VOLUME 9, ISSUE 30 | SEPTEMBER 24, 2013

Orthopedics This Week

WEEK IN REVIEW

4 Cleveland Clinic, Rothman, CORE and OrthoCarolina Team Up >> Four major systems run by surgeons have formed the first ortho/spine physician hospital organization (PHO) to catch the wave of value-based reimbursement. They promise employers a one-stop-shop for their employees. Read about PHOs and learn about these ortho leaders.

9 The Top 28 North American Shoulder Surgeons >> Separated shoulder or severe shoulder sprain…who do the best want treating them? Here are the answers! Shoulder surgeons at the top of their game let us know their thoughts on the best orthopedic surgeons in their subspecialty.

13 Pagnano Takes on Engh Over Poly Insert Exchange >> "The reasons to do a polyethylene insert exchange might include isolated liner wear, knee instability, or specific circumstances surrounding knee stiffness," argues Mark Pagnano. "Hold up," says Jerry Engh. "IF the original implant was a defective poly, and IF good poly is available for the exchange, then it is a reasonable option."

17 Landmark Study: Arthroscopy Beats Open Repair for Shoulder Repair // Lifetime Achievement Award for George Thompson, M.D // "Abscess" Study Wins Best Clinical Paper Award >> Largest study of its kind shows arthroscopic repair of shoulder instability yields better results than an open procedures. Scoliosis Society awards the remarkable George Thompson the Lifetime Achievement Award and more.

OrthoCarolina

Cleveland Clinic

ROTHMAN INSTITUTE

THE CORE INSTITUTE
Center for Orthopedic Research and Education®

BREAKING NEWS

21 Osteoporosis Drug Helps **Hip, Knee OA**

Study Shocker: **Smoking Not a TJR Risk Factor**

Consumer's Union Urges **Implant Guarantees**

FDA Device Identifying System Finalized

FDA Has Most **August "Clearances"** in Years

Dr. Phillip Yuan Testing **Innovative Approach to Back Pain**

For all news that is ortho, read on

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: NASS starts in just a couple of weeks. We've never seen such a high level of angst among a surgeon societies' membership as we are witnessing at NASS. It started with *The Spine Journal* editor in chief's Carragee's fratricidal attacks on his colleagues which were then amplified by NASS's PR department and leadership. Rumblings among key surgeon opinion leaders and corporate exhibitors are ominous.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	1	Stryker	18.71%	4.93%	Nice move this past month. Up nearly 5%. Not often noted, but certain to warm investor's wallets, SYK's dividend payout ratio is up to 34%.
2	2	Zimmer	29.28	4.54	Checking on analysts' latest earnings forecasts, we were surprised to see growth rates higher than SYK. Still lowest priced ortho equity.
3	3	Conmed	10.57	7.66	For some reason, this stock is acting like a bobber in the ocean. Will not sink—despite a "sell" recommendation from Zack's. Someone is buying.
4	4	Orthofix	16.25	(0.09)	For most of this past month OFIX was the best performing stock in our universe. Is it a dead cat bouncing or a good company on the mend?
5	6	Globus Medical	28.53	(1.89)	Wall Street bank Oppenheimer says GMED is attractive at these levels. We agree. GMED most profitable spine company in industry.
6	7	NuVasive	6.30	2.45	While GMED slipped, NUVA rose. Lots of negative headlines these days, but it isn't affecting the stock in the least. Why? Fundamentals still rule.
7	8	Smith & Nephew	20.78	2.32	Expected sales growth is 8% for the second half of the year. Pulls the full year up to 4.60%. Will the sales momentum continue into 2014?
8	9	Medtronic	28.78	1.96	Flat earnings and 2% revenue growth. Not exactly the recipe for shareholder wealth expansion. But then there is that dividend (2.10% yield).
9	10	Johnson & Johnson	26.68	0.99	Speaking of dividend yield, no one in ortho or med devices beats JNJ. The five year average yield is 3.30%. That's higher than some 30-year mortgages.
10	5	Integra LifeSciences	11.77	(6.69)	IART equity is just not in favor right now. All analysts expect Q3 EPS will be down. But 2014 EPS should rebound. Conviction, however, may be wavering.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MAKO Surgical	MAKO	$16.36	$769	13.77%
2	Alphatec Holdings	ATEC	$2.18	$212	10.66%
3	CryoLife	CRY	$6.95	$192	9.79%
4	Wright Medical	WMGI	$25.84	$1,216	8.34%
5	Conmed	CNMD	$33.58	$923	7.66%
6	RTI Biologics Inc	RTIX	$3.70	$208	6.63%
7	ArthroCare	ARTC	$35.11	$992	6.59%
8	Exactech	EXAC	$19.97	$269	5.49%
9	Stryker	SYK	$71.28	$26,953	4.93%
10	Zimmer Holdings	ZMH	$83.11	$14,091	4.54%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	$3.90	$376	-33.90%
2	Baxano Surgical Inc	BAXS	$1.60	$72	-15.34%
3	Bacterin Intl Holdings	BONE	$0.56	$29	-7.12%
4	Integra LifeSciences	IART	$39.45	$1,108	-6.69%
5	Globus Medical	GMED	$17.43	$1,618	-1.86%
6	Tornier N.V.	TRNX	$19.39	$927	-0.62%
7	Orthofix	OFIX	$22.20	$432	-0.09%
8	Johnson & Johnson	JNJ	$89.68	$252,725	0.99%
9	Symmetry Medical	SMA	$8.40	$313	1.08%
10	TiGenix	TIG.BR	$0.31	$39	1.14%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$22.20	$432	8.92
2	Zimmer Holdings	ZMH	$83.11	$14,091	13.43
3	Medtronic	MDT	$53.71	$53,574	14.60
4	Smith & Nephew	SNN	$62.07	$11,137	15.28
5	Globus Medical	GMED	$17.43	$1,618	15.46

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$24.27	$1,081	86.68
2	Symmetry Medical	SMA	$8.40	$313	33.60
3	RTI Biologics Inc	RTIX	$3.70	$208	27.57
4	ArthroCare	ARTC	$35.11	$992	23.80
5	CryoLife	CRY	$6.95	$192	19.86

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Globus Medical	GMED	$17.43	$1,618	1.03
2	Orthofix	OFIX	$22.20	$432	1.27
3	Exactech	EXAC	$19.97	$269	1.28
4	Conmed	CNMD	$33.58	$923	1.39
5	Zimmer Holdings	ZMH	$83.11	$14,091	1.46

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$24.27	$1,081	9.12
2	CryoLife	CRY	$6.95	$192	4.96
3	Symmetry Medical	SMA	$8.40	$313	2.80
4	Johnson & Johnson	JNJ	$89.68	$252,725	2.73
5	Medtronic	MDT	$53.71	$53,574	2.26

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$8.40	$313	0.76
2	Bacterin Intl Holdings	BONE	$0.56	$29	0.85
3	Orthofix	OFIX	$22.20	$432	0.93
4	Alphatec Holdings	ATEC	$2.18	$212	1.08
5	RTI Biologics Inc	RTIX	$3.70	$208	1.17

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	MiMedx Group	MDXG	$3.90	$376	13.89
2	TiGenix	TIG.BR	$0.31	$39	9.62
3	MAKO Surgical	MAKO	$16.36	$769	7.49
4	Baxano Surgical Inc	BAXS	$1.60	$72	4.96
5	Globus Medical	GMED	$17.43	$1,618	4.19

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

Cleveland Clinic, Rothman, CORE and OrthoCarolina Team Up

BY WALTER EISNER

Logos courtesy of OrthoCarolina, Cleveland Clinic, The Rothman Institute, and The Core Institute

Operating under the name of the National Orthopaedic & Spine Alliance LLC (NOSA), the Cleveland Clinic in Ohio, the Rothman Institute in Pennsylvania, the CORE Institute of Arizona and OrthoCarolina in North Carolina, have teamed up to improve the delivery of orthopedic and spine care across the nation and establish industry benchmarks for quality and value.

Times Are Changing

Healthcare organizations which were built on volume and fee-for-service in the past decades will have to adapt to a rapidly approaching wave of a value-based reimbursement systems under Obamacare. How soon will this happen—2014.

On September 10, 2013, four of the best known and most widely regarded orthopedic and spine care systems in the U.S. (which were all founded and run by surgeons) have come together to form the first-of-its-kind clinically integrated orthopedic physician hospital organization (PHO) in the U.S.

But the motivations behind this new alliance are not just economic. Equally if not more important is excellence in healthcare delivery based on setting benchmarks and demonstrating value. Indeed, the organizers of this important new alliance tell *OTW* that the success of their PHO will be depend on establishing strict clinical protocols and setting criteria which measure performance and demonstrate value to payers, employers and patients.

In addition to the four systems mentioned in the announcement, the organizers also executed a letter of intent (LOI) with two other powerhouse providers—OrthoIndy and OrthoCalifornia, Inc. Under the terms of the LOI, these groups would also be participating providers in the PHO. OrthoCalifornia's physicians are part of Hoag Orthopedic Institute's medical staff. According to the announcement, additional members who comply with the Alliance's protocols and criteria and fit geographically may also be invited to join in the future.

On day one nearly 600 physicians will be part of the Alliance. Organizers have said that they will see their first patients in January 2014.

