Development of an experimental set-up and evaluation for testing alveolar ridge distractors on mechanical stress and creep behavior

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Abstract
Purpose: With this study, mechanical displacements or creep behavior caused by pressure forces on alveolar distractors are investigated by using mechanic tests. The assertion is, that the distractor shows some kind of deformation under cyclic and constant strain in the middle part of the implant, in the transport axis, in the center as well as in the connection to the side parts, in both the base plate and the transport segment. To prove or disprove that hypothesis mechanical tests were taken.
Material and methods: A testing station was constructed by using an Instron E3000 for load and cyclic tests. Artificial corticalis bone was used with original micro screws to fix the distractor first. Both devices were manufactured by KLS Martin Group and are made out of titan alloy. Also, two aluminum angle pieces were constructed to minimalize the deformation caused by the connection between the screw and the support material. After several elastic testings destructive tests were also performed to determine the maximum load and the weak spot. To see some kind of creep behavior, long term dynamic load tests were executed up to 5000 cycles.
Results: With increasing amount of pressure, loading tests were done until fracture. One trial broke at 230N, the other one at 260N. Both had the same weak points, at the connection to the base plate and the transport segment. A change in the center, at the spindle, could not be recognized. The movement of the transport segment was totally viable with no difficulty.
Cyclic stress tests were carried out with maximum loads of about 60% of the fracture force. Even after 5000 cycles the distractor did not break, just bent at the same weak spots as it did in the ramp tests. Measuring the compression of the spindle itself showed, that just 5.8% of total position change is caused by the spindle`s creep behavior.
Conclusion: The thesis, that the distractor shows creep behavior in the spindle during load and cyclic testing could not be confirmed. Instead, nearly the total deformation, caused by pressure tests as well as by cyclic loadings, is clearly traceable at the connections to the base plate as well to the transport segment.

I. Introduction

Alveolar distraction osteogenesis (ADO) has become one of the most popular alternatives to conventional methods for bone replacement, like allogenous bone transplants or other xenogenic material for bone substitution (Enislidis et al., 2005). Originally distraction was used for lengthening long bones, e.g. the tibia. In 1992 lengthening the human mandible by gradual distraction was established by McCarthy et al. This technique showed an innovative advancement by more stabilization of the repositioned skeletal segment avoiding bone grafts (McCarthy et al., 1992), greater degree of skeletal development, yet major distraction distances are required and the possibility to apply technology on younger patients. Furthermore, reduced operative time, less need for blood transfusion and lowered morbidity makes the mandibular distraction osteogenesis also more pleasant and comfortable for patients (Figueroa and Polley, 2008; Lin et al., 2019; Millesi-Schobel et al., 2000).
Any kind of mandibular malformation can be caused genetically, accidently or due to illness. Recovering these bone defects is not only an aesthetic improvement, it is also necessary to avert functional problems like difficulties with breathing and ingestion, as well as raised intracranial pressure and visual disorders (Witherow et al., 2008). Alveolar distraction osteogenesis is a relatively new method for bone formation, used to counter inadequate bone height in the jaw between the alveolar ridge and the mandibular canal. To enhance the bone quantity for placing an appropriate endosseous implant, an alveolar ridge augmentation is essential (Veziroglu and Yilmaz, 2008).
In this process a mobile transport segment is used to lengthen the bone. In vertical distraction the base plate of the implant is fixed to the remaining bone, the flexible part is mounted overhead. So, the bone regeneration is caused by increasing the gap between the bottom and upper plate. Depending on the distraction length, this process takes approximately 12-16 weeks. Following the timetable of distraction given by KLS Martin Group, the manufacturer, one week after surgery the device is activated by the patients themselves, then 0.5-1 mm per day distraction movement and 8-12 weeks mineralization period (Gebrüder Martin GmbH & Co. KG, n.d.). During placement, the patient's nutrition is composed of liquid diet until the end of the activation period, then it continues with a diet based on soft foods (Guerrero et al., 2012).
Even if these implants are constructed correctly, in some cases there are complications like breakage of the distractor, fracture of the transport segment or instability of the distractor (Enislidis et al., 2005).
Especially a certain instability of the distractor itself was observed in several cases. It is estimated that patients do indeed not chew or bite during the alveolar distraction osteogenesis, but subconsciously some may grind their teeth while sleeping. Beginning with a normal subject, mean forces in the incisor region of 193N and in the molar region of 350N are obtained. Forces on implantations were found to be less, around 188N and 323N (Biswas et al., 2013). But grinding affects the teeth with much higher forces of up to 800N

