

Administration Case Report: Total Hip Arthroplasty (THA)

This case report represents the individual experience of Dr Jason E. Guevara, and is intended to demonstrate his methodology for using EXPAREL in patients undergoing total hip arthroplasty (THA) using a modified Hardinge antero-lateral approach.

Pacira BioSciences, Inc. recognizes that there are alternative methodologies for administering local anesthetics, as well as individual patient considerations when selecting the dose for a specific procedure.

EXPAREL is a local anesthetic that produces postsurgical analgesia in patients aged 6 years and older. It is administered via single-dose infiltration. When infiltrated into the surgical site, it produces local analgesia. It may also be infiltrated in the fascial plane to produce regional analgesia as a regional field block. Regional anesthetic techniques to produce regional analgesia include, but are not limited to, transversus abdominis plane (TAP) block, pectoralis (PEC) and serratus anterior plane (SAP) blocks, erector spinae plane (ESP) block, and quadratus lumborum (QL) block. EXPAREL may also be administered in adults as an interscalene brachial plexus nerve block, a sciatic nerve block in the popliteal fossa, and an adductor canal block to produce postsurgical regional analgesia.

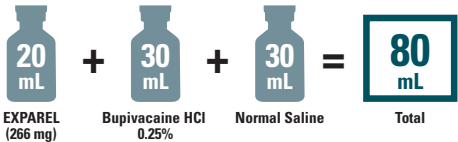
CASE INFORMATION

Physician Name	Jason E. Guevara, MD
Affiliation	Pinehurst Orthopedic Group, PA
Surgical Case Performed	Total hip arthroplasty (THA), modified Hardinge antero-lateral approach
Inpatient or Outpatient Procedure	Inpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	62 years
Patient History and Characteristics	Patient had difficulty walking and restricted ROM of the left hip. A complete workup revealed stenosis on the left side of L4-L5, high-grade spondylosis from L3-L4 to L5-S1. After failing nerve root injections, she was referred for a complete bone on bone and collapse of the left femoral head with advanced degenerative changes in the joint
Pathology	Patient had a completely degenerative hip and underwent a THA with an ERAS protocol

PROCEDURAL DETAILS

Incision Size	15 cm using a medial peel with a modified Hardinge antero-lateral approach
Preoperative Analgesics Used	PO acetaminophen 650 mg, PO gabapentin 300 mg, PO oxycodone 10 mg, and PO ibuprofen 800 mg
Intraoperative Analgesics Used	20 mL 0.25% bupivacaine injected up front 20 mL EXPAREL and 30 mL 0.25% bupivacaine infiltrated perioperatively
Dose of EXPAREL and Total Volume Used	 <p>20 mL EXPAREL (266 mg) + 30 mL Bupivacaine HCl 0.25% + 30 mL Normal Saline = 80 mL Total</p>

ERAS=Enhanced Recovery After Surgery; PO=by mouth; ROM=range of motion.

The recommended dose of EXPAREL for infiltration in adults is based on the size of the surgical site, the volume required to cover the area, and individual patient factors that may impact the safety of an amide local anesthetic. The maximum dose of EXPAREL should not exceed 266 mg. The recommended dose of EXPAREL for patients aged 6 to <17 years old is 4 mg/kg, up to a maximum of 266 mg. The recommended dose of EXPAREL in adults for interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, and adductor canal is 133 mg. The recommended dose of EXPAREL in adults for adductor canal block is 133 mg (10 mL) admixed with 50 mg (10 mL) of 0.5% bupivacaine HCl, for a total volume of 20 mL.

EXPAREL can be administered unexpanded (20 mL) or expanded to increase volume up to a total of 300 mL (final concentration of 0.89 mg/mL [ie, 1:14 dilution by volume]) with normal (0.9%) saline or lactated Ringer's solution.

Bupivacaine HCl (which is approved for use in patients aged 12 and older) may be administered immediately before EXPAREL or admixed in the same syringe, as long as the ratio of the milligram dose of bupivacaine HCl to EXPAREL does not exceed 1:2. Admixing may impact the pharmacokinetic and/or physicochemical properties of EXPAREL, and this effect is concentration dependent. The toxic effects of these drugs are additive and their administration should be used with caution, including monitoring for neurological and cardiovascular effects related to local anesthetic systemic toxicity. Other than with bupivacaine, EXPAREL should not be admixed with other drugs prior to administration.

Please see Important Safety Information on the last page and refer to accompanying full Prescribing Information, which is also available at www.EXPARELpro.com.

