

Administration Case Report: Bilateral Temporomandibular Joint Arthroplasty

This case report represents the individual experience of Dr Gary F. Bouloux, and is intended to demonstrate his methodology for using EXPAREL in patients undergoing bilateral temporomandibular joint arthroplasty.

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.

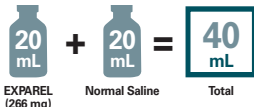
CASE INFORMATION

Physician Name	Gary F. Bouloux, MD, DDS, MDSc, FRACDS, FRACDS(OMS), FACS
Affiliation	Associate Professor of Surgery, Division of Oral and Maxillofacial Surgery, Emory University Chief of Oral and Maxillofacial Surgery, Director of Clinical Research, Grady Memorial Hospital
Surgical Case Performed	Bilateral temporomandibular joint arthroplasty with left disc plication and right discectomy with fat graft
Inpatient or Outpatient Procedure	Inpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	55 years
Patient History and Characteristics	Long-standing bilateral temporomandibular joint pain. Patient had tried conservative treatment for 12 months with little improvement in pain, and surgery was determined to be the best option at consultation
Pathology	Temporomandibular joint arthralgia with degenerative joint disease

PROCEDURAL DETAILS

Incision Size	40 mm
Preoperative Analgesics Used	5 mL 0.5% bupivacaine HCl with epinephrine
Intraoperative Analgesics Used	IV Toradol 12 mL 0.5% bupivacaine HCl with epinephrine to induce great auricular, auriculotemporal, and zygomaticotemporal nerve blocks 40 mL expanded EXPAREL for local infiltration
Dose of EXPAREL and Total Volume Used	 <p>The diagram illustrates the combination of two 20 mL vials. The first vial is labeled 'EXPAREL (266 mg)' and the second is labeled 'Normal Saline'. An equals sign follows, leading to a box labeled '40 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 the accompanying full Prescribing Information, which is also available at www.EXPAREL.com.

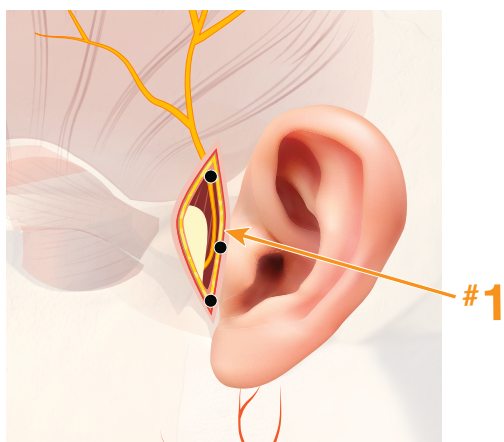
INFILTRATION NOTES

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

In this procedure, Dr Bouloux determined that he would need approximately 6 mL of 0.5% bupivacaine HCl with epinephrine for the nerve blocks and 20 mL of expanded EXPAREL® (bupivacaine liposome injectable suspension) for local infiltration around the preauricular incision on each side. Surgical sites with more incisions or larger incisions may require that EXPAREL be expanded with larger volumes of normal saline.

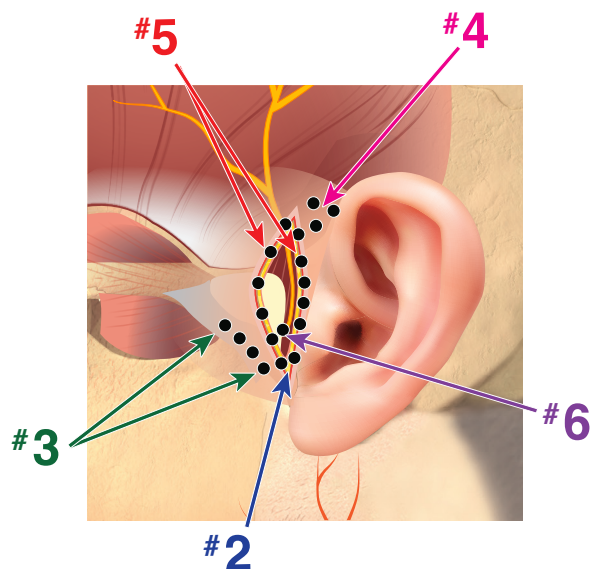
DIVIDED INJECTATE INTO SYRINGES WITH NEEDLE GAUGES APPROPRIATE FOR INFILTRATION (20- TO 25-GAUGE) AND PLANNED WHICH AREAS TO INFILTRATE WITH EACH INJECTION

