VOLUME 11, ISSUE 6 | FEBRUARY 17, 2015

Orthopedics This Week

WEEK IN REVIEW

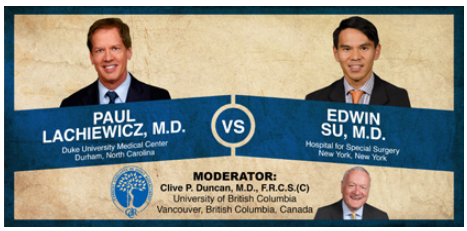
4 The Passing of Dane Miller >> Dane Miller's passing feels like a family member has died. On a personal level, he impressed, influenced and was beloved by thousands of physicians and industry executives all over the world. On a professional level, he improved the lives of literally millions of patients worldwide. How do we explain the importance and love of Dane Miller? We begin with a dream.

10 The Myth of the $87 Billion Knee Replacement Market >> In 2007, JBJS published an interesting paper which projected that the red-hot orthopedic implant business would rise at an increasing rate to a whopping 3.5 million knee implants and $87 billion in costs by 2030. What could possible derail those projections? Well, you might be surprised.

14 Gunnar Andersson, M.D., Retires // NFL Medicine Pushing Towards the Future // Rush Ortho Jumps into Urgent Care >> Gunnar Andersson, M.D., Chairman Emeritus of Orthopedic Surgery at Midwest Orthopaedics at Rush, looks back on his many years in orthopedics. The head of the NFL Physicans' Society describes major advances in the speed and accuracy of NFL player care. And Rush jumps on urgent care bandwagon.

1946-2015

17 Lachiewicz, Su Debate Dual Mobility in Primary Hip Replacement >> "All the benefits to dual mobility are theoretical," argues Paul Lachiewicz. "There's little lab data—except from the manufacturers." "Dual mobility has a proven track record," counters Edwin Su. "It could be indicated for primary hip because it provides greater stability and it can reduce your dislocation rate to less than 1%. I would consider it in high risk, primary cases."



BREAKING NEWS

20 Zimmer's 2nd Try for Euro Biomet Merger Approval

Here Comes the Dragon: China Consumes $55 Billion in Devices

Hospital Guarantees Joint Replacement **Surgery**

Study Questions **Arthroplasty for Fibromyalgia** Patients

Doc Replaces Four Joints – Using an Epidural

Titan Spine: 510(k) for Endoskeleton TCS

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Is the EuroZone economy picking up steam? Since 2009, U.S. has far outpaced Europe—mostly due to Bernanke's zero interest, flood the markets with cash approach versus the German-led austerity campaign. Europe's central bankers seemed to moderate 2014 and whadya know...the Eurozone economy posted a stronger-than-expected 0.3% in Q4. Full year 2014 was PLUS 0.9% versus a MINUS 0.4% in 2013.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Integra LifeSciences	12.57%	2.52%	How cheap is IART? It's getting to a level that even famous bargain hunters like, well, IART would find it attractive.
2	2	ConMed	10.51	4.68	Buyers are betting on the new management and pushing CNMD's price higher. Could expectations be running ahead of performance?
3	4	Stryker	11.52	1.35	Raised the quarterly dividend 13%. And is getting ready for a strong AAOS. At these prices, SYK is way too cheap.
4	7	Zimmer	29.12	1.83	ZMH is the same overall valuation as SYK. Checking PE, PEG and PSR. For the first time in 10 years, SYK and ZMH are the same. Big jump this week.
5	5	Orthofix	7.46	9.19	Given the paucity of financial data, how can anyone predict OFIX's sales? Only one analyst is hazarding a guess for 2015—+2.5% sales growth.
6	6	MicroPort Scientific	16.53	10.57	AAOS looms large for MicroPort. Who is MicroPort? This meeting will help to define this old/new company for physicians and the industry broadly.
7	3	Medtronic	28.84	4.86	Medtronic Spine is mending well. Most analysts are modeling a rise in spinal implant sales for 2015 and stable Infuse.
8	9	Exactech	10.44	(4.45)	Three-way tie for #2 valuation. EXAC, SYK and ZMH. But, as in integrated ortho these days, size matters in the Power Rankings too.
9	10	NuVasive	8.01	(1.01)	Profit taking is improving NUVA's price relative to its peers. Still in the premium range, but back in the Top 10 overall.
10	8	Smith & Nephew	19.92	2.08	Without the M&A rumors what's SNN worth? Less than this—based on past history. Looks like the rush to the altar was premature.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$0.86	$138	32.91%
2	MicroPort Scientific	853	$0.46	$651	10.57%
3	LDR Holding Corp.	LDRH	$37.73	$983	9.36%
4	Orthofix	OFIX	$32.09	$592	9.19%
5	RTI Biologics Inc	RTIX	$5.54	$315	7.36%
6	Aurora Spine	ASG	$1.27	$21	6.95%
7	Medtronic	MDT	$75.26	$106,781	4.86%
8	ConMed	CNMD	$48.98	$1,348	4.68%
9	Bacterin Intl Holdings	BONE	$3.09	$21	4.04%
10	Globus Medical	GMED	$24.85	$2,434	3.58%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	K2M Group Holdings	KTWO	$19.75	$779	-9.36%
2	CryoLife	CRY	$11.30	$316	-7.30%
3	Exactech	EXAC	$22.33	$308	-4.45%
4	Alphatec Holdings	ATEC	$1.34	$133	-4.29%
5	Johnson & Johnson	JNJ	$99.62	$278,847	-4.21%
6	NuVasive	NUVA	$46.99	$2,210	-1.01%
7	Tornier N.V.	TRNX	$25.32	$1,238	0.04%
8	MiMedx Group	MDXG	$8.65	$925	0.12%
9	Wright Medical	WMGI	$25.68	$1,311	0.47%
10	Stryker	SYK	$94.51	$35,796	1.35%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Johnson & Johnson	JNJ	$99.62	$278,847	16.69
2	Medtronic	MDT	$75.26	$106,781	19.05
3	Exactech	EXAC	$22.33	$308	19.59
4	Globus Medical	GMED	$24.85	$2,434	20.44
5	Zimmer Holdings	ZMH	$119.33	$20,209	20.64

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MiMedx Group	MDXG	$8.65	$925	862.50
2	Orthofix	OFIX	$32.09	$592	205.01
3	NuVasive	NUVA	$46.99	$2,210	121.29
4	RTI Biologics Inc	RTIX	$5.54	$315	86.96
5	CryoLife	CRY	$11.30	$316	38.69

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	$11.30	$316	1.29
2	Exactech	EXAC	$22.33	$308	1.31
3	ConMed	CNMD	$48.98	$1,348	1.49
4	Globus Medical	GMED	$24.85	$2,434	1.54
5	Medtronic	MDT	$75.26	$106,781	1.69

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	MiMedx Group	MDXG	$8.65	$925	57.50
2	Orthofix	OFIX	$32.09	$592	11.14
3	NuVasive	NUVA	$46.99	$2,210	10.61
4	RTI Biologics Inc	RTIX	$5.54	$315	5.80
5	Smith & Nephew	SNN	$35.82	$16,054	4.71

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Bacterin Intl Holdings	BONE	$3.09	$21	0.60
2	Alphatec Holdings	ATEC	$1.34	$133	0.65
3	RTI Biologics Inc	RTIX	$5.54	$315	1.20
4	Exactech	EXAC	$22.33	$308	1.25
5	Orthofix	OFIX	$32.09	$592	1.48

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$0.86	$138	24.16
2	MiMedx Group	MDXG	$8.65	$925	9.57
3	LDR Holding Corp.	LDRH	$37.73	$983	7.35
4	Medtronic	MDT	$75.26	$106,781	6.15
5	Globus Medical	GMED	$24.85	$2,434	5.28

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

The Passing of Dane Miller

BY WALTER EISNER

Courtesy of Biomet, Inc.

Dane Miller had a dream while sailing with his buddy, Jerry Ferguson, back in 1975. He dreamed of a new way to make surgical implants. At the time such a dream must have seemed crazy, improbable, somewhere off in left field.

When Dane Miller, Ph.D. died on February 10, 2015 (of MDS, a rare form of leukemia) his 40-year-old dream had not simply succeeded, it had changed the lives of millions of people. But even more than that, the way he achieved his dream made Dane a living legend.

Dr. Miller is survived by his wife Mary Louise and his daughters, Kimberly and Stephanie of Valparaiso, Indiana. In lieu of flowers, please send donations to:

Dane's Dream

Dane believed that titanium was the most biocompatible metal available for implant devices. While working for Zimmer USA, he tried to introduce the material, but couldn't convince anyone that the body wouldn't reject the metal. So he had a small rod implanted into his own arm.

