Title: Evaluating Nitinol Shape Memory Alloy for Adjustable Fixation in High Tibial Osteotomy implants based on compressive stiffness

Name(s): Nuryn Insyirah Bte Mohd Adib, Goh Ying Hao

Course: 30.108 Introduction to Materials Science (Term 6)

1.Introduction

High Tibial Osteotomy (HTO) plates are orthopaedic devices that provide stability after a HTO surgery to realign the varus knee in bowlegged individuals (Knee Joint Preservation 2016). This helps to relieve the pressure on the affected part of the knee. (Reach Researcher, 2023) The golden standard for HTO plates today is the TomoFix (Koh et al., 2019), which has 2 main components: (1) anatomically contoured T-plate and (2) locking threaded screws (citation). An engineering limitation of the TomoFix is its T-plate, which is made of Titanium and thus is very stiff and limits the variability in the interfragmentary motion (IFM) which is important throughout the healing process (Müller et al., 2015). IFM refers to the slight movement between bone fragments as they heal back together and is highly dependent on the fixation's stiffness (Müller et al., 2015). Studies suggest that increasing IFM (by using a less stiff fixation) at the proliferation stage of secondary bone healing helps to stimulate callus formation, while reducing IFM (by using a stiffer fixation) at the latter stage increases the mineralisation of callus, both of which contribute to faster healing time and reduces implant-related problems like non-union of bones (Epari et al., 2013). Current methods to modify fixation stability include removing the bolts and screws via a separate surgical procedure which is invasive and hence, not very desirable. (Müller et al., 2015)

This highlights the opportunity gap in the existing TomoFix design and leads to the objective of this study, which is to suggest an improved HTO T-plate using NiTi material, a shape memory alloy that enables adjustable fixation flexibility to manipulate the IMF at the different fracture healing stages. We believe that non-invasive manipulation of the fixation stability can be achieved by leveraging NiTi's unique thermal shape memory behaviour, whereby it returns to its stiffer austenite phase after deformation when being warmed past the transformation temperature. Our hypothesis is as follows: **<u>NiTi T-plate will demonstrate higher compressive stiffness (Modulus of elasticity, E) when subjected to controlled transcutaneous heating, thereby eliminating the need for invasive adjustment of fracture stiffness in HTO in humans.</u>**

2.Conceptualisation of Design

Of all human joints, the knee is one of the most loaded joints and the osteotomised tibia makes the knee structurally unstable. For the HTO surgery, the medial opening is an extremely unstable condition for the proximal tibia, and the TomoFix fixation device is used to stabilise the opening and enhance bone union. This leads to the main function of the HTO plate, which is to provide better stability in both torsion and compression between the femur and tibia after surgery (Li et al., 2022).

For simplicity, we will model the HTO plate as a panel in compression. The first constraint is that the NiTi wire must not break when used to replace Titanium for the HTO implant plate. This constraint is essential to ensure the mechanical safety of the plate. This implies that the modulus of elasticity (E), which is the material property associated with compressive stiffness, needs to fulfil the following criteria:

E (minimum for a HTO plate) ≤ **E (NiTi-enhanced plate)** ≤ E (Titanium)

The second constraint is that the compressive stiffness of the NiTi must increase significantly with temperature. This ensures that the stiffness of NiTi can increase with minimal thermal energy input to ensure the safety of the implant user, as too much heating can adversely affect the surrounding tissues within the body (Food and Drug Administration, 2024). The second constraint will be the focus in this report.

3.Methods

3.1 Three-point bend test and gripping approach

One way to measure the compressive stiffness of a material is to measure the extent of bending of that material when force is applied. Hence, three-point bending tests were performed using the Instron machine to investigate the bending behaviours of NiTi wires subjected to axial loading. From the tests, the modulus of elasticity was determined from the obtained flexural stress-flexural strain graphs. As shown in Fig. 1, the test specimen used was an 8cm-long NiTi wire (0.01inch or 0.254mm diameter, 50-50 composition) that was supported with retort stands and wooden sticks on both sides during the test to prevent the specimen from slipping from the fixture. The tests were carried out using the Instron machine at SUTD's Characterisation Lab, as depicted in Figure 1. Due to apprehensions of the specimen slipping, the loading was set much lower to 300N, with a loading rate of 2.5mm/min. Each experiment lasted 3 to 4 min, after which the specimen slipped and thus the test was stopped.

