VOLUME 14, ISSUE 3 | JANUARY 16, 2018

Orthopedics This Week

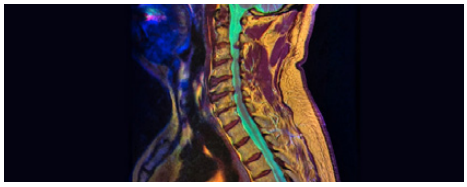
WEEK IN REVIEW

4 Top Hip and Knee Surgery Hospitals in America – Per CMS >> Best hospital for total hip or knee surgery? CMS, which pays for more arthroplasties than any other single payer, has answers. The agency just released hospital performance data. Here are their picks for the best hip/knee surgery providers. One surprise, nearly all are NOT in major metropolitan centers.

11 Rodriguez v. Springer: The Anterior Approach: *Better, Faster, Safer* >> Finally, a fair, balanced, fact-based and experiential debate about anterior hip surgery. Not for everyone. Not for every patient. Has clear advantages…for a short while. But is that what hip arthroplasty is all about? Short term outcomes? No spin zone here. One of the best anterior hip debates yet.

15 Did FDA Panel Make a Mistake on Barricaid Vote >> Did the recent FDA panel considering Intrinsic's Barricaid make a mistake? In reviewing both the FDA letter, the Barricaid's study and Instrinsic's health economics data, it appears that the panel may have missed the forest for the trees. Read this and see if you agree.

17 New Spine Study: When Images Don't Match Symptoms; New Tobramycin Study; Machine Learning Transforms Meniscal Imaging >> Major new spine study specifies what to do when radiographic images don't match clinical symptoms. Researchers from the Spine Hospital at New York Presbyterian document that tobramycin eradicates *Escherichia coli* (E. Coli) in a rabbit model. New study incorporated advanced machine learning finds that it transforms meniscal imaging and diagnosis.



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: Earnings season is still a few weeks away. Meantime the global economy is continuing to show remarkable strength. The Euro hit a fresh three-year high as optimism over jobs, profits and sales strengthens even further. Stock in Asia, Europe and the USA reaching new highs routinely—even as the talk of more restrictive central banker policies dominates the financial press. Even Japan's central banker, Haruhiko Kuroda, jumped on the bull economy bandwagon this week. No recession in Japan. It's grow, grow, grow.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Zimmer Biomet	22.28%	7.56%	On December 18 the FDA granted ZBH approval for its Sidus Stemless shoulder implant. That is the first competitor to Wright's Simpliciti and is a major boost for ZBH.
2	4	ConMed	8.92	10.94	CNMD hires Todd W. Garner as executive vice president and chief financial officer, effective immediately. Garner comes to CNMD from C.R. Bard where he served as VP investor relations and controller.
3	3	Medtronic	21.05	4.31	MDT enrolls its first patient in a study which will assess the optimum spinal cord stimulation programming to relieve pain for patients with chronic, intractable back pain.
4	2	Integra LifeSciences	15.60	1.12	Confidence rising in management's ability to beat organic growth targets in 2018. Sales and op profit contributions from recently acquired DermaSciences and Codman tracking ahead of expectations.
5	9	MicroPort Scientific	10.23	23.21	Massive equity jump in the last month—in part due to strong China markets, but also due to a 225% leap in earnings at the 6 month mark and news that a surgical robot is in the works.
6	6	Orthofix	8.01	3.40	Preannounces strong Q4 sales—up 7.7%. For all of 2017, management preannounced a 5.9% growth rate to $434 million in net sales. Outstanding results.
7	7	Stryker	22.38	3.21	SYK also preannounced 2017 results. Ortho sales rose 6.8%, in Q4 up from 5.9% in Q3. Mako Mo strong and played a role in the 10.5% jump in knee volume. Global Mako base now up to 493 units.
8	5	NuVasive	11.57	(9.85)	NUVA's management guided to lower-than-expected revenues for 2017. Spine hardware growth is decelerating. Biologics and monitoring are down. Management says case volumes continue to decline. Overall spine market is tough.
9	8	Globus Medical	26.72	11.98	Preannounces 15.8% leap in Q4 sales to $175.5 million—beating Wall Street's estimates. Also GMED management said that 2018 will also be stronger, rising by 8.7% to about $690 million in sales.
10	10	Smith & Nephew	19.53	(0.65)	No financial preannouncement from SNN, but rather a announcement saying that the date of the announcement will be February 8. Most expect modest sales growth.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	TiGenix	TIG.BR	$2.07	$570	69.52%
2	Lattice Biologics	LBL.V	$0.08	$7	50.36%
3	Alphatec Holdings	ATEC	$3.12	$52	26.32%
4	MicroPort Scientific	853	$1.20	$1,753	23.21%
5	Amedica Corp	AMDA	$3.55	$11	17.94%
6	K2M Group Hldgs	KTWO	$20.25	$877	16.18%
7	MiMedx Group	MDXG	$13.86	$1,539	15.60%
8	Nevro Corp	NVRO	$78.56	$2,328	15.19%
9	Globus Medical	GMED	$43.66	$4,207	11.98%
10	Conmed	CNMD	$56.48	$1,578	10.94%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	NuVasive	NUVA	$53.33	$2,718	-9.85%
2	Pacira	PCRX	$41.50	$1,684	-9.39%
3	Xtant Medical Hldgs	XTNT	$0.56	$10	-3.38%
4	CryoLife	CRY	$18.65	$674	-3.37%
5	Smith & Nephew	SNN	$35.17	$15,391	-0.65%
6	Wright Med Grp N.V	WMGI	$24.04	$2,540	0.97%
7	Exactech	EXAC	$50.50	$725	1.00%
8	Integra LifeSciences	IART	$50.57	$3,969	1.12%
9	Johnson & Johnson	JNJ	$145.76	$391,587	2.01%
10	RTI Biologics Inc	RTIX	$4.40	$268	2.33%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Smith & Nephew	SNN	$35.17	$15,391	19.63
2	Zimmer Biomet	ZBH	$122.10	$24,722	20.88
3	Johnson & Johnson	JNJ	$145.76	$391,587	22.66
4	Medtronic	MDT	$85.45	$115,656	23.87
5	Stryker	SYK	$158.23	$59,216	28.06

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	MicroPort Scientific	853	$1.20	$1,753	123.95
2	Orthofix	OFIX	$53.90	$983	114.97
3	MiMedx Group	MDXG	$13.86	$1,539	70.18
4	NuVasive	NUVA	$53.33	$2,718	52.68
5	Exactech	EXAC	$50.50	$725	49.93

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	CryoLife	CRY	$18.65	$674	1.56
2	MicroPort Scientific	853	$1.20	$1,753	1.80
3	Integra LifeSciences	IART	$50.57	$3,969	2.64
4	Stryker	SYK	$158.23	$59,216	2.70
5	Globus Medical	GMED	$43.66	$4,207	2.84

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$53.90	$983	11.38
2	Conmed	CNMD	$56.48	$1,578	7.72
3	Exactech	EXAC	$50.50	$725	5.20
4	MiMedx Group	MDXG	$13.86	$1,539	4.68
5	Smith & Nephew	SNN	$35.17	$15,391	3.70

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Xtant Medical Hldgs	XTNT	$0.56	$10	0.11
2	Aurora Spine	ASG.V	$0.09	$3	0.30
3	Alphatec Holdings	ATEC	$3.12	$52	0.43
4	Amedica Corp	AMDA	$3.55	$11	0.70
5	RTI Biologics Inc	RTIX	$4.40	$268	0.98

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$2.07	$570	21.27
2	Nevro Corp	NVRO	$78.56	$2,328	10.19
3	Globus Medical	GMED	$43.66	$4,207	7.46
4	MiMedx Group	MDXG	$13.86	$1,539	6.28
5	Pacira	PCRX	$41.50	$1,684	6.09

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

Top Hip and Knee Surgery Hospitals in America – Per CMS

BY ROBIN YOUNG

What makes a "top" hip and knee replacement hospital?

According to the Centers for Medicare and Medicaid Services (CMS), it is a combination of low complication rates, high patient satisfaction scores and low prices.

We would add one more criteria. Experience.

It is well accepted (and supported by hospital discharge data) that high volume hip/knee replacement hospitals tend to have the lowest complication, revision and re-admittance rates.

Fortunately, CMS' data base of hospitals, hospital complication rates and star ratings are now available. You, too, can download all these spreadsheets.

But, if you want to get right to the good stuff, here is some of it—at least as it relates to the best hospitals in the United States for hip or knee replacement surgery.

A quick note about bias. This data is biased.

Since it is from CMS, it is weighted toward Medicare patients. Not all hospitals or doctors accept Medicare patients. Also, Medicare patients are not representative of the overall U.S. population. They are typically over 65 years old. They are more likely to be female. And they are more likely to have co-morbidities like diabetes or high blood pressure.

Courtesy of Centers for Medicare and Medicaid Services and European Union

On the other hand, they are a nearly perfect demographic for hip and knee surgery. Arthritis runs rampant in this age cohort and the clear majority of hip and knee arthroplasties are performed on these patients.

So. It's good data. It will uncover the top hospitals. It just won't uncover ALL the top hospitals. Some worthy institutions are missing. And, please, don't hesitate to let us know if we did miss a noteworthy addition to this list.

The 17 Top Hip/Knee Hospitals with Best Pricing

1. **Hoag Orthopedic Institute: Irvine, California**

Average Hip/Knee Payment by CMS: $20,998. 2,911 Cases Reviewed. Lower than average complications. Lower than average cost.

For the 14th consecutive year, Hoag has been chosen as the most preferred hospital by Orange County residents, and received National Research Corporation's (NRC) Consumer Choice Award. Hoag scored above the national comparisons and ranked second out of 232 California hospitals in the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Patient Satisfaction Report.

2. **Christiana Care Health Services: Wilmington, Delaware**

Average Hip/Knee Payment by CMS: $20,193. 2,826 Cases Reviewed. Lower than average complications. Lower than average cost.

Christiana Care's orthopedic care programs were awarded "Medical Excellence" designation by CareChex where it was ranked: The No. 3 hospital in the nation for major orthopedic surgery and No. 1 in the Philadelphia metropolitan area. The No. 6 hospital in the nation for spinal fusion and No. 1 in the Philadelphia metropolitan area. The No. 7 hospital in the nation for spinal surgery and No. 1 in the Philadelphia metropolitan area. The No. 10 hospital in the nation for joint replacement care.

3. **Providence Saint John's Health Center: Santa Monica, California**

Average Hip/Knee Payment by CMS: $18,896. 2,222 Cases Reviewed. Lower than average complications. Lower than average cost.

Providence Saint John's Health Center was recognized by Healthgrades for being one of: America's 50 Best Hospitals, America's 100 Best Hospitals for Joint Replacement Award™, Patient Safety Excellence Award™, Distinguished Hospital Award for Clinical Excellence™ and Neurosurgery Excellence Award.

4. **Swedish Medical Center: Seattle, Washington**

Average Hip/Knee Payment by CMS: $19,267. 2,210 Cases Reviewed. Lower than average complications. Lower than average cost.

For the 17th consecutive year, Swedish Medical Center received the Consumer Choice award from the National Research Corporation. The annual award identifies hospitals across the United States that healthcare consumers choose as having the highest quality and image.

5. **Washington Hospital: Fremont, California**

Average Hip/Knee Payment by CMS: $18,092. 2,154 Cases Reviewed. Lower than average complications. Lower than average cost.

For 10 consecutive years, Washington Hospital has received the Healthgrades Joint Replacement Excellence Award—which is awarded to the top 5% in the nation for joint replacement. In addition, Washington Hospital received a five-star designation for Total Hip Replacement for the 13th year in row, and Total Knee Replacement for the 11th year in a row.

6. **Atlanticare Regional Medical Center – City Campus: Atlantic City, New Jersey**

Average Hip/Knee Payment by CMS: $19,067. 2,072 Cases Reviewed. Lower

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than average complications. Lower than average cost.

