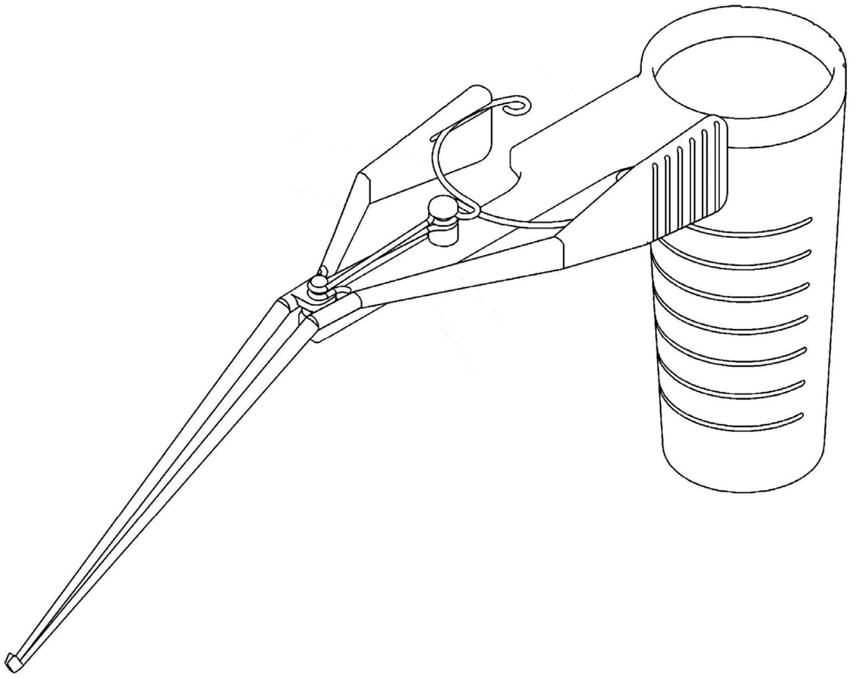
# Minimally Invasive Nerve Dissector

Design of an Instrument for Sural Nerve Harvesting in Infants



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# Minimally Invasive Nerve Dissector

## Design of an Instrument for Sural Nerve Harvesting in Infants

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**Abstract— The current method of minimally invasive harvesting the sural nerve in infants takes too much time. To reduce harvesting time a new Minimally Invasive Nerve Dissector (MIND) was designed. The MIND reduces instrument change by combining the two most used functions of the currently used instruments: firstly, the movement of the graft with the hook and secondly, the outwards motion of the micro scissors. Besides these two functions, the MIND was designed for a minimally invasive procedure and is much smaller than the current instruments. The MIND was evaluated on an artificial test facility simulating a leg of an infant. Using the test facility a test comparing the current instruments and the MIND was carried out. Measured were the time to harvest and the number of dissection instrument changes. The results of the test showed that both showed positive improvements with the MIND.**

## I. Introduction

### *A. Sural Nerve Harvesting*

For nerve transplantation the sural nerve is the most used graft. Its course is just underneath the skin on the back side of the lower leg (the calf, Figure 1). The current method of harvesting in the Leiden University Medical Center (LUMC) [1] is harvesting by a minimally invasive method (Figure 2 left). With this method three incisions are made and the sural nerve is harvested under endoscopic vision. The nerve is dissected from connective tissue with a small hook and micro scissors (Figure 2 right). A nose speculum is used to create and maintain a workspace. When the nerve is out of the body, the nerve is cleaned by removing the remaining pieces of connective tissue. The sural nerve cannot be cut before it is completely dissected from connective tissue and side branches. This is to maintain its natural tension and continuity and facilitates predicting the course of the undissected nerve inside the connective tissue.

### *B. Problems with Sural Nerve Harvesting*

The major problem with the current method of sural nerve harvesting in infants is that it takes too much time to harvest a high quality graft. It takes in total on average 103 minutes to harvest a sural nerve (n=10) with a 69 minutes time span from creating the first incision to the removal of the nerve from the body (Appendix 1). With a total operating time of 6 to 8 hours, the anaesthetic load on an infant of three months old is very high and needs to be reduced wherever possible. Because of the long harvesting time with a minimally invasive method, surgeons choose to harvest in an invasive way, resulting in large scars (Figure 1 right) and a large chance of wound healing complications.

First of all, harvesting the sural nerve takes so much time because detailed data about the effect of damage of the harvested nerve to the functioning of the nerve after the transplantation is not available. As a result, surgeons harvest as carefully as possible to avoid any nerve damage [2]. Secondly

**Figure 1. Left: drawing of the sural nerve on the back side of the lower leg, with two origins and several side branches. Right: The scar marks the course of the sural nerve that is harvested with an invasive method [1].**

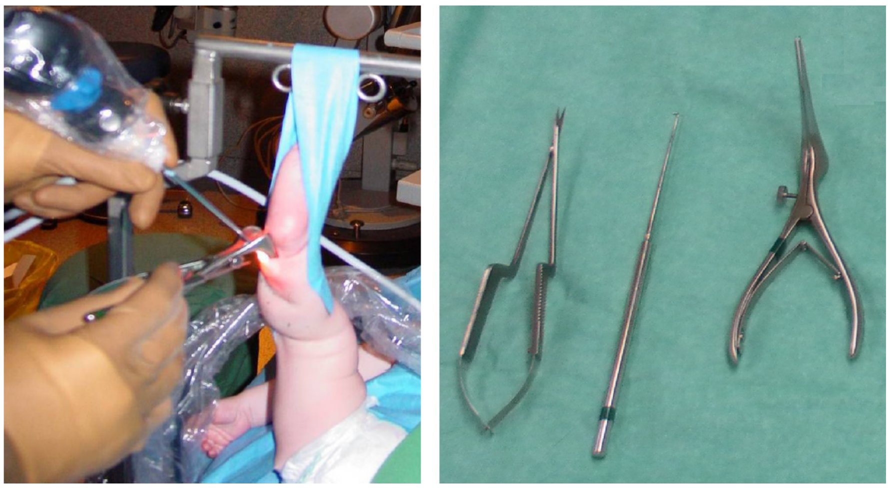

**Figure 2. Left: Current harvesting method with in the left hand the endoscope and a camera wrapped in plastic and in the right hand the hook. The leg of the infant is positioned upside-down with a nose speculum in the ankle incision [1]. Right: Current instruments used for sural nerve harvesting, with at the left the micro scissors, in the middle the hook and at the right the nose speculum.**

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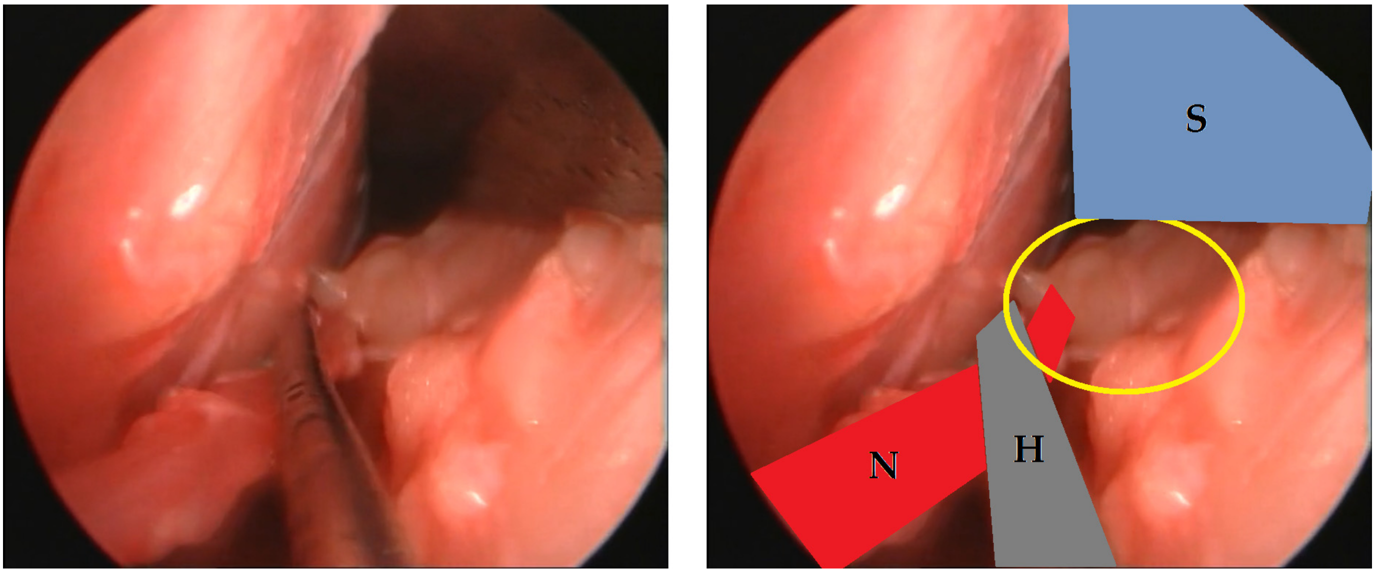


**Figure 3. Endoscopic view during a sural nerve harvesting with schematic visualisation of the different objects in the image at the right. N is the nerve, H is the hook, and S is the speculum to maintain a workspace. The yellow circle shows an attachment of connective tissue to the nerve. The top left corner shows the calf muscle and the bottom right corner shows the inner part of the skin.**

with the current visualisation methods the exact course of the undissected nerve is unknown and can only be predicted over a very short distance by extending the already dissected part. These two issues lead to very precise and elaborate dissection, with very small dissection steps and a lot of instrument actions to dissect the nerve. The third issue is that the currently used instruments have not been designed for sural nerve harvesting and are therefore not optimized for the task. This results in even more instrument actions. This project focuses on the third issue, the lack of specialised instrumentation.

### *C. Goal of this Project*

Goal of this project is to reduce the harvesting time for minimally invasive sural nerve harvesting in infants by developing and evaluating a new custom-made instrument that reduces the number of instrument actions and allows to make larger dissection steps. The instrument needs to be suitable for clinical approval.

### *D. Layout of this Paper*

The structure of this paper is as follows: Chapter 2 provides a problem analysis of why the current harvesting method with conventional instruments takes so much time. Chapter 3 discusses the design pathway of a new harvesting instrument. Chapter 4 describes the evaluation of the new harvesting instrument on a test facility. Chapter 5 contains the discussion which presents improvements and a direction for future work, and Chapter 6 gives the conclusion.

## II. Problem Analysis

### *A. Current Dissection Instruments*

#### *1) Faulty function division of current instruments*

A sural nerve is composed of the main branch, required for the nerve transplantation procedure, and several side branches. During the harvesting procedure the main branch needs to be dissected from connective tissue (Figure 3) and the side branches. To avoid damage of the main branch, the side branches must be cut sharply instead of being ripped off bluntly. The cutting is currently done with micro scissors (Figure 2 right). With the current method of dissection the surgeon uses opening (blunt dissection) and closing / cutting (sharp dissection) of the micro scissors. Besides the micro scissors, a small hook is used to displace the graft for a clear visualisation of the surroundings and for blunt dissection of weak connective tissue and nerve attachments. To avoid accidental cutting of the nerve, the surgeon primarily uses the blunt dissection option from the micro scissors and the hook.

The drawback of using the micro scissors and the hook is that the surgeon has to operate two instruments with one hand, because he holds the endoscope in his other hand. This results in frequent instrument changes or in the surgeon choosing not to change instruments and instead to use a suboptimal tool. An initial solution could be to use an endoscope holder or an assistant holding the endoscope so that the surgeon can use both hands for the scissors and the hook. However, reducing instrument actions by working with two instruments is then negated by having to instruct the assistant or adjusting the endoscope holder. Besides, special actions are required to work around an assistant or endoscope holder because the space around an infant's leg is limited. A second solution would be to attach the hook to the endoscope itself. This would, however, result in a permanent rod in the field of view, which reduces the visibility and stability of the image. Besides the reduced visualisation, the graft often needs to be displaced in the opposite direction of the endoscope, which is not possible with a hook attached to the endoscope.

As endoscope holders and endoscopes with hooks do not offer a useful solution to reduce harvesting time, it was decided in this project to develop a new type of one-handed instrument, combining the weak blunt dissection and graft displacement function of the hook and the blunt dissection function of the micro scissors. It was decided not to add a sharp dissection function to prevent accidental damage to the nerve.

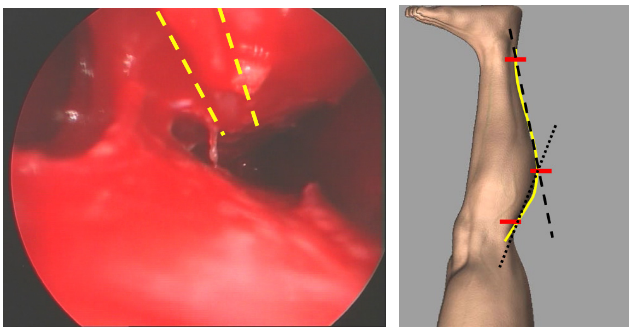

**Figure 4. Curved path of the sural nerve. Left: The sural nerve (between yellow dotted lines) stays in contact with the calf muscle, making it difficult to see. Also the nerve disappears into the deep behind the curve. Right: To overcome the curvature of the calf a second (middle) incision is made. With in red the incisions, in yellow the course of the sural nerve and the black lines are the lines of sight.**

*2) Open surgery instrument for minimally invasive procedure*

Besides the faulty function division another drawback of the current instruments is that the micro scissors have been designed for cutting during open procedures. For this purpose the pivoting point is mounted close to the tip (Figure 2 right). With the minimally invasive sural harvesting procedure the location of the pivoting point results in a large opening width at the handle / backside of the instrument. This interferes with the edges of the nose speculum and the endoscope, reducing the efficiency of the harvesting procedure. Also, because cutting is the intended use of the micro scissors, the width of the tip when opened for blunt dissection is not sufficiently large for a good dissection step.

To solve these drawbacks, the maximum opening width behind the pivoting point, at the handle of the instrument, must be limited and the opening width inside the dissection area must be increased. Discussions with two neurosurgeons at the LUMC [3] showed that they prefer a minimum opening width of the tip of 15 mm, whereas the current opening width of the used micro scissors is 7,5 mm. The neurosurgeons also commented that the opening width behind the pivot point inside the incision must not exceed 10 mm. Currently, when the tip of the used micro scissors is fully opened, the backside of the scissors opens over a distance of 15 mm.

*3) Straight instruments for a curved path*

The sural nerve runs on the back of the lower leg between the skin and calf muscle. As the calf muscle is curved, at a certain moment during the procedure the sural nerve is no longer visible because it is obstructed by the muscle (Figure 4 left). The current solution is to make a second incision at the top of the curved calf to be able to see the remaining part of the nerve (Figure 4 right). This second incision increases the damage to the patient and leads to additional instrument actions to make the incision, find the nerve and to suture the incision at the end of the procedure. Another issue with the curved calf is that the nerve remains in contact with the curved muscle even after dissection. This makes it difficult to confirm whether the nerve is fully dissected or not. To be sure whether the nerve is entirely dissected, the surgeon moves the nerve with the hook (Figure 5).

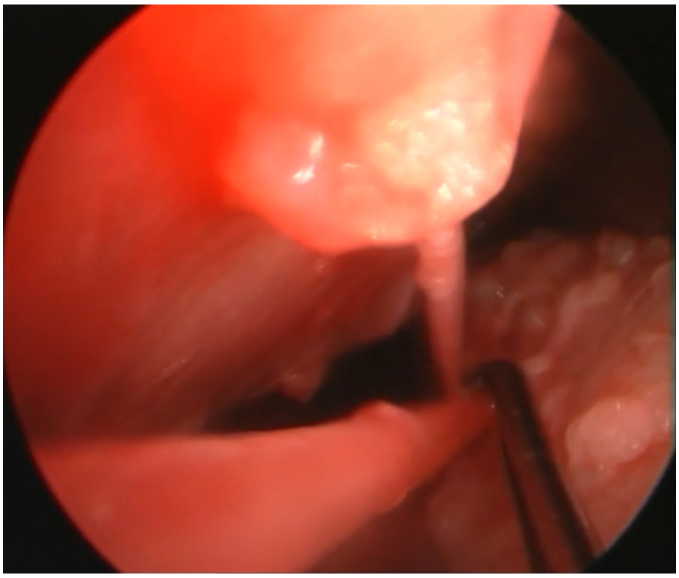

**Figure 5. With the hook (bottom right) the sural nerve is pulled away (to the bottom of the figure) from the curved muscle (top left of the figure) to visualize possible connective tissue attachments and side branches, in this figure a side branch is still present (vertical line structure in the centre of the figure).**

A solution to skip the second incision could be to use steerable instruments to work around the curve. However the nerve will then still remain in contact with the muscle. The solution for both issues would be to add a function to the new instrument which flattens the muscle. When the muscle is flattened the curve of the calf muscle is no longer present, so that the second incision is no longer needed and the nerve is not in contact with the muscle. Therefore flattening the muscle is the preferred solution for the curved path, the instead of using steerable instruments.

## B. Ideal dissection method

*1) Location of dissection*

Figure 6 shows three possible locations to separate a nerve from its connective tissue: (1) between layers of nerve tissue, (2) within the connective tissue, (3) between the nerve tissue and the connective tissue. Separation between layers of nerve tissue (1) is not an option during sural nerve transplantation because every layer of a nerve is important to its function. Therefore removing a layer results in a severely damaged nerve, which harms the outcome of the entire nerve transplantation procedure. Separation within the connective tissue (2) is not the preferred location either, because with connective tissue still attached, the nerve becomes less visible making it more difficult to predict its course. This increases the risk of damaging the graft or the number of instrument actions required to prevent this damage. The third option is separation between the transition of the nerve and connective tissue (3). Because this connection is in most patients the weakest it will automatically separate with minimal nerve damage when a pulling force is applied to it. Therefore, separation at the transition is the preferred location of dissection. Another advantage of dissecting at the transition is that less tissue is removed from the body, making it less traumatic for the

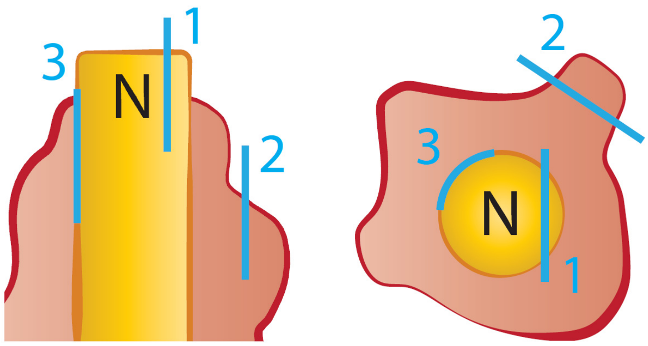


**Figure 6. Three possible locations for sural nerve dissection, with N: Nerve, CT: connective tissue, 1: between layers of nerve tissue, 2: within the connective tissue and 3: between the transition of the nerve and connective tissue. Left: Side view. Right: Top view.**

patient. A clean nerve is also easier to see and to follow and reduces the cleaning actions after removal from the body. Side branches are still cut with scissors to prevent damage to the main branch.

*2) Point, line or circle dissection*

Having chosen for separation at the transition, three dissection methods remain: point dissection, line dissection and circle dissection (Figure 7). Point dissection is separating the tissue at one point at a time. This method is currently applied when opening the micro scissors. Line and circle dissection is separating the tissue at several points along a line, where with circle dissection this line forms a circle around the entire nerve. In general, line and circle dissection are faster than local dissection because more tissue can be dissected at the same time. Generally, circle dissection is faster than line dissection because with a circle dissection shape the entire circumference of the nerve can be dissected with one action, instead of several actions with line dissection. Another benefit of circle dissection is that positioning the instrument is easier. Because with the instrument closely around the nerve, the flexible nerve moves along with the instrument. With this principle, the surgeon only needs to focus on the axial direction of the instrument, which benefits the speed of dissecting.

*3) Direction of dissection*

Separating tissues can be done in three directions (Figure 7 E)). To avoid damage of the nerve it is best to avoid manipulating the nerve to create grip, therefore attaching something to the nerve is not desired. Because of the cylindrical and continuous structure of a nerve it is not possible to directly apply an axial and tangential force on the nerve without attaching something to the nerve. The only force that can be applied directly is a normal pushing force in the radial direction. With friction resulting from this normal force, tangential and axial forces can be generated. However, nerve tissue is slippery resulting in a very low friction coefficient and therefore a high normal force is required. This high force can potentially lead to nerve damage. Therefore the radial direction is the preferred direction of dissection.

*4) One or two sided dissection*

Blunt dissection is separating tissue by tearing. Tearing tissue can only be done if at least two opposite outwardly directed forces are applied to the tissue layers. In the case of nerve harvesting, radially directed outward forces are preferred for dissection, as concluded in Section 3) above. When applying a radial pulling force at only one side to a nerve, for example with a hook, the tissue will just move instead of separating from the nerve. Therefore a counterforce is needed. This counterforce can either result from the elastic deformation of the surrounding tissue and its attachments or from the instrument itself, for example by putting the two jaws of the micro scissors between nerve and connective tissue and by opening the jaws to. Because the connective tissue and nerve tissue are highly flexible, quite a lot of displacement is needed before the tissue generates enough reaction force for separation. In the limited available workspace this displacement is too large to separate the tissue properly. Therefore a counterforce from the instrument itself is needed. To introduce such a counterforce, the instrument needs to have a second side just like the two jaws of the micro scissors.

## *C. Design Requirements*

From the problem analysis above a list of design requirements can be derived:

1. One handed instrument.
2. Combination of the two most used functions: the blunt dissection function of the micro scissors and the movement function of the hook.
3. Outer diameter of the tip when opened: 15 mm.
4. Maximum width behind the pivot point inside the incision: 10 mm.
5. Incorporates a component for calf muscle-flattening.
6. Uses blunt dissection at the transition between the nerve tissue and connective tissue.
7. The tip has an circular dissection shape.
8. Dissection forces are in the radial direction.
9. Introducing a counterforce with a two-sided tip.

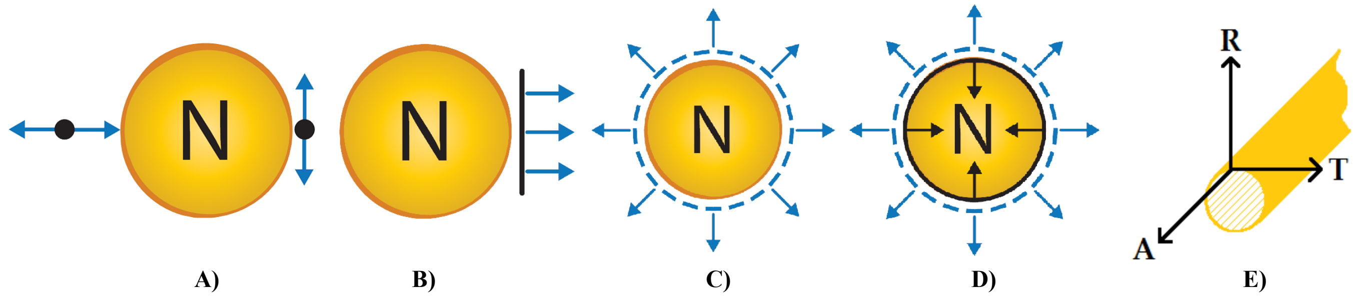


**Figure 7. Methods of dissection between sural nerve and connective tissue, with N representing the nerve; A) point dissection, visualized in two directions; B) line dissection; C) one-sided circle dissection; D) two-sided circle dissection; and E) direction of dissection in relation to the yellow nerve: A=Axial, R=Radial, and T=Tangential.**

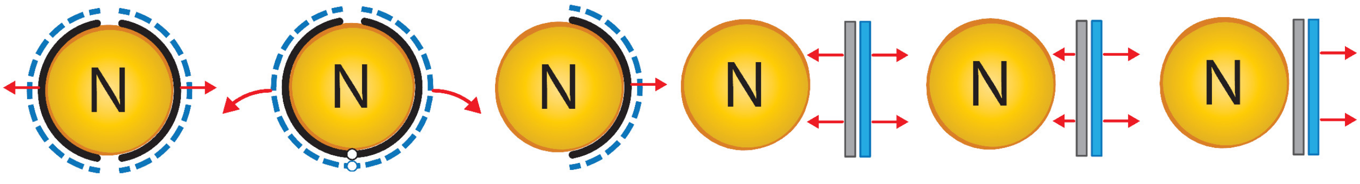


**Figure 8. Simplified tip design. The red arrows represent the direction of motion. A) A nerve cannot be cut before dissecting, the tip can get around the nerve by having two parts that can translate. B) Another possibility to get around the nerve with a rotating, unfolding tip design. C) Simplified tip design by dissecting only half a circle. D) Further tip simplification by using line dissection instead of half a circle. E) Decoupled line dissection. F) Decoupled line dissection with only one side moving while the other side remains stationary.**

The second part of the goal of this project is to come up with a design suitable for clinical approval. That is a first step in the process of using the instrument in an operating room. This means that the instrument can be cleaned and sterilized properly. For an instrument suited for sterilization small places should be avoided where tissue and body fluids can accumulate in such a way that disinfectant solution and steam cannot remove them. Steam sterilisation involves a temperature of 134°, this limits material usages.

## III. Development of the Minimally Invasive Nerve Dissector (MIND)

### *A. From Design Requirements to Concept Design*

#### *1) Simplified tip design*

The focus of this project is to develop a Minimally Invasive Nerve Dissector (MIND) that is suitable for clinical approval. Designing a one-handed instrument that combines the blunt dissection function of the micro scissors and the movement function of the hook provides sufficient challenges for the time span of this project. It was therefore decided to move Design Requirement 5 (component for muscle-flattening) to future work.

As mentioned in Section I.A the sural nerve can only be cut after dissection, therefore the circle dissection method needs an opening ability so that it can be placed around the nerve (Figure 8 A) or B)). Adding this opening function will result in a complex design because it still needs to be controlled by one hand and be sterilizable, while maintaining a proper dissection function. Therefore the requirements were simplified by moving from a complete circle to half a circle (Figure 8 C)). The other side of the nerve is then dissected with the same instrument rotated over 180°. However, with the small amount of space available in and near an infants leg it is not easy to rotate the entire instrument over half a circle. For this reason, it was finally decided to discard around dissection completely and use line dissection instead (Figure 8 D)). In order to dissect the entire circumference of the nerve the surgeon first dissects the left and right side with a small translation and then rotates over only 90° to dissect the top and bottom.

In the case that the connective tissue attachment to the nerve is weak but wrapped around the nerve, the surgeon has the option to put the nerve in the middle of the two-sided tip and open the two sides simultaneously to separate the connective tissue from itself. If the connective tissue has a appears to have a strong connection to the nerve, only one side of the nerve is dissected while the other side is still attached to the instrument.

#### *2) Controlling the tip motion*

There are two design possibilities to move the two-sided tip: coupled motion or decoupled motion. A coupled motion is currently applied in a standard laparoscopic grasping forceps, meaning that one control action results in an identical movement of both jaws (Figure 8 D)). A decoupled motion means that each side can be moved individually (Figure 8 E)). Decoupled motion could be very useful in the MIND as it reduces the change of damage to the nerve by allowing the surgeon to use only one-sided motion of the connective tissue (Figure 8 F)). It was therefore decided to design the MIND in a way that the surgeon uses two fingers independently to control the two sides of the tip. Following the intuition of the pincer grip, it was decided to select the thumb and index finger for control of the two-sided tip.