NOSA's Board President and Chairman of the Cleveland Clinic Orthopaedic and Rheumatologic Institute, Joseph Iannotti, M.D., Ph.D., said, "This is a monumental step in ensuring that patients around the nation in need of orthopedic or spine care will be able to receive it and have peace of mind knowing there is a high-quality provider located nearby. The fact that these leading groups are working together to offer the highest quality, peer-reviewed service that employers and patients can have access to is really unprecedented."

Joseph Iannotti, M.D.
Cleveland Clinic

Iannotti said NOSA will be the first clinically integrated network of independent centers of excellence in orthopedic and spine surgery that have agreed to define and follow best practices, share clinical outcome data in addition to patient quality and safety data across a broad spectrum of procedures.

Standardized, Evidence-Based Care Protocols

CORE Institute's (Center for Orthopedic Research and Education) Chairman and CEO David Jacofsky, M.D., is a leader in developing an integrated system which follows a strict protocol for surgeon practice and procedures based on previously measured outcomes. CORE's protocol, according to Jacofsky, has demonstrated cost savings.

The only rub with some surgeons is that they seem to think that some of their clinical decision-making is taken out of their hands as strict protocols must be followed, but these are based on a group consensus of the evidence in the published literature. They are also measured.

David Jacofsky, M.D.
The CORE Institute

"The CORE Institute is a national leader in the deployment of standardized, evidence-based care protocols managed via a proprietary IT infrastructure that allows meticulous tracking of quality metrics and key performance indica-

tors," said Jacofsky. "The organization has experience with pay for performance, bundled payment concepts, and full at-risk capitation."

Jacofsky believes this PHO will help define the way in which top orthopedic groups are able to share data and improve quality in a more comprehensive, automated, and integrated way and will redefine the way in which employers can access medical care for employees based on outcomes data.

He added that surgeons should recognize that their professional fees are only a small part of the overall procedure costs, but ultimately drive significant spending. He notes that many health insurers and Medicare are experimenting with bundled payments, which creates an incentive for the physician and health system is to optimize the outcomes and the cost of the entire episode. "One major way to do this is by reducing variation in care and focusing on the aspects of care outside of the surgical suite."

Patients, Employers and Providers

Organizers state that the alliance will benefit patients, employers and participating providers in these ways:

- Patients – gives them access to a network of top-tier programs, which are geographically dispersed across the country
- Employers – allows employers to provide a consistent level of quality care for employees conveniently located throughout the U.S. and align with a network of physicians who are focused on quality care and cost control
- Participating Providers – establishes quality standards and ensures quality improvement and benchmarks through data sharing, in an area where few quality benchmarks exist today.

After an employer has joined NOSA, the alliance will give employees seeking orthopedic care a phone number which puts them in touch with staff members who will deliver "concierge-level service" regarding their treatment plan, including helping the employees with travel to and from centers. The alliance is also offering employees follow-up care utilizing evidence-based guidelines and which tracks cost and quality outcomes for each patient.

Iannotti said employers will be offered a single contract which provides access to all providers. Other providers who want to join the alliance must first agree to share data regarding outcomes and quality improvements.

NOSA plans to publish clinical outcome, patient safety and patient satisfaction data using an annual outcome publication—not unlike the current Cleveland Clinic publication system, he said.

Governance

The PHO will be governed by a board, led by Iannotti. There are also three primary operating committees.

- Quality Committee – To establish metrics, by which all participants will be measured, reviews compliance and develops new ways to improve PHO performance. Daniel Murrey, M.D., M.P.P., CEO of OrthoCarolina is the chair
- Financing Committee – To monitor PHO financial performance. Mike West, CEO of Rothman Institute, chair
- Nominating/Membership Committee – To identify potential participating providers. To evaluate those prospective providers for fit with the PHO's vision and ability to meet outcome standards. Jason Scalise, M.D., vice chairman, National Physician Integration of the CORE Institute, chair.

Physician Hospital Organizations

While the formation of an orthopedic and spine based PHO is new, the concept of the PHO is not.

PHOs were created in the early 1990s as a legal entity generally formed by physicians and one or more hospitals with the intention of negotiating contracts with payers and sharing in the financial rewards of controlling costs. An estimated 15 to 20% of hospitals had a PHO in 1994, and many others planned to start one, according to a Medicare report.

According to the trade group, Health Care Lawyers, a PHO is a viable alignment model, with three big "ifs":

- First and foremost, if it's clinically integrated (meaning doctors and hospitals collaborate to provide better care at lower cost) not to leverage higher fees from payers, so that the PHO can offer a compelling value proposition to payers
- Second, a PHO can succeed if it meets independent doctors' professional and economic needs
- Third, a PHO can work if the right market conditions exist, notably that health plans are willing to share savings with clinically integrated providers who deliver care more efficiently.

Avoiding Price Fixing, Showing Cost Effectiveness

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*Data is available on file.

IMPORTANT SAFETY INFORMATION

HUMANITARIAN DEVICE

OP-1 IMPLANT is authorized by Federal law for use as an alternative to autograft in recalcitrant long bone nonunions where use of autograft is unfeasible and alternative treatments have failed. The effectiveness of this device for this use has not been demonstrated.

OP-1 PUTTY is authorized by Federal law for the repair of symptomatic, posterolateral (intertransverse) lumbar spine pseudoarthrosis in patients for whom autologous bone and/or bone marrow harvest are not feasible or are not expected to promote fusion and who have at least one of the following compromising factors: osteoporosis, diabetes or nicotine use. The effectiveness of OP-1 PUTTY for this use has not been demonstrated.

Brief summary of contraindications and warnings:

- OP-1 IMPLANT/OP-1 PUTTY is contraindicated in patients who (1) are pregnant (2) have or have had a malignancy (3) are skeletally immature (4) are pregnant or want to become pregnant within 2 years of treatment (5) have a known hypersensitivity to the active substance or to collagen (6) have an autoimmune disease or immune suppression (7) have been previously treated with OP-1 IMPLANT or OP-1 PUTTY.
- The use of OP-1 IMPLANT/ OP-1 PUTTY may result in (1) the formation of localized ectopic or heterotopic bone outside of the treatment site (2) development of an immune response against BMP-7 or Type I collagen.
- There are no adequate well controlled studies of OP-1 IMPLANT/OP-1 PUTTY in (1) pregnant women (2) patients with autoimmune disease or immune suppression (3) patients with renal impairment.

Please see the package insert for the complete indication, contraindications, warnings, precautions, adverse events and other important medical information.

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fully in contract talks with payers. They will also be better positioned for new Medicare and Medicaid payment models that require hospital and physician cooperation, such as global payments, bundled payments, episode-based payments, accountable care organizations, and reductions of readmissions.

Once formed, the PHO contracts directly with managed-care plans, which now have a one-stop-shopping type of arrangement with the PHO in one contract. The managed care plan simultaneously arranges for the PHO provision of hospital tertiary-care and specialty-physician services. The managed care organization (MCO) would no longer need to enter into several agreements with individual specialists; instead, the MCO would have an agreement for the entire scope of services from the PHO.

In a 2009 article entitled "Clinically Integrated Physician-Hospital Organizations" Barry Bader writes, "To be seen as cost-effective by purchasers, the PHO must have active utilization management, sophisticated information systems, and intensive involvement of physicians in developing standards of care. PHOs have not yet developed this infrastructure. To avoid concerns of antitrust, the PHO must entail significant elements of risk sharing for both parties."

In a 2010 paper titled "Physician-Hospital Integration in the Era of Health Reform" prepared for California Health Care Foundation, the authors noted that PHOs were not initially successful at developing the infrastructure needed to manage utilization cost-effectively, and they failed to sign many contracts with health plans. What's more, the Federal Trade Commission (FTC) found fault with the way most PHOs negotiated fees for doctors, finding that in practice they amounted to price fixing.

In a consent order issued in 2006, the FTC opened a door by allowing Advocate Physician Partners to continue contracting through the program of "clinical integration" it had started several years earlier. In this ruling, staff opinion letters, and other statements, the FTC offered guidance to other PHOs on how to join forces lawfully in a way that drove better quality, greater efficiency, and lower overall cost.

Birth of Clinical Integration

Thus was born the Clinically Integrated PHO.

The FTC in essence said it would not pursue antitrust charges against PHOs that were truly organized to achieve collaboration among physicians and hospitals to "control costs and ensure quality."

By early 2010, wrote the authors, integration was again on the upswing in response to Obamacare and the introduction of accountable care organizations and expansion of other value-based payment methodologies.

But they had a warning as they said some industry stakeholders are cautious about embracing physician-hospital integration, because there is data to suggest that integration may lead to higher costs through increased market leverage with payers.

The costs of integration, which include practice acquisition, administration, information technology, operating infrastructure development, and ongoing practice support, can also pose a barrier. Also, given that most payers do not substantially reward for efficiency or quality, it is difficult for most organizations to begin the necessary care redesign without reducing revenue.

Riding the Wave

Because of the growing consensus that fee-for-service is a major contributor to ever-rising costs, new payment methodologies are emerging that emphasize managing cost and quality of care for an identified population of patients or diagnoses. This has led to an increase in physician-hospital integration to better coordinate care and align their financial incentives.

