

Outpatient Joint Replacement and Achieving The Triple Aim

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Background

Patient outcomes demonstrate that outpatient joint replacement (OJR) provides an alternative site of care for patients suffering from chronic osteoarthritis. With the Triple Aim Objectives of healthcare reform firmly planted at the forefront of the national debate, OJR has been less costly than joint replacement performed in an inpatient hospital setting for our practice. By streamlining care in the outpatient setting, and contracting with local insurance providers with a bundled offering, Excelsior Orthopaedics decreased the top line reimbursement for total joints from approximately \$38,000 to \$26,000. A savings of 32%. Physician leadership, diligent patient selection, standardized clinical pathways, multi-modal pain management, aggressive care coordination, and the alignment of financial incentives through bundled payments are the critical success factors in achieving improved patient outcomes and significant cost reduction for our practice in Buffalo, NY.

Total joint replacement (TJR) has been traditionally performed as an inpatient procedure accompanied by a several night hospital stay and admission to a rehabilitation facility upon discharge. The demand for TJR among younger, healthier, and more active patients, combined with an aging population, has greatly impacted cost trends for musculoskeletal pathologies and driven a seismic shift toward value based care. More than 50% of TJA patients are now under the age of 65, and overall demand for hip and knee replacement is expected to grow 174% and 673% respectively by the year 2030¹. The Centers for Medicare and Medicaid Services (CMS) paid \$7B for 400,000 hip and knee replacements in 2014², prompting the release of national programs like the Bundled Payments for Care (BPCI) initiative and the Comprehensive Care Model for Joint Replacement (CJR) as efforts to bend the cost curve. In a long awaited move, CMS removed total knee arthroplasty (TKA) from its “inpatient only” list starting in 2018 with hospital outpatient departments³. Additional changes as to what site of care CMS will reimburse total joint replacements are expected in the coming years.

These market forces, along with our personal experience that OJR performed in an ambulatory surgery center (ASC), for our practice delivered exceptional outcomes with lower infection rates and fewer complications than hospitals, have led to an increase in outpatient joint arthroplasty in our practice. An analysis of national trends found that between 2012 and 2015 there was a 47% increase in elective outpatient hip and knee procedures. These numbers are projected to increase by 633% and 453% respectively in the next decade.⁴

Between 2015 and 2017, joint surgeons at Excelsior Orthopaedics performed 330 outpatient hip and knee replacements at Buffalo Surgery Center (BSC), a physician owned ASC.

Patient Selection and Education

Decreasing the risks of the most common complications of TJR in an outpatient setting depends greatly on patient selection and education. Candidates for Excelsior’s outpatient protocol should have a body mass index (BMI) <40, an uneventful medical history, few, if any, comorbidities, and must be motivated, resilient, and narcotic naïve. Patients with well-controlled sleep apnea may qualify, but individuals with a history of cardiothoracic problems, diabetes, pulmonary embolism (PE), deep vein thrombosis (DVT), Methicillin resistant *Staphylococcus aureus* (MRSA), gastric by-pass surgery, or who are taking blood thinners are excluded in most circumstances. All OJR candidates are screened by a triumvirate that includes the primary surgeon, Excelsior’s clinical care coordinator, and a BSC anesthesiologist. Patients must also demonstrate that caregiver support is available to assist with rehabilitation and to help manage the transition home.

Since OJR patients bear more responsibility for their own rehabilitation and recovery, tremendous emphasis is placed on patient education and care coordination throughout the entire episode of care. Prior to surgery, all patients and caregivers are required to attend a patient education class taught by Excelsior staff,

including a clinical care coordinator, registered nurse, physical therapist and athletic trainer. The patient education class and accompanying materials focus on everything patients need to know before, during and after surgery. Patients also receive personalized coaching and education from Excelsior's clinical care coordinator and from registered nurses during a one night stay at an off-site Surgical Recovery Suite (SRS) following discharge from BSC. SRS nurses focus primarily on monitoring patient recovery and preparing them both physically and mentally for a safe transition home.

More recently, Excelsior introduced a digital care navigation system called CareSense to lead patients through their entire OJR journey. The CareSense mobile application delivers timely information, reminders, and educational content to patients through e-mails, texts, alerts, and notifications. The application also enables patients to interact with their clinical care team. Digital care navigation delivers critical information to patients exactly when they need it as well as reinforcing key messages taught in the patient education classes.

