VOLUME 9, ISSUE 14 | MAY 7, 2013

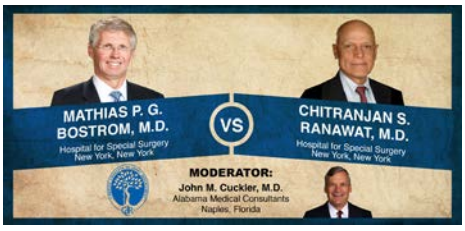
Orthopedics This Week

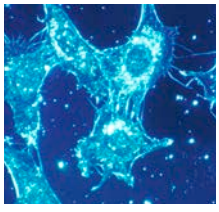
week in review

4 Certification: Scam or Public Safety? ♦ New Jersey continues to be ground-zero for credentialing battles as the Association of American Physicians & Surgeons sues the American Board of Medical Specialties over the Board's certification program. The complaint? Certification programs principally enrich private corporations at the expense of doctors. Really? We lift the veil.

8 High Flexion TKA Designs: Bostrom v. Ranawat ♦ "I believe high flexion designs have no appreciable difference. I used to be excited about these designs, mainly because we like new things," says Mathias Bostrom. "Not only do I believe in high flexion designs, I have designed one," counters Chitranjan Ranawat.

12 Urgent Plea From AAOS PAC! If you read nothing else, read this. Mayo Clinic Sets Efficient Quality of Care Standard and more… ♦ Stuart Weinstein, M.D., says not being involved in politics hurts the field. A Mayo Clinic orthopedic surgeons tells how they reduced LOS by nearly a day and a half. The latest on fellowship accreditation…and more.





breaking news

15 **ISTO** and **Zimmer** Part Ways

Major Study Update: **Stem Cells Ease Back Pain**

India Surgeon **Reconstructs Ankle Bones**

Wenzel Launches In-Situ Expandable **Fusion Device**

Molecule, **Odiferous Gas** Help Arthritic Joints

Zimmer Buys Subchondroplasty **Procedure**

NuVasive and **Globus** Report **Healthy First Quarters**

For all news that is ortho, read on.

Orthopedic Power Rankings

Robin Young's Entirely Subjective Ordering of Public Orthopedic Companies

THIS WEEK: Globus Medical is #1 as David Paul and company soundly beat Wall Street's estimates for the first quarter. Globus Medical's disruptive technologies sector leaped 31.5% which has to be the best performing sector in orthopedics this quarter. Two companies that are showing the importance of sales quality are back on the Power Rankings this week—Wright Medical and Orthofix.

RANK	LAST WEEK	COMPANY	TTM OP MARGIN	30-DAY PRICE CHANGE	COMMENT
1	2	Globus Medical	27.80%	14.70%	Sales increase 10.9% for Q1; 13% rise in earnings; $220 million in cash, no debt. Expansion opportunities are significant.
2	1	Johnson & Johnson	25.58	4.48	Sales of orthopedics products rose 12% (+ 2.1% adjusting for Synthes). Growth rate is "ok" and with DePuy's efficiencies, profits continue strong.
3	5	Zimmer	29.49	3.41	ZMH and ISTO part ways, then ZMH buys very creative set of technologies with Knee Creations. Clearly strategic moves. Up 2 spots this week.
4	4	Stryker	23.68	1.66	Hip recalls hit SYK's earnings to the tune of $32 million. Also costs from digesting Trauson, Surpass Medical and BSX's neurovascular business.
5	7	NuVasive	4.04	8.41	Q1 5.2% sales increase. Slight earnings rise. Growth rate was half the Q4 pace and reflects pricing strains in spine.
6	6	Medtronic	28.65	1.49	The #1 spinal implant company in the world is winding up its latest series of lay-offs. Goal: smaller, more nimble competitor.
7	NR	Wright Medical Group	(0.35)	2.87	Yes, sales down 3.3% YOY, but quality of sales improving. Where WMGI has market leadership, like foot & ankle, sales rose 20% YOY.
8	8	Conmed	11.20	(7.17)	More profit on less sales. That was CNMD's first quarter story and will, it appears, be the narrative for the rest of this year as well.
9	10	Alphatec	(4.29)	(7.84)	Sales growth not in GMED's league, but at 4.1% close to NUVA. Earnings beat forecast. The Les Cross formula taking effect. Piper thinks ATEC is a $3 stock.
10	NR	Orthofix	19.68	(9.00)	Cheap. That's basically the appeal. This equity is cheap. Lowest P/E in orthopedics. Lowest P/E to expected growth rate.

Robin Young's Orthopedic Universe

TOP PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	MiMedx Group	MDXG	$6.75	$633	35.00%
2	Globus Medical	GMED	$16.39	$1,496	14.70%
3	NuVasive	NUVA	$22.42	$991	8.41%
4	RTI Biologics Inc	RTIX	$4.10	$231	7.05%
5	Johnson & Johnson	JNJ	$85.75	$239,846	4.48%
6	Zimmer Holdings	ZMH	$77.00	$13,040	3.41%
7	Wright Medical	WMGI	$23.93	$1,118	2.87%
8	Stryker	SYK	$66.33	$25,015	1.66%
9	Smith & Nephew	SNN	$58.38	$10,588	1.50%
10	Medtronic	MDT	$47.72	$48,379	1.49%

WORST PERFORMERS LAST 30 DAYS

	COMPANY	SYMBOL	PRICE	MKT CAP	30-DAY CHG
1	Symmetry Medical	SMA	$10.07	$376	-15.80%
2	Exactech	EXAC	$18.21	$243	-12.24%
3	Integra LifeSciences	IART	$34.70	$971	-11.03%
4	Orthofix	OFIX	$32.15	$625	-9.00%
5	TiGenix	TIG.BR	$1.05	$105	-8.28%
6	TranS1	TSON	$1.97	$54	-7.94%
7	Alphatec Holdings	ATEC	$1.88	$182	-7.84%
8	Conmed	CNMD	$31.21	$876	-7.17%
9	Bacterin Intl Holdings	BONE	$0.82	$35	-5.74%
10	Tornier N.V.	TRNX	$18.07	$754	-2.59%

LOWEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	Orthofix	OFIX	$32.15	$625	10.61
2	Zimmer Holdings	ZMH	$77.00	$13,040	12.35
3	Medtronic	MDT	$47.72	$48,379	13.60
4	Globus Medical	GMED	$16.39	$1,496	14.18
5	Smith & Nephew	SNN	$58.38	$10,588	14.52

HIGHEST PRICE / EARNINGS RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	P/E
1	NuVasive	NUVA	$22.42	$991	59.00
2	Symmetry Medical	SMA	$10.07	$376	34.72
3	RTI Biologics Inc	RTIX	$4.10	$231	24.12
4	ArthroCare	ARTC	$33.96	$957	22.20
5	Exactech	EXAC	$18.21	$243	18.21

LOWEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	Orthofix	OFIX	$32.15	$625	0.85
2	Globus Medical	GMED	$16.39	$1,496	0.95
3	Conmed	CNMD	$31.21	$876	1.29
4	Exactech	EXAC	$18.21	$243	1.30
5	Zimmer Holdings	ZMH	$77.00	$13,040	1.31

HIGHEST P/E TO GROWTH RATIO (EARNINGS ESTIMATES)

	COMPANY	SYMBOL	PRICE	MKT CAP	PEG
1	NuVasive	NUVA	$22.42	$991	4.76
2	CryoLife	CRY	$5.85	$161	4.06
3	Symmetry Medical	SMA	$10.07	$376	2.89
4	Johnson & Johnson	JNJ	$85.75	$239,846	2.55
5	Medtronic	MDT	$47.72	$48,379	2.18

LOWEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	Symmetry Medical	SMA	$10.07	$376	0.91
2	Alphatec Holdings	ATEC	$1.88	$182	0.93
3	Bacterin Intl Holdings	BONE	$0.82	$35	1.06
4	Exactech	EXAC	$18.21	$243	1.08
5	Conmed	CNMD	$31.21	$876	1.14

HIGHEST PRICE TO SALES RATIO (TTM)

	COMPANY	SYMBOL	PRICE	MKT CAP	PSR
1	TiGenix	TIG.BR	$1.05	$105	25.75
2	MiMedx Group	MDXG	$6.75	$633	23.39
3	MAKO Surgical	MAKO	$10.65	$503	4.90
4	Globus Medical	GMED	$16.39	$1,496	3.88
5	TranS1	TSON	$1.97	$54	3.69

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

Advertise with Orthopedics This Week

Orthopedics This Week

RV Publications

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

Certification: Scam or Public Safety?

By Walter Eisner

"It's all a big scam," the gravel-voiced orthopedic surgeon from the Pennsylvania coal country told us at the recent AAOS (American Academy of Orthopaedic Surgeons) annual meeting.

"I've been a practicing surgeon for over 30 years and I'm forced to pay thousands of dollars each year to a private credentialing organization for something which has nothing to do with my licensing, doesn't make me a better surgeon nor proves I'm still competent. "

"Above and Beyond Licensing"

The organization is the ABMS (American Board of Medical Specialties). On its website, the ABMS says that board certification "is a voluntary process that goes above and beyond licensing requirements—it's a commitment to continually expand knowledge in a medical specialty."

American Board of Medical Specialties
Higher standards. Better care.

http://www.abms.org/

Our surgeon continued that the ABMS has agreements with 24 other corporations such as the Board of Orthopaedic Surgery (https://www.abos.org/) to impose enormous recertification burdens on physicians, which are not justified by any evidence of better patient care. "And it's not voluntary if you want to practice medicine at a hospital," he added.

Photo creation by RRY Publications LLC

He told us AAPS (Association of American Physicians & Surgeons Inc.) is going to sue the board (ABMS) for restraint of trade. Then the story got better. He said, "Their lawyer is Phyllis Schlafly's 'kid' [Andrew Schlafly]."

The AAPS is an avowed conservative political organization of physicians formed in 1947. It doesn't run in the lofty circles of the big medical organizations like the AMA (American Medical Association) and AAOS. Throw in the name Schlafly and this promised to line up as a conservative versus liberal fight.

AAPS

Wikimedia Commons and Association of American Physicians and Surgeons

But, our Pennsylvania surgeon was a lifelong and proud Democrat. The issue of credentialing is bigger than partisan politics as we've seen in New Jersey where the Attorney General is trying to permanently revoke a medical license because a physician was not properly credentialed.