Looks like NOSA has the resources and expertise to catch the wave. ♦

The Top 28 North American Shoulder Surgeons

BY OTW STAFF

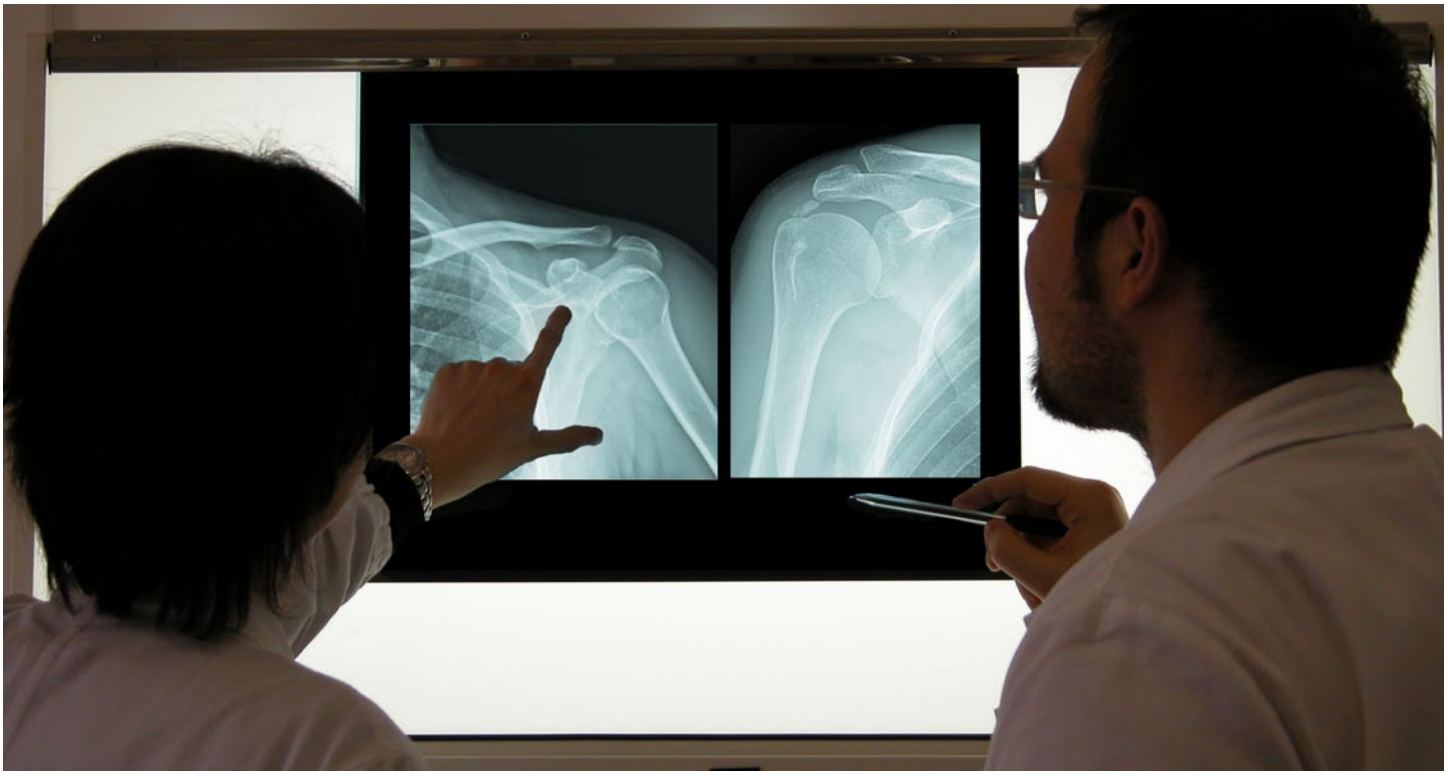

Image created by RRY Publications, LLC / Sources: Morguefile and Calrita

Separated shoulder or severe shoulder sprain…who do the best want treating them? Here are the answers! Shoulder surgeons at the top of their game let us know their thoughts on the best orthopedic surgeons in their subspecialty.

Here is that list. We don't have "the market" on lists…this isn't the be-all and end-all list—but it is a list of the most impressive shoulder surgeons in North America. This information was obtained via a telephone survey of thought leaders in the field. The information in quotes is what we heard about these surgeons.

In alphabetical order, here are the top 28 shoulder surgeons in North America.

Christopher S. Ahmad, M.D. is associate professor of Clinical Orthopaedic Surgery at Columbia University and an associate attending in Orthopaedic Surgery at New York Presbyterian Hospital. "He is the head team physician for the Yankees, and is also known for doing very good basic science studies of the methods of rotator cuff repair. His computer aided shoulder replacement studies are also very interesting."

April D. Armstrong, M.D. is associate professor of Orthopaedic Shoulder and Elbow Surgery at Penn State Hershey Bone and Joint Institute in Pennsylvania. She is also vice-chair of quality of the Department of Orthopaedics, as well as associate chief medical officer for surgery with Penn State Milton S. Hershey Medical Group. "Her research on shoulder replacement has highlighted glenoid imaging, something that is very new. And she is doing excellent work in her administrative position where she is in charge of quality measures for the department of orthopedics."

George Athwal, M.D., F.R.C.S.C is an orthopedic surgeon at the University of Western Ontario in Canada. "He is a younger, but very well respected surgeon who is increasingly invited to speak at international meetings. He is doing innovative research in shoulder instability and elbow replacement."

John-Erik Bell, M.D., M.S. is an orthopedic surgeon with Dartmouth-Hitchcock Medical Center in New Hamp-

shire. He is also assistant professor in the Department of Orthopaedic Surgery and The Dartmouth Institute. "He is exceptional, and is the only shoulder and elbow surgeon in that area of the U.S. doing complex surgery. He is an incredible teacher and has stimulated a lot of Dartmouth residents to go into shoulder and elbow. He does a nice job of combining the clinical and educational aspects of being an academic shoulder and elbow surgeon."

Jonathan P. Braman, M.D. is assistant professor in the Department of Orthopaedic Surgery at the University of Minnesota. "He is a rising star and a great surgeon. He is heavily dedicated to education, and is the resident education section leader for shoulder and elbow."

Stephen S. Burkhart, M.D. is an orthopedic surgeon with The San Antonio Orthopaedic Group in Texas. He is also clinical associate professor in the Department of Orthopaedic Surgery at The University of Texas Health Science Center at San Antonio and clinical associate professor at Baylor College of Medicine. He is a past president of the Arthroscopy Association of North America. "He is a pioneer in arthroscopy, and is well known for his interesting concepts of the biomechanics of rotator cuff repair. He is a very clear thinker and a great educator."

Brian J. Cole, M.D. is an orthopedic surgeon at Midwest Orthopaedics at Rush, as well as professor in the Departments of Orthopaedics and Anatomy and Cell Biology. Dr. Cole is section head of the Cartilage Restoration Center at Rush (Rush University Medical Center). "His novel shoulder techniques have really advanced what we can do for our patients. He is widely known for his exceptional cartilage work."

Edward V. Craig, M.D., M.P.H. is an orthopedic surgeon at Hospital for Special Surgery in New York and professor of Clinical Surgery (Orthopaedics) at Weill Cornell Medical College. Dr. Craig is a past president of the American Shoulder and Elbow Society (ASES). "He is a spectacular physician and surgeon. He is a tremendous leader in shoulder surgery."

T. Bradley Edwards, M.D. is an orthopedic surgeon with Fondren Orthopedic Group, LLC in Dallas, Texas. He is a clinical instructor in the Department of Orthopedic Surgery at the University of Texas Health Sciences Center at Houston and a clinical assistant professor in the Department of Orthopedic Surgery at Baylor University. He is Attending Faculty, Shoulder and Elbow Surgery Fellowship at the University of Texas Health Sciences Center at Houston. "He is one of the 'go to' guys for shoulder

surgery. He is known for arthroscopy and for doing revisions for instability. He is a well rounded thinker who considers all aspects of the situation. He is the founder of the Houston Shoulder Society."

Neal S. Elattrache, M.D. is an orthopedic surgeon and director of the Sports Medicine Fellowship at the Kerlan Jobe Orthopedic Clinic in Los Angeles. He is also associate clinical professor in the Department of Orthopaedic Surgery at the University of Southern California. "He is a good decision maker and is excellent at managing patients. He is very good technically, and his research on rotator cuff repair techniques is very clinically relevant."

Evan Flatow, M.D. is the Bernard J. Lasker Professor and chair of the Department of Orthopaedics and chief of shoulder surgery at The Mount Sinai School of Medicine in New York. Dr. Flatow is a past president of the ASES. "He is an outstanding educator and researcher who is known for important prospective studies on rotator cuff surgery."

Mark A. Frankle, M.D. is an orthopedic surgeon with Florida Orthopaedic Institute in Tampa and director of the Biomechanical Shoulder and Elbow Research Lab at the University of South Florida College of Engineering. "He is a gifted surgeon who has an excellent understanding of implant biomechanics. He is a unique thinker and has been extensively involved with implant development."

Leesa M. Galatz, M.D. is associate professor of Orthopedic Surgery and program director of the Shoulder and Elbow Fellowship at Washington University School of Medicine in St. Louis. "She has an extensive knowledge of a wide range of shoulder problems, and is an excellent clinician. She is a genuine leader in our field."

Laurence Higgins, M.D. is chief of the Sports Medicine/Shoulder Service in the Department of Orthopedic Surgery at the Brigham and Women's Hospital. He is the Fellowship Director for the Brigham and Women's/Massachusetts General Shoulder and Elbow Fellowship Program. "He can handle the full spectrum shoulder problems, and is a real leader in the economics of shoulder care. He is well known for being both a sports shoulder surgeon and for his arthroplasty work…not many surgeons do both well."

