Design of a maternal phantom model

For trauma measurement and experimental purposes

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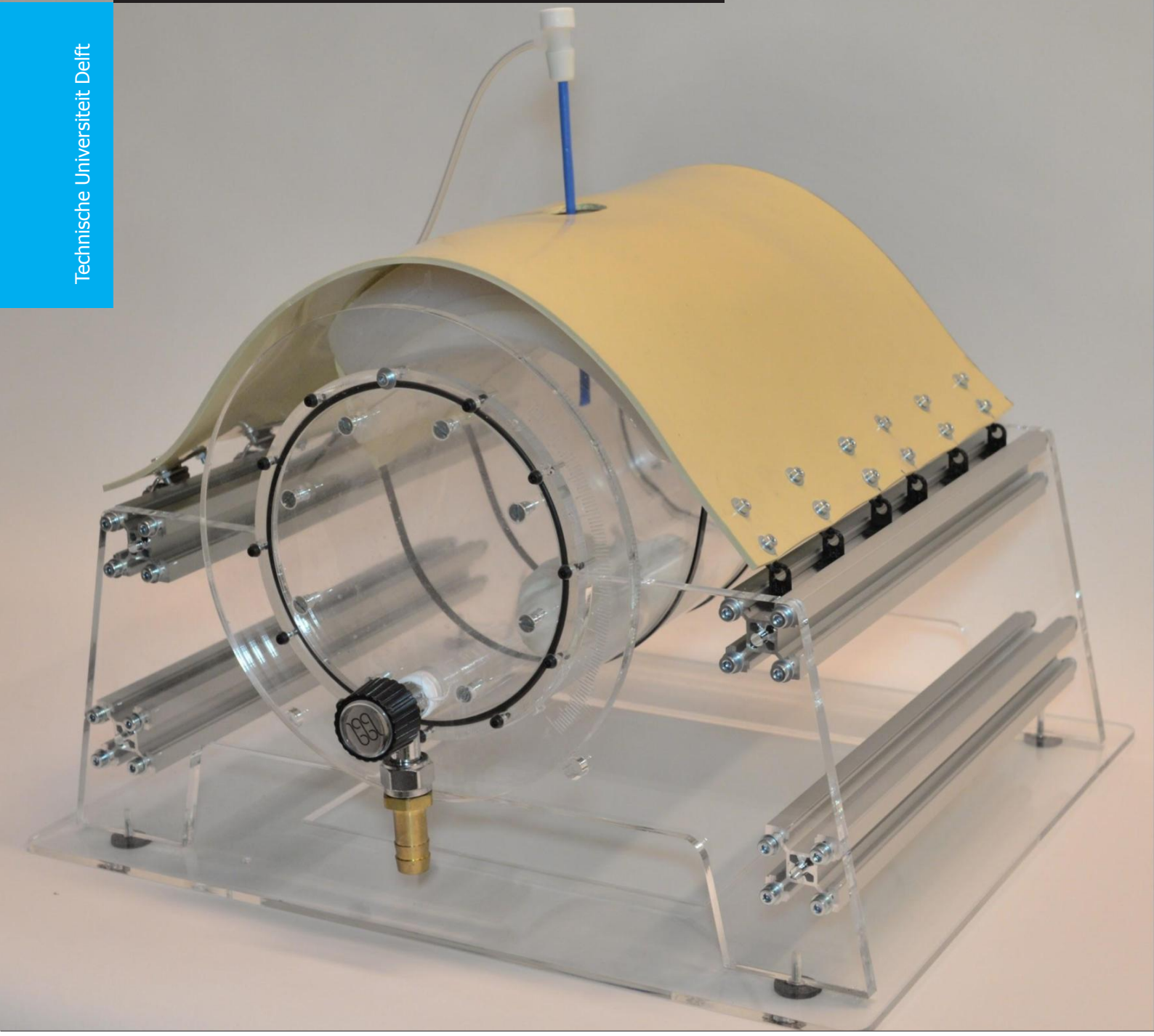
Technische Universiteit Delft



TU Delft Delft University of Technology

Challenge the future

Design of a maternal phantom model

For trauma measurement and experimental purposes

by

J.P.A. van Leijsen

For fulfillment of the requirements for the degree of

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in Biomedical Engineering

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Preface

First of all I would like to thank my supervisor John van den Dobbelsteen for giving me the necessary support for completing this thesis. When I was stuck in the material he would coach to get me back on track. When there were times it was a bit too much, there was room and time to figure things out, making these last months of my study career a pleasant experience. Lisette Tas, who was a researcher at this faculty during a period of my thesis, was also a great help. When I started to drift away and lose track of what needed to be done I could always count on an email saying ”How are you?” with the suggestion to plan a meeting to discuss the current situation. Furthermore, I would like to thank Arjan van Dijke who was very helpful with assembling the experimental setups. Other people who also contributed to make this a time to look back and smile upon were my lab buddies from the Clinics lab Paulien, Vincent and Rhea. The trips and walks outside were a nice change of scenery and kept the morale high. I would also like to thank my family, my proud parents for giving me their full love and support. And lastly my girlfriend Roos, for believing in me and always seeing the positive side.