Dane, Ferguson, Niles Noblitt and Ray Harroff founded Biomet, Inc. in 1977. Biomet—Bio for Body, met for metallurgical implants.

Acting on that dream took some courage and was a family affair with the young group. Dane and his wife, Mary Louise, took a long-range view. Her father was a physician and she knew about long hours.

As newlyweds, the couple lived in an 8-foot by 40-foot trailer. So when they started Biomet in a converted barn in Warsaw, Indiana, the family just scaled back and lived frugally. "The children and I were willing to make any sacrifice," she said in a published interview. "We knew if we did it right we could achieve this goal."

The group had just $725,000 of their own money, including a $500,000 loan from the Small Business Administration. They posted a $63,000 net loss the first year.

Innovative Cancer Therapy Fund Dr. Yogen Saunthararajah Cleveland Clinic 9500 Euclid Avenue, R40 Cleveland, Ohio 44195	St. Anne's Episcopal Church 424 W. Market Street Warsaw, IN 46580	Women's Care Center Foundation 360 N. Notre Dame Ave. South Bend, IN 46617

Left to right: M. Ray Harroff (seated), Dane A. Miller, Jerry L. Ferguson, and Niles M. Noblitt (seated)/Biomet, Inc.

The wives took turns baby-sitting so they could go to the office and sweep the floors, type out invoices or answer phones. The men scrubbed toilets, picked up garbage, took orders and shipped product.

Garry England, the company's 41st employee said in a published interview, "I remember Dane doing wiring, office construction, sweeping, shoveling snow. It was a 'get-it-done' attitude that was very motivational to us (employees). In those days, you knew everybody who worked here by their first name; you knew their spouses' names and half their kids' names."

The financial risk was big and the families put it all on the line. Dane and Mary Louise had personal guarantees of over $1 million dollars in debt and at the time had a net worth of $100,000.

Dane's Tenacity

Instead of intimidating him, the prospect of failure inspired Dane. "Webster's dictionary really should carry his picture next to 'tenacity' because Dane never gives up," Ferguson said in a published interview. "I mean he never gives up. It doesn't matter how bad things get." As a devout Presbyterian, Dane said he's not alone. "I rely on my spiritual underpinnings to keep me upright and moving forward."

"If we tried and failed, we were still young enough to pick ourselves up and try again," Dane told students at the Kelley School of Business as part of the Distinguished Entrepreneur-in-Residence Series. "You don't want to look back and say, 'I wish I'd tried.' The risk of failure for start-up companies is very high. So? You start over again."

Biomet Culture

One of the goals of the new company was to take suggestions from orthopedic surgeons and come out with improved implants faster than their big competitors. Right from the start, the priorities were: solid engineering, customer responsiveness, superior clinical results and top-notch quality.

Dane said the company's culture was about taking a hands-on approach to their business. "Our employees get it done. There is no job at Biomet that isn't everyone's job. It's our company. As we grow larger, we don't want to drift into a habit of acting as if we're all managers, not employees or shareholders."

By early 1979 most of their seed money was gone. But the group was able to obtain $500,000 in equity from a venture capital investor and kept Biomet afloat until the first profitable year was realized in 1980 and a move into a new facility.

Dane: "They All Thought I Was Nuts"

By 1980, Biomet earned $1.1 million in net sales. The company went public in 1981, had Wall Street's attention by 1983, and in 1987, with $96.7 million in net sales, was deemed a "hot growth company." In 1984, Dane predicted Biomet would be a billion dollar company by 2000.

"They all thought I was nuts," said Dane. "How could anyone imagine by the year 2000 we'd be doing a billion dollars? And, in fact, in the fiscal year 2000, we reached a billion dollars."

There were some technology hiccups.

In 1983, came the Dermizip, which was lauded as the "sizzle" that sold the August 1983 public offering of 3 million shares. This product was supposed to catapult Biomet into the surgical wound closure market. So, of course, Dane had the new "attachment apparatus" used on his own arm.

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But, it didn't hold. Not one to quit, Dane flew to O'Hare Airport to meet John Sheehan, M.D., the surgeon who had designed the product. There, in the hallway, Dane had the original product replaced and flew off to Europe. After ten days and no healing, he had the Dermzip removed in Sweden.

Dermizip never formally went to market and in-house it became known as "Dermiscar." Said one former team member, "I think Dane was the only person we left a scar on."

But it was also around this time that Dane had the test titanium rod removed from his arm. Histology and biocompatibility tests proved exactly what he had predicted—metallurgically, the titanium came out exactly like it went in. Dane didn't just use his own devices on himself, his grandmother, Grace Shumaker, was the first recipient of a Biomet-made artificial hip.

Dane and Mary Louise

Dane was born in Bellefontaine, Ohio. He and the former Mary Louise Schilke met as teens in Springfield, Ohio, at a swim club. They were married on February 19, 1966. They were married just nine days short of 49 years.

In the beginning the young couple moved every six weeks between Dayton, Ohio, where Miller worked, and Flint, Michigan, so he could attend General Motors Institute (now Kettering University). He followed his passion to a master's degree and, later, a Ph.D. in bio-medical engineering from the University of Cincinnati.

With those credentials, the couple began his professional career at the Frigidaire Division, GMC in Dayton, Ohio, from 1964 to 1969, working as a cooperative engineering student. From 1972 to 1975 he was employed as the director of biomedical engineering at Zimmer. His responsibilities included engineering, prototype design and fabrication, as well as basic research support for all new product development programs. He was also responsible for coordinating and developing a custom and special product group, including marketing, sales, and manufacturing of custom products.

From 1975 to 1977, he was Director of Biomedical Engineering for Cutter Biomedical, a division of Cutter Laboratories, Inc. Dane and Mary Louise left Cutter Biomedical to serve as president and CEO of the new company.

Dane Miller, Ph.D and his wife, Mary Louise/Biomet, Inc.

Ortho Love

Surgeons and industry professionals loved Dane.

Among surgeons, Dane was known for his engineering savvy and responsiveness. Merrill Ritter, M.D., a Mooresville, Indiana, orthopedic surgeon, said this about Dane: "He is just a regular guy, but he is a very brilliant guy. He doesn't push his brightness; it just flows out of him."

Todd Albert, M.D., Surgeon in Chief and Medical Director at Hospital for Special Surgery in New York said Dane was an "amazing man—innovative, brilliant yet extremely down to earth.

"Dane is in the DNA of Biomet and Biomet is in his," wrote *OTW* Publisher Robin Young in 2006.

"Where Dane ended and Biomet began has always been hard to see. Customers who needed to call him could reach Dane Miller at home. Dane was, perhaps, the only major orthopedic company CEO who handed out his home and cell phone numbers to customers. And for anyone else, he listed the number in the Warsaw, Indiana, phone book. He also, famously, answered his own phone in the office."

Dane built Biomet into a company with 6,000 worldwide employees under his watch.

Fighting for the Team

As a public company, Biomet was no longer entirely under Dane's control. In 2006, the company's board of directors

suggested he retire after 28 years of service, and he did.

But Dane and Mary Louise didn't want to abandon their team members and planned their comeback.

"My wife and I talked seriously about riding off into the sunset," Dane said. "Then we started thinking about people. Biomet wasn't a company. It was a collection of very talented, very motivated, very dedicated people. And I wasn't comfortable with simply turning my back and riding off into the sunset. So I began 'my little project' of putting together about $10 billion in capital to take the company private."

In 2007, with a consortium of private equity firms, Miller bought back Biomet for $11.4 billion, again living up to his credo of not wanting to look back and wish he'd tried. In 2014, Zimmer offered over $13 billion to acquire Biomet. The deal is expected to be completed this spring.

In his semi-retired role, Dane said he's doing exactly what he wanted to do as "Biomet's grandfather."

His actual grandson, Dane said, wants to be just like him when he gets older. Then, in true Dane style, he added, "That makes my wife very unhappy."

Community

Dane's community activities have included serving as a director of Kosciusko Community Hospital, a member of the President's Council for Grace College and Seminary, a board member of the Kosciusko Leadership Academy and a board member of the University of Chicago Hospitals and Health System, according to a *Forbes* magazine profile.

Retha Hicks, Winona Lake's Clerk/Treasurer said, "There is no way to put into words to describe what he's put into the community, and he didn't want anything in return except to live in a nice community. The entire community has changed in outlook and image. Everyone pitches in and is inspired to help because they saw the results of the revitalization."

