Inherently Safe Water Jet Dissector

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Challenge the future

Inherently safe water jet dissector

Master thesis

of

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Abstract

Open revision surgery is the standard treatment for patients with a loosened hip prosthesis. The current practice is to remove the hip prosthesis and to insert a new one through open surgery. Aseptic[1] loosening is the most common type of loosening. During aseptic loosening, a mechanically weak tissue called interface tissue is formed between bone and prosthesis. The downside of this open surgery is that it cannot be used on patients with poor general health, since the risk of complications are too high. A minimally invasive approach to remove the interface tissue is being developed at the department of Orthopaedics at Leiden University Medical Center (LUMC). The proposed minimally invasive approach applies water jet dissection using a water pressure of up to 120 bar to remove the interface tissue. Subsequently, the resulting cavity is filled with bone cement to refixate the prosthesis without the need for a new prosthesis.

Using failure mode and effect analysis two major failure modes for the water jet dissector were identified, namely blocking and clogging of the suction channel. Both will result in discontinuation of waste removal, while water is still being added to the cavity, thus increasing the pressure. If the pressure inside the cavity rises above 2.7 bar, the risk of embolisms forming in the bone increases. Embolisms can cause a fatality when they block a vessel in a critical organ. Trials with the water jet dissector determined that blocking of the suction channel is the main problem and it was seen that clogging will not be an issue if the suction channel does not become narrower. From these trials the major functions of the ideal instrument were defined and a functional overview was created. The functions the instrument will fulfill are the high pressured water output, an anti-blocking mechanism and two functions as additional safety measures, namely a sensor and a function to close off the water jet. The additional safety functions were added, since the risk of the primary safety functions not providing the inherent safety required.

Using the functional overview to facilitate a brainstorm session, a morphological overview was created. The morphological overview could be reduced to a single concept by applying the restrictions found in the system requirement and the trials. This concept uses a water jet located on the outer wall on one side, a single nozzle with a water jet under an angle directed towards the suction channel, a pressure sensor, and a valve to close off the water jet. By applying a water jet under an angle, the goal was to find if the water jet could push away large pieces of tissue in order to keep the suction channel open.

In order to find the ideal water jet angle which allows a safe usage of the water jet

[1] Aseptic: Free of illness causing microorganisms

dissector a proof of concept experiment was constructed. The angle of the water jet was varied from straight ahead (90°) in steps of 10° to a sharp angle with the tip of the suction channel (10°) and the water jet was turned off if the pressure in the cavity reached above 2 bar. It was found that only when using extreme sharp angles (10° and 20°) the maximum cavity pressure remained below the safety pressure of 2.7 bar, while blocking remained an issue.

Adding a pressurized air to the suction channel to remove the blockage was thought to be a solution. Since only the 10° and 20° remained below the safety pressure, a 2.5 bar relative pressure pulse is added when the device is blocked. The value of 2.5 bar was chosen as air pressure, since this pressure is above the peak cavity pressure of 2 bar and below the safety pressure of 2.7 bar. The test showed that with the pressurized air settings applied, the pressure increased above the safety pressure. It is seen that with the current settings, the water jet dissector cannot be safely applied for hip revision surgery.

If we would change the pressure where the water jet is turned off to a lower value, the pressurized air may be able to remove the blocking waste. It may then be possible to continue the removal of interface tissue without having to extract the water jet dissector from the cavity. In order to find which settings can provide inherent safety, more experiments will need to be performed. The goal of creating an inherently safe water jet dissector has been reached with the initially tested settings (excluding the pulsating suction air flow) in this thesis, although blocking is still a problem.

Contents

CHAPTER 1

Introduction

Open revision surgery is the standard treatment for patients with a loosened hip prosthesis. The current practice is to remove the hip prosthesis and to insert a new one through open surgery. Aseptic[1] loosening is the most common type of loosening. During aseptic loosening, a mechanically weak tissue called interface tissue is formed between bone and prosthesis.

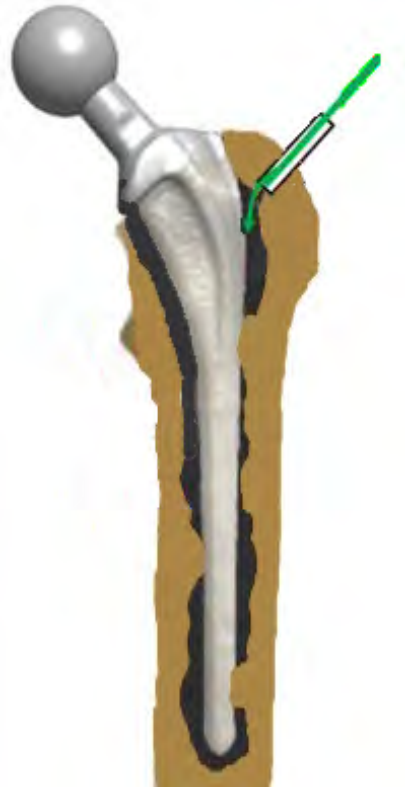
Open revision surgery has a high risk of complications for patients with poor general health. The department of Orthopaedics of Leiden University Medical Center is developing a minimally invasive approach to refixate the prosthesis. During this procedure, a minimally invasive approach (shown in Fig. 1.1a) is used to remove interface tissue and to inject bone cement into the resulting cavity. To perform the minimally invasive revision procedure, an instrument needs to be developed that can remove the interface tissue through a needle with an inner diameter of 3-4 mm. This instrument will make use of a combination of a water jet dissector and an aspirator to remove the interface tissue. When the water jet dissector will be used to remove interface tissue there is no direct visual feedback possible to see whether there is waste tissue blocking the opening, and there is no room for additional instruments in order to remove the blocking tissue.

G. Kraaij applied a commercially available water jet dissector in a similar situation. During this test, the main failure mode was the blocking of the suction channel with tissue, such that no waste was removed. However, water was still being injected into the cavity and thus the pressure increased above the maximum cavity pressure. The increasing of pressure inside the cavity can cause small particles to be pushed into the blood flow and can cause an obstruction(embolism). An embolism can result in fatalities when the embolism blocks a blood vessel in the heart, the lungs or the brain. The pressure inside the cavity may not exceed above 2.7 bar[1]. Above this pressure, the chance of an embolism forming will increase rapidly. The water jet is required to have a pressure of 120 bar to remove interface tissue, but will not damage bone which requires 700 bar[2] to be drilled.

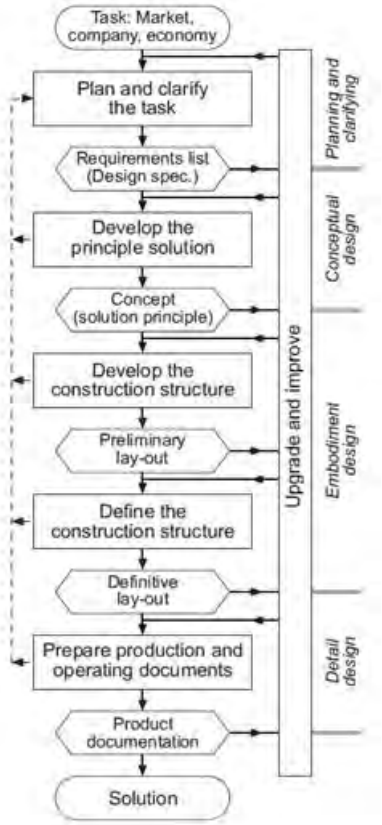
Therefore, the goal of this thesis is to implement a system that will create a water jet dissector whereby the pressure inside the cavity will not increase above 2.7 bar. The Pahl

[1] Aseptic: Free of pathogenic microorganisms

& Beitz [3] design method, shown in Figure 1.1b, will be followed as a guideline for this research.



(a) Black resembles interface located between bone (brown) and prosthesis (grey), adjusted from [4]



(b) Pahl & Beitz design process

Figure 1.1

CHAPTER 2

Task Clarification

Before system requirements can be found, the definition of interface tissue should be addressed and also a choice needs to be made how the water jet dissector will be applied. From the system requirements a functional overview is constructed.

2.1 Interface Tissue

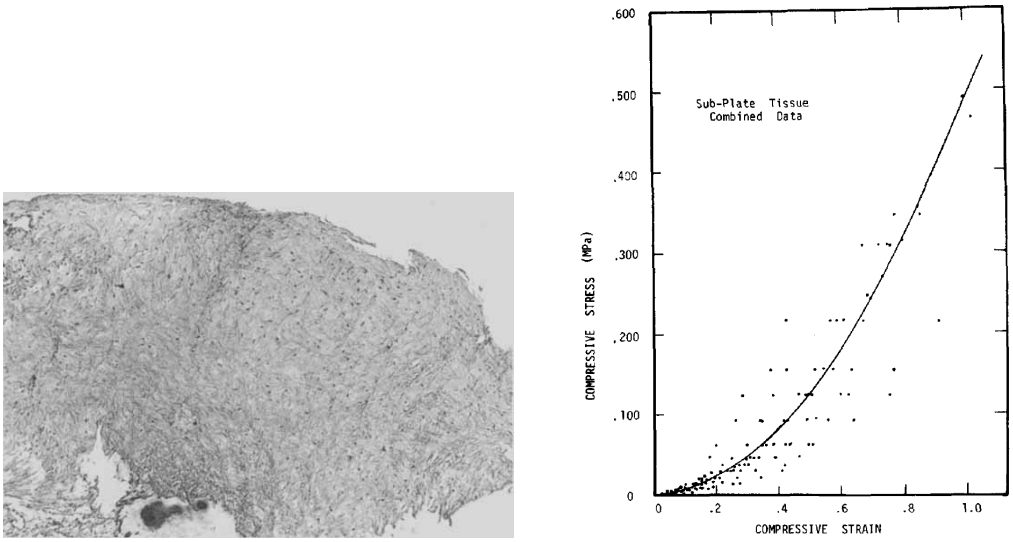
The interface tissue is formed due to loosening of the prosthesis and consists of fibrous tissue containing collagen fibers, and phagocytized wear particles from the cement layer or the prosthesis[5–9]. Multiple theories exist on aseptic[1] loosening and formation of tissue. These can be categorized into two different categories according to Pizzoferrato et al. [7], namely biological and mechanical. The biological aseptic loosening is characterized by pain during passive movements. In this situation bone resorption occurs when healthy tissue is replaced by the interface tissue. In this tissue layer, wear debris is found at prosthesis-bone interface and at the cement-bone interface, where phagocytized cement particles are found. Mechanical aseptic loosening is characterized by pain during loading phases of movement and mild bone resorption is observed. Low amount of wear debris is found in the tissue layer at the prosthesis-bone interface, while at the cement-bone interface cement particles are frequently observed.

Properties

Fibrous tissue is randomly distributed and is analogously woven as a mat, see Figure 2.1a. Hori and Lewis [5] tested the fibrous tissue by placing prostheses in dogs and then harvesting the fibrous tissue. Compression tests were performed by using an anvil to compress the tissue where the distance of compression and force were measured. This tissue has the property of having high deformation under low loads, and it requires a long time to return to its original form. Under high loads the fibrous tissue behaves as a stiff

[1] Aseptic: Free of pathogenic microorganisms

material[5]. This translates to a non-linear strain-stress graph, see Figure 2.1b, where up to 0.5% strain the graph is non-linear and above the 0.5% strain the graph behaves linear.



(a) (b)

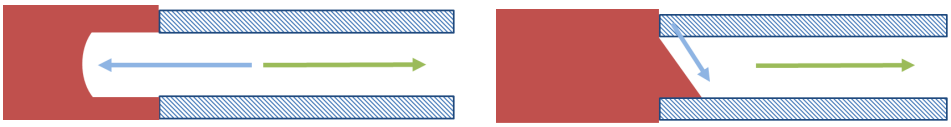
Figure 2.1: **a** Fibrous tissue collected from animal specimen in the study of Hori; **b** Stress-strain curve for unconfined uniaxial compression tests of subplate tissue

2.2 Water jet dissector

Water pushed through a nozzle with a diameter of 0.3 mm can cut tissue just as a knife when a pressure of 120 bar is applied. A water jet dissector contains a water channel with a nozzle at the tip and a suction channel to remove all the waste. In order to remove the interface tissue the water jet can be configured in two different ways: (1) the water jet direction is following the line of the instrument and the tissue in front of the instrument is cut or (2) the water jet is countering the line of the instrument where the tissue is pulled into the instrument and then cut by the water jet, see Figure 2.2. In this master thesis only the water jet direction following the line of the instrument will be dealt with, because not all tissue can be reached by the water jet when using counter flow. In Figure 2.2b the water jet will only cut the tissue which is pulled into the suction channel of the instrument.

2.3 System requirements

The water jet dissector system, which will be used for the removal of interface tissue, has resemblance to the Erbe Jet II[10–12] and will contain a pressure generator, a vacuum source, hoses connecting all the devices and the dissector itself. In Figure 2.3 the system is shown schematically. The arrows indicate the material flow, where water is shown with a blue arrow and waste is resembled by the green arrow. The vacuum source also contains a collection basket where the waste from the cavity is collected.



(a) (b)

Figure 2.2: The two cases of water jet direction **a** The water jet direction is in line with the instrument. **b** The water jet direction is in counter with the instrument. The green line is the direction in which suction is applied and the blue line is the direction in which the water jet is applied. The blue rectangles with stripes are the walls of the instrument and red resembles tissue.

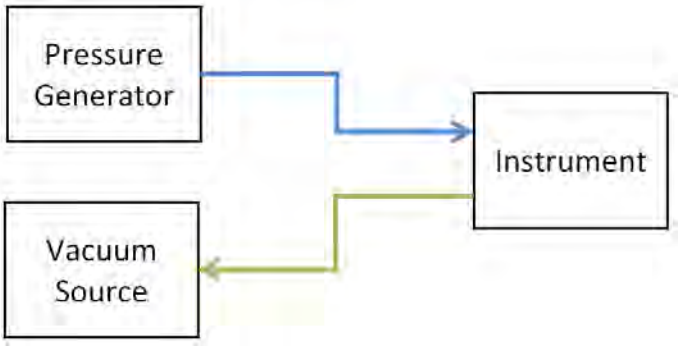


Figure 2.3: System Overview. Green: waste flow, blue: water flow

The instrument will need to fulfill the requirements listed in Table 2.1

Table 2.1: System requirements

Pressure in cavity (relative)	$p_{max,cav} \leq 2.7[bar]$
Volume flow out	$Q_{out} \geq Q_{in}$
Outer diameter	$D_{outer} \leq 3[mm]$
Flexible instrument	
Tube length	$200[mm]$

A flexible instrument is needed to allow insertion into the cavity, as shown in Figure 2.4. The Figure shows insertion of the instrument through a needle. The needle is used to drill through the bone and to be able to allow the insertion of the instrument to the patient. When inserting the instrument perpendicular to the prosthesis, the tip of the instrument will rotate with a small radius. A small radius will limit the movement of the instrument further into the cavity, so an insertion under a small angle, as shown in the top right of Figure 2.4, is desired. In order to perform such an angle and to be able to steer the instrument into place a flexible instrument is required. During the design process flexibility will be an issue, since compared with a rigid instrument different types of materials have to be used. Therefore, the material should be considered flexible and thus the properties of the material will cause design limitations for the wall thicknesses.

In order to minimize the damage to surrounding tissues and bone, the instrument diameter should be kept to a minimum. From the studies of de Poorter [14] and Pruis [4]

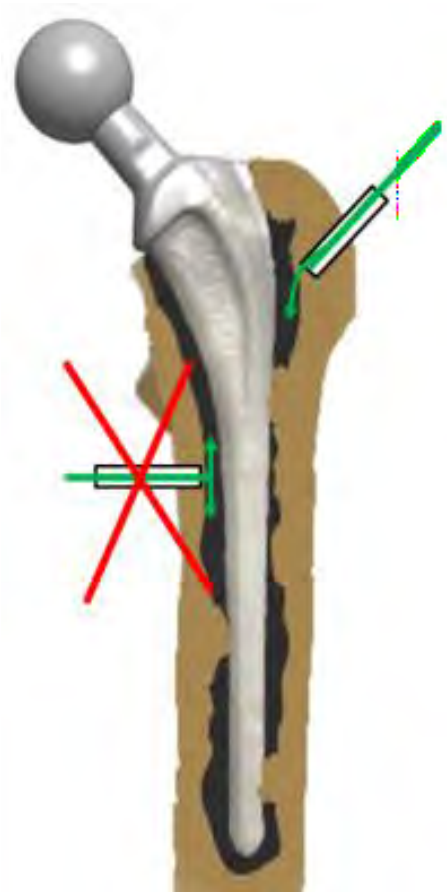


Figure 2.4: Insertion of the instrument, copied from [13], green represents the instrument, black the tissue, and brown the bone.

it becomes clear that the maximum diameter for the instrument is 3 mm.

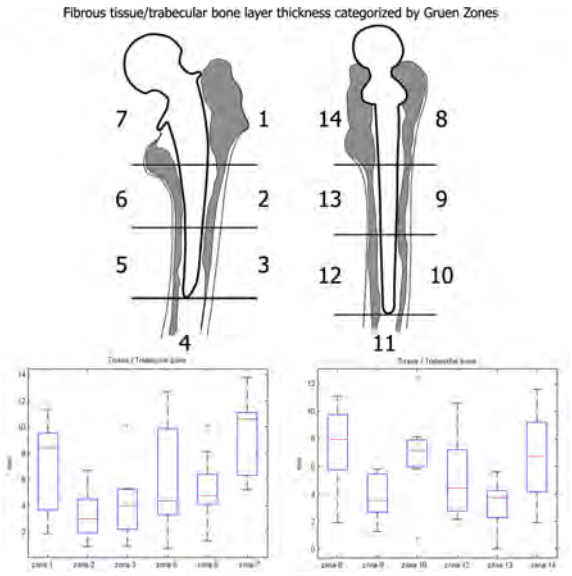


Figure 2.5: Thickness of the fibrous tissue/trabecular bone layer, copied from [4].

The pressure in the cavity should never exceed a threshold, because when the intramedullary pressure increases the risk of embolisms increases[1, 15]. In the case of the study of Schmidutz et al. [1] cement is injected through the prosthesis when the prosthesis is placed and the maximum used injection pressure is 2.7 bar (relative). In the study of Porsch et al. [15] the maximum pressure of 1.3 bar (relative) is used, where the assumption is made that pressures above this value result in a higher risk of embolisms. Based on that the study of Schmidutz et al. [1] is used to inject cement upto a cut-off pressure and that the study of Porsch et al. [15] only states that the risk increases; the maximum pressure inside the cavity will be set at 2.7 bar.

To prevent an increase in intramedullary pressure the amount of particles should not increase, to be able to keep a constant pressure the volume out should be larger than the volume in, defined as: $Q_{out} \geq Q_{in}[m^3/s]$, because the decompression of water will have a very low influence on the volume expansion (compressibility factor is $5 * 10^{-10}$ [Pa^{-1}]). This would mean that the volume flow in is also the volume added to the system. The volume of water injected into the cavity should at all times have a lower volume than the volume which is removed. The removed volume includes water, interface tissue, and other foreign particles.

It will most likely not be possible to remove all the tissue from one insertion point. The wish is however to reach as far as possible, the common needle lengths are 100 and 150 mm in length[16].

2.4 Functional Overview

The system can be divided into multiple functions which will provide the starting point for a brainstorm session to create conceptual solutions. A schematic overview of the functions is shown in Figure 2.6. The black dashed line indicates the functions which are not performed directly by the instrument, but are a result of its workings. These function blocks are a consideration while designing and the other blocks indicate physical functions which the instrument will need to fulfill.

The first function instrument has to fulfill is to transport water to a part which can inject a coherent water jet into the cavity. In the cavity the tissue is destroyed and will be transported to the suction channel. At the suction channel the first function is to prevent blocking of the suction channel after which the waste is removed and during this removal the function of prevention of clogging is active. In the end the waste is collected in a waste basket. While the instrument is in operational status it is possible to take measurements at two points in the functional diagram, namely in the cavity and in the suction channel. These measurements can be used to decide whether the water supply channel should be closed off or left open.

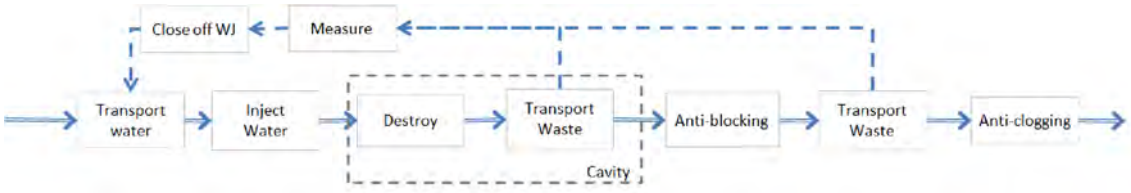


Figure 2.6: Functional overview of a water jet dissector; solid lines indicate material flow and dashed lines indicate flow of information

CHAPTER 3

Failure Modes and Trial

In the first section of this chapter the failure modes will be searched by using a technique called Failure Modes and Effect Analysis (FMEA). From this analysis, trials are conducted to determine the flow capacity of the suction channel depending on the diameter of the channel and also to show whether clogging is an issue.

3.1 Failure Modes and Effect Analysis

In the previous sections the problem of blocking was found by tests performed with a commercially available water jet dissector. To be able to create an inherently safe water jet dissector it is needed to look into other possible errors or failures by using a technique similar to failure modes and effect analysis (FMEA). FMEA is a technique to be used by a team of experts to find all the possible failure modes and scenarios and identify their causes, consequences and rate of occurrence. I decided to use the technique of FMEA to look at the possible failure modes of the water jet dissector in order to identify other possible failure modes.

