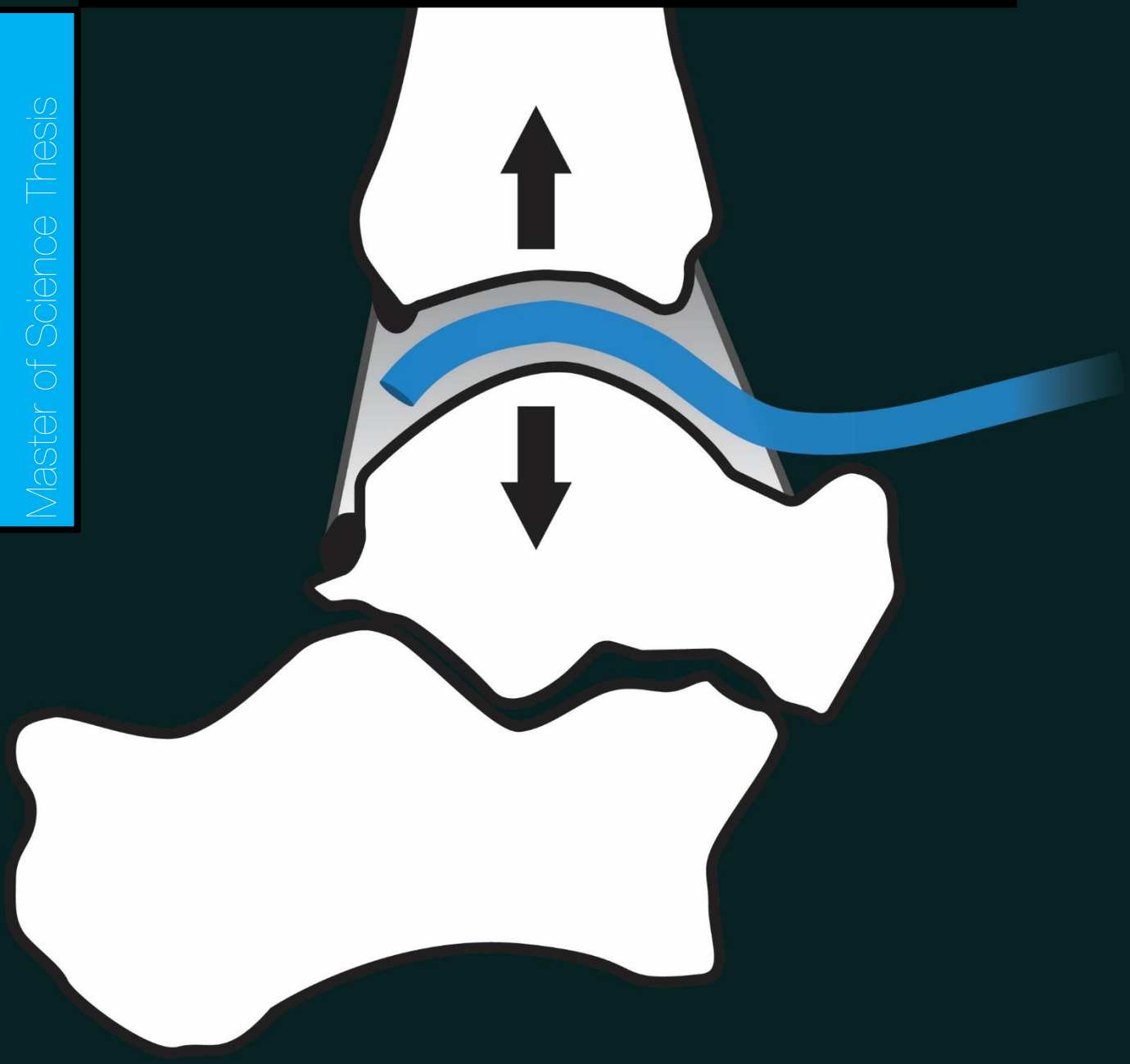
Development of a Flexible Steerable Needle

Master of Science Thesis



TU Delft

Development of a Flexible Steerable Needle

By

T. Schrier

in partial fulfilment of the requirements for the degree of

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Preface

This report is my last accomplishment of the master BioMechanical Design at Delft University of Technology. After 8 years of studying in Delft it is now time to complete this period and take the next step in life. I am proud to present my graduation thesis on the flexible steerable needle. I feel blessed to have been able to design a completely new device from scratch. I would like to thank Tim Horeman for being my daily supervisors from the TU Delft. It has not been smooth sailing during this project and miscommunications have happened more than a couple of times. However, I valued our meetings. At moments, I thought everything was clearly described, Tim would always find new points of improvement, wanted or unwanted. Next, I want to thank Jenny Dankelman, the head of my graduation committee, for the time taken to review my documents and to join the official meetings with welcoming insights. Furthermore, I want to thank my wife Joleen for her help, encouragement and perspective. It has been a busy period with both of us graduating and at one point Joleen starting a new job, but I am proud that we (almost) never were highly stressed and had a lot of free time. I wish my report contributes to the further development of the Chondro project and will eventually help patient rehabilitate much faster from damaged cartilage.

T. Schrier

Rotterdam, September 2017

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Paper

Development of a flexible steerable needle

Tim Schrier • Tim Horeman • Jenny Dankelman

Abstract

Background Current procedures for repairing damage to the articular cartilage in the ankle are not satisfying patient needs and have a minimum rehabilitation time of 4 months. The Chondro project aims to develop an all-in-one polyclinical procedure where diagnosis, treatment and rehabilitation can be performed in one session reducing the rehabilitation time greatly.

Methods This project aims to develop a flexible steerable needle used in the treatment of the damaged cartilage. The needle will have to apply a two-component hydrogel to the lesion. The device is designed at 5mm diameter with the aim to downscale this to 3mm in the future. The bending radius of the device needs to be at least 16mm at the 3mm scale. These and other requirements were tested in several setups and a pilot study with 15 participants.

Results Several materials were used to produce different prototype. The best performing prototype was successfully used in the pilot study. The best performing prototype was produced with NinjaFlex and had a bending radius of 25mm at 5mm scale, bucking strength of 3.2N, rotational stiffness of 5.8 μNm/deg and was able to reach the target areas with a mean absolute distance to the centre of the target of 1.5mm.

Conclusion The designed device is highly precise, relatively stiff in axial direction and could certainly be used to successfully perform the procedure. Rotational stiffness should however be improved. Stiffer material could be used in the future after adaptations have been made to the geometry of the actuator

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Keywords Minimally invasive surgery • Bellows type actuator • Flexible • Steerable • Needle • Ankle • Arthroscopy

Introduction

Figure 1 hyper-inverted ankle of a

Every year 1 million people with cartilage trauma are treated in the EU and US combined. A big part of these injuries is caused by sports accidents when someone makes a misstep, as shown in Figure 15, or when someone else steps on the ankle. When this happens the two bones in the ankle are forcefully in contact with each other resulting in damage to the articular cartilage among other possible injuries. It is commonly known that minimal invasive surgery (MIS) techniques are preferable over traditional surgery for treating these types of injuries. The benefits of MIS are less bleeding, less trauma, less pain and therefore faster recovery of the patient which in turn results in lower healthcare costs[1]. Because of all these benefits arthroscopic surgery has become increasingly popular for cartilage repair within orthopaedic surgery in the US, especially knee arthroscopies[2]. Current techniques have a minimum revalidation time of 4 months for professional athletes and the new fibrocartilage has insufficient structural, biomechanical, and biochemical properties to sustain normal joint function over the long term [3-5]. The Chondro project aims to develop an all-in-one polyclinical procedure where diagnosis, treatment and rehabilitation can be performed in one session. This research is focussed on the tibiotalar joint of the ankle. A sono-elastography based system will provide diagnosis and imaging during the procedure. A flexible steerable needle will then apply a 2-component hydrogel onto the lesion which will glue the damaged cartilage in place. After the treatment, a load sharing ankle brace is put on the patient for further rehabilitation. Within this research project

the flexible needle, which should apply the hydrogel, was developed. The device should be able to reach the lesion in the articular cartilage as fast as possible without doing any damage to the inside of the ankle. The procedure is depicted in Figure 3. The device will first navigate in the sagittal plane through a path predefined by the bony structures. After the axial location is reached the device is rotated to make lateral actuation of the device possible. When the tip of the device has reached the lesion in the articular cartilage inside the ankle the tubes that run through the device are used to apply the hydrogel onto the lesion.

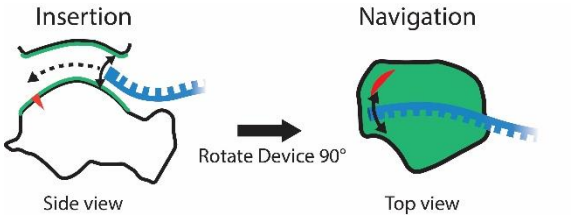


Figure 3 Graphic representation of the procedure

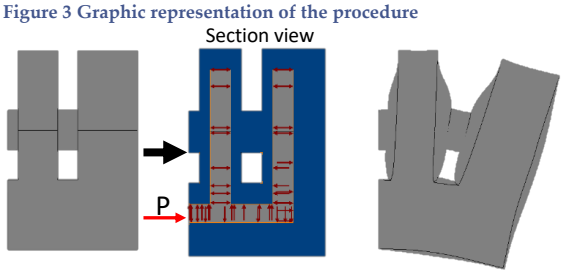


Figure 2 Actuation of device by pressurizing of bellows

Requirements

The design of a flexible steerable needle that will be inserted into the tibiotalar joint and will rotate whilst inside the joint (Figure 3) should meet the requirements as shown in

Table 1. Based on these requirements several versions of the prototype were made using different types of elastomers with different shore hardness values. The prototype is a bellows type actuator which uses inflatable bellows and reinforcing rods which press against each other when the device is pressurized to create a curvature in the device as shown in Figure 2. The pressure can also be inverted so the bellows are deflated and a curve in the opposite direction is created.

Table 1 Performance criteria

Criteria	
Size/scalability	Max 5mm, scalable to 3mm [6-8]
Bending/radius	Max 16mm [9, 10]
Buckling strength	Withstand buckling during insertion
Safety	Absence of sharp edges and overall high compliancy
Precision	Max 4mm absolute distance from lesion [11]
Rotational stiffness	Sufficient for free rotation inside ankle joint
Reliability	At least usable once without failing
Production cost	As few parts as possible

Materials & Methods

Production

The prototype was made by a three-step moulding process. During the first step, the plastic was melted into a basic bar shape which could be inserted into the more complex mould. Next the bar was inserted into the more complex 4-piece mould. This mould, as shown in Figure 5, was CNC-milled out of aluminium. During production, the side-pieces are partially inserted into the central mould to create a closed are for the plastic. Then the plastic bar is inserted and the combined mould is heated until the plastic melts. When the plastic has reached the appropriate temperature the side- and top-pieces are fully inserted into the central mould. After cooling down the top mould is removed after which the tubes are inserted and the flaps are folded over. A heat gun is then used to melt the flaps and seal the device.

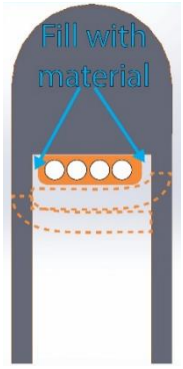


Figure 4 Second step of the production process

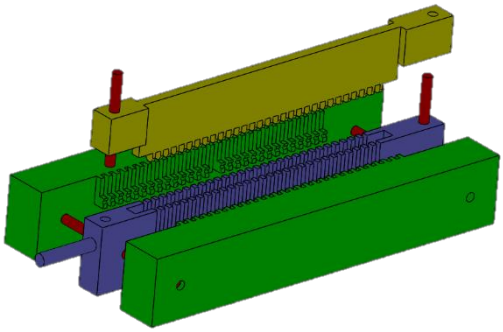


Figure 5 Four-piece production mould

TPE materials

Different prototypes were made of different kinds of thermoplastic elastomer. These elastomers have a high elongation at break and are therefore very stretchable. The prototypes were all tested to determine the best performing material. 3D-printing filament was mainly used due to the preferable cylindrical shape and commercially available high performing properties.

Table 2 Materials used to produce actuator

Name	Shore	Melting Point	El@ Break	El@ Yield
LariPUR 7025	70A	185° C	680%	?
NinjaFlex	85A	216°C	660%	65%
SemiFlex	98A	168°C	600%	49%
FPE-40	40D	159° C	270%	?
FPE-45	45D	180° C	350%	?
FPE-65	65D	210° C	220%	?

Actuation

Actuation was done by using 5ml syringes with a luer tip which are connected via a silicone connector to 0.4mm*0.6mm PEEK tubes enclosed in the actuator that have holes for the actuation fluid to fill the bellows. The syringes were actuated manually with the handle shown in Figure 6. This handle allows for individual actuation of the two sections of the device. The device is actuated by using the rack-spur mechanism controlled by the index- and middle finger, shown in blue. The hydrogel is applied by pressing against the ring shown in red which is connected to the syringes filled with the hydrogel components. The handle was 3D-printed out of PLA and was used during the pilot study.

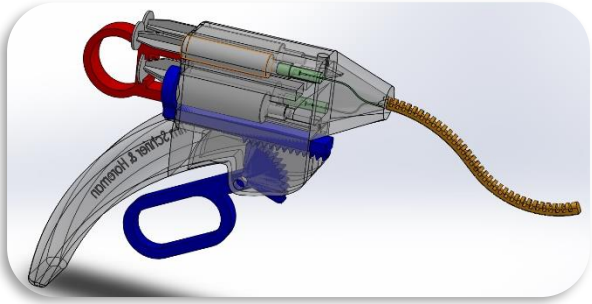


Figure 6 Handle for actuating the device and application of the hydrogel (red: push-pull handle; blue: rack-spur mechanism)

Bending radius

The bending radius was measured by photographing the actuator in actuated state at 60kPa. The background for the photograph was made of a 3mm black and white checkered paper. The photograph was then put in the computer and analysed using a measuring program. The radius was measured at the surface of the actuator that touches the talus during insertion.

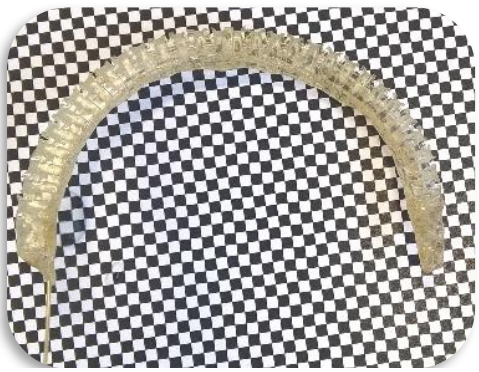


Figure 7 Bended LARIPUR actuator on checkered background

Buckling strength(resistance)

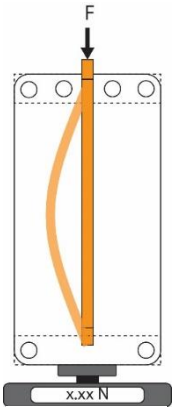


Figure 8 Buckling strength test setup

The buckling strength during the procedure is mainly determined by the lateral stiffness because during the procedure the device will be enclosed between the bony structures. In order to simulate this the buckling strength was measured by keeping the device between two layers of plexiglass as shown in Figure 8. The device was restricted from lateral movement at the base, the tip was put in a tapered hole at the bottom of the test setup so it could rotate but could not move in downwards or lateral direction. The whole setup was placed horizontally against a force sensor and the force at the base of the device was gradually added until buckling to find the buckling strength per device. The maximum amount of force determines the buckling strength of the device. All measurements were done with a Futek Loadcell calibrated to 20N. Sensor values were measured every 50ms and from this the maximum value was taken.

Rotational stiffness

During the middle part of the procedure the device needs to be turned 90°. Therefore, the rotational stiffness needs to be sufficient so the surgeon can easily rotate the device. To test this the device was put in a tube to prevent lateral movement and the tip was locked in a moment-meter setup as shown in Figure 9. The base was rotated to 90° and the exerted moment was measured. From this the rotational stiffness was calculated.

All measurements were done with a Futek Loadcell calibrated to 400mN. Sensor values were measured every 50ms and from this the maximum value was taken.

Figure 9 Rotational stiffness test setup with FPE45 actuator inserted

Pilot Study

During the pilot study 15 different participants were asked to perform a procedure where they had to manoeuvre the tip of the actuator to two predefined points on the joint surface in the artificial ankle setup. The ankle setup consisted of a tibia and talus bone without tendons and ligaments. The two bony parts were spaced 8mm apart and two targets were placed on them as targets for the participants. The participants had to enter the joint through a hole on the right side of the setup as shown in Figure 11.The participants were shown the procedure explanation as depicted in Appendix A. After this the workings of the instrument were explained and the participants had time to establish a learning curve for both the instrument and the test setup. Since buckling of the needle could not be observed well without looking very closely at the participant during the procedure and could not be recorded properly by camera, the participants were asked to pause between each step of the procedure and answer the question: "How often did buckling occur?". It should be noted that it was explained beforehand that this question would be asked but did not affect how well they performed the task so that the participant was aware of this but not anxious of buckling the needle. Buckling was only counted when unwanted and was explained to the participant as moving the handle of the instrument axially into the joint without the tip moving thus causing lateral/sagittal translation of the middle of the needle of minimally 4mm. After step 4 and 5 the distance between the tip of the needle and the centre of the target was noted. The measuring of the distance was done by eye using a bullseye type target as shown in Figure 10. The target has rings of 1mm in different colours so the distance between the tip of the instrument and the centre of the target could be measured by eye to be either 1,2,3 or 4mm.

Figure 10 8mm target used in the ankle setup

During the procedure, the participant's hands were recorded by camera, observable parameters were noted afterwards using the camera footage. The parameters that were noted were:

- The procedure time per step of the procedure
- The number of clockwise and counter-clockwise rotations of the handle
- The number of inward and outward axial movements
- The number actuations of the needle by extending or pulling on the blue handle of the instrument.

Figure 11 Artificial ankle setup with inserted actuator

If two of the same actions were performed with a pause in between of 0.5s is was counted as 2 actions.

After the procedure, the participants were given a questionnaire containing questions about the performance of the device and possible improvements the questionnaire can be found in appendix A. In the questionnaire, the participants were asked to rate the performance of the device per step of the procedure and they were also asked to rate the ease of rotating and bending the needle during the procedure. At the end of the questionnaire there was a section about possible improvements to the actuator. The participants were asked a set of questions designed to find out their thoughts on having two individually actuatable segments of the needle, thus making it possible to make an S-curve with it. They were also asked a second set of questions designed to find out their thoughts on the hardness of the plastic that was used to produce the needle.

Correlations

To establish which parameters from the pilot study, interact with and influence each other scatter plots were made and correlation factors and p-values were calculated for each relevant set. Ordinal regressions were performed to find the relation between:

Performance and **actuation effort, actuation force, steering angle, ease of bending/turning, precision, amount of actions** to find out which of these variables influences the perceived performance and should thus be improved.

Ease of bending and **actuation effort, Actuation force and bending radius** to find whether the perceived ease of bending is mainly determined by actuation effort, actuation force or bending radius of the instrument.

Preferred hardness of plastic and **actuation effort, actuation force, steering angle and ease of bending and rotating during navigation to point #1 and #2** to find out which parameter is mainly responsible for the expressed need for harder/softer plastic used to produce the actuator.

Results

Materials test

Bending radius

The result of the bending radius at 60kPa are listed in Table 3. It should be noted that this is not the minimum bending radius for the actuators.

Buckling Strength

The mean values for the test results of the buckling resistance tests are shown in Table 3. The spread of the data is small, the highest coefficient of variance was found in the results for the FPE-40 actuator which is 0.07.

Rotational Stiffness

The mean values for the test results of the measured force in rotational stiffness setup are shown in Table 3. The spread of the data is relatively small, the highest coefficient of variance was found in the results for the FPE-45 actuator which is 0.11.

Pilot Study

Performance

Insertion and axial navigation have a mean of 8.5(STD=0.8) and 7.4(STD=0.8) there are 3 outliers, one in the insertion and one in axial navigation. Navigation to point 1 and 2 have a larger spread so less consensus and a mean of 6.7(STD=1.4) and 6.8(STD=1.6).

Table 3 Materials test results

Material	Shore	Bending Radius	Buckling Strength**	Rotational Stiffness
LariPUR 7025	70A	27mm	1.7 N	3.7 µNm/deg
NinjaFlex	85A	66mm	3.2 N	5.8 µNm/deg
SemiFlex	98A	93mm	6.5 N	17.6 µNm/deg
FPE-40	40D (90A)	53mm	4.8 N	7.9 µNm/deg
FPE-45	45D (95A)	107mm	8.2 N	36.4 µNm/deg
FPE-65	65D (~105A)	160mm	15.8 N	52.7 µNm/deg

Precision

All participants were able to reach the target within 4mm from the centre. Most of the people were able to reach the target within 1mm which was the minimum distance that was possible. The mean distance from the target was 1.5(STD=0.8) for point 1# and 1.5(STD=1) for point 2

Hardness of plastic

The participants were asked to rate 4 parameters of the needle related to the hardness of the plastic:

- Actuation effort (hand power needed)
- Actuation force (ease of bending the needle)
- Steering angle (minimum bending radius)
- Harder/softer needle

The mean values for actuation effort, actuation force and steering angle are 3.3(STD=1.1), 3.4(STD=0.8) and 3.5(STD=0.8) respectively this corresponds with “neutral to good”. Most participants thought that the needle should be made of a plastic that is “a little harder”, the mean value was 2.7(STD=0.8).

Bending & Turning

Most participants scored the ease of rotation and bending between 2 and 3 which corresponds to “easy” and “medium”. Overall the ease of rotation of the device has a greater spread than the ease of bending. The mean values for ease of bending and rotating during navigation to point #1 are 2.5 (STD=0.6), 2.6(STD=0.9), and for #2 2.9(STD=0.7) and 2.7(STD=0.9) respectively.

Buckling

There was one occurrence of buckling during the whole study. This was during insertion into the joint with subject 3. During any other part of the pilot study no buckling of the needle occurred.

S-Curve

The participants were asked if they agreed with the following statements:

- Making an S-curve with the "needle" is necessary to be able to reach difficult spots inside the ankle.
- Requiring two hands to operate the instrument would make it a lot harder to use.
- The above explained added S-Curve feature would improve the overall performance of the device.

Overall the participants "slightly agreed" to all statements but a significant spread is noticeable. The mean values for the above-mentioned questions are 2.3 (STD=1.1), 2.6(STD=1.4) and 2.3(STD=1.1).

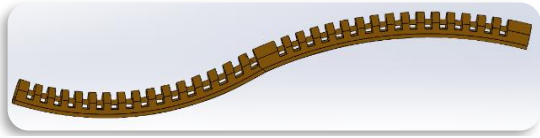


Figure 12 Actuated device in S-curve

Amount of actions during procedure

During the pilot study, the amount of actions the participants made were counted. Bending, straightening, inward axial movement, outward axial movement, clockwise rotation and counter clockwise rotation were counted. The number of actions were noted for navigation to target #1 and #2. Figure 13 gives a graphic representation of the number of actions per target.

Insertion - All participants were able to enter the joint with a maximum of 2 bending actions and 3 inward axial movements. 8 out of the 15 participants were able to do this with just one bending action and one inward axial movement.

Axial navigation - All participants were able to reach the far side of the joint with a maximum of 2 bending actions and 3 inward axial movements. 12 out of the 15 participants were able to do this without any bending action and one inward axial movement.

Navigation to #1 - During navigation to point #1 more actions were made by the participants than during insertion and axial navigation. Except for two outliers all amounts of actions are closely spread without much deviation. 5 out of the 15 participants used just one bending action and only 4 participants used the straightening action.

Navigation to #2 - During navigation to point #2 more actions were made by the participants than during insertion and axial navigation. Inwards and outwards axial movement of the device have a larger spread than the amount of rotations. 6 out of the 15 participants used one bending action and 6 out of the 15 participant used 2 bending actions. Only 2 participants used the straightening action which causes it to appear as an outlier in the boxplot.

Correlations

No significant correlations between any of the parameters, number of actions or participant responses were found using ordinal regression.

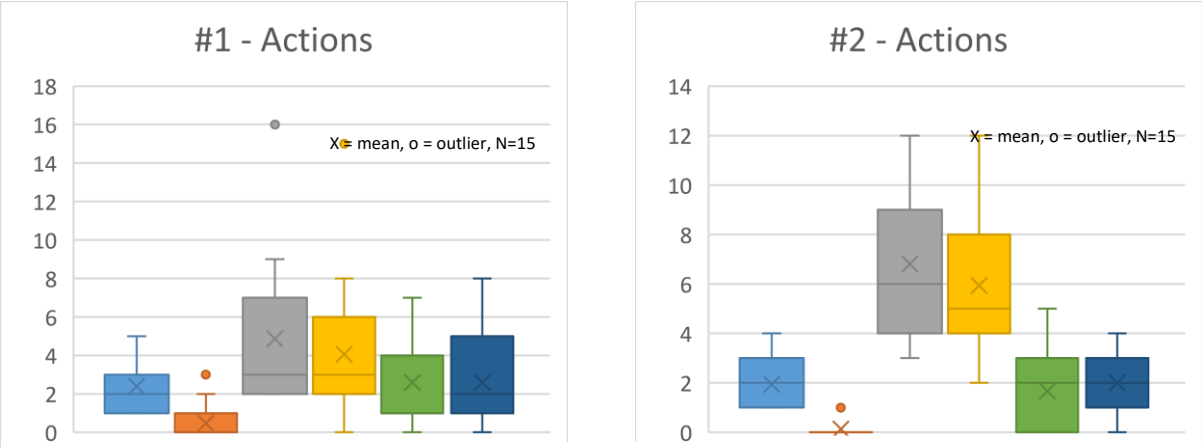


Figure 13 Amount of actions during navigation to point #1 and #2 (from left to right: Bending, Straightening, Inward movement, Outward movement, Clockwise rotation, Counter clockwise rotation)

Discussion

The assessment of the instrument is done by criteria that have been set at the beginning of the research project. After the instrument is assessed the pilot study is also reviewed

Criteria

Size/scalability
The device was successfully produced at the predetermined 5mm scale. The production at a 3mm scale is deemed possible given the right equipment and some adaptations to the production process

Bending Radius
The bending radiuses of the different actuators show a clear correlation with Shore hardness, except for the radiuses of the FPE-40 and SemiFlex actuators. A possible explanation for the deviation is that the shore A or D hardness is not directly correlated to the Young's modulus of a material. Another possibility is that the geometry of both devices is not exactly similar, since most of the production was done by hand.

The bending radius as shown in Table 3 are at 60kPa. The actuators can however be pressurized to higher pressures causing lower minimum bending radiuses. The determining factor for the minimum bending radius was observed to be the seals between the PEEK tubing and the silicone connectors and the actuator as shown in. The minimum bending radius at maximum pressure for the NinjaFlex actuator was 25mm. When this radius is scaled to a 3mm actuator this would be 25/5*3= 15mm. This is within the set 16mm criterion. It is deemed possible to make a seal that can withstand higher pressures so that the harder plastics up to FPE-45 could be used to make an actuator that has a minimum bending radius of 15mm at a 3mm scale.

Figure 14 Reinforced seal between silicone and PEEK

Safety
The actuator was designed with a lack of sharp edges and high overall compliancy and is therefore safe to use inside the ankle joint. However, during the pilot study it became clear that the bellows on the actuator might get stuck on skin at the insertion point causing discomfort to the patient. There are several ways of working around this problem like a smooth insertion portal in the skin. Another possible concern for the safety of the instrument could be leakage of the actuator. Therefore, the actuator can be filled with either water or a saline solution that is safe to use inside the body. Since pressure of the device does not exceed 200kPa there is no threat of leaking water damaging the cartilage at high pressures.

Reliability
The criterion that was set up states that the actuator has be able to withstand at least one procedure. The actuator used in the pilot tests was used for more than 15 procedures without critical failure. A failure that was noted was the seals started leaking more often and under lower pressures after 10 procedures.

Production cost
Since the device will be made disposable it will have to be produced as cheap as possible. The monolithic actuator is not expensive to produce in large batch sizes since no assembly costs are necessary.

Rotational Stiffness
During the pilot study, it became clear that the overall rating of the rotational stiffness was "neutral to good" and several participants noted a lack of rotational stiffness and would have liked the device to be stiffer around the central axis. Therefore, it can be said that the current rotational stiffness of 5.8 µNm/deg of the NinjaFlex actuator is not sufficient for a good performance of the instrument.

