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Bone cement flow analysis by stepwise injection through medical cannulas

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ABSTRACT

Cement leakage is a serious adverse event potentially occurring during vertebroplasty. Pre-operative in-silico planning of the cement filling process can help reducing complication rates related to leakage. This requires a better understanding of the cement flow along the whole injection path. Therefore, the aim of the present study was to analyze bone cement flow behavior by stepwise injections through medical cannulas.

Sixteen cannulas were assigned to four groups for stepwise injection of differently colored cement portions of 1 ml volume. Each group differed in the amount of injected cement portions with a range of 1–4 ml. After cement curing longitudinal cross-sections of the cannulas were performed and high-resolution pictures taken. Based on these pictures, quadratic polynomial interpolation was applied to the marked intersections between the last two injected cement portions to calculate the leading coefficients.

Leading coefficients in the groups with three cement portions (0.287 ± 0.078), four portions (0.243 ± 0.041) and two portions (0.232 ± 0.050) were comparable and significantly higher than the group with one cement portion (0.0032 ± 0.0004), $p \leq 0.016$. Based on these findings, cement flow through medical cannulas can be considered as predictable and can therefore be excluded as a source of risk for possible cement leakage complications during vertebroplasty procedures.

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1. Introduction

Vertebroplasty is an established standard procedure for treatment of osteoporotic vertebral compression fractures. With this minimally invasive surgical technique the affected vertebral bodies are augmented by percutaneous injections of bone cement through cannulas with the main goals to increase mechanical resistance of the former and alleviate pain [1–3]. Besides these advantages, the application of bone cement is related to some risks for the patient. With an occurrence of up to 67% the main hazard of this procedure is leakage of bone cement or bone marrow into the surrounding venous system [4–7]. This could lead to life-threatening pulmonary embolism. Moreover, cement leakage can cause spinal cord and nerve root compression [4,5,8]. In the worst case scenario the procedure could lead to paraplegia or even to death [9].

The risks of leakage are influenced by bone cement injection biomechanics, which itself is affected by some distinct parameters, such as cement viscosity, injection volume and speed,

grade of osteoporosis, type of fracture and eventually existence of tumor tissue [4,10,11]. To reduce these risks, one should develop a tool that enables the surgeon to pre-operatively define an optimal patient-specific cement distribution. Such a tool would be highly beneficial, because it would reduce the complication rates and help avoiding incomplete fillings. However, its development requires a better understanding of the cement flow during injection procedures. There are numerous studies addressing bone cement distribution in open porous media [4,10,12–14]. On the other hand, the process of cement flow distribution through medical cannulas has not been investigated yet.

Therefore, the aim of the current study was to examine the bone cement flow behavior through medical cannulas during a simulated stepwise vertebroplasty procedure.

2. Methods

2.1. Study groups

Sixteen 8-gauge cannulas with length 150 mm (Unimed S. A., Lausanne, Switzerland) were assigned to four study groups (1–4)

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Table 1

Test series with color assignment to each cement portion and indication of totally injected cement volume in the study groups.

Injected cement	Group 1	Group 2	Group 3	Group 4
First portion	Green	Green	Green	Green
Second portion	–	Red	Red	Red
Third portion	–	–	Yellow	Yellow
Fourth portion	–	–	–	Blue
Total volume	1 ml	2 ml	3 ml	4 ml

with four cannulas each ($n = 4$, Cannula 1–4) for a stepwise injection of differently colored 1 ml cement portions. The groups differed in the number of injected cement portions and the volume of totally injected bone cement as shown in Table 1.

2.2. Cement preparation

Bone cement with composition described by Deusser et al. [15] was used in the current study. This cement is applicable within 20 ± 1 min (mean \pm standard deviation) post mixing at $18\text{--}26^\circ\text{C}$ ambient temperature. It completely cures after 27 ± 2 min. The hardening time decreases significantly to $43\text{--}74\%$ at 37°C body temperature [15].

All cement portions were prepared with a total volume of 10 ml applying a uniform manual mixing procedure under the same conditions. Five mg acrylic powder (Kremer Pigmente GmbH & Co KG, Aichstetten, Germany) was used for single-color coloration. The powder was utilized in the intense colors red (#23,180), yellow (#23,310) and blue (#23,050). In addition, green acrylic powder was assembled by mixing yellow and blue powders at a 10:1 mixture ratio. The powder and the liquid component of all cement portions assigned to the same specimen were simultaneously mixed in a separate beaker for twenty seconds, assuring the same start of polymerization for all portions. Each bone cement portion was filled in a separate 1 ml syringe (Vertecem V+ Syringe Kit, DePuy Synthes, Zuchwil, Switzerland). In addition, 3 ml cement with the same color as assigned for the last respective specimen portion was used for viscosity measurements.

