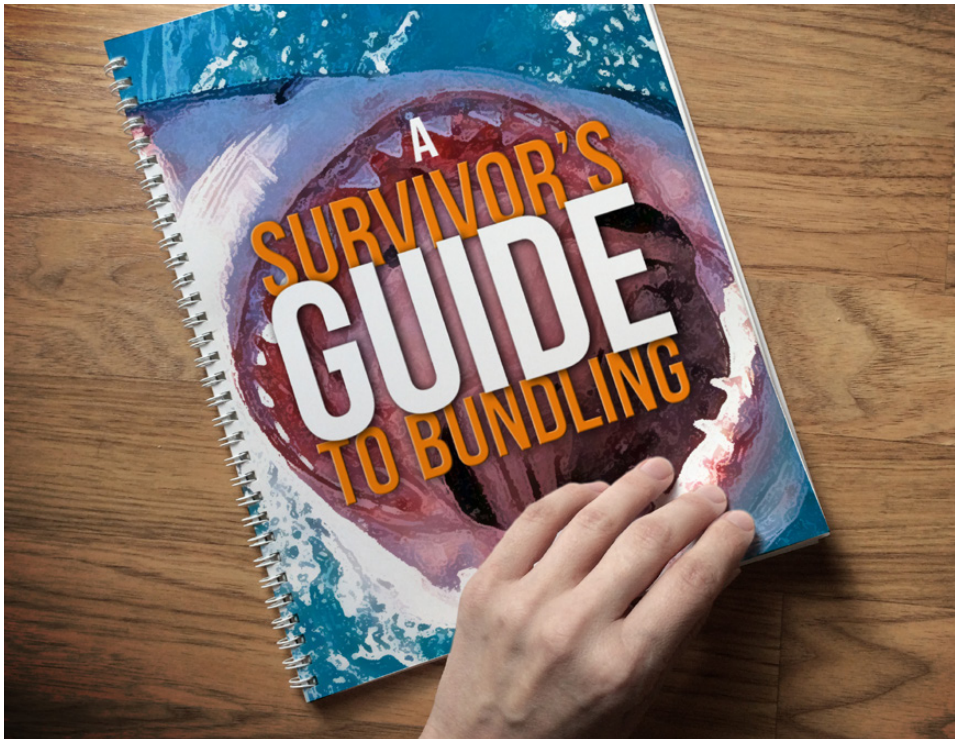
VOLUME 10, ISSUE 16 | MAY 20, 2014

Orthopedics This Week

WEEK IN REVIEW



BREAKING NEWS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: This is a notably jittery market. S&P 500 P/E multiples are 19.6% above historic averages (data source: Robert Shiller and Factset). Using cyclically adjusted P/Es, the market is 54% above historic averages. Using forward P/E averages, the S&P 500 is still undervalued. Orthopedic equities are at a weighted average 19.94 trailing P/E ratio, which is 5% above the S&P 500 P/E. Bullish investors are hoping earnings beat expectations. Bears are looking for dividend havens.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Zimmer	27.31%	9.87%	First Needham upgraded ZMH last week to a Strong Buy, then Suntrust moved from Neutral to BUY. Yup, analysts like the Biomet deal.
2	2	ConMed	10.19	2.90	Is ConMed the next gal to get invited to dance. We're pretty sure the answer is yes and institutional equity buyers seem to agree.
3	6	Smith & Nephew	20.25	6.29	The four private equity firms exiting Biomet have to redeploy those billions. SNN is an attractive, debt free 2nd bite at the ortho market.
4	3	Medtronic	28.84	3.25	This week we see the numbers for FY 2014 (March). Consensus is that spine implant and instrument sales declined another 2-3%.
5	5	Orthofix	6.75	3.07	Better-than-expected Q1 results hint at the potential under new CEO Mason. Investors need to be patient, but the trend is in the right direction.
6	4	Johnson & Johnson	26.58	1.85	For the first time in history, JNJ's price has cleared $100/share. Dividend yields now below historic levels. Getting expensive.
7	8	Stryker	15.71	1.33	Can SYK rebound from the disappointing first quarter? That's the question investors will be asking in coming weeks.
8	7	Integra LifeSciences	11.77	(2.31)	IART is the cheapest equity in all of orthopedics. Why? Analyst consensus is that Q2 sales will rise 11.60%. What is Wall Street missing?
9	9	Exactech	10.15	(3.62)	Interestingly, EXAC may well be big beneficiaries of the ZMH/Biomet deal. The Petty's are old school ortho managers in the Dane Miller mold.
10	10	NuVasive	6.30	0.00	With so many newly public spine companies, investors will have a wealth of comparative spine industry data. For NUVA, this is a positive.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	RTI Biologics Inc	RTIX	$4.31	$244	14.63%
2	Tornier N.V.	TRNX	$20.86	$1,013	14.36%
3	Zimmer Holdings	ZMH	$100.61	$16,884	9.87%
4	Globus Medical	GMED	$24.68	$2,306	7.12%
5	Smith & Nephew	SNN	$78.22	$13,982	6.29%
6	Wright Medical	WMGI	$29.59	$1,477	4.24%
7	Medtronic	MDT	$60.39	$60,439	3.25%
8	Orthofix	OFIX	$32.18	$593	3.07%
9	ConMed	CNMD	$49.61	$1,350	2.90%
10	Johnson & Johnson	JNJ	$100.58	$284,551	1.85%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Aurora Spine	ASG	$2.97	$47	-38.76%
2	Baxano Surgical Inc	BAXS	$0.71	$34	-29.70%
3	CryoLife	CRY	$8.72	$245	-11.11%
4	Symmetry Medical	SMA	$8.04	$301	-9.15%
5	MiMedx Group	MDXG	$5.38	$570	-6.76%
6	TiGenix	TIG.BR	$0.67	$108	-5.21%
7	Bacterin Intl Holdings	BONE	$0.67	$37	-4.30%
8	Alphatec Holdings	ATEC	$1.34	$131	-4.29%
9	Exactech	EXAC	$21.83	$298	-3.62%
10	Integra LifeSciences	IART	$44.47	$1,448	-2.31%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Medtronic	MDT	$60.39	$60,439	16.38
2	Zimmer Holdings	ZMH	$100.61	$16,884	17.24
3	Johnson & Johnson	JNJ	$100.58	$284,551	17.88
4	Exactech	EXAC	$21.83	$298	17.96
5	Stryker	SYK	$80.10	$30,365	19.36

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$32.18	$593	143.66
2	NuVasive	NUVA	$33.43	$1,558	107.85
3	Symmetry Medical	SMA	$8.04	$301	72.42
4	ArthroCare	ARTC	$48.53	$1,674	33.48
5	ConMed	CNMD	$49.61	$1,350	28.11

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Exactech	EXAC	$21.83	$298	1.00
2	Globus Medical	GMED	$24.68	$2,306	1.58
3	Zimmer Holdings	ZMH	$100.61	$16,884	2.10
4	Stryker	SYK	$80.10	$30,365	2.13
5	ConMed	CNMD	$49.61	$1,350	2.16

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$33.43	$1,558	9.73
2	Orthofix	OFIX	$32.18	$593	7.64
3	CryoLife	CRY	$8.72	$245	6.58
4	Symmetry Medical	SMA	$8.04	$301	6.04
5	ArthroCare	ARTC	$48.53	$1,674	2.79

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Alphatec Holdings	ATEC	$1.34	$131	0.64
2	Symmetry Medical	SMA	$8.04	$301	0.75
3	Bacterin Intl Holdings	BONE	$0.67	$37	1.10
4	RTI Biologics Inc	RTIX	$4.31	$244	1.12
5	Exactech	EXAC	$21.83	$298	1.24

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.67	$108	18.90
2	MiMedx Group	MDXG	$5.38	$570	8.48
3	Wright Medical	WMGI	$29.59	$1,477	5.74
4	Globus Medical	GMED	$24.68	$2,306	5.31
5	ArthroCare	ARTC	$48.53	$1,674	4.39

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

A Survivor's Guide to Bundling

BY WALTER EISNER

If you are an orthopedic provider considering entering into a bundled payment relationship with a commercial or private payer, you need to power-up. This week, a seasoned and successful administrator experienced in bundled payment from the Hoag Orthopedic Institute, Gabrielle White, RN, CASC, helps *OTW* readers do just that.

