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Experimental analysis of pedicle screws

Guido La Rosa*[1], Carmelo Clienti[1], Rosalia Mineo[2], Alberto Audenino[3]
[1]Department of Industrial Engineering, University of Catania, Viale Andrea Doria, 6 - 95125 Catania, Italy
[2]MT Ortho s.r.l., Via Fossa Lupo, 95025 Aci S.Antonio,Catania, Italy
3 Department of Mechanical and Aerospatial Engineering, Polytechnic of Turin, Italy

Abstract

Aim of this study is to examine the mechanical properties of pedicle screws in titanium alloy obtained by the process of additive manufacturing (Electron Beam Melting, EBM) and compare them with those of screws obtained with traditional techniques. EBM is a methodology able to process metallic powders layer-by-layer. Pedicle screw-produced by the EBM process by the MT Ortho (VS), and commercial screws (VC and VT) were examined.
VS screws showed lower resistance to pull-out tests than VC and VT screws. This behavior can be attributed to a lower sharpness and a lower depth of thread. These features, which may be negative from the point of view of the resistance to pull-out tests, could have positive effects from the point of view of stress concentration on bone. To analyze these effects, fatigue pull-out tests were also carried out and the different screw-bone interface behavior was evaluated using photoelasticity and finite element analysis.
The results obtained by numerical simulation confirm what was previously stated, a thread with a geometry less sharpened ensures a better distribution of the loads and reduces the notch effect, allowing a balance of the disadvantage due to the lower primary stabilization.
The fatigue limit and fatigue curve were obtained by the thermographic (Risitano) method. Even with a limited number of tests, the thermographic technique allows the prediction of the limit of fatigue and of the whole fatigue curve.

Keywords: Pedicle screw; EBM; pull out test; bending test; photoelasticity; FE analysis

1. Introduction

The pathologies of the spine are the most common causes of disability in adults over forty five. These diseases distort the individual function and the quality of life, further stake the progress of working and recreational activities. Spinal arthrodesis has been used for many years to treat painful condition of the spine and it is still considered the most proper treatment in case of degenerative spine diseases, which do not meet the common conservative treatment.

In the past, the spinal arthrodesis was performed mainly without any internal fixator. Today, there are different kinds of devices that can be used to execute it. These devices connect two or more vertebrae, hold them in the correct position and prevent them from moving until the arthrodesis does not take place. Over the past two decades, ingenious

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devices are designed, that have changed the way in which the surgeons make arthrodesis spine. The majority of current devices that surgeons prefer to use are based on metal screws, which are placed through the pedicle and into the vertebral body. The screws are connected to plates or metal rods in the back of the spine. The combination of these instruments create a solid bridge holding the vertebrae in the correct position, blocking the various movements between the vertebral segments, allowing to occur a solid fusion (Rolander (1966), Weinstein et al. (1992), Yuan et al. (1994), Gaines (2000)).

The additive manufacturing (AM) is a powerful new tool that offers the necessary competitiveness to companies that produce prototypes or highly complex products (Geetha et al. (2009), Marin et al. (2013)). The AM great strength, from which comes the real added value of technology, takes root particularly in the field of realization of medical products. In this field, there is the possibility to realize porous materials with controlled pore size combined with massive parts, these features give to the device excellent ability to osseointegrate for the secondary stability. Another feature is the high hardness of the materials used, guaranteed by the manufacture in a controlled environment (vacuum with minimum presence of oxygen) which makes also the melting process even more stable.

The purpose of this work was to examine the mechanical characteristics of pedicle screws in titanium alloy, obtained by additive manufacturing process EBM (Electron Beam Melting) and to compare these with pedicle screws obtained with traditional technologies.

The work was conducted in collaboration with the Sicilian company MT Ortho, producer of custom made device, which provided prosthetic components tested.

2. Description of the investigation

The pedicle screw here examined have been obtained by EBM process. The EBM is one of the AM process, capable of processing metal powders using the principle of layer-by-layer. During the EBM process, metal powders are selectively melted, layer by layer through an electron beam. Pedicle Screws tested in this work have been constructed by Arcam system.