For this procedure, Dr Bouloux drew the 12 mL of 0.5% bupivacaine HCl with epinephrine into a 20-mL syringe for the nerve blocks. He expanded 20 mL of EXPAREL with 20 mL of normal saline for a total volume of 40 mL and divided the EXPAREL injectate evenly into two 20-mL syringes using a 25-gauge needle. He then infiltrated as follows:



NERVE BLOCKS WITH BUPIVACAINE HCl

- **Step #1:** Great auricular, auriculotemporal, and zygomaticotemporal nerve blocks



LOCAL INFILTRATION WITH EXPAREL

- **Step #2:** Beneath the earlobe
- **Step #3:** Medial capsule and lateral pterygoid muscle
- **Step #4:** Temporalis muscle and auricle
- **Step #5:** Along anterior and posterior aspects of incision site
- **Step #6:** Behind condyle

INFILTRATION NOTES (cont)

■ Step #1:

3 mL of 0.5% bupivacaine HCl with epinephrine was injected into the great auricular nerve to provide anesthesia to the inferior aspect of the incision site.

2 mL of 0.5% bupivacaine HCl with epinephrine was injected behind the neck of the condyle into the auriculotemporal nerve.

1 mL of 0.5% bupivacaine HCl with epinephrine was injected into the zygomaticotemporal nerve as it exits medial to the zygomatic arch.



FIGURE 1. Great auricular, auriculotemporal, and zygomaticotemporal blocks

■ Step #2:

2 mL of expanded EXPAREL was infiltrated beneath the earlobe at a depth of 10 mm.



Utilize multiple overlapping injections and continue to inject as you withdraw the needle to ensure adequate analgesic coverage. Each injection should be approximately 1 mL.



FIGURE 2. Beneath the earlobe

■ Step #3:

4 mL of expanded EXPAREL was infiltrated into the medial capsule and lateral pterygoid muscle.



FIGURE 3. Medial capsule and lateral pterygoid muscle

■ Step #4:

3 mL of expanded EXPAREL was infiltrated into the belly of the temporalis muscle and into the auricle.



FIGURE 4. Temporalis muscle and auricle

■ Step #5:

10 mL of expanded EXPAREL was infiltrated along the anterior and posterior aspects of the incision at a depth of about 7 to 8 mm per injection.



When injecting along the incision, infiltrate parallel to the cut edge of tissue until there is visible swelling. This step may need to be repeated at a depth of 15 mm in the anterior aspect of the incision if the tissue is thick.

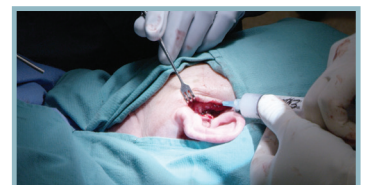


FIGURE 5. Along anterior and posterior aspects of incision site

■ Step #6:

1 mL of expanded EXPAREL was infiltrated posterior and medial to the mandibular condyle, 15 mm below the superior surface of the condyle.

Once completed, infiltration steps were repeated on the other side with the remaining 20 mL of expanded EXPAREL.

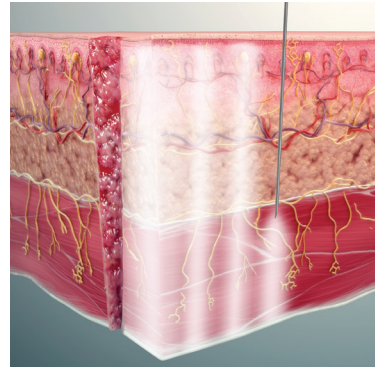


FIGURE 6. Behind condyle

INFILTRATION NOTES (cont)

PROPER TECHNIQUE IS CRUCIAL FOR ANALGESIC COVERAGE

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

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