Pilot Study

Performance
The result for the pilot study show high values for insertion and axial navigation with means of 8.5 and 7.4 respectively. The scores for both navigation to target 1# and #2 were rated at around 6.5 which is a decent score and fulfils the criteria set before the pilot study. There is however room for improvement which will have to come in the form of adaptations to the instrument.

Hardness of plastic
During the pilot study the actuation effort, actuation force and steering angle were rated "neutral to good" which is just within the criteria that were set before the pilot study. Therefore, the criteria can be regarded as fulfilled. Moreover, at the 3mm scale the steering angle will be smaller since the actuator will be scaled down to 3mm. Also, the actuation force is determined mostly by the static friction between the actuator and the joint which will be much lower in a human joint than in the test setup. During the pilot study, the participants noted that the hardness of plastic should be "slightly harder". The reason for

this was indicated by some participants to be the rotational stiffness. Buckling almost never occurred during the study and is thus not seen as a significant factor for the hardness of the plastic.

Precision

The precision of the device during the pilot study was well within the 4mm criterion that was set. Most of the participants was able to reach the centre of the target within 1mm. Therefore, the precision is regarded as much better than needed for this procedure.

S-Curve

As mentioned in the "results" section, the participants "slightly agreed" to all statements regarding the addition of an S-curve feature. The "slight agreeance" to these statements means that overall the participants felt that an S-curve is needed to reach difficult spots inside the ankle and that this will make operation of the device more difficult but will overall improve the performance of the device. The need for the instrument to make an S-curve is made slightly less significant by the fact that a surgeon is able to choose an insertion port at any side of the joint and therefore might be able to pick a port that will allow him to reach difficult point inside the joint without needing the device to make an S-Curve.

Actions

The main reason for measuring the amount of actions was to get a measure for the mental load during the procedure which could then in turn be linked to the perceived performance of the device. This correlation was therefore examined but no significant correlations were found between any of the amount of actions and the performance for the corresponding task. The sample size of 15 participants for this pilot study is not high enough to exclude any correlation between the amount of actions and the mental load and therefore the performance of the device. A larger study could either confirm or deny the absence of correlation. Based on the amount of actions still some conclusion can be made. For instance, the straightening action was almost never used by the participants during the pilot study. This can be contributed to the fact that most participants straightened the needle by simply rotating it around its axis forcing it back into its straight form by the bony structures.

Correlations

The ordinal regressions that were performed on the different variables did not result in any significant correlations. The main reason for this is because the sample size is only 15 in this study. However, a few trends can be found when looking at the scatter plots of some of the variables. One of the trends that can be seen is found between **performance and precision**. The first trend is that all participants that weren't able to reach the centre of the target scored the performance 6 or lower for both tasks indicating that when the centre could not be reached performance was considered barely sufficient or less. This seems logical since reaching the centre of the target was the main goal of the procedure. The second trend is the correlation between **ease of bending and performance for navigation to target #2**. No such correlation can be seen for navigation to the other target. However, it is possible that the second task relied more on bending the actuator than the first task. If this is the case then ease of bending is a strong determinant for the perceived performance in certain tasks.

Conclusions

A 5mm flexible steerable needle with ergonomic handle was developed that was able to reach the targeted areas inside an artificial ankle test setup within 1.5mm absolute distance. Overall the device performed well in the pilot study. Production costs of the device can be kept low due to the monolithic design of the actuator which also ensures good reliability of the device. The weakest link in the design was identified to be the seals between the PEEK tubing and silicone connectors. This problem can be resolved by relatively simple solutions and does therefore not compromise the quality of the design. The best performing actuator was made from NinjaFlex 3D-print filament with a shore value of 85A. It is recommended that for future designs with stronger seals the SemiFlex or FPE-40 material is used. The ergonomic handle that was designed for the actuator performed well during the pilot studies. The handle will have to be redesigned to account for better seals and easy assembly. The main point of improvement for the actuator should be the rotational stiffness. Geometrical redesign and material choice should be focused on increasing rotational stiffness of the actuator.

References

[1] A. Cuschieri and G. Berci, "Laparoscopic biliary surgery," *Surgical Laparoscopy Endoscopy & Percutaneous Techniques,* vol. 1, p. 58, 1991.

[2] S. Kim, J. Bosque, J. P. Meehan, A. Jamali, and R. Marder, "Increase in outpatient knee arthroscopy in the United States: a comparison of National Surveys of Ambulatory Surgery, 1996 and 2006," *J Bone Joint Surg Am,* vol. 93, pp. 994-1000, Jun 1 2011.

[3] G. D. Smith, G. Knutsen, and J. B. Richardson, "A clinical review of cartilage repair techniques," *J Bone Joint Surg Br,* vol. 87, pp. 445-9, Apr 2005.

[4] L. Alparslan, C. S. Winalski, R. D. Boutin, and T. Minas, "Postoperative Magnetic Resonance Imaging of Articular Cartilage Repair," *Semin Musculoskelet Radiol,* vol. 05, pp. 345-364, //
17.12.2001 2001.

[5] J. R. Steadman, W. G. Rodkey, S. B. Singleton, and K. K. Briggs, "Microfracture technique forfull-thickness chondral defects: Technique and clinical results," *Operative Techniques in Orthopaedics,* vol. 7, pp. 300-304, 10// 1997.

[6] J. F. Guhl, "New concepts (distraction) in ankle arthroscopy," *Arthroscopy,* vol. 4, pp. 160-7, 1988.

[7] K. T. M. Opdam, R. Zwiers, and C. N. van Dijk, "Anterior Ankle Arthroscopy: General Setup and Portal Options," in *Arthroscopy: Basic to Advanced*, P. Randelli, D. Dejour, N. C. van Dijk, M. Denti, and R. Seil, Eds., ed Berlin, Heidelberg: Springer Berlin Heidelberg, 2016, pp. 955-963.

[8] P. A. Dowdy, B. V. Watson, A. Amendola, and J. D. Brown, "Noninvasive ankle distraction: relationship between force, magnitude of distraction, and nerve conduction abnormalities," *Arthroscopy,* vol. 12, pp. 64-9, Feb 1996.

[9] J. Medley, D. Dowson, and V. Wright, "Surface geometry of the human ankle joint," *Engineering in medicine,* vol. 12, pp. 35-41, 1983.

[10] O. Magerkurth, M. Knupp, H. Ledermann, and B. Hintermann, "Evaluation of hindfoot dimensions: a radiological study," *Foot & ankle international,* vol. 27, pp. 612-616, 2006.

[11] F. R. Noyes and C. L. Stabler, "A system for grading articular cartilage lesions at arthroscopy," *The American Journal of Sports Medicine,* vol. 17, pp. 505-513, 1989.

Report

Introduction

Every year 1 million people with cartilage trauma are treated in the EU and US combined. A big part of these injuries is caused by sports accidents. On the most common injuries is a “twisting” of the ankle where the foot is hyper-everted/inverted. This can happen when someone makes a misstep, as shown in Figure 15, or when someone else steps on the ankle. When this happens the two bones in the ankle are forcefully in contact with each other resulting in damage to the articular cartilage among other possible injuries.

Figure 15 hyper-inverted ankle of a soccer player due to a misstep

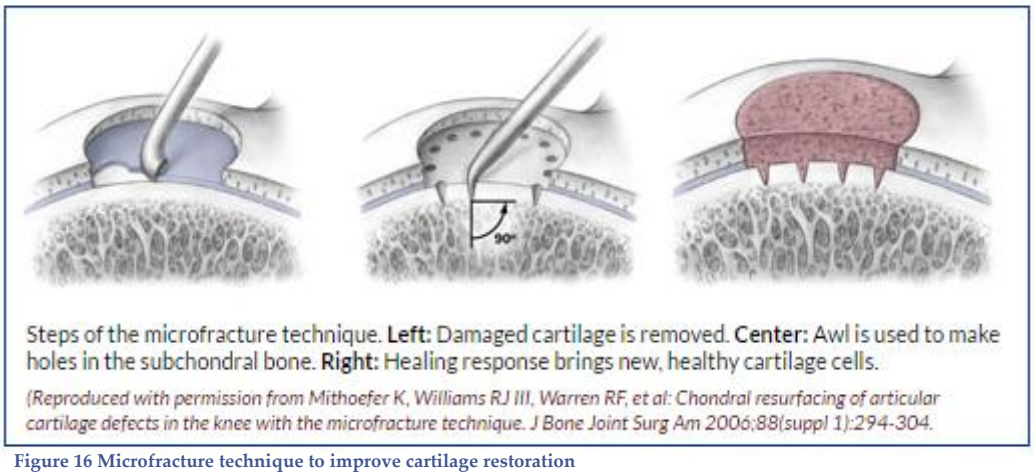
It is commonly known that for treatment of these types of injuries minimal invasive surgery (MIS) techniques are preferable over traditional surgery. The benefits of MIS are less bleeding, less trauma, less pain and therefore faster recovery of the patient which in turn results in lower healthcare costs[1]. Because of all these benefits arthroscopic surgery has become increasingly popular for cartilage repair within orthopaedic surgery in the US, especially knee arthroscopies [2] .

Current Cartilage Regeneration Treatments

A number of procedures is used to treat damaged cartilage, most of these are performed arthroscopically. The commonly used procedures are:

Bone Marrow Stimulation [1-4cm^2]

Several techniques may be used to stimulate the growth of new fibrocartilage from bone marrow stem cells. These techniques include abrasion, subchondral drilling, and micro fracture. All of these techniques essentially inflict controlled damage in the form of pits to the bone beneath the cartilage to migrate multipotent stem cells from marrow beneath these pits to the cartilage defect. Each of these techniques eventually leads to the formation of fibrocartilaginous repair tissue[5, 12-14].



Steps of the microfracture technique. **Left:** Damaged cartilage is removed. **Center:** Awl is used to make holes in the subchondral bone. **Right:** Healing response brings new, healthy cartilage cells.

(Reproduced with permission from Mithoefer K, Williams RJ III, Warren RF, et al: Chondral resurfacing of articular cartilage defects in the knee with the microfracture technique. J Bone Joint Surg Am 2006;88(suppl 1):294-304.

Figure 16 Microfracture technique to improve cartilage restoration

Figure 16 shows a standard micro fracture procedure. Micro fracture remains the most commonly performed cartilage repair procedure. No absolute contraindications or unique risks to the micro fracture technique have been established[4]. Despite the popularity of the technique, few prospective studies have been performed and only limited information is available about clinical outcomes [15, 16]. The new fibrocartilage has insufficient structural, biomechanical and biochemical properties to sustain normal joint function over the long term[3-5]. Mithoefer et al. [17] found that micro fracture effectively improved knee function in all studies during the first 24 months after micro fracture, but the reports on durability of the initial functional improvement were conflicting.

Tissue-based Cartilage Repair [1-4cm^2]- *Osteochondral Auto- or Allograft Transplantation*

In osteochondral autograft transplantation, cartilage is transferred from one part of the joint to another. Healthy cartilage tissue - a graft - is taken from an area of the bone that does not carry weight (non-weight bearing). The graft is taken as a cylindrical plug of cartilage and subchondral bone. It is then matched to the surface area of the defect and impacted into place as shown in Figure 17 [3, 13, 18]. The same procedure can be done to transplant cartilage from a cadaver. This type of graft is useful for repairing large defects, and there is no donor-site morbidity [4, 13, 19]. These procedures produce good short term results [20] but is dependent on available donor tissue either from the patient or a cadaver.

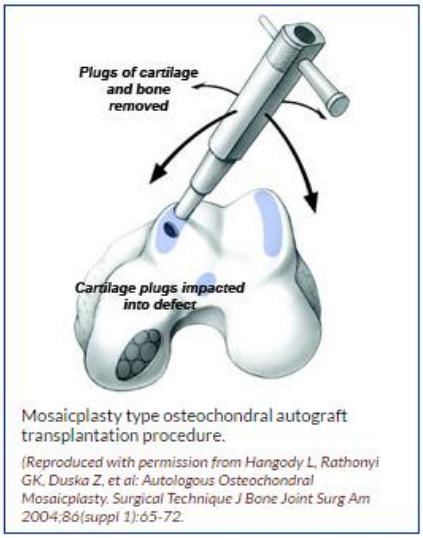


Figure 17 Osteochondral Autograft Transplantation

Cell-based Cartilage Repair: Autologous Chondrocyte Implantation [2-12cm^2]

The classic procedure of autologous chondrocyte implantation was first described in the mid-1990s [21]. Healthy chondrocytes harvested from a non–weight-bearing cartilaginous surface are implanted via an arthrotomy and covered with a periosteal flap, the edges of which are secured in place with fibrin glue or sutures. If successful, it results in the formation of fibrocartilage that is similar to natural hyaline cartilage [22-27]. Peterson et al. [23] reported that autologous chondrocyte implantation resulted in well-integrated reparative tissue and successful clinical results. Brown et al. [27] reported that filling of a defect was consistently better with autologous chondrocyte implantation than with the micro fracture technique. However, autologous chondrocyte implantation may be complicated by graft hypertrophy, which usually has been observed within 6 months after the procedure.

There are many possible variations of the implantation procedure. Handl et al. [28] reported that among five patients who received autologous chondrocyte implants (solid chondral grafts fixed with fibrin glue) the procedure resulted in a significant improvement of ankle joint function in three patients but no clinical change in one patient during the follow-up period (6–24 months).

Fixation with Biodegradable Pins

Biodegradable pins made of polydioxanone may be used to stabilize osteochondral fractures, chondral flap tears, and osteochondritis dissecans lesions. These pins generally resorb within 6–24 months, with the resultant synthetic debris being cleared predominantly by macrophages [4].

The Chondro project

Within the Chondro project the aim is to develop a new technology for the repair of cartilage damage (tear/lesion) immediately after a sports injury. This treatment will prevent more invasive surgery and potentially prevents further erosion and damage, reducing the rehabilitation time significantly.

First an echography-based system is used to identify the location of the damage and next a 2 component hydrogel is applied to the damaged area. The gel has a high viscosity and is an almost water-like substance. when the components mix the gel hardens and glues the tear in place. After this polyclinical procedure a load-bearing brace will spread and partially relieve the loading on the damaged joint during rehabilitation.

To be able to reach the distal parts inside the joint an “intelligent” needle needs to be developed. This is a needle which is either steerable or will find its own way to the tear in the cartilage. It then becomes possible to follow a path as shown in Figure 18. The instrument should remain controllable in the in-plane direction in order to be able to reach every part inside the joint. The inside of the ankle joint, specifically the talus, is chosen as target area for this graduation project since the ankle is the smallest joint where lesions are typically found and has a complex geometry. If a working prototype can be designed for use inside the ankle it can be scaled to larger joints like the knee and hip joint.

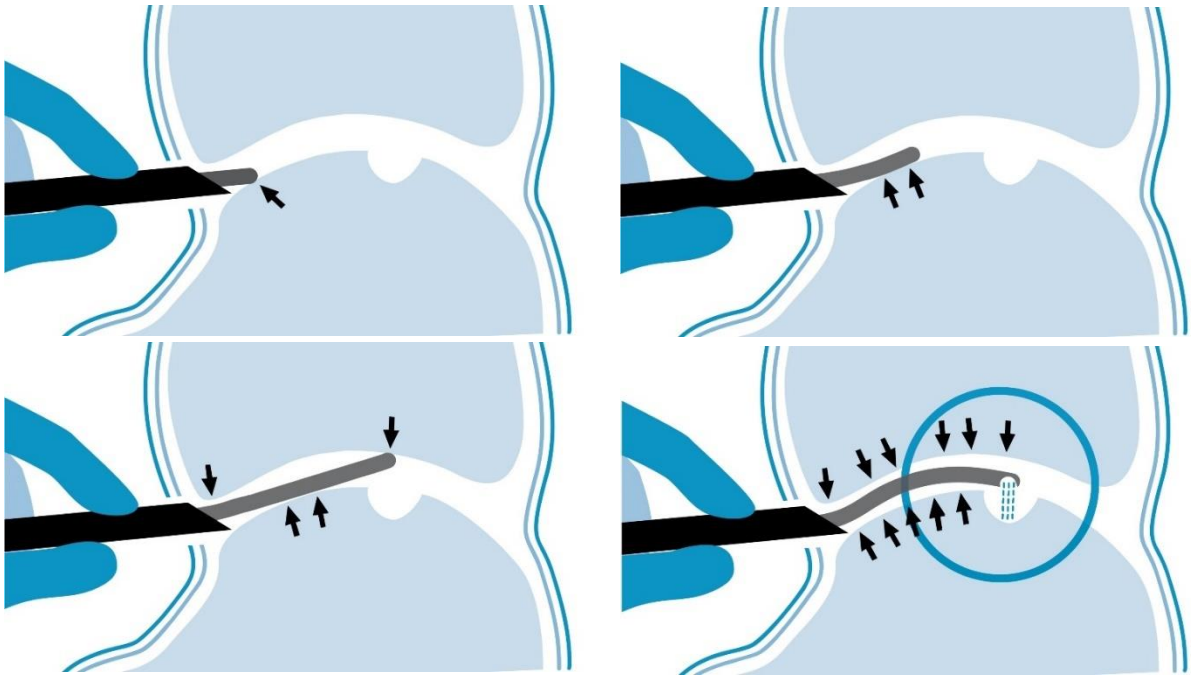


Figure 18 Graphic representation of inserting the “intelligent” needle during the Chondro procedure

Concept Development

In this chapter, the concept development will be explained. The five main steps are shown in Figure 19. It should however be kept in mind that designing a device is an iterative process with many steps back and forth between different parts of the process. The results of this process are listed in this chapter. The first step was to determine the requirements of the device. Once these had been established a literature search was performed to learn the state of the art of current technologies that could be implemented in this procedure. During the ideation phase, multiple design options were considered with a focus on finding a way to implement these technologies into a viable concept. Out of the abundance of possible concepts one was selected to be tested in a controlled environment to determine the performance of the prototype. The prototype was evaluated throughout the whole project, adjustments were made and even new requirements were made. The cycle as described here and shown in Figure 19 is very linear. However, many times the process required taking two steps back and one forward in order to come to the optimal solution.

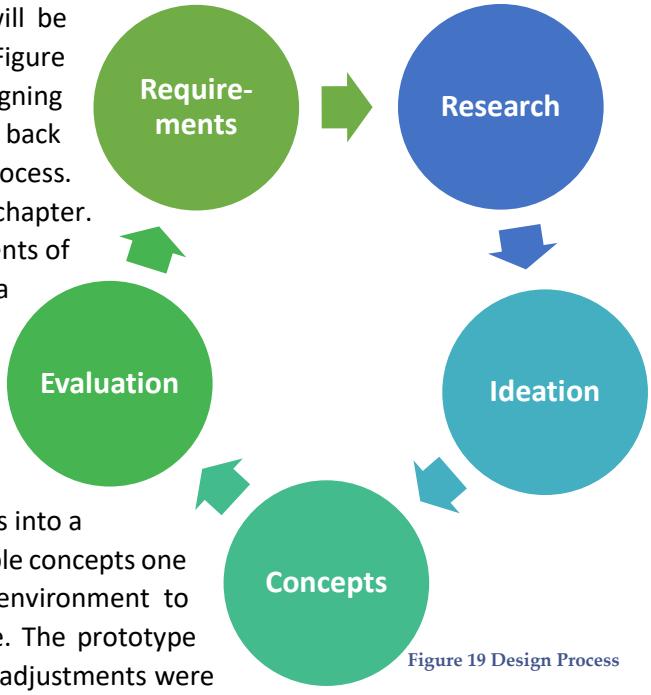


Figure 19 Design Process

Function Analysis of Needle

In order to design an instrument, the exact function must be clear. The tasks this instrument must perform are divided into different sub-tasks which are listed below and partially depicted in Figure 20.

1. Insertion into ankle joint
2. Navigation in sagittal plane
    a. Axial direction
    b. Vertical direction
3. Navigation in lateral plane
4. Mix & apply hydrogel
5. Retract

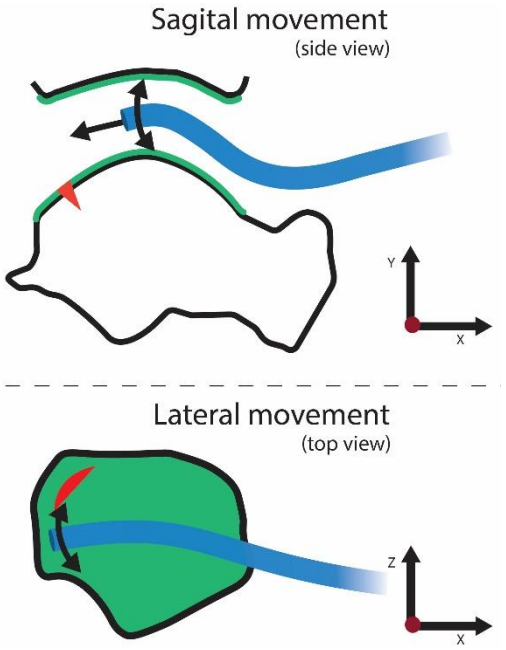


Figure 20 Sagittal and lateral movement of the device during the procedure (green = cartilage, red=lesion)

After the instrument is inserted into the ankle it must navigate along the bony structures towards the lesion. This means that it must first navigate in the sagittal plane (the plane that divides the body into a left and right half). After, and possibly during, the sagittal movement lateral navigation must be performed in order to reach the tear so that the hydrogel can be applied to the lesion. The narrow space though which the device must navigate might not the same size at every point so the device should be able to push through narrow spaces when needed. When the target area is reached, the hydrogel is guided through tubes through the device in two components. In order for the two components to mix the tip should contain a room with possibly some kind of mixing canals where these components can interact with each other. After application of the hydrogel the device is retracted.

Dimensional/geometrical Criteria

The functions of the device and the environment in which it has to operate lead to some physical requirements for the device. These requirements define the geometrical parameters of the instrument which can eventually be scaled in order to make the device suitable for other procedures. The requirement list is:

1. Height 5mm
2. Width 15mm (assuming elliptical shape)
3. Bending radius 16mm
4. Length of 100mm
5. Two hollow tubes Ø0.5mm
6. Volume for mixing tip
7. No sharp edges

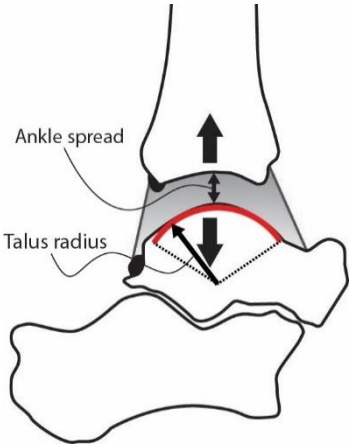


Figure 21 Ankle spread & Talus radius

The size of the tubes for guiding the hydrogel is predefined by the developer of the hydrogel, 0.5mm should be large enough for the hydrogel to flow through a 10cm long tube. The Length of the device is set to approximately 100mm to fit the largest ankles. The volume of the mixing tip is something to be determined at a later stage of research.

Size/Scalability

The area where cartilage damage often occurs is between the tibia and the talus. During the procedure the ankle can be distracted leaving about 7-8mm of space between the Talus and the Tibia for 45-60 minutes without permanent damage [6]. Currently used instrument for surgery therefore vary between 2.7mm and 5.2mm in size [7]. However, this instrument is to be used in a polyclinical procedure where the device is to be inserted via a needle without extra incisions into the ankle this means that the device will preferably have a diameter of approximately 3mm. For the first prototype, the aim is to make a device that is **5mm in height**. Assuming an elliptical shape of the instrument and a Talus radius of 16mm [9, 10] the maximum width of the instrument is 15mm as shown in Figure 22**Fout! Verwijzingsbron niet gevonden.**. This is the absolute maximum size that can fit into the ankle. However, a round device with a diameter of 5mm would be preferable since this can be rotated around its axis inside the ankle. Eventually the device will have to be downscaled to 3mm to be able to use it in a polyclinical procedure. Future/professional technologies might be able to produce the device in a smaller scale. Also, a non-invasive ankle spreader could be developed to enlarge the workspace during a polyclinical procedure allowing the use of a larger device, non-invasive ankle spreading can lead to an ankle distraction of 4-8mm [6-8].

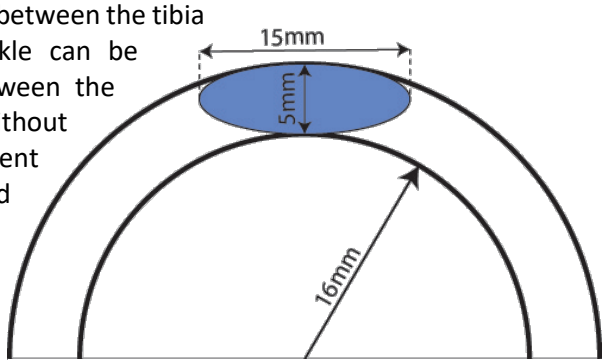


Figure 22 Size of the instrument inside the ankle

Bending Radius

The main determinant for the shape of the ankle joint is the radius of the Talus since this will determine the bending radius that the instrument must be able to make. The Average human has a Talus radius of about 16-19mm [9, 10] (see Figure 21). Other joints in the body have similar radii which determine the shape but all are larger than the talus radius[29], which means that the instrument will be usable in procedures in other joints if it is designed for insertion into the ankle joint. The instrument will be inserted either via the anterolateral, anteromedial or the posterolateral portal at the ankle. Looking at the gathered information concerning the geometry of the ankle the conclusion is that the instrument must be able to bend with a **radius of 16mm** to be able to reach every part of the ankle considering that the angle of approach and choice of portal are variable.

Safety/Avoiding Peak Loading

Cartilage is a relatively strong but soft material. A literature search puts the tensile strength between 10-40MPa and the shear modulus between 0.2-4.1GPa[30-34]. This is quite a broad spectrum. The reason for that is that the strength and stiffness of cartilage is highly dependent on the direction of the load and age of the patient[32, 33]. The stiffness of cartilage is roughly comparable to be in between those of the human skin and medium soft plastics like HDPE [35].

Uniform loading does not pose a great threat since cartilage is relatively strong, but sharp edges might cause damage. Therefore, the safety aspect of the instrument is defined by the chance of peak loading on the cartilage. A peak loading can be avoided by designing an instrument with a **lack of sharp edges or high overall compliancy**.

Performance Criteria

The goal of the device is to reach a lesion in the cartilage inside the ankle joint as fast as possible without harming the patient or causing extra damage to the cartilage. To assess the quality of the design a set of objective criteria was used to determine the performance of the device for this goal. These criteria will have to be kept in mind during the conceptualization phase. The criteria are set up as objective as possible since this will lead to a clear determination of the performance of the device. All criteria should directly lead to the goal of the device.

Buckling strength

During the procedure, the instrument will likely encounter some narrow spaces inside the ankle. This means that the instrument must be pushed through these spaces in order to reach the desired location. This requires a certain buckling strength of the device. The device will have to be able to **withstand buckling during insertion and navigation through the joint**. Since this is a completely new procedure and there are no clear standards for buckling strength of an instrument for similar procedures, a post-production testing of the device will have to determine the exact strength that is required.

Precision

Precision describes how accurately the device will be able to locate the lesion (tear) inside the ankle and is in this report determined by the absolute distance between the tip of the instrument and the lesion. During the procedure, the nozzle in the tip of the instrument should touch the lesion at some point in order to be able to fill the gap with the hydrogel. So, to be able to set a parameter for the precision first some information is needed about the size and shape of the lesion. Literature puts the length of fissures between 5mm and >20mm [11] and the total damaged area between <100mm^2 and >400mm^2 [36]. The average width of the lesion is very small. The lesion can have many different shapes ranging from a linear fissure to a flap to a central crater with radiating fissures [37]. Worst case scenario for precision is a linear fissure in axial direction with negligible width. In this case the required precision is fully determined by the size of the nozzle in the tip of the instrument. In order to have an increased precision the nozzle could be designed for diffuse application of the hydrogel. When the nozzle is pressed against the lesion it should touch the lesion at some point. Therefore, the precision that is required is **determined by the width of the instrument tip**. The mixing tip that is going to be placed at the end of the instrument is going to have a width of 8mm. So, the instrument should be able to **locate the lesion within 4mm absolute distance**. If the design of the tip is altered it could result in an altered required precision of the instrument.

The precision that the device is able to reach is determined by a couple of factors. Firstly, compliancy of the device. A very compliant device won't be able to locate the tear accurately since the flexibility results in a high uncertainty of the position of the instrument tip due to play in the system. Secondly, the static friction in the system. When 2 components slide over each other there is always an amount of static friction and dynamic friction between the two. These two friction components will deliver a force contrary to the actuation force resulting in stick-slip behaviour and thus an inaccuracy of the movement. And thirdly, yielding of the material. This occurs when a material is stretched beyond its yielding point which causes the material to not completely return to its starting position which also result in an inaccuracy of the movement.

