomenal Q1 performance plus Globus's IPO bringing fresh and enthusiastic capital into spine. By contrast MAKO, the pioneer of robotics in orthopedics, missed numbers and was hammered by, first investors—down 44%—then the plaintiff's bar. Lesson: Sales growth plus profits attracts buyers. Missed sales growth with no profits attracts sellers and plaintiffs.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Orthofix	16.23%	10.04%	Best valuation in ortho. Building the balance sheet with Breg sale. Double-digit earnings growth this year.
2	2	Conmed	10.09	(4.88)	Second best valuation in ortho. Also making interesting strategic moves to build shareholder wealth—like cut costs and add biologics.
3	3	NuVasive	6.63	30.41	Q1's sales and earnings surprise coincides with Globus's IPO and is attracting new buyers into spine. Tide's rising.
4	5	Integra LifeSciences	13.34	9.18	New FDA clearance for spine. Expanding in Europe. Raised guidance. Ummm...why is IART trading at 13x this year's EPS estimate?
5	4	Johnson & Johnson	24.93	0.33	Overall—no top line growth. No bottom line growth. But the dividend grows 7%. Why split JNJ up? To uncover growth—which is hidden somewhere in Indiana.
6	7	Symmetry Medical	5.29	14.00	SMA's strategic moves are paying off in this tough large joints market. Gross margin rose 500 basis points in Q1.
7	6	Zimmer	24.95	(2.04)	Funny headline about ZMH: A stock to forget you own for the next 10 years. Exactly right.
8	8	Stryker	23.68	(1.21)	Also a stock to forget you own for the next 10 years. Providing they have a CEO that will stay 10 years. Will it be an insider?
9	10	Medtronic	28.24	0.82	Lowest P/E in ortho, lowest PE to growth rate too. High PSR however. Why the difference? 28% profit margins. Cash pours in.
10	9	Smith & Nephew	21.50	0.51	BioVentus spin off bold concept which should pay off in 3 to 5 to 7 years. Should have done this with ATSI? Or Richards?

## Robin Young's Orthopedic Universe

### TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Kensey Nash	KNSY	\$38.50	\$335	34.80%
2	NuVasive	NUVA	\$20.67	\$892	30.41%
3	Symmetry Medical	SMA	\$8.06	\$295	14.00%
4	Wright Medical	WMGI	\$20.91	\$822	12.18%
5	Orthofix	OFIX	\$39.45	\$739	10.04%
6	Integra LifeSciences	IART	\$35.32	\$954	9.18%
7	Exactech	EXAC	\$16.36	\$216	8.63%
8	RTI Biologics Inc	RTIX	\$3.72	\$208	6.29%
9	TranS1	TSO1	\$3.53	\$96	5.69%
10	Medtronic	MDT	\$38.03	\$39,574	0.82%

### WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MAKO Surgical	MAKO	\$23.20	\$988	-43.68%
2	Bacterin Intl Holdings	BONE	\$1.61	\$68	-33.20%
3	TiGenix	TIG.BR	\$0.66	\$60	-20.14%
4	Alphatec Holdings	ATEC	\$1.92	\$172	-14.29%
5	Tornier N.V.	TRNX	\$20.98	\$825	-13.45%
6	Conmed	CNMD	\$27.51	\$778	-4.88%
7	Zimmer Holdings	ZMH	\$61.90	\$10,903	-2.04%
8	Synthes	SYST.VX	\$169.36	\$20,116	-1.36%
9	Stryker	SYK	\$53.18	\$20,258	-1.21%
10	ArthroCare	ARTC	\$24.60	\$680	-0.61%

### LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	\$38.03	\$39,574	11.85
2	Zimmer Holdings	ZMH	\$61.90	\$10,903	12.56
3	Johnson & Johnson	JNJ	\$64.34	\$176,702	12.82
4	Stryker	SYK	\$53.18	\$20,258	13.96
5	ArthroCare	ARTC	\$24.60	\$680	14.06

### HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Wright Medical	WMGI	\$20.91	\$822	53.62
2	NuVasive	NUVA	\$20.67	\$892	48.07
3	Symmetry Medical	SMA	\$8.06	\$295	32.24
4	Kensey Nash	KNSY	\$38.50	\$335	26.92
5	Exactech	EXAC	\$16.36	\$216	23.04

### LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	\$39.45	\$739	0.82
2	Stryker	SYK	\$53.18	\$20,258	1.30
3	ArthroCare	ARTC	\$24.60	\$680	1.32
4	Zimmer Holdings	ZMH	\$61.90	\$10,903	1.35
5	Integra LifeSciences	IART	\$35.32	\$954	1.43

### HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Wright Medical	WMGI	\$20.91	\$822	6.36
2	NuVasive	NUVA	\$20.67	\$892	4.96
3	CryoLife	CRY	\$5.08	\$140	4.54
4	Symmetry Medical	SMA	\$8.06	\$295	2.69
5	Johnson & Johnson	JNJ	\$64.34	\$176,702	2.18

### LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	\$8.06	\$295	0.82
2	Alphatec Holdings	ATEC	\$1.92	\$172	0.87
3	Exactech	EXAC	\$16.36	\$216	1.05
4	Conmed	CNMD	\$27.51	\$778	1.07
5	CryoLife	CRY	\$5.08	\$140	1.17

### HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	\$0.66	\$60	52.48
2	MAKO Surgical	MAKO	\$23.20	\$988	11.69
3	Synthes	SYST.VX	\$169.36	\$20,116	5.06
4	TranS1	TSO1	\$3.53	\$96	5.02
5	Kensey Nash	KNSY	\$38.50	\$335	4.68

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

Advertise with Orthopedics This Week




Click Here for more details  
or email [tom@ryortho.com](mailto:tom@ryortho.com)  
Tom Bishow: 410.356.2455 (office)  
or 410.608.1697 (cell)

## SNN and BMET Stand Out in Robust First Quarter

By Walter Eisner



*RRY Publications LLC*

**S**ales results for the first quarter of 2012 for the “big five” orthopedic device companies (The Big Bones) are now in. Those five manufacturers—Biomet, Inc., DePuy Orthopaedics, Inc., Smith & Nephew, plc, Stryker Corporation and Zimmer Holdings, Inc.—make up about 90% of the orthopedic market for hips, knees, extremities and trauma.

Who won the battle of the Big Bones and who lagged behind? Which product categories moved the market? We'll tell you how Wells Fargo Analyst Larry Biegelsen called the quarter in a minute.

First the good news.

Based on quarterly SEC reports, Biegelsen estimates the worldwide orthopedic reconstructive market grew by 2.1%, while patient visits to hospitals for hip, knee and shoulder procedures are all up since the first of the year. In the U.S.

recon growth was only 1.1%, but up from a 2.1% decline in the last quarter of 2011.

Commentary from the companies has generally been positive, but most have cautioned about reading too much into this quarter's results. Biegelsen believes first quarter results were a positive for the ortho industry, and is cautiously optimistic that the industry will continue to rebound in 2012.

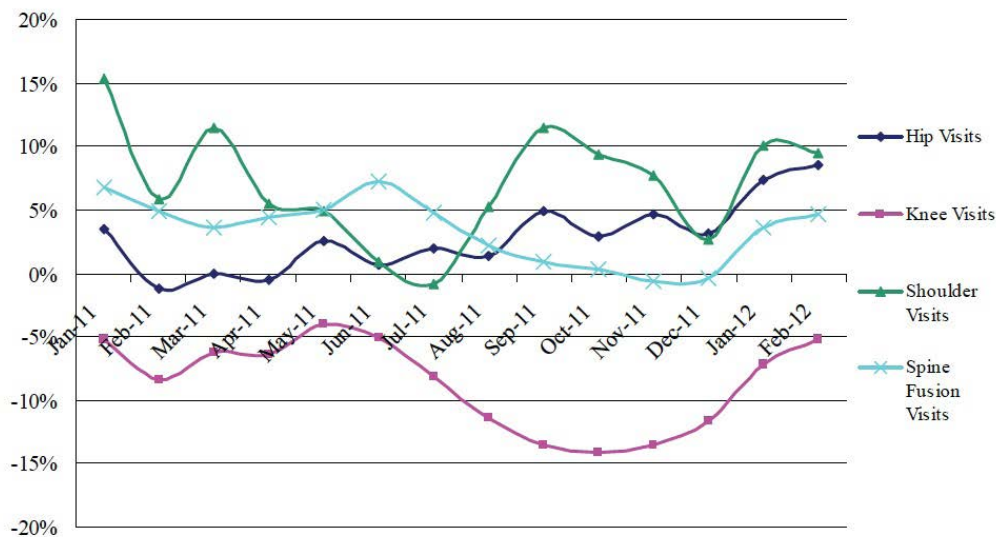
### Patients Returning

Ortho procedure volumes are trending upward. On a rolling three-month basis, Wells Fargo's hospital procedure volume shows that knees, hips and spine procedure volume has improved for the last two months (Figure 9).

Shoulder procedure growth has leveled recently but is still hovering around 10%.

Biegelsen believes the data shows a positive trend and is consistent with recent management commentary suggesting stable to slight improvement in procedure volume.

**Figure 9: Rolling 3-Month Orthopedic Volume**



Source: IMS Health and Wells Fargo Securities, LLC estimates  
Note: Adjusted for one extra day in February 2012

The bad news? It was hard to find, but one quarter doesn't make a trend and caution remains as the Supreme Court wrestles with a health insurance mandate, Congress dithers over a broken public purse and, trying to push new technologies through the FDA remains an expensive proposition for device makers.

### Recon Recovery?

Companies are cautiously optimistic. Figure 1 shows year-over-year (YOY) and sequential growth rates for hips, knees and extremities. Spine and trauma are not included in this article. Biegelsen provides comments on the market categories:

**Figure 1: Recon (Hip+Knee), Knee And Hip Y/Y Growth Analysis**

Category	Worldwide CC Growth			Comments
	Q4 11A	Q1 12E	Delta	
<b>Recon</b>	0.1%	2.1%	1.9%	Signs of market improvement, but companies remain cautiously optimistic
<b>Knees</b>	(0.8%)	2.8%	3.6%	Growth is positive sign; Q1 begins string of easy comps
<b>Hips</b>	1.3%	1.2%	(0.1%)	Volumes and pricing appear to be stable
<b>Spine</b>	(3.7%)	(2.2%)	1.5%	NUVA significant acceleration; Other companies slight sequential improvement
<b>Extremities</b>	8.3%	7.4%	(0.9%)	Six quarters of high single-digit growth; Shoulders still fastest growing extremities segment
<b>Trauma</b>	3.1%	3.6%	0.6%	Second straight soft quarter; Warmer winter in U.S. had negative impact

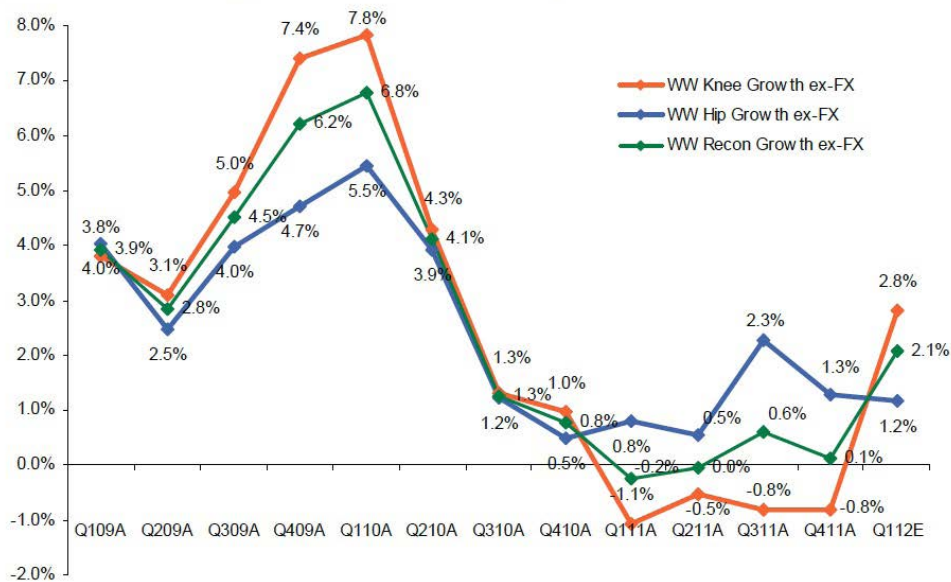
Source: Company reports and Wells Fargo Securities, LLC estimates  
Note: Q1 2012 growth excludes the impact of one extra day selling day for applicable companies; quarterly market growth figures include Wells Fargo Securities estimates for the companies that have not yet reported or information is not available

Biegelsen said all five ortho companies saw sales growth accelerate during the quarter and the orthopedic market appears to be “stable at worst and likely improved slightly” in the quarter.