Joseph P. Iannotti, M.D., Ph.D. is chairman of the Orthopaedic and Rheumatologic Institute at Cleveland Clinic in Cleveland. He is also co-director of the Orthopaedic Research Center and has a joint appointment in the Department of Biomedical Engineering. Dr. Iannotti is a past president of the ASES. "I think he is the best shoulder researcher on earth. He is a very creative thinker and a finisher."

Jay D. Keener, M.D. is assistant professor of orthopedic surgery at Washington University School of Medicine in St. Louis. "He is widely known for his expertise on the management of rotator cuff tears. Additionally, he has brought a lot of clarity to the natural history of rotator cuff tears and their post-operative rehabilitation."

Keith Kenter, M.D. is associate professor of orthopedic surgery at the University of Cincinnati College of Medicine. He is associate professor of physical medicine and rehabilitation at the Uni-

versity of Cincinnati College of Medicine, and is also director of the Orthopaedic Surgery Residency Program. "He is an excellent shoulder surgeon, he does a large volume of surgeries and is a passionate educator. He is helping to design a novel curricula for educating trainees in the shoulder content domain."

W. Ben Kibler, M.D., F.A.C.S.M. is the medical director for at the Lexington Clinic in Kentucky. He is also a former vice president of the American College of Sports Medicine. "His knowledge of the biomechanics of the shoulder and of the scapula is extremely impressive. He is quite an innovator in terms of thinking of scapular function in overhead throwing athletes."

William N. Levine, M.D. is professor of clinical orthopedic surgery at Columbia University in New York. He is also vice chairman of education in the Department of Orthopaedic Surgery at Columbia, as well as director of sports medicine. In addition, Dr. Levine serves as associate director of the Center for Shoulder, Elbow & Sports Medicine and director of the orthopedic surgery residency program at Columbia University Medical Center. "He is a great surgeon who has an in-depth knowledge of the nuances of shoulder surgery. He has written extensively, including numerous textbooks on shoulder surgery."

Peter J. Millet, M.D., M.S.C. is an orthopedic surgeon and partner at the Steadman Clinic in Vail, Colorado. He also serves as a shoulder and sports medicine consultant to the country of Bermuda. "He is a true innovator in the realm of arthroscopy. He has developed a number of novel approaches to teach other surgeons how to do things. He is especially well known for handling sternoclavicular injuries, and is a respected sports shoulder surgeon."

Bradford O. Parsons, M.D. is assistant professor and residency program director in the Department of Orthopaedic Surgery at the Mount Sinai hospital in New York. "He is a superstar, and is technically very gifted. He is a great researcher, especially in the areas of arthroplasty and rotator cuff repair."

Anthony A. Romeo, M.D. is an orthopedic surgeon at Midwest Orthopaedics at Rush. He is also associate professor and director in the section of Shoulder & Elbow at Rush University Medical Center. "He is a true innovator, and has validated a lot of principles of shoulder arthroplasty. He is also a super educator in that he can distill complex topics down to their basic elements. He has also contributed much to the field through his numerous publications."

Felix H. "Buddy" Savoie, III, M.D. is chief of the section of sports medicine and professor of clinical orthopedics at Tulane University in New Orleans. He is a past president of the Arthroscopy Association of North America. "There is no one better than Buddy. He is a wonderful surgeon who is known for arthroscopic surgery and can do things that others cannot. He is a great speaker and administrator."

John W. Sperling, M.D. is professor of orthopedics at Mayo Clinic in Minnesota. "He is known for being an outstanding researcher and a true innovator. He has played a major role in designing a shoulder replacement system. He is an excellent speaker and a wonderful physician."

Robert Z. Tashjian, M.D. is associate professor of orthopedic surgery at the University of Utah. "He is doing some very unique, well thought-out research on the genetics of rotator cuff disease. He is quite a good surgeon, and a very sought after speaker."

Jon J.P. Warner, M.D. is chief of the Harvard Shoulder Service and co-director of the Harvard Shoulder and Elbow Fellowship. He is also professor of orthopedic surgery at Harvard Medical School, and a past president of the ASES. "He does important translational research and has terrific clinical judgment. He brings an objective academic approach to managing patients."

Russell F. Warren, M.D. is surgeon-in-chief at Hospital for Special Surgery (HSS). He is an attending orthopedic surgeon at HSS and a professor of orthopedic surgery at Weill Cornell Medical College. He is a past president of the ASES, as well as the American Orthopaedic Society for Sports Medicine. "He has tremendous experience and insight, and is known for his work on sports injuries in the shoulder. He has invented multiple devices for shoulder replacement."

Gerald R. Williams, Jr., M.D. is director of the Shoulder and Elbow Center at Rothman Institute in Philadelphia and professor of orthopedic surgery at Jefferson Medical College. He is a past president of ASES. "He is known for being a great educator and an outstanding technician. He can do live surgery with a skill that rivals anyone in the country. He has been a tremendous, thoughtful mentor to many fellows, and has a good vision of where the field of shoulder and elbow surgery should go." ♦

Pagnano Takes On Engh Over Poly Insert Exchange

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

"The reasons to do a polyethylene insert exchange might include isolated liner wear, knee instability, or specific circumstances surrounding knee stiffness," argues Mark Pagnano. "Hold up," says Jerry Engh. "IF the original implant was a defective poly, and IF good poly is available for the exchange, then it is a reasonable option."

This week's Orthopaedic Crossfire® debate is "Polyethylene Insert Exchange: Not the Chip Shot It Seems." For the proposition is Mark W. Pagnano, M.D. of Mayo Clinic in Minnesota; against the proposition is Gerard A. Engh, M.D. from the Anderson Orthopaedic Clinic in Virginia. Moderating is Daniel J. Berry, M.D. from Mayo Clinic in Minnesota.

Current Concepts in Joint Replacement/RRY Photo Creation

Dr. Pagnano: "While there is justified enthusiasm for the long term success of total knee arthroplasty [TKA], the polyethylene remains the weak link for many patients. We recognize that modular tibial trays were developed at least in part to allow surgeons to swap out or exchange the tibial poly in selected patients with malfunctioning TKA, particularly for problems due to wear."

"The reasons to do polyethylene insert exchange might include isolated liner wear, knee instability, or specific circumstances surrounding knee stiffness. All of these isolated revisions typically require the presence of a well-aligned and well-fixed set of components."

"There is limited data looking at whether this design concept has substantial merit. If we go back to 2000, Jerry Engh presented some good initial data, looking at 48 insert exchanges; 22 of those were done for wear and 26 were done for other reasons. Follow up at midterm suggested that seven of those knees failed within five years. Jerry's conclusions from that study remain useful today: 'Isolated polyethylene exchange should not be performed when there is accelerated wear of the insert…and you must consider multiple variables when contemplating limited revision.'"

"A 2006 study from Denmark included 27 late tibial poly exchanges; there was some emerging evidence that late exchanges might be a better group to look at. They looked at patients at a mean of nine years from the original knee; 20% failed at three years. In 2010 Cliff Colwell did a study on 42 knees; 30% were re-revised at three years and at ten years 50% were either revised or had pain. Cliff's conclusion was: 'Even with well-defined, narrow indications, isolated exchange should be done with caution.'"

"We at Mayo Clinic have done a number of studies on this, our purpose being to evaluate the effectiveness of isolated tibial exchange. From 1985-1997 we looked at 63 insert exchanges. A total of 24 were done for poly failure, seven for stiffness; the mean age was 66. Most of the exchanges were done relatively early, a mean of 4 years after surgery; some extended all the way to 12 years from the index arthroplasty. The follow up was substantial: from 2-14 years, with an average of 8 years."

"The probability of implant survival for any reason was 64% at five years. We did not find a difference based on gender, age, BMI [body mass index], or the type of knee arthroplasty. There was a trend toward poorer outcomes in those insert exchanges that were done relatively early."

"Patients with instability had about a 50% failure rate at three years; 33% failed for wear at a mean of four years. As for the patients revised for motion problems, it was an inconsistent operation where the gains in motion after an isolated insert exchange and removal of scar tissue were modest at best."

"Jerry's latest paper included 135 knees revised for wear. He looked at isolated exchange, single component revision, and full revision, with success rates at midterm being 82%, 89%, and 88%, respectively. There is a selection bias in this study that should be addressed. The poly exchanges should be the highest performers; there was no loosening and no substantial bone loss in that group. They should be the easiest revisions and should have the best outcomes. Interestingly, none of the full revision cases failed for wear or instability, and only one full revision failed before ten years."

"So I think that for most failed TKAs in 2012 you should look for any reason to do a complete revision. If the knee is perfectly aligned, well-fixed, with an intact locking mechanism…and you can ensure that a new, high quality polyethylene is available, then you can consider polyethylene exchange."

Dr. Engh: "I think we'd all agree that polyethylene insert exchange as an operative procedure really is a chip shot. It's a very easy operation with low morbidity…and it's a less expensive alternative than a full knee revision."

"Unfortunately, there were two early articles condemning isolated insert exchange; I apologize for being the lead author on one of those. The other one came from Mayo Clinic. Ours had 48 isolated insert exchanges, 22 of which were for wear of the original insert. The time to insert exchange was 7.4 years. We had a 27% re-revision rate within five years. The problem was that the new inserts were also sterilized by gamma radiation in air, and we had no idea that shelf age was a problem."

