

FATIGUE PROPERTIES OF CF/PEEK CORTICAL BONE SCREWS PRODUCED BY COMPOSITE TRANSFER SQUEEZE FORMING (CTSF)

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SUMMARY: The Composite Transfer Squeeze Forming (CTSF) [10, pp.109-112] allows the processing of high volume fraction composites with thermoplastic matrix. Cortical bone screws (CTSF-3.0) and specially designed screws with a rod-like design (CTSF-3.5) have shown promising mechanical properties. The 3-point bending strength of a 3.0 mm core diameter CTSF-3.0 screw is 700 MPa compared to 900 MPa ($F_{0.02}$) for a similar screw made out of commercially pure titanium. For fatigue, the CTSF-screws have shown better performance than Titanium screws, being much less notch sensitive. Compared at 500'000 cycles, Titanium screws achieved approx. 12%, CTSF-3.0 60% and CTSF-3.5 90% of the static load.

KEYWORDS: net-shape processing, composite transfer squeeze forming (CTSF), fastener, screw, PEEK, carbon fibre, implant, translaminar screw fixation.

INTRODUCTION

Single-step, net-shape processing is the key to a cost-effective production of composite fasteners like screws. The Composite Transfer Squeeze Forming (CTSF) [10, pp.109-112] allows the processing of high volume fraction composites with thermoplastic matrix. The achieved fibre volume fraction is 61 vol% i.e. with PEEK and carbon fibres. Unlike standard injection moulding, the fibres will hardly be damaged by the process and can be as long as the fastener itself.

Cortical bone screws (CTSF-3.0: core Ø3.0mm, outer Ø4.5mm, see Fig. 2) and specially designed screws with a rod-like shape (CTSF-3.5: core Ø3.5mm, outer Ø4.3mm) have been used for the evaluation of the new manufacturing technique and their possible application in the medical sector. These screws (CTSF-screws) have shown promising mechanical properties. The 3-point bending strength of a CTSF-3.0 screw was 700 MPa compared to 900 MPa ($F_{0.02}$) for a similar screw made out of commercially pure titanium. Tensile strength was 400 MPa for the CTSF-3.0 screw. Torsion testing according to ISO 6475 showed a torque of $1.24 \pm$

0.07 Nm [7]. In a new, rod-like screw design, optimised for translaminar fixation, mean strength of 850 MPa and peak strength of 1000 MPa were found.

The first medical application for that new implant to be addressed was the fixation of vertebrae in the lower lumbar spine, as the technique (Translaminar Screw Fixation [6]) only uses two screws with no plates or other implants. Furthermore, the proximity of the spinal cord might make the use of NMR (Nuclear Magnetic Resonance) and CT (Computer Tomography) crucial in case of complications. The CTSF-Formed Screws have shown less artefacts than commercially available Titanium or Stainless Steel screws (Fig. 1) [3].

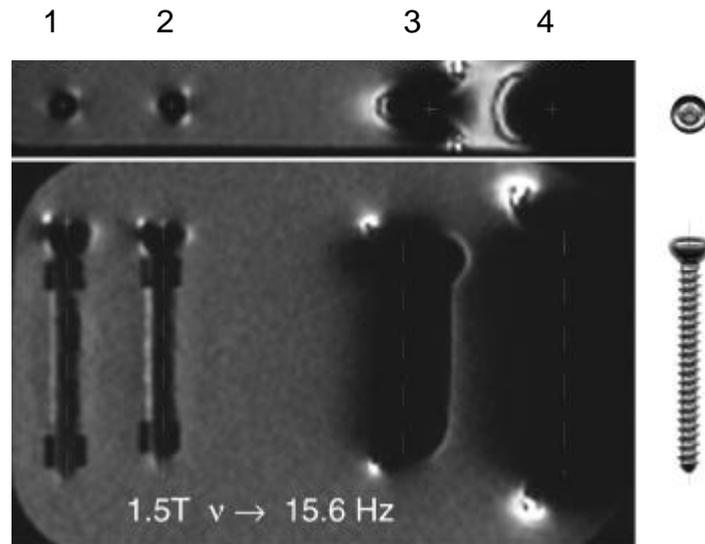


Fig. 1: NMR artefacts (in AGAR-Gel) of a CTSF-3.0 Screw (1) made of CF/PEEK, CTSF-3.0 Screw with the supplement of an x-ray marker (2), Titanium Screw (3) and a Stainless Steel Screw(4). All screws are of the same shape as seen on the right.