J.P.A. van Leijsen
Delft, December 2017

Summary

Due to technological advancements in ultrasound screening techniques and genetic technologies, congenital anomalies can be diagnosed more frequently and in earlier stages of the pregnancy. On top of that, since 2007, large prenatal population studies conducted in the Netherlands increase detection of congenital diseases. These two factors cause an increase in the number of diagnosed congenital anomalies. In some cases it can be desirable to treat these anomalies prenatally, for it can prevent or minimize the deformities of the neonate. Minor interventions like medicines or supplements can have enough effect, but in some cases fetal surgery is required. A literature study was conducted to explore the effects of fetal surgery. In this study was found that performing fetal surgery is challenging since operating on a fetus and perforating the uterus and amniotic sac increases the chances of preterm premature rupture of the membrane (PPROM) or can be harmful to the unborn child. A second observation was that an increase of invasiveness in a fetal procedure results in an increased risk of causing PPROM. From this study it is believed that the amount of trauma inflicted upon the amnion, the membrane that surrounds the fetus and the amniotic fluid, is the cause for this increase in PPROM. However little is known about the amount of trauma a fetoscopic surgery inflicts upon the Amnion. Therefore this study has focused on designing an artificial maternal model which is specialized for measuring the stress in the amnion. This maternal model could then be used to test and develop fetoscopic instruments. For this goal the phantom model had to simulate the abdominal wall and mimic the different tissue layers such as, amnion, uterus, fat, muscle and skin. However, from an experiment conducted to retrieve the mechanical properties of amniotic tissue to simulate this layer it appeared that the mechanical contribution of the amniotic sac with respect to the abdominal wall was negligible. For this study was therefor decided to exclude the amniotic sac from the phantom model. The amount of stress in the amnion could not be measured, however the amount of trauma could be indicated by measuring the displacements of the amnion at the point of perforation. This was accomplished by measuring the displacements of a trocar port through the abdominal with respect to the position of the amnion. These displacements correspond with the actual displacements when manipulating through the abdominal wall. These measurements are performed by measuring the location of three sensors. Two sensors measure the position of the trocar port and the third sensor is fixed on the inside of the artificial uterus and functions as a reference point at the location where the amniotic sac would be. Using a real time magnetic tracking system the position of the trocar with respect of the original position of the amnion can be determined. This way the phantom model accomplished the goal of measuring an indication of the amounts of stress on the amnion. To verify the design of the phantom model, it was demonstrated with four fetal surgeons. These medical specialists who participated in this user validation study judged the phantom model to be a useful product with a large spectrum of future possibilities in research and training.

Contents

1 Introduction **1**
- 1.1 Fetal surgery . . . 1
- 1.2 Existing maternal models . . . 2
  - 1.2.1 Surgical touch . . . 2
  - 1.2.2 Other maternal models . . . 2
- 1.3 Anatomy 20 week pregnancy . . . 2
  - 1.3.1 Fetus . . . 3
  - 1.3.2 Amniotic sac . . . 3
  - 1.3.3 Placenta . . . 4
  - 1.3.4 Uterus . . . 4
  - 1.3.5 Abdominal wall . . . 4

2 Concept and requirements **7**
- 2.1 List of requirements . . . 7
- 2.2 Conceptual design . . . 9
  - 2.2.1 Shape . . . 10
  - 2.2.2 Components . . . 10

3 Methods and materials **11**
- 3.1 Materialization . . . 11
  - 3.1.1 Abdominal wall . . . 11
  - 3.1.2 Uterus . . . 13
  - 3.1.3 Amniotic sac . . . 13
  - 3.1.4 Trestle frame . . . 16
  - 3.1.5 Uterine cavity . . . 17
  - 3.1.6 Measurement system . . . 17
- 3.2 User evaluation . . . 20

4 Results **23**
- 4.1 Requirements verification test . . . 23
  - 4.1.1 Dimensional . . . 23
  - 4.1.2 Ergonomical . . . 23
  - 4.1.3 Experimental . . . 24
  - 4.1.4 Technical . . . 24
  - 4.1.5 Measuring system . . . 24
  - 4.1.6 Wishes . . . 24
- 4.2 User experience test . . . 25
  - 4.2.1 User evaluation survey . . . 25
  - 4.2.2 Debatable questions . . . 25
  - 4.2.3 Other interesting remarks . . . 26

5 Discussion **27**
- 5.1 Comparison with requirements . . . 27
- 5.2 Evaluation of user experience test . . . 27
- 5.3 Improvements of the phantom maternal model . . . 27
- 5.4 Societal relevance . . . 28
- 5.5 Future research . . . 28
- 5.6 Commercial purpose . . . 29
- 5.7 Conclusion . . . 29

A Appendix A: Fetoscopic procedures **31**
A.1 Prenatal Surgeries . . . 31
A.1.1 Twin-to-twin transfusion syndrome (TTTS) . . . 31
A.1.2 Twin reversed arterial perfusion sequence . . . 31
A.1.3 Spina bifida . . . 32
A.1.4 Congenital diaphragmatic hernia . . . 32
A.1.5 Aortic stenosis, pulmonary stenosis . . . 32
A.1.6 Bilateral lower urinary tract obstruction (LUTO) . . . 32
A.1.7 Congenital cystic adenomatomoid malformation, pulmonary sequestration . . . 33

B Appendix B: Technical drawings **35**

C Appendix C: Questionnaire for model evaluation **39**

D Appendix D: Data sheets silicone rubbers **49**

Bibliography **55**

1

Introduction

This chapter begins with explaining different kinds of fetal surgery and certain trends in this field to give insights in the background and motivation of this study. This is followed with the goal for this study which will be leading throughout this report. This chapter ends with relevant anatomy to give the basic knowledge as a staring point for the rest of this report.

1.1. Fetal surgery

Due to technological advancements in ultrasound screening techniques and genetic technologies, congenital anomalies can be diagnosed more frequently and in earlier stages of the pregnancy. [1–4] On top of that, since 2007, large prenatal population studies conducted in the Netherlands increase detection of congenital diseases.[5] These two factors cause an increase in the number of diagnosed congenital anomalies.[6] In some cases it can be desirable to treat these anomalies prenatally, for it can prevent or minimize the deformities of the neonate. Non-invasive treatment like medicines or supplements can have enough effect, but in some cases fetal surgery is required. Fetal surgery is an option for the following syndromes and anomalies.

