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

Francesco Costa [a], Alessandro Ortolina[a], Fabio Galbusera [b], Andrea Cardia[a], Giuseppe Sala[c], Franco Ronchi[d], Carlo Uccelli[d], Rossella Grosso [d], Maurizio Fornari[a]

[a] *Neurosurgery Department, Humanitas Clinical and Research Hospital, via A. Manzoni 56, 20089 Rozzano (Milan)- Italy*

[b] *IRCCS Galeazzi Orthopedic Institute, Milan, Italy*

[c] *Department or Aerospace Sciences and Technologies, Politecnico di Milano, Milan, Italy*

[d] *Sintea Plustek, Assago, Italy*

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.

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

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; 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 pi- lot 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, so that the waiting time was longer than the polymerization time in order not to affect the cement performances.

Standard X-ray projections in two orthogonal planes aligned with the sides of the test block were taken in order to visualize cement distribution before the screw pull-out tests. The distribution of the cement along the screw stem was evaluated using the shape factor "Aspect Ratio", defined as the ratio between the smallest diameter and the largest diameter orthogonal to it. The normalized aspect ratio varies from approaching zero for a very elongated distribution (maximum size >> minimum size), to near unity for an equiaxed distribution (circular shape, maximum size ≈ minimum size). The Aspect Ratio was calculated in both orthogonal planes for each sample of Group 2, Group 3, Group 4 and Group 5 using Digimizer, an image analysis software package (MedCalc Software, Ostend, Belgium). Mean value and standard deviation (SD) of the Aspect Ratio were calculated for each group, then a one-way analysis of variance (ANOVA) was per- formed (post-hoc Tukey tests to assess the significant differences, differences were considered significant at $p < 0.05$).

The screw pullout test was performed using a MTS 858.02 Mini Bionix Servo-controlled testing machine (MTS, Minneapolis, MN, USA). The applied loads were measured by a MTS axial load cell (model 661.19F-03, 15 kN maximum axial load); the displacement transducer was a MTS LVDT transducer (model: 359, 50 mm; sampling rate, 10 Hz). The test block, with a screw inserted, was placed under a specially designed fixture system, in order to axially constrain the foam block to the testing machined fixed part, as is generally the case in the tests pullout, even in those described by ASTM F 543. The pedicle screw was attached to the moving part of the testing machine by a threaded stem and a fork acting as a hinge (Fig. 2a).

Once the specimen was mounted, the pullout load was applied under displacement control at a cross-head rate of 2 mm/min, until pullout of the screw from the bone was observed. Values measured by the load cell and the linear transducer sensor were plotted in a load–displacement curve for each tests and each setup performed. The pullout force was defined as the first peak force measured dur- ing axial ramp loading of the pullout testing which was followed by a drop in force of greater than 5% of the total applied force (Fig. 2b). Mean value and standard deviation (SD) of the pullout load were calculated for each group. For statistical analysis, six specimens for each group were tested. After checking the normality of the results for each group with the Shapiro–Wilk test, a one-way analysis of variance (ANOVA) was performed. Post-hoc Tukey tests were performed to assess the significant differences among the specific five groups. Differences were considered significant at $p < 0.05$. The analysis was performed with R software (R Development Core Team-2011 -: a language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria.)

Results

The screws inserted in the test blocks with different augmentation techniques have been radiologically examined before the pullout test (Fig. 3, top), as well as after the pullout test (Fig. 3, bottom). The de- tailed Aspect Ratio results of the analysis performed on radiographic images, as well average and standard deviation (SD) are detailed in Table 1; the relative statistical analysis is summarized in Table 2. The radiological images analysis showed that the Group 2, Group 4 and Group 5 had a more elongated distribution along the screw stem with respect to Group 3 ($p < 0.05$). This means that the area of cement/screw interface is superior for solid screws with vertebroplasty and retrograde cement filling (Groups 4 and 5) with respect to cannulated fenestrated screws (Group 3), due to the fact that, the quantity of cement being equal, a more elongated distribution guarantees a higher lateral surface with respect to a spherical distribution. Group 3 significantly differed from the others concerning the aspect ratio due to the fact that cement penetrated the foam in correspondence of the screw fenestration, thus minimizing proximal filling. In particular, the cement leakage was mainly through the proximal lateral fenestrations than through the distal hole. In Group 5, the distribution of the cement around the screw stem seemed to be distributed in a more repeatable way in comparison with Group 4. It should be noted that in Group 2 a lower amount of cement was used, thus reducing the contact area even if the aspect ratio was not significantly affected.

