

Administration Case Report: Hip Fracture Fixation

This case report represents the individual experience of Dr Nirav H. Amin, and is intended to demonstrate his methodology for using EXPAREL in patients undergoing hip fracture fixation.

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 as an interscalene brachial plexus nerve block in adults to produce postsurgical regional analgesia in total shoulder arthroplasty (TSA) and rotator cuff repair (RCR) procedures.

CASE INFORMATION	
Physician Name	Nirav H. Amin, MD
Affiliation	Associate Professor, Sports Medicine and Adult Knee Reconstruction Loma Linda University
Surgical Case Performed	Left unstable intertrochanteric hip fracture fixation
Inpatient or Outpatient Procedure	Inpatient
PATIENT CHARACTERISTICS	
Gender	Female
Age	89 years
Patient History and Characteristics	The patient sustained a hip fracture as the result of a fall. She was using a rolling walker before the fall due to balance concerns
Pathology	Left unstable intertrochanteric hip fracture; determined that intramedullary nail fixation would allow for greatest healing potential
PROCEDURAL DETAILS	
Incision Size	5 cm for nail entry site 4 cm for hip screw site 1 cm for each distal locking site
Preoperative Analgesics Used	IV acetaminophen 1 g IV tranexamic acid 1 g
Intraoperative Analgesics Used	fentanyl 50 mcg EXPAREL expanded to 120 mL
Dose of EXPAREL and Total Volume Used	<p>20 mL EXPAREL (266 mg) + 20 mL Bupivacaine HCl (0.5%) + 80 mL Normal Saline = 120 mL Total</p>

IV=intravenous.

The recommended dose of EXPAREL for 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 maximum dose of EXPAREL for interscalene brachial plexus nerve block in adults should not exceed 133 mg.

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 HCl, 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.EXPAREL.com.