A past winner of the Malcolm Baldrige National Quality Award—the nation's highest presidential honor awarded to organizations for quality and organizational performance excellence, Atlanticare is consistently ranked by *U.S. News and World Report* as one of the best hospitals in the United States for Orthopedics.

7. St. Francis Hospital and Medical Center: Hartford, Connecticut

Average Hip/Knee Payment by CMS: $20,915. 1,987 Cases Reviewed. Lower than average complications. Lower than average cost.

Saint Francis Hospital and Medical Center was named one of America's 100 Best Hospitals for Patient Experience by the Women's Choice Award®. It was also named one of Healthgrades America's 100 Best Hospitals for Joint Replacement™, named among the top 5% in the nation for Joint Replacement, a Five-star recipient for Total Knee Replacement, and a Five-star recipient for Total Hip Replacement.

8. Arkansas Surgical Hospital: North Little Rock, Arkansas

Average Hip/Knee Payment by CMS: $20,649. 1,972 Cases Reviewed. Lower than average complications. Lower than average cost.

Arkansas Surgical Hospital is the only CMS double five-star rated hospital in Arkansas and one of only 19 in the United States. It is a physician-owned facility with 11 state-of-the-art operating rooms, 41 private patient suites, a lower than average infection rate and one of the highest nurse-to-patient ratios in the country.

9. Poudre Valley Hospital: Fort Collins, Colorado

Average Hip/Knee Payment by CMS: $18,982. 1,951 Cases Reviewed. Lower than average complications. Lower than average cost.

UCHealth at Poudre Valley has consistently been ranked in the top 10% nationally for Clinical Outcomes (Thomson Reuters), Patient Satisfaction (HCAHPS), Staff Engagement (MSA), Physician Engagement (Gallup) and Financial Results (Ingenix).

10. Mount Carmel New Albany Surgical Hospital: New Albany, Ohio

Average Hip/Knee Payment by CMS: $18,622. 1,802 Cases Reviewed. Lower than average complications. Lower than average cost.

Mount Carmel New Albany was also one of the rare hospitals to receive five stars for patient satisfaction scores from the Centers for Medicare & Medicaid Services.

11. Huntsville Hospital: Huntsville, Alabama

Average Hip/Knee Payment by CMS: $21,675. 1,782 Cases Reviewed. Lower than average complications. Lower than average cost.

One of two hospitals in Alabama with the highest rating for knee replacement surgery by *Consumer Reports* magazine. Also awarded Blue Cross Blue Shield's Blue Distinction Center+ recognition for knee and hip replacement. Rated "High Performing" in hip replacement and knee replacement by *U.S. News and World Report.*

12. Cedars-Sinai Medical Center: Los Angeles, California

Average Hip/Knee Payment by CMS: $20,636. 1,765 Cases Reviewed. Lower than average complications. Lower than average cost.

For the 20th year in a row, Cedars-Sinai has won NRC Health's Consumer Choice Award for providing the highest-quality medical care in the Los Angeles region based on a survey of area households. Cedars-Sinai is ranked 10th nationally in orthopedics and has been named to the "Honor Roll" in *U.S. News & World Report*'s "Best Hospitals 2017-18."

13. The Christ Hospital: Cincinnati, Ohio

Average Hip/Knee Payment by CMS: $19,450. 1,726 Cases Reviewed. Lower than average complications. Lower than average cost.

The Christ Hospital is consistently recognized by *U.S. News & World Report* as one of the nation's top hospitals, has been named Cincinnati's Most Preferred Hospital for 21 consecutive years by National Research Corporation (NRC), and achieved Magnet® status from the American Nurses Credentialing Center in recognition of outstanding nursing care.

14. Mayo Clinic: Rochester, Minnesota

Average Hip/Knee Payment by CMS: $19,230. 1,724 Cases Reviewed. Lower than average complications. Lower than average cost.

Mayo Clinic's Rochester campus has more No. 1 rankings than any other hospital in the nation, with No. 1 rankings in six specialties including orthopedics. *U.S. News & World Report* ranked Mayo Clinic in Rochester, Minnesota the best hospital in the nation in their 2017-2018 rankings and has been at or near the top of "Honor Roll" hospitals

through the history of *U.S. News and World Report*'s best-hospital rankings.

15. St. Francis – Downtown: Greenville, South Carolina

Average Hip/Knee Payment by CMS: $21,709. 1,724 Cases Reviewed. Lower than average complications. Lower than average cost.

St. Francis has received numerous awards including being ranked among America's 100 Best Joint Replacement centers, 100 Best Orthopedic Surgery, Healthgrades, Five-Star for Hip and Knee Replacement, Joint Replacement Excellence Award, Orthopedic Surgery Excellence Award, Blue Cross Blue Shield Blue Distinction Center+ for Hip and Knee Replacement.

16. Boone Hospital Center: Colombia, Missouri

Average Hip/Knee Payment by CMS: $21,027. 1,571 Cases Reviewed. Lower than average complications. Lower than average cost.

Boone has consistently received top rankings from IVantage Health, Thomson Reuters/Solucient, National Research Association and, of course, *U.S. News and World Report*, where it is the No. 1 rated hospital in central Missouri.

17. University of Maryland St. Joseph Medical Center: Towson, Maryland

Average Hip/Knee Payment by CMS: $18,766. 1,571 Cases Reviewed. Lower than average complications. Lower than average cost.

UM SJMC's 6th Floor Orthopaedic nursing team received the 2017 Orthopaedic Nursing Award from the National Association of Orthopaedic Nurses—first time this honor was bestowed on a hospital in Maryland. UM SJMC is in the top 5% of hospitals in the nation, as evaluated by Healthgrades.

The 3 Top Hip/Knee Hospitals When Price Is Not a Consideration

1. Hospital for Special Surgery: New York City, New York

Average Hip/Knee Payment by CMS: $22,946. 8,862 Cases Reviewed. Lower than average complications. Higher than average cost.

Hospital for Special Surgery (HSS) is the No. 1 ranked hospital for orthopedics in the United States according to the *U.S. News & World Report*, (2017-2018). HSS also received nursing excellence recognition for a fourth consecutive time by the American Nurses Credentialing Center—the New York state hospital to win four times in a row. Finally, CareChex®—an information service of Quantros, Inc.—ranked HSS No. 1 in the nation for medical excellence in both major orthopedic surgery and joint replacement for three consecutive years.

2. Ocala Regional Medical Center: Ocala, Florida

Average Hip/Knee Payment by CMS: $23,545. 2,082 Cases Reviewed. Lower than average complications. Higher than average cost.

U.S. News and World Report reports that Ocala Regional Medical Center has earned a "high performer" rating for its hip and knee reconstruction programs.

3. Sentara Leigh Hospital: Norfolk, Virginia

Average Hip/Knee Payment by CMS: $24,198. 2,043 Cases Reviewed. Lower than average complications. Lower than average cost.

Sentara Leigh has been named a "Best Hospital" by *U.S. News and Report* for more than 17 years. The hospital also received Blue Cross Blue Shield's Blue Distinction for Knee and Hip Replacement and a Distinguished Hospital Award for Clinical Excellence by Health Grades. The Leapfrog Group named Sentara a "Top Hospital" in part for its safety scores. Finally, the Virginia Hospital and Healthcare Association awarded Sentara its Distinguished Service Award.

The Top 200 Hip/Knee Hospitals Organized by State *(See table on page 8.)*

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Orthopedics This Week

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Alabama	Florida, cont.	Michigan, cont.	Ohio, cont.
Huntsville Hospital	Doctors Hospital of Sarasota	St. Joseph Mercy Hospital	Toledo Hospital
St. Vincent's Birmingham	Bethesda Hospital East	Providence – Providence Park Hospital	**Oklahoma**
Jack Hughston Memorial Hospital	**Georgia**	Spectrum Health Butterworth Campus	McBride Orthopedic Hospital
Arkansas	Northeast Georgia Medical Center	**Minnesota**	Oklahoma Surgical Hospital
Arkansas Surgical Hospital	St. Joseph's Hospital Savannah	Mayo Clinic Hospital Rochester	St. Anthony Hospital
Arizona	Saint Joseph's Hospital of Atlanta	**Missouri**	St. John Broken Arrow, Inc.
O.A.S.I.S. Hospital	St. Mary's Hospital	Boone Hospital Center	**Oregon**
Tucson Medical Center	University Hospital	Mercy Hospital Springfield	St. Charles Bend
Mayo Clinic Hospital	Wellstar Kennestone Hospital	Missouri Baptist Medical Center	Sacred Heart Medical Center Riverbend
Northwest Medical Center	Piedmont Hospital	North Kansas City Hospital	**Pennsylvania**
Banner Boswell Medical Center	Emory University Hospital	Barnes Jewish Hospital	Lehigh Valley Hospital
Scottsdale Thompson Peak Medical Center	**Iowa**	SSM Health DePaul Hospital St. Louis	Lancaster General Hospital
Scottsdale Shea Medical Center	Iowa Methodist Medical Center	St. Luke's Hospital	Thomas Jefferson University Hospital
Oro Valley Hospital	Mercy Medical Center Des Moines	**Mississippi**	Main Line Hospital Bryn Mawr Campus
California	Mercy Hospital	Mississippi Baptist Medical Center	Pinnacle Health Hospitals
Hoag Orthopedic Institute	**Idaho**	Forrest General Hospital	**Rhode Island**
Providence Saint John's Health Center	St. Luke's Regional Medical Center	**Montana**	South County Hospital
Washington Hospital	Saint Alphonsus Regional Medical Center	St. Vincent Healthcare	**South Carolina**
Cedars-Sinai Medical Center	**Illinois**	**North Carolina**	St. Francis Downtown
Fresno Surgical Hospital	Evanston Hospital	New Hanover Regional Medical Center	Roper Hospital
St. Helena Hospital	Central Dupage Hospital	Carolinas Medical Center / Behav Health	Providence Health
Eisenhower Medical Center	Rush University Medical Center	First Health Moore Regional Hospital	**South Dakota**
Stanford Health Care	Advocate Lutheran General Hospital	The Moses H Cone Memorial Hospital	Sioux Falls Specialty Hospital

Continued on page 9...

John Muir Medical Center Walnut Creek Campus	Northwestern Memorial Hospital	Rex Hospital	Sanford USD Medical Center
Scripps Green Hospital	Memorial Medical Center	Carolina East Medical Center	**Tennessee**
Huntington Memorial Hospital	Northwest Memorial Hospital	Novant Health Forsyth Medical Center	Memorial Healthcare System
Sutter Medical Center Sacramento	Memorial Medical Center	Vidant Medical Center	Methodist Healthcare Memphis Hospital
El Camino Hospital	Northwest Community Hospital	Carolina Healthcare System Pineville	Parkwest Medical Center
Los Robles Hospital & Medical Center	Advocate Christ Hospital & Medical Center	**North Dakota**	Saint Thomas West Hospital
Colorado	**Indiana**	Sanford Medical Center, Fargo	Tristar Centennial Medical Center
Poudre Valley Hospital	OrthoIndy Hospital	**Nebraska**	Tennova Healthcare
Centura Health Penrose St. Francis Health Services	Franciscan Health Mooresville	Nebraska Orthopaedic Hospital	**Texas**
Centura Health Porter Adventist Hospital	St. Vincent Evansville	Lincoln Surgical Hospital	Baptist Medical Center
Sky Ridge Medical Center	Orthopaedic Hospital at Parkview North	Chi Health St. Elizabeth	Texas Orthopedic Hospital
Ortho Colorado Hospital at St. Anthony Med Campus	Franciscan Health Lafayette	**New Hampshire**	Houston Methodist Hospital
Connecticut	Saint Joseph Regional Medical Center	Concord Hospital	Texas Health Harris Methodist Hospital Southwest
St. Francis Hospital & Medical Center	**Kansas**	Mary Hitchcock Memorial Hospital	Memorial Hermann Hospital System
Yale – New Haven Hospital	Kansas Surgery & Recovery Center	**New Jersey**	Texas Spine and Joint Hospital
Hartford Hospital	Stormont Vail Hospital	Virtua West Jersey Hospitals Voorhees	Seton Medical Center Austin
Washington DC	**Kentucky**	Morristown Medical Center	Quail Creek Surgical Hospital
Sibley Memorial Hospital	Baptist Health Louisville	Atlantic Care Regional Medical Center City Campus	Texas Health Presbyterian Hospital Plano
Delaware	Norton Hospital / Norton Healthcare Pavilion / Nor	Hackensack University Medical Center	Baylor University Medical Center
Christiana Care Health Services, Inc.	**Louisiana**	Valley Hospital	St. David's Medical Center
Beebe Medical Center	Our Lady of the Lake Regional Medical Center	Ocean Medical Center	**Utah**
Florida	**Massachusetts**	University Medical Center of Princeton at Plainsboro	Dixie Regional Medical Center
Florida Hospital	New England Baptist Hospital	**New Mexico**	**Virginia**
Naples Community Hospital	Mass General Hospital	Presbyterian Hospital	Sentara Leigh Hospital

Continued on page 10...