Lawsuit: "Constraint of Trade"

As the coal country surgeon predicted, on April 24, 2013, AAPS filed suit in

federal court in New Jersey against the ABMS for restraining trade and causing a reduction in access by patients to their physicians.

AAPS is suing to end antitrust law violations and misrepresentations by ABMS concerning its proprietary recertification program, which they argue, reduces that access by patients to physicians.

ABMS, Hospital, Medical Society Collusion

In addition to the agreement with the 24 separate corporations, AAPS argues that ABMS has acted in concert with a standard-setting organization, The Joint Commission, to compel physicians to spend enormous amounts of time and money to comply with ABMS's proprietary ABMS Maintenance of Certification®. "There is no justification for requiring the purchase of Defendant's product as a condition of practicing medicine or being on hospital medical staffs, yet ABMS has agreed with others to cause exclusion of physicians who do not purchase or comply with Defendant's program," states the suit.

ABMS, according to the suit, also makes false and misleading statements in disparagement of physicians who decline to participate in the ABMS program. "ABMS enriches itself, its executives, and its coconspirators by promoting falsehoods that its proprietary product is somehow indicative of the professional skills of a physician, when it is not."

Defendant ABMS and 24 separate corporations have agreed to impose on physicians a recertification program called the ABMS Maintenance of Certification® (also known as "ABMS MOC®").

These 24 corporations are:

- **The American Board of Allergy and Immunology,**
- **The American Board of Anesthesiology,**
- **The American Board of Colon and Rectal Surgery,**
- **The American Board of Dermatology,**
- **The American Board of Emergency Medicine,**
- **The American Board of Family Medicine,**
- **The American Board of Internal Medicine,**
- **The American Board of Medical Genetics,**
- **The American Board of Neurological Surgery,**
- **The American Board of Nuclear Medicine,**
- **The American Board of Obstetrics and Gynecology,**
- **The American Board of Ophthalmology,**
- **The American Board of Orthopaedic Surgery,**
- **The American Board of Otolaryngology,**
- **The American Board of Pathology,**
- **The American Board of Pediatrics,**
- **The American Board of Physical Medicine and Rehabilitation,**
- **The American Board of Plastic Surgery,**
- **The American Board of Preventive Medicine,**
- **The American Board of Psychiatry and Neurology,**
- **The American Board of Radiology,**
- **The American Board of Surgery,**
- **The American Board of Thoracic Surgery, and**
- **The American Board of Urology.**

"Moneymaking Scheme"

In fact, they argue that ABMS' program is a "moneymaking, self-enrichment scheme that reduces the supply of hospital-based physicians and decreases the time physicians have available for patients, in violation of Section 1 of the Sherman Act."

The Case of "Dr. J.E."

The suit was filed in New Jersey, because an AAPS member (Dr. J.E.) was exclud-

Advertisement

ed from the medical staff at SMC, a hospital in Somerville, New Jersey. He had refused to be recertification with one of the private corporations. According to the suit, he runs a charity clinic that has logged more than 30,000 visits, but now none of those patients can see him at the local hospital "because of the money-making scheme of recertification."

Dr. J.E. had been on the SMC medical staff for 29 years. (A Google search for hospitals in Somerville showed one hospital with the initials "SMC"—the Somerville Medical Center.) The hospital's website states that it has been designated as a Primary Stroke Center by the Joint Commission and received the Joint Commission's Gold Seal of Approval for total hip and total knee replacement.

According to the suit, Dr. J.E. had been board certified by The American Board of Family Practice, which subsequently changed its name to The American Board of Family Medicine ("ABFM").

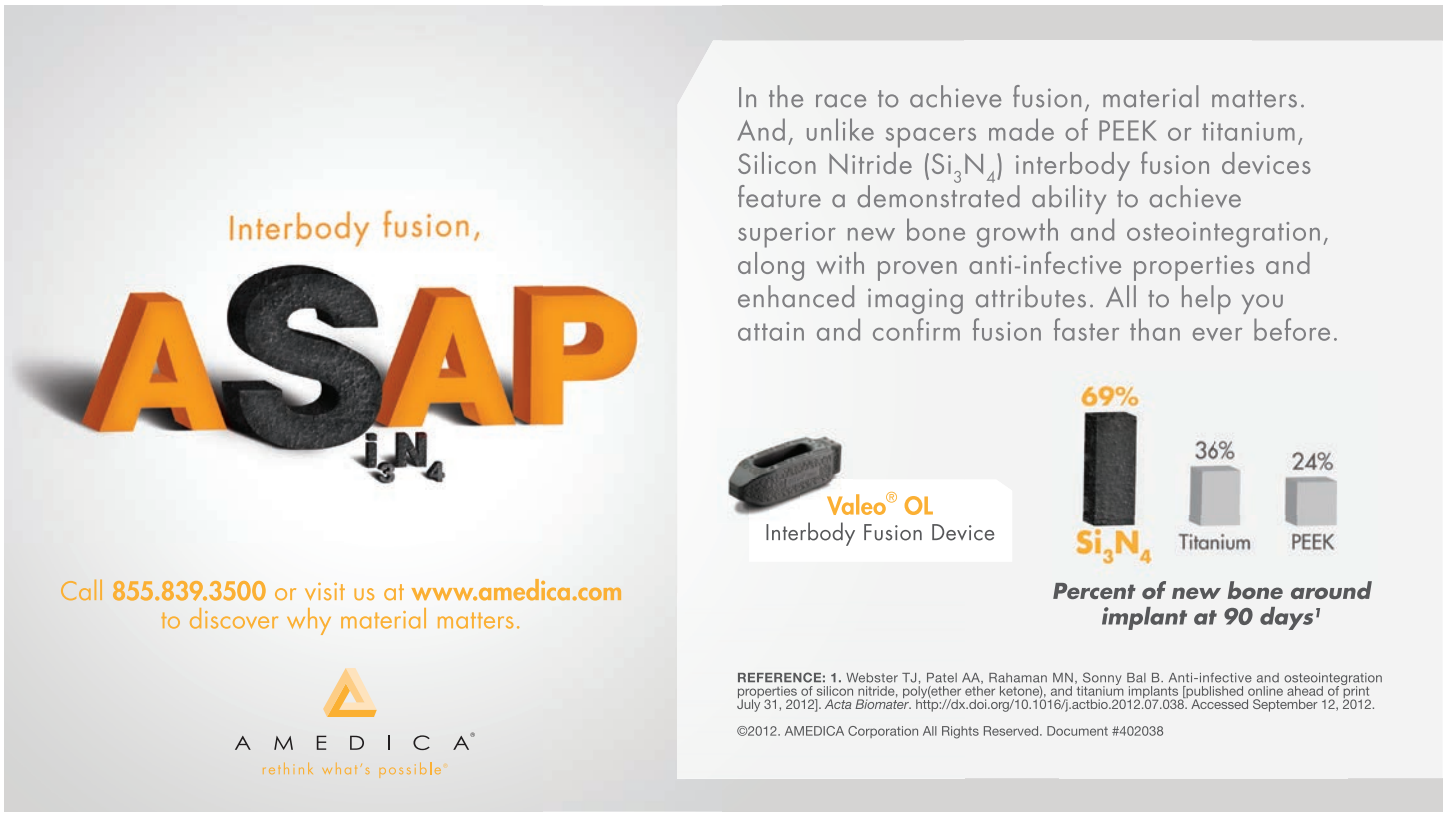
In 2011, claims the suit, SMC refused to allow Dr. J.E. to remain on its medical staff "unless he complied with an extremely burdensome and impractical recertification procedure under the ABMS MOC®."

ABMS Requirements

"Although J.E. had been fully certified in good standing with the predecessor to ABFM, Defendant's agreement with ABFM required imposing the following extremely burdensome requirements for recertification under ABMS MOC®:

- Completion of 50 MC-FP points (acquired by doing modules)
- Minimum of 1 Part II Module
- Minimum of 1 Part IV Module
- One additional module of [his] choice (Part II or Part IV)
- Completion of 150 credits of acceptable CME (minimum 50% Division I), acquired in last three years
- Compliance with ABFM Guidelines for Professionalism, Licensure, and Personal Conduct which includes holding a currently valid, full and unrestricted license to practice medicine in the U.S. or Canada
- Submission of three MC-FP Process Payments; one payment at the start of each module
- Submission of application and accompanying full examination fee for the MC-FP Examination
- Successful completion of the MC-FP Examination."

AAPS claims this demand is far in excess of 100 hours for a typical physician. Furthermore, there is the possibility of an "unjustified rejection of recertification for reasons having no proven connection with patient care and imposes many thousands of dollars in fees and travel expenses."



Advertisement

Since complying with the recertification requirements would result in an hour-for-hour reduction in his ability to provide care to many charity patients, Dr. J.E. decided to serve his patients rather than comply with the recertification burdens.

As a result, the suit claims that effective June 24, 2011, SMC excluded Dr. J.E. from its medical staff, as a result of "Defendant ABMS's agreements with other entities to require the ABMS MOC® program."

Pecuniary Interests

It's all about the money, argues AAPS. "Defendant and its co-conspirators have a substantial pecuniary interest in requiring physicians to purchase their products."

According to publicly available IRS Form 990, AAPS divulges the "immense self-enrichment by executives at Defendant ABMS and its co-conspirators," including the following:

- Kevin B. Weiss, ABMS Executive $562,456 (2011)
- James Puffer, ABFM Executive $727,885 (2011)
- Christine Cassel, American Board of Internal Medicine (ABIM) Executive $794,852 (2010)

AAPS charges AMBS with the following counts:

COUNT I - Restraint of Trade in Violation of Section 1 of the Sherman Act

By seeking and obtaining agreement by The Joint Commission to require enforcement by hospitals of formal recertification requirement, AAPS charges that ABMS has restrained trade by inducing health insurance companies and plans to exclude physicians who do not purchase and comply with the certification program.

AAPS alleges that ABMS has further restrained trade by acting in concert with the previously referenced 24 corporations to "seek an endorsement by the influential Federation of State Medical Boards (FSMB) of "maintenance of licensure" (MOL), in order to impose Defendant's ABMS MOC® as a requirement of licensure by state medical boards."

In 2011, AAPS claims the FSMB formed an MOL Implementation Group that has "acted in concert with Defendant ABMS in order to require parts of Defendant's ABMS MOC® program as a condition of licensure by state medical boards."