"The Mayo Clinic study involved 56 isolated exchanges, with a mean follow up of about 4.5 years; there was a 25% re-revision rate at only three years. The exchanges for wear did poorly, with a survivorship of only 71% at 5.5 years. Once again, those were revisions done mostly in the early 90s, a time when we didn't know the shelf-age of the new poly; we didn't even know any of the polys then."

"I would argue, however, that isolated insert exchange was reasonable if the original implant was defective poly… and if good poly was available for the exchange. This was supported by Baker's 2012 study where he had 45 poly exchanges with a mean follow up of about 58 months. Most revisions were for poly wear (76%); there was a 9% failure rate when he used gamma and inert poly. I would argue that replacing bad poly with good poly was a good idea."

"In 2007 Bill Griffin did a study on 68 PFC (press-fit condylar) TKAs and

found a 16% failure rate (mostly aseptic loosening); there was no progression of osteolysis in 97%. He still argued that this was a good operation. In our 2012 study, when we used gamma in air as the poly, our failure rate was 43%; when we used relatively good poly (gamma inert and non-gamma) we only had one failure."

"A 2011 study by John Callaghan looked at liner exchange for wear and lysis with 25 knees…only one revised. So I would say that isolated insert exchange is not reasonable for an implant that has good poly, yet failed prematurely. This would indicate that you have a poor modular tibial locking mechanism, generating backside and topside wear. Or it would indicate that something was not done well in the beginning."

"How do you decide? First of all, make sure the implant is stable and well-aligned, and that it has a satisfactory time to revision with reasonable poly. If it's an old implant, verify the method of sterilization and the shelf-age. Then examine the failed implant. If you have delamination on the topside then you probably have irradiated poly—which is oxidized—and if you see protrusions/screw holes and wear on the backside of the implant, know that you cannot address that problem with a poly exchange."

"In conclusion, an insert exchange is a simple, safe way to change bad poly to good. It does not correct an unstable knee or a bad tibial locking mechanism. I believe that you should not commit your patients to a complex revision and a potentially poor outcome if it's not absolutely necessary."

Moderator Berry: "Please go through with us the specific situations in which you think it's reasonable for the audience to do an isolated poly exchange. Acute infection?"

Dr. Pagnano: "If there is an acute infection and there's a modular knee in place you need to get at that undersurface of the poly to do a complete debridement. It's not an advantage, it's a necessity."

Moderator Berry: "Jerry, acute infection?"

Dr. Engh: "Yes, if you get to it early."

Moderator Berry: "So the person that presents with late polyethylene wear, well-fixed implants, not a lot of osteolysis, synovitis. Is there a role for poly exchange there if you have a good locking mechanism and a good piece of poly?"

Dr. Pagnano: "It's trying to go through that list of 'How many if's' so I think Jerry and I have the same philosophy, namely, if we can find a compelling reason to think about taking out the femur or tibia, then I'll do that. I'll do it if I have a brand new plastic that's going

to be great and a good locking mechanism, and the implants are well aligned and well fixed. In my practice that's one or two patients per year."

Moderator Berry: "What is the role of poly exchange in instability?"

Dr. Engh: "If the instability was poor surgical technique and ligament imbalance, rarely can you correct that with poly exchange."

Moderator Berry: "Mark?"

Dr. Pagnano: "I think an isolated exchange for instability is a very unpredictable operation. The only circumstance where that's applicable is when the patient has equal instability in flexion and extension so that you're not compromising one to fix the other."

Moderator Berry: "What if someone has a thick piece of poly and somebody could downsize the poly to try to get a looser flexion and extension gap? Is there a role for isolated poly exchange in that patient? Mark?"

Dr. Pagnano: "That's typically a loser because it's going to be pretty rare that the reason the knee got stiff initially was because the plastic was too thick. It's very uncommon for someone to put in a 12 or 15 plastic just for fun. So taking that out and putting in a thinner one makes it easier to do a better debridement and remove scar tissue. At best I think you can expect a 20-35 degree increase in range of motion."

Moderator Berry: "So if you're going to operate on a knee for stiffness, Mark, you're usually going to do more than just address scar adhesions and downsize the poly?"

Dr. Pagnano: "Correct."

Moderator Berry: "Jerry, what about stiffness? Is there a role to take out the poly and do just a scar removal?"

Dr. Engh: "I'm not sure there's any good operation for stiffness. Just removing the poly probably isn't enough because you can't get up in the back of the knee, so I usually will go for a full revision in that situation."

Moderator Berry: "In your current practice, what percent of your knee revisions were isolated poly exchanges? Jerry?"

Dr. Engh: "It's become unusual because we corrected the problem of bad poly that those of us with gray hair lived through in the 80s and 90s; since we went to good poly, non-irradiated poly or gamma inert poly, we're seeing few cases where poly wear necessitates a revision."

Moderator Berry: "Is that less than 5%?"

Dr. Engh: "Yes."

Dr. Pagnano: "Definitely less than 5%… probably more like 1%."

Moderator Berry: "Thank you both." ♦

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

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Landmark Study: Arthroscopy Beats Open Repair for Shoulder Repair // Lifetime Achievement Award for George Thompson, M.D // "Abscess" Study Wins Best Clinical Paper Award

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

Landmark Study: Arthroscopy Beats Open Repair for Shoulder Repair Well, 200 shoulders can't be wrong…In the largest study of its kind to date, James P. Bradley, M.D., M.S., has found that in athletes, arthroscopic repair for posterior instability of the shoulder yields better results than an open procedure. Dr. Bradley, a sports medicine specialist with Burke & Bradley Orthopedics at the University of Pittsburgh Medical Center, is also head orthopedic surgeon for the Pittsburgh Steelers. He told *OTW*,

> "Our results, just published in the *American Journal of Sports Medicine*, show that an arthroscopic repair for posterior shoulder instability has a very high success rate in athletes. In the 1990s many people were looking at anterior stability, but I could see that posterior instability had not been examined closely. Fast forward to today and we have results indicating that arthroscopic repair for posterior instability does indeed appear have better results in athletes than does an open procedure.
>
> We evaluated patients prospectively, and we utilized the American Shoulder and Elbow Surgeons (ASES) scoring system. At 36 months we found an improvement in the mean ASES score, better stability, less pain, and improved function. A full 90% of patients were able to return to play, with 64% of patients able to return to the same level of preoperative play. We also found that using bone suture-anchors in capsulolabral reconstruction meant that patients had even higher ASES scores and a higher rate of return to play."

Wikimedia Commons and Mike Durkin

New Study Documents Outpatient Partial Knees Safety There are not many facilities doing same day partial knee replacement surgery. For some orthopedic surgeons, however, it is becoming more routine. Robert S. Gorab, M.D. and Steven Barnett, M.D. are orthopedic surgeons and managing partners of Orthopaedic Specialty Institute in Orange, California and practicing orthopedic surgeons at the Hoag Orthopedic Institute in Orange County, California. Dr. Gorab shared his new results with *OTW*:

> "We performed outpatient partial knee replacement on more than 200 patients; we experienced no readmissions and had excellent outcomes. This work, which has just been accepted by the *Journal of Arthroplasty*, is unique in that no other research has shown success and safety in an entirely outpatient setting. There are strong implications with respect to safety and cost because patients do not have to remain in the hospital.
>
> We had no adverse events, no infections, and no readmission for DVTs.

Most impressive is the fact that we were able to perform this surgery on patients in their 80s in an outpatient setting very safely. These individuals do well if they are in good health and if they receive solid perioperative care.

Those patients who aren't eligible for this surgery in an outpatient setting are those who have no help at home, those who are physically incapable of managing their recovery and those cases where there is multiple joint involvement. Also, if it is not clear whether the person needs a full or partial replacement, then we will do that in an inpatient setting.

Years ago most lumbar disc procedures were done in an inpatient setting—no longer. The same transition has occurred with ACL [anterior cruciate ligament] reconstruction of the knee. I think we will see the same thing happen with partial knee replacement surgery at other highly specialized outpatient orthopedic facilities in the near future."

George Thompson, M.D. Wins Lifetime Achievement Award The Scoliosis Research Society (SRS) has honored pediatric orthopedic surgeon George Thompson, M.D. with a Lifetime Achievement Award for his work in pediatric spinal disorders. Dr. Thompson is chief of the Department of Pediatric Orthopaedic Surgery at University Hospitals (UH) Rainbow Babies & Children's Hospital in Ohio and professor of Orthopaedics and Pediatrics at Case Western Reserve University School of Medicine. He is only the 11th recipient of this prestigious award.

This award commemorates Dr. Thompson's extensive career, which has led to innovations in everything from surgical techniques to ways for preventing or decreasing blood loss, making operations safer for children, according to Randall E. Marcus, M.D., Charles H. Herndon professor and chairman, Department of Orthopaedic Surgery, UH Case Medical Center and Case Western Reserve University School of Medicine.

"Abscess" Study Wins Best Clinical Paper Award Christopher Bono, M.D., chief of spine at Brigham and Women's Hospital, and deputy editor of *The Spine Journal*, He tells *OTW,*

"I'm thrilled that our paper, "Predictors for Success of Nonoperative Management of Spinal Epidural Abscesses," was honored as Best Clinical Paper at the recent International Society for the Advancement of Spine meeting. The research, a 150 person retrospective study, demonstrates that someone who is neurologically intact can be treated nonoperatively for epidural abscesses. The article is currently under review at *The Spine Journal*.