Warsaw Celebrates a Legacy

Zimmer President and CEO Dave Dvorak told *OTW*, "On behalf of the entire Zimmer team, we are deeply saddened

by the loss of Dane Miller. Dane was a well-respected leader in our industry and in our community. I considered him a friend, as did so many who have had the opportunity to get to know him over the years…. Dane will be greatly missed."

"The Biomet family is profoundly saddened by the passing of Dane A. Miller, Ph.D.," wrote current Biomet CEO, Jeff Binder.

"It is impossible in one short statement to give justice to his impact on our company, on our industry, and on the communities where we operate—especially Warsaw and Winona Lake, Indiana. It is also impossible to describe adequately Dane's impact on the lives of our team members and on the members of the orthopaedic community with whom he worked and developed friendships over many years."

He added that Dane used his biomedical engineering background to drive advancements in biomaterials and implant design that helped patients around the world.

On the cultural side, Binder wrote, "Dane thought of himself as an 'environmental engineer,' and he fostered an ownership culture where team members were empowered to make decisions, take reasonable risks and actively respond to the needs of our customers and their patients. Dane was one of industry's first leaders to use the phrase 'team member' to describe his company's employees. He once told me that the best description of Biomet's culture was that of a 'can-do family.'"

February 20th Memorial Service

"A great man has gone to be with the Lord," said a statement from Grace College where a Memorial Service to celebrate Dane's life will be held on February 20, 2015 at the Manahan Orthopaedic Capital Center. The service will be streamed live at: http://www.grace.edu/dane-miller

"We know that he and his wife, Mary Louise, have impacted many of you personally…We are so thankful for the life Dane led while on earth. His legacy will have a lasting impact on the entire community.

The dream born on the sailing boat remains alive. ♦

The Myth of the $87 Billion Knee Replacement Market

BY ROBIN YOUNG

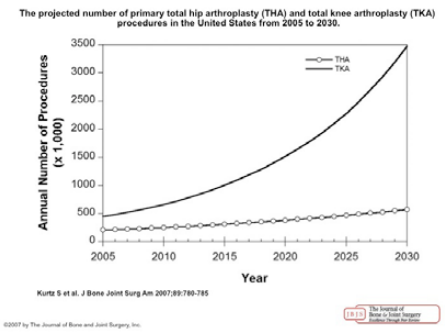
Spreadsheets are dangerous. In the wrong hands, they can become runaway trains—careening along a single trajectory to ridiculous heights or ignominious bottoms. And the more complex the calculations, the more reasonable the direction appears. As if complexity improved the probability of success or reduced the presence of risk.

Yes, spreadsheets can be downright diabolical.

Case in point. *Journal of Bone and Joint Surgery* (*JBJS*). April, 2007. Authors Kurtz S, Ong K, Lau E, Mowat F and Halpern M. Title: *Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030.*

According to the authors, by 2015 there should be approximately 1 million knee arthroplasties worldwide. And by 2030, that number—moving along a Poisson regression track—should reach 3.48 million. Assuming approximately $25,000 per knee replacement, that is an $87 billion market.

Here's the chart of those projections. Isn't that a smooth line? So clear. So direct.



Journal of Bone and Joint Surgery

Wikimedia Commons and Dave Hagarth

What could possibly put wiggle into those projections?

Alternatives to Total Knee Replacement

For both primary care physicians and orthopedic surgeons American Academy of Orthopaedic Surgeons (AAOS) has guidelines for how to treat patients with knee osteoarthritis (OA).

Those guidelines recommend four treatments for knee OA.

1. Lose weight
2. Low-impact aerobic exercise
3. Intra-articular corticosteroids (for short-term relief)
4. Non-steroidal anti-inflammatory drugs (NSAIDs – like 3,000 mg of acetaminophen each day)

But not these 5 treatments:

1. Intra-articular hyaluronic acid (HA) injections
2. Custom made lateral wedge insoles
3. Glucosamine and/or chondroitin sulfate or hydrochloride
4. Needle lavage
5. Acupuncture

Three treatments were neither recommended for or against:

1. Bracing
2. Growth factor injections
3. Platelet rich plasma (PRP)

OK. So, lose weight, exercise, have a steroid and a non-steroid anti-inflammatory like acetaminophen. And maybe try bracing, growth factors or PRP.

Then…total knee surgery?

The Catch 22

But life in a busy clinic doesn't always fit neatly into such guidelines. Here's the view from one busy orthopedist,

Vinod Dasa, M.D., associate professor of Clinical Orthopaedics at LSU; "Most patients, by the time they see the orthopedic surgeon, have already tried weight loss, exercise, and NSAIDs/pain medications. Oftentimes patients say they can't exercise in order to lose the weight. From the physician's perspective reconciling what the patient is capable of doing with the AAOS guidelines only leaves us with NSAIDs and pain medications."

Like intra-articular corticosteroid injections?

Says Dr. Dasa: "Steroid injections (per the AAOS recommendations) are considered to be inconclusive which is somewhat confusing because this is one of the main treatments for rheumatology, primary care, and orthopedics for knee OA. Essentially when a patient comes to see me they've exhausted the first line treatments recommended by the AAOS."

OK. So the patient already tried to lose weight, is taking NSAIDs and can't exercise.

Then…total knee surgery?

The Role of Injections for Knee OA

Injections cost anywhere from $100 to $2,000 depending on whether the injectate is a corticosteroid, hyaluronic acid (HA), the patient's own platelet rich plasma (PRP), growth factors and whether it is performed outpatient or inpatient.

Last year, tens of thousands of physicians (or their staff) performed tens of millions of injections into OA knees in the fervent hope of relieving each patient's pain and stiffness—and delaying, perhaps, the vastly more expensive ($20-60k) and traumatic knee surgery.

Every candidate for knee surgery has, we'd be so bold as to say, had one or more knee injections.

But not every recipient of a knee injection goes on to have total knee surgery.

Checking the PearlDiver Technologies, Inc. (PD) data base (www.pearldiverinc.com), we find that of 198,391 Medicare patients who'd had a diagnosis of OA of the knee, 1 out of 12 (8.1%) returned to have a total knee replacement within 24 months. The following table gives the results of the PearlDiver analysis.

Again, Dr. Dasa: "As far as hyaluronic acid injections, I think most physicians

Patient Group	Time Period	Knee Replacement	% of Population with Knee Replaceme
Medicare			
	Hyaluronan Base Population	198,391	
	3 Months	2,140	1.1%
	6 Months	6,821	3.4%
	9 Months	10,321	5.2%
	12 Months	12,559	6.3%
	18 Months	14,806	7.5%
	24 Months	15,975	8.1%

PearlDiver Technologies, Inc.

will tell you their experience is quite different from what the AAOS guidelines recommend. In my opinion, these injections do work and work very well in the appropriate patient population i.e. isolated mild/moderate knee OA."

The Acid Test – What Do Payers Think?

CMS' (Centers for Medicare and Medicaid Services) partner agency, the Agency for Healthcare Research and Quality (AHRQ) Technology Assessment (TA) program, issued an assessment report of HA in late December 2014 where they reviewed 141 peer reviewed studies regarding HA and concluded:

- There is not enough evidence that HA can or cannot reduce the rate of knee replacement surgery
- The strength of evidence that HA improved knee function was low
- The evidence showed that HA relieved knee pain but that it was of minimal clinical importance
- The evidence that HA improves a patient's quality of life was insufficient

When added to AAOS' comment from June 2013: "We cannot recommend using hyaluronic acid (HA) for patients with symptomatic OA of the knee,"—a conclusion that came with a "Strong" rating because the evidence supporting that clinical guidance came from 3 high-quality and 11 moderate-quality research studies that met AAOS's inclusion criteria—the natural question is, what do payers think?

That is the acid test.

And so far, it appears, payers are for the most part paying for HA injections. UnitedHealthcare. Medicare Advantage. Aetna. And so forth.

The physicians who use HA, as Dr. Dasa pointed out, in the appropriate patient populations—i.e., mild/moderate knee OA—want to keep it as part of their treatment plans.

And they are making their voices heard at the payers.

