

10 Orthopedic Surgeon Moves

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Zimmer-Biomet \$14B Merger Complete

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BECKER'S
ORTHOPEDIC

REVIEW

July/August 2015 • Vol. 2015 No. 1

The Biggest Innovations in Outpatient Joint Replacement

By Brandon Howard

Six orthopedic surgeons discuss the biggest innovations in outpatient joint replacement and where the industry is headed.

Benjamin Domb, MD, of Hinsdale (Ill.) Orthopaedics: Robotic joint replacement is the biggest innovation in outpatient total joint replacement. Current studies show non-robotic replacements result in more than 50 percent

of joints being inaccurately placed. With robotics, we can be 100 percent accurate. Robotics have taken surgery from being an operation done by the human hand, subject to human error, to being a much more precise procedure done with the aid of computerized three-dimensional planning and robotic precision. It is a complete game-changer, in terms of accuracy and enhanced speed of recovery.

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18 Statistics on Orthopedic Surgeon Salary & Bonus

By Anuja Vaidya

Here are 18 statistics on salaries and bonuses for orthopedic surgeons from Salary.com.

Five statistics on the national average annual salary plus bonus for orthopedic surgeons, as of January 2015:

1. Bottom 10 percent: \$280,965
2. 25th percentile: \$372,237
3. 50th percentile: \$472,487
4. 75th percentile: \$617,115
5. Top 10 percent: \$748,791

continued on page 8

Where Shoulder Surgery is Headed: Patient-Specific Implants, Faster Recoveries & Outpatient Surgery

By Laura Dyrda

Joshua Dines, MD, Hospital for Special Surgery, New York City, talks about the biggest innovations in shoulder surgery and where the field is headed in the future.

Dr. Joshua Dines: Over the last five to 10 years, there has been a trend toward doing things more arthroscopically, making things less morbid to the patient and providing quicker recoveries without sacrificing outcomes. While we've gotten better with minimally invasive techniques, we've also done better research-wise by looking at and critically evaluating our outcomes. For some pathologies,

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Zimmer-Biomet \$14B Merger Finally Complete — 6 Things to Know

By Laura Dyrda

The U.S. Federal Trade Commission granted clearance for Zimmer's acquisition of Biomet.

Here are six things to know:

1. More than a year after announcing plans to merge, the Zimmer-Biomet combination is complete. Zimmer also sold the Zimmer Unicompartmental High Flex Knee system to Smith & Nephew.
2. Zimmer acquired Biomet for \$14 billion in a cash and equity transaction. The combined companies' corporate name is Zimmer Biomet Holdings and the company began trading on the New York Stock Exchange and SIX Swiss Exchange under the ZBH ticker symbol June 29.

3. After the combination, Zimmer Biomet is the leading innovator in the \$45 billion musculo-skeletal healthcare market. Zimmer Biomet's scale will increase competitiveness in core franchises and strengthen its presence in emerging markets.

4. Zimmer Biomet expects to reach net annual synergies of around \$350 million by the third year after the combination; \$135 million is expected in the first 12 months. The transaction is expected to be double-digit accretive to the Company's adjusted earnings per share in the first year.

5. Excluding Biomet-acquired revenue, the second quarter constant currency revenue growth is expected to reach 1 percent to 1.5 percent. The

full year 2015 revenue is expected to increase 1.5 percent to 2 percent compared to pro forma 2014 revenues.

6. Zimmer Biomet's board is now 12 members, with Michael W. Michelson and Jeffrey K. Rhodes appointed to the board. Both were members of the Biomet board of directors.

"The coming together of Zimmer and Biomet is a momentous achievement," said Zimmer Biomet President and CEO David Dvorak. "We are excited to move forward as one company and to pursue new opportunities that benefit patients, healthcare professionals and employees around the globe." ■



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10 Orthopedic Surgeons on the Move

By Brandon Howard

Here are 10 orthopedic surgeons recently joining new practices or hospitals.

James M. Worthington, MD, joined New Bedford, Mass.-based Southcoast Health. Dr. Worthington will see patients at Southcoast Orthopedics at Truesdale Clinic in Fall River, Mass.

Auburn Orthopaedic Specialists added **Ronald S. DeThomas, MD**, according to a report by *The Citizen*.

Thomas A. Fusco, DPM, a podiatrist, joined Orthopaedic Associates in Fort Walton Beach.

Edgefield (S.C.) County Hospital added **R. Vaughan Massie, MD**, to its physician team.

Green Bay, Wis.-based Prevea Health added **Matthew Colligan, DO**, to its physician team.

Middletown, N.Y.-based Orange Regional Medical Group added **Michelle Fontaine, MD**, to its physician team.

Ozarks Community Hospital of Gravette (Ark.) added **Edwin Roeder, MD**, to its physician team.

Fresno, Calif.-based Sierra Pacific Orthopedics welcomed **Richard J. Lamour, MD**, to the team.

Steve Jordan, MD, joined the Andrews Institute for Orthopaedics & Sports Medicine in Gulf Breeze, Fla.

Brian Seng, DO, joined three other orthopedic physicians at Northside Cherokee Orthopedics & Sports Medicine's new location in Woodstock, Ga. ■

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How to Optimize the Value of Orthopedic ASCs

By Brandon Howard

Gregory F. Hagood, Senior Managing Director at SOLIC Capital Advisors, discusses how to optimize the value of your ASC and shares insights on the best opportunities for orthopedic centers in the future.

Q: How do you optimize the value of a center?

Gregory F. Hagood, Senior Managing Director at SOLIC Capital Advisors: There are two different avenues you go down to answer that question. One is the service mix. The other element, which is equally if not more important today, is the partnership mix. Who are the investors?

We sold the Siouxland Surgery Center last summer, a surgery center and short stay hospital in Sioux City, Iowa, which was owned by physicians and had a minority interest owned by the local health system. The center was anchored by a very productive group and had historically been very profitable; however the physicians felt compelled to explore expanding its partnership with the local health system primarily because they were worried about getting cut out of some of the reimbursement panels.

Historically patients had come from all over the region to use the center's top spine and neurosurgeon physicians, but they were very concerned that as managed care plans and even Medicare became more restrictive and instituted much higher copays and deductibles for out-of-network services, a key part of their core commercial payer base would be forced out of their system.

We negotiated a deal there where Trinity Healthcare along with United Surgical [Partners International] expanded their ownership allowing Siouxland to be part of Trinity's network so that patients they had been seeing or physicians that had been historically referring to them could continue to do so.

So one element that I think any surgery center, as you look out over the next five years, will need to do is ask 'which regional health network should I

affiliate with?' Obviously you are seeing physician hospital consolidation with more risk-bearing associated with payer contracts, so it will be very difficult for the stand-alone surgery center without that affiliation with the regional network to maintain the commercial payer base.

Q: Where do you see the biggest opportunities for orthopedic centers in the future?

GH: One trend we are seeing there really is the integrated care approach. Historically you may have some really good physicians who were doing [surgery] in a surgery center; you checked in, you had your procedure, you checked out. What we are seeing in a lot of these places is that it's more integrated care. You come in for your pre-surgery physical therapy, and then you keep coming back to that center for all your after care. It is feels more like a spa service, where you check in and have a concierge care approach — a model Mayo has pioneered.

Especially for elderly patients, having that spa-like experience really does make a difference. Adding amenities is critical. Historically doctors were looking for an alternative site where they can be more efficient with their surgery. Now, I think after-care and follow-up care associated with the surgery center is critical to differentiate it going forward, if you are competing for commercial payers.

Q: Is computer navigation and robotics a good investment?

GH: I think clearly you are going in the direction of more robotics, and quite honestly, more data-driven protocols. So if you have a condition, there is going to be a prescribed treatment protocol by the insurance company, by the health system, etc. The physicians have less latitude to prescribe alternatives. Another one to look at is new therapies like stem cell for hips to regenerate bone growth. Is that going to become more of a standardized



Gregory Hagood

therapy over the next five years? I don't know, but these are the kinds of things to keep your eye on.

Q: Which mergers or additions have not worked out the way you hoped? And if so, what do you think could have been done differently?

GH: We advised on the sale of a hospital in bankruptcy in Massachusetts. It was an older facility, and if you know much about Boston, every 10 miles you have another hospital. The acquirer believed that by integrating the facility into its regional network it could achieve the clinical and financial synergies to keep the hospital open; however, given the age of facility and excess capacity in market, the buyer ultimately elected to close facility.

Typically the hospital demographics are shifting and a system will buy the hospital hoping they can stabilize it, but sometimes it doesn't work out. That was the only one I've been involved in where they actually closed the hospital. ■

Where Shoulder Surgery is Headed: Patient-Specific Implants, Faster Recoveries & Outpatient Surgery (continued from cover)

orthopedic surgeons were tending to do more repairs arthroscopically in lieu of more traditional open surgeries but we are finding that in some cases the open surgeries were providing better outcomes.