To examine the mechanical properties of pedicle screws, we refer to standard ASTM F 543-02 (Standard Specification and Test Methods for Metallic Medical Bone Screws), especially the Annex A3 (Test Method for Determining the Axial Pullout Strength of Medical Bone Screws). In the study, the following pedicle screws were examined:

- AM screw, 6.25x 50mm size, produced by EBM process from MT Ortho (Fig. 1.a) (VS);
- Medtronic screw, size 6.5mm x 45mm (Fig. 1.b) (VC);
- Medtronic screw, 5.0mm x 50mm size (Fig. 1.c) (VT);
- Medtronic screw, size 4.5mm x 40mm (Fig. 1.d) (VF).

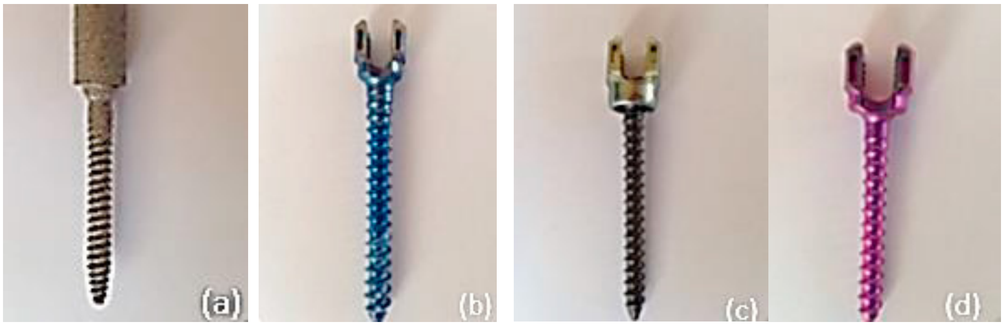

Fig. 1. (a) VS screw; (b) VC screw; (c) VT screw; (d) VF screw.

3. Static pull out tests

This testing method was used to measure the axial tensile force required to fail or remove a bone screw from a block of a defined material. The results obtained are not intended to predict the force required to remove the subject bone screw from human or animal bone, rather measuring the uniformity of the products tested or comparing the strength of different products (Daftari et al. (1994), Pfeiffer et al. (1996), McLain et al. (1995)).

The test blocks used, in conformation with the requirements of ASTM F1839, were made up of polyurethane foam (ASTM F-1839-08 "Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments").

The tests were performed with three different density foams (grade 15, 25, 40); the three different density allow to simulate more or less osteoporotic bone tissues. Three tests for each grade, and for each screw, for a total of 18 tests, were carried out. Static tests were performed on the VS, VC and VT screws.

In order to execute the tests, it was necessary to realize a gripping mechanisms for the test machine. The mechanical components were created using the 3D CAD software SolidWorks^{TM}, and then they were made of stainless steel (AISI 304) by a mechanical processing.

Two gripping mechanisms for the screws, by which it is possible to constrain the head (Fig. 2.a) and a mechanism allowing to hold in the correct position the test block were manufactured (Fig. 2.b). A hollow free cylinder was also mounted around all the pedicle screws in order to assure the perpendicularity of the screw relative to the block.

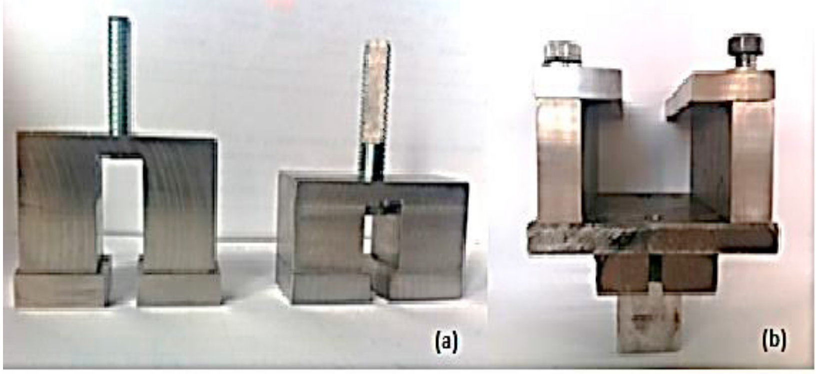

Fig. 2 (a) Gripping mechanism for the screws; (b) Gripping mechanism for the test block.