Pain Management, Pharmacological Therapies and Clinical Protocols

OJR is possible because of the emergence of multi-modal pain management, including regional anesthesia blocks and intra-operative injections that reduce incidence of post-operative nausea and vomiting, promote early ambulation, and facilitate rapid rehabilitation. Meticulous pharmacological therapies include anti-inflammatories, antibiotics, antiemetics, prophylaxis for venous thromboembolism (VTE), constipation, urinary retention, and blood loss, and extended and short acting narcotics for break-through pain. Excelsior's OJR clinical protocols for multi-modal pain management and pharmacological therapies have resulted in low rates of infection, readmission, and surgical complication as evidenced by patient outcomes.⁵

Between 2014 and 2017, Excelsior surgeons performed 182 knee replacements and 148 hip replacements at BSC. Total knee patients received the DePuy Synthes ATTUNE® Primary Total Knee System with a mobile-bearing platform using the gap balancing technique. Total hip patients received the DePuy Synthes CORAIL® Total Hip System PINNACLE® Cup with a highly cross-linked polyethylene acetabular liner and a BIOLOX® *delta* Ceramic Femoral Head. The muscle sparing direct anterior approach using a Hana® table was used for all 148 total hips patients. Operating room time for both procedures

was scheduled for 120 minutes, allotting 30 minutes for preparation, 60 minutes of operative time, and 30 minutes to close. Actual average total OR time (wheels in to wheels out) was 128.9 minutes for knees and 106.6 minutes for hips. Total average skin to skin procedure time was 104.5 minutes for knees and 83.7 minutes for hips. Detailed policies and procedures were developed for patient screening, pre-operative testing, and anesthesia clearance. All patients, with the exception of two, were discharged from BSC the same day, admitted to the SRS for a 1 or 2 night stay, and prescribed an accelerated outpatient rehabilitation protocol.

Pre-operative orders include the use of Hibiclens® wash for three days prior to surgery, a 1-2 gm Ancef® IV pre-op, a 10 mg Decadron® IV at time of induction, knee high TED stockings, and a sequential decompression device placed in recovery. Total hip patients also received a 1gm IV of hemostatic agent prior to surgery. The anesthesia protocol includes general anesthesia and an adductor canal block for total knees. A tourniquet is used for total knees and antibiotic irrigation using vancomycin and sodium chloride (NaCl) is administered intra-operatively. Risk of infection is also reduced through the use of iodine wash, Chloraprep™, and 3M™ Ioban™ drapes.

To improve post-surgical pain management and reduce the need for opioids, 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) is expanded with bupivacaine HCl and normal saline to a total volume of 90 mL and infiltrated intra-operatively around the surgical site. The EXPAREL mixture is divided into three (3) 30 mL syringes each with 22-gauge needles. For Total Knee Arthroplasty 1/3 (one-third) of the expanded EXPAREL mixture is injected into the posterior capsule prior to placing the tibial component, and the remaining 2/3 (two-thirds) is distributed liberally in ligaments, tendons, fat pads and subcutaneous tissues surrounding the joint. For Total Hip Arthroplasty, the same mixture is injected into the ligaments, tendons and subcutaneous tissues prior to placing the femoral stem. For more detailed EXPAREL infiltration protocols, please visit www.depuyorthopaedics.com.

To manage and control blood loss, multiple steps are taken including but not limited to patient selection – to screen out patients on blood thinning medication, meticulous hemostasis, the use of a tourniquet and other medications or agents used peri-operatively.

For closure, a combination of antibacterial sutures, the DERMABOND® PRINEO® Skin Closure System, and

Aquacel® dressings are used to address risk factors associated with surgical site infection. Post-operative medication therapies focus on managing breakthrough pain, anti-inflammation, VTE prophylaxis, infection control, and preventing constipation, urinary retention, and nausea. Post-operative orders also include cold and compression therapy, outpatient rehabilitation, and incentive spirometry.