3.2 Heating the specimen during the test

Resistive heating was done to maintain a certain elevated temperature of the specimen during the experiment. As such, a DC power supply was used to deliver current to the specimen by supplying a voltage across the specimen using two electrical leads. As current is supplied across a short circuit (i.e. no load), resistance, R= 0 Ω and thus current, I is (supposedly) very high (i.e. infinite), enabling heating. Based on the display on the DC Supply, the current measured was **2.31A** (regardless of voltage supplied). For safety, one of the electrical leads was secured onto the wire while the other was prodded onto the specimen regularly throughout each experiment. It can be assumed that the temperature is relatively constant as the diameter of the wire is small enough (0.26-0.28mm) to minimise heat dissipation.

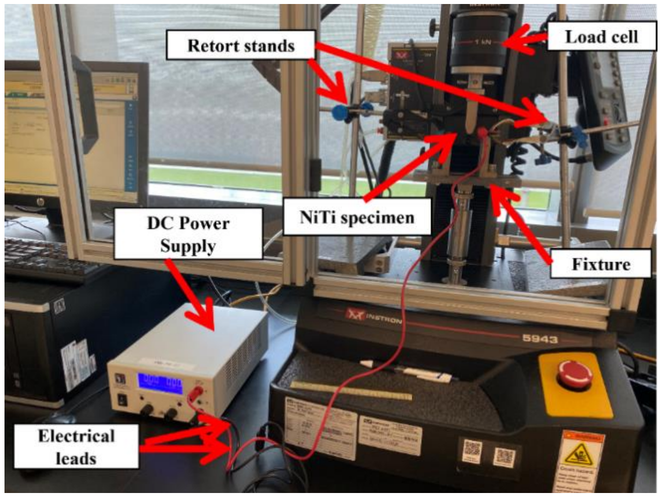

Figure 1: Three-point bend test setup.

4. Test Results and Discussion

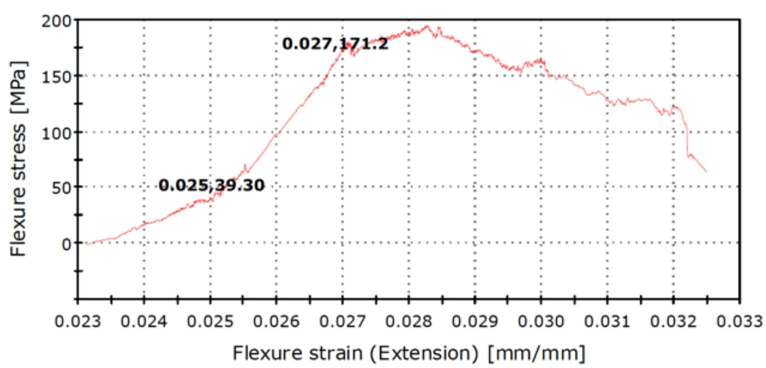

Figure 2: Compression stress-strain curve of NiTi specimen (First test).

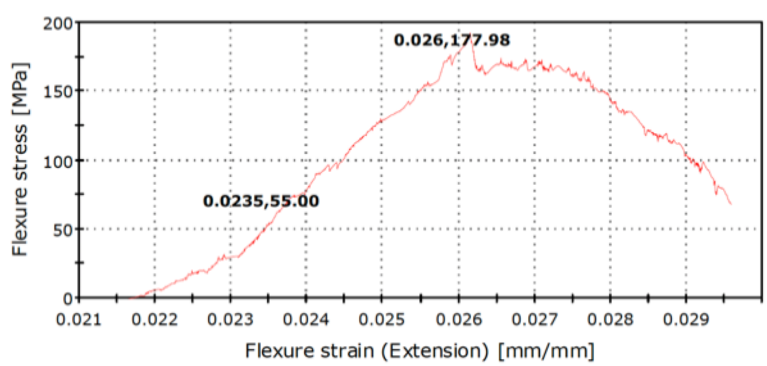

Figure 3: Compression stress-strain curve of NiTi specimen (Second test).