Additionally, no discussion about where the field is going is complete without talking about biologics. As surgeons we have gotten better technically at repairing things. We are using stronger implants and repair constructs which help, however continuing to improve or even speed up recoveries will hinge on improving the biology of the repair milieu. We have made some progress over the last few years and that's where research will be focused.

Another topic of interest centers on patients-specific implants to give people the best possible outcomes and speedier recoveries. The quicker patients

recover, the less time they are out of work. If I can get my patients back to work more quickly, there is the emotional benefit and the financial benefit.

As we do more procedures with patient-specific instrumentation and implants, we may make surgeries technically easier which will increase reproducibility and lead toward better outcomes. If we can do surgeries more easily, there might be less blood loss and time under anesthesia, which can lead to outpatient shoulder replacements.

I think eventually the overwhelming majority of shoulder procedures in my practice will be performed on an outpatient. I do probably 400 shoulder surgeries per year and 325 could be outpatient. The other 75 are shoulder replacements that require patient stays now, but there is no reason why patients without more medical issues can't be shifted to outpatient surgery. ■

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Fracture Fragility Programs Help Hospitals Meet the Triple Aim for Challenging Patients

By Laura Dyrda

Fracture fragility is a huge concern for hospitals and surgeons, as one-year mortality rates are estimated around 30 percent, according to a TeamHealth white paper titled “The Fragility Fracture Program: Improving Quality of Care for a Challenging Population.” The at-risk population includes patients 65 years or older and those with osteoporosis. There are around 10 million people in the United States with osteoporosis according to the National Osteoporosis Foundation and another 34 million who are at risk because of low bone mass. High fracture rates cost hospitals in clinical quality, outcomes, patient satisfaction and financial performance. However, a dedicated fragility fracture program can avoid some of these instances in the future.

Fragility fracture patients need care from orthopedic surgeons, anesthesiologists, internal medicine physicians and many others to achieve stabilized discharge. The pharmacy department is also often handling multiple medications for those patients and there isn’t always coordinated care. But, a fragility fracture program allows hospitals to “create an integrated process of care in which every provider in the chain of care knows his or her individual role and expectations,” according to TeamHealth. The

program includes evidence-based medicine protocols and pathways to manage high-risk patients and deliver better, more efficient and coordinated care. Hospitals with a fragility fracture program can reach the Triple Aim goals of improving care for the geriatric population and providing a better experience while also reducing costs.

When high-risk patients come to the hospital with specific fractures, diagnosing physicians identify their issue and begin the specific protocol for the each patient’s condition. For example, elderly patients who arrive in the emergency department with a hip fracture will be assigned a specific pathway for care. The diagnosing physician notifies the medicine department, orthopedic surgeon and anesthesia department and potentially admits the patient. The anesthesiology department can then begin a preoperative assessment and surgical preparations; at the same time, the therapy department is notified and begins to prepare for post-surgery rehabilitation. A fracture Liaison Service adds the patient to the fragility fracture database and begins assessing and treating the patient’s osteoporosis. Finally, the discharge planning department begins to work with the team on when the patient can safely discharge from the hospital.

“With all required departments coordinating with one another, many patients may be able to receive surgery the very same day,” according to the white paper. The improved communication between providers ultimately streamlines the patient experience. Hospitals with a fragility fracture program often see reduced length of stay, lower infection risk, fewer complications, fewer readmissions, reduced secondary fracture rate and increased patient satisfaction.

Hospitals with 100 hip fracture patients per year or more would benefit most from the program, as there is high enough volume to establish protocols with consistency. Recruiting the right leadership for the program is essential and clinical champions across each service line ensure the program is successful. Then the champions can achieve buy-in from other providers to implement the program, typically over a six-month period.

“In total, a successful fragility fracture program can help hospitals reach the Triple Aim of improved patient experience, better population health and lower costs due to reduced length of stay, better HCAHPS scores and fewer complications and readmissions,” according to the whitepaper. ■

Robotic Technology: The Next Frontier in Orthopedics?

By Brandon Howard

Steven F. Harwin, MD, FACS, chief of adult reconstruction and total joint replacement at Mount Sinai Beth Israel in New York City, discusses the biggest advancements in orthopedic surgery heading into the future.

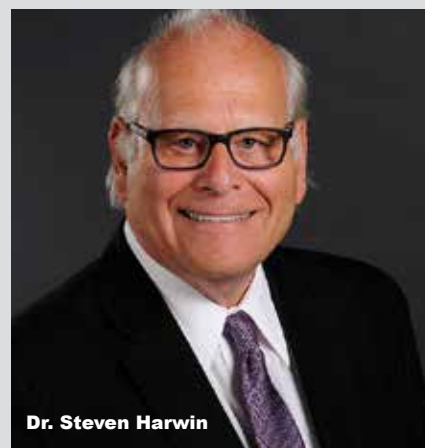
Dr. Steven Harwin: Advances in implant technology can now allow for a biological (cementless) fixation to bone. This can potentially provide life-long stable fixation. Newer highly cross-linked polyethylene and ceramic bearings resist wear and maintain strength. These innovations combine to reduce the incidence of these common failure modes.

The future also lies in the promise of robotic assisted surgery. While the thought of a robot ‘doing’ surgery may be off-putting to some, we need to educate our patients about exactly what the technology involves. It is analogous to the way that the aviation industry has evolved. In the past pilots would manually fly a plane hav-

ing to determine exactly where they were and what adjustments had to be made moment to moment. Now all modern aircraft have sophisticated computer systems that instantaneously make these decisions and determinations, but the pilot oversees the computer. He remains the “captain of the ship.”

With robotic surgery, precise preoperative planning maps out our “flight plan” and the robot assists us during the procedure to have a smooth, safe flight and most importantly, a perfect landing. As surgeons we strive to standardize our surgical procedures and yet we have to modify our technique to each individual patient. Robot-assisted surgery allows us to accomplish both standardization and individualization by providing precise placement, alignment and accuracy for each unique patient.

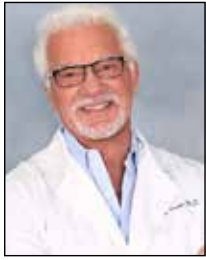
There will be hurdles for full adoption of this technology, including cost, surgeon and patient edu-



Dr. Steven Harwin

cation and the need to advance the technology to make it easy for surgeons to transition from traditional surgery. However I believe in five to 10 years this will be “standard operating procedure.” ■

The Biggest Innovations in Outpatient Joint Replacement (continued from cover)



Ralph J. Venuto, MD, FACS, of California Orthopaedic Specialists in Newport Beach, Calif.: A machine called a CPM machine, which is a continuous passive motion machine, which keeps the swelling down and helps regain the range of motion after surgery. CPM has been around a long time, so it has been used in TKR in a long time, but the combination of that plus the ability to prescribe medication to control pain, and add to that some preventative measures for blood clots in the leg, with a compression device that is put on the calves. You are really looking at the ability to do these as outpatient now.

Peter Gleiberman, MD, of Gleiberman Orthopedics in Torrance, Calif.: I believe that there are two major reasons why we could now do outpatient total joint replacement.

The two main reasons that we had previously for maintaining patients in the hospital were the associated blood loss with surgery as well as difficulty in controlling postoperative pain. The issue of blood loss is currently being addressed with medication such as tranexamic acid which greatly decreases blood loss as well as with custom knee arthroplasty (ConforMIS Custom Total Knee) which also decreases blood loss because we don't have to enter the femoral canal which causes increased blood loss.

Pain control is now much better with nerve blocks as well as the use of Exparel, which is available in the outpatient surgery center but has not yet been put on formulary at any of the major hospitals. I think that we are already moving towards doing a large percentage of total joint arthroplasties in the outpatient surgery center. I recently gave a talk at the International Congress for Joint Reconstruction last year and this is a very hot topic.



Jonathan Vigdorich, Associate Fellowship Director, Joint Preservation and Arthritis Center and Assistant Professor of Orthopaedic Surgery at NYU - Hospital for Joint Diseases: I think the biggest innovations in outpatient joint replacement are pain management and minimally invasive surgical techniques. We now use multi-modal analgesia, meaning we use several different types of medications which act on dif-

ferent parts of the pain pathway as well as a new type of pain relief injection called Exparel. This has significantly benefited patients and the pain control after surgery requiring less narcotic use and the ability to go home the same day.

Combine this with minimally invasive surgical techniques in hip replacement, such as direct anterior or minimally invasive posterior approaches, which have both been proven to be more friendly to the soft tissues and both show the ability for same day discharge. Additionally, the advent of robotic assisted partial knee replacement and robotic hip replacement allow the implants to be placed in a more reproducible way and with less damage to the surrounding tissues.