2.3. Test setup

The pre-filled syringes were attached to the proximal end of the cannulas. A material testing machine (Instron 5866, Instron, Norwood, USA) equipped with a 1 kN load cell was used with a custom-made holder to inject the cement portions into cannulas (Fig. 1). The distal end of each cannula was immersed 90 mm deep into a 37°C thermostatic bath (Y6, Grant Instruments Ltd, Shepreth, UK). A rounded headless pin was attached to the machine actuator with the load cell for central load transmission to the syringe plungers.

2.4. Test protocol

The parameters for injection of one milliliter bone cement were adopted from previous measurements by Gisep and Boger [16]. Two test protocols were set in the operating software of the testing machine for this purpose. The first one featured a constant cross-head speed of 43.2 mm/min for a path of 27.0 mm , equaling a volume flow of 0.75 ml/min . The second test protocol assured holding of the machine actuator for 10 s to mimic a break for radiographical assessment.

The first injection step started 140 s after the beginning of cement polymerization. Cement injection in all groups excluding group 1 was performed with replacement of the syringe after each

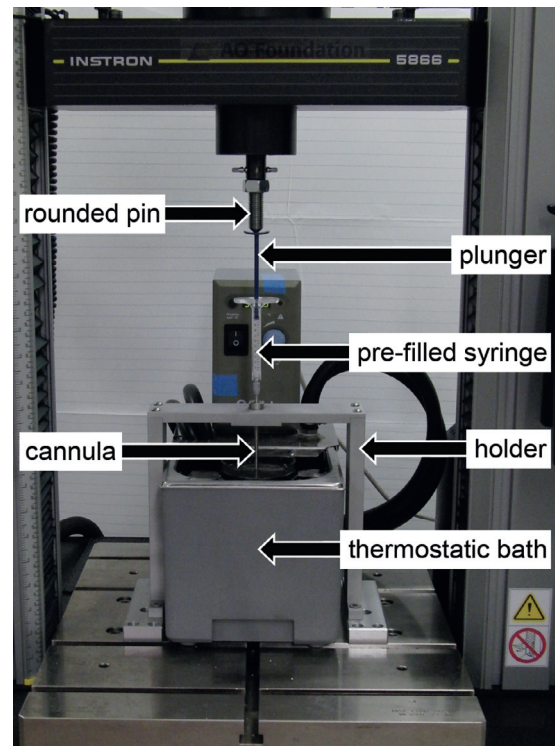


Fig. 1. Test setup with pre-filled syringe mounted for injection.

1 ml step with a pre-filled one for the subsequent step. The injection steps were repeated until the last cement portion was injected. Each injection step consisted of 0.5 ml cement injection, followed by 10 s pause and then repeated injection of the remaining 0.5 ml cement. The test protocols described above were utilized for this purpose. The 10 s break for radiographical assessment in the middle of each step was performed to better mimic the clinical practice for cement leakage assessment.

Continuous viscosity measurement of the bone cement related to the respective specimen was conducted as described by Deusser et al. [15], using a rheometer (VISCOSAFE Viscometer, DePuy Synthes, Switzerland). Each measurement started simultaneously with the start of the first step and continued until the end of the injection procedure.

2.5. Post-processing

After curing of the injected bone cement, the cannulas were cross-sectioned longitudinally along their midplane using a milling machine (Aciera F3 Precision Universal Miller, Aciera, Le Locle, Switzerland). High-resolution images of the cross-sections were taken under a microscope (AxioCam HRC; Carl Zeiss Microscopy GmbH, Jena, Germany) with image processing software (AxioVision, v. 4.8.2, Carl Zeiss Microscopy GmbH, Jena, Germany) at a resolution of $6.79 \cdot 10^{-3}\text{ mm/pixel}$.

2.6. Data acquisition and evaluation

Machine data in terms of time (s), cross-head displacement (mm) and injection force (N) were acquired from the machine actuator and the load cell at a rate of 20 Hz. Viscosity measurements included recording of time (s) after the start of polymerization and dynamic viscosity η (Pas) at a rate of 1.3 Hz. In addition, peak injection force (N) of the last injected cement portion was determined for each specimen separately together with the corresponding time point of the peak. The dynamic viscosity of each specimen

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