Gabrielle White, RN, CASC/ Hoag Orthopedic Institute

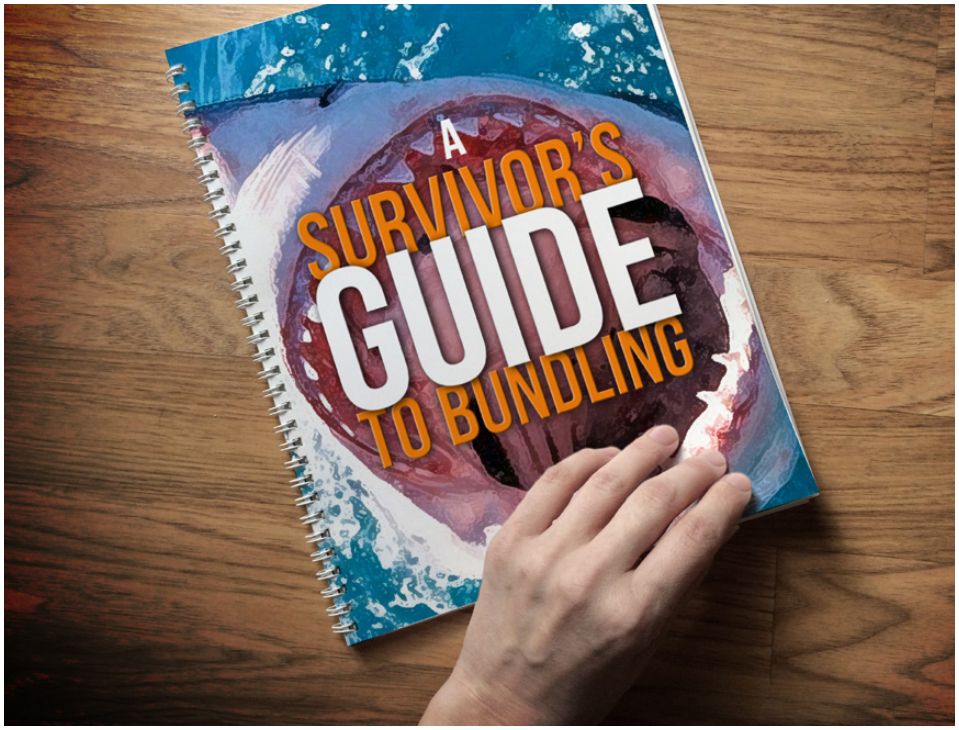


Photo creation by RRY Publicaitons LLC

Risk Shifting

There is only one reason a payer would agree to a bundled payment for an orthopedic procedure—shifting the risk monkey off their back onto yours. And the only reason a provider would agree to a bundled payment is if they think they can cut expenses through a more efficient and redesigned care system with improved quality and outcomes.

When a clinic or physician enters into a bundled payment program with a commercial payer, they are playing the game with the masters of risk management. Providers can't win in this game unless they know how to manage and reduce their risks.

If you are a provider, to reduce your risk, White says, you have to pick high volume and predictable procedures. Hip and knee replacements, for example. You must also pick the right patients and the right surgeon. The patients need to meet predetermined selection criteria. The surgeons need to stay within the metrics of a standardized delivery program and meet quality metrics.

Then, you have to have great data to know what things cost.

Only then are you ready to start.

White has clinical, business and administrative oversight of the Orthopedic Surgery Center of Orange County, California and leads Network Development for Hoag Orthopedic Institute (HOI) with a primary focus on bundled payment programs and growth strategy with self-insured employers. Her roadmap will save you money, time and aggravation. Hoag Orthopedic Institute has bundling programs with private employers as well as commercial insurers like Blue Shield, Cigna and Aetna.

The Push to Bundle

Let's start with the basics. A bundled payment is an all-inclusive price that covers the cost of facility and professional services related to a specific procedure over a specified period of time.

It may include a warranty!

As Medicare pushes pilot programs to move away from the fee-for-service model and healthcare reform legislation demands more data and quality metrics, providers are jumping on the bundle bandwagon. According to a March KPMG poll, 44% of respondent

providers said they are already working with bundled payments. And that percentage is growing as 20% said they plan to do it in the near future.

Standardization and the Surgeon

Controlling expenditures and harnessing performance data was listed as the main reason for not yet jumping into the pool. In a word, that is about "standardization."

Standardizing processes within episodes of care has been a tough pill for some physicians to swallow because it takes away options that fall outside predetermined procedures.

White told us that a bundle shouldn't take away a surgeon's autonomy for delivery of care. "When we work on standardizing they could feel this way. We share the data and results peer-to-peer to demonstrate what happens when we use best practices. When surgeons compare their results to others and when they see that they have room to improve, then they usually are happy adjusting to what works best for their patients."

She says when the standardized care results in better care it makes a big difference. "It really depends on what the goal is for the individual surgeon. I think sharing outcomes or quality data with a surgeon can result in demonstrably solid results and reduced risk of error. That helps him or her reconcile the feeling of simply being a mechanic. Joint replacement is pretty standardized and predictable already so it comes down to the individual physician and how we present the information to them."

Also, she adds, make sure that the physicians contribute their ideas. "While the ideas may not always be accepted the opportunity to help is especially important." She says the pathways for standardized care do not fit every patient, and there are some outliers for whom the care must be modified. "But the objective is always the same—proven outcomes."

Show Me the Money

White also addressed a major concern raised about bundling—rationing care to save money.

"Cutting the level of care doesn't necessarily cut costs," says White. Providers need to provide all necessary care because if they don't they are "shooting themselves in the foot." The clinic and the physician, under a bundling type of program, owns the risks of complications and will only pay for them in the end if they cut out necessary care. Results are gained when managing or removing waste within the care process.

The payers know these objections and therefore don't want to pay as much.

"That's not realistic," says White. "Bundling doesn't mean you have to charge less for what you do. You might even add a percentage to cover the risks and costs of the warranty."

The savings to payers is in the provider carrying the warranty, the complications and managing the costs and waste. Payers are also not billed for ancillary services. "They'll save money right there," says White. "What they want is predictability and the bundle gives them that."

The most important piece of advice White gives is to start small. Try to find a large employer and offer bundled services for a small number of procedures as a pilot.

To keep it simple, White offers up an example of a total knee arthroplasty.

Andrew Huth and RRY Publications LLC

Getting Started

First identify the DRG, CPT and ICD codes and decide on a timeframe for the episode. Do you include pre-admission and post-discharge costs? White says stay with only care related to the index procedures and only what you can control. She also cautions to make sure it's clear, unless you can cover the risk, that skilled nursing, home health and services not related to the index are excluded. You don't want to assume risk for services you can't control.

You are warrantying the outcome and will keep paying until you have completed the episode of care. Hoag Orthopedic Institute keeps some of each payment to cover the outliers. But others chose reinsurance. If there are pieces of the bundle over which you don't have complete control, seriously consider reinsurance, says White.

Then make sure that the payers, facility, professional and administrative staffs all understand the episode. They will manage the risks and costs, track outcomes, manage and submit claims and monitor the overall program.

Care Redesign

Care redesign by the clinical team is a critical component in ridding the episode of waste and poor outcomes. "Poor outcomes are one of the biggest cost items today. Reduce complications, reduce your costs," says White.

Care redesign must align all the providers from the surgeon to the surgeon assistant to the anesthesiologist. You must also account for other providers in the hospital including the hospitalist, radiologist, pathologist and cardiologist consults.

Qualified Surgeons and Patients

The redesigned care model begins in pre-admission screening with the patient's medical history and various healthcare measures for safe, elective surgery. If patients don't meet the

White's 14-Step Program

Before approaching potential customers, White outlines a 14-step program:

1. Align Providers
2. Build the Team
3. Select High Volume, Predictable Procedures
4. Develop Patient Selection Criteria
5. Define the Episode of Care – Start to Finish and What is Included
6. Determine the Bundle Price – What is Included and Excluded in the Price
7. Set Provider Selection Criteria
8. Define Quality Metrics to be Met and Monitored
9. Determine Who Will Manage Claims and Payments
10. Identify Interested Payers
11. Educate All Involved Parties
12. Monitor the Program
13. Communicate Between Silos
14. Keep It Simple

benchmarks you've set, exclude them from the bundled program.

Same thing for surgeons. Hoag Orthopedic Institute only allows surgeons to participate in the program if he or she is at or above the quality benchmarks established by the clinical team.

The bundled program is no place for experimentation in the operating room.

The added benefit of care redesign, adds White, is that it applies to all patients, not just those in the bundled program. The clinical team doesn't treat a bundled patient any different from a fee-for-service patient. But the administration office does. So make sure the billing office is in the loop.

Squeezing Device Makers

Managing vendor relationships is particularly important for orthopedic devices because surgeons have favorite devices and vendors. White says only the surgeons know which new technologies are valuable and which are fluff. Hoag Orthopedic Institute surgeons have played an active role in working with vendors and they have been successful in limiting the number of vendors and have cut good deals for hips and knees. But not yet in spine. "Too many vendors," said White.

Vroom, Vroom

White suggests that the entire bundle team meet for an hour once a month at the start of the program so that all the dots are connected and as the process becomes more understood and stable, taper down the meetings.

If you decide to go bundling, White's engine: keep it simple, start with a pilot, know your costs and benchmarks, keep the clinical, professional and administrative teams on the same page and keep your eye on the costs and data, will give you the power to swim with the sharks.

