

Administration Case Report: Abdominoplasty

This case report represents the individual experience of Dr Allen Rosen, and is intended to demonstrate his methodology for using EXPAREL in patients undergoing an abdominoplasty.

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.

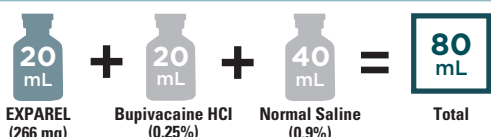
CASE INFORMATION

Physician Name	Allen Rosen, MD
Affiliation	Plastic Surgeon, The Plastic Surgery Group, PA, Montclair, NJ
Surgical Case Performed	Abdominoplasty
Inpatient or Outpatient Procedure	Outpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	59 years
Patient History and Characteristics	A patient with no significant past medical or surgical history presented with postpartum cosmetic abdominal wall contour irregularity, including rectus diastasis, fascial skin laxity, and dermatolipodystrophy

PROCEDURAL DETAILS

Incision Size	Curvilinear, extended Pfannenstiel (bikini line) incision: 45 cm
Preoperative Medications Used	IV cefazolin 1 g IV tranexamic acid 1 g
Intraoperative Medications Used	IV dexamethasone 1 g EXPAREL 80 mL expanded
Postoperative Medications Used	PO acetaminophen 500 mg PO diazepam 5 mg prn
Dose of EXPAREL and Total Volume Used	 <p>20 mL EXPAREL (266 mg) + 20 mL Bupivacaine HCl (0.25%) + 40 mL Normal Saline (0.9%) = 80 mL Total</p>

IV=intravenous; po=by mouth; prn=as needed.

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 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.

INFILTRATION NOTES

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

In this procedure, Dr Rosen determined a total volume of 80 mL would be needed to cover the surgical site. He admixed 20 mL of EXPAREL® (bupivacaine liposome injectable suspension) with 20 mL of 0.25% bupivacaine HCl and 40 mL of normal saline in a stainless steel basin before drawing into 10-mL aliquots (8 syringes). He used a 25-gauge, 1.5-cm needle on a 10-mL luer lock syringe with thumb plunger and finger rings to facilitate 1-handed aspiration and injection.



In cases that require a higher total volume, Dr Rosen may add normal saline to increase the total volume to 100 mL.

MARKED THE SURGICAL SITE FOR INFILTRATION

Dr Rosen used a surgical marker to mark the midline and paramedian lines on the abdominal wall. This vertical grid pattern served as a guide for Dr Rosen as he distributed the admixture to ensure complete and uniform analgesic coverage.

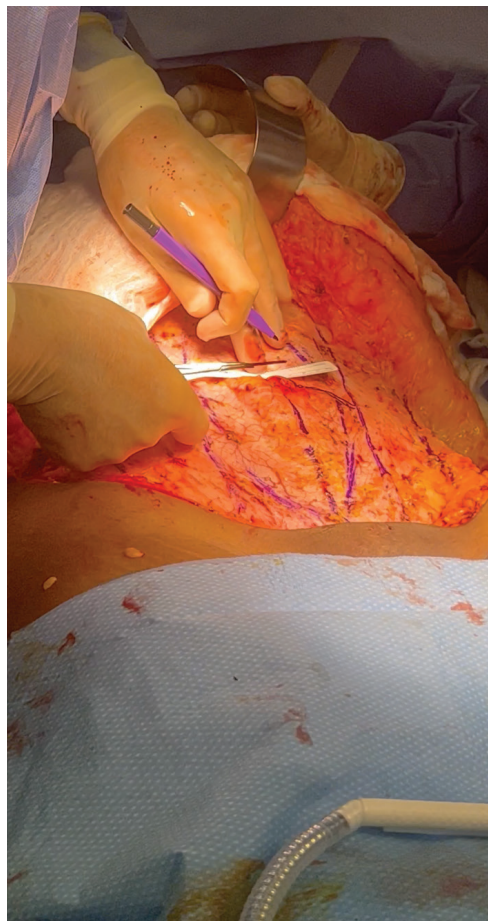


FIGURE 1. Marking the midline and 2 paramedian lines to guide infiltration.

INFILTRATION NOTES (cont)

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

Dr Rosen performed all cases with his physician assistant operating simultaneously. In the abdominoplasty procedure, the lower incision was made by the primary surgeon, then both operators used cautery to dissect down to the fascia, raising the flaps on their respective sides. The primary surgeon performed the fascial plication in 2 layers, and then EXPAREL was infiltrated by both surgeons simultaneously.

EXPAREL was infiltrated under the entire abdominal wall fascia from pubis to xiphoid and laterally to the lateral border of the external oblique muscles.



To ensure complete analgesic coverage of the surgical site, Dr Rosen assumed that 1 mg of expanded EXPAREL would be infiltrated into the abdominal wall fascia for every 2 cm of surgical incision.



FIGURE 2. Infiltration of EXPAREL under the abdominal wall fascia.

IMPORTANT SAFETY INFORMATION

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 Rosen is a paid consultant for Pacira BioSciences, Inc.

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