Richard Buch, MD, The Dallas Limb Restoration Center in Plano, Texas: The biggest innovation in outpatient joint replacement is how we can now minimize surgeries. We control pain with new programs and can decrease complications to a minimum. This allows us to get patients up the same day of surgery allowing them to recover quickly. Two essential elements to this process are patients must be educated on what to expect after surgery and a team in the hospital that is dedicated to the process. If these criteria are met the majority of patients can go home within 24 hours of surgery.



Stephen Kayiaros, MD, University Orthopedic Associates in Somerset, N.J.: More and more, I am performing total joint replacement procedures in outpatient settings. One factor enabling that is effective postoperative pain management techniques. Methods for controlling pain have certainly come a long way in the past five to 10 years. Effective non-opioid pain management solutions have been a game-changer in terms of how I reduce and control my patients' postoperative pain levels.

Typically, patients receiving these types of procedures required strong narcotics to recover, causing intense side effects such as nausea, drowsiness and constipation, and prolonging the length of hospital stay. My patients get adductor canal blocks with Halyard Health's ON-Q Pain Relief System. ■

18 Statistics on Orthopedic Surgeon Salary & Bonus (continued from cover)

Five statistics on average orthopedist salary only:

6. Bottom 10 percent: \$260,145
7. 25th percentile: \$343,588
8. 50th percentile: \$435,238

9. 75th percentile: \$562,903

10. Top 10 percent: \$679,134

Two statistics on the national average core compensation for orthopedists:

11. Base salary: \$435,238
12. Bonuses: \$37,249

Six statistics on national average value of benefits for orthopedic surgeons:

13. Time off: \$58,152

14. Pension: \$16,695

15. Social Security: \$14,198

16. 401K/403B: \$9,540

17. Healthcare: \$6,592

18. Disability: \$4,252 ■

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Shoulder Reconstruction Device Market to See Rapid Growth — With DePuy Synthes at the Helm

By Anuja Vaidya

The shoulder reconstruction device market was the fastest growing segment within the orthopedic small bone and joint market — with DePuy Synthes leading the way in terms of market share, according to a recent iData Research.

Here are five key trends in the shoulder reconstruction device market:

1. Increased surgeon experience and education, as well as improved device technology, is driving market growth.
2. The largest sub-segment within this market in 2014 was the reversed shoulder implant market due to higher average selling price.
3. The reversed implant segment growth is due to surgeons using these devices to fix previously failed surgeries as well as leveraging device efficacy.
4. DePuy Synthes is the market leader of the shoulder reconstructive market with more than 20 percent market share. But, the company is expected to lose market share unless they further expand the current product line.
5. Other competitors in the market include Tornier, Zimmer Biomet, DJO, Exactech, Arthrex and Smith & Nephew. ■

Orthobiologics, OR Tools & Outpatient Shoulder Surgery: Where We Are Now & Where We're Headed

By Laura Dyrda

Two shoulder surgeons discuss the biggest trends in shoulder surgery and where it's headed over the next five years.

Q: What is the biggest innovation in shoulder surgery today?

Orr Limpisvasti, MD, Kerlan-Jobe Orthopaedic Clinic, Los Angeles: In my opinion, the most significant innovations in shoulder surgery in the last few years have been in the minimally invasive arthroscopic techniques for soft-tissue repair as well as in rehabilitation of shoulder pathologies treated with or without surgery. Our ability to study and compare repair constructs biomechanically has allowed us to optimize soft-tissue repair in the shoulder. The propagation of research in shoulder rehabilitation has improved outcomes of shoulder pathologies treated with or without surgery.

Dr. Gregory Tchejyan, MD, Los Robles Hospital, Thousand Oaks, Calif.: The biggest innovation in shoulder surgery today is the advent of arthroscopy. This camera and video system technology allows the surgeon to thoroughly evaluate all types of shoulder pathologies such as rotator cuff tears, cartilage tears, bone spurs and shoulder dislocations to name a few. More importantly arthroscopic technology and respective tools allows the surgeon to repair the corresponding pathology with effective minimal invasive techniques.

Q: Where do you see shoulder surgery headed over the next five years?

OL: Over the next five-plus years, the research on orthobiologic treatments will likely progress to the point of truly guiding us shoulder surgeons on how to best use the new technologies to improve outcomes. Early results of using orthobiologic treatments such as platelet-rich plasma and mesenchymal stem cells have been promising. The research that follows this early implementation will help us optimize the applications for optimal outcomes.

GT: Over the next five years the use of biologics to augment shoulder repair at the time of surgery will likely be more prevalent. These technologies will include tissue engineering, stem cells, platelet rich plasma, and growth factors. These biologics will be helpful to increase the predictability and rate of rotator cuff and cartilage healing.

Q: Will there be more shoulder surgery performed outpatient next year?

OL: The decision to perform shoulder surgery on an outpatient basis depends upon multiple factors. Surgical factors include the extent of the surgery, the availability of appropriate surgical support (anesthesia, equipment, etc.), and surgeon comfort level. Medical and logistical factors include patient health, anesthesia (comfort with regional anesthesia), nursing and transport capabilities, and economic factors to include insurance coverage for the patient. ■



Dr. Orr Limpisvasti



Dr. Gregory Tchejyan



Orthopedic

Products to Know

Arena-C HA. SpinalFrontier's Arena-C HA is an anterior cervical fixation implant manufactured with PEEK-OPTIMA HA Enhanced. It's the first implant of its kind to receive FDA clearance. The implant is designed to increase the chance of bony growth with the truly integrated hydroxyapatite.

encOR-m.i.s Surgical Trainer. Encoris' encOR-m.i.s. Surgical Smart Trainer is a minimally invasive training model platform that helps clinicians and medical device professionals train in the latest surgical techniques for continuing medical education. The system is integrated with an illuminated anatomy to provide X-ray-like hands-on training apparatus for placing surgical implants.

eShield. This FDA-approved device is a sterile cover for hand-held electronic devices used in or near the sterile field. The eShield is available for devices including digital cameras, SLR cameras, tablets and smart phones.

Hinged Ring Frame. The Hinged Ring Frame from Thompson MIS was developed for providers who prefer a ring frame set-up. The device is in a circular shape for a small procedure or expands to an oval frame for larger procedures. The Hinged Ring Frame can be used in place of the Thompson Quick Frame or Spine Frame and can be set up bilat-

erally in place of the Bilateral Frame.

NeuroEnterprises Chicago Tip. The NeuroEnterprises ChicagoTip is a disposable self-cleaning suction device that can be used in an array of surgeries. The tip is designed to remove clogs without detaching the suction tip from the hose, which saves time and eliminates interruptions from the procedure. It has a stainless steel chip resistant tip and tear drop vent for noise reduction.

NovoCut Suture Manager. Ceterix Orthopaedics' NovoCut Suture Manager is designed to push knots in size two to zero or zero suture created during arthroscopic surgery as well as cut the resulting suture tails and retrieve or manage sutures arthroscopically. The product enables side loading so there is no need to thread the needle and access to tight spaces.

Precision Spectra. The Precision Spectra from Boston Scientific is a spinal cord stimulator demonstrating significant overall pain reduction when compared to previous generations — the Precision Plus SCS System. The device's advanced technology enables increased precision with a proprietary algorithm to assist physicians in the neural targeting process.

Prohesion. Biosutures, a privately-held orthobiologics company, announced

the first application of Prohesion, a surgical wound technology. Prohesion is an activated type I collagen wound filler indicated for managing surgical wounds.

SpineDriver. SpineDriver is a medical device company in Marina del Rey, Calif., that revealed their battery-powered surgical driver at last year's NASS annual meeting. The Inline battery-powered driver is designed for drilling and driving pedicle screws into the spine.

Talos-C (HA). Meditech Spine's Talos-C (HA) is designed for anterior cervical fusion for skeletally mature patients with degenerative disc disease at one level C2-T1. The device is made with PEEK-OPTIMA HA Enhanced fully integrated throughout the device. Initial studies suggest the HA PEEK material helps provide an environment to produce faster bone formation and better bone quality.

True Position XL. The True Position XL from Atlas Spine is a pivoting TLIF device developed for surgeons seeking the benefits of ALIF or LLIF-sized footprints through an advanced posterior approach. The system provides direct decompression, single incision and controlled placement with a minimally invasive technique. ■

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Company: Meditech Spine, LLC.
Product Name: Talos®-C (HA) IBF
Email: support@meditechspine.com
Phone: (678) 974-5287
Website: www.meditechspine.com

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in Hydroxyapatite (HA) that enhances bone apposition. The HA is found on all surfaces and is fully integrated throughout the implant. Initial studies suggest that the HA Peek material helps provide an environment to produce faster bone formation as well as better bone quality. By combining two clinically proven biomaterials (HA and PEEK) together into one homogenous compounded polymer, Meditech Spine is able to offer a superior solution, the Talos®-C (HA) interbody system.