Those agreements and concerted actions are, alleges AAPS, a per se violation of Section 1 of the Sherman Act because they are plainly anticompetitive, like a group boycott of a supplier.

AAPS is asking the judge to declare null and void the agreements between ABMS and medical societies and a triple refund of fees received from AAPS members.

COUNT II - Negligent Misrepresentation

ABMS uses phrases like "Not Meeting MOC Requirements" to describe physicians who decline their product. This, claims AAPS, creates the "false impression that Defendant's ABMS MOC® is indicative of the medical skills of physicians, and that as a result physicians who decline to purchase Defendant's product are likely to be less competent."

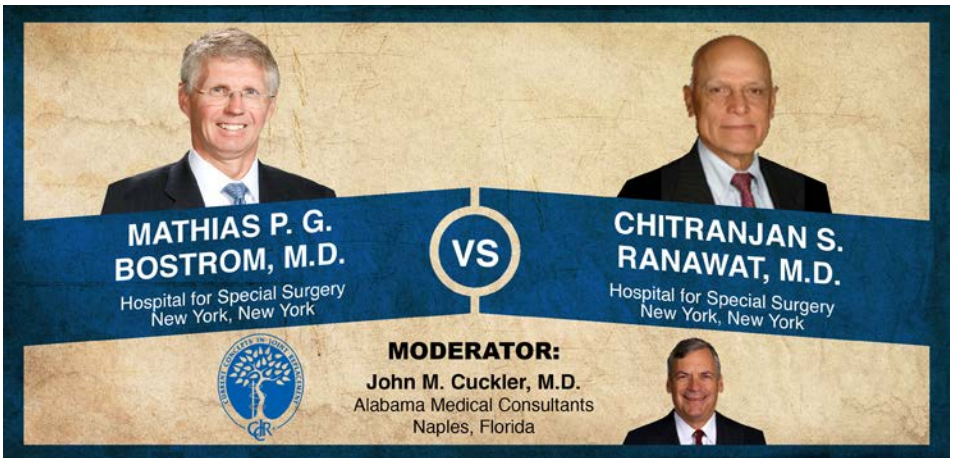
"Many of the questions asked of physicians as part of Defendant's ABMS MOC®, for which physicians must provide the preferred answers in order to be recertified, have no relevance to the quality of care that the physician provides, and there is no meaningful public accountability or transparency as to whether the answers preferred by Defendant are really the best answers."

AAPS wants the Court to make ABMS to take down such statements from their website and stop identifying which physicians have recertified and which ones have not. And they want a jury trial.

The Court has not made any rulings on AAPS's lawsuit, nor has a trial date been set. If a trial is allowed, New Jersey will continue to be ground-zero for fights over credentialing. ♦

High Flexion TKA Designs: Bostrom v. Ranawat

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



Current Concepts in Joint Replacement/RRY Photo Creation

"I believe high flexion designs have no appreciable difference. I used to be excited about these designs, mainly because we like new things," says Mathias Bostrom. "Not only do I believe in high flexion designs, I have designed one," counters Chitranjan Ranawat.

This week's Orthopaedic Crossfire® debate is "High Flexion TKA Designs: No Appreciable Difference." For the proposition is Mathias P. G. Bostrom, M.D. and against the proposition is Chitranjan S. Ranawat, M.D., both from Hospital for Special Surgery in New York. Moderating is John M. Cuckler, M.D. from Alabama Medical Consultants in Naples, Florida.

Dr. Bostrom: "I believe that high flexion designs have no appreciable difference. I used to be excited about these designs, mainly because we like new things. Basically, these designs were modifications—they're not radical differences. There's a modification of the anterior tibial tray and polyethylene insert, of the tibial post geometry, and some modifications of the posterior femoral geometry."

"The cutout on the polyethylene gives a bit more room for the patellar tendon. That makes a lot of sense because you wouldn't have impingement of the patellar tendon on the implant. And when you're flexing at 90 degrees there's a fairly high patella contact force, however at higher flexion angles there is less contact force in this region."

"There were some modifications of the post geometry so that it's slightly smaller, there was some material removed anteriorly, and there was improved rotation. Some of the companies have had this sort of approach."

"Finally, you can modify the femoral component itself with a smaller posterior radius, with the thought being that you can get better flexion and less impingement and greater contact areas. There are some reasonably well done studies showing that the high peak stresses at extreme degrees of flexion such as 155 was less with this smaller radius of curvature of the femoral condyle. Again, the idea is to increase the contact area so that there's better flexion and less impingement."

"These modifications have been made on both fixed and mobile bearing designs. The articular surface modification is to increase surface contact area in flexion, provide patella relief, and to increase tibial polyethylene component stability."

"Now, the clinical data. In a prospective study from Scotland where they compared the NextGen standard to high flex components. There was, unfortunately, no significant difference in outcome, including the maximum knee flexion, between those receiving the standard and high flexion designs. Looking at a meta analysis from Canada we also see that there was no clinically relevant difference. There was only about a two degree increase in flexion with the high flex designs. In vitro analyses have shown that there may be a higher degree of loosening; the forces were greater in the high flex designs."

"So implants that allow a high degree of flexion showed a marked rate of early loosening of the femoral component, which was associated with weight bearing in maximum flexion. My conclusion is that there is no difference. The real determinants of postoperative knee flexion are: preoperative flexion, surgical technique, patient motivation, rehabilitation regimen…and then only a distal fit is implant design itself."

Dr. Ranawat: "Not only do I believe in high flexion designs, I have designed one. So why use a high flexion knee? We want to obtain motion greater than 120 degrees in most of our patients, especially east of Turkey (i.e., India and other regions) want more motion for activities of daily living. So you want to design a knee which will not have excessive polyethylene wear, will not create problems in the patellofemoral joint, and will not have loosening."

"So we designed a knee to achieve these goals: The PFC Sigma RP-F. We created the modification in the posterior third of the condyle so that the contact stresses are better after 110 degrees to 155 degrees of motion. It is a modification of a PFC RP knee; there are six sizes. The post has been moved 2mm posteriorly, the jump height is 16mm, and the third condyle is a load-bearing cam and post."

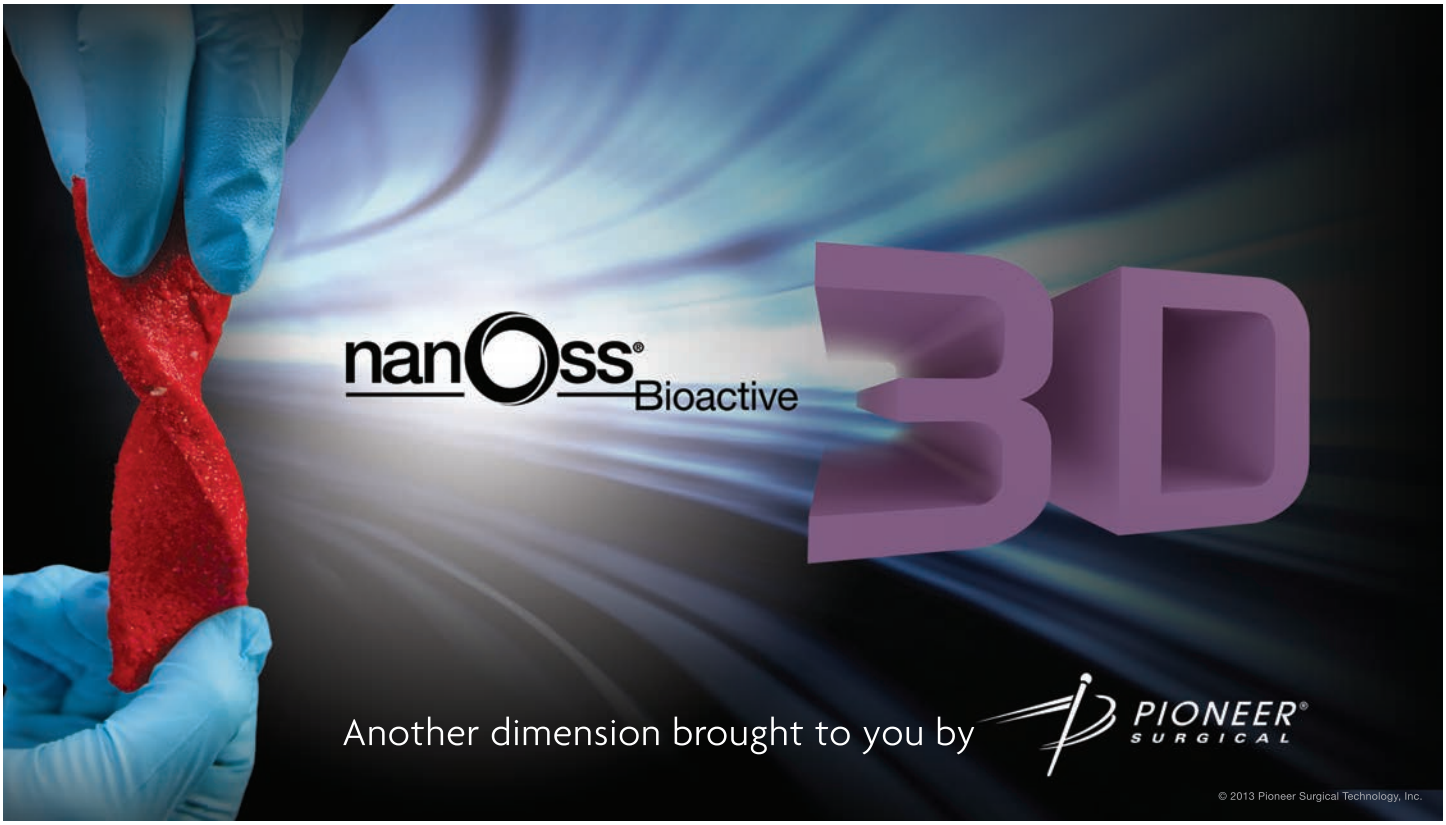
"In a prospective study we used a patient administered questionnaire, which picks up more detailed information. Between March 2004 and December 2006 we had 106 knees (88 patients; 18 bilaterals); a third of these patients were of Indian or Asian descent. We found that pain was significantly better. The pre-operative range of motion (ROM) was 110.7 degrees; post-op ROM was 124.3; 41% of patients had greater than 130 degrees ROM; 10% had greater than 140 degrees of ROM."