("Bruxismus: Zähneknirschen und Kieferpressen | GZFA," n.d.). Nocturnal bruxism happened subliminally, caused by stress in daily life, so higher forces on their jaws may occur in patients with alveolar distraction implants.
Therefore, the thesis was postulated that these alveolar implants show some kind of creep behavior or any other deformation and alternation in the center of the implant. Under stress and pressure loads the spindle was tested related to life-like conditions.
In order to prove that, different stress and cyclic test were implemented.

II. Material and methods

In this thesis the creep and deformation behavior in the middle of the distractor is analyzed. Therefore, a new breadboard construction is designed. With raw data from the Instron E3000, all tests were recorded and subsequently evaluated with Python.

A. Material

The test material was given by the department of oral and maxillofacial surgery from the university clinic in Regensburg. All tests were implemented with a surgery set from KLS Martin Group (MIRO-ALVELOAR-DISTRACTION, Module 1.0, 55-948-50) (Gebrüder Martin GmbH & Co. KG, n.d.), containing different kinds of TRACK distractors, micro screws M1x7mm, instruments for fastening the implant, screwdrivers, drill bits, plate holding tweezers various pliers and a patient screwdriver.

All distractors behave according to the same functional principle: a fixed base plate and a movable transport segment, that can be appointed to adjusted length by turning the transport screw with the original screwdriver from KLS Martin, in clockwise direction. Each turn causes a length variation of 0.3 – 0.5mm, depending on the distractor size (Gebrüder Martin GmbH & Co. KG, n.d.). In the center there is the spindle, where the transport segment is fixed.

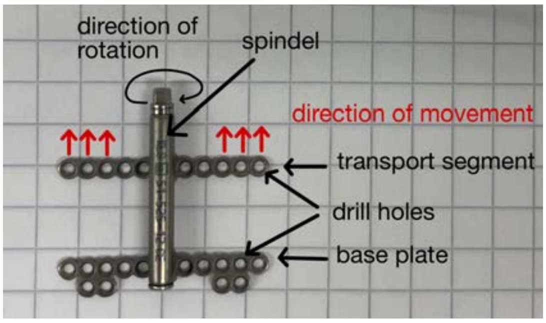

Figure 1: Illustration of a distractor from KLS Martin with its components

The first selection of tests was performed with distractor 1 and original screws, both made of titanium alloy. In order to fix the distractor to the bone plates, eight holes were drilled in the material and eight monocortical mini screws were inserted. Afterwards, first initialization tests with artificial cancellous bone were performed.
In the particular tests 3 distractors were used:

- distractor 1 KLS 51-525-12 with a length of 12mm
- distractor 2 KLS 51-525-09 with a length of 9 mm
- distractor 3 KLS 51-525-06 with a length of 6 mm

For fixing the implant an artificial cancellous bone was used. The geometry of the artificial bone for testing was adjusted. To prevent any moments of reaction, an angle was constructed for best fitting. Both sides have the same lever arm (tagged with an x in Figure 2), so the pressure force acts in the center where the distractor is placed.