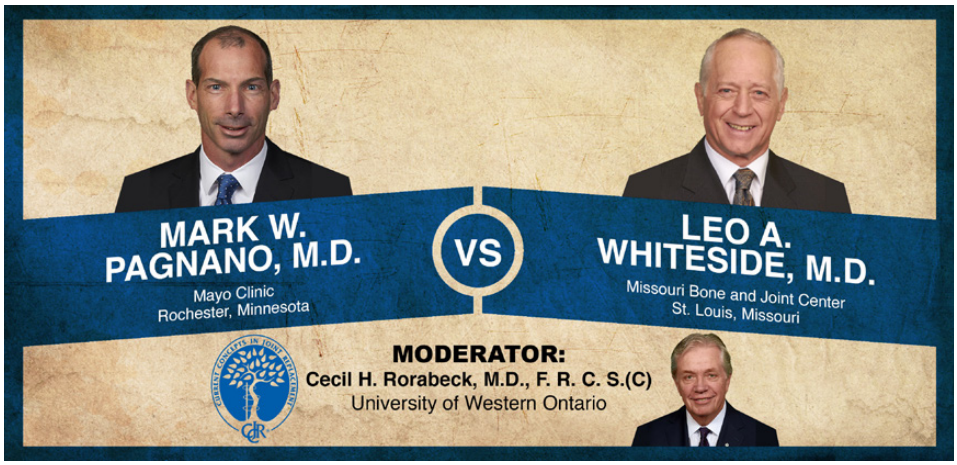
If you want to listen to Ms. White's 60 minute presentation courtesy of Wellbe, Inc., and view her slides, click here: http://www.orthoserviceline.com/free-webinar-getting-started-with-bundled-payments-for-orthopedics/ ♦

Is a Dash of Varus/Valgus Acceptable? Pagnano v. Whiteside

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

"It's time to end the tyranny of the tibia," argues Mark Pagnano. "Let's consider the *femur* as the prime driver of function." "Wait," says Leo Whiteside. "I suggest that you get ligament balancing and alignment—both in flexion and extension—and don't settle for anything less."

This week's Orthopaedic Crossfire® debate is "Thou Shalt Not Commit Varus or Valgus: Challenging This Dictum." For the proposition is Mark W. Pagnano, M.D. from Mayo Clinic in Rochester, Minnesota; against the proposition is Leo A. Whiteside, M.D. from The Missouri Bone and Joint Center in St. Louis. Moderating is Cecil H. Rorabeck, M.D., F. R. C. S.(C) from the University of Western Ontario.



Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Pagnano: "It's time to end 'the tyranny of the tibia.' Historically in TKA [total knee arthroplasty] our main focus has been on the durability of the construct. That was appropriate because the early designs had some problems. Most of our surgeries 30 years ago were for marked deformities in older patients with low demands or for RA [rheumatoid arthritis]. Now we tend to deal with smaller deformities and shorter hospital stays; the overall risks associated with TKA are substantially different than 20-30 years ago."

"Moving forward I think that we should devote more attention to the function part of TKA and maybe a bit less to durability. There's been lots of interest in the last five years in identifying the 'satisfaction gap' between TKA and THA [total hip arthroplasty], recognizing that a subset of TKA patients are not satisfied. Surgeons have many thoughts on how to improve function after TKA…with computers, ligament tensioning devices, new implant designs."

"The typical tibia is in slight varus, but there is substantial variability from some degree of valgus to marked degrees of varus. The typical femur is in 5-10 degrees of valgus, but that is variable."

"When we go to a total knee replacement we tend to take a monolithic approach. We cut the tibia perpendicular to its long axis and we cut the femur perpendicular to the mechanical axis. This often results in a 5 to 6 degree valgus angle, but that varies. I contend that the 3D position of the femoral component in space is the prime driver of TKA function; by that I mean the size, the rotation, the joint line, extension and flexion, and the position of the trochlea. I contend that we systematically get this position wrong in most total knee replacements."

"For three decades of TKA surgery the tibia has ruled. The goal has been to cut the tibia at 90 degrees (zero degree varus or valgus), and to minimize the thickness of the bone you cut. When you follow these dictates you have unintended consequences that occur on the femoral side that I believe ultimately impair the best function of a TKA."

"Why have these rules emerged over the last three decades? First, zero degrees varus/valgus on the tibia; in the early 1980s some total knee designs failed when the tibia was in more than three degrees of varus. And why a minimal thickness cut? Because in the 1980s, biomechanics suggested that a weaker tibial bone resulted in greater levels of resection."

"What's wrong with these? Most are based on old knee designs, so today many knee replacements have good coronal plane conformity and have done alright in mild varus and valgus. Also, the early total knees had few sizes on the tibia, so that meant many tibial

components were undersized. So it's not surprising that some of those undersized, mal-aligned components failed. The unintended consequences: if you cut it at zero—and most knees are in a mean of three degrees of varus—you end up over-resecting the lateral side in both extension and flexion. Then that dictates changes on the femur. You have to under-resect laterally or do a medial release…and you must add more external rotation in flexion."

"If those changes aren't made on the femur, then in most knees the lateral side will be lax and will result in varus tilt. The minimal tibial cut also causes relatively tight extension and flexion gaps. So most surgeons cut a bit more distal femur than the thickness of the implant, and they tend to undersize the femur to make more room in flexion. These biases are often built into the instruments that we use today. So systematically in a varus knee we over-resect the femur medially in extension and flexion. We change the joint line position in extension and flexion, underestimate the AP size of the femur…all to compensate for a minimal thickness cut of the tibia at 90 degrees."

"We should explore a new paradigm where the femur assumes the most importance and we try to reproduce a patient's native femoral anatomy, at least within some limits…and make the tibia accommodate the femur. That perfectly sized femur has to be positioned ideally. Then we can match the valgus angle to the native femoral anatomy; we also want to match the AP size. And we want to make the femoral rotation as close to native anatomy as possible. Compared to a typical knee this will result in a knee that's in slight valgus, an AP size that's slightly bigger, and a slightly distal joint line."

"So modern TKA is durable enough to let us explore new ways to get better function…and one approach is to consider the *femur* as the prime driver of function."

Dr. Whiteside: "The goal should be to achieve ligament balancing and alignment—both in flexion and extension—and you should not settle for anything less. I discovered a long time ago that if you put a rod in the femur and one in the tibia, cut the tibia perpendicularly and cut the femur at 5 to 7 degree

valgus, you will achieve proper alignment most of the time. I suggest that you never slope the tibia because just a couple of extra degrees might make a difference. Aim for the center and then you will accept a bit of error. Clinically, that little bit of error is often just right."

"As for flexion, the tibia points through the patellar groove and toward the lateral aspect of the femoral head. Dr. Arima and I found that the AP axis (1995, *JBJS*) was easily located. What's the difference between the AP axis and the epicondylar axis? You can't miss the AP axis; the epicondylar axis…you can't find it."

"Using an intramedullary rod for the varus knee leads you to resect and correct the femur; with an intramedullary rod in the tibia you can resect and correct the tibia. When in flexion you can use the AP axis; if you cut perpendicular to it then that will take the error out of the knee. Using bone landmarks will give you about equal loads medially and laterally. If you put it in a little too much varus, you may end up with high loading on the medial side, no loading on the lateral side, and a buckling, messy knee. So do your bone cuts first, followed by ligament balancing. Anybody can find a tight ligament and poke at it until it corrects."

"With a valgus knee, the AP axis is particularly handy because it gives you correct alignment in flexion. I'd suggest using intramedually alignment rods and drawing the AP axis. If you take the foot out of the holder and hold the knee in correct alignment, that shows you that the AP axis points toward the floor. And you want to make the tibia point toward the floor as well (in flexion). The good thing about anatomic landmarks is that they allow you to correct these deformities separately so that posteriorly you may not have much correction to make on the femur."

"So don't settle for less than aligned in extension and flexion, and ligaments balanced in flexion and extension."

Moderator Rorabeck: "Dr. Pagnano, would you like to rebut?"

Dr. Pagnano: "It's a relatively nuanced approach. I'm not proposing any major things that would go against those principles. But small changes are necessary if we're going to improve things for that sub-group of 15-20% of knee replacements that don't work well. Leo's technique of picking these landmarks works most of the time—85% is what our satisfaction data tells us. So if we want to look at things over the next 3/5/7 years I don't think we can just repeat the same things. The group that is the most responsive to any technique are the patients that are in the greatest degrees of varus and valgus."

Moderator Rorabeck: "Leo?"

Dr. Whiteside: "I can appreciate Mark's way of looking at things, but I think it's risky. Finding correct alignment and doing correct ligament balancing works in 100% of cases, not 85%. We should not be saying, 'Well, I'm going to do a little constitutional varus…I'll tilt the tibia down three degrees.' You won't be happy as the carpenter redoing your kitchen says, 'I'm going to leave your floor sloped in a constitutional north-south direction.'"

Moderator Rorabeck: "Nothing works 100% of the time."

Dr. Whiteside: "Measurement is something that you must do 100% of the time; there will be errors that are acceptable within tolerance of measurement. Occasionally you will have tolerance stacking. So if you accept three degrees of varus on the tibia, that will actually go into five degrees. Then you say, 'I'll take three degrees of valgus on the femur.' That turns into zero. Then you have a crooked knee. Measure for perfect alignment and ligament balance; then you have to accept some deviation."