- twin-to-twin transfusion syndrome (TTTS) and twin reversed arterial perfusion (TRAP). In both situations the twins share arteries in the placenta which causes one fetus to pump more blood to the other fetus than it receives. This can be treated by using a laser to coagulate the communicating vessels under fetoscopic guidance. (See figure 1.1) [7–10]
- Spina bifida, a syndrome where the spinal chord of the fetus is not fully closed during gestation. With minimal invasive surgery the open wound can be sutured.[11–13]
- Congenital diaphragmatic hernia (CDH), a defect of the diaphragm where intestines protrude the diaphragm. CDH can be treated prenatally with fetoscopic tracheal occlusion (FETO) therapy, a procedure where a balloon is placed inside the fetus' trachea to restore the pressure in the lungs.[14–16]
- Aortic stenosis or pulmonary stenosis, narrowing of the ducts and vessels. With the use of balloons and stents, the blood vessels the ducts can be opened.[17–20]
- Urinary tract obstruction which can be treated with percutaneous vesicoamniotic shunting so provide drainage. [21–23]
- Congenital cystic adenomatomoid malformation, pulmonary sequestration. Which can be treated with fetoscopic laser coagulation (FLC) to coagulate blood vessels leading to the malformation. [24]

More elaborate descriptions of these syndromes can be found in appendix A.

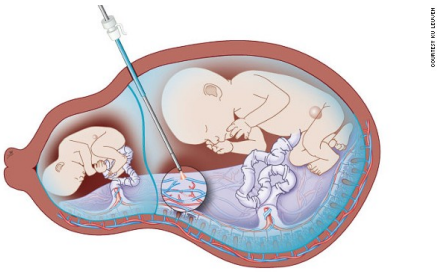


Figure 1.1: Cut section of the FLC procedure to treat TTTS. [1]

Treating these anomalies is challenging since operating on a fetus and perforating the uterus and amniotic sac (as during TTTS treatment which can be seen in figure 1.1) increases the chances of preterm premature rupture of the membrane (PPROM) or can be harmful to the unborn child.[12, 25–27] An increase in the invasiveness of a fetal procedure results in an increased

[1] http://www.gift-surg.ac.uk/project/medical-conditions/FLC

risk of causing PPROM. For example, when comparing FLC with minimal invasive surgery of spina bifida, the latter has a higher incidence of PPROM than the first. This difference is also observable within variations of the procedure of TTTS, where the procedure with an anterior located placenta has a higher rate of PPROM than a posterior located placenta. It is believed that this is caused by the increased movements of the trans-amniotic instruments to visualize and reach the anterior placenta compared to a posterior placenta. This increase in PPROM is reduced when the anterior placenta is approached from a dorsal entry point which can be created under laparoscopic guidance. This recline in PPROM from this alternative procedure funds the earlier belief. [28, 29]

For this reason it is essential to know what kind of trauma is inflicted on the amnion during surgery since it believed to be a driving factor for the chances of PPROM. Therefore this study aims to develop a phantom maternal model which is specialized for testing and the development of fetoscopic instruments and measuring the stress on the amnion. With these stresses it is possible to indicate the trauma caused by movements performed in certain procedures or by the use of certain instruments. In addition this trauma indication can be used to optimize currently used, or for the development of new, instruments and procedures.

1.2. Existing maternal models

Current solutions for a test environment for fetoscopic instruments and procedures are clinically driven. They provide training environments for the procedures that are already performed in vivo, but lack the capability to perform measurements on and have limited possibilities to experiment with new tools. Also these maternal models are expensive and the number of repetitive tests that can be performed on them are limited. After a certain amount of perforations of the abdominal wall of these phantom models they start to leak fluids from inside the uterine cavity. With these models the abdominal wall is integrated with the rest of the model making it impossible to replace this component.

1.2.1. Surgical touch

Currently there is a solution by surgical touch which is shown in figure 1.2. This artificial maternal model is capable of providing a test environment for the practice of procedures under echo- and fetoscopic guidance. It approaches realism regarding the look and feel of the woman's abdomen. This model is used by the LUMC national centre for fetal therapy, one of the largest centres for fetal therapy world wide. Downsides of this model are that it is expensive compared to other simulation models like laparoscopic trainers and there is no imitation of the multiple layers of the abdominal wall. This is because multiple layers can trouble the visual feedback of an echo due to air bubbles between the layers.

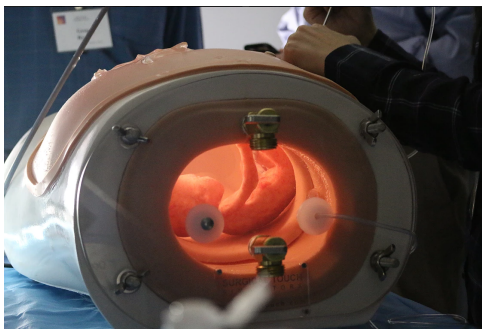


Figure 1.2: The artificial maternal model from Surgical Touch[2].

1.2.2. Other maternal models

Other maternal models focus on obstetrics instead of fetal surgery. These models are developed to simulate contractions, fetal heart rates, health of the mother and almost every other feature, except provide a test environment for fetal surgery. These maternal models are produced by companies like, skills Meducation or Medical-X.

From this we can conclude that there is no existing maternal model suitable for measurements on the amnion.

