

# HIGH CEMENT VISCOSITY REDUCES LEAKAGE RISK IN VERTEBROPLASTY

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**Introduction:** Individuals suffering of low back pain due to osteoporotic fractures and metastatic disease have been treated successfully with transpedicular vertebroplasty. However successful the procedure currently is at relieving pain, the risk of bone cement (PMMA) leakage is a common occurrence. Extravasation of PMMA can lead to pulmonary cement and fat embolisms, nerve root compression as well as spinal cord compression sometimes even requiring revision surgery.

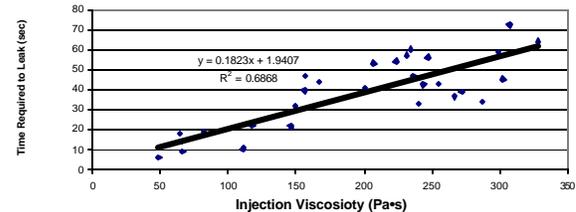
To study the leakage phenomena in cadaveric experiments would require a large sample size due to the variability with living tissue and adding in the limited accessibility to human tissue results in a costly study. Consequently, the possibility of developing and implementing a physical model may be of interest. Such a model proposed by Bohner et al (2003) accompanied a theoretical model and together attempted to characterize the parameters most influencing cement leakage. The model showed that viscosity plays a major role upon the leakage of cement with higher viscosities of cement reducing the risk of extravasation. However, no quantitative values were given for a safe viscosity. In addition, this model does not indicate if the leakage occurs early or later on in the procedure, which Yeom et al (2002) found to be important. Cement leaking through perforating blood vessels, as apposed to cortical shell defects, occurred early and more frequently. However, they were more often over seen and thus were potentially more dangerous. Ultimately, a physical model for determining the vessel leakage frequency for a spectrum of bone cement viscosities and other properties is required.

**Materials and Methods:** A physical leakage model of a vertebra was created to observe the leakage phenomenon due to a range of injection viscosities of bone cement. Aluminum foam blocks 50 mm x 50 mm x 25 mm containing open cell structures with a porosity of 90% with average pores of 500 microns were used to model the trabecular structure of osteoporotic bone pore structure. A thin layer 1.8mm layer of PMMA coated the surface of the aluminum foam and acted as a cortical shell. A 4mm diameter hole was located at the center of a 25 mm x 50 mm face of the model referenced as the top of the block and used for the placement of the cannula. A 2mm diameter hole representing a blood vessel was drilled perpendicular to the cannula hole and located 10mm from the top of the cannula hole. Also located on the top face of the model were 4 small 2mm holes (hydraulic resistance holes) in the shell to vent the internal pressure of the model to a value of 3.45 kPa during injection. Finally, the model was completely filled with a gelatin to simulate the bone marrow component of the vertebral body. Various concentrations of gelatine were tested to reproduce the same extrusion loads from a cored bone sample as for the initial marrow. To simulate blood flow through the model, a blood substitute with a viscosity similar to blood (around 3-4cps) was passed through a tube supplied by a reservoir to provide 80mm of Hg pressure. At the outlet of the blood vessel was a photosensitive transducer with a laser trained onto its surface. The time of leakage was determined when the laser beam is broken by the flowing bone cement.

Each test was comprised of a 20cc syringe full of DP Pour PMMA (DenPlus Inc., Longueuil, QC, Canada) injected through a 100mm long 8 gauge syringe at a flow rate of 0.1ml/sec. A second identical syringe was filled with bone cement from the same batch. Both syringes were connected to a material testing machine (Mini Bionix 858, MTS, Eden Prairie, MN, USA) with individual load cells (60001-2k, Intertechnology Don Mills ON, Canada) used to record the extrusion loads of the cement thru the syringes. The second syringe served as a viscosity meter. This way the viscosity of the cement could be recorded throughout the course of the experiment. A test would commence with only the injection of the viscosity syringe and when the bone cement attained a desired viscosity, the syringe connected to the leakage model was attached to the MTS and the injection began.

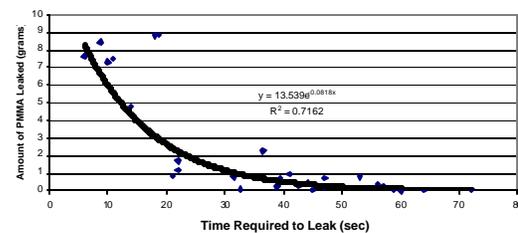
**Results:** A total of 33 tests were performed and results of interest were the time required to leak for a certain initial injection viscosity, the amount of cement leaked and the distribution of the cement spread

within the model. Figure 1 shows cements with viscosities starting around 50 Pa·s would leak early around 10 to 20 seconds after injection while higher viscosities around 325 Pa·s would leak after 60 seconds. Most importantly, but not shown on either figure, is the fact that bone cements with viscosities greater than 350 Pa·s did not leak.



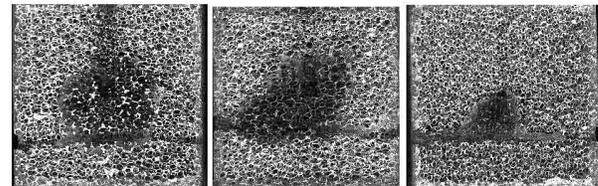
**Figure 1:** Time Required to Leak as a Function of Injection Viscosity

The amount of cement leaked (grams) with respect to the time required to leak showed an exponential relationship (Figure 2). The lower viscosity cement which leaked early in the injection procedure would tend to leak larger amounts of cement than the higher viscosity cements which leaked very little cement later on.



**Figure 2:** Amount of Cement Leaked as a Function of Time

Finally, in Figure 3, the distribution of the cement within the leakage model would tend to fall into three categories: high, medium, and low viscosity spreads.



**Figure 3:** Section views of the leakage model exhibiting three different initial cement viscosities (from left to right: high, medium, low).

**Conclusions:** This model is unique in that it is the first to both simulate blood flow and the hydraulic resistance due to marrow and thus making the model more representative of a vertebroplasty vessel leakage. The model has shown a strong correlation between cement viscosity and leakage frequency and thus clearly identified bone cement viscosity as a key parameter influencing leakage. More importantly, our model suggests that a critical bone cement viscosity of 350 Pa·s results in no leakage and by using this value clinically may reduce the risk of extravasation. Presently cements are not used at this high viscosity one of the reasons being the high forces required to inject them. Consequently, the use of force assisted devices may overcome this problem. Finally, the reproducibility of the model allows for standardized evaluation of commercial cements. In addition, parameters which can be controlled by the surgeon such as injection speed, pressure and continuous versus paused injection patterns can be systematically assessed using our model.

**References:** (1) Bohner, M et al; Biomaterials 24(2003);2721-2730  
(2) Yeom, J.S. et al; JBJS (Br); 85-B (2003); 83-89