"We asked patients, 'How much does the knee affect your sense of well being?' and 83% said 'never, rarely, or occasionally.' We asked, 'Do you have difficulty putting on shoes/socks?' and 95% could do it. Also, 'Do you have difficulty getting in and out of a car?' and 83% said 'never, rarely, or occasionally.' Also, 60% could kneel and 60% could squat."

"Pain and crepitation was a weakness of this study, as was lack of a control group. Also, it was a non-consecutive series and there was selection bias for patients of Asian descent. There was no instability, manipulations, infections, revisions, spinout; there was one reoperation for persistent anterior knee pain and stiffness."

"So in conclusion, a high flexion knee design can achieve higher flexion."

Moderator Cuckler: "Gentlemen, I don't know what to think. Chit, you said 16% of your patients were unsatisfied, 17% had trouble getting in and out of a car, 40% can't kneel…and the two prospective, randomized studies in the peer-reviewed literature show no difference. So why are we still fooling with this high flex design? Have we proven that it works?"



Advertisement

Dr. Bostrom: "The answer is 'no.' As much as I would have loved it to work, the data doesn't support it in randomized studies. In case control studies they get high flexion, but you can argue that that may be surgical technique. The pre-operative ROM in your series, Dr. Ranawat, was actually pretty good… so they ended up with a pretty good ROM."

Moderator Cuckler: "Chit, would you agree that we need a prospective randomized study with a blinded assessment of your particular design?"

Dr. Ranawat: "Any prospective study brings out the truth in any design or technique, so the answer to your question is 'yes.' But remember one thing: literature meta analysis or other prospective studies shows that all high flexion knees are not the same. What I'm saying is a design which has a cam and a post as a load bearing structure where the knee rolls back can't be compared."

Moderator Cuckler: "Patient satisfaction. Chit, you said 16% were dissatisfied with the outcome of the surgery. Let's say an Asian patient comes to you and would like to be able to kneel/squat. What do you tell them in terms of expectation in terms of your RP/PS knee high flexion femoral design?"

Dr. Ranawat: "You say you're going to get good motion. If they have 115 degrees I tell them they can get up to 125-145 degrees…and that the chance is about 40-50%. Then, after any total knee, if you ask, 10% of all patients have some anterior knee pain. If you don't ask, the Knee Society Score does not pick up those kinds of pain issues. So I'll say, 'You have a chance of pain interpretation and the risk is 2-3%.'"

Moderator Cuckler: "Mathias, how do you handle patient expectations?"

Dr. Bostrom: "The key thing is having the discussion with them pre-operatively so they understand that this operation is a great surgery, but you will always remember that you have a knee replacement. It's very different than hips where often they forget they've had their hip done after a couple of years."

Moderator Cuckler: "Is there something different we should do in our rehabilitation routine in order to produce improved flexion…something that's independent of knee design?"

Dr. Bostrom: "I don't think there's anything that's going to make a huge differ-

Advertisement

ence. I think aggressive rehabilitation post-operatively is critical. But the ones that get really stiff are going to get stiff whether you have aggressive rehabilitation, a high flexion design…a lot of the really stiff knees we see post-op are idiosyncratic and we can't really predict those cases."

Moderator Cuckler: "Chit?"

Dr. Ranawat: "Rehab after these surgeries has been overemphasized. I've done a prospective randomized study where one group of patients got everything (in house physical therapy, etc.). The other group was just shown how to walk and sent home with no physical therapy (PT). At six weeks the group with no PT was a little behind; at three months there was no difference."

Moderator Cuckler: "Continuous Passive Motion post-op?"

Dr. Bostrom: "Yes."

Dr. Ranawat: "I give it because everybody else does, but there is no data to support it."

Moderator Cuckler: "Thank you." ♦

Please visit www.CCJR.com to register for the 2013 CCJR Spring Meeting, May 19 – 22 in Las Vegas, Nevada.

"You may now view content from the CCJR Meetings on the CCJR Mobile™ App. Please scan the QR code to download the CCJR Mobile App to your Android or iOS mobile device, or visit www.ccjrmobile.com."

Advertisement

Urgent Plea From AAOS PAC! If you read nothing else, read this. Mayo Clinic Sets Efficient Quality of Care Standard and more…

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

Your Voice Is Required NOW and the AAOS PAC Is HOW There's no way around it, says Stuart Weinstein, M.D., chair of the American Association of Orthopaedic Surgeons Political Action Committee (AAOS PAC)…the world of politics DOES affect your practice. And he thinks it's downright shameful that some doctors don't get involved. Dr. Weinstein tells *OTW*, "The number of changes occurring in both the legislative and regulatory arenas is astounding, and demands involvement from all doctors. Although many physicians have seen themselves as being on the sidelines when it comes to politics, we have reached the point where NOT trying to help our patients and our profession by getting involved is downright irresponsible. 'But this is not part of being a doctor,' many say… yet political problems affect their practices daily. Take the issue of the sustainable growth rate formula. Since 2002 every physician has clamored to get rid of this. Now that we have a real chance of it being repealed and replaced, it is more important than ever to be actively involved."

"We can't hide from the fact that our daily lives are being driven by those in the state and federal legislatures. Look at the health exchange situation. The implementation of the Accountable Care Act [ACA] has so many things that we don't even know about yet. These 'warts' may come out in upcoming year as the federal government tries to implement the ACA, meaning that being involved and staying in touch with politicians is important. Even they are behind the eight ball…they're trying to figure out if they and their staff members have to buy insurance on the exchanges. If they are in the dark where does that leave us?"

Wikimedia Commons

"And for those in private practice who are essentially small business owners, they especially need to be participating on a political level. How does the healthcare law apply to you practice business? Can you afford the increased insurance premiums for your employees? Will you face the penalty? Will these increased costs prevent you from expanding your practice? Get involved! Host an event for a member of Congress, attend a town hall meeting…and if you can only do one thing contribute to the AAOS PAC, but…do something."

Fellowship Accreditation: Coming Soon? Residents are accredited uniformly by the ACGME (Accreditation Council for Graduate Medical Education)…why not all fellowships? Harry N. Herkowitz, M.D. is chair of the Department of Orthopaedic Surgery at Beaumont Health System in Michigan and is a senior director of the American Board of Orthopaedic Surgery (ABOS). He tells *OTW*, "Accreditation of spine fellowships will insure that a balance exists between service and education in the fellowship year. At present, only a handful of fellowships are accredited. In order to move toward uniform accreditation for spine fellowships it may be necessary to pursue subspecialty certification in spinal surgery. This process has already occurred for hand surgery and orthopedic sports medicine. Both of these subspecialties have certification and 100% fellowship accreditation. The idea of spine certification has been discussed for many years. Because orthopedic spine surgery and neurosurgery are coming closer together, the timing to consider certification may be here. The fellowship year is critical for a

trainee and fellows need to have a good balance between operating, patient care, education and research."

"As a member of the ABOS board of directors I am working with orthopedic spine surgeons and neurosurgeons to bring the discussion to a higher level and find common ground. The issue is that many surgeons don't feel the need to do this and don't want to go through this process because it requires testing and data gathering. We need to know what is being taught in that all-important last year of training. Some fellowships might be service heavy, so they're getting a lot of clinical time…but it may be at the expense of research or education opportunities. We have no oversight of these programs and that needs to change."

New Technique = Better ACL Outcomes in Young Athletes James Lubowitz, M.D. is director of the Taos Orthopaedic Institute, Taos Orthopaedic Institute Research Foundation, and Taos Orthopaedic Institute Sports Medicine Fellowship Training Program. He tells *OTW*, "I'm pleased to say that my ACL [anterior cruciate ligment] outcomes have improved in my most difficult patients. It is well known that in patients over the age of 25, the re-rupture rate after surgery is about 1%; however, in young athletes, the re-tear rate approaches 10%. Given this extraordinarily high ACL graft failure rate in young athletes, I have changed the way I practice, and I am collecting prospective data to test the hypothesis that we can substantially improve our outcomes in this cohort. The changes have been in three areas: the first involves our knowledge of anatomy. Even though the study of anatomy dates to the times of Leonardo Da Vinci, and even the ancient Egyptians, the endoscopic ACL technique popular at the end of the 20th century placed the ACL femoral and tibial footprints in the wrong position. Now, by placing our grafts at the centrum of the anatomic footprints, I think that we are achieving better outcomes. Second, there are rehabilitation issues. We are paying a lot more attention to this. Now, instead of just focusing on strengthening the knee, we are also paying attention to core strength, hip abductor strength, and proprioceptive, plyometric, and perturbational training. Finally, we have improved ACL fixation with second generation, adjustable loop length, cortical suspensory fixation devices. Such devices, as opposed to interference screw fixation, allow graft collagen to fill the entire area of the ACL graft socket footprints, and in addition, are the only ACL fixation option that allows graft tensioning after graft fixation has been achieved. To date we have published our anatomical studies, and our adjustable loop length, cortical suspensory fixation device techniques, and colleagues have

Visit Us Online At:
www.centinelspine.com

Experience the
GOLD
STANDARD
In Integrated Interbody Fusion®

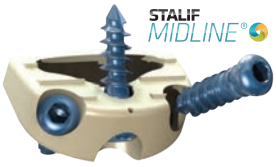
STALIF MIDLINE® & STALIF C®
No Profile® Integrated Interbody Fusion® Systems

Or Call: 484-887-8810

EASE OF IMPLANTATION.
SHORT OPERATIVE TIMES.
SEGMENTAL FIXATION.

These are just 3 of the many reasons why STALIF MIDLINE® & STALIF C® are considered the premier Integrated Interbody Fusion® devices.

STALIF MIDLINE® & STALIF C® are part of totally integrated systems, with implants and instruments designed to work in harmony to reduce surgical times. Utilizing Centinel Spine's™ highly aggressive ABO® anti-backout cancellous screws, the converging 3 screw design of both STALIF MIDLINE® & STALIF C® was engineered with the AO principles in mind to capture areas of concentrated bone density. The devices provide the maximum end plate / implant contact—allowing for "lag fixation". STALIF® devices are meant to rest on the apophyseal rim of the vertebral body, making them both true "no-profile".



Let us show you why your medically indicated DDD patients will benefit greatly from your use of the STALIF® family of Integrated Interbody Fusion® devices. For more information, contact Centinel Spine™ Customer Service at 484-887-8810.