1.3. Anatomy 20 week pregnancy

To comprehend the reasoning in this report it is necessary to understand the basics of the pregnant female anatomy. For example the location and size of the organs and the terminology. This anatomy was also relevant for achieving the goal of constructing a phantom maternal model. Therefor this section explains the anatomical environment of this study divided per organ relevant for this study. This section is dedicated to give a straightforward explanation of the female reproductive system in its 20th week of gestation. The 20th week is primarily chosen for this is the moment where the mother is considered for the public survey earlier mentioned in section 1.1. Secondly, the anatomy at this time does not vary a lot around this period of time with respect to tissue layers and

[2] https://www.surgicaltouch.com/

organ positions of mother and fetus. Therefore it is comparable to the situation that is attempted to imitate in the maternal model.

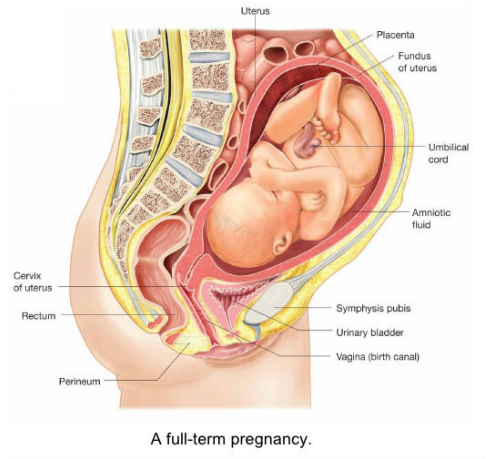


Figure 1.3: Anatomy of a pregnant female.[3]

1.3.1. Fetus

In the 20th week of gestation a fetus' sex can be determined in nearly all cases. At this time the fetus is about 25.6 [cm] and weighs approximately 300 [g].[30] In the Netherlands this is the moment where the pregnant mother is considered for the population study and is therefor the age in which most congenital anomalies are detected.[5] The skin of a fetus is covered in vernix caseosa, which is the white, cheesy looking substance seen on a neonatal infant. This substance protects the fetus' skin while residing in the amniotic fluid during gestation. The blood flow of the fetus flows via veins and arteries in the umbilical chord through the placenta, where gas and nutrients are exchanged with those in the blood of the mother. This blood flow is provided by shunts in the fetus that bypass its lungs and liver. During birth these shunts are occluded, allowing blood flow only to pass through the fetal circulatory system. The bloodflow through the placenta provides all nutrients for the fetus, however the gastrointestinal (GI) tract is prepared to function in utero. This happens when the fetus swallows small amounts of its own amniotic fluid, which contain chemicals that stimulate the development and maturation of the GI tract. By the third month of fetal life, the fetus starts to produce urine and most of the amniotic fluid that surrounds a developing fetus is fetal urine.[31]

1.3.2. Amniotic sac

The amniotic sac is the tissue that contains the amniotic fluid and the fetus. It consists of multiple

[3]https://www.slideshare.net/

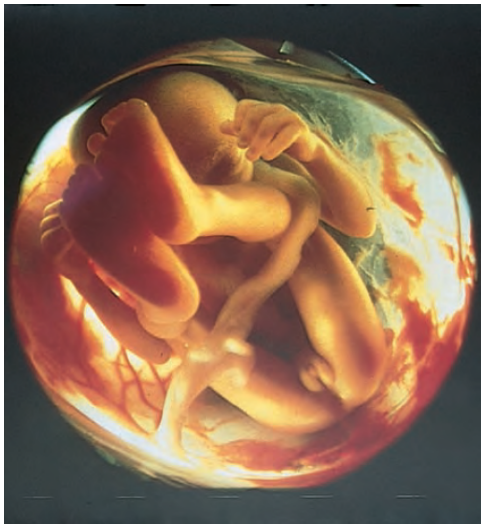


Figure 1.4: The human fetus, at 20th week of gestation, around 19 [cm] in length. [31]

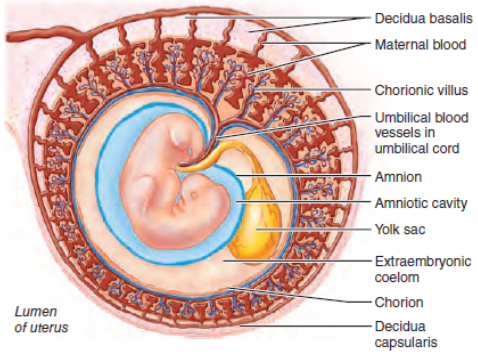


Figure 1.5: The human fetus between the 4th and the 5th week of gestation. [31]

layers. In the first weeks of gestation the fetus is surrounded by amniotic fluid contained in the amnion, the inner layer. The amnion containing the fetus, is surrounded by chorion containing the extra-embryonic coelom in which the yolk sac is located. This chorion is in turn surrounded by the chorionic villi, in which the gas and nutrients are exchanged with the maternal blood. This "package" is located in the lumen of the uterus. This is shown in figure 1.5 During gestation the configuration changes as seen in figure 1.6. As the fetus grows and the volume of amniotic fluid increases, the amnion expands and makes contact with the chorion. The chorionic villi, earlier surrounding the chorion now make up the placenta to provide the exchange of nutrients and gas with the maternal blood.[31] The thickness and mechanical properties of the amniotic sac are unknown, therefore measurements of this tissue are needed to be performed to find a surrogate of the amniotic membrane.

