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Technical note

Pedicle screw cement augmentation. A mechanical pullout study on different cement augmentation techniques

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ABSTRACT

Pedicle screws with polymethyl methacrylate (PMMA) cement augmentation have been shown to significantly improve the fixation strength in a severely osteoporotic spine. However, the efficacy of screw fixation for different cement augmentation techniques remains unknown. This study aimed to determine the difference in pullout strength between different cement augmentation techniques. Uniform synthetic bones simulating severe osteoporosis were used to provide a platform for each augmentation technique. In all cases a polyaxial screw and acrylic cement (PMMA) at medium viscosity were used. Five groups were analyzed: I) only screw without PMMA (control group); II) retrograde cement pre-filling of the tapped area; III) cannulated and fenestrate screw with cement injection through perforation; IV) injection using a standard trocar of PMMA (vertebroplasty) and retrograde pre-filling of the tapped area; V) injection through a fenestrated trocar and retrograde pre-filling of the tapped area. Standard X-rays were taken in order to visualize cement distribution in each group. Pedicle screws at full insertion were then tested for axial pullout failure using a mechanical testing machine. A total of 30 screws were tested. The results of pullout analysis revealed better results of all groups with respect to the control group. In particular the statistical analysis showed a difference of Group V ($p = 0.001$) with respect to all other groups. These results confirm that the cement augmentation grants better results in pullout axial forces. Moreover they suggest better load resistance to axial forces when the distribution of the PMMA is along all the screw combining fenestration and pre-filling augmentation technique.

1. Introduction

Spinal fixation in the elderly population is sensibly increased in the past years (doubled in the 80s and tripled in the 90s) and is expected to increase more and more [1]. For this reason, together with the request of surgical treatment, a growing interest is put on surgical techniques aimed to reduce the higher morbidity related with instrumented surgery. In particular, the crucial point of this surgery is represented by the solid fusion rate, and the loosening at the bone-screw interface is the prevalent complication in the osteoporotic population [2–4]. In fact the holding power of screws in osteoporotic bone decreases with decreasing bone mineral density [5,6].

Consequently, to date polymethyl methacrylate (PMMA) is used to interdigitate with surrounding trabecular bone to augment fixation strength and firmly anchor the screw, granting approximately twofold increase in pullout strength [3,7]. This solution allowed for obtaining low loosening rates in osteoporotic patients [8,9]. Different augmentation techniques are commonly used: 1) slowly pouring of cement directly into the prepared pilot hole prior to screw insertion, 2) the kyphoplasty/vertebroplasty technique, wherein the cement is injected under lower pressure in the vertebral body, just before screw insertion, and 3) cement injection through the inserted cannulated screw. While the role of the augmentation is well established, till now is difficult to determine the best augmentation technique. Indeed, the biomechanical studies present in the literature are heterogeneous, and a comparative study of all augmentation technique is lacking. In fact studies usually analyze two different techniques and correlate other characteristics (i.e. screw dimension [10]; and screw shape [11]).

This study assessed the biomechanical properties of the most common augmentation techniques, determining the difference in screw strength through side-by-side pullout test. Moreover, the use

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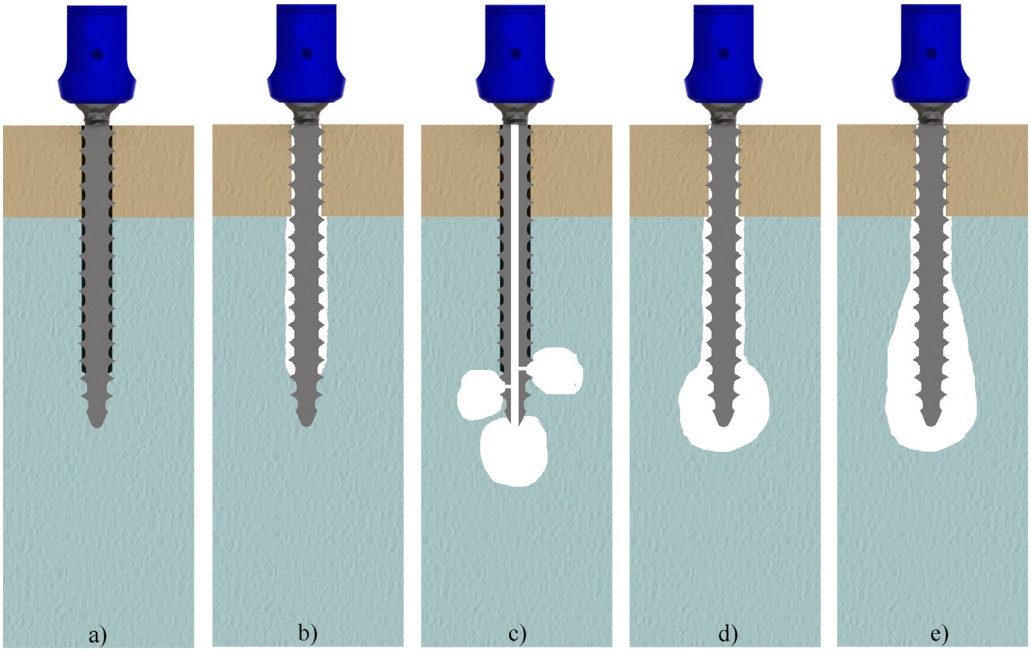