STALIF C®

from Centinel Spine™

Advertisement

published the advances which I now employ with regard to rehabilitation techniques, but it will take more time to achieve adequate clinical follow-up on large cohorts of cases until we can truly test the hypothesis that our failure rates are lower."

Mayo Clinic: Quality Care Delivered More Efficiently The joint replacement folks at Mayo Clinic have figured out how to cut length of stay and maintain quality…and "optimization" is the key word, says Henry Clarke, M.D., of Mayo Clinic. Dr. Clarke, an associate professor of Orthopaedic Surgery at Mayo Clinic in Arizona, tells *OTW*, "We have undertaken an innovative program at Mayo Clinic to improve quality and to reduce costs. The program, which has been in effect for about two years, is a comprehensive effort to improve the consistency of care delivered at our facility. One way we do this is to thoroughly prepare patients preoperatively, something that involves a mandatory medical evaluation and a class on the procedure and the postop experience. This class involves our nurses, therapists and others, and is important so that patient better understand what will actually occur."

"Essentially, we took a look at group of practitioners who had their own way of approaching knee replacement surgery, and we began integrating more standard measures into their practices, best practices if you would. For example, we can optimize patients' preoperative blood count and use medication (tranexamic acid) to reduce the bleeding associated with total knee. This has essentially eliminated the need for transfusion in total knee patients. In addition, we do our best to lower the risk for DVT [deep vein thrombosis] by having each patient screened preoperatively by a nurse practitioner. I'm thrilled to say that through this integrated approach we have reduced our length of stay for these surgeries by nearly a day and a half while maintaining low complication rates."

Terrific New Orthopedics Program in Bolivia Orthopedic training is ramping up in Bolivia, thanks to Health Volunteers Overseas (HVO) and HOPE *worldwide*. At the Hospital Arco Iris (HAI) in La Paz, Bolivia, there is a group of well-organized orthopedic surgeons who would like to host volunteer surgeons who can help provide training in desperately needed specialty areas. These skills would help them provide up-to-date orthopedic care to the surrounding communities who have limited access to health care. It would also, says Dr. Rex Haydon, help them care for the victims of the mass casualty accidents that occur frequently along the Yungas Highway (aka, Highway of Death, the most dangerous stretch of highway in the world). Rex Haydon, M.D., Ph.D. is an associate professor of orthopedic surgery at the University of Chicago reviewed the new orthopedics program for HVO. He tells *OTW*, "This program was put in place to help broaden the skills and knowledge of practicing surgeons, interns and nurses. The group, including five orthopedic surgeons, would like to learn advanced techniques in arthroscopy, complex trauma, pediatric spine, microsurgery, and other areas. To date these surgeons have not had CME [continuing medical education] opportunities so they would like to host specialists in these areas to sharpen their skills. This program will address that."

"HVO will offer three training courses each year, each of which will last from six to eight weeks. Two to three HVO volunteers—most from the U.S. and Canada—will lead each course and volunteer assignments will be for a minimum of two weeks during the training course. Retired orthopedists may also volunteer, and final-year residents and fellows could be eligible if they agree to work with an attending physician."

"La Paz is safe, the accommodations are excellent, and there is a well-organized and motivated support group on sites in Bolivia all year. The hospital has well-equipped ORs, with a C-arm, microscope and arthroscopy tower, among other essential equipment. I believe that this could be a very meaningful and educational volunteer opportunity for a variety of surgeons." ♦

For more information, please contact Andrea Moody, Volunteer Coordinator for HVO: a.moody@hvousa.org

Advertisement

company

Zimmer Buys Subchondroplasty Procedure

Zimmer Holdings, Inc. announced on May 2, 2013 that the company has acquired the assets of West Chester, Pennsylvania-based and Viscogliosi Brothers, LLC-founded, Knee Creations, LLC.

Knee Creations was founded in 2007 to focus on integrating cutting-edge scientific research into first-of-a-kind surgical solutions to treat defects associated with subchondral bone marrow edema (BME). The company was funded with an angel equity round and a Series A equity round of financing, together with debt, led by Viscogliosi Brothers, LLC, Praefinium and Philadelphia Medical Investment Group, LLC.

The company said the acquisition of Knee Creations' Subchondroplasty procedure enhances Zimmer's product portfolio of knee treatment. "Subchondroplasty is an innovative, proprietary joint-preservation treatment that has been shown to deliver sustained relief to patients with knee pain, with or without arthritis. It is the first procedure to address an unmet clinical need between early interventions, including NSAIDs (nonsteroidal anti-inflammatory drugs) and arthroscopy, and total joint replacement," stated the company announcement.

"Zimmer is committed to developing the most comprehensive range of therapies for knee patients, from early intervention and joint preservation products to patient specific instrumentation and personalized joint replacements," said Jeff McCaulley, president, Zimmer Reconstructive. "The acquisition of Knee Creations' revolutionary Subchondroplasty treatment provides Zimmer with another clinically differentiated offering that addresses an unmet clinical need."

Marc Viscogliosi, a founder and chairman of Knee Creations, LLC, stated, "As a global leader, we believe Zimmer can make the greatest impact with the revolutionary Subchondroplasty procedure platform."

According to the Zimmer press release, Subchondroplasty is a percutaneous outpatient intervention that addresses the defects associated with subchondral bone marrow edema (BME). BMEs are related to stress fractures or microfractures and are diagnosed using MRI. Left untreated, these defects have been shown to lead to cartilage degeneration, limited function, pain and greater risk for joint deterioration.

In this minimally invasive, arthroscopically assisted procedure, navigation instruments are used to inject a specialized bone void filler to treat the bone defect and begin the healing process, without violating the joint. Since its introduction in November 2010, more than 1,500 Subchondroplasty procedures have been completed.

—WE (May 3, 2013)

Knee Creations, LLC

NuVasive and Globus Report Healthy First Quarters

NuVasive, Inc. and Globus Medical, Inc., involved in litigation with each other and in a fight for market share with Medtronic, Inc., reported 5.2% and 10.9% revenue increases, respectively, for the first quarter of 2013.

NuVasive reported total sales of $159.5 million while Globus reported $105 million in sales.

NuVasive's Chairman and CEO Alex Lukianov said first quarter results are in line with the company's expectations. He noted several positive developments in the form of strong clinical data to support fusions for degenerative disc disease, in conjunction with the ongoing formulation of new clinical guidelines have the potential to improve long term U.S. spine market growth.

"And regardless of what U.S. market growth ultimately looks like, NuVasive has massive opportunities to drive sustainable top and bottom line growth globally," said Lukianov. He expects the company to execute its plan for growth toward $1 billion in revenue with an improved profitability profile.

Lukianov reiterated 2013 revenue guidance for $655 million.

David Paul, Globus' chairman and CEO, said the "superior growth" was due to the company's ability to "deliver innovative products, attract top sales force talent and maintain financial discipline." The company launched two products during quarter and is on track to reach their annual target of 5-10 new products annually.

He was also comfortable with current consensus sales estimates of $432 million for the year.

NuVasive – "Year Looks Fine"

NuVasive management announced a partial settlement in the ongoing patent litigation with Medtronic. The settlement resolves all disputes related to cervical plate patents and affords NuVasive broad access to Medtronic's portfolio of cervical plate patents.

In exchange, NuVasive agreed to a $7.5 million up-front payment to Medtronic to settle Phase II of the litigation, all of which will be offset against any damage award ultimately paid in connection with Phase I. As well, NuVasive will assume an effective go-forward royalty rate of 3% on certain cervical plates that rely on the patents licensed.

Jefferies LLC analyst Raj Denhoy said NuVasive beat expectations on the strength of U.S. cervical and international sales. The company recently announced the opening of its Japanese headquarters. International sales increased +47% and continued to benefit from uptake of XLIF in Japan, said Denhoy.

Added Denhoy, "With Japan still ramping, PCM (porous coated motion cervical disc) rolling out, and potential contribution from other new products, the year looks fine"

Courtesy of NuVasive nd Globus/RRY Publications LLC

Globus – "Shaping Up to a Good Year"

Globus management told analysts that on the margin, some of the pressures on the overall spine market, such as payor pressure, pricing pressure, and POD's (physician-owned distributorships), appear to be showing signs of easing.

Bank of America analyst Bob Hopkins said several things contributed to Globus' solid quarter, but new product flow and an ability to hire competitive reps were the two most important, in his view. Hopkins said DePuySynthes is admitting to losing share as a result of integration issues with Synthes and Globus' proximity to Synthes and their close relationship with individuals from Synthes positions them well to take advantage. Globus management suggested that the company is hiring from across the spectrum of larger spine players with no real concentration.

Hopkins added that pricing pressure for Globus was no different than it has been over the last few quarters and the spine market growth rate remains weak. However he noted that Globus management suggested they were seeing some positive signs.

Overall, Hopkins said he continues to be skeptical about the spine market and believes that the larger companies will ultimately be tougher competitors again, "but that day is not today or near term in our view. 2013 is shaping up to be a good year for Globus."

—WE (May 3, 2013)

Wenzel Launches In Situ Expandable Fusion Device

Wenzel Spine, Inc. has launched its VariLift-C stand-alone zero-profile expandable cervical interbody fusion device in the U.S. The company received FDA clearance in January 2013.

The device is an interbody fusion device for stand-alone use and is indicated to be implanted as a single device or bilaterally via an anterior approach which may be implanted without supplemental fixation.

Andy Redmond, M.D., Neurosurgeon at Precision Spine Care in Tyler, Texas, said the device simplifies ACDF procedures during cervical fusion surgery by expanding in situ once it's properly positioned, without the need for anterior plating. "The ease and simplicity of VariLift-C make it an ideal technology for ACDF procedures, particularly in use with adjacent segment disease cases as it allows for the treatment of adjacent levels without the need to remove and replace previous constructs."

The device, according to the company is the only FDA cleared stand-alone device that expands in situ.

Wenzel Spine CEO Chad Neely said the device, "is the only expandable cervical IBFD that provides surgeons with a true stand-alone, zero profile technology for use in ACDF cases. VariLift-C also expands options for surgeons to migrate appropriate cases to ambulatory care settings." Neely added, "Proven stand-alone solutions like VariLift-C that don't require supplemental fixation are essential for reducing healthcare costs and improving clinical outcomes for today's surgeons and patients."