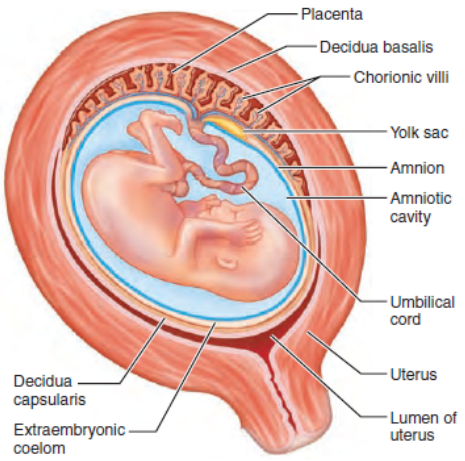


Figure 1.6: The human fetus in the 13th week of gestation. [31]

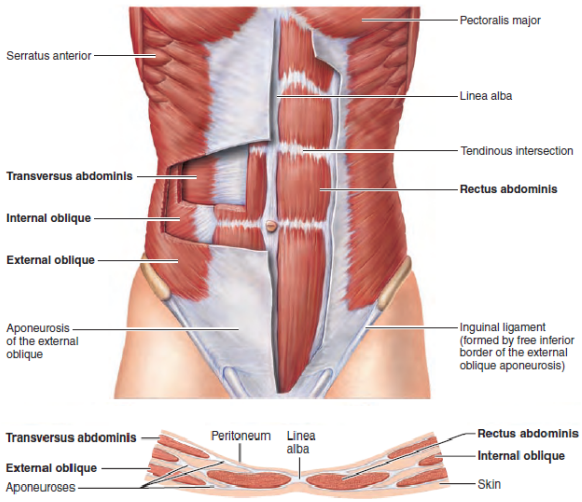


Figure 1.7: Cut section of the muscle layer of the abdominal wall [31]

1.3.3. Placenta

As mentioned earlier, The purpose of the placenta is to provide the exchange of nutrients and gas between the fetus' and the maternal blood. Besides that, steroids and protein hormones are secreted to influence the progress of the pregnancy. These hormones include estrogen, progesterone and human chorionic gonadotropin. The placenta grows during gestation and at labor it is excreted after the infant is born, a process also known as afterbirth. [31] The volume of a placenta at 20th week of gestation is approximately 200 [mL].[32]

1.3.4. Uterus

The uterus is a smooth muscle normally the size and shape of a pear. In the lumen of the uterus, the fertilized egg nestles. As the fetus grows the uterus stretches to provide enough volume to contain the amniotic sac with the fetus. In figure 1.3 the size of the uterus is shown at a full-term pregnancy. In this period contractions start and labor begins where after the infant is delivered.[31] The uterus has a wall thickness varying between 5 and 17 [mm].[33] At the anterior site, where most of the procedures penetrate the abdominal wall, the uterus is in the thinner part of this range. [34] The uterus contains a volume of around 1[L].[35]

1.3.5. Abdominal wall

The abdominal wall contains the abdominal and pelvic cavity and consists of four main layers. These are the peritoneum, muscle, fat and skin layers. For this study, only the anterior abdominal wall is considered, since this is the area where the entry ports for the fetal therapy are made. As seen in figure 1.7 the location of the abdomen, determines the different layers and their thickness.

Peritoneum The peritoneum is a slippery and flexible serous membrane which covers the interior of the abdominal cavity and abdominal organs like the uterus, and urinary bladder, and contains the intestines.

Muscle Layer The muscle layer in the abdominal wall consists of the following muscle groups: Rectus abdominis, internal Oblique, external oblique and transversus abdominis. It has an average thickness of 7,7 [mm].[36] However due to the different orientations of the muscle groups this thickness can vary depending on the location in the abdominal wall. These differences can be seen in figure 1.7 where besides the muscle groups also a cross section can be seen through the umbilical section.

Subcutaneous Fat layer The layer of fat, or adipose tissue, can be found throughout the body, although most of the fat tissue is located subcutaneous, and on top of the muscles as is the case in the abdominal wall. Its functions are shock absorbing, insulation and energy storage. The thickness of the fat layer varies depending on the physical condition of the person but has an average thickness of 24 [mm]. [36]

Skin The skin exists of three layers, respectively the epidermis, dermis and hypo-dermis, see figure 1.8. The epidermis is the outer most layer and has a protective function. The underlying layer is the dermis which makes up for the thickest

[4] https://www.webmd.com/

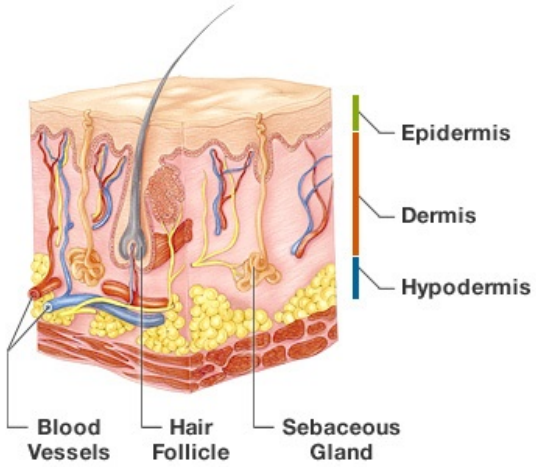


Figure 1.8: Cut section of the skin layer [4]

part of the skin and is composed of mainly connective tissue. The most inner layer the hypo-dermis, shares some of the protective functions of the skin but might as well be regarded as part of the subcutaneous fat layer.

2

Concept and requirements

In the previous chapter the goal of this study was stated as the design of a phantom maternal model for measuring the trauma in the amnion and developing new tools and procedures. This was followed by an explanation of the different medical conditions and anatomical elements relevant for achieving the goal of constructing a phantom maternal model for measurements and training. These prerequisites can be translated in a program of requirements. A program of requirements is a list of all requirements that can be formulated before the start of designing the phantom maternal model. By complying to these requirements the model can achieve the earlier stated goal of developing a phantom maternal model which is specialized for testing and the development of fetoscopic instruments and measuring the stress on the amnion. It is important that in formulating these requirements the S.M.A.R.T. method is pursued, where the acronym stands for: Specific, Measurable, Attainable, Realistic and Time-based. This prevents the requirements from being vague and multi-interpretive. From this program of requirements, an early concept will be composed, which is the starting point of further design and optimization of the phantom maternal model. The final materialization from this concept to the physical model can be read in chapter 3.

