Functionalization of Screw Implants with Superelastic Structured Nitinol Anchoring Elements

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Abstract

Demographic change is leading to a increase in the number of osteoporotic patients, so that a rethink is required in implantology in order to be able to guarantee adequate anchoring stability in the bone. The functional modification of conventional standard screw implants by the use of superelastic, structured Ti6Al4V anchoring elements promises great potential for increasing anchoring stability.

For this purpose, conventional screw implants were mechanically machined and extended so that structured-superelastic-positionable-Ti6Al4V anchoring elements could be used. The set-up of the anchoring elements was investigated in CT studies in an artificial bone. In a subsequent handling test, the handling of the function samples was evaluated under surgical conditions. The anchorage stability to standard screw implants was investigated in a final pull-out test according to "ASTM F543".

The functionalization of conventional screw implants with structured superelastic Ti6Al4V anchoring elements is technically realizable. It has been demonstrated that the anchoring elements can be set up in the artificial bone without any problems. The anchorage mechanism is easy to handle under operating conditions and the anchoring elements have no negative impact on the surgical procedure. It was shown that, compared to conventional standard screws, more mechanical work is required to remove the functional patterns completely from the bone.

In summary, it was shown that conventional standard screw implants can be functionalized with Ti6Al4V structured NiTi anchoring elements and are suitable for orthopedic and neurosurgical use. A first biomechanical test showed that the anchoring stability can be increased by the anchoring elements.

Introduction/background

Demographic change is leading to an increase in patients and despite an older population with greater comorbidities (e.g. osteoporosis) the number of spine procedures has increased too. This circumstance makes it more difficult to provide patients with optimal and stabile bone care [1–3]. Therefore, the focus of implant research is currently on the further development and adaptation of screw implants to increase anchorage stability in osteoporotic bone. The use of thermally activated and superelastic nitinol (NiTi) is the subject of current research. Its special properties - one-way, two-way effect or deformation by up to 8% from the initial position - enable the functionalization of conventional standard implants through to the development of new implants and instruments. Especially because of its good biocompatibility, it is suitable for use in the human body.

Initial approaches showed that the use of thermally activated Nitinol (NiTi) as an anchoring element has great potential for increasing anchorage stability [4].

Deficit of the thermal NiTi anchoring elements is a complex and expensive temperature management (cooling during assembly, storage and implantation). Furthermore, although its smooth surface of the

NiTi anchoring elements causes an increase in anchorage stability, a textured (enlarged) surface could further increase anchorage stability.

To address these deficiencies, NiTi anchoring elements were manufactured with superelastic Nitinol and structured with Ti6Al4V elements. The structuring of the NiTi sheets is produced using the laser powder bed fusion (LPBF) technology manufacturing process already established in medical technology [5, 6]. In this process, Ti6Al4V powder is fused onto the NiTi anchoring element via the laser beam process. The manufacturing process is already state of the art and is mainly used for patient-individualized implant fabrications or for implant functionalizations [5, 7, 8]. The used Ti6Al4V is a conventional implant material and is also biocompatible in its powder form and suitable for use in the human body [5, 7]. In order to realize the largest possible, but also safest surface increase and thus the anchoring in the bone, pyramid-shaped structures were fabricated on the NiTi sheet.

The use of superelastic instead of thermally activated NiTi eliminates the need for complex temperature management. In addition, the revision process and the travel range of the anchoring elements are increased due to the superelasticity.

How these structured NiTi anchoring elements can be applied into a conventional bone screw implant and how it behaves in the osseous and human environment is investigated in the present study.

Methods

The aim of the present study was to functionalize standard screw implants to increase anchorage stability in bone and revision capability by using superelastic, structured anchorage elements.

NiTi-screw

To functionalize the screw implants, standard monoaxial pedicle screws were refined along the principles of the dowel and based on our own preliminary work [4]. The basis for this was the use of superelastic NiTi as an anchoring element and the structuring of these to exploit the interlocking effect. The structuring of the NiTi elements were implemented using the manufacturing process of laser beam melting with Ti6Al4V. Functional samples were made to investigate and evaluate the screw design.

The aim of the study was to increase the anchorage stability by structuring the NiTi anchorage elements with Ti6Al4V pyramid structures, as well as increasing the diameter by 2mm of the screw implant after setting up the anchorage mechanism.

Proof of function

Test 1: Functional proof of the installation mechanism

The set-up mechanisms of the structured NiTi anchoring elements were tested in an artificial bone. For this purpose, the screw functional samples were implanted in a pre-drilled artificial bone cube with unset

anchoring elements. Subsequently, the anchoring elements were set up so that a diameter increase of 2 mm results in the non-implanted state. For the evaluation and verification of the set-up of the anchoring elements, the artificial bone cuboid with set-up anchoring structure was analyzed in a µCT (vItomelx s, GE Sensing & Inspection, Germany).

Test 2: Handlings-Test

In a following evaluation, an experienced neurosurgeon and orthopedic surgeon assessed the handling of the functional samples and the anchoring mechanism on human specimens of the lumbar spine (Fig. 1). The focus was on implantation, set-up mechanisms of the anchoring elements and imaging.

A questionnaire was developed to evaluate the handling, which had to be completed by the two experienced neurosurgeons. The following were evaluated

- Differences in handling and feeling during implantation and anchorage in the bone after implantation (before placement of the anchoring elements) compared to conventional standing screws
- The anchorage situation after placement of the anchorage elements in comparison to cement augmentation
- The additional work involved in setting up the anchoring mechanisms during implantation
- The handling of the rotation mechanism for setting up the anchoring elements
- The intraoperative imaging

Test 3: Functional proof of the anchoring mechanism

A screw pullout test according to "ASTM F543_ Specification and Test methods for Metallic Medical Bone Screws" [9] in artificial bone (Block 10 PCF Cellular, SawBones, Sweden) was performed to investigate the increase in primary stability. The results of the NiTi functional samples were compared with those of the standard screw implants in terms of their pullout force and mechanical work. A 4-clamp jaw system was used to clamp the screws at the screw head. The artificial bone cube was fixed in a servo-electric static tension/compression and torsion testing machine (servo-hydraulic design 10 kN/200 Nm, DYNA-MESS Prüfsysteme GmbH, Germany) in a stainless steel test block clamp to prevent displacement. The screws were aligned with the center of the pre-drilled SawBone cube. At a speed of 18°/sec and a feed rate of 2.5 mm/sec, the screws were rotated 28 mm deep into the test specimen (Fig. 2 A). After the screw was inserted into the artificial bone cube, the anchoring elements were set up so that the increase in screw diameter in the non-implanted state was 2 mm (Fig. 2 B). This step was not necessary when testing the standard screws. The pullout speed was 0.083 mm/sec. The screws were pulled out by 28 mm to ensure complete removal of the screw bodies (Fig. 2 C).