Lee Memorial Hospital	Brigham and Women's Hospital	**Nevada**	Mary Immaculate Hospital
Sarasota Memorial Hospital	Baystate Medical Center	St. Rose Dominican Hospitals – Siena Campus	Inova Mount Vernon Hospital
Ocala Regional Medical Center	**Maryland**	**New York**	Carilion Roanoke Memorial Hospital
St. Vincent's Medical Center Riverside	Anne Arundel Medical Center	Hospital for Special Surgery	Bon Secours St. Mary's Hospital
Holy Cross Hospital	University of Maryland St. Joseph Medical Center	NYU Hospitals Center	CJW Medical Center
Physician's Regional Medical Center Pine Ridge	Mercy Medical Center	St. Joseph's Hospital Health Center	Cetnra Health
Orlando Health	Suburban Hospital	St. Peter's Hospital	Mary Washington Hospital
Morton Plant Hospital	Medstar Union Memorial Hospital	North Shore University Hospital	August Health
St. Lucie Medical Center	**Maine**	Lenox Hill Hospital	**Washington**
North Florida Regional Medical Center	Maine Medical Center	**Ohio**	Swedish Medical Center
Indian River Medical Center	**Michigan**	Mount Carmel New Albany Surgical Hospital	Providence Sacred Heart Medical Center
Mayo Clinic	Beaumont Hospital, Royal Oak	Christ Hospital	Providence St. Peter Hospital
Leesburg Regional Medical Center	Munson Medical Center	Riverside Methodist Hospital	Virginia Mason Medical Center
Tampa General Hospital	Mclaren Greater Lansing	Kettering Medical Center	Valley Medical Center
			Wisconsin
			Bellin Memorial Hospital

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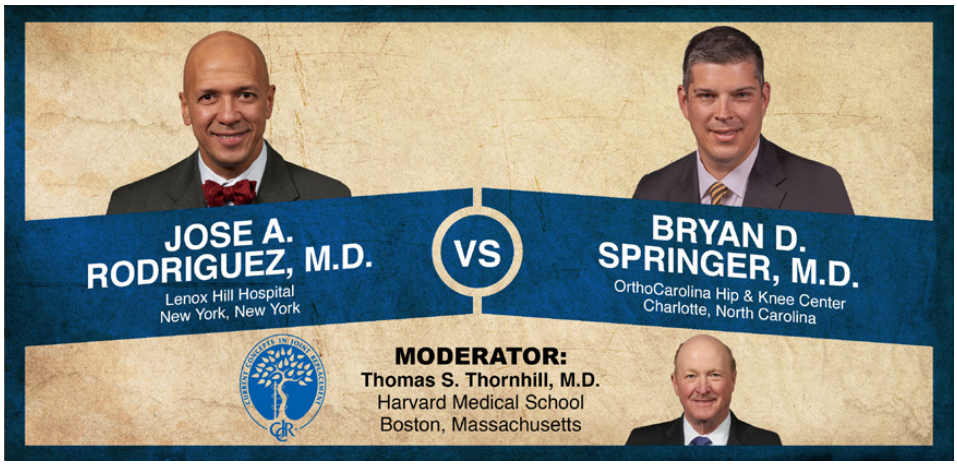
Rodriguez v. Springer: The Anterior Approach: *Better, Faster, Safer*

BY OTW STAFF

This week's Orthopaedic Crossfire® debate was part of the Annual Current Concepts in Joint Replacement® (CCJR), Winter meeting, which took place in Orlando. This week's topic is "The Anterior Approach: Better, Faster, Safer." For is Jose A. Rodriguez, M.D., Hospital for Special Surgery, New York, New York. Opposing is Bryan D. Springer, M.D., OrthoCarolina Hip & Knee Center, Charlotte, North Carolina. Moderating is Thomas S. Thornhill, M.D., Harvard Medical School, Boston, Massachusetts.



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Dr. Rodriguez: So better, faster, safer… in my hands. I don't know about you guys, but my decision making is limbic. How we perceive data is how we feel, but how we feel influences how we perceive the data.

I have presented this data from this podium previously on comparing anterior and posterior approaches by two very good surgeons (*Clin Orthop Relat Res*, 2014), using the objective measures of the Timed-up and Go (TUG) test, Functional Independence Measures, as well as a milestone diary.

We found that in the hospital there was a significant improvement in total score in the Functional Independence Measures and the time to achieve that peak score with the anterior approach. The TUG test was better with the anterior approach.

There was no difference in this study in the length of stay.

By two weeks, most of those measures had normalized. The TUG test remained significantly better for the anterior approach and by six weeks everything was basically the same.

More recently a much better study was presented by the folks at Mayo Clinic (Taunton et al., AAHKS 2016); 100 patients came to all surgeons; they were then randomized to go to either an anterior surgeon or a posterior surgeon, with similar in-hospital assessments.

In all the assessments that were made—discontinued walker, discontinued gait aids, opioids, stairs and walking six blocks, there was a marked improvement in the anterior group. They concluded, obviously in a familiar way, that both approaches provided excellent recovery. The anterior approach was faster at two weeks. How that matters? That's up to you.

What about gait? We looked at gait analysis in two cohorts pre-operatively and at six months (*J Arthroplasty*, 2014). Of all the variables that we measured, the only difference that we found was in the range of motion during the gait cycle.

Both groups significantly improved in the frontal and sagittal planes, but there was no improvement with the posterior approach in the transverse plane. That is the amount of internal and external rotation that occurs during gait. This is not surprising given the dislocation precautions we had imposed on these people.

What about muscle strength? We measured muscle strength in the two cohorts using a technique that's well published (Thorborg et al., *Scan J Sci Sports*, 2010). And we found that between pre-op and six weeks, the posterior group had a significant external rotation weakness and the anterior group had a notable flexion weakness. By three months, the flexion weakness had resolved in the anterior group. The external rotation weakness had improved with the posterior group, but there were still some clear measurable changes.

Precision. Looking at acetabular component anteversion for my anterior group patients—as I critically analyze my X-rays—I got better. I only had two dislocations within the first 100 cases. We then measured muscle volumes.

What we found was that there was relative comparability between the two cohorts in terms of anterior and posterior muscle volumes. For the anterior group, all the muscle volumes improved except for the obturator internus which we routinely release during the procedure. With the posterior approach, in addition to the obturator internus, there was also the obturator externus, piriformis and quadratus, a drop which is sustained post-operatively in the muscle volumes. All other volumes improved.

The question is whether you should use it and I would give you maybe not because there is no free lunch. Everything has downsides.

What are the downsides? First is wound healing. In the cases that we've published we've documented a 1.9% reoperation rate mostly due to the BMI [body mass index]. There is a dose response curve to their BMI and diabetes has a very significant effect as well.

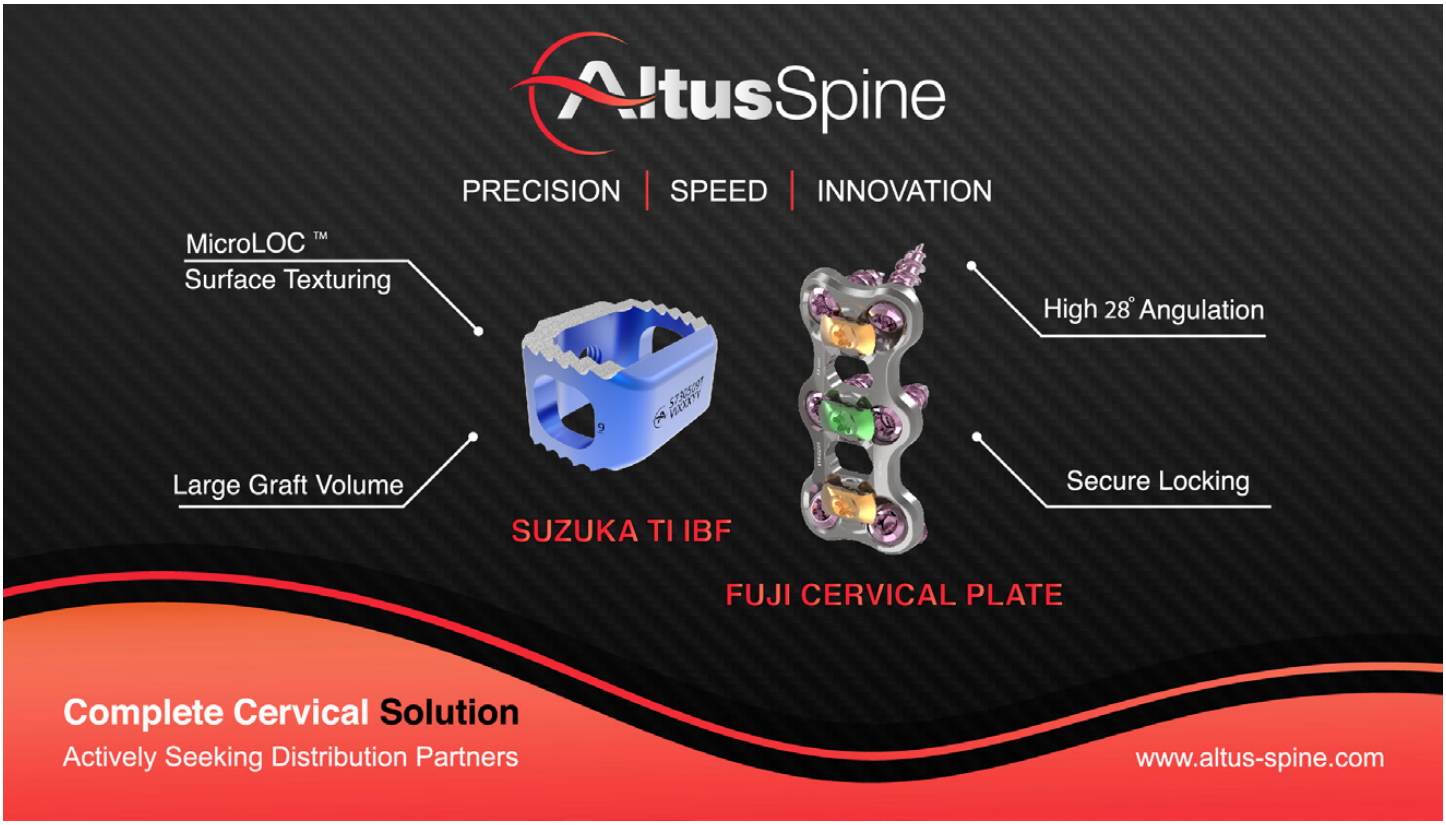
The other issue is fracture. Very real. We had 13 fractures in 1,000 patients. This is double our posterior approach cohort. And what we found was that 9 of them were over 70 years, under 25 BMI, females. So, we've changed our practice and in that age cohort, we only use cemented femoral stems. We eliminated this issue.