This study proves that while nonoperative treatment has a higher failure rate, if someone fails at that level he or she can go on to surgery and be no worse off than if they had first taken the surgical route. The big fear has always been that if you treat this nonoperatively then the patient will experience a catastrophic decline in neurological status, but the truth is that this is exceedingly rare. How will this affect practice? I predict that this work can be of assistance in community hospitals where until now orthopedic surgeons have been immediately transferring patients to surgery because they think that's what they have to do."

Baron Lonner, M.D. New Head of Spine at Beth Israel Medical Center Dr. Baron Lonner is the new chief of the Division of Spine Surgery in the Department of Orthopedic Surgery at Beth Israel Medical Center and director of the hospital's Spine Institute of New York. He comes to Beth Israel from the NYU Hospital for Joint Diseases where he was a senior attending surgeon and clinical professor of Orthopaedic Surgery. In addition, Dr. Lonner holds leadership positions in the Scoliosis Research Society and sits on the editorial boards of four of the leading spine journals. He has authored more than 70 peer-reviewed publications, regularly presents his research findings at national and international meetings. He has won several prestigious research awards. Dr. Lonner's research has focused on ways of improving patient care and outcomes in spinal deformity surgery including scoliosis and kyphosis in the pediatric and adult patient. Dr. Lonner received his undergraduate and medical degrees from Boston University, where he completed the accelerated six-year medical program. He completed his residency in orthopedic surgery at Montefiore Medical Center and a fellowship in spine and scoliosis surgery at the Hospital for Special Surgery.

He told *OTW*,

"I am looking forward to the challenge of expanding the spine divi-

sion at Beth Israel. I see a great opportunity to serve patient needs and further research in spine. We want to take a multi-tiered, multidisciplinary approach that takes into account clinical outcomes and value measurements, which are so important to patients and their families. We have established non-operative protocols for conditions such as degenerative diseases in the cervical, thoracic, and lumbar spines, and spinal deformity in children and adults. We have incorporated innovative diagnostic tools such as light-based (radiation-free) surface topography that allows us to follow patients with scoliosis for signs of progression without X-ray in some cases. We have implemented a collaborative approach incorporating multiple team members for the surgical care of patients including the anesthesiologist, pain management, nursing, rehabilitation and physical therapy, social workers, and even specialists in relaxation techniques.

I look forward to growing the spine division with the goal of providing the highest quality of care and utilizing therapies, both non-operative and operative that rely on the highest level of evidence, i.e., evidence-based care. Along with my team, I want Beth Israel's Spine Institute to be a jewel of spine care providing treatment that is carefully tailored to each patient. In my new role I will draw upon a very important lesson that I have learned over the years, namely, the value of collaboration. Spine care must be well-coordinated and relies on a dedicated team." ♦

COMPANY

Trinity Orthopedics Acquires Expanding Concepts Patents

Trinity Orthopedics LLC, based in San Diego, California, has acquired Expanding Concepts LLC's patent portfolio.

In a September 16, 2013 press release, Trinity CEO James Marino, M.D., said acquiring the Expanding Concepts patents is an essential step in completing the development of an expandable interbody technology offering. In addition to founding Trinity in 2004, Marino is a founder of NuVasive, Inc. No details of the patent portfolio or terms of the acquisition were provided.

The company statement said the U.S. market for spinal implants expects the interbody fusion market to remain in the low single digits through 2019. The expandable sub-segment will see CAGRs (compounded annual growth rate) approaching 30%. This surge in demand, according to the company, is largely attributed to the benefits of minimizing complications due to larger surgical sites and over distraction of involved nerves. In addition, time in the operating room and reducing postoperative pain for patients is sited as major contributors.

"We believe we have a very strong proprietary position in this area of intense industry interest," added Marino.

Trinity Products

Trinity's products include the ReStor posterior fixation system and the Corex minimally invasive autograft bone harvester. According to the company, the ReStor system features the first and only sagittally stable, monoplanar polyaxial pedicle screw.

The ReStor implants were designed to minimize the risk of developing adjacent segment degeneration (ASD) following lumbar fusions. Recognizing postoperative hypolordosis as the primary "provocateur" of ASD, the company says the proprietary design of the implants eliminates the inherent weakness found in all polyaxial screws (universal joint yielding or slippage) when subjected to both static and dynamic flexion loads. In addition, the implants will not dampen lordotic contouring of the connecting rods, as is seen when polyaxial screws are articulated toward adjacent levels to facilitate connecting rod attachment. By eliminating "tulip" sagittal articulation and migration relative to the screw shaft axis, the implants enable surgeons to restore and maintain physiologic lordosis.

Seventeen U.S. patents have previously been granted to Trinity, and 17 patents are pending surrounding minimally invasive surgical technique, implantable devices, and supporting instrumentation.

Scientific Advisors

Trinity's scientific clinical advisors include: Carl Lauryssen, M.D., director of spine research and development at the Olympia Medical Center in Los Angeles; Alpesh Patel, M.D., assistant professor, Department of Orthopedic Surgery at the University of Utah School of Medicine; Robert Eastlack, M.D., of the Scripps Clinical Medical Group; and, Steven Garfin, M.D., clinical professor and chairman, Department of Orthopedic Surgery at the University of California in San Diego.

Trinity Orthopedics LLC

—WE (September 17, 2013)

LEGAL

FDA Device Identifying System Finalized

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The FDA announced a final rule for the unique device identification system (UDI) on September 20, 2013. "UDI represents a landmark step in improving patient safety, modernizing our postmarket surveillance system for medical devices, and facilitating medical device innovation," said Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health.

The FDA worked closely with industry, the clinical community and patient and consumer groups in the development of the rule.

UDI System

The UDI system consists of two core items.

The first is a unique number assigned by the device manufacturer to the version or model of a device, called a unique device identifier. This identifier will also include production-specific information such as the product's lot or batch number, expiration date, and manufacturing date when that information appears on the label.

The second component is a publicly searchable database administered by the FDA, called the Global Unique Device Identification Database (GUDID) that will serve as a reference catalogue for every device with an identifier. No identifying patient information will be stored in this device information center.

The FDA plans to phase in the UDI system, focusing first on high-risk medical devices. Many low-risk devices will be exempt from some or all of the requirements in the final rule.

Recalls, Adverse Events and Electronic Records

The agency says the new system will enhance the ability to quickly and efficiently identify marketed devices when recalled, improve the accuracy and specificity of adverse event reports and provide a foundation for a global, secure distribution chain, helping to address counterfeiting and diversion. It will also offer a clear way of documenting device use in electronic health records and clinical information systems.

The FDA issued the proposed rule requesting input from industry, the clinical community and patient and consumer groups on July 10, 2012.

The UDI system builds on current device industry standards and processes, and reflects substantial input from the clinical community and the device industry during all phases of its development. In addition, the agency says it worked to reduce the burden on industry by building upon systems already in place. The system is a key component of the National Medical Device Post-Market Surveillance System proposed in September 2012.

In general, high-risk medical devices (Class III) will be required to carry unique device identifiers on their label and packaging within one year and this number and corresponding device information must be submitted to the new database. Manufacturers will have three years to act for most Class II (moderate risk) devices. Manufacturers of Class I devices not exempt from UDI requirements will have five years to act.

Comment on Submission Guidance

Included with the announcement was the publication of draft guidance for manufacturers outlining how to submit information to the database.

Click here to read the draft guidance: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM369248.pdf

If you have suggestions for the agency on the guidance, you have 60 days to comment.

—WE (September 20, 2013)

FDA Has Most August "Clearances" in Years

The FDA "cleared" 284 devices in August 2013 through the 510(k) program. Of those, 45 were orthopedic or spine related.

During the same August period in 2010, 2011 and 2012, the agency cleared 241, 271 and 257 devices, respectively. Clearances are for products that have shown to be "Substantially Equivalent" to previously approved products.

The list of companies receiving recent clearances included familiar names:

- Biomet
- DePuy
- Medtronic
- Orthofix
- NuVasive
- Arthrocare
- Zimmer
- Aesculap
- Globus
- Spineguard
- Spine Wave
- Centinel Spine
- X-Spine
- Spinal USA

Other less well-known names included:

- Ascension Orthopedics
- Osseus Fusion
- Captiva Spine
- Iconacy Orthopedic Implants
- Core-Nexus
- FX Solutions
- Southern Spine
- Orthohelix Surgical Designs
- Tissue Regeneration Systems
- Accel Spine
- Ortho Development
- Medacta International
- Flower Orthopedics
- Neurostructures
- Medyssey
- Ingen Orthopedics
- Next Orthosurgical
- Neosteo
- Rotation Medical
- United Orthopedic

Cleared devices ranged from personalized care systems, fixation devices, interbody systems, nerve detectors, hip and shoulder systems, coblation wands, navigation instruments, bone fillers to bone staplers.

To see the entire list of all cleared devices, click here: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm366994.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

—WE (September 17, 2013)

FDA

BIOLOGICS

Harvard, Charité to Speed Translational Work

The Wyss Institute for Biologically Inspired Engineering at Harvard University and Berlin-based Charité have joined forced in order to help speed up the clinical translation of new materials and tissue engineering technologies for orthopedics and connective tissue regeneration. The Wyss Institute will gain access to Charité's large animal models, patient populations for clinical trials, and Good Manufacturing Process (GMP) level cell culture and material processing facilities.