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TECHNOLOGIES

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Meeting the Triple Aim With New Pain Management Protocols

By Laura Dyrda

The outpatient ambulatory surgery center is the next frontier for orthopedic surgery. Knee arthroscopies and ACL repairs have been done in the outpatient setting for years, and now technology is moving total joint replacements and spine surgeries into ASCs.

"The outpatient surgery centers are focused on orthopedics and spine procedures," says Paul Jeffords, MD, a spine surgeon at Re-surgen Orthopaedics in Atlanta. "There is a definite patient benefit because everyone on the team is focused on one thing as opposed to at the hospital where all types of procedures are going on. The ASC is more efficient and we're doing fewer cases, so we can really give patients more attention."

The higher patient satisfaction is an important aspect of delivering high quality care, and will be crucial as providers are graded on their outcomes and patient experience.

"I think as time goes on, you'll see more of these cases going into the outpatient center," says Dr. Jeffords. "Technology is driving that change, and surgeons are becoming more familiar with minimally invasive techniques and managing postoperative pain. Patient demand is also driving change; as more surgeons are doing outpatient cases, other surgeons will feel the need to learn these techniques and keep up. Thirdly, payers will eventually demand that procedures are done in the most cost-effective setting — the outpatient center."

Meeting the Triple Aim

Healthcare providers across the board are focused on providing quality care at a lower cost to meet the Triple Aim. ASCs cater to otherwise healthy patients undergoing elective procedures and thus patient selection is important. The sterile environment in the ASC reduces infection and complication risks. ASCs are also reimbursed at a lower overall rate than hospitals.

"With the healthcare system going in the direction it's going in, there is a push towards taking patients out of the hospital and into the outpatient centers where the cost is reduced," says Dr. Jeffords. "There is a lower overall cost for surgeries done in the outpatient centers, and physician owners see the financial advantage of ownership stake."

ASC and hospital physicians are concerned with achieving high patient satisfaction and a quality healthcare experience. They can implement a favorable nurse-to-patient ratio, manage patient expectations and use a strong pain management regimen to improve the surgical experience. In centers where the operating rooms and staff are dedicated to joint replacement surgery, everyone is able to focus on improving patient care.

Anthony J. Berni, MD, an orthopedic surgeon with St. Charles Orthopaedic Surgery Associates in Missouri hasn't experienced readmissions for any of his joint replacement cases performed at the surgery center; nor have patients needed admission to skilled nursing facilities. Readmissions add significant cost to orthopedic cases and lower patient satisfaction. Pain is the second leading cause for readmission in spine surgery, right behind wound complications. Tanya M. Hague, RN, administrator of the St. Louis Surgical Center/Total Joint Center of St. Louis, opened a total joint-focused center in partnership with United Surgical Partners International last fall and experienced success with the program.

"We hired a total joint coordinator who has been an essential asset to the program," says Ms. Hague. "She is the point person for the patient before surgery and follow-up with them postoperatively."

Transitioning to outpatient

Surgeons making the transition often begin performing outpatient cases in the hospital. When surgeons are comfortable achieving good outcomes there, they begin taking cases to an ASC.

"The surgeon has to be comfortable with his ability to perform minimally invasive techniques and comfortable with his patients going home the same day," says Dr. Jeffords. "I performed 40 to 50 outpatient spinal fusions in the hospital to assess how comfortable I was that I could achieve reproducible results sending patients home the same day."

The surgeon is also responsible for anticipating issues and setting patient expectations, as well as making arrangements ahead of time. For example, if the patient experiences postoperative nausea at the hospital, a nurse can take an order the medication; if they're at home, the

patient needs the prescription for that medication in advance.

"Anticipate any complications to try to avoid having issues," says Dr. Jeffords. "Make sure you've walked through every step of the process so you can prepare the patient and staff."

Performing outpatient joint replacements and spine procedures require a philosophy change, especially for nurses and surgical teams familiar with three- to four-day hospital stays.

"Joint replacement surgeons aren't of the mindset of outpatient procedures," says Dr. Berni. "Many of them have PAs and other midlevel providers that do hospital rounding and dressing changes. Those people have their mindset that the patient needs to be in the hospital for a certain length of time."

The patients may also need education about outpatient procedures if they are good candidates for the outpatient setting. Reducing readmissions and doing what is best for the patient comes down to patient selection criteria and setting the right expectations.

"There are patients who have friends that stayed in the hospital for several days after joint replacement surgery, and that's their mindset as well," says Dr. Berni. "For procedures that are traditionally viewed as inpatient procedures by the public, it's a big challenge to dispel the myth that every case requires a long hospital stay. Once you get over that hurdle, patients really have a positive experience."

The surgeon can set expectations about going home within 24 hours of surgery from the very beginning using educational material. Their nurses reinforce the outpatient education in subsequent interactions gathering patient information and preparing patients for surgery. There are some programs that require patients to undergo "pre-habilitation" before surgery, learning the physical therapy they'll do after surgery.

"We worked about three months on protocols, patient selection criteria and pain management to make sure patients could be brought safely into the ASC environment and then transitioned safely home with the resources they needed to go forward," says Ms. Hague.

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Important Safety Information

EXPAREL is contraindicated in obstetrical paracervical block anesthesia. EXPAREL has not been studied for use in patients younger than 18 years of age. Non-bupivacaine-based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL if administered together locally. The administration of EXPAREL may follow the administration of lidocaine after a delay of 20 minutes or more. Other formulations of bupivacaine should not be administered within 96 hours following administration of EXPAREL. Monitoring of cardiovascular and neurological status, as well as vital signs should be performed during and after injection of EXPAREL as with other local anesthetic products. Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at a greater risk of developing toxic plasma concentrations. In clinical trials, the most common adverse reactions (incidence $\geq 10\%$) following EXPAREL administration were nausea, constipation, and vomiting. Studies demonstrating the safety and efficacy of EXPAREL were conducted in hemorrhoidectomy and bunionectomy; EXPAREL has not been demonstrated to be safe and effective in other procedures.

Please see brief summary of Prescribing Information on reverse side.

For more information, please visit www.EXPAREL.com or call 1-855-RX-EXPAREL (793-9727).

References: 1. How DepoFoam® works. Pacira Pharmaceuticals, Inc. website. <http://www.exparel.com/how-to-use/about-depofoam.shtml>. Accessed February 25, 2015. 2. Process for handling elastomeric pain relief balls (ON-Q PainBuster and others) requires safety improvements. Institute for Safe Medication Practices website. <https://www.ismp.org/newsletters/acutecare/articles/20090716.asp>. Accessed June 19, 2014. 3. I-Flow ON-Q pump with ONDEMAND bolus button. US Food and Drug Administration website. <http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm317826.htm>. Accessed January 5, 2015. 4. Continuous peripheral nerve blocks in outpatients. NYSORA—The New York School of Regional Anesthesia website. <http://www.nysora.com/regional-anesthesia/foundations-of-ra/3055-continuous-peripheral-nerve-blocks-in-outpatients.html>. Accessed January 5, 2015. 5. Frost & Sullivan. New opportunities for hospitals to improve economic efficiency and patient outcomes: the case of EXPAREL™, a long-acting, non-opioid local analgesic. <http://www.frost.com/prod/servlet/cpo/252218999>. Accessed January 5, 2015. 6. Data on file. Parsippany, NJ: Pacira Pharmaceuticals, Inc.; February 2015.

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Brief Summary (For full prescribing information refer to package insert)

INDICATIONS AND USAGE

EXPAREL is a liposome injection of bupivacaine, an amide-type local anesthetic, indicated for administration into the surgical site to produce postsurgical analgesia.

EXPAREL has not been studied for use in patients younger than 18 years of age.

CONTRAINDICATIONS

EXPAREL is contraindicated in obstetrical paracervical block anesthesia. While EXPAREL has not been tested with this technique, the use of bupivacaine HCl with this technique has resulted in fetal bradycardia and death.

WARNINGS AND PRECAUTIONS

Warnings and Precautions Specific for EXPAREL

As there is a potential risk of severe life-threatening adverse effects associated with the administration of bupivacaine, EXPAREL should be administered in a setting where trained personnel and equipment are available to promptly treat patients who show evidence of neurological or cardiac toxicity.

Caution should be taken to avoid accidental intravascular injection of EXPAREL. Convulsions and cardiac arrest have occurred following accidental intravascular injection of bupivacaine and other amide-containing products.

Using EXPAREL followed by other bupivacaine formulations has not been studied in clinical trials. Other formulations of bupivacaine should not be administered within 96 hours following administration of EXPAREL.

EXPAREL has not been evaluated for the following uses and, therefore, is not recommended for these types of analgesia or routes of administration.

- epidural
- intrathecal
- regional nerve blocks
- intravascular or intra-articular use

EXPAREL has not been evaluated for use in the following patient population and, therefore, it is not recommended for administration to these groups.