Moderator Rorabeck: "Mark, you might be leaving the odd knee in varus. Is that ever acceptable?"

Dr. Pagnano: "It's acceptable in the sense that even in Leo's hands he is aiming for the middle, but he occasionally leaves a knee in some degree of varus/valgus. Over time we are trying to slant the patients in the direction that's going to give them the best level of function. So some knees probably do deserve to be in a slight amount of valgus/varus. We did a 15 year study looking at three modern total knee designs. At 15 years we couldn't show a difference in survival rates in knees that were zero +/- three versus slightly outside that range."

Dr. Whiteside: "I agree that a little bit of error is acceptable. Plus or minus three degrees is just tolerance stacking of 1.5 degree error on each bone."

Moderator Rorabeck: "The take home message?"

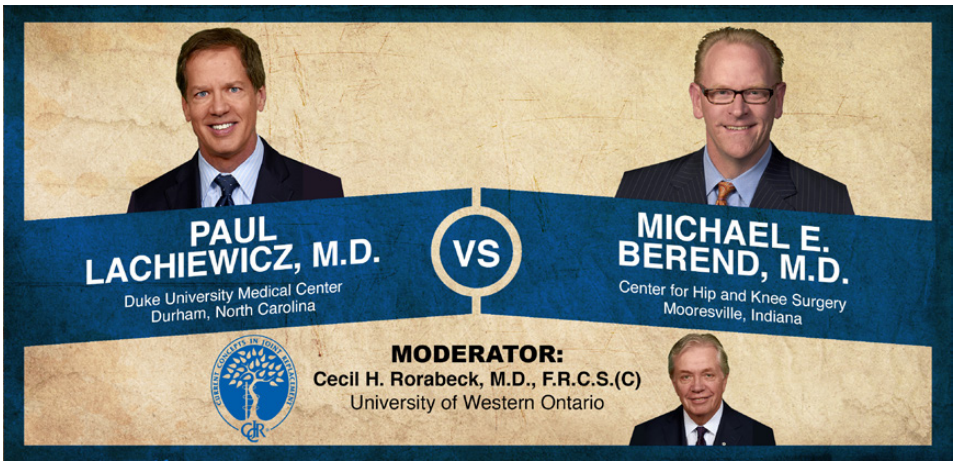
Dr. Pagnano: "Today it's reasonable to do things like Leo said, but we should support research efforts that look at efforts to care for that last 15% of patients."

Moderator Rorabeck: "Thank you." ♦

Please visit www.CCJR.com to register for the 2014 CCJR Winter Meeting, December 10 - 13 in Orlando.

Patient Specific Instruments: Overpromised, Under Delivered

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



Current Concepts in Joint Replacement/RRY Photo Creation

"Is patient specific instrumentation (PSI) *less* expensive? Is it easier for you? The answer is definitely 'no,'" argues Paul Lachiewicz. "PSI provides a way to position the implants specific to that patient's anatomy (preop valgus, patient height, hip pathology, etc.)," says Mike Berend. And you can do it before you enter the OR…with templating this means it is time neutral."

This week's Orthopaedic Crossfire® debate is "Patient Specific Instruments: Overpromised, Under Delivered." For the proposition is Paul Lachiewicz, M.D. from Duke University Medical Center in Durham, North Carolina; against the proposition is Michael E. Berend, M.D. from the Center for Hip and Knee Surgery in Mooresville, Indiana. Moderating is Cecil H. Rorabeck, M.D., F.R.C.S.(C) from the University of Western Ontario.

Dr. Lachiewicz: "In their brief lifespan these instruments have overpromised and under delivered. There are now five bad ideas in total knee arthroplasty (TKA): carbon-reinforced polyethylene, metal-backed patellae, low-molecular weight heparin, and gender-specific knees…and now, patient-specific instruments (PSI). This is a reincarnation of computer-assisted surgery that shifts the work from intraoperative to preoperative. You must do a CT or MRI, the surgeon has to do a lot on both the input and after the technician returns the plan. You have to adjust the plan for deformity, contractures, and ligament imbalance."

"The marketed advantages of PSI are the same ones that were touted 15 years ago for CAOS [computer assisted orthopaedic surgery]. There was never any proof that avoiding IM instruments affected blood loss, emboli, or cognition. The claim that they avoid outliers has not been proven. The claim that they get better outcomes and deliver better patient satisfaction has not been proven. These instruments are even marketed as being less stressful for the surgeon…are you kidding me?"

"The disadvantages? The MRI is going to cost approximately $1,000 and the jigs are $1,500. You have to take into account the time it takes your office staff to schedule the MRI, the learning curve, and the time it takes you to review and adjust these plans. Is it $500/hour? Are you getting $500 more when you do these? Certainly not."

"In North Carolina, one insurance company is fighting back when surgeons are ordering MRIs. Who will pay for this? Several studies show that these will work, but the vast majority in North America and Europe show that they don't work. Stronach and Peters et al. (*CORR* [*Clinical Orthopaedics and Related Research*], 2013) have done a study where he had to change the size of the vast majority of femurs and tibias (roughly 2.5 per knee). There was no difference in tourniquet time, and he cautioned against using PSI plans."

"A cost effectiveness study by Slover et al. (*Journal of Arthroplasty*, 2012) looked at the Markov decision model and found that the PSI plans were much more expensive. They calculated that you would have to reduce your revision rate by 50% to be cost effective—not going to happen."

"Do PSIs improve alignment? Robert Barrack and Ryan Nunley have done multiple studies on this, one of which is a three cohort study (one conventional versus two PSI systems) published in *CORR* in 2012. One of the PSI systems is no longer available. They did postop CTs and found that the number of outliers was the same in all groups; there was perhaps even more valgus outliers with both PSI systems."

"Are they cost effective? The thinking is that there will be fewer trays and that it will save the hospital money. In this study, they spent 12 minutes less in the OR, there was no difference in align-

ment, and they saved the hospital $25 per case because they processed four fewer trays."

"PSIs are not going to balance the knee or do ligament releases; neither will they tell you the proper tibial component rotation. They are not going to resect the patella and they're not going to cement the components. And it's these steps that determine the long term durability of TKA!"

"In a study I conducted with Drs. Del Gaizo and Soileau (*Journal of Knee Surgery*, 2009) we found that you should template your total knees for both primary and revisions. Template the sizes and the amount of resection…and have a plan going in. Brett Levine has taken this one step further. He has done digital templating and supplied the sizes to three vendors and told them to reduce the number of trays. In 97% of his cases the prepared sizes and three trays (prepared by the implant manufacturer) were all that were needed."

"When you consider any new technology for TKA, ask yourself: 'Does it provide better outcomes and decreased revisions for your patients? Is it *less* expensive? Is it easier for you? For PSI the answer is definitely 'NO.' Put the onus on the implant companies. They should do something to decrease their instrument trays and weight."

Dr. Berend: "Obviously, my friend Paul is stressed even thinking about PSI, thus it's probably not the best tool for his OR. We've studied this for 15 years and found that tibial component varus greater than three degrees in patients with a BMI over 33 meant over a 100-fold increase in failure (Berend et al., *CORR*, 2004). So the conclusion of alignment as an independent variable not affecting outcome may be valid. But when you combine it with other patient and implant factors it is critical."

"If you look at the precipitous drop in survivorship in the patients with whom we missed the mark (that had a BMI over 33) there was a failure rate of 0.4% at 15 years… unacceptable. In our database of over 6,000 total knees, for those in neutral alignment there was a 0.5% failure rate regardless of alignment. We can now say—with data to back this up—that the target we're aiming for is between 2.5 and 7.2 degrees of valgus. All had a similar failure rate: +/- 3 degrees from the mean of 4.5. For those patients who tip into varus we found a four-fold increase in failure at 1.8%. And if you tip into valgus we've seen an increased failure rate go to 1.5%."

"Regarding the mechanism of failure, on the varus side we saw tibial collapse with overload on the medial tibial bone, and on the valgus side we saw instability. If you look at the numerator, we only hit the mark in 72% of the knees. This has been backed up by many studies of conventional instrumentation. So the data indicate that alignment has a huge effect on outcomes. It's multifactorial, with alignment, patient factors, and implant factors being important. We need cost effective, time efficient, reproducible, and transferable technology."

"The next generation of navigated knee is preop imaging with preop planning to get six degrees of freedom to align your implants. The big message? This is an important tool that in a free society one should be able to use to plan bone cuts and the operation. And you can do this in the leisure of your own office… away from the stress of the OR."

"So what were the promises of PSI? To provide a method or tool to position the implants specific to that patient's anatomy (preop valgus, patient height, hip pathology, etc.). It allows you to do this before you enter the OR…and with templating this means it is time neutral. The goal of reducing instrumentation needs is an important one. Cost reduction is important, as is the improvement of alignment."