MATERIALS AND METHODS

Composite Transfer Squeeze Forming

Composite Transfer Squeeze Forming (CTSFF) has been shown to be able to shape a fibre reinforced rod-like blank above the melting point to nearly any kind of fastener design (Fig. 2) as described in detail in [5], [4]. Briefly, the rod is heated above melting point in the rod-chamber and axially squeezed into the pre-heated moulding cavity. Forming temperature and cavity pre-heating will vary according to the matrix used and the geometry of the part. The rod used might be of any kind of fibre/thermoplastic matrix combination and content, produced via extrusion or pultrusion technique. The fibre length will normally be similar to the rod length. The achieved cycle time on a prototype production facility is approx. 8 minutes for a CF/PEEK composite (APC-2/IM7, Fiberite GmbH, processing temperature 400°C, consolidation at 300 MPa, cooling rate between 50°C and 150°C, see Fig. 2). In an automated process, the cycle time is expected to be reduced to 3 minutes for a single cavity tool.

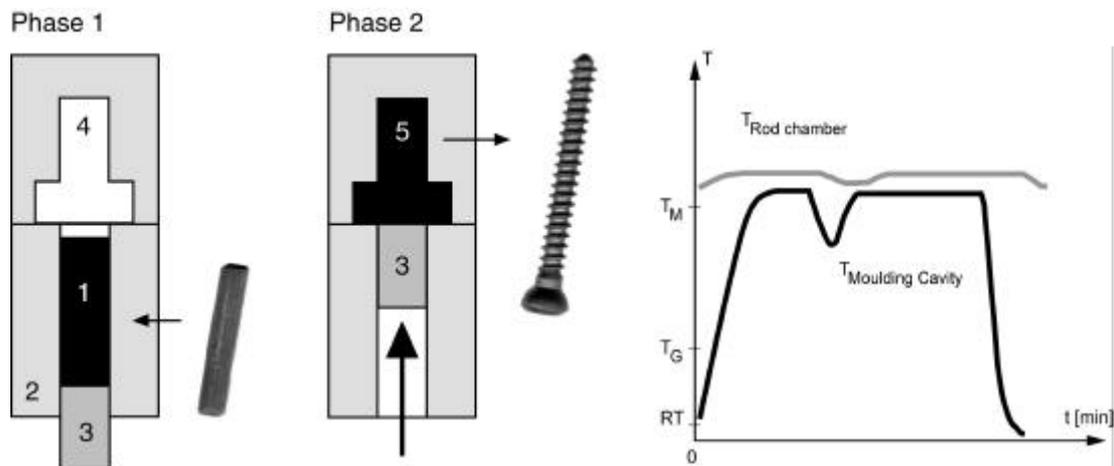


Fig. 2: Principle of TSF: The rod (1) is heated above melting point in the rod-chamber (2) squeezed by a stamp (3) into the moulding cavity (4). Stamp, rod-chamber and moulding cavity are the parts forming the fastener (5).

Simulated Translaminar Screw Fixation

The Translaminar Screw Fixation Technique was developed in order to permanently join two vertebrae by placing one screw through each facet joint. [1], [6]. As seen in Fig. 3, the screws will go through the joint in an angle of approx. 30° , with a gap of cartilage tissue in between (approx. 2mm). This geometric setup was used for fatigue testing the screws, as it was considered to be the most relevant load case for this particular application.

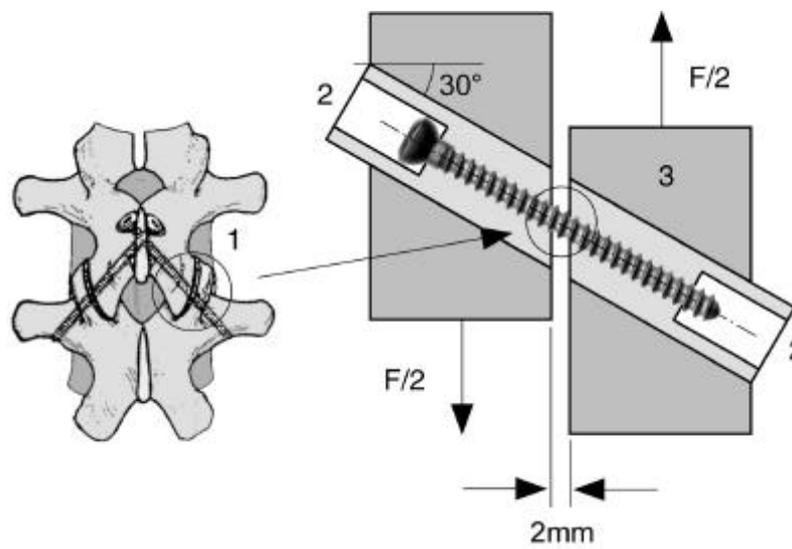


Fig. 3: Simulated Translaminar Fixation. The screws penetrate the joint in an angle of approx. 30° , with a gap of cartilage tissue in between (approx. 2mm). The rod used to simulate the bone is made out of polyamide 6.6.