### Knees Lift Market

The increase in recon sales was largely driven by knee sales, which rose 2.8%. Knees also recovered in the U.S. where sales rose 1.1%, recovering from a 2.1% decline in sales the last quarter in 2011. Hips, extremities and trauma sales were essentially in line with the previous quarter. (Figure 2).

**Figure 2: Quarterly Recon, Knee And Hip Growth\***



Source: Company reports and Wells Fargo Securities, LLC estimates

\* Market growth rates include Biomet, JNJ, SNN, SYK, WMGI, ZMH and others

Note: Growth excludes the impact of one extra day selling day for applicable companies

### Winners and Laggards

#### Reconstructive

Biegelsen estimates that Biomet's 3.2% rise in recon sales topped The Big Bones, followed by Smith & Nephew and Stryker, both up 2.5%, and Zimmer rising 2.4%. All beat the estimated 2.1% market growth. DePuy sales only rose 1.3%, while Wright Medical Group, Inc., not quite big enough for the Big Bones club, saw sales decline 15.2%.

In the U.S., Stryker grew the fastest at 3.9% and Wright continued to see sales drop by 15.2%.

Figure 4 provides an eight quarter breakdown of global and U.S. recon and hip and knee sales (See next page)

**Figure 4: Global And US Recon (Hip & Knee) Growth****Global Recon Growth - Constant Currency**

	Q110A	Q210A	Q310A	Q410A	Q111A	Q211A	Q311A	Q411A	Q112A
Biomet	9.4%	11.0%	3.8%	1.8%	-0.6%	-0.6%	-0.3%	3.1%	3.2%
DePuy	9.9%	5.5%	2.6%	-4.8%	-3.2%	-3.8%	-1.7%	-0.8%	1.3%
Smith & Nephew	7.6%	1.6%	3.2%	-0.1%	1.8%	3.8%	2.4%	0.2%	2.5%
Stryker	6.2%	0.9%	0.5%	4.4%	-0.1%	1.4%	2.4%	-1.1%	2.5%
Wright	6.8%	6.6%	-0.4%	6.9%	-1.7%	-0.9%	-8.2%	-14.2%	-7.9%
Zimmer	2.8%	3.0%	-1.3%	1.7%	1.5%	0.4%	1.4%	1.7%	2.4%
<b>WW Recon Growth ex-FX</b>	<b>6.8%</b>	<b>4.1%</b>	<b>1.3%</b>	<b>0.8%</b>	<b>-0.2%</b>	<b>0.0%</b>	<b>0.6%</b>	<b>0.1%</b>	<b>2.1%</b>

**US Recon Growth**

	Q110A	Q210A	Q310A	Q410A	Q111A	Q211A	Q311A	Q411A	Q112A
Biomet	9.2%	9.9%	5.3%	1.9%	-3.2%	-3.2%	-1.5%	1.9%	1.9%
DePuy	8.8%	2.7%	0.6%	-7.4%	-6.1%	-5.8%	-5.6%	-2.9%	1.0%
Smith & Nephew	9.7%	-0.3%	3.2%	2.7%	3.8%	4.7%	0.2%	-2.1%	0.2%
Stryker	10.0%	3.3%	2.6%	5.5%	-0.7%	0.7%	0.8%	-2.3%	3.9%
Wright	3.4%	1.5%	-6.9%	-1.1%	-13.0%	-10.3%	-0.4%	-16.6%	-15.2%
Zimmer	3.7%	3.3%	-0.5%	2.0%	-0.1%	-2.6%	-2.6%	-2.4%	0.0%
<b>US Recon Growth</b>	<b>7.7%</b>	<b>3.6%</b>	<b>1.6%</b>	<b>0.3%</b>	<b>-2.0%</b>	<b>-1.9%</b>	<b>-1.8%</b>	<b>-2.1%</b>	<b>1.5%</b>

**Global Knee Growth - Constant Currency**

	Q110A	Q210A	Q310A	Q410A	Q111A	Q211A	Q311A	Q411A	Q112A
Biomet	13.0%	13.0%	5.0%	3.0%	-1.0%	-1.0%	-2.0%	1.0%	2.4%
DePuy	9.0%	4.8%	3.0%	-3.7%	-4.2%	-4.2%	-4.2%	-2.5%	1.6%
Smith & Nephew	9.0%	3.0%	6.0%	4.0%	5.0%	7.0%	6.0%	2.0%	6.0%
Stryker	8.0%	0.0%	0.0%	3.0%	-2.0%	-1.0%	-0.5%	-2.4%	3.4%
Wright	5.0%	6.0%	-1.0%	12.0%	0.0%	2.0%	-10.0%	-13.0%	-5.0%
Zimmer	4.0%	3.0%	-3.0%	0.0%	-1.0%	-0.8%	-0.5%	0.2%	2.4%
<b>WW Knee Growth ex-FX</b>	<b>7.8%</b>	<b>4.3%</b>	<b>1.3%</b>	<b>1.0%</b>	<b>-1.1%</b>	<b>-0.5%</b>	<b>-0.8%</b>	<b>-0.8%</b>	<b>2.8%</b>

**US Knee Growth**

	Q110A	Q210A	Q310A	Q410A	Q111A	Q211A	Q311A	Q411A	Q112A
Biomet	13.0%	11.0%	6.0%	3.0%	-5.0%	-5.0%	-4.0%	-1.0%	2.4%
DePuy	10.4%	3.3%	2.1%	-4.2%	-6.0%	-4.6%	-6.7%	-4.6%	2.3%
Smith & Nephew	11.0%	2.0%	5.0%	9.2%	10.0%	10.0%	5.0%	0.0%	3.0%
Stryker	12.2%	4.2%	2.2%	4.2%	-2.0%	-2.0%	-1.8%	-3.5%	3.3%
Wright	4.0%	1.0%	-5.0%	6.0%	2.5%	0.4%	-2.2%	-21.7%	-10.7%
Zimmer	3.8%	3.2%	-2.3%	-0.4%	-2.9%	-4.9%	-4.0%	-3.8%	0.3%
<b>US Knee Growth</b>	<b>9.1%</b>	<b>4.4%</b>	<b>1.6%</b>	<b>1.4%</b>	<b>-2.3%</b>	<b>-2.6%</b>	<b>-3.0%</b>	<b>-3.4%</b>	<b>1.8%</b>

**Global Hip Growth - Constant Currency**

	Q110A	Q210A	Q310A	Q410A	Q111A	Q211A	Q311A	Q411A	Q112A
Biomet	4.0%	8.0%	2.0%	0.0%	0.0%	0.0%	2.0%	6.0%	4.4%
DePuy	11.0%	6.3%	2.1%	-6.2%	-2.2%	-3.4%	1.0%	1.2%	1.0%
Smith & Nephew	6.0%	0.0%	0.0%	-5.0%	-2.0%	0.0%	-2.0%	-2.0%	-2.0%
Stryker	4.0%	2.0%	1.0%	6.0%	2.0%	4.0%	5.4%	0.4%	1.5%
Wright	8.0%	7.0%	0.0%	3.0%	-3.0%	-3.0%	-7.0%	-15.0%	-10.0%
Zimmer	1.0%	3.0%	1.0%	4.0%	5.0%	2.0%	4.0%	3.6%	2.5%
<b>WW Hip Growth ex-FX</b>	<b>5.5%</b>	<b>3.9%</b>	<b>1.2%</b>	<b>0.5%</b>	<b>0.8%</b>	<b>0.5%</b>	<b>2.3%</b>	<b>1.3%</b>	<b>1.2%</b>

**US Hip Growth**

	Q110A	Q210A	Q310A	Q410A	Q111A	Q211A	Q311A	Q411A	Q112A
Biomet	3.0%	8.0%	4.0%	0.0%	0.0%	0.0%	3.0%	7.0%	5.4%
DePuy	7.0%	2.0%	-1.2%	-11.7%	-6.3%	-7.2%	-4.3%	-0.5%	-0.6%
Smith & Nephew	8.0%	-3.0%	1.0%	-5.0%	-4.0%	-2.0%	-6.0%	-5.0%	-4.0%
Stryker	7.2%	2.5%	3.2%	7.2%	1.2%	4.3%	4.5%	-0.7%	4.7%
Wright	3.0%	-4.6%	-9.0%	-9.0%	-25.4%	-19.7%	1.5%	-10.1%	-20.0%
Zimmer	3.7%	4.8%	3.0%	6.5%	5.3%	1.8%	-0.1%	0.2%	-0.5%
<b>US Hip Growth</b>	<b>5.7%</b>	<b>2.6%</b>	<b>1.5%</b>	<b>-1.4%</b>	<b>-1.6%</b>	<b>-1.0%</b>	<b>-0.1%</b>	<b>0.0%</b>	<b>1.0%</b>

Source: Company reports and Wells Fargo Securities, LLC estimates

Note: Q1 2012 growth excludes the impact of one extra day selling day for applicable companies

### Knee Winner - Smith & Nephew

The U.S. knee market rebounded as all five large ortho companies reported that sales growth rates improved during the quarter. As we mentioned earlier, worldwide knee sales rose 2.8%

Smith & Nephew blew away the field by announcing that sales of knee implants rose 6% during the quarter. Stryker also beat market growth, advancing 3.4%. The rest trailed the market, with Wright at the bottom reporting a 5% year-over-year decline in knee implant sales.

In the U.S., all companies except Wright and Zimmer (down 10.7% and up 0.3%, respectively) beat the market growth rate of 1.8%. Stryker and Smith & Nephew grew 3.3% and 3.0%, respectively, while Biomet and DePuy sales rose 2.4% and 2.3%

Bieglens did not see a meaningful shift in knee market share in the quarter.

