

Administration Case Report: Posterior Spinal Fusion for Adolescent Idiopathic Scoliosis

This case report represents the individual experience of Dr Sundeep Tumber and is intended to demonstrate his methodology for using EXPAREL in patients undergoing posterior spinal instrumented fusion for adolescent idiopathic scoliosis.

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	Sundeep Tumber, DO
Affiliation	Chief, Department of Anesthesiology Shriners Hospitals for Children—Northern California Sacramento, CA
Surgical Case Performed	Posterior spinal fusion (PSF) for adolescent idiopathic scoliosis
Site of Care	Inpatient

PATIENT CHARACTERISTICS

Gender	Female
Age	16 years
Weight	50 kg
Patient History and Characteristics	Otherwise healthy 15-year-old female with a history of adolescent idiopathic scoliosis. Preoperative radiograph demonstrated a thoracic dextroscoliosis measuring 50 degrees from T5-L1 (see image on page 3).

PROCEDURAL DETAILS

Location of Incision	Posterior spinal incision, midline from T5-L2
Preoperative Analgesics Used	Oral acetaminophen 650 mg Scopolamine transdermal patch for prevention of nausea Carbohydrate drink the day before and the morning of surgery to help with postsurgical ileus
Patient/Parent Education Regarding Pain Management	Dr Tumber discussed the multimodal pain plan, including the plan for bilateral thoracic and lumbar ESP blocks for pain management. The plan for postsurgical pain management included Dr Tumber's standard scoliosis enhanced recovery after surgery (ERAS) protocol, which includes scheduled PO acetaminophen, IV ketorolac, and PO gabapentin. Opioids are only prescribed prn.
Needle Size, Number of Syringes	21-gauge, 90-mm echogenic Tuohy needle with extension tubing

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

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.

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

PROCEDURAL DETAILS

<p>Relevant Prep Instructions</p>	<p>Dr Tumber performed ESP blocks bilaterally at T5 and T12 (4 injections total). For each block a 20 mL syringe was used containing 15 mL of the local anesthetic solution (see below). The syringe was connected to a 3-way stopcock and a 10 mL syringe containing normal saline was attached. The saline was used to hydrolocate the ESP before injection of the local anesthetic solution. The block was performed prone, after induction of anesthesia and after the patient was positioned by the surgical team on the Jackson table and prior to incision.</p> <p>After induction and positioning, but before ESP block placement, baseline spinal neuromonitoring was performed and adequate somatosensory evoked potentials and motor evoked potentials were obtained. The neuromonitoring signals remained at baseline for the entire case, including after injection of the local anesthetic mixture.</p>
<p>Admix or administer EXPAREL[®] (bupivacaine liposome injectable suspension) separately</p>	<p>EXPAREL admixed with 0.25% bupivacaine HCl</p>
<p>Dosing and Administration</p>	<p>A total of four ESP blocks were performed (bilateral at T5 and T12)</p> <p>For each block, EXPAREL 13.3 mg/mL, 8 mL* of 0.25% bupivacaine HCl, and 3 mL of normal saline were admixed for a total volume of 15 mL for each block. 75 mcg of epinephrine (5 mcg/mL) was added as a vascular marker to each syringe.</p> <p>The total dose of EXPAREL 13.3 mg/mL administered was 15 mL, or 195 mg. This was under the recommended maximum dose of 4 mg/kg or 200 mg.</p> <p>The total dose of 0.25% bupivacaine HCl administered was 32 mL, or 80 mg. Maximum dose of 0.25% bupivacaine HCl that can be administered is 2 mg/kg or 100 mg.</p>
<p>Other Intraoperative Analgesics</p>	<p>Induction: 100 mg IV propofol, 200 mcg of IV remifentanyl, and 100 mg of IV ketamine</p> <p>Maintenance: TIVA with propofol (80-100 mcg/kg/min), remifentanyl (0.05-0.1 mcg/kg/min), and ketamine 5 mcg/kg/min</p> <p>Other: Before incision, a total of 250 mcg of fentanyl was administered. Before extubation, a total of 0.4 mg of IV hydromorphone, 30 mg of ketorolac, 750 mg of IV acetaminophen, and 16 mcg of IV dexmedetomidine were administered. The patient was extubated in the operating room and was immediately cooperative with a neurological exam.</p>

