Marie C. Foelkel*, Vitali Herzog, Markus Meier, and Michael M. Morlock

Influence of application parameters of ultrasonic-assisted bone instruments on the tear force of a substitute material for spinal dura mater

Abstract: An ultrasonic-assisted bone instrument can be used for the dissection of bone in spinal surgery. During surgery, the tip of such a bone instrument can touch spinal dura mater. Especially during critical re-operations, high forces can be unintentionally applied on spinal dura mater. To prevent dural tears, the influence of application parameters on the tear force shall be analyzed. Collagen foil is used as a substitute material for spinal dura mater because of its similar mechanical properties and structure. Sponge cloth is placed below collagen foil to imitate cerebrospinal fluid and nerve tissue. A 3-axis CNC-machine is used to automate the movement of the bone instrument. In a full factorial experiment the influence of amplitude, shape of movement and velocity of movement on the tear force is analyzed. Amplitude has the strongest effect because of the increase in input energy. Velocity also has a significant influence, probably because of the strain rate increasing with velocity. Thus, a surgeon should mainly reduce the amplitude and furthermore the velocity of movement to generate higher safety in critical areas.

Keywords: ultrasonic surgery, bone instrument, spinal dura mater, dural tear

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1 Introduction

Approximately 111,000 surgeries for decompression of the spinal cord were performed in Germany in 2015 [1]. For parts of these an ultrasonic-assisted bone instrument was used. It cuts bone at relatively low temperatures by performing an axial ultrasonic vibration. Because of its low abrasion of soft tissue, it is gentle on critical structures like ligaments and spinal dura mater (SDM). Usually no soft tissue damage occurs, especially less than in surgeries performed with conventional methods like the high-speed drill [2]. During critical re-operations or unintended movements, still high forces can be unintentionally applied on SDM that can lead to a tear. Consequences can be infections like meningitis, pinched nerves with neurological damage or a leakage of cerebrospinal fluid (CSF).

Figure 1: Ultrasonic-assisted bone instrument 92-050 (Söring GmbH, Quickborn, Germany)

Until now, no *in vitro* experiments were performed to analyze the influence of different application parameters on the tear force of SDM. This paper should quantify the influence of application parameters on a substitute material for SDM to contribute to further increasing the safety of the Söring ultrasonic-assisted bone instrument on SDM.

2 Materials and methods

2.1 Substitute material

To increase the possible number of conducted experiments, industrially produced collagen foil is used as a substitute

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material for SDM. Collagen foil is made up of collagen and elastin fibers like SDM and shows a similar stress-strain behavior like SDM in a tensile test based on DIN 53504 (figure 2) (KOSY 3 – MAXcomputer GmbH, Schömberg, Germany; force sensor K3D120 (50N) - ME-Meßsysteme GmbH, Henningsdorf, Germany; data acquisition with LabVIEW - National Instruments, Austin TX, USA; evaluation with MS EXCEL 2010 - Microsoft Corporation, Redmond, Washington, USA). SDM is stronger "J-shaped" than collagen foil, which can arise from higher undulation of its collagen fibers [4] in contrast to the industrially produced collagen foil, or from the different strain rates during the tensile test. Nevertheless, the strain needed for a tear is similar.

CSF and nerve tissue are imitated by sponge cloth soaked in water and placed below the collagen foil.

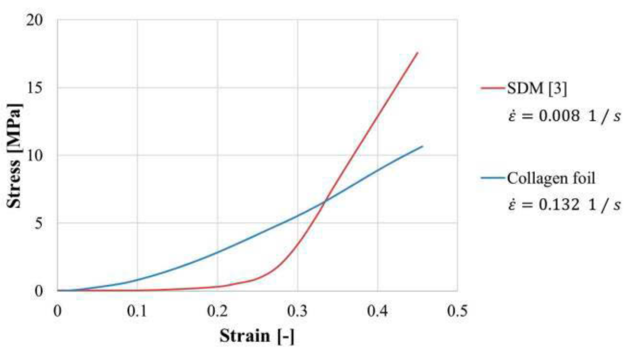

Figure 2: Stress-strain relationship for SDM and collagen foil

2.2 Set-up

The experiment set-up (figure 3) should imitate the *in vivo* situation as good as possible. During surgery on spinal canal stenosis, the spinal cord can move inside the horizontal spinal canal. An ultrasonic-assisted bone instrument is held almost orthogonal to the bone surface and spinal cord. The surgeon uses a sawing motion to cut through bone. During this movement, the tip of the bone instrument is moved towards and away from SDM. Especially when perforating the medial cortical bone of a lamina, the bone instrument can touch SDM. If the forces on SDM become too large, a dural tear can occur.

In this set-up, the ultrasonic-assisted bone instrument 92-050 (Söring GmbH, Quickborn, Germany) (figure 1) is used. The movement of the bone instrument is automated with a KOSY 3 similar to the *in vivo* movement. The collagen foil is clamped without initial tension on top of the sponge cloth. The measured quantity in this experiment is force. It is obtained at the clamping of the bone instrument. Because of the relationship between the measured force and the strain of the tissue, it is possible to link tear force results to a maximum possible depth of penetration of the bone instrument into the tissue.