The FMEA overview is shown in Table 3.1 on page 13. The FMEA table is created by looking at each process after the pressure generator and before the vacuum pump. Each failure is treated separately, even though some failures might occur at the same time. The FMEA is divided into three functional parts, which are treated separately in the coming sections. The three different parts have different cross sectional areas and flow properties:

- Water Channel
- Nozzle
- Suction Channel

3.1.1 Water Channel

For the water channel three possible types of failures were identified:

- Fouling
- Wall burst
- Leakage

According to research performed in the industrial sector, a possible failure with the water channel is fouling[17, 18]. Fouling is the accumulation of unwanted material on the instrument walls. For Rowe et al. [17] and Beek et al. [18] the time before fouling would occur was several days. The effective diameter decreases and therefore the consequences of fouling are deemed low.

The burst failures of a wall of the water channel are caused by a wall which is too weak. There are three possible scenarios for a wall which has burst open with different severity, as shown in Figure 3.1:

(1) Water is getting pressed into the needle which in turn pushes the water towards the user

(2) Water is getting pressed into the needle which pushes additional water towards the cavity of the patient

(3) Water is getting pressed into the suction channel and removed to the collection basket

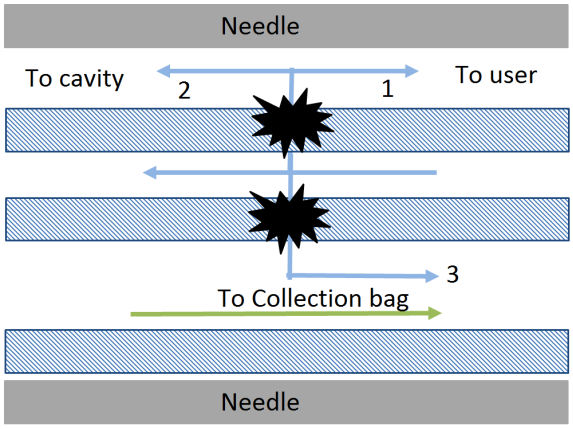


Figure 3.1: Figure schematically showing the three scenarios for a wall which has burst open

In case of burst scenario **1**, water will spill out of the needle at the users end, but will not cause any damage since the leak will not be a coherent water jet. The discovery mechanism is the user, whom is able to notice immediately when the wall has burst and water pours out of the needle. Burst scenario **2** is the most severe, since the water will leak into the cavity and will cause a pressure build up that could cause an embolism. This scenario does not have a discovery mechanism. Burst scenario **3** can cause the amount of waste removed from the cavity to become too low and in that case the pressure could increase in the cavity increasing the risk of an embolism being formed. The discovery mechanism is the rapid filling of the suction bag with water, however it should be noted

that during normal surgery when no other errors occur it could seem as if the instrument was functioning properly. When waste is already in the suction bag the color will not alter rapidly and thus the staff might not notice anything. All these scenarios can be seen as engineering problems, since these can be prevented by determining a wall thickness where the burst pressure is higher than the working pressure.

The last possible failure for the water channel is a leak at the connection of the hose which leads to the pressure generator. The main reason for this to occur is by incorrect connection by the user. The discovery mechanism is seen as visible since the leaking of water can be seen by the user.

3.1.2 Nozzle

There is only one possible failure identified for the nozzle which is fouling. When fouling occurs no water will enter the cavity and the vacuum source will still remove waste. To check whether vacuum induced laceration during surgery is severe. A literature search was performed with the following keywords in PubMed: vacuum, injury, damage, tissue, cavity, and/or laceration. There were no results showing injury due to vacuum pressure.

3.1.3 Suction Channel

For the suction channel there are three possible failures identified:

- Leakage
- Clogging
- Blocking

Leakage is when water or waste material can flow out of a connection of two tubes or connection to instrument or suction bag. This error causes waste to be deposited on top of the instrument, user or patient. The user can become ill if the patient has pathogens that can cause illness are leaked. A literature search resulted in no relevant literature to determine whether it is a problem, the following keywords where used: connection, failure, fluid, and/or vacuum. Also with the experiment performed in section 3.2 it was seen that when the tubes are connected in a proper way there is no leak. The leak can visually be observed if there is a large leak, however if the leak is so small that only tiny droplets emerge no visual observation can be made. This failure is a design criteria and can be solved by choosing the correct connection types.

Clogging (Fig. 3.2c) is defined as a material build up inside the suction channel, the tip of the instrument is not considered to be part of this failure. Clogging is seen as a problem for equipment that has to operate continuously for several days [17, 18]. This problem is also described in the task specification, but there is no evidence of it occurring during the experiments conducted where blocking was observed (Appendix C). If clogging is present water will still enter the cavity and would cause that the pressure inside the cavity will

increase above the safety value of 2.7 bar. Thus, the risk of an embolisms will increase. The visual observation can take place if the tube is transparent, but the observation is in delay. From the graphs resulted in the experiments conducted thus far the pressure increase is instantaneous and the observation of no waste being transported through the suction channel or tube will be too late.

Blocking is defined as a large chunk of waste that gets stuck on the tip of the instrument, effectively blocking the suction channel (see Figure 3.2b). It is seen in experiments conducted, as in Appendix C, that blocking will happen. The severity of this problem is as described in the task specification (Section 2) and as shown in Figure C.1 the pressure will increase beyond the safety threshold almost instantaneous. The discovery mechanism is the same as for clogging.

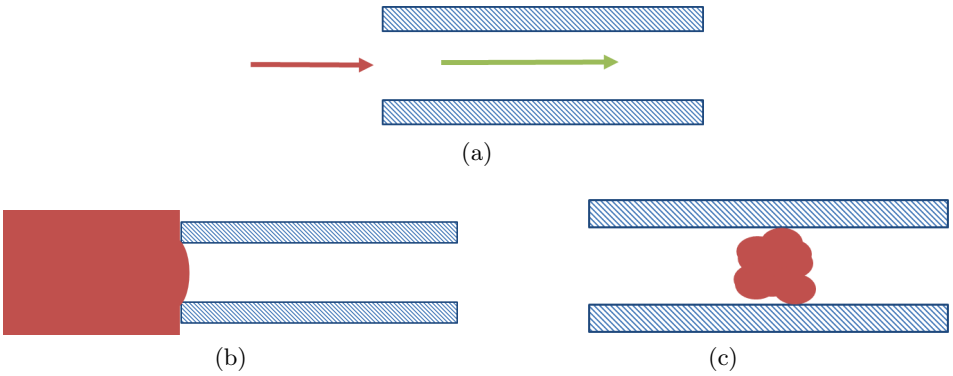


Figure 3.2: **a** Normal situation where there is flow possible as shown by the red and green arrow; **b** Blocked situation, waste blocks the entrance of the suction channel; **c** Clogged situation, waste blocks the inside of the suction channel

Table 3.1: FMEA

Part/Process	Function	Possible failure	Cause	Effect	DM
Water Channel	Provide transport of water to the tip of the instrument	Fouling	Particles attach on wall of transport channel	Clogging of water channel	none
		Burst	The wall is too weak	Water is pressed into the needle, which pushes water in direction of user	visible
				Water is pressed into the needle, which pushes water into cavity, causing pressure build up	none
				Water is pressed into the suction channel	none
		Leak	Connection failure	Water leaks on patient/user	visible
Nozzle	Expel water in cavity	Fouling	Particles attach on wall of nozzle	Blocking of water jet into cavity	none
Suction Channel	Removal of waste	Leak	Connection failure	Removed material starts leaking on the surface of the instrument or user, patient	visible
		Clogging	Material buildup in front and inside part	Increase of pressure in cavity	none
		Blockage	Material buildup in front of part	Increase of pressure in cavity	none

DM: Discovery Mechanism.

3.2 Trial: Clogging

The previous section showed that the principle of clogging can be a considerable problem. However, clogging has not been observed yet or discussed in literature for a water jet dissector, since it may not be an issue.

3.2.1 Method

To be able to test whether clogging is an issue; chicken liver was used as substitute material for interface tissue, due to its resemblance to interface tissue. Other tissues can also be used, such as muscles of animals, but these will most likely require a higher pressure source than chicken liver. Liver has the closest resemblance to the mat-like structure of the interface tissue, while muscles have fibers in a single direction. Chicken liver is selected due to its availability at the supermarket and that at the Leiden University Medical Center I was allowed to use this type of tissue. The tissue was dissected using a scalpel whereby particles up to 5 mm in cross-section were created.

The suction applied is based on measurements conducted with two different suction tubes, namely a 1.1 mm and a 1.6 mm inner diameter tube. These two sizes were determined from half of the maximum diameter, assuming half the instrument can be used as suction channel and that the opening will be non-circular. To have a circular tube as replacement the hydraulic diameter needs to be calculated by using Equation 3.1. Where D_H is the hydraulic diameter, A is the area of the non-circular duct and P is the perimeter of the non-circular duct. When assuming a wall thickness of 0.1 mm for the suction channel 1.4 mm (radius) is left for the suction channel. We will find a hydraulic diameter of 1.7 mm, 1.6 mm is present at the workshop just as 1.1 mm tubes. Smaller is also tested to be able to find if it is possible to create a smaller instrument.

$$D_H = \frac{4 * A}{P} \tag{3.1}$$

3.2.2 Results

During removal of the water and tissue mixture, clumps of tissue were blocking the opening of the suction channel. But when the tissue was able to pass through, it did not attach to the inner wall of the suction channel. To check which types of tissue is able to pass through, it was noticed that particles of 2mm would block the 1.1 mm suction tube(Fig. 3.3), but the same size particles were able to successfully pass through the 1.6 mm suction tube. In case of the 1.6 mm suction tube, the 400 mbar vacuum pressure caused the particle to travel through slowly. To verify, a large hose (inner diameter 6 mm) was used to remove all large particles. Hereby internal blocking was spotted at the narrowed parts where the tubes were connected via a narrowed connection tube.

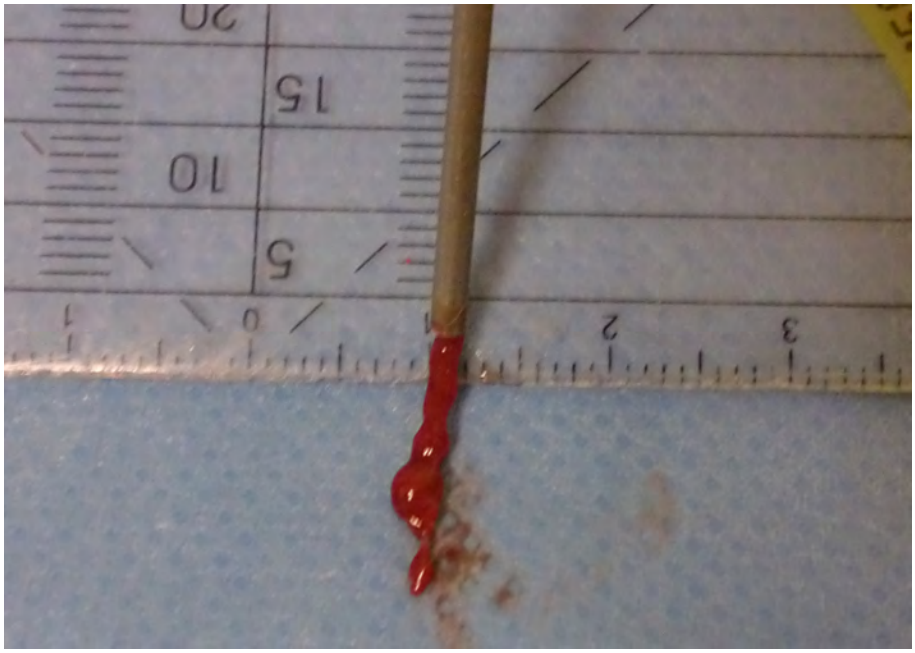


Figure 3.3: Inner diameter 1.1 mm: Waste size 2 mm

It is seen that cutting of particles smaller than 2 mm in cross-section is necessary. However, when attempting to cut particles near the size of 1 mm in cross-section the liver turned into a state whereby the form and size depended on how one would treat or touch the liver. This caused that the particles would change size and shape depending on what forces are applied on the tissue. To be able to solve this issue, the Erbe water jet applicator is used to cut the tissue and continues suction is applied. Whereby the pedal is used to control the water jet dissector of the Erbe water jet applicator and the 1.1 mm or 1.6 mm suction tubes are used to remove the waste with continuous suction of 800 mbar, see Figure 3.4. The following steps are taken:

- Empty suction bag
- Use Erbe Jet to cut tissue
- Filter waste
- Remove filtrate using suction

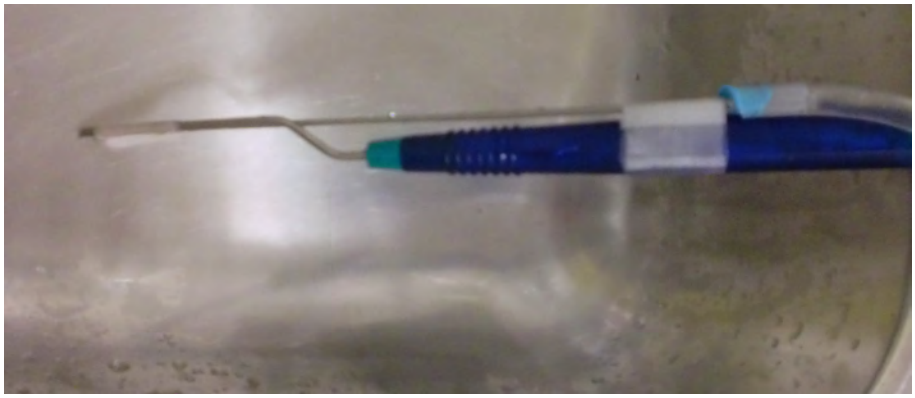


Figure 3.4: Erbe water jet applicator with suction tube connected

During the use of the Erbe applicator, it was noticed that the suction tube was blocked by larger particles of tissue. In some cases removing the applicator from the material was enough to pull the waste particles through the suction channel. In case the particle was too large for the suction tube the use of tweezers to remove the large tissue was required. The waste for both the 1.1 mm and 1.6 mm suction tubes was filtered using coffee filters (Figure 3.5), and the residues are respectively shown in Figure 3.6 and Figure 3.7. The waste size of the 1.1 mm tube is smaller than the waste particle size of the 1.6 mm suction tube. During the removal of the filtrate no blocking of the tubes was noticed.

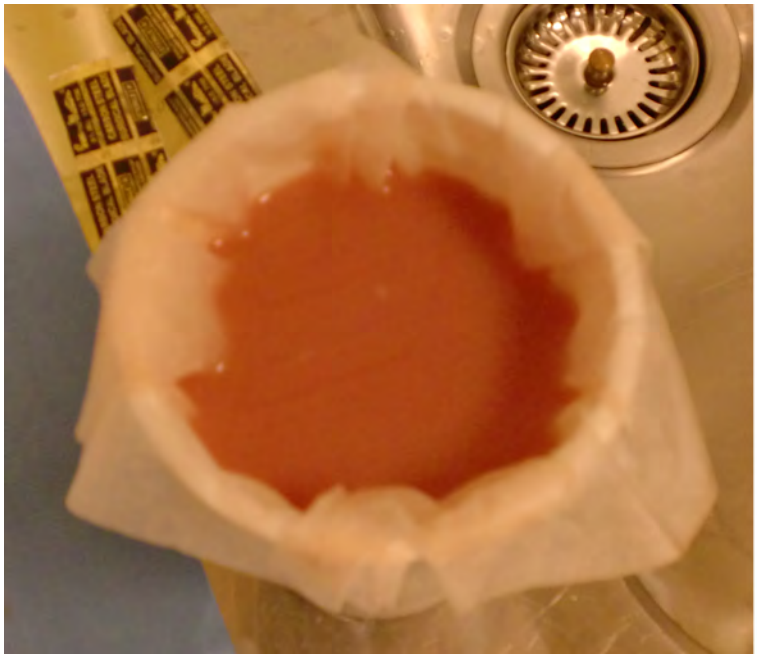


Figure 3.5: Filtering the waste

To check whether particle size is a dependency on blocking/clogging, sugar grains were used. In case of the 1.6 mm suction both of the particles were able to pass through without a problem. However, when using the 1.1 mm tube the sugar blocked the opening of the tube whereby it seemed that it got suspended by water and sugar mixture. When using a

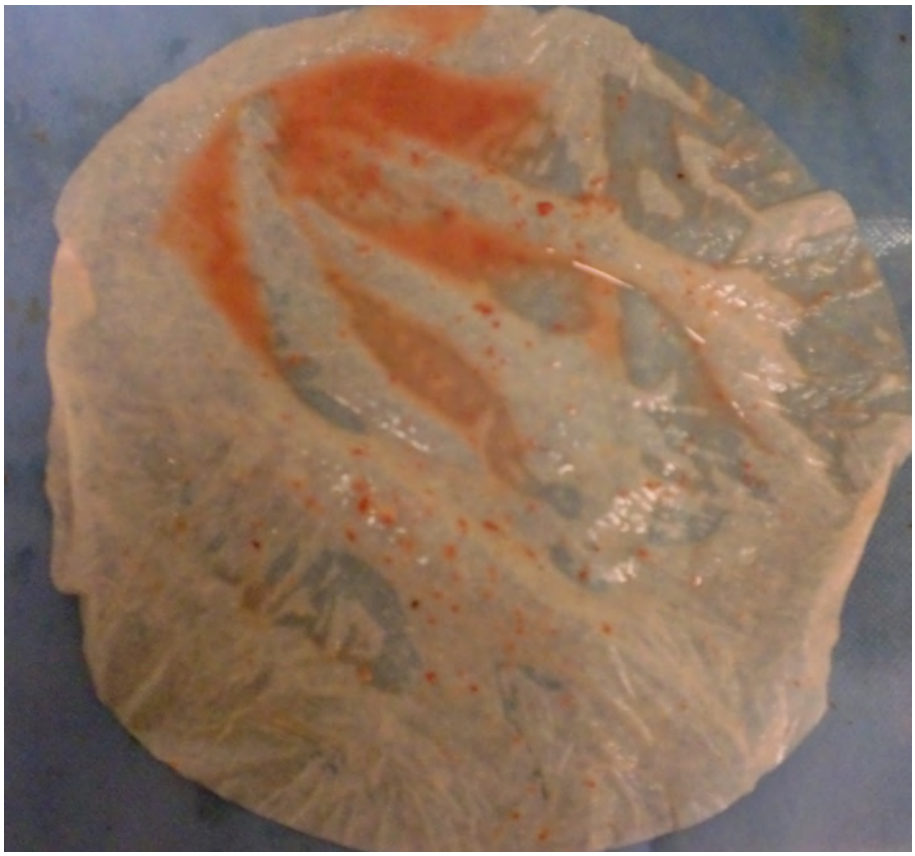


Figure 3.6: Liver waste when suction tube with 1.1 mm inner diameter

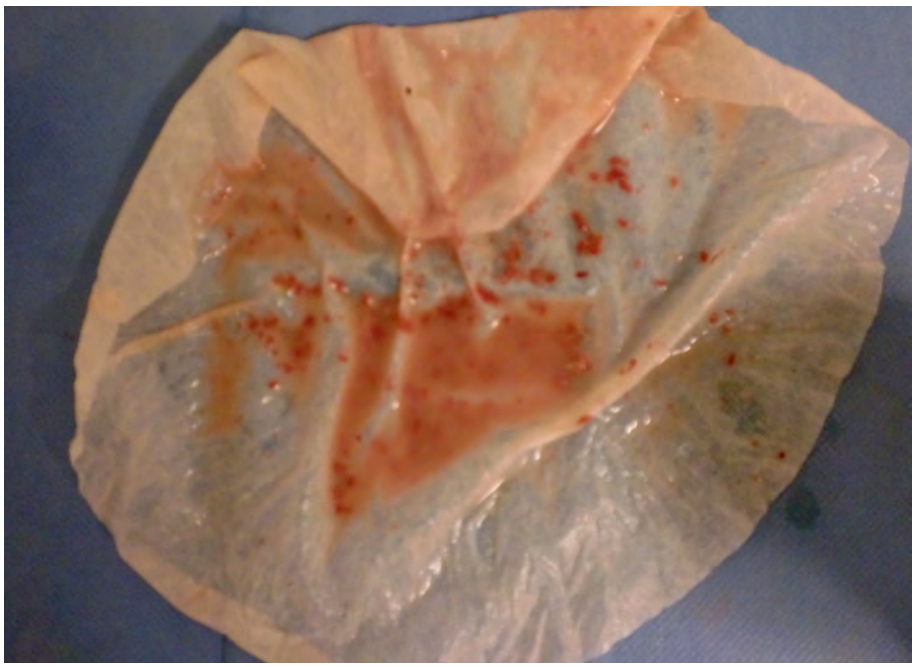


Figure 3.7: Liver waste when suction tube with 1.6 mm inner diameter

needle to poke a hole through the sugar the blockage was cleared.

Concluding, blocking causes the main problems, whereby it is seen that the smaller the waste, the easier it is pulled through the suction tube. It can take a while for waste to transport through the tube when the size of the waste reaches the size of the channel, whereby in that time no other waste is transported. From the measurements with vacuum flow (section A) with water and this experiment it can be found that a higher vacuum generated flow than inlet water flow is required.

3.3 Conclusion

At the end of this chapter the problem has been defined as the blocking of the opening of the suction channel, whereby the pressure inside the cavity increases above the safety pressure value of 2.7 bar. This problem is found by experiments performed with the Erbe Jet II [10–12, 19] and by performing the experiment to check whether clogging of the interior of the suction channel is a problem, see Section 3.2. By using FMEA it is found that also only blocking will be the main source of severe problems and should be addressed first. The other failure modes can be addressed during the engineering stage of the design.