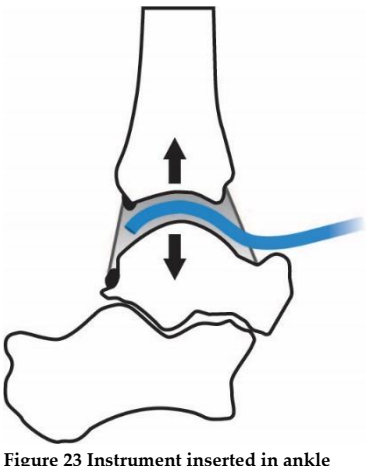


Figure 23 Instrument inserted in ankle

Reliability

The reliability is a very important aspect of the design. It includes robustness but also durability of the instrument. It is not directly related to operation speed but an unreliable instrument cannot be used effectively in a medical environment. When an instrument is made reliably it can withstand relative high forces making it safe to use. The reliability of the instrument is determined by the reliability of its individual parts. In other words, the weakest link determines the strength of the system. Since the device will be disposable the device will only have to be **able to withstand one procedure** without failing. It must be noted that this is during normal intended use. The Exact amount of force that the instrument should be able to withstand will have to be determined at a later stage of the development but this should be a criterion to bear in mind during conceptualization.

Production cost

The last criterion mentioned here is the production cost. Since the device will eventually have to be sold to hospitals the cost needs to be as low as possible in order to make it appealing for the hospital to purchase this device. During production, the cost is mainly determined by amount of parts, production process, materials used and the amount of actions that are needed to assemble the device. Monolithically production using injection moulds is only preferable at a certain number of products per year. Since the current demand is unknown the goal is to design the device with **as few parts as possible and simplistic assembly**.

Table 4 criteria for designing and assessing the device

Criteria	
Size/scalability	Max 5mm*15mm elliptical shape, scalable to 3mm
Bending/radius	Max 16mm
Buckling strength	Enough to withstand buckling during insertion
Safety	Absence of sharp edges and overall high compliancy
Precision	Max 4mm absolute distance from lesion
Reliability	At least usable once without failing during normal intended use
Production cost	As few parts as possible

Concept research

The concept research included both research in literature to find the current state of the art but also research into the mechanisms themselves. To be able to properly design an instrument based on certain mechanisms first theses mechanisms should be understood. If the underlying mechanisms of a concept are understood the brainstorm process for new concepts can be guided by insight and the ideation process will produce concepts which are both implementable and novel.

From a previous literature study performed for this project two concepts were selected as “most promising”. In this graduation project, the most viable of these concepts is determined and developed into a functional concept which can be tested based on a set of performance criteria.

The Soft Fluidic Actuator (SFA) and the Double Rotating Soft Screw (DRSS) are the two proposed technologies to be used for the task.

The mechanical principals of both mechanisms are explained in the following paragraphs. Each part starts with the current concepts and explains the underlying mechanics that need to be understood in order to generate different innovative mechanisms during the ideation phase.

Soft Fluidic Actuator (SFA)

The first technology to be reviewed is the Soft Fluidic actuator. The starting point for this soft hydraulic device is a concept from the field of soft robotics that was developed at Harvard University. This device uses a partially reinforced elastic tube which is pressurised to initiate bending [38]. The bending radius that can be achieved with this 15mm wide tube is 25mm. This design is closely related to Pneumatic Artificial Muscles (PAMs) of which many are being developed at the moment and some are already miniaturized [39].

Mechanical Principal

The concept as found in literature was designed at the soft-robotics department at Harvard, Figure 24 shows a 3-compartment variation on this concept. The device consists of 3 main parts. The first is a bottom layer which is relatively rigid. This layer is thin so it is able to bend but it cannot be extended in axial direction during actuation. The second part is the flexible outer layer of the device. During actuation, this layer expands in axial direction due the enlarging of the pressurized chamber. If the third part, the reinforcing braiding, would not be present the flexible layer would mainly expand in normal direction like a balloon but the reinforcements as shown in Figure 24 make sure that the instrument retains its original diameter. In the original concept, this reinforcement consists of 2 counter turning springs. The basic mechanism that creates the bending action of the device is that the outer layer becomes longer than the core and that both ends are attached to each other. So, the main principle that should be obtained in a new design is **a length differential initiated by fluidic pressure**. This can be done in different ways which will be explored during the literature search and brainstorm sessions in the ideation phase.

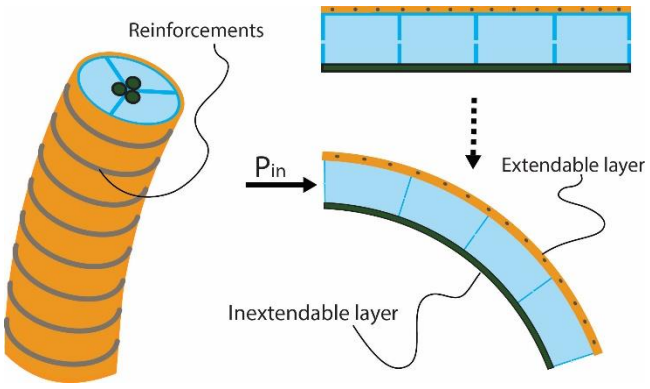


Figure 24 multi-steerable 3-compartment concept of the SFA

Pro's/Con's

The bending-radius/diameter ratio of the actuator depicted in Figure 25 is already very good with approximately 8/3 and could be improved with scaling the overall size of the device. Precision is the only drawback for this concept due to the compliancy of the inflatable tube. This same compliancy does however provide great safety since abrupt movements won't cause high forces on the cartilage inside the joint. Since problems might arise when precision is needed the technology could be combined with variable rigidity mechanisms to eliminate inaccuracy caused by compliancy while retaining the safe aspect of compliancy. However, even when the device is designed stiffer the soft exterior of the device has no perturbing edges and is highly compliant which will eliminate most possibilities of damaging the cartilage. A trade-off must therefore be made in the final design between complexity and precision. The overall compliancy also accounts for good operability; in compliant state, the tube should be easy to push through the joint. In its current form, the device might be prone to buckle due to a low axial stiffness, by placing a NiTinol rod in the middle of the tube or adding other reinforcements this could be resolved. The control might however pose a challenge; manual control is preferable but this device currently works on pneumatic pressure so a manual control system should be designed which is able to create hydraulic pressure which can be used to bend the instrument. The current device can bend in one direction and make twisting motions. For this operation, a different set of movements might be preferable. One of the possible concepts is depicted in Figure 24 and consists of 3 compartments giving the instrument a full range of motion in 3 directions. In future conceptualization, the choice must be made between steerability and simplicity by adding or subtracting compartments. The monolithic design of the actuator is very simplistic which is positive for the reliability and production cost. This simple design leaves a lot of room for added features, like reinforcements, without overcomplicating the device.

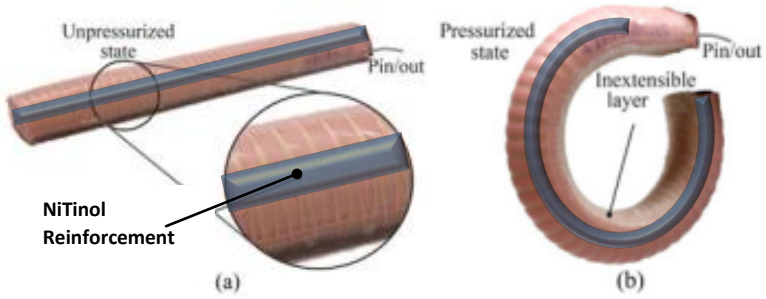


Figure 25 SFA concept with NiTinol reinforcement rod

Double Rotating Soft Screw (DRSS)

The double rotating soft screw concept is based on screw-propulsion vehicles and uses turning screw-like parts to convert a turning motion into a forward force using the friction with the cartilage. This is quite a challenge because of the slippery cartilage but a high turning speed and novel screw shape might be able to provide enough force. The inspiration for this concept came from screw-propelled vehicles which use two turning screws to create forward movement[40, 41]. These vehicles use 2 parallel mirrored screws to achieve forward motion and are typically used in environments where the ground is soft so the thread can plough through the surface.

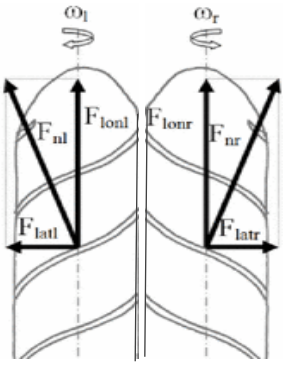


Figure 26 Force analysis of a double screw propulsion

Mechanical Principal

The instrument is self-propelling, which means that there is no extra pushing action is needed to move it forward. It pulls itself into the joint using the force created at the thread of the screw. This thread is at a near 45-degree angle with the axis. By the turning of the screw and the angle of the thread two force components are generated, one in axial direction and one in lateral direction. Since the two screws have an opposite turning thread and are rotated in opposite direction there are two positive axial force components forward and two lateral force components which cancel each other out as can be seen in Figure 26. The force on the thread of the screws is generated by friction with the environment. This means that the propelling force is dependent on the friction coefficient between the material of the thread and the environment and the normal force exerted by the instrument on the environment. The ratio between the axial and the lateral force components is determined by the angle of the thread with the central axis. All these parameters can be altered in order to have a screw with optimal properties for this application.

Because the instrument consists of two screws with an opposite turning thread multiple steering options are available as shown in Figure 27 Steering options for DRSS. Steering can be done by alternating turning speed and turning direction of the individual screws. When the screws are turning in opposite direction the lateral forces cancel each other out and the axial forces are working the same direction creating a net force in the positive axial direction. If one of the screws turns faster than the other the device will be able to move sideways in a diagonal direction since the lateral and axial forces will be unequal. If both screws are turning in the same direction the lateral forces are in the same direction thus creating a pure sideways motion. The axial forces will cancel each other out and will also create a small moment around the medial axis of the device. When the procedure is finished the screws will turn in the opposite direction with respect to the initial, forward, motion and will thus generate a force to retract the device from the joint.

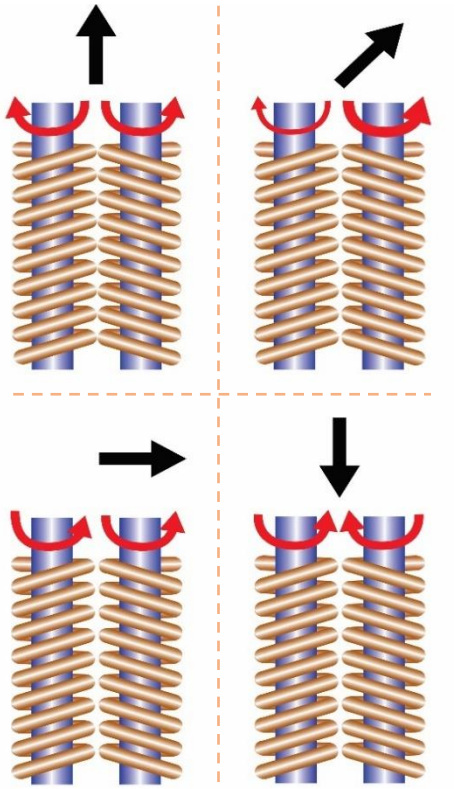


Figure 27 Steering options for DRSS

Pro's/Con's

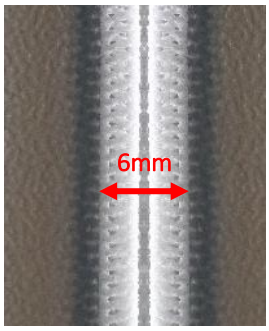
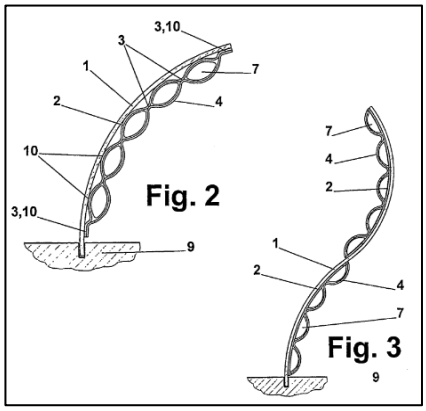


Figure 28 close-up photo of miniature plastic spirals

Current plastic spirals can be manufactured at a diameter of 3mm or even smaller which makes the current size limits for this concept approximately 6mm wide and 3mm high as shown in Figure 28. The two screws should be connected at certain points to keep the screw at an even distance, this can be done by replacing the screw geometry for a solid shaft at some points and make a clip to hold the two shafts together. The size to bending-radius ratio of this concept is mostly going to be determined by material strength and screw geometry, a thinner core would mean a better ratio but might cause the device to buckle or even break during use. A well-designed instrument might be able to make the desired bends at 5mm diameter scale. At this diameter, the device is very compliant in vertical direction which prevents risk of damaging the cartilage with sudden movements. However, the screws as shown in Figure 28 do have a lot of sharp edges and are turning inward so there is a risk of tissue getting pinched in between the two screws. A soft material could prevent this from leading to damages but whether the production of a soft screw at this scale is possible must be determined in further research. The precision of this concept is hard to determine beforehand, as stated in the previous paragraph the alternating turning speeds gives a lot of control but the slippery cartilage might cause unpredictable and sudden movements to happen when the screw is turning at high speed. The control should be made intuitive by making an electronic handle of joystick that can direct the device forward or sideways by a simple moving of the stick or push of a button. This does however make the controlling part of this device non-manual in terms of energy consumption. Electromotors will have to power the device which causes the device to have a lot of parts. These parts can however be stock-made so they are more reliable that custom made parts.

Literature search

Additional to the literature study that was done previous to this graduation project, a literature search was done into different kinds of fluid actuated and screw propelled mechanisms. This yielded a lot of options for extendable layers for the SFA. Information about screw propelled devices was however scarcely available. A graphic overview of the results is depicted here below in Figure 30Figure 36. These mechanisms will serve as inspiration for the ideation of concepts.



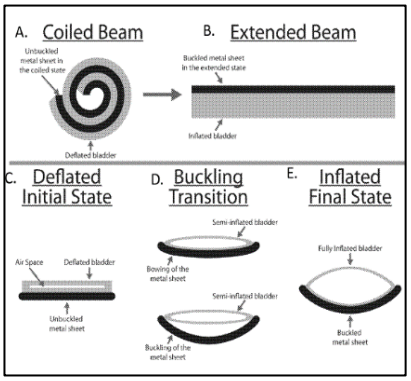
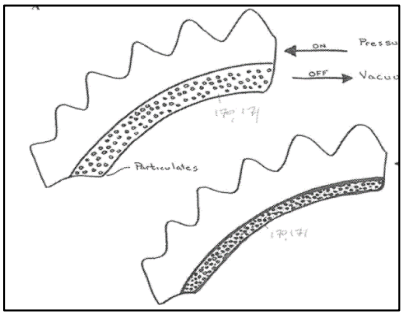


Figure 31 Rigidized inflatable structures [44]



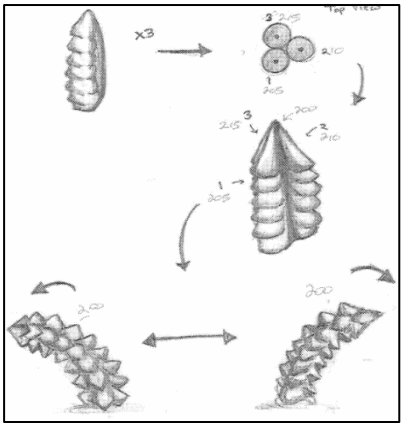


Figure 30 Soft robotic actuators using asymmetric surfaces [44]

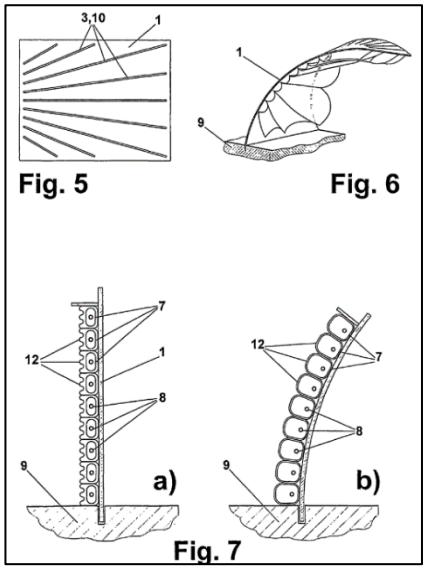


Figure 32 Pneumatic actuator [42,43]

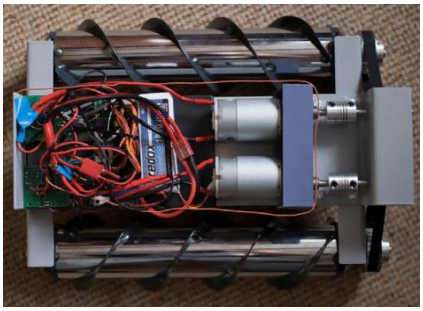


Figure 33 Remotely operated screw propelled vehicle [41]

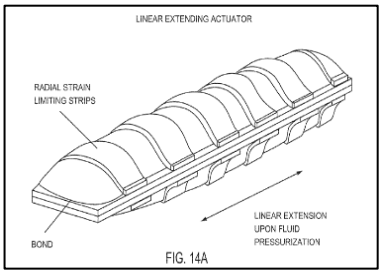


Figure 34 Flexible and stretchable electronic strain-limited layer for soft actuators [47]

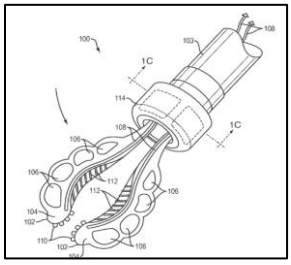
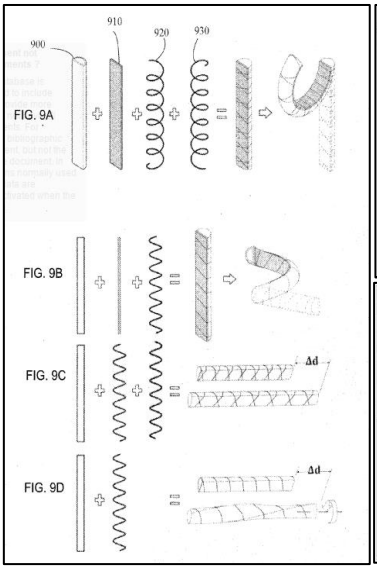
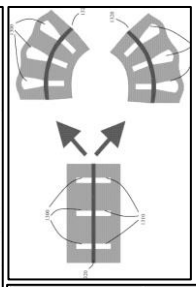


Figure 29 Soft conformal laparoscopic instrument [46]





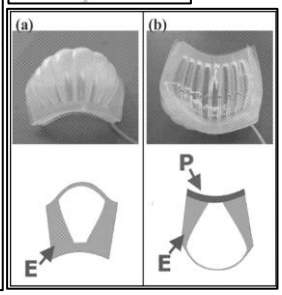


Figure 35 Soft robotic actuators [48]

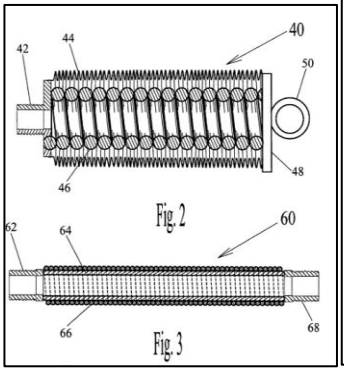
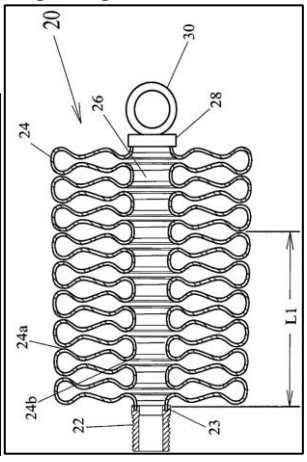


Figure 36 Flexible hydraulic muscle [49]



Ideation

This chapter show the ideation process of the different mechanisms that make up the concepts. This phase is supported by the previously explained concept research by first understanding the mechanical principals of the system and then looking into literature for inspiration. The goal of this phase is to generate feasible concepts for the sub-parts of the concepts. In this chapter, first the SFA will be examined and then the DRSS.

SFA sub-parts

In this paragraph, the SFA will be examined. Multiple design options will be displayed and elaborated. Out of these options many combinations can be made which will be assessed in the next chapter.

Outer layer

The original SFA concept is based on a flexible radial chamber being expanded by fluidic pressure. Since the top layer restricts the chamber from extending in lateral direction but does allow axial expansion, and the bottom layer is in-extendable, the chamber is forced to bend. The main principal behind this is that the top layer of the device becomes longer than the bottom layer forcing the device to bend downwards.

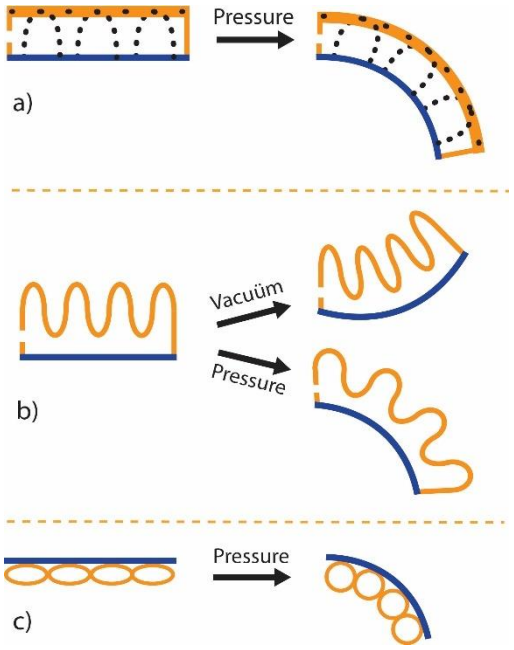


Figure 37 Outer surfaces of SFA (a: braided, b: folded, c: sacks)

The original concept works with a **reinforcement braiding** (Figure 37,a) consisting of two springs with a counter directional thread [48]. This braiding makes sure that the top layer is only able to extend in axial direction so when the volume of the chamber is increased the top layer expands in axial direction making it longer. With the bottom layer being inextensible in axial direction the length differential causes the chamber to bend. There are plenty of variations on the braiding as various types of braiding were found in literature [47].

One of the other possibilities to create a length differential is to make the top layer out of a **folded surface** (Figure 37,b) which when the volume is increased expands and when the volume is decreased shrinks in lateral direction[45, 49]. The medial length of the top layer changes and therefore makes the chamber bend. This concept has a larger diameter than the braided concept making it less suitable for this application, however the folds are flexible and can thus be pushed through a smaller diameter. Another big advantage of the folded surface is the fact that just one chamber can bend back and forth generating an extra DOF reducing the number of chambers that are needed for the same range of motion. This can in turn also reduce the size of the device.

Another possibility is to use an outer layer that is made out of **non-flexible sacks** (Figure 37,c) [42, 43]. These sacks will, when volume is increased due to fluidic pressure, assume a round shape thus shortening with respect to a deflated state. This concept has the downside that it increases in lateral size when inflated. However, the deflated instrument can be made very small which is a big advantage.

Compartments

As shown in Figure 38 there are four basic options for the orientation of the compartments. The trade-off is mostly between size/complexity and number of compartments. More compartments means a larger range of motion and typically more DOFs which increases steerability. It is important to notice that more steerability is not inherently better because the added movement options might not be needed for the application. Using more than 3 compartments is unnecessary since with 3 compartments a full range of motion can be achieved. Therefore only 3 or less compartments will be considered.

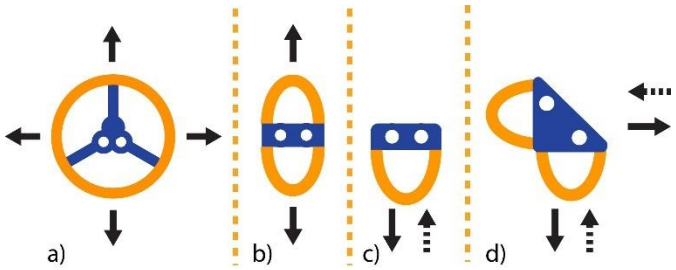


Figure 38 Compartments related to steering options in the SFA

The first option is to make the device out of **3 compartments**. This gives the device the maximum amount of DOFs and a full range of motion in the frontal plane. It is however also the largest of the four options and since the rigid inner part has a triangular shape the device will not be able to push through spaces smaller than the outer diameter because of the flexibility of the outer layer.

The second option is to make the device out of **2 compartments** in this option the device only has one DOF and can thus only move in one line. However, if the device can rotate around its central axis the range of motion is enlarged giving it a full range of motion in the frontal plane. Because of the flexible outer layer, the device can also be pushed through small gaps limited only by the size of the rigid core.

The third option is to only have **1 compartment** and make use of the flexibility of the core. This way ½ DOF is reached, the device can move in one direction and use the flexibility of the core for the way back. The same rotational option as for the 2-compartent design can be implemented here. This gives the device a full range of motion in the frontal plane and makes it even smaller than the 2-compartment option.

The last option depicted here is one with **2 asymmetrical compartments**. It is the last remaining option which aims to make use of both the flexibility of the core and 2 compartments to accomplish half of a full range of motion in the frontal plane. This option aims to take the best of 2 concepts but also takes the worst of those two concepts. The core is shaped triangularly because of the asymmetrical shape so the instrument is hard to push through small gaps even with the flexible outer layer.

Core

Another basic part of the design is the core. The core gives the device added structural integrity and makes sure that it has enough stiffness so that it will not buckle during insertion and navigation. The device will have to be pushed through some small gaps due to the unevenly shaped surface of the joint. Therefore, it is important that the device has a stiffness that is high enough so that the device will not buckle and get damaged during the procedure. However, a higher stiffness of the core also means a higher counterforce against the actuation force of the inflatable chamber(s). This could result in less steerability which is needed to reach the target area. Four basic options are proposed for the core.

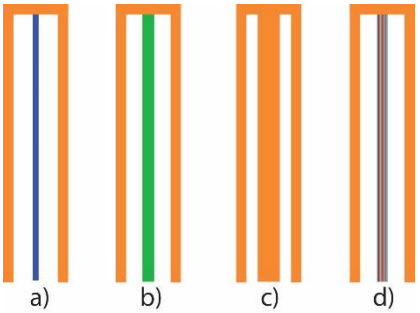


Figure 39 types of cores in SFA (a: nitinol, b: plastic, c: same as outer layer, d: variable rigidity)

The first option is a **nitinol core.** Nitinol is a highly flexible metal which has a high stiffness but also a very high maximum strain compared to other metals. This makes it perfect for this type of application

where the core should be able to bend without getting permanently deformed. The downside is that nitinol is expensive and hard to produce in custom shapes.

The second option is the use of a **plastic core**. Plastic is a cheaper option than nitinol and plastic comes in a great variety of material properties and can also be produced in custom complex shapes. The ratio between stiffness and maximum strain is however smaller than that of nitinol.

The third option is to make the outer layer and core of the device out of the same material thus making it possible to produce **monolithically**. This is the simplest option production-wise. Since the outer layer of the device should be flexible the stiffness of the core should be established by having a different geometry than the outer layer. The downside is that with a flexible material this might result in a larger size of the core.

The last and most innovative option is to implement **variable rigidity** technology into the core. Variable rigidity gives the core two states either a soft/compliant or a stiff state. In the stiff state, the device could be pushed through a small gap and when the device is pushed through it could retain its original steerability in its compliant state. The downside is that this is a lot more complex than a simple solid core and will thus take a lot more space.

Multi-steering

The last option that will be explored here is multi-steerability. This means that the instrument will have more than one steerable part and will thus be able to make sequential bends. If this option is implemented it would result in a more complex device which has more versatile steering. Complexity is increased with every steerable segment so a maximum of two segments will be considered here. This is because the size of the instrument should remain inside de 5mm parameter that was set. Moreover, it also must be scalable to a smaller size in the future.

The first option is to have **1 steerable segment.** This is the simplest option. With this simplicity comes a small size and reliability due to minimal amount of parts. However, the device will be less steerable and may have difficulties steering around obstacles.