As the primary function of the MIND's handle is to open the tip for separation, as opposed to a conventional pincers in which the primary function is to close the tip for grasping, it was decided to design a pivoting point between handle and tip so that the surgeon can use the closing motion between his thumb and index-finger to open the tip. To maintain a small width of the instrument inside the incision and having one pivot point is to move the pivot point outside the incision. This results in two thin rods that are inserted into the incision and move outwards in a radial direction when the surgeon closes his hands.

#### *3) Handgrip design*

The instrument has two individual controlled sides, when the surgeons wants to dissect with one side it creates a reaction force on the stationary side. The method to neutralize this reaction force that is used with current instruments, like scissors, is done by adding one or several fingers to the side that is controlled by the index or middle finger. If the stationary rod is required on the other (thumb) side, the surgeon rotates his arm 180°. During nerve harvesting rotating the instrument is difficult because of the limited space inside and outside the incision. The solution to divert the reaction forces from both sides to the other fingers is to add a pistol grip to the instrument that is held between the three remaining fingers and the palm of the hand.

After opening the instrument there should also be a possibility to close the two-sided tip. This can be done actively, in which case the surgeon spreads his fingers, or passively with a spring mechanism. For active closing the rods could be

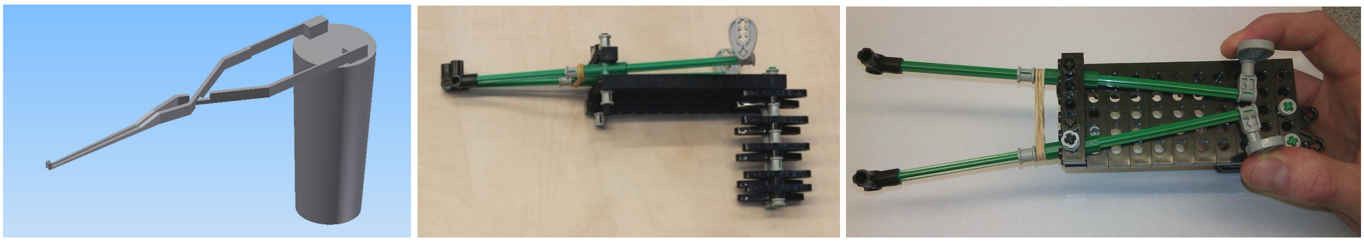

**Figure 9. Left: Elastic deformation prototype with the joint behind the surgeons fingers. Middle: Inspiration model made from Lego. Right: Motion function of the Lego model.**

equipped with rings through which the thumb and index finger are inserted to enable transfer of forces in both directions from these fingers to the tip. To be able to move the fingers easily in and out of these rings a little play is needed. This play, however, is unwanted as it reduces the dissection accuracy. Therefore it is better to use a passive spring mechanism which returns the rods into the rest position when the thumb and index finger are moved away from each other. Another advantage of the spring mechanism is that when the instrument is not in use the rods are always closed, which makes it easy to safely insert or withdraw the instrument from the incision.

There are two basic methods of creating a joint in surgical instruments: by an axis such as used in scissors or by an elastic joint as used in tweezers. If an elastic joint is placed behind the surgeons thumb / index finger as with tweezers (Figure 9 left), the rods become very long resulting in an unwanted elastic behaviour of the instrument when separating the tissue. Therefore the joint must be placed between the surgeons fingers and the tip. Designing an elastic joint that is small, durable, reliable and has the right elastic properties is complex. Therefore it was chosen to work with a simple axis. Figure 9 middle and right show a Lego model of the MIND concept incorporating the above mentioned design choices for real time feeling and demonstration to surgeons.

### *B. From Concept Design to Prototype*

#### *1) Testing models*

To support dimensioning with feedback from surgeons several physical test models were built. At first handles were made from salt-dough and pieces of paper were cut to indicate the locations for the rods (Figure 10). Tests with the dough models showed that the optimal handle-shape is a tapered cylinder. See Appendix 2 for more information about the testing models.

For further customization the dimensions of the Lego and dough models were combined. With a rapid prototyping printer several new testing models were printed and evaluated (Figure 11). During the design process different ring sizes and ring placements were printed, tested by surgeons and compared to a passive, pre-loaded spring model. With the previously mentioned arguments the spring model was chosen. See Appendix 2 for detailed construction drawings of the rapid prototype models.

#### *2) Detailed tip design*

The current and simplest solution to move the nerve with an instrument that is inserted in axial direction in the leg is by bending the tip 90° to form a create a hook. Another option is to increase the width of the rods at the tip like a spatula. In both cases the edges of the tip need to be rounded to avoid accidental damage by cutting. To reduce the pressure on the

**Figure 10. Dough testing models. Top: Several dough models of the handle of the MIND. Bottom: A dough model in use with cardboard to determine a position for the rods.**

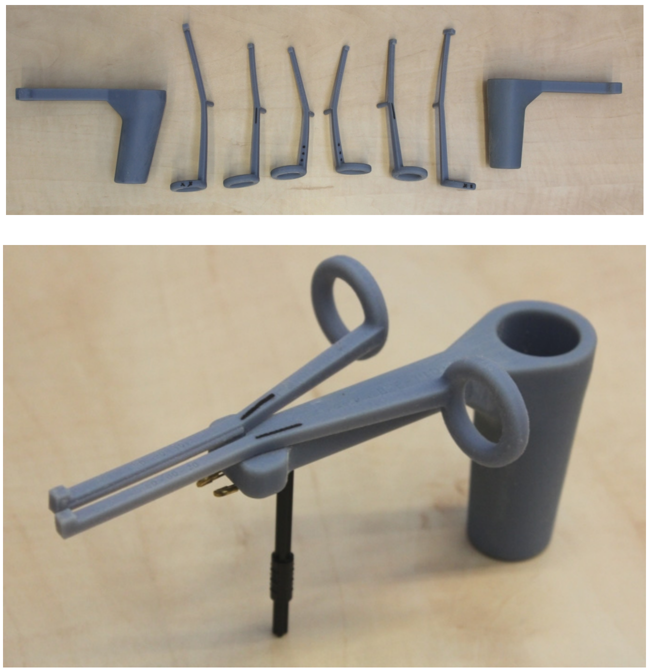

**Figure 11. Rapid Prototype models. Top: First set of Rapid Prototype components; two handles and three pair of rods. Bottom: An assembled Rapid Prototype model. The black rod is for support and is not part of the model.**

nerve tissue and to enable larger dissection steps a large tip surface is wanted. Simply bending the tip does not create enough surface area, therefore a slightly thickened tip is the best option.

*3) Detailed hinge and spring design*

Designing a potentially sterilizable instrument tackles two important design topics: material selection and eliminating small holes and other unreachable areas for cleaning fluids. The used material must withstand cleaning with several disinfectant solutions and steam sterilization of 134° C. Therefore it was decided to make the instrument from surgical steel.

The instrument should not incorporate small holes, cracks or other difficult-to-reach places in which tissue and body fluids can accumulate and cannot be removed properly. Containing two moving rods, an axis and a spring mechanism, designing a potentially sterilizable version of the MIND seemed feasible by creating the possibility to disassemble all the components. To reduce the number of components the spring was used as locking component for the rods. The rods were designed with extrusions with a hole that can be placed around extrusions mounted to the base of the handle (Figure 12 Top). The springs are placed in slots on the two handle-extrusions, clamping both rods to the base of the handle.

The spring is bent from a thread of spring steel. This has the advantage that it is easy to make different springs because different diameters of spring steel thread are easy available. A finite element analysis (Appendix 3) of the spring shows that a thickness of 0,6 to 1 mm in principle satisfies the requirements and it is up to the opinion of the surgeon if he wants a stronger or weaker spring.

The springs curves have been designed in such a way that the they lock the spring onto the extrusions on the base of the handle (Figure 13). The open parts of the first and second curve are in different directions and positioned in such a way that, together with the third curve, closing the instrument results in a stronger lock of the springs. On the back of the spring a fourth curve is present to create grip for an gripper for assembling or

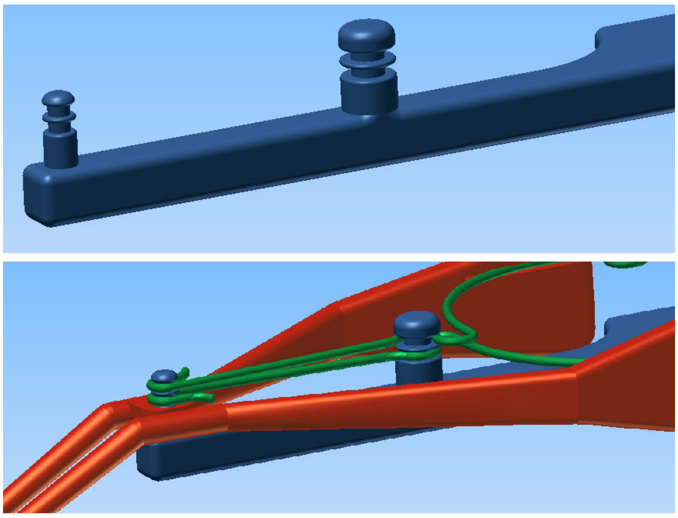

**Figure 12. Top: Extrusions on the base of the handle (blue) for rods and spring placement. Bottom: On the front extrusion the two rods (red) are placed and clamped with two springs (green).**

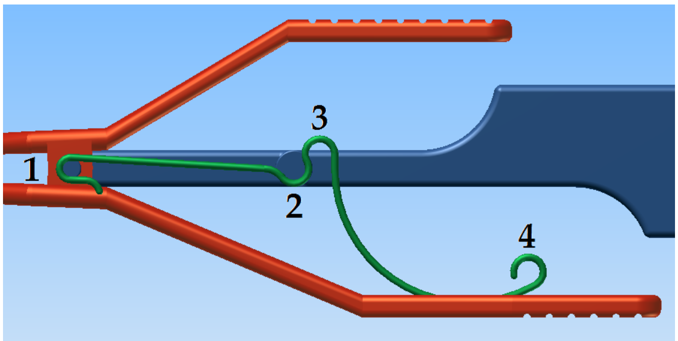


**Figure 13. Top view of the instrument. In green the shape of the spring, which locks itself in place around with two curves (1 and 2) on the extrusions on the base of the handle. The third (3) curve is to prevent accidental disassembling and the fourth (4) curve is for easy assembling and disassembling. The thickening of the base of the handle (blue) creates stops for the rods.**

removing the spring. At the inside of the rods grooves are applied to fit the spring. This ensures that the spring stays at the correct place during use.

*4) Further refinements*

To finalize the instrument several other design steps are required. To overcome interference outside the incision between the MIND and the endoscope an angle was applied on the front end of the rods, as can be seen in Figure 14. Besides overcoming this interference, the angle increases the comfort of the surgeon because his hand is more in line with the wrist, creating a more natural arm position.

On the base of the handle stops were placed, creating the possibility to push one rod to the base. If one rod is stabilized against the stop, the surgeon can focus on the movement of the other rod (Figure 13).

Grooves have been designed in the handle and on the rods, where the surgeon places his fingers, to create more grip (Figure 14). The tip has the shape of a rectangular spatula with the edges rounded to prevent the sharp edges. At the front of the tip, the part of the tip that touches the tissue first, the radius is made smaller. This creates a V-shape instead of a rectangle when looking from above. Now the tip can be moved closer to the connective tissue attachment to the nerve for improved dissection.

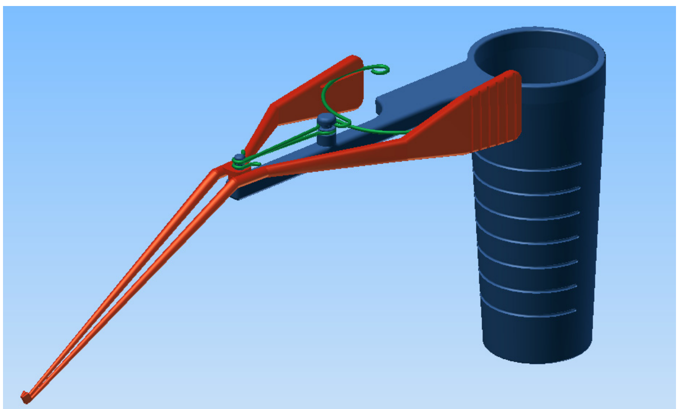

**Figure 14. The final design of the MIND.**

*5) Final design and evaluation prototype*

Figure 14 shows the final design of the MIND. Detailed drawings of the MIND can be found in Appendix 4. Based on these drawings, the Instrument Development Department (IDD) of the LUMC constructed an evaluation prototype (Figure 15). The goal of this prototype was to built a simplified version of the MIND design to evaluate the working principle. This prototype is not for clinical use or clinical testing.

The evaluation prototype is a simplified version of the MIND concept. The main simplification presents itself by bolt connection of the rods and springs to the handle, instead of the spring clamping the rods. Besides that, the front part of the rods were taken from existing, used surgical instruments that already had the required stiffness properties. The downside of these decisions at IDD was that the tip was bent and therefore smaller than designed. The stops on the base of the handle were manufactured narrower, creating a larger opening width of the tip. Besides these changes to the design there are some other minor dimensional differences.

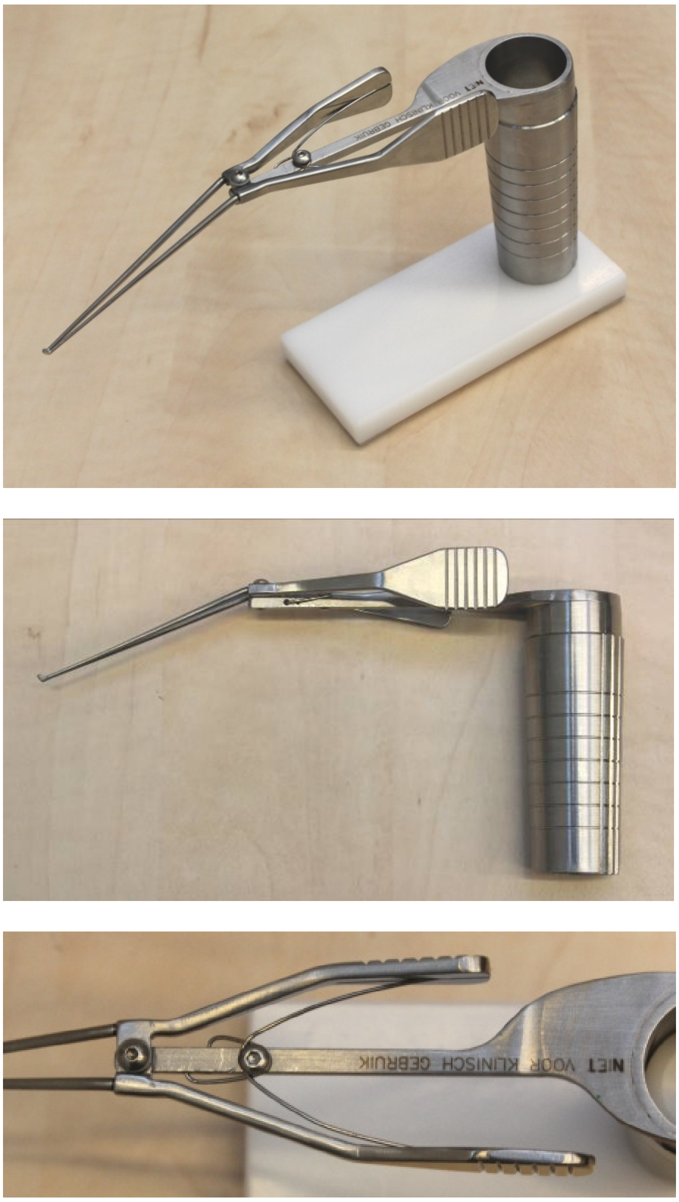

**Figure 15. The evaluation prototype.**

## IV. Evaluation of the MIND

### A. Test Facility

The goal of this project was to make an instrument which reduces the harvesting time. The best method to evaluating the MIND is by comparing the time analysis from the current instruments (Appendix 1) with a time analysis when harvesting with the MIND. Within the time span of this project it was not possible to get approval for clinical use and to have enough nerves harvested for a proper comparison. Therefore a test facility was built to simulate sural nerve harvesting in infants. See Appendix 5 for a detailed description of the test facility. The design of the test facility was based on observations made during harvesting procedures of the sural nerve and frequent discussions and tests with the neurosurgeons performing the harvesting procedure.

The test facility (Figure 16) consists of a wooden basis with a vertical board. On this board, a curved sponge covered in tape acts as a simulated calf muscle. A soft yellow wool thread was used to simulate the main branch of the sural nerve. Three white sewing threads are attached to the main branch to simulate the side branches. The artificial nerve thread is wrapped in dough, which simulates the connective tissue. This artificial nerve is placed on top of the sponge and is attached with elastic bands to the vertical board to mimic the elastic properties of a nerve. The vertical board with the sponge and with the artificial nerve is wrapped with elastic bandage to simulate the skin.

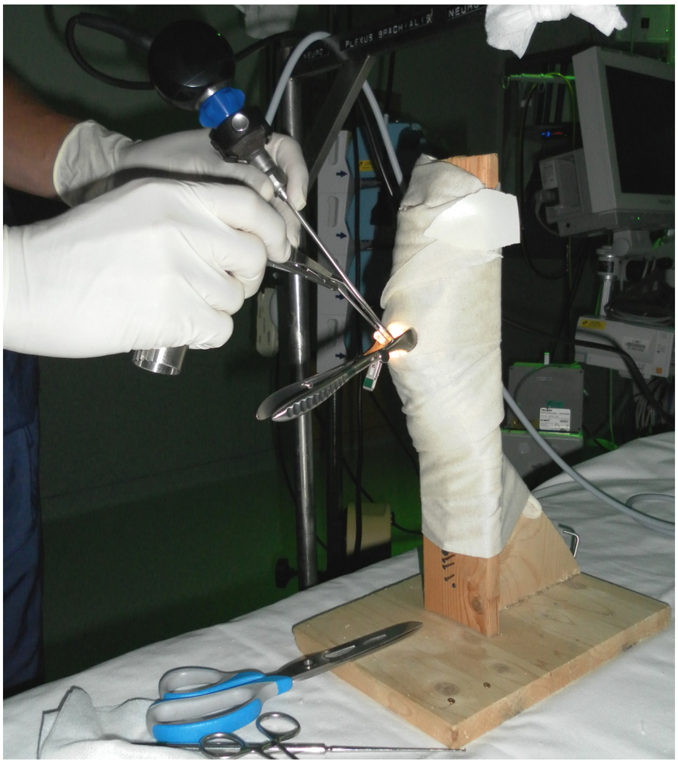

**Figure 16. The test facility in use. The speculum is inserted in the middle incision of the test facility. The surgeon has in his right hand the MIND and in his left hand the endoscope with the camera attached to it.**

### B. Test Procedure

Two neurosurgeons of the LUMC with experience in sural nerve harvesting in infants took part in two separate tests. The first test was executed with the current instruments and the second with a combination of the current instruments and the MIND. The objective of the test was to remove the dough from the thread, to cut the three side branches and to cut the thread at the highlighted locations.

To compare the current instruments with the MIND, the time to remove the thread from the test facility was measured and the number of instrument changes needed for dissection was counted. After the test a workload questionnaire (NASA TLX) was filled in as well as a questionnaire about the surgeons opinion about the MIND and test facility. Both the harvesting procedure and the endoscopic camera images were recorded for analysis.

### C. Test Results

Table 1 shows the results each test, detailed test results can be found in Appendix 5. The table shows that the harvesting time as well as the number of instrument changes are reduced with the MIND. The result of the NASA TLX questionnaire is that the workload remains the same with Surgeon 1 and is reduced with the Surgeon 2. The questionnaire about the surgeons opinion learns that the overall opinion about the MIND is positive.

## V. Discussion

### A. Lessons Learned

With only one comparison per surgeon the test is statistically weak because of the small dataset and the presence of a learning curve with the MIND. Regardless of the few data available, however, both surgeons show a clear decrease in time and instrument changes. After the tests a discussion with the surgeons about the MIND learned that it is a very different instrument than the conventional instruments, however with some practice can definitely reduce the harvesting time. This is also conformed by the results of the test. To make statistically stronger conclusions, especially about the learning curves, more data is needed. The reason for the small amount of data is that the surgeons had only limited time.

**Table 1. Results of the tests done with the test facility and the evaluation prototype.**

| | **Time[1]** | **Dissection instr. changes[2]** |
|---|---|---|
| **Surgeon 1 C.I.[3]** | 16:27 | 8 |
| **Surgeon 1 MIND[4]** | 14:26 | 2 |
| ***Difference*** | *2:01* | *6* |
| | | |
| **Surgeon 2 C.I.** | 31:27 | 12 |
| **Surgeon 2 MIND** | 19:44 | 2 |
| ***Difference*** | *11:43* | *10* |

[1] Time from first endoscope and instrument insertion up to removal of the thread.

[2] Dissection instr. change: Number of instrument changes needed for removing the dough from the thread, so not to cut side branches or palpate for a new incision.

[3] c.i.: The first test is done with the use of connectional instruments only.

[4] MIND: The second test is done with the conventional instruments and the MIND.

The main remark of the surgeons about the evaluation prototype were the dimensions of the tip. The tip of the evaluation prototype is smaller than designed, but after the tests the opinion of both the surgeons was the tip needs to be even larger than designed. This was confirmed by watching the video recordings, the small tip pushes itself for a part in the dough instead of moving it. This effect can be reduced by increasing the size of the tip. During the test it was also noted that the bolt fixation of the rods and springs is not a an option for the instrument. Because if the bolt is too loose, there was play between the rods causing the rods to scissor and if the bolt was too tight the rods have too much friction preventing the spring to close the rods. Besides that, the bolt had the tendency to loosen over time, this results in frequent adjustment of the bolt during testing, something that cannot happen during a surgical procedure.

The evaluation prototype was made for evaluating on a test facility. With the test facility promising results were achieved. This means that the current design can be improved with the results of the evaluation and input from the surgeons, and a new instrument can be manufactured for clinical approval.

### B. Further Use of the MIND

The MIND is a minimally invasive tunnel instrument designed for separating two soft tissue layers by means of an outwards motion, with individual controlled rods, without the use of trocars and for a tunnel with a maximum length of 7 cm. In general, during open surgical procedures the MIND could be used to dissect tissue deep inside the body or underneath important structures. However, the MIND can probably only improve very specific proceedings because if, for example, individual controlled rods are not needed a large range of laparoscopic instrument can be used has the desired dissection properties. Another example is that if the tunnel has somewhat of a funnel shape, a wide variety of long scissors could be used.

For laparoscopic procedures the MIND can be adjusted to fit through a trocar without deflating the abdomen, however the distance from the trocar to the tissue is too long in an inflated abdomen. This results in very long rods with unwanted elastic properties. To reduce the rod length the MIND can be adjusted with a joint that goes also through the trocar. However, this would result in almost a complete redesign of the MIND.

In neurosurgery the MIND could also be used to harvest other nerves for nerve transplantation in infants. When the sural nerve does not provide enough graft length, nerves in the arm and leg can be harvested in a similar way to the sural nerve. During the nerve transplanting procedure, the MIND can facilitate exploring the brachial plexus underneath the clavicle. Sural nerve harvesting in adults is an obvious procedure for the MIND, however the position of an adult patient is different compared to an infant and an adult nerve harvesting procedure does not make use of an endoscope. Therefore the MIND is not usable for sural nerve harvesting in adults.

In cardiac surgery vessels resemble nerves: long and thin structures which need to be dissected from connective tissue and side branches. Discussing with cardiac surgeon M. Palmen [4] learns that there are few minimally invasive cardiac procedures. For procedures that are minimally invasive, like vessel grafting,

### C. *Pathways for Improvements*

#### *1) Addressing remaining problems*

To further improve sural nerve harvesting the remaining problems from the problem analysis (Section II) can be addressed: the unknown course of the nerve, the lack of knowledge about the damage of the nerve and the curved shape of the calf muscle. The unknown course of the nerve can be improved with improved preoperative imaging or by using a contrast agent during harvesting to improve the contrast between the nerve and surrounding tissue. Current preoperative imaging modalities (MRI and ultrasound) are at the moment unfortunately not accurate enough to visualize the small sural nerve of around 1 mm in diameter and its even smaller side branches of around 0,1-0,3 mm. If the side branches and the place where the sural nerve has his division is preoperatively known, the surgeon is aided in predicting the course of the nerve in the connective tissue. This will not contribute much to a shorter harvesting time, therefore it is not needed to focus on improvement of imaging modalities. However if for other prepuces the imaging modalities improve, sural nerve harvesting profit from it.

Another problem is the lack of applicable data of damaging a nerve. If a nerve graft can handle more forces than currently assumed, the harvesting can be rougher and larger dissection steps can be made. If a nerve graft can handle less than currently assumed, a more gentle dissection means a better outcome of the entire nerve transplantation procedure. This is preferred by most surgeons, instead of a faster harvesting time. If the harvesting can be a lot rougher, simple and fast harvesting techniques like a tendon stripper can be used. To get more insight in the damage of harvested nerves and especially its effect on the nerve repair a large clinical research is needed. In the authors opinion this would be of great use, however from surgical point of view there are still more important questions that needs to be answered about the entire nerve transplantation than the relative unimportant harvesting part of the procedure.

The last remaining problem from Section II is the curved shape of the calf muscle. This problem causes the sural nerve to stay in contact with the muscle making it harder to see the nerve is free from connective tissue and side branches. To solve this problem a muscle pusher can be attached to the instrument. Redesigning the MIND with a muscle pusher is a challenge but is possible and can contribute to a significantly shorter harvesting time. The main problem with a pusher is where to place the pusher on the instrument so that it does not negatively interferes with the dissection. If by means of a muscle pusher the problem with the curved calf shape is no longer an issue, it is also possible that middle incision at the top of the calf can be left out of the procedure. This does not only reduce the scar, but it can also reduce the harvesting time because the steps of making the incision, finding the nerve and suturing can be left out.

#### *2) Improving the MIND*

With the MIND the side branches of the sural nerve still need to be cut with a scissor. Though limited, this still requires some instrument change. In order to solve this, the MIND can be expanded with a cut function such as a sharp surface or a coagulation surface. Just like the muscle pusher, this function is not a simple one to add, but can be add as a next step in the design process in further reducing the harvesting time. The challenge of the cut function will be to apply it without increasing the damage of accidently cutting or coagulating the nerve.

During the design stage the choice was made for a spring mechanism instead of thumb/index finger-rings to return to the closed position. The argument was that the ring size and ring placement results in a highly custom-made instrument. Instead of a ring a conical bowl can be used. Because of the conical shape the finger of the surgeon will always fit at a certain point in the cone. With such a shape the size is no longer a factor only the placement of the bowls. If the bowls can be placed at the right position for a diverse range of hands it is a proper option next to the spring mechanism. It is up to the opinion of the surgeon which option is preferred.

During the design process an axis was chosen for simplicity to create the desired motion. Another option is to apply an elastic joint. If an elastic joint can be designed in a way that it fulfils the sterilization requirements, the MIND does not need to be disassembled for sterilisation or assembled in the operating room. It is an advantage in the operating room is assembling is not needed and always preferred by the operating assistants, however designing such a elastic joint is difficult and harvesting time will not be reduced.

Currently, the MIND is equipped with V-shape tip jaws. Different alternative shapes are possible like a hollow tip for more circle dissection or an inverted V shape to create more grip on the tissue. The best method to improve the tip shape is an empirical method by analyzing the use of the instrument with the current tip shape in a real patient and then trying different tip shapes. In the opinion of the author a different tip shape does not change the harvesting time much, because with for example a hollow tip the dissection shape may be circular, however the motion of the jaw remains in a line.