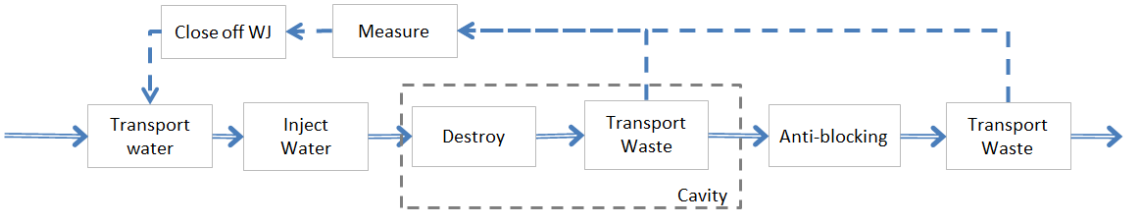


Figure 3.8: Altered functional overview of a water jet dissector from Figure 2.6; solid lines indicate material flow and dashed lines indicate flow of information

CHAPTER 4

Concept Solutions

This chapter will show the conceptual solutions based on the functional overview created. The morphological with the main categories based on the functions given in Section 2.4 is shown in Figure B.1 in Appendix B. In the following sections the solutions to the different functions will be shown and discussed, the best solution will be chosen. To be able to create a morphological overview a brainstorm session is held, described in Section 4.1. After which the water jet, the anti-blocking mechanism, the anti-clogging mechanism, measurement system and the switch off mechanism will be discussed respectively. Even though it was found that clogging does not represent a problem, a solution space was already created before the trial of clogging was performed.

4.1 Brainstorm

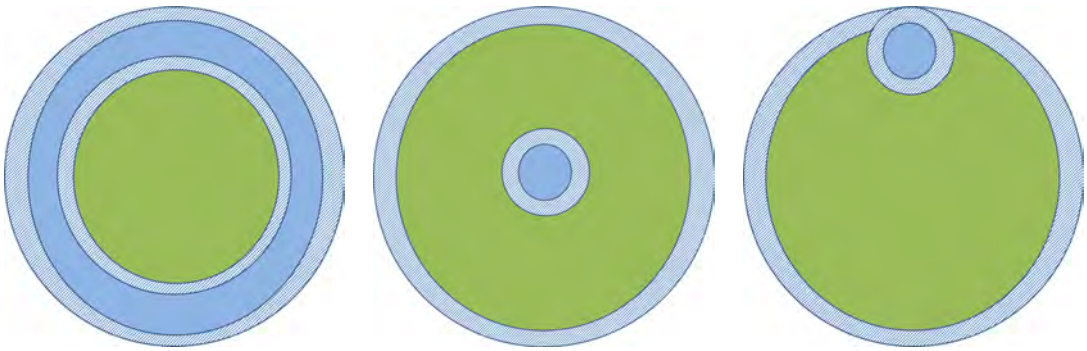
Before the morphological overview can be constructed the function overview should be translated to a physical overview, as shown Table 4.1. The physical overview is created to structure the brainstorm session. There are two functions which are called transport, located in the systems Water Jet and Suction, both of them will not be part of the brainstorm session, since the transport of water/waste will only occur through a tube.

Table 4.1: Physical overview

System	Function	Mechanical	Electrical	Thermal	Optical	Chemical
Water Jet	Transport	✓				
	Inject water	✓				
	Anti-blocking	✓	✓	✓	✓	✓
Suction	Transport	✓				
	Anti-clogging	✓	✓	✓	✓	✓
Fail-safe	Measurement	✓				
	Switch-off	✓				

4.2 Water Jet

The water jet location and thus the location of the nozzles can be divided into three main solutions. The first being a ring of water surrounding the suction channel (Fig. 4.1a). The second is a water channel in the center of the suction channel, similar to the Erbe Jet II (Fig. 4.1b) and the last solution is the use of a water channel to the side of the suction channel (Fig. 4.1c).



(a) (b) (c)

Figure 4.1: The three solutions for the water channel, water ring around suction channel, water channel in the center, and the water channel on the side. Green: waste channel, blue: water channel, striped blue: wall

The main goal for the suction channel is allowing as large as possible chunks of tissue to pass through. This would result in the desire that the diameter of the suction channel will be as large as possible. Two of the three solutions will not suffice, making the solution where the water channel is to the side of the instrument the only feasible one (Fig. 4.1c).

The water channel in the center will cause the maximal diameter of the suction channel to be limited since this diameter will be cut into half by the water channel. The maximal size of waste particles which can pass through is thereby limited in such a way that the design of an anti-blocking mechanism is limited in size. Also, the risk of blocking will increase. The risk of blocking will increase due to the increasing diameter of the water channel and the increasing thickness of the wall. The thickness of the walls is increased since the flexibility property of the wall will have a significant effect on the required wall thickness. The higher the flexibility required, the lower the yield strength is and thus the thicker the wall needs to be to be able to allow high pressure water. When taking into account that the wall needs to be flexible, materials such as plactic (Polyurethane) can be chosen, with a yield strength of 59 MPa [20]. The wall thickness can be calculated using Equation 4.1[21] with the variables listed in Table 4.2.

$$t_{wall,WJ} = \frac{P_{WJ} * OD * SF}{2 * S} \tag{4.1}$$

Tissue removal by water jet dissection is dependent on the water pressure and the nozzle diameter. These two parameters are tested and it is preliminary found that a

Table 4.2: Variables for equation 4.1

Symbol	Unit	Description
P_{WJ}	MPa	Pressure of the water jet
$t_{wall,WJ}$	mm	Wall thickness of the water channel
OD	mm	Outer diameter
SF	-	Safety factor
S	MPa	Yield strength

nozzle diameter of 0.2 mm will need a 150 bar water pressure and a nozzle diameter of 0.6 mm will require 80 bar water pressure. The data is linearly interpolated between these two values, as seen in Table 4.3. Linear interpolation is the only method which can be used, since only two points are available. By using the Equation 4.1, linear interpolation and the yield strengths of steel (steel 316: 205 MPa[22]) and plastic (polyurethane: 59 MPa[20]) the Table 4.3 is made. In Table 4.3, it can be seen that when using the solutions where four thicker water channel walls are needed; the instrument will lack a suction channel or water channel. Only in the case of the water channel on the outer wall to one side of the instrument this will create a larger area for both the suction and water channels.

Table 4.3: Values for steel and plastic walls of the water jet channels at different pressures found for different nozzle diameters, based on Safety Factor of 2[23]

Diameter [mm]	Pressure [bar]	Steel [mm]	Plastic [mm]
0.1	167.5	0.245	0.852
0.2	150	0.220	0.762
0.3	132.5	0.194	0.674
0.4	115	0.168	0.585
0.5	97.5	0.143	0.496
0.6	80	0.117	0.407

4.3 Anti-blocking

The anti-blocking mechanism will either remove or prevent tissue from blocking the suction channel opening. In total there are seven different solutions, shown in Figure 4.2.

- Fig. 4.2a Rotational shaft with water jets at the tip, as a sprinkler. The jets are slightly deflected inwards, so they can cut the tissue in front of the suction channel.
- Fig. 4.2b Rotational shaft with teeth at the tip can create a grinder which can tear the tissue apart that is blocking the suction channel
- Fig. 4.2c A harpoon which shoots a rigid spear-like body through the suction channel to clear the blockage when it is present and is retracted to remove the tissue.
- Fig. 4.2d The water jet is diverted inward to be able to push away or destroy the tissue in front of the suction channel.
- Fig. 4.2e A chemical solution delivered through an additional channel to the tip to dissolve the tissue.
- Fig. 4.2f Optical energy to destroy the tissue, also requiring additional channel(s).
- Fig. 4.2g Electrical contacts at the tip to remove the blockage.

Only the water which is diverted (Fig. 4.2d) is seen as a feasible solution. The rotational shafts and the harpoon solution, Figures 4.2a-4.2c, require rigid shafts to function. The harpoon cannot bend when shot through the suction channel. The rotational shafts can have a slightly flexible shaft, but when the shaft becomes very flexible a solution should be provided to allow the rotational motion to be transferred to the tip. A solution for the grinding teeth is to create a Cardan shaft-like suspension. For Figure 4.2b, this will create a solution where an additional shaft should be introduced into the system where the water jet and suction channel should be separated while preferably the rotating shaft with teeth should enclose the opening of the suction channel. The teeth will only be able to remove tissue directly in front of the opening of the suction channel. A solution for the rotating nozzles is to create a sprinkler head, where only the tip of the device rotates such as shown in Figure 4.3. This sprinkler head should be built into the tip in a groove, whereby a hydro-bearing should be created allowing water to pass on the side of the sprinkler head. Creating a small slot allowing water to pass the sprinkler head for the hydro-bearing and multiple nozzles will most likely create a large flow of water into the cavity which will be larger than the allowed volumetric waste flow.

Using a chemical solution(Fig. 4.2e) to dissolve the blocking tissue has two downsides. The first drawback is a need for additional safety measures, namely to insure the safety of the surgeon and of the patient. Adding a chemical solution which is able to dissolve tissue can dissolve the skin of the user/patient. This will result in an instant hazardous situation whenever a leak would occur. There is a dependency if the leak can be spotted by the user/support staff. In that case the risk will be minimized. The second is an additional channel is needed to be able to transport the chemical solution to the tip of the instrument. The additional channel will decrease the size of the suction channel, which is defined as a negative effect. There is a solution to circumnavigate these downsides namely by adding the chemical solution to the water jet. The possible negative side effect is that the chemical solution can deteriorate bone, cement or even the prosthesis. This

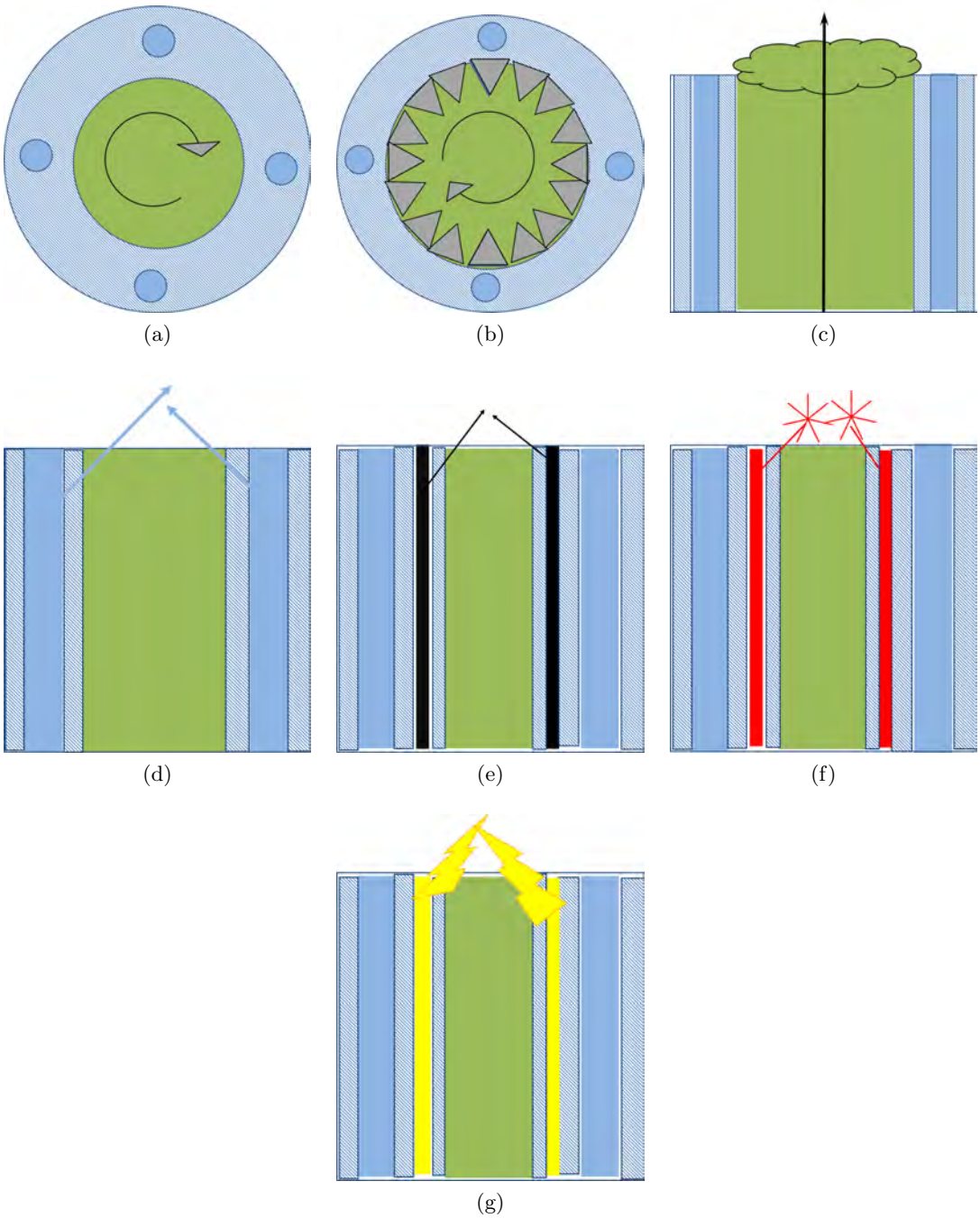


Figure 4.2: Solutions for anti-blocking mechanism

Figure 4.3: Cross sectional view of a sprinkler head showing the features of how a nozzle is created.

could cause more healthy tissue or material to be removed and could loosen the prosthesis even more. When adding a chemical solution directly to the cavity, the cavity will require a good cleansing afterwards with water to remove all solutions to lessen the chance of remainders, which could cause damage in the long run after the fixating cement has been placed.

The reason to eliminate the optical solution (Fig. 4.2f) is that additional channel(s) need to be created for the fibers[24, 25]. This will result in the creation of additional walls and would therefore limit the area of the suction channel. Also the need for additional equipment at the surgeon's location will cause the device to become complex to handle. Kraaij et al. [19] states that using a laser (350 ms pulse, 2000 mJ power and frequency 8 Hz) to remove tissue can cause thermal damage to surrounding tissue/bone as temperatures above 50 °C were measured. Concluding, adding an optical system to the water jet dissector will not create an inherently safe device.

When using electricity in the cavity to burn tissue by using a technique called surgical diathermy, the issue is that the current should have positive, and negative (or ground) electrode. In procedures besides the one discussed in this thesis, this is done by placing a ground pad externally on the skin to function as return negative electrode. There is a chance that the prosthesis has better electrical conductance than the ground pad, placed externally. The ground pad could cause a current to run through the body and possibly cause damage to tissue on any point near the prosthesis [26, 27]. In case bipolar electrosurgery is used instead of mono-polar, as described previously, the main issue besides the previous mentioned is charring. The prevention of charring mentioned by Ramamurthi et al. [28] is the rinsing of the instrument with a saline solution or completely turning off the device. The decision of turning off the device is made by detecting the increase of impedance on the system. This has a drawback for the application as described in this thesis, namely that the safety system should then be terminated and the instrument will have to be removed and cleaned before re-positioned back into the cavity. The anti-blocking mechanism will work either by a pulse measurement to determine the rise of pressure in the cavity or by using a full or pulse continuous system which will be working during the entire surgery procedure.

4.4 Anti-clogging

The next issue that needs to be tackled is the clogging problem. For this problem there were seven different solutions found:

Fig. 4.4a	Conveyor belts to pull the waste through the suction channel.The conveyor belt will contain a numerous gears and parts to allow flexibility of the system.
Fig. 4.4b	An Archimedes screw which pushes the waste through the suction channel.
Fig. 4.4c	A peristaltic movement is created by inflating a structure which pushes the waste through the suction channel.
Fig. 4.4d	Water jets that are facing inward to the rear of the suction channel to push the waste through. This solution can have only nozzles placed at the tip or have nozzles placed all along the length of the channel.
Fig. 4.4e	A chemical solution is inserted to dissolve tissue located close to the wall of the instrument.
Fig. 4.4f	Optical rays to incinerate tissue that could clog the suction channel.
Fig. 4.4g	An electrical mechanism to burn tissue.

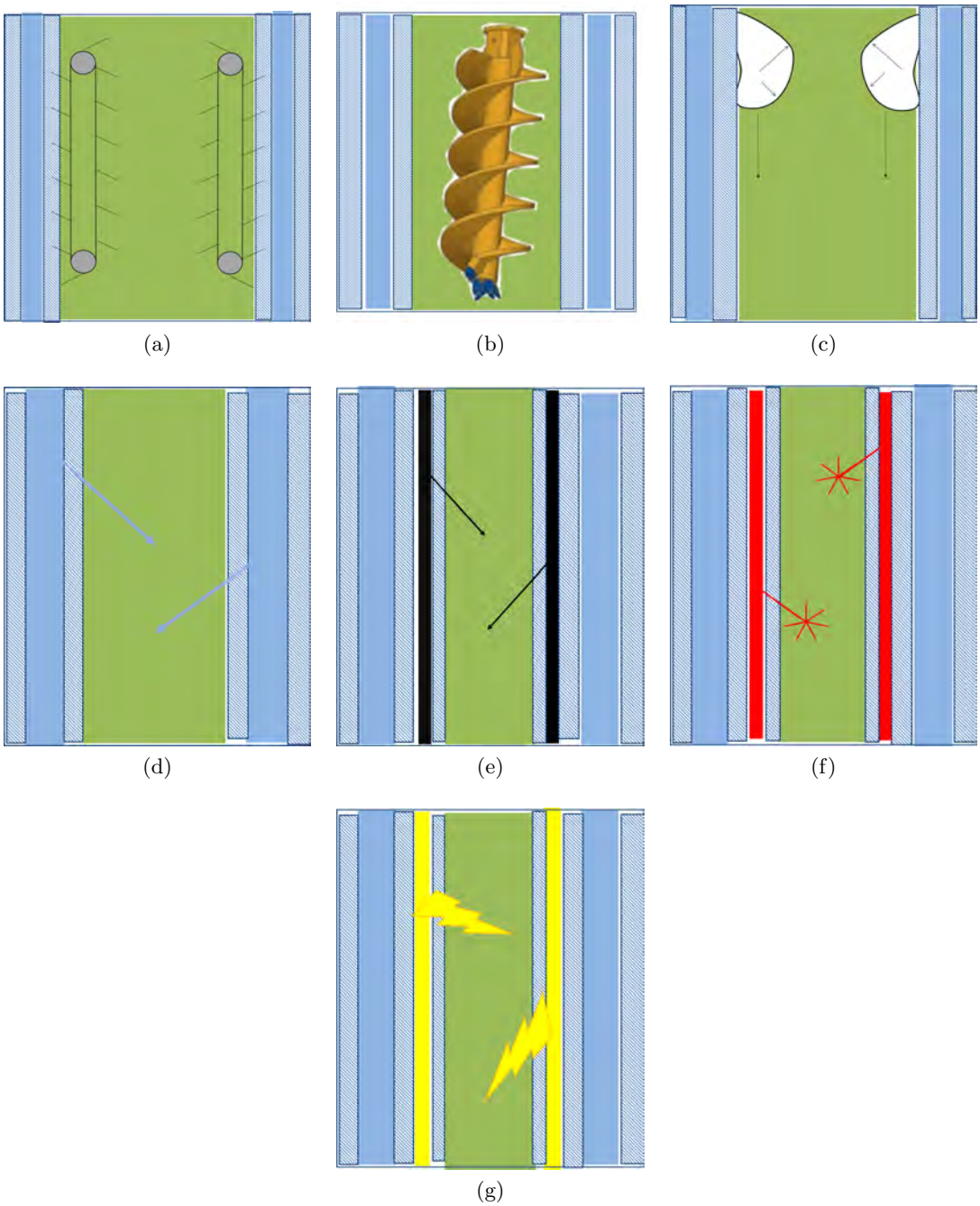
The solutions as given in Figures 4.4a-4.4c are mechanically complex solutions. The conveyor belt solution will consist of many parts and even if its built into the wall, the solution will create a loss of hydraulic diameter[1] of the suction channel. The same holds for the peristaltic solution (Fig. 4.4c), because the solution will require a complex solution of inflatable parts and will include an additional high pressure source. The Archimedes screw (Fig. 4.4b) will require a stiff shaft and while the design requires that the instrument is flexible. These two properties contradict, thus the option is excluded.

The chemical concept as shown in Figure 4.4e and the optical solution as shown in Figure 4.4f are removed as concepts for the same reasons as described in section 4.3. In these cases the additional equipment, channels and safety measures are the main reasons for removal.

The solution where an electrical mechanism is used can be seen as multiple contact points along the length and around the perimeter of the instrument. These points will cause the tissue to char. Hereby lies also the problem that conductivity of the contact points reduce due to charring[28] and thus creating an ineffective solution.

The only viable concept, if clogging should present as a problem, is using a water jet facing inwards as seen in Figure 4.4d.

[1] Hydraulic diameter: commonly used term when handling fluid calculations for noncircular ducts.



(a) (b) (c)

(d) (e) (f)

(g)

Figure 4.4: Solutions for anti-clogging mechanism

4.5 Measurement

In the fail safe system there is a measurement module present that will check if the pressure inside the cavity does not rise above the maximum allowed pressure. Pressure, flow and mass are the three properties that can be measured. The pressure can be measured at two locations, namely directly inside the cavity and indirectly inside the suction channel. Inside the cavity the pressure can be determined, for example, by using a pressure sensor that is also used for measuring arterial pressure inside mice[29]. The second measurement is the pressure of the suction channel. When the suction channel is blocked internally or externally, the pressure will decrease inside the suction channel. The measurement probe is located inside the handle of the instrument which is located outside the patient. Flow of the suction channel can be measured and compared to the inward flow of water. The mass property will compare the weight of waste taken out of the cavity to the water inserted into the cavity.

The property of pressure is the only property that is directly correlated to the pressure increase in the cavity. The other two properties are depending on the waste that flows from the cavity to the collection basket. The waste has no uniform properties, as seen in Section 2.1 the contents of the interface tissue were described as cement particles, wear debris, and fibrous tissue. The waste flow contains these particles, but also water from the water jet. Density will fluctuate during removal of the waste, this will cause that the measurements taken with the properties of flow and mass to be considered inaccurate. Volumetric flow is more important than mass flow for safety of the patient. The mass measurement will only give information about the mass removed, but not whether there is enough material taken out to prevent the pressure increase. The flow measurement is dependent on the material used and since the consistency of waste removed is not known the measurement will give an unreliable measurement.