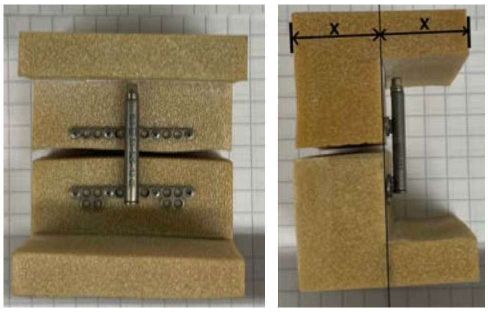

Figure 2: Adjusted cortical pieces for fixing the distractor to prevent torque and reaction moments

The focus of this thesis is the stability of the distractor itself, its spindle in the center and the connections to the lateral baseplates and the transport segment, not to test the connection between screws and bone. After some ramp tests with cortical bone the set-up was changed.
Therefore, the breadboard construction was adapted by using an aluminum angle and new mini screws made out of stainless steel. Using M1 machine screws, flush mounted with a clearance hole and a female screw, the distractor is fixed on the aluminum angle pieces to get the maximum stiffness in the side wings.

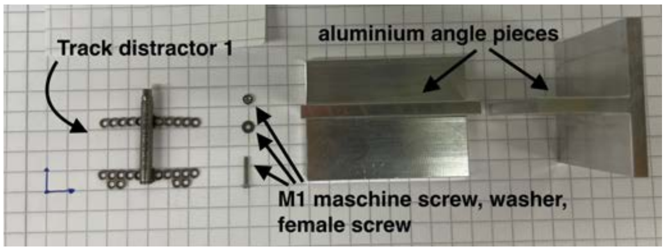

Figure 3: Material for fixing the distractor on two aluminum angle pieces

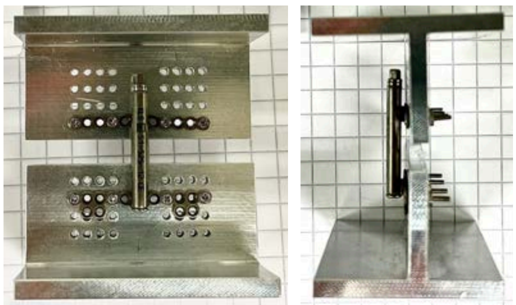

Figure 4: Distractor 1 fixed on 2 aluminum angel pieces for a maximal stiffness

In late cyclic tests a caliper was additionally used for measuring the length between the upper and lower part of the central spindle. The reason for this is, to detect creep behavior in the spindle, even if the transport segment screw is still functional in rotation after load.

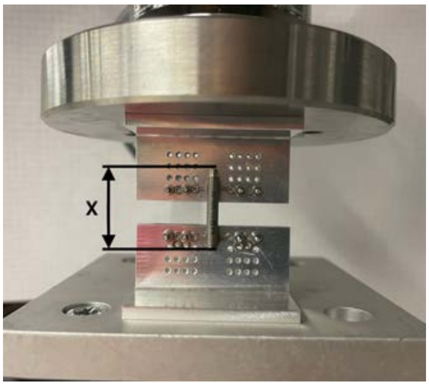

Figure 5: Altered set-up for measuring the spindles altitude, measurement from screws of transport segment to the corresponding vertical bottom end (see mark)

B. *Experimental set-up:*

For load and cyclic testing an Instron E3000 was used. Because of the estimated force range a load cell of max 500N was installed. Pressure forces were upset vertically on the trial with the Instron E3000. Force reactions and distance variations were saved on the server of the control computer.

Figure 6: Experimental set-up with the Instron E3000 and the test object

The components of the set-up are shown in Figure 6:
There is the Instron E3000 with the load cell and underneath the test object with the mounted distractor. Because of the small height of the distractor and the corresponding level range of the load cell a massive metal block was used to raise the level of measurement.

C. *Data storage*

Before each test the control computer was started for steering the Instron E3000. There are two modules necessary to run a test. The Instron Console version 8.4 controlled the installed load cell. There are position and force limits to protect the testing sample, as well as applications to calibrate the load cell and an adjustment for position or load controlled testing.

The Instron WaveMatrix is an application for programming a testing method and data storage. The methods vary from holding a position/ a force, ramp-, cyclical-, trapeze-shaped tests and much more. The data storage can be adjusted by filtering the necessary data, data compression, hysteresis and tracking data and trends.
To edit these data, Python 3.1 was used to filter, to align and plot graphically. Because the data storage depends on the variety of the initial position as well as on the type of test, an algorithm was written to get a comparable visualization of the forces, positions, time and cycles.