2.1. List of requirements

The list of requirements form the guidelines for the development of the maternal model. When the maternal model is built, it can be compared to these requirements to see if they are met and the model accomplished its goal. These requirements can be seen as the translation of the medical demands into the technical specifications. These requirements are backed up by findings in literature where possible. Some demands are retrieved from interviews with medical specialists or observations of surgeries. Where these fundamentals are missing an assumption is made. It is expected that these assumptions can be verified when the phantom model is actually built.

Requirements Phantom Maternal Model

1. **Dimensional**

   1.1. The phantom model should mimic the different layers needed to perforate for entry to simulate the force needed to move instruments penetrating these layers. These layers include: amnion uterus, muscle, fat and skin layer.

   1.2. To give a realistic experience to the user of the phantom model, the outer dimensions of the model should be within the range of a 16 to 24 week pregnant human.

   1.3. Because the dimensional relation between instruments and the phantom model should be realistic, the elements of the model which come in contact with the instruments should not be scaled.

   1.4. The phantom model should have an abdominal cavity capable of containing around 1 [L] of fluid since that volume approaches the intrauterine volume during the 20th week of pregnancy. [35]

   1.5. The phantom model must be transportable and therefor fit in a suitcase with volume of 500x350x250 [mm]. To accomplish this, the model might be taken apart.

2. **Ergonomical**

   2.1. Filling the model with liquids can be performed using a standard water faucet. This is required to accommodate filling the model in a wide variety of locations

where a water faucet is available. Alternatively, the model should be able to be filled with the use of a funnel. This provides for filling the model with other fluids than tap water.

2.2. The phantom model must be rinsable so it can be cleaned after a test is performed. This ensures that the phantom model can be reused in other tests.

2.3. Insert-able artificial components should be rinsable so they can be reused in other setups.

2.4. The phantom model should be able to be taken apart with only one type of tool to limit the tools needed to assemble the device.

2.5. The model must be able to be unpacked and assembled and vice versa, within an hour. To make it possible to build the setup and perform an experiment within one day.

2.6. To record and monitor the performed procedure on the phantom model, it is required that the model is transparent where possible, to provide visual inspection of the intrauterine volume.

3. Experimental

3.1. The model should be able to contain an artificial fetus the size of a 16 - 25 week old fetus, since that is the period the fetoscopic procedures regularly take place.

3.2. The phantom model should be able to contain at least 1[L] of fluid without leaking.[35]

3.3. One must be able to perform the experimental procedure for treatment of spina bifida on the model.

3.3.1. A 3 [mm] trocar must be fitted through the abdominal wall of the model since that is the most common trocar used in fetoscopic procedures.[37]

3.3.2. An artificial fetus must be displaceable within the abdominal cavity for simulating purposes.

3.3.3. Abdominal cavity must be able to be reached under angles perpendicular to the bodies length axis.

3.4. One must be able to imitate the fetoscopic laser coagulation procedure since this is one of the most common fetoscopic procedures and is used in TTTS, TRAP and treatment of congenital cystic adenomatomoid malformations.[7–10, 24]

3.4.1. The phantom model should be able to contain an artificial placenta the size of an real placenta corresponding to the simulated gestational age. For 20 weeks the placenta has a volume of around 200 [mL].[32]

3.4.2. The artificial placenta should be attachable in both posterior and anterior position for the simulation of TTTS and TRAP with an anterior located placenta.[38]

3.5. Insert-able artificial components like the artificial placenta, umbilical chord and the fetus should be exchangeable to simulate congenital defects as well as healthy situations in varying stages of the pregnancy.

4. Technical

4.1. The artificial abdominal wall must have comparable mechanical properties compared to that of the human abdominal wall. The shear modulus is used as an indicator of the rigidity of the material.

- Fat: Shear modulus 1.9 - 31.9 [GPa][39–42]
- Muscle (Relaxed): Shear modulus 4.6 - 23.8 [GPa][39, 40, 43–45]

4.2. The artificial abdominal wall should have an anatomically correct layer buildup. This means the artificial uterus is covered with;

- 7,7 [mm] artificial muscle layer.[36]
- 24 [mm] artificial fat layer.[36]
- Aesthetic skin layer.

4.3. The abdominal wall should have a thickness between 20 [mm] to 35 [mm] since that is the range of thickness of the abdominal wall during the 20th week of pregnancy. [36]

4.4. An entry port through the artificial abdominal wall should be movable in x and y direction up to 10 [mm]. Where

x is lateral and y is supero-inferior displacement. This is the estimated translation range in which the fetoscopic procedures are performed.

4.5. The entry port through the artificial abdominal wall should be rotatable over xz and yz in 0° where xz is the supero-anterior axis and yz is the lateral anterior axis.

4.6. The model and insertable components of must be manufacturable with the production methods facilitated by TU Delft.

4.7. On behalf of transportation of the model, it should be able to be transported in a suitcase and weigh no more than 20 [kg].

5. Measuring System

The requirements 5.1 - 5.3 were not found in literature, but these estimates are made from watching footage of procedures or estimations. These values are validated at the end of this study.

5.1. Accuracy of the measurements must be within ± 0.5 [mm] to give an accurate measurement of the performed movements.

5.2. Measure displacements within a range of x, y 0-10 [mm], where x is lateral and y is supero-inferior displacement. This is needed to measure the possible movements the model provides.

5.3. Measure rotations within a range zx, zy, 0°-60°, where xz is the supero-anterior axis and yz is the lateral anterior axis. This is needed to measure the possible rotations the model provides.

5.4. The measurement system can be detached from the abdominal model. This way the measurement system can be used in other experiments as well as making it detachable in favor of transporting the experimental setup.

