


Pedicle screw concept with shape memory components for improved bone anchorage, DGNC 2015

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Motivation, Medical Background

Statistic

- **Degenerative disease of the cervical spine**
  Majoritiy of patients > 65 years
- Demographic aging:
  - Germany 2005 *: > 65 years: 16 Mio.
  - Prognosis 2030 *: > 65 years: 22 Mio.
    (about 40 percent more than in 2005)

** (Angaben Statistische Bundesamt Wiesbaden, 2007)*

Motivation, Medical Background

Problems from the perspective of the surgeon (spinal surgery in general):

- High expectations regarding the patient´s **functional outcome**, nonunion, cage dislocations, adjacent segment degeneration, implant failure or malpositioning such as persistent complaints after successful osseous restoration of the fused segment
- Limited selection of implants
  (Side effects trough compromise: mobility restrictions, **loosening of the implant**)
- **Revision rate between 10 - 20% (McAfee et al., Cinotti et al.)**
- Objectives: „…improved preoperative planning, Less stress on the faciet joints, **improved revision capability**…“ (C. Hopf, Abteilung für Wirbelsäulenchirurgie, Kinder, Rheuma- und onkologische Orthopädie , Lubinus Clinicum)

Motivation, Medical Background

State of the art

- Use of screws with larger cross-section

  → <u>Problems:</u>

  - Long-term stability in degenerative disease is not ensured
  - Further erosion of the damaged bone

- Use of bone cement (PMMA)

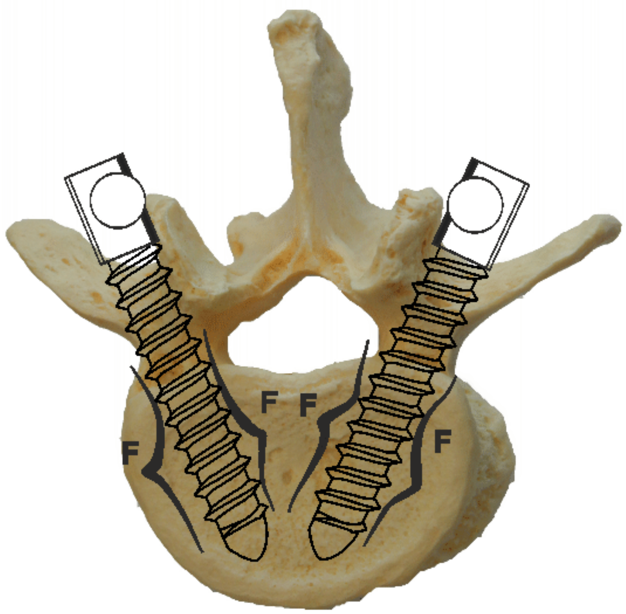
  → <u>Problems:</u>

  - Monomer of PMMA (MMA): toxic unless polymerized
  - High polymerization temperature → tissue necrosis possible
  - At explantation: spacious destruction of the bone

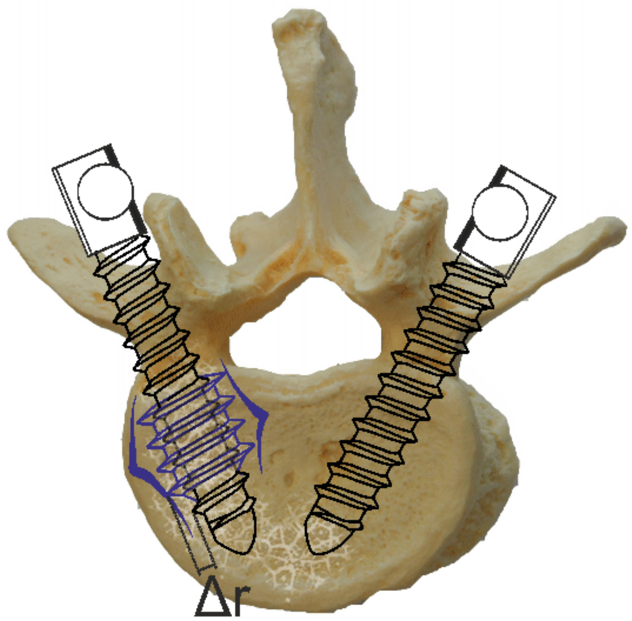
Objectives

- Improved anchorage of the pedicle screw in the bony surface by force and tight fit
- For use in degenerative (e.g. osteoporotic) bone or damaged bone after revision