The screws were anchored in polyamide 6.6 cylinders, with drilled and tapped holes according to the common operation technique. The length of the thread was 20mm on both sides. The implants have been tested at RT, 5Hz with $R=0.1$. for at least 500'000 cycles, as this time was considered to be clinically relevant for the comparison with Titanium screws.

RESULTS

Current investigations (see Fig. 4) show that the maximum load for Titanium screws will drop from $6033\pm 44\text{N}$ static strength ($n=3$) (out of scale in the figure) to 600 - 800 N at 500'000 cycles as the notch sensitivity is very relevant for that particular material/design combination. CF/PEEK screws with the same design (CTSF-3.0) will also drop to 600 - 800 N, but starting from a static strength of $1140\pm 152\text{N}$ ($n=5$), thus characterising them as much more fatigue resistant. Best results were achieved with the CTSF-3.5 screws (rod-like design), with a static value of $1270\pm 110\text{N}$ ($n=4$) and a dynamic value above 1100N.

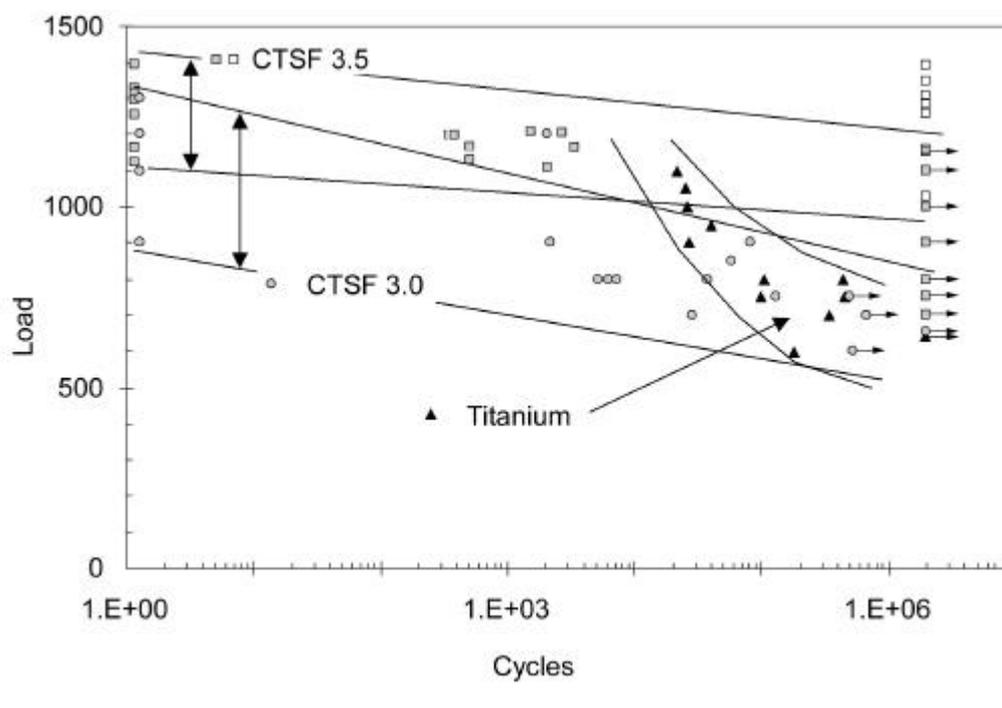


Fig. 4: Fatigue testing of bone screws in a simulated vertebrae fixation. The CTSF-3.0 screws are of the same design than the Titanium screws. The CTSF-3.5 screws are optimised for the TSF application. The residual strength is marked by empty symbols.

DISCUSSION

The CTSF screws have shown better fatigue properties than Titanium screws. The comparison of similar designs (Titanium vs. CTSF-3.0) has shown that the CTSF-formed material is less notch sensitive than Titanium. With an optimised design (CTSF-3.5) the sensitivity can even be lowered to a load level being quite near to the static load. To get a stronger correlation to the in-vivo situation, the screws will have to be tested at 37°Celsius in simulated body fluid. However, extensive research regarding the environmental stability of CF/PEEK composites (1 year, 90°C, simulated body fluid) revealed no influence of ageing, [8, 9].

The static strength achieved makes the screws very competitive, as they are a four to five higher mechanical performance than comparable part made by injection moulding. With a density of 1.6 g/cm^3 they will surpass metallic counterparts when it comes to the specific

mechanical properties, making them particularly interesting in weight limited applications, like aircraft or cars. Furthermore, they are corrosion resistant, non-magnetic and can be used at temperatures up to 200° Celsius when PEEK is used as a matrix [2]. For a medical application, a careful approach has to be selected, as the lower static strength makes the implant less resistant to loads occurring during the implantation procedure.

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