Post-Operative Recovery and Rehabilitation

While several models for post-acute care exist, including 23 hour ASC stays, direct discharge to home, or recovery in a hotel room, Excelsior's OJR patients are admitted to an off-site Surgical Recovery Suite (SRS) for a concierge-like and clinically focused recovery experience. At the two bedroom, well-appointed SRS, patients receive 24 x 7 nursing observation and coaching, assistance with medications, education to prepare for a safe transition home, and on-site physical therapy focused on early motion and ambulation. Patients also enjoy gourmet catered meals, room for overnight guests, and daily visits from their surgeon. Patients have no access to IVs, no urinary catheters, and self-administer medications that are delivered directly to the SRS. While Excelsior's initial OJR patients stayed at the SRS for two nights, patient length of stay has been reduced to one night. Excelsior's surgeons believe there to be a direct correlation between patient outcomes and the SRS component of the OJR program, especially given its focus on care coordination, patient education and early ambulation.

Post-operative focus on strengthening and achieving full range of motion begins with on-site physical therapy at the SRS within four hours of discharge from BSC and on post-op day one prior to discharge to home. Within three days, patients return to Excelsior for outpatient physical therapy to continue their progression through four distinct phases of rehabilitation, each with established goals, defined exercises and progression criteria. Outpatient knee and hip replacement patients average 15 and 12 physical therapy visits respectively. Prior to discharge from therapy, Excelsior Orthopaedic patients are asked to self-report their improvement in pain and functionality compared to before surgery. Outpatient knee replacement patients achieved an 83% improvement in self-reported joint pain and functionality. Outpatient hip replacement achieved an 89% improvement in self-reported joint pain and functionality.

Excelsior's rapid rehabilitation and standardized recovery protocols are critical to achieving positive outcomes and successfully returning patients to normal activities of daily living.

Patient Outcomes

Concurrent with the launch of its OJR program, and as a pre-requisite for obtaining payer support, Excelsior deployed a data collection system through CareSense to collect and analyze patient demographic information, intraoperative data, satisfaction scores, and outcomes. Through touch screen devices, web-interfaces, and its digital care navigation mobile application, CareSense enables Excelsior to report on program safety and effectiveness. This outcome data is critically important to securing and maintaining stakeholder support, managing risk, and preparing for the seismic shift to value based reimbursement. Patient demographics and outcomes for Excelsior's 330 OJR patients are presented below.

Conclusions

There is a revolution happening in joint replacement. Getting a new hip or knee replacement without ever stepping foot inside a hospital is becoming more and more commonplace. It's a progressive approach to care, which provides patients who are in general good health an accelerated process for surgery and recovery. OJR is possible because of minimally invasive surgical techniques, advancements in pain management, diligent care coordination, and structured clinical and rehabilitation protocols. Of the 330 hip and knee replacements performed by Excelsior surgeons at BSC, there were no complications, no infections, no incidents of DVT or PE, and no hospital re-admissions. There was only 1 accidental post-operative fracture (.3% of the total), 2 hospital transfers (.6% of the total), and 2 returns to BSC for manipulation under anesthesia (.6% of the total). Knee and hip patients reported 83% and 89% improvement respectively prior to discharge from physical therapy based on a self-reported patient scoring system. When polled, 99% of patients treated stated that they would return to Buffalo Surgery Center if they required treatment in the future. Finally, patient reported outcomes measuring pain, physical, and mental health meet or exceed established benchmarks. Patient outcomes clearly demonstrate that OJR has become a value driven treatment option for patients suffering from chronic osteoarthritis.

Demographics, Intraoperative Data and Results

– Excelsior Orthopaedics – Buffalo, NY

Patients (2015-2017)

	Male	Female	Total
Knees	86	96	182
Hips	96	52	148
			330

Averages

Mean Age (Range)	Mean BMI (Range)	Average LOS
57 (21-81)	30.2 (18.6 – 44.6)	1.25 days in Surgical Recovery Suite

Comorbidities

Asthma	Diabetes	Hypertension
7%	2%	21%

Intraoperative Data

Categories	Knees	Hips
Operative Time - Wheel In Wheels Out (min.)	128.9	128.9
Skin to Skin Procedure Time (min.)	104.5	83.7
Anesthesia Time (min)	145.7	131.6
Incision Length (cm)	15.3	15.1
Blood Loss (ccs):	127.9	402
Tourniquet Time (min)	58.93	–

Patients (2015-2017)

