



Composite time-lapse computed tomography and micro finite element simulations: A new imaging approach for characterizing cement flows and mechanical benefits of vertebroplasty



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ABSTRACT

Vertebroplasty has been shown to reinforce weak vertebral bodies and reduce fracture risks, yet cement leakage is a major problem that can cause severe complications. Since cement flow is nearly impossible to control during surgery, small volumes of cement are injected, but then mechanical benefits might be limited. A better understanding of cement flows within bone structure is required to further optimize vertebroplasty and bone augmentation in general. We developed a novel imaging method, composite time-lapse CT, to characterize cement flow during injection.

In brief, composite-resolution time-lapse CT exploits the qualities of microCT and clinical CT. The method consists in overlaying low-resolution time-lapse CT scans acquired during injection onto pre-operative high-resolution microCT scans, generating composite-resolution time-lapse CT series of cement flow within bone.

In this *in vitro* study, composite-resolution time-lapse CT was applied to eight intact and five artificially fractured cadaveric vertebrae during vertebroplasty. The time-lapse scans were acquired at one-milliliter cement injection steps until a total of 10 ml cement was injected. The composite-resolution series were then converted into micro finite element models to compute strains distribution under virtual axial loading. Relocation of strain energy density within bone structure was observed throughout the progression of the procedure. Interestingly, the normalized effect of cement injection on the overall stiffness of the vertebrae was similar between intact and fractured specimens, although at different orders of magnitude.

In conclusion, composite time-lapse CT can picture cement flows during bone augmentation. The composite images can also be easily converted into finite element models to compute virtual strain distributions under loading at every step of an injection, providing deeper understanding on the biomechanics of vertebroplasty.

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1. Introduction

Percutaneous vertebroplasty consists of injecting a cement, usually a derivate of Polymethylmethacrylate (PMMA), into a vertebral body through one or two percutaneous cannula [1–6]. Percutaneous vertebroplasty was first described by Galibert in 1987 [3,7] and since then has become the method of choice to stabilize vertebral compressions. The incidence of vertebroplasty is estimated at 2/100,000 person years [8–10], while the incidence of vertebral compression fractures is estimated at 22/100,000 person years in the population,

up to 150/100,000 in elderly women [3,9,10]. In 80 to 90% of the patients, pain and disability disappear immediately after the procedure [1,3–7,11]. The same technique is also used to reinforce weak vertebral bodies and reduce fracture risks.

The major risk associated with percutaneous vertebroplasty is cement leakage [1–6]. The incidence of cement leakage is estimated around 20% [3,7], but data vary widely between 3% [8–10] and 65% of the cases [3,9,10] depending on the context. While most leakages are asymptomatic, serious complications can arise in some cases, such as nerve root compression, spinal cord compression or even pulmonary embolisms [1,3–7,11].

Balloon kyphoplasty is an alternate procedure, where an inflatable tamps is inflated within the vertebrae until the vertebrae reaches its normal size. The cavity is then filled with cement at low pressure. There is still debate over whether vertebroplasty or kyphoplasty is superior and clinical trials have failed to show a significant

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difference in functional improvement between these two interventions, also reporting similar risks for subsequent fracture and cement leakage [12].

To prevent leakages in percutaneous vertebroplasty, operating guidelines suggest using jet lavage and injecting small amounts of cement [7,11,13]. Jet lavage consists of forcing phosphate buffered saline (PBS) through the cannula to flush away the bone marrow and fat. It creates an easy-flow route for the cement injection, which permits more regular cement distributions [1,2,14]. Similarly, more viscous cements were shown to generate more uniform distributions [7,15,16]. Besides these general guidelines, vertebroplasty is frequently performed under live fluoroscopy. This also favors leakage prevention, as it gives a real-time 2D visualization of the cement distribution and the injection can be stopped if an abnormality is detected [7,8].

The downside of reducing cement volume or stopping the injection preventively is that no mechanical benefit may be obtained. Indeed, using finite element models, it was shown that to obtain a mechanical benefit in stiffness or strength, endplate to endplate cement contact should be ensured [5], which is the case with a cement volume greater than approximately 25% of the cancellous bone volume [17]. Only then most of the mechanical load is borne by cement and not anymore by the bone structure [18].

In summary, for optimum percutaneous vertebroplasty, the injected cement should not leak, but enough cement should be injected to have it in contact with both endplates. Unfortunately, cement flow is difficult to control as it depends on the injection point, bone microstructure and macrostructure. A better understanding of cement flow in bone requires new tools to characterize it in four-dimensions considering both space and time. We propose here a novel method, combining microCT and time-lapse clinical CT scans to generate series of composite scans that reveal the penetration of cement within bone over time.