D. *Testing methods*

To protect the experimental set-up, load forces were slowly increased, starting with 30N of pressure. Distractor 1 was used for initial tests to construct the experiment set-up and get a testing standard. The initial tests are not shown.
The first five suitable tests were done with the distractor 1 fixed on the artificial cortical angle pieces. All five tests were ramp tests, starting at a load force of 0N and then increasing the load with a velocity of 0,5N/s until the test settings are reached. To detect creep behavior, a time span of holding the load was implemented. Even after 130N load, no significant change in geometry could be detected. Hence, load forces were increased until the first distractor broke, to confirm the load limit.
Cyclic tests were implanted to investigate creep behavior. Therefore, the tests were started with a ramp until a certain load level, then the cycles were conducted. During the tests the load pressure was always negative. Due to the compression forces the scales of the axis in the diagrams are both in negative range.

III. Results

A. *Point of fracture*

The fracture point was determined by an obvious breakage of parts of the distractor or triggering either the position limit or the force limit. To detect smaller deformations, pictures of the same distractor were taken before and after each test on square paper, so the deflection could be traced visually.

Figure 7 shows a chart for five load tests with different forces on distractor 1 mounted on the cortical pieces. The test methods and setting are explained in II. Material and Methods in D. Testing methods.

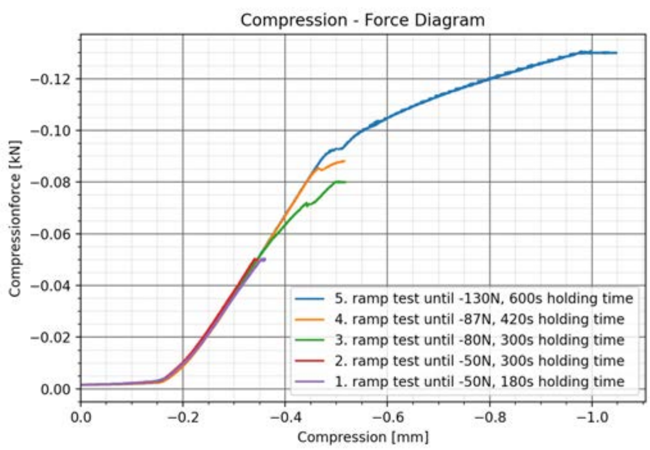

Figure 7: Position – force line chart with several load and retention forces

The line chart is scaled in millimeter on the x–axis and in kilo Newton on the y-axis. Both are in negative range because tensile and compressive forces are specified with plus- or minus-signs of the numbers. Due to compression forces only, the position starts also at point zero and shifts into a negative range.

All five tests have nearly the same trend of gradient of the slope. Initially there is a flat beginning due to the convergency of the load cell from the Instron E3000 to the upper side of the trial´s angle piece. In the following, tests 1 and 2 show equal behavior even if in test 2 the holding time is much longer. Test 3 and 4 are nearly the same, there is just a conspicuous peak at the end of both graphs. After a compression length of around 0.55mm a little change in the material behavior is visible, which may occur from the material behavior of the cortical pieces and the loss of setting at the screw connection.

Load test number 5 has the highest strain on the distractor. At the beginning the graph behaves coherent to the first 4 tests. There is also the same little peak after a position change of 0.55mm, but afterwards the slope of the curve is flattening. That indicates the range of elastic formation is left and plastic deformation is introduced. It is not clear whether the plastic deformation is caused by the distractor itself or by the screw connection to the artificial cancellous bone. Finally, there is a short, completely plane part, which is caused by the 600s of holding time at the end of the load tests.

With a visually control, the deformation parts are found at the horizontal connections to the transport segment shown in figure 8, but if and in what way that affects the total deformation has not been proven.

Figure 8: Distractor 1 before intermitted load (left), Distractor 1 after serval ramp tests with a maximum load of 130N (right)

Figure 8 shows a new distractor, made by KLS Martin Group. After all strain tests mentioned above a little change in geometry at the transport segment is visible. Especially the right wing is plastically deformed and is twisted downwards, marked with the angle phi.