The Role of Injections for Knee OA

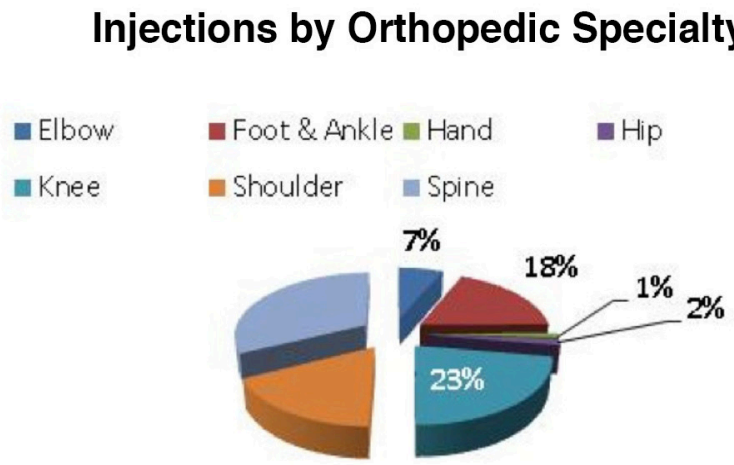
While exact numbers may be difficult to come by, using Medicare and Healthcare Cost and Utilization Project (HCUP) data, PearlDiver analysts estimated some time back that there were about 35 million injections performed annually in orthopedics.

According to PearlDiver's data, injections into the knee comprised 23% of the orthopedic specialty total. Spine, at 32%, used the most injections of all orthopedic specialties.

Injections are motherhood and apple pie for physicians treating orthopedic pain problems.

Checking with *WebMD*, one of the largest patient reference sites on the Internet, here is the advice patients receive regarding injections:

> "If you have knee osteoarthritis… One option is to inject medication into your knee.



PearlDiver Technologies, Inc.

There are different types of injections, and they're an important part of treating knee osteoarthritis for many people, says Roy Altman, M.D., an osteoarthritis expert at UCLA. Injections can be especially helpful for people who haven't gotten relief from NSAIDs like ibuprofen, or people who can't take those drugs due to side effects."

"Corticosteroid injections are useful for treating flare-ups of OA pain and swelling with fluid buildup in the knee, says John Richmond, M.D., an orthopedic surgeon at the New England Baptist Hospital in Boston.

These injections help relieve symptoms by reducing inflammation in the joint. But they're not a perfect solution in every case.

In most cases, Richmond tells his patients they can use these shots two to three times a year. Using them too often may damage cells in the knee that make cartilage."

Your doctor can inject more hyaluronic acid into your knee to boost the supply.

Studies have shown that hyaluronic acid injections may help more than pain-relief medications for some people with OA. Other studies have shown they may improve symptoms as well as corticosteroid injections do. If you're considering hyaluronic acid injections, keep these in mind:

Another treatment getting attention is platelet-rich plasma (PRP). This requires drawing a sample of your blood and processing it to create a fluid that contains a higher-than-normal amount of platelets, tiny disks that help clot the blood. The doctor then injects the fluid back into your injured area.

The platelets in your blood contain natural chemicals that help heal injuries. Doctors have been treating other problems—like tendon damage—for more than a decade with PRP.

However, experts still know little about whether it works for knee osteoarthritis."

And, following this advice, patients with knee pain are a mainstay of orthopedic and pain practices in the U.S. Not to modify the disease, but rather to, hopefully, restore at least some amount of normalcy to life.

For a long, long time this has been the treatment paradigm. In 2007, when the *JBJS* authors were calculating future knee replacement volumes this was the frame of reference they were operating in.

Making a Myth Come True

A knee replacement, at $20,000 – $60,000 per surgery, is a capital investment—as, if memory serves, Warren Buffett once quipped. A knee injection, at $200-$2,000 is an expense. The former, like any good capital investment, should last 20 years or longer. The latter, like any wise expense, should delay the need for capital investment by a couple years or more.

Knee injections, it would seem, are a key part of the orthopedic eco-system—and for many practitioners and patients—wise expense decisions. What happens, however, if knee injections lose the support of both AAOS and AHRQ—especially such a mainstay as HA?

What is the alternative…3.5 million knee replacements at an $87 billion price tag? ♦

Gunnar Andersson, M.D., Retires // NFL Medicine Pushing Towards the Future // Rush Ortho Jumps into Urgent Care

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

Gunnar Andersson, M.D., Retires
He first came to the U.S. on a research fellowship in 1976 and rose to be the president of the Orthopaedic Research Society in 2000. Gunnar Andersson, M.D., Chairman Emeritus of Orthopedic Surgery at Midwest Orthopaedics at Rush, has just retired at the age of 72. We stole a few minutes of his time, however, and asked him to reflect on his years of service to the orthopedic community. As for the most important thing that he has created at Rush, Dr. Andersson told *OTW*, "It's the fact that I was able to maintain the private practice model in an academic setting while being successful in education and research. I am strongly supportive of the private practice model in patient care. To be successful in competing with other private groups and academic centers educational and research excellence is critical. While being hugely successful clinically we have been able to attract the best residents and fellows in the country and being one of the best funded and most successful research groups in orthopedics. It's not my doing, but I am very proud of the accomplishments of my department members."

"I'm also pleased to have built a premier practice group by careful recruitment and support for all missions in an academic practice. Recruitment is critical and strongly dependent on buy in from the practice partners and their help in finding the right people. Additionally, I have created a destination for orthopaedic patients and a home for the surgeons by building a private office building on Rush campus with availability of ancillary services. This could not have happened without the support of Rush University Medical Center, whose administrators eventually realized that this was beneficial to both parties—the group and the medical center. They leased us land and allowed us to build."

Asked about one of his fondest memories of his time at Rush, Dr. Andersson noted, "I have a 30/30 memory, meaning I remember everything from 30 years ago and everything from the last 30 seconds. Since I have been at Rush for 30 years I cannot remember the fondest memory. I only remember good things!! The success of surgical interventions is highest on my list, followed by the recruitment of wonderful partners, graduation of well trained residents and fellows, and the success of research and new discoveries. Having a period as president of the medical staff, senior vice president of medical affairs and vice dean all created memorable experiences."

When we asked Dr. Andersson what gives him the most hope for the future of orthopedics, he reflected, "The strong technology advancement including biologic solutions and minimally invasive surgical procedures have an opportunity to change the profession from the old description 'big hands and small brains' to something much more sophisticated and successful. Will we be able to cure the most common orthopedic problems—arthritis, back pain, overuse injuries and traumatic injuries? Probably not…but we will make huge advances."

Gunnar Andersson, M.D.

As for what gives him pause him about the future of orthopedics, Dr. Andersson added, "I am concerned that the private practice model is disappearing. Hospitals are buying physicians and the graduating residents are increasingly choosing an employed position. There are short term benefits, but long term physician independence will suffer. And developing new technology is increasingly difficult because of cost and regulatory difficulties. Venture capital in orthopedics is drying up because the return on investment is unpredictable. Advancements outside the U.S. cannot easily transfer to our patients. Funding for research is a tremendous problem. NIH [National Institutes of Health] has had no significant increase in its budget for almost a decade and the cost of doing research keeps increasing. I fear we are losing a generation of researchers who are frustrated that their efforts do not result in funding."

"As for me, I will not retire from many aspects of my professional activities. I will continue to consult, participate in meeting activities, and in research activities. And I will continue to publish. I will however have the luxury of spending more time with my family, travel with my wife, work on my golf game (which needs a lot of work) and spend a lot of time outdoors."

Technology Pushing NFL Into the Future What are the latest technological advances helping team doctors do their jobs? Find out from Matthew Matava, M.D., president of the NFL Physicians Society. He tells *OTW*, "Improved communication and a more rapid response pretty much sums up our most recent progress in the technological realm. The sidelines are so crowded—53 players, 10 coaches, trainers, the media, etc.—we needed someone above it all to assess the field from an enhance perspective. We now have what's called an 'eye in the sky'—a certified athletic trainer at the press box level who peruses the entire field. Those of us on the sidelines can't always see an injury until after the fact, so the trainer calls down to the sidelines and speaks to the head physician. He might say, '#42 was staggering as he came out of the tackle.' Then I can pull the player aside and question him or use the new sideline video monitor to review the event from multiple angles, in slow motion, and even backwards."

"Often, the player doesn't know what exactly is causing the pain. He may be holding his shoulder, but in reality it could be an elbow injury. This is why it is so helpful to see the replay…it can be useful in guiding the questioning and examination of the player."

"In addition, we now have two-way walkie talkies and everyone on the

medical team has headsets that allow for immediate communication. If I'm at the 20 yard line and the head athletic trainer is at the other end of the field evaluating a player, then he doesn't have to send someone to me to give me that information. As of just one year ago we didn't have these walkie talkies. Also, if the player goes for an X-ray and we are wondering about his status, I can call someone in X-ray on the walkie talkie and say, 'What does it show?' Then I can relay that to the head coach and the athletic trainer."