2.3 Design of experiments

The full factorial design of the experiment with n=10 repetitions per combination of parameters, considers three parameters: amplitude of the ultrasonic vibration, surgeon induced movement shape of the tip of the bone instrument, and the velocity of movement. Amplitude is tested on lowest and highest possible value (21 µm, 83 µm). The two tested movement shapes are a periodically increasing and nearly vertical loading and unloading of the tissue (figure 4 – continuous line), and a periodically increasing triangular movement with the same nearly vertical loading and an additional contact of the saw teeth during unloading (figure 4 – dashed line). Velocity of movement is tested on a low and

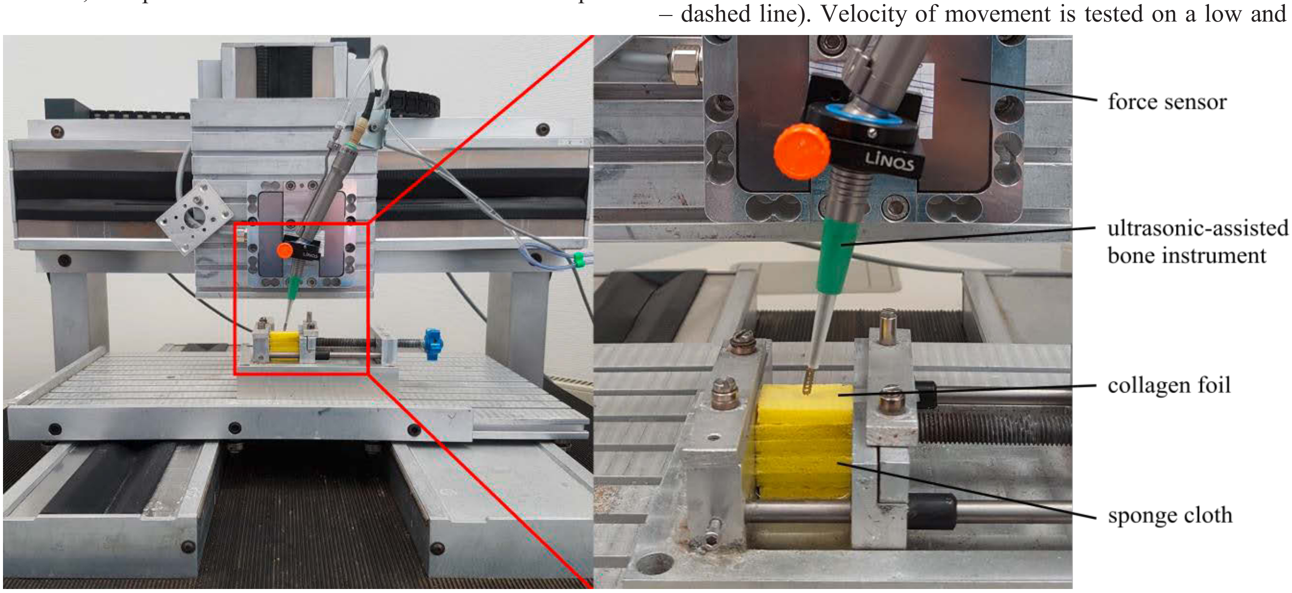

Figure 3: Experiment set-up to imitate *in vivo* situation

high value, based on the technique of an experienced surgeon (15 mm/s, 25 mm/s).

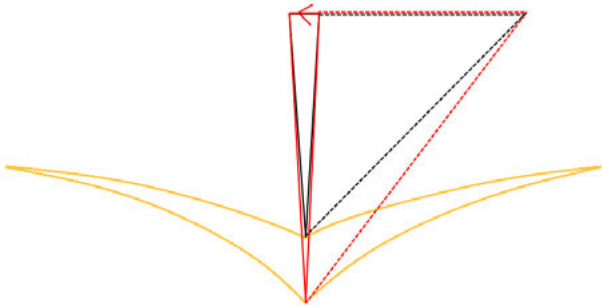

Figure 4: Periodically increasing movement of the bone instrument on collagen foil (yellow): Nearly vertical loading and unloading (continuous) and vertical loading with an additional contact of the saw teeth during unloading (triangular - dashed)

Another adjustable application parameter is the irrigation rate. However, in a screening experiment carried out in advance, the variation of this parameter (3 ml/min – 150 ml/min) was not significant (p=0.959, α=0.05).

2.4 Statistic Evaluation

Evaluation of the results was done with Minitab 18 (Minitab Inc., State College, Pennsylvania, USA). To determine the statistical significance of the standardized effects, t-tests were carried out. A Grubbs test was used to find outliers, normal distribution of the standardized residuals was tested with an Anderson-Darling test.

3 Results

In the experiments, no outliers occurred and the standardized residuals are distributed normally. Figure 5 shows the standardized effects of the parameters. Amplitude has the highest effect on the tear force of collagen foil, velocity and interaction between velocity and movement are just above significance threshold. Movement and the other interactions are not significant.