### Hip Winner - Biomet

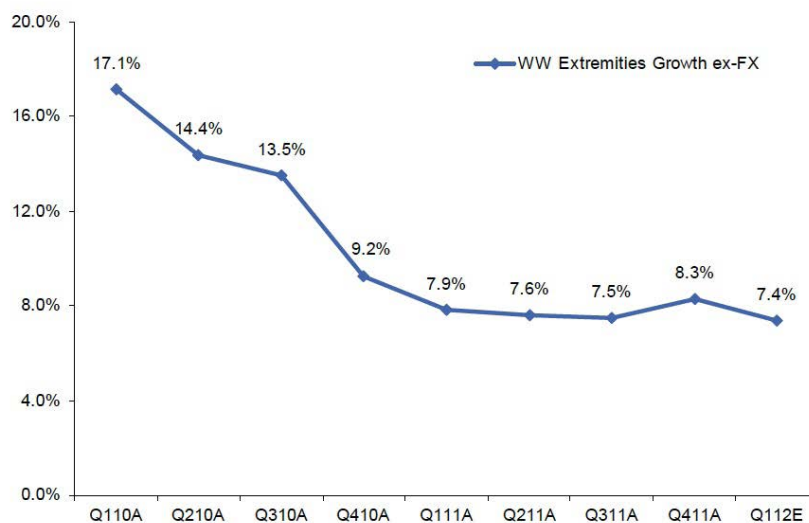
Worldwide, Biomet, Zimmer and Stryker (4.4%, 2.5% and 1.5%) beat market rate growth of 1.2%. DePuy sales rose 1%. Wright and Smith & Nephew saw sales decline by 10.0% and 2.0%. Smith & Nephew attributed its decline in sales to being associated with the metal-on-metal hip controversy.

In the U.S., where the hip market grew 1%, Biomet and Stryker reported sales increases of 5.4% and 4.7%, respectively. Everybody else reported declines. Wright's sales fell the most, declining 20%, followed by Smith & Nephew, off 4%, and DePuy and Zimmer dropping 0.6% and 0.5%.

### Extremities – Exactech By a Mile

The extremities market appears stable with high single-digit growth. (Figure 7). Bieglens estimates that extremities growth was 7.4% in the first quarter, slightly lower than 8.3% growth reported in the last quarter of 2011.

**Figure 7: WW Extremities Market Growth**



Source: Company reports and Wells Fargo Securities, LLC estimates

\* Market growth rates include ARTC, Biomet, JNJ, EXAC, TRNX, WMGI, ZMH and others

Note: Q1 2012 growth excludes the impact of one extra day selling day for applicable companies; quarterly market growth figures include Wells Fargo Securities estimates for the companies that have not yet reported or information is not available

Exactech is pretty much lapping the field when it comes to growth rates (see Figure 8) as their sales rose 37% during the quarter. They've been crushing the competition since the third quarter of 2010. Biomet and Tornier, Inc. are the only others with steady double-digit sales growth with increases of 16.4% and 11.3% in the first quarter.

DePuy was the laggard with sales rising only 3% during the quarter. DePuy's growth rate has been below market growth in eight out of the last nine quarters.

**Figure 8: Quarterly WW Extremities Growth By Company**

Global Extremities Growth - Constant Currency									
	Q110A	Q210A	Q310A	Q410A	Q111A	Q211A	Q311A	Q411A	Q112E
Arthrocare	18.1%	10.1%	13.8%	0.5%	-7.0%	1.2%	-0.8%	4.0%	4.9%
Biomet	27.0%	33.0%	27.0%	23.0%	18.0%	15.0%	16.0%	14.0%	16.4%
DePuy	15.0%	12.0%	9.0%	3.0%	5.0%	6.0%	9.0%	6.5%	3.0%
Exactech	22.0%	30.0%	33.0%	32.0%	33.0%	34.0%	33.0%	29.0%	37.0%
Stryker	15.0%	8.8%	10.5%	12.7%	12.0%	4.0%	6.0%	4.0%	4.4%
Tornier	20.0%	16.0%	18.0%	11.0%	13.1%	14.4%	11.9%	17.1%	11.3%
Wright Medical	15.0%	15.0%	18.0%	15.0%	13.0%	9.0%	6.0%	4.0%	5.5%
Zimmer	14.0%	13.0%	4.0%	10.0%	11.0%	3.6%	4.4%	9.0%	4.8%
<b>WW Extremities Growth ex-FX</b>	<b>17.1%</b>	<b>14.4%</b>	<b>13.5%</b>	<b>9.2%</b>	<b>7.9%</b>	<b>7.6%</b>	<b>7.5%</b>	<b>8.3%</b>	<b>7.4%</b>

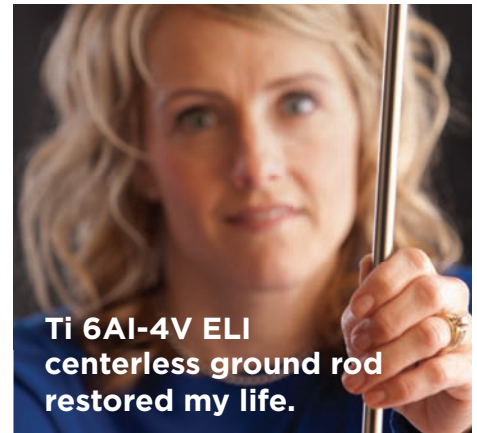
Source: Company reports and Wells Fargo Securities, LLC estimates

Note: Q1 2012 growth excludes the impact of one extra day selling day for applicable companies; quarterly growth in indicate Wells Fargo Securities estimates the companies that have not yet reported or where information is not available

## 2012

Despite a strong first quarter, Biegelsen says device manufacturers have been hesitant to update guidance. He thinks the companies are remaining conservative as they wait for additional signs of sustained improvement before declaring a recovery.

One quarter doesn't make a year, but it's a good start. ♦



**Ti 6Al-4V ELI  
centerless ground rod  
restored my life.**

When you need the highest grade centerless ground rod and wire products for your orthopaedic application, call the world leader.



**FORT WAYNE METALS**

Turning knowledge into solutions.

Advertisement

## Smith & Nephew's Bold Spin Off

By Robin Young



Bioventus LLC / Photo Creation by RRY Publications LLC

**F**acing a tough Wall Street crowd where every quarter's earnings report is scrutinized, Smith & Nephew plc was looking for a way to make a bold strategic investment in biologics and injectables. But how to "sell" a 3 or 5 or 7 year investment? Answer: create a spin-off and partner with one of largest most respected private equity firms. It's a bold move. What makes SNN (and their new partner, Essex Woodland) think this will succeed?

Smith & Nephew's deal with Essex Woodlands to spin off its clinical therapies business (DUROLANE - Hyaluronic Acid, Stabilized Single Injection, EXOGEN Ultrasound Bone Healing System, Scoliscore and SUPARTZ Joint Fluid Therapy) into a new com-

pany called Bioventus LLC raises the specter of a well capitalized and newly re-constituted biologic/injectables challenge to the metal and plastic implant business.

Considering that 61% of Smith & Nephew's business comes from products like the Anthony Hip and the Genesis, Journey or Legion knee systems—which could theoretically compete with Bioventus's biologic injectables—this is a bold and interesting move.

### Orthopedic Biologics

The spun-off company, 49% owned by Smith & Nephew and 51% owned by \$2.5 billion private equity firm Essex Woodlands and management, has one

of the largest Ambulatory Surgery Center (ASC) and outpatient distribution platforms in the United States. CEO Mark Augusti is setting his new company's sights on various biologic and other injectable technologies which will, if not modify the underlying osteoarthritis disease, at least delay major surgery.



CEO Mark Augusti

“People are looking for biologics solutions and a company that can be the largest and most trusted brand for orthopedic biologics,” commented Augusti to OTW. “Fundamentally, what we bring is a comprehensive regulatory, reimbursement and health economics approach to biologics products for orthopedic healthcare.”

Bioventus starts life with \$250 million in annual sales, a global distribution footprint and a 500 employee payroll—of which 300 are direct sales people serving the ASC and outpatient orthopedic markets in the United States. That makes Bioventus among the top five biologics companies supplying orthopedic surgeons—along with Musculoskeletal Transplant Foundation (MTF), AlloSource, LifeNet Health and RTI Biologics, Inc..

### Product Lines

Bioventus is, essentially, Smith & Nephew’s clinical therapies division and its new CEO was that division’s president. Now spun off, the former clinical therapies team is hoping to create a more nimble, risk taking, action oriented culture which, with access to Essex Woodlands deep pockets, could create a leading biologics and regenerative medicine business in orthopedics. Bioventus’s inherited product lines, which increased sales by about 7% last year, are:

#### **DUROLANE - Hyaluronic Acid, Stabilized Single Injection:**

A hyaluronic acid (HA) containing product used for the symptomatic treatment of mild to moderate knee and hip osteoarthritis. DUROLANE differs from SUPARTZ and other multi-injection hyaluronic acid products in that one single

injection represents a full course of treatment.

#### **EXOGEN Ultrasound Bone Healing System:**

The EXOGEN Ultrasound Bone Healing System is the only bone healing device approved to accelerate fracture healing of certain (see indications) fresh fractures, speeding the process in those indicated cases by 38%. EXOGEN has also been demonstrated to heal 86% of particular non-union fractures in clinical study.

**SCOLISCORE:** A prognostic test (and winner of OTW Spine Technology Award) that is the first and only genetic test proven to give physicians and parents insight into the progression of a child’s Adolescent Idiopathic Scoliosis (AIS). Until SCOLISCORE, a diagnosis of AIS was frightening and uncertain for patients and their parents. But this test gives families answers for the future and allows physicians to make informed recommendations for treatment. The test is adminis-



EXOGEN Ultrasound Bone Healing System/ Bioventus LLC



SUPARTZ Joint Fluid Therapy/ Bioventus LLC

tered by a physician and requires a saliva sample from the patient, which is sent to a lab for analysis.

#### **SUPARTZ Joint Fluid Therapy:**

SUPARTZ is a solution made of highly purified, sodium hyaluronate (hyaluronan). SUPARTZ is used for the treatment of pain in osteoarthritis of the knee in patients who have failed to get adequate relief from simple painkillers or from exercise and physical therapy. SUPARTZ was the first hyaluronan joint fluid therapy commercially available for human use in treating osteoarthritis. More than 143 million SUPARTZ injections have been sold worldwide since its introduction in 1987.

#### **Recent Performance**

Interestingly, as the spin-off date got closer, SNN's clinical therapies division seemed to increase sales growth rates with each passing quarter.

To wit:

Quarter 2011	YOY Sales Growth %
First Quarter	+2%
Second Quarter	+5%
Third Quarter	+10%
Fourth Quarter	+11%

For the March quarter just ended, the future Bioventus reported sales of \$58 million and a nifty profit of \$10 million.

For the full year last year SNN's clinical therapies business posted up sales of \$237 million and trading profit of \$48 million, with net operating assets of \$99 million. The U.S. business had

sales of \$199 million and trading profit of \$48 million, with net operating assets of \$95 million

#### **Strategic Direction**

According to CEO Mark Augusti, Bioventus's growth strategy rests on three pillars:

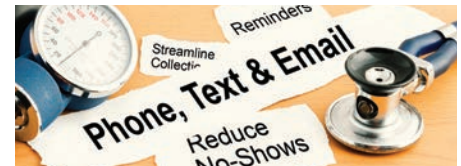
1. "We plan grow our current business by investing in our current technologies and in the process expand indications and labeling."
2. "We plan to invest in our U.S. distribution and build outside the U.S. Of our 500 employees, 300 are direct sales to outpatient orthopedic healthcare providers in the U.S. With good clinical support, we plan to build a similarly successful distribution system outside the U.S."
3. "Licensing promising technologies as well as acquiring technologies or companies which complement the distribution pipeline we've built in the U.S. and OUS. The kinds of technological innovation we are looking for include active biologic technologies, orthopedic injectables, allogeneic, biomaterial, cellular...really any promising biologic technology that lends itself to a strong regulatory, reimbursement and health economics platform in orthopedics."