The learning curve is real. But the issue is not approach, it is newness and unfamiliarity. The better and more consistent you are with your clinical results, the less benefit you will have to change.

Dr. Springer: First I must state that I really have no problem with the anterior surgical approach. I think if we want to say it's different, then fine, let's say it's different. I think what most people and surgeons have a problem with is the sensationalism and the overzealous promotion of this approach. And I would argue that emerging evidence would suggest that this is a high risk, no reward operation.

So, what are the benefits and concerns? Resource utilization, dislocation risk, better function…is it safe? I for one am certainly waiting to be overwhelmed by the literature.

Resource utilization… my operating room during a posterior approach… myself, my PA, my scrub tech…it's one of the most relaxing operations I do.



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Every time I walk by my partner's operating room, it looks like they were in there separating Siamese twins or something like that much less doing a hip replacement.

And then we have the issues with the X-ray and the table. In our place, fluoro is billed out in one-hour increments, so even if you use it for one minute, it's a $1,000 charge. Now, I will say I've found these tables to be very comfortable between cases for taking a nap and stretching out my tight hamstrings.

What about evidence for better stability? The initial data suggested higher rates of instability with the direct anterior approach, probably somewhat relative to the learning curve. The three prospective randomized studies (Taunton et al. and Barrett et al.) don't show any difference. The registry data published in the *Journal of Arthroplasty* this year—out of Michigan (Maratt, et al., 2016)—no difference in dislocation rates. Both approaches less than a half a percent.

What about better functional recovery? Well, I think most people got excited about some of the initial data that came out comparing this to an anterior lateral approach where you take down a third of the abductors. Even in those studies there was no benefit functionally beyond six weeks in those patients.

What about versus the posterior approach? A meta-analysis—17 studies, 2,300 patients (Higgins, et al., 2014)—conclusions: current evidence comparing outcomes following anterior versus posterior total hip does not demonstrate clear superiority of one approach over the other.

And let's look closely at thes prospective randomized studies, because if you just read the abstracts, you'll be swooned. If you read the articles, you'll be more reserved.

Bill Barrett's study—walks further on day one and day two; did the direct anterior; less pain but took the same amount of pain medicines; stayed three-quarters of a day less in the hospital; and sub-function scores of their HOOS and HSS scores were better at six weeks as Jose demonstrated. No difference in any parameter at three months, and yet they had longer operative times; more blood loss; longer incision; and worse cup inclination—when using fluoro.

A study out of our institution where we looked at 12 different parameters, prospectively randomized by a single surgeon. The only difference was quicker cessation of gait aids with the direct anterior approach. The mental scores favored posterior approach. And there was no difference in any other parameter at any other time point during this study that was measured.

And in the study that Jose brought up at AAHKS I was able to get a hold of the paper…again if you read the abstract you'd have swooned. A hundred patients randomized DA [direct anterior] or posterior approach, but if you look at the numbers only a three to six-day difference in gait aids and walking distance. They did have better advanced activity at two weeks, but no difference in any parameter beyond two weeks.

And I think part of this is that these are expert surgeons doing these cases.

When you read the literature, you have to take into account expertise bias. That's a surgeon with a higher competency and a higher volume, has better familiarity and is more likely to have better outcomes.

But is this generalizable to the community where 60% of primary total hips are done by surgeons that do less than 25 a year?

We've seen concerns in the literature for community surgeons adopting direct anterior approach with, I would argue, extremely high complication rates.

Other data:

No difference in resource utilization on post-acute care.

No difference in patient-reported outcome measures.

Higher wound and infection complications in the direct anterior approach particularly in the obese patient population.

Early proximal femoral fractures in the total hips with the direct anterior approach.

And I would also argue that I think the femoral side of this approach is a real problem, both with fractures and loosening.

We went back and looked at nearly 7,000 primary total hips. Very low overall revision rate between the two groups—1.5-2%—and these were all patients that had early revisions at less than five years. No difference in the overall revision rate by approach; slightly higher in the direct anterior group. But a dramatically higher rate of femoral failures for aseptic loosening, particularly in the Dorr Type A femurs along with a higher rate of return to the operating room and revisions for other reasons in the anterior approach group.

Remember, total hip replacement was deemed the operation of the century and we should not let short-term objec-

tives compromise our long-term performance.

Let's be honest about a high risk, no reward operation that essentially serves as a great marketing tool. And not forget the principles of total hip, which are long-term fixation; low wear; and be very careful about allowing a small part of the procedure—the approach—to dictate the whole procedure.

Moderator Thornhill: Those were both very good. And Jose, I truly congratulate you. I think you gave a very, very balanced perspective, which I think is wonderful.

Bryan was talking about the problems of using the table, but you don't use a table, at least not as it showed in your pictures. Tell me about that. If somebody comes to you and says, "I'm going to start anterior hips, should I do this with a table or not a table, and why?"

Dr. Rodriguez: A table gives you a mechanical advantage. People that use the table and don't know how to do the operation, have complications. So, you must understand the soft tissue aspect before the table becomes truly useful.

Moderator Thornhill: Do you think it is the lack of exposure to the femur or do you think it's the predilection to use a shorter, stubbier stem because it's easier to get in? Is it stem-dependent or vision dependent?

Dr. Springer: Jose showed their data about peri-prosthetic fractures and, in our data, our rates of aseptic loosening were increased, but peri-prosthetic fracture wasn't any different. My suggestion is…you put a bunch in too tight, you break a bunch of femurs, so then you go in the opposite direction. You start putting them in too loose and you have a bunch of them loosening. You're chasing your tail a little bit. I do think it is somewhat stem-dependent/design-dependent.

Moderator Thornhill: Jose?

Dr. Rodriguez: The exposure of the femur is clearly the greatest challenge and there are certain body morphologies in which it is particularly challenging. As far as the stem, there's not going to be a lot of bloodshed here because Bryan and I basically believe you should absolutely not change your stem based on your choice of exposure. Learn how to do a stem and learn how to do it with that exposure. There is risk in changing a design that has long years of experience. Shortened stems by themselves are not necessarily good.

Moderator Thornhill: Okay, so why did you change and go to the anterior approach?

Dr. Rodriguez: Both of my mentors—Chit Ranawat and Reinhold Ganz taught me you've got to be able to get into the hip every single way. So, because of my work with peri-acetabular osteotomies, I had comfort in the front and I had a board member who said I want this and I couldn't offer it to him. So, I decided I wanted to learn. That's my personal answer.

Moderator Thornhill: So would you agree that if you're happy and your results are good, and you've looked at them with a mini-posterior approach, there's no need to change to anterior?

Dr. Rodriguez: What I stated is the better you are at what you do, the less benefit there will be to change because when you change there will be a definite drop in your clinical outcomes until you understand what you're doing. It's like starting all over again.

Moderator Thornhill: Bryan, I've got a real problem though. I tend to use a mini-posterior approach. Most of my patients don't go home with any precautions. Yet, when they come back at four weeks, they've been told not to bend more than 90 degrees and sit on the toilet, and one floor up, and not do anything. Do you have that same problem?

Dr. Springer: We have that exact same problem. It's a cultural issue with the therapist. It's about not wanting something to occur on their watch. We still fight that exact same issue of the therapist wanting to give them precautions.

Dr. Rodriguez: For what it's worth, so do I.

Moderator Thornhill: Oh, good. It's interesting. I want to thank both the speakers. ♦

Please visit www.CCJR.com to register for the 2018 CCJR Spring Meeting, – May 20 - 23 in Las Vegas.

Senior Editor: *Jay D. Mabrey, M.D., whose 35 year career in orthopedics included residency at Duke University Medical Center, service in the United States Army Medical Corps, Fellowship at the Hospital for Special Surgery and a long, distinguished career at Baylor University Medical Center where, in addition to his overall leadership at that institution, developed the Joint Wellness Program that helped patients get up after surgery more quickly, developed the first virtual reality surgical simulator for knee arthroscopy and chaired the FDA Orthopaedic Device Panel, is Orthopedics This Week's newest contributing writer and editor.*

Did FDA Panel Make a Mistake on Barricaid Vote?

BY ROBIN YOUNG

Even before the committee voted, it was not looking good for Intrinsic and its annular closure device for discectomy patients, Barricaid.

Then the committee voted, and by a margin of 9 to 5, the committee said that there was insufficient evidence of Intrinsic's annular closure device's safety when implanted to prevent disc re-herniation.

It did vote 12-1 that Barricaid was effective at preventing reherniations following discectomy.

When asked, however, whether the benefits outweighed its risks, the committee said "no" by a vote of 8 to 5.

The vote by the FDA's Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee occurred on December 12, 2017.

Did the Panel Miss the Forest for the Trees?

There is one big problem with the Panel's decision. The efficacy measure in this study included, in fact, safety observations such as reductions in adverse events and re-operations.

The full data from the study showed that using Barricaid cut recurrent disc herniations 56%, reduced re-operations 49% and, finally, lowered serious adverse events 33%.

So, what were the safety concerns that caused the panel to vote "no"?

Barricaid's RCT Study

Barricaid's study, which was a prospective, randomized investigation, recruited 554 discectomy patients of which 276 were randomized to Barricaid after a discectomy while the remaining 278 received discectomy alone. This is the largest ever conducted for an annular closure device with 24-month endpoints that included re-herniation and a composite of safety and effectiveness.

Barricaid ® / Courtesy of Intrinsic

This type of composite score is the acid test for any device and all previous premarket approval (PMA) spine studies have included five or six composite components. In this trial, the bar was elevated to eight components, all of which had to be successful to demonstrate statistical superiority. Barricaid did that. Superiority.

Patients were followed for a minimum of twp years post-op with a significant number going out as far as five years—again, a record follow up for review by a PMA spine device Panel.

The FDA noted in their instructions to the panel, that CT imaging showed bone changes to the vertebral endplates for some of the Barricaid patients.

Endplate Changes

Endplate changes are a well-known observation following discectomy, and are not generally associated with clinical symptoms.

Eighty-eight percent of the patients receiving Barricaid had endplate changes versus 40% of control patients. The control patient's changes were smaller on average and appeared to stabilize sooner than the Barricaid patient's. The Barricaid endplate changes were larger and had a distinctive radiographic feature—according to the FDA's radiologist. What those distinct features were, however, remain unclear.

Intrinsic carefully analyzed these endplate changes and found no correlation to measured study outcomes, pain or function.

Difference Without a Distinction

The panel seems to have missed the point that the efficacy endpoints were, in fact, measures of adverse events, readmissions and risks associated with secondary or tertiary surgery.

Barricaid's data showed a dramatic drop in symptomatic adverse events and expensive repeat surgeries. But the panel determined that a non-symptomatic potential adverse event was more important.

So, a clinician could be able to reduce the risk of reherniation by more than 50% on average and serious adverse events by 33% but won't have that choice because an FDA panel is worried about non-symptomatic endplate changes that are visible only by CT scan and occur half as often in the control group.

Bad Timing

This FDA panel vote comes just seven months after Intrinsic raised $49 million in a debt/equity deal to fund the commercialization of Barricaid.

That particular round consisted of a $28 million equity financing led by New Enterprise Assoc. and Delos Capital, plus a $21 million debt facility with CRG. Other backers included Greenspring Associates, Quadrille Capital and a "corporate strategic."

Back in December, when Intrinsic revealed an $18 million raise in a regulatory filing, the company had filed its premarket approval application with the FDA for the Barricaid device.

Back to the FDA

Intrinsic intends to provide additional safety information to the FDA and will reiterate some of the data it didn't have the opportunity to clarify with the 14-member Panel.