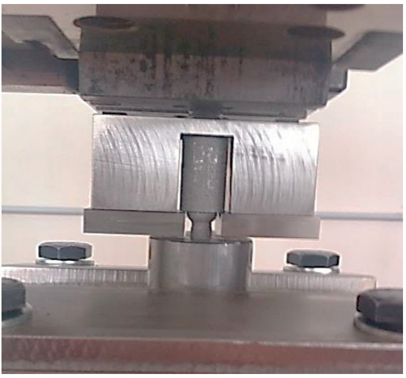

Fig. 3 Specimen mounted on the testing machine.

The test blocks were drilled by a milling cutter with a tip of 3 mm and afterwards a screws were inserted manually. Zwick/Roell Z100 electrical testing machine was used to carry out experimental tests. The specimen was positioned in the testing machine (Fig. 3) and a tensile load was applied at a rate of 5mm/min until the screw failed or released from the test block.

Table 1 shows the load values, for each screw and for each grade, in which the screws were pulled out in static tests. Fig. 4 shows, as an example, the graphs of the static pull out test obtained for the VS screw insert in a Grade 40 block.

Table 1. Results of static pull out test.

Screw	Grade 15	Grade 20	Grade 40
VS	470 N	902 N	1633 N
	454 N	663 N	1988 N
	461 N	706 N	1948 N
VC	585 N	581 N	3215 N
	593 N	762 N	3367 N
	585 N	852 N	3220 N
VT	575 N	875 N	3063 N
	504 N	826 N	3451 N
	595 N	902 N	3390 N

Table 2. Cyclic failure load values.

Screw	Grade 15	Grade 20	Grade 40
VS	250N	650 N	2300 N
	250 N	350 N	1900 N
VC	500 N	700 N	3000 N
	400 N	700 N	3000 N
VF	300 N	600 N	2750 N
	300 N	500 N	2500 N

The VS screws have shown at all grades a lower resistance to pull-out tests respect to the VC and VT ones. This behavior can be attributed to the lower height of the thread profile and to the smoother fillets. These characteristics, negative for the resistance to pull-out tests, on the contrary, become positive to avoid the stress concentration in bone.

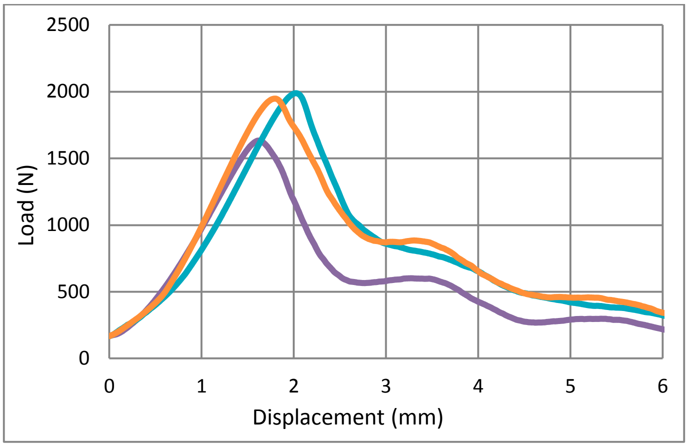

Fig. 4. Results of the pull out test for the VS screw in the grade 40

4. Fatigue investigation

To analyze the different behavior of the screws, pull-out fatigue tests were carried out as well. In addition, the different screw-bone interface behavior was evaluated both by photoelasticity and by finite element analysis.

4.1. Fatigue pull out tests

The pull-out tests under dynamic load conditions have been performed on two specimens for each grade, and for each screw. The experimental apparatus was the same as that used for the static tests. The tests were performed on the screws VS, VC and VF. VF substituted VT screws because of the difficulty to lock the mobile head of the latter.

The loading procedure was performed in following steps of increasing value. Loading cycles starting from an initial value calculated as a percentage of the breaking load obtained in the static case, incrementing the value of the applied force until the failure of the screw. Each loading step applies 100 times a sinusoidal tensile force with constant amplitude and loading ratio R=0. The tests were carried out by the Zwick-Roell Z100 again, programming the sequence of the train pulses under displacement control. The cross-head speed was set at 200N/s.