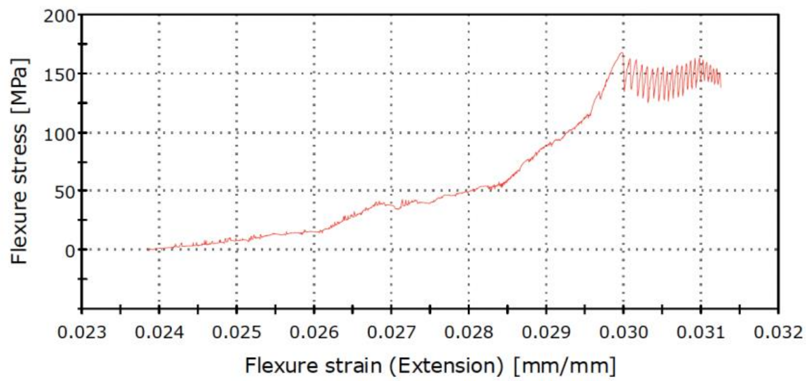

Figure 4: Compression stress-strain curve of NiTi specimen (Third test).

Figures 2 and 3

After many tests, the graphs obtained in Figures 2 and 3 were selected in this study as they most closely resembled a stress-strain curve, thereby making it easier to analyse. The last graphs was also selected to show contrast and provide some possible explanations why such a graph was obtained.

From the first two graphs (Figures 2 and 3), the elastic region was first identified, which corresponds to the relatively straight-line part on each graph. After which, two coordinate points that lie within this region were identified from the raw data, and the coordinates were labelled in the graphs correspondingly. The values were plotted in an Excel table to calculate the Modulus of Elasticity of the specimen in each test (as shown below).

Specimen_test	x_1	x_2	y_1	y_2	*Modulus of Elasticity/Mpa*	*Average/Mpa*
Specimen_test1	0.025	0.027	39.3	171.2	65950	
Specimen_test2	0.0235	0.026	55	177.98	49192	57571

Figure 4: Table showing Modulus of elasticity (E) of the test specimen for two different tests.

As seen in Table 4, the calculated modulus of elasticity for the specimen was 57 571 MPa or 57.6 GPa. This corroborates with existing studies that found the modulus of elasticity of NiTi to be 41-75 GPa for austenite phase (Šittner et al., 2014).

Secondly, as seen from the graphs, in both tests, the NiTi specimen has a similar ultimate tensile strength (UTS) of around 180 MPa. Necking is also exhibited, with the second test exhibiting earlier necking at a strain of around 0.026 mm compared to 0.028 mm in the first test. These results make sense as the same NiTi specimen was used, and as such the necking from the first test affected its mechanical properties as shown in the second test with earlier onstage of necking.

Figure 4

As seen in Figure 4, the graph does not follow the typical shape of a stress-strain curve as it exhibits an exponential growth at the typical elastic region, and secondly exhibits oscillatory trend right after UTS. Firstly, the exponential region is likely due to improper alignment of the wire with the axial force and as such, the axial force was applied off-centre ("Important Aspects of the Flexure Test," 2022). Another possible reason is that the stress-induced phase transformation during resistive heating created internal interfaces that are highly responsive to external stress/load (Šittner et al., 2014). These interfaces may exist in NiTi's microstructure even at temperatures far from the transformation temperature (Šittner et al., 2014). Consequently, the region that is supposed to be elastic is no longer linear. Secondly, the oscillating region which shows the serration behaviour of the material or 'noise after yield' could be due to the strain rate, based on previous studies (Zhang et al., 2021). Although the strain rate is supposed to be constant based on preset settings, it is likely that the specimen slipped from retort stand's grips, and thus this affected the strain rate and led to this erroneous oscillating portion.

Limitations

1. Non-linearity of the Elastic portion can occasionally be obtained
   As seen in Figures 4, the graph exhibited a non-linear region which makes it not possible to calculate the elastic modulus. As mentioned, apart from the misalignment, it is possible that the resistive heating process altered the microstructure of NiTi in a complex and unpredictable manner, resulting in a non-linear (exponential) region, making it difficult to evaluate the elastic properties of NiTi using this macroscopic test method.

2. Gripping approach
   Due to gripping approach using retort stands, slippage in the grips of the specimen is highly likely to occur which can cause a reduction in the required load. Thus, this leads to erroneous data as seen in Figure 4.