The second option is to have **2 steerable segments**. This is a more complex option. It will increase steerability and the device might be able to steer around objects more easily. However, it will also be more complex resulting in a larger size and less reliability due to an increased number of parts and more complex geometry of the tubes. If this option is implemented the actuator fluid should be transported past the first segment to the second which will means that either the design will increase in size or the geometry of the chambers is compromised. There is also the possibility that the second steering part is designed smaller than the first resulting in a steerable tip on the instrument.

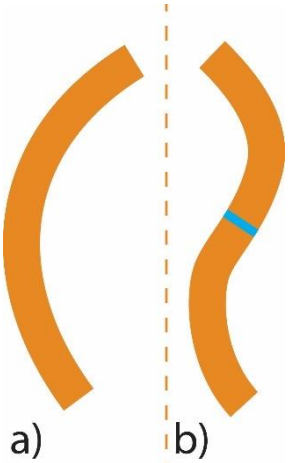


Figure 40 Multi steerability in SFA (a: one segment, b: 2 segments)

DRSS sub-parts

The double-rotating-soft-screw principle is based on two turning screws that generate a force axially and laterally. Since the two threads are in different directions the axial forces are combined and the lateral forces are cancelled out. This makes the device self-propelling since it pulls itself into the joint. Steering can be achieved by changing rotation speed and direction of the individual screws which gives the instrument a variety in steering options as can be seen in Figure 41. To make sure the two screws don't touch or drift away from each other they need to be connected at an even space at a certain interval. These connections create segments of the device which immediately gives the first design option of actuation different segments.

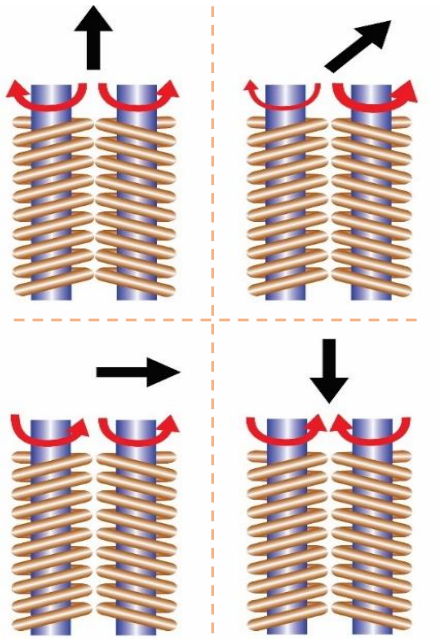


Figure 41 Steering options for DRSS

Segments

The first design option is the amount and orientation of actuating segments. This means the number of segments that have thread on them and where they are positioned on the device. Assuming a constant length of the segments there are multiple options to be assessed. The number of segments that have thread will determine the actuation force that can be exerted by the device but more actuation segments also leads to a different kind of steering for the device. The shafts that are non-threaded can be made flexible so the device remains steerable. Four options will be assessed here as depicted in Figure 42.

The first option that will be discussed is where only the tip of the instrument is actuated. In this case there will only be **one actuating segment.** This means that that only one thread produces the propulsion and steering force for the device, calculations or tests will have to show if one segment can produce enough force to steer the whole device. With this design only the tip of the instrument is actuated which gives it a lot of steerability. If the shaft is flexible enough the tip can move almost freely.

The second option is that **multiple segments in the tip are actuated**. In this case multiple segments produce the actuation force and generally more segments means more force. This gives the instrument more propulsion force and also more steering force. The downside is that the tip can move less freely so making bends around obstructions is harder.

The third option is to make the **whole instrument threaded**. This gives the maximum amount of actuation force in both the axial and lateral direction. Steering is however limited to moving the whole instrument at once so moving around obstacles becomes difficult.

The last option is to **alternate the actuating segments** with shaft segments. This way still half of the segments are threaded and the other half can be made with flexible shafts. This gives a middle way between steerability and actuation force.

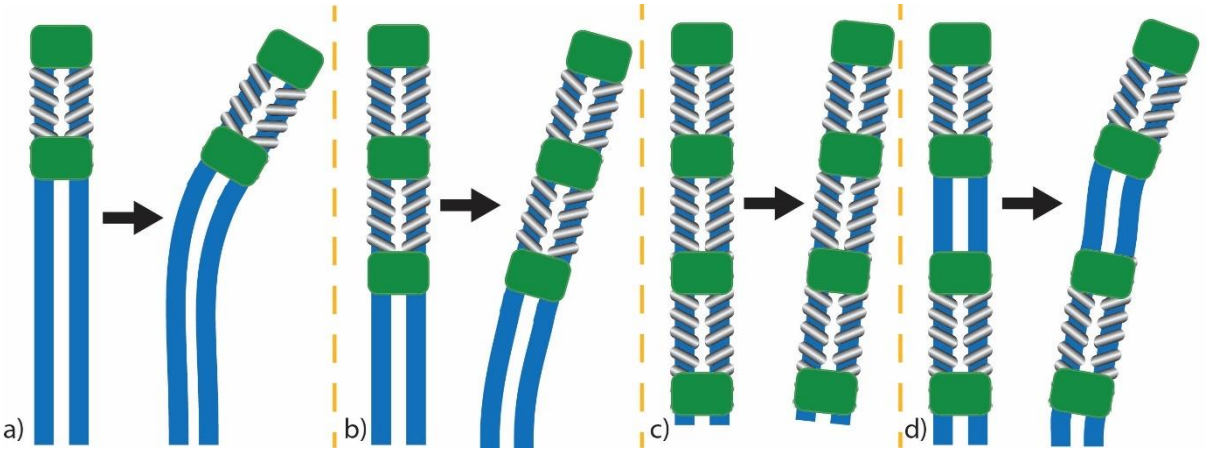


Figure 42 Actuating segment in DRSS (a: One threaded segment at the tip, b: multiple threaded segments at the tip, c: whole instrument threaded, d: alternating threads)

Thread

Another design option is the material and geometry of the thread. The thread should produce as much force as possible but cannot do damage to the cartilage during the procedure. The material of the shaft and the thread will be the same with these options since manufacturing a device where the thread and the shaft are different materials is considerably more difficult. For every kind of thread, the pitch, helix-angle and thread profile can be varied to some extent and will be optimized after one of the options is chosen. In this case two general options are reviewed.

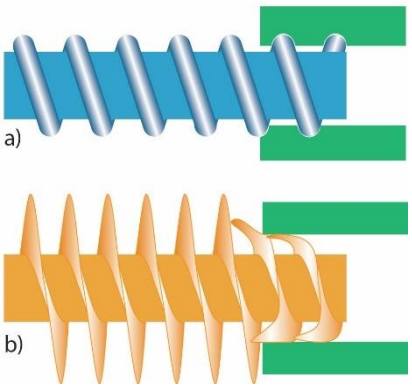


Figure 43 DRSS threads (a: Steel thread with rounded profile, b: Flexible thread with deep profile)

The first option is a thread made of **steel**. In this case the material is very hard and a **rounded thread profile** is needed to prevent damage to the cartilage. The rounded edges might result in a low friction with the cartilage thus providing a low propulsion force but the thread will be able to dig into the flexible cartilage when a narrow space is entered. A steel device is also relatively strong and can withstand high forces.

The second option is a thread made of a **flexible** material, for instance soft plastic. In this case the thread will have a **deep profile** to provide maximum friction with the cartilage. The thread can be bend when narrow spaces are entered which will enlarge the contact surface between the instrument and the surroundings. The shaft is a lot more flexible than with the steel option and could be reinforced with a steel core if needed. The optimal material and profile should be determined at a later stage.

Multi-steering

Another option that will be explored here is multi-steerability. This means that the instrument will have more than one steerable part and will thus be able to make sequential bends. If this option is implemented it would result in a more complex device which has more versatile steering. Complexity is increased with every steerable segment so a maximum of two segments will be considered here. This is because the size of the instrument should remain inside de 5mm parameter that was set. Moreover, it also must be scalable to a smaller size in the future.

The first option is to have **1 actuated shaft** per side. In this case, there is only one actuating shaft on each side which is connected to all segments, the segments cannot be actuated individually. This is the simplest option. With this simplicity comes a small size and reliability due to minimal amount of parts. However, the device will be less steerable and may have difficulties steering around obstacles.

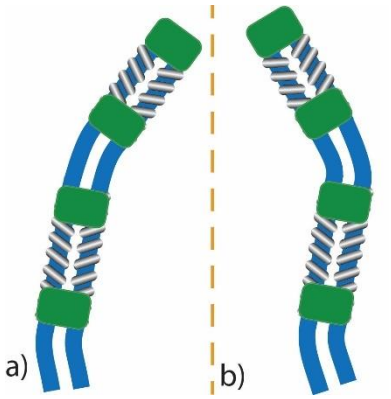


Figure 44 Multi steerability in DRSS (a: one segment, b: 2 segments)

The second option is to have **2 steerable shafts within each other** per side which will give the device the ability to move 2 segments individually. This is a more complex option. It will increase steerability and the device might be able to steer around objects more easily. However, it will also be more complex possibly resulting in a larger size, less reliability due to an increased number of parts and more complex geometry of the shafts. If this option is implemented the shafts must be made concentric, this might lead to a compromised stiffness and might create friction between the two concentric shafts. The second steering part could be designed smaller than the first resulting in a steerable tip of the instrument.

Shaft

The last design option that is considered in this paragraph is the geometry of the shaft, to be specific the parts of the shaft that are not threaded. As can be seen in Figure 42 some parts of the shaft can be non-threaded. These parts can be designed differently than the threaded segments. The option that is considered here is whether to make these parts more flexible than the threaded parts. If the clean parts are more flexible the threaded segments can move more freely and manoeuvre around obstacles more easily. The shaft could be made more flexible by making the shaft thinner. This would however result in a lower buckling resistance and lower maximum torque.

Concept Generation

During the concept generation, the mechanisms that were generated in the ideation phase will be combined into multiple concepts which must be assessed. A morphologic chart is used to guide the design process. Two morphologic charts are used, one for the SFA and one for the DRSS. Some combinations will immediately be discarded and the others will have to be reviewed and compared with each other. The final goal is to compare one concept for both the SFA and the DRSS

Selecting 2 final concepts

If all possible concepts were to be combined there would be 96 SFA concepts and 32 DRSS concepts which would be too many to assess. Therefore, the first objective is to narrow down the number of concepts. After that the remaining combinations are rated based on a set of selection criteria matching the function analysis described earlier in this chapter. A graphic representation of the design options is showed in the morphological chart in Figure 45.

SFA

The first cut will be made by eliminating two compartment options for de SFA. Since the device will mostly be actuated in the lateral direction the 3-compartment and asymmetrical compartment option will be less useful since it adds DOFs that are not essential. This is emphasized by the fact that the instrument will be able to rotate around its axis making a full range of motion possible with fewer compartments. And furthermore, the fewer compartments the device has the simpler it becomes which will benefit the reliability of the device as well as the production cost and the size of the device.

Also, the plastic core will not be considered because a nitinol core would provide more stiffness and more maximum bending with smaller size. The only positive side to a plastic core would be that it could have more complex shape but this will probably not be needed. If, however a more complex shape of the core is required a plastic shell could be designed around a nitinol core.

And at last the choice was made to use two steerable segments of the device. This is because adding a segment will give the device more versatile steering which is thought to be needed in order to fulfil the task. If during testing the added segment turns out to be redundant the choice could be made to redesign the device with one steerable segment.

These design choices narrow down the number of concepts for the SFA to 18. From here different combinations of concepts will be assessed to determine if certain combinations will or will not be compatible.

Using the folded surface in combination with the double compartment would result in useless extra DOFs so that combination is discarded. Also using the non-flexible sacks in combination with the double compartments would be difficult since the sacks cannot be stretched when the device is actuated in opposite direction. And finally, the combination of using a flexible core and one compartment would be difficult since the core might not provide enough force to bring the device back to its original position and axial stiffness would be too small so the instrument would be prone to buckle.

After assessing these combinations there are 9 concepts left to be reviewed. These concepts will be reviewed individually and then compared with a set of criteria to determine the final concept for the SFA.

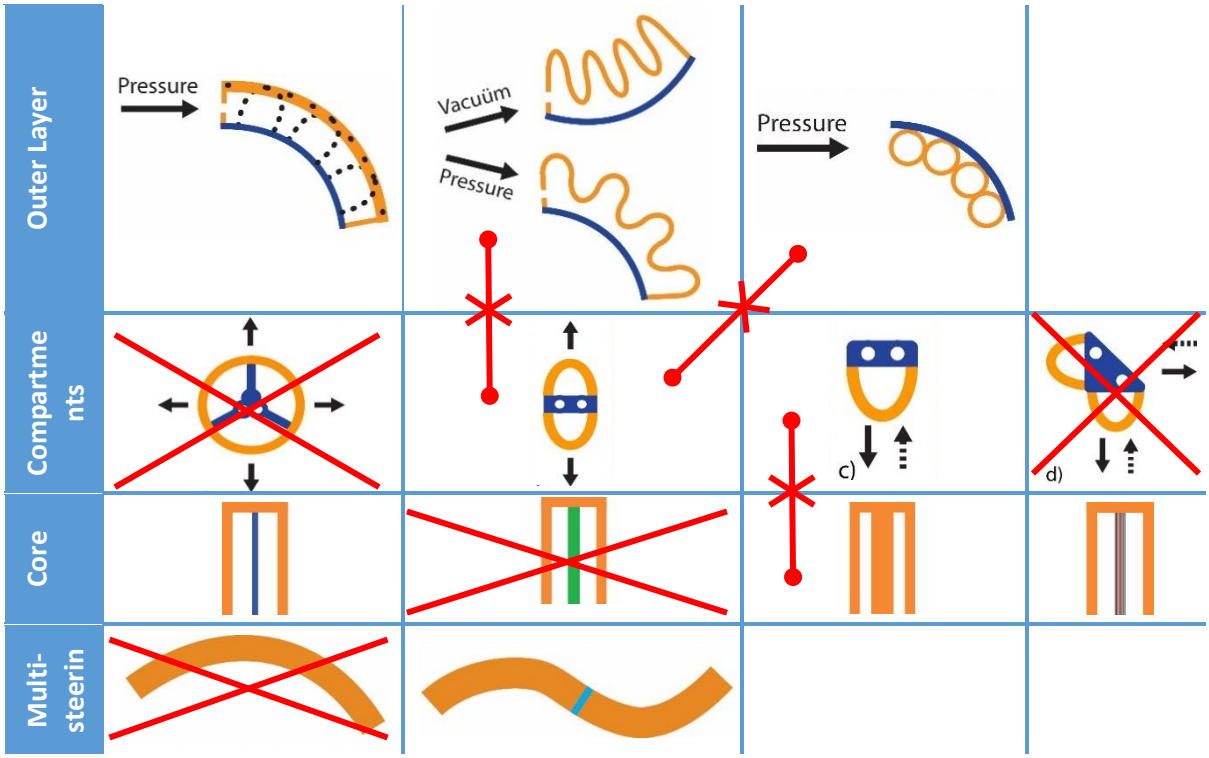


Figure 45 Morphologic chart of design option for SFA (red crosses indicate sub-parts and combinations that have been omitted)

1: B-D-F: Extension of device: The first concept to be reviewed is one containing the braided outer layer, double compartments and a flexible core. All other concepts with a flexible core have been discarded due to a lack of axial stiffness. This concept experiences the same problem in terms of stiffness but due to an extra functionality it might still be useful.

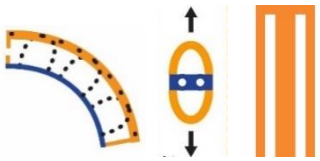


Figure 46 B-D-F- configuartion of SFA

If the compartments are symmetrical and the core is flexible the device will be able to extend itself by simultaneously actuating all compartments. This will force both chambers to expand and since the core is flexible the whole instrument will expand in axial direction. This is only applicable for the braided outer layer because the folded layer would expand in normal direction and the non-flexible sacks can only contract in axial direction. Using this feature the axial stiffness can temporarily be increased and during this process the device expands further. When the instrument is pushed into the joint this extending action of the instrument might make axial propulsion easier for the operator.

2 B-D-N: The concept that is portrayed here consists of the braided outer layer, double compartments and a nitinol core. The main advantage of this concept with respect to the other double compartment options is that it has a nitinol core which results in a smaller device than a flexible or variable rigidity core. The nitinol core gives the device axial stiffness so that it can be pushed through the joint without buckling. The double compartments make the device a bit larger than with a single compartment and might on first sight not add any features since a single-compartment device can have a full range of motion due to rotation around the axis. However, the double compartments add one useful feature and that is a mode where axial stiffness is increased. If both compartments are under pressure the overall stiffness of the device increases which enables it to be pushed through more forcefully.

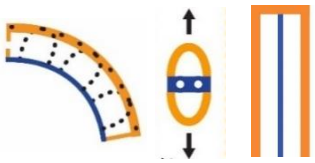


Figure 47 B-D-N configuration of SFA

3 B-D-V: This concept is the same as the previous concept apart from the variable rigidity core. This core will probably take a lot more space than the nitinol core but gives the device the unique ability to be rigidized while steering remains possible. There are a lot of options for the variable rigidity core, the main challenge will be to find a mechanism at this scale that lets the device retain its shape while being rigidized. Also retaining steering possibility in rigidized mode will give the device a lot of versatility. In compliant state, the device will be able to make sharp bends and in rigid state it can be pushed through the joint more forcefully. The nitinol-core concept also has some variable rigidity options but in order to have those, both compartments have to be inflated eliminating the elastic properties of the chambers. The variable rigidity core can make the device rigid without inflating the compartments which enables it to be pushed through smaller gaps. The use of a variable rigidity core also opens up a new way of navigation where the core is rigidified in bended state and the rest of the device is able so slide over it creating an angled forward movement also known as telescoping[50] which is shown in Figure 55.

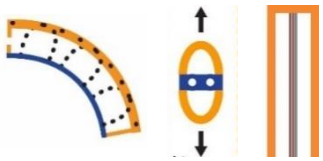


Figure 48 B-D-V configuration of SFA

4 B-S-N: Now the single compartment concepts are assessed starting with the combination of a braided outer layer, single compartment and a nitinol core. This concept is one of the smallest due to its single compartment and nitinol core. The core acts both as a rod for axial stiffness to the device can be pushed through the joint without buckling and as a spring to ensure that the device returns to its original position after actuation. The diameter of the nitinol core will have to be determined by a trade-off between axial stiffness and steerability since a thicker core might increase the bending radius.

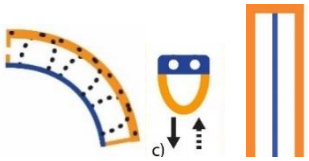


Figure 49 B-S-N configuration of SFA

5 B-S-V: The concept containing the braided outer layer, single compartment and a variable rigidity core is comparable to the same concept with a double compartment. The variable rigidity account for a slightly larger core and thus larger instrument but when only one compartment is used in the design the size is drastically reduced. The main question is whether the core can provide enough stiffness in compliant state to ensure that the device can return to its original position after actuation. This might however also be achieved by rotating the device around its axis inside the joint. Some form of axial stiffness is always needed to be able to push the device through the joint during actuation. Also the variable rigidity core enables telescoping as shown in Figure 55.

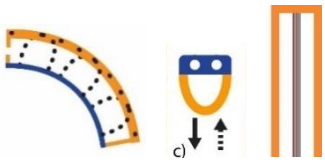


Figure 50 B-S-V configuration of SFA

6 F-S-N: The following concept consists of the folded outer layer, single compartment and a nitinol core. This concept can be compared to the B-S-N configuration. A possible advantage for this concept could be that is it steerable in both directions since a vacuum in a chamber will result in an opposite bending action with respect to pressure inside the chamber. This extra action might seem obsolete since turning the device around its axis also result in an opposite bending action. However the vacuum bending action has a larger bending radius but also makes the device more rigid which could be useful when the device needs to be pushed through a gap in bended state. The folded outer layer is larger and more compliant than the braided layer so effectively the difference in size is negligible since the folded outer layer will fold away when the device is pushed through a small surface. The nitinol core makes for a small device with sufficient axial stiffness.

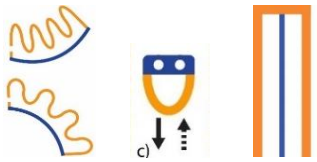


Figure 51 F-S-N configuration of SFA

7 F-S-V: This concept is the same as the previous except the nitinol core is replaced by a variable rigidity core. This change will enlarge the device a little but will also give it increased stiffness or compliancy when needed. The question is whether the variable rigidity core can be produced small enough and provide enough. In the braided variant of this concept the stiffness of the core should be high enough to straighten the instrument after actuation but in this case the folded outer layer provides the option of inducing a vacuum instead of a positive pressure to straighten the device to its original position. Also, the variable rigidity core enables telescoping as shown in Figure 55.

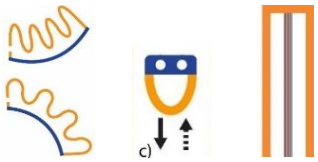


Figure 52 F-S-V configuration of SFA

8 S-S-N: The final two concepts are based on the non-flexible sack principle combined with a single compartment. This concept has a nitinol core. In deflated mode, this concept is very small since the sacks take no rigid space at all. But when actuated the size of the device is defined by the diameter of the pressurized sacks. The bending radius of the device is determined by the diameter of the sacks since the core will follow the circumference of the sacks where is it attached. So, in theory the bending radius is half of the sack diameter. Which could be as small as 2.5mm assuming the sacks need to fit in the 5mm gap. The nitinol core of the device will provide the stiffness that is needed to bring the device back to its original position after inflation of the sacks. The biggest hurdle in this concept is the design of the sacks and attachment to the core which might be complex and unreliable.

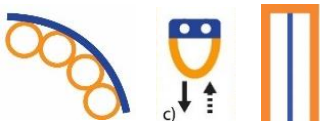


Figure 53 S-S-N configuration of SFA

9 S-S-V: The final concept is comparable to the previous one apart from the variable rigidity core. This core will enable the device to be compliant or rigid at will making manoeuvring easier. It will however increase complexity and size of the device and therefore reduce reliability. Since the sack have no stiffness at all the variable rigidity core should be designed such that is has enough stiffness in compliant state to straighten the device after actuation.

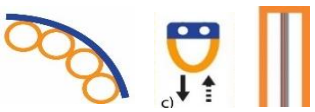


Figure 54 S-S-V configuration of SFA

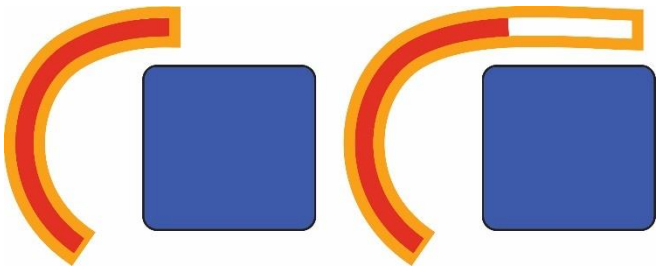


Figure 55 Telescoping SFA, the rigidified core (in red) stays in place as the outer layer (in orange) progresses

Table 5 Grading of SFA concepts based on predetermined criteria

			Concepts								
			1 BDF	2 BDN	3 BDV	4 BSN	5 BSV	6 FSN	7 FSV	8 SSN	9 SSV
Criteria	Size/scalability		o	+	o	+ +	+	+ +	+	++	+
	Bending radius		+ +	+	+ +	+	+ +	+	+ +	+	+ +
	Buckling strength		- -	+ +	+ +	+	+ +	+	+ +	+	+ +
	Safety	Compliancy	+ +	+	+ +	+	+ +	+	+ +	+	+ +
		Sharp edges	+ +	+ +	+ +	++	+ +	+ +	+ +	o	o
	Precision		- -	+	+	+	+	+	+	+	+
	Simplicity	Reliability	+	+ +	o	+ +	o	+ +	o	o	- -
		Production Cost	+	o	-	o	-	+	-	-	- -

Looking at Table 5 there is an overwhelming amount of information available but certain conclusions can be made right away. Concept 1 and 9 both score a double minus respectively in precision and simplicity and are therefore discarded which leaves seven concepts to be graded. Next to be noticed is that concepts with double chambers score lower on size because of the extra chamber that needs space and score higher on buckling strength since inflating both chambers can increase stiffness of the device. Based on this the double chambered concepts are also discarded since the size is a more important factor than bucking strength and the buckling strength of single-chamber devices can be improved in different ways if necessary while only slightly increasing size. And at last the choice is made to discard all variable rigidity core concepts. The use of a variable rigidity core will enhance the operating speed by enabling telescoping of the instrument as show in Figure 55. However, the same core also is a lot larger than a nitinol core and makes the instrument more complex increasing the production cost and decreasing reliability. Therefore, the variable rigidity option is discarded for now, if later in the testing phase the instrument lacks steerability or if telescoping turns out to be a necessary action the variable rigidity core can still be implemented.

Figure 56 Final SFA concept (F-S-N configuration)

These three selections leave three concepts to be compared to each other; the BSN, FSN and SSN concepts. The FSN and BSN concept score very similar on almost every aspect. The SSN concept however scores lower of safety and simplicity and is therefore regarded as less optimal and therefore discarded. So now two concepts are left to be reviewed, the FSN and BSN. A paper comparing both types of actuators [51] show that the bending radius is very similar so this does not help with selecting one concept. The only difference in score between the FSN and BSN concept is the production cost. The FSN is assumed to be a bit easier to produce since it can be produced with a mould in one piece. The BSN concept needs an additional step in production since the braiding has to be applied to the moulded piece and the and extra layer has to be added to contain the braiding. Therefore, the **Folded outer layer-Single compartment-Nitinol core concept is chosen as the final concept**. In the same manner as for the SFA a final concept for the DRSS must be selected.

DRSS

The selection process for the DRSS is a lot different than the selection for the SFA. Since the DRSS is a more specific concept and has less influential design options a single concept can be chosen out of the different combinations by omitting certain options. The options from Figure 58 will be assessed from top to bottom.

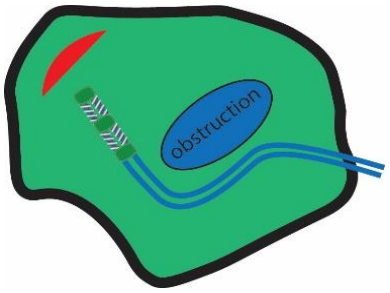


Figure 57 Obstacle avoidance of DRSS

The segments of the DRSS determine the steerability, amount of grip and flexibility of the device. This first thing to notice is that, as shown in Figure 57, the instrument might have to be able to avoid obstacles inside the joint, these could be gaps that are too narrow to navigate through. When the whole instrument is segmented in will not be able to make bends in the lateral direction since the length of a threaded segment is constant and the coupling pieces ensure that it won't be able to slide. The coupling pieces could be designed in such a way that there is some sliding possible but this will probably not only allow a small amount of bending. Therefore, the completely segmented and alternative segmented options are discarded. Then the choice remains between one or multiple threaded segments at the tip. Having only one segment might result in a low grip and steerability of the device since the thread will be in contact with cartilage which is very slippery. Therefore, the choice is made to use multiple segments. How many segments are necessary to provide enough force will have to be determined at a later stage.

The next option to be assessed is the thread material and geometry. There are only two options for this, the rigid steel thread with a rounded profile and the flexible plastic thread with a sharper and larger profile. The instrument will need as much friction as possible to be able to propel and steer the tip. In theory, the steel variant should be designed larger so that it digs into the cartilage, this is necessary since the rounded profile will not provide enough grip otherwise. The plastic variant should have a smaller shaft and larger thread so that the thread is pushed into the cartilage but since the cartilage is stronger than the plastic the thread will bend when a narrow section of the joint is entered. The plastic variant seems to be a lot safer than the steel one since the plastic cannot do significant damage to the cartilage where the steel variant might be able to crush the cartilage when a very small space is entered. Therefore, the plastic variant is selected.

With only an actuated tip the diameter of the remaining shaft must be determined. Assuming a small diameter due to the large thread in the threaded tip, the diameter of the shaft should be as small as possible in the threaded part. In the non-threaded part of the instrument the shaft should also be as thin as possible to ensure that the tip can move freely. Further calculations on torsion strength will have to determine the exact diameter.

At last the multi-steerability of the device is assessed. Since there is only an actuated tip multi-steering is no longer an option. Furthermore this option would have introduced too much complexity in the design and would have been discarded regardless.

