# Vertebral Augmentation with a Flexible Curved Needle: Preliminary Results in 17 Consecutive Patients

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**This report details a trial demonstrating the viability of a blunt-tipped curved needle for use as a cement injection device for vertebral body augmentation. Between January and September 2007, 17 consecutive patients (eight men and nine women; average age, 76 years; age range, 52–97 years) underwent vertebral body augmentation with a blunt-tipped curved nitinol injection needle via a single pedicle to treat pain due to acute vertebral body compression fractures. All patients were successfully treated without complication. The results of the trial demonstrate that a curved blunt-tipped nitinol needle is a viable alternative to a rigid injection cannula when performing vertebral body augmentation with cement.**

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**Abbreviations:** BCN = blunt-tipped curved needle, VAS = visual analog scale

PERCUTANEOUS augmentation of vertebral body compression fractures has been performed since the early 1980s (1). Until recently, this has been accomplished by using a rigid needle to inject cement. Commonly, the middle and anterior two-thirds of the vertebral body are targeted for augmentation. This is frequently accomplished by using a bipedicular technique (2). To achieve adequate cementing in complex fractures and clefts, a more targeted approach is sometimes necessary. Recently, a blunt-tipped curved needle (BCN) (AvaFlex; Cardinal Health, Dublin, Ohio) has been introduced. This device facilitates targeted cementing of lesions and/or multiple areas within the vertebral body by means of single cannula placement and a unipedicle approach. Herein, we report on our experience using the BCN with our first 17 consecutive patients in 18 treated levels from January to September 2007.

## MATERIALS AND METHODS

The institution's review board approved this prospective study. Informed consent was obtained, and all patients completed a pretreatment pain questionnaire.

The BCN was used in 17 consecutive patients referred for pain secondary to acute vertebral body compression fractures. Referring physicians requested the procedure after they determined that the patient failed maximal medical therapy, which included bed rest and oral or intravenous pain medicine. All patients referred for vertebroplasty became either unacceptably drowsy on opioid analgesics or were unable to ambulate and transfer from bed to chair without severe pain. Acute compression was defined as new or increased pain with magnetic resonance (MR) imaging demonstrating vertebral body height loss and marrow edema. In patients in whom MR imaging was not feasable (pacemaker or claustrophobia), comparison with current spine computed tomographic (CT) scans to prior plain radiographs demonstrating vertebral body height loss coincident with pain symptoms and a supporting bone scan was used to confirm an acute compression fracture. A unilateral pedicle approach was used in all patients. The senior author performed all procedures.

### Patient Demographics

There were eight men and nine women. Fifteen patients had osteoporosis-related compression fractures and two had malignancy-related compression fractures. The average patient age was 76 years (range, 52–97 years). Eighteen levels were treated, 90% of which were lumbar. The remaining levels were thoracic (**Table**). The preprocedure pain, as determined with a visual analog scale (VAS) (3), was rated as 8.8 (range, 8–10) (**Fig 1**).

### Device/Cement

A blunt-tipped flexible curved nitinol needle was used in all patients (**Fig 2**).

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**Summary of Patient Demographics**

| Patient No./Sex/Age (y) | Diagnosis | Level | Follow-up |
|---|---|---|---|
| 1/M/52 | Osteoporosis | L3 | 1 y |
| 2/M/59 | Lung cancer | L2 | 20 wk |
| 3/F/60 | Osteoporosis | L4 | 12 wk |
| 4/M/61 | Osteoporosis | T10 | 30 wk |
| 5/M/66 | Myeloma | L3 | 12 wk |
| 6/F/69 | Osteoporosis | L4 | 40 wk |
| 7/F/73 | Osteoporosis | L3/L2 | 1 y |
| 8/F/79 | Osteoporosis | L3 | 40 wk |
| 9/F/79 | Osteoporosis | L1 | 16 wk |
| 10/F/80 | Osteoporosis | L1 | 24 wk |
| 11/M/80 | Osteoporosis | L5 | 14 wk |
| 12/F/81 | Osteoporosis | T8 | 24 wk |
| 13/F/87 | Osteoporosis | L2 | 24 wk |
| 14/M/89 | Osteoporosis | L5 | 14 wk |
| 15/M/91 | Osteoporosis | L2 | 12 wk |
| 16/M/91 | Osteoporosis | L2 | 12 wk |
| 17/F/97 | Osteoporosis | L3 | 30 wk |