Force fit



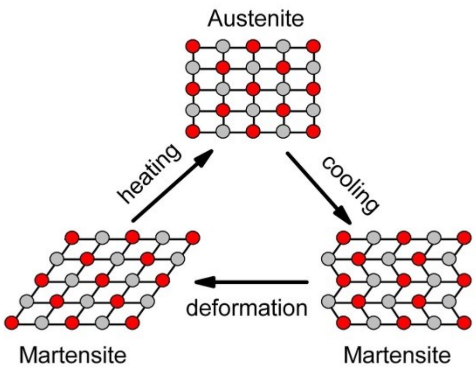
Tight fit



Background

Nitinol

- Metall alloy of nickel and titanium, *N*ickel-*Ti*tanium *N*aval *O*rdnance *L*aboratory
- Shape memory and superelasticity
- Shape memory: ability to undergo deformation at one temperature, than recover its original shape
- Highly biocompatible, properties suitable for use in orthopaedic implants



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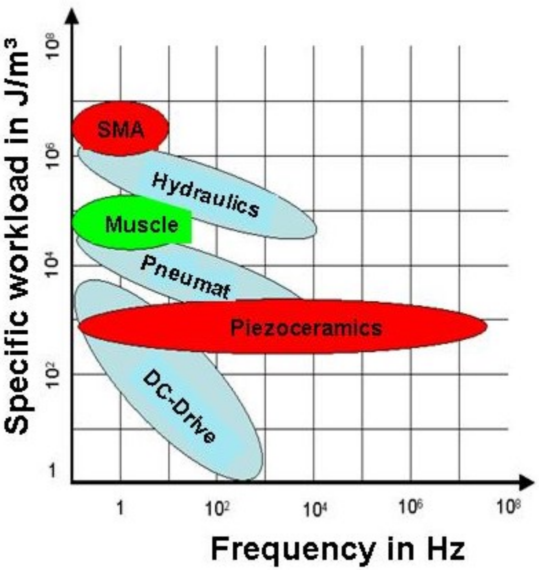
Idea

- Integration of actuators

→ Conception of a pedicle screw with active components bases on **shape memory alloys (SMA)**

Benefit of SMA:

- Specific workload and active behaviour is comparable to the natural muscle
- Materials are biocompatible
- Additional coating possible
- Super elastic and shape memory effect



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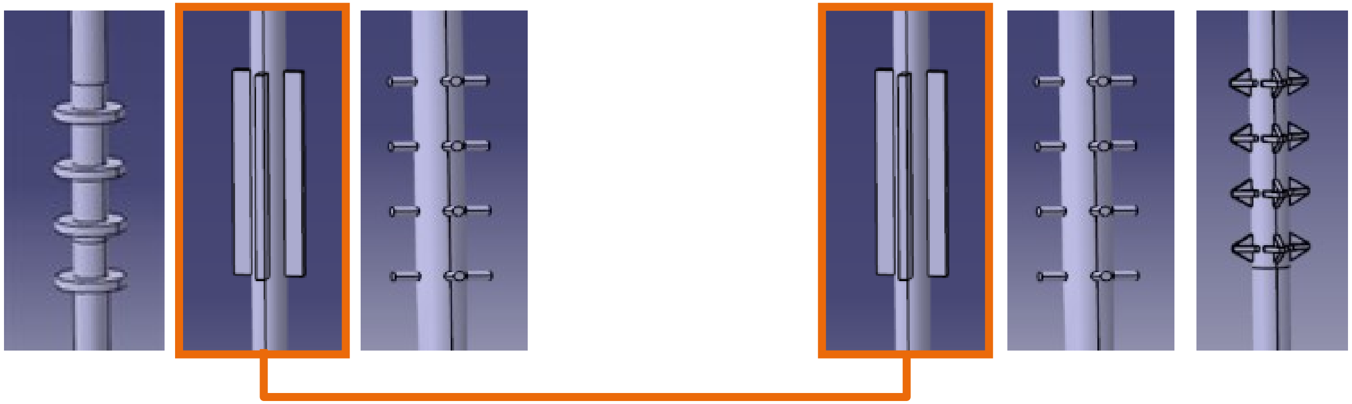
Studies on the optimal actuator geometry