"Even if it is 12 minutes per case, that's important. There have been a number of studies showing that time in the patient in the OR has been reduced by 12 – 28 minutes (versus standard instrumentation)…and in a multiple joint center that is critical. (Barrack et al., *JBJS*, 2012; Nunley et al., *CORR*, 2012; Watters et al., *J Surg Ortho Adv*, 2011) Lowering the processing time is important if you're paying for the staff's salaries. And obviously there's an additional cost with any new technology."

"The studies show no difference in coronal alignment. They're not worse, so if you choose to use this tool and avoid intramedullary guides then it's important. There have been fewer outliers reported in some studies, depending on the parameters measured…the central third or three degrees from neutral. Our data suggests that anything outside of 2.5 – 7.2 may involve a higher failure rate. And perhaps for lower volume surgeons this tool may be quite helpful. But we still have to act as a surgeon and adjust things as necessary such as bone cuts or soft tissue balance. What we don't know is if the things we adjust during surgery are important or if they have a long-term benefit."

"Adolph Lombardi's group has looked at custom versus conventional guides and found—head to head—a lower incidence of outliers (6% with conventional; 1.5% with PSI). In a multicenter series of 564 patients from the DeClaire Institute they found a higher percentage of people hitting the central third target (87% with PSI versus 77% with conventional)."

"PSI may be needed in routine workflow when there is extra articular deformity,

periarticular hardware, or you want to avoid the IM canal."

Moderator Rorabeck: "Paul, one minute."

Dr. Lachiewicz: "There may be a role for this in rare cases. Mike, now I'm teaching residents to use the PAX machines to draw their cuts on the tibia and the femur…and we don't have a lot of outliers."

Dr. Berend: "We've heard that from every series and if you go back and look you will see that 0.25% of your knees will be outside of 2.5 – 7.5. If you aggregate every series, conventional versus navigation, then it's 28%. We've done 18,000 total knees and we're running at 28%...so we must improve."

Moderator Rorabeck: "Mike, can you outline the indications for PSI?"

Dr. Berend: "I only use it in cases where I feel that my standard tools are contraindicated. We've used it in cases where postop confusion was an issue with the first knee…thinking that perhaps fat embolism had a role in that. We've used it in more severe deformities where there is metaphyseal/diaphyseal mismatch and in cases where we feel the sizing of the components is something unique to that patient's anatomy."

Moderator Rorabeck: "Paul, your view on that?"

Dr. Lachiewicz: "I'm not sure. Most of the surgeons in the audience can probably do these difficult knees without PSI. Cost and value are critical. I don't think it's been proven that patient satisfaction and longevity are improved with PSI."

Moderator Rorabeck: "How much does it add to the cost of an operation?"

Dr. Berend: "It's somewhere between $500 to $1,000. I agree with Paul's concern about who is going to pay for that."

Dr. Lachiewicz: "What about preoperative time? Where does that get figured in? And 12 minutes saved in the OR?"

Dr. Berend: "For me, saving 12 minutes per case is to be able to do another case…that is more access to the OR, which is the major limitation to patient access in this country."

Moderator Rorabeck: "I applaud your leadership, but at the end of the day we're dealing with +/- three degrees. Is that going to change functional outcomes?"

Dr. Berend: "We don't have data on that yet."

Moderator Rorabeck: "Thank you." ♦

Please visit www.CCJR.com to registry for the 2014 CCJR Winter Meeting, December 10 - 13 in Orlando.

The Downside of Rotator Cuff Surgery? // You Will be Inspired by Dr. Metzler's Story! // OrthoCarolina Finds Better, Cheaper Way to do Knee Replacement

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

Joint, Cartilage Damage Caused by Rotator Cuff Surgery? A new study indicates that patients showing up in your office for joint replacement or other surgery may have had earlier damage done to their joint structures due to a previous rotator cuff tear. Louis J. Soslowsky, Ph.D. is the Director of McKay Orthopaedic Research Laboratory at the University of Pennsylvania. Dr. Soslowsky, who is also the Director of the Penn Center for Musculoskeletal Disorders, told *OTW*, "We received a grant from the NIH/NIAMS [National Institutes of Health/ National Institute of Arthritis and Musculoskeletal and Skin Diseases] to study when one should operate on a rotator cuff tear and the effects of that tear or surgery on the whole joint. There are patients who—even if the joint *function* is intact—had cartilage and other joint damage. A particularly interesting aspect of this was that we looked at the role of the biceps."

"One group of surgeons typically cuts the biceps in the presence of a rotator cuff tear, believing that the biceps is a key source of pain and functionality wasn't adversely affected without the biceps; the other group doesn't cut. One of the things we did in our rat model was to hypothesize that detachment of the biceps in the presence of a supraspinatus or infraspinatus tear would affect the functioning and mechanical properties of other tissues like the glenoid articular cartilage. To our surprise, we found that detachment of the biceps actually improved shoulder function and created less damage when we already had an infraspinatus of supraspinatus tear. In the presence of either of these tears there was a disruption of force balance at the joint, both superiorly and posteriorly. The biceps is anterior but when the force is disrupted you are actually altering the anterior force, which seems to create better balance."

Remembering the victims of the Boston Marathon bombing/Image courtesy: Jeffrey Metzler, M.D.

"This work is especially important because this associated joint damage can go unrecognized for years until someone shows up for a joint replacement or other surgery."

Boston Marathon: Motivated Doctor Takes Up the Challenge When the bombs went off at the Boston Marathon in 2013, a young physician from Wisconsin was one of those who ran to the aid of those in need. A year later, Jeremy Metzler, M.D., a family medicine and sports medicine physician at Prevea Health in Green Bay, ran the marathon himself. Dr. Metzler tells *OTW*, "I was in the medical tent, shadowing a physician and learning about sports medicine. We were half a block away from the first explosion, and one block away from the second explosion. The sides of the tent shook, but at first I thought it might be a canon fired in honor of Patriot Day. The whole tent fell silent, however, and people started coming in looking panicked. I grabbed some gloves and ran toward the finish line."

"I ran past the gentleman whose photo everyone saw…the one in the wheelchair wearing a cowboy hat. I reached the finish line where there were a lot of wounded people; my job was basically keeping pressure on people's wounds. Frankly, I blocked out a lot of what happened. I don't even know how long I was there. The police cleared us out due to concerns about the possibility of more explosions. I helped transfer patients back to medical tent, helped get people in ambulances, and attended to others while they waited for ambulances. The police came in with bomb sniffing dogs…it was like nothing I had ever experienced."

"I had always taken care of runners and had considered doing a marathon. So many lives being changed in such a radical way made up my mind, however, and I decided to run the Boston Marathon this year. On the day of the race the atmosphere was unbelievable…very emotional there were signs everywhere supporting those who had been killed and injured. There were groups running in honor of the 8-year-old boy who was killed and his charity. We had 36,000 runners from all over the world…all feeling the same powerful emotions. It was a real honor to be a part of this event."

OrthoCarolina, BCBSNC Team Up to Coordinate Knee Replacement

For North Carolina residents in need of knee replacement, things might be getting easier...and cheaper. Steve Hendrick is the Chief Operating Officer of OrthoCarolina. He tells *OTW,* working with Blue Cross Blue Shield of North Carolina (BCBSNC), "we have developed a coordinated care approach where patients pay a single price for the entire episode of a knee replacement that will save 10 to 30% on the cost of surgery. This came about because we were hearing from BCBSNC that the total cost of care within our market was out of line regionally and nationally. We also began seeing employers in our area getting aggressive about exploring lower cost options. Lowe's Home Improvement—which has its corporate headquarters nearby—struck a deal with Cleveland Clinic that encouraged employees and their dependents to travel to Ohio for elective cardiology procedures. PepsiCo did a similar deal with John Hopkins for patients to travel to Maryland for joint replacements. OrthoCarolina saw the writing on the wall, and we started looking into how we could evolve our practice from the traditional fee-for-service model into a value based model where reimbursement is tied to quality outcomes."

"Several hospitals declined to work with us on this but after BCBS approached us we were able to find some willing to take this on together. Our doctors realized that we had to do something or all the elective orthopedic procedures would be referred out of state!"

"This program has received high satisfaction and praise from the initial patients that have participated. Not only is it lowering the cost of care, but it is a much better experience for them and their family members. Within the coordinated care program, each patient is assigned two navigators, one for clinical issues and one for administrative issues. The administrative navigator takes care of coordinating all registration, billing, and other administrative details for the patient with all parties involved. This allows the patient to know up front what everything is going to cost and ensures they will receive only one simple bill for the entire surgical episode from OrthoCarolina. The clinical navigator explains everything that is going to happen upfront and is with the patient thru the entire process to address any questions or concerns. This single coordinated approach, focused centrally on the patient, really helps the care team be efficient while providing the best experience possible for the patients."

"On the cost side, if you look at the national data on the total cost of elective joint replacements you will see that the surgeon's portion of it is only 6-8% of the total episode cost. However, the doctor controls a large portion of the remaining cost but does it unknowingly. We got all of our joint replacement surgeons in a room and they developed a standard protocol on how to care for these patients. We looked at all of the fixed and variable costs for each of the surgeons across various hospitals they performed surgeries in. We focused in on things they all did the same as well as things done differently. When then focused on the differences and associated supply cost to get the doctors to weigh in on things such as, 'Why do you use this? Is it more effective? Is there any research data to justify using it? Is the more expensive option better? How much better?', etc."