Among the data not presented to panel is the health economics analysis—which looked squarely at the issues of re-herniation and a higher rate of adverse events when NO annular closure device is used.

An independent economist conducted the analysis using two-year follow up data from the Barricaid RCT study. Here is a summary of the findings.

- Barricaid's QALY (quality-adjusted life year) score was $6,826 versus $76,023 for conventional lumbar discectomy
- After performing 1,000 simulations as part of a sensitivity analysis, 93.3% of the simulation results were below the $100k Willingness-to-Pay threshold with Barricaid.

According to an Intrinsic write-up:

> "Most of the cost savings—approximately 85%—came from the reduction of reoperations due to the reduction in reherniations. The majority of the remaining 15% of the cost savings came from lower rates rehospitalizations (due to fewer SAE's). Lower rates of reoperation mean fewer diagnostic tests, less physical therapy, and reduced medication." [1]

In health economic terms, this kind of data represents dominance over conventional lumbar discectomy—where, as the economist described it to *OTW,* "dominance" is defined as when a procedure is both more efficacious and cheaper than the alternative—"you get more for less."

Stay tuned, for sure. ♦

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[1]Thomas Michal, Vice President of Market Access, Health Economics & Reimbursement Intrinsic Therapeutics, Inc. 30 Commerce Way, Woburn, MA 01801 USA

New Spine Study: When Images Don't Match Symptoms; New Tobramycin Study; Machine Learning Transforms Meniscal Imaging

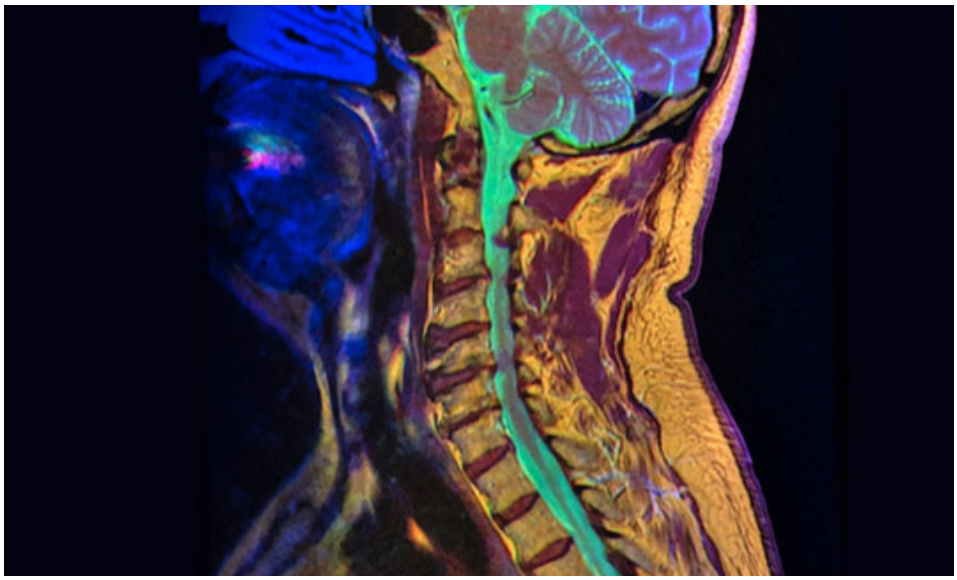
BY ELIZABETH HOFHEINZ, M.P.H., M.ED.

Study: When Spine Images Don't Match Symptoms Researchers from the UK are stressing that there is no gold standard for diagnosis and the related indication for surgery in chronic lumbar back pain patients. Their study, "Predictability of the effects of facet joint infiltration in the degenerate lumbar spine when assessing MRI scans," appears in the November 21, 2017 edition of the *Journal of Orthopaedic Surgery and Research.*

Ulf Krister Hofmann, M.D., orthopedic surgeon with University Hospital of Tübingen in Germany and co-author on the study, told *OTW*, "Due to advances in surgical techniques and perioperative management, spine surgery has seen great improvements over the past three decades. This is a blessing for many patients suffering from chronic lumbar back pain who in many cases today can be treated successfully by surgery."

"The danger of being so successful with surgery is, that when your only tool available is a hammer, every problem tends to look a bit like a nail."

"To identify patients who will actually benefit from surgery remains challenging. There are also many conditions that can manifest themselves as chronic lumbar back pain, and that can not be addressed by surgery, such as psychiatric disorders like depression, a nonspecific functional instead of a physical etiology, or referred pain from extraspinal causes (e.g., ovarian cyst, pancreatitis, ulcer)."



Cervical Spine MRI / Source: Wikimedia Commons and Nevit Dilmen

"In many patients, clinical history and symptoms and radiologic findings are conclusive, which makes the decision-making process easier. There are, however, also these patients where quite a discrepancy can be observed between their clinical presentation and the morphologic changes present in MRI or CT."

"Like laboratory tests or histopathological findings, imaging results are often considered to be solid evidence by physicians and patients. The confidence in these imaging findings with respect to their ability to predict a painful condition appears however, somewhat anticipated given the available data in the literature."

"In our centre of orthopaedic surgery we see many patients with a discrepancy between clinical and radiological findings."

"It is in these patients that we additionally perform image-guided local analgesic or anti-inflammatory infiltrations at possible sites of pain generation to temporarily simulate the effect of surgery."

"Such possible sites are, for example, the facet or sacroiliac joints, the epidural space, the deep back muscles, or the spinal nerves at their exit through the intervertebral foramen, as well as the hip as a differential diagnosis for chronic lumbar back pain."

"From the achieved improvement reported by the patient, the specialist can draw further conclusions as to the cause of the patient's symptoms. This allows to better identify patients who might and who might not benefit from surgery, and to define the actual scope of the planned surgery."

"Reimbursement of these infiltrations can, however, be tedious since many insurance companies do not appreciate the diagnostic value of these procedures before surgery."

"We, therefore, wanted to evaluate the ability of modern 3 tesla MRI to predict reported pain relief after facet joint infiltration in patients with chronic lumbar back pain. We hypothesized that, as pathological grading increased in MRI scans, pain alleviation would also increase after bilateral facet joint infiltration."

"In our study we graded 50 MRI scans of patients with chronic lumbar back pain using a wide range of classification and measurement systems. The reported effect of facet joint injections at the site was recorded, and a comparative analysis performed."

"When we allocated patients according to their reported pain relief, 27 showed no improvement (0–30% improvement on the NRS), 16 reported good improvement (31–75%) and 7 reported excellent improvement (>75%).

"MRI features assessed in this study did, however, not show any relevant correlation with reported pain relief after facet joint infiltration."

"Although we did not expect perfect agreement between reported pain relief and imaging findings, we were surprised to see this total lack of correlation between these two modalities!"

"If you do not assume that one of these two modalities is completely meaningless, our results can only mean, that the information provided by infiltrations and imaging are complementary."

"We do need to point out that the patients analysed in this study were all part of the cohort of patients, where clinical presentation and imaging findings did not match. It is likely, that in a group of patients with matching symptoms and MRI or CT findings the results would have been different."

"Our investigated collective is, however, a relevant subset of those patients presenting with chronic lumbar back pain and it is usually these patients where it is such a challenge to identify the best treatment strategy."

"Specialists are accustomed to having some 'gold standard' they can refer to in their decision-making process. It is important to understand that there is no such gold standard for formulating a diagnosis and a resulting indication for surgery in chronic lumbar back pain patients."

"Each modality—such as thorough clinical history, clinical examination, imaging techniques and local targeted infiltrations—has its strengths but also its flaws.

Advertisement

It is the critical synopsis of all results obtained that allows one to identify the best treatment strategy for each patient."

"To refer to the analogy mentioned above: only if you have all the tools in your toolbox available can you clearly see which problem is a nail, and which one isn't."

Study: Intra-Wound Tobramycin Shows Promise Researchers from Columbia University Medical Center, The Spine Hospital at New York Presbyterian have completed research in a rabbit model indicating that tobramycin does a good job of eradicating *Escherichia coli* (E. Coli). Their work, "Intra-wound Tobramycin Powder Eradicates Surgical Wound Contamination: An *In Vivo* Rabbit Study," appears in the December 15, 2017 edition of *Spine*.

Co-author Daniel Riew, M.D., co-chief of the spine division and director of cervical spine surgery at The Spine Hospital, commented to *OTW,* "We had previously published a study using a similar model and using vancomycin powder. While vancomycin is great for gram-positive organisms, it doesn't work for gram-negatives such as E. Coli. So we thought we could do this study to determine if local tobramycin could eradicate E. Coli in a contaminated wound model."

"We inoculated rabbits who had undergone a laminectomy and implantation of a titanium wire with E.Coli; 10 rabbits got intra-wound tobra and 10 did not. They were sacrificed on post-operative date #4. None of the rabbits who got tobra were infected whereas all of the ones without tobra got infected; 39 out of 40 culture specimens in the control and none out of 40 in the tobra group grew E. Coli."

"This is a preliminary study and it only tells us that tobramycin is effective at eradicating E. Coli in rabbits. So, I cannot make recommendation for clinical usage yet. We are doing further studies regarding toxicity and dose. In the meantime, we do know that tobramycin impregnated cement does a nice job of treating wound infections and is not toxic. So, based on that information, I personally have used 70-140mg of intra-wound tobramycin when I was concerned about a gram-negative surgical contaminant."

Dr. Riew concludes, "Stay tuned for more studies on this topic by our team."

Machine Learning Transforms Meniscal Imaging In the assessment of osteoarthritis (OA) progression, says new research from the UK, it would help to utilize 3D imaging to determine which meniscal pathologies undergo the most change. The study, "Where does meniscal damage progress most rapidly? An analysis using three-dimensional shape models on data from the Osteoarthritis Initiative," is published in the January 2018 edition of *Osteoarthritis and Cartilage.*

Philip Conaghan M.B.B.S. Ph.D., professor of musculoskeletal medicine at the University of Leeds and deputy director of the National Institute for Health Research Leeds Biomedical Research Centre and co-author of the study, told *OTW*, "The meniscus is an integral part of the osteoarthritis process but much less studied than cartilage or even subchondral bone. In part this has been because it's difficult to visualize even with MRI, which relies on a reader looking at a sequence of 2D images and which often fails to adequately show its 3-dimensional appearance."

"This study included MRI images from people with definite OA and careful manual segmentation of the menisci in these images—but with the added value of supervised machine learning to enable correct placement of the menisci relevant to the tibia. And we were able to examine a number of different meniscal shapes as they degenerate over time."

The authors wrote, "Knee images were selected from the progression cohort of the Osteoarthritis Initiative choosing participants with risk factors for medial OA progression. Medial and lateral menisci were manually segmented then analysed using a statistical shape model of the tibia as a reference surface."

"Responsiveness was assessed at 1 year using standardized response means (SRMs) for four constructs: meniscal volume, extrusion volume, thickness and tibial coverage; anatomical subregions of these constructs were also explored. Paired images from 86 participants (median age 61.5, 49% female, 56% obese) were included."

According to Dr. Conaghan, "Posterior medial meniscus was the location of most pathology. Despite relatively small numbers for a 12-month OA follow-up, there was responsiveness demonstrated for two of the meniscal measures."

"There has been little investment in the OA field because demonstration of progression has been difficult in feasible time frames."

"Modern image analysis has already provided the most responsive measures of OA progression in clinical trials, using either cartilage thickness or bone shape. This study provides a third responsive measure, meniscal shape. And it may add to the other measures."

"This work underpins the benefits of modern 3D image analysis, which is not only being used for pre-joint replacement planning, but for understanding the importance of specific OA pathologies. In future we will be able to look at the range of meniscal pathologies and their relationship with symptoms." ♦

COMPANY

The Economic Value of a Single U.S. Physician

The American Medical Association (AMA) hired IQVIA, the data, marketing and research outsourcing firm formerly known as IMS/Quintiles and headquartered in Durham, North Carolina, to answer a simple question: What is the economic value of U.S. physicians?