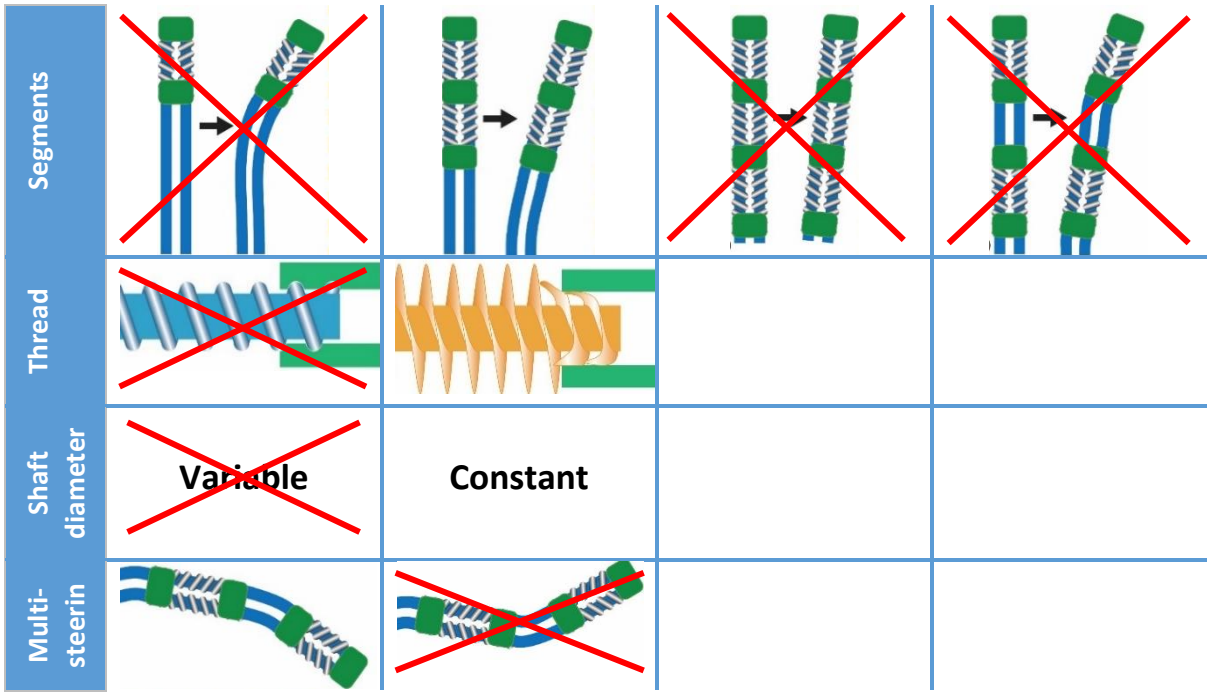


Figure 58 Morphologic chart of design option for DRSS (red crosses indicate sub-parts that have been omitted)

The final concept for the DRSS will therefore be a combination of a threaded tip with multiple segments, compliant plastic thread, solid shaft with constant diameter and one steerable segment. This concept has the most steerability, safety and simplicity and will therefore be easy and safe to use. The use of plastic also enables 3D-printing for prototyping which will significantly speed up the design process.

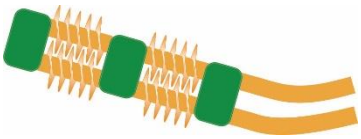


Figure 59 final concept DRSS

Selecting final concept

The final selection that must be made is between the final SFA and DRSS concepts. A more in-depth analysis of both concepts will be the basis of a final selection based on performance criteria.

SFA

Figure 60 Final SFA concept (F-S-N configuration)

The field of Soft Robotics is rapidly expanding and similar types of actuators to the SFA are currently being developed at different institutions. This means that there is already some information about the properties of this concept. Wakimoto et al. have already miniaturised a similar concept to the scale of 1-2mm [52]. This device has a bending radius of 6mm which would be sufficient for our application. Larger version with asymmetrical cross-sections [53], dual chambers [54] and alternative geometry [48] have also been developed. These instrument all function at pneumatic pressures between 50 and 180 kPa. These devices are however not stiff enough in axial direction for our purpose and the length-diameter ratio is not enough for what is needed for insertion into the ankle.

For the **production** of the actuator Galloway et al. [51] used moulding-silicone in a negative mould with a flexible positive mould inside. Wakimoto et al. [52] used two separate negative moulds to create the baseplate and bellows to later joint them using excimer light irradiation. On a 5mm scale the choice could also be made to use a dipping process to create the actuator. In this case a positive

mould is inserted into a basin of mould material and then retracted creating a thin layer of material on the mould. This process can be repeated until the desired thickness is reached. Afterwards the flexible actuator can be peeled from the mould. Another option is to use a prefabricated tube and a negative mould to thermoform the tube into a specific shape. Different moulding processes could be used to produce this device, the exact process should be determined at a later stage.

The cross-section of the actuator reveals the basic **dimensions**. Different thicknesses and geometries have already been used in previous devices. The miniature version by Wakimoto et el. [52] has a uniform wall thickness of 150µm an outer diameter of the bellows of 1 by 2mm and an inner diameter of 550 by 1100µm. Other researchers found that increasing the bottom thickness of the actuator increased bending efficiency[55]. Udupa et al. took it a step further by using an geometrically eccentric design for their bellows[53]. The theory behind this is that thinner material is more prone to stretch therefore a thinner outer layer than the bottom layer will cause only the outer layer to stretch when the actuator is put under pressure, however if the bottom layer is thickened it also produces more stiffness which will reduce bending motion. Therefore, there is an optimum for the ration between the outer and bottom layer thickness. Suzimori et al. [55] put this ratio at 2.5 which is used for an actuator with a diameter of 8 by 16mm[54] and Udapa et al. [53] used a ratio of 1.43 for an actuator with a diameter of 5.1mm. Since our actuator must fit through a 5mm gap with the bellows pointed to the side and the cross-section geometry is similar to that used by Udapa et al. the maximum bellow height is put at 8mm with a cross section as shown in Figure 61.

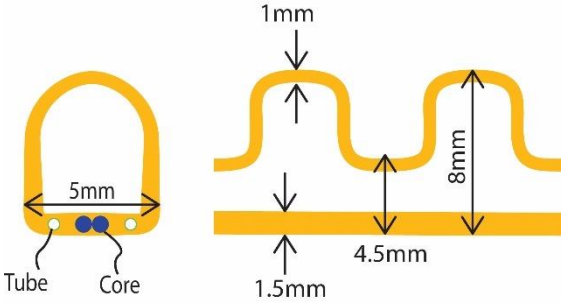


Figure 61 Preferred dimension for SFA cross-section based on literature

Since the device in its current form is only able to bend with a continuous curve the choice could be made to make the core (partially) retractable to **enable more complex steering**. This will enable the device to have a kind of steerable tip since the tip of the instrument will not have a core and will be more prone to bend than the rest of the device. This might make steering around bends easier.

DRSS

The DRSS concept is a less researched concept than the SFA. During the research phase, no prior comparable technology was found in literature. No screw-propelled apparatus whatsoever was found at this scale. This means that there are no previous technologies that this concept can be based upon. All challenges will have to be faced with a blanc view of the problem.

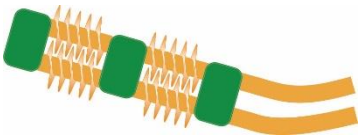


Figure 62 final concept DRSS

The first hurdle is the **friction coefficient** between the cartilage and the soft plastic. Cartilage on cartilage has a kinetic friction coefficient of 0.003 which is extremely low. Researchers have come close to replicating it using a specific combination of polymers and lubricants. This low friction will make it very hard for the DRSS to get enough friction force to be able to navigate. Higher turning speeds might be a solution for this. Since static friction is not an option, increasing turning speeds might cause enough dynamic friction force to propel and steer the device. The problem with this is that it is very hard to model since there are many factors involved such as lubrication, asymmetric surface areas and the manual pushing force of the user. Therefore, the way to validate the working principal of the DRSS would be to test it inside a test-setup. The test will have to take place at different turning speeds of the instrument to determine optimal conditions. To emulate the inside of an ankle

joint during the test, the setup-joint can be sprayed with Teflon(PTFE) spray which has a very low friction coefficient of around 0.04.

The fastest and probably most viable way of **producing the DRSS is by high-tech 3D-printing**. This will put a limit to thread placement and geometry and will only allow a small selection of materials to be used. A moulding process could also be used, this would enlarge the selection of materials and might give better options for the geometry of the thread a shaft. The specific geometry of the shaft and thread will have to be determined at a later stage. The shaft should be designed as thin as possible limited by the torsional forces it needs to withstand, the thread geometry can be adapted to that. When the thread is designed large the choice could be made to let the two threads overlap as shown in Figure 62 to make the device smaller in lateral direction. It should be noticed that overlap the threads brings the risk of interlocking when the threads touch each other. Since both shafts are individually actuated this could lead to damaging the device. The spacers keeping the shafts at equal distance can also be 3D printed and made to click both shafts into place as shown in Figure 63.

Figure 63 DRSS cross-section

In theory, the instrument should be able to propel itself. In practise, however the device might have to endure some pushing of the user. This means that the shaft might need some **added axial stiffness**. The choice could be made to add a nitinol or steel core to the shaft to account for this. This core could also be made retractable in the same manner as is proposed for the SFA. This might allow the instrument to make **more complex movements** comparable to telescoping as explained in Figure 55.

Final concept

At last the choice must be made between the SFA and the DRSS. To do this, the same performance criteria as stated earlier in this report are the basis for the final choice. The results of this assessment can be seen in Table 6. The two concepts score similar in bending radius and both safety aspects. The buckling strength for the DRSS is differently scored that for the SFA since the device is intended to propel itself. Therefore, the buckling strength that is required is much lower. The most important difference between the two concepts can be seen in both the size/scalability and simplicity aspects. Because the DRSS is a more complex device with small perturbing edges and a long shaft which has to be actuated by electromotors the concept scores significantly lower than the SFA in Size/scalability and Simplicity. The SFA is a much simpler device and therefore scores higher on these criteria. Because of this the choice can be made to further develop the SFA and discard the DRSS Concept. Moreover, as shown in the table, the precision aspect cannot be graded for the DRSS. This is because the slipperiness of the cartilage makes it very hard to predict the behaviour of the device. The screws might or might not have enough grip on the cartilage to produce enough force to steer the device. Therefore, taking the higher scoring of the SFA and the uncertainty of the DRSS concept into account, the SFA is chosen as the final concept.

Table 6 Grading of final SFA and DRSS concept based on performance criteria

			Concepts	
			SFA	**DRSS**
Criteria	**Size/scalability**		**++**	**o**
	Bending radius		**+ +**	**+**
	Buckling strength		**+**	**+ +**
	Safety	**Compliancy**	**+**	**+**
		Sharp edges	**+ +**	**+**
	Precision		**+**	**?**
	Simplicity	**Reliability**	**+ +**	**o**
		Production Cost	**+**	**o**

Final Concept

Now that the final concept has been chosen there is still a choice to be made. As depicted in Figure 64 there are 3 mechanisms at work in the system. The geometry of the outer layer will determine which of the mechanisms will be dominant. One of the mechanisms will have to be chosen and the geometry will have to be adapted to optimise for this mechanism.

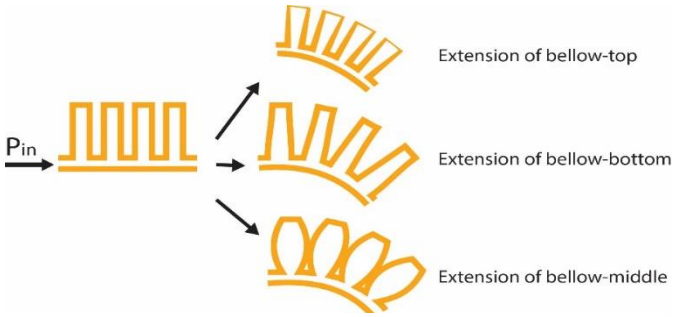


Figure 64 Mechanisms at work in the SFA

The first mechanism that could be used is the **extension of the top of the bellow**. In this case the top material will stretch expanding the top of the bellow creating an angle at the bottom. This principle has already been utilised by Harvard researchers and uses almost the same mechanisms as the braided-top-layer-concept which is mentioned earlier in this report [48] on this case the chamber wall functions as the braiding, keeping the radius of the outer layer somewhat constant. The thin outer layer parts are however still free to inflate and if the device comes into contact with its surroundings or a nitinol core is inserted into the base there is a risk of radial inflation instead of extension of the outer layer.

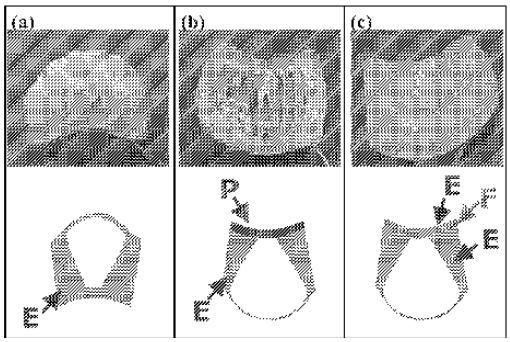


Figure 65 Bellow actuator using top-extension

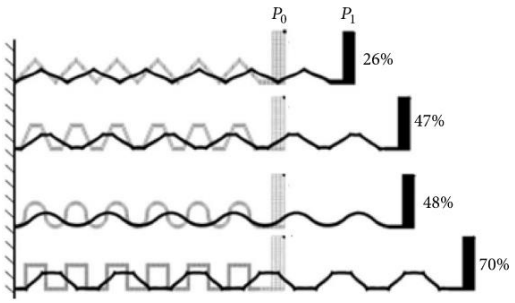


Figure 67 Bellow actuator using bottom-extension (different shapes give different extension)

The second mechanism that can be utilised is **extension of the bottom of the bellow**. In this case the bending motion is generated by changing the shape of the entire bellow and thus extending the bottom part creating an angle. This principal is based on the fact that if a structure is inflated it wants to assume a state of maximum volume. These types of mechanisms have been researched in multiple papers and have already been miniaturised [51-55]. These mechanisms might encounter the same kind of problem as the top-extension type where inflation rather than extension happens when internal pressure is increased and a counterforce is present. Therefore, extra reinforcements might be needed to make the mechanism reliable. This would however increase the complexity of the device.

The last mechanism that could be used is the **extension of the middle of the bellow**. In this case the bellow functions like a balloon where the middle expands under pressure and makes contact with the next bellow therefore pushing it further and creating an angle at the bottom. Some conceptual soft actuators are known to use this mechanism[42, 43]. There are also some steel variants of this mechanism. This mechanism is more robust than the other two. If the side and top layers of the bellows are made thicker than the inflatable part a counter force will only cause the bellows to change shape a little but since they are closely pact together an increase of pressure will counteract this force.

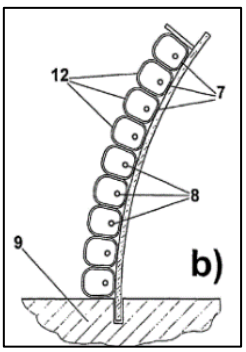


Figure 66 Bellow actuator using middle-extension

The mechanism relying on extension of the middle of the bellow is deemed more robust than the other two mechanisms. Therefore, the middle-extension type mechanism is assumed to be the best for our application. The outer layer geometry has therefore been optimised for this mechanism. As shown in Figure 68 reinforcing rods are placed in between the bellows connecting them at the middle of the inflation parts. This has a couple of effects. Firstly, the effectiveness of the actuator is increased. Without the rods, the bellows would have to inflate a certain amount until they would touch each other and bending of the device starts taking place. By placing the rods, the bellows touch each other right at the start of inflation. Secondly the actuator has an increased rotational stiffness. This is beneficial for the part of the operation where the device must be rotated as show in Figure 70. A downside of this geometry is that it limits the production processes that could be used to produce the device.

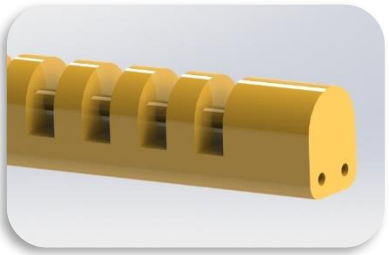


Figure 69 3D model of bellows actuator

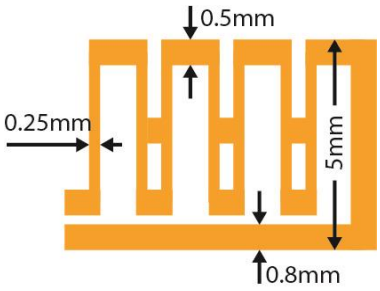


Figure 68 Variable wall thickness for optimal inflation

Since the bellow will be inflated in the axial direction, the shape of his bellow should be made rounded since the inflated surface will assume a natural round shape. Therefore, a half cylindrical bellow is the smallest and most optimal shape for the device. Moreover, the rounded shape omits any sharp edges in the geometry which might cause peak loading. A rounded shape is also easy to turn around its axis inside joint during the procedure.

To be able to get the largest possible movement at the tip the bellows need to be as thin and placed as close to each other as possible. How thin and close this is will be determined by the limits introduced by the production process. Also, the inflatable surface needs to be thinner than the outer layer of the bellows, as shown in Figure 68, this to prevent the whole bellow inflating like a balloon. The initial wall-thicknesses are shown in Figure 68, these are based on similar devices found in literature [53-55]. The inflatable wall is to be made at 0.25mm wall thickness initially. During production adaptations can be made to this geometry if necessary.

Since the final concept only has one DOF rotation of the device around its axis is needed to achieve a full range of motion. The procedure when using this device will be as shown in Figure 70. Firstly, the device is inserted into the joint and navigation in the sagittal plan take place until the right depth of insertion is reached. After this the device is rotated 90° around its central axis and the navigation in lateral direction can be done. The added rotating of the device necessary because the device only has one compartment and can thus only bend in one direction. By turning the device, a full range of motion is possible for the device.

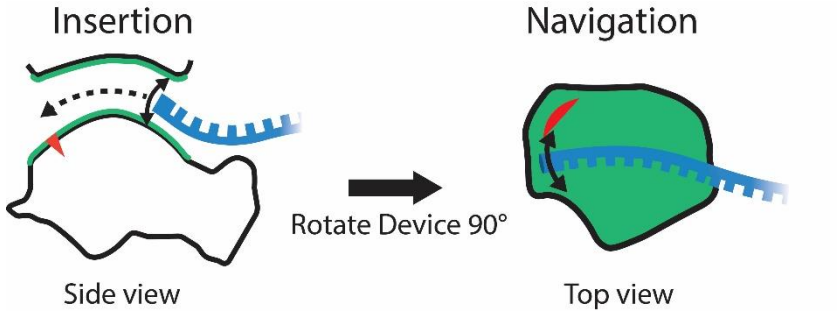


Figure 70 Graphical representation of the procedure with a single-DOF actuator

Prototype

After developing the final concept, a functioning prototype had to be developed. This chapter will explain the process of making the final prototype. This includes material choice, production process of the actuator and the development of an ergonomic handle.

Due to the geometry of the device the production process is limited to thermoplastic moulding. Professional injection moulding is also possible but this would be very expensive and would only be an option for final production in large batch sizes. So, in order to be able to produce a working prototype a creative multi-step production process was developed where thermoplastic elastomers are molten to eventually create an air-tight actuator.

Omitting Nitinol core and double segments

In the final version of the device there are four plastic tubes present in the device. Two for actuation and 2 for application of the hydrogel. This adds a little to the bending stiffness and limits the room for other parts to be present inside the actuator. Therefore, due to the lack of space and presence of plastic tubes, the choice is made to make the first prototype without the Nitinol core and to use high stiffness plastic (shore >85A) to ensure proper stiffness of the device. If buckling turns out to be an issue during the procedure the nitinol core can be added to the recommended design options.

During production of the prototype it was found that the double segmented design was very hard to produce manually. Creating an airtight seal in the middle of the device was not possible without damaging the rest of the actuator. Therefore, the testing and pilot study have been done with a one-segment actuator. During the pilot study, the participants were asked whether two segments were deemed necessary in order to reach the distal parts inside the ankle joints and recommendations have been made accordingly.

Material choice

Because the production process is done in several steps and the actuator must be made airtight the material that is used should be thermoplastic. This is because use of glue is less reliable and could also compromise the biocompatibility of the device making it hazardous to use inside the body. Because a high stiffness of the device is required a high shore plastic is preferred. Lower shores might result in a device that is too flexible. Higher shores might inhibit actuation because the bellows will be harder to inflate. Therefore, multiple materials will be tested to find the best performing material for the device. Since large deformation occurs in the device the elongation-till-break will have to be high (>100%). The elongation-till-yield is also preferably high to ensure a constant performance of the device however this material property is not commonly mentioned in datasheets. Considering all these requirements for the material, the choice was made to use Thermoplastic Elastomers (TPE) to create the prototype.

Filament/Granules

The options for moulding material are either to use ø3mm flexible filament as is used in 3D printers or using granules which are used in conventional high-pressure injection moulding and extrusion. An array of materials was ordered with different shore values from 63A to 65D(>100A). The materials and their properties are listed in Table 7. Since these elastomers are highly non-linear making a calculated prediction is hard therefore the different materials will be tested individually and assessed accordingly.

Table 7 materials used for the prototype and their properties

Name	Shore	Melting Point	El@Break	El@Yield
LariPUR 7025*	70A	185° C	680%	?
NinjaFlex**	85A	216° C	660%	65%
SemiFlex**	98A	168° C	600%	49%
FPE-40**	40D (90A)	159° C	270%	?
FPE-45**	45D (95A)	180° C	350%	?
FPE-65**	65D (100+A)	210° C	220%	?

*granules, **filament

Formation of bubbles

The main problem with using TPE filament or granulate is that air/moisture bubbles can form or be trapped in the molten base material, these bubbles will have to be addressed since it could cause the actuator to leak when one of these bubbles is present in a thin-walled part. In conventional extrusion techniques, a high pressure (+300 bar) moulding process is used to ensure that bubbles are compressed to such a small size that they will not form a problem but these conditions are hard to mimic using non-professional tools. Therefore, a test was done with the filament where it is put into a slot and heated to its melting point. The first test using ø4mm holes of 15mm depth resulted in a lot of air bubbles being formed. The Ninja- and SemiFlex materials had the most severe bubbles where the FPE-45 had almost none. It was later found that the Ninja- and SemiFlex filaments had not been stored properly so moisture was sucked into the material which would then evaporate during the melting process. A second test confirmed these results. In this test, a 6.5mm deep rounded slot was milled into an aluminium block and this mould was then heated up using an acythelene torch while the temperature was monitored with an IR-thermometer. When the clear FPE-40 material was heated up the air/moisture bubbles that were trapped could clearly be seen, these bubbles were about 0.1mm in diameter so barely visible with the naked eye.

The first attempt to **remove the bubbles** was done by placing the mould with the molten material into a vacuum chamber. Theoretically this should enlarge the bubbles so that they float to the top and are extruded from the material. However, the molten plastic has a relatively high viscosity therefore the air bubbles only become larger but do not fully float to the top. This resulted in a bar of material with large (0.5cm) bubbles inside it. The second attempt to handle the air bubbles was done by placing the mould with the molten material into a pressure chamber at 5 bar pressure. This should reduce the air bubbles to microscopic size so they will not form a problem. Note that this works better with stiffer materials, if a material would be very compliant and the hardened material would be taken out of the pressure chamber the pressure difference would cause the compressed air bubbles to expand. A stiff material would keep these bubbles compressed.

Production Process

The most obvious option for the moulding process would be to use a flexible insertion mould to create the bellows in the device, this technique has been used before in similar larger devices. However, because the wall thickness of this device is so thin a flexible insertion mould would result in a high chance of inaccuracies in the process with a leaking actuator as result. Therefore, a non-conventional 3-step moulding process was developed. In the first step, a basic bar of material is produced by a simple moulding process or 3D-printing. In the second step, this bar is inserted into a more complex mould and heated until the material becomes soft. The bellows are created by inserting the side-moulds and a supported top-mould. At the end of the second step the actuator has an open bottom with flaps perturbing from the side. In the third step, the bottom of the actuator is sealed by folding over the flaps and applying heat thereby encasing the tubes inside.

Design

The actuator consists of 30 bellows divided into two separately actuatable parts, a tip of solid non-functional material which simulates the mixing tip and an internalized set of tubes which will guide the actuation liquid and hydrogel components through the actuator.

The mould shown in Figure 72 produces the bellows along with the side-flaps. These flaps will be folded over each other with the tubes inside. Then heat will be applied and the flaps will be joined together creating an airtight system.

Figure 71 Top- and side-moulds partially inserted

The mould will consist of 3 parts and 4 axes to guide the insertion of the different parts. The central mould consists of a central half-round slot over the length of the mould with orthogonal cuts where the side moulds will have to be inserted. The two side moulds fit into the central mould and will form the space in between the bellows, the hole in the centre is to create the reinforcements between the bellows as shown in Figure 71. The last part is the top mould which will be inserted into the combined moulds. Inserting this mould creates the insides of the bellows and the side flaps.

Figure 72 3-part mould used for the production of the actuator

First step: Basic bar

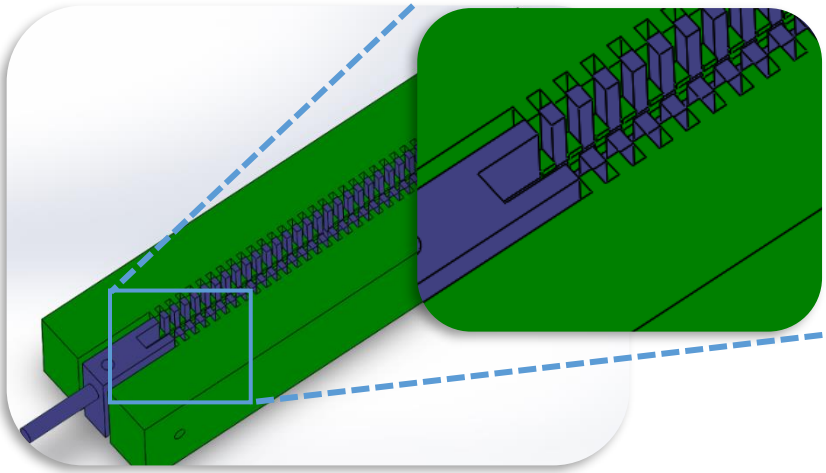
In the first step, a basic bar of material is moulded or 3D-printed. This bar will be inserted into the more complex mould in the second step. If the actuator would be produced by directly using 3mm filament or granules in the complex second mould there would be a high chance of air being trapped in several places. Therefore, this basic bar is made beforehand in a more basic mould with better control over the amount of trapped air. This basic mould, as shown in Figure 73, consists of two blocks of aluminium which both have a half of a 4mm slot made with a round headed milling tool. The other option for the filament is to directly print a bar in the desired shape. There is however a high risk of delamination of the layers or other unwanted artefacts while 3D printing with some of the materials, therefore the basic mould was used for most materials.

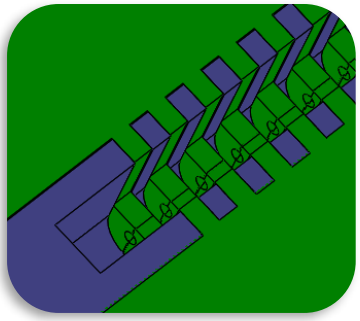
Figure 73 Mould for the basic bar

Second step: Bottom-open actuator with flaps

The second step of the production process consists of several subs-steps which will be explained in this section.

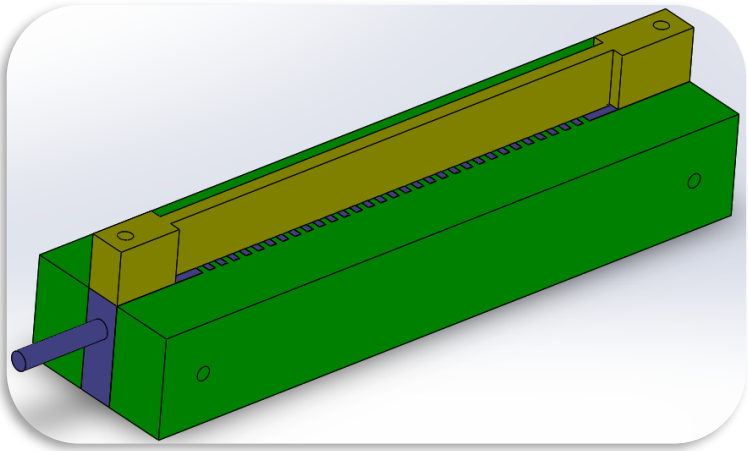
Partially insert side-moulds to create enclosed space. After inserting the basic bar into the central mould, the side moulds can be inserted partially. The resulting space can hold the material during heating without risk of the molten material leaking out of the mould.