- 15 geometries tested mechanically

Favorites pull-out test

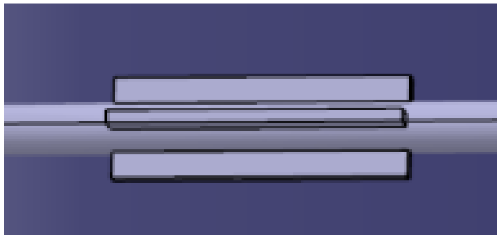
Favorites torsion test

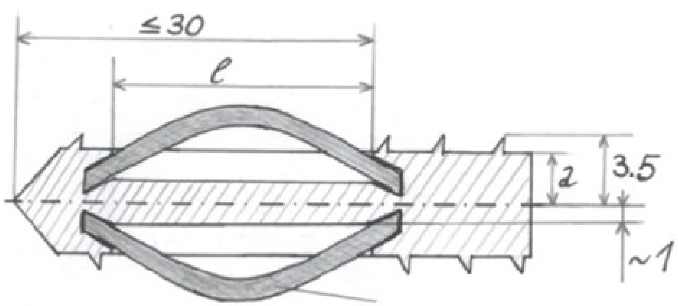


Structure along the screw axis

Design and construction

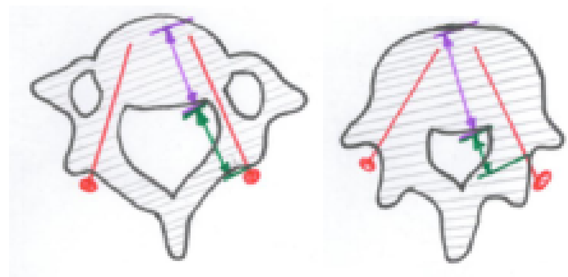
Favored geometry



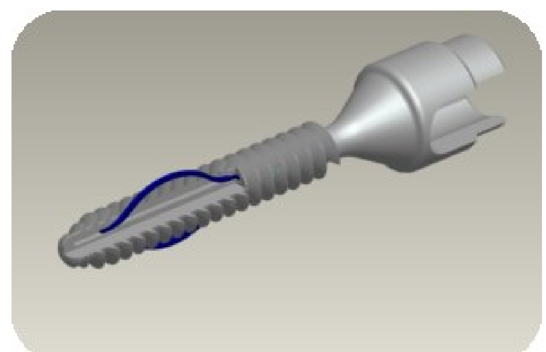


Position of the pedicle screw

Thoracic and Lumbar | Cervical

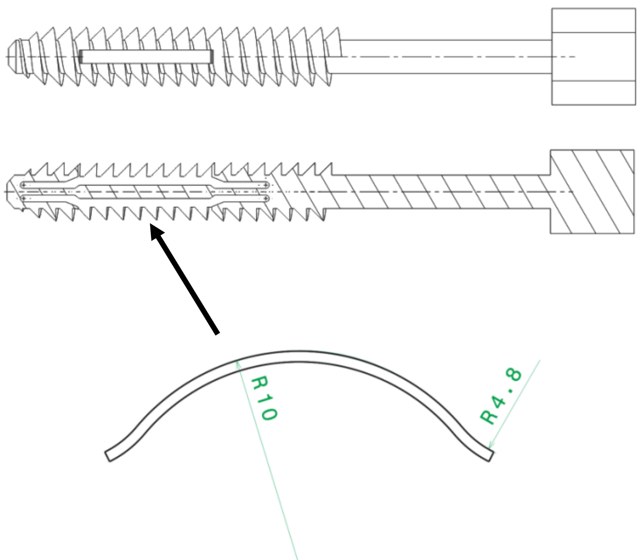


- Pedicle screw
- Area with SMA
- Area without SMA



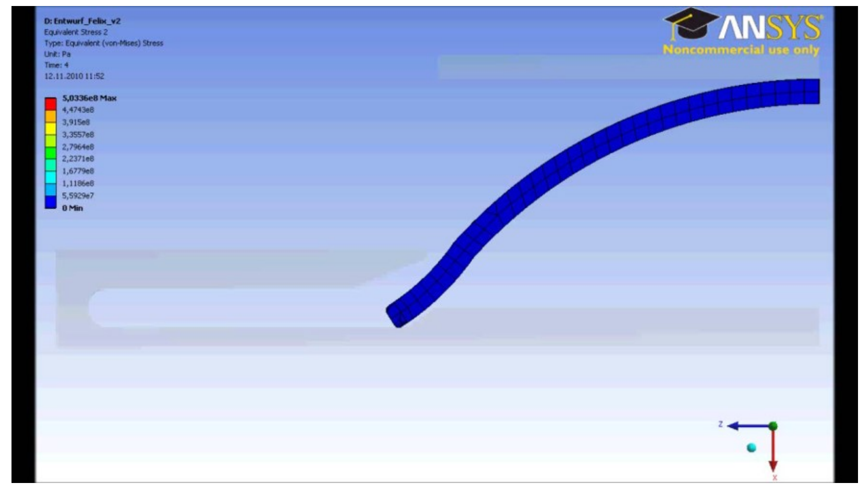
Design and construction

CAD



- Core-Ø: 4 mm
- Thread height: 1,5 mm
- Thread length: 40

FEM



FEM compression test
(von Mises equivalent test in Pa)

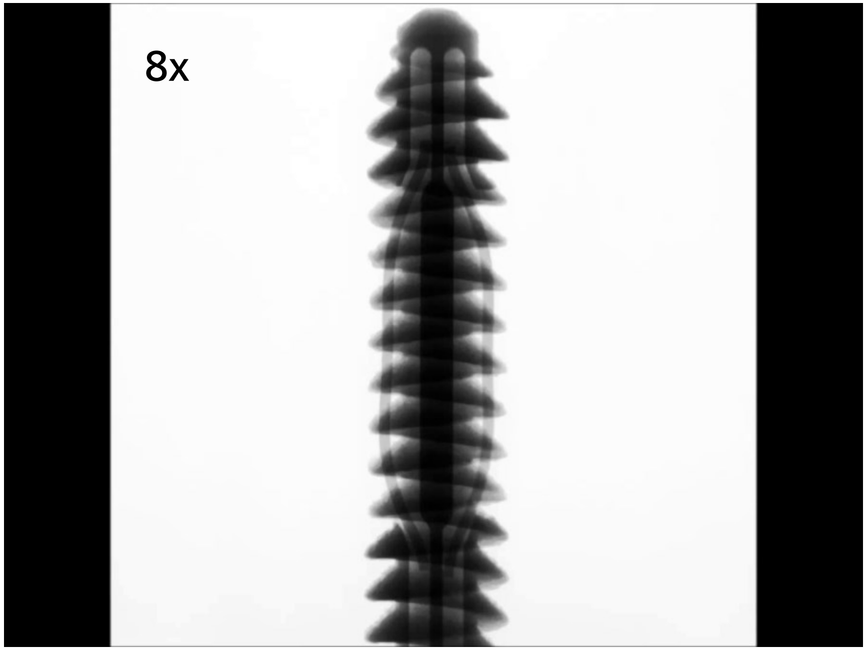
Design and construction

Functional Model

- Manufactured by laser beam melting

Design and construction

Activation under X-Ray



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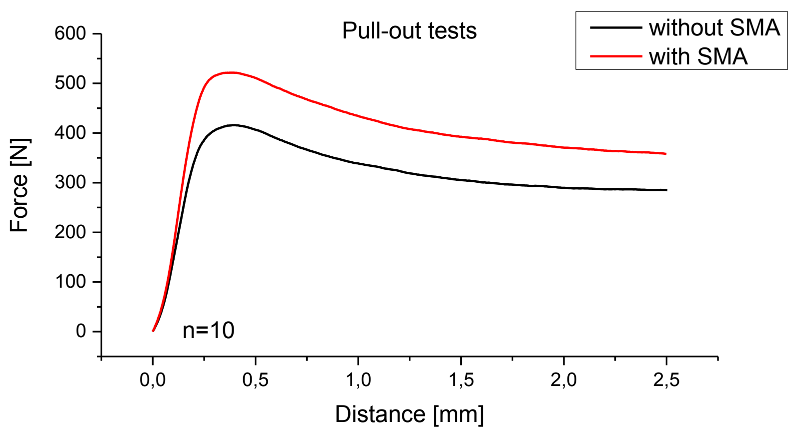
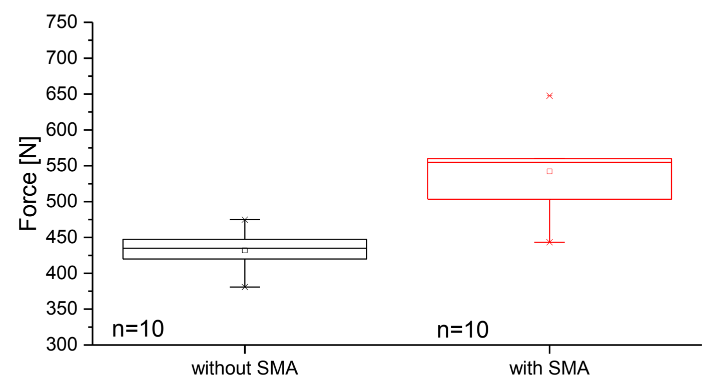
Pull-out tests in homogeneous bone substitute material