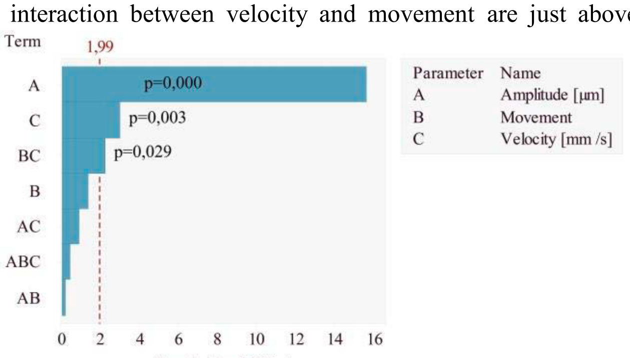

Figure 5: Standardized effects of the parameters and interactions on the tear force of collagen foil

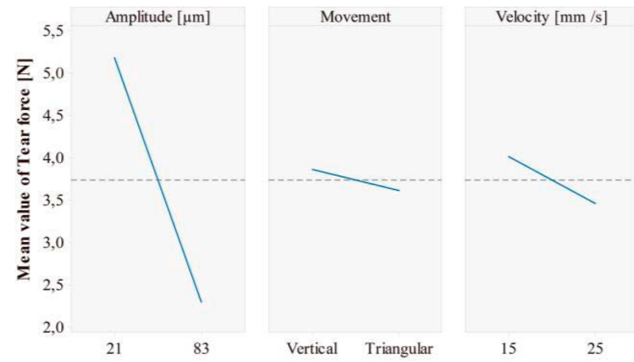

Figure 6: Influence of the main effects on the tear force

An increase in amplitude and velocity separately leads to a significant reduction of the tear force (figure 6).

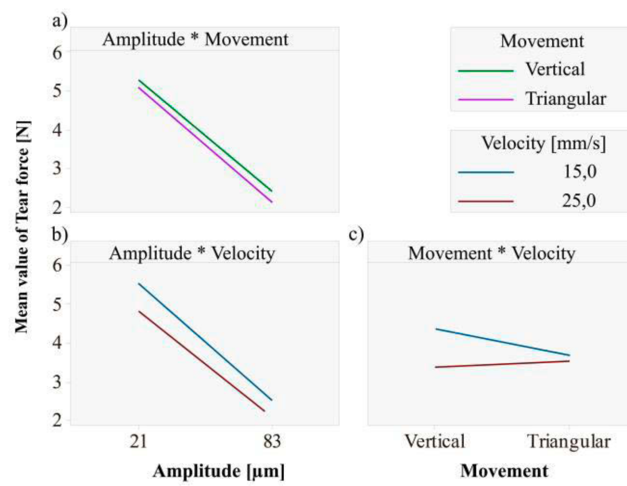

Figure 7: Influence of interactions on the tear force

Figure 7c shows that when moving the bone instrument nearly vertically there is a difference in tear force depending on velocity. When moving the bone instrument triangular with increased saw teeth contact, the tear force is less influenced by velocity.

4 Discussion

Amplitude is the dominant parameter influencing the tear force. The amplitude leads to an input of external energy into the tissue that leads to a local heating, mechanical vibrations with shear forces and acoustic streaming [6]. When amplitude rises, input energy also rises and the effect of the fragmentation methods increases, leading to a reduced tear force (figure 6).

Another significant main effect influencing the tear force is velocity. It directly affects the strain rate of the tissue, which may influence the tear force. Persson *et al.* found no influence of strain rates up to 1.0 1/s on the maximum stress in bovine SDM in a tensile test [5]. This contradicts the result of a significant influence of velocity (strain rate < 1.0 1/s) on the tear force in this experiment. Possibly, there is a difference in behavior for collagen foil and SDM even if the composition of the viscoelastic materials is similar. Another difference is that the tissue in this experiment and *in vivo* is loaded orthogonal in combination with notch effects of the bone instrument so that the results of this experiment possibly cannot be compared to the results of Persson *et al*.

The influence of the interaction between movement and velocity on the tear force is just above significance threshold. This could be due to the fact, that the tear takes place at different positions of the movement. Both tested movements have the same loading phase and just differ in unloading. Thus, a difference in tear force indicates a tear at different positions of the movement. A collagen foil tested with vertical movement of the bone instrument always tears during loading. A collagen foil tested with triangular movement with additional saw teeth contact can tear during loading or saw teeth contact. Possibly at low velocities (≙ low strain rates) the collagen foil tears during saw teeth contact as this is the critical phase of movement, and at high velocities (≙ high strain rates) tears already during loading as this phase of movement becomes more critical. This assumption is supported by the nearly identical tear forces for both movements combined with high velocity and the different tear forces for both movements combined with low velocity (figure 7c). In the recorded force data, this assumption could not be seen as maybe the sampling rate of the sensor was not high enough.

All together, the results on collagen foil can probably be transferred to SDM because of their structural similarity. By reducing mainly the amplitude but also the velocity close to critical structures like SDM, surgeons can reduce the risk of dural tears significantly. This is especially important during critical surgeries like re-operations.

Author Statement

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