INFILTRATION NOTES

ASSESSED THE SIZE OF THE SURGICAL SITE AND DEPTH OF TISSUE, THEN PREPARED INJECTION MATERIALS ACCORDINGLY

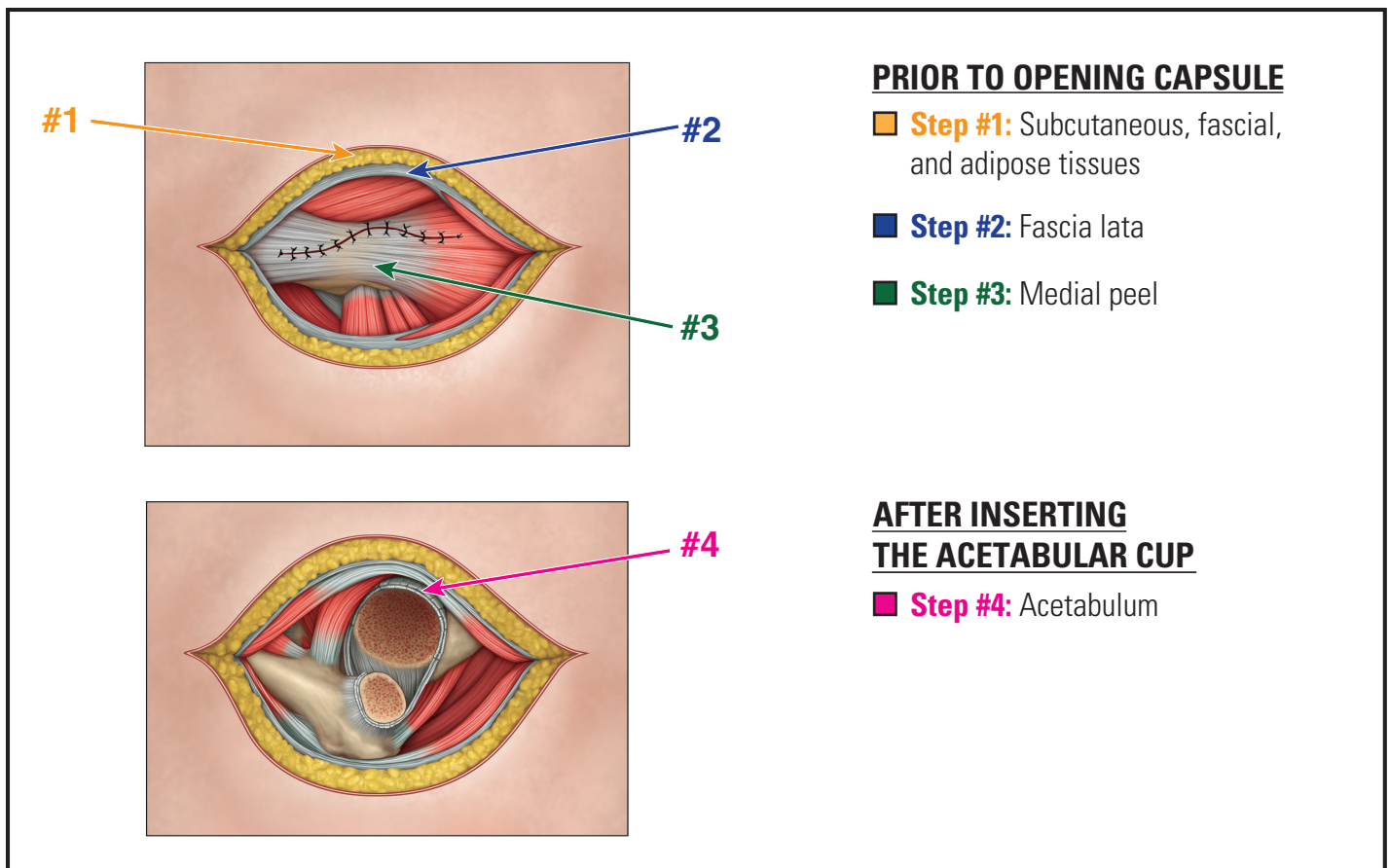
In this procedure, Dr Guevara determined that a total volume of approximately 80 mL would be needed to cover the surgical site. He expanded 20 mL of EXPAREL[®] (bupivacaine liposome injectable suspension) with 30 mL of normal saline and 30 mL of 0.25% bupivacaine. Dr Guevara also prepared a separate syringe with 20 mL of 0.25% bupivacaine to be injected up front. The use of 0.25% bupivacaine up front and as part of the EXPAREL cocktail was to provide short-term local analgesia that overlapped with the long-term local analgesia provided by EXPAREL.



In patients who have large surface area, have a lot of adipose tissue, are extremely muscular, or have a large hip, Dr Guevara adds an additional 30 mL of saline to expand the volume of EXPAREL to 110 mL.

DIVIDED INJECTATE INTO SYRINGES WITH NEEDLE GAUGES APPROPRIATE FOR INFILTRATION (20- TO 25-GAUGE) AND PLANNED WHICH AREAS TO INFILTRATE

For this procedure, Dr Guevara mixed the injection materials in a bowl and then divided the injectate between two 10-mL syringes with a 21-gauge needle. He refilled each syringe as needed throughout the procedure.