The needle's outer diameter is 0.077 inch (12–13 gauge), and the inner diameter is 0.062 inch. The needle is 19 cm long (7 cm longer than the delivery cannula). It straightens to pass through an 11-gauge rigid delivery cannula and regains its 95° curve as its tip exits the end of the outer cannula. Radiopaque cement (Avamax; Cardinal Health) was mixed for 3 minutes, according to provided instructions, and injected through a side hole near the blunt tip of the delivery needle. An arrow located on the needle handle allows directional control of the curved needle.

Conscious sedation and continuous vital sign monitoring were provided by nurses. A radiology suite equipped with a BV3000 Integris Biplane unit (Philips, Bothell, Washington) was used to visualize the needle and vertebra. An 11-gauge rigid hollow cannula was placed by using a standard transpedicular approach (2). The pedicle chosen to access the vertebral body was picked on the basis of the visibility of its cortical boundry on the anteroposterior flouroscopic image rather than the laterality of the fracture at proprocedure imaging. The outer delivery cannula was targeted by using a standard technique modified to place the tip in the posterior one-third (instead of the mid- to anterior third) of the vertebral body, thus allowing the safe insertion of the BCN through the hollow cannula.

Cement was injected to achieve adequate and safe filling (2). Ideal preprocedure cement placement parameters included targeting areas of edema, fracture, or fluid/air cleft on MR images or CT scans and end-to-end, top-to-bottom cement filling of the anterior third of the vertebral body. The procedure was stopped if there was basivertebral or paraspinal venous filling, cement approaching the posterior third of the vertebral body, cement entering disk space, or the ideal preprocedure criteria were met. After the 3 minute recommended mixing time, the cement was allowed to set for an additional 5 minutes to achieve a "toothpaste" consistency.

### Targeting

The BCN is inserted and directed by using the arrow on the handle to target the contralateral aspect of the vertebral body (relative to the pedicle chosen for insertion). The needle tip can be directed in a 360° plane. Care must be taken to avoid inserting too far along an incorrect path a few degrees off from the intended path in the vertebral body, as the needle tends to follow the first path created. Superior or inferior targeting is completely controlled by the operator and accomplished by a few degrees turn of the handle while the BCN tip is within the outer cannula. The BCN is inserted by using intermittent flouroscopy as with a standard rigid needle (**Fig 3**).

Contralateral vertebral body cementing was accomplished in all patients. Ipsilateral filling required withdrawing the BCN to bring the side hole to the required location. Ipsilateral superior and inferior targeting was accomplished by withdrawing the BCN into the delivery cannula and turning the handle before reinsertion (**Fig 4**).

### Follow-up

All patients were followed up with office visits and telephone interviews thereafter. This was performed at a minimum of 1 and 3 months. Interviews addressed patient pain perception as reported on the VAS. Pain medicine requirements were also reported. Patient self-reported activity level was monitored. The ability to ambulate, assistance required, and the ability to perform activities of daily living was discussed.

## RESULTS

There were no complications or technical failures. Cement volume was between 2 and 8 cc for each level. Average procedure time (measured from initial local anesthetic skin injection to the removal of the cannula) was 28 minutes (range, 14–47 minutes). The two-level procedure was completed in 33 minutes.

There was no instance of clinically significant cement leak or embolus. Four cases demonstrated one of the following: minor paraspinal vein filling, minor disk space filling, or cement approaching the posterior third of the vertebral body. In these cases, the BCN was retargeted, allowing complete treatment as defined earlier. All procedures resulted in side-to-side filling of the anterior third of the vertebral body.

All patients except one (patient 2) obtained pain relief following recovery from procedure-related sedation (immediate VAS score). The patients' VAS scores were recorded after recovery for a minimum of 4 hours before discharge from an ambulatory surgery unit or were evaluated the following morning if admitted for pain control before the procedure. With a signed rank test, the reported pain using the immediate VAS was significantly less after augmentation than before treatment (**Fig 1**) (average VAS score before treatment, 8.7 [range, 5–10]; average VAS score after treatment, 2.7 [range, 0–10]; $P < .0001$). In general, the female patients were older than the male patients (76 vs 73 years) and