Heat-up and insert side-moulds fully. When the side moulds are partially inserted the moulds and material can be heated. When the material has become soft enough the side-moulds can be inserted fully. The side-moulds will also have to be heated so that the material won't solidify when it comes into contact with them.

Insert top-mould. After the side moulds have fully been inserted the top mould can also be inserted, creating the bellows. This mould should be pre-heated to prevent local solidifying of the molten material. During the inserting of the top mould the material will overflow over the rim of the mould. This excess material can be removed after cooling of the mould.



When all parts are inserted the mould with the molten material has to be reheated to the melting temperature of the plastic and then put into the 5-bar pressure chamber to shrink the possible air/moisture bubbles that could have been enclosed in the material.

Third step: Folding the flaps

After the second step of the process the tubes for actuation and hydrogel application need to be inserted into the actuator and the flaps will need to be folded over to create a closed space inside the device. As show in Figure 74 there are 3 critical points in the device which will need to be airtight during actuation. At these points, molten material should be applied before folding de flaps and/or a hot press can be used to melt the material in these specific points in order to create a good seal.

To be able to fold the flaps and seal them together they need to be heated without heating the rest of the device. In order to do this the whole prototype is put back into the mould excluding the top mould. After the prototype is in place the tubes are inserted and messing plate is put on top of the tubes. This leaves only the flaps exposed which can then be heated by a small heat gun which blows 200˚C air on the plastic.

The flaps will then become soft and can be folded over the tubes and over each other. The first flap must be pressed firmly in the critical spots and possibly molten material has to be applied. During this step, it is crucial that the plastic is not heated to much since this might cause the material to flow into the bellows which need to be clear of material to be able to inflate. After the first flap is secured the second flap can be pressed firmly throughout the whole length of the device. The second flap can be heated up further than the first flap so the fully molten plastic ensures a good seal.

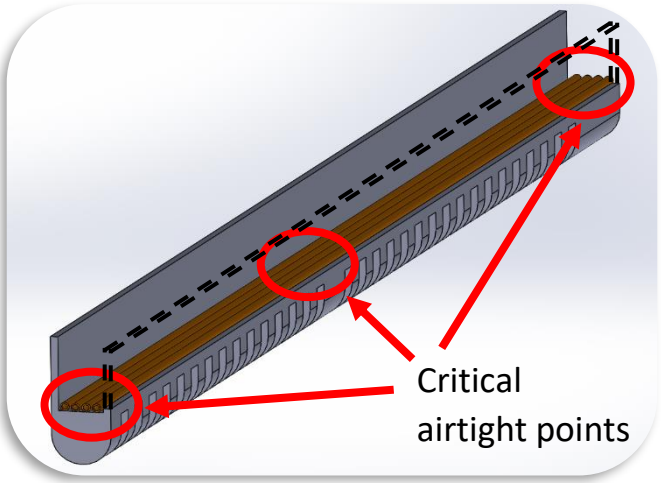


Figure 74 Critical airtight spots which need to filled with material before the flaps are folded over

Actuation

For the actuation of the prototypes 5ml medical syringes will be used. These will be connected to 0.4*0.6mm PEEK tubing which is partially inside the device. The syringe and the tubing will be connected by a silicone connector as shown in Figure 75. The holes in the silicone connector are smaller than the outside diameter of the syringe tip and the tubing and will therefore clamp both parts together by its elasticity.

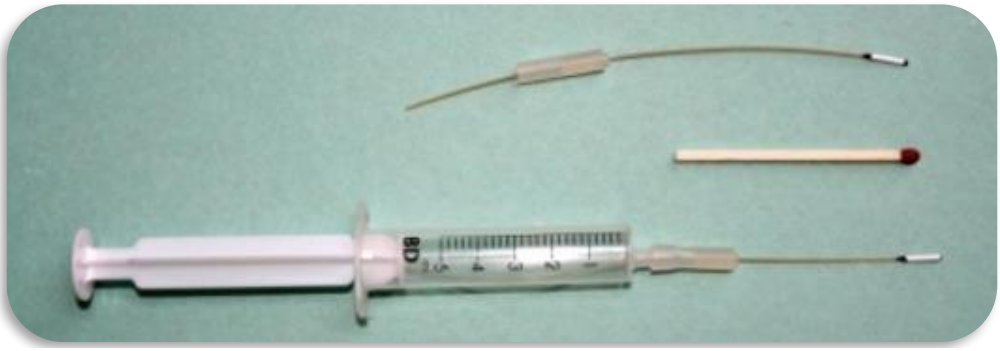


Figure 75 5ml syringe with silicone connector and PEEK tubing

Handle

To be able to actuate the both segments at the same time a handle was designed where the two syringes are integrated and can be separately actuated (see Figure 76 and Figure 77). In this design, the left hand can be used to actuate the segment at the tip of the device using the red slider and the index finger of the right hand can be used to actuate the base-segment via the blue rack-spur mechanism inside the handle. The remaining 3 fingers of the right hand can be used to get a firm grip on the device. All parts of this handle were 3D-printed out of PLA using a more solid fill for the parts that have to withstand higher forces.

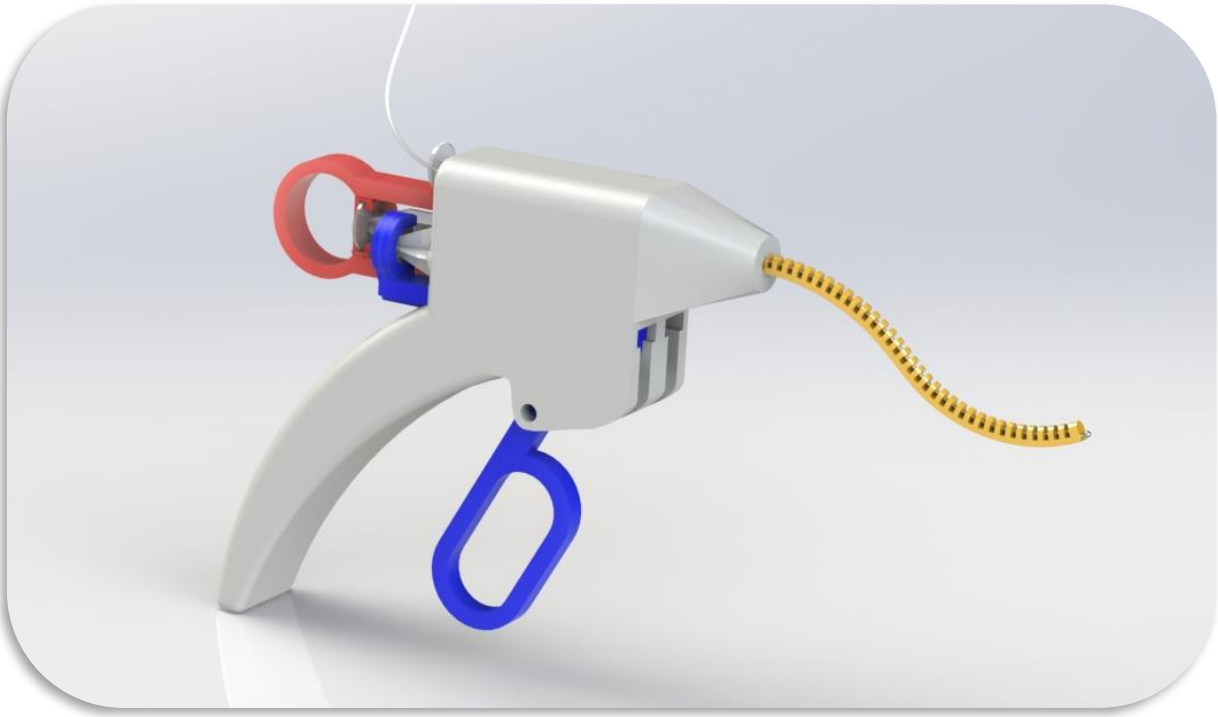


Figure 76 Render of 3D-printed handle

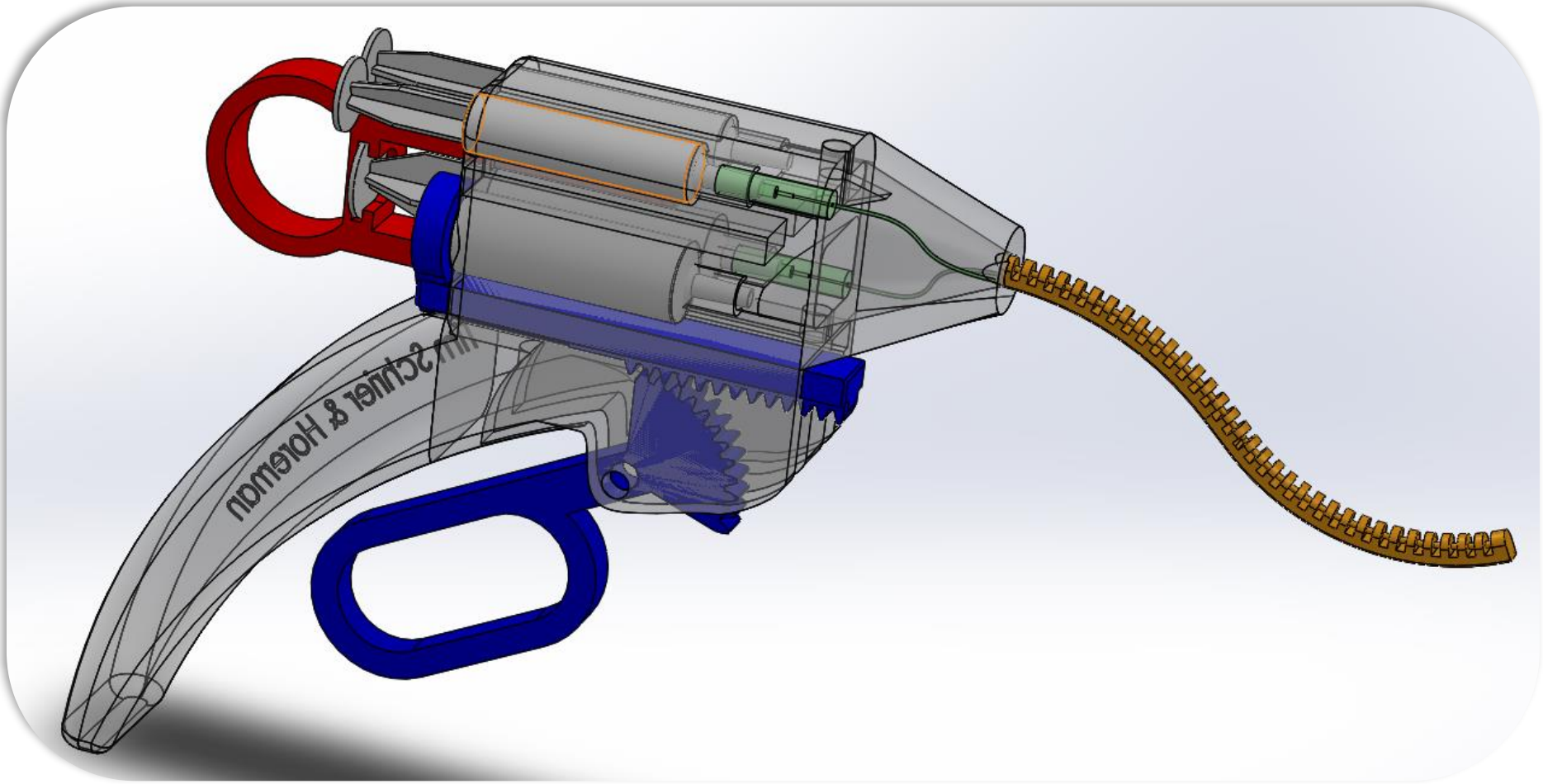


Figure 77 Transparent view of handle showing internal mechanisms

Testing

In order to test the prototype, the physical requirements and performance criteria are reviewed and translated into different test setups to assess the prototype. Firstly, several test setups were designed to find the best performing material for the actuator out of the six possible materials. After this additional tests and a pilot study were performed to investigate whether the prototype made from the best performing material meets the performance criteria. Table 8 shows the criteria that were set earlier in this report in the "performance criteria" section under the "concept development" chapter. It must be noted that rotational stiffness is added to the criteria, this is because the single-chamber concept makes rotation of the device essential during the procedure. These criteria are the goals, the tests will reveal whether these goals were met or not.

Table 8 Performance criteria for assessment of the instrument

Criteria	
Size/scalability	Max 5mm*15mm, scalable to 3mm
Bending/radius	Max 16mm
Buckling strength	No buckling during procedure
Safety	No sharp edges, overall high compliancy
Precision	Max 4mm absolute distance from lesion
Reliability	Usable once during normal intended use
Production cost	As few parts as possible
Rotational Stiffness	Easy rotation of actuator inside the joint

Materials test & pilot study

Materials test

In order to establish the best performing material for the actuator multiple tests were done based on several material based criteria. The three criteria that have been tested are:

- Bending radius
- Buckling strength
- Rotational stiffness

The material that had the best performance was used during the pilot study.

Pilot study

At last the actuator made from the NinjaFlex material was tested in a pilot study with an artificial ankle setup that is shown in Figure 78. The NinjaFlex actuator was chosen as it was the hardest material that could make a small enough bend to be used in the pilot study. Participants were asked to insert the device into the ankle and try to reach two predefined spots inside the ankle joint. Afterwards the participants had to grade the performance of the device in each stage of the procedure: insertion, Axial Navigation into the ankle joint, Turning the device 90°, Lateral navigation to spot #1 and Navigation to spot #2. The questionnaire can be found in Appendix A

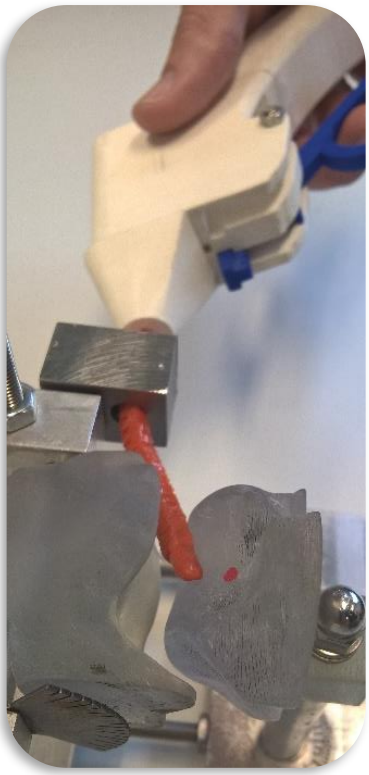


Figure 78 Artificial ankle setup with inserted actuator

The minimum required **performance** for each of the tasks must be above 6. This is considered a satisfactory value for tests scored 1-10 in the Netherlands[56] where this research was conducted.

The minimum required rating of the **actuation effort, actuation force and steering angle** is "neutral to good" this would correspond to a value of 3.5. The **hardness of plastic** rating does not have a preferred outcome.

The minimum required rating of the **ease of bending/turning** is "medium to easy" which corresponds to a value of 2.5.

There are no minimum required ratings for the **S-Curve** questions since the questions are regarding suggested future improvements to the device not the performance of any of the aspects of the current device. However, a small spread would be preferable since this would indicate a consensus between the different participants.

Since the procedure for which the device is being developed is completely new there is no benchmark for the amount of actions that is acceptable or desired. There is therefore no maximum **amount of actions** that are allowed for a satisfactory result. However, the amounts of actions can be used as an indicator for the mental load of the user which might be correlated with the perceived performance. It is therefore interesting to know which actions determine the perceived performance in order to know which improvements should be made to the device. Counting the amounts of actions also sets a benchmark for this device in this procedure which can be used as a reference to find if a redesigned device performs better with regard to amounts of cations.

Correlations

To establish which parameters from the pilot study, interact with and influence each other scatter plots were made and correlation factors and p-values were calculated for each relevant set.

Common practice for a dataset with ordinal variables is to use **ordinal regression or Spearman's Rho test** to determine correlation and significance. There is however a lot of debate about which test are viable for interpreting Likert scale responses. Carifio&Perla [57] and Lubke&Múthen[58] published papers arguing that stepwise **multiple regression** would be a better model. They argue that for social research like this, the small bias that multiple linear regression will show in its results can be neglected while the analysis is less complex and shows clearer results. However, this assumption only stands when the sample size is large enough to ensure a small bias. This sample size should be over 30 samples which is more than the 15 samples for this study. Therefore, only ordinal regression is used to interpret the results of the pilot study.

Ordinal regressions were performed for:

- The dependent variable **performance** and independent variables: **actuation effort, actuation force, steering angle, ease of bending/turning, precision, amount of actions** to find out which of these variables influences the perceived performance and should thus be improved.
- The dependent variable **ease of bending** and the independent variables: **actuation effort, Actuation force and bending radius** to find whether the perceived ease of bending is mainly determined by actuation effort, actuation force or bending radius of the instrument.
- The dependent variable **preferred hardness of plastic** and the independent variables: **actuation effort, actuation force, steering angle and ease of bending and rotating during navigation to point #1 and #2** to find out which parameter is mainly responsible for the expressed need for harder/softer plastic used for the production of the actuator.

Test set-ups

The test setups were specifically designed and build for the actuators. A different test setup was designed to test each aspect of the device.

Bending Radius

The bending radius was measured by photographing the actuator in actuated state when a force of 15N was applied to the syringe. This means that the actuator was inflated to a pressure of approximately 60kPa.The syringe and actuator were filled with water during this test. The background for the photograph was made of a 1mm black and white checkered paper. The photograph was then put in the computer and analysed using a measuring program. The radius was measured at the surface of the actuator that touches the talus during insertion as shown in Figure 79.

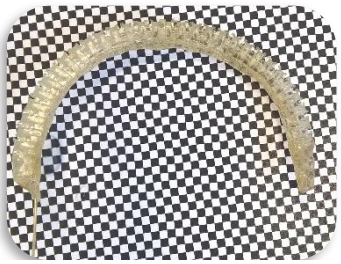


Figure 79 Bended LARIPUR actuator on checkered background

Buckling Strength

The buckling strength during the procedure is mainly determined by the lateral stiffness because during the procedure the device will be enclosed between the bony structures. In order to simulate this the buckling strength was measured by keeping the device between two layers of plexiglass as shown in Figure 80. The device restricted from lateral movement at the base, the tip was put in a tapered hole at the bottom of the test setup so it could rotate but could not move in downwards or lateral direction. The whole setup was placed horizontally against a force sensor and the force at the base of the device was gradually added until buckling to find the buckling strength per device. The maximum amount of force determines the buckling strength of the device. All measurements were done with a Futek Loadcell calibrated to 20N. Sensor values were measured every 50ms and from this the maximum value was taken. The device was not filled with anything except air for this test.

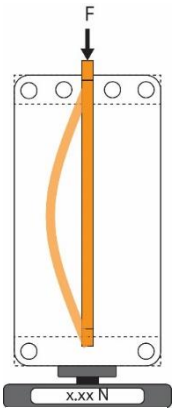


Figure 80 Buckling strength test setup

Rotational stiffness

During the middle part of the procedure the device needs to be turned while being inside the joint. Therefore, the rotational stiffness needs to be sufficient so the surgeon can easily rotate the device. To test this the device was put in a tube to prevent lateral movement and the tip was locked in a moment-meter setup as shown in Figure 81. The base was rotated to 90° and the exerted moment was measured. From this the rotational stiffness was calculated.

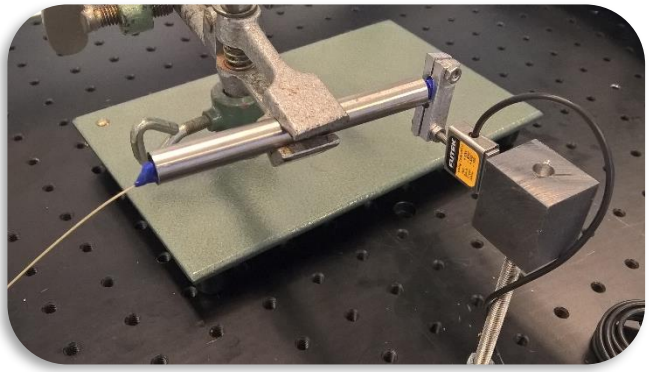


Figure 81 Rotational stiffness test setup with FPE45 actuator

All measurements were done with a Futek Loadcell calibrated to 400mN. Sensor values were measured every 50ms and from this the maximum value was taken. The device was not filled with anything except air for this test.

Pilot Study

During the pilot study 15 different participants were asked to perform a procedure where they had to manoeuvre the tip of the actuator to two predefined points on the cartilage in the artificial ankle setup.

The ankle setup consisted of a tibia and talus bone without tendons and ligaments. The two bony parts were spaced 8mm apart and two targets were placed on them. The participants had to enter the joint through a hole on the right side of the setup as shown in Figure 78.

It was explained that the procedure consisted of 5 steps: Insertion, Axial navigation, counter-clockwise turn+ Lateral navigation to point #1 and navigation to point #2. The participants were shown the procedure explanation as depicted in Appendix A. After this the workings of the instrument where explained and the participants had time to inspect and play around with the instrument until they felt that they knew how it worked. After this the participants could insert the instrument into the ankle setup without having to reach the targets. When the participant felt that they understood the task and workings of the instrument they could proceed with the procedure.

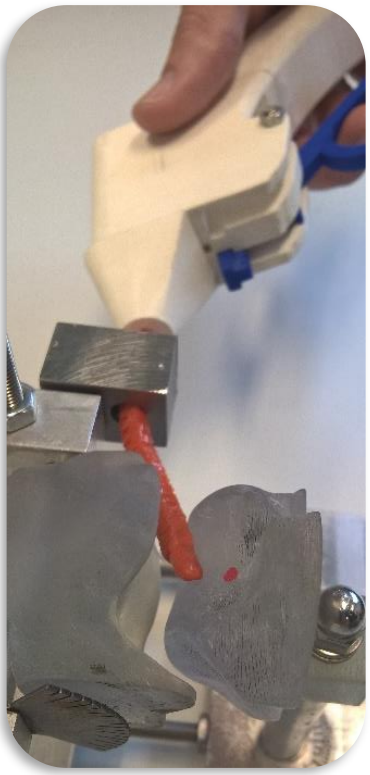


Figure 82 Artificial ankle setup with inserted actuator

During the procedure, there was as little interaction with the participant as possible to ensure that the participant would be at ease and not make unnecessary mistakes due to peer pressure. Therefore two cameras were used to record the hand movements of the participants instead of direct visual observation. However, since buckling of the needle could not be observed well without looking very closely at the participant during the procedure and could not be recorded properly by camera, the participants were asked to pause between each step of the procedure and answer the question: “How often did buckling occur?”. It should be noted that it was explained beforehand that this question would be asked but did not affect how well they performed the task so that the participant was aware of this but not anxious of buckling the needle. Buckling was only counted when unwanted and was explained to the participant as moving the handle of the instrument axially into the joint without the tip moving thus causing lateral/sagittal translation of the middle of the needle of minimally 4mm.

After step 4 and 5 the distance between the tip of the needle and the centre of the target was noted. The measuring of the distance was done by eye using a bullseye type target as shown in Figure 83. The target has rings of 1mm in different colours so the distance between the tip of the instrument and the centre of the target could be measured by eye to be either 1,2,3 or 4mm. By pausing the procedure after each step, the participants were aware that the procedure consisted of several steps which is necessary to properly fill in the questionnaire afterwards.

Figure 83 8mm target used in the ankle setup

During the procedure, the participant's hands were recorded by camera, **observable parameters were noted afterwards using the camera footage**. The parameters that were noted were:

- The procedure time per step of the procedure
    - The procedure time is defined as: the time in seconds between the moment the observers tells the participant to start a part of the procedure until the participant responds that the part of the procedure is finished. The parts of the procedure are defined as:
        - Insertion (starting with the tip of the instrument inside the metal insertion point at the right of the setup until the tip of the needle is inside the joint),
        - Axial navigation into the joint (starting with the tip of the needle just inside the joint until the tip of the needle touches the far left inside surface of the joint)
        - Counter-clockwise turn + lateral navigation to point #1 (starting with the tip of the needle touching the far left inside surface of the joint until the participant says he has reached the target as close as possible)
        - Navigation to point #2 (Starting with the tip at point #1 until the participant says he has reached the target as close as possible)
- The number of clockwise and counter-clockwise rotations of the handle
    - A rotation is defined as a rotation of the instrument handle (around the central axis of the hole in the metal insertion block at the right of the ankle setup) of more than approximately 10°. This is to omit hand tremors of the participant. The camera footage is reviewed to find the amount of rotations. The rotations are measured by eye from the protractor which is mounted to the test setup.
- The number of inward and outward axial movements
    - A movement is defined as and axial displacement of the needle at the metal insertion block at the right of the ankle setup of at least 5mm. A ruler is mounted to the test setup to be able to measure the insertion depth.
- The number actuations of the needle by extending or pulling on the blue handle of the instrument.
    - An actuation by pulling is defined as an observable movement of the handle in the proximal direction with the fingers touching the proximal part of the handle.
    - An actuation by extending is defined as an observable movement of the handle in the distal direction with the fingers touching the distal part of the handle. Since the needle straightens automatically when the handle is released releasing the handle is not counted as an actuation since the distal end of the handle is not in contact with the fingers.
    - Movements are observed by looking at the camera footage.

  (If two of the same actions were performed with a pause in between of 0.5s is was counted as 2 actions.)

After the procedure, the participants were given a questionnaire containing questions about the performance of the device and possible improvements the questionnaire can be found in appendix A. In the questionnaire, the participants were asked to rate the performance of the device per step of the procedure and they were also asked to rate the ease of rotating and bending the needle during the procedure. At the end of the questionnaire there was a section about possible improvements to the actuator. The participants were asked a set of questions designed to find out their thoughts on having two individually actuatable segments of the needle, thus making it possible to make an S-curve with it. They were also asked a second set of questions designed to find out their thoughts on the hardness of the plastic that was used for the production of the needle.

Results

In this section, the results are listed. Firstly, the results related to the materials test and secondly the result of the pilot study conducted with 15 participants are listed.

Materials test

The first test results that are reviewed are the tested criteria. An overview of the test results is showed in Table 9.

Table 9 Materials test results

Material	Shore	Bending Radius	Buckling Strength***	Rotational Stiffness***
LariPUR 7025*	70A	27mm	1.7 N	3.7 µNm/deg
NinjaFlex**	85A	66mm	3.2 N	5.8 µNm/deg
SemiFlex**	98A	93mm	6.5 N	17.6 µNm/deg
FPE-40**	40D (90A)	53mm	4.8 N	7.9 µNm/deg
FPE-45**	45D (95A)	107mm	8.2 N	36.4 µNm/deg
FPE-65**	65D (~105A)	160mm	15.8 N	52.7 µNm/deg

*Granules,**Filament,*** Mean values

Bending Radius

The result of the bending radius at 60kPa are listed in Table 9. It should be noted that this is not the minimum bending radius for the actuators. The relation between the bending radius and Shore A hardness is shown in Figure 84.

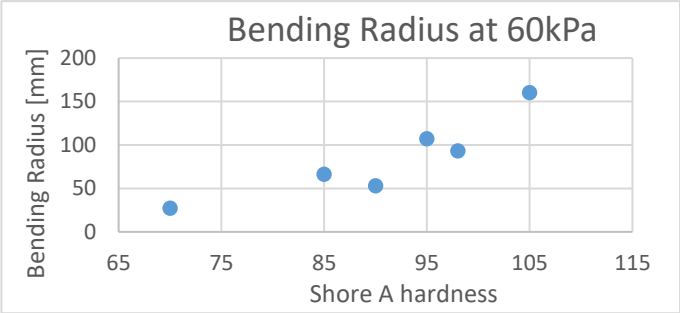


Figure 84 Bending radius vs Shore A hardness

Buckling Strength

The results of the buckling resistance tests are shown in Figure 85Figure 85, the mean values are included in Table 9. The box plot depicts 5 test values for each actuator. As can be seen in the boxplot the spread of the data is small, the highest coefficient of variance was found in the results for the FPE-40 actuator which is 0.07.