#### *3) Improving the harvesting procedure*

The MIND was designed for separating two tissue layers with an outwards motion. It might be faster, however, if a difference in tissue properties is used for dissection. An example is by use of a water jet [5] that flushes the connective tissue from the nerve. If this principle does not damage the nerve, it could be a fast and easy method of dissecting a nerve. However, this techniques is still under development and still has a long way to go before it can be used in humans.

Instead of reducing the harvesting time or reducing the scar length, another parameter of a nerve harvesting procedure is to increase the graft length by harvesting further into the foot and harvest more and longer side branches. Currently, the length harvested nerve is not the maximum length of the nerve because harvesting the small side branches and branches in the foot takes too much time for the amount of graft length gained. If the harvesting time is reduced enough it is profitable to harvest more graft length, which can be beneficial for the outcome of the entire nerve transplantation procedure.

### D. *Future Work*

Future work should firstly consist of constructing a new MIND with lessons learned from the evaluation. The next step is to get clinical approval for using the MIND in an operating room. When the MIND is approved, it can be tested and compared with the time analysis from Appendix 1. If there is still room for improvement needed, the MIND can be redesigned with the solutions presented in Section V.C.

## VI. Conclusion

The goal of this project was to reduce the harvesting time for minimally invasive sural nerve harvesting in infants by developing and evaluating a new custom-made instrument that reduces the number of instrument actions and allows to make larger dissection steps. When using the MIND in a test facility resembling an infant's leg, the number of instrument actions was reduced by reducing the number of instrument changes needed for dissection. Besides the instrument change, the MIND makes larger dissections steps because of the larger opening width and the interference with the edges of the incision and the endoscope is reduced because of the reduced instrument width. Though there are several points that can be improved, the MIND is ready to improve sural nerve harvesting in infants.

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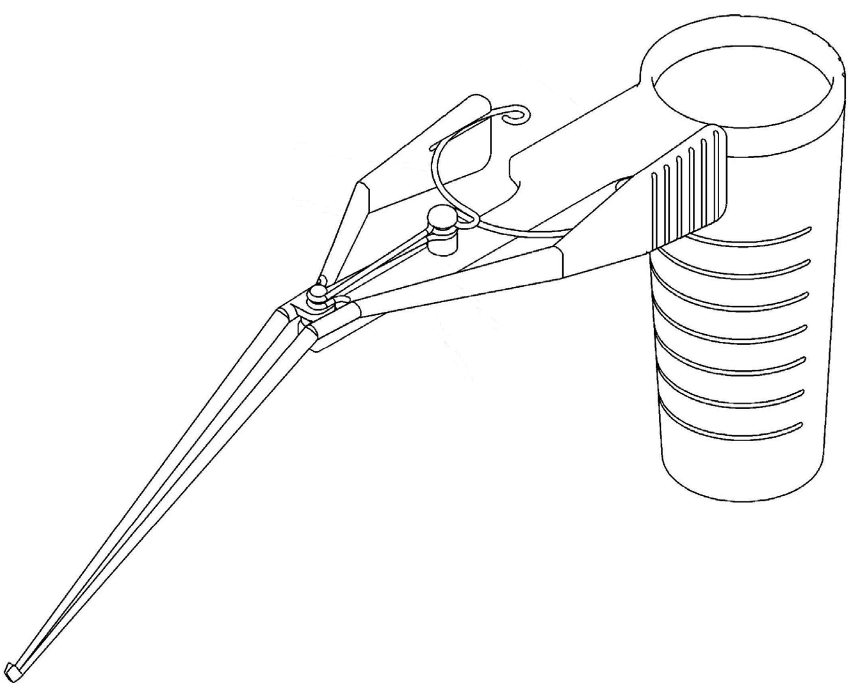
# Minimally Invasive Nerve Dissector

Design of an Instrument for Sural Nerve Harvesting in Infants

# Appendices



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# Appendix A: Time analysis

## A.1. Time analysis of current harvesting procedures

Early in this project a time analysis was start to give a quantitative overview of the current method of sural nerve harvesting. After this project the neurosurgeons have starting data for evaluation of the MIND. The sural nerve harvesting was divided in several phases, inspired by which incision is used. The detailed phase division can be found in Section A.2 and A.3. An easy fill in form (in Dutch) can be found in Chapter A.4. Detailed data can be found in Chapter A.5. The summery of the time analysis is in Table 2.

Table 2. Summery time analysis (n=10)

| | Time [hh:mm] | Time [min] | Std[1] [min] |
|---|---|---|---|
| **Total** | 1:43 | 103,1 | 20.57 |
| **T1-T5[2]** | 1:09 | 69,4 | 16,90 |
| **P1-P7[3]** | 1:35 | 95,10 | 17,31 |

[1]STD with Excel: =STDEV()
[2]T1-T5 is "single harvesting" time from making first incision to cutting of the nerve without preparation and closing,.
[3]P1-P7 is harvesting, with the cleaning of the nerve outside the body excluded.

Because of the educational role of the department of neurosurgery in the LUMC the harvesting gets often delayed by explaining things to residents, invited surgeons from all over the world and curious students mechanical engineering. This process will continue in the future therefore the comparison can be made.

# A.2. Phase division

Phase division sural nerve harvesting during OBPL.

T = point in time

*T0: begin mounting suspension rod / plexus rod*
    Phase 1: Preparation
*T1: Making distal (ankle) incision*
    Phase 2: Distal incision
*T2: Making middle (calf) incision*
    Phase 3: Distal and middle incision
*T3: Introduce speculum into mid incision*
    Phase 4: Middle incision
*T4: Making proximal (popliteal) incision*
    Phase 5: Middle and proximal incision
*T5: Cutting sural nerve in distal (ankle) incision*
    Phase 6: Stitching
*T6: Last stitch*
    Phase 7: Completion
*T7: All dressing applied*

*T8: Begin cleaning*
    Phase 8: Cleaning
*T9: End cleaning*

# A.3. Phase division [Dutch]

Fase indeling nervus suralis uit name tijdens OBPL.

**Fase 1: Voorbereiding**
*T0 tijdstip: Ophang stellage bevestigen aan tafel.*
Beentje ophangen/fixeren aan de plexus boog, scopie toren en endoscoop klaarmaken.

**Fase 2: Distale incisie**
*T1 tijdstip: Distale incisie maken.*
V. saphenous en n. suralis opzoeken, ruimte maken en suralis vrij prepareren met een schaar, neus speculum plaatsen, verder vrij prepareren met o.a. scoop, microschaar en haakje, tot het punt waar de suralis de fascie ingaat. Vessel loop bevestigen (kan ook eerder). Scoop eruit, midden incisie palperen.

**Fase 3: Distaal en midden incisie**
*T2 tijdstip: Midden incisie maken.*
Vessel loop doorschuiven totdat de uiteinden uit midden incisie komen. Door midden incisie kijken en vrij prepareren totdat vessel loop op het punt zit waar de suralis de fascie ingaat en/of de scoop in de distale incisie verder vrij prepareren totdat vessel loop op het juiste punt zit. Speculum en evt. scoop uit boven incisie, zonder scoop suralis in midden incisie zo ver mogelijk vrij prepareren.

**Fase 4: Midden incisie**
*T3 tijdstip: Speculum introduceren in midden incisie achter de fascie.*
Met scoop en microschaar zo ver mogelijk vrij prepareren tot aan knieholte. Palperen voor proximale incisie.

**Fase 5: Midden en proximale incisie**
*T4 tijdstip: Proximale incisie maken in knieholte.*
Vessel loop doorschuiven, kijken waar die blijft steken. Via midden incisie met scoop of in proximale incisie kijken en vrij prepareren totdat vessel loop ver genoeg is. Suralis verder de knieholte in vrij prepareren en zo ver mogelijk doornemen. Suralis uit distale incisie halen, daar zo ver mogelijk distaal vrij prepareren.

**Fase 6: Hechten**
*T5 tijdstip: Doornemen en uithalen van suralis in distale incisie.*
De drie incisies worden gehecht.

**Fase 7: Afsluiting**
*T6 tijdstip: Na de laatste hechting.*
Steri strips plakken, been van stellage afhalen en verbinden.
*T7 tijdstip: klaar met verbinden.*

**Fase 8: Schoonmaken**
*T8 tijdstip begin en T9 tijdstip eind.*

# A.4. Fill in form [Dutch]

**Nulmeting zenuw uitname bij een OBPL operatie**

Datum: Leeftijd patiënt (mnd):

Chirurgen:

Tijdstip begin operatie: Tijd eerste incisie (in de nek):

---

**Donorzenuw 1**
(Door: is door welke chirurg of chirurg in opleiding of beide, zodat ook het "naast elkaar / tegelijkertijd" werken in beeld wordt gebracht)

Zenuw: Kant: Links / Rechts

T0 tijdstip stellage bevestigen aan OK tafel: Door:

T1 tijdstip maken distale incisie (enkel): Door:

T2 tijdstip maken midden incisie (op de kuit): Door:

T3 tijdstip speculum in midden incisie: Door:

T4 tijdstip maken proximale incisie (knieholte): Door:

T5 tijdstip doornemen en uithalen van suralis in distale incisie: Door:

T6 tijdstip van de laatste hechting: Door:

Lengte distale incisie: Lengte midden incisie: Lengte proximale incisie:

T7 tijdstip klaar met verbinden: Door:

T8 Begin tijdstip schoonmaken van zenuw: Door:

T9 Einde tijdstip schoonmaken zenuw: Lengte van de Graft:

Moeilijkheidsgraad anatomie (1= makkelijk, 5 = moeilijk):

---

**Donorzenuw 2**
Zenuw: Kant: Links / Rechts

T0 tijdstip begin ophanging: Door:

T1 tijdstip maken distale incisie (enkel): Door:

T2 tijdstip maken midden incisie (op de kuit): Door:

T3 tijdstip speculum in midden incisie: Door:

T4 tijdstip maken proximale incisie (knieholte): Door:

T5 tijdstip doornemen en uithalen van suralis in distale incisie: Door:

T6 tijdstip van de laatste hechting: Door:

Lengte distale incisie: Lengte midden incisie: Lengte proximale incisie:

T7 Eind ingreep tijdstip klaar met verbinden: Door:

T8 Begin tijdstip schoonmaken van zenuw: Door:

T9 Einde tijdstip schoonmaken zenuw: Lengte van de Graft:

Moeilijkheidsgraad anatomie (1= makkelijk, 5 = moeilijk):

---

Tijdstip laatste hechting in nek:
Sluiten gedaan door:

Tijdstip eind operatie:

Opmerkingen (bij gebrek aan ruimte gebruik de achterkant):

# A.5. Detailed Data

Detailed registration of harvesting procedures.

| Date | # | T0 | T1 | Phase1 | T2 | Phase 2 | T3 | Phase 3 | T4 | Phase 4 |
|---|---|---|---|---|---|---|---|---|---|---|
| 14-4-2011 | 1 | 11:14 | 11:22 | 0:08 | 11:34 | 0:12 | 11:45 | 0:11 | 12:01 | 0:16 |
| 14-4-2011 | 2 | 12:33 | 12:35 | 0:02 | 13:05 | 0:30 | 13:17 | 0:12 | 13:50 | 0:33 |
| 1-6-2011 | 1 | 12:00 | 12:06 | 0:06 | 12:22 | 0:16 | 12:34 | 0:12 | 13:10 | 0:36 |
| 1-6-2011 | 2 | 13:56 | 13:58 | 0:02 | 14:14 | 0:16 | 14:24 | 0:10 | 14:45 | 0:21 |
| 10-11-2011 | 1 | 11:22 | 11:27 | 0:05 | 11:45 | 0:18 | 11:57 | 0:12 | 12:14 | 0:17 |
| 10-11-2011 | 2 | 13:00 | 13:02 | 0:02 | 13:26 | 0:24 | 14:00 | 0:34 | 14:10 | 0:10 |
| 5-1-2012 | 1 | 10:49 | 10:54 | 0:05 | 11:15 | 0:21 | 11:22 | 0:07 | 11:45 | 0:23 |
| 5-1-2012 | 2 | 12:19 | 12:21 | 0:02 | 12:38 | 0:17 | 12:44 | 0:06 | 12:58 | 0:14 |
| 19-1-2012 | 1 | 12:17 | 12:21 | 0:04 | 12:36 | 0:15 | 12:47 | 0:11 | 13:13 | 0:26 |
| 19-1-2012 | 2 | 13:49 | 13:50 | 0:01 | 14:06 | 0:16 | 14:17 | 0:11 | 14:43 | 0:26 |
| | | | | | | | | | | |
| **MEAN:** | | **[hh:mm]** | | **0:03** | | **0:18** | | **0:12** | | **0:22** |
| **MEAN:** | | **[min]** | | **3,70** | | **18,50** | | **12,60** | | **22,20** |
| STD: | | **[min]** | | 2,26 | | 5,21 | | 7,81 | | 8,30 |

| Date | # | T5 | Phase 5 | T6 | Phase 6 | T7 | Phase 7 | T1-T5 | P1-P7 |
|---|---|---|---|---|---|---|---|---|---|
| 14-4-2011 | 1 | 12:13 | 0:12 | 12:29 | 0:16 | 12:33 | 0:04 | 0:51 | 1:19 |
| 14-4-2011 | 2 | 14:08 | 0:18 | 14:25 | 0:17 | 14:29 | 0:04 | 1:33 | 1:56 |
| 1-6-2011 | 1 | 13:35 | 0:25 | 13:52 | 0:17 | 13:55 | 0:03 | 1:29 | 1:55 |
| 1-6-2011 | 2 | 15:15 | 0:30 | 15:32 | 0:17 | 15:36 | 0:04 | 1:17 | 1:40 |
| 10-11-2011 | 1 | 12:22 | 0:08 | 12:56 | 0:34 | 13:00 | 0:04 | 0:55 | 1:38 |
| 10-11-2011 | 2 | 14:30 | 0:20 | 14:52 | 0:22 | 14:55 | 0:03 | 1:28 | 1:55 |
| 5-1-2012 | 1 | 11:56 | 0:11 | 12:12 | 0:16 | 12:19 | 0:07 | 1:02 | 1:30 |
| 5-1-2012 | 2 | 13:06 | 0:08 | 13:20 | 0:14 | 13:22 | 0:02 | 0:45 | 1:03 |
| 19-1-2012 | 1 | 13:25 | 0:12 | 13:41 | 0:16 | 13:46 | 0:05 | 1:04 | 1:29 |
| 19-1-2012 | 2 | 15:00 | 0:17 | 15:13 | 0:13 | 15:15 | 0:02 | 1:10 | 1:26 |
| | | | | | | | | | |
| **MEAN** | | **[hh:mm]** | **0:16** | | **0:18** | | **0:03** | **1:09** | **1:35** |
| **MEAN** | | **[min]** | **16,10** | | **18,20** | | **3,80** | **69,40** | **95,10** |
| STD: | | **[min]** | 7,32 | | 6,03 | | 1,48 | 16,90 | 17,31 |

| Date | # | T8 | T9 | Phase 8 | TOTAAL |
|---|---|---|---|---|---|
| 14-4-2011 | 1 | 13:43 | 13:56 | 0:13 | 1:32 |
| 14-4-2011 | 2 | 14:29 | 14:56 | 0:27 | 2:23 |
| 1-6-2011 | 1 | 15:37 | 15:40 | 0:03 | 1:58 |
| 1-6-2011 | 2 | 15:40 | 15:45 | 0:05 | 1:45 |
| 10-11-2011 | 1 | 14:57 | 15:01 | 0:04 | 1:42 |
| 10-11-2011 | 2 | 15:01 | 15:06 | 0:05 | 2:00 |
| 5-1-2012 | 1 | 13:45 | 13:49 | 0:04 | 1:34 |
| 5-1-2012 | 2 | 13:46 | 13:49 | 0:03 | 1:06 |
| 19-1-2012 | 1 | x | x | 0:08 | 1:37 |
| 19-1-2012 | 2 | x | x | 0:08 | 1:34 |
| | | | | | |
| **MEAN:** | | **[hh:mm]** | | **0:08** | **1:43** |
| **MEAN** | | **[min]** | | **8,00** | **103,10** |
| STD: | | **[min]** | | 7,35 | 20,57 |

# Appendix B: Testing Models

## B.1. Salt-Dough Models

To support in concept decision making and to give rough indications for basic dimensions, physical models were built. The first models were made from salt-dough. This dough has clay like properties: it can be shaped and dried to create a solid form.
The recipe for salt dough is simple: three cups of flower, one cup of salt and approximately one cup of water. Mix the flower and salt, knead and add water until you get a lump of dough that is soft enough to shape it at your wishes, but not too soft that it cannot maintain your wished form. Knead the dough in the wanted shape and let it dry in the oven at 100 degrees for a couple of hours. Drying is also possible by means of the sun or by placing it on the radiator, however they require more time. Thicker shapes also need more drying time. Keep in mind that you cannot prevent the dough from sagging in a little bit and that the bars from the oven shelf are printed in the shapes. Pins can be used to attach the dried dough pieces to each other, note that such a connection is very brittle.

The built models (Figure 17) are focussed on creating a handle and give rough approximations for placement of the rods. During discussions with the surgeons (Figure 18), the best handle is a tapered cylinder with a top diameter of 35 mm and a bottom diameter of 27,5 mm. Cardboard shapes were pinned on the handles and learns that the rods must be 4 cm apart with a closed tip and the places for the fingers must be 6 cm from the back of the handle.

**Figure 17. Salt-dough models, where the outer two handles have cardboard extrusions.**

**Figure 18. Testing with a salt dough handle and cardboard, for the placement of the rods.**

# B.2. Lego Model

After several tryouts (Figure 19) a representative Lego model was built (Figure 20 top). The goal of this model was to make a handheld model with the desired motion function. The wanted motion is that when the surgeon closes his hands, the rods open.

The Lego model has the correct movement function that is smooth, stable and repetitive (Figure 20 Bottom). When the surgeons closes his hands the rods are opened, to complete the cycle the rods are closed with an elastic band. The downsides of this model is that it is a large and bulky model with a uncomfortable handle.

During designing the Lego model it was found that when the back part of the rods (from hinge to finger placement) have a different in height, the rods can cross each other creating a larger opening width (Figure 21). This principle was not applied in future models and prototypes because there was no problem reaching the minimum opening width of the tip.

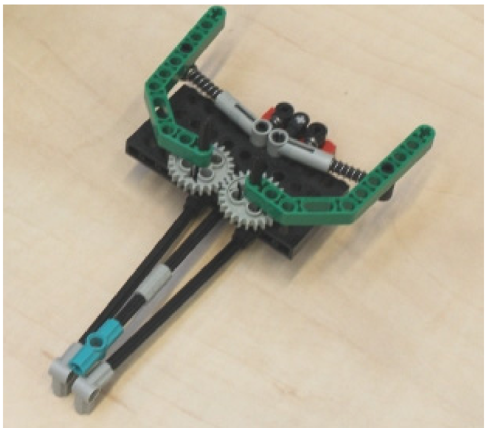


**Figure 19. A tryout Lego model, when the two green bars are squeezed, two rods open. Between the rods with the light blue tip is a wiggle rod, a rejected function.**

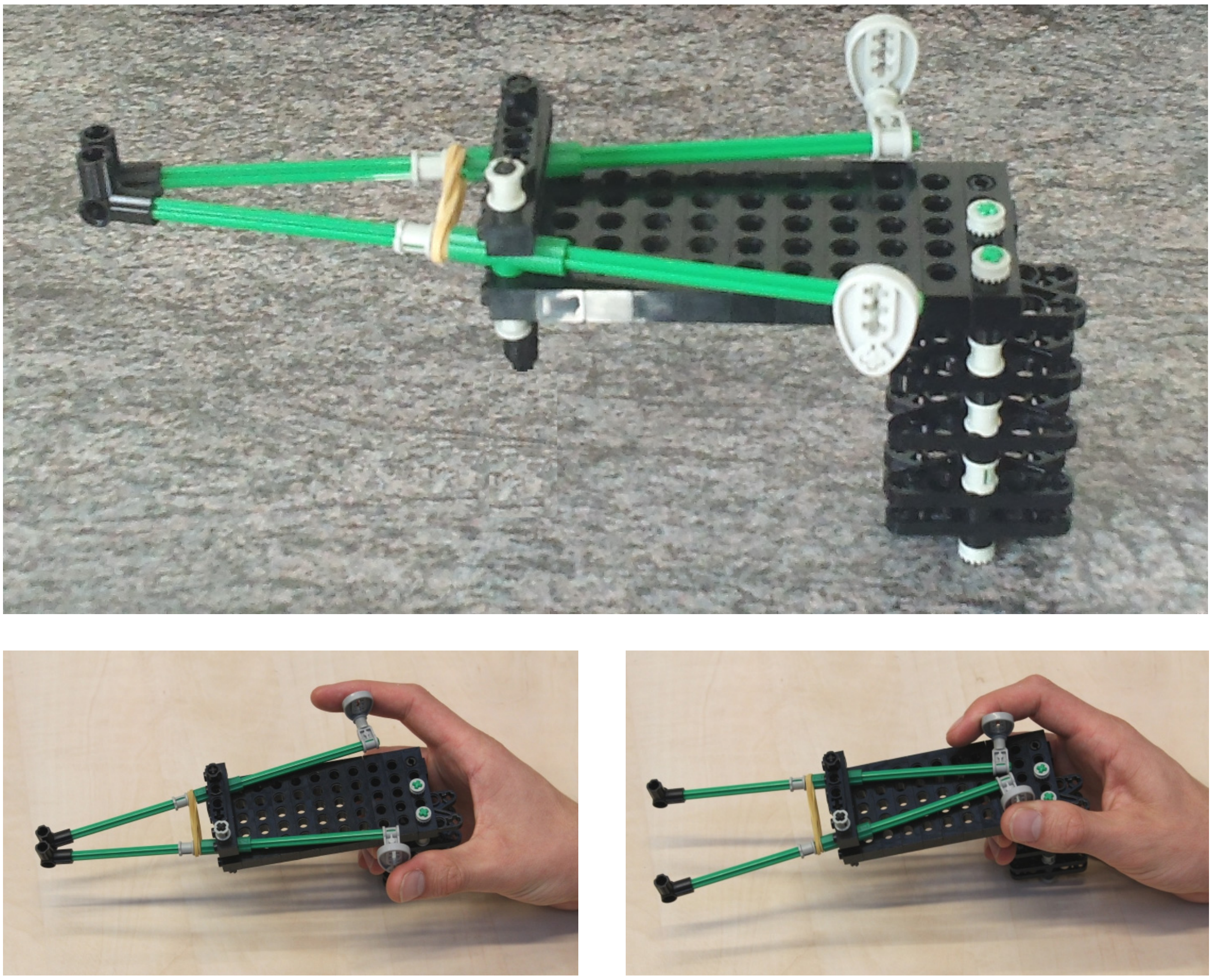


**Figure 20. The Lego model (top) that opens when the hand is closed (bottom).**

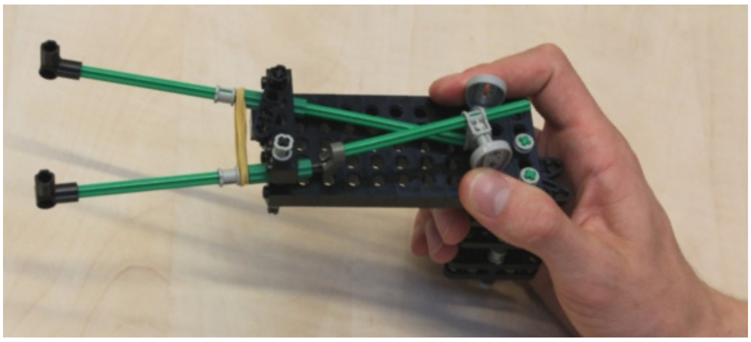


**Figure 21. By having a different in height of the back end of the rods, the can be crossed. This creates a larger opening width of the tip.**

# B.3. Mecano model

To get rid of the bulkiness of the Lego model, a thinner model was designed and built using Mecano for the basis of the handle, a piece of broomstick for the handle, two bended bicycle spokes as rods and elastic bands to guide the rods. The advantage of the Mecano model was a more comfortable handle and an overall smaller model with a more representative size of the rods. The disadvantage of this model was that the movement functions did not work as expected. Where the Lego model allows only one degree of freedom of the rods, the rods mecano can move in several directions because most degrees of freedom are limited by a low friction force.

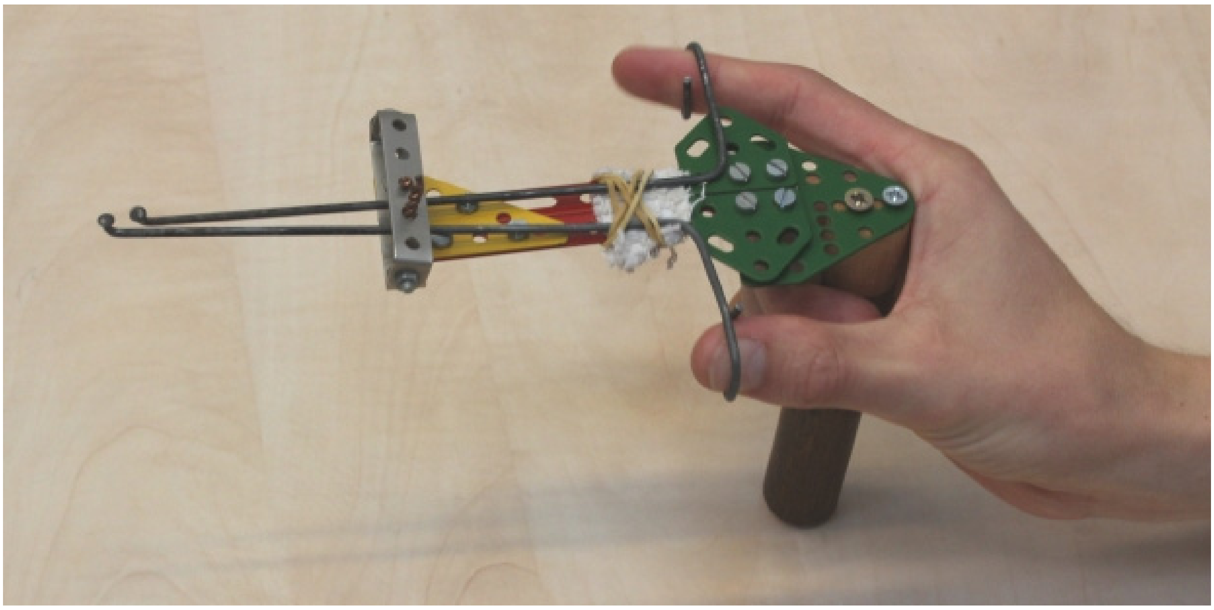


**Figure 22. The Mecano model**

# B.4. Rapid Prototype Models

The next step in concept support and further dimensioning, several prototypes where printed using a rapid prototype printer (Figure 23 and Figure 24), in section B.5 are the drawings of all the components. The advantage of rapid prototyping is that very difficult shapes can be printed. The main downside is that the material used is plastic and therefore weak and brittle. Therefore the dimensions are larger then they would be for the real instrument.

At first two handles and six rods where printed. The handles differ in the angle of the handle with respect to the basis. One handle is called straight (90° angle between the axis of the handle and the basis) while the other has an angel of 10° compared to the straight one (80° between axis of the handle and basis). Because the leg of the infants is in a vertical position, with a straight handle the forearm of the surgeon must also be vertical or he needs to rotate his wrist. This is an uncomfortable position and can be made more comfortable with an angle in the handle.