5.5. The measurement system is outside of the abdominal model. This way it can not interfere with the performed procedure.

6. Wishes

6.1. Simultaneous entry of 3 [mm] ports the artificial abdominal wall should be possible, to increase the different procedures that can be performed. For example laparoscopic assisted fetoscopic procedures.

6.2. Intra-abdominal pressure should be measurable. For future research it could also be a measure of the risk of PPROM.

6.3. Intra-abdominal pressure must be able to to be increased to a minimum of 12 [mmHg]. 12 [mmHg] is the pressure used for inflation during laparoscopic procedures[36]

2.2. Conceptual design

For the creation of a concept phantom model which is the starting point of the development of the experimental phantom model, a number of aspects were chosen to be important and were used as driving arguments. One of these driving arguments was that the model must be versatile, therefore a modular system would be favourable. Another driving argument was that the focus in this phantom model would be on the simulation of the different abdominal layers. In return other anatomical elements were simplified on behalf of production time and costs. A third important driving argument was the choice to abandon the use of ultrasound imaging to visualize the intra-abdominal volume. This was done because during fetoscopic procedures, the ultrasound imaging techniques are only used for entering the intra-uterine cavity. After an entry point is achieved the ultrasound imaging techniques are obsolete. The advantage of this choice is that creating a phantom model that is compliant with ultrasound imaging, has a lot of limitation regarding material choice. Hard plastics and metals reflect the ultrasound waves in a way that does not represent a realistic situation. Also a multi layer wall is difficult for sound waves to penetrate due to the multiple layer transitions and microfilm air layers. With these driving arguments in mind, the conceptual phase was started. This section continues with other choices that lead to the creation of the final concept.

2.2.1. Shape

The shape of the abdominal cavity of the maternal model is in reality an amorphous shape. However to benefit the production of the model and improve the water containing properties, this cavity is simplified as a cylindrical shape.

The shape of the entry port to the cavity is also a simplification of the real situation. Where one can puncture a female abdomen anywhere in the abdominal area, in the model this is limited to a small area of operations. This design choice is made to improve the watertight properties of the model. Since most procedures enter the abdomen via the umbilical area, at this location entry is facilitated.[46] To provide access to the abdominal cavity from other directions then umbilical, the artificial abdominal cavity can be rotated. These two decisions, rotating and cylindrical, were driving in designing the shape of the model.

In the end the conceptual phase resulted in a cylindrical artificial abdomen, covered with sample layers tot mimic the abdominal wall positioned in a trestle as shown in figure 2.1.

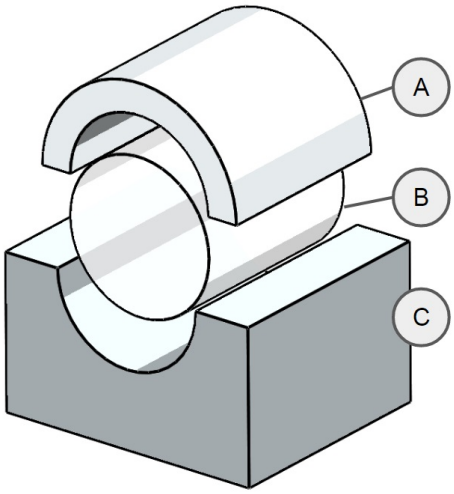


Figure 2.1: The three main conceptual components, from top to bottom: A: artificial abdominal wall, B: artificial abdominal cavity and C: the trestle frame.

2.2.2. Components

From the choice to have a modular system, it is possible to derive that there are certain components or sub-assemblies needed to be present in the model. In combination with the earlier determined shape, three components or sub-assemblies were categorized. Each with their own set of functions. From top to bottom these are respectively, artificial abdominal wall, uterine cavity and the trestle frame. Per component the conceptual details are discussed below. Each component is labelled from A to C, corresponding with the labels in figure 2.1.

A - Artificial abdominal wall The top layer, the artificial abdominal wall, is the part where the different tissue layers are simulated. This component can consist of the amniotic-, uterus-, muscle-,
fat-, and skin layer, depending on the type of experiment. This layer needs to provide an entry point inside the artificial uterine cavity which facilitates the movements described in the list of requirements. This is a separate component of the concept layer composition therefore layer types can easily be interchanged or altered depending on the type of experiment.

B - Artificial uterine cavity The uterine cavity is the centre part which supports the artificial abdominal wall as well as contains the intrauterine fluids. Inside this cavity multiple test scenarios must be able to be placed. Regarding the list of requirements, this component needs to be transparent to facilitate visual feedback during experiments. Besides transparency, this part also needs to be capable to rotate to facilitate angle of entry as a variable.

C - Trestle frame The trestle frame, is the component that supports the experimental setup as well as housing a measurement system. It should provide for the artificial uterine cavity to be rotated as well as being able to fixate the construction. It also provides mounting possibilities for the different abdominal layers.

3

Methods and materials

This chapter discusses how the final experimental design is accomplished from the conceptual starting point described in section 2. The concept resulting from section 2.2 was further specified into a conceptual experimental setup which can be seen in figure 3.1. Per component of the experimental setup is explained why a certain material is chosen and how it is produced so that it can be recreated in future studies. Per component is also mentioned what choices are made to comply with the earlier formulated requirements. Within this chapter a study is included, which is performed to find out how to optimally represent the amniotic sac in this particular experimental setup. This study can be seen in 3.1.3. This chapter continues with a description of the final experimental setup. This setup will be compared to the requirements described in chapter 2.1 as well as being subjected to the opinion of medical specialists, which can be read in section 4.2.