For the pullout test, N=12 standard and N=12 NiTi screw implants were examined. For each screw implant, a separate artificial bone test block with a size of 400x400x800 mm was used. The artificial bone blocks were all from the same production batch (Block 10 PCF Cellular, SawBones, Sweden).

Results

NiTi-screw

For the integration of NiTi anchoring elements, conventional standard monoaxial pedicle screws (45x6.5 mm) were drilled with a 40 mm long hole (ø 3 mm) and two opposing identical pockets were eroded from the base body. In addition, an M3.5 thread with a depth of 5 mm was countersunk into the hole (Fig. 3 A).

The anchoring elements were made of 0.3 mm thick, 1.8 mm wide and 20 mm long superelastic nitinol from Ingpuls GmbH, which were structured with 0.5 x0.5 x1 mm Ti6Al4V-pyramids. The titanium structures were fabricated using additive manufacturing of the laser melts (Laser power: 130 W; scanning speed: 1000 mm/s and respective average metallurgic fusion depth: 33,3 µm. For the assembly and guidance of the NiTi anchoring elements (red) inside the base body, titanium guide sleeves (yellow) were additively manufactured (Concept Laser M2 Cusing, Germany), see Fig. 3 B and C. A standard threaded cone (orange) is used as the final component, which realizes the positioning of the sheets and the same time acts as an anti-twisting device (Fig. 3 D).

Proof of function

Test 1: Functional proof of the installation mechanism

The set-up mechanisms of the NiTi anchoring elements in artificial bone was successfully demonstrated in CT (Fig. 4).

Test 2: Handlings-Test

The evaluation of the questionnaire showed that there were no haptic differences in the handling and feel of the NiTi screws during implantation compared to conventional, unmachined screw implants. The eroded pockets do not affect the hold in the bone.

No haptic changes were noted prior to placement of the anchoring elements with regard to anchorage compared to standard screws.

The haptic comparison of the primary stability of the NiTi screws compared to the cement augmentation was rated by one of the two neurosurgeons with 7 out of 10 possible points (10=high primary stability) and a noticeable improvement was observed. Neurosurgeon two abstained from comment.

The additional effort to set up the anchoring elements due to the rotation mechanism can be negligible.

The rotation mechanism for positioning the anchoring elements was rated as intuitive, so that very good haptic feedback was felt when the anchoring elements were applied to the bone. The torque was also rated as just right. It was not too low and not too high to allow optimal adjustment. It was well adjusted especially for osteoporotic bone tissue.

Very good imaging without artifacts of the NiTi screws as a whole, as well as of the individual anchoring elements, were demonstrated.

Test 3: Functional proof of the anchoring mechanism

Preliminary results of the pullout test in artificial bone showed a tendency for anchorage stability increase of the NiTi screw compared to standard screws.

The pullout force of the standard screws was 57.22 N ± 17.13 N and that of the NiTi screws was 62.36 N ± 18.55 N (Fig. 6).

The mechanical work (energy that must be applied to break out the screw) done by the standard screws was 4241.541 Nm ± 42.549 Nm and that of the newly developed screws was 5464.796 Nm ± 435.508 Nm (Fig. 7).

Discussion

In our study, it could be shown that a functionalization of conventional screw implants using Ti6Al4V-structured NiTi anchoring elements is implementable. Furthermore, it could be demonstrated that the NiTi screws are suitable for pre-clinical tests and are not inferior to standard screw implants.

In addition to the production-related investigation of the integration of the NiTi anchoring elements in standard screws, it was particularly important to evaluate whether the functionalization can be implemented for larger batch sizes. This is the only way to satisfy the increasing demand for alternative screw implants for patients with osteoporosis due to demographic change [10, 11] and to make screw implants affordable [12].

The screw base body could be machined using conventional standardized manufacturing technologies, such as drilling and EDM (electrical discharge machining), so that no further special tools were required. These process steps are currently already applicable for series production [13]. It would also be conceivable to use a milling machine for the deep hole drilling and the production of the pockets for the anchoring elements. This could combine the two individual steps and thus reduce manufacturing time and effort [13–15].

The sleeves, which are additively manufactured for assembly, are of significant advantage for guiding the NiTi elements, as they align the elements and fix them against twisting during implementation. Series production is possible due to the small components and the associated large batch size on the build plate [16–18]. Reworking is not necessary. Additive manufacturing is an additional advantage here because medically biocompatible Ti6Al4V is used, which is approved for use in medical technology [5]. In addition, the geometry of the sleeves can be made and adapted to the given implants without additional tools and complex design planning [16, 19]. Additive manufacturing is therefore already considered forward-looking in medical technology [19].

Due to the high deformability, without plastic deformation of superelastic Nitinol, the greatest possible set-up mechanisms and revision can be allowed.

Due to its superelastic properties, the NiTi elements can be stretched up to 8% [20, 21], which results in a maximum set-up travel per element of s = 17,7 mm (Calculation according to DIN ISO 178 [22]).

However, this is limited by the applied Ti6Al4V structures, which have a lower elasticity and can flake off if the deflection is too large [23]. Therefore, a limitation of the anchoring mechanism is necessary to prevent excessive deflection.

Furthermore, the superelastic properties simplify the revision surgery, as the NiTi elements reset themselves in the screw after loosening the anchoring mechanism and assume their initial position during implantation. In addition, there is no need for complex temperature management.