#### **The Injectable Market Opportunities**

Conservatively, there are more than 30 million steroid, HA and other orthopedic injections performed annually in the U.S. to treat everything from osteoarthritis of the knee to facet pain in the spine to elbow and shoulder pain. Given the changing nature of healthcare economics, the injection market seems ripe for technological innovation. Flex-

ion Therapeutics, Inc., the Boston-based innovator of time release steroid injections and other new injections to treat arthritic pain and the rise of cell based anti-inflammatory injections are giving "needle jockeys" new ways to treat chronic disease like joint arthritis or even soft tissue pain.

But the injection market is not like the orthopedic implant market. As one experienced sales person described it to OTW, the call is not at all like a metal implant call. Not only is the buyer typically an outpatient service provider, but the purchaser is often an "office"—not an individual surgeon. Purchasing and reimbursement issues are also quite different from the more traditional implant call. Is the injectable on a drug plan or is it a straight up procedure reimbursement? Is this a pharma or a biologic?



#### **Customized Automated Messaging**

##### *What we do*

- Reduce No-Shows
- Streamline Collections
- Improving Patient Outcomes
- Help Stimulate Patient Understanding

##### *What sets us apart*

- Money Back Satisfaction Guarantee
- Superior In-House Customer Support
- Hosted & Hardware Solutions Available
- No Hidden Fees, Flat Rate Plans Available



**Call or Visit us at:**  
[phonetree.com/OTW12](http://phonetree.com/OTW12)  
 877.259.0658

Advertisement

The best sales people in the injectable markets are those that treat the sales call and an entire office call—paying attention and attending to every member of the office from the receptionist who takes the incoming calls to the nurses.

This market also requires sales people who are fully expert on not only their injectable product but also the patient's condition and all of the alternative treatments.

In other words, it is a market designed for a dedicated effort like the one envisioned by Bioventus.

### Essex Woodlands

Bioventus's new majority owner is Essex Woodlands and, according to CEO Augusti, one of the most important strategic advantages of the new company.

With \$2.5 billion under management, Essex Woodlands is one of the largest and oldest growth equity and venture capital firms pursuing investments in pharmaceuticals, biotechnology, medical devices, health care services, and health information technology. Since its founding in 1985, Essex Woodlands

has founded, invested, and/or managed over 120 health care companies ranging across all sectors, stages and geography. The team is comprised of 25 senior investment professionals with offices in Palo Alto, Houston, New York and London.

### SNN's Strategy

Perhaps strategic obsolescence is a more accurate description of SNN's objective with this Bioventus spin off. Clearly the goals are ambitious if not also really interesting. ♦



**SPINE DESK REFERENCE**

**GET LISTED NOW!**

**PUBLISHING THIS SUMMER. | DEADLINE: June 25, 2012**

For more information contact [suzanne@ryortho.com](mailto:suzanne@ryortho.com)

Advertisement

# Pagnano V. Berend on TKA Malalignment

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

**Y**es, says Mark Pagnano, there are really very few issues with regards to malalignment in total knee arthroplasty (TKA) because, frankly, it is irrelevant to long term outcomes. Counters Dr. Michael Berend: “We do know that there are many factors regarding long term survivability. I say that alignment is the most important.”

This week’s Orthopaedic Cross-fire® debate is “The Consequences of Malalignment in TKA: Few If Any.” For the proposition was Mark W. Pagnano, M.D. from Mayo Clinic in Minnesota. Against the proposition was Michael E. Berend, M.D. of the Center for Hip & Knee Surgery in Indiana; moderating was Steven J. MacDonald, M.D., F.R.C.S.(C) of the University of Western Ontario.

**Dr. Pagnano:** “The title is preposterous. The prefix ‘mal’ comes from Latin and it means ‘abnormal or defective.’ By definition alone, no one wants a malaligned knee. But can we routinely tell what malalignment really looks like?”

“Mr. Smith: 64 at the time of his total knee [arthroplasty] (TKA); his tibia was left in a bit of varus. His overall limb alignment was in varus; but his one year knee score was 95. Mrs. Jones: 64 at the time of her TKA; a 90 degree tibial cut, a perfect neutral mechanical axis, and a one year knee score of 95. Mr. Smith died 22 years into his total knee—with a perfect knee score. Mrs. Jones was revised last week at five years for loosening of her tibia.”



Wikimedia - KaihsuTai and Current Concepts in Joint Replacement/RRY Photo Creation

“In 2009, if we’re intellectually honest, we’ll admit that our knowledge about ideal limb alignment isn’t better off than it was in the 1970s. And if you’re intellectually curious, that is not acceptable. If we continue to accept broad, average targets, we can expect broad, average results.”

“What is the ideal limb alignment after TKA? Is there really one simple target for all patients? Is that a broad target like a mechanical axis within three degrees? Or is it a narrow target that is specific for each patient...that has a penalty if you deviate even one degree?”

“Some of the scientific support for always aiming at a neutral mechanical axis is weak. Some of the reports routinely quoted involve a rudimentary

knee design with an all-polyethylene tibial component...and that’s fairly routine for many of these studies.”

“We looked at the effect of the mechanical axis alignment on the 15 year survival of modern cemented total knee designs. We looked at 399 knees...our results showed that survival was not better at 15 years with a neutral mechanical axis when we looked at revision for any reason, for aseptic loosening, or wear. We were unable to confirm the premise that underlies the use of the computer in TKA; we couldn’t show improved durability with a neutral mechanical axis...suggesting that factors other than alignment are more important.”

“The ideal alignment after total knees is likely specific for any given patient...”

and it's based on individual differences in gait dynamics...involving a complex interplay between limb alignment, component rotation, sizing, and ligament balancing. Also, implant specific things, particularly with 'flat-on-flat' designs."

"What we can say in 2009 is that the obsessive pursuit of broad target values like a neutral mechanical axis +/- 3 degrees is unlikely to pay off with better survival. Our understanding of ideal limb alignment after TKA remains rudimentary. While alignment is one factor in determining durability, factors other than axial alignment appear to be more important to survival."

"You still need to aim for something, and the traditional target of a neutral mechanical axis is a reasonable guide until we know more. Ultimately, patient-specific targets that account for individual variations in gait are required to improve function and durability."

**Dr. Berend:** "I believe that alignment is the central variable in the failure of TKA. A number of other factors work in conjunction with alignment to predict failure in TKA, like surgical technique, patient factors, and how well we do as surgeons...all critical factors for long term survivability."

"From our data...When you combine varus malalignment of the tibial component in patients with a BMI [body mass index] greater than 33, you can see a precipitous drop in survivorship at mid- and long-term intervals."

"We looked at the most common mechanisms of failure in our cohort and varus malalignment leading to tibial collapse was the single most common failure mechanism we observed. Alignment

based failure represented only 0.6% of all total knee replacements implanted. So while alignment is the most common predictor of failure, it continues to be quite rare in our series and in Dr. Pagnano's series."

"In our data the failure rate in varus malalignment below 2.5 degrees is 1.8%. The failure rate of knees aligned between a single standard deviation of the mean is 4.5 degrees in our series. So between 2.4 and 7.2 degrees of tibial femoral valgus, the failure rate is exactly the same at roughly 0.5%. The interesting finding here is that if we shot for excessive valgus, greater than 7.2 degrees, we also had a higher failure rate at 1.5%. So there's no question in a cohort of 6,000 total knee replacements that varus malalignment has increased failure rates somewhere between 2 and 4%."

"If you look at the failure mechanism, failure itself, if it's infection or instability, may or may not be related to alignment. In our series varus malalignment less than 2.5 degrees had significantly increased failure through a certain mechanism of medial tibial collapse. The converse was true for valgus malalignment, with instability being more common; if you look in aggregate, varus knees failed almost 7x more commonly with medial collapse. And valgus knees failed 3.7x more frequently through instability. So malalignment predicts a certain mode of failure. If you look at this in survivorship, those between 2.4 and 7.2 had improved survivorship compared to the valgus and varus outliers."

"In an example of one of our knees... where it is one degree of varus, six degrees on the femur, seven degrees varus malalignment on the tibia... and look-

ing at the long term response of varus malalignment in the medial tibia... we saw an increased uptake—we believe—related to the abnormal loading conditions in the medial tibia. We looked at neutral aligned knees compared to varus malaligned knees and when we quantified the strain in the proximal tibia with a photoelastic coating mechanism, we saw a large hot spot in the posterior medial aspect of the tibia, which we believe is related to increased bone turnover, increased strain, which leads to implant loosening. Neutral alignment in the laboratory seemed to have the protective effect of no significant overload in the medial tibial bone."

"When we performed a finite element analysis we found that both metal-backed and all-polyethylene implants provided relatively balanced predicted strains in the medial and lateral tibia.



VerteBRIDGE™  
PLATING TECHNOLOGY

ROIA™ ROIC™

Innovative design for simple insertion and stable fixation

OLDR  
a passion for innovation

Advertisement

Then with varus condylar loading we did see significantly increased strain in the medial tibia. So, we concluded, alignment overloads the medial tibia and predicts a certain type of failure mechanism. As you examine the literature it is critical to look at the reason for failure more than alignment itself. So alignment remains the single most important variable in long term survivorship.”

**Moderator MacDonald:** “We need a target when we go in the OR. What is your target and when do you look at a film and say, ‘I missed my target.’”

**Dr. Pagnano:** “Use the same target values that you’ve looked at for the past 35 years because we don’t have better evidence on what to select for any individual patient. We’re really arguing over the difference between 0.5% failure and 1.5% failure, according to Mike’s data. What I’m trying to figure out is an explanation for those 0.5% as well because it’s only when we understand why the 0.5% fail that we’ll also be able to address the 1.5%.”

**Moderator MacDonald:** “Mike, your target?”

**Dr. Berend:** “4.8 degrees. But other factors are also important. Is a modest tibial resection important? We used to cut below any defect—and we’ve now found with 16mm polys and higher, a 4% failure rate...so we think a modest tibial resection, larger tibial surface area is important. We think metal backing of the implant plays a significant role; we think the size of the

femoral component compared to the tibial component also plays a role, as well as the patient’s BMI in correlation with the size of their tibia. So I think the target’s bigger—2 to 7—however in certain patients it may be related to their gait, to their preoperative deformity, and it’s most likely related to the bone that the tibia rests on.”

**Dr. Pagnano:** “I’m thinking over time that the target is very narrow and is specific for any individual patient, and as soon as you deviate even one degree from that ideal you will incur a penalty. And that’s why some of your knees that are aligned between 2 and 7 do fail because of aseptic loosening. It’s because 2 to 7 doesn’t describe the perfect alignment for that subset of patients. I think some of those 0.5% failures have something different about their gait mechanics that changes the pattern of alignment so that 2-7 degrees of valgus is no longer the appropriate target.”

**Moderator MacDonald:** “We focus on the alignment visible on a radiograph... how do you judge interoperatively your femoral component rotation?”

**Dr. Berend:** “We look at the flexion gap and make it a rectangle in the knees that have an intact cruciate...so for nonfixed deformity we’ll do a balanced gap technique. We’ll also draw a Whiteside’s line, draw the upper condylar axis, and most importantly we’ll go with a rectangular flexion gap. So rotation in the femur is just as important for all kinds of problems rather than coronal alignment of the tibia or overall alignment of the leg.”