The rods differ in the length (Table 3) from the hinge to the tip (Front length) and in the length from hinge to the finger placement (Back length). The inner diameter is the inner diameter of the rings. Based on observations during harvesting procedures it was noticed that the surgeon stands with his elbows outwards, thus rotating his under arms if looked from above. As an option a set of rods was printed with an ability to compensate for this angle by having an angle in the tip. Now the tip points parallel to the sagittal plane of the surgeon.

The advantage of the printed models are that the important dimensions are present: the handle diameters and placement of the rings. The movement function is stable and smooth enough for testing. Testing with this first set of rods and the handles learns that the straight handle has the preference of the surgeon. The angle is best to be in the front part of the rods instead of the handle. For ring placement it is best to have different length of rods, because the thumb is shorter than the index finger. Besides the back length, also the inner diameter of the thumb rod can be bigger. The angle in the tip is not wanted because when opening the rods, the tip does not move outwards over a line perpendicular to the line of dissection but moves under an angle reducing the efficiency of the dissection.

With input from the first set of rods, a second set of rods is printed (Table 4 and Table 5); one pair as an improvement of the ring concept (Figure 25 Left) and one pair used for the spring concept (Figure 25 Right). The straight handle is used with both concepts. For the spring model a spring from a pen was used and put between extrusions on the inside of the rods. Testing with both concept and discussing with the surgeon, the spring concept with less customization is chosen instead of the intuitive control of the ring concept.

**Figure 23. A rapid prototype model with rods from the first set. At the inside of the rods the size of the real rods are printed (difficult to see). The black rod was used as support and is not part of the model.**

**Figure 24. Two handles and the first set of rods. The handle of the left handle is under an angle of 10 degrees.**

Table 3. First set of rods

| **Rod** | **Front length** | **Back length** | **Inner diameter** | |
|---|---|---|---|---|
| Left | 60 | 60 | 20 | |
| Right | 60 | 60 | 20 | |
| Left | 60 | 50 | 20 | |
| Right | 60 | 50 | 20 | |
| Left | 70 | 70 | 20 | Tip angle |
| Right | 70 | 70 | 20 | Tip angle |

Table 4. Second set of rods, rings concept.

| **Rod** | **Front length** | **Back length** | **Inner diameter** | **Front angle** |
|---|---|---|---|---|
| Left | 70 | 70 | 25 | 30° |
| Right | 70 | 40 | 20 | 30° |

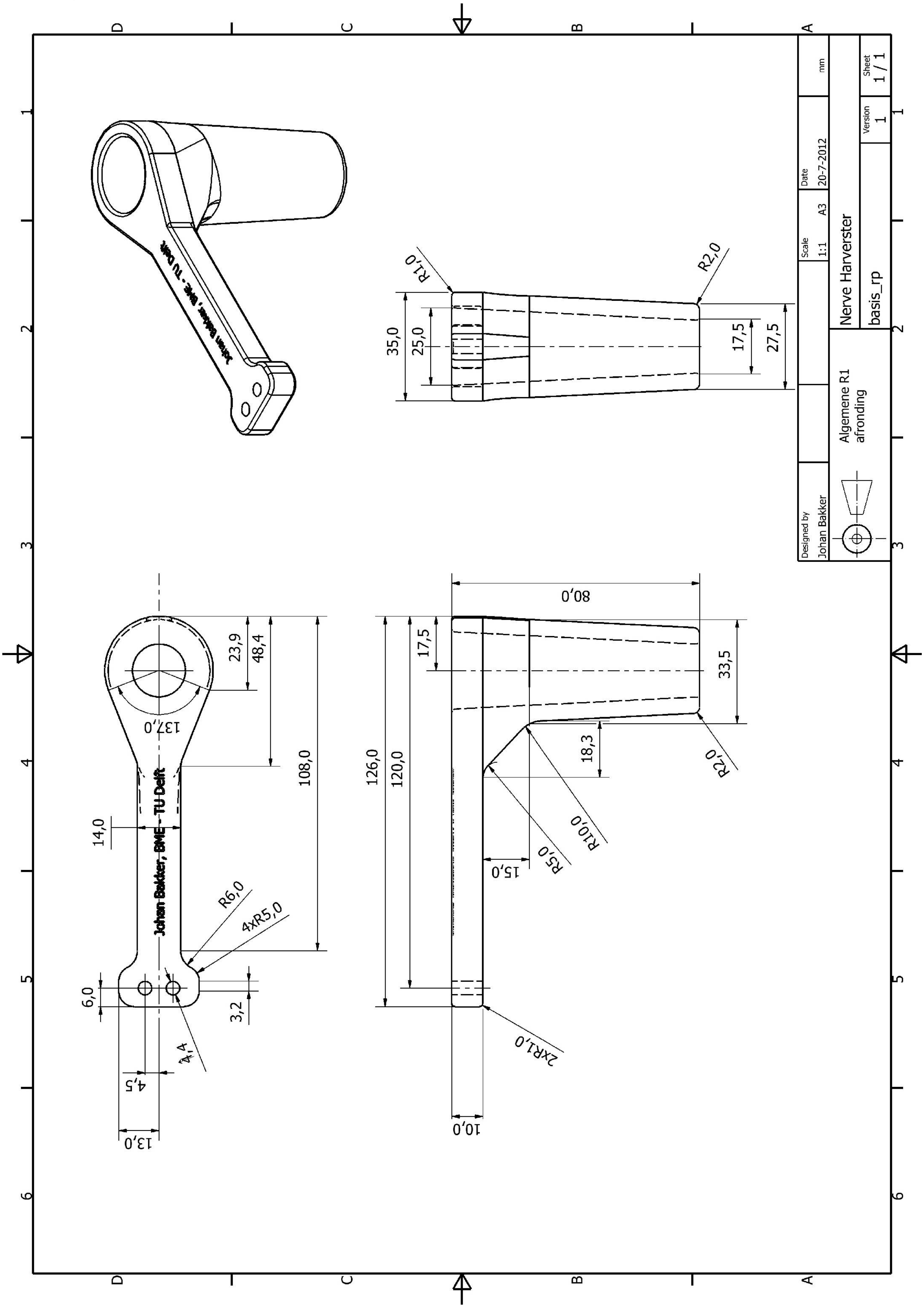
Table 5. Second set of rods, spring concept.

| **Rod** | **Front length** | **Back length** | **Back width** | **Front angle** |
|---|---|---|---|---|
| Left | 70 | 80 | 12 | 30° |
| Right | 70 | 60 | 12 | 30° |

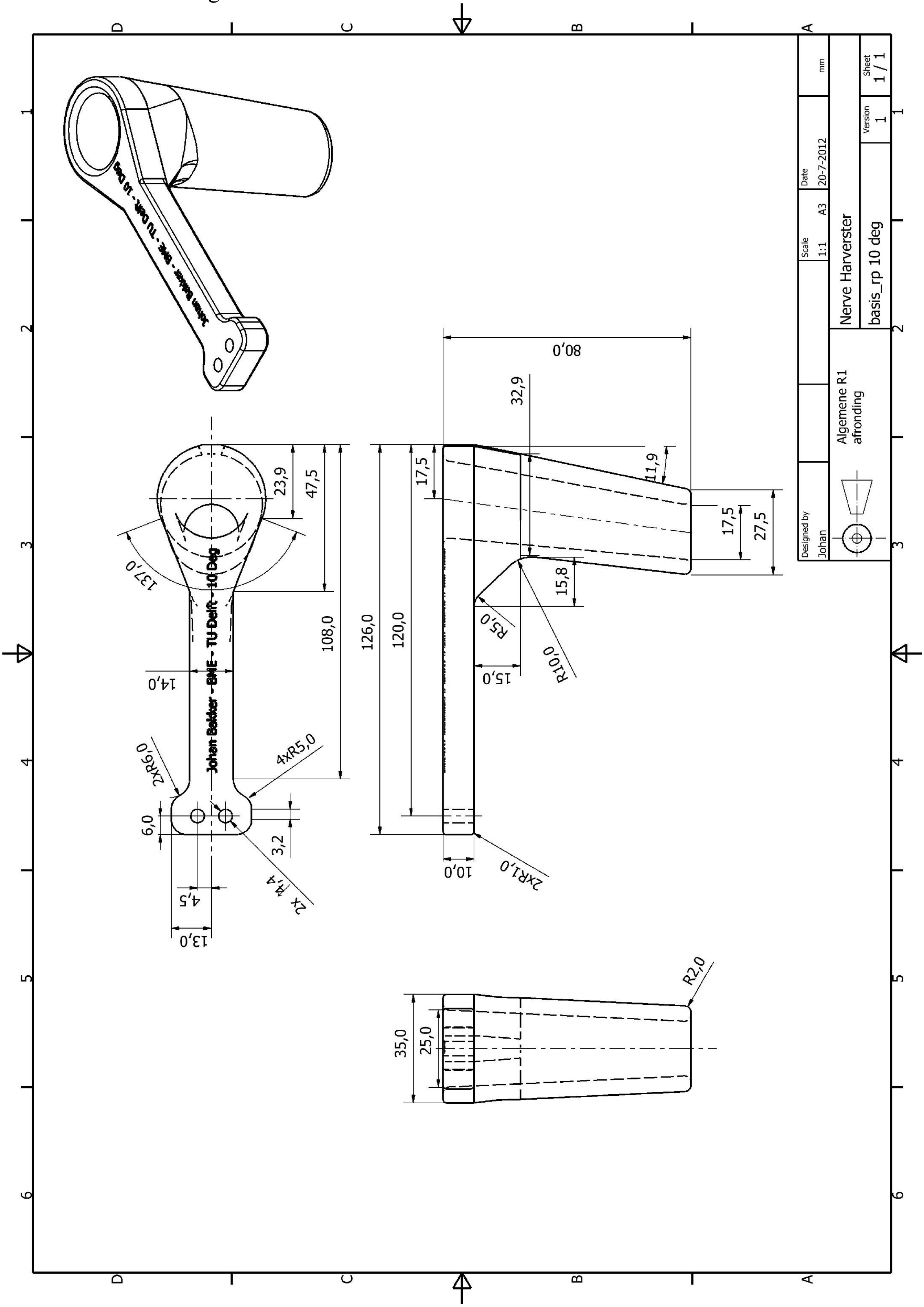
**Figure 25. Left: the ring concept from the second set of rods. Right: the spring concept from the second set of rods.**

# B.5. Rapid Prototype Drawings

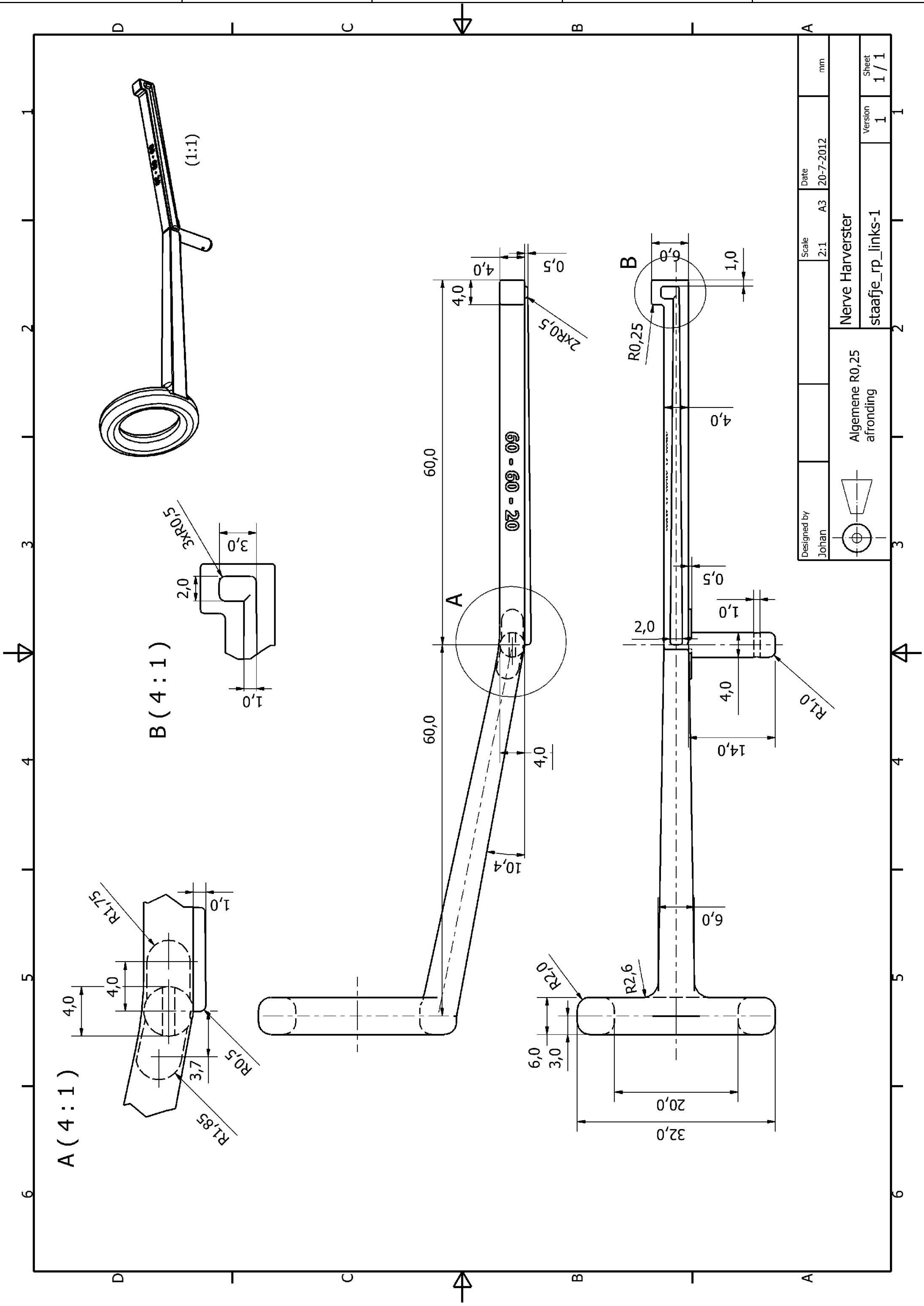
The straight handle.



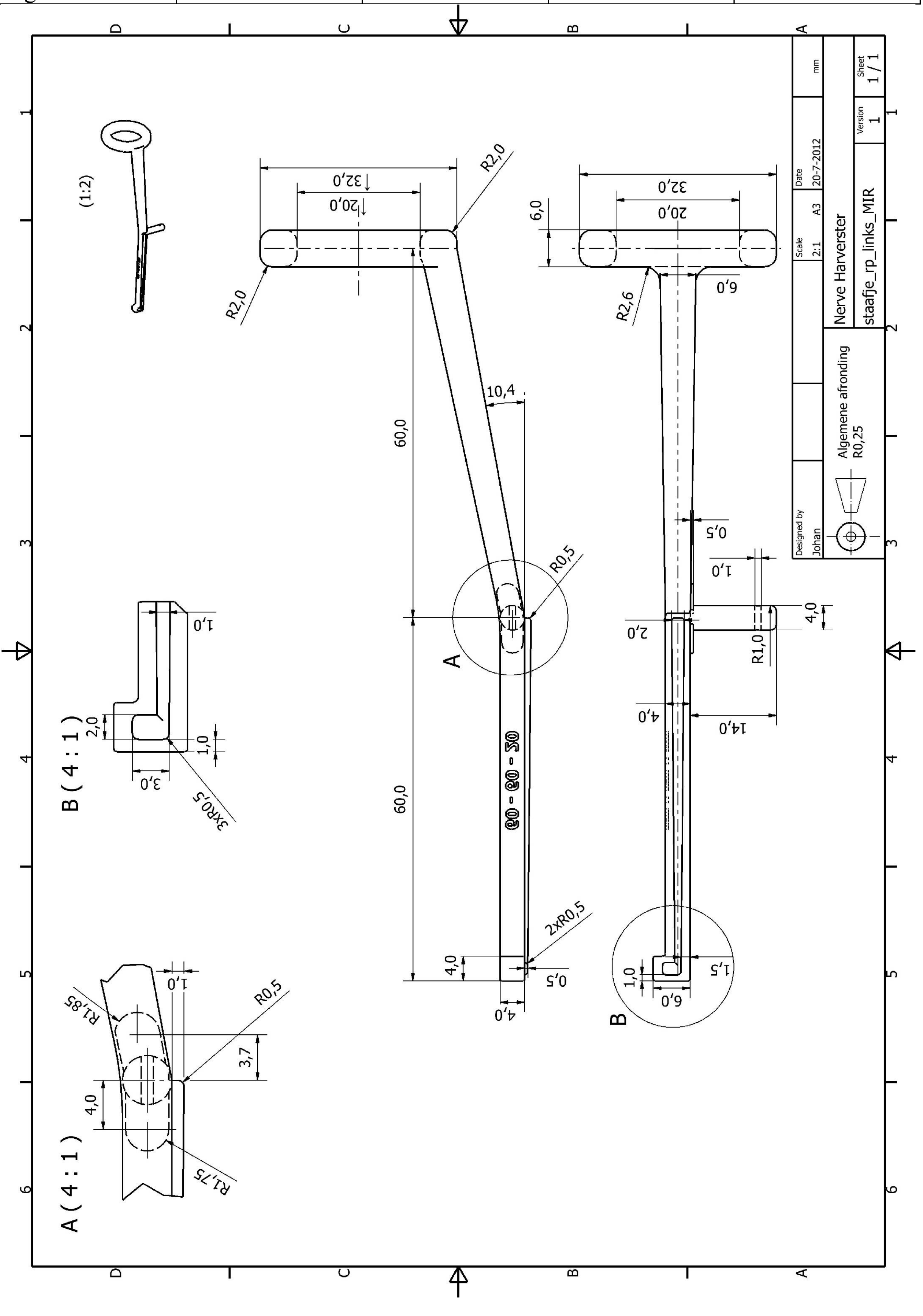
The handle with an angle.



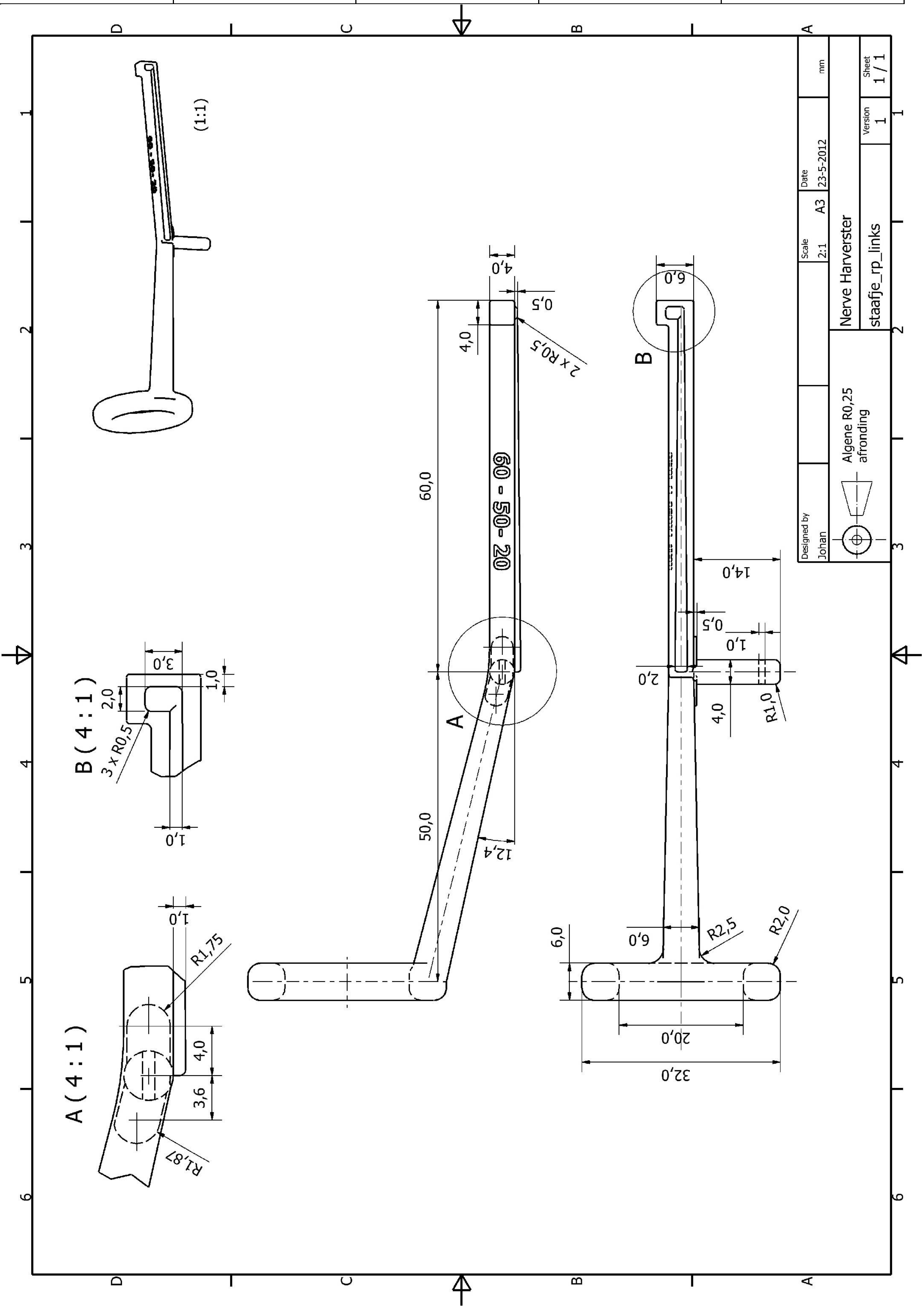
| Rod | Front length | Back length | Inner diameter | |
|---|---|---|---|---|
| Left | 60 | 60 | 20 | |



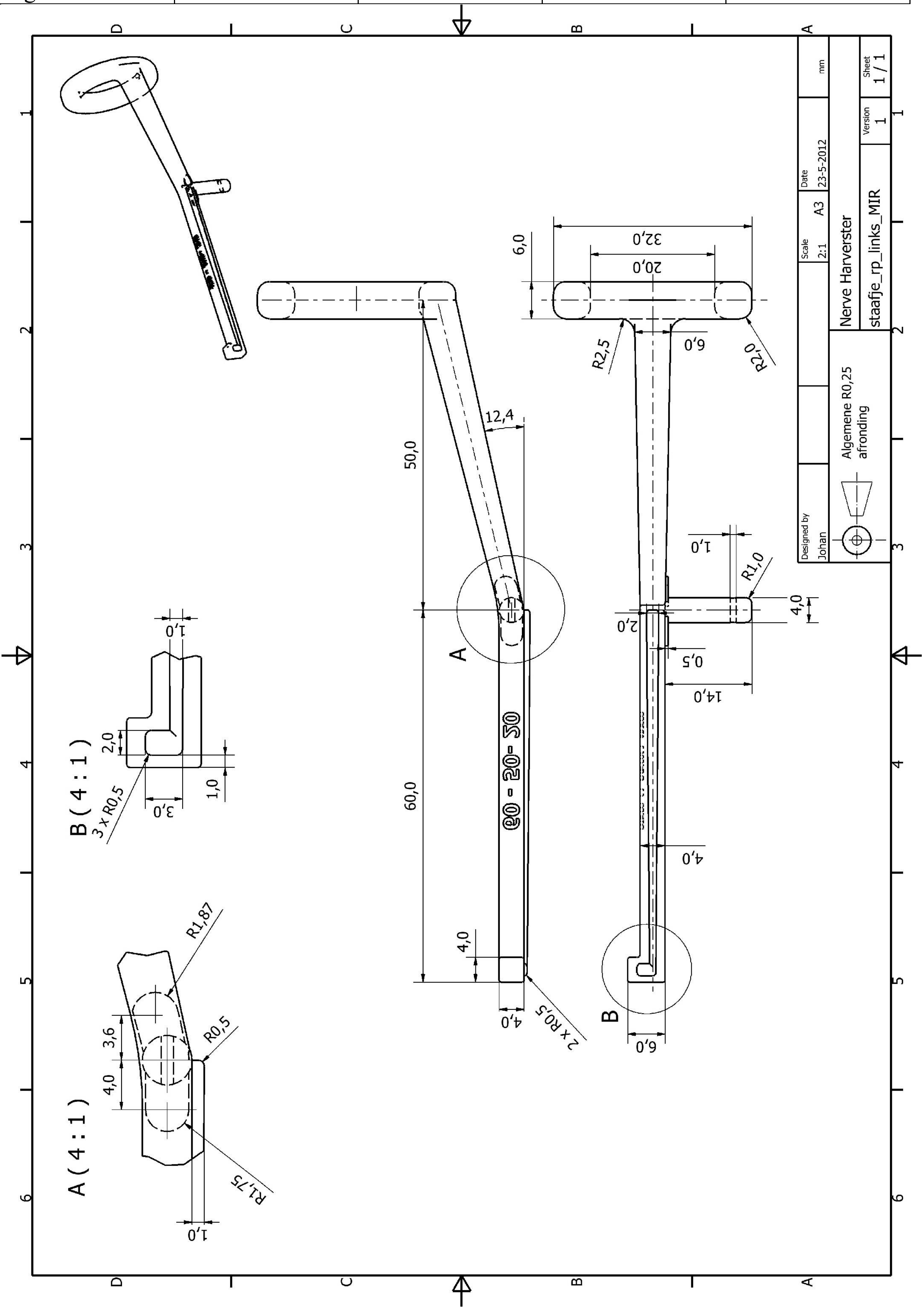
| Rod | Front length | Back length | Inner diameter | |
|---|---|---|---|---|
| Right | 60 | 60 | 20 | |