- patients younger than 18 years old
- pregnant patients
- nursing patients

The ability of EXPAREL to achieve effective anesthesia has not been studied. Therefore, EXPAREL is not indicated for pre-incisional or pre-procedural loco-regional anesthetic techniques that require deep and complete sensory block in the area of administration.

ADVERSE REACTIONS

Adverse Reactions Reported in All Wound Infiltration Clinical Studies

The safety of EXPAREL was evaluated in 10 randomized, double-blind, local administration into the surgical site clinical studies involving 823 patients undergoing various surgical procedures. Patients were administered a dose ranging from 66 to 532 mg of EXPAREL. In these studies, the most common adverse reactions (incidence greater than or equal to 10%) following EXPAREL administration were nausea, constipation, and vomiting.

The common adverse reactions (incidence greater than or equal to 2% to less than 10%) following EXPAREL administration were pyrexia, dizziness, edema peripheral, anemia, hypotension, pruritus, tachycardia, headache, insomnia, anemia postoperative, muscle spasms, hemorrhagic anemia, back pain, somnolence, and procedural pain.

DRUG INTERACTIONS

EXPAREL can be administered undiluted or diluted up to 0.89 mg/mL (i.e., 1:14 dilution by volume) with normal (0.9%) sterile saline for injection or lactated Ringer's solution. EXPAREL must not be diluted with water or other hypotonic agents as it will result in disruption of the liposomal particles.

EXPAREL should not be admixed with other local anesthetics.

EXPAREL may be locally administered after at least 20 minutes following local administration of lidocaine.

Bupivacaine HCl, when injected immediately before EXPAREL, may impact the pharmacokinetic and/or physicochemical properties of the drugs if the milligram dose of bupivacaine HCl solution exceeds 50% of the EXPAREL dose. The toxic effects of these drugs are additive and their administration should be used with caution including monitoring for neurologic and cardiovascular effects related to toxicity.

EXPAREL should not be admixed with other drugs prior to administration.

USE IN SPECIFIC POPULATIONS

Pregnancy Category C

Risk Summary

There are no adequate and well-controlled studies of EXPAREL in pregnant women. Animal reproduction studies have been conducted to evaluate bupivacaine. In these studies, subcutaneous administration of bupivacaine to rats and rabbits during organogenesis was associated with embryo-fetal deaths in rabbits at a dose equivalent to the maximum recommended human dose (MRHD). Subcutaneous administration of bupivacaine to rats from

implantation through weaning, also at an MRHD-equivalent dose, produced decreased pup survival. EXPAREL should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Clinical Considerations

Labor or Delivery

Bupivacaine is contraindicated for obstetrical paracervical block anesthesia. While EXPAREL has not been studied with this technique, the use of bupivacaine for obstetrical paracervical block anesthesia has resulted in fetal bradycardia and death.

Bupivacaine can rapidly cross the placenta, and when used for epidural, caudal, or pudendal block anesthesia, can cause varying degrees of maternal, fetal, and neonatal toxicity. The incidence and degree of toxicity depend upon the procedure performed, the type, and amount of drug used, and the technique of drug administration. Adverse reactions in the parturient, fetus, and neonate involve alterations of the central nervous system, peripheral vascular tone, and cardiac function.

Data

Animal Data

Bupivacaine hydrochloride was administered subcutaneously to rats at doses of 4.4, 13.3, and 40 mg/kg/day and to rabbits at doses of 1.3, 5.8, and 22.2 mg/kg/day during the period of organogenesis (implantation to closure of the hard palate). No embryo-fetal effects were observed in rats at the doses tested with the high dose causing increased maternal lethality. An increase in embryo-fetal deaths was observed in rabbits at the high dose in the absence of maternal toxicity. This dose is clinically relevant as is comparable to the MRHD based on Body Surface Area (BSA) comparisons.

In a rat pre- and post-natal development study conducted at subcutaneous doses of 4.4, 13.3, and 40 mg/kg/day with dosing from implantation through weaning (during pregnancy and lactation), decreased pup survival was observed at the high dose, a clinically relevant dose as it is comparable to the MRHD based on BSA comparisons.

Nursing Mothers

Published literature reports that bupivacaine is present in human milk at low levels; however, the drug is poorly absorbed orally. Exercise caution when administering EXPAREL to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients below the age of 18 have not been established.

Geriatric Use

Of the total number of patients in the EXPAREL wound infiltration clinical studies (N=823), 171 patients were greater than or equal to 65 years of age and 47 patients were greater than or equal to 75 years of age. No overall differences in safety or effectiveness were observed between these patients and younger patients. Clinical experience with EXPAREL has not identified differences in efficacy or safety between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Hepatic Impairment

Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, these drugs should be used cautiously in patients with hepatic disease. Patients with severe hepatic disease, because of their inability to metabolize local anesthetics normally, are at a greater risk of developing toxic plasma concentrations.

Renal Impairment

Bupivacaine is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Care should be taken in dose selection of EXPAREL.

OVERDOSAGE

In the clinical study program, maximum plasma concentration (C_{max}) values of approximately 34,000 ng/mL were reported and likely reflected inadvertent intravascular administration of EXPAREL or systemic absorption of EXPAREL at the surgical site. The plasma bupivacaine measurements did not discern between free and liposomal-bound bupivacaine making the clinical relevance of the reported values uncertain; however, no discernable adverse events or clinical sequelae were observed in these patients.

DOSAGE AND ADMINISTRATION

EXPAREL is intended for single-dose administration only. The recommended dose of EXPAREL is based on the surgical site and the volume required to cover the area.

Surgery	Dose of EXPAREL	Volume of EXPAREL
Bunionectomy ¹	106 mg	8 mL
Hemorrhoidectomy ²	266 mg	20 mL

¹Infiltrate 7 mL of EXPAREL into the tissues surrounding the osteotomy and 1 mL into the subcutaneous tissue.

²Dilute 20 mL of EXPAREL with 10 mL of saline, for a total of 30 mL, and divide the mixture into six 5 mL aliquots. Perform the anal block by visualizing the anal sphincter as a clock face and slowly infiltrating one aliquot to each of the even numbers.

Administration Precautions

Admixing EXPAREL with other drugs prior to administration is not recommended.

- Non-bupivacaine based local anesthetics, including lidocaine, may cause an immediate release of bupivacaine from EXPAREL if administered together locally. The administration of EXPAREL may follow the administration of lidocaine after a delay of 20 minutes or more.
- Bupivacaine HCl, when injected immediately before EXPAREL, may impact the pharmacokinetic and/or physicochemical properties of the drugs if the milligram dose of bupivacaine

HCl solution exceeds 50% of the EXPAREL dose. The toxic effects of these drugs are additive and their administration should be used with caution including monitoring for neurologic and cardiovascular effects related to toxicity.

- When a topical antiseptic such as povidone iodine (e.g., Betadine®) is applied, the site should be allowed to dry before EXPAREL is administered into the surgical site. EXPAREL should not be allowed to come into contact with antiseptics such as povidone iodine in solution.

Studies conducted with EXPAREL demonstrated that the most common implantable materials (polypropylene, PTFE, silicone, stainless steel, and titanium) are not affected by the presence of EXPAREL any more than they are by saline. None of the materials studied had an adverse effect on EXPAREL.

Non-Interchangeability with Other Formulations of Bupivacaine

Different formulations of bupivacaine are not bioequivalent even if the milligram dosage is the same. Therefore, it is not possible to convert dosing from any other formulations of bupivacaine to EXPAREL and vice versa.

Dosing in Special Populations

EXPAREL has not been studied in patients younger than 18 years of age, pregnant patients or patients who are nursing.

CLINICAL PHARMACOLOGY

Pharmacokinetics

Local infiltration of EXPAREL results in significant systemic plasma levels of bupivacaine which can persist for 96 hours. Systemic plasma levels of bupivacaine following administration of EXPAREL are not correlated with local efficacy.

CLINICAL STUDIES

The efficacy of EXPAREL was compared to placebo in two multicenter, randomized, double-blinded clinical trials. One trial evaluated the treatments in patients undergoing bunionectomy; the other trial evaluated the treatments in patients undergoing hemorrhoidectomy. EXPAREL has not been demonstrated to be safe and effective in other procedures.

Bunionectomy

A multicenter, randomized, double-blind, placebo-controlled, parallel-group study evaluated the safety and efficacy of 106 mg EXPAREL in 193 patients undergoing bunionectomy. The mean age was 43 years (range 18 to 72). Study medication was administered directly into the wound at the conclusion of the surgery, prior to wound closure. Pain intensity was rated by the patients on a 0 to 10 numeric rating scale (NRS) out to 72 hours. Postoperatively, patients were allowed rescue medication (5 mg oxycodone/325 mg acetaminophen orally every 4 to 6 hours as needed) or, if that was insufficient within the first 24 hours, ketorolac (15 to 30 mg IV). The primary outcome measure was the area under the curve (AUC) of the NRS pain intensity scores (cumulative pain scores) collected over the first 24 hour period. There was a significant treatment effect for EXPAREL compared to placebo.