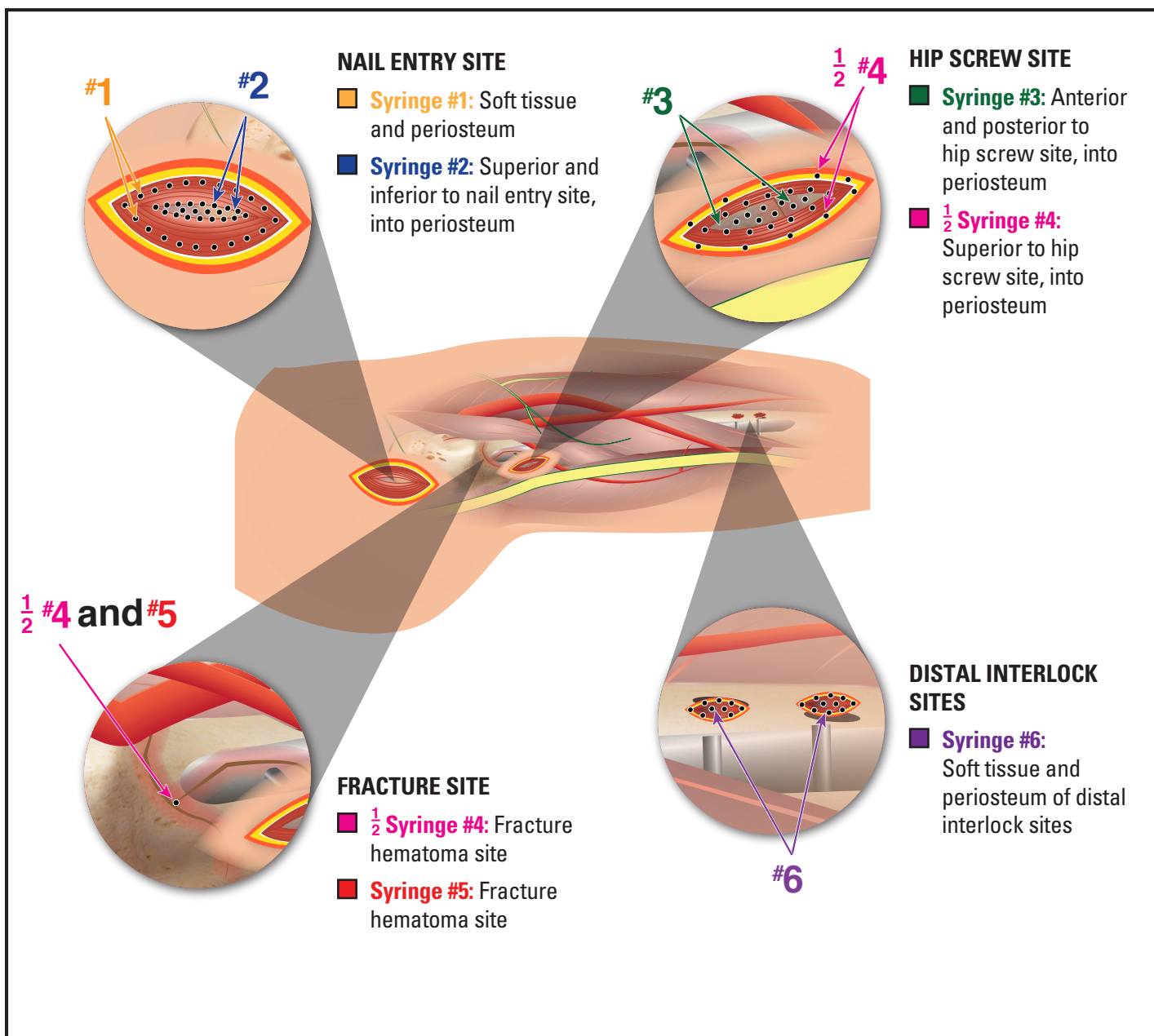
INFILTRATION NOTES

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

In this procedure, Dr Amin determined that a total volume of 120 mL would be needed to cover the surgical sites. He expanded 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) with 80 mL of normal saline and admixed the solution with 20 mL of 0.5% bupivacaine HCl. Dr Amin added bupivacaine HCl to provide short-term local analgesia in the postanesthesia care unit that overlapped with the long-term local analgesia provided by EXPAREL.

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

For this procedure, Dr Amin divided the injectate into six 20-mL syringes using a 22-gauge needle and infiltrated as follows:



INFILTRATION NOTES (cont)

■ Syringe #1:

Infiltrated 20 mL of expanded EXPAREL® (bupivacaine liposome injectable suspension) into the soft tissue surrounding the nail entry site and the periosteum. Needle was advanced deep into the tissue until tip of great trochanter region was felt, and approximately 1 to 3 mL of expanded EXPAREL was injected as the needle was pulled back. This was repeated several times until the entire syringe was injected.

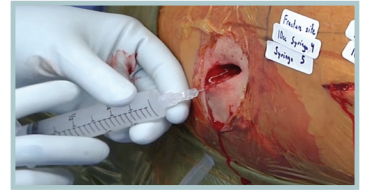


FIGURE 1. Soft tissue and periosteum around nail entry site

■ Syringe #2:

Infiltrated 10 mL superior and 10 mL inferior to the nail entry site, directly into the periosteum. Any remaining injectate was infiltrated into the surrounding superficial soft tissue. 1- to 2-mL injections were spread approximately 1 cm apart to ensure infiltration of the entire soft tissue envelope.

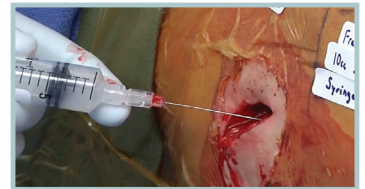


FIGURE 2. Superior and inferior to nail entry site, into periosteum

■ Syringe #3:

Infiltrated 10 mL anterior and 10 mL posterior to the lateral cortex of the hip screw site, directly into the periosteum. Injected in approximately 1- to 2-mL increments to ensure analgesic coverage of the proximal screw site and surrounding soft tissue.

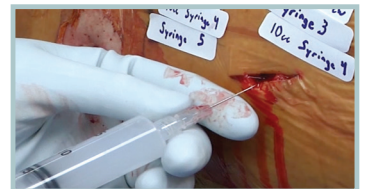


FIGURE 3. Anterior and posterior to hip screw site, into periosteum

■ Syringe #4:

Infiltrated 10 mL into the superficial tissue planes of the hip screw site in 1- to 2-mL increments spread 1 cm apart.

Under direct fluoroscopic imaging, infiltrated remaining 10 mL into the fracture hematoma site.



FIGURE 4. Superior to hip screw site, into periosteum

■ Syringe #5:

Under direct fluoroscopic imaging, infiltrated 20 mL into the fracture hematoma site.



Avoid injecting posteriorly due to the proximity to the sciatic nerve and other neurovascular structures.



FIGURE 5. Fracture hematoma site

■ Syringe #6:

Infiltrated 10 mL into the periosteum and soft tissue of each distal interlock site (total of 20 mL).



If there are fewer than 2 distal locking screws, use 10 mL at the distal interlock site and infiltrate remainder of syringe #6 into either the hip screw site or the nail entry site.

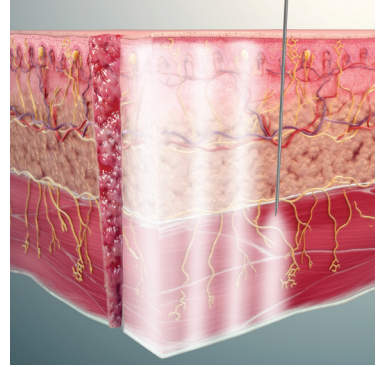


FIGURE 6. Soft tissue and periosteum of distal interlock sites

INFILTRATION NOTES (cont)

PROPER TECHNIQUE IS CRUCIAL FOR ANALGESIC COVERAGE

Dr Amin infiltrated EXPAREL® (bupivacaine liposome injectable suspension) into all tissue layers using a moving needle technique. With a moving needle technique, the injections were spread in a fan-like pattern and occurred as the needle was withdrawn to maximize the coverage area. This technique was systematically and meticulously repeated at each injection site, with overlapping diffusion of EXPAREL to ensure there were no gaps in analgesic coverage.



Watch Dr Amin infiltrate with EXPAREL at www.EXPAREL.com

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 interscalene brachial plexus nerve block were nausea, pyrexia, 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.

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 populations: patients <6 years old for infiltration, patients younger than 18 years old for interscalene brachial plexus nerve block, 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.

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

Full Prescribing Information is available at www.EXPAREL.com.