Wyss Institute

The partnership formalizes an existing collaboration between Wyss faculty member David Mooney, Ph.D., and Georg Duda, Ph.D., vice director of Charité's Berlin-Brandenburg Center for Regenerative Therapies. Over the last two years, they have worked together on various musculoskeletal tissue engineering research projects, according to Wyss Institute. Dr. Duda has been appointed a Wyss Associate Faculty member as part of the new agreement.

The goal of Dr. Duda's research is to understand the body's own processes and to reproduce natural regenera-

tion of the musculoskeletal system. Dr. Mooney's current projects focus on therapeutic angiogenesis, regeneration of musculoskeletal tissues, and cancer therapies.

Asked about near-term goals, Dr. Mooney told *OTW*, "The complementary expertise of the two institutions will accelerate the development and clinical translation of new therapies. In the short-term, the utility of several new technologies to promote musculoskeletal regeneration will be explored using animal models developed by Charité scientists."

—EH (September 20, 2013)

Cartilage Cell Repair System Granted U.S. Patents

PUR Biologics, LLC announces that it had been granted two patents by the U.S. Patent office covering multipotent stem cell-derived material. The new inventions were developed by PUR to assist physicians with the repair and regeneration of tissue. The office issued the patents to PUR's joint venture partner, Histogen, Inc. in early September.

The patents describe the very novel Histogen technology for de-differentiation of fibroblast cells into multipotent stem cells by way of low oxygen and special culture conditions. The patent also covers methods of inducing tissue repair and regeneration by contacting cells with the naturally-secreted multipotent cell conditioned media (CCM) and extracellular matrix (ECM) materials.

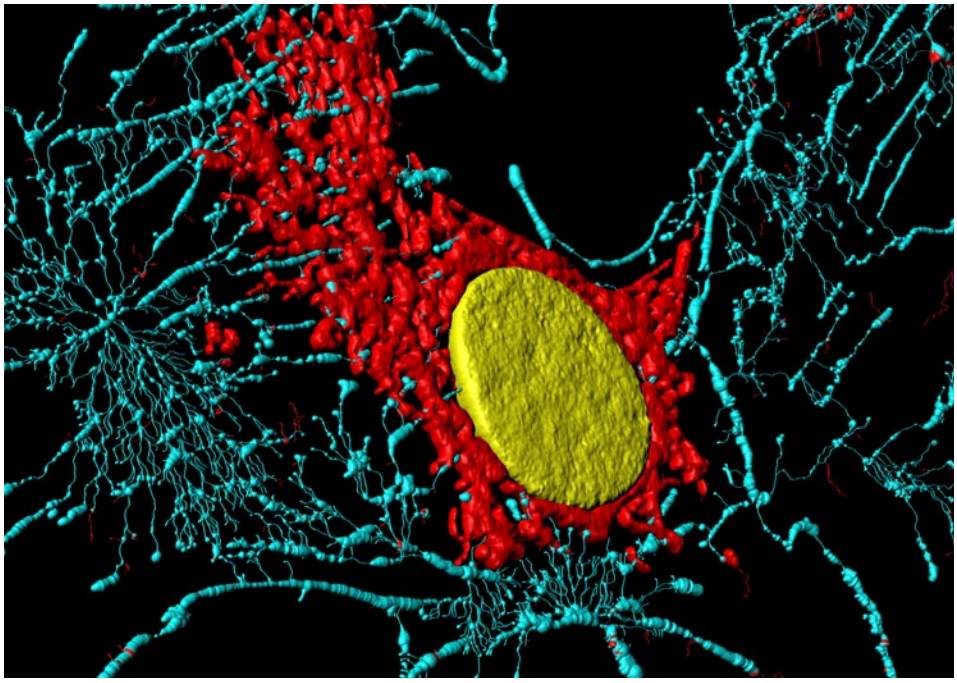
Histogen's officials explain that through this now patented process, newborn cells naturally produce the vital proteins and growth factors from which the company has developed its rich product portfolio. Histogen's technology focuses on stimulating a patient's own stem cells by delivering a proprietary complex of multipotent human proteins that have been shown to support stem cell growth and differentiation

"These novel multipotent cell-derived materials hold tremendous potential in orthopedic applications, where we seek to regenerate musculoskeletal tissues and support stem cell growth," said Ryan Fernan, CEO of PUR Biologics. "Particularly exciting to us is the ability of the material to induce angiogenesis, which is not addressed with currently available orthopedic products."

Fernan explains that unlike other stem cell-derived therapies, Histogen's process uniquely begins with newborn fibroblast cells, a safe, well-established and non-controversial cell source, and converts the cells into multipotent stem cells without genetic manipulation. PUR Biologics is currently researching and developing products based upon the CCM and ECM materials produced by these multipotent cells, which have potential benefit in a number of orthopedic applications such as bone and cartilage regeneration.

Burak Ozgur, chief of Neurosurgery Spine Service at Hoag Hospital, said, "While there is a lot of excitement and promise around stem cell-derived treatments in orthopedics, therapies utilizing embryonic stem cells or genetically manipulated induced pluripotent stem cells carry inherent ethical and potential safety concerns for patients. Products that could capture the benefits of stem cell treatments without these concerns, such as the multipotent cell materials being developed by PUR, hold tremendous potential as the future of orthopedics."

—BY (September 18, 2013)



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LARGE JOINTS

Study Shocker: Smoking Not a TJR Risk Factor

Another presupposition is challenged. The reported association of smoking with the risk of undergoing a total joint replacement (TJR) due to osteoarthritis is not consistent enough to qualify as a risk factor, according to a major study in Australia.

Australian researchers examined the electronic records of 54,288 men and women who were initially recruited for the Second Australian National Blood Pressure study. They linked those records to the Australian Orthopaedic Association National Joint Replacement Registry to detect cases of total hip replacement (THR) or total knee replacement (TKR) due to osteoarthritis.

The result? They found an **inverse** association between smoking and risk of THR and TKR in both men and women. Compared to non-smokers, male and female smokers were 40% and 30% less likely to undergo a TJR. This significant association persisted after controlling for age, co-morbidities, body mass index, physical exercise, and socioeconomic disadvantage.

Wikimedia Commons and Tibor Veigh

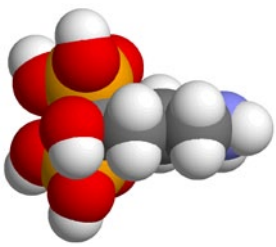
They did find that the overweight and obese were significantly more likely to undergo a TJR compared to those with normal weight. However, socioeconomic status was not independently associated with a risk of either a THR or TKR.

—BY (September 16, 2013)

Osteoporosis Drug Helps Hip, Knee OA

St George's, University of London research has found that a drug normally given to osteoporosis sufferers could provide effective pain relief to patients with knee and hip osteoarthritis (OA). The researchers used existing studies to assess the effectiveness of a variety of bisphosphonates in patients suffering from osteoarthritis of the hand, knee, spine and hips.

The researchers looked at 3,832 patients; in most cases these drugs showed limited pain relief. However, a few studies did show benefit; the bisphosphonate alendronate was found to be more effective for patients with hip osteoarthritis than existing pain relieving drugs. Moreover, the use of zoledronate and alendronate, specific forms of bisphosphonates, improved pain in patients with knee and hip osteoarthritis at six months—but longer term studies are needed.



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Dr. Nidhi Sofat, lead researcher, said in the September 5, 2013 news release, "Osteoarthritis is the most common form of arthritis worldwide. It causes damage to bone and cartilage in the joints of affected people. Most treatment is focused around pain relief, as no robust treatments have been discovered that slow down the progression of the disease.

"Our study looked at whether there were any bisphosphonate drugs that have been shown to influence pain and/or disease progression that could be used in osteoarthritis treatment.

"We found that, generally, bisphosphonates are ineffective at managing pain associated with osteoarthritis. But zoledronate and alendronate, which are specific forms of bisphosphonates, do show the potential for effective pain management specifically in patients with knee and hip osteoarthritis.

Dr. Sofat told *OTW*, "We looked at the use of bisphosphonates in osteoarthritis since OA pain is a major public health concern and there are currently no long-term disease-modifying drugs that are used in OA with proven efficacy. Our most surprising finding was that although we reviewed data from 3,832 patients in studies worldwide, there was high variability in patient selection and different studies looked at different sites of OA, including the hand, knees, hips and spine. Future studies are needed of bisphosphonates in osteoarthritis in clearly defined subsets of patients, coupled with robust radiographic analysis by cartilage integrity, BML size/composition, synovitis, joint space narrowing and evaluation of clinical biomarkers to more fully evaluate agents that could halt the onset and/or progression of osteoarthritis."

—EH (September 18, 2013)

Consumer's Union Urges Implant Guarantees

In a clear challenge to the orthopedic industry, the official publication of the Consumer's Union, *Consumer Reports,* called on implant manufacturers to offer warranties for their implants so that patients and taxpayers would not have to pay for a replacement when an implant fails.

According to the article, 20% of hip replacements and 10% of knee replacements are revisions—in many cases done because the original surgery or device or some combination of the two failed in some way. The author, Joel Keehn, argues that consumers of joint implants should have the same privilege as automobile purchasers have to take their cars back to a dealer to get a defective part fixed by the manufacturer/dealer.