This leaves the pressure measurement as the only option, but it has two locations. Measuring the pressure of the suction channel will result in some difficulties, namely that the suction channel pressure is an indirect property of pressure in cavity, and pressure decrease is minimal compared to increase in cavity. The pressure inside the suction channel will be dependent on how much waste is inside the channel. When a large piece is pulled through the channel, it may result in the pressure gradient not to be linear at all times. If not, the pressure will become equal inside the channel from the vacuum source up to the piece of tissue. This will cause a false warning during the removal of waste when it is fully blocked. However, when in normal operating conditions where waste is flowing through the channel, the pressure will become dependent on how different particles will interact in the process. This could cause a false warning as well, leaving a pressure measurement inside the cavity itself as the only option left. This can be done with a intravascular pressure sensor [29]. This sensor requires a single channel, but it may also be possible to integrate this into the wall of the instrument.

4.6 Switch-off

After the measurement has been taking and the increase of pressure inside the cavity reaches hazardous conditions the water jet should be turned off, this can be done with the following solutions:

- Fig. 4.5a A valve, located in the handle of the instrument, to shut off the water channel.
- Fig. 4.5b The piston or membrane, located in the handle of the instrument, will pull a block through the water channel to close it off.
- Fig. 4.5c The piston or membrane, located at the tip of the instrument, will enable a structure to block the flow of water towards the nozzle.
- Fig. 4.5d An overflow channel is present that allows waste to flow out when the pressure increases.
- Fig. 4.5e A scoop-like structure to allow an equal amount of water into the cavity as waste is removed from the cavity.

The piston or membrane solution as shown in Figure 4.5b will need a large area in the suction channel if its located in the handle which the surgeon holds. Equations 4.2 - 4.5 show that the length of a square as surface area for the piston or membrane will become very large when compared to the size of the suction tube. The pressure at the location of the piston/membrane will decrease to the vacuum pressure. Only the pressure drop due to blocking will be used for calculating the area of the piston/membrane, since the static pressure will be compensated by, for example, a spring.

$$F_{h2o} = A_{block} * p_0 \tag{4.2}$$

$$F_f = mu_d * F_{h2o} \tag{4.3}$$

$$\Sigma F = F_{piston} - F_f = 0 \tag{4.4}$$

$$A_{piston} = \frac{F_{piston}}{dp_{membrane}} \tag{4.5}$$

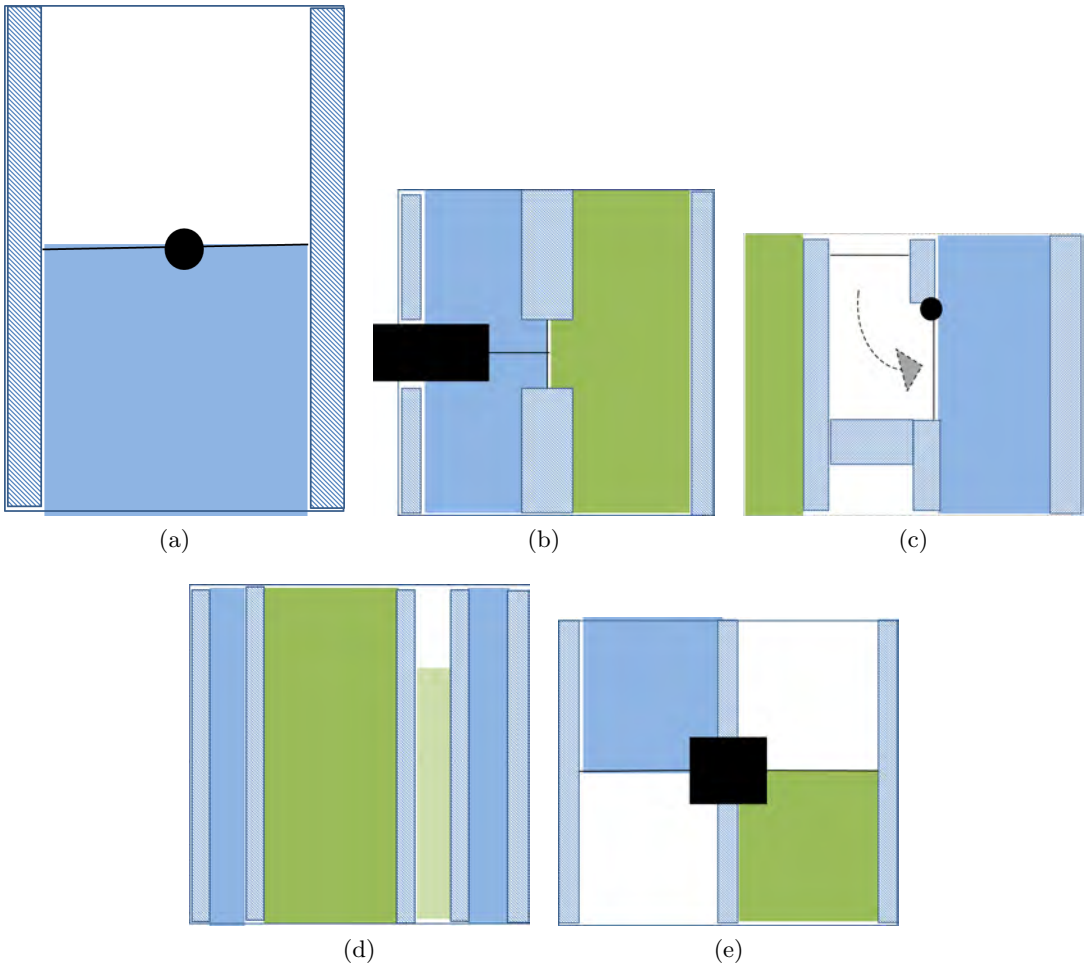


Figure 4.5: Solutions for closing off the water jet channel

Table 4.4: Symbols and values for evaluating size of piston

Symbol	Name (unit)	Starting Value
A_{block}	Area of block inside water jet channel ($[m^2]$)	-
A_{piston}	Area of piston or membrane ($[m^2]$)	-
F_{h2o}	Force of water on the block in the water channel	-
F_f	Friction force of block inside its casing	-
$A_{waterjetchannel}$	diameter of a circular water jet channel ($[mm]$)	5
p_0	Water pressure ($[bar]$)	100
mu_d	friction coefficient ($[-]$)	0.6[30]
$dp_{membrane}$	Pressure loss at location of membrane/piston ($[mbar]$)	200

-: calculated value

Using Equations 4.2 - 4.5 and the values listed in Table 4.4, the minimal length of a side of a square that is able to pull an object through the water jet channel is 76 mm. The diameter of a suction tube is 10 mm, thus the length needed for the piston or membrane when these are able to fit all around the tube is 367 mm.

The piston/membrane solution can also be applied at the tip of instrument where the pressure increase is allowed to be 2.7 bar (as mentioned in the requirements). By applying Equations 4.2 - 4.5, it is found that the length of a square membrane/piston should be 14.9 mm. Since the area exceeds the size of the tip of the instrument other solutions are required for the desired design. We could think of a spring system that pushes a part into the water jet. The water pressure will push the part to its maximum position so that the water channel is blocked. There are some difficulties with designing a system as such, especially when it needs to be combined with a water and suction channel. The main issue becomes placing the system into the size requirements given in the system requirements (Section 2.3) whereby the maximum diameter is 3 mm and the water channel walls need to be at least 0.4 mm thick as found in Section 4.3. The solution should be placed inside the water channel to be able to keep the suction channel opening as large as possible. Furthermore the length of a spring mechanism cannot become to large in order to keep the pressure loss to a minimum, by keeping the flow speed and spring mechanism length to a minimum. The water channel only has 1 nozzle at the tip and this nozzle can be placed at any point.

An overflow channel (Fig. 4.5d) will not provide the safety level needed for this device, since the chance of the overflow channel getting blocked by a piece of tissue is too large, as shown in the Failure Mode and Effect Analysis in section 3 for the problem of blocking. After deducing, the only feasible solution left is the valve, as shown in Figure 4.5a.

4.7 Concept

In the end the concept solution contains the following items:

Water Jet	Water jet to the side (Fig. 4.1c)
Anti-Blocking	Deflecting water jet (Fig. 4.2d)
Measurement	Pressure measurement in cavity
Close-off	Valve (Fig. 4.5a)

CHAPTER 5

Embodiment Design

The initial size requirements will be set by providing calculations. The second step is providing proof of concept for the deflection of the water jet, since it is still unknown whether this is feasible. Finally, the modes of operation will be discussed.

5.1 Calculations

The calculations will be separated into two sections, namely the number of nozzles which can be used and how the cross section of the instrument will look as.

5.1.1 Number of nozzles

Tissue removal by water jet dissection is dependent on the water pressure and the nozzle diameter. These two parameters are tested and it is preliminary found that a nozzle diameter of 0.2 mm will need a 150 bar water pressure and a nozzle diameter of 0.6 mm will require 80 bar water pressure. Using the data provided, the flow through the nozzles can be calculated by using the Equation 5.1[31] with symbols listed in Table 5.1. The equation is valid for nozzles which have a 2.5:1 - 3:1 ratio of nozzle diameter to nozzle length. The results from Equation 5.1 with input from the interpolation are listed in Table 5.2.

$$Q = \frac{1}{4}\pi D^2 \sqrt{\frac{2 * p}{\rho}} \tag{5.1}$$

In Appendix A the maximum flow when using a 1.6 mm diameter suction tube is 852 ml/min. This eliminates all nozzles with a diameter larger than 0.3 mm. Combining this information with the information from Table 4.3, it can be seen that for nozzles diameters 0.1 and 0.2 mm the required wall thickness will become 1.7 and 1.5 mm, respectively. This

Table 5.1: Symbols for Equation 5.1

Symbol	Unit	Description
Q	$^{ml}/_{min}$	flow rate
D	mm	nozzle diameter
p	bar	working pressure
ρ	$^{kg}/_{m^3}$	density of water.

would mean that less than 1.5 mm is left for the suction and water channels, including the suction wall thickness. Concluding, only a single 0.3 mm diameter nozzle can be used.

Table 5.2: Interpolation of nozzle diameter dependent pressures, preliminary data.

Diameter [mm]	Pressure [bar]	Flow $[^{ml}/_{min}]$
0.1	167.5	86
0.2	150	326
0.3	132.5	690
0.4	115	1143
0.5	97.5	1645
0.6	80	2145

5.1.2 Channel design

Using Equations 5.2 - 5.8 the pressure loss inside the water channel can be determined for designs that consist of two separate circle segments for the channels, as shown in Figure 5.1. The Equations 5.2 - 5.4 describe the design of arc segments. Since the water and suction channel are both non-circular channels the pressure decrease cannot be calculated by just using the diameter. A new parameter is introduced namely the hydraulic diameter (Eq. 5.5 [32]), which uses the area and perimeter to find an equivalent diameter for a circular cross section that can be used with the Reynolds equation (Eq. 5.6), and also the moody chart (Eq. 5.7). The Reynolds equation and the moody function can be used to find the pressure loss. The pressure loss inside the tubes prior to the instrument will not be taken into account at this point, since these will not influence the design of the instrument. In Table 5.3 the different symbols used in Equations 5.2 - 5.8 are listed.

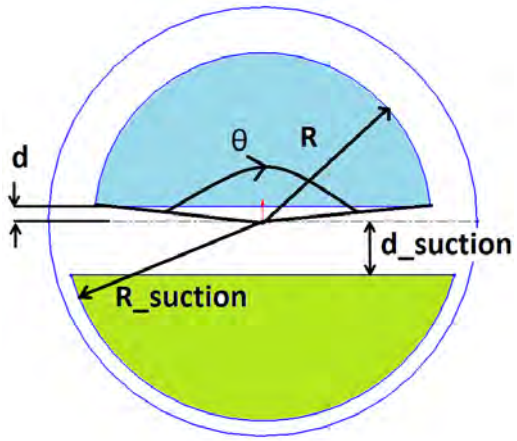


Figure 5.1: Arc segment geometry[33]

Table 5.3: Equation symbols

Symbol	Unit	Description	SV
θ	$[rad]$	Angle of the arc segment	π
d	$[m]$	Distance of the arc segment to the center of the circle	0
R	$[m]$	Radius of the circle	$0.003 - t_{wall}$
$A_{circle,segment}$	$[m^2]$	Area of circle segment	-
$P_{circle,segment}$	$[m]$	Perimeter of circle segment	-
D_H	$[m]$	Hydraulic diameter	-
Re_{DH}	$[-]$	Reynolds number based on hydraulic diameter	-
Q	$[m^3/s]$	Volumetric flow	-
v	$[m^2/s]$	Kinematic viscosity	1E-6
f	$[-]$	Friction factor	-
ϵ	$[m]$	Roughness	0.0015
dp	$[Pa]$	Pressure loss	-
L	$[m]$	Length of instrument	0.2
ρ	$[kg/m^3]$	Density of water	1000

SV: Starting value; -: calculated by using the Equations 5.2 - 5.8

$$\theta = 2 * \cos^{-1}\left(\frac{d}{R}\right) \tag{5.2}$$

$$A_{circle,segment} = R^2 * \frac{\theta}{2} - R^2 * \frac{\sin(\theta)}{2} \tag{5.3}$$

$$P_{circle,segment} = 2 * R * \sin(\frac{\theta}{2}) + R * \theta \tag{5.4}$$

$$D_H = \frac{4 * A_{circle,segment}}{P_{circle,segment}} \tag{5.5}$$

$$Re_{DH} = \frac{\frac{Q}{A_{circle,segment}} * D_H}{v} \tag{5.6}$$

$$f = moody\left(Re_{DH}, \frac{\epsilon}{D_H}\right) \tag{5.7}$$

$$dp = \frac{f * \left(\frac{Q}{A_{circle,segment}}\right)^2 * L}{2 * \rho * D_H} \tag{5.8}$$

A pressure of 143 bar is needed when using the 0.3 mm nozzle. The pressure is determined by using an iteration in Excel to find the optimal wall thickness. While using multiple distances for d it was determined that a starting value of 0 (as shown in Table 5.3) creates a pressure loss of 2.93 bar, as shown in Table 5.4. In case d is increased, the pressure loss will increase, since the area will decrease more rapid than the perimeter and thus the hydraulic diameter will decrease. With chosen value of $d = 0.3mm$ the iteration yielded in a numerical error, therefore any other values for d were not considered.

Table 5.4: Changing distance d for the water channel

$d[mm]$	$A[mm^2]$	$P[mm]$	$dp[bar]$
0	1.03	4.17	2.93
0.1	0.84	3.90	5.19
0.2	0.604	3.44	13.3
0.3	NUM	NUM	NUM

NUM: numerical error, d: distance from center, A: Area of water channel, P: perimeter of water channel, dp: Loss of water pressure

From these calculations we can determine the size of the suction channel by using the same equations for the geometry as with the water jet channel. Filling in the following values: Radius $R = 1.4mm$, distance $d_{suction} = 0.7mm$ and $d = 0mm$ (Fig. 5.1), a value for hydraulic diameter of 0.88 mm was obtained. This diameter is smaller than the value of 1.6 mm (estimate in the flow experiment Section A) and is thus smaller than was desired. Since a larger hydraulic diameter would mean higher possible waste flow, the $d_{suction}$ is changed to 0.5 m which means that $d = 0.2mm$ and this would yield a hydraulic diameter of 1.26 mm. This hydraulic diameter is still too small to confirm a safe waste flow. During each step in the Pahl and Beitz method it is required to look back and alter the previous steps if necessary. Until this point the process did not require revision, but now the requirement of maximum diameter needs to be altered. In Section 2.3 the outer diameter has been limited to 3 mm, but with the calculations done above this system will not be feasible. In Section 2.3 the maximum outer diameter was based on assumption based on research, however, it remained an assumption since no 3D-data was analyzed to check the thickness of interface tissue. From CT data obtained of patients with aseptic loosening of the hip prosthesis it can be found that a 3.5 mm outer diameter will still give sufficient removal to re-stabilize the hip prosthesis.

By changing the outer diameter to 3.5 mm, the previous design calculations are recalculated based on the new dimensions. Table 5.5 shows the newly obtained parameters, and it can be seen that when increasing d and (thus decreasing the Area of the water channel) the hydraulic diameter of the suction channel ($D_{H,suction}$) is increasing and the pressure loss of water is increasing as well. From Section 3.2 and Table 5.2 a minimum diameter of the suction channel is selected, namely 1.6 mm. In this case the hydraulic diameter is used. The effect of a different shape on the removal of waste from a cavity is not known.

Table 5.5: Results with D = 3.5 mm

$d[mm]$	$D_{H,suction}[mm]$	$dp[bar]$
0.0	1.24	0.675
0.1	1.36	0.977
0.2	1.47	1.50
0.3	1.58	2.48
0.4	1.69	4.66
0.5	1.75	13.4
0.6	NUM	NUM

NUM: numerical error

5.2 Proof of Concept

In Section 4.3 the water jet which is deflected under an angle was selected as only option for the anti-blocking mechanism. To be able to confirm whether this is working, method trials should be conducted to give a proof of concept.

5.2.1 Variables

In the proof of concept multiple variables can be used, namely:

a Location of nozzle

1 Along length shaft
2 Tip

b Material - wall behavior

The location of the nozzle is the only instrument dependent variable left. Therefore, only the angle of the nozzle at the position of the tip will be important. Then again the height of the nozzle compared to the outer wall is the main changing variable. When the nozzle is placed along the length of the shaft the water jet will fill part of the suction channel, taking away useful removal area space. Therefore the angle of the nozzle will be altered at the tip of the instrument, as shown in Figure 5.2, and this will be done in steps of 10 degrees. The expectation is that a sharper angle will push tissue away from the opening of the suction channel.

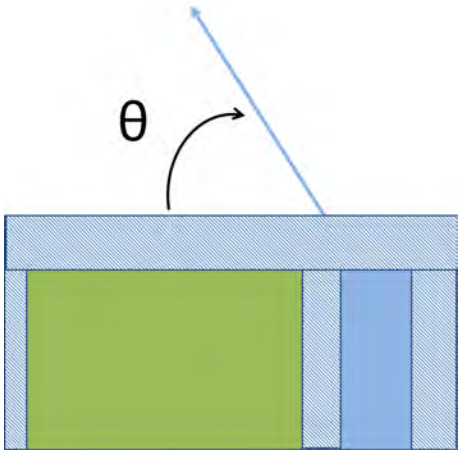


Figure 5.2: Angle of water jet compared to tip of instrument

The variable material - wall behavior determines how the interface tissue will behave when forces act upon it. If the material does not attach to the wall, it will float around in the space and cause the waste to be pushed away by the nozzle causing large debris to float in the open space. If the material attaches to the wall, it may provide smaller debris of material which would cause less chance of blocking. If the material is loose in the tissue holder the worst case scenario will be tested. If the tissue sticks/attaches to the wall of the tissue holder the tissue could remain attached to the wall while other pieces are removed. How the interface tissue behaves in these situations has not been investigated, thus the worst case scenario will be used, namely the case where there is no attachment of tissue to the wall.

5.2.2 Method and Materials

The following checkpoints will have to be dealt with prior to the experiment:

1. Test for leaks with tap water pressure (estimated 2-4 bar)
2. Test for leaks with high water pressure (100 bar)
3. Check suction with same protocol as seen in Appendix A
4. Test sensors by testing the full setup without suction and water jet
5. Test entire setup with only water, no tissue

During experiment the following steps will be followed:

1. Remove sample from freezer
2. Bring sample back to room temperature by placing in a bath of 30°C
3. Place weighed sample in tissue holder
4. Attach sensors/water jet
5. Start suction and start high pressure generator via Labview
   (a) if pressure in cavity goes above 2 bar, turn off high pressure generator
   (b) if pressure in cavity reaches above 2.7 bar, alert via led
6. End after 1 minute
7. Remove and weigh remaining tissue
8. Dispose remaining tissue as biological waste

Tissue

The instrument is designed to remove interface tissue in the patient. Because of the limited availability of this type of tissue for research, liver is used as a substituted for the measurements. Liver is a soft tissue which can resemble interface tissue[34]. While animal muscle tissue could also be used, these type of tissues require higher working pressures of the water jet than interface tissue. It is important to note that liver tissue requires lower working pressure than human interface tissue. During testing the pressure required for the interface tissue will be used so that the pressure rise will be similar to the actual situation. Furthermore muscle tissue consists of fibrous material in one direction, whereby the structure of the interface tissue is woven analogously as a mat[35]. Liver contains a cellular structure which is similar to that of the interface tissue. This will cause a different behavior on how the material will respond. Livers from Specific Pathogen Free (SPF) pigs will be used, as can be seen in the bio-safety protocol in Appendix D.

Setup

In Figure 5.3 a schematic overview is given of the setup. The pressure generator used is the Nilfisk p160.2, the vacuum source used is the Leybold SV 25, and two pressure sensors,

one with a range of 0 to 10 bar and one with a range of 0 to 160. The other components where created with the help of J. van Frankenhuyzen, mechanical workshop of 3mE[1] and DEMO. The Solidwork drawings are located in Appendix E. A schematic overview of the experimental setup is given in Figure 5.3 and the setup is shown in Figure 5.4.

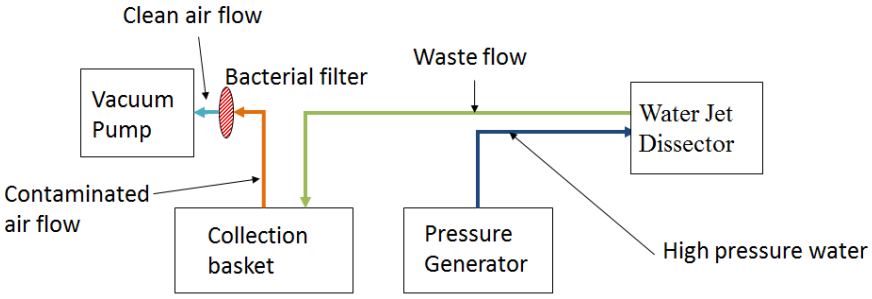


Figure 5.3: Figure schematically showing the experimental setup.