The structuring of the NiTi anchoring elements with Ti6Al4V by the LSM process can be implemented well and the fabrication over large areas is possible [18]. Another study has already shown that the structuring technology of the anchoring elements is suitable for implantology due to its good biocompatibility [24].

The structuring of the anchoring elements was chosen so that the greatest possible interlocking can take place. The larger the surface of the structure, the greater the interlocking effect [25, 26]. In terms of its optimum mechanical force dissipation, with an acting surface force, the pyramid structure was therefore chosen.

Our investigation showed that the NiTi anchoring elements could be set up in the artificial bone and also in the human specimen without any problems. Surrounding bone and tissue structures did not result in disruption of the mechanism. One advantage of the mechanical set-up was that it was haptically detected when the anchoring element was applied to the bone (increase in torque). The surgeon thus has direct feedback on the anchorage status.

At the same time, the experiments showed that the NiTi elements did not affect the imaging. No radiation overlaps occurred, was easily controllable in lateral x-rays and the set-up mechanisms could be evaluated without restrictions. This is particularly important for neurosurgical and orthopedic use, as the screw implants and their anchoring elements must not over-radiate surrounding tissue structures, because of proximity to the spinal canal [27–29].

Furthermore, the handling test and the evaluation of the functional samples by the surgeons showed that the NiTi screws - despite the missing thread due to the eroded pockets - could be compared with standard screws during implantation (compressed spongiosa in the pedicle) and that there was no haptic difference. This is particularly important for users, as they can continue to rely on their typical haptic feel and experience when screwing in screw implants.

The haptic feel is also important for the correct torque when setting up the anchoring elements and could be optimally reproduced with the present mechanism. In this way, the surgeon can already detect an increase in stability during setup.

The screw extraction test according to ASTM F543 [9] showed that the extraction force as well as the mechanical work did not provide significantly higher results. However, there is a trend that the NiTi screws require a higher pullout force and mechanical work to pull the implant out of the artificial bone remove the screw and loosen it.

The use of artificial bone material makes it difficult to make a clear statement. The material has a foam-like structure, so that not every block is clearly reproducible with regard to its mechanical properties and thus mechanical and material deviations can occur. For initial tests (proof of a tendency) and functional proof, the artificial bone material is sufficiently adequate. Further investigations, such as toggeling tests in human specimens, are currently being carried out in order to optimally simulate and evaluate the anchoring stability under biomechanical movements.

Conclusion

In summary, conventional monoaxial standard screws can be functionalized with Ti6Al4V structured NiTi anchoring elements. The fabrication of the screw base body and integration of the NiTi anchoring elements is suitable for series production and the handling does not differ from standard screws. A first biomechanical test showed that the anchoring stability can be increased by the anchoring elements.

Limitations

For implantation and revision, conventional screwdrivers must be extended to mechanically set up the anchoring elements.

Furthermore, there is currently no locking mechanism installed for the maximum set-up mechanisms of the anchoring elements, which prevents the elements from bending too much. This must take place in further adjustments to prevent the Ti6Al4V structures from flaking.

For further statements regarding the anchorage stability, toggle tests (ASTM 1717-15 [30]) must be carried out with human specimen, because pull-out tests provide only limited information about the anchorage stability and optimal interlocking in the bone.

Declarations

Ethics approval

All donors originated from the Institute of Anatomy of the Leipzig University and had given written consent to dedicate their bodies to medical education and research purposes. Being part of the body

donor program regulated by the Saxonian Death and Funeral Act of 1994 (3rd section, paragraph 18, item 8), institutional approval for the use of the post-mortem tissues of human body donors was obtained. The authors declare that all experiments were performed according to the ethical principles of the Declaration of Helsinki.

Consent for publication

The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

Availability of data and material

The datasets supporting the conclusions of this article are included within the article.

Conflicts of interest/Competing interests

The authors declare that they have no competing interests.

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Authors´information

I.H.: Formulation or development of overall research objectives; development or design of methodology; verification of results; preparation of published work, especially writing the first draft and visualization.

S.S.: Develop or design methodology for usability testing; create models for usability testing, provide test set-up handling testing, critical review, comment and revision - including before or after publication.

C.R.: critical review, commentary and revision – including pre- or post-publication stages, Acquisition of the financial support for the project leading to this publication.

W.D.: Verification of functional sample/implant fabrication, critical review, commenting and revision - including pre- or post-publication phases, oversight and leadership responsibility for the planning and execution of the research activity, including mentorship outside of the core team.

C.H.: Verification of the handling of the implants regarding usability test, provision of testset-up handling test, critical review, comment and revision - also before or after publication, management and coordination responsibility for the planning and execution of the research activity.

M.L.: Verification of the handling of the implants with regard to usability testing, critical review, commenting and revision - also before or after publication, management and coordination responsibility for the planning and implementation of the research activities.

References

1. Heyde C-E, Rohlmann A, Weber U et al. (2010) Stabilisierung der osteoporotischen Wirbelsäule unter biomechanischen Gesichtspunkten (Stabilization of the osteoporotic spine from a biomechanical viewpoint). Orthopade 39:407–416. https://doi.org/10.1007/s00132-009-1574-8

2. Okuyama K, Abe E, Suzuki T et al. (2000) Can insertional torque predict screw loosening and related failures? An in vivo study of pedicle screw fixation augmenting posterior lumbar interbody fusion. Spine (Phila Pa 1976) 25:858–864. https://doi.org/10.1097/00007632-200004010-00015

3. Becker S, Chavanne A, Spitaler R et al. (2008) Assessment of different screw augmentation techniques and screw designs in osteoporotic spines. Eur Spine J 17:1462–1469. https://doi.org/10.1007/s00586-008-0769-8

4. Werner M, Hammer N, Rotsch C et al. (2020) Experimental validation of adaptive pedicle screws-a novel implant concept using shape memory alloys. Med Biol Eng Comput 58:55–65. https://doi.org/10.1007/s11517-019-02059-x

