Osteoporosis is the most common ailment affecting the skeletal system. About 25-30% of all women over 60 years of age suffer from vertebral fractures due to the loss of bone density in osteoporosis.1 Some of the patients suffering from these fractures experience relief of their symptoms within weeks and can be managed with conservative care. In a subgroup however, the pain persists and along with deformity of the spine results in a reduction of function, quality of life, and increased mortality.2,3,4

Originally developed for the treatment of vertebral haemangioma by Deramond in 1987, percutaneous vertebroplasty has expanded to become a procedure for the treatment of recalcitrant pain caused by osteoporotic vertebral compression fractures in patients that failed conservative and medical treatment.5,6

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Vertebroplastic™ Cement V-MAX™ Mixing and Delivery System

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Originally developed for the treatment of vertebral haemangioma by Deramond in 1987, percutaneous vertebroplasty has expanded to become a procedure for the treatment of recalcitrant pain caused by osteoporotic vertebral compression fractures in patients that failed conservative and medical treatment.5,6
Today PMMA cements are commonly used to augment the vertebral body. These cements need to fulfil certain requirements to be suitable for vertebroplasty.

- Viscosity must allow injection through a cannula
- The cement must be workable for an extended period of time
- The cement must be radiopaque to allow visualisation under CT or fluoroscopic guidance

Injection of the cement usually takes place utilising syringes or dedicated application devices.

Even though the risks of this procedure are considered to be low, both Vertebroplastic™ Cement and the V-MAX™ Mixing and Delivery System were developed to simplify the procedure and reduce the risks commonly associated with vertebroplasty.
Vertebroplastic™ Cement

- Extended injection time of up to 10 minutes (from the start of mixing)
- Setting time: 14-20 minutes at 23°C, allowing the surgeon more time to complete the procedure
- A viscosity that allows injection through a narrow cannula using appropriate delivery methods*
- Pre-mixed with measured amounts of radiopaque agent (barium sulphate) for optimal radiological visualisation
- Low exothermic reaction with a peak temperature typically 21% less than other leading PMMA orthopaedic bone cements
- No pre-chilling required resulting in easier storage

* For complete instructions on the variables of cement mixing and injection please consult the Vertebroplastic™ instruction for use leaflet contained in the cement box.

V-MAX™ Mixing and Delivery System

- V-MAX™ Mixing and Delivery System is a disposable surgical procedure pack that allows both mixing and injecting from a single chamber thus minimising and simplifying the steps required to prepare the cement
- It is pre-packaged with two 11 gauge bone needles to carry out a single level percutaneous vertebroplasty procedure
- Contained mixing procedure reduces cement fumes to a minimum
- V-MAX™ Mixing and Delivery System gives complete dosage control, delivering a maximum of either 0.25 ml or 0.5 ml per pump (surgeon’s preference)
- V-MAX™ Mixing and Delivery System never delivers more than 0.5 ml per pump. Cement injection ceases immediately when manual pressure is released
Indications

The use of Vertebroplastic™ Cement and the V-MAX™ Mixing and Delivery System is indicated for filling defects of a vertebral body in patients with recalcitrant pain. This may be due to:

- Symptomatic osteoporotic compression fractures of the vertebral body
- Symptomatic vertebral angioma
- Symptomatic vertebral body tumours

Contraindications

The use of Vertebroplastic™ Cement and the V-MAX™ Mixing and Delivery System is contraindicated in:

- Cases of active or incompletely treated infection
- Patients with coagulopathy or inability to reverse anti-coagulant therapy for percutaneous vertebroplasty procedure and post-procedure (approximately 24 hours), or severe pulmonary insufficiency
- Acute compromise of the vertebral body or the walls of the pedicles
- Patients with sensitivity to any of the components of Vertebroplastic™ Cement material

Required Materials

- 1 Box of Vertebroplastic™ Cement (= 24-24.5 ml after mixing), Product Code 5900-01-000
- 1 V-MAX™ Mixing and Delivery System, Product Code 5900-02-000
- Skin prep
- Drapes
- Cotton gauze
- Suture for wound closure
- Small wound dressings for incision sites
- 1 sterile marker
- 1 mallet
- Local anaesthetic if no general anaesthesia is used
- Sterile saline
Needle Placement

The procedure is carried out under general anaesthesia or under local anaesthesia with additional pain medication. The patient is placed on a standard radiolucent operating table, leaving enough room under the table for a C-arm to be manoeuvred in two planes. The patient’s skin is prepped and draped.

The affected level is located using fluoroscopy and the corresponding pedicles are marked.

Following a skin incision, a Kirschner wire (2 mm diameter) is placed well within the pedicle.

Placement of the K-wire is verified in both planes.

The 11 gauge needle is placed over the K-wire and carefully advanced using a surgical mallet. Orient the bevelled tip of the needle to facilitate delivery of the cement in the desired direction, usually medially. Verify with fluoroscopy (or other appropriate imaging modality), the appropriate location of the needle. Remove the K-wire. Do not allow further penetration of the needle during the remainder of the procedure. Place all needles before initiating mixing of the cement.

Note: It is an advantage to use bi-planar fluoroscopy with two high resolution C-arms for vertebroplasty procedures.

Note: It is important to verify that the needle does not penetrate the medial pedicle wall.
Cement Preparation using the V-MAX™ Mixing and Delivery System

Retract the spring handle at the base of the mixing/delivery chamber and rotate the handle counter clockwise 90° to lock the chamber spring in the compressed position.

Open the liquid monomer vial and pour the entire contents into the mixing/delivery chamber.
Add the entire contents of the powder pack. Gently tap the funnel to ensure that all the powder enters the mixing/delivery chamber.

