EXPAREL®
(bupivacaine liposome injectable suspension)

Administration Case Report: Rotator Cuff Repair

This case report represents the individual experience of Dr Paul Sethi, and is intended to demonstrate his methodology for using EXPAREL in patients undergoing rotator cuff repair.

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.

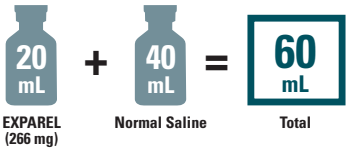
CASE INFORMATION

Physician Name	Paul Sethi, MD
Affiliation	Orthopaedic and Neurosurgery Specialists
Surgical Case Performed	Rotator cuff repair
Inpatient or Outpatient Procedure	Outpatient

PATIENT CHARACTERISTICS

Gender	Male
Age	46 years
Patient History and Characteristics	History of successful rotator cuff repair on the contralateral shoulder
Pathology	Rotator cuff tear

PROCEDURAL DETAILS

Incision Size	Arthroscopic
Preoperative Analgesics Used	Acetaminophen
Intraoperative Analgesics Used	Multimodal protocol of pregabalin 150 mg celecoxib 400 mg dexamethasone 10 mg bupivacaine 0.5% HCl 20 mL for interscalene nerve block (single shot) EXPAREL expanded to 60 mL for local tissue infiltration
Dose of EXPAREL and Total Volume Used	

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 the 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 Sethi determined a total volume of approximately 60 mL would be needed to create a field block at the surgical site. He expanded 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) with 40 mL of normal saline. No additional bupivacaine HCl was added to the EXPAREL mixture because the patient received an interscalene nerve block with bupivacaine HCl.

20 to 30 mL of 0.5% bupivacaine HCl may be added to the EXPAREL mixture if the patient is not receiving an interscalene nerve block.

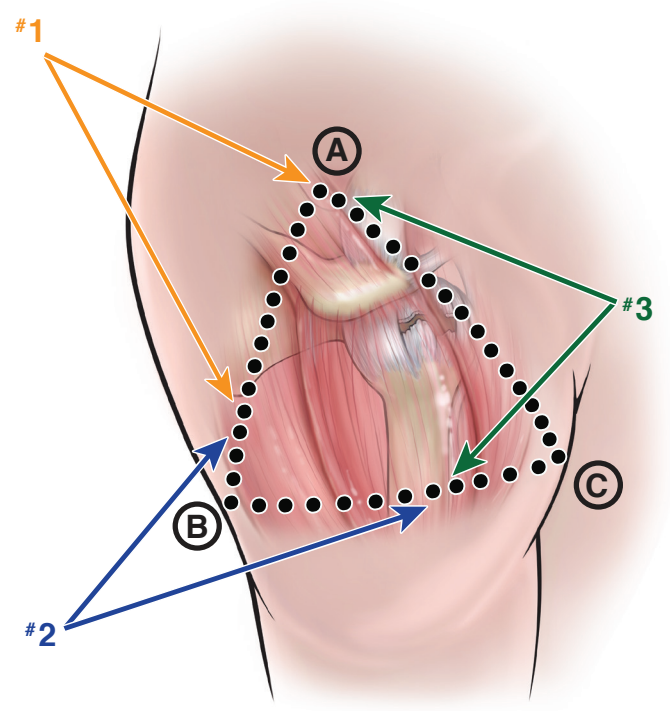
DIVIDED INJECTATE INTO SYRINGES WITH NEEDLE SIZES APPROPRIATE FOR INFILTRATION (20- TO 25-GAUGE) AND PLANNED WHICH AREAS TO INFILTRATE WITH EACH INJECTION

For this procedure, Dr Sethi divided the injectate into three 20-mL syringes with 20-gauge spinal needles.

He then marked off the surgical site as follows:

- Made standard marking of acromion, scapular spine, and clavicle
- Marked a spot 2 cm medial to the medial acromion in the Neviaser portal area, labeled "Point A"
- Drew a line from Point A over the posterior portal, ending at the patient's axilla, and named that spot "Point B"
- Drew a line from Point B to the long axis of the humerus carried anteriorly. Line should be perpendicular to the line drawn between Points A and B
- Drew a line from Point A lateral to the coracoid process. Line should be perpendicular to the line drawn between Points A and B
- Marked where lines from Point A and Point B intersected, and labeled it "Point C"

After these lines were drawn, Dr Sethi planned to infiltrate as follows:



PRIOR TO INCISION

- **Syringe #1:** Point A to Point B
- **Syringe #2:** Point B to Point C
- **Syringe #3:** Point C to Point A

INFILTRATION NOTES (cont)

Syringe #1:

Inserted syringe 10° anteriorly at Point A until the tip of needle encountered the bony floor of the scapula. After aspirating to ensure needle was not intravascular, Dr Sethi injected 10 mL of expanded EXPAREL® (bupivacaine liposome injectable suspension). He then continued to inject 1 to 1.5 mL every 1 to 1.5 cm along the line between Points A and B.

FIGURE 1. Point A to Point B

Syringe #2:

Inserted needle at Point B down to the bone and injected 7.5 to 10 mL of expanded EXPAREL. Then Dr Sethi continued to inject 1 to 1.5 mL every 1 to 1.5 cm along the line between Points B and C.

You will likely run out of injectate in Syringe #2 before reaching Point C. Use Syringe #3 to complete infiltration to Point C.

FIGURE 2. Point B to Point C

Syringe #3

Infiltrated 1 to 1.5 mL of expanded EXPAREL every 1 to 1.5 cm until Point C was reached. Then Dr Sethi continued to infiltrate along the line between Points C and A until all remaining injectate was used.

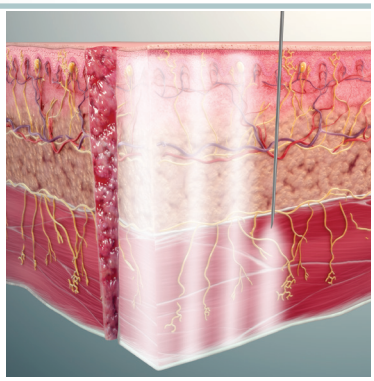
Injections from Points C to A must be lateral to the coracoid and should not be carried to the bone.

FIGURE 3. Point C to Point A

INFILTRATION NOTES (cont)

PROPER TECHNIQUE IS CRUCIAL FOR ANALGESIC COVERAGE

Dr Sethi 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 Sethi 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 Sethi 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.