5. Markhoff J, Krogull M, Schulze C et al. (2017) Biocompatibility and Inflammatory Potential of Titanium Alloys Cultivated with Human Osteoblasts, Fibroblasts and Macrophages. Materials (Basel) 10. https://doi.org/10.3390/ma10010052

6. Grunert R, Lichtenstein J, Preßler N et al. (2016) Development of Patient-specific Orbital Floor Implants Made of Shape Memory Alloys. Procedia CIRP 49:143–146. https://doi.org/10.1016/j.procir.2015.11.004

7. Ginestra P, Ferraro RM, Zohar-Hauber K et al. (2020) Selective Laser Melting and Electron Beam Melting of Ti6Al4V for Orthopedic Applications: A Comparative Study on the Applied Building Direction. Materials (Basel) 13. https://doi.org/10.3390/ma13235584

8. Grunert R, Wagner M, Rotsch C et al. (2017) Concept of patient-specific shape memory implants for the treatment of orbital floor fractures. Oral Maxillofac Surg 21:179–185. https://doi.org/10.1007/s10006-017-0615-4

9. ASTM International Standard Specification and Test Methods for Metallic Medical Bone Screws 11.040.40(F543). ttp://www.astm.org/cgi-bin/resolver.cgi?F543

10. Sobotka T, Fürnkranz-Prskawetz A (2020) Demographic change in Central, Eastern and Southeastern Europe: trends, determinants and challenges. In: Holzmann R, Ritzberger-Grünwald D, Schuberth H (eds) 30 Years of Transition in Europe. Edward Elgar Publishing, pp 196–222

11. Calahorrano L, Rebeggiani L, Stöwhase S et al. (2019) Demographic change and income tax revenues – results from a large microsimulation model for Germany. Journal of Economic Policy Reform 22:399–419. https://doi.org/10.1080/17487870.2018.1469984

12. Herbert Kölbel, Joachim Schulze (2007) Kurzfristige Produktionsplanung. In: Tiedtke JR (ed) Allgemeine BWL. Gabler, Wiesbaden, pp 458–466

13. Böllinghaus T, Byrne G, Cherpakov BI et al. (2009) Manufacturing Engineering. In: Grote K-H, Antonsson EK (eds) Springer Handbook of Mechanical Engineering. Springer Berlin Heidelberg, Berlin, Heidelberg, pp 523–785

14. Kramer TR (1992) Pocket milling with tool engagement detection. Journal of Manufacturing Systems 11:114–123. https://doi.org/10.1016/0278-6125(92)90042-E

15. Asghar E, Zaman UKu, Baqai AA et al. (2018) Optimum machine capabilities for reconfigurable manufacturing systems. Int J Adv Manuf Technol 95:4397–4417. https://doi.org/10.1007/s00170-017-1560-y

16. Tofail SAM, Koumoulos EP, Bandyopadhyay A et al. (2018) Additive manufacturing: scientific and technological challenges, market uptake and opportunities. Materials Today 21:22–37. https://doi.org/10.1016/j.mattod.2017.07.001

17. Klahn C, Meboldt M, Fontana F et al. (eds) (2018) Entwicklung und Konstruktion für die Additive Fertigung: Grundlagen und Methoden für den Einsatz in industriellen Endkundenprodukten, 1. Auflage. Vogel Business Media, Würzburg

18. Gebhardt A, Kessler J, Schwarz A (2019) Produktgestaltung für die Additive Fertigung. Hanser, München

19. Haleem A, Javaid M (2019) Additive Manufacturing Applications in Industry 4.0: A Review. J Ind Intg Mgmt 04:1930001. https://doi.org/10.1142/S2424862219300011

20. Johnson Matthey (2017) JMB Overview: Nitinol

21. Wagner MF-X (2005) Ein Beitrag zur strukturellen und funktionalen Ermüdung von Drähten und Federn aus NiTi-Formgedächtnislegierungen. Zugl.: Bochum, Univ., Diss., 2005. Maschinenbau, vol 4. Europ. Univ.-Verl., Bochum

22. Beuth Verlag GmbH (2019) Kunststoffe - Bestimmung der Biegeeigenschaften (ISO 178:2019)(178). Accessed 26 May 2021

23. Wanhill R, Barter S (eds) (2012) Fatigue of Beta Processed and Beta Heat-treated Titanium Alloys. SpringerBriefs in Applied Sciences and Technology. Springer Netherlands, Dordrecht

24. Hamann I, Hempel U, Rotsch C et al. (2020) Biological Cell Investigation of Structured Nitinol Surfaces for the Functionalization of Implants. Materials (Basel) 13. https://doi.org/10.3390/ma13153264

25. Kim W-S, Yun I-H, Lee J-J et al. (2010) Evaluation of mechanical interlock effect on adhesion strength of polymer–metal interfaces using micro-patterned surface topography. International Journal of Adhesion and Adhesives 30:408–417. https://doi.org/10.1016/j.ijadhadh.2010.05.004

26. Bindal AK, Das A, Das A (2020) Study on Effect of Particle Shape on Interlocking. In: Prashant A, Sachan A, Desai CS (eds) Advances in Computer Methods and Geomechanics, vol 56. Springer Singapore, Singapore, pp 455–466

27. Stradiotti P, Curti A, Castellazzi G et al. (2009) Metal-related artifacts in instrumented spine. Techniques for reducing artifacts in CT and MRI: state of the art. Eur Spine J 18 Suppl 1:102–108. https://doi.org/10.1007/s00586-009-0998-5

28. Secchi F, Cecco CN de, Spearman JV et al. (2015) Monoenergetic extrapolation of cardiac dual energy CT for artifact reduction. Acta Radiol 56:413–418. https://doi.org/10.1177/0284185114527867

29. Kotsenas AL, Michalak GJ, DeLone DR et al. (2015) CT Metal Artifact Reduction in the Spine: Can an Iterative Reconstruction Technique Improve Visualization? AJNR Am J Neuroradiol 36:2184–2190. https://doi.org/10.3174/ajnr.A4416