The failure mode was the same for all the tested samples: the cement, leaked into the open cell of the foam and solidified, led up to a composite made of cement and foam and the failure always occurred at the interface between the composite and the surrounding foam that simulates osteoporotic bone. This suggests that the interface composite/foam was weaker that the interface composite/screw for all the screws and the augmentation technique tested.

The detailed pull-out load results as well average and standard deviation (SD) are detailed in Table 3 and shown Fig. 4. One-way ANOVA showed a highly significant difference between the five groups ($p < 0.0001$). Post hoc tests documented that all the augmentation techniques led to a statistically significant increment of pull- out load of the screw ($p < 0.05$) with respect to the not-augmented screw (Group 1) used as control (Table 4). The use of cannulated fenestrated screws (Group 3) guaranteed pull-out results comparable to those achieved with standard augmentation technique (Group 2), whereas the vertebroplasty of the soma before the filling of the pedicle (Group 4) led to an increment of the pull-out value without any statistical difference with respect to Group 2 and Group 3. Only in Group 5 the pull-out load was statistically significant higher in respect of the other techniques ($p < 0.001$).

Discussion

Our results, which are consistent with previous investigations [3,7,10,11], confirm that screw augmentation with PMMA (independently by the techniques adopted) shows a pull-out strength superior than not-augmented screws. This is due to the fact that the grip of a screw in a low density substrate, such as the open cell foam simulating osteoporotic bone, is poor. The cement, filling the voids of the foam, is able to create a composite material which improves the grip of the screw and maximize the interface with the osteoporotic bone.

In particular, the analysis of the different techniques showed that in Group 5 the average pull-out load is higher than those of all the other group ($p < 0.001$). This can be explained from radiographic and failed specimens observations (Fig. 3): in Group 5 the cement is distributed around the screw stem in a very repeatable way in comparison to the Group 4, up to the seat between the two different foams, therefore resulting in a higher contact area in all the samples analyzed (low standard deviation). Similarly Group 2 and 3 led to com- parable pull-out loads because the size of the bone-cement interface was similar, as proved by the x-ray examination, despite the lower quantity of cement in Group 2. Group 4, combining the distribution of Group 2 (along the stem) and Group 3 (around the distal tip), has better performance respect them, but this difference is not statistically significant ($p = 0.21$).

As mentioned previously, the fact that pull-out load for Groups 2 and 3 is not significantly different suggests that a uniform and elongated distribution of cement along the screw stem overcomes the less quantity of cement injected. This result is in contrast with other studies [7,10], and may be related to the fact that the pre-filling of the tapped area (Group 2) optimizes the area of the bone/cement inter- face. As a matter of fact, a spherical cement distribution similar to those achieved for Group 3 presents the minimal interface area which could be obtained for a specific cement volume.

The use of synthetic materials mimicking cancellous bone allows for having a standard experimental set-up in each group eliminating the variability encountered when human cadaveric bones are tested [13]. Nevertheless, in vitro testing of cadaveric specimens is still considered to be the gold standard in spine biomechanics, and is preferably used to assess the risk of pedicle screw loosening [7,10]. To partially overcome the limitations related to the use of an artificial material, we created a two-layer composite structure which resembles the anatomy and mechanical properties of the pedicles and vertebral body. It should be noted that this solution was not validated yet by comparison with cadaver specimens and thus the measured values of the pull-out force should be considered only in a comparative way, with minor consideration for the absolute values. The aim of the present study was to compare several augmentation techniques through side-by-side pullout tests, using a simple test method and repeatable test conditions, rather than find absolute values or replicate in vivo conditions. Nevertheless the test method is believed reliable and meaningful, since it was performed mainly according to ASTM F543, except for the exemption on the substrate which was changed for simulating the cement distribution phenomenon into the bone.