Unscrew the funnel and replace it with the mixing cap. Screw on the mixing cap until it is finger tight.
Shake the mixing chamber vigorously so that the ball bearing within repeatedly travels the full length of the chamber.

Once the ball bearing begins moving freely (indicated by a repeated audible “clack”), continue shaking for 30 seconds.

Place the mixing chamber on a sterile surface for 2 minutes (120 seconds) to allow the powder and liquid components to interact and reach proper consistency.
Shake the device vigorously again for 5 seconds before attaching the dispensing head. The audible “clacks” should not be heard due to the increased viscosity of the material at this stage. If “clacks” are heard, wait until the ball does not move freely prior to proceeding to the next step.

Unscrew the mixing cap and replace it with the dispensing head. Screw on the dispensing head until it is finger tight.

**Note:** It is important to follow these steps exactly. Inadequate mixing will result in uneven mixing of the components and potentially early cement setting.

**Note:** Never attempt to mix the cement with the dispensing head in place as this would result in a complete blockage of the system.
Grasp the mixing/delivery chamber by the grey base and retract the spring handle until it is free to rotate.

Then rotate the handle clockwise 90° to release the chamber spring and compress the cement.

With a firm and brisk activation of the delivery handle, eject 2 pumps of cement from the V-MAX™ Mixing and Delivery System.

Screw the winged end of the tubing onto the luer lock on the V-MAX™ Mixing and Delivery System until it is finger tight.

Note: The delivery handle should be retracted to allow air to escape when releasing the spring handle and compressing the cement.
Prime the V-MAX™ Mixing and Delivery System until the cement begins to appear at the end of the tubing (three full “pumps” of the device). Extrude about 1 ml of cement (2 pumps) and evaluate its consistency. Typically a toothpaste-like consistency is desirable. Keep a small portion of cement on the back table for later determination of cement setting time. Use a sterile gauze to carefully wipe the luer lock connector clean of any cement before connection to the needle.

The V-MAX™ Mixing and Delivery System typically delivers 0.5 ml cement with each full pump. Cement delivery stops immediately once depression of the handle is stopped. If there is a need to apply less than 0.5 ml of cement, this can be achieved in two ways:

1. By not depressing the handle the entire length of the delivery piston.
2. By adding a reduction clip to the delivery piston. Adding a reduction clip to the piston will reduce the amount of cement delivered to 0.25 ml.
To avoid injection of air, it is recommended that the needle is filled with sterile saline and the flexible tubing is filled along its entire length with cement before connecting the tubing to the needle.

Screw the other end of the tubing onto the luer lock of the needle until it is finger tight.
Cement Injection

Carefully begin pumping to inject cement into the vertebral body, constantly evaluating its distribution with bi-planar fluoroscopy or other appropriate imaging modalities. After cement appears in the vertebral body, each subsequent complete pumping motion of the handle will dispense 0.5 ml (or 0.25 ml if the reduction clip is in place) of cement into the vertebral body.

Slowly continue cement injection verifying distribution after each pump until the vertebral body is filled as required. Close attention needs to be paid to the posterior wall and the potential for cement extrusion into the spinal canal.

If cement extrusion is observed the injection must be stopped immediately to evaluate the clinical significance of the location of the leakage.

Never use excessive force when depressing the handle. If increased resistance is felt during injection, disconnect from the needle and use the stylet to push the cement out of the needle into the vertebra. Reconnect the V-MAX™ Mixing and Delivery System or use the contra-lateral needle to continue injection.

Note: Some surgeons recommend waiting several minutes in cases of non-critical cement leakage, as the cement inside the body sets faster due to the patient’s body temperature than the cement in a dispenser, thus blocking the site of leakage as the cement follows the path of least resistance. This should not be attempted when the leakage is in the direction of neural elements.
Surgical Technique

The graduations on the mixing chamber are approximate. To determine the actual amount of material delivered, count the total number of complete pumping motions after the material first appears within the vertebral body and multiply this number by 0.5 ml (or 0.25 ml respectively if the clip is used).

It may not be necessary to completely fill the vertebral body as finite element studies have demonstrated that 3-4 ml of PMMA cement will stiffen the vertebral body sufficiently.

The cement contained in the needles needs to be cleared using the stylet before the cement sets and the needle is removed. When assembling the stylet to the cannula, it is important that the stylet's length matches the cannula's length. For example when using a 13 cm needle, the 13 cm stylet must be used with the 13 cm cannula. The length designation can be found on the top of both the cannula and stylet.

The needles in the V-MAX™ Mixing and Delivery System set typically will hold approximately 0.5 ml of cement. This volume should be included in any calculation of the total amount of cement injected.

The patient may be transferred once the cement has set. Use the cement left on the back table to determine this time point.

Results

The goal of a vertebroplasty procedure is to relieve pain and to stabilise the vertebral body. Even though the mechanisms by which the pain is relieved are not clear to date, there are numerous reports on the efficacy and safety of the procedure. Significant and immediate pain reduction has been found in 80-90% of treated patients.

Complications

Even though the incidence of complications is considered to be low, the main complications reported are:

- Cement extrusion, particularly when the posterior wall is damaged or in tumorous lesions resulting in radiculopathy or dural compromise
- Pulmonary embolism through cement expression into the paraspinal veins

Furthermore, increased pain, rib fractures and infections have been reported in the literature. Adequate measures should be undertaken to reduce these complications. These include but are not limited to:

- Use of high resolution radiological equipment
- Slow and careful injection of the cement under constant fluoroscopic evaluation
- Use of highly radiopaque cement (e.g. Vertebroplastic™ Cement)
- Use of a delivery system that allows complete control over the amounts of cement injected (e.g. V-MAX™ Mixing and Delivery System)

It is recommended that vertebroplasty procedures are only carried out in settings equipped to manage these complications.
References:


