Experimental analysis on the resistance of fixing nails for spine cages

G La Rosa, R Mineo, R Barbagallo and C Tosto

Dept. of Civil Engineering and Architecture, University of Catania, Via S. Sofia 64, 95125 Catania – Italy

guido.larosa@unict.it

Abstract. Arthrodesis is one of the most common surgical treatment for the management of pathologies concerning the intervertebral discs. Special cages replace the intervertebral disc and realize the fusion between the vertebral body, often together with a fixing plate, screws, and rods. An alternative method is a cage that contains integrated screws, designed with suitable holes, it allows an easier insertion of fixing system during surgery. Mt Ortho company offers a cage equipped with two diverging locking nails in Ti6Al4V-ELI titanium alloy. These nails are placed directly inside the cage inclined by 30° with respect to the horizontal. This paper, performed in collaboration with Mt Ortho, reports the experimental tests aimed at evaluating the performance of locking nails under pull-out stresses. To evaluate the nails pull-out in a more physiological way, together to the standard condition, tests were performed on a composite layer made of wood and foam. Furthermore, the notch effects generated by the locking nails are qualitatively evaluated by photoelastic analysis, in view of a geometry able to reduce the stress concentration factor on the bone tissue, without reducing the pull-out resistance.

1. Introduction

One among the most important pathologies of the vertebral column concerns the intervertebral discs. The surgical treatment that can reduce these pathologies is arthrodesis, realized by the interbody (or intervertebral) fusion. Since its introduction in 1911, lumbar fusion has proven to have excellent clinical outcomes in treating several pathological spine conditions, such as spinal stenosis, spondylolisthesis, degenerative disc disease, spinal deformity, and trauma [1]. Nowadays intervertebral fusion is obtained distracting the intervertebral space enough to implant cages stabilizing the adjacent vertebral bodies until complete fusion occurs. The stretching of the annulus and ligaments provides stability and restore the disc height and spinal lordosis. The time for fusion varies, but is 6–12 months at minimum, therefore immediate stabilization could be required [2, 3, 4].

Special cages were designed to replace the intervertebral disc but, to allow the primary stability (biomechanical stability until the bone remodeling can assure a permanent locking) the cages are often mounted together with a fixing plate between the bodies of the two adjacent vertebrae, to prevent forces causing the ejection of the cage [5, 6].

Pedicle screws and rods are sometimes required for maintenance spinal stability until fusion occurs. However, some interbody devices used during anterior and lateral approaches may be combined with plate fixation or contain integrated screws that ensures primary stabilization and avoid the need for posterior patient repositioning [5, 6].
EBM (Electron Beam Melting) is a 3D printing technique in which a high energy source (concentrated beam of electrons) hits a bed of titanium powder causing its fusion. Mt Ortho designs and produces customized prostheses and orthopedic components in Titanium alloy by EBM additive manufacturing, to replace or substitute parts of the skeleton or as a support for surgical operations.

Aim of this study was to compare the pull-out forces of new cage integrated fixation system with traditional screw. The new fixation system was evaluated in two different manufacturing solutions.

2. Materials and methods
The traditional fixation element is a long screw with the appropriately shaped thread (Figure 1 (a)), used for mounting orthopaedic plates, in this study, two different fixation elements were compared to the traditional one: a nail with sawtooth ridges to prevent ejection (Figure 1 (b)), used in other fields of orthopedics and a similar nail made with EBM technology (Figure 1 (c)).