- Test according to ASTM F1839 (Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments)
- Frozen screw is screwed in a bone substitute (Sawbones®)
- Pull-out tests



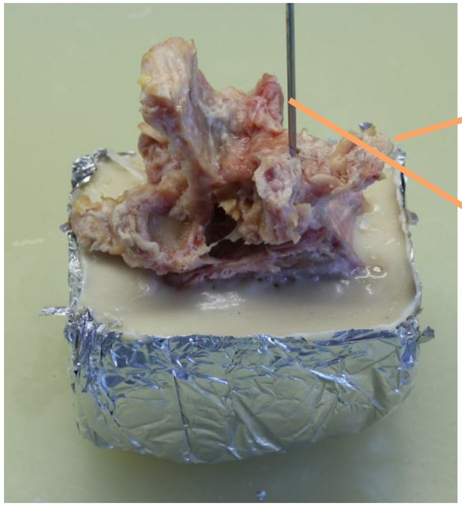


Average pull-out force:

- Without SMA: 442 N (±29 N)
- With SMA: 542 N (±53 N)

Pull-out tests on human specimen

- One spine, 4 cervical, 11 thoracic and 5 lumbal vertebrae
∑ 20 vertebrae
- left / right randomized



1. Alignment and embedding of the vertebra and a threaded sleeve in polyurethane composite

2. Marking the target position of the screw via Kirschner wire

3. Freezing of the vertebra for transport

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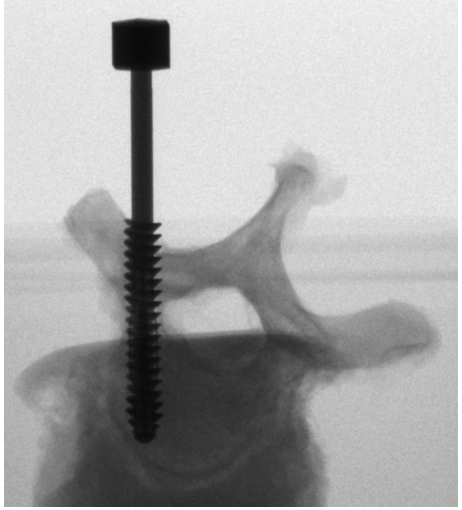
Pull-out tests on human specimen

4. Drill out the hole to 4 mm

5. Integration of a cooled screw with or without SMA



6. X-ray control of the screw position

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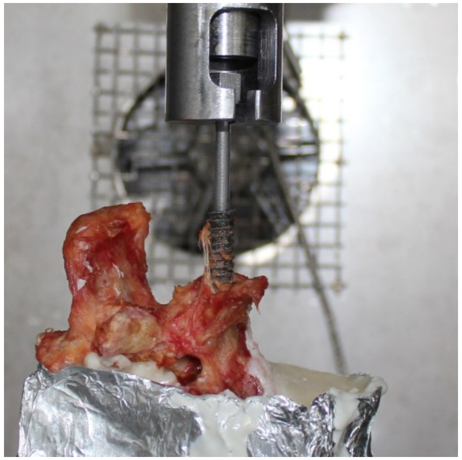
Pull-out tests on human specimen