Despite the generally low SDs obtained in the tests, which were thus found to have a good repeatability, the manual injection of ce- ment is affected by inaccuracies, which lead up to a bigger variability of results and a higher standard deviation of pull-out loads of Groups 2, 3, 4 and 5 with respect to Group 1. For Group 3 the SD is lower than that the other groups because the injection through the screw itself is probably more repeatable than Group 2, Group 4 and Group 5, since the phase of manual retrograde cement injection is not performed.

Another major limitation pertains to the simple axial pull-out testing protocol, which is not well representative of the complex loading scenario acting on pedicle screws and on the bone-implant interface in vivo. Other types of tests were implemented, such as ap- plying an extraction torque [14,15], a toggle test [16] and more com- plex cyclic loads [7]. Kueny et al. [10] observed that the pull-out test was more sensitive to small differences between implants and augmentation techniques with respect to the toggle test, and concluded that the simple pull-out test may be not suitable for the preclinical testing of screw loosening. Despite these open questions, no specific technique did emerge yet among the newer testing methods and axial pull-out is still widely used for the biomechanical investigation of screw loosening.

In conclusion, the present study confirmed that pedicle screw augmentation with PMMA allows for a significant increase of the pull-out strength of the screws when implanted in osteoporotic bone. Between the different augmentation techniques analyzed, the use of cannulated and fenestrated screws did not increase the mechanical pull-out performances of the screw with respect to the standard technique, which used solid screw with only retrograde filling; on the other hand, solid screws with vertebroplasty and retrograde cement filling guaranteed the highest pull-out forces, even if only the ad hoc fenestrated trocar provide significantly different results.

Conflict of interest

The authors F. Costa, A. Ortolina, F. Galbusera, A. Cardia, G. Sala and M. Fornari do not have any conflict of interest. The authors F. Ronchi, C. Uccelli and R. Grosso are employees of Sintea Plustek.

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Ethical approval

Not required.

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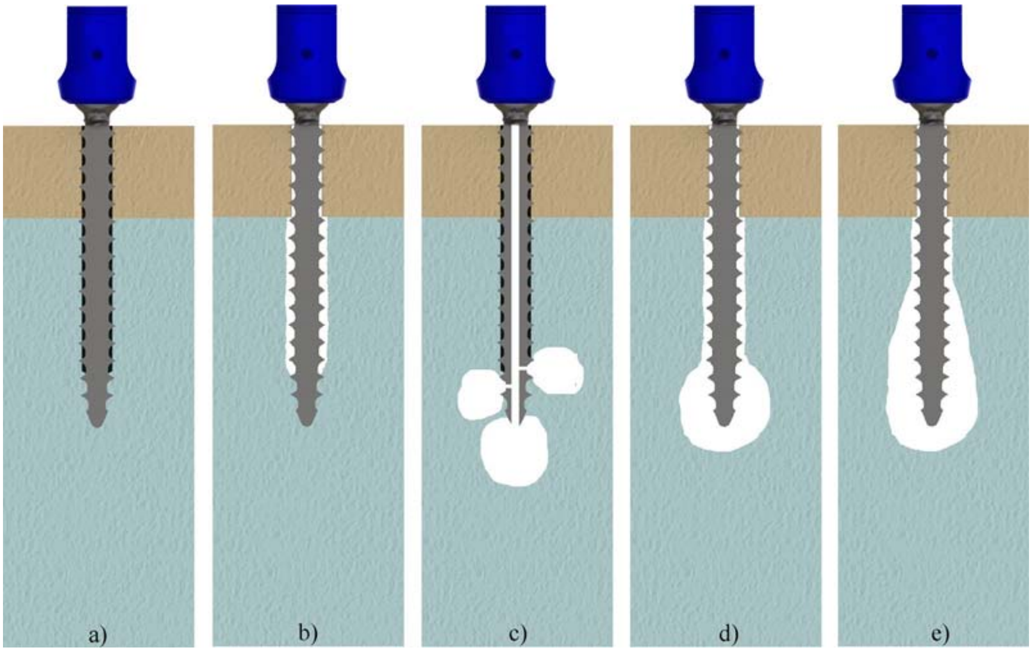

Fig. 1. Different augmentation technique schematization. (a) Only screw without PMMA (control group). (b) Retrograde cement pre-filling of the tapped area. (c) Cannulated and fenestrate screw. (d) Injection using a standard trocar (vertebroplasty) and retrograde pre-filling. and (e) Injection through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