"Another significant technological advance for the NFL has been the league-wide use of electronic medical records (EMR). We have each player's records on eClinicalWorks. If a player is traded from a team or gets cut then the original team no longer has access to the records. The players were initially concerned about their information being leaked, but the firewalls have proven to be more secure than paper records."

"If there is an injury, we also now have electronic hand-held tablets on the sidelines containing all of the players' prior orthopedic injuries. This involves a real time app where in five minutes we can thoroughly assess a player for a concussion and can compare the current injury to the previous baseline testing scores. Other health information is there as well (medication allergies, etc.) in the event that the player has to be transported to the hospital."

"In terms of research, investigators are placing sensors in helmets in order to track the forces involved in hits to the head. Unfortunately, we don't yet know what the threshold is for injury. If we put a monitor on a helmet and after 6 games and 200 head hits there might be 20% rotational hits, 30% direct blows, and 40% to the top of the head…but we don't have a correlation as to which of the hits are relevant and what is the threshold that will lead to long term injury.

Pronto Ortho From Rush Why stand around moaning in an ER when you can receive immediate care at a high quality facility? Midwest Orthopaedics at Rush (MOR) is now offering such treatment. MOR, doctors to the Chicago Bulls and the Chicago White Sox, have a new option for patients—OrthoCare Now—available to treat everything from simple injuries, such as sprains, strains and muscle pulls, to more complex ones.

Mary F. Rodts, DNP, CNP, ONC, FAAN is chief operating officer at Midwest Orthopaedics at Rush. She tells *OTW*, "We saw that our patients were trying to access our services on evenings and weekends, and we wanted to find a way to be more readily available to them. Now, instead of waiting in the ER for several hours or going to multiple doctors before getting to an orthopedic surgeon, they can see one of our providers right away."

"The clinic is open until 7 p.m. on weekdays and 8 a.m. to noon on Saturdays, and can accommodate everything from sprains, strains and muscle pulls, to fractures and concussions. This is not to replace emergency services for major trauma. Those patients should still seek care at an emergency room."

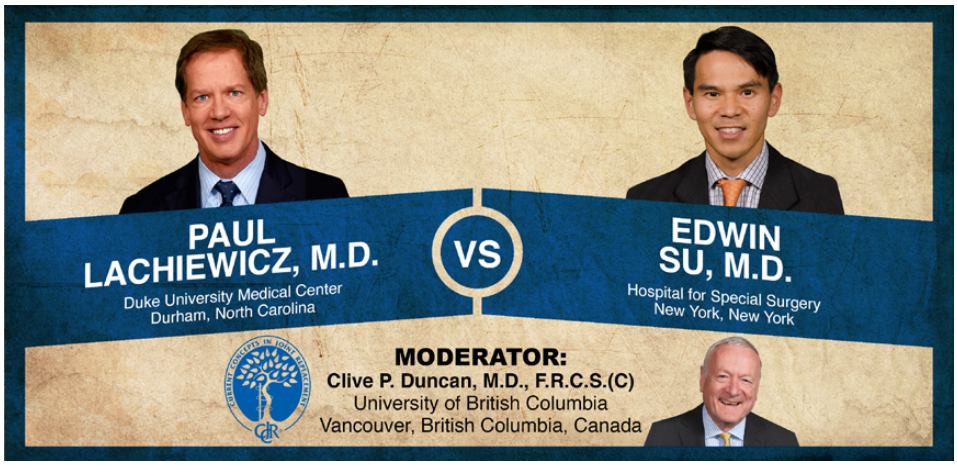
"The biggest challenge to organizing this was having the right team available to our patients. We were able to establish our doctor and advanced practitioner coverage as well all other services (X-ray, casting, bracing, MRI, etc.)"

"OrthoCare Now will help us to continue to provide the correct care at the correct time. We are excited that we will be able to offer this new service to orthopedic patients in the Chicago area." ♦

Lachiewicz, Su Debate Dual Mobility in Primary Hip Replacement

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

"All the benefits to dual mobility are theoretical," argues Paul Lachiewicz. "There's little lab data—except from the manufacturers." "Dual mobility has a proven track record," counters Edwin Su. "It could be indicated for primary hip because it provides greater stability and it can reduce your dislocation rate to less than 1%. I would consider it in high risk, primary cases."



Current Concepts in Joint Replacement/RRY Photo Creation

This week's Orthopaedic Crossfire® debate is "Dual Mobility in Primary THA: Yet to be Justified." For the proposition is Paul Lachiewicz, M.D. from Duke University Medical Center in Durham, North Carolina. Edwin Su, M.D. of Hospital for Special Surgery in New York is in opposition. Moderating is Clive P. Duncan, M.D., F.R.C.S.(C) of the University of British Columbia.

Dr. Lachiewicz: "Dual mobility components should not be routinely used in primary total hip arthroplasty (THA). The basic issue is, 'What should we do to prevent dislocation in primary THA?' You need correct acetabular placement (what is a 'safe zone' is debatable). You want to restore leg length and offset, and if you do a posterior approach, you want to repair the capsule."

"The first dual mobility hip tried to combine the low friction of a Charnley with a 22mm head against a polyethylene, larger ball that articulated with stainless steel. The supposed biomechanics states, 'There is greater range of motion (ROM) if you have two articulations.' I will submit that there is a third articulation with contact between the neck and polyethylene. There is supposedly increased jump distance with a large polyethylene head, and there's very little lab data—except from the manufacturers."

"However, last year a 3D CT cadaver model came out, stating that there is no difference in ROM between the 36mm head and a dual mobility. The other interesting thing is that there is little lab data on wear. This is a new concept, namely, the inner polyethylene ball and the outer polyethylene surface."

"I think there is a place for these in revision situations, especially for recurrent dislocation. What about in primary total hips? Yes, perhaps high risk patients such as those with fractures and neurological disorders."

"The initial data on dual mobility came from Europe. In a study of nearly 400 hips with a high survival rate, an unusual and new complication reared its head—intraprosthetic dislocation. In this series it was only 14 hips, however, Moussa Hamadouche has a series of 168 hips with no dislocations. But at 5-7 years there were four intraprosthetic dislocations, presumably due to wear and impingement; all required revision."

"There is recent data from the lab at Massachusetts General Hospital looking at whether there was iliopsoas impingement with dual mobility. In one patient the multiple wires are in a poly head, and the single wire (anteriorly) is in the psoas tendon. The radiograph supposedly shows impingement or pressure on the psoas tendon. Could this lead to persistent groin pain in patients who have dual mobility in primary situations?"

"At the closed meeting of the 2014 Hip Society gathering Peter Sharkey presented 100 modular dual mobility hips, most of which had 22mm metal heads. At only two years of follow up 13 patients had elevated cobalt levels, and 7 had elevated chromium levels."

"They can still dislocate; there are those who dislocate the metal head from the polyethylene. You can't eliminate all dislocations, but in our series we had no recurrence and no revisions. We looked at this at a minimum of five years, and found no late dislocations and no liner fractures. We're looking at our 10 year results now and we have not seen anyone with trunionosis or component loosening. Osteolysis has been an issue with highly crosslinked polyethylene (XLPE), but as of now we don't see any major difference with the smaller heads."

"So I think dual mobility in primary THA is yet to be justified. Yes, there are theoretical advantages, and I use them for recurrent dislocation, but not for primary cases."

Dr. Su: "The dual mobility principle was introduced in the 1970s and it combines Charnley's principle of low friction arthroplasty with the McKee-Farrar theory of a large head. Both articulations can move, theoretically dividing the possibility of friction, wear and dislocation. And most mobility—at least in simulator studies—comes from the smaller inner bearing. I believe that dual mobility can impart an increased hip stability, provide excellent ROM, and reduce impingement (if you have a greater head/neck ratio)."

"Dislocation as a reason for hip revision is on the rise, probably because patients are younger and more active these days. Constrained liners have been proposed as a solution for dislocation, however most would agree that dual mobility is preferable to constrained liners because the latter have multiple interfaces that can fail."

"My indications for a dual mobility hip in a primary setting are those patients who are at risk for dislocation. The current designs could be anatomic. In one such design it is sided for right and left; there is a cut-out for the iliopsoas tendon in order to avoid soft tissue impingement. It has a large head size and the thickness of the cup is about 3mm, so there's a 6mm differential between the head and the cup."

"The inner head is large diameter and the inner head is constrained within this outer polyethylene head. The inner head could be ceramic or cobalt chrome; heads now are generally highly crosslinked polyethylene and the construct is assembled on the back table to ensure that the head isn't going to come out of the polyethylene. Most of the movement is coming from the inner bearing and when it gets to the extremes then

the movement comes from the outer bearing."