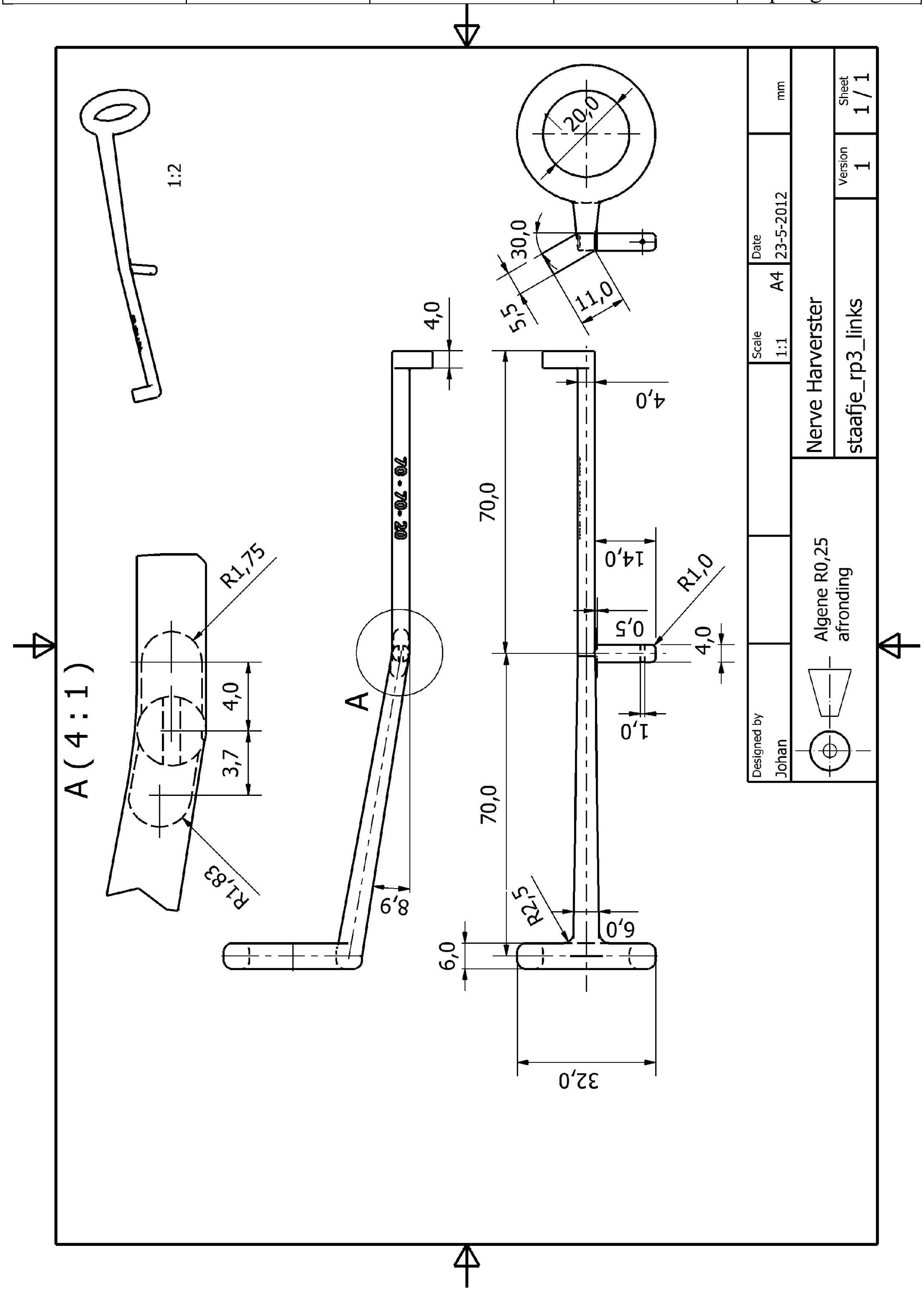
| Rod | Front length | Back length | Inner diameter | |
|---|---|---|---|---|
| Left | 60 | 50 | 20 | |



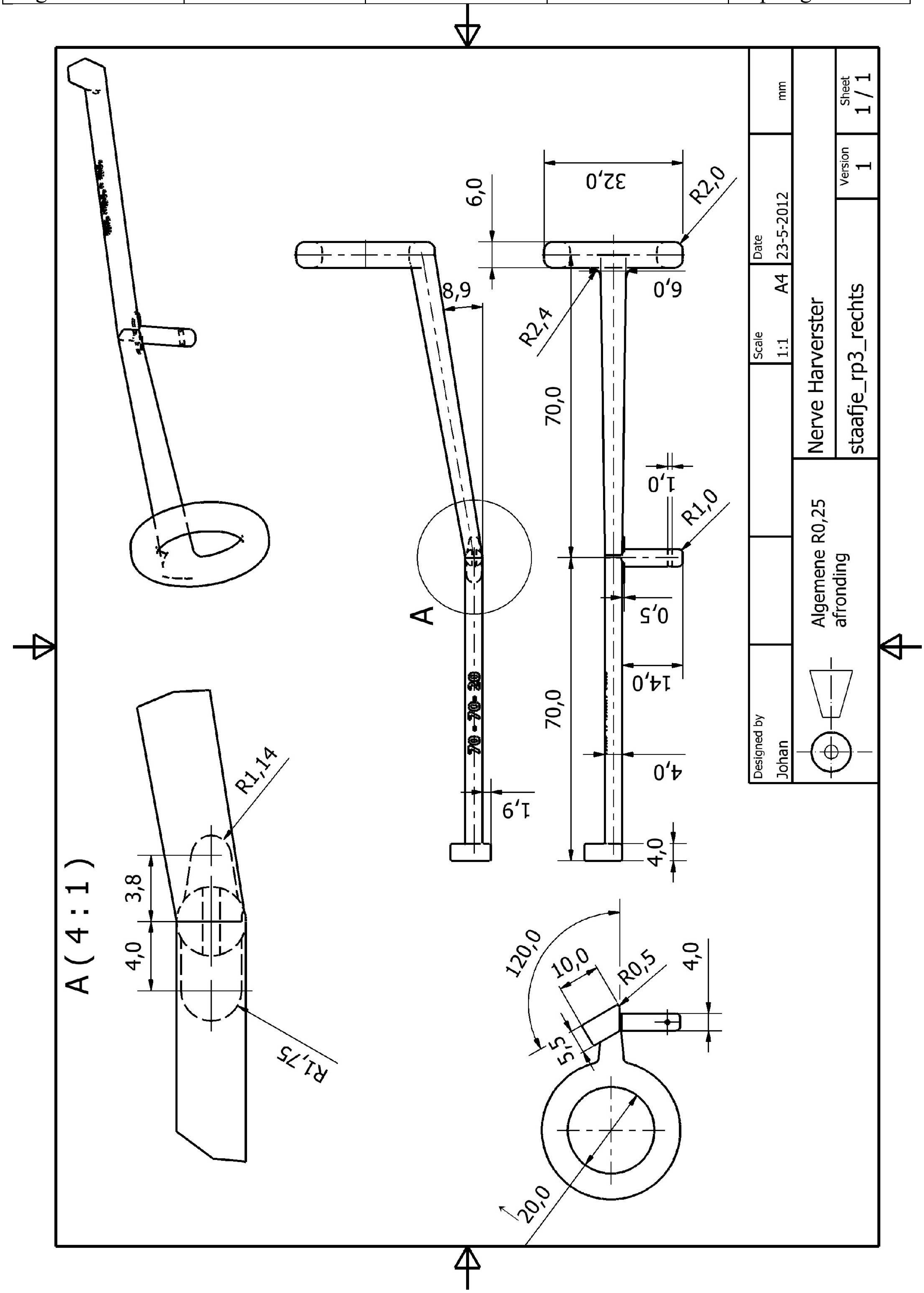
| Rod | Front length | Back length | Inner diameter | |
|---|---|---|---|---|
| Right | 60 | 50 | 20 | |



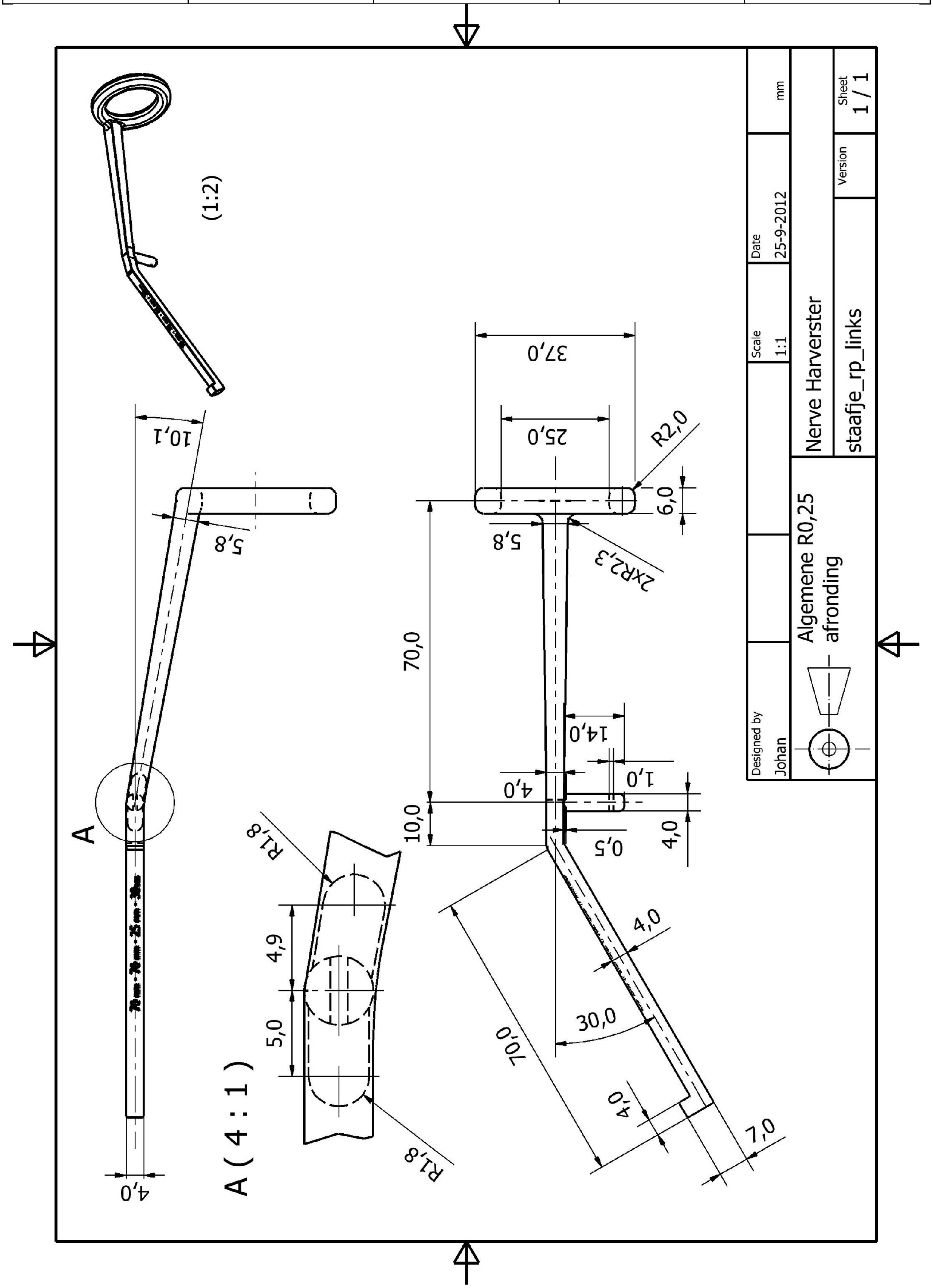
| Rod | Front length | Back length | Inner diameter | |
|---|---|---|---|---|
| Left | 70 | 70 | 20 | Tip angle |



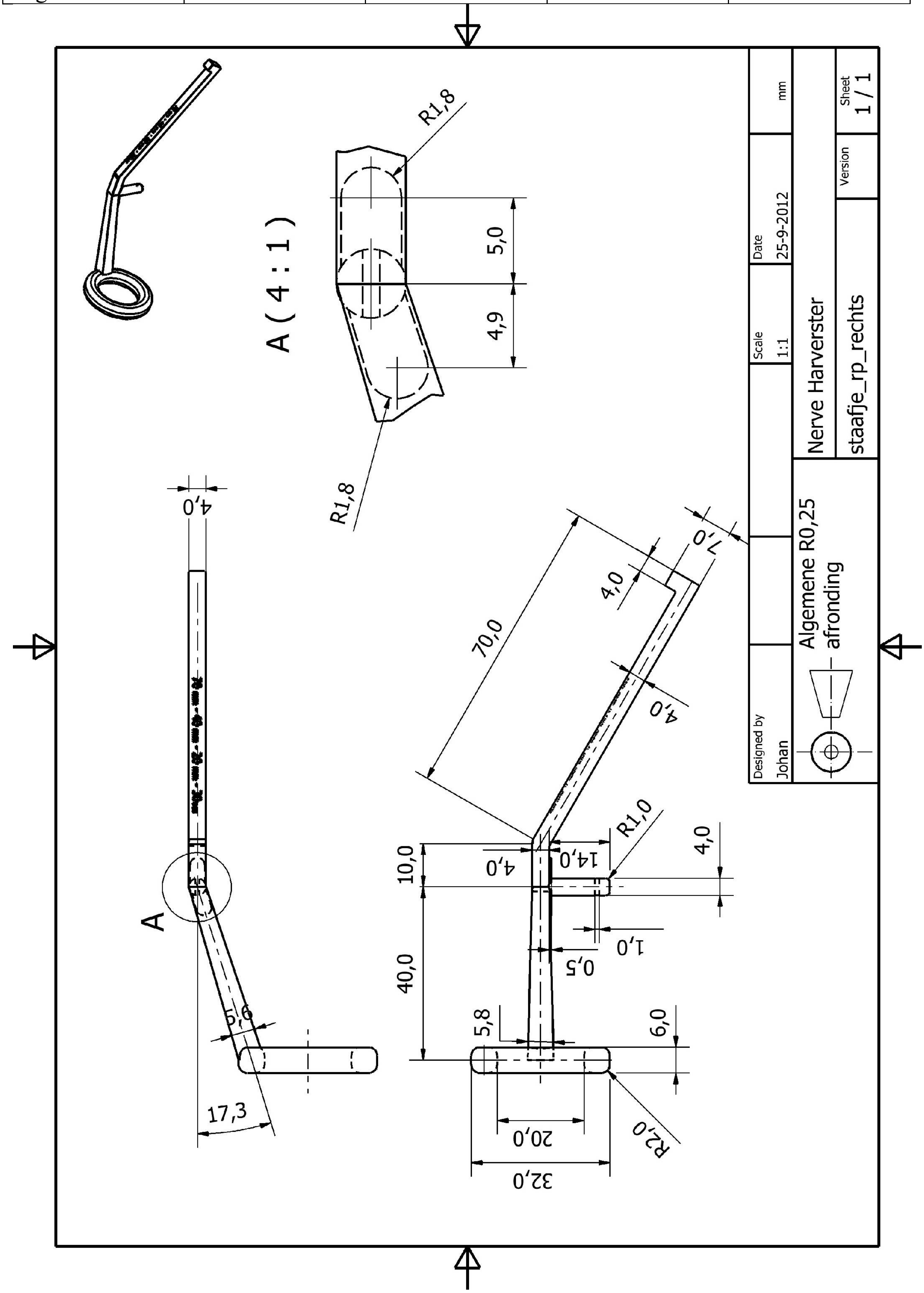
| Rod | Front length | Back length | Inner diameter | |
|---|---|---|---|---|
| Right | 70 | 70 | 20 | Tip angle |



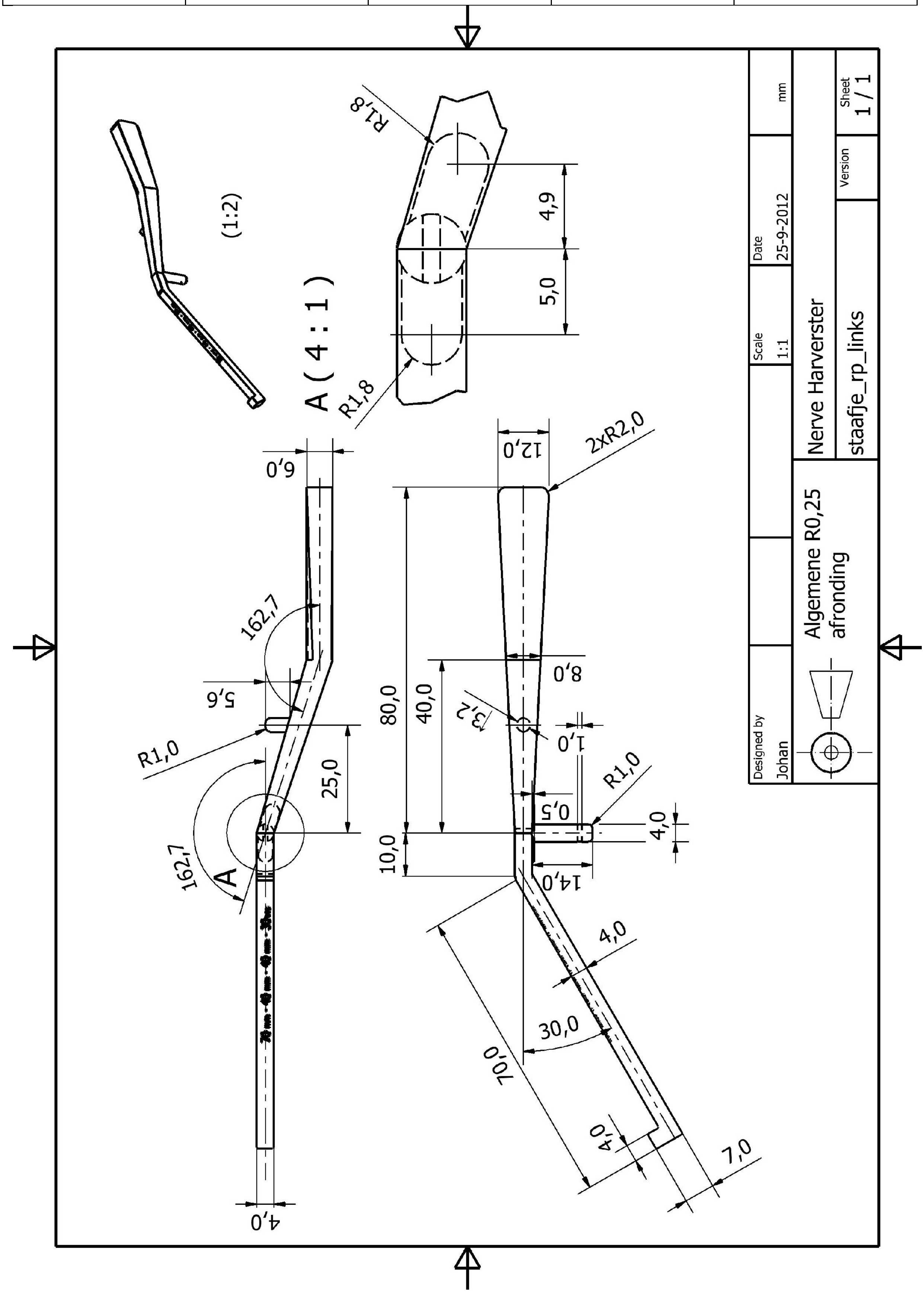
| Rod | Front length | Back length | Inner diameter | Front angle |
|---|---|---|---|---|
| Left | 70 | 70 | 25 | 30° |



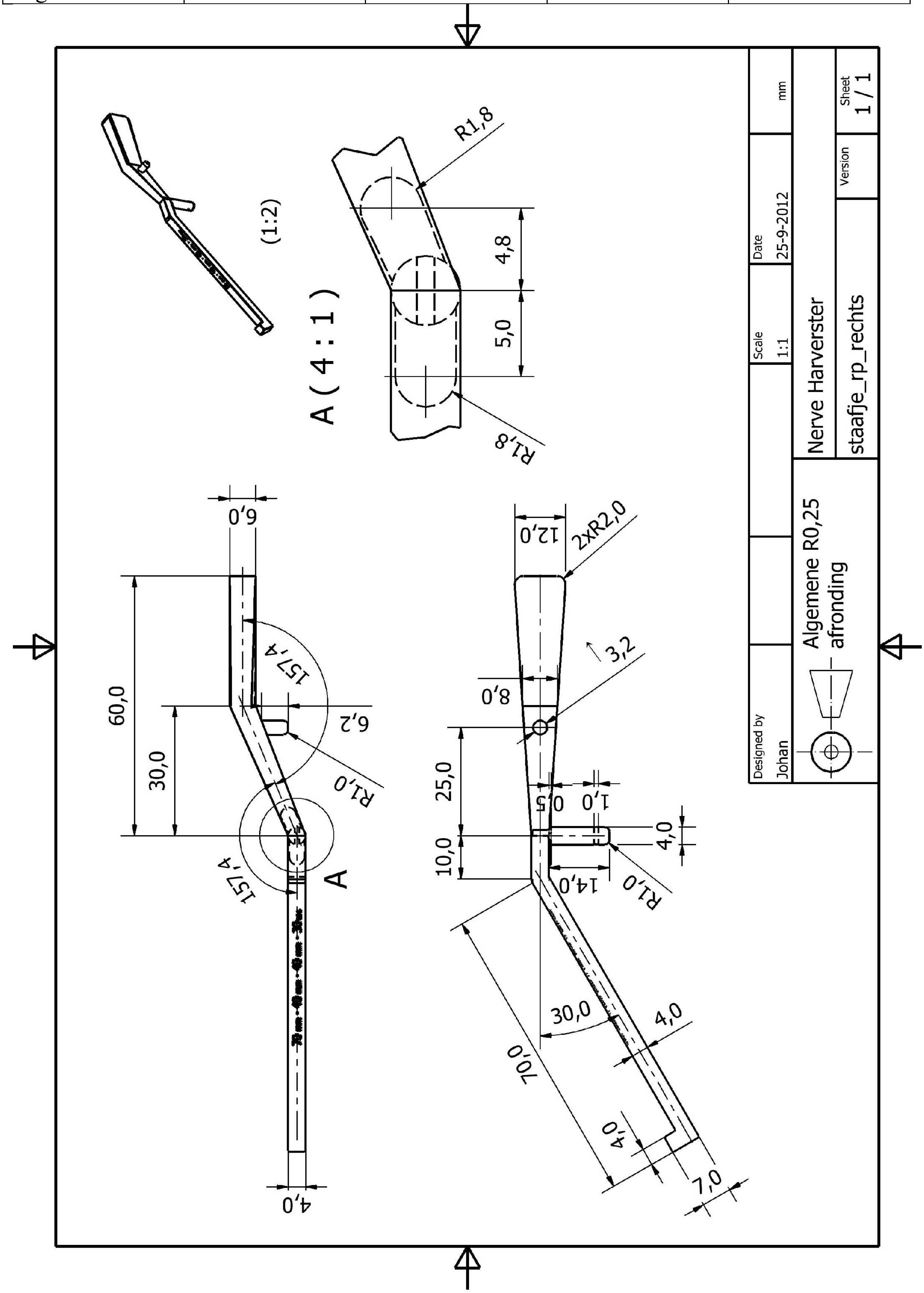
| Rod | Front length | Back length | Inner diameter | Front angle |
|---|---|---|---|---|
| Right | 70 | 40 | 20 | 30° |



| Rod | Front length | Back length | Back width | Front angle |
|---|---|---|---|---|
| Left | 70 | 80 | 12 | 30° |



| Rod | Front length | Back length | Back width | Front angle |
|---|---|---|---|---|
| Right | 70 | 60 | 12 | 30° |



# Appendix C: Finite Element Analysis Spring

## C.1. Results

To give an impression for the thickness of the spring thread a finite element analysis (FEA) is done with Autodesk Inventor 2012. The FEA feature is an extension of the 3D drawing program used for making the 3D model, drawings and rapid prototyping models.
A simple experiment with a kitchen scale and two different surgical forceps learns that the closing mass of those forceps is roughly 200 and 500 grams. This means a closing force of approximate 2 and 5 Newton. The spring force needs to be high enough for easy closing of the tip, however as weak as possible not to damage the nerve by accident, to retain force feedback of the tissue and to prevent fatigue of the surgeons hands. The best solution is somewhere in the middle and depends on a high amount of the opinion and feeling of the surgeon.

The desired displacement is around 6 mm. With the FEA the two loads are applied on different spring thicknesses, where the three most important thicknesses are in detailed reports further on. The summery can be found in Table 6 and Table 7. With three different set of springs the surgeon has a wide range of motion to his disposal. These thicknesses will be made and given to the neurosurgeons for evaluation.

Table 6. Load of F = 5 N

| **Thread thickness** | **Max Displacement** |
|---|---|
| 0,6 mm | 42,0 mm |
| 0,8 mm | 14,1 mm |
| 1 mm | 5,9 mm |

Table 7. Load of F = 2 N

| **Thread thickness** | **Max Displacement** |
|---|---|
| 0,6 mm | 16,8 mm |
| 0,8 mm | 5,6 mm |
| 1 mm | 2,4 mm |

# Stress Analysis Report

Autodesk®

| | |
|---|---|
| Analyzed File: | veer_draad_berekening.ipt |
| Autodesk Inventor Version: | 2012 (Build 160160000, 160) |
| Creation Date: | 5-9-2012, 13:43 |
| Simulation Author: | Johan |

## Project Info (iProperties)

### Summary

| | |
|---|---|
| Title | Nerve Harvester |
| Author | Johan Bakker |

### Project

| | |
|---|---|
| Part Number | veer_draad_berekening |
| Designer | Johan Bakker |
| Date Created | 1-5-2012 |

### Physical

| | |
|---|---|
| Material | Copy of Default |
| Density | 7,8 g/cm^3 |
| Mass | 0,000570764 kg |
| Area | 294,412 mm^2 |
| Volume | 73,1749 mm^3 |
| Center of Gravity | x=-4,48041 mm<br>y=-30,5696 mm<br>z=0 mm |

Note: Physical values could be different from Physical values used by FEA reported below.