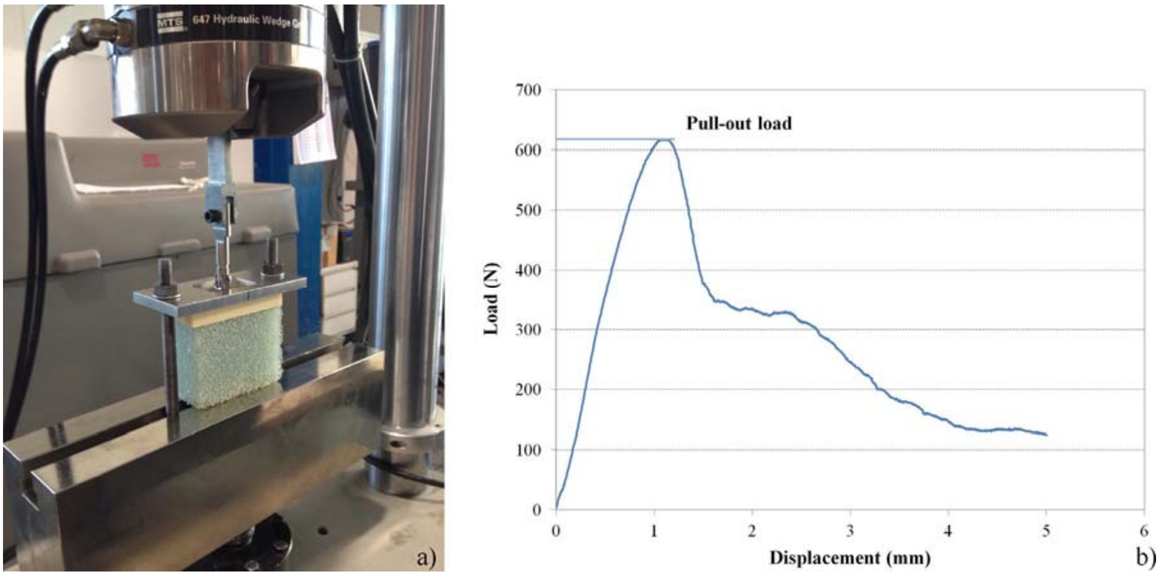

Fig. 2. Example of a Pull-out test. (a) Standard test apparatus and (b) identification of pull-out force in a typical load-displacement curve.