Lisa McGiuffert, director of Consumers Union's Safe Patient Project, notes that joint replacement patients do not get a warranty or guarantee in writing from the manufacturer of their device advising them as to how long their implant should last.

Consumers Union's Safe Project Patient Project reports that hundreds of knee implant components have been recalled by their manufacturers for problems such as shipping a wrong size or a device with a missing part. The Union is urging the device manufacturers to provide patient purchasers of their devices with a 20 year warranty that would cover the entire cost of revision surgery, should it be needed, and an understandable system for patients to use in making claims—including toll-free telephone numbers. Doctors would charge the manufacturer of the implant, not the patient, for the costs associated with revision surgery.

—BY (September 18, 2013)

Consumer Reports®

Courtesy of Consumer Reports

EXTREMITIES

Hot Chilies for Carpal Tunnel

Got carpal tunnel syndrome? Try a Szechuan pepper. It may sound bizarre but when researchers rubbed pepper extract on the lips of volunteers, almost none of them could tell whether they were eating peppers or experiencing mechanical stimulation. Munching on a Chinese peppercorn felt the same as did pressing a vibrator to their lips.

Wikimedia commons and McKay Savage

Scientists at University College London (UCL), one of the United Kingdom's top universities, believe this phenomenon may lead to new ways of reducing the pain of conditions like carpal tunnel syndrome.

Szechuan peppercorn is unique in producing the sensation of vibration on the lips. But the researchers discovered that the stimuli caused by chemicals in

the pepper have the same effect on the human brain as does actual touch.

The peppers are not spicy but they cause a sensation of about 50 taps per second which may be brought about by an active ingredient called sanshool.

The scientists now believe that their findings could be used to find treatments for people with nerve-related chronic pain like carpal tunnel syndrome or diabetic neuropathy.

Tom Mendelsohn, a writer for *The Independent*, reported that the lead author of the study, Nobuhiro Hagura, and hs colleagues wanted to see whether human 'light-touch' nerve fibers were activated in the same way by the peppers as they are through mechanical stimulation.

They tested how participants reacted to Szechuan peppers, alcohol, water and vibrators applied to their lower lips. Most struggled to tell the difference in sensation between peppers and vibrators.

"We knew from studies in animals that the active ingredient in Szechuan pepper selectively activates the light touch fibers," said Hagura. "This made us interested in whether this unusual way of activating light touch fibers actually produces a conscious sensation of touch."

"Tingling sensations occur in many chronic pain conditions, but remain poorly understood," he said. "We hope that laboratory studies of the tingling sensations caused by sanshool could help to clarify the brain processes underlying these sensations, and how they are related to pain."

—BY (September 18, 2013)

SPINE

VEXIM Publishes SpineJack Results

VEXIM, an enterprise specializing in the minimally invasive treatment of vertebral fractures, has announced that the results of a comparative biomechanical study carried out by Marburg University's Traumatology department (Germany) were published in the August issue of the *CLINICAL BIOMECHANICS* international journal.

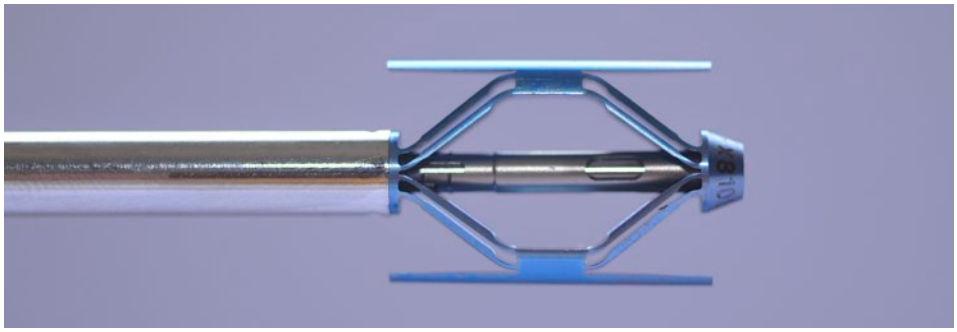
The aim of this study was to evaluate the anatomic restoration of 36 fractured vertebral bodies with osteoporosis and the maintaining of the gained height after recompression by comparing the SpineJack and balloon kyphoplasty techniques. The results obtained demonstrate a significant advantage in favor of the SpineJack regarding the restoration of vertebral height that is carried out to reestablish the spinal column's balance.

"The vertebral height restoration was over 93% for the groups treated with SpineJack even after recompression", said Dr. Antonio Krüger, orthopedic trauma surgeon in trauma and reconstructive surgery at the Philipp's University (Marburg) and the study's main investigator, in the September 12, 2013 news release.

Vincent Gardès, CEO of VEXIM, added: "I would first and foremost like to congratulate Dr. Antonio Krüger's team for the publication of their study in this highly recognized journal for clinicians and scientists. These results clearly show the advantages of the SpineJack, and further increase our confidence in the pursuance of our clinical program."

Gardès told *OTW*, "As communicated during the IPO in spring 2012 our goal is to become a leader in the treatment of vertebral compression fractures in Europe. By the end of 2014, we will have 10% of market share in Europe thanks to our direct operations in France, Germany, Spain, UK & Italy. We are today the only company having a fully dedicated sales force focusing on spine traumatology only. Several prospective and retrospective clinical studies will show in the very near future the outstanding performances of the Spine Jack device when compared to conventional surgery or conservative treatment. In terms of R&D, we are expanding our portfolio to be able to treat all kinds of vertebral fractures including more severe and unstable high energy ones. This includes innovative work on vertebroplasty, cements and arthrodesis. We will launch two new products every year in this specific arena during the next three years."

—EH (September 16, 2013)



VEXIM

Pet Remedy Tested For Humans

If it works on pets, why not try it on humans? That is what the manufacturer of BoneCure, an artificial membrane that speeds and simplifies bone re-growth in pets, is asking. BoneCure is a membrane rolled into a sleeve that encases the space where lost bone should grow and is anchored in place with bolts or sutures. According to RegeneCure Ltd, the Israeli company that developed it, it is the only solution of its kind on the market.

Karin Kloosterman , writing for the *ISRAEL21c* journal, reported that BoneCure's thin membrane is made from the same artificial materials that are used to coat slow-release aspirin. The material is loaded with a positive charge and is designed to disintegrate over time. BoneCure is said to encourage new bone cells to "sit" on its surface. The sleeve is made in Israel in 150, 200 and 350 millimeters in thickness and comes as a sheet that can be cut to size.

RegeneCure Vice President Harry Langbeheim says that small perforations in the material allow growth factors to pass in and out of the area where the bone should grow and also prevents unwanted tissue from entering the future bone zone.

Complete instructions on how to set it in place are available on the company website, meaning that no complicated tutorials or training sessions are needed, said Langbeheim, who earned a Ph.D. in immunology from Israel's Weizmann Institute of Science.

Dr. Itamar Tsur, an Israeli veterinarian, has used the technology in five dogs and a few cats. The product, he says, "seems to do the job without a second operation. "This is in contrast to the standard

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procedure of taking a bone graft from the pet's buttocks area, which means another operation, more pain and more cost.

Tsur says the regenerating membrane product could aid in cases where broken bones are not knitting as they should. "This membrane draws in the stem cells with its positive charge on the membrane of this medical device, and reboots this process," Tsur says.

Langbeheim says his company's solution can create accelerated bone growth 43% faster than without it, and the company is working on a yet-to-be-named product to help accelerate bone re-growth in humans. The cost for the human market will range from $200 to $500 per sheet of material, much less than an allograph.

RegeneCure is targeting the orthopedics markets and is starting clinical trials in orthopedics at Hadassah and at Leeds General Infirmary Hospital in England, a clinic that specializes in guided bone regeneration.

—BY (September 16, 2013)

Dr. Philip Yuan Testing Innovative Approach to Back Pain

Can zapping the basivertebral nerve, located inside the bony part of the spine, get rid of low back pain for good? Doctors with Memorial Orthopaedic Surgical Group in Los Angeles hope to find out.

"All pain is derived from nerves, but there can be a nerve within the bone itself called the basivertebral nerve that we think may be the cause or the source of discogenic back pain," said Philip Yuan, M.D. Yuan is investigating a new procedure in which doctors use a small radio-frequency probe, inserted through the back, to deaden the nerves.

"We burn those nerve endings and enervate that painful disk and remove the probe. The patient will wake up with a little band aid on his skin, and that's it," said Yuan. The trial is called the SMART Clinical Study. Researchers hope to recruit 200 patients nationwide for the minimally invasive, one-hour procedure.

Yuan says earlier European trials showed it can be quite effective. "I was skeptical at first, but the results are so good. It's truly a minimally invasive surgery and patients are doing well," he said. Researchers are looking for participants who have had low back pain for at least six months, those who have not responded to conservative treatment, and those who have not had previous surgery. Participants also need to be between the ages of 25 and 70.

Yuan's practice is based in Long Beach. There are two local sites for the SMART Trial, including one in Los Angeles. Individuals interested in additional information on the SMART study can visit www.smartclinicalstudy.com, or call (888) 978-8396.

Dr. Phillip Yuan/Memorial Orthopaedic Surgical Group

—BY (September 16, 2013)

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