Wenzel Spine, Inc. /VariLift-C

The company made the device available to five U.S. clinical sites in a controlled release. "Surgeon feedback was highly encouraging as they identified that VariLift-C provides a streamlined ACDF procedure that does not require the use of supplemental fixation," stated the company announcement.

Wenzel Spine is backed by the Austin-based healthcare venture capital firm TEXO Ventures.

—WE (May 1, 2013)

Millstone Medical Expands Distribution

Millstone Medical Outsourcing. LLC has announced that the company will offer customers an expanded medical device distribution service, which includes the ability to distribute directly to patients and to provide wholesale distribution to distributors, hospitals, and sales representatives. Millstone Medical has been securing medical device distribution licensing in all states that require the licensing. In addition, Millstone Medical has instituted a robust program for the continuous monitoring of requirements for the two types of licenses, direct to patient and wholesale distribution, in 50 states.

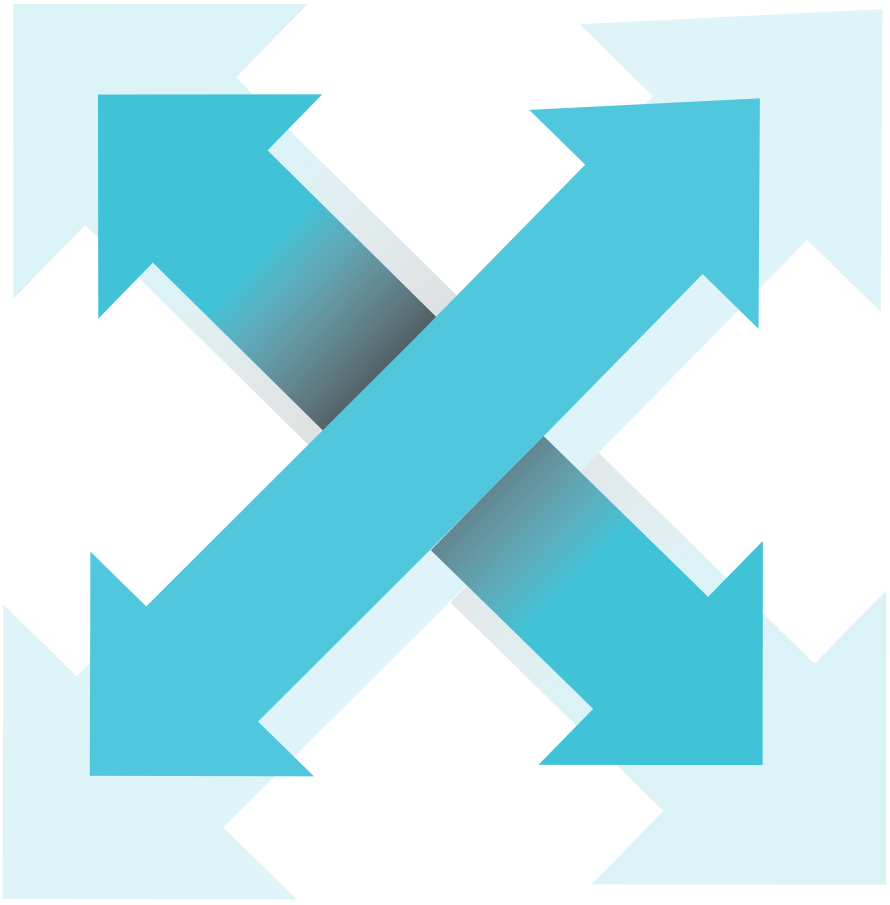
The impetus for development of the service was the complexity of licensing requirements, which differ from state to state. Some states require a simple application, while others include finger printing of senior leaders and background checks, certification of designated representatives, surety bonds, and Verified-Accredited Wholesale Distribution (VAWD) accreditation. In addition, the processes and timeframes for renewal are state dependent and the regulations governing medical device distribution are regularly reviewed and updated.

Millstone is aiming to help manufacturers deal with things such as licensing fees and redirection of key personnel. This new offering is designed to deliver streamlined distribution, reduced costs, and increased speed to market.

"Distributing medical devices, even those used at home to improve circulation or enhance mobility after surgery, requires licensing in most states. The licensing process, though, can be onerous for device manufacturers," said Chris Ramsden, chief executive officer of Millstone Medical Outsourcing, in the April 23, 2013 news release. "Our goal is to remove obstacles for our customers and to help them get their products to market faster. Our licensing, in conjunction with the federal and state requirements, allows our OEM partners to address regulatory hurdles and significant costs without cutting corners on quality."

Asked about those obstacles, Ramsden told *OTW*, "Two obstacles Millstone Medical clears for customers with the expanded distribution service are: first, approval from the Federal Drug Administration to store and distribute bone and tissue product, and, second, the licensing required to ship bone and tissue product and medical devices to every state in the country."

—EH (May 1, 2013)



RRY Publications LLC

NLT SPINE: Red Herring Award Winner

A certain stamp of approval…NLT SPINE has announced that it was recently selected as a Red Herring Top 100 award winner. The list of winners represents Europe's leading private companies and startups, with innovative technologies across their respective industries.

"Selecting startups that show the most potential for disruption and growth is never easy," said Alex Vieux, publisher and CEO of Red Herring, Inc., in the April 23, 2013 news release. "We looked at hundreds and hundreds of candidates from all across the continent, and after much thought and debate, narrowed the list down to the Top 100 Winners. Each year, the competition gets tougher but we believe NLT SPINE demonstrates the vision, drive and innovation that define a Red Herring winner."

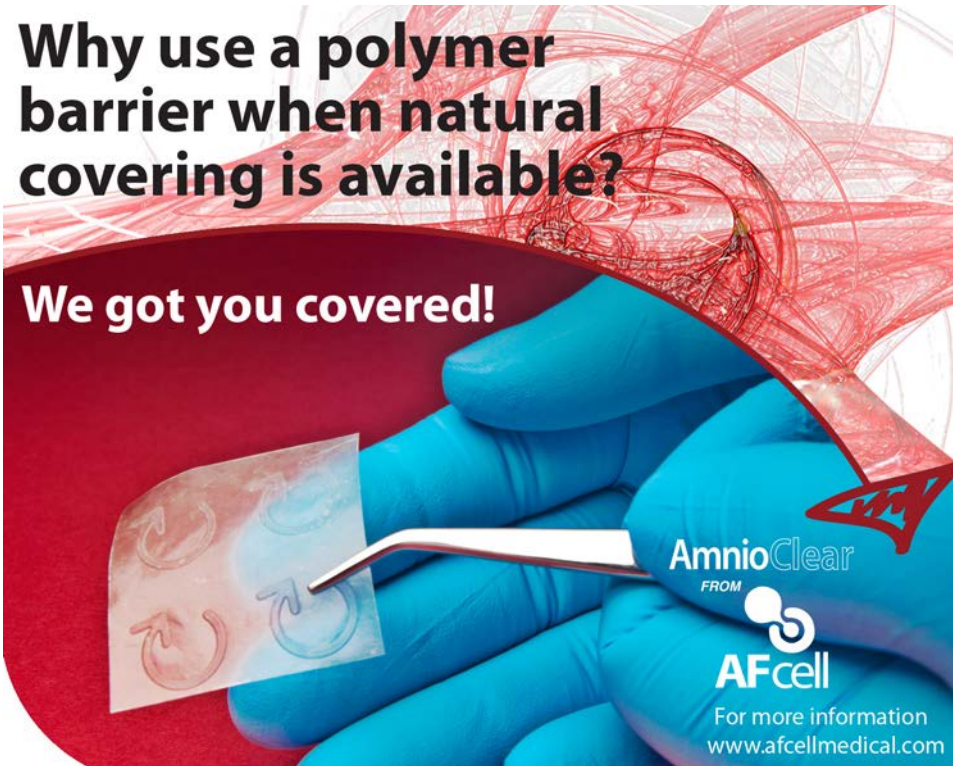
Red Herring, Inc.

NLT SPINE has developed the "non-linear" technology platform enabling implantation of large spinal implants and instruments through small incisions for the treatment of degenerative conditions of the spine. With the "non-linear" technology platform, which is applicable to a wide variety of surgical spine procedures, implant and instrument size is not limited by the incision size.

Red Herring's editorial staff evaluated the companies on both quantitative and qualitative criteria, such as financial performance, technological innovation, management quality, overall business strategy and market penetration. This assessment was complemented by a review of the track records and standings of similar startups in the same verticals, allowing Red Herring to see past the "buzz" and make the list a valuable instrument of discovery and advocacy for the most promising new business models in Europe.

Didier Toubia, CEO of NLT SPINE, told *OTW*, "To be included in the company of many great technologies that have received Red Herring awards in the past, makes all of us at NLT SPINE, very proud. Each recognition the company receives reinforces the team's confidence in our innovative products and technologies and increases the motivation to continue developing unique solutions for the spinal market."

—EH (April 30, 2013)



Advertisement

ISTO and Zimmer Part Ways

ISTO Technologies, Inc. and Zimmer Holdings, Inc. have reached a fork in the road. And they're taking it.

On April 29, 2013, ISTO announced that the companies have called off their collaboration and will go their own ways to develop products to repair cartilage defects. ISTO is assuming full control of the DeNovo ET engineered tissue program. Zimmer will get ownership of DeNovo NT, a particulated juvenile cartilage allograft tissue implant product. ISTO is renaming DeNovo ET to RevaFlex.

We asked ISTO Chief Financial Officer Scott Gill why the companies were parting ways.

Wikimedia Commons and Nigel Brown/Parting of the Ways

Strategic Objectives and Time Horizons

Gill said after working with Zimmer for several years on both the DeNovo ET and DeNovo NT programs, "it became apparent to both parties that it made more sense for each of us to take full control of the program that best fit the strategic objectives and time horizons for each company. ISTO believes that the patented cell-expansion technology and manufacturing scalability behind the newly named RevaFlex program will enable us to better deliver an off-the-shelf knee cartilage repair solution capable of meeting the large demand for such a product better than other cartilage programs currently available or in development."

He added that his team believes that the RevaFlex program and the company's NuQu program, an early intervention treatment for degenerative disc disease, represent the future of orthopedics and spine. "These innovative biologic products have the ability to regenerate and restore function and address some of the leading causes of disability in the U.S."

Phase III Clinical Program

RevaFlex is an engineered cartilage implant intended to repair cartilage defects in the knee. ISTO will proceed independently with further development of the program through a Phase III clinical program.