"The doctors were stunned when they saw the cost information, i.e., what some of their patients and/or insurance companies were being billed. Doctors typically have no idea how much a total episode of care costs their patient as they only have information on their charge for the surgery and post-op follow up care. What really got their attention was when the BCBSNC people said, 'No offense, but if you did the surgeries for free it would not move the needle on the cost problem we have in the market.' OrthoCarolina is actively working with BCBSNC to expand the program to include hip replacements and other common surgical procedures."

"In addition to the BCBSNC deal, OrthoCarolina also just reached a state-wide exclusive agreement with one of the region's largest employers to provide care thru the coordinated care program to its 28,000 employees and their dependents. The program is for 20 different orthopedic conditions relating to total joint replacement, back and spine care. This deal is very unique in that it is a 'hard-steerage' program in which the company decided that its employees will only have benefit coverage for those conditions if they see OrthoCarolina physicians and have the surgery performed at specific Center of Excellence hospitals."

"The bottom line is that doctors must step up take a leadership position. The national migration to a value based reimbursement system (which needs to occur) is underway. They are better positioned than anyone else to do this."

Mohit Bhandari, M.D., M.Sc., Ph.D., FRCSC Receives Distinguished Alumni Award MacMaster University has announced that Dr. Mohit Bhandari has been selected to receive the 2014 Distinguished Alumni Award for the Sciences. Dr. Bhandari has dedicated many years of outstanding service to the medical profession and has been instrumental in raising the standards of orthopedic care. Dr. Bhandari currently serves as Professor and Academic Head of the Division of Orthopaedic Surgery as well as the Department of Surgery Associate Research Chair at McMaster University. He also holds a Canada Research Chair in Musculoskeletal Trauma and Surgical Outcomes.

The Distinguished Alumni Award recognizes McMaster University graduates who have attained a high level of distinction and achievement through scholarship, research, teaching, creative contributions to the arts or sciences and/or service to society. This award is intended to honor alumni whose accomplishments and contributions are of national and/or international significance, and/or have had a seminal or transformative impact on their field of endeavor. ♦

COMPANY

K2M IPO Nets $120 Million

K2M Group Holdings, Inc. went live on NASDAQ on May 8, 2014 and is trading under the symbol "KTWO."

The company's initial public offering (IPO) pricing was at $15 per share for approximately 8.8 million shares. According to a company announcement, the IPO was to net approximately $120 million. A few days after the listing, the stock was trading at around $15 per share with a market cap of $427 million. That compares to a $611 million market cap to another spine company that recently went public, LDR Holding Corporation.

The net proceeds from the offering are expected to be used to retire all indebtedness outstanding under the notes held by certain of its shareholders, to repay all of the outstanding borrowings under its asset-based revolving credit facility, to pay all accumulated and unpaid dividends on its Series A redeemable convertible preferred stock and its Series B redeemable convertible preferred stock, and for working capital and general corporate purposes.

Piper Jaffray & Co., Barclays Capital Inc. and Wells Fargo Securities, LLC are acting as joint book-running managers for the offering. William Blair & Company, L.L.C. and Cowen and Company, LLC are acting as co-managers.

The company was co-founded by K2M Chairman and Chief Medical Officer John Kostuik, M.D. and President and CEO Eric Major. Welsh, Carson, Anderson & Stowe acquired controlling interest in 2010. The company nearly $157.6 million in revenue last year, but also saw a $37.9 million loss. Welsh, Carson, Anderson & Stowe will continue to own a majority of shares in the company, according to a *Washington Business Journal* report.

—*WE (May 13, 2014)*

NASDAQ Studio/Wikimedia, K2M and RRY Publications LLC

AlloSource Donates a "Miracle"

Twenty-seven children in Ahmedabad, India, who had been suffering from complex spinal and upper extremity deformities, are better today thanks to a team of surgeons from Cincinnati Children's Hospital Medical Center and bone grafts donated by AlloSource. For the second year in row, a medical team from the Pediatric Orthopaedic Department of the hospital traveled to India to offer crucial and complex surgeries at no cost to the young patients.

Wikimedia Commons and Ritisha

These were procedures that local surgeons were unable to offer the children because of the complicated nature of the problems and the high cost associated with them. The U.S. surgeons used the donated AlloSource bone grafts in the operations on the six children with complex spine deformities. Doctors said that without the surgery, the children with spinal deformities faced potential paralysis.

The Polio Foundation, a non-profit charity hospital in Ahmedabad, provided assistance during the spine surgeries—each of which lasted from six to eight hours. Local surgeons and anesthesiologists assisted with the procedures.

"Because of the hard work of the surgeons, donated tissue made a huge difference in the lives of these children," said Thomas Cycyota, president and CEO of AlloSource. "We are proud to have provided the bone grafts used in these procedures and we admire the dedication of the team from Cincinnati Children's Hospital Medical Center." The team plans to continue its annual trips to provide advanced medical care for pediatric patients in areas of need in India.

AlloSource is a non-profit company that offers more than 200 types of bone, skin, soft-tissue and custom-machined allografts for use in an array of medical procedures. Company officials say that AlloSource is the world's largest processor of cellular bone allografts.

—BY (May 12, 2014)

LEGAL

Former Wright VP Demands Separation Pay

Alicia Napoli, the former clinical & regulatory vice president of Wright Medical Technology, Inc. is suing her former employer for breach of contract, according to a 10-Q SEC regulatory filing issued by the company on May 1, 2014.

As we previously reported, Napoli was part of the group of employees who left the company in 2011 after a tumultuous DPA (deferred prosecution agreement) period with the U.S. Department of Justice over company relationships with surgeon customers. New management has made peace with the feds after previous senior executives resigned or were fired.

Napoli resigned shortly after the change in management. At the time, the company reportedly stated Napoli resigned "without good reason."

According to the regulatory filing, Napoli sued the company in state court in 2012 asserting "claims for retaliatory discharge and breach of contract based upon her separation pay agreement." In addition, Napoli asserted a "claim for defamation related to the press release issued at the time of her termination and a wrongful discharge claim alleging violation of the Tennessee Public Protection Act." Napoli claims she is entitled to attorney fees in addition to other unspecified damages.

On October 23, 2013, Napoli moved to voluntary dismiss her lawsuit, without prejudice. On April 4, 2014, she refiled her case in the United States District Court for the Eastern District of Missouri.

"He Said, She Said"

According to a May 7, 2014 *MassDevice* report, Napoli's lawsuit claims that she was one of the Wright representatives who inked a product research and study contract with Paul Lux, M.D. a St. Louis orthopedic surgeon, in July 2010.

"In approximately August 2010, Wright Medical investigated Ms. Napoli for possible compliance violations with respect to the above surgeon's contract…. From its investigation, Wright Medical found a purported appearance of impropriety involving Ms. Napoli, but no violation of law," according to her complaint.

Napoli was issued a letter of reprimand by the company in March 2011. According to Napoli's lawsuit, she claims all her actions in connection with the surgeon's contract, "Where at all times performed with the knowledge and consent of authorized representatives of Wright Medical."

Her lawsuit further alleges that, "Thereafter, without prior notice or justification, Wright Medical delivered a purported letter of resignation to Ms. Napoli on May 3, 2011, with a demand for her to sign it, or be terminated under threat of a negative press release…. Ms. Napoli signed the purported letter of resignation under compulsion and duress, without benefit of counsel."

Demand for Separation Pay Package

The lawsuit argues that the allegedly forced resignation amounts to an involuntary termination that should have triggered her separation pay package. Napoli is seeking an award "that would compensate her for all severance benefits," pre-judgment interest and legal costs and fees, according to the documents.

—WE (May 16, 2014)

Photo reaction for RRY Publications LLC

Zimmer/Biomet Merger Roadblock to Device Tax Repeal

There is a new excuse for not repealing the medical device tax; Zimmer Holdings, Inc.'s purchase of Biomet, Inc.

U.S. Senate Democrat Majority Leader Harry Reid of Nevada reportedly said recently that he would block a Republican demand to vote on repealing the tax. According to rollcall.com, Reid said on May 13, 2014:

> "I'm not going to cry any big tears over the device folks. Their profits were huge last year. Remember, there was one deal, I think it was a $15 billion deal, where they were consolidated, a merger. So, the device tax folks are doing extremely well. They're doing extremely well with Obamacare. Their profits have gone up significantly since Obamacare."

It's a little ironic in that David Dvorak and Jeff Binder, the respective CEOs of Zimmer and Biomet, have been two of the most vocal critics of the tax. Dvorak was the main spokesperson for AdvaMed against the tax during his tenure as chairman of the trade group's board of directors last year. Now their decision to combine Zimmer and Biomet is being used against them in Congress. Reid didn't credit Obamacare for the merger.