30. F04 Committee Test Methods for Spinal Implant Constructs in a Vertebrectomy Model 11.040.40(F1717-15)

Figures

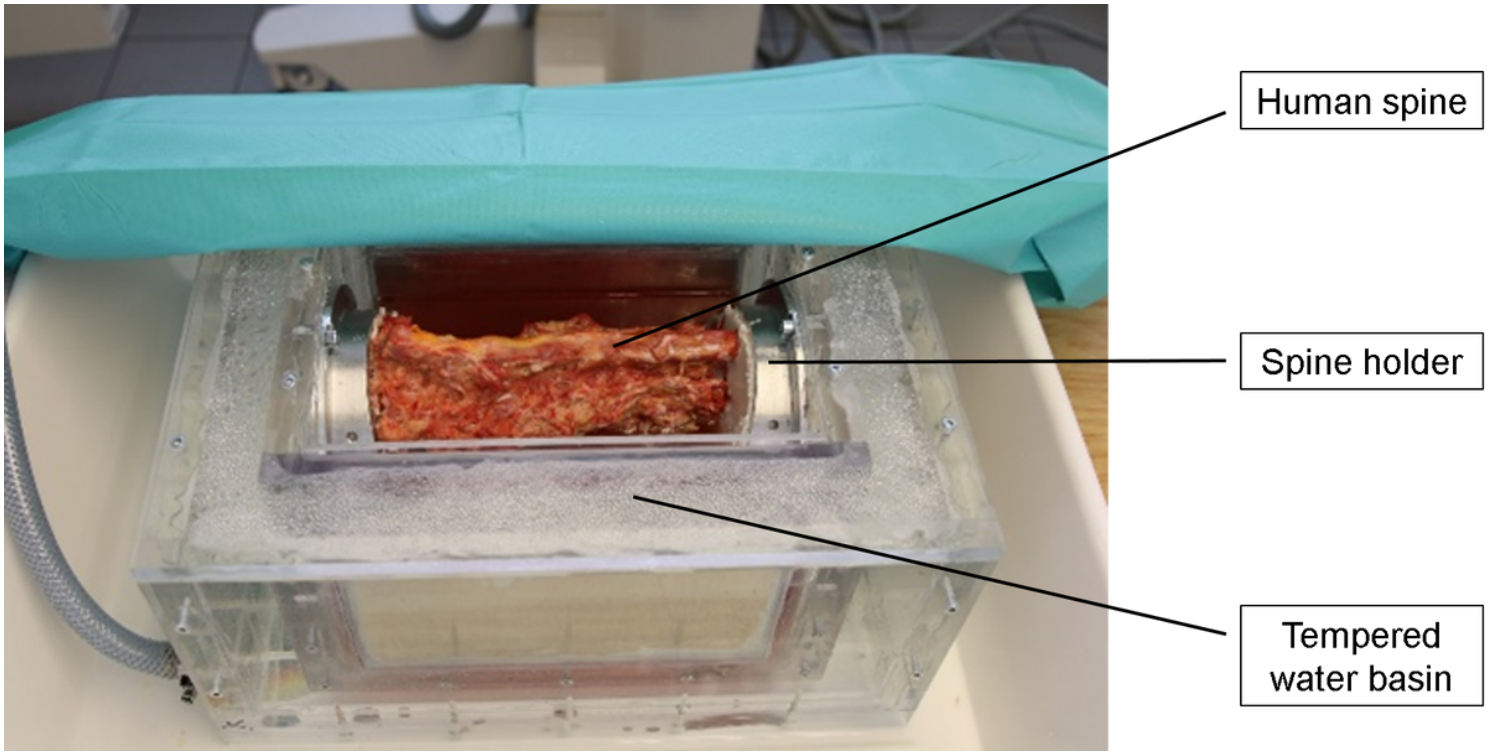

Figure 1

Test setup of the handling test

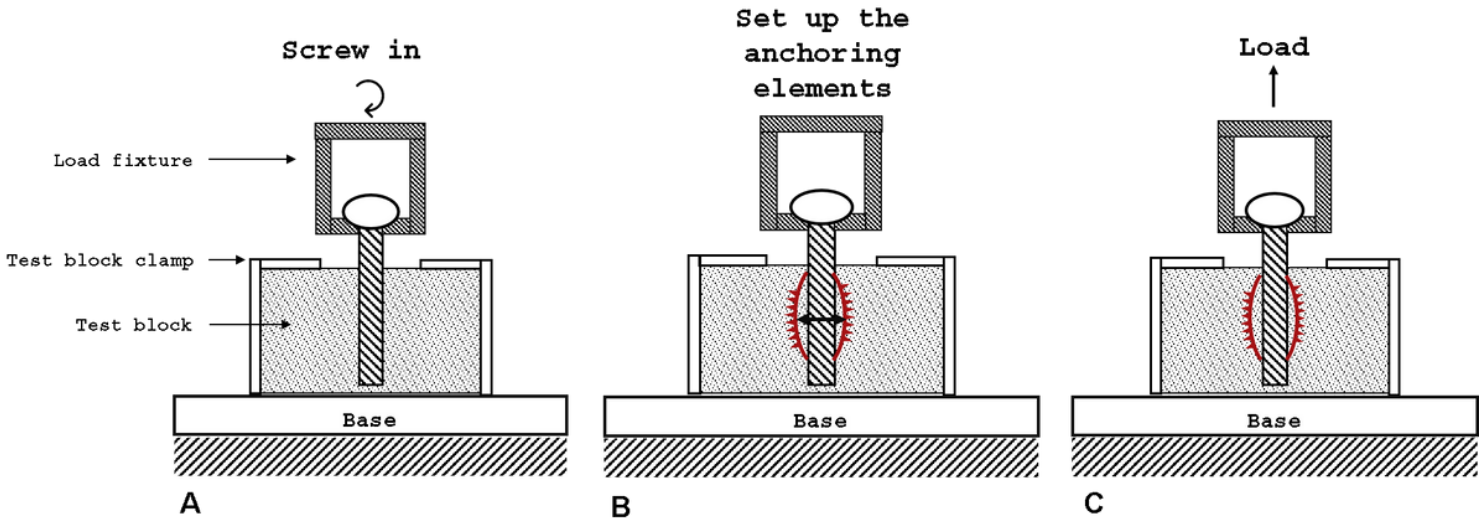

Figure 2

Pullout-Test-Setup; A: Screwing in the screw; B: Setup the anchoring elements; C: Pullout the set up screw