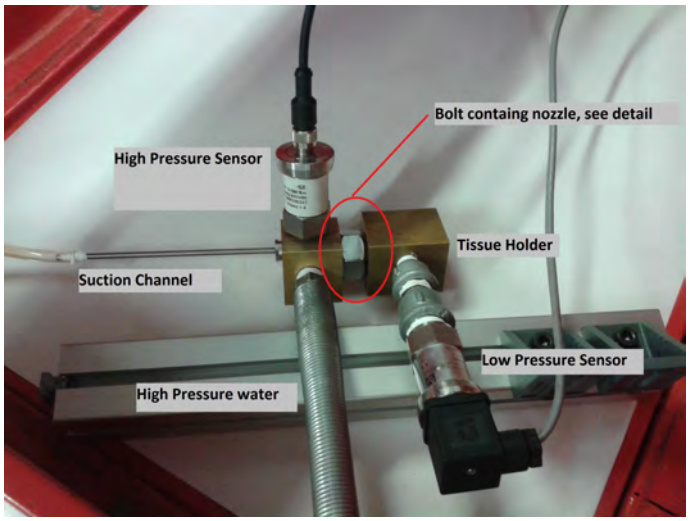
By using the same method as in the vacuum flow trial (App. A) the vacuum source in combination with the suction tube is tested. The flow for a 2 mm inner diameter suction tube is 1020 $^{ml}/_{min}$, which is larger than the flow of a 1.6 mm inner diameter tube.

5.2.3 Results

During the start-up of the proof of concept it was found that testing the application can cause the water jet to turn on and off rapidly. In those cases the start-up current of the high pressure generator caused the fuses to blow and a relay to be overheated in such a way that it welded itself in the on position. The solution was to use a 32A fuse, and a solid state relay with the following specifications: 20A maximum continuous current and 250A peak current. During a fault where the relays was welded in the on position it was seen that the cavity pressure went above 10 bar and all of the tissue was removed during that run, example of measurement is shown in Figure 5.5. However, when comparing the sample measurement prior to the fault to other samples, it was found that the suction tube was blocked (Fig. 5.6). After filtering the waste of the sample shown in Figure 5.5 there were no large particles found.

In Table 5.6 the results are shown. For the setting of 10° the results have been split into two categories, since either the device was blocked or not. It is chosen that when at least 90% of the weight was removed that it was considered not to be blocked, since in one case where 94% of the weight was removed, there was only a small piece of tissue stuck in a groove. Only the first peak or time the water jet was on is considered in Table 5.6. In some cases there were other peaks, but these were short of time frame. Only with a few cases there were longer secondary times the water jet went on. The sample of Figure 5.5 is taken into account for the 90° setting, but only with the peak cavity pressure and the time the water jet is turned on. Since no material was left in the end due to the fault with a relay, the mass measurement is not considered. In similar cases the same actions were undertaken.

[1]Faculty of Mechanical, Maritime and Material Engineering



(a)

(b)

Figure 5.4: Showing the experimental setup (a) and the detail of the spark machined nozzle (b).

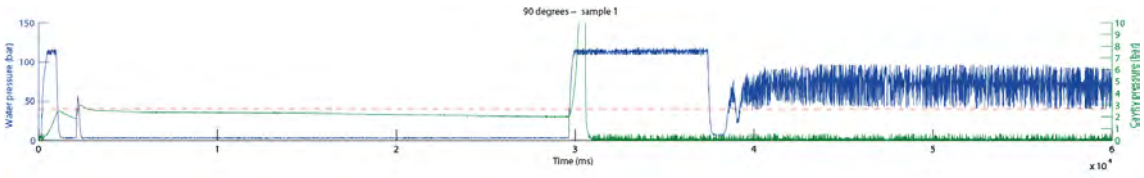


Figure 5.5: Measurement of sample where the relays caused the cavity pressure to rise above 10 bar. Blue: water jet pressure, left y-axis; green: cavity pressure, right y-axis; red dotted line: 2.7 bar threshold, right y-axis

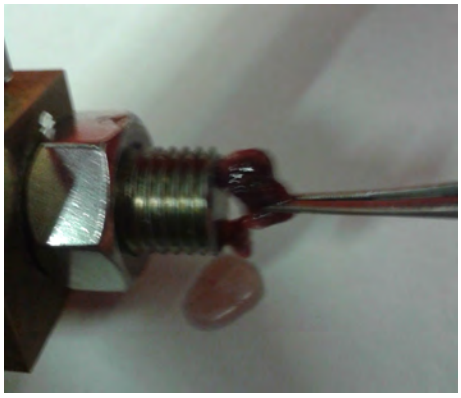


Figure 5.6: Blocked suction tube

Table 5.6: Results: peak cavity pressure, time water jet dissector turned on, weight removed

Angle [°]	$p_{peak}[bar]$			$t_{WJ,on}[ms]$			$\Delta m[\%]$		
	mean	min	max	mean	min	max	mean	min	max
10*	2.16	1.67	2.35	2303	1417	3169	55	28	64
10**	1.61	1.19	2.30	37670	3033	59900	99	94	100
20	2.52	2.17	2.70	1256	1096	1581	23	13	29
30	2.58	2.38	2.76	1404	839	2437	34	22	49
40	3.50	3.08	4.03	1426	661	1990	49	18	42
50	2.85	2.21	3.17	1126	930	1417	32	27	41
60	3.41	3.08	3.63	1280	908	1576	33	12	77
70	2.61	1.33	2.95	1869	699	59857	62	27	100
80	4.59	4.13	5.24	719	583	802	46	24	63
90	2.69	2.50	3.11	846	657	995	26	18	31

* Includes all measurements where less than 90% weight was removed

** Includes all measurements where 90% or more weight was removed

With the setting of 10° the tissue was pushed away leaving an opening large enough to remove waste. Only with the 10° setting it was possible to remove all of the waste in half of all the cases. Figure 5.7 shows that for the settings of 10° and 20° the pressure remains below 2.7 bar.

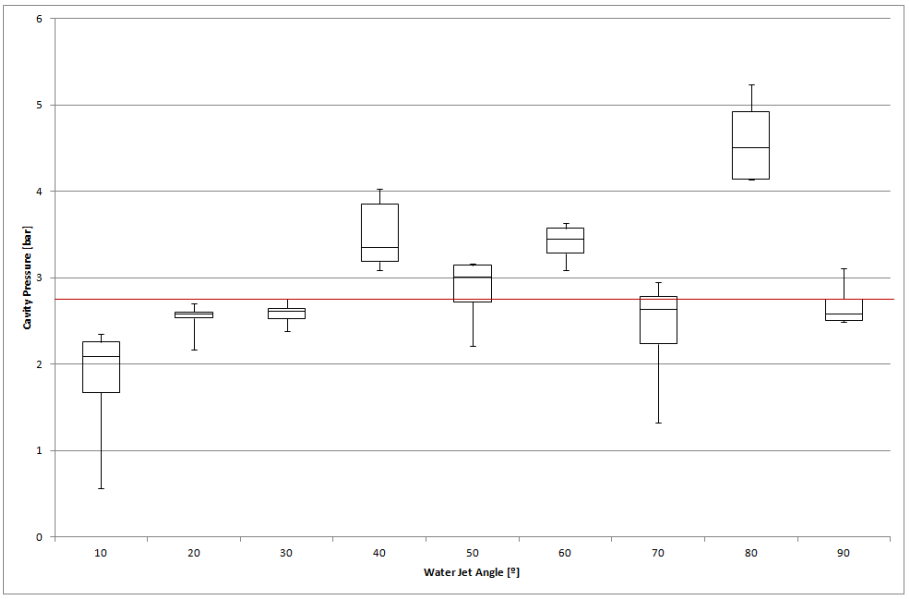


Figure 5.7: Boxplot of peak cavity pressure data for each water jet angle

From the results it is derived that only the setting with 10° has potential, since in half of the cases blocking did not happen. Also the same setting had the lowest peak value and longest on time for the water jet. It is seen that blocking occurs within the first seconds of turning the device on. Due to a small leak in the viewing disk in the tissue holder the pressure could drop to water pressure, since disabling the high pressure source did not turn off the tap water faucet and thus did not close off the water supply to the nozzle. It is also seen that the additional safety feature of a pressure sensor and a valve to close off the water jet can create a safe working environment.

5.3 Operational modes

At the start the operational modes of the instrument were not included in the design process, however, during the process the question was asked: "Will any of these solutions work?" The answer was not clear if any of the solutions will create an inherent safe design, therefore the operational modes need to be discussed. For both the water jet and the suction channel there can be modes defined.

5.3.1 Water jet

In case of the water jet there are two operational modes that can be used. The first mode is a continuous mode. Since this mode was the assumption from the beginning it will

not be discussed any further in this section. The second mode is a pulsating mode where the pulse can have different frequencies. The physical principle of these systems can also be found in High Frequency Oscillation (HFO) respiratory systems, which are used for neonatal treatment[36, 37]. HFO ventilators use the principle of a flow with one part of a high relative pressure and with another part of a low relative pressure. The high pressure is used to inflate the lung (inspiratory phase) and the low pressure part is used as the expiratory phase. The frequency of the HFO ventilators ranges from 3 to 20 hertz.

When this technique is applied on the water jet, the frequency and duration of the pulse are the variables which can be manually adjusted. Both of these properties are unknown. Another variable which needs to be investigated is whether the water jet will have a on/off pulse or a high/low pressure pulse. The main difference being whether a continuous, low pressure flow is present. In the industry this has already been applied, namely by Foldyna et al. [38] and this research showed the promise of a working pulse water jet. However, the use of pulse was created by an ultrasonic piezoelectric transducer and was placed inside the tip of the nozzle. S. den Dunnen advised not to use such pulsating water jet system for water jet dissection due to the restrictive parameters for the dissection properties, therefore it will not be investigated any further.

5.3.2 Suction Channel

The theory described for the water jet from the HFO ventilators [36, 37] can also be used for the suction channel. For the suction channel this is different since the oscillation has different flow directions. Also the theory from Rowe et al. [17], Beek et al. [18] can be used where the removal of sludge is stopped for a time where the debris can settle again and the opening is cleared once more. The downside is the use of large diameters and long on-times compared to the off-times. These researchers showed a down time of one night compared to operational time of days.

To be able to determine if pulsation of the waste flow is a viable solution, the Womersley number (α) should be calculated, Equation 5.9[39]. The Womersley number is dimensionless number which describes how the flow will develop in a tube. If $\alpha \leq 1$ the flow and pressure gradient will be in phase and the flow will have a parabolic flow profile. If $\alpha > 1$ the flow will lag the pressure gradient with 90 degrees and the flow profile will be flat.

$$\alpha = D_H \sqrt{\frac{2\pi f}{v}} \tag{5.9}$$

When using $D_{H,suction} = 1.75$ (From Table 5.5) and using frequencies ranging from 1 to 10 Hz we can find the Table 5.7. The kinematic viscosity, v, used is the one of water, since for the waste flow the kinematic viscosity is unknown and for simplification water is one of the main components of the waste. All of the values are larger than 1 and therefore the flow gradient will lag the pressure gradient with 90 degrees and the flow profile will be flat. The consequence being that first the pressure increase will reach the cavity and then

the flow. The flow described would be the waste flow which is being pushed back into the cavity.

Table 5.7: Womersley number for different frequencies

Frequency [Hz]	α
1	4.4
2	6.2
3	7.6
4	8.8
5	9.8
6	10.7
7	11.6
8	12.4
9	13.2
10	13.9

5.3.3 Proof of Concept

By applying the same protocol as seen in section 5.2 the pulsation will be tested by using a ball valve to manually add a burst of air to the suction flow, without turning off the vacuum pump. Only the settings with 10° and 20° can be tested, since these allow at least a 0.5 bar margin between the safety value (2.7 bar) and the mean peak cavity pressure.

Materials

The setup of Section 5.2 is altered by adding a y-piece to allow air to be connected to the suction tube, as seen in Figure 5.8. A pressure regulator was used to reduce it to 2.5 bar. A ball-valve is used for manual control of the pressure pulse.

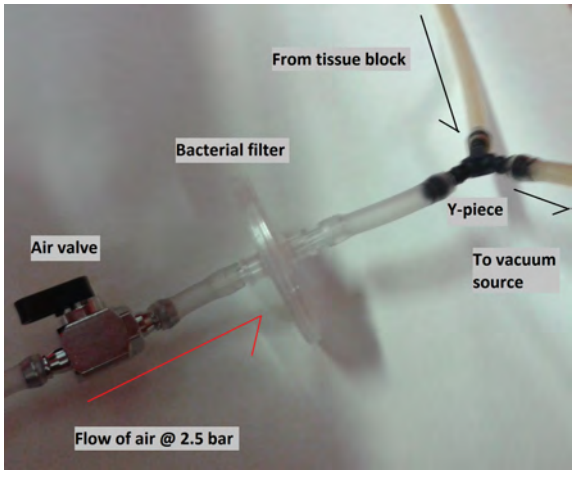


Figure 5.8: Connection of air connection to waste removal

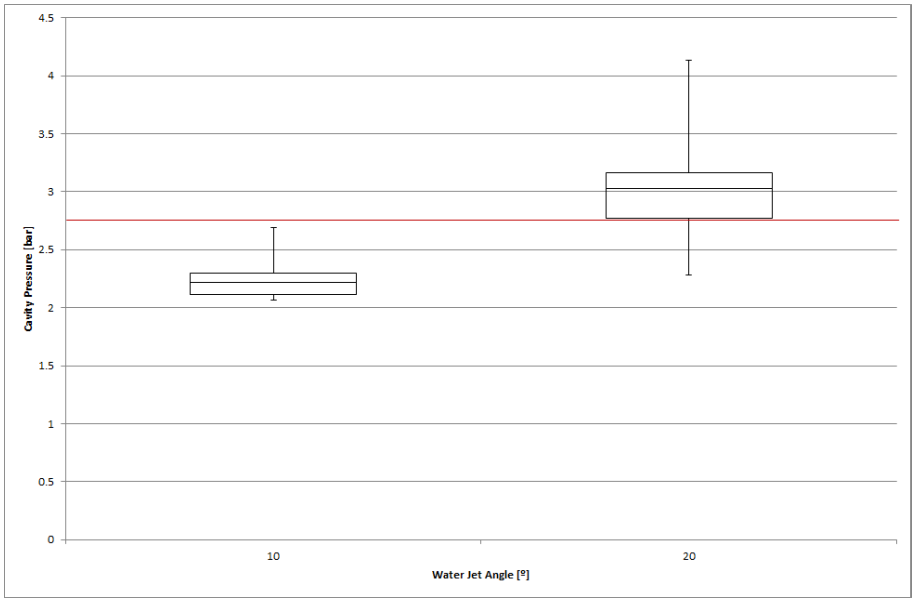


Figure 5.9: Boxplot of the peak cavity pressures for each water jet angle combined with an air pulse

Results

The results from the experiment are shown in Table 5.8 and the peak cavity pressure is also shown in Figure 5.9. The results only show the data from the first peak. In all cases when a pulse of pressurized air was added the pressure in the cavity increased well above 3 bar upto peaks of 5 bar.

Table 5.8: Results: peak cavity pressure, time water jet dissector turned on, weight removed

Angle [°]	$p_{peak}[bar]$			$t_{WJ,on}[ms]$			$\Delta m[\%]$		
	mean	min	max	mean	min	max	mean	min	max
10	2.25	2.07	2.69	7323	961	32122	87	57	100
20	3.04	2.28	4.13	710	379	1401	49	20	90

For the 20° there is an increase of waste removed, but the additional waste loss is caused by the lengthened runs, since it was about showing the effect of adding a pressure pulse on the suction channel. In Section 5.2 it was seen that a constant pressure was achieved at tap water pressure(2-4 bar). When adding a 2.5 bar pressure it can it is possible to push the blocking waste particle aside if it is small, but when the blocking waste particle is large, the particle would not move. In case the blocking waste particle was too large, it could happen that the waste bag would be blown out of the casing. Thus resulting in loss of vacuum. To move a waste particle the total force on the particle should be greater than 0, in direction of the cavity. This results in the equations 5.10 and 5.11 with the symbols listed in Table 5.9.

Table 5.9: Equation symbols

Symbol	Unit	Description
F_{WP}	$[N]$	Axial forces on the waste particle
m_P	$[g]$	Mass of waste particle
a_{WP}	$[m/s^2]$	Axial acceleration of waste particle
p_{SC}	$[Pa]$	Pressure in the suction channel
p_{Cavity}	$[Pa]$	Pressure in the cavity
A_{WP}	$[mm^2]$	Surface area of the waste particle in axial direction
A_{SC}	$[mm^2]$	Surface area of the suction channel in axial direction

$$\sum F_{WP} = m_{WP} * a_{WP} = p_{SC} * A_{SC} - p_{WP} * A_{WP} > 0 \tag{5.10}$$

$$p_{SC} > p_{Cavity} * \frac{A_{WP}}{A_{SC}} \tag{5.11}$$

From the results it is shown it is not possible to create a safe water jet dissector with the applied settings. A definition is found for the pressure pulse of air compared to the waste particle size and cavity pressure. The size of the particles is not known and the setting used for maximum cavity pressure (2 bar) was too high.

CHAPTER 6

Discussion/Conclusion

The first prototype for testing an angled water jet dissector has been completed. The results and the procedures of the proof of concepts introduced new insights into how the instrument should be designed to become inherently safe. First these new insights will be discussed, from which a conclusion will be given.

6.1 Discussion

6.1.1 Experimental Protocol/Design

The used prototype design showed the effect of an angled water jet dissector on the blocking of the opening of the suction channel. By having a sharp angle of 10° between the surface of the instrument and the water jet, the chance of blocking of the instrument was reduced. In half the cases all of the waste was removed, while in the other half blocking occurred. To prevent blocking, a 2.5 bar air pulse was added to the suction channel. Only the 10° and 20° showed peak pressures below 2.7 bar and could therefore be used with the pulsating suction flow. By adding a pulse to the suction channel it was found that a safe water jet dissector cannot be created with the settings used. The possible reasons for negative results for both of the concepts of proof, provided in Section 5.2 and Section 5.3.3, are:

1. Unable to fully turn off water jet
2. Leak in viewing window of tissue block
3. Manually applied pressure pulse

The expectation is that when the water jet is turned off that the pressure will become a constant value, but when water is continuously supplied at a tap water pressure between 2 and 4 bar, the pressure will fluctuate with the pressure of the tap water. Due to a leak in the viewing window (Fig. 6.1) of the tissue block, the increase in pressure from the tap water is slightly counteracted. However, the pressure would still increase to a higher value than would be expected.

Figure 6.1: Red circle showing the viewing window in the tissue holder

In the second proof of concept where a pressurized air was added to the suction channel, the manual application resulted in some cases of bad timing, whereby the pressure could increase above 3 bar. In other cases the blocking waste particle would not move, but the suction bag would be lifted out of its casing resulting in loss of vacuum. To prevent the lifting of the suction bag, the suction channel should be closed while the pressurized air channel is opened. In Equation 5.11, the relationship between the pressure of the air pulse and the cavity pressure and surface areas is shown. The air pulse pressure used is only 1.25 times higher than the cut-off pressure, which can also be interpreted as the pressure the cavity will have once the water jet is turned off. This would indicate that the area of the suction channel is 1.25 smaller than the surface area of the waste particle. It was seen that the surface area of the waste particle is much larger than 1.25 times the suction channel area, as can be observed from Figure 5.6.

To create a feasible water jet dissector the water jet turn-off pressure should be decreased and an automated system to provide the positive pressure pulse in the suction channel should be applied. The lowering of the water jet turn off pressure can cause the water jet to turn on for a very short time and could create very low removal rates, whether this is an issue should be researched in future work.

6.1.2 Embodiment Design

During the embodiment design phase the flexibility and the feasibility of thin walls have not been taken into account. To control the movement of the instrument, it will be necessary to create a steering mechanism. A steering mechanism will most likely require wires to run through the wall and therefore increase the overall wall thickness, especially of the suction wall. The suction wall has been assumed to be 0.1 mm thick, whether such a thin wall can be constructed showed inconclusive. However, this should be addressed in the detailed design phase. During the calculations in Section 5 the addition of the pressure sensor was not included in the drawings of the instrument. When considering a steering mechanism, the suction wall thickness, the addition of a pressure sensor and the materials

available today, it will most likely be required that the diameter of the instrument needs to be increased to 4 mm. An example of a possible cross section is shown in Figure 6.2.

Figure 6.2: Cross-section of instrument (Outer diameter: $4[mm]$): green: waste channel ($D_{H,suction} = 2.1[mm]$), blue: water channel ($D_{H,WJ} = 1.5[mm]$), grey: wall, and red: pressure sensor ($D = 0.2[mm]$[29])

6.1.3 Tissue Selection

In Section 5.2 the assumption was made that no attachment of tissue to the surroundings was the worst case scenario. Whether this is the case in the human body is uncertain. Hereby, a worse scenario could have been tested while the tissue does not behave in such a way. Research should be conducted on the effects of tissue attachment to its surroundings, including how this can influence the removal rate and chance of blocking.

Liver was chosen as a replacement tissue for fibrous interface tissue, but whether this is a fully functional replacement is not known. Hori and Lewis [5] showed the interface tissue properties known thus far, but have only limited data available. Further research is needed to show in detail the mechanical properties and to determine how well the liver can be compared to fibrous tissue. It is recommendable to do prototype testing with a tissue which is readily available and allowed to be used in the facilities provided at the TU Delft, such as specific pathogen free pig liver. Supermarket bought liver will not be allowed, since it is not known what micro-organisms these tissues carry and working with these tissues will require micro-biologist training. Human fibrous tissue is difficult to acquire and requires strict protocol for use within the facilities available at the TU Delft.

