

Case Series: SpineAssist Miniature Robotic Guidance in Treatment of Spinal Compression Fractures

B. Silberstein, MD ^{*1}, R. Dietl, MD ^{*2}, Y. Barzilay, MD ^{*3}

¹ Carmel Medical Center, Haifa, Israel; ² Klinikum Muenchen, Munich, Germany; ³ Hadassah Medical Center, Jerusalem, Israel;

GENERAL: 34 patients with spinal compression fracture pathologies were treated with cement injection into the fractured vertebral bodies. Various injection systems were utilized; Mazor SpineAssist – a novel bone-mounted, miniature robotic guidance system - was used for planning a trajectory and guiding the injection devices into the vertebral bodies in all cases.

BACKGROUND CONTEXT: About 500,000 Americans suffer from vertebral compression fracture. These fractures are characterized by a loss of height in the anterior posterior or central region of the vertebral body.

Modified techniques are being developed and introduced regarding cement augmentation of the vertebrae; some are focused on developing new cement compounds while others focus on the injection technique. The cement is injected percutaneously, under pressure, typically utilizing transpedicular or similar approach. Traditionally, positioning the surgical tools and targeting the fracture area percutaneously requires high precision and intensive utilization of fluoroscopy. A robotically-assisted technique is introduced which enhances accuracy and precision while significantly reducing the need for fluoroscopy in positioning the tools.

PURPOSE: To evaluate the feasibility and accuracy of a cement injection into fractured vertebral bodies using miniature robotic guidance for the placement of the needle, and to evaluate the exposure to X-Ray radiation per each injection of cement.

STUDY SETTING: Retrospective, multi-center, case series.

PATIENT SAMPLE: 34 patients (5 male, 29 female, ages 48-94) underwent one-level to five-level cement augmentation, using a minimally invasive approach in most cases (28 cases) and a less-invasive (LIS) approach in the rest (6 cases). A certain midline exposure was used as part of a more complex procedure. Patients were treated with various commercially-available cement augmentation systems including Vertebroplasty (4 cases), Kyphoplasty (28), Spineoplasty (1 case) and STAXX (1 case).

METHODS Pre-operatively, the desired positions of the screws were mapped on a 3-D computer model of the patient's spine, based on a CT scan and created by the robotic-system software. Intra-operatively, two fluoroscopic images (anterior-posterior and oblique) with targeting devices were taken and automatically coupled with the CT data per vertebra. The miniature robotic

device was then attached to a proprietary platform mounted onto the patient's bony anatomy. The device then directed the surgeon in accurately introducing the injection needle at the designated entry points and trajectories according to the preoperative plan. Accuracy of placements was assessed by means of lateral and anterior-posterior fluoroscopic images during & at the conclusion of instrumentation and compared to the pre-operative plan.

RESULTS: 63 cement augmentation trajectories were planned, 55 were executed (87.3%). The cement injection trajectories which were not executed were aborted due to unmatched Fluoro-to-CT images or poor CT quality (6 trajectories), operator mistake (1 trajectory), and mechanical failure (1 trajectory). Of the 55 executed cement injections, 54 were accurately placed in perfect alignment with the preoperative plan. A single deviation of 2mm inferiorly relative to planning occurred due to breathing movements of the patient. No breaching of the pedicle was identified and cement was injected successfully.

X-Ray radiation timing measurement was read from the C-Arms post-operation for 47 cement injections. The average exposure time for single needle placement with SpineAssist was 16 seconds; total average single procedure (needle placement and cement injection) is 26.8 seconds.

CONCLUSIONS: Robotic-assisted treatment of spinal compression fractures is feasible and beneficial. The SpineAssist yielded highly accurate placements with minimal use of fluoroscopic imaging, hence improving clinical outcomes while reducing radiation exposure to the surgeon and team. Moreover, the pre-operative planning software allowed the surgeons to determinate the trajectory for the cement injection in a way that ensured no breaching of the pedicle (when relevant) and accurate targeting of the cement injection site in the vertebral body. In several cases it was possible to plan a trajectory such that the fracture was treated with a single, unilateral access rather than the traditional bi-lateral approach. This in turn saved OR time and reduced the use of fluoroscopy even further.

SpineAssist miniature robotic guidance is highly adapted for working with a variety of cement augmentation systems, utilizing a variety of approaches. These results verify the system's accuracy and support its use for treatment of spinal compression fractures with vertebral augmentation techniques.

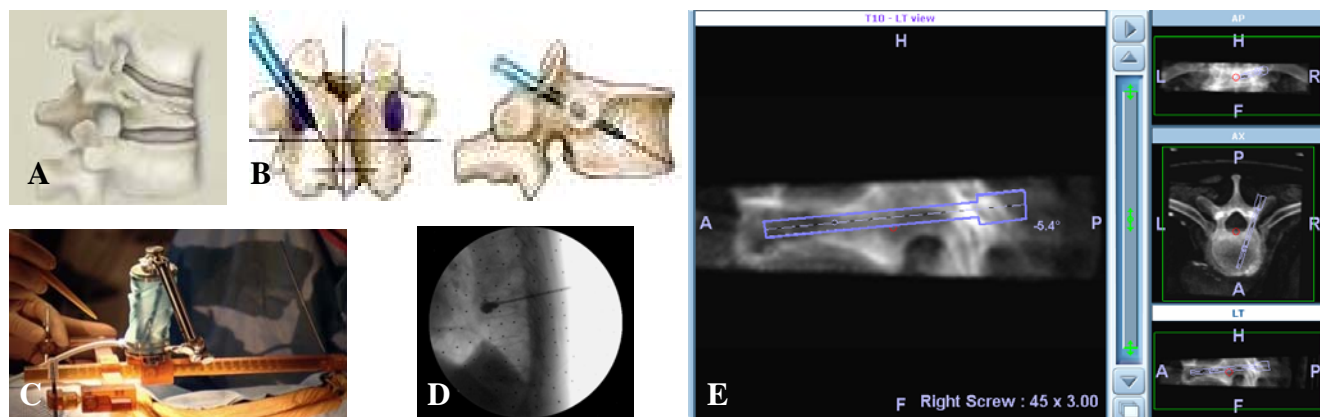


Figure: (A) Vertebral compression fracture. (B) Cement augmentation injection. (C) The Hover-T frame anchored to the patient's bony anatomy via three small incisions. (D) Fluoro image, showing injection needle and cement in a vertebral body. (E) Planning for cement injection