

Administration Case Report: ACL Arthroscopic Reconstruction

This case report represents the individual experience of Dr Scott A. Sigman and is intended to demonstrate his methodology for using EXPAREL in patients undergoing a quadriceps tendon anterior cruciate ligament (ACL) arthroscopic reconstruction procedure.

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.

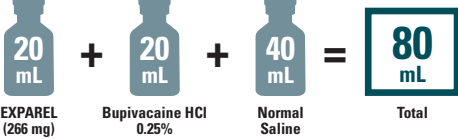
CASE INFORMATION

Physician Name	Scott A. Sigman, MD
Affiliation	Orthopedic Surgeon Lowell General Hospital, Lowell, MA
Surgical Case Performed	Quadriceps tendon ACL arthroscopic reconstruction
Inpatient or Outpatient Procedure	Outpatient

PATIENT CHARACTERISTICS

Gender	Male
Age	26 years
Patient History and Characteristics	Patient had a history of substance use disorder and sought out Dr Sigman for opioid-minimization strategy
Pathology	ACL tear

PROCEDURAL DETAILS

Incision Size	Midline 4-cm incision
Preoperative Analgesics Used	PO celecoxib 400 mg IV acetaminophen 1 g
Intraoperative Analgesics Used	20 mL of 0.25% bupivacaine HCl for short-term local analgesia 60 mL of expanded EXPAREL for local tissue infiltration
Dose of EXPAREL and Total Volume Used	 <p>The diagram illustrates the total volume used: 20 mL of EXPAREL (266 mg) plus 20 mL of Bupivacaine HCl 0.25% plus 40 mL of Normal Saline equals a total of 80 mL.</p>

IV=intravenous; PO=by mouth.

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, 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.

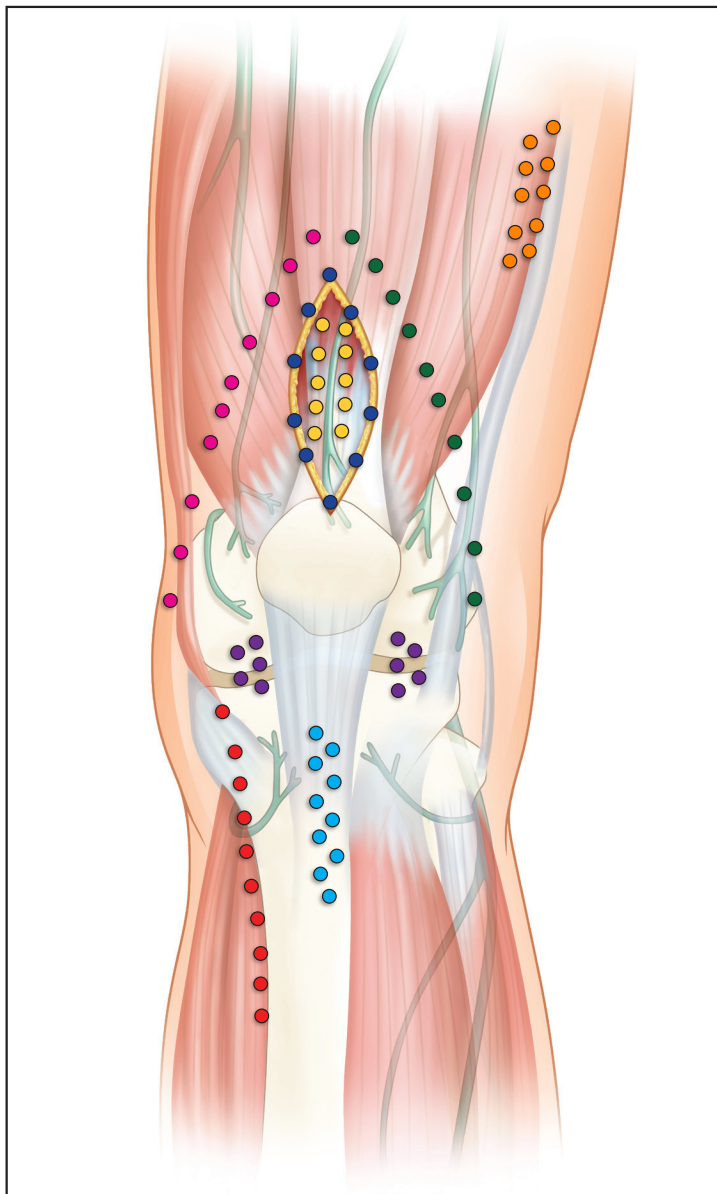
INFILTRATION NOTES

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

In this procedure, Dr Sigman determined that a total volume of 80 mL would be needed to cover the surgical site. He expanded 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) with 40 mL of normal saline and then admixed 20 mL of 0.25% bupivacaine HCl. Dr Sigman added bupivacaine HCl to provide short-term local analgesia 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 Sigman divided the injectate into eight 10-mL syringes with 22-gauge needles. He then infiltrated as follows:



- Step #1:**
Quadriceps tendon
- Step #2:**
Subcutaneous tissue along incision
- Step #3:**
Femoral nerve field block (lateral)
- Step #4:**
Femoral nerve field block (medial)
- Step #5:**
Saphenous nerve field block
- Step #6:**
Arthroscopy portal incision sites
- Step #7:**
Tibial tunnel incision
- Step #8:**
Femoral exit pin incision

INFILTRATION NOTES (cont)

■ Step #1:

Dr Sigman infiltrated 10 mL of expanded EXPAREL® (bupivacaine liposome injectable suspension) into the quadriceps tendon along the midline incision into the deep tissue.

■ Step #2:

Dr Sigman infiltrated 10 mL of expanded EXPAREL into the subcutaneous tissues along the length of the incision, injecting every 1 to 1.5 cm to achieve consistent coverage throughout the soft tissue.

■ Step #3:

Dr Sigman infiltrated 10 mL of expanded EXPAREL in an arch across the lateral side of the patella, into the skin, soft tissue, and retinaculum. This created a field block of the anterior femoral cutaneous nerve where it branches into the intermediate and medial branches of the lateral femoral cutaneous nerve.

■ Step #4:

Dr Sigman infiltrated 10 mL of expanded EXPAREL in an arch across the medial side of the patella, into the skin, soft tissue, and retinaculum. This created a field block of the lateral and intermediate branches of the anterior femoral cutaneous nerve.

■ Step #5:

Dr Sigman infiltrated 10 mL of expanded EXPAREL along the medial aspect of the knee just below the patella, establishing a field block of the infrapatellar branch of the saphenous nerve. He infiltrated expanded EXPAREL every 1 cm.

■ Step #6:

He then infiltrated 5 mL of expanded EXPAREL into the subcutaneous tissue along each of the planned incisions for the 2 arthroscopy portals. Infiltration at these points also provided analgesia of the fat pad.

■ Step #7:

Dr Sigman infiltrated 10 mL of expanded EXPAREL around the planned site for the tibial tunnel, being sure to infiltrate into the periosteum and the subcutaneous tissues.

■ Step #8:

Following removal of the femoral exit pin, Dr Sigman infiltrated 10 mL of expanded EXPAREL into the periosteum and subcutaneous tissues in that area. He infiltrated prior to placement of the instrumentation to avoid potentially cutting the eventual suture.



FIGURE 1.
Quadriceps tendon



FIGURE 2.
Subcutaneous tissue along incision



FIGURE 3.
Femoral nerve field block (lateral)



FIGURE 4.
Femoral nerve field block (medial)



FIGURE 5.
Saphenous nerve field block



FIGURE 6.
Arthroscopy portal incision sites



FIGURE 7.
Tibial tunnel incision

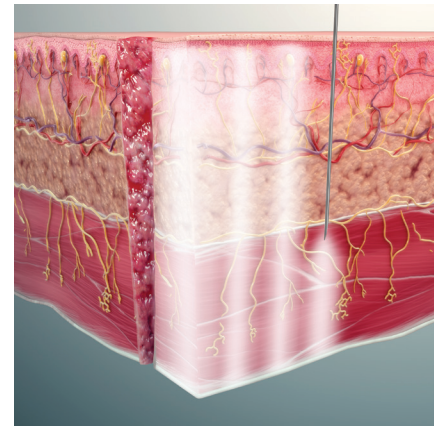


FIGURE 8.
Femoral exit pin incision

INFILTRATION NOTES (cont)

PROPER TECHNIQUE IS CRUCIAL FOR ANALGESIC COVERAGE

Dr Sigman 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 Sigman 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 Sigman is a paid consultant for Pacira BioSciences, Inc.

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