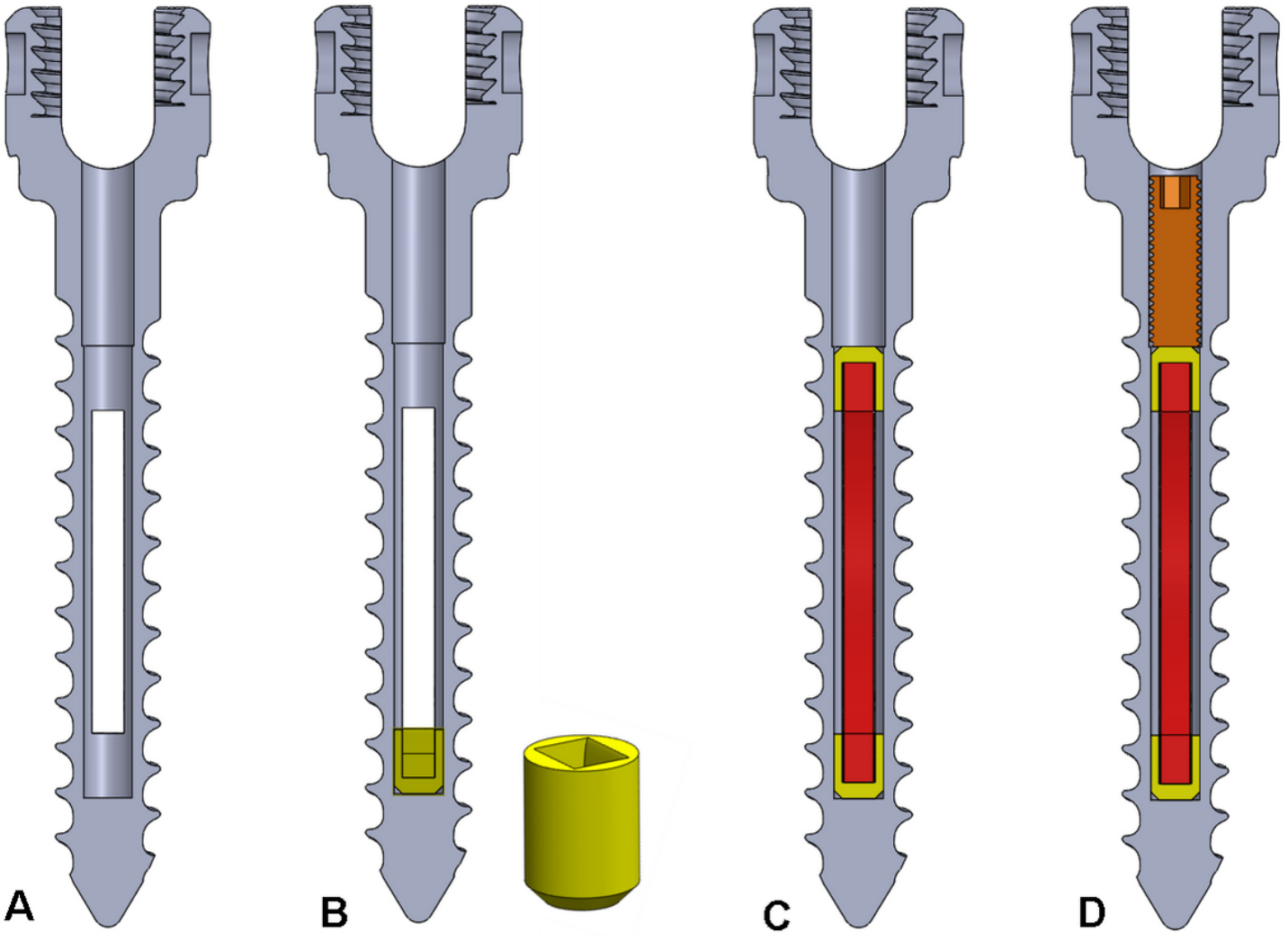

Figure 3

Structure of the NiTi screw; A: screw base body with hole; B: additively manufactured guide sleeve (yellow); C: structured NiTi anchor element (red) with guide sleeves (yellow); D: threaded cone (orange)