**Dr. Pagnano:** “I use the trans-epicondylar axis...I want to be within 1-2 degrees of that for simplicity during surgery. Oftentimes I will start in a varus knee with 3 degrees of external rotation relative to the posterior condyle; in a valgus knee I start with 5 degrees, but then compare it to the trans-epicondylar axis and to the flexion gap.”

**Moderator MacDonald:** “Obese patients...how do you set your tibial jig?”

**Dr. Berend:** “I draw a ‘t’ on the preoperative X-ray to note where the perpendicular exits the tibial metaphysis; then we place the center of the cutting block on the proximal tibia at that same mark...trying to reestablish the rotation of the tibia on our proximal cut. The most important thing we’ve changed in the last 10 years is to always check the tibial cut with a long alignment rod.”

**Dr. Pagnano:** “I do preoperatively plan the resections so I get a quick check during the surgery. In the MIS realm these smaller cutting guides have been helpful. Also, I make sure there are no drapes on the anterior part of the tibia. Lastly, if I have questions after checking with the long alignment rod, I will get an intraoperative x-ray in really heavy patients.”

**Moderator MacDonald:** “Thank you.” ♦

*Please visit [www.CCJR.com](http://www.CCJR.com) to register for the 2012 CCJR Spring Meeting, May 20-23 in Las Vegas, Nevada.*

“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.cjrmobile.com](http://www.cjrmobile.com).”





# ON AND OFF THE RECORD

*A upper right femur Bone-allograft with associated tissues around the hip joint./Source: Wikimedia Commons and BennyK95*

## On (and Off) the Record By Elizabeth Hofheinz

**N**ew Certification Requirements... Breakthrough Approach to Stimulate Bone Formation and Repair... Preventing Joint Replacement Surgery... First-of-Its-Kind Global Trauma Database Effort Launched... and more.

### New Certification Requirements

Greg Mencio, M.D. is chair of the AAOS Board of Specialty Societies (BOS), an entity comprised of the leaders of 22 North American musculoskeletal specialty societies. How are they helping your “average” orthopedist? Dr. Mencio tells *OTW*, “One of the major things our fellows are dealing with now is

maintenance of certification. There are a number of new mandates that have been put forth by the American Board of Medical Specialties (ABMS) and the American Board of Orthopaedic Surgery (ABOS) around this issue. Among the latest additions to the process of recertification are performance improvement modules that track how effectively physicians are performing in caring for patients. The BOS is working with the AAOS to develop the appropriate educational modules to meet these new requirements. We are trying to ‘mine’ the critical content expertise that exists within the specialty societ-

ies to develop testing processes that are educational for surgeons and relevant to patient care. The fact is that surgical techniques have changed and will continue to change... what many of us do now is different from what we did in training. We have got to be ‘fluid’ in keeping pace with best practices—and the public wants to know that physicians are up to speed on the latest skills and training.”

“The other ‘hot button’ issue now is advocacy. Legislatively, we are in favor of policies that focus on quality of care, access to specialty care, and patient

safety. We work with the AAOS Council on Advocacy, Board of Councilors and State Orthopaedic Societies through our Office of Government Relations to deliver our messages on a continual basis. We recently co-hosted the 2012 National Orthopedic Leadership Conference (NOLC), in Washington, DC, that drew more than 200 orthopedic surgeons. These physicians attended educational symposia and participated in visits to Capitol Hill to engage their federal representatives in support of legislation to reduce the burden of professional liability insurance and to amend anti-trust laws to allow equitable negotiations between health care providers and health insurance plans to ensure continued access to quality care for our patients.”

**Anjan R. Shah, M.D. Joins Florida Orthopaedic Institute**

If there is trauma, the folks at the Florida Orthopaedic Institute (FOI) have a new specialist to help out...Dr. Anjan R. Shah is now on board as an orthopedic trauma specialist. Prior to joining FOI, Dr. Shah assisted in the development of Lawnwood Regional Medical Center's orthopedic trauma service in Fort Pierce, Florida, and was an orthopedic trauma surgeon throughout his tenure there. Dr. Shah initiated the orthopedic trauma protocols, oversaw all complex orthopedic cases that were presented in the emergency room, handled referrals and transfers from tertiary centers in the surrounding area and participated in multiple seminars on the topics of orthopedic trauma. Dr. Shah is a board-certified and fellowship-trained orthopedic trauma surgeon and received his medical degree from Boston University School of Medicine. He did a residency in orthopedic surgery at Drexel University in Philadelphia, then went on to receive fellowship training in ortho-



orthofix.com  
1-800-535-4492  
SAD-1201-US © Orthofix Holdings, Inc. 1/2012

**ORTHOFIX®**

Advertisement

pedic trauma surgery at Florida Orthopaedic Institute.

**Engineering the Bone Surface** It's sort of a 'Why didn't anyone think of this before?' situation. Well, S. Adam Hacking, Ph.D., Director of the Laboratory for Musculoskeletal Research and Innovation in the department of Orthopaedics at the Massachusetts General Hospital and Harvard Medical School, *did* think of it: *Enhanced Bone Formation and Repair by Modification of Allograft Surfaces*. Dr. Hacking, who was awarded the Orthopaedic Research and Education Foundation (OREF)/Synthes Research Grant in Trauma, tells *OTW*, "This is an entirely new approach to stimulate bone formation and repair...I call it, 'bone surface engineering' The incorporation of specific nanosize features on the surface of bone stimulates osteoblast differentia-

tion and recruitment, which ultimately leads to increased bone formation. This is very exciting because by simply manipulating the morphology of the bone surface, we have demonstrated about a twofold enhancement in bone formation in segmental defect and allograft treated defect models. With this grant from the OREF, more comprehensive trials are underway and we are looking forward to having enough data to begin clinical work."

"This entirely new approach is significant for a number of reasons. First, there are many situations where enhanced bone formation is required; second, it has the potential to integrate with and compliment a number of existing approaches and finally, bone surface engineering offers a low cost approach that may one day provide benefit to those in less developed nations—where

the incidence of trauma is high but the cost of therapeutics can be prohibitive.”

“We are still investigating how the bone surface engineering approach works. We believe that texturing the bone surface leads to the release of cytokines and intercellular messengers beneficial for bone healing. Instead of exogenously delivering growth factors, texturing the bone surface may stimulate the body to release them when and where needed...it's like braille for guiding the formation of new bone.”

**Gary Kraus, M.D. Honored as Top Doc** For the sixth year in a row, H Texas Magazine has chosen Gary Kraus, M.D., FAANS, a Houston spine and brain surgery expert, as a Top Doctor. Dr. Kraus treats a wide variety of brain and spine disorders, but has a special interest in non-surgical as well as surgical treatment of lower back pain and neck pain. He has patents pending on minimally invasive devices for the spine, and he has produced several websites: spine-surgery.com; spinehealth.com; neuro-surgery.com; neuro-surgery.com. Dr. Kraus started and directed a Gamma Knife program in Ohio in 1999, and has been director of a Gamma Knife Center in Houston for seven years. Dr. Kraus is Chairman of Neurosurgery at Memorial Hermann Memorial City Hospital, Houston, Texas. He is Director of Neuroscience and Gamma Knife at West Houston Medical Center. He is Assistant Clinical Professor, Department of Neurosurgery at the University of Texas Medical School at Houston.

**Preventing Joint Replacement Surgery** How to put the brakes on joint degeneration? A resident at the Hospital of the University of Pennsylvania—Mara L. Schenker, M.D.—is hot on the trail of an answer to that ques-

tion. Dr. Schenker, who received a 2010 Orthopaedic Research and Education Foundation (OREF) Resident Clinician Scientist Training Grant, tells OTW, “Researchers at the Penn's McKay

Orthopaedic Research Laboratory have developed a nanofibrous scaffold that mimics the scale of the meniscal extracellular matrix, as well as its anisotropic (direction-dependent) architecture. My

2012 Orthopedics This Week  
**Spine**  
technology  
Awards

*Cervical Care  
Thoracolumbar Care  
Minimally Invasive Spine Care  
Motion Preservation  
Biomaterials and Biologics*

The 4th Annual  
**SPINE  
TECHNOLOGY  
AWARDS**

Submissions for 2012 awards:  
April 2, 2012-August 31, 2012.  
Awards to be presented  
**October 25, 2012**

*spineawards.com or suzanne@ryortho.com for  
Submission forms and rules*

Advertisement

colleagues and I have been doing electrospinning, where we pull two types of polymers into an electrical field, collect them and are left with a sheet of dual polymer. We then fold that into three-dimensional structures for implants.”

“This is a novel therapy that has the potential to prevent knee patients from having to undergo joint replacement down the line. We are beginning a large animal study and have already worked out some of the ‘kinks’ such as getting the implants secured in the joint (using a three dimensional model). We are looking at a new way to thread the structures and ways to secure them in the joint, as well as ways to recreate the curved fibers of the meniscus.”

**First-of-Its-Kind Global Trauma Database Effort Launched**

A novel effort is underway at the Institute for Global Orthopaedics & Traumatology (IGOT) at the University of California San Francisco (UCSF). Amber Caldwell, Director of Outreach Development for IGOT, tells *OTW*, “We are developing a global trauma database in partnership with Mohit Bhandari, M.D. at McMaster University. While there are many estimates, we don’t know the actual global burden of trauma...those who show up at a hospital and those who don’t make it to the hospital. Some of those participating in this effort are six surgeons from Africa who recently visited IGOT through our Global Knowledge Exchange. When reviewing one of our major projects, INORMUS, an international trauma registry project, our visitors emphasized the need for a database, even locally, to better advocate for and defend resources needed to meet the ever growing demand of orthopedic trauma. The visiting surgeons’ role is



nanOss®  
Bioactive  
3D

Another dimension  
brought to you by



Advertisement

to be on-the-ground investigators and lead study directors at their respective centers. They will supervise and facilitate in data collection and growth of the research infrastructure.”

Ted Miclau, M.D., professor and vice chair of Orthopaedics at UCSF and Director of the UCSF/San Francisco General Hospital Orthopaedic Trauma Institute (OTI) tells *OTW*, “The three surgeons from Tanzania—Dr. Edmund Eliezer, Dr. Billy Haonga and Professor Musera—and three from Kenya—Dr. Anthony Nduati, Dr. Geoffrey Koech and Dr. Nedford Ongaro—began their visit with the IGOT by attending the SF Orthopaedic Trauma Course. They mixed with the 450 other attendees, and were able to have one-on-one

meetings with national trauma experts. Some of our visitors participated in a clinical research workshop and others did a clinical case study symposium. The six visiting surgeons all come from two academic centers that were already in partnership with IGOT. While here, they spent time in educational and research meetings and one-on-one research mentoring, which was extremely popular. We see these relationships as fundamental in improving the care of orthopedic trauma globally, and we hope that these projects will be the foundation for future research on regionally-important questions.”

For more information, please visit: <http://orthosurg.ucsf.edu/oti/outreach/programs/igot/> ♦

## company

**MAKO Surgical Sued in Florida**

Well that didn't take long.

Just a few days after MAKO Surgical Corporation announced that it missed consensus revenue and earnings estimates, a shareholder filed a lawsuit in U.S. District Court for the Southern District of Florida against the company, along with its President and CEO Maurice Ferré, M.D. and CFO Fritz Laporte. The company was expected to have sales of around \$23.8 million, but came in at \$19.6 million.

A day after the May 7 announcement the company's common stock price fell 37%.