![Figure 1. Specimens tested – (a) traditional fixation system, (b) traditional nail, (c) nail made with EBM technology](image)

2.1. Test procedure
Standard in vitro pull-out tests require trials to be carried out on the fixation elements inserted in different foams simulating cancellous bone with different degrees of bone density [7, 8, 9]. To approach the physiological situation, in which the fixation elements cross the cortical part of the vertebral body, tests were also carried out on a mixed system consisting of a thin layer of fresh citrus wood (simulating the cortical part) overlapped on the foam (simulant the spongy part) as shown in Figure 2. Overall, several pull-out tests have been performed on the screw/nail inserted in a material simulating the bone:

- 3 foams with different density (grade 15, 20 and 40), simulating the cancellous bone, following the standard procedures.
- 3 combinations of foam (grade 15, 20 and 40) + thin wood layer, simulating more realistically the cortical (wood) + cancellous (foam) bone

2.2. Introductory procedures
Preliminary tensile tests were carried out on the foams and the wood, in order to define their mechanical characteristics. To avoid the errors of the measuring chain, the specimen displacements were defined by DIC measurements [10]. The tests were performed in static loading under displacement control on dog-bone specimens treated for the DIC measurements by an Instron 8501 testing machine.

Figure 3 shows the stress-strain behavior of the grade 40 foam, as an example, and the wood. The results highlighted the following characteristics for the foam: $E = 0.5$ GPa, $\sigma_r = 14$ MPa, similar to those of the cancellous bone in a healthy patient and $E = 9.6$ GPa, $\sigma_r = 65$ MPa for the fresh citrus wood, similar to those of the cortical bone. Moreover, the wood presented a noticeable laminar behavior.
Figure 2. Pull-out tests on: (a) foam; (b) wood+foam; (c) experimental setup and clamping system.

Figure 3. Mechanical characteristics of the grade 40 (a) foam and of the citrus wood (b).

2.3. Experimental setup
The tests were performed by means of an Instron electrical static testing machine with a 10 kN load cell. Figure 2 shows the experimental setup highlighting the upper and lower clamps in the testing machine.

The screws or nails were inserted respectively by screwing or by compression in a preliminary hole with a diameter of 2 mm [11].

Screw and nails were also inserted in polycarbonate blocks with a thickness of 10 mm in order to evaluate the stress concentration factor around the tips due to the insertion using a photoelastic bench. Nails were inserted by compression in a previously made cylindrical hole with a diameter of 2 mm, screw was inserted by screwing on a previously made cylindrical hole with a diameter of 2.5 mm.
3. Results and discussion
As previously specified, the first tests were performed on the screw/nails inserted in the foam only. Five specimens were tested in order to mediate the results for each foam grade. Figure 4, as an example, shows the curves for the grade 40 foam for the two nails.

Figure 4. Curves force-displacement on grade 40 for the commercial nail (a) and EBM nail (b).

Figure 5 shows the pull-out forces for the three fixation components in the configuration with the thin wood layer with the different foam density. Tests performed show that the pull-out force is much greater for the screw respect to the nails but the weaker values for the nails, however, are large enough to resist to physiological loads.

Moreover, the insertion of a thin layer of citrus wood had more than doubles the pull-out forces in the grade 15 and 20, but it did not change the pull-out strength in grade 40. This is understandable due to the great density of the grade 40 foam, corresponding to a cancellous bone of high mechanical characteristics.

Figure 5. Curves force-displacement for the commercial nail and EBM nail on the composite wood+foam for the three different foam grades in the configuration with the wood layer: (a) grade 15; (b) grade 20; (c) grade 40.
The photoelastic images clearly show the high stress concentration factor of the screw and the traditional nail respect to the EBM nail, due to the rounded apex of the protrusions, then, the stress concentration factor is drastically reduced using the EBM nail.

4. Conclusions
Surgical requests were forwarded to verify the amount of nails instead of screws to fix the intervertebral cages, being the nails insertion easier and faster than the screws.

Tests were carried out to assess in vitro the pull-out forces for the two typologies of fixing systems, either on the foams (following the standard) or on a composite made of a thin layer of wood over the foam (more similar to the physiological condition).

Results verified that, even if the screw system has a greater resistance, the nail ones resist to a pull-out force large enough for the physiological use.

Among the nails, the EBM configuration show almost the same resistance than the traditional ones but a lower stress concentration effect.

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