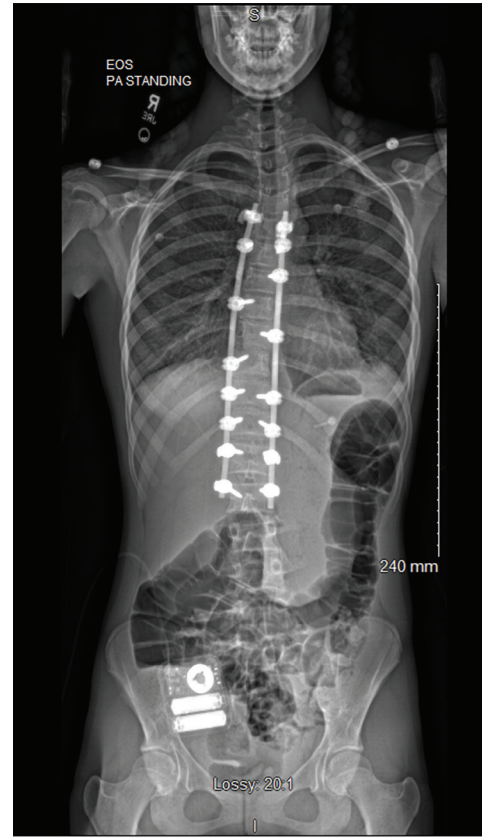
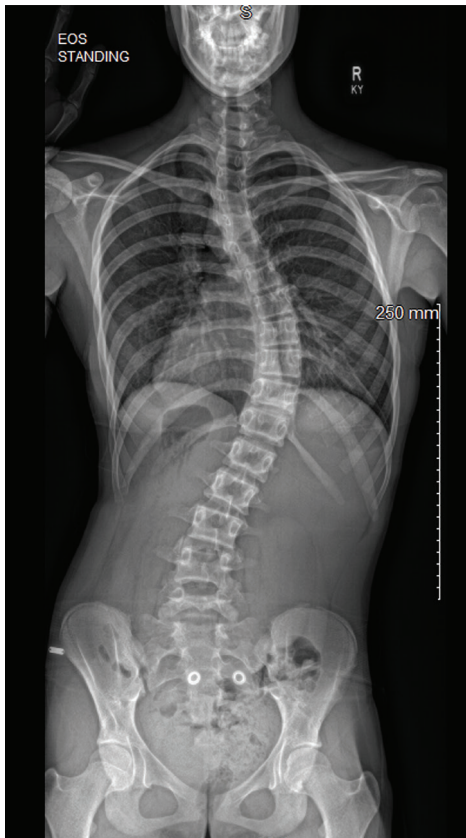
qhs=every night at bedtime; TIVA=total intravenous anesthesia.

*EXPAREL is available in 10 mL and 20 mL vials.

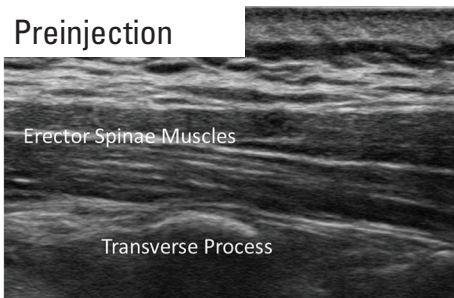
Bupivacaine HCl (which is approved for use in patients aged 12 and older) may be administered immediately before EXPAREL or admixed in the same syringe, as long as the ratio of the milligram dose of bupivacaine HCl to EXPAREL does not exceed 1:2. Admixing may impact the pharmacokinetic and/or physicochemical 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