The answer, which is in a report titled The National Economic Impact of Physicians, was released Monday, January 8, 2018.

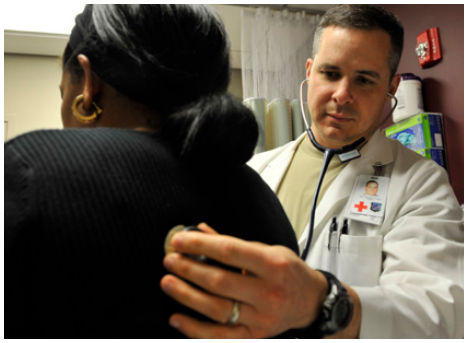
On average, each individual physician in the United States generates:

- $3.2 million in annual economic output
- 17 new jobs
- $1.4 million in wages and benefits for support staff
- $126,129 in state and local taxes

According to the AMA, there are 736,873 physicians in the United States. Therefore, physicians in the United State are responsible for $2.3 trillion of economic output annually. In terms of jobs, physicians support more than 12.5 million jobs and $1 trillion in wages and benefits. If physicians did not exist, state and local governments would be $93 billion poorer—each year.

A Few Details

Output: Physicians generated $821.6 billion in direct output in 2015. Direct output is defined as providing patient care. Adding in indirect output, that is the economic value of purchased goods and services, the total output rises to $2.3 trillion or $3,166,901 per physician.



Wikimedia Commons and Mary Norenburg

Jobs: IQVIA used several datasets including AMA data for 736,873 patient care physicians who were practicing in the U.S. as of December 2015. In aggregate across all states, the number of jobs directly created by patient care physicians (including the number of physicians themselves) was 3,545,399. The total number of jobs supported by patient care physicians at the national level was 12,575,602; the average physician supported 17.07 jobs in the economy, including his or her own.

Wages and Benefits: The value of direct wages and benefits includes compensation paid to physicians and non-physician staff who are on payroll. In 2015, physicians supported $559.6 billion in direct wages and benefits in aggregate across all states. The total amount of wages and benefits supported by patient care physicians at the national level was $1.04 trillion (including the indirect wages and benefits supported by the industry), or an average of $1,417,958 per physician.

What's the Point?

The American Medical Association is many things, but its primary mission is to represent the interests of U.S. physicians. In Washington, DC and at state capitols all over the country, the economic future of physicians is being debated.

If politicians really care about the economic life of their constituents, then U.S. physicians should be granted most favored status. In many communities, for example, the local hospital is the largest employer. These are clean, high paying and skilled jobs which support quality schools, modern police and fire departments and up-to-date infrastructures.

So, when legislatures are pondering how to fiddle with healthcare, data like this should remind them that they are messing with a golden goose.

Physicians Crush Lawyers

How golden?

IQVIA also provided similar economic output data for attorneys.

It was noteworthy that, based on the economic data in this report, physicians crush lawyers.

Here's the data. — *RRY*

Economic Data — Physicians and Lawyers

Industry	Output ($ in billions)	Jobs	Wage & Benefits ($ in billions)
Physicians	$2,333.6	12,575,602	$1,044.9
Legal Services	$724.8	4,141,197	$254.5

Source: IQVIA

LEGAL

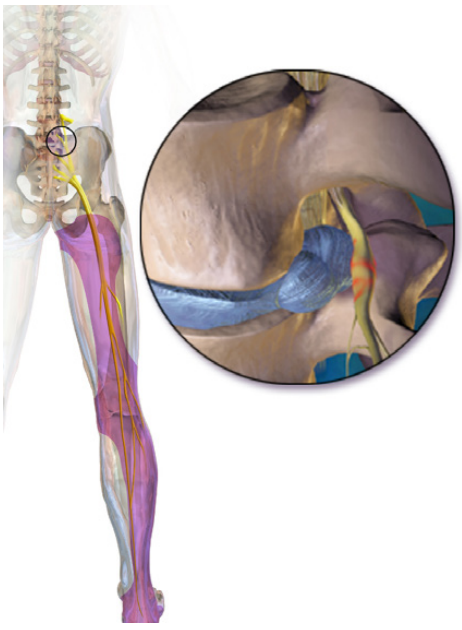
Non-Opioid Sciatica Treatment Fast Tracked by FDA

In possible good news for interventional pain physicians, the FDA has granted Semnur Pharmaceuticals, Inc., Fast Track Designation for the company's SP-102 product for patients with lumbar radicular pain/sciatica.

On January 7, 2018, the company also announced the start of a pivotal Phase 3 clinical trial in the U.S. to evaluate the product. Click here to find out if any of your patients qualify for the study. http://www.clearbackpainstudy.com/

SP-102

The company says "SP-102 is the first non-opioid corticosteroid formulated as a viscous gel injection in development for the treatment of lumbar radicular pain/sciatica, containing no neurotoxic preservatives, surfactants, solvents or particulates. The CLEAR ("Corticosteroid Lumbar Epidural Analgesia for Radiculopathy") Clinical Study is a randomized, double-blind, placebo-controlled Phase 3 trial that will enroll 400 patients with lumbar radicular pain at up to 35 sites across the U.S."



Sciatica / Source: Wikipedia Commons and Bruce Blaus

The product is injected into the lower back while at the doctor's office.

"The primary endpoint of the study, according to the company, is mean change in the Numerical Pain Rating Scale for leg pain compared to intramuscular injection of placebo over four weeks. The secondary endpoints include other measures of pain at 4 and 12 weeks as well as time to repeat injection of SP-102, safety and disability. The study includes an open-label extension to build the safety database of patients treated with SP-102."

"The FDA's Fast Track program expedites the regulatory review of therapeutic programs that seek to address significant unmet medical needs." The designation allows the company to communicate more frequently "with the FDA about the drug development plan and data necessary to expedite the development of the treatment."

Dmitri Lissin M.D., the company's chief medical officer said "We are eager to investigate what may be the first FDA-approved epidural injection that the interventional pain physicians could offer their patients for persistent relief of their pain, caused by nerve root compression usually by herniated intervertebral discs."

Interventional pain specialists and spine surgeons have had a spotted relationship as the interventionalists have expanded their scope of practice to interventions traditionally reserved for surgeons. If the therapy proves to be successful, patients won't care. — *WE*

Medical Conference Ethics Revised

On January 3, 2018, four of the top medical device industry association in the world announced they've revised their code of ethics to remove direct sponsorships for healthcare professionals' attendance at medical conferences and other third-party educational events.

Source: l.pinlmg.com

A joint statement by heads of the groups noted the revision of codes of ethics in China (the AdvaMed China Code), in Europe (the MedTech Europe Code), in the Middle East and North Africa (the Mecomed Code), and in the Asia-Pacific region (the APACMed Code).

The statement says one of the key revisions in these codes is the elimination of "direct sponsorship" of healthcare professionals' attendance at third-party educational events, such as medical conferences and congresses, effective January 1, 2018. "Direct sponsorship" means those situations in which a company selects and pays for an individual's registration fee, travel, lodging, and meals/hospitality to attend a third-party educational event.

"Effective January 1, 2018," says the statement, "companies will no longer

select or influence the selection of specific attendees at third-party educational events; directly arrange or pay for attendees' travel, accommodation and/or registration; or reimburse the expenses of specific attendees at third-party educational events."

The organizations said they were trying to strike a balance between transparent interactions and the need for healthcare professionals to "make independent decisions regarding patient care and treatment," which could be unintentionally influenced via direct sponsorships.

The ethics code revisions will change how companies support third-party educational events.

Companies can offer educational grants and sponsorship to third-party conference organizers, health care institutions, and/or professional associations to enable them to select HCPs to attend third-party educational events.

Companies will also continue to host and support technical product and procedure training, and educational meetings, which instruct attendees "on how to safely and effectively use our companies' complex, life-saving products. With the end of direct sponsorships, the organizations say the anticipate that companies will have "more resources to devote to high-impact training and education opportunities based on companies' individual educational strategies."

The statement notes that the revisions follow a global trend that began to move away from direct sponsorship some time ago, as in the U.S., Australia, and other countries such as Sweden and Russia. — *WE*

FDA Clears Anika Therapeutics' HA Bone Void Filler

At the end of 2017, Anika Therapeutics, Inc. announced FDA 510(k) clearance of its injectable hyaluronic acid (HA) based bone void filler.

Hyaluronic acid is a component of synovial fluid that acts as a joint lubricant during shear stress and a shock absorber during compressive stress.

According to the company's December 27, 2017 announcement, the bone repair treatment is an "injectable, HA-based, settable osteoconductive calcium phosphate bone graft substitute material, and is indicated for filling bone voids or defects of the skeletal system (i.e., extremities and pelvis) that are not intrinsic to the stability of bone structure."

"It is provided in a kit with two components (an aqueous solution in a preloaded syringe and a dry powder) that must be mixed, intra-operatively using the supplied mixing system, to form a cohesive paste, prior to administration. Anika's bone void filler is provided sterile for single use in volumes ranging from 1.5cc to 4cc."

Anika's CEO Charles Sherwood, Ph.D., said the new treatment represents a "promising revenue growth opportunity," for the company.

The company noted that while the use of autologous bone has been the gold standard of treatment for bone grafting, "the increased risk of complications has caused a shift towards alternate treatments, such as synthetic, resorbable bone graft substitute materials."

According to John Tierney, D.O., an orthopedic surgeon affiliated with New England Baptist Hospital, who has worked with the company's bone repair treatment: "Anika's 510(k) clearance allows for the marketing of one of only a handful of bone graft substitutes that can be administered in a minimally invasive manner. It offers physicians an additional option for treating bone defects or injuries, without the need for expensive and high-risk surgeries, while also reducing the operating room time spent on each case."

Over the past 25 years, the company says its therapies have been used in over 25 million treatments. The company's orthopedic medicine portfolio includes Orthovisc, Monovisc, and Cingal, which replenishing depleted HA, and Hyalofast, a solid HA-based scaffold to aid cartilage repair and regeneration. — *WE*

HA Treatment / Courtesy of Anika Therapeutics, Inc.

BIOLOGICS

Scaffold-Free MSC Cartilage Repair Passes Major Test

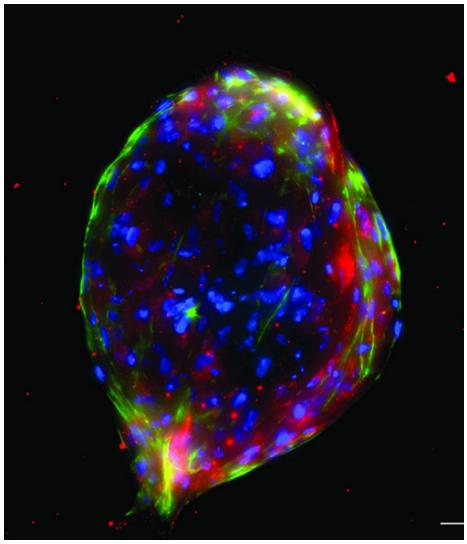
The search goes on—for a biologic solution to damaged or worn-down cartilage.

Now a group of researchers at Osaka University have passed their first-in-man test of a novel, scaffold-free mesenchymal stem cells (MSC) solution. One year after implantation, healthy cartilage.

Here are the before and after photos. *(Figure 1 below.)*

What makes this approach so innovative is that is uses only allogenic MSC cells in a novel solution (supplier Twocells Company Ltd.) and then applies mechanical forces to "firm" up the solution into an injectable living cell treatment that will adhere to the knee and, without requiring a scaffold, differentiate and grow into cartilage repair tissue.