The shareholder, James H. Harrison, Jr. is proposing a class action lawsuit by other shareholders against the company. He hired a Florida law firm, which immediately issued a press release seeking more clients. Law firms frequently

issue press releases announcing that they are "investigating" a company and fish for clients. We usually do not help them on these fishing expeditions, but in this case, Harrison has actually filed a suit.

Companies sometime do get hit with a shareholder class action lawsuit after share prices drop significantly. The issue in this case will be whether the company and its executives misled investors about material facts, and did so intentionally.

The complaint, announced on May 10, alleges that defendants issued materially false and misleading statements regarding the company's financials and future business prospects.

"Specifically, defendants misrepresented and/or failed to disclose the following adverse facts: (i) that the Company was poised to suffer a wider first quarter loss as it was experiencing higher costs and slower sales of its RIO systems; (ii) that utilization rates of the Company's RIO systems were dropping; (iii) that the Company's 2012 outlook provided

at the start of the Class Period lacked a reasonable basis when made; and (iv) that, based on the above, defendants lacked a reasonable basis for their positive statements about the Company or its outlook," said the release from the law firm.

The company reportedly did not respond to request for comment about the lawsuit from local media.

—WE (May 11, 2012)

**Bacterin International Signs Up Third GPO**

Bacterin International Holdings, Inc. has signed its third national GPO (group purchasing organization) contract, a three-year agreement with Novation LLC.





Bacterin International Holdings/Novation



[uscourts.gov/U.S. District Court for the Southern District of Florida](http://uscourts.gov/U.S. District Court for the Southern District of Florida)

Novation is a leading health care supply chain expert and contracting company. The agreement makes Bacterin's biologic portfolio, including Osteo-Sponge, OsteoSelect DBM Putty, OsteoWrap, OsteoLock, BacFast, hMatrix, Sports Medicine Allografts, and tradi-

tional allografts available to Novation's network of hospitals and medical practices.

Guy Cook, chairman and CEO of Bacterin International, said, "The inclusion of our products in Novation's network is a significant opportunity to create exposure and access for physicians to our broad portfolio of biologics."

Bacterin's proprietary technology, according to the company, optimizes the growth factors in human allografts to create the ideal stem cell scaffold to promote bone, subchondral repair and dermal growth. These products are used in a variety of applications including enhancing fusion in spine surgery, relief of back pain, promotion of bone growth in foot and ankle surgery, promotion of cranial healing following neurosurgery and subchondral repair in knee and other joint surgeries.

The company reported \$7.8 million in revenue for the first quarter of 2012, a 29% increase from the previous year. In June 2011, the company announced a five-year agreement with a GPO called ROi (Resource Optimization & Innovation), an operating division of the Sisters of Mercy Health System. The previous year, the company announced a distribution agreement with the Broadlane Group (acquired in 2010 by MedAssets, Inc.) nationwide network of hospitals and medical practices.

Novation contracts for the more than 65,000 members of VHA Inc. and UHC, two national health care alliances, and Provista, LLC. Novation provides alliance members with sourcing services, as well as information and data services. Based in Irving, Texas, Novation develops and manages competitive contracts with more than 600 suppliers. VHA,

UHC, and Provista members used Novation contracts to purchase more than \$40 billion in 2011.

—*WE (May 11, 2012)*

## MAKO's Quarter Disappoints

**M**AKO Surgical Corp.'s first quarter sales disappointed Wall Street.

The manufacturer of an advanced robotic arm technology missed consensus revenue and earnings estimates. The company was expected to have sales of around \$23.8 million, but came in at \$19.6 million. Investors punished the stock by driving it down from around \$40 per share to the mid-\$20 range.

MAKO's Robotic Arm Interactive Orthopedic surgical platform, MAKOplasty joint specific applications, and proprietary RESTORIS implant are disruptive technologies. After starting on knees, the company entered the hip market in the past year.

The story for the company has always been about how many of its systems it can get into the market. Profits later. Net

loss for the three months ended March 31, 2012 was \$11.7 million.

The company now expects to sell fewer machines than it originally thought for the rest of the year. It expects to sell 52-58 systems instead of 56-62. They still expect to perform between 11,000-13,000 procedures on the systems already out there.

During the quarter, the company sold 6 RIO Systems and performed 2,297 procedures (2,219 in U.S.). Both were below expectations. Of the domestic procedures, 211 were total hip arthroplasty (THA) procedures. The 2,297 procedures represent a 2% increase over the fourth quarter of 2011 and a



Courtesy Mako Surgical Corp.

76% increase over the first quarter of 2011.

Management cited delays (not cancellations) in customer orders as the source of the system shortfall and a drop-off in partial knee replacements as patients' deductibles were reset at the beginning of the year.

### More Credit and Abstracts

In addition to announcing sales results, on the company announced a new \$50 millionM credit facility on May 7. MAKO ended 1Q12 with cash and investments of \$47 millionM after using \$11.9 millionM of cash in the quarter. Management still expects to use \$25 million-\$30 millionM of cash during 2012 with its quarterly burn rate declining in the second half of the year.

The company currently has over 70 clinical studies in process. During the first quarter, 25 abstracts were accepted to 5five conferences and are expected to be presented in 14 podium and 11 poster presentations at upcoming conferences.

Maurice R. Ferré, M.D., president and CEO of MAKO said, "While the first quarter is typically our slowest quarter of the year and system placements are very difficult to predict on a quarterly basis, our results this quarter were at the low end of our expectations. On the positive side, we were encouraged by the continued interest shown in our hip application and the quality and quantity of clinical data that continues to be generated that supports the clinical and economic benefit of MAKOplasty."

—WE (May 10, 2012)

## Smith & Nephew: A Solid Quarter

Smith & Nephew, plc's first quarter Orthopedic Reconstructive sales rose 4%. Knees led the way, rising 6%.

Overall the company's \$1.08 billion in sales rose 3%.

In a May 3 announcement, the company cited strong revenue, profit and trading profit margin performance from both Advanced Wound Management and Surgical Devices. Management was happy with the continued growth in knee implants and momentum in Negative Pressure Wound Therapy.

Smith & Nephew 1Q12	Sales (\$ in millions)	% Change*
<b>Total Sales</b>	<b>\$1,032.0</b>	<b>3.0%</b>
Ortho Recon	\$425.0	4.00%
Knees	\$235.0	6.00%
Hips	\$179.0	down 2%
Trauma/Clinical Therapy	\$172.0	1.00%
Endoscopy	\$242.0	2.0%
Advanced Wound Mgmt.	\$240.0	5.0%

Source: BMO Capital Markets

\* On constant currency basis

Olivier Bohuon, S&N's relatively new CEO, said the company had a "good" first quarter and saw the first results of "actions to make Smith & Nephew more fit and effective. 2012 is a critical year for implementing our new strategic priorities. Our plans to progress the structural changes, additional investments and, of course, greater efficiencies, are now underway. Throughout Smith & Nephew, at every level, there is a clear sense of direction, as we work to reshape the Group for future growth."

### Sales

The company noted knee sales outperformed the market which they estimated grew at 3%. In the U.S., knee revenue increased by 3%, outpacing the market, which grew 2%. Strong sales were attributed to contributions from the Legion Revision Knee System and continued growth, albeit slowing relative to last year, from Verilast bearing technology and



Smith and Nephew/Wikimedia Commons and RRY Publications

Visionaire Patient Matched Instrumentation Sets.

Hip sales did not show a good result, declining by 2%. The company said this was largely a result of, “continuing headwinds in the metal-on-metal total hip replacement sector. Sales of our Birmingham Hip Resurfacing System continued to suffer from association, despite its strong track record demonstrated by many independent sources of data which have proved its performance over more than ten years. In traditional total hip implants we generated strong double-digit growth in revenue from products featuring our Verilast bearing technology. We also launched the Polarcup Dual Mobility Hip System in the U.S.”

Established markets (U.S., Europe, Canada, Japan, Australia and New Zealand) increased revenue by 2%, and

emerging and international markets, rose 12%. In the BRIC (Brazil, Russia, India and China) countries, revenue grew in excess of 20%. Management announced the establishment of a new headquarters for their emerging markets and international markets teams in Dubai.

### Mergers & Acquisitions

In response to an analyst’s question about use of the company’s cash, management noted that it does not intend to announce a new share buyback plan and that over the next 12 months it will focus on potential acquisitions as its primary use of cash. In the first quarter, management did make two small acquisitions: Life Modeler, Inc., a software solution that shortens time to develop recon products, and the Aderma range of Dermal Pads from Focus Product Development Limited.

The company also recently announced it was spinning off its biologics business and increasing its investment in negative pressure wound therapies.

### First Quarter Hip and Knee Markets

“All in all a solid quarter from [S&N] as it works to leverage its income statement in challenging global markets,” said BMO Capital Market Analyst, Joanne Wuensch. Now that all of the major manufacturers have reported first quarter results, Wuensch said her market models suggest that, on a constant currency basis, the knee market increased 3.4%, and S&N’s share continued to rise to 13.2% from 13.0% over the previous year. However in hips, Wuensch said the market increased 1.6% with S&N’s share declining to 12.6% from 13.1% the previous year.

—WE (May 9, 2012)

## legal

### Sunshine Postponed Until 2013

The Centers for Medicare & Medicaid Services (CMS) is postponing sunshine.

On May 3, CMS announced on a web blog that the agency will not require device manufacturers and group purchasing organizations (GPOs) to collect data of payments and gifts to physicians before January 1, 2013.

Back in December the agency published draft regulations that would implement the “Transparency Reports and Reporting of Physician Ownership or Investment Interests” section of the Patient Protection and Affordable Care Act, commonly referred to as the Sunshine



Wikimedia Commons and neuro/Sunlight

Act. In the 60-day comment period following the publication of the proposed rules, the agency received over 300 comments “from a wide range of stakeholders.”

“In order to provide time for organizations to prepare for data submission and to sufficiently address the important input we received during the rulemaking process, CMS will not require data collection by applicable manufacturers and applicable group purchasing orga-

nizations before January 1, 2013,” said the agency on a web blog.

CMS intends to release the final rule later this year. The timing will provide additional time to address operational and implementation issues to ensure the accuracy of the data that is collected.

Under the Sunshine Act, manufacturers and GPO’s were supposed to start collecting data this past January.

The Act requires drug, device, biological product, and medical supply manufacturers to disclose information regarding payments and other transfers of value to physicians and teaching hospitals. An additional provision requires manufacturers and group purchasing organizations (GPOs) to disclose all ownership or investment interests held by physicians or members of their family.

—WE (May 9, 2012)

## large joints

**Cat Scratch Fever and Rheumatoid Arthritis**

Watch out when you snuggle up to Fluffy...North Carolina State University (NC State) researchers have found that a bacterium historically associated with cat scratch fever and transmitted predominately by fleas—*Bartonella*—may also play a role in human rheumatoid illnesses such as arthritis.

*Bartonella* can be transmitted to humans both by parasites as well as by bites or scratches from infected cats and dogs. The most commonly known *Bartonella*-related illness is cat scratch disease, caused by *B. henselae*, a species of *Bartonella* that can be carried in a cat's blood for months to years.

In collaboration with Dr. Robert Mozayeni, a rheumatologist based in Maryland, and Dr. Ricardo Maggi, a research assistant professor at NC State, Dr. Ed Breitschwerdt, professor of internal medicine at NC State's College of Veterinary Medicine and adjunct professor of medicine at Duke University, tested blood samples for evidence of *Bartonella* infection.