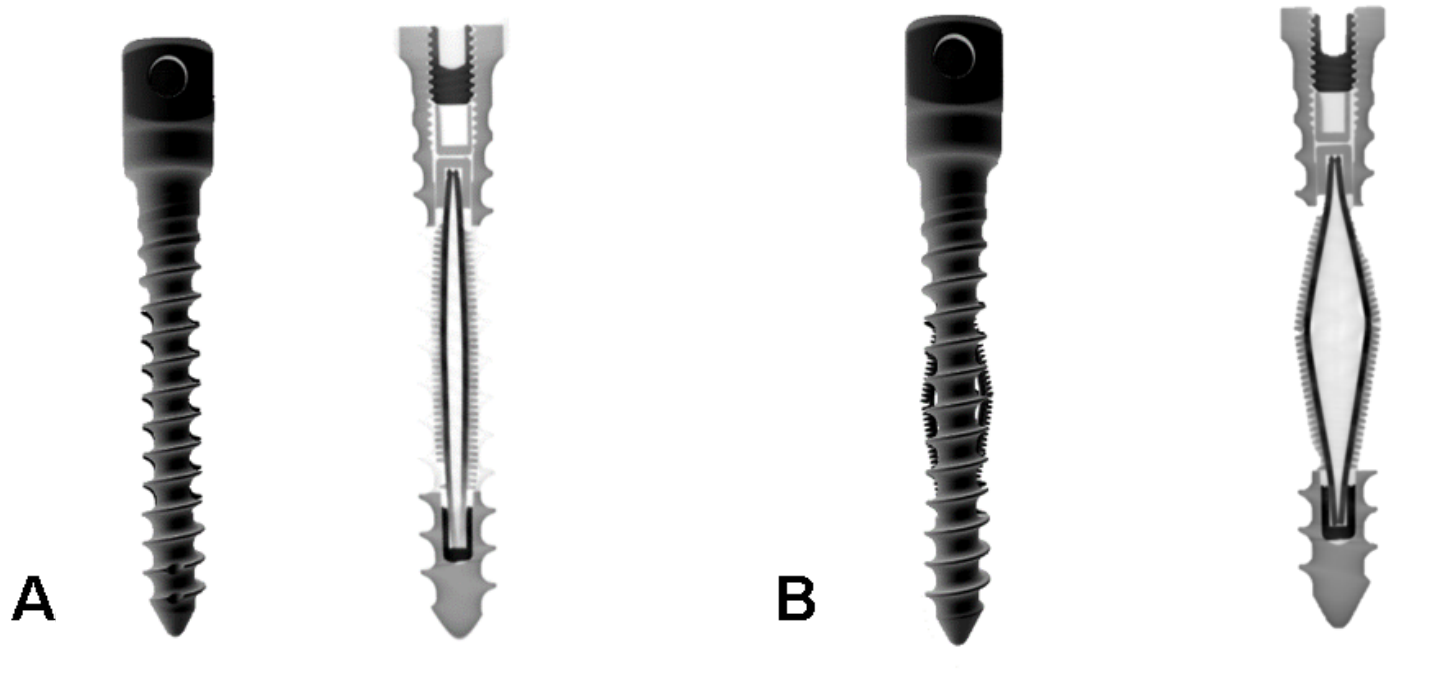

Figure 4

CT-images of the NiTi-screw; A. after implantation; B: after setup the anchoring elements

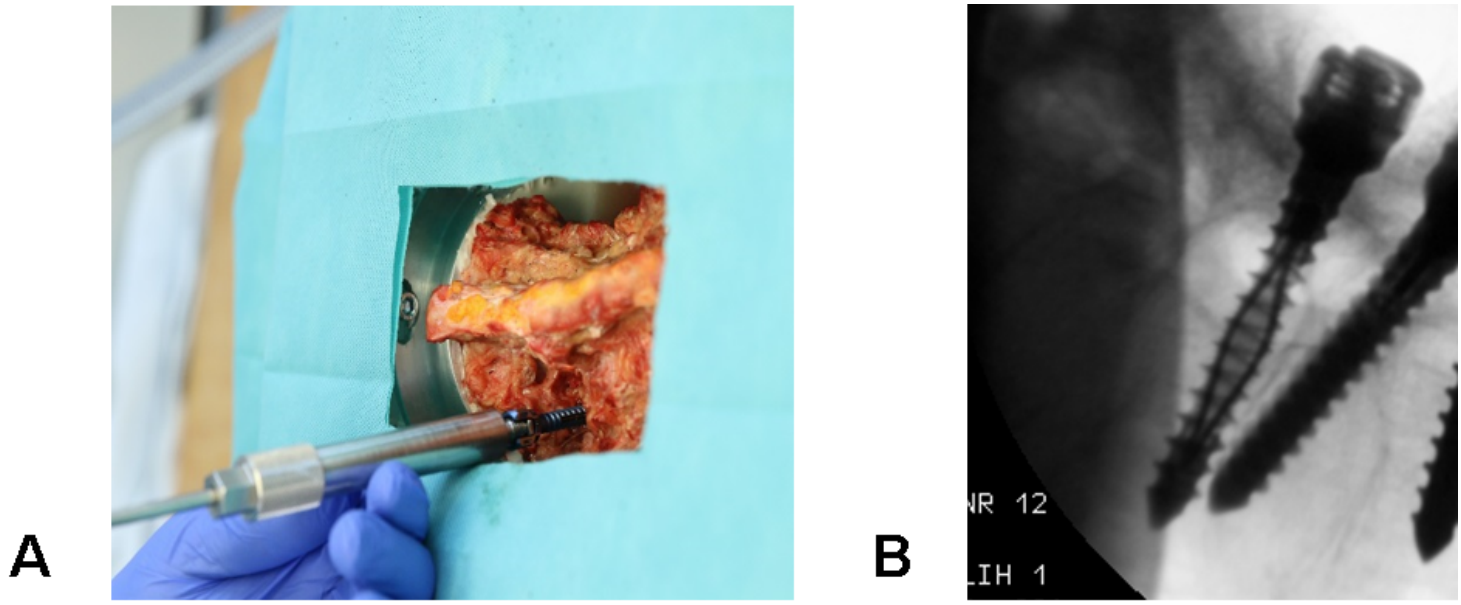

Figure 5

Handlings-test; A: Implantation of the NiTi screw; B: CT image of the implanted NiTi screw.