As part of its cell-based orthobiologic platform, ISTO is currently involved in the development of two "unique and potentially ground-breaking" cell-based products intended to treat two of the leading causes of disability in the U.S. In addition to RevaFlex, ISTO is developing NuQu, a minimally invasive early intervention treatment for discogenic back pain. The company initiated Phase II clinical trials for NuQu in late December 2012.

Both the RevaFlex and NuQu programs address significant unmet medical needs related to chronic pain and disability resulting from cartilage wear and degeneration problems that occur in the knee and lower back, respectively. ISTO's proprietary cell-expansion process provides the foundation for both programs. Through this process, allogeneic cells are expanded to create products capable of treating thousands of patients from a single donor, thus offering an economy of the scale and "off-the-shelf" therapeutic solution not possible with cartilage programs utilizing autologous cells.

—WE (May 5, 2013)

Medtronic Spine Launches at AANS

Medtronic Inc.'s spinal business launched several new product line additions to the company's Vertex Select Reconstruction system at the 81st American Association of Neurological Surgeons (AANS) Annual Scientific Meeting in New Orleans. The company also launched the MAST Aligned procedure at the meeting on April 29, 2013.

Vertex Select Reconstruction System

The additions to the Vertex system offer a selection of various size implants including pre-cut/bent rods, tapered rods, and other connecting implant options. The system is used to treat DDD (neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, spinal stenosis, fracture, dislocation, failed previous fusion and/or tumors.

The company announcement stated the new products offer more treatment options for performing posterior cervical-upper thoracic surgical procedures. The system product line was originally introduced in 2001.

Doug King, senior vice president and president of Medtronic's spinal business, said, "When you combine the implant options available in the [Vertex system] with the recently introduced CERVICAL FACETLIFT Indirect Decompression and Stabilization surgical technique, Medtronic can now offer surgeons a true innovative procedure to treat these patients."

The CERVICAL FACETLIFT ID/S surgical technique incorporates technology developed by Gary K. Michelson, M.D.

MAST Aligned Procedure

The MAST procedure is a comprehensive surgical solution which includes technologies to access the spine, such as oblique lateral, as well as interbody, navigation, and biologics options.

At the core of the procedure is the new CD Horizon Longitude II System, a multi-level percutaneous fixation system designed to provide spinal stabilization and correction as an adjunct to fusion in patients suffering from painful and function-limiting disorders of the middle and lower back.

A company statement noted the MAST procedure is the latest advancement in a series of integrated procedural solutions that complements Medtronic Spine's minimally invasive MAST portfolio to successfully treat patients for a variety of degenerative and complex spinal conditions. More than 250,000 individuals in the U.S. undergo spinal fusions annually to treat degenerative changes in the lumbar spine.

The CD Horizon system is also designed to work with the NIM-ECLIPSE System, STEALTHSTATION Navigation and O-ARM Imaging Systems, and the POWEREASE System, a system of powered instruments designed for drilling, tapping, and driving screws during spinal surgery.

Medtronic, Inc./Vertex Select System

—WE (April 30, 2013)

biologics

Major Study Update: Stem Cells Ease Back Pain

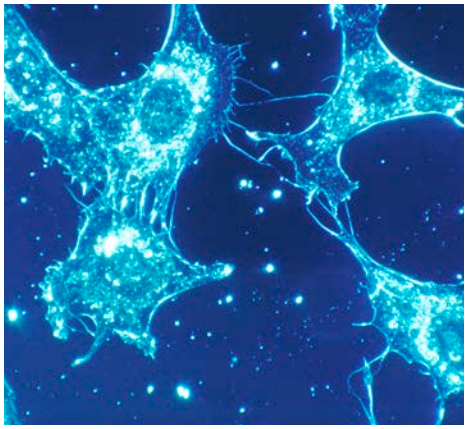
Mesoblast, the highest value stem company in the world, released the latest in string of studies examining the ability of a certain type of stem cell to treat back pain.

In its earliest test of its stem cells (known as mesenchymal precursor cells – MPCs) the company injected its MPCs into three adjacent lumbar discs in 24 adult male sheep. The MPCs were injected intradiscally. The particular sheep model that was used (*Journal of Neurosurgery: Spine* May 2012; Vol. 16; No. 5; Pages 479-488) was one where some discs were injected with chrondroitinase in order to mimic disc degeneration and other discs were left alone to represent normal discs as a control arm in the study.

In the sheep test, the degenerated discs had 45-50% less height before treatment with Mesoblast's MPCs. After MPC treatment the discs rehydrated and increased in height at rates that were statistically significant as compared to the controls. It was, in fact, a significant and highly important animal study and set up Mesoblast's human study.

This past week, Mesoblast released its second round of preliminary results from this Phase 2 human study of MPCs as an intradiscal injection treatment for back pain.

In the study, researchers injected allogeneic mesenchymal precursor cells (MPCs) into damaged intervertebral discs in what is, essentially, a one hour outpatient procedure.



Wikimedia Commons and National Cancer Instititute

This is the six-month follow-up data. All 100 patients have been enrolled.

Researchers Kasra Amirdelfan, M.D. (IPM Medical Group, Walnut Creek, California), Hyun Bae, M.D. (The Spine Institute, Santa Monica, California, Domagoj Coric, M.D. (Carolina Neurosurgery & Spine, Charlotte, North Carolina), Tory McJunkin, M.D. (Arizona Pain Specialists, Phoenix, Arizona), Michael DePalma, M.D. (Virginia I-Spine Physicians, Richmond, Virginia) and William Beckworth, M.D. (Emory Orthopaedics & Spine Center, Atlanta, Georgia) report that a single low-dose injection of MPC significantly reduced low back pain in the treated patients and did so at a statistically significant way as compared to the control group.

The control group, by the way, received hyaluronic acid injections. In terms of safety, the researchers found no cell-related safety issues.

The study has enrolled 100 patients across 13 sites in the United States and Australia. Researchers are randomizing patients to receive direct intra-disc injection of saline (n= 20), hyaluronic acid (HA, n=20), 6 million MPCs in hyaluronic acid carrier (n=30) or 18 million MPCs in hyaluronic acid carrier (n=30).

The study participants received their injection in an outpatient setting and only patients with single level degeneration were admitted into the study. The investigators are evaluating the patients for safety and efficacy at 30 days, 3 months and 6 months.

Company officials say that researchers will continue to follow the patients for a total of 36 months to evaluate long-term treatment effects.

At six months, 71% of those patients who received a low dose of MPCs met the pre-specified treatment success criteria. By contrast, only 20% and 30% of the patients in the two control arms who received hyaluronic acid and saline met the pre-specified success criteria.

Mesoblast officials expect to have full trial results by the third quarter this year. Company officials report that confirmation of the interim results supports progression of the study to Phase 3 for MPC treatment of chronic discogenic low back pain.

Over 6 million patients in the United States alone are currently dealing with chronic back pain that has persisted for at least three month, according to Mesoblast's accounting. The CDC's National Center for Health Statistics reported in 2010 that low back pain was the leading cause of pain, affecting 28% of American adults. The United States lifetime prevalence of low back pain is estimated to be at least 60-84%.

Total costs of low back pain are estimated to be between $100 billion and $200 billion annually, two-thirds of which are due to decreased wages and productivity.

—BY (May 1, 2013)

large joints

Neurotech Lands Canadian Distribution Rights

Health Canada has cleared Neurotech NA's orthopedic and pain management devices for distribution in Canada. Receiving clearance are the Kneehab XP Quadriceps Therapy System, the Neurotech Plus Surface Neurostimulation System, and the Recovery – Back Conductive Garment System.

The Kneehab XP, which was introduced in the U.S. in early 2010, is a quadriceps rehabilitation system for use following knee injury or surgery. According to company officials, the Kneehab delivers neuromuscular electrical stimulation that has been shown to provide superior rehabilitation results. Neurotech developed the Recovery – Back to strengthen and rehabilitate muscles in the low back and abdomen and to treat low back pain. Surface neurostimulation to these areas is delivered via two separate garments in conjunction with the Neurotech Plus controller.

Neurotech NA is based in Minneapolis, Minnesota and has signed distribution agreements with Rehab Matrix Canada, Inc., headquartered in Nova Scotia, Innovative Medical Supplies, headquartered in Manitoba and Medlines Inc., headquartered in Alberta.

"We are happy with the distribution partners we have in place, and feel they have the market knowledge and experience to truly represent the spirit of the Neurotech product line," said Dominic D'Arpino, director of North American sales for Neurotech. "The physician feedback they're receiving on the products, particularly from sports medicine professionals, has been extremely positive."

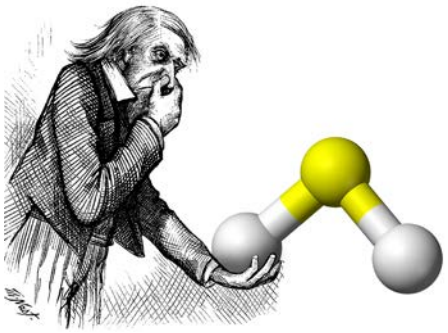
—BY (April 29, 2013)

Courtesy of Neurotech/Wikimedia Commons and Canada

extremities

Molecule, Odiferous Gas Help Arthritic Joints

That's odd. The foul smelling substance known as hydrogen sulfide (H_2S) could actually be what some people need. A team of researchers from the University of Exeter Medical School have discovered that a drug molecule, which slowly generates H_2S, reduces swelling and inflammation in arthritic joints.



Wikimedia Commons/Harper's Weekly, and Thomas Nast

Professor Matt Whiteman, of the University of Exeter Medical School, said the research, which is published online in the *Journal of Cellular and Molecular Medicine*, could pave the way for more effective treatments of arthritis and other inflammatory conditions. Professor Whiteman said in the April 30, 2013 news release: "H_2S is widely dismissed as a toxic and foul-smelling environmental pollutant, but it has recently been shown to be created in humans and animals by a specific set of enzymes. Why would the body do this if it had no benefit? Our research has shown that the key to unlocking the therapeutic qualities of H_2S is through slow release, mimicking the body's own production."

The team has previously shown that H_2S levels were increased by up to four times in the knee joints of patients with joint diseases such as rheumatoid arthritis, but intriguingly the higher H_2S levels strongly correlated with a lower number of inflammatory cells in the joint.

