NON-OPIOID
EXPAREL®
(bupivacaine liposome injectable suspension)

Administration Case Report: Pediatric Anterior Cruciate Ligament (ACL) Reconstruction

This case report represents the individual experience of Dr Paul Sethi, and is intended to demonstrate his methodology for using EXPAREL in a patient undergoing right ACL reconstruction with patellar tendon autograft and anterolateral ligament reconstruction.

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. When infiltrated in the fascial plane, it produces regional analgesia using regional techniques such as erector spinae plane (ESP) block, quadratus lumborum (QL) block, and transversus abdominis plane (TAP) block.

CASE INFORMATION

Physician Name	Paul Sethi, MD
Affiliation	ONS Greenwich, CT
Surgical Case Performed	Right ACL Reconstruction With Patellar Tendon Autograft and Anterolateral Ligament Reconstruction
Inpatient or Outpatient Procedure	Outpatient ambulatory surgery center

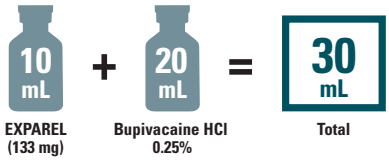
PATIENT CHARACTERISTICS

Gender	Female
Age	16 years
Patient Weight	56 kg
Patient History and Characteristics	Patient is a high school junior, 3-sport varsity athlete, committed to play Division 1 college-level lacrosse. She had an acute, non-contact knee injury with a lateral meniscal tear and a complete tear of her ACL.

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.

Please see Important Safety Information on page 4 and refer to accompanying full Prescribing Information, which is also available at www.EXPAREL.com.

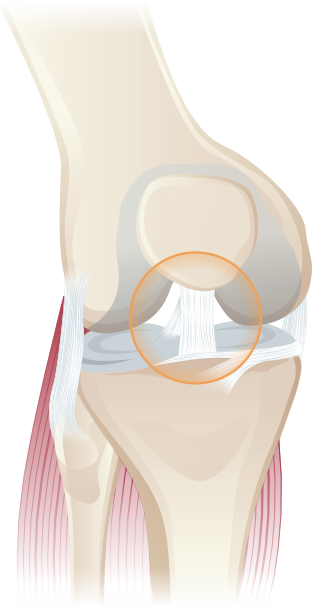
PROCEDURAL DETAILS

Incision Size	5 cm
Incision Type	Parapatellar
Preoperative Analgesics Used	600 mg of ibuprofen, 1000 mg of acetaminophen, 20 mL of 0.5% bupivacaine
Patient/Parent Education Regarding Pain Management	Patient and parent education aimed at explaining the procedure, demystifying any fears and setting expectations takes place (1) in the office prior to surgery, (2) by the nurse at discharge, and (3) reinforced as part of the POD 1 follow-up phone call.
Needle Size, Number of Syringes	22-g needle One 60-mL syringe
Premix or Administer EXPAREL® (bupivacaine liposome injectable suspension) Separately	EXPAREL admixed with 0.25% bupivacaine
Dosing and Administration	Although weight-based dosing guidance for pediatric patients allows for 4 mg/kg, in Dr Sethi's clinical judgment, in consideration of incision length and procedural technique, 10 mL of EXPAREL was appropriate for this procedure. 

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.

INFILTRATION NOTES

Prior to surgery, the patient received physical therapy and education about pain and the risks associated with opioid medications. She was educated regarding non-opioid alternatives. On the day of surgery, she was given 600 mg of ibuprofen, 1000 mg of acetaminophen, and received an ultrasound-guided adductor canal nerve block using 20 mL of 0.5% bupivacaine. In the operating room, she had meniscal repair with 3 anchors, a patellar tendon autograft affixed with 2 metal interference screws, and an anterolateral ligament reconstruction using a semitendinosus allograft affixed with two 5.5-mm suture anchors. At the end of the procedure, her wound was infiltrated with a 30-mL admixture of EXPAREL (10 mL) and 0.25% bupivacaine (20 mL). A 22-g needle was used to infiltrate the fat pad, the periosteum near the bone tunnels, the vastus medialis, the edges of the patellar tendon, and the skin edges. Small 2-mL aliquots of the mixture were delivered into the wound and a sterile waterproof dressing was applied.



POD, postoperative day.

POSTSURGICAL INSTRUCTIONS INCLUDING PRESCRIPTIONS PROVIDED AND RECOVERY MILESTONES AND GOALS

Cryotherapy (ice) was initiated in the recovery room. Patient reported a 1/10 NPRS pain score in the recovery room and was discharged to her home.

She used acetaminophen 1000 mg Q8 (three times a day), 10-mg tablets of ketorolac, and cryotherapy for 72 hours. She was given 10 tablets of oxycodone 5 mg on discharge to take for severe pain.

- Elevation
- Ice
- Acetaminophen 1000 mg PO 3 times a day for 72 hours
- Ibuprofen 600 mg PO 3 times a day (or ketorolac 10 mg PO 3 times a day) for 72 hours
- Physical therapy began at 48 hours
- Oxycodone 5 mg PO Q8 PRN for severe pain (10 tablets)

She initiated physical therapy at postsurgical day 2 (48 hours) and reported pain scores between 1/10 and 3/10 over the first 6 days. She was seen on postsurgical day 7, reporting a pain score of 1/10. She did not take any oxycodone pills during the entire event.

At 28 days postsurgical she eliminated the use of a brace, regained her full motion, and had no pain.

She was seen every 4 weeks and reported minimal pain. She has returned to competitive sports.

NPRS, Numerical Pain Rating Scale; PO, by mouth; PRN, as needed; Q8, once every 8 hours.

Important Safety Information

EXPAREL® (bupivacaine liposome injectable suspension) 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 Sethi is a paid consultant for Pacira BioSciences, Inc.

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

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