6.2 Conclusion

The goal of the thesis is to design an inherently safe water jet dissector. A water jet with an angle is chosen to prevent blocking of the suction channel in combination with a pressure sensor and valve to turn off the water jet. From Section 5.2 a water jet with an angle of 10° is found to provide the best removal rate while the cavity pressure remained

below the critical value of 2.7 bar. Blocking was still an issue and the use of a valve to turn off the water jet was proven to be useful. In an effort to remove the blocking tissue a pulsating suction flow was applied. The pulsating suction should push away the blocking tissue, but it was found by applying such pressures the cavity pressure increased to a level above the safety limit of 2.7 bar. The prototype with a 10° water jet proved to be safe when applied without a pulsating suction flow, but blocking remained an issue. The current prototype does not fulfill the outer diameter requirements set at the beginning of this research, due to the minimal water jet wall thickness requirements. Future research could proof this principle promising for use in minimally invasive interface tissue removal. The prototype created showed the working principle of safely using a water jet dissector to remove interface-like tissue from small cavities.

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APPENDIX A

Trial: Vacuum flow

In order to find the vacuum flow parameters a trial is conducted. The goal is to find what the minimum or maximum flow is in order to define which type of nozzle diameter can be used.

A.1 Method

The following steps are taken, starting with filling a cup with 200 ml of water, see Figure A.1. Before inserting the suction tube into the cup the pump is started. The stopwatch is started at the same time as the suction tube is inserted into the water. The time measurement is stopped when the suction tube is taking air and when the cup is empty. If the suction tube is taking air without the cup being empty the measurement is rejected.

There are three types of tubes tested, namely tubes with inner diameter of 1.1, 1.6 and 6 mm. Whereby the 1.1 mm and 1.6 mm tubes are similar to the size which will be used when removing interface tissue. All tubes are tested using a pressure of 200, 300 and 400 mbar. The vacuum pump used is the Erbe Jet II vacuum system with suction bag.

Figure A.1: Cup with markings to fill to 200 ml

Table A.1: Results for 1.1 mm inner diameter suction tube

D = 1.1 mm

P [mbar]	1 [s]	2 [s]	3 [s]	4 [s]	5 [s]	avg [s]	Q [L/s]	Q [ml/min]
200	94,8	95,4	96,0			95,4	2,10E-03	126.0
300	76,0	75,1	76,1			75,7	2,64E-03	158.4
400	67,1	65,0	67,0			66,4	3,01E-03	186.0

Table A.2: Results for 1.6 mm inner diameter suction tube

D = 1.6 mm

P [mbar]	1 [s]	2 [s]	3 [s]	4 [s]	5 [s]	avg [s]	Q [L/s]	Q [ml/min]
200	32,6	32,7	32,8			32,7	6,12E-03	367.2
300	28,5	27,9	27,5	27,7		27,9	7,17E-03	430.2
400	24,1	23,9	23,9			24,0	8,34E-03	500.4

Table A.3: Results for 6 mm inner diameter suction tube

D = 6.0 mm

P [mbar]	1 [s]	2 [s]	3 [s]	4 [s]	5 [s]	avg [s]	Q [L/s]	Q [ml/min]
200	4,9	4,8	5,0			4,9	4,08E-02	2448
300	4,6	4,4	4,7			4,6	4,38E-02	2628
400	4,0	4,2	4,0			4,1	4,92E-02	2952

A.2 Results

From the results it follows that the larger the diameter and higher the vacuum pressure is the more flow is generated. The results are plotted in Figure A.2 where the flow is plotted against the vacuum pressure. There are two trend lines added for the 1.6mm inner diameter tube. By using the basic fitting tool in MATLAB it shows that the residual norm for the linear fit is 4.9e-8 and for the quadratic fit is 3.2e-21. Using the quadratic fit as an estimate for the value of 800 mbar it is found that the flow of the suction channel will be 852 ml/min. With these measurements it is possible to determine the size of the suction channel and this information will need to be combined to fulfill the requirement of larger or equal waste flow than water jet inlet flow.

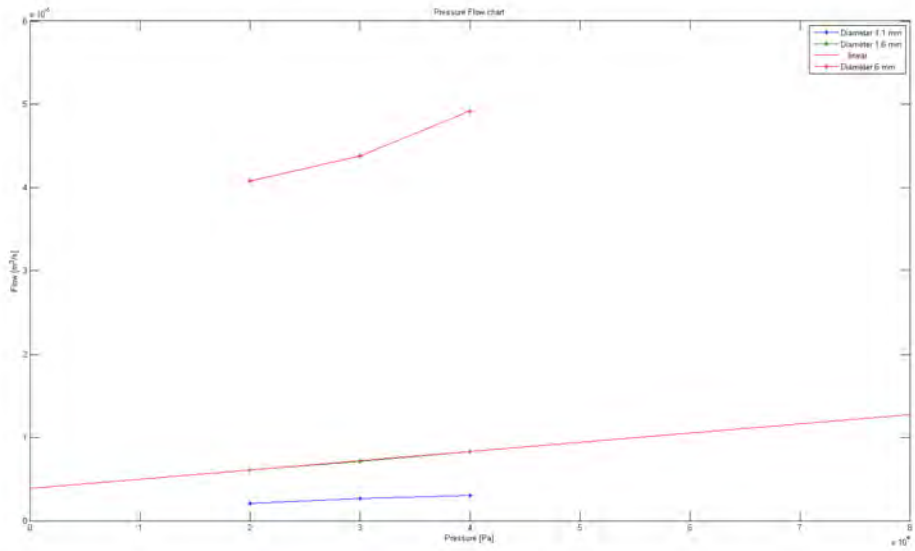


Figure A.2: Pressure Flow graph of results with linear trend line for 1.6 mm tube

APPENDIX B

Morphological Overview

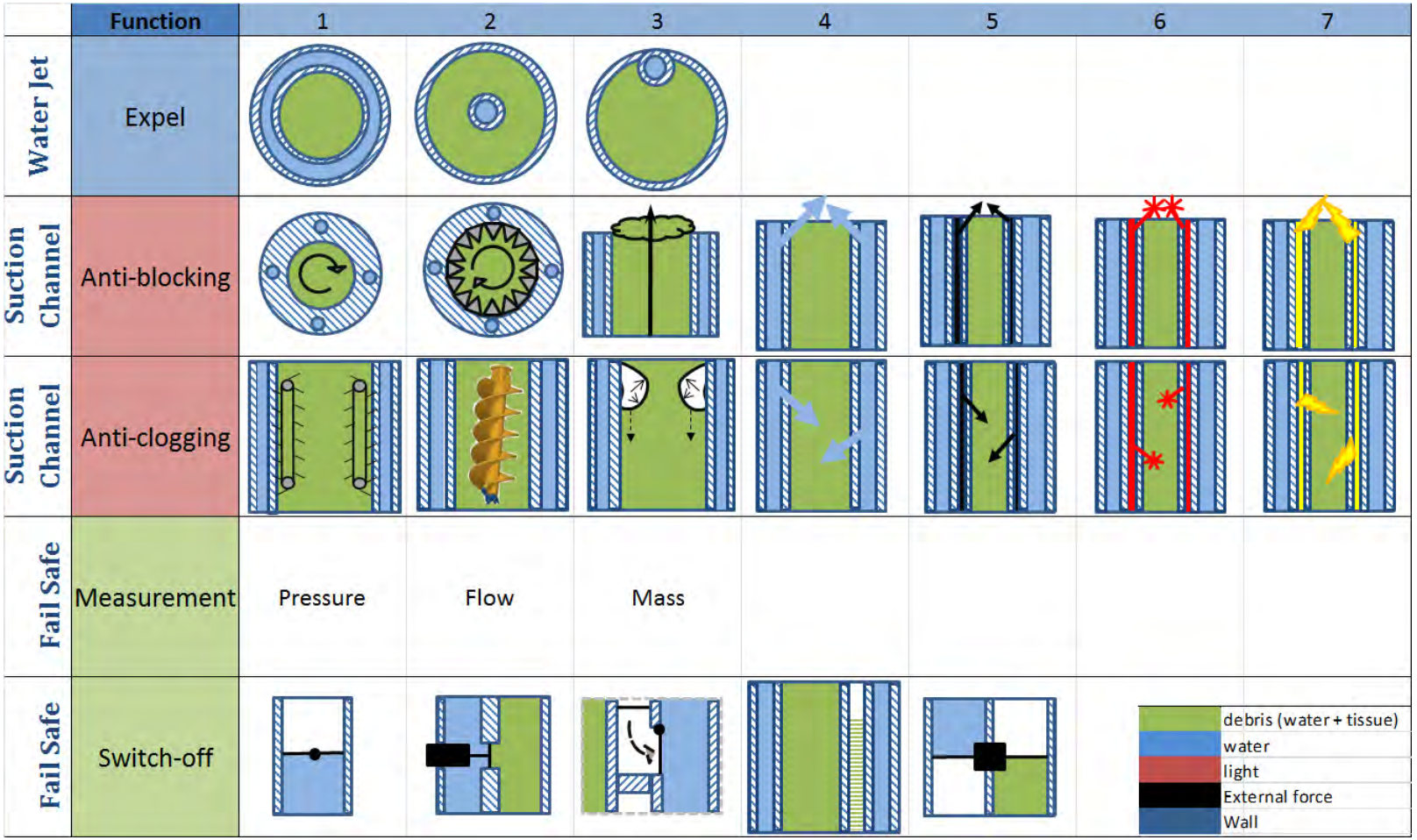


Figure B.1: Morphological overview

APPENDIX C

Erbe Trials

During the research at the orthopedic surgery department of the LUMC trials were performed to test how the commercially available water jet dissector was used. The red dotted line indicates the maximum pressure that is allowed in the cavity and the blue lines indicate the pressure inside the enclosed box.

The trials were performed within an enclosed box where chicken liver was used as mimic interface tissue. The Erbe Jet II system was used with a straight Erbe Jet water jet dissector in combination with the Erbe vacuum device. Figure C.1 shows the graphs produced when trials were conducted and Figure C.2 shows the tissue blocking the suction opening.

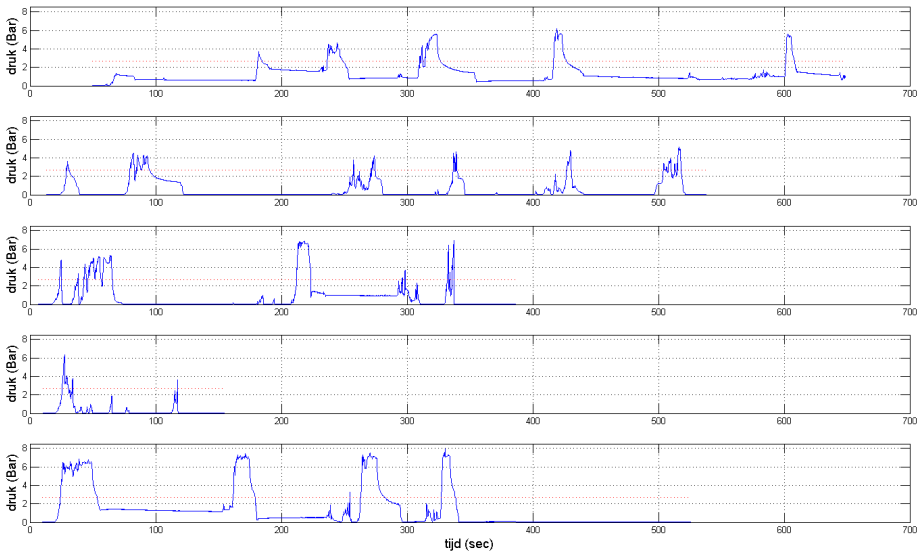


Figure C.1: Graphs showing multiple runs with the Erbe Jet 2 to remove chicken liver whereby the pressure increases above the safety threshold of 2.7 bar

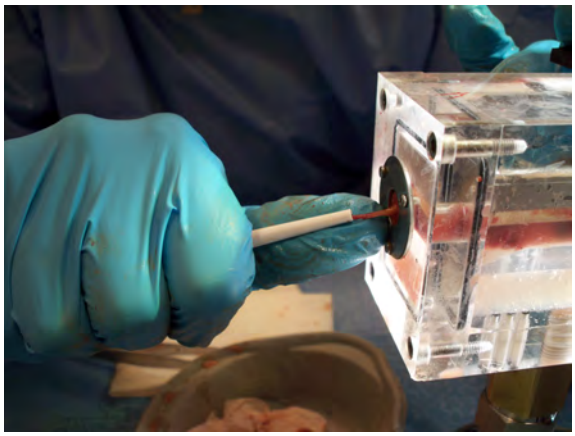


Figure C.2: Tissue blocking the opening of the Erbe Jet

APPENDIX D

Biosafety Protocol

Protocol no.:1.00 Revision no.: 001 Date:

Testing conceptual design of a water jet dissector

D.1 Background

Hip Revision Surgery is currently performed by removing the entire prosthesis and the interface tissue which caused the instability. This is a very demanding procedure for the patient and therefore research is performed in finding a minimally invasive approach. One of these approaches is using water jet dissectors to destroy interface tissue which was tested by using a commercially available water jet dissector. The result was that the instrument become blocked by large amounts of tissue and could not perform properly. Therefore the goal of this experiment is to find a nozzle design which will prevent blocking of the suction channel.

D.2 Tissue

- SPF Pig Liver

The livers originate from a pathogen free herd (van Beek SPF varkensfokkerij). Every batch is accompanied by this statement from the supplier (Amsterdam Medical Centre, Chirurgisch Laboratorium).

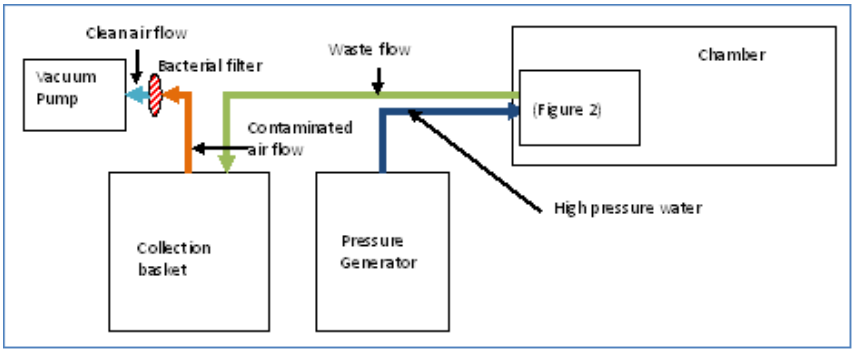
D.3 Equipment

- Experimental Set-up

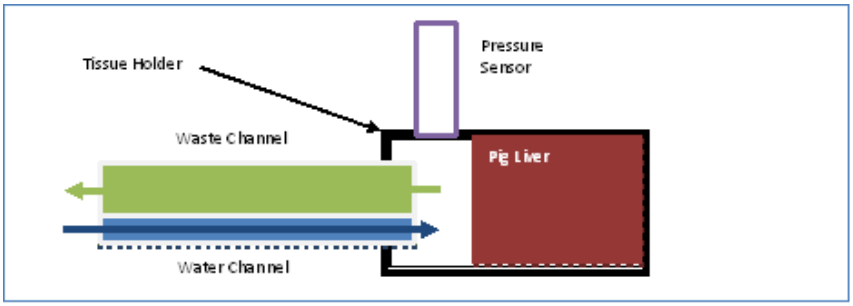
In Figures D.1a and D.1b a schematic overview is given of the experimental set-up. The chicken liver will be placed in a leak-proof tissue holder to prevent any aerosol formation to the surroundings. As a precaution the tissue holder is placed in a secondary containment, namely a leak-proof chamber with a viewport and a drain.

Dissected liver will be transported though the waste channel and gathered in the collection basket. Between the collection basket and the vacuum pump a bacterial filter will be placed to ensure the exhaust air coming from the vacuum pump is free of any bacteria.

- Scale



(a) Experimental Setup



(b) Close up of the experimental setup inside the chamber

Figure D.1: Figures schematically showing the experimental setup.

D.4 Experimental Procedure

The pig livers will be collected on the week prior of the experiment. For transportation from the AMC to TU Delft the nVWA guidelines and registration will be followed. For transportation inside the campus Appendix 3.3: Protocol for transportation of contaminated materials between labs on campus will be followed. Safety goggles and gloves will be worn and all surfaces will be covered with Benchkote. After receiving the tissue on the week prior to the experiment, the tissue will be dissected into sample sizes and stored in

the freezer, where Appendix 2.5: Freezer logbook for ML-1 Laboratory 34-J-0-460 will be followed. At the end of the day all tissue will either be disposed or bagged and stored in the freezer for disposal on a later date. In the case of the latter, Appendix 2.5: Freezer logbook for ML-1 Laboratory 34-J-0-460 will be followed.

D.4.1 Sample Preparation

- Take a pig liver out of its containment.
- Place the liver on a dissection board and cut samples.
- Place each sample in a liquid-proof weighing boat and determine its weight.
- Put samples in bag which are suited for use in the freezer.

D.4.2 Dissection Tests

A schematic overview of the experimental set-up and the components mentioned below can be seen in Figures D.1a and D.1b.

- Take a sample out of its containment.
- Place it in the tissue holder.
- Close the tissue holder.
- Run the experiment for 1 minute and record the pressure of the pressure generator and in the tissue holder.
- During the experiment, monitor through the viewport of the chamber if the tissue holder is leaking. If so, allow 15 minutes for any aerosols to settle. If not, go directly to the next step.
- Flood the tissue holder with low pressure
- Open the tissue holder and collect the sample
- Place the sample in a liquid-proof weighing boat and determine its weight.

D.4.3 Disinfecting

- Remove all Benchkote and place it in an autoclavable bag for disposal
- Drop a sufficient amount of chlorine tablets in the collection basket.
- Filter the content of the collection basket. The filtrate (water + chlorine) will be disposed as chemical waste. The residue (chicken liver + chlorine) will be disposed as biological waste.

- Flush the whole experimental set-up with 70% ethanol for 30 minutes.
- Filter the content of the collection basket. The filtrate (ethanol solution) will be disposed as chemical waste. The residue (chicken liver + ethanol solution) will be disposed as biological waste.
- Disassemble the set-up and autoclave all components that came in contact with the chicken liver according to Appendix 3.2: Protocol for decontamination by autoclaving.
- Wipe the inner surface of the chamber with 70% ethanol.
- Wipe the dissection board with 70% ethanol.

D.5 Aerosols

The tissue holder is designed to be leak-proof. Therefore it is unlikely that aerosols will be formed and released to the surroundings. After each test the whole tissue holder will be flooded and drained to prevent aerosol formation when opening the holder. In case of leakage of the tissue holder the aerosols will be contained within the leak-proof chamber situated around the tissue holder. A settling period of 15 minutes will be upheld before opening the chamber and tissue holder.

D.6 Disposal

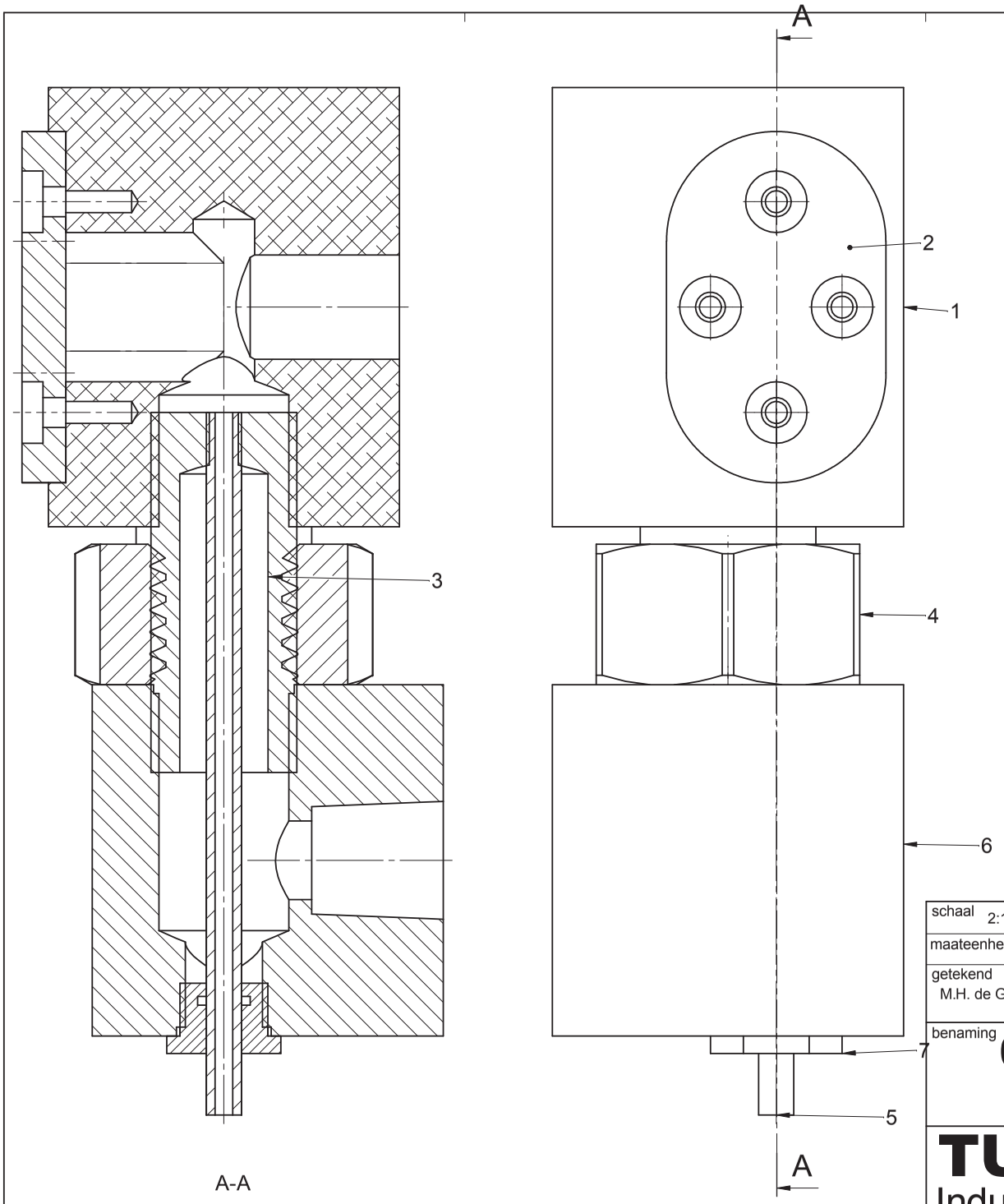
All samples and accumulated waste will be transported following all appropriate regulations to an institute with a registration for disposing the materials as described in this protocol.