To verify the breaking point, an increase of compression forces is necessary. The next trials were made with the distractor fixed on the aluminum angle pieces to exclude the deformation between screws and the artificial cancellous bone.

Two distractors were destroyed by a maximum load test. The first one, distractor 1 KLS 51-525-12, breaks at the lower left fastening of the base plate at a pressure force of about 230N (see Figure 10). The second one, distractor 2 KLS 51-525-09, had the weak points on both attachments to the transport segments with a force of around 260N (see Figure 11).

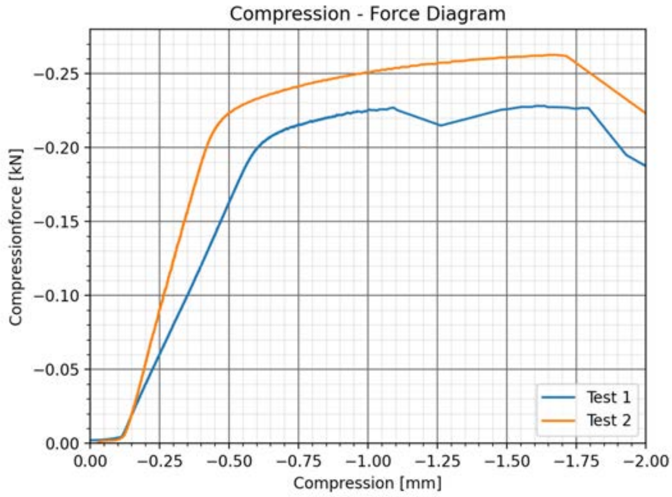

Figure 9: Line chart of 2 ramp tests of distractors number 1 (test 1) and number 2 (test 2)

There is a long elastic part, visible as a straight line, after which deformation begins. In the elastic part the Hooke's law is valid. There is a difference in the slope between the two test objects. It may be caused by several initialization tests done with distractor 1, also the breakage point occurs a bit earlier. The spike at the necking spot in test 1 is induced by loss of placement or by a measurement error. Finally, the point of fraction is characterized by a fast change of the slope, where the position raises but the force decreases. The test is finished by an automated machinery safety stop to protect the experimental set-up. It is interesting, that there is no peak or flattening of the curve after 0.55mm as shown in Figure 7, which were done with distractor 1 mounted on cortical bone. That indicates that the screw connection to the aluminum angle pieces with the female screw does affects the test results less than the screw connection to the cortical bone.

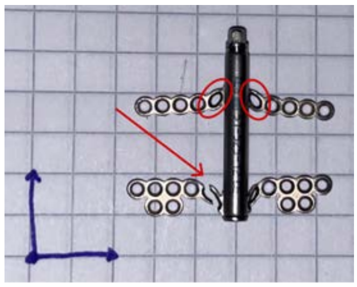

Figure 10: Distractor 1 is destroyed at a load force of 230N

As can be seen, distractor 1 broke at the left bottom connection, but also the right bottom part is significantly deformed. The connection to the transport segment were bended obviously.

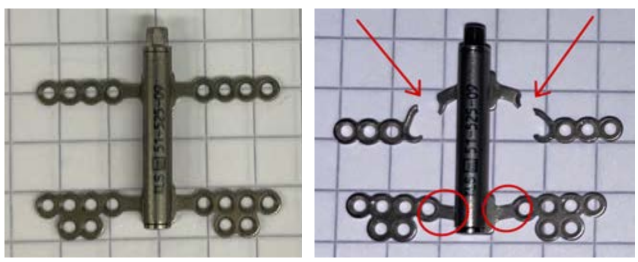

Figure 11: Distractor 2, left: before stress tests, right: after stress tests, breakage at 260N

Distractor 2 shows a different manner of destruction, in which both upper parts at the transport segment are broken. That can be caused by a minor difference in geometry of the connection to the side wings.