In this clinical study, EXPAREL demonstrated a significant reduction in pain intensity compared to placebo for up to 24 hours. The difference in mean pain intensity between treatment groups occurred only during the first 24 hours following study drug administration. Between 24 and 72 hours after study drug administration, there was minimal to no difference between EXPAREL and placebo treatments on mean pain intensity.

Hemorrhoidectomy

A multicenter, randomized, double-blind, placebo-controlled, parallel-group study evaluated the safety and efficacy of 266 mg EXPAREL in 189 patients undergoing hemorrhoidectomy. The mean age was 48 years (range 18 to 86). Study medication was administered directly into the wound (greater than or equal to 3 cm) at the conclusion of the surgery. Pain intensity was rated by the patients on a 0 to 10 NRS at multiple time points up to 72 hours. Postoperatively, patients were allowed rescue medication (morphine sulfate 10 mg intramuscular every 4 hours as needed). The primary outcome measure was the AUC of the NRS pain intensity scores (cumulative pain scores) collected over the first 72 hour period. There was a significant treatment effect for EXPAREL compared to placebo.

In this clinical study, EXPAREL demonstrated a significant reduction in pain intensity compared to placebo for up to 24 hours. The difference in mean pain intensity between treatment groups occurred only during the first 24 hours following study drug administration. Between 24 and 72 hours after study drug administration, there was minimal to no difference between EXPAREL and placebo treatments on mean pain intensity; however, there was an attendant decrease in opioid consumption, the clinical benefit of which was not demonstrated.

Pacira Pharmaceuticals, Inc.
San Diego, CA 92121 USA

Patent Numbers:
6,132,766 5,891,467
5,766,627 8,182,835

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Rx only

May 2015

Patients need to return to a safe and accessible home after joint replacement and spine surgery, and have family members who can support them. The center can also partner with outside nursing and physical therapy services to visit the patient and make sure they're following the postoperative plan.

"Education was a huge factor for us bringing in our patients," says Ms. Hague. "We also have collaborations with multidisciplinary resources we need. We start touching the patient almost three to four weeks head of the procedure for total joint replacements to make sure they fall into patient selection guidelines. They come in for a preop education class a week or two before surgery and they also get to tour the center and learn about our infection control precautions."

Key issues to address with the staff include:

- Expectations for the patient
- How long the patient will stay at the ASC
- What medications should go home with the patient
- Dressing change instructions
- Treatment and discharge protocols

"Make sure the team members have the right information," says Dr. Jeffords. "If the patient asks the same question to three different people on your team, they should get the same answer."

Not every patient is a candidate for the outpatient setting; patients with many comorbidities, sleep apnea or older patients may need access to care beyond the ASC's capabilities.

"You want a patient who is motivated to recover, not someone who is de-conditioned," says Dr. Berni. "The ideal patient has upper body strength and core strength. You have to weed out people with increased risks of medical complications, but some would argue patients who aren't fit for the ASC setting might not be a good candidate for joint replacement in general."

Developing pain management and care pathway protocols

Developing the right protocols for patient selection and treatment are imperative. Ms. Hague partnered with an outside vendor with inpatient total joint replacement protocol tweaked for the outpatient setting. The protocols include the pain management regimen as well as early ambulation.

"The anesthesia team was very involved in the process," says Ms. Hague. "They laid the foundation. There is a multi-modal pain protocol that is helping us do these procedures for patients without major pain. Any physician at our center has to use that protocol."

The presurgical protocol at Dr. Jeffords' center includes medication before the anesthesia is induced. The patient takes an oral pregabalin to reduce postoperative neuropathic pain. In some cases, depending on the patient's prior narcotic use and the extent of the surgery, his team administers a long acting oral narcotic pre-operatively. During anesthesia, his team may use IV ketamine to help reduce postoperative pain. Intraoperatively, he uses a liposomal bupivacaine that is indicated for single-dose infiltration into the surgical site to produce postsurgical analgesia.

Postoperatively, he writes a prescription for seven days of oral Celebrex, which studies show doesn't reduce fusion rates as other anti-inflammatories do. He also takes the time to call his patients the first night home from surgery.

"I call them that evening and they have my cell phone if they get worried or have issues," says Dr. Jeffords. "They can call me directly and that is reassuring."

With the appropriate protocol, the patient emerges from the operating room without severe pain. Dr. Jeffords and his staff are at the forefront of exploring non-opioid options to include in their protocol. Administering too much opioid could make the patient too dizzy and sick for early ambulation and adds cost to the procedure. Patients may also become addicted to opioids, leading to additional health issues. This protocol eliminates heavy opioid use, which makes the patient feel sick after surgery. Then they're ready to ambulate.

"Our patients see a physical therapist four-to-six hours after surgery is complete and walk through our hallways," says Ms. Hague. "They are usually able to be discharged six to eight hours after surgery."

Protocol development is an ongoing process and as more information and there is always room for improvement. This requires developing specific goals and selecting relevant outcomes that are agreed upon by the team. In addition, a thoughtful implementation program is needed to ensure the program achieves the desired impact on postsurgical pain management outcomes. It is important to identify the right procedure and patients, identify clinical outcomes measures, data sources to collect the outcomes, educate the staff and then make adjustments to the protocols.

"You really need the support of strong surgeon leadership to make these programs successful," says Ms. Hague. "We are still tweaking the program as we go and trying to find ways we can enhance it. One thing we do is patient reunion lunches to bring patients back a few months after surgery and get their feedback on our processes. We take that information back to make the program better."

Reducing opioid use

Opioid addiction is a huge problem in many communities across the United States and many addicts start taking opioids prescribed for back pain. Long term opioid use can have severe health issues, and many providers exploring ways to curtail opioid use as part of a multimodal pain management approach.

"We try to minimize opioid use as much as possible," says Ms. Hague. "We really educate patients upfront to try to keep their pain under control, and do it smartly. We are also making sure they aren't taking their old pain medications."

An article published in the Journal of the American Academy of Orthopaedic Surgeons shows orthopedic surgeons are the third-highest prescribers of opioid prescriptions in the United States. According to the National Institute on Drug Abuse, There are around 26.4 million people who abuse opioids worldwide, with 2.1 million people in the United States.

In the past 20 years, deaths in the United States due to prescription opioid pain relievers have more than tripled. But with new pain management protocols, some providers are able to significantly reduce the amount of opioid use to control pain.

Clinton Devin, MD, and Matthew McGirt, MD, determined that spine patients should be weaned off of opioids prior to surgery. Their study found that increased preoperative narcotic use was significantly associated with increased length of hospital stay, as well as age, type of surgery, and depression.

"We are finding patients use opioids so little with our current pain management protocols that we could get away from it with time," says Dr. Berni. "We are using some scheduled long-acting non-opioids and combining them with anti-inflammatories and reduced opioids if necessary. It's an evolving process and we are following our patients closely to see whether they are actually using the opioids we prescribe. We're looking into refining our protocols and keeping a very open mind for what is the best thing for our patients." ■

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[1] Field R. et al. - Prospective randomised controlled clinical trial comparing THA performed either through a posterior approach or AMIS using gait analysis - M.O.R.E. Journal 7th M.O.R.E. International symposium, Congress edition, Lugano, Switzerland, April 11-12, 2014.

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The Future is Here: Outpatient Anterior Hip Replacement Surgery

By Laura Dyrda

There are more high-acuity orthopedic procedures going to the outpatient setting today, including total joint replacements. Orthopedic technology is developing for minimally invasive procedures, and new pain management protocol and post-surgical care allow patients to leave the outpatient centers within 23 hours after surgery.

"It's been a natural progression over many years where we have seen a gradual reduction in the duration of hospital stay after joint replacement," says Robert Greenhow, MD, of Peak Orthopedics & Spine in Lone

"Over the past few years, most of our anterior approach hip replacement patients were being discharged from the hospital within 23 hours," says Dr. Greenhow. "It was a natural transition to move some of our younger, healthy patients into the outpatient center."

Drs. Loucks' and Greenhow's ambulatory surgery center offers the same surgical team, anesthesia and implants at the ASC as they do at the hospital, but the outpatient center is a more intimate setting with an environment designed to optimize personalized care.

"Over the past few years, most of our anterior approach hip replacement patients were being discharged from the hospital within 23 hours. It was a natural transition to move some of our younger healthy patients into the outpatient center."

— Dr. Robert Greenhow, Peak Orthopedics & Spine in Lone Tree, Colo.

Tree, Colo. "This has been based on less invasive and improved surgical techniques, use of regional anesthesia and peri-articular injections, less tubes and drains and a reduction in the use of narcotics."