Table 2 shows the values of loads for each grade in which the failure of the screws was observed. The VC and VT screws have comparable performances. The values of the force of extraction in dynamic loading conditions for Grade 40, are similar to those found for the static conditions for the VS screws, highlighting that, in this case, the stress concentration due to the notch does not greatly affect the pull-out force. This effect is more evident in VC screws, with more acute thread, the strength values of pull-out decline, although not markedly. This is a symptom of the stress concentration at the interface of these screws.

4.2. Photoelastic analysis

The notch effect of the thread was evaluated also by photoelastic analysis of stresses. The screws were manually inserted within the block of photoelastic elastomeric material, previously drilled with milling cutter with a tip of 3 mm, and the specimen was observed at the plane polariscope. To characterize the photoelastic material, a tensile test was performed on a narrow strip of it, obtaining a Young's modulus of 2.16 MPa and a Poisson's ratio of 0.46.

To evaluate the photoelastic effect, the specimen was placed inside a polariscope and the fringes generated around the thread were quantified *in situ*, under white and yellow (sodium lamp) lights. The specimen was initially observed in white light (Fig. 5 a), allowing to identify the zero fringe and to establish the direction of increasing ideal stress according to the sequence of colors; the order of the fringes growing from the outside towards the inside, closer to the threads of the screws. Afterwards, the specimen was observed in yellow light (Figure 5 b), this has allowed, with the aid of a magnifier, to count the fringes generated around the threads of the two screws. A similar procedure was applied using the circular polariscope with green LED light source, noting substantially the same results but with a lower definition.

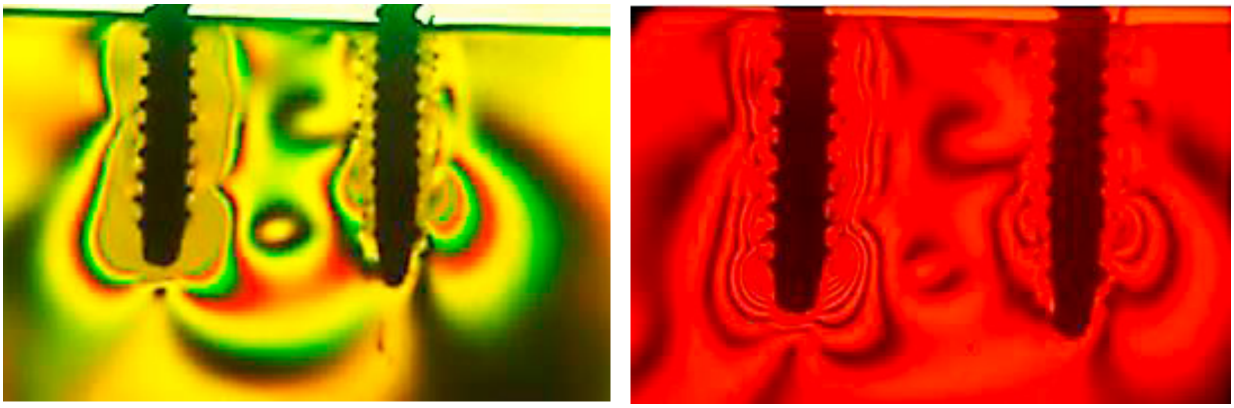

Fig. 5. (a) Fringes in white light, (b) Fringes in sodium light. VC screw on the left, VS screw on the right.

Around the thread of the VC screw the number of fringes is about 16, while for the VS screw is only 8. This result confirms what was previously stated, the thread with a blunter profile ensures a more uniform distribution of stresses and reduces the notch effect, with an obvious minor amplification of the stresses on the bone in which the screw will be implanted. It is also remarkable that the distribution of the fringes is wider in the VC screws, testifying that the effects of the concentration of stresses involving a much larger amount of material, while this effect is reduced to limited areas, only in the vicinity of the thread in the VS screw.

4.3. Finite element analysis

In order to evaluate the notch effect due to the different thread geometry for the VC and VS screws, a finite element analysis was also carried out, using the software Ansys Workbench 16.0. To simulate the stress generated at the interface due to the clamping effect, a block whose internal cavity reproduces the geometry of the screw was modeled using SolidWorks software and a normal displacement at each point at the internal surface of the cavity was applied. To reproduce the same condition studied in photoelastic analysis, the photoelastic material was subjected to the pressure generated by a displacement corresponding to the difference between the screw geometry and the cylindrical hole (3 mm diameter) previously drilled.