"With the dual mobility shell the joint is more stable (large head) and you can put the cup more anatomically with respect to version. The disadvantages of dual mobility—with the solid one at least—is that you can't visualize the acetabular floor, you can't use screws with the anatomic version, you can have intraprosthetic dislocation, and there's a question of increased wear because you have two interfaces."

"We believe that a larger head would provide more stability because of a greater jump distance. A (manufacturer) study on wear in a simulator looked at the highly crosslinked outer bearing dual mobility liners—three different models. One of the groups was microseparation and the other was with third body particles; they found that the dual mobility construct did have a high tolerance for wear (although it was more increased in the microseparation group)."

"It's not suggested that you put your cups in at 65 degrees, but if you do put them in at a higher elevation angle than intended, there is wear reduction compared to a metal-metal bearing. One study with 10 year follow-up showed no dislocations in over 200 dual mobility hips. One socket was revised for loosening at nine years, but the design was a macro texture ongrowth surface."

"Another study involved 240 dual mobility hips with a mean follow-up of over 20 years; there were no dislocations of the outer bearing. However, they did find a 4% intraprosthetic dislocation rate and some revisions for socket revision because it was a smooth design. The stem used has a very large neck and it's thought that the intraprosthetic dislocations were due to impingement of that thick neck against the poly liner. Dr. Sculco has done over 400 of these with two year follow-up and has not had any dislocations in the primary hip setting."

Moderator Duncan: "Paul?"

Dr. Lachiewicz: "Tom Sculco and Ed are superb surgeons and they can do the non modular dual mobility shell successfully. But if there is any type of anatomic abnormality then you probably need a shell with screws. Then that leads to another articulation of titanium against cobalt-chrome. I'm very concerned about other possible mechanisms of failure that we haven't even thought about."

Dr. Su: "Paul makes a good point. The solid monoblock version would be safer as far as reducing the interfaces. That's what we propose be used in the primary setting. It gives you the largest head size possible."

Dr. Duncan: "Is one of the take home messages that you must avoid the use of a 22mm head?"

Dr. Su: "I'm not sure I would go that far. You are constrained by the cup size, so there are some cases where we've used the 22mm inner bearing. My point was that the design with the intraprosthetic dislocations to a high degree had a very large neck size. So the head/neck ratio was very poor."

Dr. Duncan: "Paul, when you're approaching the problem of a recurrent dislocator how do you decide between a constrained cup that will capture the head versus a dual mobility?"

Dr. Lachiewicz: "The indications are still evolving. I reserve constrained liners for very elderly patients, those with dementia, and late dislocations where you cannot find a reason for it. I'm using the dual mobility more in young patients, but that's a moving target with regards to dislocations."

Dr. Duncan: "Ten years ago young patients came to us with a large head metal-metal because they were obsessed with dislocation…they're now coming to us for dual mobility because the information about low risk of dislocation has reached them. Anyone want to share an editorial on this?"

Dr. Lachiewicz: "I haven't seen that yet. I generally would dissuade them because we don't have long term follow-up in the U.S. on these designs."

Dr. Su: "We are getting these requests. I agree with Paul…caution them because of a lack of long term data. I'd be concerned about using this in younger patients because of wear. Theoretically it would be better because of XLPE, but all of the studies done in the past were in older patients."

Moderator Duncan: "Thank you, gentlemen." ♦

COMPANY

DePuy Synthes Acquires MIS High-Def Visualization Company

Olive Medical Corporation, a Utah-based privately held manufacturer of high definition (HD) visualization systems for minimally invasive surgery (MIS), has been acquired by DePuy Synthes.

The 20 person company was founded in 2009 and provides the HD equipment to the operating room and physician offices. Its equipment has been sold in 20 countries and all manufacturing is done in the U.S.

A February 10, 2015 announcement from DePuy Synthes said Olive Medical's visualization portfolio "augments the DePuy Synthes Mitek Sports Medicine arthroscopy line" and will allow the company to enter the arthroscopic visualization market to serve patients with shoulder, knee, hip, and small joint pain or injury.

Olive Medical's systems, according to the company, "complement the Mitek Sports Medicine procedural enablement portfolio, which includes the VAPR Radiofrequency Systems with electrodes used for tissue ablation and coagulation, and the FMS fluid management and tissue debridement system, which maximizes and maintains optimal visualization along with integrated soft tissue and bone shaving functionality. Both the VAPR and FMS systems are used alongside visualization in the operating room."

The combined portfolio and capabilities of the two companies will allow DePuy Synthes to continue development of "cost-effective" and "advanced visualization" solutions, said the company statement. Joining DePuy Synthes allows the Olive Medical technology to be provided through the larger company's extensive global distribution system.

Cost-Containment Focus

"At Olive, we continue to keep cost-containment as our focus," said Olive Medical Chairman Michael Brown in a 2012 press release. "Our endoscope repair program, which has been FDA registered since 1997, provides a significant cost savings over that of the original manufacturer's repair and exchange programs." Customers can purchase just a camera system, or an entire endoscopic tower.

The company's True HD Surgical Camera was selected as the 1st Place winner in the 2012 Visualization and Communication category for the Excellence in Surgical Product Awards.

No financial terms of the deal were disclosed. — *WE*

HD Video System/Olive Medical Corporation

Zimmer's 2nd Try for Euro Biomet Merger Approval

Zimmer Holdings, Inc. has made a second proposal to the European Commission (EC) to get the regulators to approve their planned acquisition of Biomet, Inc.

Logos courtesy of Zimmer and Biomet

The company announced on February 10, 2015, that the latest "revised remedy package" is generally consistent with the first divestiture proposal submitted to the EC in December. The original proposal called for the divestiture of one unicompartmental knee brand and one elbow brand in Europe and the divestiture of one total knee brand in two European Union (EU) countries.

The EC had effectively stopped the clock on its review of the deal on December 2, 2014 after some concerns. That's when Zimmer offered the remedy package. The EC "market tested" the initial proposal and had some concerns. Hence, the revised proposal.

The company also said the formal deadline for the EC's decision has been moved to May 26, 2015. However, the company still expects to close the deal before the end of March 2015. The company still needs approval from the U.S. Federal Trade Commission and Japan's Fair Trade Commission to close the deal.

Zimmer noted in its announcement that it is "pleased with and encouraged by the progress to date with the overall regulatory process." — *WE*

Baxano Completes Auction of Spine Portfolio

The auction ended on January 22, 2015 and Baxano Surgical, Inc. successfully completed the sale of its minimally invasive spine products.

Ken Reali, Baxano's president and CEO, told *OTW* on February 6, 2015 that the acquisition of the products is a "testament to the opportunity these technologies have to continue to help patients and drive growth as minimally invasive spine procedures continue to penetrate the spine market."

Auction Winners

Here are the auction winners:

- Amendia, Inc. – io-Flex, io-Tome and bone graft harvester lines
- Choice Spine LP – VEO direct lateral system
- City Surgical LLC – Avance pedicle screw system
- Quandary Medical LLC – AxiaLIF interbody fusion technology and the Vectre facet screw system

Quandary Medical LLC is a newly formed company out of Denver. According to its web site, two out of the three leaders of the company have Ph.D.s and hold the corporate titles of directors of biocreative design and complex visualization.

Reali said Baxano, which was formed by the merger of TranS1, Inc. and Baxano, "started to gain commercial traction in the past few quarters but struggled to gain financing due to reimbursement struggles with AxiaLIF, the original core technology of TranS1, and the impact around the settlement with the government through an OIG [Office of Inspector General] subpoena issued in 2011. While AxiaLIF successfully gained a category I code in 2013 it has not yet been able to gain widespread private payor coverage."

He added that the company settled with the government in 2013 with no admission of any wrongdoing.

According to Reali, the company hired an investment banker, Houlihan Lokey, in September 2014, to begin to look at all of its strategic options. "The company subsequently filed Chapter 11 bankruptcy protection on November 13, 2014, but continued its commercial operations until the successful close of the sales process through what is known as a 363 auction process. The buyers of the products were able to purchase them without any liens, liabilities or encumbrances."

Baxano Employees to Amendia

"The Baxano asset auction presented the perfect opportunity to expand our product portfolio to meet all of our customers' needs across the continuum of care," said Jeff Smith, CEO of Marietta, Georgia-based Amendia, Inc. "We are excited to welcome the Baxano employees, distributors, hospitals and surgeon customers to the Amendia family," said Smith.