Of the 296 patients involved, 62% had *Bartonella* antibodies, which supported prior exposure to these bacteria. Bacterial DNA was found in 41% of patient samples, allowing investigators to narrow the species of *Bartonella* present, with *B. henselae*, *B. kohlerae* and *B. vinsonii* subspecies *berkhoffii* the most prevalent. The study appears in *Emerging Infectious Diseases*.

In the April 23, 2012 news release, Dr. Breitschwerdt said, "Based upon this



Wikimedia Commons and Guylaine Brunet

one study we can't definitively say that a subset of rheumatoid illnesses have an infectious origin. However, our results thus far do implicate *Bartonella* as a factor in at least some cases. If the link between *Bartonella* and rheumatoid illnesses is valid, it may also open up more directed treatment options for patients with rheumatoid illnesses."

Dr. Breitschwerdt told OTW, "Based upon evolving epidemiological and microbiological data, it is possible that infection with *Bartonella* species can play a role in joint pain and lameness in dogs, horses and human patients.

For example, both *Bartonella henselae* and *Bartonella vinsonii* subspecies *berkhoffii* were co-isolated from joint fluid of a dog that progressed from a non-erosive to an erosive polyarthritis (Diniz PPVP et al. *Veterinary Microbiology*: 138, 368-372, 2009), indicating that direct infection of joints is possible. In addition, osteolytic lesions, at times involving bones within a joint have been reported in association with *Bartonella henselae* infection in people and *Bartonella vinsonii* subspecies *berkhoffii* infection in a cat (Varanat M., et al. *Journal of Veterinary Internal Medicine* 23:1273-1277, 2009). As our recently published data supports the possibility of persistent intravascular infection in immunocompetent patients, additional studies are needed to determine the frequency with which these bacteria can be found in patients with joint pain and polyarthritis."

—EH (May 11, 2012)

## Why use a polymer barrier when natural covering is available?

### We got you covered!

AmnioClear  
FROM  
AFcell

For more information  
[www.afcellmedical.com](http://www.afcellmedical.com)

Advertisement

## Schedule Cuts Surgery Wait Times

Wait times in Alberta, Canada, for hip and knee replacements were growing longer and longer. The cause appeared to be obvious. There were not enough surgeons and operating theaters to keep up with the demand for hips and knees from a rapidly aging population. One individual, Cy Frank, M.D., the executive director of the Alberta Bone and Joint Health Institute, saw the problem in another way.

He thought that patients were staying too long in the hospital. As Frank wrote in an article on May 2 in the *Halifax Chronicle Herald*, "Every hour an acute-care bed remains occupied by a recovering patient who doesn't really need it is an hour that bed cannot be occupied by another patient who needs a new hip or knee."

Frank's institute, working with the Bone and Joint Clinical Network of the Alberta Health Services (AHS), developed a four-day standard for a hospital stay for a joint replacement. When they studied the records they found that in

2009-2010, patients who had elective or planned hip replacements spent, on average, an extra 1.2 days in the hospital and knee-replacement patients stayed an extra three-quarters of a day. About 16,000 bed-days would have been freed up had the average stay in acute care followed the standard of four days. "If these beds had been available for hip and knee replacement patients, it would have opened up capacity for another 4,000 surgeries," Frank wrote.

Health care decision-making in Alberta is decentralized. As a way to attack the problem, in 2010-2011, the AHS organized frontline teams of surgeons, nurses, therapists and managers from 12 hospitals where hip and knee surgery was performed. Each team set out to hold patient stays to the benchmark of four days, while also striving for improved performance. They made sure that patients had a plan for coping at home after surgery. Those who were not medically ready to leave hospital, but were not at risk, they moved into sub-acute care.

The experiment produced an annualized savings of almost 11,000 acute-care

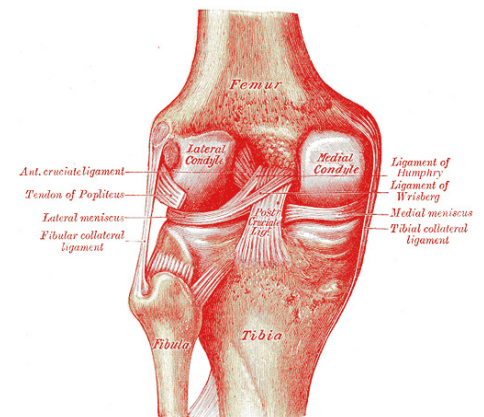
bed-days and AHS adopted it as a permanent program. Preliminary results for 2011-2012 suggest that more than 13,500 bed-days have been saved, opening up bed capacity to potentially perform an extra 3,375 hip and knee replacements.

Frank believes that the program will enable the Alberta Health Service to meet its target of a maximum 14-week wait in 2014-2015 for an elective hip or knee replacement.

—BY (May 10, 2012)

## Autograft Trumps Allograft in ACL Study

Given a choice, young athletes with an anterior cruciate ligament (ACL) injury should use their own tissue for the reconstruction procedure,



Wikimedia Commons and Grays Anatomy



Wikimedia Commons and JhlScott

rather than tissue from a donor. That is the result of a study undertaken at Keller Army Hospital, West Point, New York, and reported May 2 by Andrew M. Seaman in *Reuters Health*. The ACL, which connects the upper and lower leg bones, is most often damaged by athletes who play sports such as basketball that involve sudden quick moves.

The tissue for an autograft is typically taken from the injured person's hamstring or patellar tendon while the alternative, an allograft, consists of donated tissue from a cadaver.

Researchers at the United States Military Academy tracked members of the 2007 through 2013 classes who had ACL reconstruction before entering the Academy. The 120 students ranged in age from 18 to 23 years old and had experienced a total of 122 ACL reconstructions. Of those, 106 had their ACLs reconstructed with autografts. The remaining 16 had donor tissue.

Since the cadets were now receiving all of their medical care at the Academy, the researchers knew that 20 of the ACL reconstructions had failed at an average of 18 months after the students had entered the Academy. Of the reconstructions that failed, 13 were from surgeries using the cadets' own tissue—about 12% of all autografts—while seven were from cadavers, accounting for 44% of the reconstructions that had used donated tissue.

Dr. Brett Owens, the study's senior investigator and chief of orthopedic surgery service at Keller Army Hospital, reported that ACL allograft reconstructions failed much earlier, on average, than had the autografts and that cadets who had ACL allograft reconstruction were almost seven times as likely to need a second surgery compared to cadets whose own tissue had been used. In their report, published in the *American Journal of Sports Medicine*, they recommended the use of autografts, rather than allografts, in young athletes.

—BY (May 10, 2012)

## New ACL Surgery Hits 1000 Cases

**F**H Orthopedics, Inc., headquartered in Mulhouse, France, achieved a milestone in early May when Mark Bowen, M.D., an orthopedic surgeon at the North Shore University Health System in Chicago, performed the company's 1,000 CoLS surgery on a patient in the US.

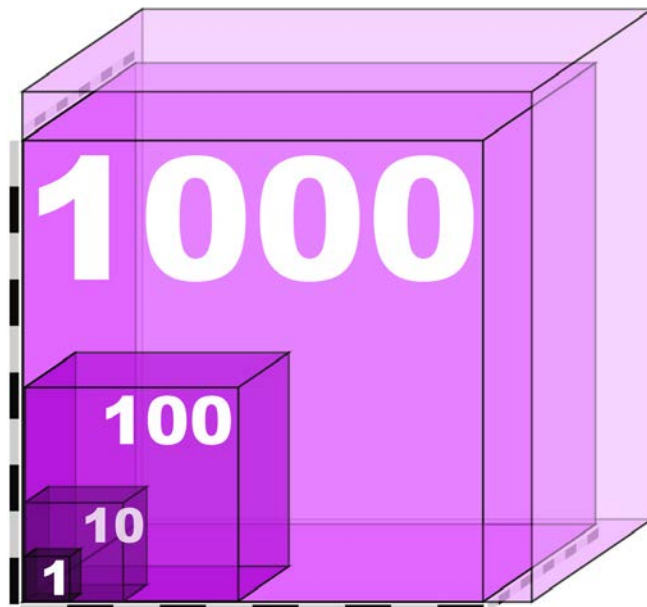
The CoLS technique is a knee ligament repair system that was first introduced in 2005 in France. It calls for the harvest of only one hamstring tendon, which is then quadrupled to produce the graft. Supporters say that it allows for almost immediate post-surgical weight bearing with no braces or crutches.

Bowen first heard about the CoLS technique in 2009 and went to Toulouse, France, to learn more about it. He returned several times to perfect his technique, and began teaching it to

other surgeons. The procedure received FDA clearance in 2008. Since then Bowen has performed the CoLS reconstructive procedure in over 300 of his own cases. More than 35 surgeons in the United States are now using the method and the company says it has been performed in over 21,000 patients worldwide.

Bowen says that he opts for this procedure in over 95% of his ACL surgeries because he has found that the success rate is superior to other options. "If your primary goal is to assure that your patient will need only one operation, then the CoLS technique the best option. The harvesting of the graft is less painful for patients post-operatively, it is structurally a stronger graft and the re-tear rate is lower. Overall there are fewer issues down the road," he said.

He added, "Although it is rare for an experienced orthopaedic surgeon to change techniques, many of my col-



Wikimedia Commons and 84 user

leagues have been intrigued by what I have shown them and convinced to adopt the CoLS technique based on the benefits that patients experience.”

Eric Hermann, managing director of FH Orthopedics, Inc., the U.S. subsidiary of the French company, said, “We are pleased that in just three years patients in the U.S. are also able to benefit from this technique.”

—BY (May 10, 2012)

## Artificial Turf Cause of ACL Injuries

Football is the leading cause of sports-related injuries in the United States, according to a study conducted by Jason Dragoo, M.D., a professor at Stanford University School of Medicine. Where knee injuries are con-

cerned, 40% more of them take place when players are playing on an artificial surface, than when they play on grass.

The findings were part of a study looking back on knee injuries among college football players to see when they might have been most vulnerable to getting hurt. The study was published in *The American Journal of Sports Medicine*.

The research team examined cases of tears to the anterior cruciate ligament (ACL) in the knee that were reported to the National Collegiate Athletic Association (NCAA) Injury Surveillance System—which includes about 10% of the schools in the NCAA. The study period spanned the 2004-2009 playing seasons.