Professor Whiteman added: "A patient will usually visit their doctor with a joint already inflamed, swollen and painful. Since the compound worked after arthritis was established, it may be useful in treating arthritis in the future. Many compounds can prevent arthritis in the laboratory, but of course nobody knows when they will get arthritis. Having a class of compounds which reduce inflammation and swelling when arthritis is already active is extremely exciting. These molecules may also be useful in other inflammatory conditions, and even in the inflammatory aspects of diabetes and obesity."

The study was part of a large collaboration funded by the Wellcome Trust and Arthritis Research UK, involving Professor Philip K. Moore and Dr. Julie Keeble from King's College London, as well as researchers at the National University of Singapore and Queen's University Belfast. The team used primary human cells as well as a model of arthritis. Rheumatoid arthritis causes some cells to proliferate too quickly in the joint and secrete substances which promote tissue inflammation, swelling and eventually joint destruction. However, the H_2S donor molecule prevented this secretion, and inhibited the activity of several enzymes which cause inflammation. In the arthritis model, the compound did not prevent arthritis, but was highly effective at reducing joint inflammation and swelling once arthritis was established, suggesting H_2S-based compounds may one day be useful in clinic.

—EH (May 2, 2013)

India Surgeon Reconstructs Ankle Bones

India has the dubious distinction of having more than 63 million people living with diabetes, according to Shobha Shukla, writing for *Citizen News Service*. India is second only to China in the number of people living with diabetes which, being a disease of the blood vessels, often results in destroyed hind foot bones.

While osteomyelitis in the diabetic foot can vary from 18% to 68%, the diabetic foot is also prone to Charcot's osteoarthropathy—a severe complication of diabetes which leads to soft and brittle foot and ankle bones. Both of these conditions can result in the destruction or excision of foot bones and in amputation of the infected part. Shukla writes that an estimated 50,000 amputations occur every year in India due to diabetes-related foot problems.

Enter diabetic lower limb and foot and ankle reconstructive surgeon Professor Ajit Kumar Varma, M.D. of the Department of Endocrinology and Podiatric Surgery at the Amrita Institute of Medical Sciences (AIMS), Kochi, Kerala. This is the only center in India where a new type of reconstructive and corrective foot and ankle surgery is being performed in large numbers in high-risk diabetic foot patients.

Wikimedia Commons and Andreas Henneman

Varma has pioneered a novel foot and ankle reconstruction surgery, using poly methyl methacrylate (PMMA) as a foot bone replacement prosthesis for severely destroyed foot and ankle bones. By employing these novel surgical techniques a large number of amputations in patients living with diabetic foot ulcers and deformed diabetic feet are being prevented. AIMS has been able to maintain a lower-limb salvage rate of 91.5%, in diabetic foot and ankle diseases.

PMMA is a powder that hardens with an exothermic reaction when a monomer reagent is added to it, forming a hard substance with a consistency similar to bone. Before setting and hardening completely it may be molded to the desired shape. This material is almost inert and has excellent tissue compatibility, according to Varma.

Poly methyl methacrylate antibiotic laden cement (PMMA-ALC) is formed when bone culture specific heat stable antibiotics are added to the bone cement in cases with osteomyelitis. According to Shukla, this modality has been shown to be very effective in chronic and acute osteomyelitis where sustained higher bone and tissue concentrations can be achieved compared to systemic administration. Prophylactic antibiotics may be added when the prosthesis is made for replacing the non-infected, destroyed bones of a Charcot foot.

In the last three years, Varma has successfully replaced the destroyed foot and ankle bones in more than fifteen patients with the help of a technique called the "Amrita Sling" devised by the Amrita

Podiatric Surgery Team. The prosthesis is fixed to the lower end of the tibia to form an ankle joint. Patients have not reported any complications after these foot and ankle reconstruction surgeries using PMMA prosthesis, and, according to the surgeon, all the operated patients are now able to walk normally, using prescribed diabetic footwear. This new surgical technique was published in the international *Journal of Diabetic Foot Complications*, in December 2012.

Dr Varma has another innovation to his credit. He did a reconstruction with PMMA for severely destroyed ankle bones, creating a mobile ankle joint. This PMMA replacement prosthesis for destroyed Charcot's foot and ankle bones is the first of its kind in the world. The surgical video can be viewed online at: http://www.youtube.com/watch?v=U4tIu6TONbo.

The technique of prosthetic replacement and arthroplasty is an effort to salvage the diabetic foot by replacing the damaged bones rather than simply removing them. With good patient compliance the results have been very encouraging. Being cosmetically more acceptable and having the potential to provide the patients with a biomechanically stable and functional foot is a major advantage of the procedure.

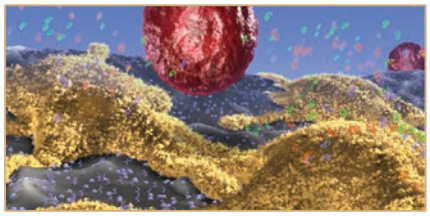
PMMA is approved by the FDA for human use, and is being extensively used in many surgeries including total hip replacement, knee replacement surgeries, spinal and maxillofacial surgeries. However, except for AIMS, PMMA replacement prosthesis has never been used by any other major diabetic foot center in the world for the replacement of destroyed foot and ankle bones, according to Shukla.

—BY (May 1, 2013)

TITAN SPINE
THE LEADER IN SURFACE TECHNOLOGY

If all you see are interbody devices, you aren't looking closely enough

The Endoskeleton® implants feature Titan Spine's proprietary surface technology that has been shown to produce a superior osteogenic response when compared to PEEK and smooth titanium*



Osteoblasts

*Olivares-Navarrete, R., Gittens, R.A., Schneider, J.M., Hyzy, S.L., Haithcock, D.A., Ullrich, P.F., Schwartz, Z., Boyan, B.D., 2012, Osteoblasts exhibit a more differentiated phenotype and increased bone morphogenetic production on titanium alloy substrates than poly-ether-ether-ketone, *The Spine Journal*, v. 12, p. 265-272.

Notice: One or more products are covered by patents

www.titanspine.com

Advertisement

Runner's Footstrike May Predict Injuries

Does the way a runner's foot strikes the ground affect the number of runner's injuries he or she may get? A recent study by Al Daoud and colleagues at Harvard University indicates that it may. According to Rich Sauza, writing in *RunSafe*, Daoud compared the difference between rearfoot strike and forefoot strike on the types and rates of injuries experienced by runners. His subjects were 52 male and female high-level intercollegiate track and cross country runners who were competing in distances ranging from 800 meters to 10 kilometers. All of the runners were either rearfoot or forefoot strikers.

Wikimedia Commons and Jim Henderson

The researchers observed that rearfoot strikers had more knee and hip injuries while the forefoot strikers had more ankle injuries. The rearfoot strikers tended to develop repetitive injuries and hip and knee injuries at a rate that was twice as often as forefoot strikers. Females with a forefoot strike were more likely to develop Achilles tendinopathy, but males were not. However, females with a rearfoot strike were more likely to develop plantar fasciitis. Sauza reported that males did not follow the same trend.

When comparing runners across a variety of common overuse running injuries, including knee pain and IT (Iliotibial) band syndrome, rearfoot-strikers were 2-3 times more likely to have problems than were the forefoot strikers. Sauza noted that, because of the small sample, these differences were not statistically significant. However, researchers note that this is one of the first studies to provide evidence that a particular strike pattern predisposes runners to more injuries.

—BY (April 29, 2013)

spine

Study Finds Titan's Cage Promotes Fusion

A study of Titan Spine, LLC Endoskeleton titanium interbody cage, presented at the 13th Annual Meeting of the International Society for the Advancement of Spine Surgery, found that the device achieved rapid lumbar fusions.

The study looked at 77 patients with a mean age of 46 years who underwent an ALIF procedure using the Endoskeleton interbody device. Physicians treated a total of 138 spinal segment levels. Radiographic analysis by two independent radiologists revealed a 100% fusion rate between 6 and 12 months, with no appreciable subsidence and an inter-observer reliability rate of 95%. Researchers also noted that clinical outcomes as determined by ODI and VNS scores improved significantly by 6 months with the improvement sustained at 12 and 24 months follow-ups.

Andrew Shepherd, vice president of marketing for Titan Spine, said, "Titan Spine is focused on optimizing the surface of interbody implants so that they can play an active role in facilitating bone integration and promoting fusion. This prospective study, which echoes similar clinical experiences from other surgeons in the U.S. and abroad, included patients of varying ages and degenerative conditions who all successfully fused and experienced excellent clinical improvement with our device."

Shepherd said that Titan Spine's Endoskeleton implants feature a proprietary acid-etched surface that is textured at the macro, micro and cellular levels to support bone purchase and new bone growth. He added that cellular research has demonstrated that the etched surface promotes a superior bone-forming response as compared to smooth titanium.

Lead author of the study Paul Slosar, M.D., of SpineCare Medical Group and the San Francisco Spine Institute in San Francisco, California, said, "This study supports the use of the Endoskeleton device for safe, effective and rapid spinal fusion. It is also important to note that fusion status was able to be determined in all patients due to the design of the implant, which is in contrast to the difficulty in assessing fusion in historical titanium threaded devices. The Endoskeleton's unique surface has been shown in published cellular research to stimulate improved osteoblast differentiation to support fusion. Our clinical data further substantiates those findings, and demonstrates the notable positive impact on patient outcomes." Titan Spine is located in Mequon, Wisconsin.

—BY (April 29, 2013)

Courtesy of Titan Spine, LLC

PearlDiver

unfathomably deep data retrieval

Remember the feeling when the data just clicks in place? Markets reveal themselves. Opportunity and risk have measurable dimensions. PearlDiver MAPS markets using actual coded procedures from today's surgeons, hospitals and payers. Isn't it time for real market data?

REAL DATA. REAL REIMBURSEMENT. SOLID MARKET STUDIES.

pearldiverinc.com | scott@pearldiverinc.com | (260) 468-3636

Orthopedics This Week | RRY Publications LLC

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

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

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

Walter Eisner
Senior Writer
walter@ryortho.com

Biloine W. Young
Writer
bgwy@msn.com

Tom Bishow
Vice President of Sales
tom@ryortho.com

Suzanne Kirchner
Production Manager
suzanne@ryortho.com

Jayme Johnson
Email, Web and
Conference Coordinator
jayme@ryortho.com

Dana Bader
Graphic Designer
dana@ryortho.com

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

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