ChoiceSpine, LP is based in Knoxville, Tennessee, and City Surgical is in San Francisco. — *WE*

Photo creation by RRY Publications, LLC

BIOLOGICS

Davis Docs Test Do-Everything Device

Surgeons at the University of California, Davis, are testing a device that seems more like a Rube Goldberg invention than a medical one. The item contains a reamer, irrigator, an aspirator system and can also be used for high speed drilling into bone.

Drilling creates heat so the device has to be continually cooled with water. The cooling water runs off the device but it is not considered to be wastewater as it contains materials that are not really waste. The water contains mesenchymal stem cells, hematopoietic and endothelial progenitor cells that can be used to make new blood vessels and potent growth factors for signaling cells to heal wounds and regenerate themselves.

So the wastewater that is not really waste is collected but, since it is too diluted to be useful as it is, it is run through another machine, about the size of a coffee maker (made by SynGen Inc.) that spins it down to isolate the stem cell components.

The idea, according to the *Helio–Orthopaedics Today* writer, is to use the machine in the operating room to rapidly produce a concentration of stem cells that can be delivered to a patient's non-union fracture during a single surgery.

Mark Lee, M.D., an associate professor of orthopaedic surgery at UC Davis said of the device, "its small size and rapid capabilities allow autologous stem cell transplantation to take place during a single operation in the operating room, rather than requiring two procedures separated over a period of weeks. This is a dramatic difference that promises to make a real impact on wound healing and patient recovery." — *BY*

Courtesy of SynGen Inc.

LARGE JOINTS

Here Comes the Drag-on: China Consumes $55 Billion in Devices

El Lae, writing for *Fierce Pharma Asia,* predicts that China's market for medical devices will pass Japan's this year, making its market second only to the United States. Access China Management Consulting wrote that China's market would pass the $55 billion mark this year, a number that is almost double what it was just two years ago.

Wikimedia Commons and Shizhou

According to Lae, China's medical device market began to grow in the 2000's. Prior to that time, from 1990 on, the healthcare market had been growing at the rate of 16% a year. Lae writes that about half of the market relies on imports, dominated by MRI and CAT scan machines.

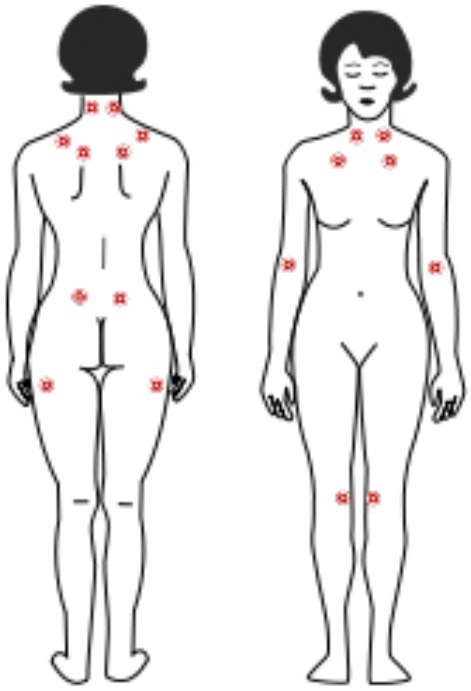
The aging of China's population, a fifth of the world's, has stimulated demand for high tech devices. The country's leaders are working to promote local medical device manufacturers who could supply China's rapidly growing network of hospitals. Concerns have grown over costs of imports and the competition with domestic producers over these high cost devices. — *BY*

Study Questions Arthroplasty for Fibromyalgia Patients

Researchers who studied the pain scores of 635 patients with self-reported fibromyalgia-like symptoms concluded that total hip or knee replacement may not be advisable for those who are experiencing severe hip and/or knee pain.

As reported by Rosemary Frei, writing for *Pain Medicine News,* the study found that patients' self-report survey for the assessment of fibromyalgia was the only statistically significant predictor of patients who went on to experience long-term postoperative pain. These patients also had more dire preoperative characteristics as well as experiencing more anxiety.

Daniel Clauw, M.D., director of the Chronic Pain and Fatigue Research Center at the University of Michigan in Ann Arbor, had found in a previous study that patients' self-reported higher scores predicted increased opioid consumption during their postoperative period. The outcome of the study led some of the researchers to speculate that the survey "may have value in screening for appropriateness for arthroplasty."



Wikimedia Commons and Sav Vas

Other doctors disagreed. Chad Boomershine, M.D., who specializes in the care of people with fibromyalgia, expressed concern that clinicians, reading the study report, might decide that fibromyalgia patients may not be appropriate candidates for knee or hip replacement.

Frei quoted Boomershine, who is assistant clinical professor of medicine at Vanderbilt University School of Medicine, in Nashville, Tennessee, as saying, "I have personal experience with many fibromyalgia patients who have arthroplasty and do quite well, but they offer special challenges. I think this screening would be valuable for identifying patients who should be targeted for better management after surgery and not used to weed out patients to avoid operating. They just need more support and better management after surgery to ensure they have good outcomes."

Lead study author Chad Brummett, M.D., director of clinical anesthesia and research director of pain research in the Department of Anesthesiology, Division of Pain Medicine, at the University of Michigan Medical School in Ann Arbor, told Frei that "he and his colleagues would like to start doing brain imaging on this cohort to see how these patients' postoperative pain scores correlate with abnormalities in the central nervous system." — *BY*

Hospital Guarantees Joint Replacement Surgery

Our Lady of the Lake Regional Medical Center in Baton Rouge, Louisiana, is the first hospital in the U.S. to offer a surgical guarantee for hip and knee replacement surgery.

Courtesy of Our Lady of the Lake Regional Medical Center

According to the news release, the guarantee promises patients, insurance providers and employers that they will not receive any additional bills for costs associated with surgery-related follow-up care that occurs within 30 days of the surgery.

Called the "Value Guarantee," the agreement covers the full range of care—admission, anesthesia, surgery and recovery—for an adult patient's hip or knee replacement. All services must be provided by Our Lady of the Lake and its physician partners.

"We strive to be the leader in quality care in our market and this Value Guarantee is our way of demonstrating quality to everyone we serve including our patients, insurance companies and employers," said CEO Scott Wester. To participate in the guarantee program, the patient must have commercial insurance coverage, and must pledge to be an active participant in his/her care and recovery.

Patients are expected to attend pre-operative education classes and other pre-surgical evaluations as well as adhere to all post-surgery instructions

and follow-up care. The guarantee does not cover costs associated with a failure of the implant.

Wester added, "Our Value Guarantee demonstrates to insurers and employers that we will address the overall cost of care by eliminating the need for post-surgical follow-up care or not charging for this care in the rare instance it is necessary. This guarantee is only possible because our team of skilled physicians and team members have shown the commitment to stand behind their work."

The joint replacement program at Our Lady of the Lake performs more than 1,500 total joint surgeries each year. In 2013, the hospital met or exceeded the quality benchmarks for these surgeries in overall quality, readmissions, mortality and patient experience, reported Wester. — *BY*

Doc Performs TKR in 10 Minutes Flat

In a hurry to get a knee joint replaced? You will soon be able to get one in ten minutes at the RAK Hospital in Dubai, performed by Vikram Shah, M.D. of Shalby Hospitals in India. Shah, who performs the "'zero technique ten-minute total knee replacement (TKR) surgery," has agreed to do the same in a partnership with RAK Hospital in Dubai, beginning in six weeks.

Wikimedia Commons and Magnus Manske

Shah explained his process to writer Suchitra Bajpai Chaudhary of *Gulf News*. "Normally, surgeons take approximately two hours to conduct a TKR surgery," he said. "The usual incision is about seven inches, but my cut is smaller, about 4 inches. When I cut less, there is less bleeding, less pain, and no requirement for blood transfusion, all of which accelerate recovery. I do the surgery under spinal anesthesia which makes recovery quicker."

"I eliminate all occasions of delay that surgeons usually have. Surgeons tend to hold several trials of the joint which takes up at least 15 minutes of extra time. When I make the incision, I complete the soft tissue balancing immediately and after placing the knee only require one trial. My patients begin walking in two hours and climbing steps in seven hours and are discharged from hospital in three days."

Shah's technique, he adds, involves prior planning, implant selection, and patient counseling. He has developed an orthopedic surgeon's needle that can easily pass through both bone and soft tissue, reducing surgery and recovery time.

Shah's success rate, according to Chaudhary, has been high. He has performed 50,000 TKR surgeries so far and he presently averages seven surgeries a day.