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INFILTRATION NOTES (cont)

INFILTRATION INTO THE SURGICAL SITE

■ Step #1:

Immediately following the incision, 20 mL of 0.25% bupivacaine was infiltrated into the subcutaneous, fascial, and adipose tissues (10 mL per side).

20 mL of expanded EXPAREL[®] (bupivacaine liposome injectable suspension) was then infiltrated into the dermis at the corners of the incision and into the subcutaneous, fascial, and adipose tissues (10 mL per side, 0.5 mL per injection).



FIGURE 1. Subcutaneous, fascial, and adipose tissues



Angle the needle downward to ensure infiltration down to the fascial tissue.

■ Step #2:

10 mL of expanded EXPAREL was infiltrated into the fascia lata (5 mL per side). It was infiltrated roughly 1 cm deep into the cut edge.



FIGURE 2. Fascia lata



Lift the subcutaneous layer up for better visualization and access.

■ Step #3:

20 mL of expanded EXPAREL was infiltrated into the full medial peel (vastus lateralis/intermedius, gluteus medius/minimus, and capsule), with care taken to aspirate before each injection to minimize the risk of intravascular injection (0.2 mL per injection).



FIGURE 3. Medial peel

■ Step #4:

After inserting the acetabular cup, 20 mL of expanded EXPAREL was infiltrated circumferentially around the acetabulum. It was also infiltrated into the periosteum and into the gluteus medius and minimus.

The remaining 10 mL was infiltrated into the vastus lateralis and transverse acetabular ligament.



FIGURE 4. Acetabulum

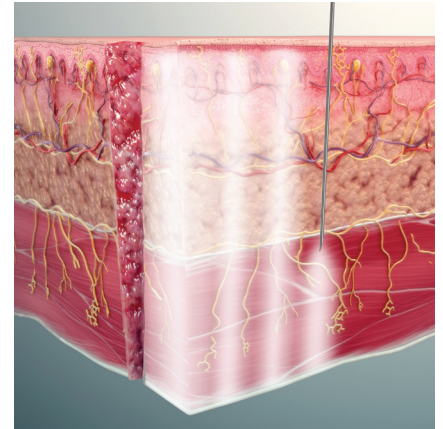


When infiltrating into the gluteus medius and minimus, take care to avoid the superior gluteal nerve.

INFILTRATION NOTES (cont)

PROPER TECHNIQUE IS CRUCIAL FOR ANALGESIC COVERAGE

When infiltrating EXPAREL[®] (bupivacaine liposome injectable suspension), Dr Guevara makes sure to infiltrate below the fascia, above the fascia, and into the subcutaneous tissue using a moving needle technique. With a moving needle technique, the injections are spread in a rapid and precise fan-like pattern to maximize the number of injection areas. Injection occurs as the needle is withdrawn, creating an EXPAREL “stripe” to maximize the coverage area. This technique should be systematically and meticulously repeated with each subsequent injection site, and the next site should overlap with the prior infiltrated area to maximize effect.



Watch Dr Guevara infiltrate with EXPAREL at www.EXPARELpro.com

Indication

EXPAREL[®] (bupivacaine liposome injectable suspension) is indicated to produce postsurgical local analgesia via infiltration in patients aged 6 years and older and regional analgesia in adults via an interscalene brachial plexus nerve block, sciatic nerve block in the popliteal fossa, and an adductor canal block. Safety and efficacy have not been established in other nerve blocks.

Important Safety Information

EXPAREL is contraindicated in obstetrical paracervical block anesthesia.

Adverse reactions reported in adults with an incidence greater than or equal to 10% following EXPAREL administration via infiltration were nausea, constipation, and vomiting; adverse reactions reported in adults with an incidence greater than or equal to 10% following EXPAREL administration via nerve block were nausea, pyrexia, headache, and constipation.

Adverse reactions with an incidence greater than or equal to 10% following EXPAREL administration via infiltration in pediatric patients six to less than 17 years of age were nausea, vomiting, constipation, hypotension, anemia, muscle twitching, vision blurred, pruritus, and tachycardia.

Do not admix lidocaine or other non-bupivacaine local anesthetics with EXPAREL. EXPAREL may be administered at least 20 minutes or more following local administration of lidocaine.

EXPAREL is not recommended to be used in the following patient populations: patients <6 years old for infiltration, patients younger than 18 years old for nerve blocks, 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, sciatic nerve block in the popliteal fossa, and adductor canal 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.

Disclosure: Dr Guevara is a paid consultant for Pacira BioSciences, Inc.

**Full Prescribing Information is available at www.EXPARELpro.com.
For more information, please visit www.EXPARELpro.com or call 1-855-793-9727.**