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Influence of screw positioning in a new anterior spine fixator on implant loosening in osteoporotic vertebrae

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STUDY DESIGN: A biomechanical study was designed to assess implant cut-out of three different angular stable anterior spinal implants. Subsidence of the implant relative to the vertebral body was measured during an in vitro cyclic loading test. OBJECTIVES: The objective of the study was to evaluate two prototypes (Synthes) of a new anterior spine fixator with different screw angulations in comparison to the established MACSTL(R) Twin Screw Concept (Aesculap). The influence of factors like load-bearing cross-sectional area, screw angulation and bone mineral density upon implant stability should be investigated. SUMMARY OF BACKGROUND DATA: Epidemiologic data predict a growing demand for appropriate anterior spinal fixation devices especially in patients with inferior structural and mechanical bone properties. Although different concepts for anterior spinal instrumentation systems have been tried out, implant stability is still a problem. METHODS: Three angular stable, anterior spinal implants were tested using 24 human lumbar osteoporotic vertebrae (L1-L5; age 84 (73-92)): MASC TL system (Aesculap); prototype 1 (MP1) with 18 degrees and prototype 2 (MP2) with 40 degrees screw angulation (both Synthes). All implants consisted of two screws with different outer screw diameters: 7-mm polyaxial screw with 6.5-mm stabilization screw (MASC TL), two 5-mm locking-head screws each (MP1 and MP2). Bone mineral density (BMD) and vertebral body width of the three specimen groups were evenly distributed. The specimens were loaded in craniocaudal direction (1Hz) for 1000 cycles each at three consecutive load steps; 10-100 N, 10-200 N and 10-400 N. During cyclic loading subsidence of the implant relative to the vertebral body was measured in the unloaded condition. Cycle number at failure (defined as a subsidence of 2 mm) was determined for each specimen. A survival analysis (Cox Regression) was performed to detect differences between implant groups at a probability level of 95%. RESULTS: High correlations were found between BMD and number of cycles until failure (MP1; r = 0.905, P = 0.013; MP2: r = 0.640, P = 0.121; MACS TL: r = 0.904, P = 0.013) and between load bearing cross sectional area and number of cycles until failure (MP1: r = 0.849, P = 0.032;MP2: r = 0.692, P = 0.085; MACS TL: r = 0.902, P = 0.014). Both Prototypes survived significantly longer than the MACS TL implant (MP1: P = 0.012, MP2: P = 0.014). The survival behaviour of MP1 and MP2 was not significantly different (P = 0.354).

CONCLUSIONS: Implant stability within each implant group was influenced by BMD and load bearing cross-sectional area. The angulation of the two screws did not have a significant influence on cut-out. As conclusion from this study, promising approaches for further implant development are: 1) increase of load-bearing cross-sectional area (e.g.,

larger outer diameter of the anchorage device), 2) screw positioning in areas of higher BMD (e.g., opposite cortex, proximity to pedicles or the endplates).

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