7. Positioning in the testing machine

8. Warm up on 36 °C



9. Pull-out test (0.1 mm/s)

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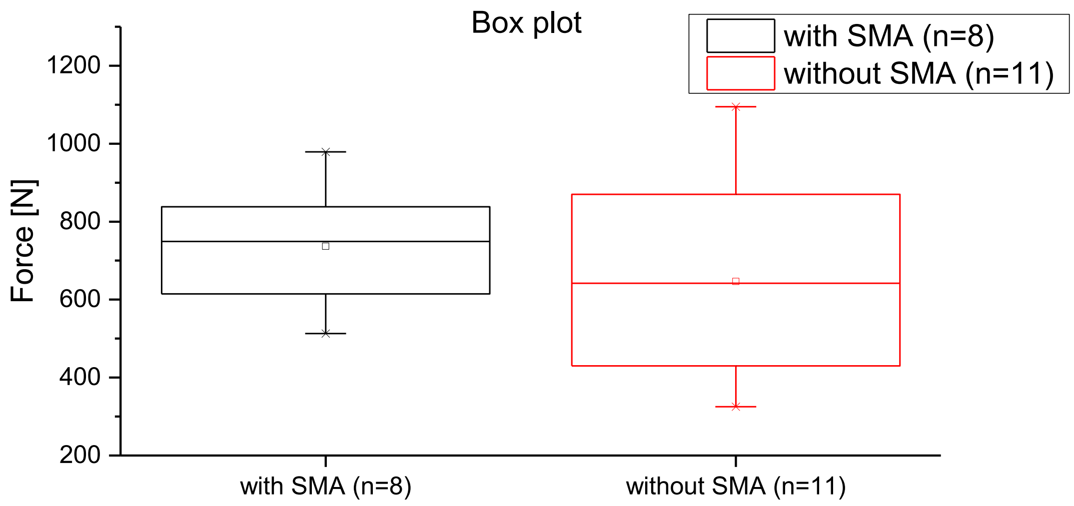
Results



- One cervical vertebra was excluded (destruction of the pedicle during the screwing)
- The Average pull-out force is 646 N for the screw without SMA and 737 N with SMA (Δ14 %)
- Spread of values is reduced

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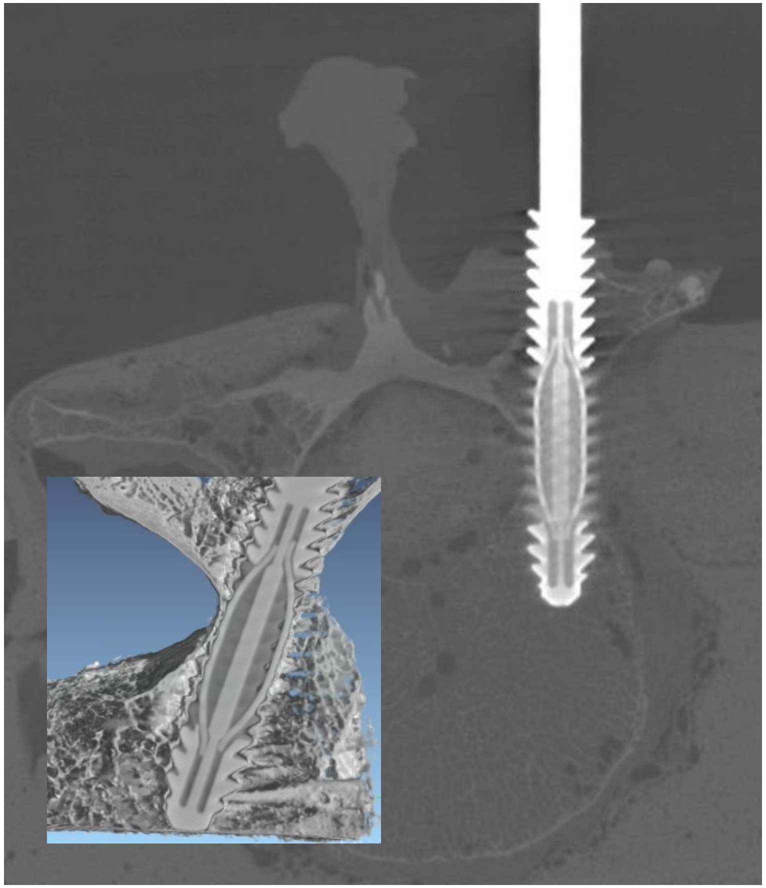
Additional work - µCT



- µCT-Investigation after integration of the pedicle screw
- Functional verification of force and tight fit
- Evaluation of the bone-implant interface

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Summary and Outlook

- 25 % increase in average pull-out force with SMA in bone substitute
- 14 % increase in average pull-out force with SMA in human specimen
- Only primary stability was tested
- No osteoporotic bone or revision case
- Handling during in-vitro test was positive (placing time , warming, etc.)
- Surface structuring and complex actuator geometry
  → Increasing of the pull-out force
- Further studies in specimen from different body donors
  → Increasing the validity of the results

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