# C.2. FEA Simulation 1: Load of 5 N

### General objective and settings:

| | |
|---|---|
| Design Objective | Parametric Dimension |
| Simulation Type | Static Analysis |
| Last Modification Date | 5-9-2012, 13:41 |
| Detect and Eliminate Rigid Body Modes | No |

### Advanced settings:

| | |
|---|---|
| Avg. Element Size (fraction of model diameter) | 0,1 |
| Min. Element Size (fraction of avg. size) | 0,2 |
| Grading Factor | 1,5 |
| Max. Turn Angle | 60 deg |
| Create Curved Mesh Elements | Yes |

### Design Constraint definition:

| Constraint Name | Constraint Type | Limit | Safety Factor |
|---|---|---|---|
| Max Displacement | View the value | | 1 |

### Parameter definition:

| Component Name | Feature Name | Parameter Name | Values | Current Value | Unit |
|---|---|---|---|---|---|
| veer_draad_berekening.ipt | | draad | 0,6;0,8;1 | 1 | mm |

## Material(s)

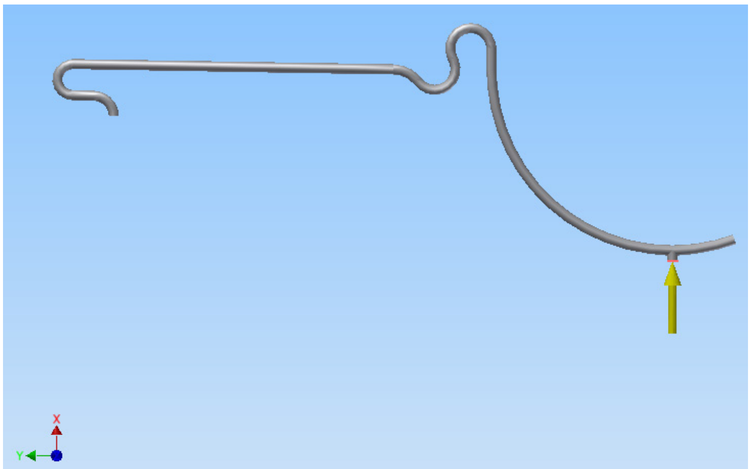
| | | |
|---|---|---|
| Name | Copy of Default | |
| General | Mass Density | 7,8 g/cm^3 |
| | Yield Strength | 235 MPa |
| | Ultimate Tensile Strength | 0 MPa |
| Stress | Young's Modulus | 206 GPa |
| | Poisson's Ratio | 0,3 ul |
| | Shear Modulus | 79,2308 GPa |
| Stress Thermal | Expansion Coefficient | 0 ul/c |
| | Thermal Conductivity | 0 W/( m K ) |
| | Specific Heat | 0 J/( kg c ) |
| Part Name(s) | veer_draad_berekening.ipt | |

## Operating conditions

### Force:1

| | |
|---|---|
| Load Type | Force |
| Magnitude | 5,000 N |
| Vector X | 5,000 N |
| Vector Y | 0,000 N |
| Vector Z | 0,000 N |

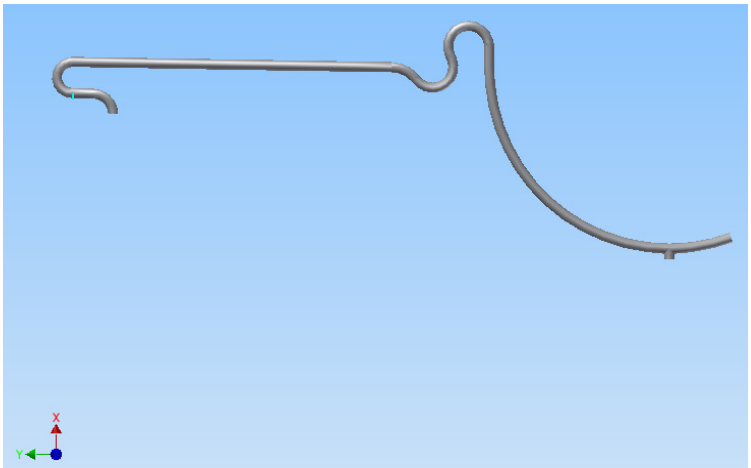
**Selected Face(s)**




**Fixed Constraint:2**

| Constraint Type | Fixed Constraint |
|---|---|

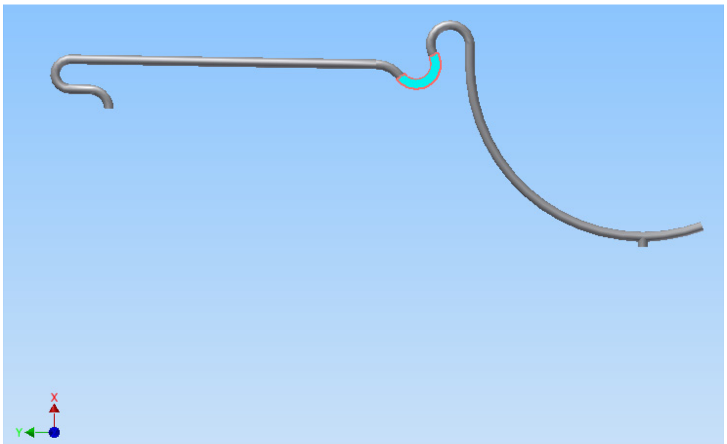
**Selected Face(s)**




**Fixed Constraint:1**

| Constraint Type | Fixed Constraint |
|---|---|

**Selected Face(s)**



## Parametric Configuration:1

### Parameter(s)

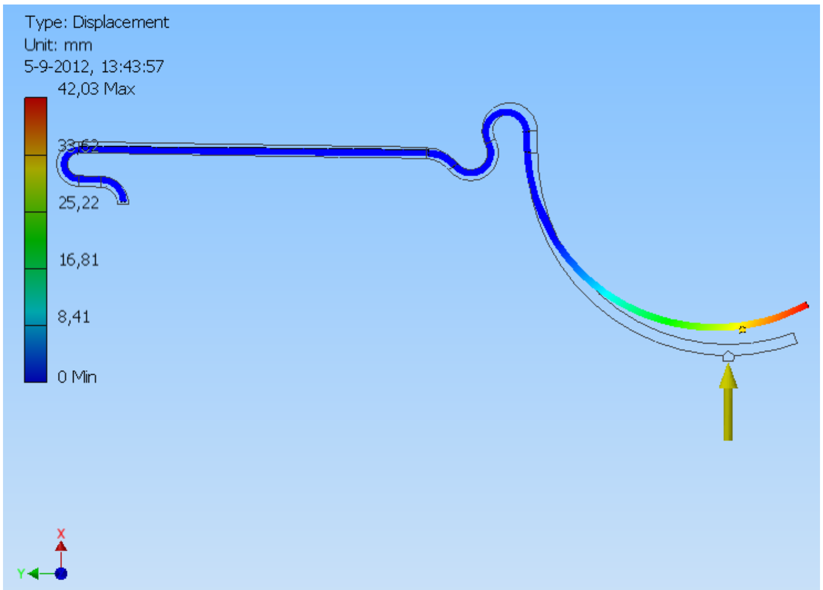
| Component Name | Feature Name | Parameter Name | Current Value | Unit |
|---|---|---|---|---|
| veer_draad_berekening.ipt | | draad | 0,6 | mm |

### Result Summary

| Name | Minimum | Maximum |
|---|---|---|
| Volume | 25,6928 mm^3 | |
| Mass | 0,000200404 kg | |
| Displacement | 0 mm | 42,0296 mm |

### Figures

### Displacement




## Parametric Configuration:2

### Parameter(s)

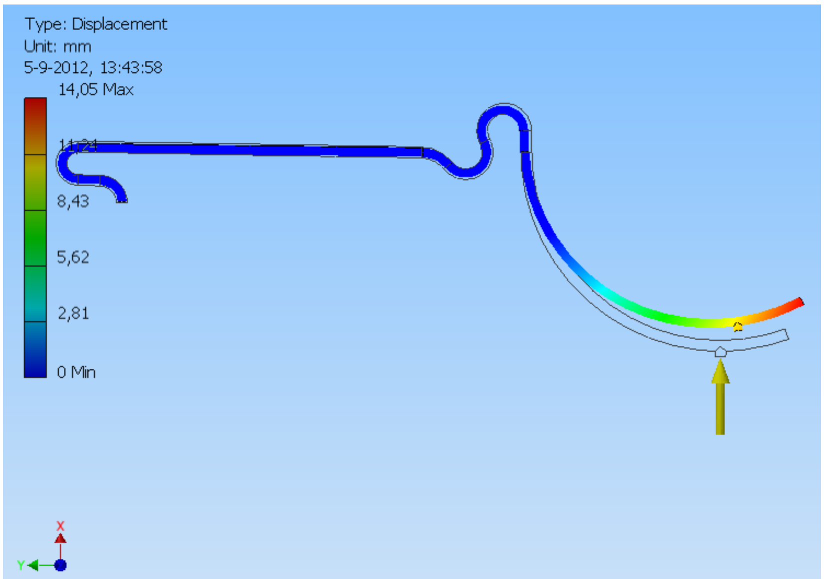
| Component Name | Feature Name | Parameter Name | Current Value | Unit |
|---|---|---|---|---|
| veer_draad_berekening.ipt | | draad | 0,8 | mm |

### Result Summary

| Name | Minimum | Maximum |
|---|---|---|
| Volume | 46,2544 mm^3 | |
| Mass | 0,000360784 kg | |
| Displacement | 0 mm | 14,0548 mm |

### Figures

### Displacement




## Parametric Configuration:3

### Parameter(s)

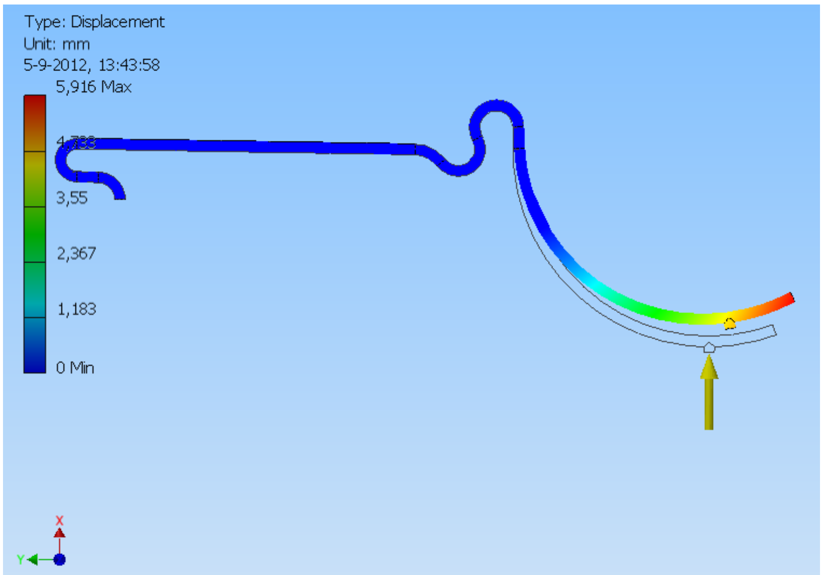
| Component Name | Feature Name | Parameter Name | Current Value | Unit |
|---|---|---|---|---|
| veer_draad_berekening.ipt | | draad | 1 | mm |

### Result Summary

| Name | Minimum | Maximum |
|---|---|---|
| Volume | 73,175 mm^3 | |
| Mass | 0,000570765 kg | |
| Displacement | 0 mm | 5,9164 mm |

### Figures

### Displacement



# C.3. FEA Simulation 2: Load of 2 N

### General objective and settings:

| | |
|---|---|
| Design Objective | Parametric Dimension |
| Simulation Type | Static Analysis |
| Last Modification Date | 5-9-2012, 13:46 |
| Detect and Eliminate Rigid Body Modes | No |

### Advanced settings:

| | |
|---|---|
| Avg. Element Size (fraction of model diameter) | 0,1 |
| Min. Element Size (fraction of avg. size) | 0,2 |
| Grading Factor | 1,5 |
| Max. Turn Angle | 60 deg |
| Create Curved Mesh Elements | Yes |

### Design Constraint definition:

| Constraint Name | Constraint Type | Limit | Safety Factor |
|---|---|---|---|
| Max Displacement | View the value | | 1 |

### Parameter definition:

| Component Name | Feature Name | Parameter Name | Values | Current Value | Unit |
|---|---|---|---|---|---|
| veer_draad_berekening.ipt | | draad | 0,6;0,8;1 | 1 | mm |

## Material(s)

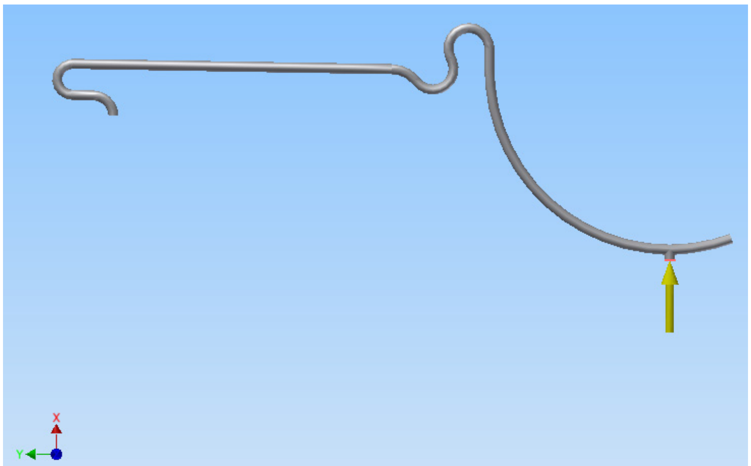
| | | |
|---|---|---|
| Name | Copy of Default | |
| General | Mass Density | 7,8 g/cm^3 |
| | Yield Strength | 235 MPa |
| | Ultimate Tensile Strength | 0 MPa |
| Stress | Young's Modulus | 206 GPa |
| | Poisson's Ratio | 0,3 ul |
| | Shear Modulus | 79,2308 GPa |
| Stress Thermal | Expansion Coefficient | 0 ul/c |
| | Thermal Conductivity | 0 W/( m K ) |
| | Specific Heat | 0 J/( kg c ) |
| Part Name(s) | veer_draad_berekening.ipt | |

## Operating conditions

### Force:1

| | |
|---|---|
| Load Type | Force |
| Magnitude | 2,000 N |
| Vector X | 2,000 N |
| Vector Y | 0,000 N |
| Vector Z | 0,000 N |

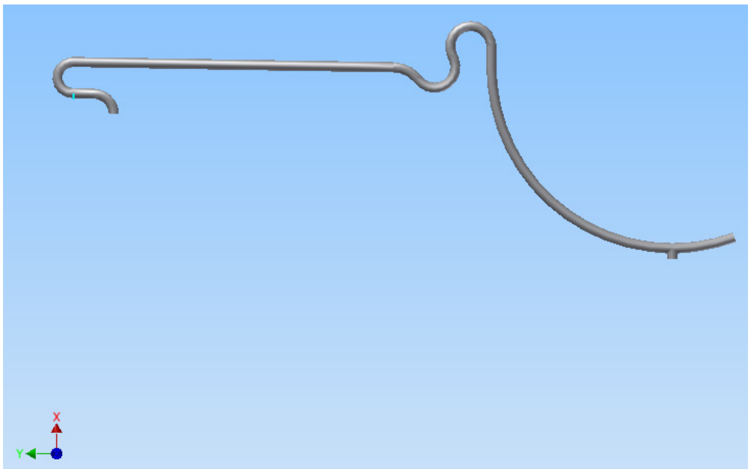
**Selected Face(s)**




**Fixed Constraint:2**

| | |
|---|---|
| Constraint Type | Fixed Constraint |

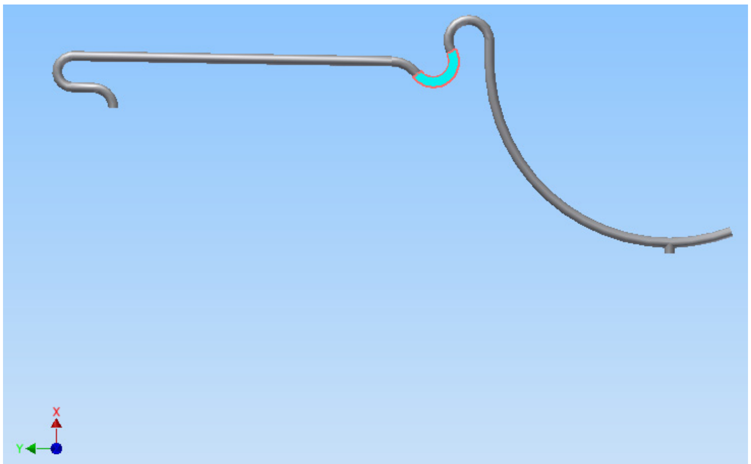
**Selected Face(s)**




**Fixed Constraint:1**

| | |
|---|---|
| Constraint Type | Fixed Constraint |

**Selected Face(s)**



## Parametric Configuration:1

### Parameter(s)

| Component Name | Feature Name | Parameter Name | Current Value | Unit |
|---|---|---|---|---|
| veer_draad_berekening.ipt | | draad | 0,6 | mm |

### Result Summary

| Name | Minimum | Maximum |
|---|---|---|
| Volume | 25,6928 mm^3 | |
| Mass | 0,000200404 kg | |
| Displacement | 0 mm | 16,8118 mm |

### Figures

### Displacement


## Parametric Configuration:2

### Parameter(s)

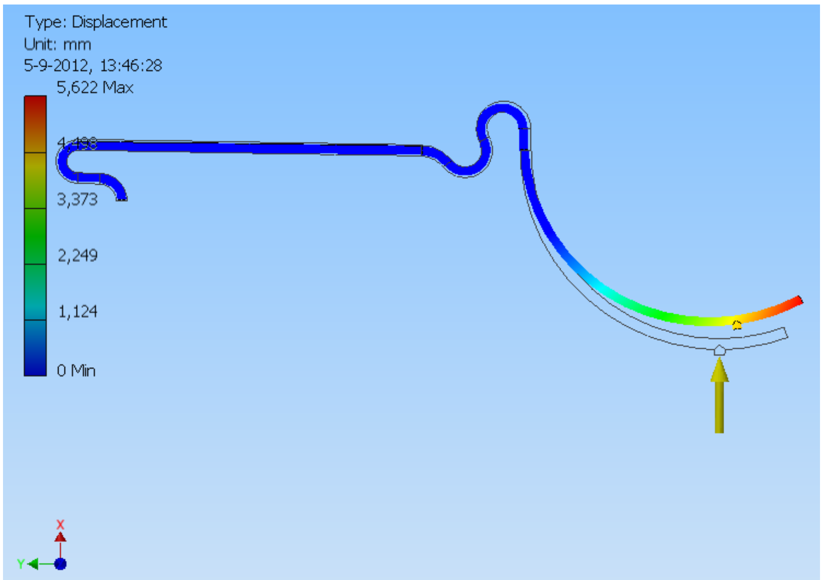
| Component Name | Feature Name | Parameter Name | Current Value | Unit |
|---|---|---|---|---|
| veer_draad_berekening.ipt | | draad | 0,8 | mm |

### Result Summary

| Name | Minimum | Maximum |
|---|---|---|
| Volume | 46,2544 mm^3 | |
| Mass | 0,000360784 kg | |
| Displacement | 0 mm | 5,62192 mm |

### Figures

### Displacement




## Parametric Configuration:3

### Parameter(s)

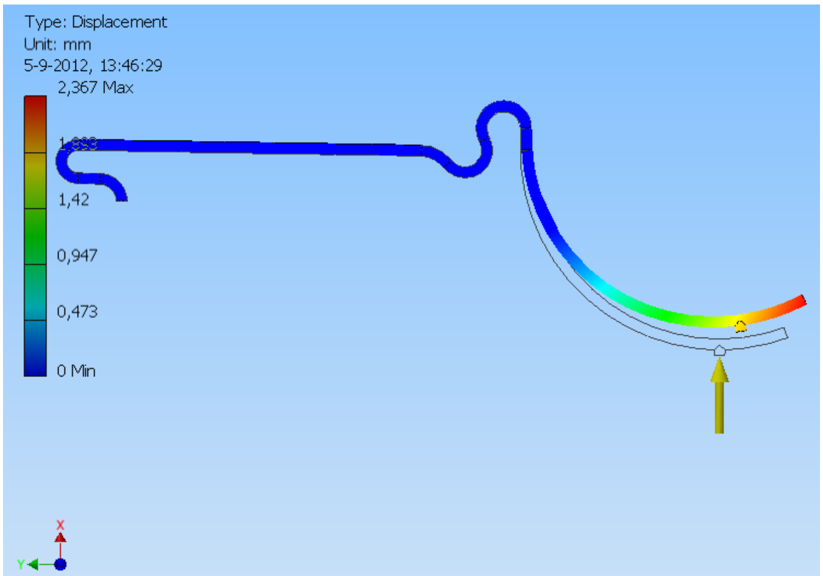
| Component Name | Feature Name | Parameter Name | Current Value | Unit |
|---|---|---|---|---|
| veer_draad_berekening.ipt | | draad | 1 | mm |

### Result Summary

| Name | Minimum | Maximum |
|---|---|---|
| Volume | 73,175 mm^3 | |
| Mass | 0,000570765 kg | |
| Displacement | 0 mm | 2,36656 mm |

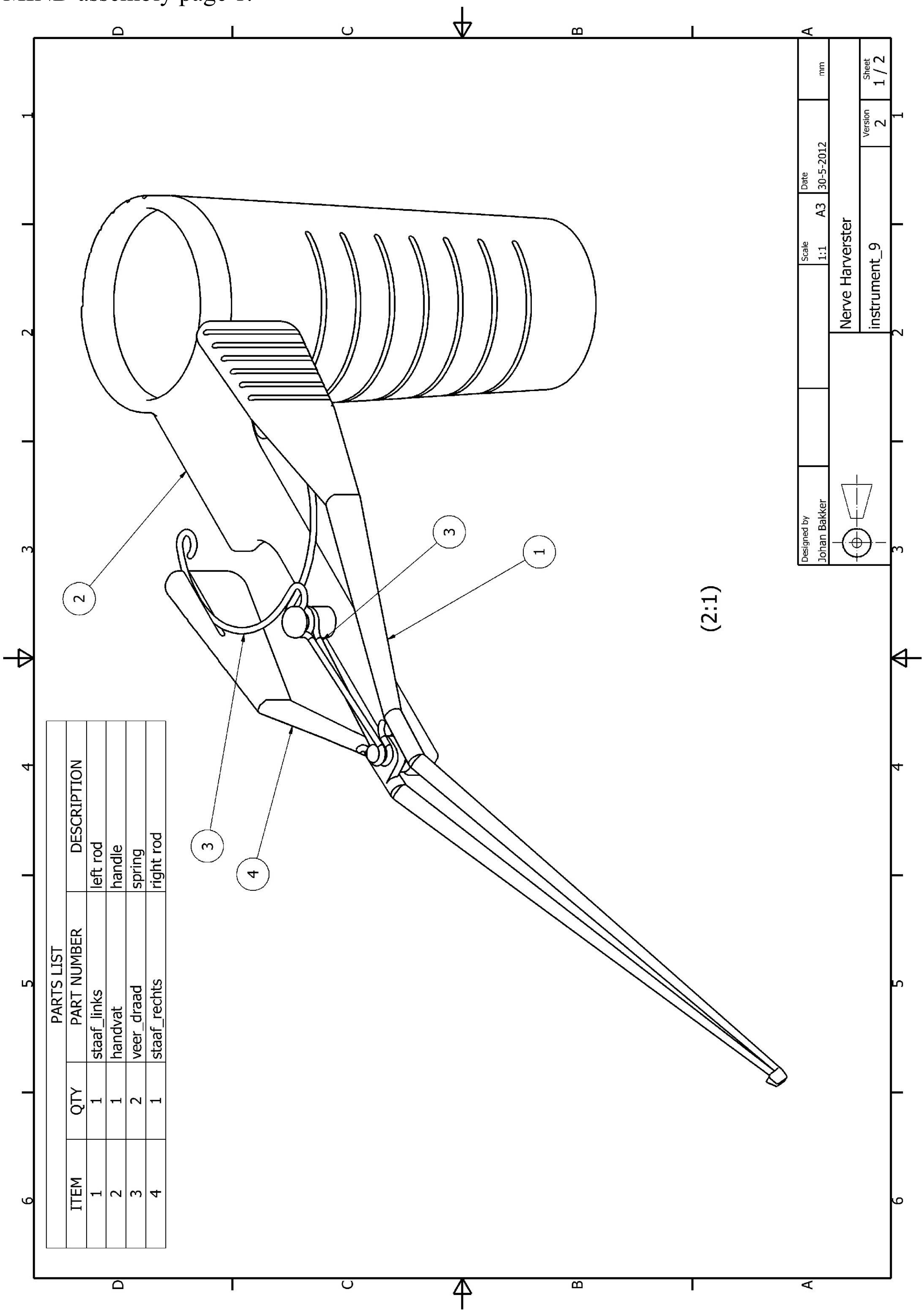
### Figures

### Displacement

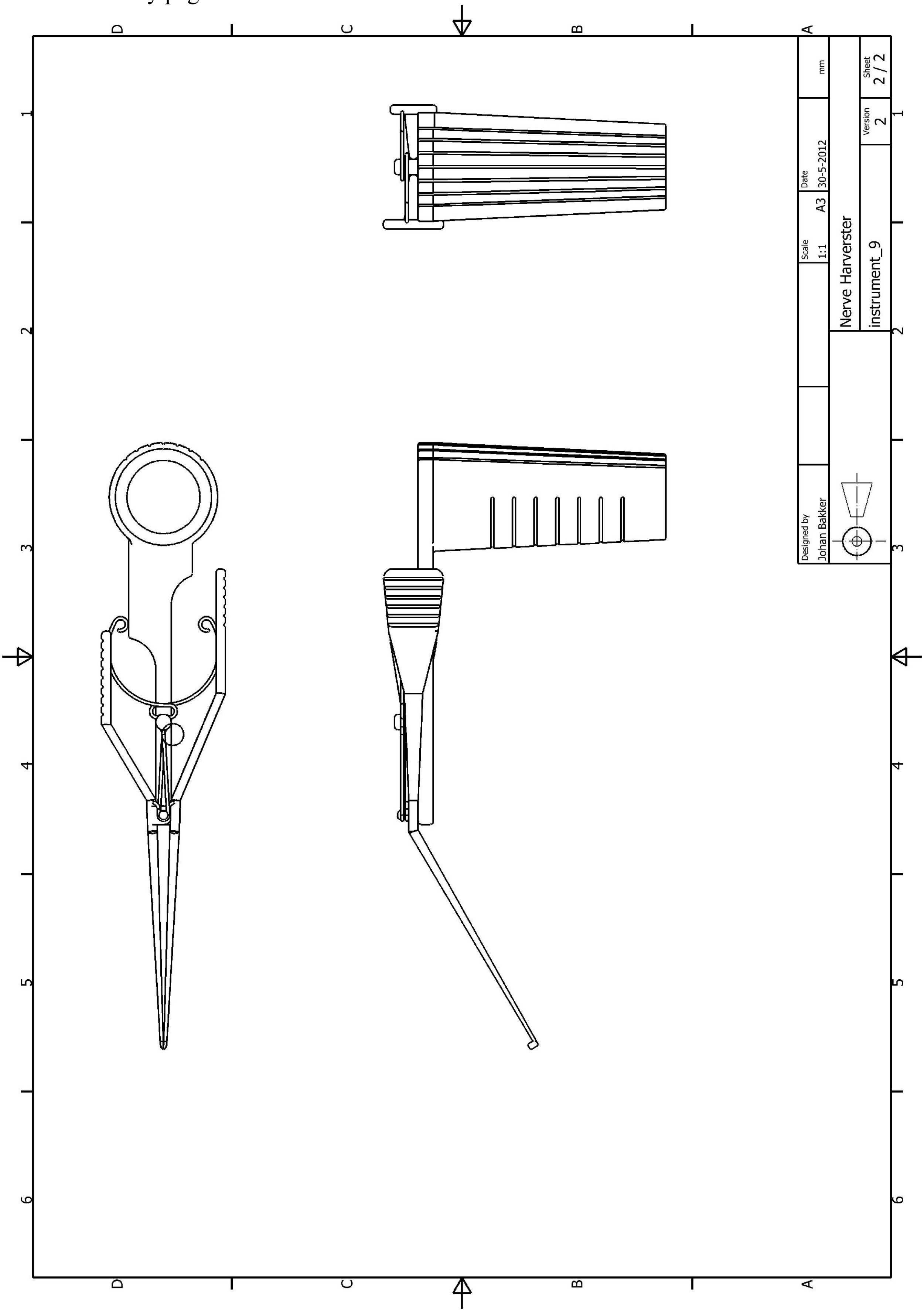


# Appendix D: MIND Drawings

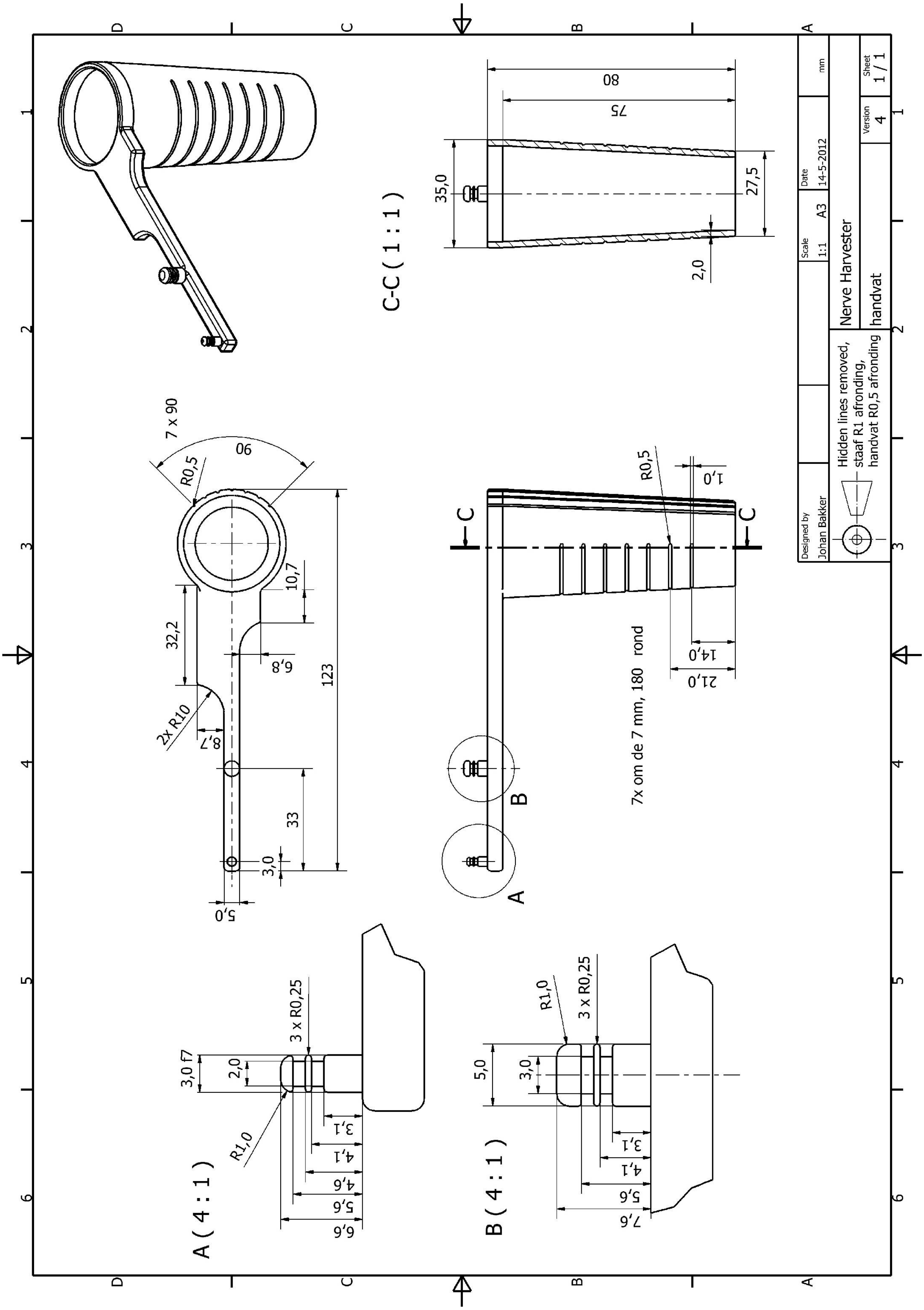
MIND assembly page 1.