D.7 Contact Persons

- Maarten de Glopper, BME, TU Delft, tel: 06 4299 6878, email: m.h.deglopper@student.tudelft.nl
- Gert Kraaij, BMechE, TU Delft, email: G.Kraaij@lumc.nl

APPENDIX E

Solidwork Drawings



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4	User Library-Nut M20	1	
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6	02_Hoge_druk_blok	1	2
7	04_Afdichter	1	4

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TU Delft
Industrial Design Engineering

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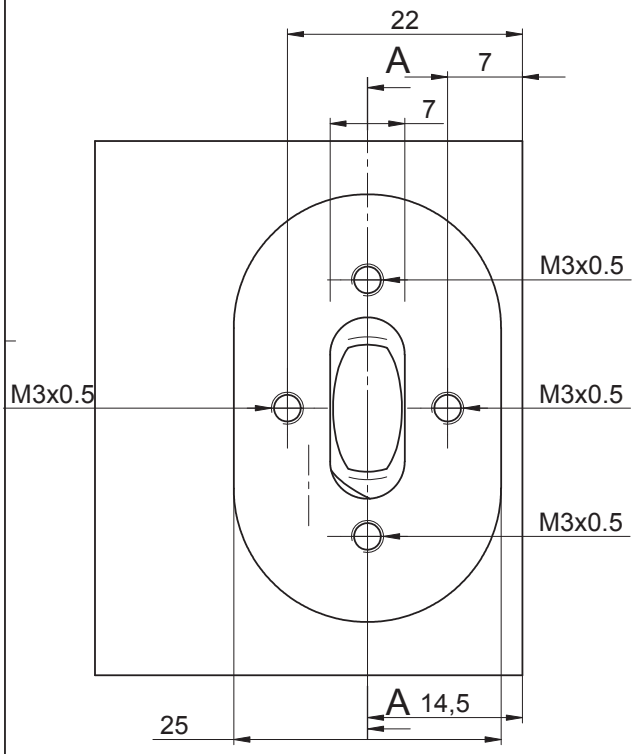

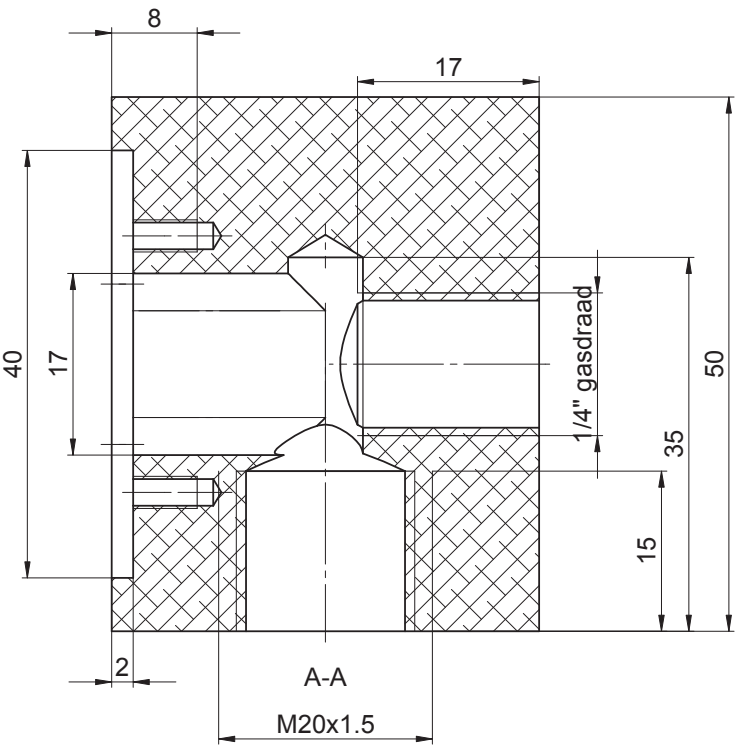

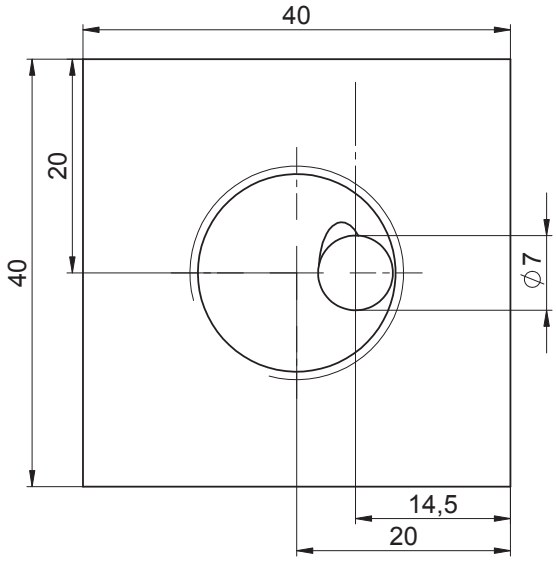

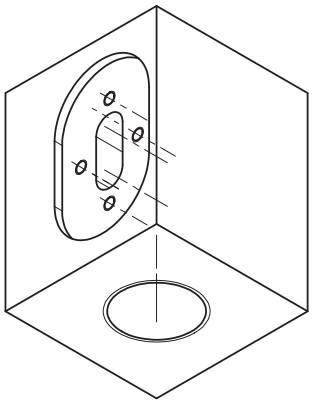

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TU Delft
Industrial Design Engineering

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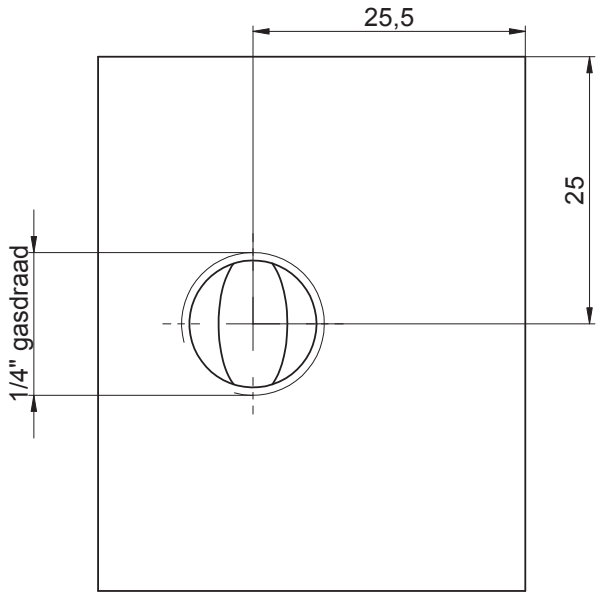

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benaming 01_Weefsel_houder

TU Delft
Industrial Design Engineering

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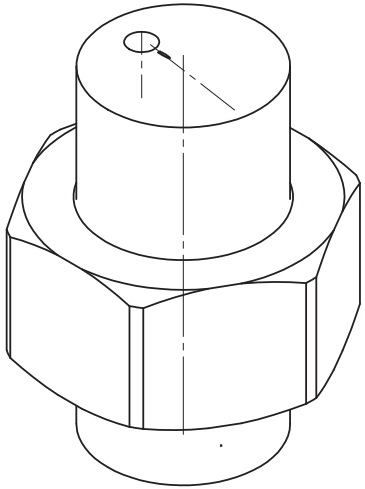

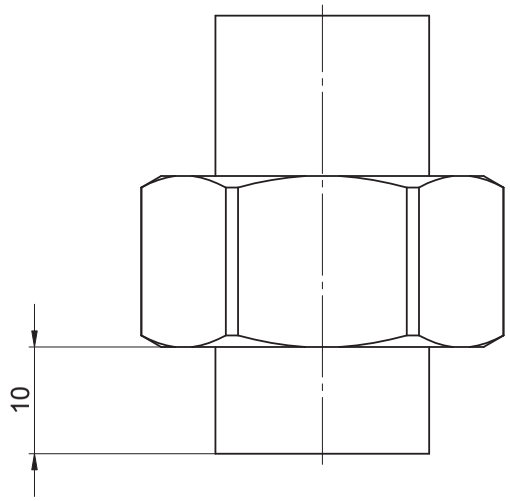

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Industrial Design Engineering

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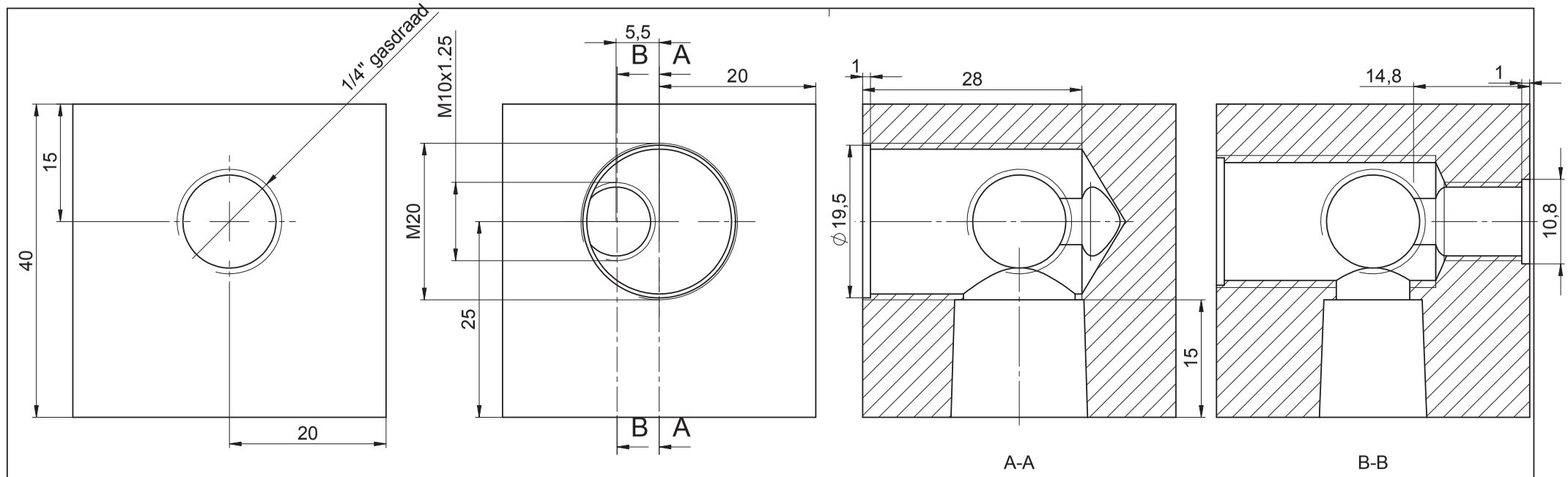

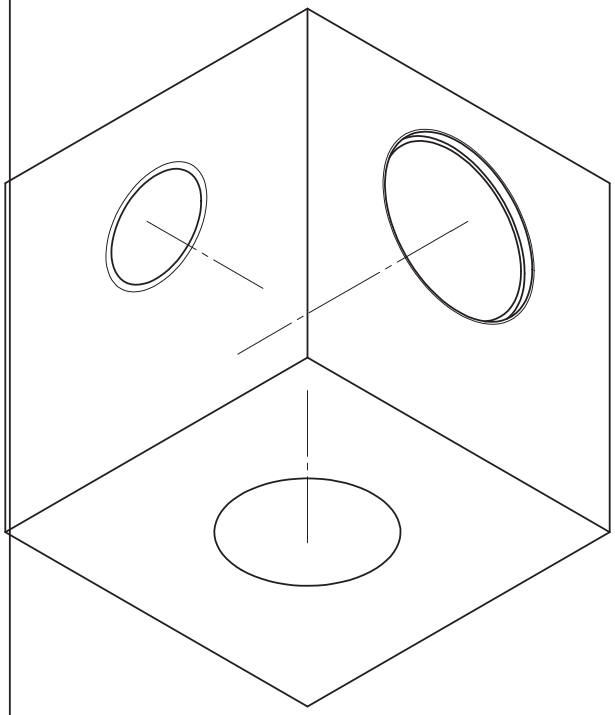

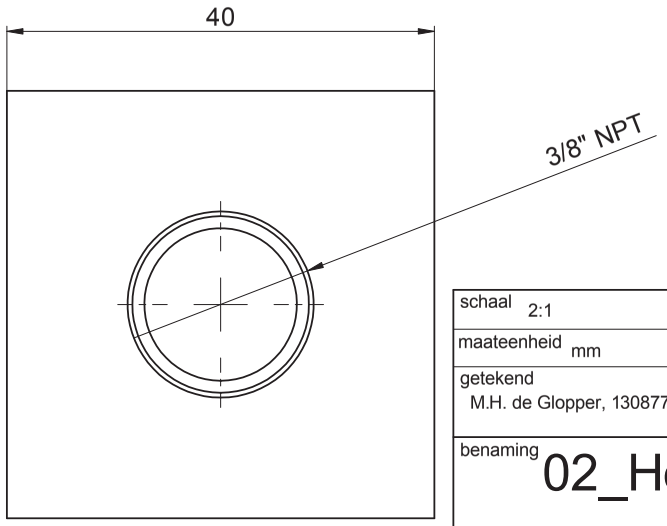

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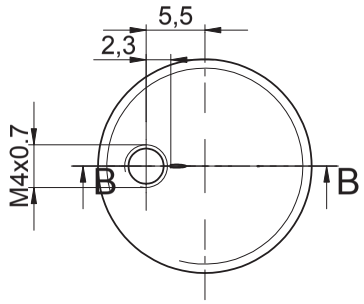

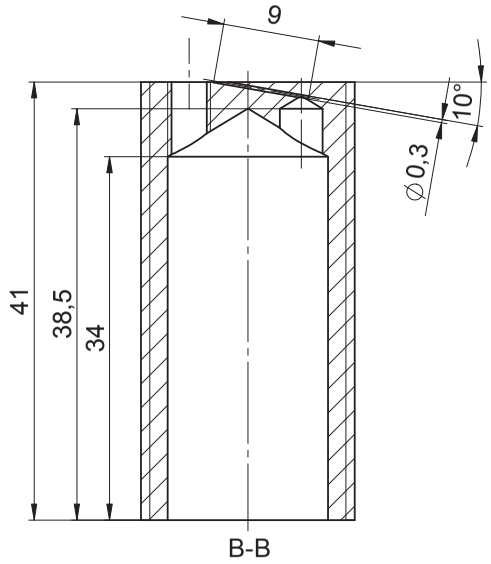

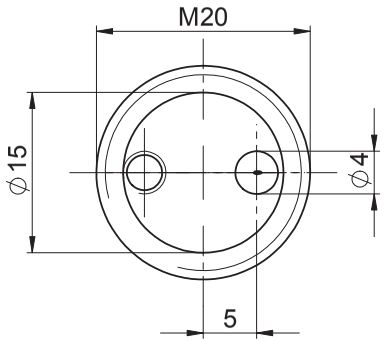

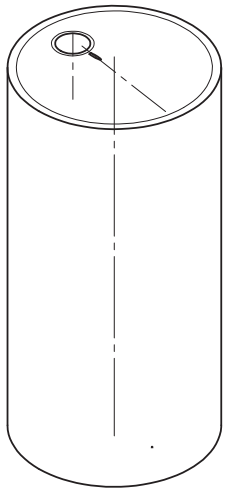

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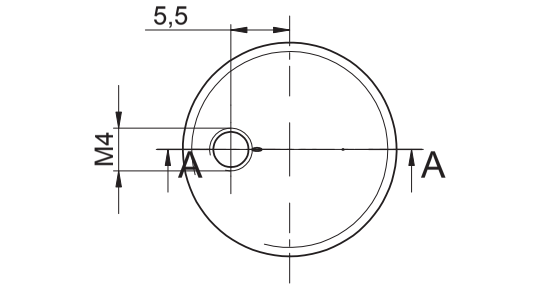
getekend M.H. de Glopper, 0642996878		groep <<dagdeel groep>>	

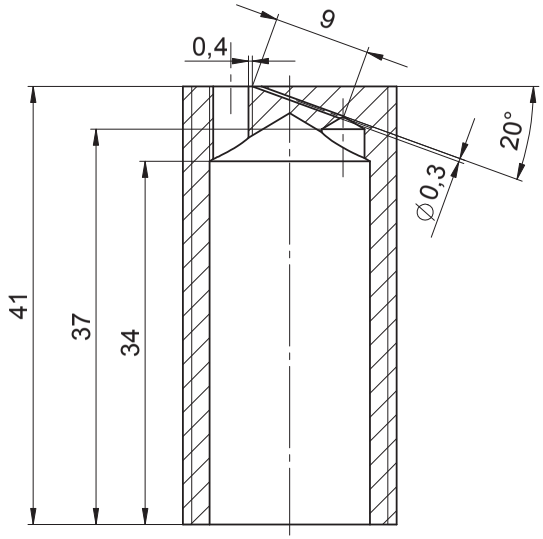
benaming 03_Spuitstuk_10_graad

TU Delft
Industrial Design Engineering

formaat	tekeningnummer
A3	<<3a>>

Mat.: Material <not specified>
Aantal: << >>





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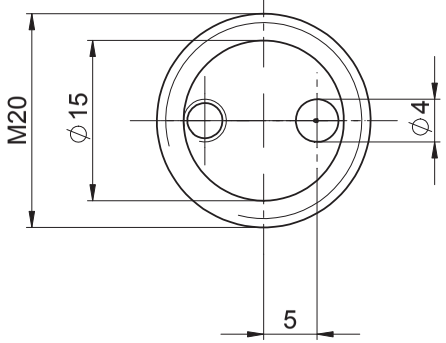
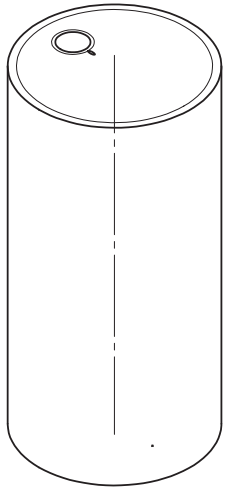




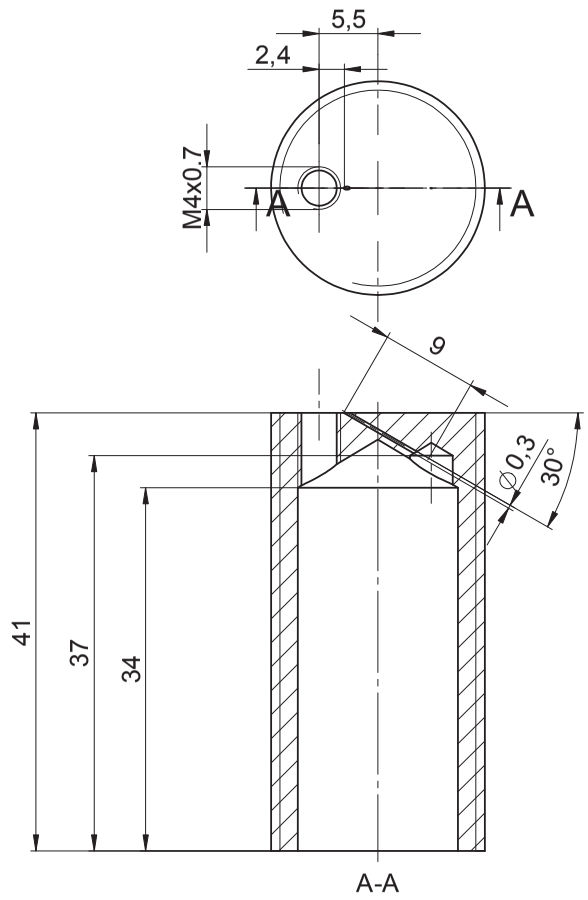
schaal 2:1		datum 13-9-2013	opmerkingen Roestvrijstaal
maateenheid mm	gewicht 0 gram		
getekend M.H. de Glopper, 1308777		groep <<dagdeel groep>>	