Raza Seddiqi, M.D., Executive Director of RAK Hospitals and CEO of Arabian Health Care Group, said: "Medical tourism is booming at our hospital as we receive thousands of tourist patients each month. We feel TKR is a surgery which is much in demand and this revolutionary new technique will be a great attraction for our patients." — *BY*

Doc Replaces Four Joints – Using an Epidural

A medical first took place on January 26, 2015 when Samih Tarabichi, M.D., replaced four joints on a patient simultaneously at Dubai's Burjeel Hospital for Advanced Surgery.

Tarabichi explained the surgery and what lay behind his decision to operate as he did. "The procedure is really rare and has never been performed in the USA or Europe," he pointed out. "The patient was suffering from severe rheumatoid arthritis and it had led to deformity in his knee and hip leaving him crippled.

"In the West, he would have gotten proper care at the onset of the condition. However in this region most seek medical help once the disease has progressed," said Tarabichi. "Initially we planned to do two surgeries—one for his hip and one for his knees. However complications arise when a patient is subject to two surgeries in a week. Also if we had only done the replacement surgery on the knees, over time the deformity would have returned because he couldn't straighten the hip. To ensure these do not happen, the surgeries had to happen simultaneously."

The anesthesiologist, Aruna Varma, M.D., did not use a general anesthetic for the surgery but opted for an epidural so that the patient was able to be interactive during the surgery. Varna said that the doctors optimized the operating time to reduce blood loss and used many blood conservation strategies. They completed the four operations in five hours, doing the knees first before moving on to the hips.

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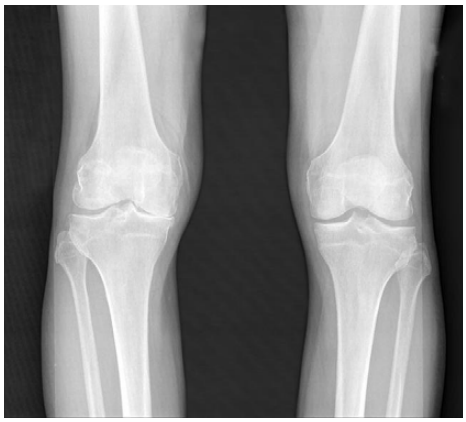
Both Varna and Tarabichi credited the patient's positive attitude as contributing to their decision to go ahead with the surgery and the positive outcome. "I had complete faith in the Doctor that the surgery would go well, said the patient, a 65-year-old man from Kuwait. He added, "I want to be able to pray, to prostrate before God. Once I am up and running, I also want to invite my entire family and host a big feast," he said.

Doctors have started the patient on physiotherapy. Though he will start out using a walker, they hope to have him walking without assistance in three to four weeks. — *BY*

Fluorescent Molecule Diagnoses, Monitors OA

At Tufts University, a team of researchers is reporting a "world's first"… the discovery that near-infrared fluorescence can be used to detect osteoarthritis changes over time. Specifically, they successfully tracked the development of osteoarthritis (OA) in mice with a fluorescent molecule "probe" that brightened as the disease progressed. The researchers—from Tufts University School of Medicine (TUSM) and the Sackler School of Graduate Biomedical Sciences at Tufts—indicated that the fluorescent molecule detected cartilage loss in the joint.



National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

"Patients are frequently in pain by the time osteoarthritis is diagnosed. The imaging tests most frequently used, X-rays, don't indicate the level of pain or allow us to directly see the amount of cartilage loss, which is a challenge for physicians and patients," said co-first author Averi A. Leahy, B.A., an M.D./Ph.D. student in the medical scientist training program at TUSM and the Sackler School, in the February 3, 2015 news release.

"The fluorescent probe made it easy to see the activities that lead to cartilage

breakdown in the initial and moderate stages of osteoarthritis, which is needed for early detection and adequate monitoring of the disease. To measure the probe's signal, we used an optical imaging system, to non-invasively look inside the knee," said co-first author Shadi A. Esfahani, M.D., M.P.H., postdoctoral fellow in the division of nuclear medicine and molecular imaging at Massachusetts General Hospital, and in the department of radiology at Harvard Medical School.

One group of mice—54 knees with OA—was given pain medication. The healthy, left knees of the mice served as the control group. Over two months the researchers imaged each knee every two weeks; they found that the probe's signal became brighter in the injured right knee each time the knee was imaged. The probe emitted a lower signal in the healthy left knee, and did not increase significantly over time.

The corresponding and senior author is Li Zeng, Ph.D., associate professor in the department of integrative physiology and pathobiology at TUSM, and member of the cellular, molecular and developmental biology program faculty at the Sackler School. The work was done in collaboration with Umar Mahmood, M.D., Ph.D., director of the Center for Translational Nuclear Medicine and Molecular Imaging, co-director of Nuclear Medicine and Molecular Imaging, both at Massachusetts General Hospital; and associate professor in the department of radiology at Harvard Medical School.

As a next step the researchers will monitor the fluorescent probe over a longer period of time to determine whether the same results are produced during the late stages of OA. — *EH*

SPINE

Titan Spine: 510(k) for Endoskeleton TCS

Titan Spine, LLC is celebrating the receipt of a 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the release its Endoskeleton TCS, an interbody fusion device for the cervical spine with integrated fixation.

The TCS utilizes Titan's proprietary surface technology. It is part of the fusion process in that it creates an osteogenic response to the implant's topography. According to the February 12, 2015 news release, "The topography consists of a unique combination of roughened topographies at the macro, micro, and cellular levels. This unique combination of surface topographies is designed to create an optimal host-bone response and actively participate in the fusion process by promoting the upregulation of osteogenic and angiogenic factors necessary for bone growth, encouraging natural production of bone morphogenetic proteins (BMPs), and creating the potential for a faster and more robust fusion."

Titan President Kevin Gemas commented, "We are proud to launch the Endoskeleton TCS as the latest addition to our surface engineered interbody device portfolio that continues to challenge the status quo in the interbody fusion marketplace. Like the rest of our products, the TCS is designed to benefit patients by affecting their healing process where it matters most—at the cellular level. The roughened surface technology featured on the TCS is created through a proprietary process that has been shown to produce a superior environment for bone growth at the cellular level when compared to PEEK. In addition, it has several advantages compared to PEEK devices with titanium plasma spray (TPS) coated devices. Most importantly, our surface is created through a proprietary subtractive process rather than an additive coating, which eliminates the potential for delamination and/or particulate debris when compared to products with a PEEK-titanium interface."

"The Endoskeleton TCS device is designed for integrated fixation with two surface-enhanced screws that provide for immediate implant mechanical stability. The screws incorporate an anti-backout feature that do not lock the screws to the implant and allow up to 39 degrees of medial-lateral (M/L) and 29 degrees of anterior-posterior (A/P) angulation post-implantation."

Titan Spine, LLC

Chief Medical Officer Paul Slosar, M.D. performed the first surgery using the Endoskeleton TCS on February 9, 2015 at Saint Francis Memorial Hospital in San Francisco, California. Dr. Slosar commented to *OTW,* "One of our biggest challenges we encountered while designing the TCS was to maintain the features of our standalone ALIF device that work well while adding an anti-backout feature to the screws. Specifically, we wanted to retain our macro anti-expulsion surface, a large hole that allows for variable angle screw trajectory, and a screw that acts independently of the cage. Using these design criteria as a starting point, our engineers were then able to incorporate an anti-backout feature consisting of an innovative collar on the screw head that deploys after crossing past a pinch point in the screw hole during insertion. This provides for a screw that is easy to insert, does not add profile to the implant, and acts as a solid anti-backout feature." — *EH*

SPORTS MEDICINE

New Sports Medicine Center Planned

The Carle Foundation, a not-for-profit, integrated healthcare system based in east central Illinois (18 outpatient locations and 2 hospitals) has announced plans to build a $23 million outpatient orthopedic and sports medicine center in the University of Illinois Research Park in Champaign, according to a report in the Champaign-Urbana *News Gazette.*

The foundation, which will celebrate its 100th anniversary in 2018, is presently providing orthopedic and sports medicine services in two separate locations. The new plans are to construct a two-story, 52,000 square foot facility will include a 32,800 square foot clinical area with 66 exam rooms, a therapy gym and x-ray rooms as well as a 19,194 square-foot non-clinical area.

The newspaper reports that the Carle Foundation has filed an application with the Illinois Health Facilities and Services Review Board for approval of the project.

In 2014, Carle Foundation was named one of America's 100 Best Hospitals by Healthgrades, the nation's leading online resource that helps consumers search, compare and connect with physicians and hospitals. The areas where Carle Foundation received its highest marks were in critical care, neurosciences, and gastrointestinal care. — *BY*

Courtesy of Carle Foundation

Orthopedics This Week | RRY Publications LLC

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