Patient readmissions	5/330 1.5%
Hospital Transfers	2 (.6%) – 1 undiagnosed atrial fibrillation and 1 for inability to stabilized blood pressure in recovery
Infections	0
DVT	0
PE	0
Fractures	1 (.3%) – Patient tripped over his dog
Post-Operative Manipulations Under Anesthesia	2 (.6%) – 1 for patient non-compliance and 1 for post-operative hemarthrosis

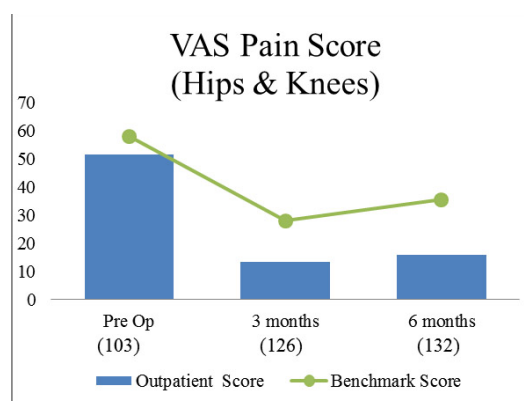
Average Visits and Percent (%) Improvement Prior to Discharge from Therapy

Knees	Hips
15 (83%)	12 (89%)

*As reported by patient

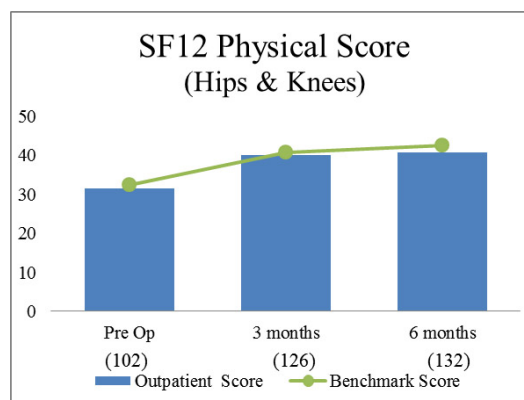
Patient Reported Outcomes

Visual Analogue Scale (VAS) Pain Scores
Measures Pain on a Scale Between 0-100 (Low-High)



Benchmark Scores above represent data from 70 CareSense customer groups, including 5,463 pre-op respondents, 4,303 respondents at 3 months, and 7,753 respondents at 6 months.

SF-12 – Physical Health (0-100)
Higher Scores Indicate Better Physical and Mental Health

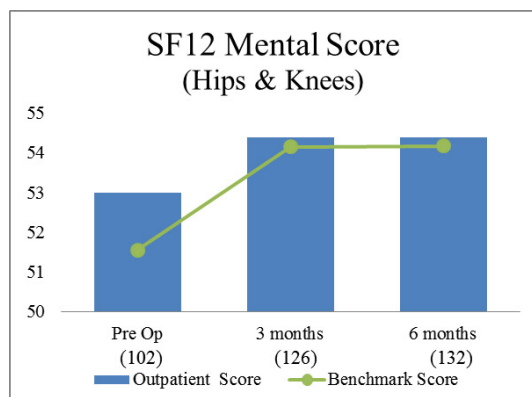


Benchmark Scores above represent data from 70 CareSense customer groups, including 11,823 pre-op respondents, 6,550 respondents at 3 months, and 7,250 respondents at 6 months.

Demographics, Intraoperative Data and Results

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SF-12 – Mental Health (0-100)
Higher Scores Indicate Better Physical and Mental Health

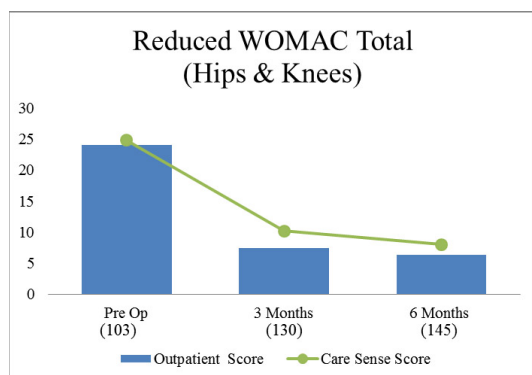


Benchmark Scores above represent data from 70 CareSense customer groups, including 11,823 pre-op respondents, 6,550 respondents at 3 months, and 7,250 respondents at 6 months.