With the purpose to compare numerical analysis results with photoelastic ones, Fig. 6 shows the trend of Tresca stresses for the two models studied.

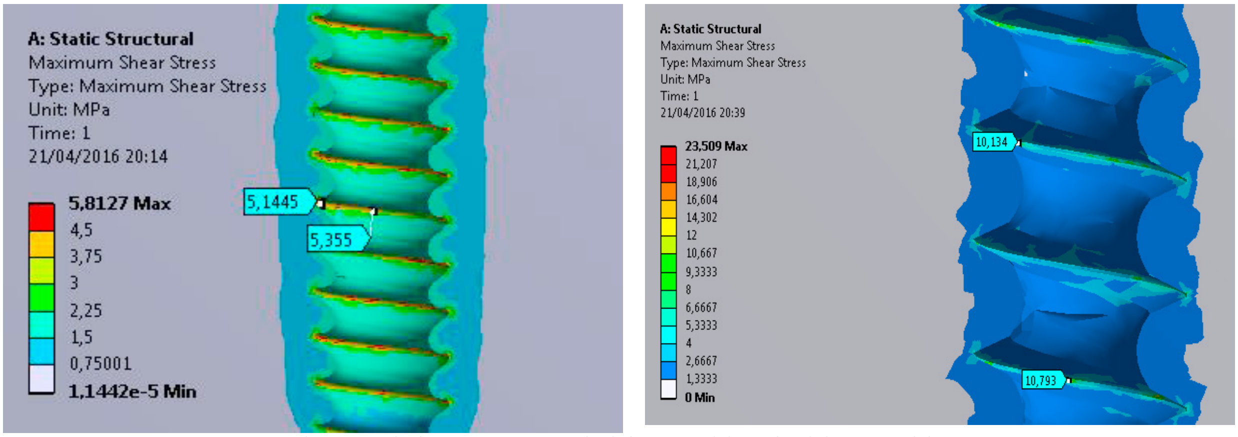

Fig. 6 Trend of Tresca stress. On the left VC model, on the right VS model

The maximum values are highlighted by the probe shown in the figure and are respectively about 5 MPa for the VS screw and about 10 MPa for the VC screw. The results obtained by numerical simulation confirm what was previously stated. The trend of the stress is also similar to that of the isochromatic observed on the photoelastic bench.

5. Bending tests

5.1. Static bending tests

To perform the static bending test, the screws were mounted inside orange wooden blocks, to simulate the insertion on the pedicular bone, then a vertical force was applied on the screw head with a 25 mm lever arm. The load was applied again by the Zwick-Roell Z100 testing machine at a rate of 2 mm/min. Two tests were carried out for each screw and load-displacement curves (Fig. 7) were obtained.

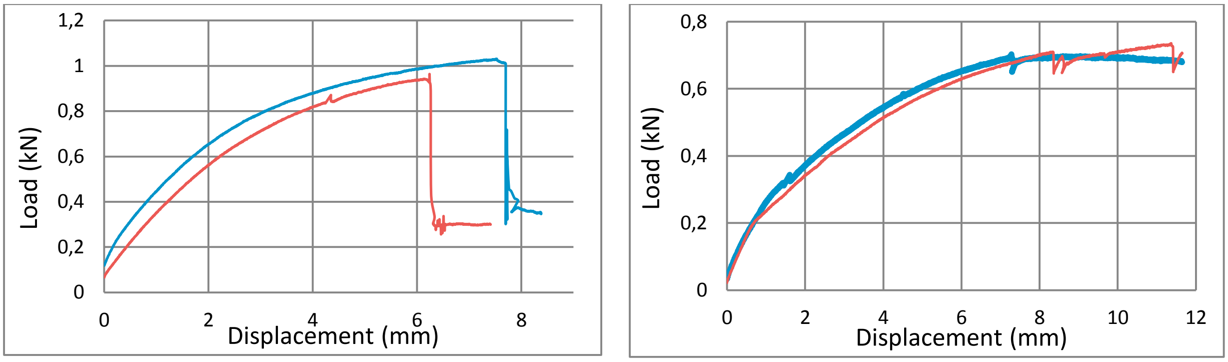

Fig. 7. Load-displacement curves: on the left VS screws, on the right VC screws.