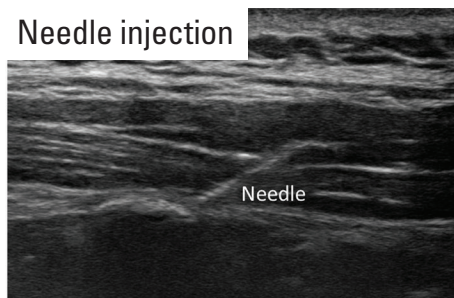
Presurgical and postsurgical radiographs



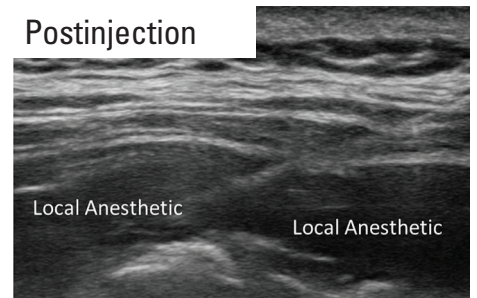
Preinjection



Needle injection



Postinjection



ESP Block Placement: With the patient in the prone position, Dr Tumber marked the top and bottom of the planned incision. After sterile prep and draping, bilateral ESP blocks were performed at T5 and T12. The Tuohy needle was advanced to the transverse process on each side. Hydrolocation with 2 to 3 mL of normal saline was done to ensure adequate spread and “lifting” of the erector spinae muscle group. Then the local anesthetic mixture was incrementally injected at each level. The 4 injections took a total of 10 minutes to perform. Epinephrine (5 mcg/mL) was added as a vascular marker and the operating room nurse continuously monitored heart rate, blood pressure, and the EKG for T-wave changes (earliest and most sensitive indicator of an intravascular injection).

EKG=electrocardiogram.

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

POSTSURGICAL INSTRUCTIONS INCLUDING PRESCRIPTIONS PROVIDED AND RECOVERY MILESTONES AND GOALS

- In the recovery room, the patient received 2 mg of IV diazepam. No additional opioids were administered and she did not complain of pain
- The patient remained comfortable throughout the evening on POD 0 and received no additional opioids
- She was placed on the standard multimodal postsurgical pain protocol consisting of:
 - Acetaminophen 650 PO Q6 as scheduled
 - Ketorolac 20 mg IV Q6 x 72 hours, then ibuprofen 400 mg PO Q6 as scheduled
 - Gabapentin 250 mg PO Q8 x 72 hours as scheduled
 - Diazepam prn for muscle spasms
 - Oxycodone PO prn for pain
 - Hydromorphone IV prn for severe pain

	Prn medications received		
	Oxycodone PO (mg)	Hydromorphone IV (mg)	Diazepam PO (mg)
POD #1	20	0	2
POD #2	17.5	0	6
POD #3	10	0	6

A patient-controlled analgesia was not prescribed.

- **Discharge instructions:** The patient tolerated physical therapy and was discharged home on POD #3. She was prescribed the following multimodal medications for pain and muscle spasms on discharge:
 - Acetaminophen 650 mg PO Q6 as scheduled
 - Ibuprofen 400 mg PO Q6 as scheduled
 - Gabapentin 100 mg PO TID as scheduled
 - Oxycodone 5 mg PO Q4 prn for pain
 - Diazepam 2 mg PO Q6 prn for muscle spasms

PATIENT FOLLOW-UP

According to the patient’s mother, the patient required about 3 doses of oxycodone for 2 days at home. She continued the acetaminophen, ibuprofen, and gabapentin for 1 week after discharge.

POD=postoperative day; Q4=once every 4 hours; Q6=once every 6 hours; Q8=once every 8 hours; TID=3 times a day.

IMPORTANT SAFETY INFORMATION

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 Sundeep Tumber 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.**