Reduced WOMAC – Activities of Daily Living (Excelsior Patients Reporting Moderate to Extreme Pain)

Activity	Pre-Op	3 Mos. Post-Op	6 Mos. Post-Op
Walking on a flat surface	83%	13%	8%
Going up or down stairs	92%	20%	19%
Sleeping	72%	18%	12%
Sitting or laying down	58%	13%	8%
Standing upright	78%	12%	9%
Difficulty going up stairs	84%	14%	17%
Difficulty rising from sitting	81%	15%	14%
Difficulty walking on a flat surface	80%	12%	5%
Difficulty getting out of bed	68%	12%	10%
Responses	103	130	145

Reduced WOMAC (0-100)
Lower scores indicate less pain, stiffness, and functional limitations



Benchmark Scores above represent data from 70 CareSense customer groups, including 15,397 pre-op respondents, 4,544 respondents at 3 months, and 10,041 respondents at 6 months.

For complete indications, contraindications, precautions, warnings and adverse reactions, please reference the full package insert.

EXPAREL® (bupivacaine liposome injectable suspension)

Important Safety Information

Indication:

EXPAREL is indicated for single-dose infiltration in adults to produce postsurgical local analgesia and as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia. Limitations of Use: Safety and efficacy has not been established in other nerve blocks.

Important Safety Information:

- EXPAREL is contraindicated in obstetrical paracervical block anesthesia.
- Adverse reactions reported with an incidence greater than or equal to 10% following EXPAREL administration via infiltration were nausea, constipation, and vomiting; adverse reactions reported with an incidence greater than or equal to 10% following EXPAREL administration via interscalene brachial plexus nerve block were nausea, pyrexia, and constipation.
- If EXPAREL and other non-bupivacaine local anesthetics, including lidocaine, are administered at the same site, there may be an immediate release of bupivacaine from EXPAREL. Therefore, EXPAREL may be administered to the same site 20 minutes after injecting lidocaine.
- EXPAREL is not recommended to be used in the following patient population: patients <18 years old and/or pregnant patients.
- Because amide-type local anesthetics, such as bupivacaine, are metabolized by the liver, EXPAREL should be used cautiously in patients with hepatic disease.

Warnings and Precautions Specific to EXPAREL:

- Avoid additional use of local anesthetics within 96 hours following administration of EXPAREL.
- EXPAREL is not recommended for the following types or routes of administration: epidural, intrathecal, regional nerve blocks **other than interscalene brachial plexus nerve block**, or intravascular or intra-articular use.
- The potential sensory and/or motor loss with EXPAREL is temporary and varies in degree and duration depending on the site of injection and dosage administered and may last for up to 5 days, as seen in clinical trials.

Warnings and Precautions for Bupivacaine-Containing Products

- **Central Nervous System (CNS) Reactions:** There have been reports of adverse neurologic reactions with the use of local anesthetics. These include persistent anesthesia and paresthesia. CNS reactions are characterized by excitation and/or depression.
- **Cardiovascular System Reactions:** Toxic blood concentrations depress cardiac conductivity and excitability which may lead to dysrhythmias, sometimes leading to death.
- **Allergic Reactions:** Allergic-type reactions (eg, anaphylaxis and angioedema) are rare and may occur as a result of hypersensitivity to the local anesthetic or to other formulation ingredients.
- **Chondrolysis:** There have been reports of chondrolysis (mostly in the shoulder joint) following intra-articular infusion of local anesthetics, which is an unapproved use.
- **Methemoglobinemia:** Cases of methemoglobinemia have been reported with local anesthetic use.

FULL PRESCRIBING INFORMATION IS AVAILABLE AT WWW.EXPAREL.COM.

References

1. Projections of Primary and Revision Hip and Knee Arthroplasty in the United States from 2005-2030. Kurtz S, Ong K, Lau E, Mowat F, Halpern M, The Journal of Bone and Joint Surgery, Apr. 1989 (4); 780-5.
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4. 16 Things to Know About Outpatient Total Joint Replacement and ASCs, Becker's ASC Review, Dydra, L, February 10th, 2017.
5. Outpatient Total Joint Arthroplasty. J Bert, J Hooper, S Moen. Curr Rev Musculoskelet Med. 2017, 10:567-574

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