In the load-displacement curves, the difference on the plastic behavior between VS and VC curve become more evident. In both the types, the curve is not linear but, in the VC screws, a plastic zone is present, practically negligible in the VS screws. For the VC screws, the test was stopped when the displacement of the cross-head exceeded 11 mm. Tests highlighted a different behavior between VS screws, produced by the EBM process and commercial screws (VC) produced with conventional metallurgical techniques. The former show a brittle behavior; the latter, instead, ductile. Then, in the first case, you have structural failure, in the second case, the functional failure.

5.2. Fatigue bending tests

In order to perform the bending fatigue test, it was necessary to lock the head of the screw with a spherical joint. The ball joint avoids overstress phenomena related to elastoplastic deformations and clearances. Moreover, the ball joint assures the position control. To allow the connection between the screw head and the ball joint, two mechanical components, have been designed and realized in K100 steel by a mechanical process. Fig. 8 shows the experimental setup, where it is possible to distinguish the ball joint and the support of the wooden block.

Fig. 8. Experimental setup of bending fatigue tests.

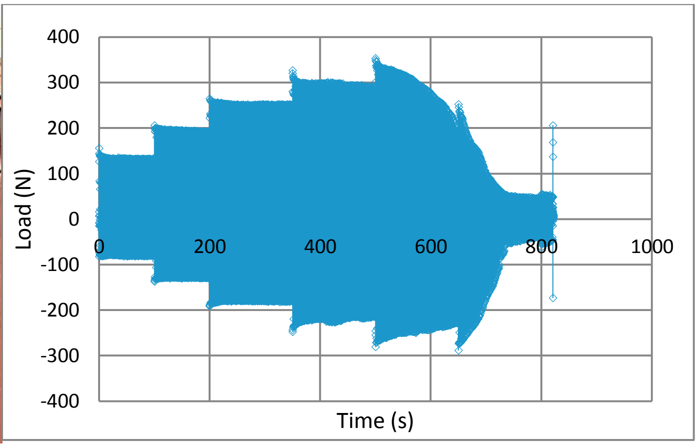

Fig. 9. Variation of applied force overtime on screws.

The bending fatigue test was performed under displacement control and the applied load and temperature over time were simultaneously recorded. From the knowledge of the load-displacement curve in the static case, it has been possible to design a sequence of increasing level displacements. Fig. 9 shows the loading sequence of cycles applied to each value of displacement.

The temperature of the specimen surface was evaluated in real time through a thermographic camera and the temperature trend in four specific points was recorded: two spots placed on the body of the screw in the area subjected to greater stress and two spots placed on the wooden block (Fig. 10). The Fig. 11 shows the temperature trend over time, in one of the spots positioned on the body of the screw VS at different steps of the loading sequence.

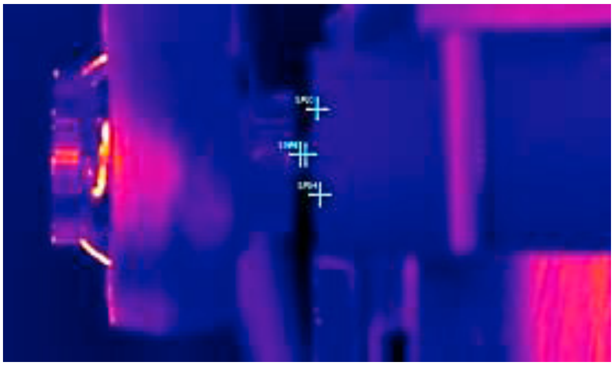

Fig. 10. Thermal image of the specimen with the location of the spots.

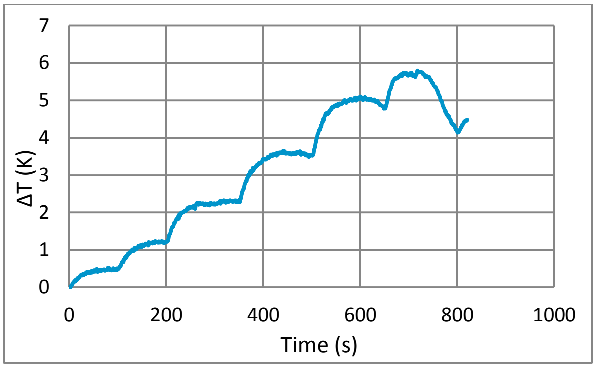

Fig. 11. Temperature variation in time VS screws.