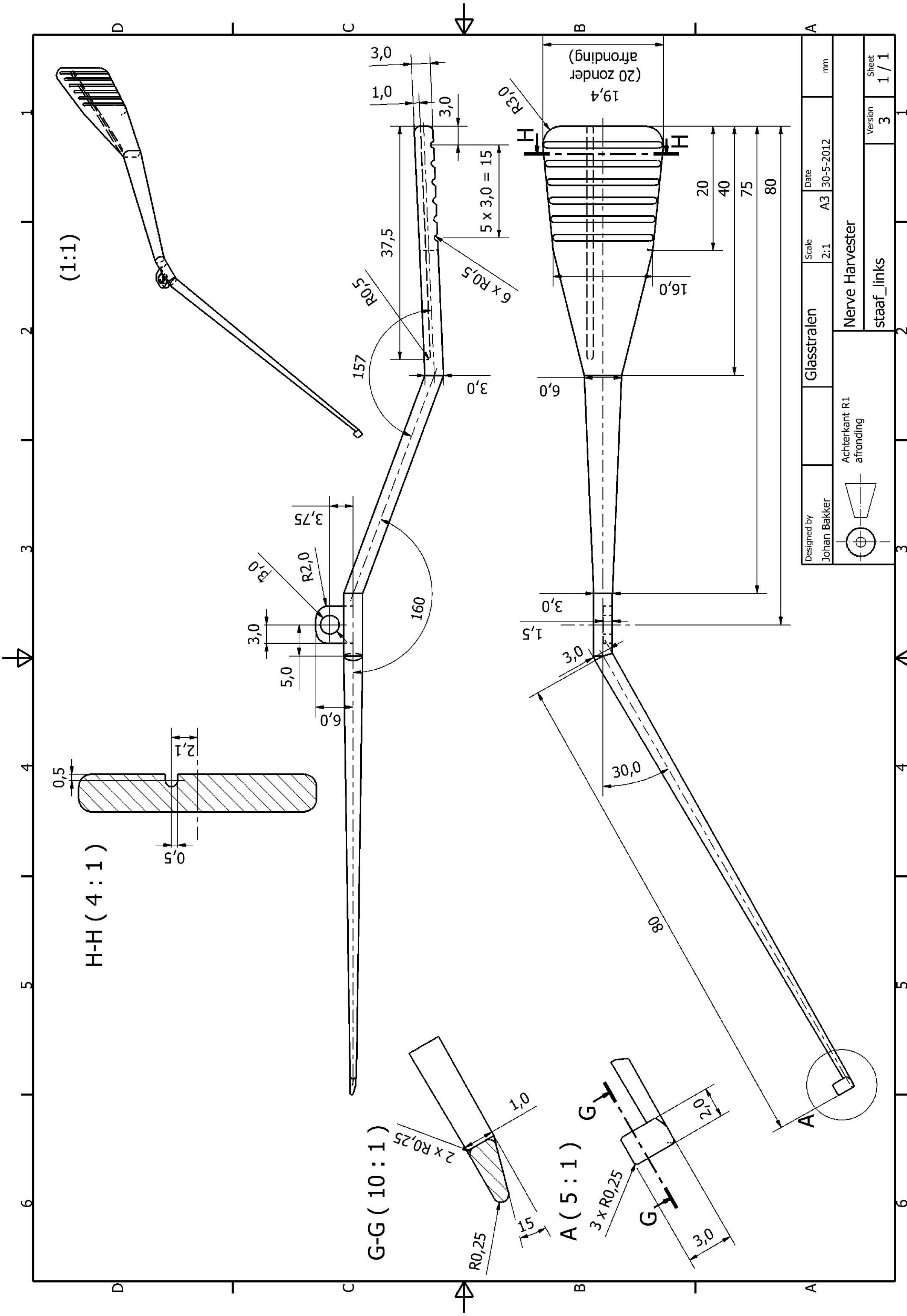
MIND assembly page 2.



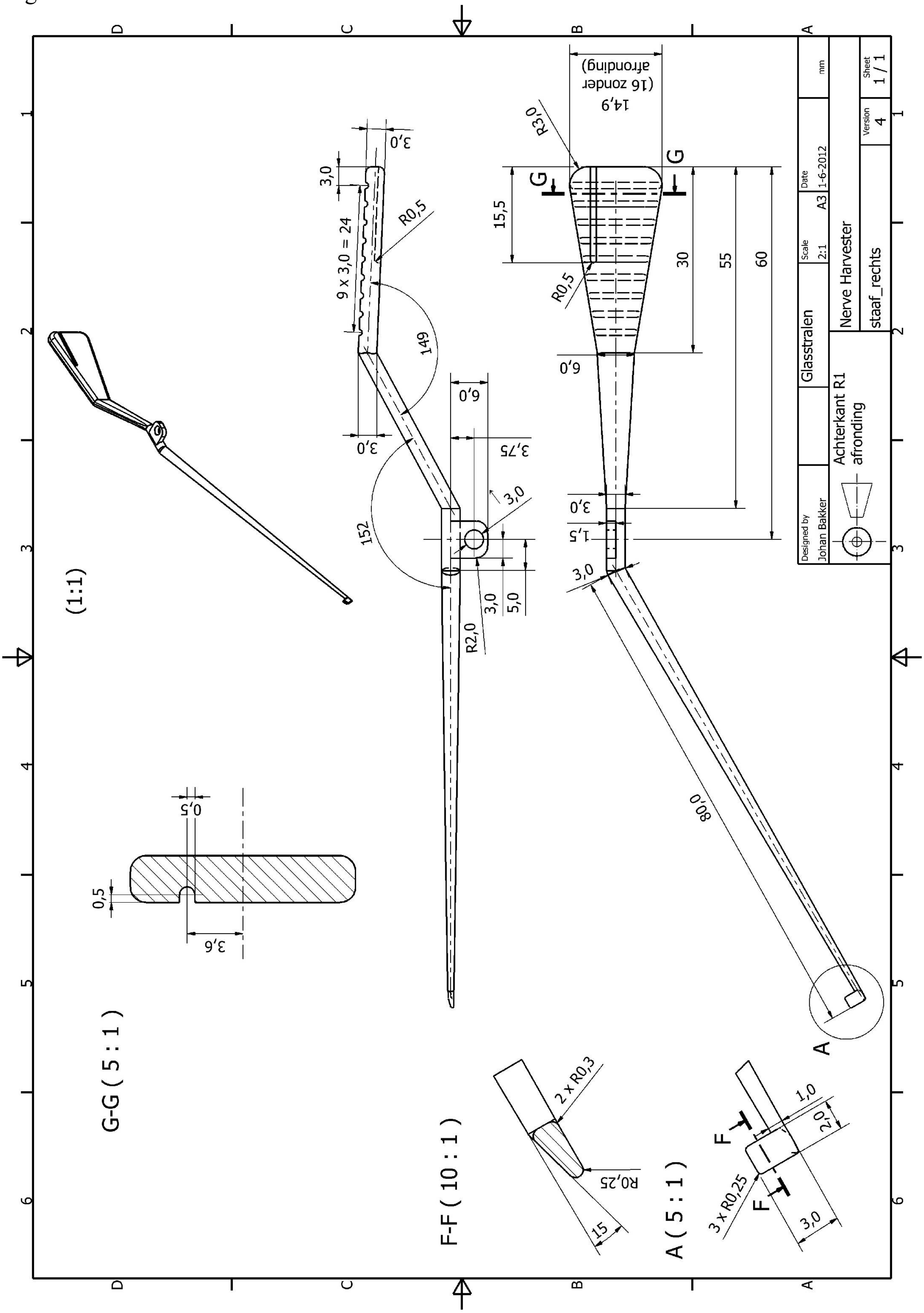
Handle.


C-C ( 1 : 1 )
A ( 4 : 1 )
B ( 4 : 1 )
7 x 90
7x om de 7 mm, 180 rond
Designed by
Johan Bakker
Hidden lines removed,
staaf R1 afronding,
handvat R0,5 afronding
Scale
1:1
A3
Nerve Harvester
handvat
Date
14-5-2012
mm
Version
4
Sheet
1 / 1

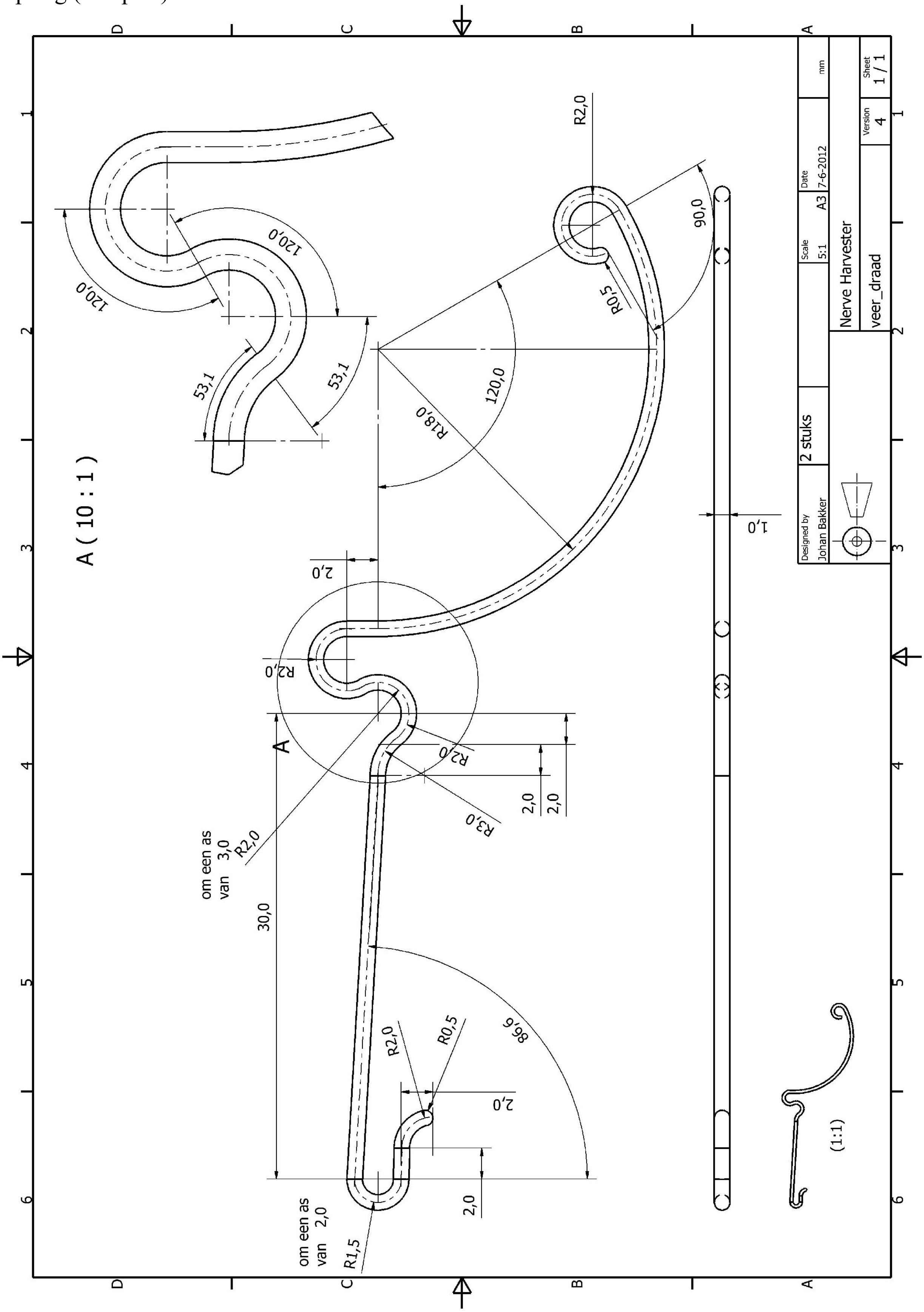
Left rod.


Glasstralen
Nerve Harvester
staaf_links
Designed by
Johan Bakker
Scale
2:1
A3
Date
30-5-2012
mm
Version
3
Sheet
1 / 1
Achterkant R1
afronding
(1:1)
H-H ( 4 : 1 )
G-G ( 10 : 1 )
A ( 5 : 1 )
19,4
(20 zonder
afronding)
5 x 3,0 = 15
6 x R0,5
2 x R0,25
3 x R0,25

Right rod.


Designed by
Johan Bakker
Glasstralen
Achterkant R1
afronding
Nerve Harvester
staaf_rechts
Scale
2:1
A3
Date
1-6-2012
mm
Version
4
Sheet
1 / 1
(1:1)
G-G ( 5 : 1 )
F-F ( 10 : 1 )
A ( 5 : 1 )
14,9
(16 zonder
afronding)
R3,0
R0,5
R2,0
R0,25
2 x R0,3
3 x R0,25
9 x 3,0 = 24
149
152
80,0
15,5
30
55
60
6,0
3,75
3,0
1,5
5,0
0,5
3,6
1,0
2,0
15

Spring (2 copies)



# Appendix E: Appendix - Test facility

## E.1. Concept Test Facilities

**Figure 26. First test facility with the second soft tissue plate.**

### E.1.1. First test facility

In an early stage of the instrument design a simple calf simulator or test facility was built with the goal to demonstrate and give some visualization and inspiration during brainstorming. Another goal was to make a first step towards a possible test and training facility. The advantages of an office/kitchen test simulator are that experiments are easy to repeat, that it has controllable variables and that it saves a lot of hassle as no animals are harmed for testing. The design of the test facility was based on observations made during harvesting procedures of the sural nerve and frequent discussions with the neurosurgeons performing this procedure.

The leg is simulated by a wooden base and a vertical board with a reinforcement rib, all screwed and glued together (Figure 26). On the vertical plank two hooks are attached to hang the soft tissue part. As a first simulated soft tissue part a large sponge was cut in the appropriate size and attached with a thread to a white plastic plate of 7 by 13 cm (Figure 28 Left). The plate contains two holes for attaching it to the vertical board of the base. For the simulated skin a yellow dishcloth was used with Velcro sewed onto it (Figure 28 Middle) for attachment around the sponge. Three cuts were made in the dishcloth to represent the incisions made in the operating room (Figure 28 Right). The wooden basis of the test facility was gives a good representation of the infants leg, but the soft tissue part does not represent the calf good enough. The dishcloth has not the elastic properties of the skin and the sponge attachment had too much play. Also the shape of the sponge and the size was not conform a real calf muscle of an infant.

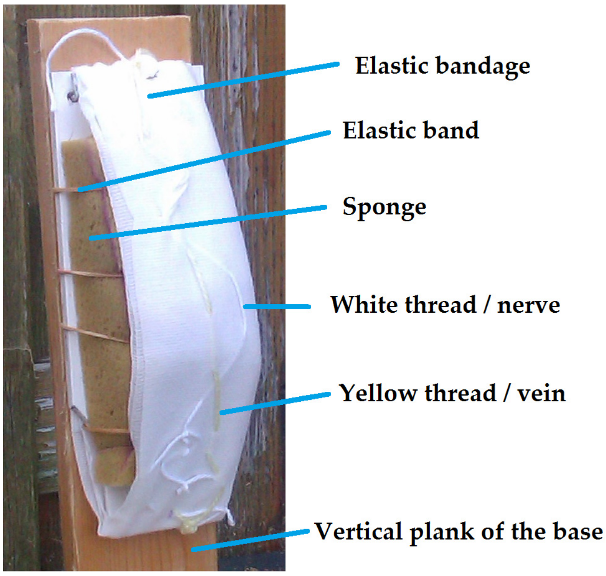



**Figure 27. Close up of the second soft tissue plate.**

To give a closer representation of the sural nerve a second soft tissue plate was built. With the second soft tissue plate (Figure 27) a larger base plate was selected (7 by 19 cm) and the

**Figure 28. First concept for the soft tissue. Left: plastic plate with sponge. Middle: Sponge wrapped in yellow dishcloth with Velcro. Right: The end result with three incisions.**

**Figure 29. Left: Artificial skin, note the black sewing seam at the bottom left corner. Middle: With the sewing seam and a inner tube the skin is is wrapped equally around the soft tissue plate. Right: The surgeon is testing rapid prototype models, he uses the first test facility to give a better feeling and visualisation. The test facility aids him in his decision making.**

sponge was cut with a scissors in the curve of a half ellipse. The sponge was attached to this plate with four elastic bands. A 6 cm wide bandage was wrapped two times around the plate with the sponge from top to bottom (from ankle to knee). To simulate the nerve a new bandage was wrapped another two times around the sponge and a white wool tread was roughly woven into it. Close to the bottom a second white wool tread was attached with a knot, to simulate the division of the common sural nerve into the medial and lateral sural nerve near the knee. Besides the white thread (the artificial nerve) a soft yellow tread was woven to simulate the small saphenous vein (Figure 27). All the threads were attached to the white base plate so that simply harvesting the nerve by pulling them out is not possible. As a skin a double layered piece of cotton was used (Figure 29 Left). To fixate the skin around the soft tissue plate, the bottom corner of the cotton has a sewing seam. When an inner tube of a racing bicycle is put through the cotton and is attached to the base plate, it creates roughly constant pulling force over the length of the sponge (Figure 29 Middle). With the elastic inner tube and the flexible cotton it has some elastic properties, giving a closer representation of the skin.

The main downside of this soft tissue plate is that the thread and the bandage does not represent the tissue connection between a nerve and connective tissue. There is no physical attachment of the thread to the bandage and therefore it cannot be used for testing but only for demonstration and inspiration.

## E.1.2. Second test facility

The goal of the second test facility was to give a closer representation of an infants leg to evaluate the instrument. The second facility (Figure 30) is refinement of the first one. The wooden base was constructed of a block and a supporting rib. The vertical board was placed between those two and is attached with pins to the block. This makes the vertical plate removable which facilitates transportation. The pin connection has some play to simulate the slightly free motion of an infants leg hanging to a suspension rod. Similar to the first test facility, two hooks were mounted to the vertical plate where the soft tissue plate can be attached. The same plate and sponge is used as with the first test facility; only the bandages and threads have been removed and replaced with transparent packing and office tape. The tape has the advantage that the sponge cannot absorb moisture and debris from the new simulated nerve. An artificial nerve can be attached with elastic band to nails on the vertical plate and base plate block. There are hooks at the vertical plate underneath the soft tissue plate to guide the thread to the nails. Now the bottom half of the artificial nerve keeps in contact with the soft tissue plate. At the base plate block several nails were mounted in the block to give the possibility for different tensions to the thread. The elastic bands simulate the elasticity of a nerve. To simulate the skin an elastic bandage is wrapped around the vertical plate an soft tissue plate.

**Figure 30. Second test facility. For visual purpose the limited bandage (artificial skin) is wrapped behind the thread (artificial nerve).**

# E.2. Concept artificial nerves

## E.2.1. Introduction

An artificial nerve is needed because meat and other animal or human tissue cannot be used for testing with the current instruments due to contamination danger. An artificial nerve consist of three things: A flexible, long, and thin structure to simulate the nerve. A flexible sticky elastic and slightly viscous substance around the nerve to simulate the connective tissue. And a weaker but present attachment between the nerve and connective tissue.

During the course of the graduation, several materials have been tried to create an artificial nerve and connective tissue. In all cases a wool thread was used as a nerve because with this thread can absorb the simulated connective tissue to create a connection. Other threads or wires do not create a strong enough attachment or a too strong attachment to the simulated connective tissue.

Several materials for connective tissue were tried but did not represent the desired connective tissue properties:

Candle wax: Easy to melt "Au bain-marie" and attached good to the thread fibers. However it was too brittle, even mixing different amounts of olive oil does not result in the right viscous mixture for connective tissue.

Gelatine: Very cheap, easy to prepare, easy to use and different concentrations are possible. The downside is that even with different concentrations (and even a second time heating and cooling) the gelatine remains too weak to simulate connective tissue. When using the evaluation prototype one can simply press through the gelatine as a hot knife trough butter. Because of extensive experimenting and still a demonstration purpose the recipe can be found in Section E.2.2.

Pre fabricated pasta: Raw pasta from the supermarket cannot be manipulated because it is too hard. Both cooked and uncooked soaked pasta (macaroni and lasagne leaves) was tried. However it was not the solution because very long soaking or cooking times were needed to come near the needed properties for connective tissue and still the attachment with the thread was too weak.

Dough: Inspired by the pasta a basic pasta recipe was plucked from the internet. A flower and egg mix was brewed and hints of water were added for the right viscosity. It has an acceptable attachment to the nerve, nice viscous properties and is easy to make, use and adapt. Testing the dough with surgeons learns that this comes close enough to real tissue to get a valid test. A detailed description can be found in the section E.4.

## E.2.2. Gelatine nerve

A promising solution for connective tissue was the use of gelatine and can still be used for demonstration purposes. To create a gelatine nerve a mold is made from a 15 cm long by 1,5 cm diameter PVC tube that is cut in half. The ends are filled with glue to create a water tight mold (Figure 31). The glue came from a glue gun, this heats a rod of glue which is sticky and becomes ridged when it cools down. Also silicone was used to close the mold, but the dry time was too long and it was not as easy to apply as the glue. Next the mold is greased in with Vaseline to prevent sticking of the gelatine. The woollen thread is placed inside the mold. Next the gelatine is prepared following the instructions on the

**Figure 31. Molds to make a gelatine nerve.**

package. For this experiment Dr. Oetker gelatine is used of 65 cent per package. With these gelatine 12 leaves are good for one litre fluid, or 83 ml water per leave. To create more concentrated gelatine 50 ml and less per leave is used. During making of the gelatine some sifted flower is added to decrease the opacity of the gelatine, just like normal tissue. Then the gelatine is poured into the mold and put in the fridge to harden. After cooling the back of a teaspoon is used to remove the gelatine from the mold, because when pulling on the wire it can be torn out of the gelatine. With the fibers of the wool the gelatine penetrates deep into the thread which results in a good attachment. If a more complex shape mold is required or a PVC tube is not available, greased paper also works as a disposable mold.

# E.3. Final Test facility

## E.3.1. Final test facility

The major goal of the test facility is to create a close representation of an infants leg to evaluate the working principle of the MIND. A second and minor goal is to create a trainings facility for for example resident surgeons. The final test facility is the first test facility improved with things from the second test facility. The wooden base from the first test facility is used, because it is firmer and the play created in the second test facility was not needed. The first test facility is improved with several nails to create the right tension for the nerve and also the hooks to guide the thread, as with the second test facility. An artificial nerve (section E.4) is placed over the top attached to the nails, guided trough the hooks and attached at the bottom of the vertical plate. The second soft tissue plate is used, with the half elliptical sponge covered in transparent tape (Figure 32 Left). As a skin wound bandage is used (Figure 32 Right and Figure 33).

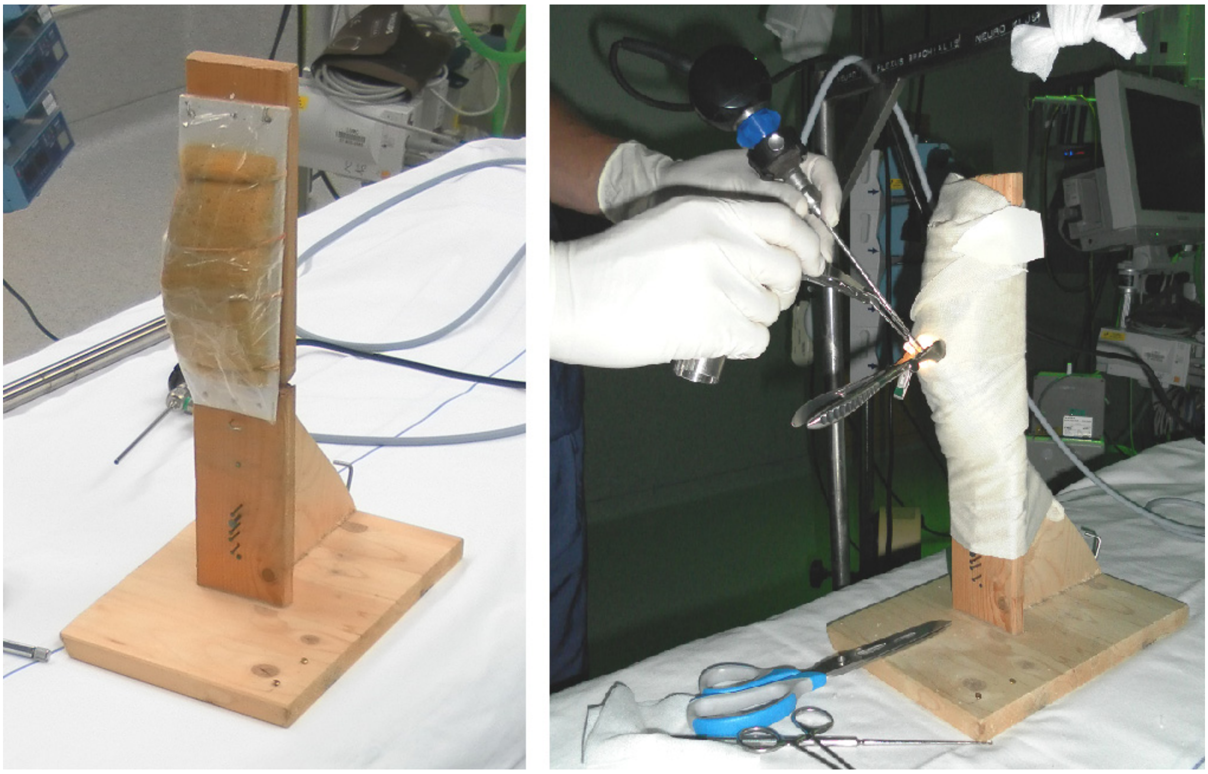


**Figure 32. Left: Final test facility without nerve and skin. Right: Test facility in use. The surgeon is using the MIND (right hand) and endoscope with camera (left hand) to dissect the nerve from the middle incision.**

**Figure 33. Test facility in use, the surgeon uses the micro scissors to dissect the nerve in the middle incision under direct visualisation. A vessel loop is placed around the nerve to see where the nerve is still attached to the connective tissue.**

# E.4. Final artificial nerve

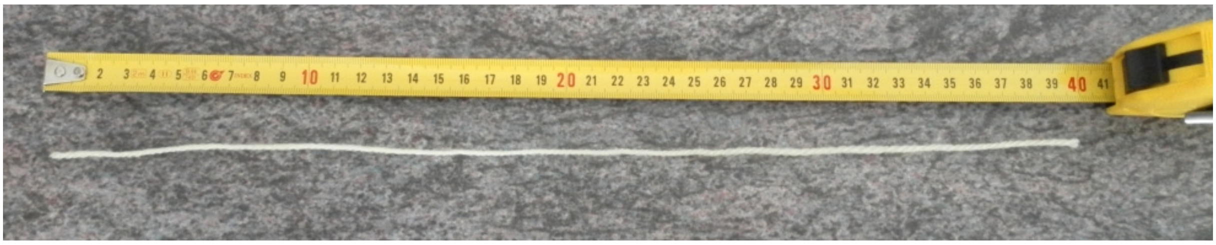
## E.4.1. Detailed making of the nerve thread

Time:
10 minutes for advanced nerve makers
< 7 minutes for expert nerve makers

Requirements:
40 cm of wool thread (soft yellow)
15 cm of sewing thread (thin, white)
Needle
Scissors (a sharp one is advised)
Permanent marker (black preferred)
Ruler / tapeline
2 elastic bands

Expiration time:
The expiration time is way more then 3 months, the most critical component for the expiration date are the elastic bands, because they can dry (note: if that happens, simply replace them).