The two key Republican senators leading the repeal charge vote are the orthopedic surgeon from Wyoming, Senator John Barrasso, M.D. and the anti-POD (physician-owned distributor) crusader, Senator Orin Hatch of Utah.

"For some reason they don't want to have that vote. A lot of companies are leaving America to go overseas," said Finance ranking member Hatch.

"It was interesting last year when we had the nonbinding vote that 34 Democrats said they wanted to remove the medical device tax because they realize it's hurting the economy, hurting jobs, hurting innovation, hurting research and development and actually driving jobs overseas," Barrasso said. "But when it comes to count the vote, when it really matters, they say…'I don't think I want to take that vote.'"

—*WE (May 15, 2014)*

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FDA Device Fees and Approvals Up, Review Times Down

Medical device companies paid the FDA $96.8 million in user fees during fiscal year 2013, up 48% from the previous year.

Pinsol.com and RRY Publications LLC

What is industry getting for that extra money? For one thing, according to an agency quarterly report, the percentage of premarket approval (PMA) applications approved by the agency grew from 59% in 2010 to 74% so far in 2014. The average time to get a decision for a PMA has dropped over 30% from a high of 464 days in 2009 to 297 in 2012. The agency has also decreased the PMA backlog by over 45% from 92 in 2010 to 49 in 2014.

In addition to more PMA approvals, FDA Commissioner Margaret Hamburg, M.D., reported on the FDA blog that review times for 510(k) clearances have declined, with nearly all of 2012 submissions now closed. The average review times for a 501(k) clearance dropped from a high of 154 days in 2010 to 144 days in 2012.

The big jump in fees was due to a new Medical Device User Fee Act (MDUFA III) that went into effect this past year.

There was an equally significant jump in user fees in 2007 when the first MDUFA period closed and MDUFA II went into effect. That year, user fees increased 65.5%, according to the report, but FDA performance got worse.

Under MDUFA III with the device industry, the FDA will collect almost $600 million in fees over five years. The agency plans to hire an additional 200 full-time employees over that time to speed up review times. Hamburg told Congress recently that since October 1, 2013, the agency has already hired 90 of those employees.

The agency is required to submit a quarterly report on performance under the new user device agreement. To read the latest report presented on April 29, 2014, click here: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM395834.pdf

—*WE (May 13, 2014)*

LARGE JOINTS

Predicting Fractures After Patients Stop Bisphosphonate

A new study indicates that age and testing of hip bone mineral density (BMD) when postmenopausal women discontinue bisphosphonate therapy can help predict the likelihood of fractures over the next five years. The study, performed by Douglas Bauer, M.D. of the University of California, San Francisco, tested methods for predicting fracture risk by measuring BMD using hip and spine duel-energy x-ray absorptiometry (DXA) and also bone turnover markers (BTMs) when women discontinue bisphosphonate therapy and a few years afterward.

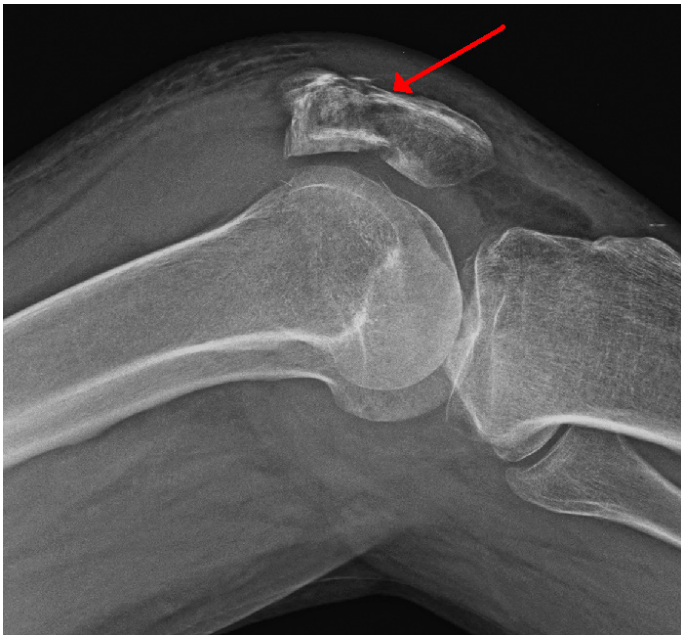
Dr. Bauer and his colleagues examined data from the Fracture Intervention Trial Long-term Extension (FLEX), and randomly assigned postmenopausal women (ages 61 to 86 years) previously treated with the bisphosphonate alendronate sodium (for four to five years) to five additional years of alendronate or placebo from 1998 through 2003. This analysis included only the placebo group. Hip and spine DXA were measured when the placebo was started and after one to three years of follow-up. Two different BTMs also were measured at baseline and after one and three years.

During five years of placebo, 22% of women (94 of 437) had one or more fractures; 82 had fractures after one year. Older age and lower hip BMD at the time alendronate therapy was discontinued were associated with higher rates of clinical fractures during the subsequent five years. However, neither BMD measures after one year nor BTM levels one to two years after discontinuing alendronate were associated with fracture risk.

The authors say in the May 5, 2014 news release, "Women with greater total hip bone loss two or three years after discontinuation may be at increased risk of fracture, but these results need to be confirmed in other studies before routine measurement of BMD after discontinuation of alendronate therapy can be recommended. … In the meantime, short-term monitoring with BMD, BAP or NTX [two bone turnover markers] after discontinuation of four to five years of alendronate therapy does not appear to improve fracture prediction."

Dr. Bauer told *OTW*, "It was surprising the bone turnover markers did not predict fracture risk after discontinuation of alendronate, as we believe the offset of efficacy should be reflected by a rise in bone turnover that translates into higher fracture risk. We know that changes in BMD do not reliably predict treatment efficacy when starting bisphosphonates, so the observations that short term changes in BMD did not predict fracture risk after discontinuation was not particularly surprising. Future studies should look at newer and perhaps more accurate bone turnover markers which might be more helpful."

—*EH (May 13, 2014)*



Wikimedia Commons and James Heilman, M.D.

Study Questions Arthroscopic Knee Surgery

Research from Finland, published in the *New England Journal of Medicine,* suggests that the thousands of people who have arthroscopic knee surgery to fix a torn cartilage could be wasting their time. The Finish team found that, though keyhole surgery to repair torn cartilage has risen significantly, there is no evidence that it actually helps.

In the typical procedure the surgeon inserts a scope through a small incision to examine the joint and, if required, also partially removes the damaged cartilage through another incision. The Finnish study found that this procedure conferred no more benefits to the patient than did a sham operation.

In their study, the Finnish team recruited 146 patients, age 35 to 65, with meniscal tears that had developed through wear and tear on the knee. None of them had an injury to the knee and none had arthritis of the knee.

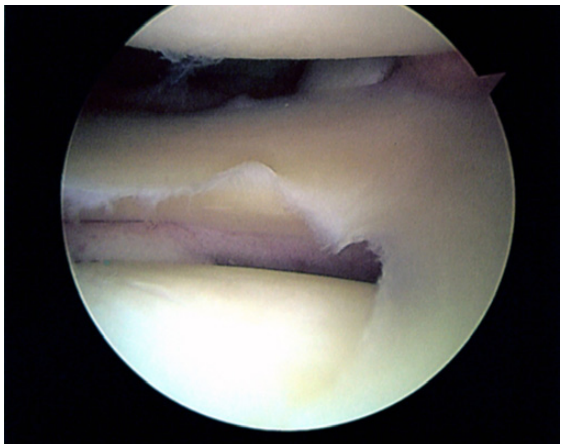
The researchers randomly assigned the patients to one of two groups. One group underwent keyhole surgery to partially remove the damaged meniscus and the other underwent a sham procedure. In the sham procedure, the surgeons simulated the real operation. They manipulated the patient's knee and handled surgical instruments near the knee so the patients were under the impression they were being operated on.

Both groups then underwent arthroscopy. Surgeons inserted a scope into the keyhole so they could look at the torn cartilage, but only one group actually had part of the cartilage removed. Neither the patients nor the people caring for them knew which patients had undergone the real procedure and which had just had the sham operation.

When the researchers interviewed the patients in both groups a year later they found that both were equally satisfied with the results. They all reported that their knees felt better than they had before the operation. Of the partial meniscectomy group, 93% said they would choose the same procedure again, as did 96% of the sham procedure group.

Lead author of the study, Raine Sihvonen, M.D., a specialist in orthopedics and traumatology at Hatanpää Hospital in Tampere in southern Finland, said, "It's difficult to imagine that such a clear result would result in no changes to treatment practices." Noting that in western countries, this operation is now the most common surgical procedure after cataract surgery, he added, "By ceasing the procedures which have proven ineffective, we would avoid performing 10,000 useless surgeries every year in Finland alone. The corresponding figure for U.S. is at least 500,000 surgeries."

—*BY (May 14, 2014)*



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EXTREMITIES

Mayo Clinic Sports Medicine Center Expands

Mayo Clinic has recently opened its Mayo Clinic Sports Medicine Center expansion at the Dan Abraham Healthy Living Center in Rochester, Minnesota. The new space offers performance solution programs, including hockey, golf, running, baseball/softball, anterior cruciate ligament injury prevention, return-to-sport, and EXOS training. The programs begin with personalized assessment and are then tailored to meet individual needs, regardless of age or level of athletic achievement.