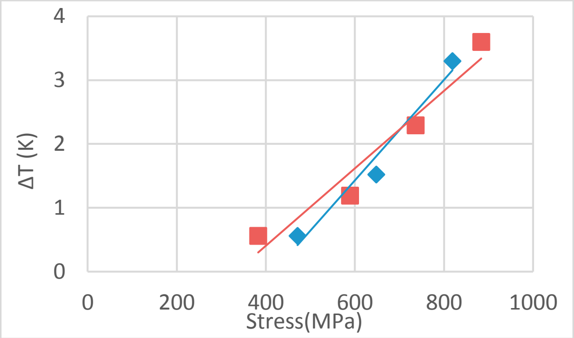

Fig. 12. Curve ΔT-σ for VS screws.

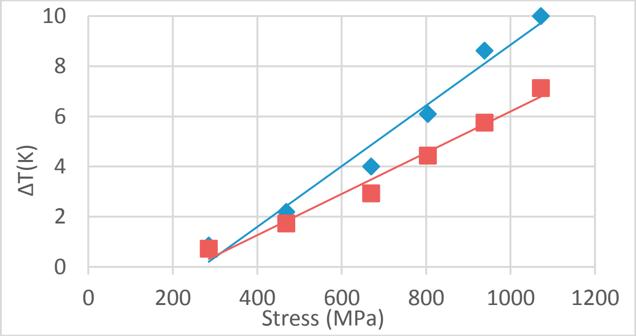

Fig. 13. Curve ΔT-σ for VC screws.

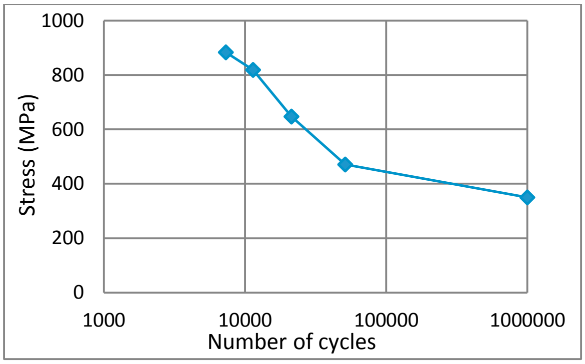

Fig. 14 Fatigue curve for VS screws.

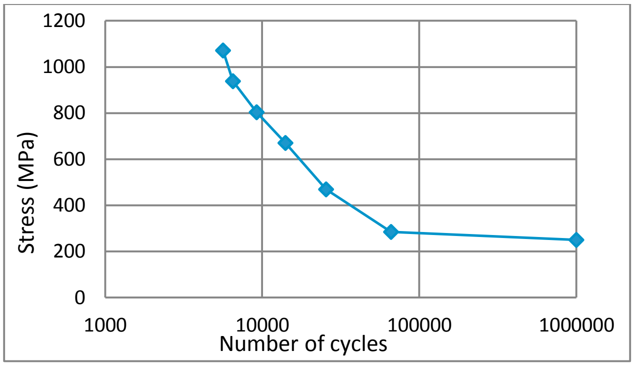

Fig. 15. Fatigue curve for VC screws.

By applying the Risitano method (La Rosa and Risitano (2000), Risitano et al. (2015)), the stabilization temperature ΔT has been plotted as a function of the stress due to the bending moment (Fig. 12-13), the fatigue limit is obtained from the intersection of the trend line with the x-axis. Using the Risitano method (Fargione et al. (2002), Risitano et al. (2012)), the fatigue curves were finally obtained for the two types of screws (Fig. 14-15). The stress indicated in the figures is the nominal bending stress considering the core diameter of the screws, without taking into account the notch effect.

Even with a limited number of tests, the thermographic technique allows the prediction of the fatigue limit, estimated around 270 MPa for the VC screws and 340 MPa for the VS screws. From bending tests, that well simulate the load conditions of the implant, the fatigue limit is substantially comparable, even better for VS screws. The fatigue curves, as only in the first approach, put in evidence how, in the LCF range, the commercial (VC) screws show a better behavior but, in the HCF range, the performances are comparable between the two types of screws.