B. Creep behavior

In figure 12 three cyclic tests are compared with different numbers of cycles and loads. The test objects were distractor 2 and 3.

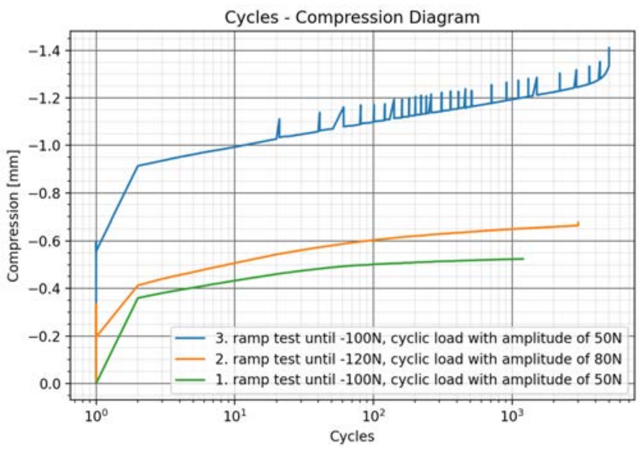

Figure 12: Logarithmical line chart of tests with 2 distractors to figure out creep behavior

The line chart is given in a logarithmical x-axis and a linear y-axis to describe the change in position after long cyclic tests.
Figure 13 illustrates the creep behavior, whereby the x-axis is displayed linearly in seconds.

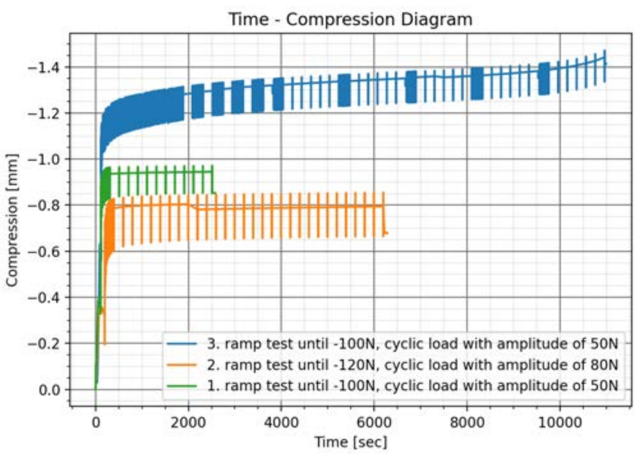

Figure 13: Line chart of 3 cyclic tests showing the change in position during testing time

Both, Figure 12 and Figure 13, show the same three tests. The testing parameters are given in the legend, all cycles had a frequency of 0.5Hz. The orange and the green line were done with distractor 2, the longer cyclic test (blue line) was executed with distractor 3.

Starting with Figure 12, in all measurement results there is a linear part at the beginning of the initialization, that originates from the ramp load of 100N to 120N. Then the cyclic test starts.
The variations in the offset of the starting point are caused by the distance between the load cell and the contact point with the test object. Compared to a normal creep test the first state, the primary creep, is not really visible, but the secondary creep with a nearly constant creep speed is obvious. The lower graph (green line) is approaching to a constant level after 0.5mm. The second test (orange line), done with the same distractor, shows a similar behavior, but the fatigue limit seems not to be reached.
Test 3 (blue line) was done with a new distractor, and it was the longest of all with 5000 cycles. After 4000 cycles the curve changes its slope and increases faster. This is called the tertiary creep period (Ahmmed, 2015). The test was finished before the set-up broke, because it was limited to 5000 cycles. While running test 2 and 3, the compression of the spindle was also measured to detect if the total deformation is caused by the junctions to the side wings or if there is also a creep deformation coming from the middle part of the distractor. The peaks in the graph originate from stopping the machine, while measuring the height of the spindle.
Figure 13 shows the creep behavior. The difference to Figure 12 is that you can see every measured and stored cycle as well as the initial ramp load at the beginning. From tests 1 and 2 no certain assertion can be made because of too short measurement time. Looking at test 3, from time 0 until 500 seconds the primary creep happened. Then, the gradient of the curve is constant until 10000 seconds, this phase is called the secondary creep. Finally, the slope increases faster, which indicates the tertiary period of creep (Ahmmed, 2015).