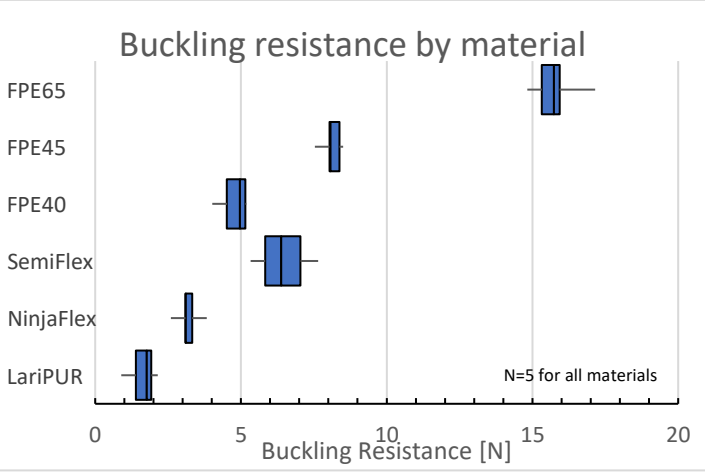


Figure 85 Buckling resistance by material

Rotational Stiffness

The results of the measured force in rotational stiffness setup are shown in Figure 86, the mean values converted to rotational stiffness of the actuator are included in Table 9. The box plot depicts 5 test values for each actuator. As can be seen in the boxplot the spread of the data is relatively small, the highest coefficient of variance was found in the results for the FPE-45 actuator which is 0.11.

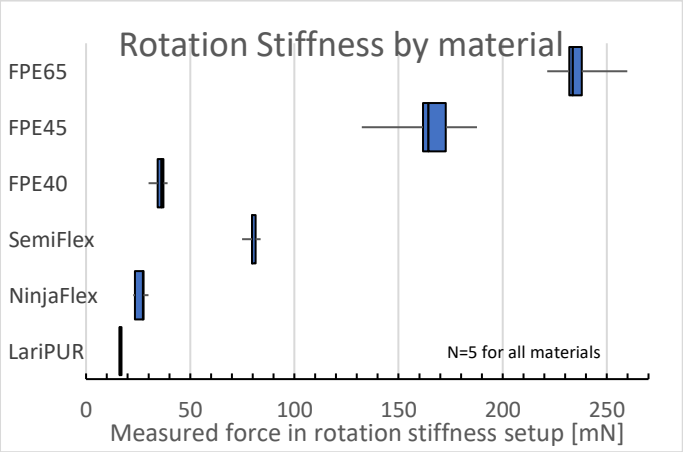


Figure 86 Rotational resistance force measured in the test setup

Pilot Study

In this section, the results of the pilot study are listed. All results are depicted in **boxplots where the mean is indicated by an X and outliers as dots**. N=15 for all parameters.

Performance

Insertion and axial navigation have a mean of 8.5(STD=0.8) and 7.4(STD=0.8), as can be seen in Figure 87 there are 3 outliers, one in the insertion and one in axial navigation. Navigation to point 1 and 2 have a larger spread so less consensus and a mean of 6.7(STD=1.4) and 6.8(STD=1.6).

Precision

All participants were able to reach the target within 4mm from the centre. Most of the people were able to reach the target within 1mm which was the minimum distance that was possible. The mean distance from the target was 1.5(STD=0.8) for point 1# and 1.5(STD=1) for point 2

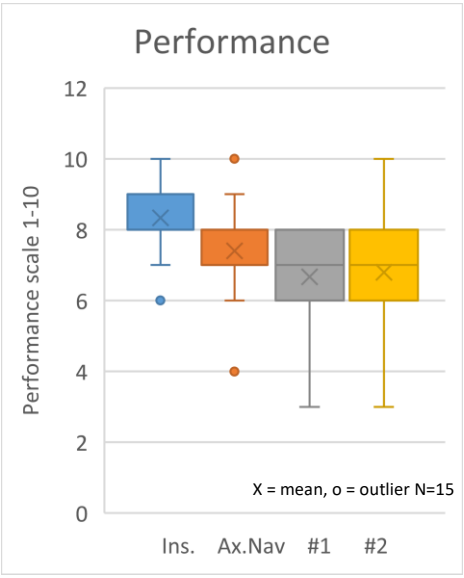


Figure 87 Performance results

Hardness of plastic

The participants were asked to rate 3 parameters of the needle related to the hardness of the plastic and after these 3 questions they were asked whether they thought a softer or either hard plastic would be a better choice. The parameters were:

- Actuation effort (hand power needed)
- Actuation force (ease of bending the needle)
- Steering angle (minimum bending radius)

As can be seen in the boxplot in Figure 88 that the actuation effort had a larger spread than both the actuation force and steering angle. The mean values for actuation effort, actuation force and steering angle are 3.3(STD=1.1), 3.4(STD=0.8) and 3.5(STD=0.8) respectively this corresponds with "neutral to good". Most participants thought that the needle should be made of a plastic that is "a little harder", the mean value was 2.7(STD=0.8).

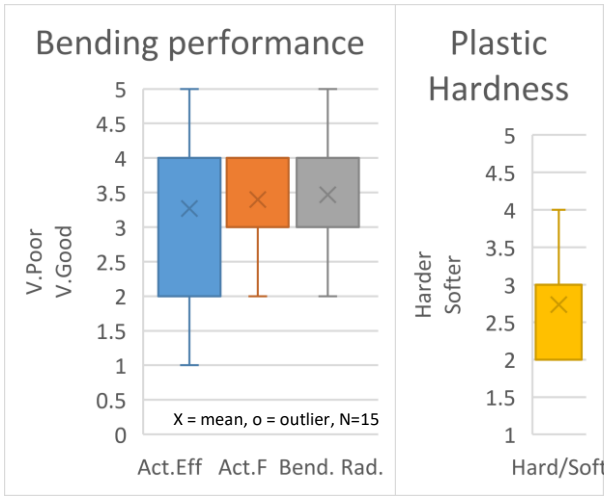


Figure 88 Bending performance and plastic hardness results

Bending & Turning

As can be seen in Figure 89 most participants scored the ease of rotation and bending between 2 and 3 which corresponds to "easy" and "medium". Overall the ease of rotation of the device has a greater spread than the ease of bending. The mean values for ease of bending and rotating during navigation to point #1 and #2 are 2.5 (STD=0.6), 2.6(STD=0.9), 2.9(STD=0.7) and 2.7(STD=0.9) respectively.

Buckling

There was one occurrence of buckling during the whole study. This was during insertion into the joint with subject 3. During any other part of the pilot study no buckling of the needle occurred.

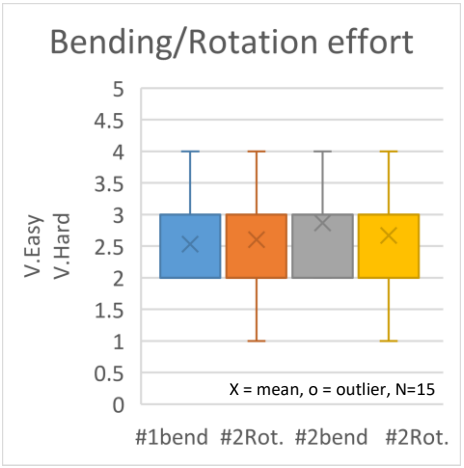


Figure 89 Bending/Rotation effort results

S-Curve

The participants were asked if they agreed with the following statements regarding the segmentation of the needle so that it would be able to make an S-curve which would require two-handed operation of the instrument:

- Making an S-curve with the "needle" is necessary to be able to reach difficult spots inside the ankle.
- Requiring two hands to operate the instrument would make it a lot harder to use.
- The above explained added S-Curve feature would improve the overall performance of the device.

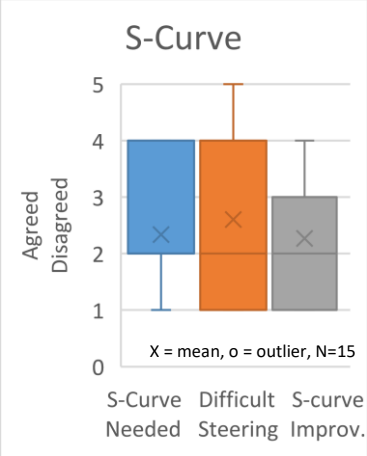


Figure 90 S-curve results

Overall the participants "slightly agreed" to all statements but a significant spread is visible in the boxplot in Figure 90. The mean values for the above-mentioned questions are 2.3 (STD=1.1), 2.6(STD=1.4) and 2.3(STD=1.1).

Amount of actions during procedure

During the pilot study, the participant hands were recorded. Afterwards the amount of actions the participants made were counted by analysing the video recordings. Bending, straightening, inward axial movement, outward axial movement, clockwise rotation and counter clockwise rotation were counted. Results are shown in Figure 91.

Insertion - All participants were able to enter the joint with a maximum of 2 bending actions and 3 inward axial movements. 8 out of the 15 participants were able to do this with just one bending action and one inward axial movement.

Axial navigation - All participants were able to reach the far side of the joint with a maximum of 2 bending actions and 3 inward axial movements. 12 out of the 15 participants were able to do this without any bending action and one inward axial movement.

Navigation to #1 - During navigation to point #1 more actions were made by the participants than during insertion and axial navigation. Except for two outliers all amounts of actions are closely spread without much deviation. 5 out of the 15 participants used just one bending action and only 4 participants used the straightening action.

Navigation to #2 - During navigation to point #2 more actions were made by the participants than during insertion and axial navigation. Inwards and outwards axial movement of the device have a larger spread than the amount of rotations. 6 out of the 15 participants used one bending action and 6 out of the 15 participant used 2 bending actions. Only 2 participants used the straightening action which causes it to appear as an outlier in the boxplot.

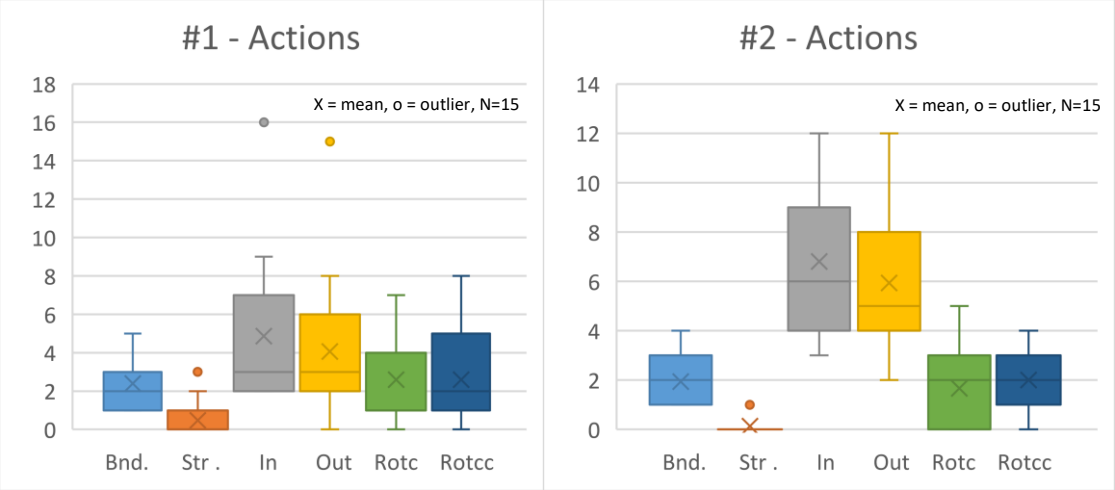


Figure 91 Amount of actions during navigation to point #1 and #2 (from left to right: Bending, Straightening, Inward movement, Outward movement, Clockwise rotation, Counter clockwise rotation)

Correlations

Ordinal and multiple regressions were performed for the dependent variable **performance** and independent variables: **actuation effort, actuation force, steering angle, ease of bending/turning, precision, amount of actions**. Ordinal regression gave no significant correlations.

Ordinal and multiple regressions were performed for the dependent variable **ease of bending** and the independent variables: **actuation effort, Actuation force and bending radius**. Ordinal regression showed no clear correlations between variables the only significant correlation that was observed was between the choice of scoring actuation effort neutral (3) or very good (5) and the ease of bending.

Ordinal and multiple regressions were performed for the dependent variable **preferred hardness of plastic and the independent variables: actuation effort, actuation force, steering angle and ease of bending and rotating during navigation to point #1 and #2** to find out which parameter is mainly responsible for the expressed need for harder/softer plastic used for the production of the actuator. No significant correlation was found with ordinal regression.

Discussion

The following chapter describes the interpretation of the results listed in the previous chapter. Conclusions based on the measured parameters will be presented and compared to the goals that were set. After this the results of the pilot study will be discussed.

Criteria

Firstly, the original test criteria have to be reviewed in order to see if the device performs the way that is needed in order to have a successful procedure.

Size/scalability

The device was successfully produced at the predetermined 5mm scale. The production has been repeated several times for different types of plastic which indicates a robust production process.

Figure 92 Moisture bubbles in LariPUR plastic

The production at a 3mm scale is deemed possible given the right equipment and some adaptations to the production process. It must however be noticed that since the wall thicknesses will be much thinner so there is a higher chance of leaks in the walls of the actuator. The main cause for this is trapped moisture inside the plastic. Thermoplastic elastomers have the tendency to absorb moisture out of the air when stored improperly. When the plastic is then heated to melting temperature, the moisture evaporates and forms bubbles inside the plastic which can be seen in Figure 92. This was observed on multiple occasions during the production of the 5mm prototype. Therefore, the production process should be carefully designed to avoid any air or moisture bubbles.

Bending Radius

The bending radiuses of the different actuators follow a clear line in Figure 84, except for the radiuses of the FPE-40 and SemiFlex actuators. A possible explanation for the deviation is that the shore A or D hardness is not directly correlated to the Young's modulus of a material. However, the Young's modulus for elastomers is highly non-linear and not always available in data-sheets. Another possibility is that the geometry of both devices is not exactly similar. Since most of the production was done by hand there might be differences in geometry of the device. A clear example of this is that the bottom layer of the actuator consists of the two folded-over layers of plastic that have been melted with a heat-gun and therefor have an irregular surface area with slightly varying thickness. This could influence the bending radius which would explain the deviations that were observed.

The bending radius as shown in the "results" chapter are at 60kPa. The actuators can however be pressurized to higher pressures causing lower minimum bending radiuses. The determining factor for the minimum bending radius was observed to be the seals between the PEEK tubing and the silicone connectors and the actuator. After reinforcing the seal between the PEEK tube and the silicone connector of the NinjaFlex actuator, by tightly winding a thread around the connector, the minimum banding radius was 25mm. When this

Figure 93 Reinforced seal between the silicone connector and the PEEK tubing

radius is scaled to a 3mm actuator this would be 25/5*3= 15mm. This is within the set 16mm criterion. It is deemed possible to make such a seal that even higher pressures are possible so that the harder plastics up to FPE-45 could be used to make an actuator that has a minimum bending radius of 15mm at a 3mm scale.

Safety

The overall safety is determined in this report as the lack of sharp edges and high overall compliancy of a device. This is to not damage the cartilage inside the joint. The actuator was designed such that it would satisfy these requirements. However, during the pilot study it became clear that the bellows on the actuator might form a risk. The bellows would tend to get stuck on the insertion point on the test setup, which was a steel block with a hole through it. The same might happen with the skin when inserting the actuator into an ankle joint. The bellows might get stuck on the skin which would at the least cause discomfort to the patient. There are however several ways of working around this problem like a smooth insertion portal in the skin. A possible concern for the safety of the instrument could be leakage of the actuator. Therefore, the actuator can be filled with either water or a saline solution that is safe to use inside the body. Since pressure of the device does not exceed 200kPa there is no threat of leaking water damaging the cartilage at high pressures.

Reliability

The criterion that was set up states that the actuator has be able to withstand at least one procedure. The actuator used in the pilot tests was used for more than 15 procedures without critical failure. A failure that was noted was the seals started leaking more often and under lower pressures after 10 procedures, this can be ascribed to deterioration of the silicone connectors. The instrument that will eventually be used will have a disposable actuator and connectors so this will not pose a risk. It should be noted that the device that was developed is at a 5mm scale where the final product will be produced at a 3mm scale. This means that the walls will be thinner which might make the actuator more prone to leaks.

Production cost

Since the device will be made disposable it will have to be produced as cheap as possible. The exact production cost cannot be determined without knowing batch size but it is assumed that the monolithic actuator is not expensive to produce since no assembly costs are necessary. During this research, the actuator was produced manually by thermoforming with a mould and a manually folding over of the flaps to make the device airtight. The final production process will most likely be done by either injection or blow moulding in large batch sizes. If, however the demanded batch size is a lot lower, professional 3D-prining might be used to print the actuator. The handle of the device will probably be a lot more expensive to produce but will also be reusable, therefore the production cost is less important.

Rotational Stiffness

The last criterion, which was added after determining the final design, is the rotational stiffness. This stiffness must be high enough for the actuator to be rotated whilst inside the ankle joint. This stiffness is determined by both the geometry and the material properties of the actuator. During the pilot study, it became clear that the overall rating of the rotational stiffness was “neutral to good” and several participants noted a lack of rotational stiffness and would have liked the device to be stiffer around the central axis. Therefore, it can be said that the current rotational stiffness of 5.8 µNm/deg of the NinjaFlex actuator is not sufficient for a good performance of the instrument.

Pilot Study

Performance

The result for the pilot study show high values for insertion and axial navigation with means of 8.5 and 7.4 respectively. Lower values were given for navigation to point #1 and #2. This could be because the insertion and axial navigation were very easy, therefore the participants scored this around 8 to leave room for improvement on the further questions and therefore gave performances of navigation to the target a lower score since they were asked later in the questionnaire. Regardless the scores for both navigation to target 1# and #2 were rated at around 6.5 which is a decent score and fulfils the criteria set before the pilot study. There is however room for improvement which will have to come in the form of adaptations to the instrument.

Hardness of plastic

During the pilot study, the participants were asked to rate 3 parameters of the needle related to the hardness of the plastic and after these 3 questions they were asked whether they thought a softer or either hard plastic would be a better choice. The parameters were:

- Actuation effort (hand power needed)
- Actuation force (ease of bending the needle)
- Steering angle (minimum bending radius)

All three parameters were rated “neutral to good” which is just within the criteria that were set before the pilot study. Therefore, the criteria can be regarded as fulfilled. However, there is a lot of room for improvement. It must be noted that both the actuation force and steering angle will inherently improve when the final product is used in an actual surgical procedure. The steering angle will be smaller since the actuator will be scaled down to 3mm and the actuation force that is needed to bend the actuator will be less inside a human joint. During the pilot study, the static friction between the actuator and the joint was sometimes to high so that the actuator could not be bend. In a human joint, the slippery cartilage will ensure that much less actuation force is needed to be able to bend the actuator.

During the pilot study, the participants noted that the hardness of plastic should be “slightly harder”. The reason for this was indicated by some participants to be the rotational stiffness. Buckling almost never occurred during the study and is thus not seen as a significant factor for the hardness of the plastic. A slightly harder plastic would however impede the actuation effort and steering angle. Both can be improved by adaptations to the design but a midway will have to be found for the hardness of the plastic.

Precision

The precision of the device during the pilot study was well within the 4mm criterion that was set. Most of the participants were able to reach the centre of the target within 1mm. Therefor a skilled surgeon with a proper training for this specific instrument would be able to reach the target within 1mm. In addition to that the actuator will be downscaled to 3mm which will allow more room inside the joint and will result in a lower bending radius giving more freedom in steering. Therefore, the precision is regarded as much better than needed for this procedure.

S-Curve

As mentioned in the "results" section, the participants "slightly agreed" to all statements listed below but a significant spread was observed between the answers:

- Making an S-curve with the "needle" is necessary to be able to reach difficult spots inside the ankle.
- Requiring two hands to operate the instrument would make it a lot harder to use.
- The above explained added S-Curve feature would improve the overall performance of the device.

The "slight agreeance" to these statements means that overall the participants felt that an S-curve is needed to reach difficult spots inside the ankle and that this will make operation of the device more difficult but will overall improve the performance of the device.

The need for the instrument to make an S-curve is made slightly less significant by the fact that a surgeon is able to choose an insertion port at any side of the joint and therefore might be able to pick a port that will allow him to reach difficult point inside the joint without needing the device to make an S-Curve. However, as some participants noted it is hard to answer these questions without having tested a device that can actually make an S-curve.

Actions

The main reason for measuring the amount of actions was to get a measure for the mental load during the procedure which could then in turn be linked to the perceived performance of the device. This correlation was therefore examined but no correlation was found between any of the amount of actions and the performance for the corresponding task. The sample size of 15 participants for this pilot study is not high enough to exclude any correlation between the amount of actions and the mental load and therefore the performance of the device, a larger study could either confirm or deny the absence of correlation. Based on the amount of actions still some conclusion can be made.

Insertion

Most participants were able to insert the actuator into the ankle joint with just one bending action and one inward axial movement. The insertion port for the insertion was placed in such a way that a bending action was needed for insertion. During surgery, the surgeon is able to choose the location of the port so the bending action might not be necessary during surgery. However, the option of insertion with bending gives the surgeon more options for port placement which could be beneficial.

Axial navigation

Most participants were able to reach the far side of the joint without any bending action and one inward axial movement. This can be attributed to the fact that the device has a relatively high axial stiffness and high lateral compliancy therefore the device "finds its way" when it is simply pushed into the joint. This is a clear benefit for this device over mechanical devices. This actuator is pressure based and can therefore deform when it encounters any form of obstacles. Mechanical devices often have the property of shape locking, which means that when an obstacle is encountered or the device must make a bend of a small radius the device gets stuck unless the middle part can be actuated separately. This device, since it is one long pressurized chamber automatically has an even pressure distribution throughout the whole device.

Navigation to #1

Except for two outliers all actions closely spread without much deviation during navigation to point #1. A bending action was done 2 times by most participants and only 4 participants used the straightening action. The relation between the amount of actions and performance score was reviewed but no significant correlation was found between any of the actions and the performance for that task. The bending action was clearly necessary to reach the target. The straightening action was not. It was observed that most participants retracted the actuator when they wanted to straighten it. This is also a viable option but might cause more discomfort to the skin around the insertion port. A skilled surgeon can keep this in mind while using the device.

Navigation to #2

During navigation to target #2 a bending action was done 2 times by most participants and only 2 participants used the straightening action which causes it to appear as an outlier in the boxplot. The relation between the amount of actions and performance score was reviewed but no significant correlation was found between any of the actions and the performance for that task. The same conclusion as with navigation to target #1 regarding the straightening of the device can be made for navigation to target #2. More inward and outward movements were needed for this task than the previous one. This can be explained by the fact that the starting point was different so the instrument had to be retracted first and reinserted after that in some cases.

Correlations

The ordinal regressions did not result in any significant correlations. The main reason for this is because the sample size is only 15 in this study. However, a few trends can be found when looking at the scatter plots in Figure 94 and Figure 95.

The only trends that can be seen are found between **performance and ease of bending and precision**. The first trend is that all participants that weren't able to reach the centre of the target scored the performance 6 or lower for both tasks indicating that when the centre could not be reached performance was considered barely sufficient or less. The correlation between perceived performance and precision seems logical especially since reaching the centre of the target was the main goal of the procedure. The second trend is the correlation between ease of bending and performance for navigation to target #2. It seems to be out of place since no such correlation can be seen for navigation to the other target. However, this correlation is very clear as can be seen in the scatter plot in Figure 94. A possible explanation for the correlation could be that the second task relied more on bending the actuator than the first task. If this is the case then ease of bending is a strong determinant for the perceived performance in certain tasks.

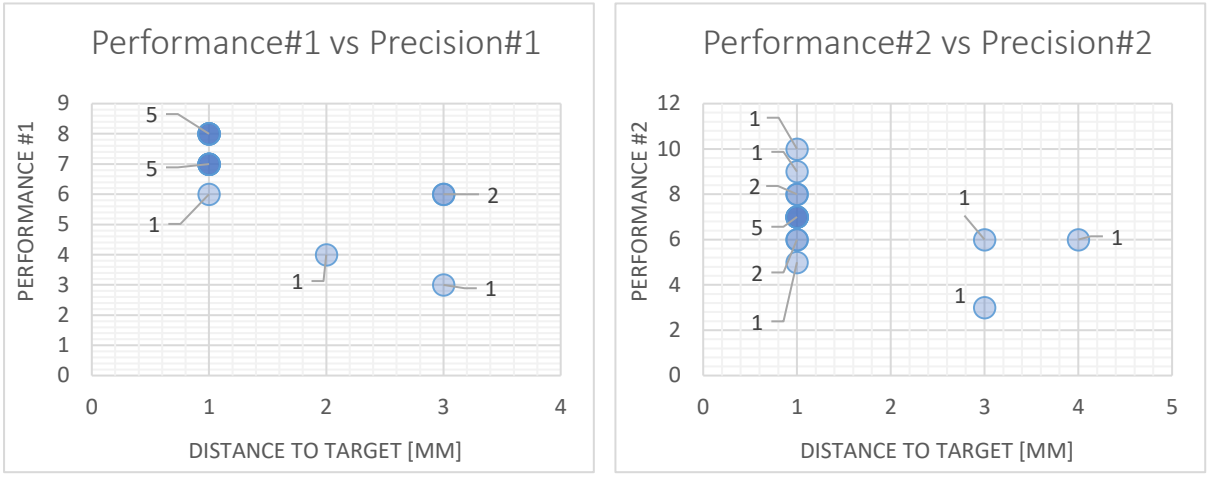


Figure 94 Scatterplots of trends found between performance score given by participants and the distance to the target they achieved (N=15)

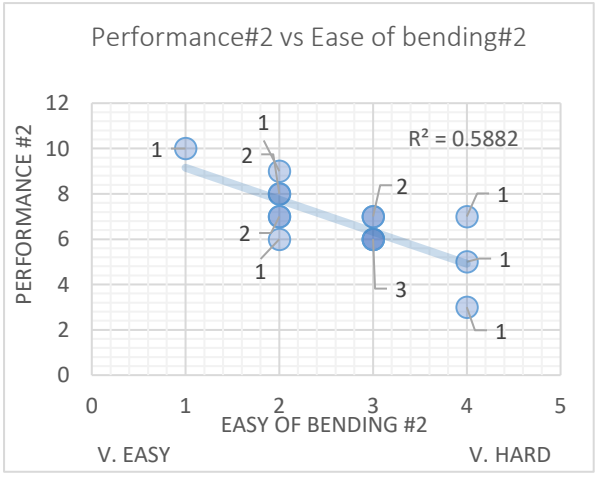


Figure 95 Scatter plot of trend found between performance and perceived ease of bending the actuator (N=15)

Recommendations

Production process

Since the device will have to be downscaled to 3mm the production process will have to be adapted. The current production process contains a lot of manual work which can result in human errors and dissimilarities between the produced products. It is advised to explore multiple different ways to produce the actuator before continuing with the final design. The first possible production process that should be explored is high performance 3D-printing. It might be possible to produce the actuator using high performance 3D-printers that can handle filament. Since most of the material that were used are flexible 3D-printing filaments this could be a good way to make different prototypes fast and check which geometry works best for the procedure. For the final production, a professional plastic moulding company should be contacted to explore the options. The hollow centre of the actuator makes several production techniques hard to apply but a company specialised in injection, extrusion of blow-moulding should be able to choose the most feasible production process for the device.

Improving seals & handle

During the testing of the device is became clear that the seals are the of paramount importance for the performance of the device. Better seals means that higher pressures can be used which means that a harder plastic can be used to produce the actuator. This will improve rotational stiffness. It was observed that the seals between the PEEK tubing and the silicone connector would be the first to leak. This seal can easily be improved by some form of clamping on the silicone connector. During the research, this was done by tightly winding a thread around the silicone connector. The final product could either make use of a similar concept using steel thread for clamping or a small tube-clamp could be used. However, there is very limited space inside the handle for such a clamp. It is recommended that the handle of the device is re-designed so that is includes a clamping part for the silicone connectors. The second part that was observed to be leaking was de connection between the actuator and the PEEK tubing. This connection can be reinforced in a similar manner as the connection between the PEEK tubing and the silicone actuator. It is advised to spilt the handle into two identical mirrored pieces. This will not only allow the handle to clamp both connection points but also will make the assembly of the device a lot faster and easier.

Improving rotational stiffness

As noted in the result and discussion several participants clearly stated that the rotational stiffness rotational stiffness of the device was not sufficient for a comfortable use of the device. There are several ways to improve rotational stiffness. Firstly, the most obvious choice is to use a plastic with a higher shore a hardness. This does indeed improve rotational stiffness but at the same time degrades the actuation effort and bending radius. Therefore, the rational stiffness should also be improved by changing the geometry of the device. One possible improvement could be to make the base of the device solid plastic instead of having bellows throughout the whole device. During testing, it was observed that only the far 5cm enters the joint therefore the rest on the actuator can be made solid which would improve rotational stiffness significantly. Also, one of the participants inspired a new idea which should be researched. The idea is to make the device tapered along the central axis. So, the diameter at the base is 3mm but in the tip only 1mm. Then the tip would then have a smaller bending radius than the base which would improve precision and steerability at the tip where this is needed. This might allow for a stiffer material to be used for the production therefore improving the rotational

stiffness at the base. And since the tip would be smaller than the base these parts would not be pinched by the bony structures in the joint therefore rotational stiffness in the tip is not needed anymore.