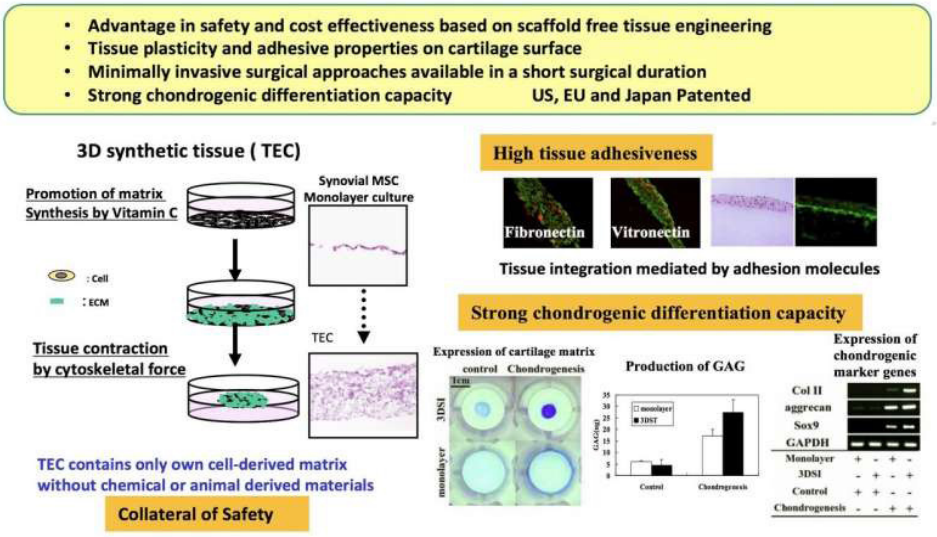
The lead investigators at Osaka University have progressed to Phase III in their clinical trial and this first-in-man test is highly encouraging.



Wikimedia Commons and BioTek Instruments

Importantly, this is a direct result of the stem cell bank at Osaka University's Medical Center for Translational Research.

Researchers Norimasa Nakamura, Hideki Yoshikawa, and Yoshiki Sawa tested this novel approach which, in some ways, mimics nature's approach to driving progenitor cell differentiation. The Osaka team started with cell bank sourced MSCs, cultured them using a new form of cell culture solution, then, in a move which mirrors the natural forces which signal progenitor cells to differentiate—applied mechanical forces to the culturing cells and created a scaffold-free, three-dimensional gel-like, injectable living tissue.



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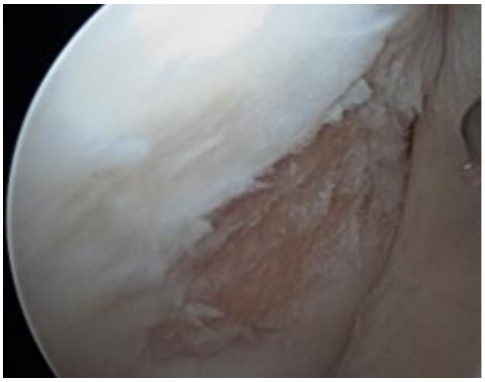


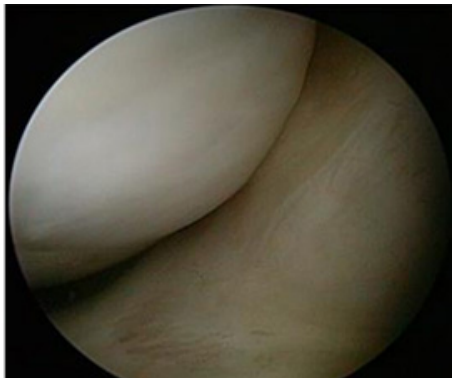


Figure 1. Courtesy of Osaka University

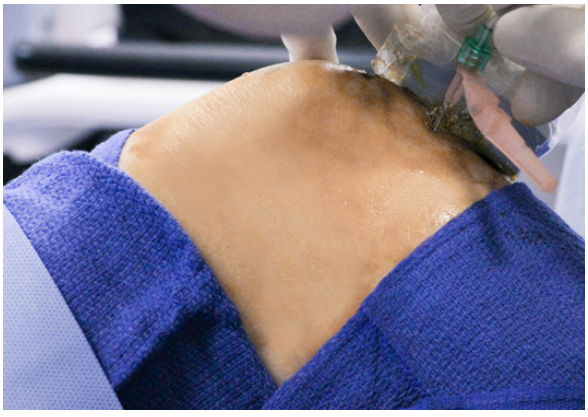
Here is a chart which illustrates the technique. *(Figure 2 above.)* — *BY*

Zimmer Biomet APS Kit Offers Better Pain Relief for Knee OA

Zimmer Biomet Holdings, Inc. announced in a recent press release the results from the PROGRESS II Trial on the safety and efficacy of autologous protein solution prepared with its nStride APS Kit for treating osteoarthritis (OA) of the knee. The study titled "Clinical Outcomes of Knee Osteoarthritis Treated With an Autologous Protein Solution Injection: A 1-Year Pilot Double-Blinded Randomized Controlled Trial", which originally appeared in *The American Journal of Sports Medicine* in October 2017, showed that solutions prepared with the kit offer significant improvement in pain, and has a comparable safety to saline.

In this prospective, randomized, double-blind, saline-controlled pilot study, the researchers used the nStride APS (autologous protein solution) Kit to concentrate anti-inflammatory cytokines and growth factors from a sample of the patient's blood into the autologous protein solution so it can be delivered back to the patient through an intra-articular injection into the knee joint.

A total of 46 patients with unilateral, mild to moderate symptomatic knee osteoarthritis pain from four trial sites across Europe were enrolled in the trial and randomized to receive either a single injection of APS prepared by the nSTRIDE APS kit (n = 31) or a single injection of saline (n = 15).



Wikimedia Commons and PainDoctorUSA

Both patient-reported outcomes and adverse events were measured at two weeks, one month, three months, six months and 12 months after the injection. Visual Analog Scale (VAS), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Knee Injury and Osteoarthritis Outcome Score (KOOS) were used to measure clinical effectiveness. X-ray and magnetic resonance imaging (MRI) were also taken at baseline and again at three and 12 months after the injection.

According to the press release, patients in the APS group had a 65% change in WOMAC pain score from baseline to 12 months compared to the 41% change seen in the saline group (p = .02). Using the VAS, the APS group had a 49% improvement compared to a 13% improvement in the saline group (p = .06). In addition, no serious adverse events were seen either related to the procedure or to the device.

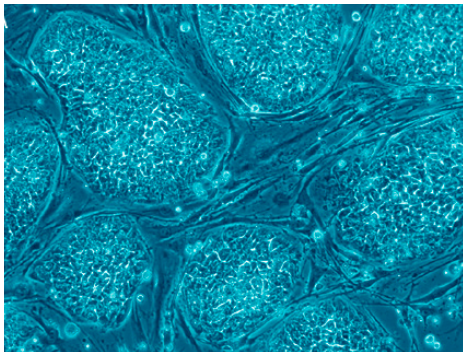
"Inflammation is a critical factor in the pain and cartilage breakdown associated with knee osteoarthritis, and research has established that APS derived from the patient's whole blood contains a host of powerful anti-inflammatory and anabolic proteins," said Elizaveta Kon, M.D., associate professor, Humanitas University, Milan, Italy, and lead investigator of the PROGRESS II trial, in a press release.

Currently the nSTRIDE APS Kit is not commercially available in the United States, but holds the CE Mark in Europe and is approved as the APS Kit in Japan. The PROGRESS IV trial is currently enrolling patients and the PROGRESS V trial is being conducted in Europe.

Zimmer Biomet, headquartered in Warsaw, Indiana, is a global leader in musculoskeletal healthcare. For more information, visit here. — *TR*

Stem Cells to Regrow Bone in Israeli Trial

In a procedure being called "science fiction" an Israeli man became the first ever to receive a surgical procedure intended to regrow a section of his shin bone.



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Eight months earlier, following a car accident, the patient had had a part of his shin bone surgically removed. Earlier this December, surgeons successfully dealt with his prior injury with a new, never before accomplished procedure.

The operation performed on the patient was developed several years ago by Bonus BioGroup, an Israel-based biotechnology company that produces tissue-regenerating bone grafts.

The company's medical team harvested fat tissue cells from the patient's leg and grew them in their laboratory. The fat

cells were then injected back into his leg to regenerate the bone's missing parts.

"We created thousands of tiny bone particles, each one of them alive, which enables us to inject them into the missing part where they join to form a fully functional bone," said Shai Meretzky, M.D., CEO of Bonus BioGroup, according to *The Times of Israel.*

"Our patient arrived with a missing part in his shinbone that his body could not regenerate on its own. In the surgery I transplanted the cells we extracted from him two weeks ago, and within six weeks the bone will regrow itself and his shin will function normally again. This surgery is truly science fiction. It changes the entire game in orthopedics. Today I can grow any bone in a lab," Meretzky claimed.

Australian scientists have also reprogramed fat cells for an adult's bone through a new stem cell treatment. Like Bonus BioGroup's procedure, it could provide a way to regenerate any form of damaged tissue in the body.

Further research conducted into the effectiveness of stem cells could provide potential solutions for health conditions such as diabetes, Alzheimer's and Parkinson's.

Former President George W. Bush vetoed a bill from the U.S. Senate in 2001 that would have provided more funding for stem cell research, Former President Barack Obama overturned Bush's regulation in 2009 saying, "Medical miracles do not happen simply by accident. They result from painstaking and costly research; from years of lonely trial and error, much of which never bears fruit and from a government willing to support that work."

Announcement of the procedure's success pushed Bonus BioGroup's publicly traded stock up 18.66% on the Tel Aviv Stock exchange at market close, according to CTech.

Bonus BioGroup's procedure will not hit the market for a while. Many questions remain about the procedure and implant including: Was it properly absorbed by the body and not rejected?

More clinical trials will need to be run to determine the procedure's long-term safety and effectiveness. — *BY*

LARGE JOINTS

Simultaneous Bilateral TKA Less Risky Than Staged?

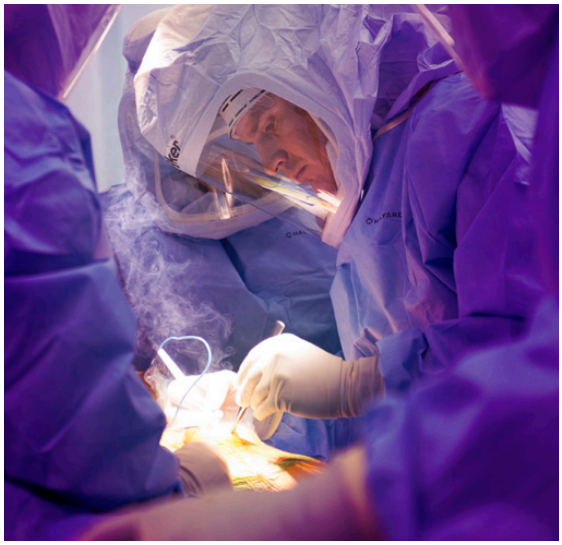
Stiffness that requires manipulation under anesthesia postoperatively is a problem for patients with bilateral knee arthritis. Turns out, says new research, that it's more of an issue for those who undergo staged bilateral total knee arthroplasty (B-TKA) or unilateral TKA than for those who have simultaneous bilateral TKA.

The study, "Postoperative Stiffness Requiring Manipulation Under Anesthesia Is Significantly Reduced After Simultaneous Versus Staged Bilateral Total Knee Arthroplasty," was published in the December 20, 2017 edition of *The Journal of Bone and Joint Surgery.*

Study co-author and member of the Department of Orthopaedic Surgery at the University of California, Davis in Sacramento, California, John P. Meehan, M.D. told *OTW*, "In a 2011 article published in *Journal of Bone and Joint Surgery (JBJS)*, we developed a sophisticated methodological model to minimize the bias associated with studies that compared outcomes of patients who underwent simultaneous bilateral total knee arthroplasty (simultaneous-BTKA) versus patients who underwent staged bilateral TKA (staged B-TKA)."