To detect the compression of the spindle itself, after a constant number of cycles the difference in height was measured with a caliper. Because of the measurement inaccuracy the same sample underwent two equal tests to get a mean value with a measurement tolerance.

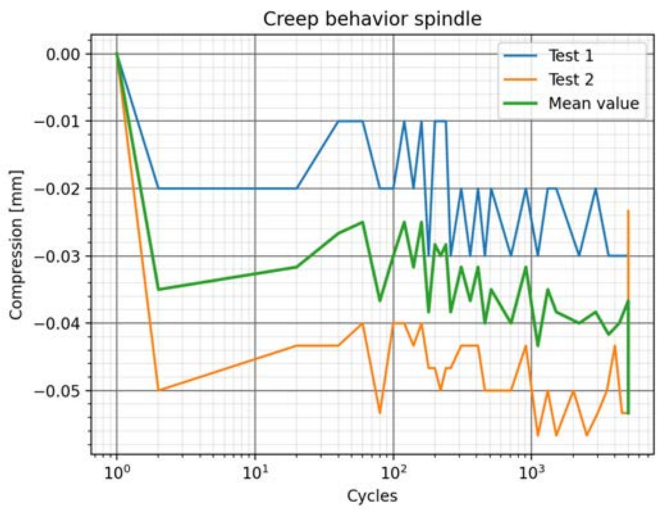

Figure 14: Creep behavior measured in compression of the spindle in the center in tests 1 and 2

In the first decade there was an average loss of height of about 0.035mm. With a growing number of cycles, the compression of the spindle is nearly constant until approximately 400 cycles. A very slow descending is visible towards the end of the experiment. Due to the caliper, the measurement has a relatively high measurement accuracy. The measurement was performed to visualize a trend in the compression of the spindle. If the compression would have been higher, a more precise measuring device would have been chosen.

IV. Discussion

Considering the thesis, it should be investigated whether the distractor shows any kind of creep behavior or deformation in the spindle of the implant under various types of stress, and if this is the case, to detect the weak spot.
In the majority of literature distraction implants were tested for standard material resistant tests, like bending resistance and torque strength (Lin et al., 2019). Here more realistic stress conditions were simulated with pressure and cyclic tests.
Examining distractor 1, there is a deflection in the welding edge to the transport segment after a maximum load of 130N (see Figure 7). A plastic deformation can be recognized in the progression of the graph, but it cannot be stated if the deformation is the result of superposition of deformation affected by the implant itself or the screw connection to the artificial cortex bone. The same distractor was used for further tests, mounted on aluminum angle pieces until it broke at a load amplitude at 230N. Figure shows no peak or flattening of the curve after 0.55mm like the curves Figure 7 do. That indicates that the change in the slope of the curves done with distractor 1 mounted on the cortex bone, is not coming from the distractor itself, but from material weakness of the cortex. Therefore, it was necessary to continue the tests with the aluminum angle pieces. The breakage point is not the welding edge of the transport segment, instead it breaks at the connection to the base plate. No change in geometry or bending of the spindle is visible. Moreover, the total functionality of it is still given, even after rupture. The transport screw is free in movement and the transport segment can be moved up and down. The second distractor shows a similar behavior, but it broke symmetrically on both parts of the transport segment at a force to 260N (see Figure 9 and Figure 11). The force difference until fracture may be caused by the number of tests taken additionally with distractor 1 and the geometry of the distractor. The first one was used for all initialization tests and the ramp tests as shown in Figure 7. Moreover, the geometry is different, it has five optional screw holes in parallel very close to the spindle. The second one has just four screw holes with a distance to the center connected with a massive horizonal junction. Hence, the forces for bending the massive connections are higher than the resistance of the screw holes next to the spindle. Obviously, the vulnerability of the distractors are the drill holes for fixing it to the bone under constant stress above 230N.
Considering Figure 12, test 1 and 2 were implemented with distractor 2. Some kind of creep behavior can be seen, but the number of cycles is insufficient to make a definite statement. In Figure 13, the loss of height during the tests depending on the time passed were recorded, but there was nearly no change in positioning.