3. Lack of data regarding the effect of temperature on NiTi' s compression stiffness
   As resistive heating was done, the only way to increase the temperature across the wire is to increase the current across the wire. However, during experiments, the voltage was increased instead, which made no difference as the wires are short circuit. As such, it was realised that the measurements were done at the same temperature only after the experiments were done. This led to only one set of results (Figures 2-4) where only Figures 2,3 exhibited good result and Figure 4 is being considered erroneous data due to slipping.

5. Conclusions

Drawing on experimental study, this research investigated the axial compression performance of NiTi wire specimens, yielding the following conclusions:

1. Results show that the stiffness of an 8cm NiTi wire (0.254mm diameter, 50-50 composition) with resistive heating of 2.31A current is 57.6 GPa, which corroborates with existing studies.

2. Raising the temperature of the NiTi wire should theoretically increase the wire's compressive stiffness and, consequently, its modulus of elasticity, E. However, due to mistakenly increasing the voltage instead of the current, this meant that the experiments were all done at the same temperature. Due to time constraints to repeat the experiments, there is insufficient data to evaluate the effect(s) of temperature on the stiffness of the NiTi wire and thus its suitability for HTO implants.

References

1. Researcher, R. (2023, September 30). High Tibial Osteotomy (HTO) Plates Market Research Report Provides thorough Industry Overview, which offers an In-Depth Analysis of Product Trends and. https://www.linkedin.com/pulse/high-tibial-osteotomy-hto-plates-market-research-report

2. Miessen, L. (2023). A workflow for in-house design of a patient-specific fixation device in malalignment surgery with 3D-technology in patients for whom off the shelf solutions do not fit. Design of a Patient-Specific Knee Osteotomy Plate. In University of Twente, Universitair Medisch Centrum Utrecht, Orthopaedics Department & 3D-Lab, Graduation Committee, N. J. J. Verdonschot, R. J. H. Custers, N. Van Egmond, E. E. G. Hekman, H. C. Nguyen, E. M. Walter, & H. B. J. Karperien, Master Thesis Technical Medicine [Thesis]. University of Twente. https://essay.utwente.nl/97180/1/Miessen_MA_TNW.pdf

3. Wähnert, D., Greiner, J., Brianza, S., Kaltschmidt, C., Vordemvenne, T., & Kaltschmidt, B. (2021). Strategies to Improve Bone Healing: Innovative Surgical Implants Meet Nano-/Micro-Topography of Bone Scaffolds. Biomedicines, 9(7), 746. https://doi.org/10.3390/biomedicines9070746

4. Li, O. L., Pritchett, S., Giffin, J. R., & Spouge, A. R. (2022). High tibial osteotomy: an update for radiologists. American Journal of Roentgenology, 218(4), 701–712. https://doi.org/10.2214/ajr.21.26659

5. Evaluation of thermal effects of medical devices that produce tissue heating and/or cooling; Draft guidance for industry and food and drug administration staff; availability. (2024). Federal Register, 89(52), 2024–05584. https://www.govinfo.gov/content/pkg/FR-2024-03-15/pdf/2024-05584.pdf

6. Šittner, P., Heller, L., Pilch, J., Curfs, C., Alonso, T., & Favier, D. (2014). Young's modulus of austenite and martensite phases in superelastic NITI wires. Journal of Materials Engineering and Performance, 23(7), 2303–2314. https://doi.org/10.1007/s11665-014-0976-x

7. Important aspects of the flexure test. (2022, June 29). Important considerations for successful flexure tests on plastics, with or without displacement transducer. https://www.zwickroell.com/news-events/news/important-aspects-of-the-flexure-test/

8. Zhang, X., Dong, R., Zhao, Y., Liu, D., Yang, L., & Hou, H. (2021). Serrated flow behaviors in a Ni-based superalloy. Materials Research Express, 8(2), 026515. https://doi.org/10.1088/2053-1591/abe0f2

9. Henderson, E., Nash, D., & Dempster, W. (2011). On the experimental testing of fine Nitinol wires for medical devices. Journal of the Mechanical Behavior of Biomedical Materials/Journal of Mechanical Behavior of Biomedical Materials, 4(3), 261–268. https://doi.org/10.1016/j.jmbbm.2010.10.004