Improving actuation effort

As mentioned in the discussion the actuation effort should be improved in order for surgeon to be able to maintain a comfortable grip during a lengthy procedure. The actuation effort can be improved by either using a softer material or by using a different gear ratio in the rack-spur mechanism inside the handle. Since a softer material would impede the rotational stiffness it is advised to use a different gear ratio for the rack spur mechanism. When the actuator is fully filled with water the stroke that has to be made by the syringe in order to bend the actuator is approximately 5mm. The same stroke can be made in the other direction to straighten the needle. Therefor only a stroke of 10mm is needed for the current device to be able to function. The stroke that the syringe is able to make in the current device is around 5cm therefore the gear ratio can be varied plenty to find a comfortable gear ratio for the user.

Large scale studies

Because the pilot study did not find any significant correlations due to the number of participants it is advised that a larger study is conducted for the final design. The large scale could either be obtained more participants or by interviewing experts over a longer period of time. In this way, significant correlations can be found between the different parameters of the test which would clarify which improvements would have to be made to the device. During these test a couple of improvements should be made on the test setup. Firstly, the joint surfaces should be made to have a lower friction coefficient since this would emulate the real situation better. Secondly, a more realistic insertion hole should be made with a piece of fake skin to emulate the difficulties this might impose on the insertion of the device, also multiple ports should be available for the participant to choose. These ports should be placed at the realistic conventional places with respect to the ankle joint. And Thirdly, the minimum noticeable distance that could be measured more precisely that during the pilot study that has been conducted. It was noticed that 11 out of the 15 participants were able to reach the spot within 1mm. This was also the minimum noticeable distance. In the new test setup, an electronic target could be used to seen how close the tip is to the centre of the target.

S-curve

Based on the answers from the participants and the other possible improvements to the device it is not advised to develop an actuator which can make an S-Curve. The main reasons for this is that while it might improve the ability of the device to reach certain points inside the joint it will also compromise simplicity of steering and degrade reliability. It could be reasoned that adding an S-curve feature would reduce the amount of inward and outward movements but this will be compensated by more bending actions. Moreover, the surgeon had the freedom of choosing insertion ports at all sides of the ankle so a downscaled 3mm actuator with 15mm bending radius might be able to reach all spots inside the ankle. An improved test with multiple ports on the test setup and a 3mm actuator should confirm this.

Material choice

From the materials test it was concluded that the Young's modulus cannot be directly related to the Shore hardness of a material. Although there is a strong correlation between the two properties. Therefore, it is advised to determine the material choice based on Young's modulus not shore hardness in further research. The participants of the pilot study indicated that a slightly harder material than NinjaFlex was preferable for a device of 5mm. It is recommended that high tech 3D

printing is used to print an improved version of the actuator in several materials using either FPE40 or SemiFlex as a baseline. 3D-printing provides a fast way to determine the approximate optimal material out of 3D-printing filament. For the final production granules can be used which give a broader spectrum of materials to choose from. Based on previous results from the 3D print the optimal material can then be selected.

Bibliography

1. Cuschieri, A. and G. Berci, *Laparoscopic biliary surgery.* Surgical Laparoscopy Endoscopy & Percutaneous Techniques, 1991. **1**(1): p. 58.
2. Kim, S., et al., *Increase in outpatient knee arthroscopy in the United States: a comparison of National Surveys of Ambulatory Surgery, 1996 and 2006.* J Bone Joint Surg Am, 2011. **93**(11): p. 994-1000.
3. Smith, G.D., G. Knutsen, and J.B. Richardson, *A clinical review of cartilage repair techniques.* J Bone Joint Surg Br, 2005. **87**(4): p. 445-9.
4. Alparslan, L., et al., *Postoperative Magnetic Resonance Imaging of Articular Cartilage Repair.* Semin Musculoskelet Radiol, 2001. **05**(04): p. 345-364.
5. Steadman, J.R., et al., *Microfracture technique forfull-thickness chondral defects: Technique and clinical results.* Operative Techniques in Orthopaedics, 1997. **7**(4): p. 300-304.
6. Guhl, J.F., *New concepts (distraction) in ankle arthroscopy.* Arthroscopy, 1988. **4**(3): p. 160-7.
7. Opdam, K.T.M., R. Zwiers, and C.N. van Dijk, *Anterior Ankle Arthroscopy: General Setup and Portal Options*, in *Arthroscopy: Basic to Advanced*, P. Randelli, et al., Editors. 2016, Springer Berlin Heidelberg: Berlin, Heidelberg. p. 955-963.
8. Dowdy, P.A., et al., *Noninvasive ankle distraction: relationship between force, magnitude of distraction, and nerve conduction abnormalities.* Arthroscopy, 1996. **12**(1): p. 64-9.
9. Medley, J., D. Dowson, and V. Wright, *Surface geometry of the human ankle joint.* Engineering in medicine, 1983. **12**(1): p. 35-41.
10. Magerkurth, O., et al., *Evaluation of hindfoot dimensions: a radiological study.* Foot & ankle international, 2006. **27**(8): p. 612-616.
11. Noyes, F.R. and C.L. Stabler, *A system for grading articular cartilage lesions at arthroscopy.* The American Journal of Sports Medicine, 1989. **17**(4): p. 505-513.
12. Choi, Y.S., H.G. Potter, and T.J. Chun, *MR Imaging of Cartilage Repair in the Knee and Ankle.* RadioGraphics, 2008. **28**(4): p. 1043-1059.
13. Miller, M.D. and B.J. Cole, *Atlas of chondral injury treatment.* Operative Techniques in Orthopaedics, 2001. **11**(2): p. 145-150.
14. Bert, J.M., *Abrasion arthroplasty.* Operative Techniques in Orthopaedics, 2001. **11**(2): p. 90-95.
15. Mithoefer, K., et al., *The Microfracture Technique for the Treatment of Articular Cartilage Lesions in the Knee.* A Prospective Cohort Study, 2005. **87**(9): p. 1911-1920.
16. Becher, C. and H. Thermann, *Results of microfracture in the treatment of articular cartilage defects of the talus.* Foot Ankle Int, 2005. **26**(8): p. 583-9.
17. Mithoefer, K., et al., *Clinical efficacy of the microfracture technique for articular cartilage repair in the knee: an evidence-based systematic analysis.* Am J Sports Med, 2009. **37**(10): p. 2053-63.
18. Hangody, L., et al., *Autologous osteochondral mosaicplasty. Surgical technique.* J Bone Joint Surg Am, 2004. **86-A Suppl 1**: p. 65-72.
19. Sirlin, C.B., et al., *Shell Osteochondral Allografts of the Knee: Comparison of MR Imaging Findings and Immunologic Responses.* Radiology, 2001. **219**(1): p. 35-43.
20. Williams, R.J., 3rd, et al., *Fresh stored allografts for the treatment of osteochondral defects of the knee.* J Bone Joint Surg Am, 2007. **89**(4): p. 718-26.
21. Brittberg, M., et al., *Treatment of deep cartilage defects in the knee with autologous chondrocyte transplantation.* New england journal of medicine, 1994. **331**(14): p. 889-895.

22. Erggelet, C., et al., *[Autologous chondrocyte transplantation for treatment of cartilage defects of the knee joint. Clinical results].* Zentralbl Chir, 2000. **125**(6): p. 516-22.
23. Peterson, L., et al., *Treatment of osteochondritis dissecans of the knee with autologous chondrocyte transplantation: results at two to ten years.* J Bone Joint Surg Am, 2003. **85-A Suppl 2**: p. 17-24.
24. Henderson, I., J. Gui, and P. Lavigne, *Autologous chondrocyte implantation: natural history of postimplantation periosteal hypertrophy and effects of repair-site debridement on outcome.* Arthroscopy, 2006. **22**(12): p. 1318-1324.e1.
25. Alparslan, L., T. Minas, and C.S. Winalski, *Magnetic resonance imaging of autologous chondrocyte implantation.* Semin Ultrasound CT MR, 2001. **22**(4): p. 341-51.
26. Henderson, I.J., et al., *Prospective clinical study of autologous chondrocyte implantation and correlation with MRI at three and 12 months.* J Bone Joint Surg Br, 2003. **85**(7): p. 1060-6.
27. Brown, W.E., et al., *Magnetic resonance imaging appearance of cartilage repair in the knee.* Clin Orthop Relat Res, 2004(422): p. 214-23.
28. Handl, M., et al., *[Autologous chondrocyte implantation in the treatment of cartilage lesions of ankle joint].* Acta Chir Orthop Traumatol Cech, 2007. **74**(1): p. 29-36.
29. Dargel, J., et al., *Side differences in the anatomy of human knee joints.* Knee Surgery, Sports Traumatology, Arthroscopy, 2009. **17**(11): p. 1368-1376.
30. Athanasiou, K., G. Niederauer, and R. Schenck Jr, *Biomechanical topography of human ankle cartilage.* Annals of biomedical engineering, 1995. **23**(5): p. 697-704.
31. Little, C.J., N.K. Bawolin, and X. Chen, *Mechanical properties of natural cartilage and tissue-engineered constructs.* Tissue Engineering Part B: Reviews, 2011. **17**(4): p. 213-227.
32. Kempson, G.E., *The mechanical properties of articular cartilage.* The joints and synovial fluid, 1980. **2**: p. 177-238.
33. Woo, S.L.Y., W.H. Akeson, and G.F. Jemmott, *Measurements of nonhomogeneous, directional mechanical properties of articular cartilage in tension.* Journal of Biomechanics, 1976. **9**(12): p. 785-791.
34. Asanbaeva, A., et al., *Articular cartilage tensile integrity: modulation by matrix depletion is maturation-dependent.* Archives of biochemistry and biophysics, 2008. **474**(1): p. 175-182.
35. *Ultimate tensile strength of materials.* 2016.
36. Hjelle, K., et al., *Articular cartilage defects in 1,000 knee arthroscopies.* Arthroscopy: The Journal of Arthroscopic & Related Surgery, 2002. **18**(7): p. 730-734.
37. Bauer, M. and R.W. Jackson, *Chondral lesions of the femoral condyles: A system of arthroscopic classification.* Arthroscopy: The Journal of Arthroscopic & Related Surgery, 1988. **4**(2): p. 97-102.
38. Polygerinos, P., et al., *Modeling of Soft Fiber-Reinforced Bending Actuators.* IEEE Transactions on Robotics, 2015. **31**(3): p. 778-789.
39. Bryan, N.P., et al., *3D printing antagonistic systems of artificial muscle using projection stereolithography.* Bioinspiration & Biomimetics, 2015. **10**(5): p. 055003.
40. Ilon, B., *Directionally stable self propelled vehicle*. 1973, Google Patents.
41. Osiński, D. and K. Szykiedans, *Small remotely operated screw-propelled vehicle*, in *Progress in Automation, Robotics and Measuring Techniques*. 2015, Springer. p. 191-200.
42. Seto, T. and K. Takagi, *Pump-integrated flexible actuator*. 2004, Google Patents.
43. Kerekes, L. and T. Moor, *Pneumatic actuator*. 2008, Google Patents.
44. GALLOWAY, K.C., R. KNOPF, and J.A. LESSING, *Rigidized inflatable structures*. 2015, Google Patents.
45. LESSING, J.A., R.R. KNOPF, and N. Mclellan, *Soft robotic actuators utilizing asymmetric surfaces*. 2015, Google Patents.
46. VAUSE, C.E., J.A. LESSING, and R.R. KNOPF, *Soft conformal laparoscopic instrument*. 2015, Google Patents.

47. LESSING, J.A., et al., *Flexible and stretchable electronic strain-limited layer for soft actuators*. 2016, Google Patents.
48. Ilievski, F., et al., *Soft robotic actuators*. 2014, Google Patents.
49. Ragner, G.D., *Flexible hydraulic muscle*. 2009, Google Patents.
50. Loeve, A.J., *Shaft-guidance for Flexible Endoscopes*. 2012.
51. Galloway, K.C., et al., *Soft Robotic Grippers for Biological Sampling on Deep Reefs.* Soft Robotics, 2016. **3**(1): p. 23-33.
52. Wakimoto, S., et al. *Miniature soft hand with curling rubber pneumatic actuators*. in *2009 IEEE International Conference on Robotics and Automation*. 2009.
53. Udupa, G., et al., *Asymmetric Bellow Flexible Pneumatic Actuator for Miniature Robotic Soft Gripper.* Journal of Robotics, 2014. **2014**: p. 11.
54. Rehman, T., et al., *Design and analysis of bending motion in single and dual chamber bellows structured soft actuators.* Jurnal Teknologi, 2016. **78**((6-13)): p. 17-23.
55. Suzumori, K., et al. *A Bending Pneumatic Rubber Actuator Realizing Soft-bodied Manta Swimming Robot*. in *Proceedings 2007 IEEE International Conference on Robotics and Automation*. 2007.
56. Nuffic, *Grading systems in the Netherlands, the United States and the United Kingdom.* 2011.
57. Carifio, J. and R.J. Perla, *Ten common misunderstandings, misconceptions, persistent myths and urban legends about Likert scales and Likert response formats and their antidotes.* Journal of Social Sciences, 2007. **3**(3): p. 106-116.
58. Lubke, G.H. and B.O. Muthén, *Applying multigroup confirmatory factor models for continuous outcomes to Likert scale data complicates meaningful group comparisons.* Structural Equation Modeling, 2004. **11**(4): p. 514-534.

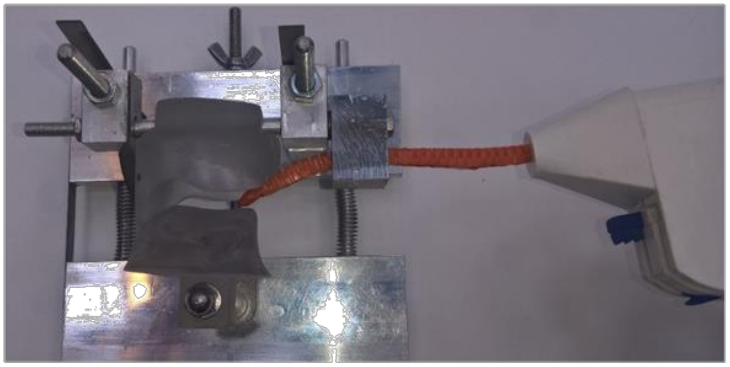
Appendix A

Questionnaire used during pilot study

Procedure

Insertion

The first step is inserting the needle into the joint. The starting point is the hole in steel block on the right of the setup. The needle has to be maneuvered through this hole into the joint.

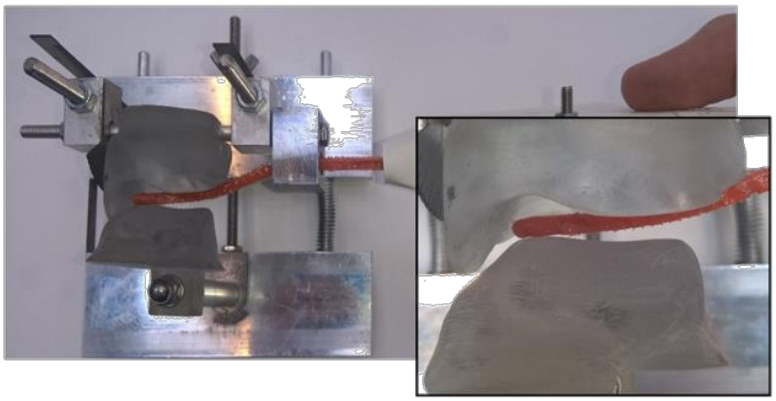


Axial navigation into the joint

Next the needle has to be inserted to the right depth into the joint. Once this depth has been reached the device can be rotated as shown in the next step.

Turning the Needle 90°

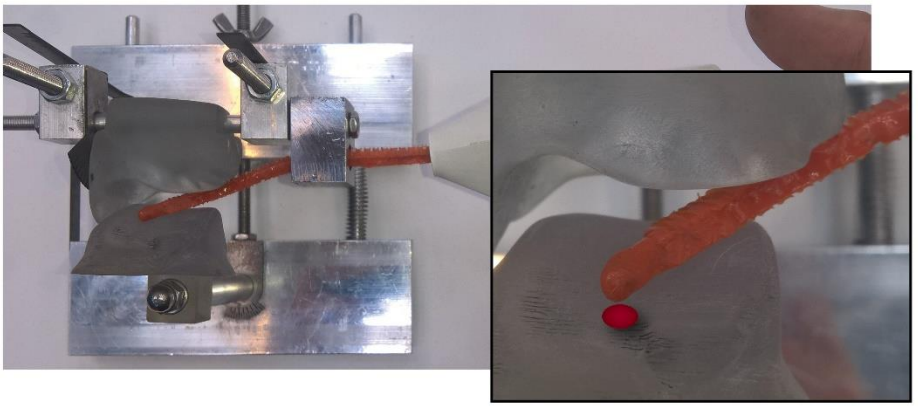
The third step is rotating the needle 90° whilst being inside the joint. This is so that in-plane lateral navigation of the needle becomes possible.



This procedure continues on the other side of this paper
Please, turn over!

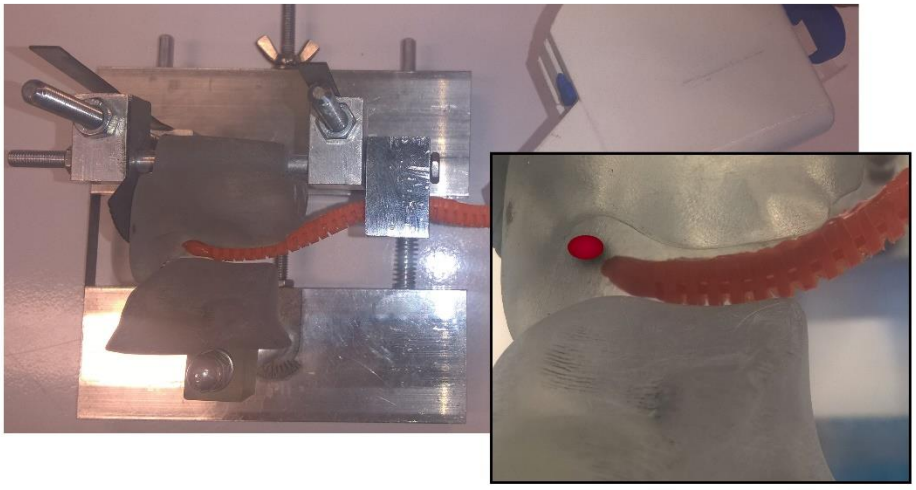
Lateral navigation to point #1

The fourth step is reaching the first target with the tip of the needle. In order to do this the needle can be actuated in either direction and moved back and forth in axial direction.



Turning the Needle + Lateral navigation to point #2

The last step is reaching the second target with the tip of the needle. In order to do this the needle can rotated and actuated in any direction and moved back and forth in axial direction.



This is the end of the procedure.

Questionaire Flexible Steerable Needle

Juli 2017

TU Delft

This research is conducted by the Delft University of Technology. We are researching the user experience of this recently developed medical instrument to be able to improve it in the nearby future. **This survey will take you 10 to 15 minutes to complete.** Thanks is advance!

Insertion

The next few questions will be regarding the navigation of the needle during insertion into the ankle joint setup. Please limit your answers to this part of the procedure.

How well did the instrument perform during insertion?

1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○

Are there any extra comments on the instrument with regards to insertion?

What could be (a) possible improvement(s) to the instrument with regards to insertion?

Axial navigation into the joint

The next few questions will be regarding the axial navigation of the needle into the joint. Please limit your answers to this part of the procedure.

How well did the instrument perform during axial navigation into the joint?

1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9 ○ 10 ○

Are there any extra comments on the instrument with regards to axial navigation into the joint?

What could be (a) possible improvement(s) to the instrument with regards to axial navigation into the joint?

This survey continues on the other side of this paper
Please, turn over!

Lateral navigation to point #1

The next few questions will be regarding the lateral navigation of the needle to point #1 inside the ankle joint setup. Please limit your answers to this part of the procedure.

How well did the instrument perform during lateral navigation to point #1?

1 2 3 4 5 6 7 8 9 10

	Very Easy	Easy	Medium	Hard	Very Hard
How easy was it to turn the needle successfully 90°?	○	○	○	○	○
How easy was it to bend the needle using the blue handle?	○	○	○	○	○

Are there any extra comments on the instrument with regards to lateral navigation to point #1?

What could be (a) possible improvement(s) to the instrument with regards to lateral navigation to point #1?

Lateral navigation to point #2

The next few questions will be regarding the navigation of the needle to point #2 inside the ankle joint setup. Please limit your answers to this part of the procedure.

How well did the instrument perform during navigation to point #2?

1 2 3 4 5 6 7 8 9 10

	Very Easy	Easy	Medium	Hard	Very Hard
How easy was it to turn the needle successfully?	○	○	○	○	○
How easy was it to bend the needle using the blue handle?	○	○	○	○	○

Are there any extra comments on the instrument with regards to navigation to point #2?

What could be (a) possible improvement(s) to the instrument with regards to navigation to point #2?

This survey continues on the other side of this paper
Please, turn over!

Possible improvements

A possibility for extra operability is to divide the needle into two individually actuatable segments so the needle is able to make an S-curve. This will require extra motor skills but also gives more steering options.

To what extent do you agree with the following statements?:

	Agree	Slightly agree	Neutral	Slightly disagree	Disagree
Making an S-curve with the needle is necessary to be able to reach difficult spots inside the ankle.	◯	◯	◯	◯	◯
Requiring two hands to operate the instrument would make it a lot harder to use.	◯	◯	◯	◯	◯
The above explained added S-curve feature would improve the overall performance of the device.	◯	◯	◯	◯	◯

Added comments on adding the S-curve feature:

For the production of this device harder or softer plastics could be used. Softer plastics are more flexible so the needle will buckle more easily but will also be able to make tighter curves. For harder plastics the opposite is true.

	Very Poor	Poor	Neutral	Good	Very Good
How would you rate the current actuation effort of the instrument (hand power needed during the procedure).	◯	◯	◯	◯	◯
How would you rate the current actuation force of the needle (ease of bending the needle).	◯	◯	◯	◯	◯
How would you rate the current steering angle (minimum bending radius) of the needle.	◯	◯	◯	◯	◯
	Harder	A little harder	Same	A little softer	Softer
Do you think harder/softer plastic would be better?	◯	◯	◯	◯	◯

Added comments on harder/softer plastic for the production of the needle

This is the end of the survey.
Thank you very much!

Questionaire Flexible Steerable Needle

Observation form

Insertion

How often did buckling occur?		
Pressurizations		
De-pressurizations		
Amount of rotations	Clockwise	Counter-clockwise
Axial movements	In	Out

Axial navigation into the joint

How often did buckling occur?		
Pressurizations		
De-pressurizations		
Amount of rotations	Clockwise	Counter-clockwise
Axial movements	In	Out

Lateral navigation to point #1

How often did buckling occur?		
Pressurizations		
De-pressurizations		
Amount of rotations	Clockwise	Counter-clockwise
Axial movements	In	Out
Spot reached within:	mm	

Lateral navigation to point #2

How often did buckling occur?		
Pressurizations		
De-pressurizations		
Amount of rotations	Clockwise	Counter-clockwise
Axial movements	In	Out
Spot reached within:	mm	

Appendix B

Results of the pilot study

Parameter/Subject#	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	Mean	STD
Interview																	
Ins. performance	10	8	6	8	8	8	9	8	8	9	9	9	8	7	10	8.3	1
Ax. Nav. performance	10	7	4	7	7	8	7	6	8	9	7	9	7	7	8	7.4	1.4
Nav. #1 performance	8	6	4	3	8	7	7	7	8	8	7	7	6	8	6	6.7	1.4
Nav. #2 performance	10	8	7	6	6	9	8	7	6	7	5	6	3	7	7	6.8	1.6
S-curve necessary (agree-disagree)	2	2	1	2	1	2	4	4	1	4	2	4	2	2	2	2.3	1.1
Two-handed difficult (agree-disagree)	1	5	4	1	4	2	1	2	2	4	4	3	4	1	1	2.6	1.4
S-curve improv. perf. (agree-disagree)	2	3	1	2	1	2	4	3	2	1	1	4	4	2	2	2.3	1.1
#1 - Turning (V. Easy - V.Hard)	2	3	3	3	3	2	3	2	2	2	4	2	3	2	2	2.5	0.6
#1 - Bending (V. Easy - V.Hard)	1	2	4	3	2	2	2	2	3	2	2	3	4	3	4	2.6	0.9
#2 - Turning (V. Easy - V.Hard)	3	2	2	3	3	2	3	3	4	3	4	3	4	2	2	2.9	0.7
#2 - Bending (V. Easy - V.Hard)	1	2	2	2	3	2	2	4	3	3	4	3	4	3	2	2.7	0.9
Actuation effort (V. Poor - V. Good)	4	4	3	3	4	5	4	4	2	4	2	1	3	4	2	3.3	1.1
Actuation force (V. Poor - V. Good)	4	4	4	2	2	4	4	3	3	3	4	4	2	4	4	3.4	0.8
Bending radius (V. Poor - V. Good)	3	5	4	2	4	4	3	4	4	4	3	4	2	3	3	3.5	0.8
Harder/softer plastic (Harder-Softer)	2	2	4	3	2	2	2	3	2	3	4	3	3	4	2	2.7	0.8
Observation																	
Insertion - buckling	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0.1	0.5
Insertion - bending	1	1	0	1	1	1	1	1	1	0	1	1	0	2	1	0.9	0.5

Insertion - straightening	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Insertion - axial-movement-in	1	2	1	2	3	2	2	1	1	2	1	1	1	3	1	1.6	0.7
Insertion - axial-movement-out	0	0	0	1	2	0	0	0	0	0	0	0	0	1	0	0.3	0.6
Turn - Clockwise	0	1	0	0	0	0	1	0	0	0	0	0	0	0	0	0.1	0.3
Turn - Counter-clockwise	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0.1	0.2

Axial navigation - buckling	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Axial navigation - bending	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0.2	0.5
Axial navigation - straightening	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Axial navigation - axial-movement-in	1	1	1	2	0	1	1	2	3	1	1	1	1	1	1	1.2	0.7
Axial navigation - axial-movement-out	0	0	0	1	0	0	0	1	1	0	0	0	0	0	0	0.2	0.4
Turn - Clockwise	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0.1	0.5
Turn - Counter-clockwise	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0.1	0.2

Navigation #1 - buckling	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Navigation #1 - bending	1	3	3	2	4	1	5	3	2	1	5	1	1	2	2	2.4	1.4
Navigation #1 - straightening	0	0	0	0	3	2	0	1	0	0	0	0	0	1	0	0.5	0.9
Navigation #1 - axial-movement-in	4	2	2	2	16	7	7	7	6	2	9	2	2	3	2	4.9	3.8
Navigation #1 - axial-movement-out	4	2	0	2	15	6	7	2	5	2	8	2	3	3	0	4.1	3.7
Navigation #1 – spot reached	1	1	2	3	1	1	1	1	1	1	1	1	3	1	3	1.5	0.8
Turn - Clockwise	1	3	1	2	4	3	7	1	6	1	7	1	1	0	1	2.6	2.3
Turn - Counter-clockwise	0	2	1	2	5	2	7	1	6	0	8	1	1	2	1	2.6	2.5
Total actions	10	12	7	10	47	21	33	15	25	6	37	7	8	11	6	17	12.4

Navigation #2 - buckling	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Navigation #2 - bending	1	2	2	1	1	2	2	3	1	3	2	4	1	1	3	1.9	0.9
Navigation #2 - straightening	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0.1	0.3

Navigation #2 - axial-movement-in	4	8	4	6	4	7	6	9	12	8	12	12	3	4	3	6.8	3.2
Navigation #2 - axial-movement-out	5	8	2	4	4	5	5	7	9	8	10	12	3	5	2	5.9	2.9
Navigation #2 – spot reached	1	1	1	4	1	1	1	1	3	1	1	1	3	1	1	1.5	1
Turn - Clockwise	2	1	1	2	2	0	3	0	3	2	3	5	0	1	0	1.7	1.4
Turn - Counter-clockwise	1	3	1	2	1	2	3	3	2	3	2	2	1	0	4	2	1
Total actions	13	22	10	15	12	16	19	23	27	24	29	35	8	11	13	18.5	7.6