# Biomechanical Evaluation of an Injectable and Biodegradable Copolymer P(PF-co-CL) in a Cadaveric Vertebral Body Defect Model

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**Statement of Purpose:** Vertebral bodies with lytic lesions from metastases have an elevated risk of fracture and associated neurologic compromise. Prophylactic vertebroplasty has the potential to reduce pain and the risk of burst fracture in the metastatic spine. A biodegradable and injectable copolymer of poly(propylene fumarate) (PPF) and poly(caprolactone) (PCL), namely P(PF-co-CL), has been shown to possess the appropriate mechanical properties for bone defect repair [1]. However, the feasibility of using the P(PF-co-CL) copolymer for vertebroplasty has not been assessed. The purpose of this study was to evaluate the biomechanical properties of the copolymer in simulated metastatic lytic lesions in cadaveric vertebral bodies.

**Methods:** Forty vertebral bodies from fresh-frozen cadaveric thoracolumbar spines were randomly divided into four groups: intact vertebral body (*positive control, n=8*), simulated defect without treatment (*negative control, n=5*), defect treated with P(PF-co-CL) (*copolymer group, n=16*), and defect treated with polymethylmethacrylate) (*PMMA group, n=11*). The simulated metastatic lytic defects were made by removing a central core of the trabecular bone in each vertebral body with an approximate volume of 25% through an access hole in the side of the vertebrae. Defects were then filled by injecting either P(PF-co-CL) or PMMA *in situ* crosslinkable formulations.

Following the defect filling, the whole spine was imaged by quantitative CT scan (QCT) in the presence of a calibration phantom with known hydroxyapatite densities. Parameters such as vertebral body average area, average height and bone mineral density were calculated from the QCT scans using the image analysis software Analyze™ (Biomedical Imaging Resource, Mayo Clinic, Rochester, MN) Each vertebral body was stripped of soft tissue, the posterior elements removed and embedded in PMMA on both top and bottom surfaces. The samples were compressed until failure or to 25% reduction in body height using a mechanical testing system (MTS) and the force-displacement data were recorded. Ultimate strength and elastic modulus of each segment were then calculated. Data is presented as mean ± standard deviation. The Kruskal-Wallis analysis of variance was used to test for significant differences at $p<0.05$..

**Results and Discussion:** Simulated lytic defects were successfully created in cadaveric vertebral bodies with controlled volume (~ 25% v/v) (Figure 1). The defects were then filled with P(PF-co-CL) copolymer or the clinically used PMMA bone cement. Figure 2 shows the ultimate strength of the vertebral bodies. The average ultimate strength of copolymer-treated vertebral bodies was 1.83 times stronger than the untreated negative group, and it closely matches the failure strength of the intact vertebral bodies (positive control).

The PMMA treated vertebrae, however, had an ultimate strength 1.64 times larger than that of the positive controls. The data for elastic modulus followed the same trend, where filling the defects with copolymers restored the vertebrae to normal value, but filling with PMMA resulted in significantly higher elastic modulus. This modulus mismatch between PMMA-treated vertebrae and the host vertebrae could potentially induce fracture in the levels adjacent to the treated segment.

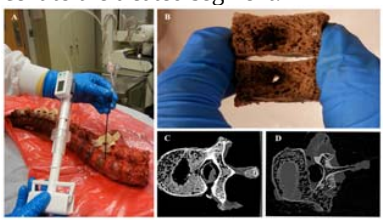

Figure 1. Creating simulated defects and filling with copolymers in cadaveric vertebral body. (A) Vertebral body defects were created using a lateral approach. (B) Picture of the simulated defect. (C) QCT scan showing the empty defect. (D) QCT scan showing the filled defect with P(PF-co-CL) copolymer.

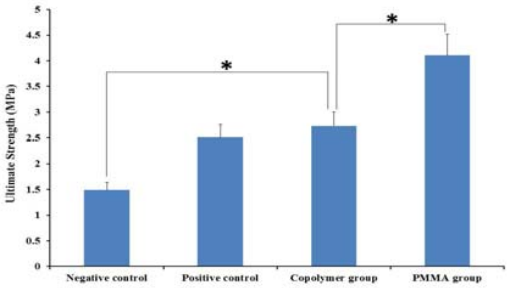


Figure 2. Ultimate strength of vertebral bodies with lytic defects (negative control), intact bone (positive control), lytic defects treated with P(PF-co-CL) (copolymer), and lytic defects treated with PMMA (PMMA). *indicates significant difference ($p<0.05$) between the groups.

**Conclusions** The injectable and biodegradable copolymer, P(PF-co-CL), was successfully used to augment vertebral bodies with simulated lytic lesions. P(PF-co-CL) was able to restore the mechanical properties of the treated segment to be similar to the normal vertebrae. It overcomes the current clinical problem associated with the use of PMMA bone cement which results in modulus mismatch. Therefore, P(PF-co-CL) copolymer may be a suitable alternative for vertebroplasty to prophylactic burst fracture of metastatic vertebral bodies.

**Reference:** [1] Yan et. al Biomater Sci Polym 2011; 22: 489-504.

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