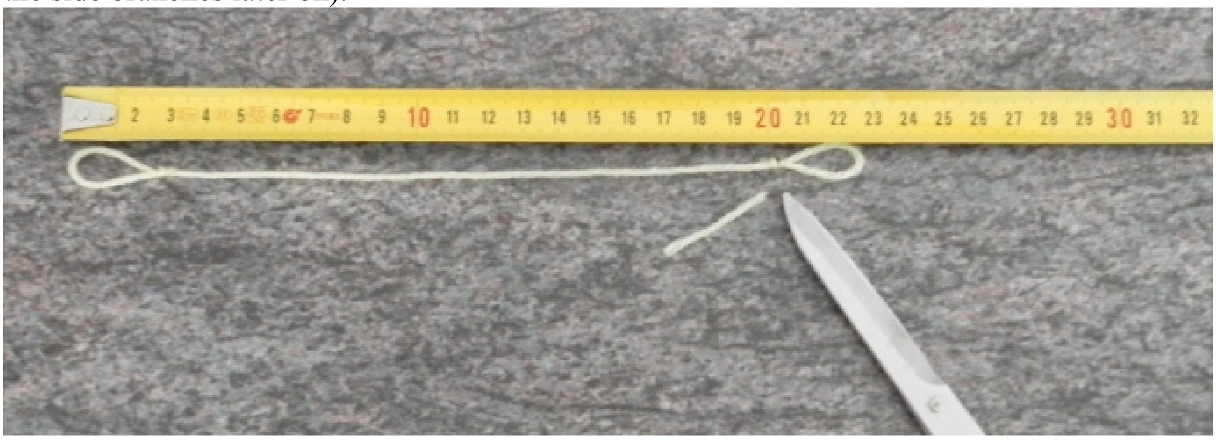
1. Take around 40 cm of thread



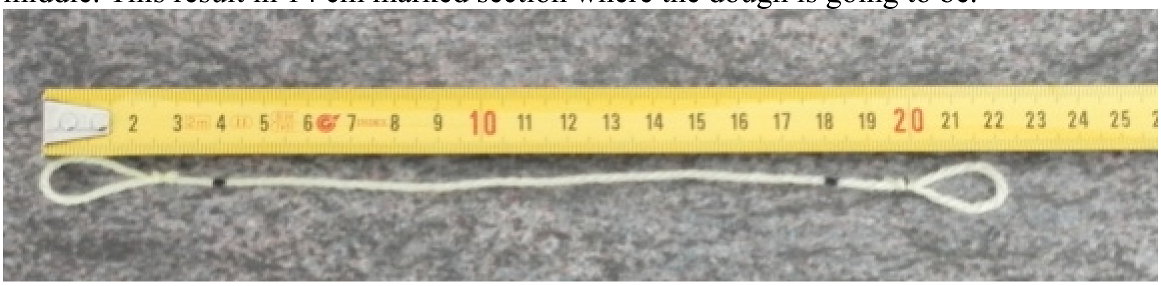
2. Make a loop of about 2,5 to 3 cm

3. Cut the excess end (note: the short end not the “nerve”). Move the knot at 0 cm of the ruler and highlight the thread at 18,5 cm (note: place a piece of paper underneath the thread to prevent unwanted decoration of your desk).

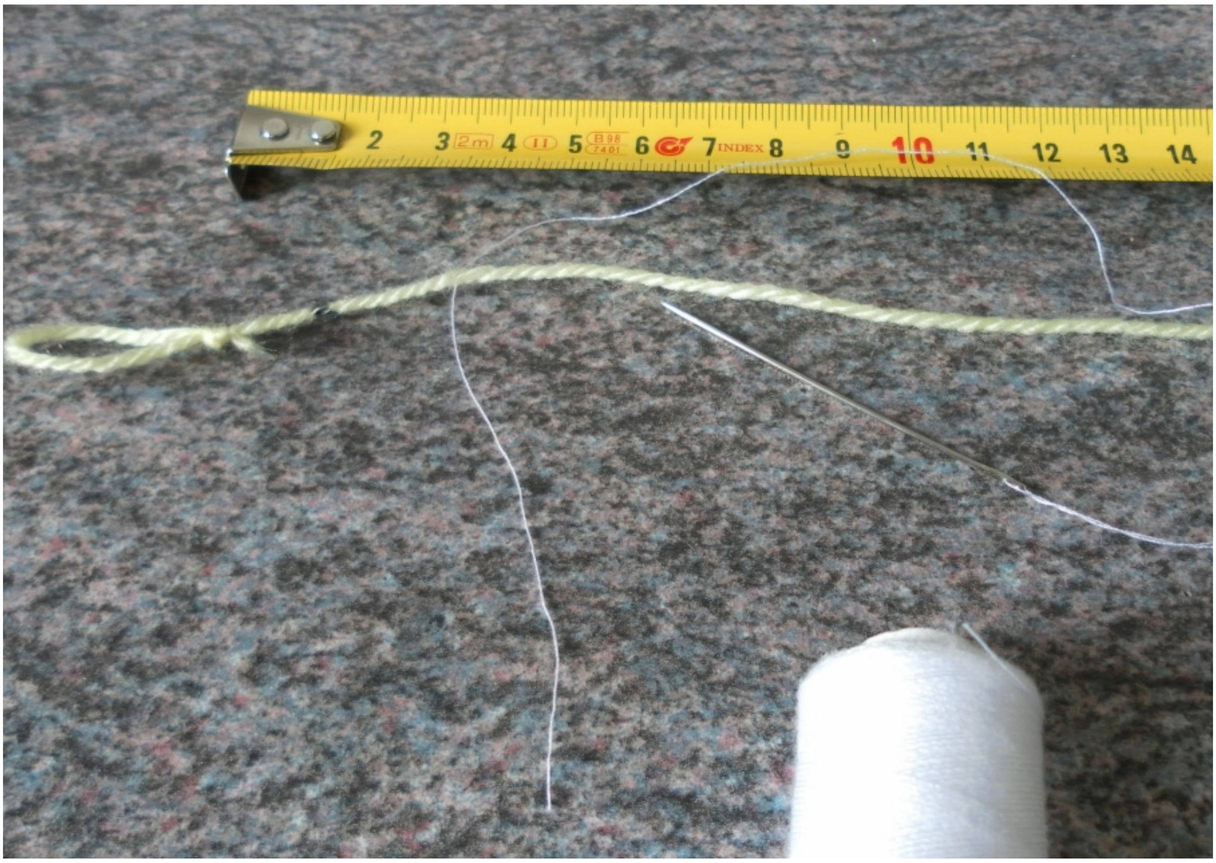
4. Make a loop of about 2,5 to 3 cm with the knot at the highlight, cut of the excess end (pay attention: do not cut the nerve, you can start over). Make sure the highlight is still visible, if not mark the knot again, this way you can recognise the top (can be important for the place of the side branches later on).



5. Measure the distance between the two knots it should be around 17-18 cm, calculate the middle (if you want to be sure, use a calculator) and highlight 7 cm to both sides from the middle. This result in 14 cm marked section where the dough is going to be.



6. Grab the white sewing thread and the needle. Cut a large section of it and put it through the needle. Stitch the sewing thread through the woollen thread 3 times (first stitch is shown in picture) with an excess end of ≥ 3 cm (note: 5 cm or more is advised, than it is easier to make the knots), make 3 knots between the excess end and the needle end to fixate the sewing thread to the woollen thread.



7. Cut the excess end at 3 cm . Cut the needle end close to the knots (note: doe not cut through the knots).

8. Repeat step 7 another two times to create 3 side branches (if wanted, more or less side branches are possible, depending on the requirements of the test). I placed one side branch in the first half and, one in the second half and one at a random location.

9. Place two elastic bands to the end of the loops of around 3 to 4 cm (my elastic bands where too long so I knotted them in half)

11. Repeat for the number of nerves needed (and perhaps a spare one).

## E.4.2. Detailed making of the dough

Time:
15-20 minutes

Requirements:
>110 gram of flower (the white powder, not the vegetation)
1 egg (preferred from a chicken or at least the same size)
1 egg yolk (preferred from a chicken or at least the same size)
Water (not more than a cup is needed, but a crane/faucet is advised, also for washing hands)
Bowl
Scale

Expiration time:
<12 hours if kept in a closed bag or container, after the expiration time the dough start to smell and gets a lot softer. If the dough is not kept in a bag or container it dry's out making it less flexible and harder. There is no experience with a refrigerator, however it can perfectly maintained in the freezer inside a plastic bag or container for more than a week (probably a couple of months or perhaps years).

1. Mix 110 gram of flower with the egg and egg yolk in the bowl until you get a nice lump of dough. It must be a consistent mixture which is light sticky and must not crumble (note: if advanced cooking/baking skills and experience are present, use them). If the dough is not consistent; knead more. If the dough is too sticky add more flower and knead. If the dough is too crumbly; add water and knead.

## E.4.3. Detailed making of artificial nerve: combining the nerve thread and the dough

Time:
10 minutes

Requirements:
Nerve thread (section E.4.1)
Dough (section E.4.2)
PVC tube cut in half (15 cm long & 1,5 cm in outer diameter, open ends)
Teaspoon (with a small back end)
Rolling pin / dough roller (or other cylindrical object)

Expiration time:
Same as for the dough (<12 hour, approximates infinity when frozen) prevent drying out and prevent sticking to the plastic bag or container.

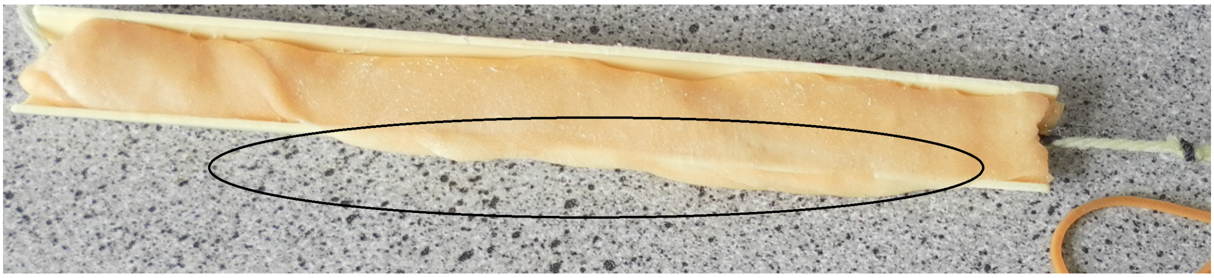
1. Take around 15 grams of dough and the PVC tube.

2. Take the dough roller and roll the lump of dough in roughly a rectangle, a little bit smaller then the PVC tube and approximately 3 times as wide. Use the roller to decrease the thickness at the outer thirds of the dough. Theoretically half of the dough should be in the middle and a quarter of the dough at both sides (note: stretching with your hands is also possible but only in the length). Blow a touch of flower into the PVC tube to prevent too much sticking (note: too much flower causes the outer layer of the dough to dry out to much).

3. Place the thick part of the dough in the middle of the PVC tube. Make the nerve thread soaking whet by pressing and rubbing water into it (don't rub so hard that the side branches can damage) and place it in the dough. Make sure the side branches are inside the dough and not sticking out. Drop around 5 droplets of water onto the nerve thread.

4. Fold the edges of the dough over the nerve and pres on it. The issue at this point is a natural seam inside the dough. This separates easily during the test and is unwanted. Therefore press your finger onto the dough and rub it several times a couple of millimetres. Not too much because that can tear the dough. Because the length of the dough was somewhat shorter than the PVC tube you can rub outwards.

5. Excess dough can be rubbed to the outside and can easily be chucked by the edges of the PVC.



6. Remove the artificial nerve out of the PVC tube with the back of a small tea spoon. Try not to pull onto the nerve thread because that can weaken it. Rotate the nerve to make it a spiral and place it back into the PVC tube. Start rubbing and pressing again.

7. Remove the nerve out of the PVC tube and rotate it (without making a spiral) 90 or 270 degrees around its axis and place it again in the tube for the last pressing and rubbing session. Because of this actions the watery nerve thread and the dough attaches to each other creating a consistent artificial nerve.

8. Pet yourself on the shoulder for this accomplishment and repeat this process for the number of artificial nerves required (and perhaps a spare one).

# E.5. Performed Tests

## E.5.1. Requirements

MIND + springs
Test facility
Video camera
Picture camera
Video standard
Artificial nerves
Scissor
NASA TLX test
Pen and paper
Test protocol and questionnaire
Water
Stopwatch

<u>Spare components:</u>
Dough
Flower
Molds
sew tread & needle
Elastic bands
Ruler
Hammer
Pincers
Nails
Calliper (Shove-buddy / "schuifmaat")
Spare test facility (second concept)

<u>Provided by the Hospital (in Dutch)</u>
Scopienet optiek + Scopie toren
Scopienet plexus instrumenten
Zenuw transplantatie set
Plexus boog
Vessel loop
Verband
Niet steriele gaasjes
Brandbare DVD-R
Steriele handschoenen

The most important instruments provided by the hospital are the micro scissor, the hook, endoscope and its visualisation equipment, and a forceps.

## E.5.2. Pre-test information

The tests on test facility have three goals:

1. Verify the test facility; is the facility representative enough compared to a real patient and therefore can this test prove the working principle of the MIND?
2. Compare the dissection between the current instruments and the current instrument with the MIND.
3. Has the test facility the potential to train residents.

After the first test two major differences were known: Dough accumulation; there is more dough then connective tissue in a real patient, this reduces visualisation and the dough plug needs to be removed. The second one is that there is no tension on the side branches because they are distally not attached; detecting the sew thread side branches cannot be done by haptic feedback and can only be seen with the endoscope, which is pretty tough. Those two differences were given before the remaining tests.

## E.5.3. Test protocol

The surgeons mission is to dissect the nerve thread from dough between the two black highlights on the nerve thread, cut the three side branches and cut the thread at the black highlights. The first test is with the current instrument. The second test is with the current instruments and the MIND. Measured is the time to remove the dissected nerve thread from the facility and the number of instrument changes.

# E.6. Detailed test results

## E.6.1. Quantitative results

Time analysis

During the procedure the time of harvesting is measured (Table 8). Time is measured from the first endoscope with instrument insertion up to cutting the nerve at the second black highlight. The difference between the surgeons is first of all because in general Surgeon 2 is a faster surgeon then Surgeon 1. Secondly Surgeon 1 approached the real harvesting procedure more closely: he made a third incision and used a vessel loop to check for still present attachments. The MIND is not involved in those extra actions and the surgeons used the same method during both of their tests, therefore those actions do not bias the test results. However a quantitative comparison between the surgeons cannot be done properly but that was not a goal of these tests.

Table 8. Time analysis

| | C.I.[1] | MIND | Difference |
|---|---|---|---|
| **Surgeon 1** | 31:27 | 19:44 | 11:43 |
| **Surgeon 2** | 16:27 | 14:26 | 2:01 |

[1] C.i: the Current Instruments.

Number of instrument changes

As can be seen in Table 9 and Table 10 for both surgeons the total number of instrument chances as well as the number of instrument changes for dissection are reduced.

Table 9. Surgeon 1

| **Task** | **C.I.[1]** | **MIND** |
|---|---|---|
| Side braches | 4[2] | 6 |
| Palpation[3] & cutting main branch | 3 | 4 |
| Changing dissection instrument | 12 | 2 |
| *Total* | *19* | *12* |

[1] C.i. Current Instruments. The number of instrument changes between micro scissor and hook.
[2] Surgeon and me didn't spot the one side branch, therefore 4 instead of the predicted 6 instrument changes
[3] Palpation is by pushing the hook outwards against the skin, by feeling on the skin the place for the second and third incision can be determined.

Table 10. Surgeon 2

| **Task** | **C.I.** | **MIND** |
|---|---|---|
| Side braches | 6 | 6 |
| Palpation & cutting main branch[1] | 3 | 5 |
| Changing dissection instrument | 8 | 2 |
| *Total* | *17* | *13* |

[1] With the current instruments the palpation is less because he was already holding the hook in his hand for dissection.

## E.6.2. NASA TLX mental workload test

Introduction

To give an overview of the mental workload of the surgeons they where ask to fill in the NASA TLX mental workload test. The results are in Tables 11-16. This test consist of a questionnaire beforehand to give a scale factor (weight) to the questions after the tests. These questions consists of giving a rating to seven workload parameters. These parameters are multiplied by there weight, add up and compared to the other test.

The results of the NASA TLX tests are that the workload for Surgeon 1 was decreased with the MIND from 11,3 to 5.9. The workload for Surgeon 2 remains the same: 8,8. The conclusion from the NASA TLX test is that the MIND does not increase the workload compared to the current instruments. Because one comparison is done per surgeon, learning curves are not measured. Probably when the surgeon gets familiar with the MIND, the mental workload drops.

Surgeon 1

Table 11. Source of workload tally sheet

| **Scale Title** | **Tally** | **Weight** |
|---|---|---|
| Mental Demand | 2 | 2/15 |
| Physical Demand | 1 | 1/15 |
| Temporal Demand | 0 | 0 |
| Performance | 5 | 5/15 |
| Effort | 3 | 3/15 |
| Frustration | 4 | 4/15 |

Table 12. Weighted Rating Worksheet - Current instruments

| **Scale title** | **Weight** | **Raw Rating** | **Adjusted Rating (Weight x Raw)** |
|---|---|---|---|
| Mental Demand | 2/15 | 15 | 2 |
| Physical Demand | 1/15 | 13 | 0,87 |
| Temporal Demand | 0 | 4 | 0 |
| Performance | 5/15 | 4 | 1,33 |
| Effort | 3/15 | 17 | 3,4 |
| Frustration | 4/15 | 14 | 3,73 |
| *TOTAL* | *1* | *67* | *11,33* |

Table 13. Weighted Rating Worksheet - MIND

| **Scale title** | **Weight** | **Raw Rating** | **Adjusted Rating (Weight x Raw)** |
|---|---|---|---|
| Mental Demand | 2/15 | 9 | 1,20 |
| Physical Demand | 1/15 | 6 | 0,4 |
| Temporal Demand | 0 | 9 | 0 |
| Performance | 5/15 | 4 | 1,33 |
| Effort | 3/15 | 7 | 1,40 |
| Frustration | 4/15 | 6 | 1,60 |
| *TOTAL* | *1* | *41* | *5,93* |

Surgeon 2

Table 14. Source of workload tally sheet

| **Scale Title** | **Tally** | **Weight** |
|---|---|---|
| Mental Demand | 5 | 5/15 |
| Physical Demand | 1 | 1/15 |
| Temporal Demand | 1 | 1/15 |
| Performance | 4 | 4/15 |
| Effort | 1 | 1/15 |
| Frustration | 3 | 3/15 |

Table 15. Weighted Rating Worksheet - Current instruments

| **Scale title** | **Weight** | **Raw Rating** | **Adjusted Rating (Weight x Raw)** |
|---|---|---|---|
| Mental Demand | 5/15 | 10 | 3,33 |
| Physical Demand | 1/15 | 5 | 0,33 |
| Temporal Demand | 1/15 | 8 | 0,53 |
| Performance | 4/15 | 5 | 1,33 |
| Effort | 1/15 | 10 | 0,67 |
| Frustration | 3/15 | 13 | 2,60 |

| | | | |
|---|---|---|---|
| *TOTAL* | *1* | *51* | *8,79* |

Table 16. Weighted Rating Worksheet - Current instruments + MIND

| Scale title | Weight | Raw Rating | Adjusted Rating (Weight x Raw) |
|---|---|---|---|
| Mental Demand | 5/15 | 10 | 3,33 |
| Physical Demand | 1/15 | 4 | 0,27 |
| Temporal Demand | 1/15 | 10 | 0,67 |
| Performance | 4/15 | 5 | 1,33 |
| Effort | 1/15 | 9 | 0,60 |
| Frustration | 3/15 | 13 | 2,60 |
| *TOTAL* | *1* | *51* | *8,80* |

## E.6.3. Opinion of the surgeons

After the tests the surgeons where asked questions about the test facility and the MIND (Table 17) and the dimensions of the MIND (Table 18). Both agree that with some small adjustments it is an instrument which has the potential to decrease harvesting time and they want to test the MIND on real patients.

Table 17. Evaluation of the test facility and the MIND

| Questions | Surgeon 1 | Surgeon 2 |
|---|---|---|
| Spring thickness: 0.6 mm, 0.8 mm or 1.0 mm | 0.8 mm | 0.8 mm |
| After test with current instruments: is the test facility real enough to make the conclusion of the test significant? | Yes, not perfect but good enough | Yes, close enough. |
| After test with the MIND: did the test went good. i.e. can a comparison with the first test be made? | Yes | Yes |
| Is it easier with the MIND? | Yes, | It is very different, needs to get familiar with the instrument. |
| Would you use the MIND during a surgery? (With minor adjustments) | Yes | Yes |
| Could the MIND contribute to less incision? | No | No |
| Is it possible to harvest more graft length with the MIND? | Maybe | No |
| Can the MIND (with slight adjustments) be used for other procedures? | Other nerve grafts in leg and arm, exposing the brachial plexus underneath the clavicle. | Other nerve grafts in leg and arm |
| Can the test facility be used for training resident surgeons or foreign surgeons? | Yes | Yes |
| Problem with the grip (i.e. enough grooves)? | No problem | No problem |
| Translation of the tip useful? | Not used | |
| Did you use the individual control of the rods or always both at the same time? | Sometimes used individual control | |
| Problems with light reflection? | No | No |
| Mass of the MIND? | Slightly heavy and to much mass in the hand; more mass in the front for easier tilting | Somewhat heavy |

Table 18. Dimension evaluation of the MIND

| | MIND | Evaluation prototype | Surgeon 1 | Surgeon 2 |
|---|---|---|---|---|
| **Rods** | | | | |
| Front length | 80 mm | 75 mm | 75 mm was sufficient | 80 mm |
| Front angle | 30 deg | 20 deg | 30 deg | 20 deg was |

| | | | | |
|---|---|---|---|---|
| | | | | sufficient |
| Back length left | 80 mm | 80 mm | Good | Good |
| Back length right | 60 mm | 60 mm | Good | Good |
| Outer diameter at joint | 10,5 mm | 14 mm | No problem with 14 mm | 10,5 mm |
| Outer diameter back of the rods when closed | 40 mm | 37 mm | good | Good (not bigger) |
| Maximum opening width | 15 mm | 20 mm | 15 mm is sufficient | 20 mm |
| **Tip** | | | | |
| Height | 3 mm | 2,7 mm | 4 mm | 4 mm |
| Thickness | 1 mm with v shape | 1 mm with slight v shape | Good | Good |
| Length | 2 mm | 1,5 mm | 2,5 – 3 mm | 3 mm |
| **Handle** | | | | |
| Length | 80 mm | 89 mm | 89 mm | 89 mm |
| Bottom diameter | 27,5 mm | 27,5 mm | Good | Good |
| Top diameter | 35 mm | 31,5 mm | 31,5 mm | 31,5 mm |
| Length from back of handle to joint | 120 mm | 115 mm | Make it less, but keep finger surface in place / i.e. change the ratio | 115 mm was good |

# E.7. Discussion

## E.7.1. Difference between test facility and real tissue

The major goal of the test facility was to create a close representation of an infants leg with non living material to evaluate the working principle of the MIND. Non living material is desired because on a cadaver or animal tissue the current instruments are not allowed to be used and there is no second set of instruments available. Another advantage is that no animals are harmed. A second and minor goal is to create a trainings facility for resident or foreign surgeons.

The main and obvious difference between the test facility and the real harvesting procedure with a patient (infant) is that the test facility is made from non living material and the patient is a human. When harvesting with the test facility the surgeons are careful because they must pretend it is a nerve. However with an infant they are double careful, because the success of an 8 hour procedure depends highly on the quality of the graft and the outcome of the procedure is of great influence on level of disability of the infant. That's why there is always a difference in experience.

As already mentioned two difference between the test facility and an infants leg is dough accumulation and the lack of tension in the side branches. Dough accumulation is because there is more dough then that there is connective tissue in an infant. This can be reduced by reducing the dough, however with too little dough the test becomes too easy. In an infant the tension on the side branches is present because it is distally attached to the end point of the nerve. This tension gives a little haptic feedback to the surgeon that it is a side branch instead of connective tissue. This feedback is in the test facility not present and detection of side branches only relies on visual feedback. Even with the author standing next to the Surgeon 1 one of the side branches was overlooked. It is possible but a lot of hassle to attach the side branches to something outside the dough, therefore a trade off must be mate between this hassle and the use of haptic feedback for harvesting side branches.

A conscious difference was that with the test facility the begin and end points of the nerve where not covered in dough and are marked. When making an incision in an infant, the sural nerve is not directly visible and need to be searched. This results in real life in more dissection under direct visualisation at the beginning of an incision.

Another difference, but one with less influence, is that tissue is white, red and shiny whet. Where the test facility with the dough, sponge and threads consists of yellow and brown colours and is not shiny whet.

# E.8. Conclusion

For evaluating the working principle of the MIND a test facility was built. The test facility approaches a real patient good enough for proper evaluation. Evaluating the MIND with the test facility learns that the harvesting time can be reduced and there is less need for instrument change. The evaluation prototype was evaluated for improvements for the final design. The test facility is good enough for training resident surgeons or foreign surgeons.