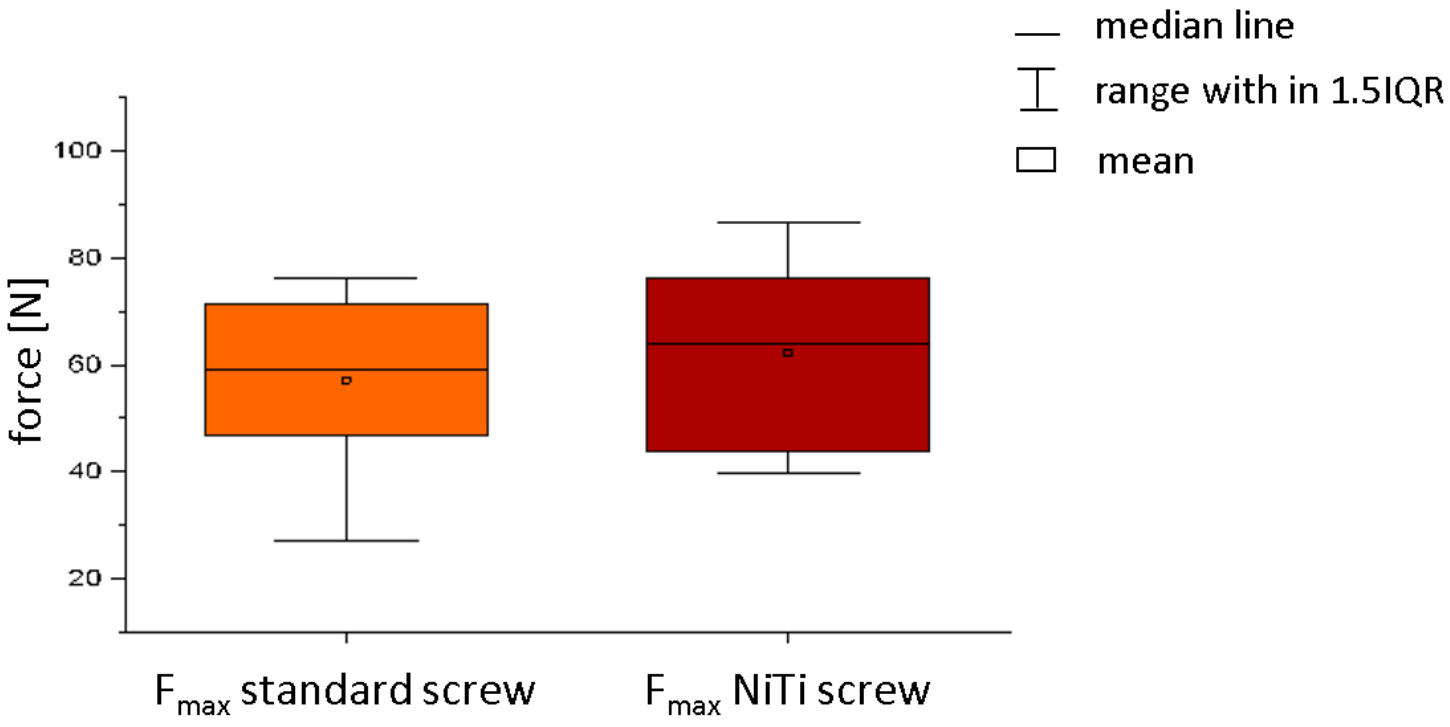

Figure 6

Pullout force of the standard screw (orange) and NiTi screw (red)

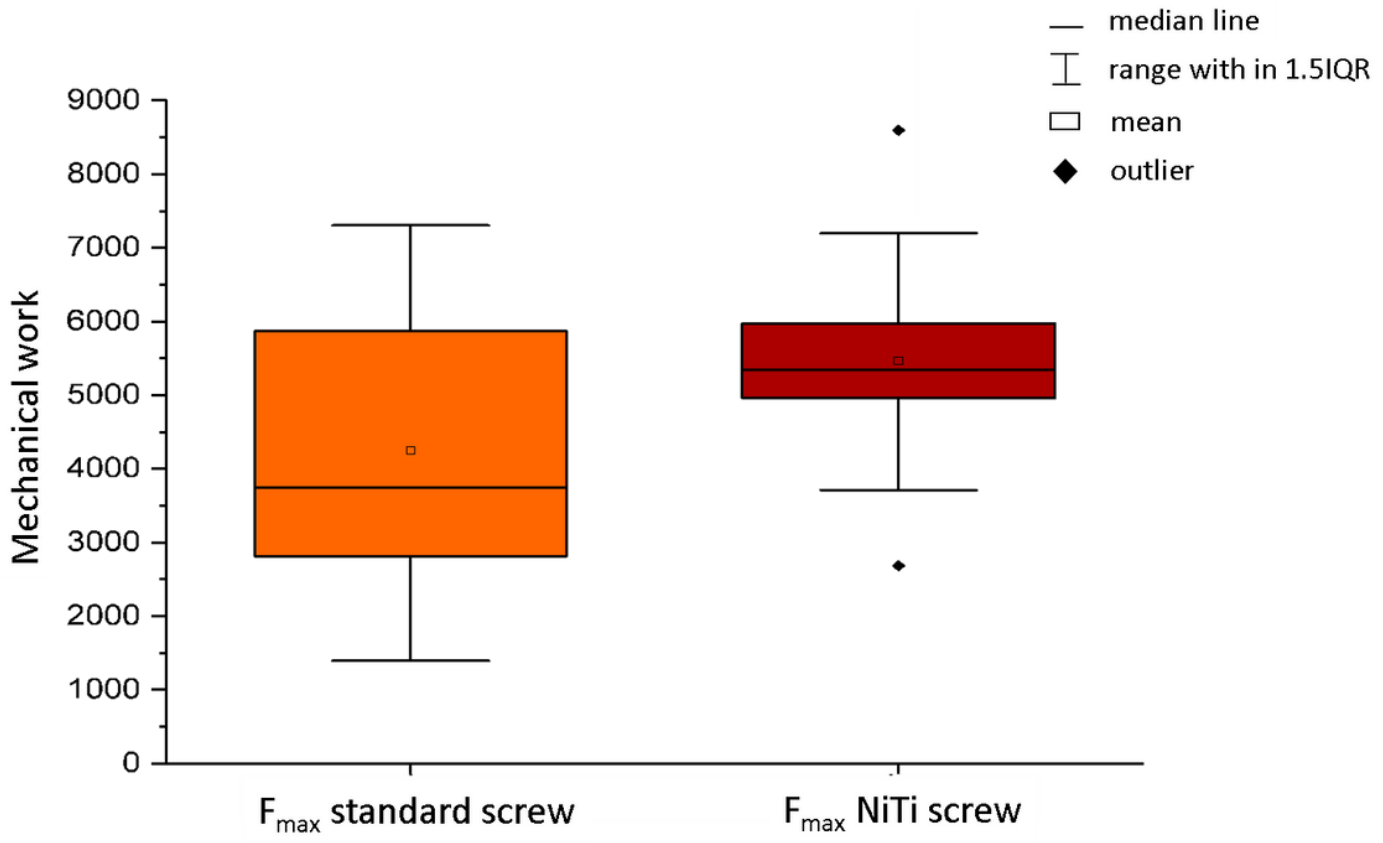

Figure 7

Mechanical work of the standard screw (orange) and NiTi screw (red)

Supplementary Files

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