In this paper we describe composite time-lapse CT imaging, using a sample of thirteen human cadaveric vertebrae undergoing vertebroplasty. We also illustrate the potential use of composite time-lapse CT series by converting the composite scans into micro finite element (microFE) models to evaluate the mechanical benefits for the vertebrae at each step of the vertebroplasty procedure.

2. Materials and methods

In brief, the composite-resolution time-lapse CT method consists in overlaying low-resolution time-lapse CT scans acquired during cement injection onto pre-operative high-resolution microCT scans to generate a composite-resolution time-lapse CT series of cement flows. Here, time-lapse scans were acquired after each milliliter of cement injection. The composite-resolution series were then converted into micro finite element models to compute strains distribution under virtual loading.

2.1. Specimens

Thirteen fresh-frozen human cadaveric vertebrae (6 thoracic, position 9–12; 7 lumbar, positions 1–4) from seven different donors (age 69 ± 11 years, 4 males and 3 females) were dissected from full cadaveric spines. The vertebrae were thawed 24 h at room (20 °C) temperature before soft tissue and all processes were removed to enable proper testing. Only vertebral bodies and pedicles were preserved. Eight vertebrae were processed intact and five fractured to mimic compression fractures prior to the injections. The donations were received via an ethically approved process (Platinum Training, Dallas, TX, USA).

2.2. Compression fracture creation

Five vertebrae were fractured prior to vertebroplasty by axial compression in stroke control [19,20]. To ensure even loading, the endplates were embedded with a thermoset polymer (SCS-Beracryl D 28, W. Troller AG, Fuluibach, Switzerland), with 1:2 of hardener in the mixture to have parallel polymer surfaces. The embedded vertebrae were installed and preloaded with 5 N in a biaxial servo hydraulic testing machine, (MTS Mini Bionix II 858, MTS Systems Corp., Eden Prairie, MN, USA) with a 4 kN load cell (Huppert 6, Huppert GmbH, Herrenberg, Germany). A gimbal joint was used in the compression setup to ensure homogeneous load distribution. A displacement of 5 mm/min was applied until compression fracture occurred. Machine data were recorded at 100 Hz and axial stiffness was obtained by linear regression in the elastic part of the load–displacement curve. The data was used to validate finite element modeling.

2.3. Specimens preparation for vertebroplasty

All vertebrae were prepared for transpedicular vertebroplasty by an experienced surgeon using Vertecem V+ System (DePuy Synthes, Solothurn, Switzerland) with the application of the *direct access technique* as described in the manufacturer's technique guide. An 8-gauge trocar-enclosing needle was inserted into each pedicle. Proper placement of the needle was verified radiographically prior to lavage. The specimens were irrigated with 100 ml Ringer solution using a standard 10 ml syringe through one pedicle. The solution and debris were collected simultaneously with a similar syringe from the other pedicle.

2.4. Micro computed tomography

After preparation, the vertebrae were scanned using a High-Resolution peripheral Quantitative Computed Tomography scanner (HRpQCT, XtremeCT, Scanco Medical AG, Brüttisellen, Switzerland) operated at 59.4 kVp and 900 μ A, 750 projections, 200 ms acquisition time with 126 mm field of view. The slices were reconstructed across an image matrix size of 1536×1536 voxels, with a nominal voxel size of 82 μ m.

2.5. Time-lapse computed tomography

The vertebrae were mounted in the clinical CT bore (SOMATOM Emotion 6, Siemens AG, Forchheim, Germany) on a custom-made carbon holder to be injected with bone cement (Vertecem V+ Cement Kit, Ref. 07.702.016S, DePuy Synthes, Solothurn, Switzerland). This cement contains 40% of zirconium dioxide as contrast agent and 15% hydroxyapatite for a total of 55% ceramic components and 45% PMMA. It was chosen because it remains easily injectable throughout the experiment, with a viscosity at room temperature that does not exceed 250 Pa·s for 20 min following mixing [21]. Cement mixing and injection through the pedicle were performed following the manufacturer's instructions and application kit, except for a generic self-machined PEEK cannula to allow artifact-free CT scanning. The cement was injected using a syringe driver (Model '44', Harvard Apparatus Inc., Holliston, MA, USA) set at 1 ml/min. After each milliliter of injection, a helical CT scan of the vertebrae was acquired at 110 kV tube voltage, 130 mA tube current, with a planar resolution of 0.63 mm, slice thickness and separation of 0.5 mm, and pitch of 1 mm. The CT images were then reconstructed with the manufacturer's reconstruction filter H70S in series of 512×512 matrix. The acquisition time was approximately 1 min long. The protocol was repeated for 18 min to ensure constant viscoelastic properties of the cement throughout the experiment. After the last injection, the vertebrae were microCT scanned again to verify if their shape had changed during augmentation, then stored at -20 °C.

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