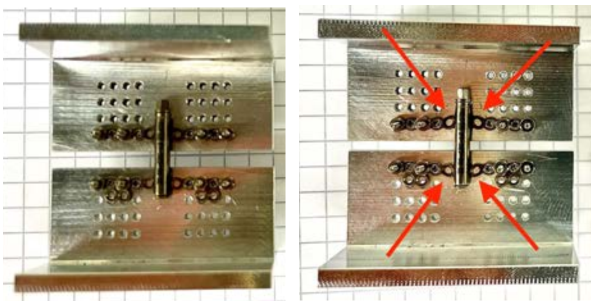

Figure 15: Distractor 3 before (left) and after (right) cyclic load test

A deformation can be optically recognized on all four connections after cyclic loading (see Figure 15).
As shown in Figure 12, the creep curve of test 3 shows the same character in the beginning as test 1 and 2, but changes with raising numbers of cycles. Also, in Figure 13 a clear creep behavior can be recognized after 10000 seconds. It can be assumed that with still rising number of cycles the distractor would have reached fatigue fracture. No change in the spindle either in length or in mobility and functionality could be detected.
Furthermore, the size of the distractor is not relevant for its mechanical properties, considering distractor 1 with 12mm, distractor 2 with 9mm and distractor 3 with 6mm of distraction length.
To compare the relation of creep behavior coming from the base plate and the transport segment with the compression in the spindle, in test 3 both parameters were recorded. According to Figure 14, the total difference in length variation is 0.8mm. The initial loss of placement is already deducted. The compression length of the spindle itself is on mean value maximal 0.044mm. Therefore, the percentage of the deformation coming out of the spindle is just:

$$\frac{0.044mm}{0.8mm-0.044mm} = 0.058 \rightarrow 5.8\%$$

Comparing the deformation of the spindle with the connection to the side wings, nearly the total deformation comes from the connection, especially the drill holes.
Finally, pertaining to the measurements and data in this paper, the thesis, that the spindle in a distractor shows creep behavior under stress can be discarded.

V. Conclusion

With this paper, the creep behavior in the spindle of a distractor was investigated. The hypothesis, that a major part of creep originates in the middle part of the implant could not be confirmed.
According to the literature, the range of load forces executed in thesis tests are realistic in healthy person´s jaws. But in reality, forces on implants may be much lower because the patients get liquid nutrition only, and the implantation area is sensitive to pain (Ugurlu et al., 2013). Hence, it can be assumed that there are very low reaction forces on the implant. Nevertheless, there are many case studies, describing fracture of the transport segment and base plate as well as fracture of the basal and transport bone. (Mazzonetto et al., 2005; Saulačić et al., 2007; Ugurlu et al., 2013). That indicates that there are indeed high forces on the implants. Some patients are grinding their teeth subconsciously while sleeping, which may cause forces in the range of the measured tests to occur.

Moreover, the tests were just made with load forces, no rotation or bending resistance were examined, which could also affect the creep behavior of a distractor. It must be specified in more detail in what way loadings stress the implants, as well the duration of implementation period should be considered.
In summary, it can be said, that these implants serve their purpose well, even if they have weak points that can be improved.

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EIDESSTATTLICHE ERKLÄRUNG

1. Mir ist bekannt, dass dieses Exemplar der Bachelorarbeit also Prüfungsleistung in das Eigentum der Ostbayrischen Technischen Hochschule übergeht.

2. Ich erkläre hiermit, dass ich diese Bachelorarbeit selbstständig verfasst, noch nicht anderweitig für Prüfungszwecke vorgelegt, keine anderen als die angegebenen Quellen und Hilfsmittel benutzt, sowie wörtliche und sinngemäße Zitate als solche gekennzeichnet habe.

Regensburg, den 08. Juli 2021

J. Schwar

Julia Schwar