Fig. 1. Different augmentation technique schematization. (a) Only screw without PMMA (control group). (b) Retrograde cement pre-filling of the tapped area. (c) Cannulated and fenestrate screw. (d) Injection using a standard trocar (vertebroplasty) and retrograde pre-filling. and (e) Injection through a fenestrated trocar (Kolibri – SinteaPlustek) and retrograde pre-filling.

of a specific fenestrated trocar able to combine the effect of the vertebroplasty with cement distribution observed in cannulated screw is analyzed.

2. Materials and methods

Synthetic bone (Sawbone; Pacific Research Laboratory Inc., Vashon Island, WA, USA) was used as substitute for cancellous bone of vertebral soma because of its homogenous and uniform structural properties. Each synthetic bone part was cut in rectangular blocks with the dimensions of 40 mm × 90 mm × 70 mm of open cell rigid foam grade 7.5 pcf (density of 0.12 g/cm^3; Sawbone model #1522-507), suitable for simulate osteoporotic bone [11], with a superimposed of solid rigid closed-cell polyurethane foam grade 15 pcf (density of 0.24 g/cm^3; Sawbone model #1522-02) of 40 mm × 90 mm × 15 mm in order to simulate the presence of pedicle cortical bone. As a matter of fact, in presence of osteoporotic bone, the cancellous bone of the pedicle is completely removed in order to guarantee a better screw grip to the pedicle cortical bone. The superimposed closed cell layer simulated this standard cancellous bone removal. The closed cell was chosen in order to simulate and emphasize the different and smaller diffusion of cement within the cortical bone of pedicle in respect to the cancellous bone of vertebral soma, so to reproduce the creation of a cement sleeve between the screw and the pedicle cortical wall which occurs after the cancellous bone removal.

The height of the solid rigid closed-cell polyurethane foam is such to reproduce the mean length of a lumbar pedicle [12], whereas the height of the open cell rigid foam was chosen in order to have a sufficient substrate for the full insertion of the 50 mm length screw, which is the most commonly implanted screw in the surgical use.

The superimposed blocks were constrained to each other with two small drops, one per side, of silicone glue (volume of silicone glue = 0.4 cc per drops), in order to guarantee stability during the cement injection and the screw insertion.

A 3-mm pilot hole was drilled in each test block at very low speed in order not to heat the foam and alter material's properties and acted just as a small pilot for the screw tip before the tapping procedure, thus not influencing at all the substrate properties where the screw would subsequently gripped. Then the pilot hole was tapped with a Ø 5.5 mm tap for 40 mm length, according to the standard surgical technique.

Multi-axial pedicle screws (3LOCK Multi-axial Screw: diameter 6 mm, length 50 mm, double-lead; Sintea Plustek, Assago, Italy) and medium viscosity PMMA cement (Sinplus S, Sintea Plustek, Assago, Italy) were employed in the study.

Different augmentation techniques were tested:

- *Group I: only screw without PMMA (control group)* – the screw was fully inserted into the tapped pilot hole without cement, Fig. 1a;
- *Group II: retrograde cement pre-filling of the tapped area* – 1.5 cc of PMMA was poured into the tapped pilot hole and the screw fully inserted, Fig. 1b;
- *Group III: cannulated and fenestrate screw* – 3LOCK Dual-lead Multi-axial Cannulated Fenestrated Screw (length 50 mm, ø6 mm; Sintea Plustek, Assago, Italy) was fully inserted into the tapped pilot hole and the standard quantity (3 cc) of PMMA cement injected through the perforation of the screw using the standard cement injector system (an *ad hoc* needle designed to be inserted into the screw stem) for 3LOCK Cannulated Screw that exerted pressure on the cement, Fig. 1c;
- *Group IV: injection using a standard trocar and retrograde filling* – 3 cc of PMMA cement was injected under pressure using a standard trocar and an injection system at 50 mm of depth (such as for the vertebroplasty technique); retrograde filling of the tapped area was performed before screw full insertion, Fig. 1d;
- *Group V: injection using a fenestrated trocar and retrograde filling* – 3 cc of PMMA cement was injected under pressure using a fenestrated trocar (Kolibrì, Sintea Plustek, Assago, Italy) and an injection system at 50 mm of depth; retrograde filling of the tapped area was performed before screw full insertion, Fig. 1e.

The screws, for each group, were inserted by hand, applying a sufficient torque for overcoming the resistance offered by the foam.

The time of polymerization of bone cement is 20 min, according to the manufacturer's IFU. The pullout tests were performed, for all the specimens of each group, the day after the one of cement insertion,