"The most important part of the model was that we accounted for patients who planned to undergo two knee replacements in a staged manner (planned staged B-TKA) but did not undergo the second knee procedure due to medical, surgical complications or simply decided after the first knee replacement that they did not wish to undergo the procedure a second time. Our results indicated that surgical complications, especially periprosthetic joint infection and aseptic loosening, were significantly reduced in people who underwent simultaneous-BTKA versus staged B-TKA."

"In our recent study published in *JBJS*, we utilized the same methodological model to assess for a difference in postoperative stiffness requiring manipula-



Wikimedia Commons and William Cousins

tion under anesthesia (MUA). Using the California Patient Discharge Database (PDD) linked with the California Emergency Department (ED), Ambulatory Surgery (AS), and master death file databases, we were able to acquire records on 95-97% of all discharges in the state. From this, we performed hierarchical, risk adjusted, multivariate models of the outcome of undergoing MUA within 90 and 180 days after TKA."

"We specifically wanted to determine if a person with symptomatic bilateral knee osteoarthritis would have less postoperative stiffness and by inference improved recovery if they underwent a single operative event, simultaneous B-TKA, or two separate operative events, staged B-TKA."

"While numerous textbooks describe bilateral knee osteoarthritis with contractures as an indication to perform simultaneous B-TKA, to the best of our knowledge this recommendation has not been scientifically validated."

"Our results supported the hypothesis that performing a simultaneous B-TKA in patients with symptomatic bilateral knee osteoarthritis would allow for an improved functional recovery with a statistically significant reduction in hospital readmissions for postoperative stiffness requiring MUA when compared to staged B-TKA."

"With stiffness being associated with an increased need for revision surgery and decreased patient satisfaction, combined with the financial burden of hospital readmissions for MUA, the benefits of performing simultaneous B-TKA in appropriately selected patients with symptomatic bilateral knee osteoarthritis are even more justified by our findings." — *EH*

EXTREMITIES

FDA Clears Zimmer Biomet's Stem-Free Shoulder

Zimmer Biomet Holdings, Inc. receives a lot of FDA clearances each year. The company does not usually issue press releases for each clearance.

But on January 3, 2018, the new CEO of the company, Bryan Hanson, announced the FDA 510(k) clearance of the Sidus Stem-Free Shoulder system. The system is a total shoulder arthroplasty solution "for patients with good bone stock that have either osteoarthritis, post-traumatic arthrosis, focal avascular necrosis of the humeral head or who had previous surgeries of the shoulder that do not compromise the fixation."

The system, says the company, is designed to "anatomically restore a patient's anatomy, preserve bone stock and allow for improved pre to postoperative patient outcomes."

According to the company's British website, the humeral component is positioned independent to the location of the humeral canal, enabling optimal coverage and placement. Eleven humeral head options allow for patient-matching flexibility. The system also has the flexibility to mate with either Anatomical Shoulder Glenoids or Bigliani Flatow Glenoids, including the Trabecular Metal Glenoid.

Ryan Krupp, M.D., an orthopedic surgeon at Norton Orthopedic Specialists in Louisville, Kentucky, said the system is offers a "novel approach to total shoulder arthroplasty requiring minimal bone resection." He added that the system is designed to reduce pain and restore range of motion and is "clinically proven to help suitable patients."

Hanson said the clearance comes at a time when Zimmer Biomet is "accelerating the pace of innovation." He noted the Sidus was launched in Europe in 2012 and a clinical study was initiated in the U.S. in 2015. "During that time, the product has demonstrated strong clinical performance. The addition of the Sidus system to Zimmer Biomet's U.S. portfolio reinforces the company's leadership in the innovation of shoulder solutions."

The company submitted the clearance notification in June 2017 and the clearance decision was made in December. —*WE*

Sidus Stem-Free Shoulder / Courtesy of Zimmer Biomet Holdings, Inc.

SPINE

FH's ESP Disc Hits 6,000th Implant Milestone

FH Orthopedics has announced that sales of its Cervical Prosthesis (CP-ESP) and Lumbar Prosthesis (LP-ESP) have exceeded 6,000 units.

According to the company, "ESP discs combine two titanium end plates with an elastomeric cushion made of polycarbonate urethane. This structure imitates the natural disc, in which bony segments are connected by a spongy disc that provides flexibility while withstanding the pressures of compression and torsion."

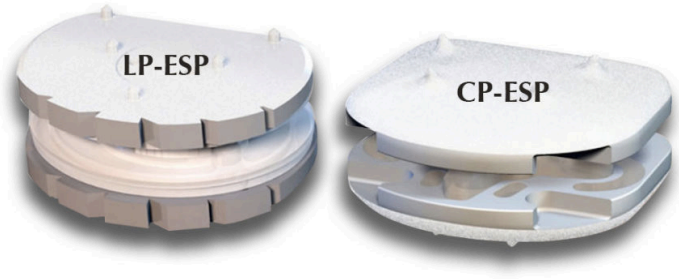
"Specific features of the end plates—short spikes, a rough outer surface, and a coating of hydroxyapatite (HA), which is proven to enhance bone ingrowth—help to ensure stability and bony fixation of the implant over time."

"This design provides a number of benefits for orthopedic surgeons and their patients: Adaptive center of rotation, shock absorbing, improved stability, no surface bearing for increased lifetime, designed to fit and restore patient lordosis (spinal curvature), range of sizes to fit different patients, minimally invasive surgical technique and shorter hospital stay."

"The CP-ESP prosthesis—indicated for use in cases of symptomatic cervical discopathy that have not responded to other medical treatments for at least six months—offers 7 degrees of flexion/extension, 5 degrees of lateral flexion, and 4.5 degrees of axial rotation. The LP-ESP prosthesis—indicated for use in cases of lumbar disc disease, typically related to disc herniation, that have not responded satisfactorily to other treatments—offers 6 degrees of flexion/extension, lateral flexion, and axial rotation."

Spine Business Unit Director Eric Hermann told *OTW*, "This milestone means that we get a great market recognition for our advanced technology of viscoelastic prosthesis which allows surgeons to avoid compromising when they treat their patients. Due to its technology, the ESP prosthesis provides similar properties to natural disc. It allows six degrees of freedom while offering resistance as the natural disc."

"This level—6,000 prosthesis since the start (lumbar CE mark in 2006, cervical CE mark in 2012) and half of them within the last three years—means more than 30% growth per year. We plan, at least, to triple this number in the next five years. We also have plans to start to offer the ESP prosthesis in the U.S. and are currently working on an action plan to get FDA approval." — *EH*

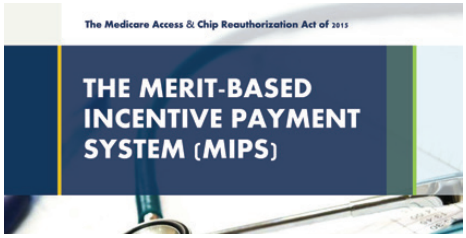


Lumbar Prosthesis (LP-ESP) and Cervical Prosthesis (CP-ESP) / Courtesy of FH Orthopedics

REIMBURSEMENT

CMS Approves Ortho Association for MIPS Clinical Data Registry

Centers for Medicare and Medicaid Services (CMS) has approved the American Association of Orthopaedic Executives (AAOE) as a Qualified Clinical Data Registry (QCDR).



MIPS Payment Program / Courtesy of CMS

This is a big deal because the registry allows providers to collect the data needed to participate in the Merit-Based Incentive Payment System (MIPS) coming in 2019, and qualify for higher payments.

MIPS came out the ashes of the much-despised Sustainable Growth Rate (SGR) formula used to determine reimbursement rates for medical providers. The new reimbursement system consolidated numerous quality measurement programs so providers could be measured on quality outcomes.

Transition to MIPS

As CMS began to phase out of the Fee-for-Service (FFS) program it continued to apply a Value-Based Payment Modifier (Value Modifier) for differential payments to physicians based on the quality and cost of care they furnish to beneficiaries enrolled in the traditional Medicare Fee-for-Service program.

Under the Value Modifier, performance on quality and cost measures translated into increased payment for physicians

who provide "high quality, efficient" care and decreased payment for "low-performing" physicians who underperform. The Value Modifier will expire at the end of 2018, as MIPS begins in 2019.

To prepare for 2019, the Association is touting a "truly affordable" rate to help providers measure such things as:

- Patient Satisfaction
- Patient Reported Outcomes
- Quality Measures

The cost is only $100 per provider for 2018 and $200 for the following three years if you sign up by April 17, 2018. This rate includes access to one or all elements of the data warehouse, depending on your level of participation.

For more information on the AAOE QCDR, Data Warehouse, and Benchmarking Survey, visit www.aaoe.net/datawarehouse or contact AAOE Director, Data Solutions Vicki Sprague, Ph.D., at vsprague@aaoe.net or 317-749-0626.

AAOE President Ron Chorzewski, PT, MBA, Executive Director, Agility Orthopedics, said 19 practices and 243 providers are already participating. He added the registry "is an important addition to the resources AAOE members can use to better manage our practices and set the standard for excellence in the industry."

In a December 27, 2017 press release, the Association said this is an important initiative of AAOE to "give back to the orthopaedic community" by providing all members, no matter their practice size, with a one-stop-shop for their data collection, benchmarking, and reporting needs.

The association was founded in 1969 as practice management association serving the orthopedic industry. Membership includes more than 1,600 orthopedic practice executives, administrators, physicians, and their staff. The association is loosely affiliated with the American Academy of Orthopaedic Surgeons (AAOS), dealing with the business side of orthopedic practices.

To study up on the MIPS program, click here.. — *WE*

PEOPLE

William J. Robb, III, M.D.: New Orthopedic Director, CMO at IBJI

William J. Robb, III, M.D. has been appointed orthopedic director, chief medical officer of Illinois Bone & Joint Institute (IBJI). Dr. Robb joined IBJI in 1995 and has 40 years of surgical experience, specializing in adult knee disorders.

"Dr. Robb is one of America's leading orthopedic surgeons and has been repeatedly recognized for his leadership qualities and contributions to the orthopedics field. Since joining IBJI he has played an integral role in directing the mission, focus and growth of our practice," said Andre Blom, IBJI chief operating officer. "In his new role as orthopedic director, chief medical officer, Dr. Robb will take the lead in overseeing clinical operations as IBJI continues to deliver optimal outcomes for our patients."

According to IBJI, "Dr. Robb, a graduate of University of Iowa Medical School, completed his internship and initial residency in general surgery at Duke University Medical Center in North Carolina, then returned to Iowa to complete the orthopaedic surgery residency at University of Iowa Hospitals and Clinics."

"He has published numerous pieces of scholarly research and his contributions to the field have been lauded with a number of industry awards, including the 2017 W.W. Tipton Leadership Award from the American Academy of Orthopaedic Surgeons."

"He has held leadership positions at the American Association of Hip and Knee Surgeons, the American Academy of Orthopaedic Surgeons and Illinois Orthopaedic Society; and from 2005-2012, he served as Chairman of the NorthShore University Health System's Department of Orthopaedic Surgery."

William J. Robb, III, M.D. / Courtesy of Illinois Bone & Joint Institute

Dr. Robb told *OTW*, "Five years ago IBJI began evaluating the opportunity to participate in the Bundled Payment Care Initiative (BPCI) program with CMS [Centers for Medicare and Medicaid Services]—an innovative payment program for IBJI's total hip and knee replacement patients based upon the redesign of rehabilitation care following hospital discharge."

"As the medical director of this very successful IBJI program, IBJI is now positioned to expand these efforts through similar care redesign which can improve the quality of outcomes for many of our patients."

"Based upon our experience and successes with the BPCI program designed primarily for hip and knee replacement patients, new centers of excellence will be developed for other common orthopedic and musculoskeletal diseases including spine care, shoulder care and sports care. I look forward to working closely with all IBJI surgeons and administrative leaders to improve care for our many patients across the Chicago area." — *EH*

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