Mayo Clinic Sports Medicine Center

The space features multiple playing surfaces, such as hardwood and artificial ice, and specialized lifting platforms. Michael Stuart, M.D., co-director of the Sports Medicine Center, said in the April 29, 2014 news release, "Our team of physicians, athletic trainers, physical therapists, and strength and conditioning specialists will help prevent injury, refine skills and speed recovery so people can spend more time doing what they love at the highest level possible."

Mayo Clinic notes that training capabilities in the new space are enhanced through collaboration with EXOS, a training organization based on mindset, nutrition, movement and recov-

ery. Mayo Clinic and EXOS staff will work together to deliver sports medical care and human performance training solutions.

—*EH (May 16, 2014)*

Eli Manning's "Sprain"

Eli Manning is one of the most durable quarterbacks in the National Football League (NFL) having started an astonishing 151 consecutive NFL games.

But that ended in the fourth quarter of the final game of the 2013-2014 season—one of Manning worst years so far in the NFL, Manning, who'd guided his team to two Super Bowls, was facing a disappointing 7-9 finish when Washington's 333lb nose tackle Christopher Isaiah Baker came barreling over Manning's defender and appeared on the verge of smashing the frail quarterback into the ground.

Manning pivoted, twisted and jumped to avoid Baker but in the process suffered a season ending high ankle "sprain."

Dr. Robert Anderson of OrthoCarolina treated Manning. According to news reports Dr. Anderson performed endoscopic surgery to remove calcium deposits, scar tissue and bone chips from the high ankle area.

This is a "sprain?"

Dr. Steven Weinfeld, an orthopedic surgeon and the chief of the foot and ankle service at the Icahn School of Medicine at Mount Sinai in New York told the *New York Times* writer Ken Belson that it would take months to determine whether the injury had completely healed. Furthermore, Manning will most likely wear a protective boot for weeks and only begin running after about six weeks. Several more weeks of activity will be needed to find out if Manning can move without pain.

Joe Alper, reporting for *NBC Sports,* quotes Manning as saying that he has a lot of work to do. "But I'm enjoying the competition of it all, the urgency we're having right now." Alper further reports that the Giants new offensive coordinator, Ben McAdoo, is designing a new offense which means that Manning will have a great deal of homework to do while he rehabilitates his ankle.

Manning is saying that his ankle is healing quickly and that it was a wise decision to have the surgery at the time that he did.

—*BY (May 13, 2014)*

Eli Manning/wikimedia commons and AJ Guel

NHL's Tallest Goalie Tears a Wing

"Big Ben" Bishop, the tallest goaltender to ever play in the NHL at 6 feet 7 inches, tore a ligament in his right wrist while getting the Tampa Bay Lightning to the first round of the Stanley Cup Playoffs. Various news reports state that Bishop chose Dr. Thomas Graham, Cleveland Clinic's "Chief Innovation Officer" as his surgeon.

Wikipedia and Jaime4Jesus

ESPN News reports that Bishop's wrist is much better and next year, Tampa Bay Lightning hope not to get knocked out in the first round—like this year.

Bishop, who hurt his wrist in early January, wore a cast while playing but aggravated it again in February. Bishop did not initially seek treatment, preferring instead to play through the pain. His coach Jon Cooper commented, "He had so many things break down, it was tough. He gamed it out. We can gripe about getting swept in the first round, but without Bishop we probably would not have been in the first round."

Hockey has never seen a professional goalie with a "wing span" like Bishop's. As a freshman for the University of Maine, Bishop had a record of 21 wins, 8 loses and 2 ties and a 2.28 goals against average. That same year Bishop led Maine to a sweep of the back-to-back

national champions Denver. In October 2005 and February 2006 he was awarded Rookie of the Month as well as Goaltender of the Month by Hockey East. He was also named Rookie of the Week four separate times.

The Sarah Palin Connection

Bishop's debut in the NHL with the St. Louis Blues wasn't nearly so auspicious. He gave up two goals over the final 40 minutes in a 4-0 loss to the Los Angeles Kings.

Before that game was played, however, vice presidential candidate Sarah Palin was invited to drop the ceremonial first puck. The team's starting goalie, Manny Legace, tripped on the carpet that was laid out for Palin and injured himself. Bishop filled in for Legace. It was his first official NHL game.

Bishop was subsequently traded to the Ottawa Senators in early 2012 where he, again, replaced an injured starting goalie. This time it was Craig Anderson. Anderson, it turns out, cut his hand in a kitchen accident before the game. After a while, Bishop was traded again. This time to Tampa Bay.

With Tampa Bay, Bishop seems to have found a home. He was named a finalist for the top NHL goaltender honors this season, the Vezina Trophy.

Wing Span

Extending those long arms and legs is part of Bishop's effectiveness as a goalie. Unfortunately, it has caused elbow and wrist injuries. Bishop had a 2.23 goals-against average and .924 save percentage this season. He did not play in the playoffs due to an elbow dislocation. The Lightning were swept by the Canadians in the first round.

Those injuries combined with being left off the U.S. Olympic team despite superlative numbers in 2013-14 has meant that this year was a real roller coaster ride for 'Big Ben'.

The team expects Bishop to be ready for the 2014-15 season's training camp.

Mr. Innovation

Bishop's surgeon for the torn ligament in his wrist was Cleveland Clinic's Mr. Innovation, Dr. Thomas Graham.

Dr. Graham is recognized worldwide for his clinical expertise in hand, wrist and elbow surgery and has worked with many professional athletes. Graham holds nearly 40 patents on implants and other devices and has started several medical device and service companies. Dr. Graham completed his residency at the University of Michigan Hospitals, a fellowship in hand surgery at the Indiana Hand Center and his medical degree from the University of Cincinnati College of Medicine.

—BY (May 12, 2014)

TRAUMA

Thought-Controlled Arm Approved by FDA

The FDA has approved the first prosthetic arm that its wearer can control with his or her own thoughts, according to John Gever, deputy managing editor of *MedPage Today*. The device, which is manufactured by DEKA Integrated Solutions Corp. of New Hampshire, translates electromyographic activity in muscles near the prosthesis into signals that direct specific movements in the prosthetic arm. The user of the arm can consciously control those signals.

A trial with 36 participants, patients in the Veterans Affairs medical system, led to the FDA approval. According to Gever's report, the prosthetic arm is about the same size and weight as a human adult arm and is capable of making ten different movements.

Gever quotes the FDA report as stating, "The study found that approximately 90% of study participants were able to perform activities with the DEKA Arm System that they were not able to perform with their current prosthesis, such as using keys and locks, preparing food, feeding oneself, using zippers, and brushing and combing hair."

The device appeared able to function in adverse environmental conditions and to survive impacts. It also will allow users to perform more complex tasks than are currently possible. Configurations are available for a variety of arm amputations including the loss of the entire arm up to the shoulder joint.

According to Gever's report, the FDA has determined that failure of this device while in use would not put patients at severe risk, which allows DEKA to apply through the de novo classification process for first-in-class products.

—BY (May 14, 2014)

DARPA, U.S. Government

SPINE

Surgeon Trio Invents Expandable Spine Cage

Expanding Orthopedics Inc., a venture backed, medical device company in Or Akiva, Israel, presented for the first time its new spinal cage—the FLXfit TLIF 3D—at the late April 2014 annual meeting in Miami of the International Society for the Advancement of Spine Surgery (ISASS). The new device, described as a "novel expandable and articulated intervertebral TLIF cage with optimized lordosis correction," is the work of three international colleagues, Professor and M.D. Jean Charles Le Huec, Klaus Schnake, M.D. and Ory Keynan, M.D.

Courtesy of Expanding Orthopedics Inc.

As Le Huec, head of the Ortho-Spine Department, Bordeaux University Hospital, France, and former president of ISASS and EuroSpine explained, "correcting anatomical balance in the lumbar spine is imperative, particularly in the lower disc spaces." He said that current cages have limited possibilities for lordosis correction and are sometimes difficult to maneuver. In addition, he added, the contact between the implant and endplate is not always optimal, leading to improper stability after the surgery.

The third member of the design team, Schnake, head of the Spine Surgery Center at the Nurenberg Schoen Klinik, Germany, added that, "the FLXfit successfully passed all relevant international biomechanical testing, with equivalent or superior results compared to alternative devices in all measures. In cadaver studies performed with my colleagues, all cages were successfully implanted, positioned and expanded." Schnake said that expansion of the device was easily reversed allowing for safe removal.

Ofer Bokobza, CEO of Expanding Orthopedics, said that "we are honored to have this close collaboration with a top notch group of renowned surgeons enabling our continuous release of unique minimal invasive expandable devices to the market." The FLXfit, he said, will soon be available internationally.

—BY (May 15, 2014)

Orthopedics This Week | RRY Publications LLC

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