This behavior allows to revalue the performances of the VS screw, mainly for the secondary stabilization. Consequently, the VS screws, that ensuring a better osseointegration grace to the higher roughness, could offer increased security in the post-operative phase.

6. Conclusions

This work, conducted in collaboration with the company Mt Ortho, has the purpose of carrying out a preliminary analysis to assess the viability of a future commercialization of pedicle titanium screws obtained by additive manufacturing process EBM. To this aim, experimental and numerical tests have been performed to compare the EBM screws (VS) with commercial screws currently in clinical use (VC). The tests carried out have shown encouraging results.

The VS screws exhibited a lower resistance to pull-out tests with respect to VC screws, but it is known that a rough and microporous surface, such as that of the VS screws, provides to the implant osseoinductive capacity, improves cell adhesion, proliferation and the differentiation of osteoblasts, thus ensures a better secondary stability.

It was also demonstrated that the geometry of the VS screws allows a better distribution of the stresses at the bone-implant interface and reduces the notch effect, with obvious benefits on the host bone tissue. VS screws have a resistance to bending comparable with the VC screws, but the first show a brittle behavior, while the second ductile.

References

ASTM Designation: F 543 – 02 Standard Specification and Test Methods for Metallic Medical Bone Screws.

ASTM Designation: F 1839 – 01 Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments.

Daftari, T.K.; Horton, W.C.; Hutton, W.C., 1994, Correlations Between Screw Hole Preparation, Torque of Insertion, and Pullout Strength for Spinal Screws, Journal of Spinal Disorders, 7, 2, 139-145.

Fargione, G., Geraci, A., La Rosa, G., Risitano A., 2002, Rapid determination of the fatigue curve by the thermographic Method, International Journal of Fatigue, 24, 11–19.

Gaines, R.W. Jr., 2000, The Use of Pedicle-Screw Internal Fixation for the Operative Treatment of Spinal Disorders, J Bone Joint Surg Am, 82 (10), 1458 -1458.

Geetha, M., Singh, A.K., Asokamani, R., Gogia, A.K., 2009, Ti based biomaterial, the ultimate choice for orthopedic implants. A review, Progress in Materials Science, 54, 397-425.

La Rosa, G., Risitano A., 2000, Thermographic methodology for rapid determination of the fatigue limit of materials and mechanical components. International Journal of Fatigue, 22, 65–73.

Marin, E., Pressacco, M., Lanzutti, A, Turchet, S. , Fedrizzi L., 2013, Characterization of grade 2 commercially pure Trabecular Titanium structures, Materials Science and Engineering C, 2648-2656.

McLain, R.F., Fry, M.F., Moseley, T.A., Sharkey, N.A., 1995, Lumbar Pedicle Screw Salvage: Pullout Testing of Three Different Pedicle Screw Design, Journal of Spinal Disorders, 8, 1, 62-68.

Pfeiffer, M., Gilbertson, L.G., Goel, V.K., Griss, P., Keller, J.C., Ryken, T.C., Hoffman, H.E., 1996, Effect of Specimen Fixation Method on Pullout Tests of Pedicle Screws, Spine, 21, 9, 1037-1044.

Risitano, A., Corallo, D., Risitano, G., 2012, Cumulative damage by Miner’s rule and by energetic analysis, SDHM Structural Durability and Health Monitoring, 8, 2, 91-109.

Risitano, A., La Rosa, G., Geraci, A., Guglielmino, E., 2015, The choice of thermal analysis to evaluate the monoaxial fatigue strength on materials and mechanical components, Proceedings of the Institution of Mechanical Engineers, Part C: Journal of Mechanical Engineering Science, 229, 7, 1315-1326.

Rolander, S.D, 1966, Motion of the lumbar spine with special reference to the stabilizing effect of posterior fusion. Acta Orthop Scand; 90, 1-144.

Weinstein, J.N., Rydevik, B.L., Rauschning, W., 1992, Anatomic and Technical Considerations of Pedicle Screw Fixation, Clinical Orthopaedics & Related Research, 284, 34-46.

Yuan, H.A., Garfin, S.R., Dickman, C.A., Mardjetko, S.M., 1994, A Historical Cohort Study of Pedicle Screw Fixation in Thoracic, Lumbar, and Sacral Spinal Fusion, Spine 19, 20, 2279S-2296S.