INTRODUCTION: Vertebroplasty is a successful and effective procedure for treatment of pathologic osteoporotic compression fractures.\(^1\)\(^2\) During Vertebroplasty, bone cement is percutaneously injected into the vertebral body restoring the mechanical strength and stabilizing the fracture. There are disadvantages associated with this procedure despite the rapid pain relief following cement injection. The high exothermic character of the reaction may result in thermal osteomorcellation. Additionally, there is a risk of cement extravasation due to the low viscosity of the cement at the time of the injection and there is an unpredictable wait time following the preparation of the cement. Two-solution bone cements containing cross-linked poly(methyl methacrylate) PMMA nanospheres and microspheres have been developed as an alternative to commercial cements in current use.\(^3\)\(^4\) Clinical advantages of two-solution cements include ease of use in which no special mixing or waiting is required, better control of setting characteristics in which setting time can be optimized by variations in the initiation chemistry, high pseudoplasticty (shear-thinning) and adjustable viscosity to meet the specific need by variations of the cement constituents.\(^5\) The goal of this study was to investigate maximum polymerization temperatures and mechanical performance of these novel two-solution cements in a cadaver vertebroplasty model in comparison to a commercial cement.

METHODS: Thirty-one vertebrae (T7-L4) were harvested from four cadavers (two males, two females, age range 72–77 years, t-score range -0.8 to -2.0). Vertebrae were dissected free of soft tissue and disarticulated following a clinical lumbar DEXA scan. Two-solution bone cements containing PMMA microspheres (100 μm) or nanospheres (300 nm) were prepared as described elswhere.\(^3\)\(^4\) Both cements contained a fixed polymer-to-monomer ratio of 1:1, and a cross-linked to the low viscosity of the cement at the time of the injection and there is an unpredictable wait time following the preparation of the cement. Two-solution bone cements containing cross-linked poly(methyl methacrylate) PMMA nanospheres and microspheres have been developed as an alternative to commercial cements in current use.\(^3\)\(^4\) Clinical advantages of two-solution cements include ease of use in which no special mixing or waiting is required, better control of setting characteristics in which setting time can be optimized by variations in the initiation chemistry, high pseudoplasticty (shear-thinning) and adjustable viscosity to meet the specific need by variations of the cement constituents.\(^5\) The goal of this study was to investigate maximum polymerization temperatures and mechanical performance of these novel two-solution cements in a cadaver vertebroplasty model in comparison to a commercial cement.

Thirteen vertebrae were used for determination of polymerization temperatures. Thermocouples (J-type) were placed midbody (T\(_B\), between the superior and inferior endplates) along the intersection of the midsagittal and midsagittal axis, and midbody (T\(_T\)) along the intersection of the midsagittal axis and the posterior vertebral body wall (close to the spinal canal). After temperature equilibration of the vertebral body in a water bath at 37°C cement was injected and the temperatures were recorded for one hour. A fixed volume of 5 mL of cement (nanospheres, microspheres, or KyphX) was injected bipedicularly via the pedicle. Cement delivery was performed using a 15 cm 12G needle introduced through a cannula. Two-way analysis of variance (ANOVA) with simple effect analysis and Tukey’s post hoc comparisons were used to assess the effect of thermocouple positioning and cement type on the measurement of maximum temperatures. Only vertebral bodies, in which injected cement touched the central thermocouple, were considered for comparison (3 vertebral bodies from each cement type). Selected vertebrae were sectioned and a morphological analysis of cement placement and interdigitation with cancellous bone was performed using scanning electron microscopy (SEM).

Eighteen vertebrae, six from each group, were mechanically tested.\(^6\) Compressive force was applied to the superior endplate of each specimen at a rate of 5 mm/min along the neutral axis of the vertebral body up to 25% of the specimens’ mean height. The maximum failure load and stiffness of each specimen were measured using load displacement curves. After compression, the vertebrae were injected with 5 mL of cement (nanospheres, microspheres, or KyphX) and then placed in a 37°C water bath for 20 hours to ensure complete polymerization. The treated vertebrae were tested again with the same protocol. The pre- and post-cementing measurements were statistically analyzed and compared using two-way analysis of variance (ANOVA) with simple effect analysis and Tukey’s post hoc comparisons.

RESULTS: Comparing the average maximum polymerization temperatures, the two-solution cements exhibited lower exothermal temperature in comparison to KyphX. The temperature in the central region (T\(_C\)) was significantly lower (p<0.05) for the nanospheres cement in comparison to KyphX and microspheres cements (Table 1). The temperature for the nanospheres-containing cement at the central region (T\(_C\)) did not differ significantly from the temperature reached near the spinal canal (T\(_S\)). There was a significant drop (p<0.05) in the temperature from the center (T\(_C\)) of the vertebral body towards the spinal canal (T\(_S\)) for KyphX and microspheres cements. The three cement types showed adequate interdigitation with the cancellous bone. The nanospheres and microspheres-containing cements exhibited no evidence of shrinkage or porosity when assessed by SEM. A significant difference was not noted between the pre- and post-cementing mechanical properties (p>0.05) of the three groups (Figure 1). Tukey’s post hoc comparisons showed no significant difference between the average values of stiffness among the three cements (p<0.05), however there was a significant difference between the average intact stiffness compared to the average treated stiffness (p<0.05).

DISCUSSION: In this ex vivo experimental model, nanospheres-containing two-solution cement reached significantly lower exotherm than the commercial and microspheres-cements at the center of the vertebral body. This is an important observation considering that previous studies have reported temperatures in the center of the vertebral body above 70°C when cemented with an approximate volume of commercial cement, suggesting the vertebrae are at high risk of thermal injury at these temperatures.\(^7\) The temperatures measured distally, close to the spinal canal, are in agreement with previous values from the literature.\(^7\) The results from the compression testing confirmed that the two-solution cements containing microspheres and nanospheres performed mechanically as well as the commercial control. As observed in other studies,\(^6\) strength was recovered, while stiffness was not restored. In conclusion, the present research showed that two-solution bone cements perform as well or better than the commercial cement in terms of exotherm and mechanical strength. In addition to its added flexibility, it is a viable prospect for future research.

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