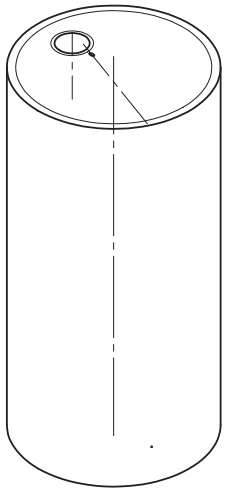
benaming 03_Spuitstuk_20_graad

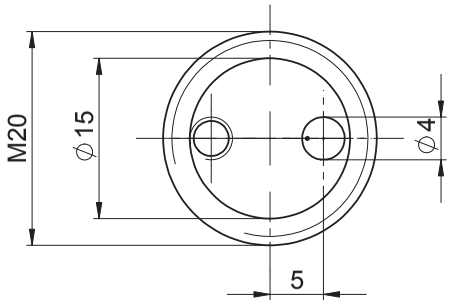
TU Delft
Industrial Design Engineering

formaat	tekeningnummer
A3	<<3b>>

Mat.: Material <not specified>
Aantal: << >>





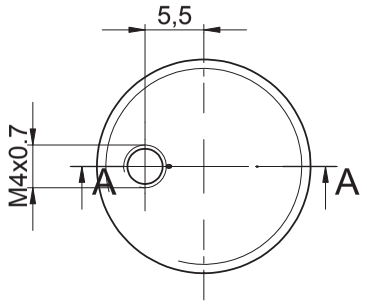


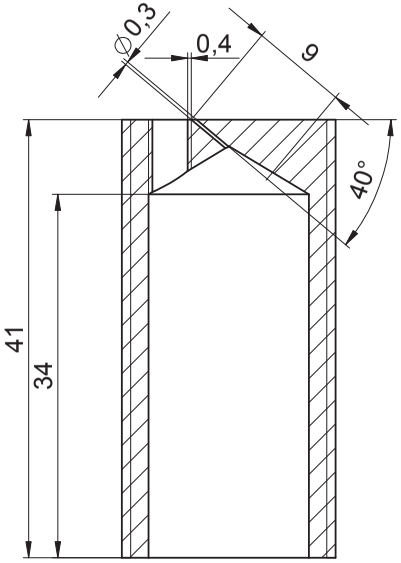
schaal 2:1		datum 20-9-2013	opmerkingen Roestvrijstaal
maateenheid mm	gewicht	0 gram	
getekend M.H. de Glopper, 0642996878		groep <<dagdeel groep>>	

benaming 03_Spuitstuk_30_graad

TU Delft
Industrial Design Engineering

formaat	tekeningnummer
A3	<<3c>>





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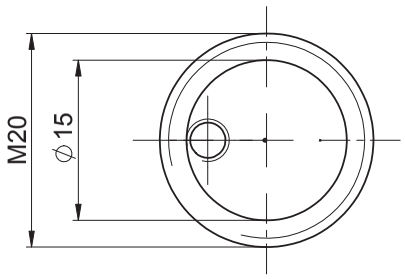

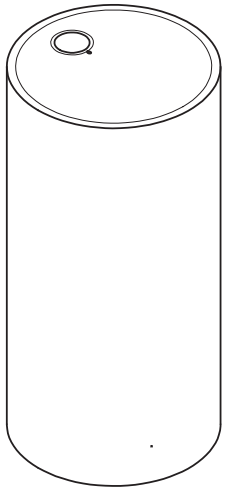

Mat.: Material <not specified>
Aantal: << >>

schaal 2:1		datum 13-9-2013	opmerkingen Roestvrijstaal
maateenheid mm	gewicht	0 gram	
getekend M.H. de Glopper, 1308777		groep <<dagdeel groep>>	

benaming 03_Spuitstuk_40_graad

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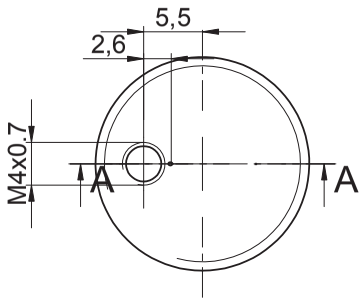
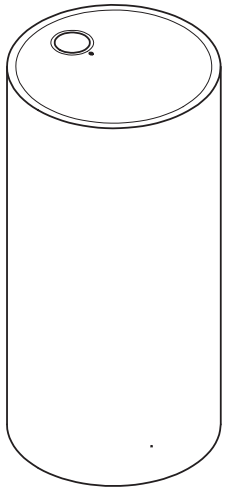
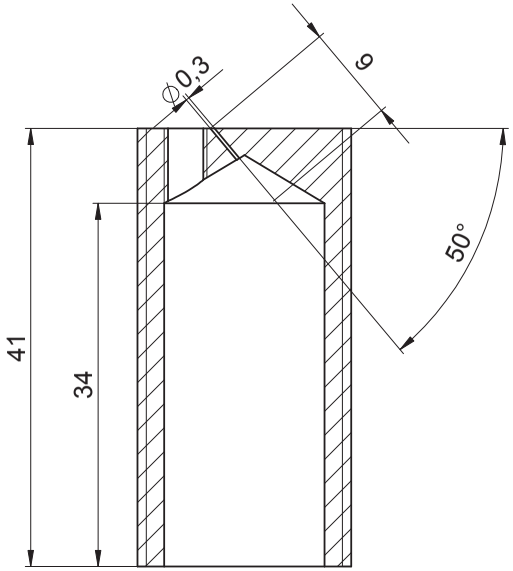
Industrial Design Engineering

formaat	tekeningnummer
A3	<<3d>>





Mat.: Material <not specified>
Aantal: << >>



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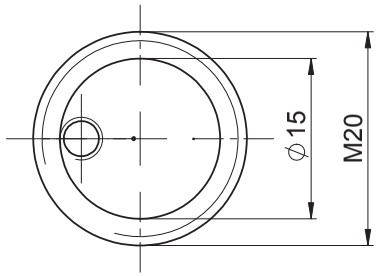
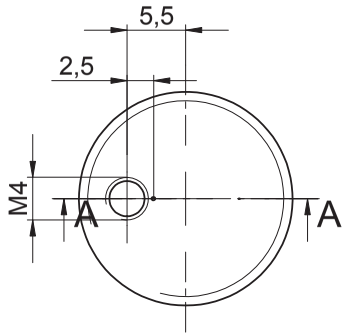


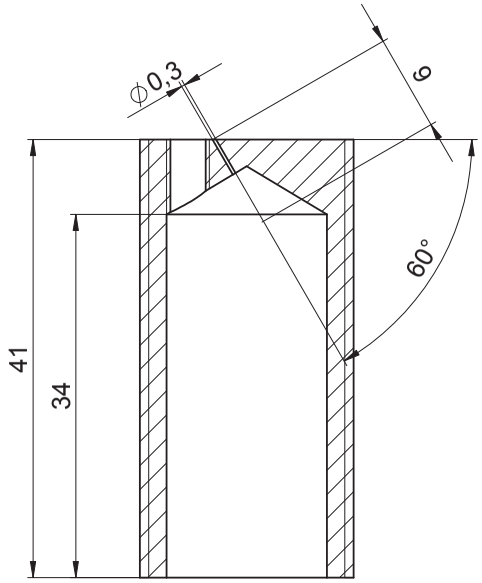
schaal 2:1		datum 20-9-2013	opmerkingen Roestvrijstaal
maateenheid mm	gewicht 0 gram		
getekend M.H. de Glopper, 0642996878		groep <<dagdeel groep>>	

benaming 03_Spuitstuk_50_graad

TU Delft
Industrial Design Engineering

formaat	tekeningnummer
A3	<<3e>>





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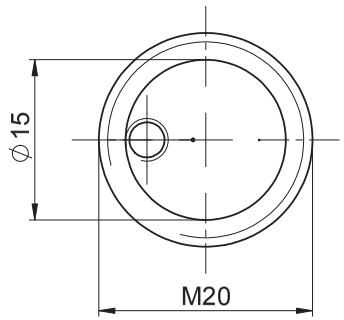
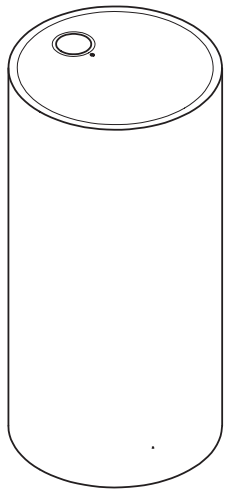




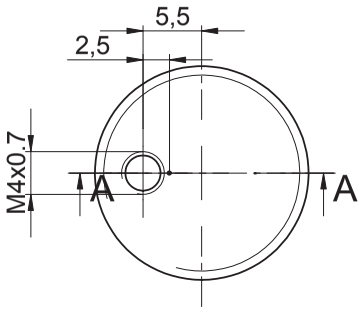
Mat.: Material <not specified>
Aantal: << >>

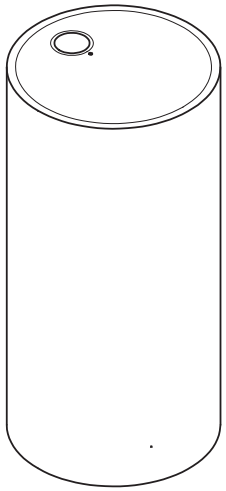
schaal 2:1		datum 20-9-2013	opmerkingen Roestvrijstaal
maateenheid mm	gewicht	0 gram	
getekend M.H. de Glopper, 0642996878		groep <<dagdeel groep>>	

benaming 03_Spuitstuk_60_graad

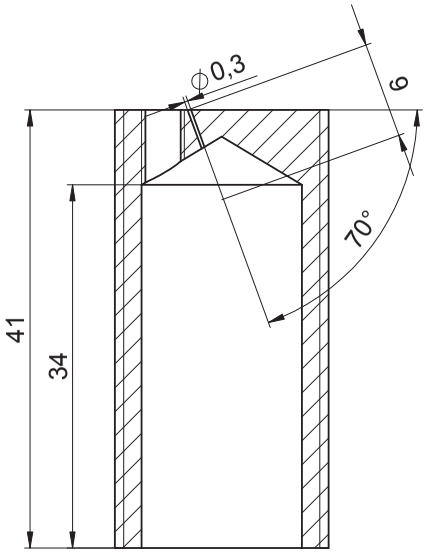
TU Delft
Industrial Design Engineering

formaat	tekeningnummer
A3	<<3f>>





Mat.: Material <not specified>
Aantal: << >>



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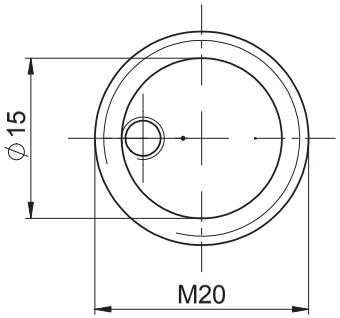
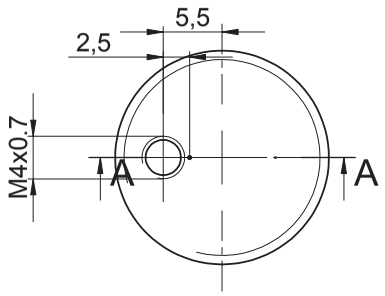


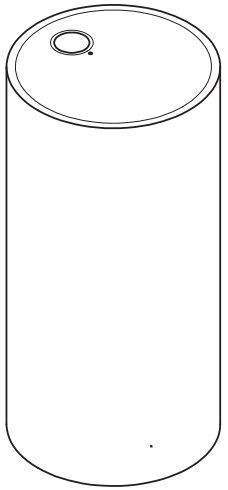
schaal 2:1		datum 20-9-2013	opmerkingen Roestvrijstaal
maateenheid mm	gewicht 0 gram		
getekend M.H. de Glopper, 0642996878		groep <<dagdeel groep>>	

benaming 03_Spuitstuk_70_graad

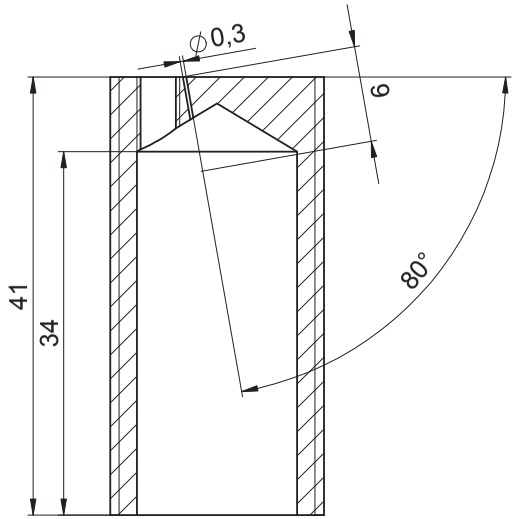
TU Delft
Industrial Design Engineering

formaat	tekeningnummer
A3	<<3g>>





Mat.: Material <not specified>
Aantal: << >>



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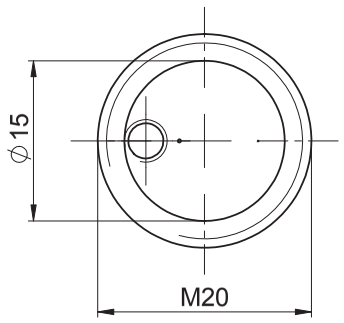


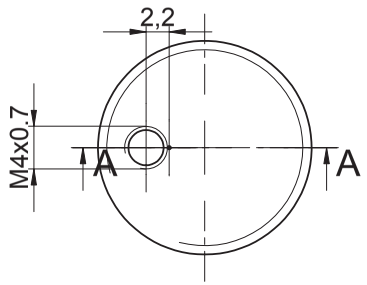
schaal 2:1		datum 20-9-2013	opmerkingen Roestvrijstaal
maateenheid mm	gewicht	0 gram	
getekend M.H, de Glopper, 0642996878		groep <<dagdeel groep>>	

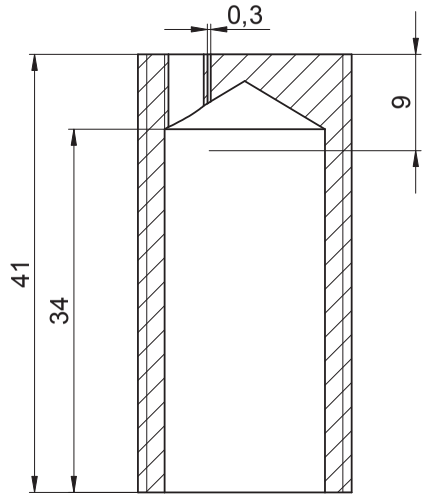
benaming 03_Spuitstuk_80_graad

TU Delft
Industrial Design Engineering

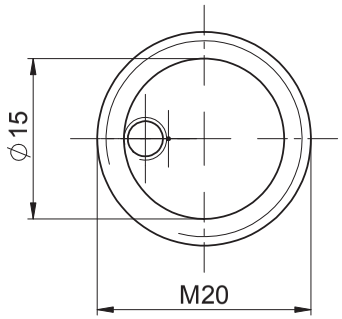
formaat	tekeningnummer
A3	<<3h>>

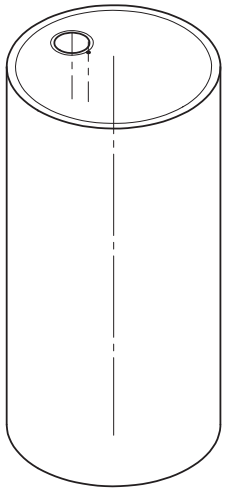
Mat.: Material <not specified>
Aantal: << >>





A-A



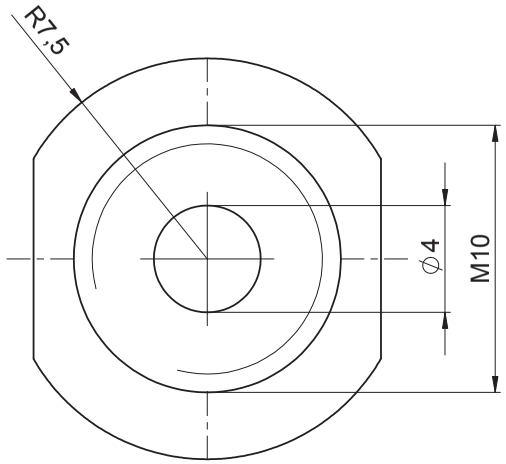


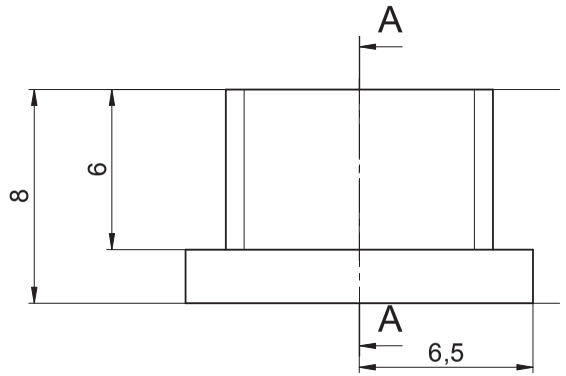
schaal 2:1		datum 20-9-2013	opmerkingen Roestvrijstaal
maateenheid mm	gewicht	0 gram	
getekend M.H. de Glopper, 0642996878		groep <<dagdeel groep>>	

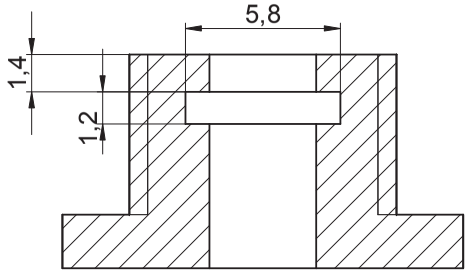
benaming 03_Spuitstuk_90_graad

TU Delft
Industrial Design Engineering

formaat	tekeningnummer
A3	<<3i>>







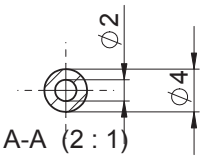
A-A

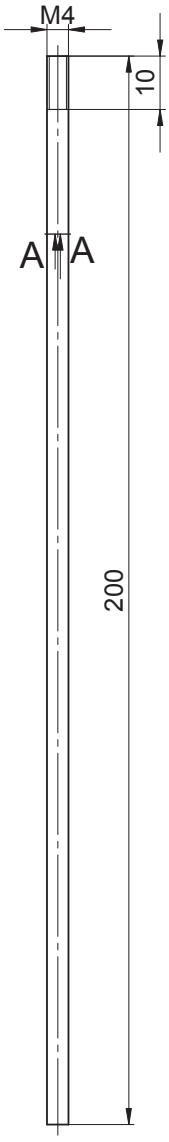
schaal 5:1		datum 16-9-2013	opmerkingen Roestvrijstaal
maateenheid mm	gewicht gram		
getekend M.H. de Glopper		groep <<dagdeel groep>>	

benaming 04_Afdichter

TU Delft
Industrial Design Engineering

formaat	tekeningnummer
A3	<<4>>



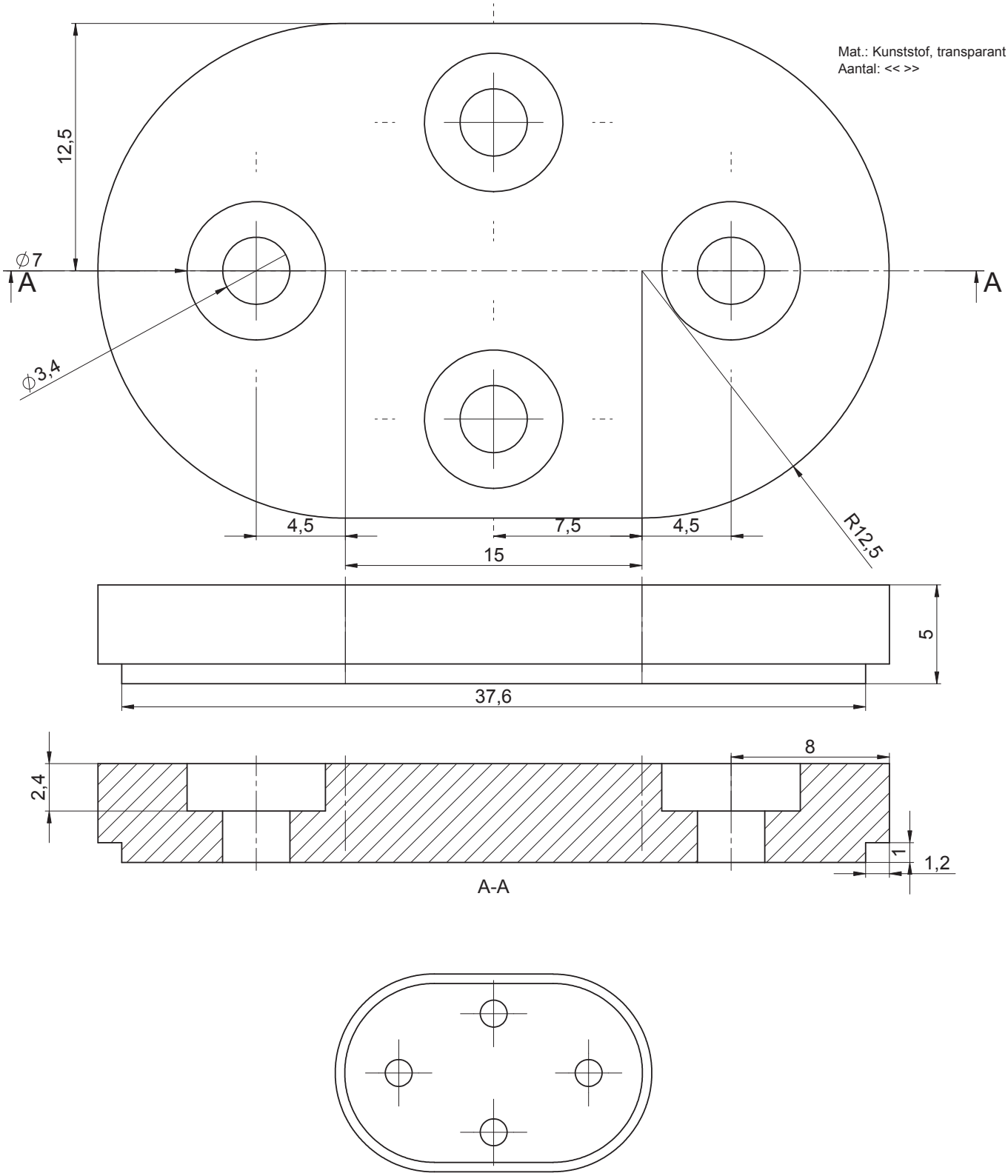


schaal 1:1		datum	opmerkingen
maateenheid mm		15-11-2013	Roestvrij staal
getekend M.H. de Glopper, 0642996878			
groep <<groep>>		gewicht	gram

benaming 05_Afzuigbuis

TU Delft
Industrial Design Engineering

formaat	tekeningnummer
A3	<<5>>



schaal 5:1		datum 17-9-2013	opmerkingen Kunststof
maateenheid mm			
getekend M.H. de Glopper, 1308777			
groep <<groep>>		gewicht 4 gram	

benaming 01c_afdekplaat

TU Delft
Industrial Design Engineering

formaat	tekeningnummer
A3	<<6>>