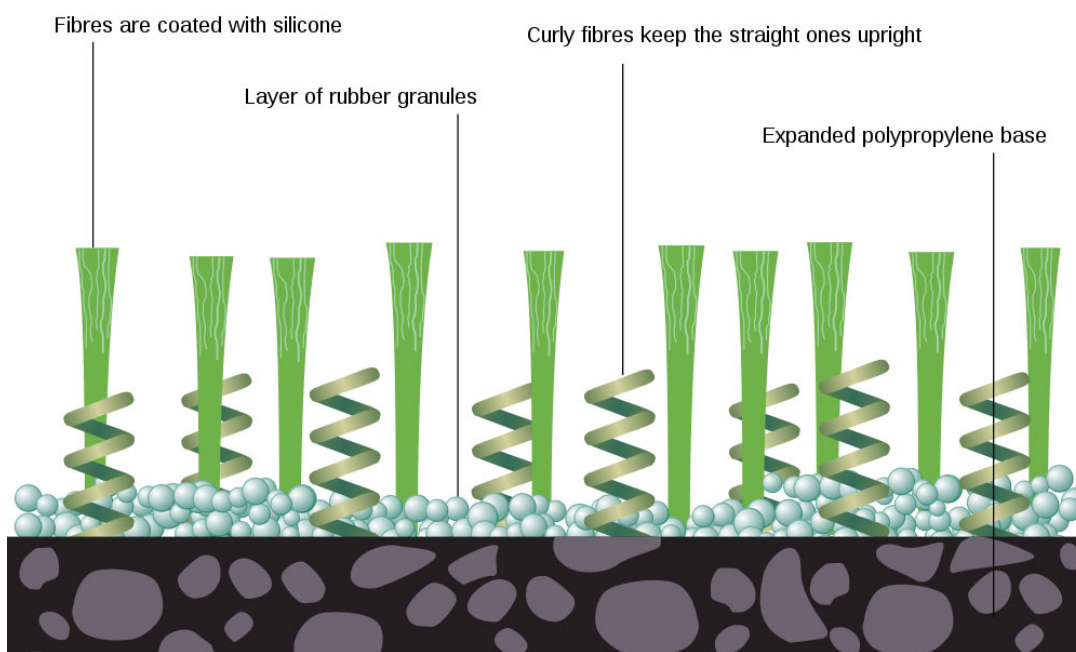
Kerry Grans, reporting for *Reuters*, wrote that Dragoo’s group found 318 injuries to the ACL during those seasons, which translated to a rate of 14

injuries for every 100,000 “exposures.” Each time a player practiced, scrimmaged or played a game was counted as one exposure. ACL injuries were 10 times more common during games than during practices. Athletes were 1.39 times as likely to be injured when playing on artificial turf as they were when playing on grass. “The bottom line is anything we can get from these statistics will help us understand why players are getting these injuries and what we can do about it,” Dragoo said in the April 30 news release.

Not all artificial turfs are the same. One, a newer type called an “infill surface” has a layer of synthetic grass over a field of rubberized pellets called fill. There were close to 18 injuries for every 100,000 exposures among athletes playing on infill surfaces, compared to 14 injuries for every 100,000 practices or games that took place on artificial turf without fill or on natural grass.

James Bradley, M.D., the chief orthopedic surgeon for the Pittsburgh Steelers and a clinical professor at the University of Pittsburgh, said that the problem is the shoe-surface interface. Players are able to get a better grip on turf than on grass—perhaps too good a grip, he explained. “So if you are in the wrong position, because your leg doesn’t give way as it does on grass, it can distribute that force to your knee and cause an injury.” He said that the NFL is working with shoe makers to design footwear that can mimic the grip that players get on grass.

—BY (May 10, 2012)



Wikimedia commons and Pbroks13

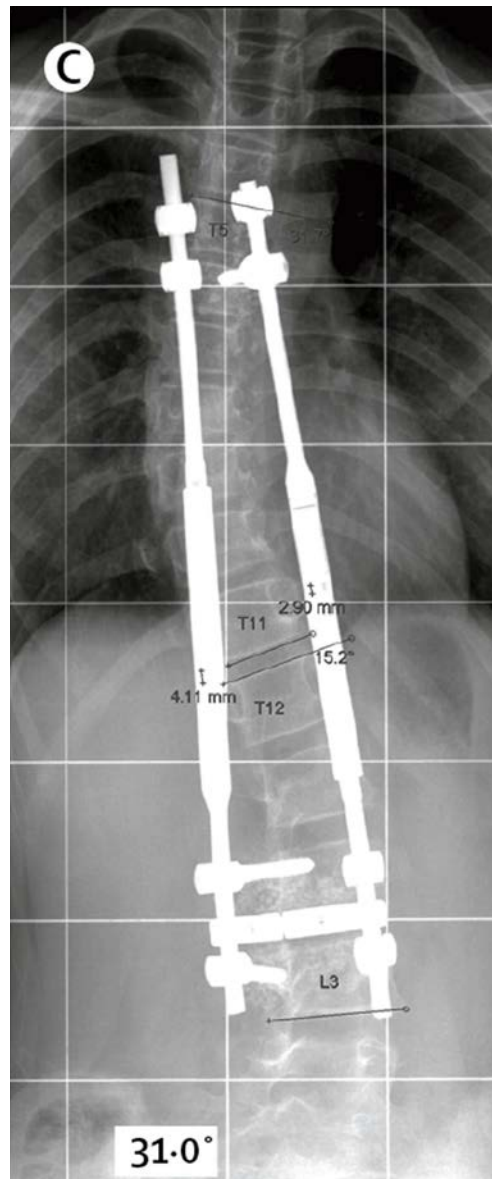
## spine

**New Growing Rods:  
No Repeat Surgery**

A new study from Hong Kong, recently published in *The Lancet*, found that new magnetically-controlled growing rods (MCGR) can treat scoliosis in children by being extended using a non-invasive technique as their spine grows. The bottom line: no repeated invasive surgery. The study is by Professor Kenneth Cheung and Dr. Dino Samartzis, from the Department of Orthopaedics and Traumatology at The University of Hong Kong, and colleagues.

The team implanted the MCGR in five patients, two of whom have now reached 24 months' follow-up. Each patient underwent monthly distractions. In the two patients with 24 months' follow-up, the mean degree of scoliosis was 67° before implantation and 29° at 24 months. Length of the instrumented segment of the spine increased by a mean of 1.9 mm with each distraction and in congruence with their normal growth. Throughout follow-up, both patients had no pain, had good functional outcome, and were satisfied with the procedure. No MCGR-related complications were noted.

In the April 18, 2012 news release the authors stated, "MCGR will eliminate the need for repeated operations under general anaesthesia, wound complications, and socioeconomic and health-care costs associated with the procedure. The preliminary results from the first two patients to undergo the treatment for a minimum of 24 months suggest that this non-invasive outpatient procedure is effective and safe. Whether MCGR leads to significantly better out-

*The Lancet*

comes than traditional growing rods is not yet known, but early results are positive and the avoidance of open distractions is a great improvement. Additionally, this new growing rod system has potentially widespread applications in other disorders that could benefit from a non-invasive procedure to correct abnormalities. MCGR could assist with correction of limb abnormalities, thoracic insufficiency syndrome, limb lengthening, limb salvage procedures,

or any disorders or injuries in which slow, progressive change to bone structures is needed."

Dr. Samartzis told *OTW*, "This technology represents a giant leap forward and new hope in the management of children with severe spinal deformity. The concept of growing rods was initially introduced over 40 years ago by such pioneers as Paul Harrington and John Moe; however, such technology has yet to be approved by the FDA. In the United States, obtaining approval of new devices for such a small subset of the population, as young children, requires one to undertake a complex maze of procedural and regulatory steps by the FDA. In that process, establishing clinical trials to assess the efficacy of investigational technology for children can be quite lengthy, unpredictable and costly. Furthermore, there are substantial ethical issues in performing randomized controlled trials on children and denying them a certain standard of care, even if it carries a high complication rate. Nonetheless, knowing the limitations of 'traditional' growing rods, there is indeed a need to develop new devices and methods that would provide better outcomes, decrease complication risk, reduce health-care costs, and avoid the traumatic experience of frequent operations endured by both child and parent. As our knowledge of the safety and efficacy of growth preserving technology increases, such as with the magnetic controlled growing rods, we hope this would be an impetus to overcome the economic and regulatory hurdles of the FDA."

—EH (May 8, 2012)

## people

**War's Lessons Make All the Difference for One Patient**

She flew through the air and was Spinned under a taxicab. Then there were OR lights and mutterings of amputation. Some said that Dominique Gambale would never walk again. But more than 12 months after being struck by a car, this wife and mother of two kept her leg and has approached her recovery with gusto. Her “Angel in Disguise?” Dr. Paul Girard, an orthopedic traumatologist with the University of California, San Diego.

Dr. Girard, former lieutenant commander in the Navy, doesn't just know how to treat “regular” fractures...he has treated the worst—severely wounded patients who survived bomb blasts in Iraq. He tells *OTW*, “Dominique's wounds needed to be approached with flexibility because she had multiple fractures in the same bone, all associated with a massive soft tissue injury. I had to use different techniques and implants to simplify the injury; using one implant or technique would have been more difficult and more prone to complications. That's one of the most important things I brought home from Iraq, namely that in treating such severe wounds you must be able to look at



*Dominique Gambale and Dr. Paul Girard  
Source: UC San Diego Health System*

the whole picture and not get yourself pigeon holed into the same treatment used for simpler injuries.”

Dominique tells *OTW*, “I was in a wheelchair for months; then I used a cane. And while I am much improved, I still struggle with daily aches and throbs that often are quite physically draining. I often reflect on how fortunate I am to have had a surgeon with military experience. My trauma was severe, but Dr. Girard never flinched. In fact, when I had to chance to speak at the American Academy of Orthopaedic Surgeons meeting this February, I made a point of telling the audience that what helped me so much from a psychological standpoint was the fact that my entire

treatment team remained calm no matter the situation. I knew that chaos and the unknown were surrounding me, but when I looked at their calm faces I found comfort.”

Dr. Girard adds, “Dominique has been a model of strength, and is so blessed to have a loving family to stand by her side. She has hit her recovery milestones earlier than anticipated and is an inspiration to others who suffer severe trauma.”

Asked how much she knew about orthopedics before this experience, Dominique told *OTW*, “Dr. Girard was so talented, and had such a great bedside manner that he became my idea of what all orthopedic surgeons are like.”

How has she changed? “I am able to see who I really am, and I am proud to have been told by many other people that I have inspired them. I am not dwelling on why this happened...I'm just moving forward.”

Dominique Gambale wants this message to go out to orthopedists: you alter the course of patients' lives. There is nothing more powerful.

For more information on Dominique and her story, please visit [www.orthoinfo.org/Dominique](http://www.orthoinfo.org/Dominique)

—EH (May 9, 2012)



And she reads Orthopedics This Week.

THE ORTHOPEDICS THIS WEEK PHYSICIAN  
HONEST. EXCELLENT. IRREPLACEABLE.

ADVERTISE. HERE.



[ryortho.com](http://ryortho.com)

To advertise contact Tom Bishow at [Tom@ryortho.com](mailto:Tom@ryortho.com) and to subscribe contact Jayme@ryortho.com. | Follow us on Twitter: @ryortho1  
©2012 RRY Publications LLC. All rights reserved.

## Orthopedics This Week | RRY Publications LLC

**Main Contact Information:**  
**RRY Publications LLC**  
 116 Ivywood Lane • Wayne, PA 19087  
 TOLL FREE: 1-888-749-2153  
 Fax: 610-260-6451

**Robin R. Young, CFA**  
 Editor and Publisher  
 robin@ryortho.com

**Elizabeth Hofheinz, M.P.H., M.Ed.**  
 Senior Writer  
 elizabeth@ryortho.com

**Walter Eisner**  
 Senior Writer  
 walter@ryortho.com

**Tom Bishow**  
 Vice President of Sales  
 tom@ryortho.com

**Biloine W. Young**  
 Writer  
 bgwy@msn.com

**Suzanne Kirchner**  
 Production Manager  
 suzanne@ryortho.com

**Jayne Johnson**  
 Production Coordinator  
 jayne@ryortho.com

**Dana Bader**  
 Graphic Designer  
 dana@ryortho.com



**Don't miss your chance!**  
**Advertise with Orthopedics This Week**

Orthopedics This Week

Click Here for more details or email [tom@ryortho.com](mailto:tom@ryortho.com)  
 Tom Bishow | 410.356.2455 (office) or 410.608.1697 (cell)