

BIOMECHANICAL EVALUATION OF A NEW BIORESORBABLE POLYMER FOR SCREW AUGMENTATION IN THE OSTEOSYNTHESIS OF OSTEOPOROTIC CANCELLOUS BONE

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Introduction: Osteoporotic fractures of the proximal femur and the vertebral bodies are frequently associated with poor mechanical properties of the cancellous bone in the femoral head. The safe anchorage of osteosynthesis materials like dynamic hip screws or intramedullary nails is therefore jeopardized and the likelihood of failure of the fracture fixation is increased. Polymethylmethacrylate (PMMA) has previously demonstrated to improve the mechanical competence of trabecular bone and to increase the cut out strength of fracture fixation devices. However, as PMMA is inert and not biodegradable it will persist within the trabecular bone and is very likely to influence bone remodeling by affecting bone metabolism and by changing bone's mechanical environment. As fracture repair is finished within the first year after osteosynthesis, resorbable bone augmentation might have advantages in patients with longer life expectancies. The purpose of this study was to assess the mechanical efficacy of a new resorbable polymer to improve the anchorage of osteosynthesis material in cancellous bone.

Material & Methods: The effect of screw augmentation was tested on AO steel screws (45mm length, 6.5 mm diameter, Synthes) for cancellous bone which were inserted in bovine as well as in human vertebrae. The screws were augmented with a new polymer that consists of a resorbable monomer based on Alkylenbis (dilactoyl)-methacrylate (1).

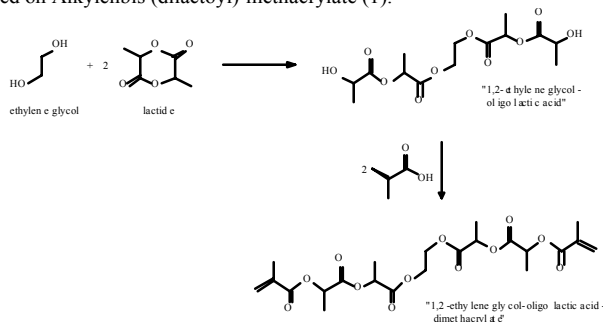


Fig. 1: Chemical structure of the new polymer

The new polymer was compared with standard PMMA bone cement (positive control) and with bone screws without augmentation (negative control) After predrilling, augmentation, and insertion of the screws to a depth of 20mm the specimens were stored for 24h in a humid, 37°C incubator to allow curing. To determine the removal torque after augmentation eight human femoral condyles were separated in the sagittal plane. One site of each condyle was instrumented employing the new polymer, the other site served as control without augmentation. In a second experiment bone screws were inserted in 24 bovine vertebrae and afterwards loaded at an amplitude of 100N and at a frequency of 2Hz. After 1000 loading cycles the removal torque of polymer augmented, PMMA augmented, and non-augmented bone screws was compared. Finally in a third experiment 12 human vertebrae were instrumented with and without the new polymer to test the influence of the augmentation on the pull out strength of the bone screws. The pullout force was measured at a displacement rate of 4mm/min along the axis of the bone screw until failure. Apparent bone mineral density (BMD) was assessed with quantitative computed tomography (XCT960, Stratec).

Results: Augmentation with the new polymer increased the removal torque of cancellous bone screws in human femoral bone by 77% ($p < 0.01$). Compared to the non-augmented control screws, in bovine vertebrae the

removal torque after 1000 load cycles was 88% larger for the new polymer and 92% larger for PMMA ($p < 0.001$) with no significant difference between PMMA and polymer (Fig. 2).

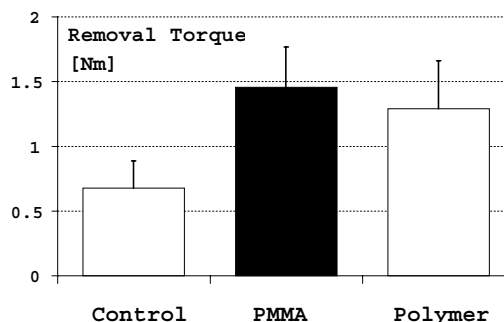


Fig. 2: Removal torque of cancellous bone screws from bovine vertebrae using no augmentation, PMMA, and Polymer respectively.

Polymer augmentation increased the pullout force of bone screws from human vertebrae by 118% ($p < 0.01$). The assessment of BMD indicated that polymer augmentation was most effective in low density, osteopenic specimens (Fig. 3).

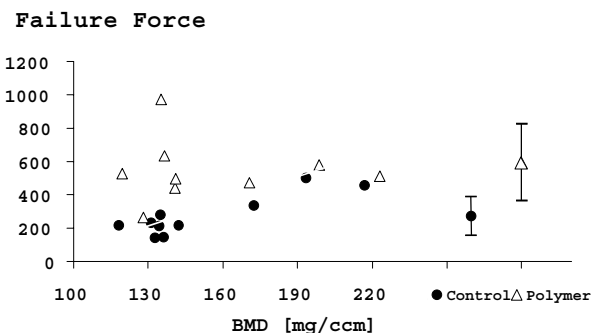


Fig. 3: Force at failure during pullout tests from human vertebral bodies.

Discussion: Augmentation by the new polymer significantly enhanced anchorage and attachment of bone screws in cancellous bone. Especially in osteopenic cancellous bone the polymer effectively improved holding power of bone screws that are typically for osteosynthesis in osteoporotic patients. While the mechanical properties of the new polymer were comparable to PMMA, its biodegradable properties may comprehend some advantages for osteosynthesis applications in osteoporotic patients.

References: (1) Wenz R. First Results with a bioresorbable bone screw In: Walenkamp G.H.I.M. Biomaterials in Surgery New York, Thieme 1998, p132

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