Outpatient surgery benefits

The direct anterior approach has become a powerful tool in the realm of outpatient hip surgery. Surgeons are able to approach the hip anteriorly for less blood loss and postoperative pain, which makes rehabilitation quicker and easier.

There was a study performed in Oregon showing more consistency with cost-per-case with the anterior approach when compared to the lateral approach. The anterior approach was also associated with reduced time in the operating room.

"These outpatient centers are usually much less intimidating for patients compared to large, acute care hospitals," says Craig Loucks, MD, of Peak Orthopedics & Spine. "Most patients are amazed at how good they feel after surgery and how mobile they are just a few hours postop."

The infection rates are also historically lower in outpatient surgery centers and patient satisfaction is higher. One study comparing anterior and posterior approaches in the same patient — one hip was posterior and one hip was anterior — shows the patient preferred the anterior approach. When patients are satisfied, they refer their family and friends.

"There are numerous clinical benefits to the anterior approach for patients," says



Dr. Robert Greenhow



Dr. Craig Loucks

Dr. Greenhow. "These benefits have been determined through prospective, randomized trials and other peer-reviewed literature. These benefits include less muscle and tendon damage, lower dislocation rates, less pain early on, shorter requirement for a walking aid, earlier return of muscular strength, quicker return of normal gait and quicker return to work."

But not every patient is well-suited for outpatient procedures. “Currently, our outpatient joint replacement practice is limited to younger, healthy and motivated patients,” says Dr. Greenhow. “Most commercial payers are participating but not government-based payers, such as Medicare, at this time.”

Since Medicare won’t reimburse for outpatient total hip replacements in the ASC, even healthy patients older than 65 are taken to the hospital. “Eventually it is conceivable that Medicare and other government plans will recognize the tremendous clinical and economic benefits of outpatient joint replacement,” says Dr. Loucks.

Dr. Loucks and Dr. Greenhow counsel their patients on outpatient surgery options, and some patients arrive at their office already requesting surgery in an ASC.

“The majority of patients are thrilled at the prospect of going home the same day of surgery,” says Dr. Greenhow. “Having done outpatient joint replacement for over two years, we have more and more patients coming to us specifically for the outpatient program.”

Economic benefits

In addition to the clinical benefits, taking cases to outpatient surgery centers also have an impact on the healthcare economy. ASCs cost less than performing cases in hospitals — even hospital outpatient departments — and the lower infection and complication rate means there is less spent on additional healthcare to fix those issues.

The ASC doesn’t have the same infrastructure needs as the hospital, so cases can be done more efficiently and cost-effectively.

“We believe outpatient joint replacement surgery is a great example of how we can control costs while maintaining or perhaps improving quality in these new settings,” says Dr. Greenhow. “Outpatient joint replacement in the right patients will eventually become the standard of care.”

The country is moving more toward value-based care, paying close attention to quality and cost metrics. This shift in healthcare philosophy will drive the move to outpatient surgery centers. But, the transition isn’t always easy.

“Our first and biggest hurdle was convincing the hospitals and insurance companies,” says Dr. Loucks. “Traditionally these cases have always been performed in an inpatient hospital setting. Often, getting approval by the insurance carrier to perform these procedures in an ASC can be a challenge. However, this is improving. Insurance carriers are slowly recognizing that these cases can be performed safely and effectively in an ASC setting.”

Since these cases are reimbursed less in the outpatient ASC, hospitals stand to lose money from the transition. However, some hospitals are partnering with physicians for joint venture surgery centers to retain a percentage of the reimbursement and form a relationship with the surgeons in their community.

“We believe that those hospitals systems that embrace and support this trend proactively will fare well long-term,” says Dr. Greenhow. “Hospitals and ASCs can successfully partner with surgeons to help control costs and improve outcomes.”

Making the transition

The preoperative and postoperative protocols are similar for the ASC and the hospital, making the transition smooth. If surgeons have experienced staff around them in both settings, their workflow doesn’t change much.

“Once surgeons have mastered the technique, they have reported improved implant position, accurate leg length reduction, earlier discharge home and improved patient satisfaction.”

— Craig Loucks, MD, of Peak Orthopedics & Spine in Lone Tree, Colo.

“Really the only difference is the location where we perform the surgery and the mindset of the staff and expectations of the patient,” says Dr. Loucks. “The ASC staff is accustomed to early mobilization and same-day discharge.”

There are tools that can improve the procedure; a special operating table facilitates the procedure, but it’s an expensive capital expenditure.

“Medacta provides a leg positioner for all cases and this can be a nice opportunity for surgeons and ASCs where the capital cost of an expensive, special operating table is prohibitive,” says Dr. Greenhow.

There is a learning curve for new surgeons incorporating the anterior technique in their practice. Some surgeons find the learning curve so steep they abandon the technique and revert back to the posterior approach.

“A formal education program is important for new adapters where they can visit a reference center to watch live surgery — we have visiting surgeons almost every week in Denver; attend a cadaveric lab course; and then have a surgeon come to their hospital to help proctor them on their first cases,” says Dr. Greenhow. “Medacta International has been a leader in the field of anterior approach hip replacement education. They have a very comprehensive educational and proctoring program with a very high conversion rate for surgeons adopting the anterior approach.”

Both Dr. Loucks and Dr. Greenhow have trained hundreds of surgeons over the years on the anterior approach to hip surgery. The muscle-sparing technique, combined with intra-operative X-ray guidance, can have excellent results.

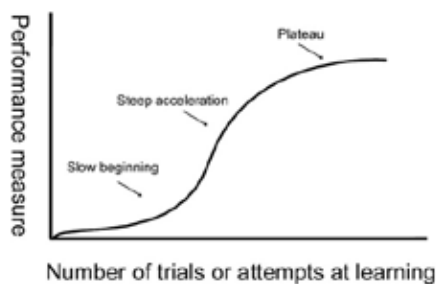
“Once these surgeons have mastered the technique, they have reported improved implant position, accurate leg length reduction, earlier discharge home and improved patient satisfaction,” says Dr. Loucks. “Our technique has evolved significantly over the last 11 years and we are at the point where we truly are muscle-sparing in our AMIS approach. In the anterior hip world, we are seeing variations in the technique that have surgeons cutting selected muscles and tendons to get exposure and perform the subtle, yet important, details in surgical technique will likely be differentiated clinically over the years to come.” ■

A Comprehensive Education Program and its Impact on Reducing the Learning Curve for the Anterior Approach to Total Hip Arthroplasty

By Tyler D. Goldberg, MD

As with all orthopedic procedures, surgeons must endure a “learning curve” while they become more proficient with a procedure. The anterior approach to total hip arthroplasty is no different. Many surgeons cite the complex learning curve during the early phases of adoption as the reason to not adopt the approach. As surgeons, we all go through formal training to become orthopedic surgeons. We learn the procedures our mentors are comfortable with. The majority of practicing orthopedic surgeons today were never exposed to the anterior approach during residency or fellowship.

To learn new techniques, we must either rely on professional societies or industry. These training opportunities are valuable in that we are exposed to the techniques, get hands on experience, and discuss the pros and cons of the technique. Unfortunately, most training courses are generally a “one and done” course without any ongoing support to master the technique.



The anterior approach is a complex procedure and thus has a “complex learning curve.” The S-shaped curve exhibits a graphical representation of the learning curve to be expected with the anterior approach. The initial part of the curve rises slowly as the surgeon becomes familiar

with basic components of the procedure. The steep ascending phase occurs when there is enough experience with the technique to start “putting it all together.” Rapid progress follows until the skill “hits a ceiling” or stabilizes at a high level. However, it is my opinion that a “flat” plateau of the skill is never realized and continual gradual improvement will occur with increasing experience of the surgeon.

As busy surgeons, how do we adopt a new technique safely, efficiently, and accurately? The simple answer is to engage an educational platform that will support us through all phases of the learning curve. The simple answer is an education platform that supports the surgeon through all phases of the learning curve.

With this in mind, Medacta International has created a multi-phased educational program to educate surgeons of the AMIS technique for THA. The M.O.R.E. (Medacta Orthopedic Research & Education) Institute was established specifically with the goal of teaching and supporting surgeons in a structured and engaging manner.

Medacta has designed a phased training program to educate and support surgeons in learning and adapting the AMIS Technique.

First, surgeons are given initial exposure to the technique through a Congress, a live surgery presentation, or a visit to a current AMIS-trained surgeon, known as a Reference Center. If the surgeon expresses interest in the procedure, then they proceed to the next step – Learning Center Training. A Learning Center allows the surgeon to once again view a live (or recorded) surgical demonstration, receive didactic education, and finally perform the procedure on cadavers. The cadaver course provides for

a unique one-on-one experience with the trainers and the course attendees, unlike other trainings where the attendees may be one of four or five attendees at a station. Every surgeon that attends the course will go through the entire procedure with a trainer. Third, surgeons will have the opportunity to have an experienced AMIS user to be present for their first procedures. This allows dedicated one-on-one mentorship of real-time surgery which subsequently fosters confidence in the trainee’s mind regarding the procedure. Fourth, an aggressive post-surgical review is performed with the surgeon via tele-conferencing and another site visit may occur after the surgeon has performed additional cases. This site visit may be another visit to a Reference Center by the training surgeon or via a visiting AMIS surgeon to his/her hospital. Even after the initial training and proctoring, Medacta will continue to support surgeons utilizing the AMIS technique with advanced education opportunities including round table discussions, revision training, and even further.