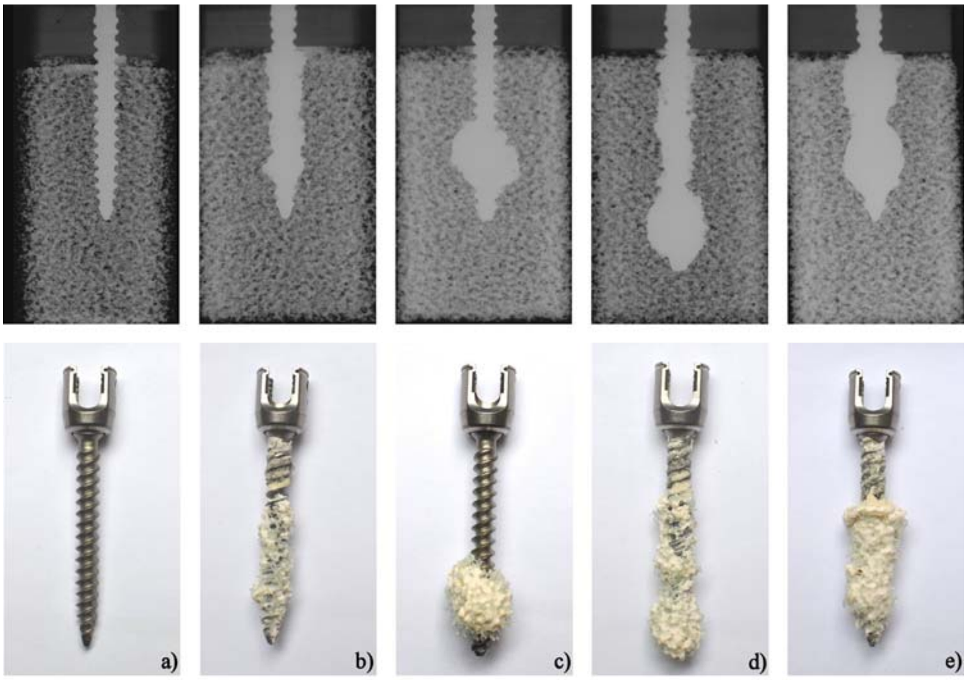

Fig. 3. Radiological images showing the test block (closed cell and open cell foam layers are easily identifiable) and the inserted screw (top); and failed specimens after the pull-out test (bottom) for each augmentation technique tested.

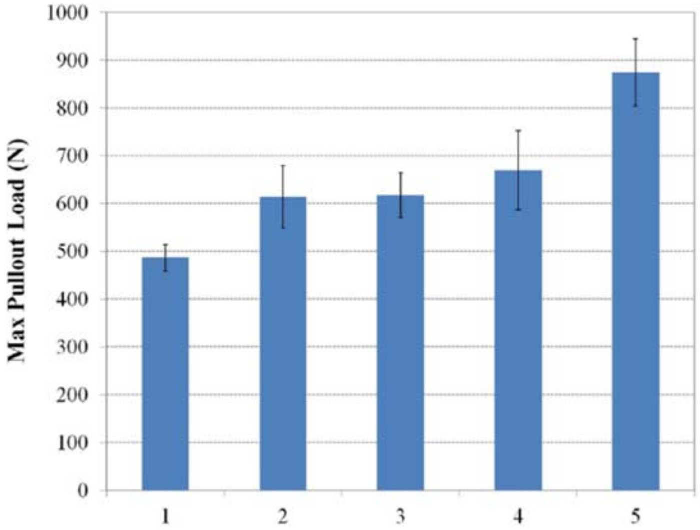

Fig. 4. Average screw pull-out load and standard deviation of different augmentation technique

Table 1
Detailed aspect ratio results (average and standard deviation SD). P1 and P2 represent the measurements taken in two orthogonal planes aligned with the sides of the test block.

Specimen number	Aspect ratio							
	Group 2		Group 3		Group 1		Group 1	
	P1	P2	P1	P2	P1	P2	P1	P2
1	0.66	0.31	0.82	0.99	0.24	0.25	0.55	0.37
2	0.34	0.34	0.92	0.82	0.27	0.74	0.45	0.60
3	0.30	0.27	0.86	0.77	0.31	0.54	0.32	0.31
4	0.37	0.35	0.98	0.99	0.84	0.27	0.35	0.51
5	0.31	0.51	0.90	0.82	0.91	0.28	0.60	0.39
6	0.51	0.68	0.88	0.82	0.22	0.31	0.35	0.70
Ave.	0,41		0,88		0,43		0,46	
SD	0,14		0,08		0,26		0,13	

Table 2
Statistical analysis of aspect ratio results: differences were considered Significant at $p < 0.05$.

Aspect ratio	Group 2	Group 3	Group 4	Group 5
Group 2	–	–	–	–
Group 3	< 0.05	–	–	–
Group 4	> 0.05	< 0.05	–	–
Group 5	> 0.05	< 0.05	> 0.05	–

Table 3
Detailed pull-out load results (average and standard deviation SD)

Specimen number	Ultimate pull-out load (N)				
	Group 1	Group 2	Group 3	Group 4	Group 5
1	457	635	617	768	871
2	522	568	691	600	845
3	469	635	567	605	1002
4	471	505	591	631	893
5	475	667	583	630	808
6	518	671	653	782	825
Ave.	**486**	**614**	**617**	**669**	**874**
SD	**28**	**64**	**47**	**83**	**70**

Table 4
Statistical analysis of pull-out load results: differences were considered significant at $p < 0.05$.

Pull-out load	Group 1	Group 2	Group 3	Group 4	Group 5
Group 1	–	–	–	–	–
Group 2	< 0.05	–	–	–	–
Group 3	< 0.01	> 0.05	–	–	–
Group 4	< 0.001	> 0.05	> 0.05	–	–
Group 5	< 0.001	< 0.001	< 0.001	< 0.001	–