To date, Medacta International has created 200 International Reference Centers and National Reference Centers. Since 2005, nearly 200 Learning Centers have been held. Thus far, over 2200 surgeons have been trained through the program. Medacta boasts a 70 percent successful conversion rate of surgeons performing the AMIS technique regularly.

In conclusion, the AMIS technique can be a difficult procedure to become proficient in. However, with proper directed training, the surgeon may speed their learning curve and realize the benefits of this technique in a more effective, efficient, and safer method. ■

AMA Names Dr. Andrew Gurman President-Elect

By Anuja Vaidya

The American Medical Association elected Andrew W. Gurman, MD, as president-elect.

Here are five key notes:

1. Dr. Gurman will assume the office of AMA president in June 2016.
2. He is in private practice in Altoona, Pa., and he has served as the speaker and vice speaker of the AMA's House of Delegates for the last eight years.
3. He represented Pennsylvania physicians in the AMA House of Delegates for nearly two decades.
4. He also represented the AMA at the Physician Consortium for Performance Improvement and the National Association of Boards of Pharmacy Stakeholders Group on Opioid Prescribing and Dispensing.
5. Dr. Gurman completed his residency in orthopedic surgery at the combined Montefiore Hospital/Albert Einstein program in New York and a fellowship in hand surgery at the Hospital for Joint Diseases Orthopaedic Institute, also in New York. ■

Hand Prosthetics, ACA, Big Data & More — The Issues Impacting Hand Surgeons Today

By Brandon Howard

Brian P. Wicks, MD, of The Doctors Clinic of Kitsap County in Washington discusses new technology in hand surgery and how healthcare reform is impacting the field.

Dr. Brian Wicks: Over the past few years the field of hand surgery has been fairly quiet in terms of new devices and technology game-changers. While issues such as hand transplantation have opened new therapeutic doors, equal attention has been dedicated to the ethical issues of having a patient on long-term anti-rejection drugs in order to regain some hand functions.

With the war-driven advancements in prosthetic design and production the discussion of ethics about innovations such as hand transplantation will continue. The proliferation of biologic medications in the treatment of inflammatory conditions such as rheumatoid and psoriatic arthritis have fundamentally changed patients' lives as well as surgeons' case mixes. The relief of much of this disease burden is welcomed by all as there is still plenty of hand surgery work to be done but practices dedicated to rheumatoid hand surgery will likely become a thing of the past.

A development that paralleled the roll out of the ACA, the proliferation of high-deductible health plans with a health savings account component, is bringing change to the relationship between the surgeon and patient, in a generally beneficial way. No longer can the patient afford to do everything that a surgeon might have classically thought needed. Now, issues such as the cost of the procedure, implants and anesthesia as well as the chosen location for the surgery is becoming a topic for discussion and negotiation.

In an effort to "bend the curve" of healthcare spending there has been a return to discussion of some type of bundled or capitated care, similar to that seen first in the 1990s. With physicians standing to benefit financially from more intense focus on the global patient "experience," decisions have to be made by hand surgeons that were thought to be part of our responsibility a few years ago. "Could this surgery be done in an ambulatory surgery center instead of the much more expensive hospital facility?" "Could this ASC case be switched to an office procedure room using straight local anesthesia?" "Is that expensive gadget or gizmo really needed to get the case done in an effective fashion?"

Putting these financial decisions in the hands of hand surgeons (with appropriate patient input) is certainly a step in the right direction but there will be a need to revisit the fundamentals of how decisions are made concerning the "how and where" of a particular patient's surgery.

The need to be able to do more for more patients with fewer hand surgeons will lead to increased focus on the efficiency of the operating room and the surgeon. Unnecessary consumption of resources will not be tolerated in healthcare systems funded by a fixed number of dollars coming from an employer or insurer.

The application of "big data" processing to information collected in electronic health records will allow the identification of trends and patterns that will allow for quality decision-making in a less emotional environment. These developments, although new and not initially comfortable, will go a long way to improving on



Dr. Brian Wicks

the 'cottage industry' mentality of a profession that accounts for nearly 20 percent of our nation's gross domestic production.

Advances will continue in the fields of nerve/tendon repair, trauma reconstruction and molecular modification of disease states but these will occur under the umbrella of a national change in the healthcare delivery system. Integration of the developments coming from the lab and industry will need to be merged with the developing fiscal realities of the healthcare marketplace. In the minds of many such changes are needed, overdue, and in the best interest of patients, hand surgeons and the U.S. economy. ■

The Connecticut Orthopaedic Society Names Dr. F. Scott Gray President

By Anuja Vaidya

The Connecticut Orthopaedic Society named F. Scott Gray, MD, president, according to a *News Times* report.

Here are four quick facts:

1. Dr. Gray practices with Connecticut Family Orthopedics in Danbury, which he joined in 1987. He previously served as managing partner of the practice.
2. He also established the Danbury Foot and Ankle Center along with Michael Fein, DPM, which provides comprehensive foot and ankle care.
3. He provides care at Danbury Hospital, where he served as orthopedic trauma coordinator for seven years.
4. Dr. Gray completed specialty training in foot and ankle surgery at Tufts University School of Medicine in Boston. ■

Dr. David Porter Performs Ankle Surgery on Chicago Bulls' Taj Gibson

By Anuja Vaidya

David Porter, MD, performed ankle surgery on Chicago Bulls forward Taj Gibson, according to a *CBS Chicago* report.

Here are five things to know:

1. Dr. Porter performed arthroscopic surgery on Mr. Gibson's left ankle.
2. Mr. Gibson is expected to miss four months, but will return to full basketball activities.
3. Dr. Porter practices with Methodist Sports Medicine in Indianapolis and is the founding president and a board member of Methodist Sports Medicine Research & Education Foundation.
4. He is a member of the American College of Sports Medicine and American Orthopedic Foot & Ankle Society.
5. Dr. Porter has completed a foot and ankle fellowship at the Foundation for Orthopedic, Athletic and Reconstructive Research in Houston. ■

Dr. Thomas Fusco Joins Orthopaedic Associates

By Mary Rechteris

Thomas A. Fusco, DPM, has joined Orthopaedic Associates in Fort Walton Beach.

Here are five things to note about Dr. Fusco:

1. Dr. Thomas Fusco, a podiatrist, is the newest surgical podiatrist addition to the practice.
2. Dr. Fusco aids patients who are in need of specialty foot and ankle care.
3. Dr. Fusco received his doctorate of podiatric medicine at Ohio College of Podiatric Medicine.
4. After receiving his doctorate, Dr. Fusco completed his residency in podiatric medicine and surgery at the Cleveland Clinic Foundation and the Mercy Regional Medical Center in Lorain, Ohio.
5. Dr. Fusco is currently a member of the American Podiatric Medical Association, the Florida Podiatric Medical Association and the American College of Foot and Ankle Surgeons. ■

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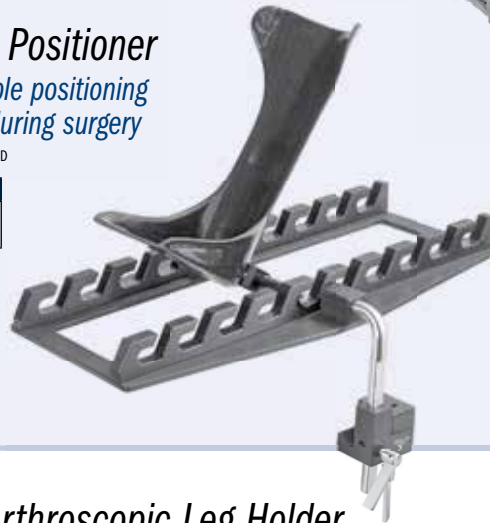


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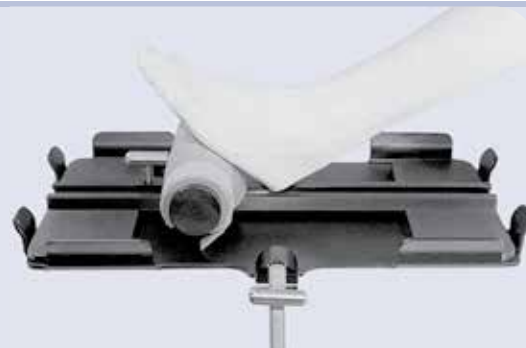
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