3.1. Materialization

3.1.1. Abdominal wall

The phantom model produced by surgical touch, currently used in the LUMC, has an abdominal wall which consists of a single layer of silicone.[1] However, in the requirements formulated in chapter 2.1 it is determined that the different tissue layers in the abdominal wall should be mimicked to achieve a realistic environment and mechanical behaviour. Therefore, in this study, a multi-layer structure is chosen to represent the muscle, fat and skin layer. If the abdominal wall would prove to differ from a realistic situation or if the composition of this wall needs to be changed on behalf of other studies, this layer configuration also provides for simple adjustments without the need of redesigning or rebuilding the entire phantom model. Per layer a material is found for mimicking the corresponding layer in a representative way and fulfilling the corresponding requirements. The skin layer is chosen to be only an aesthetic layer in this study. Therefore its mechanical behaviour is integrated in the fat layer. The other two layers; fat and muscle, had to resemble the mechanical properties of the abdominal wall. These layers are wrapped around the artificial uterine cavity and held in place with straps. The end result of these layers in the phantom model can be seen in figure 3.2, and the descriptions can be read in the section below.

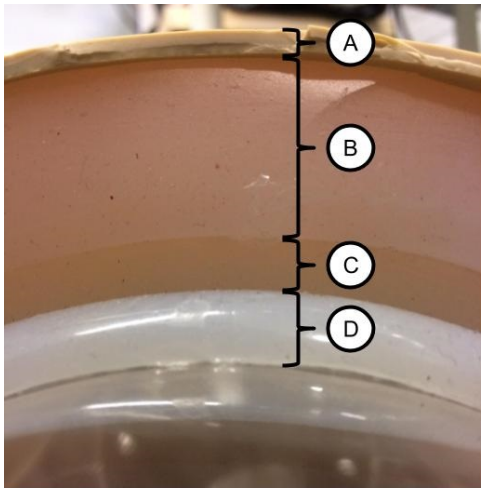


Figure 3.2: Side view of the four different layers. A: Skin, B: Fat, C: Muscle and D: Uterus

Skin

For an aesthetic representation of the skin, a skin colored rubber layer is used with a thickness of 3 [mm]. The material is of a color and flexibility used in other phantom models or box trainers. For replication, any type of rubber that meets these requirements will suffice. The sheet of material is cut into a rectangle of 280x400 [mm].

At the area where the wall is penetrated with the trocar, material is removed so it will not interfere with the instruments. This provides the degrees of freedom and magnitude of translations

[1] https://www.surgicaltouch.com/

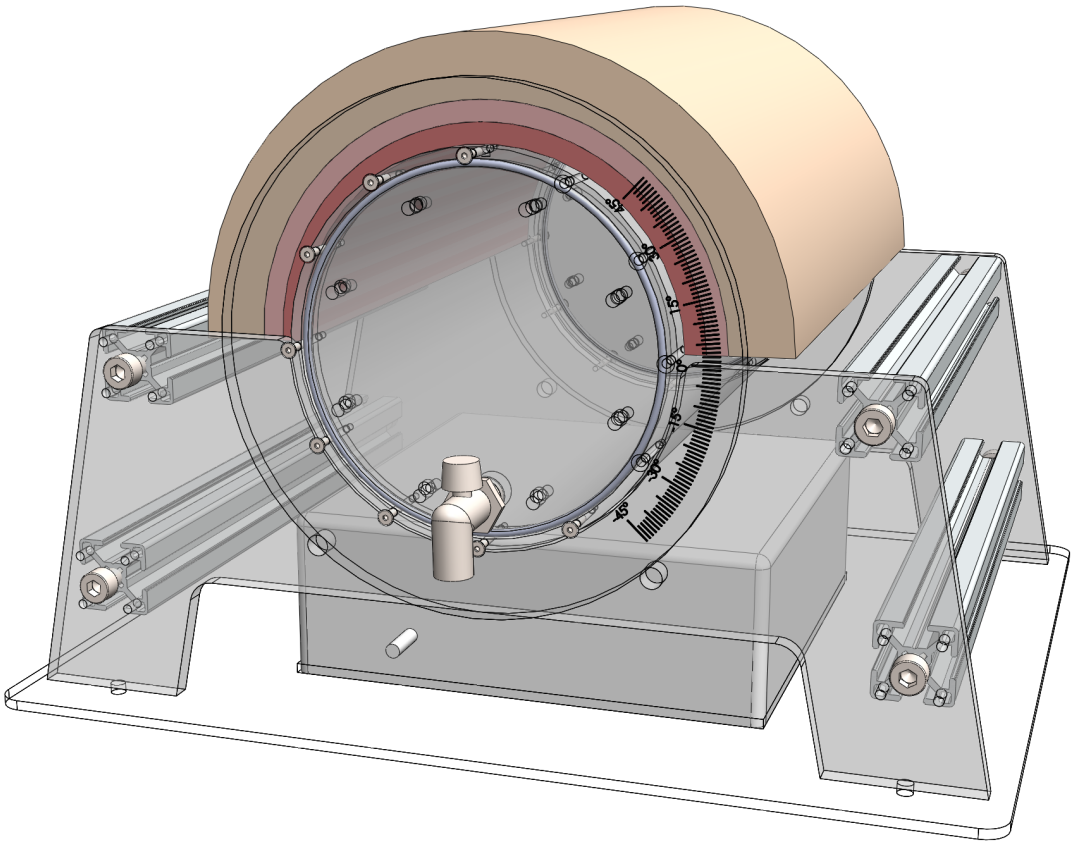


Figure 3.1: Schematic image of the experimental setup.

and rotations. Since the skin layer has an aesthetic function, a mechanism is used to facilitate the possibility to fold up this layer so it does not interfere with the experiment. This is accomplished by on one side six, 3D printed hinges, and on the other side of the layer four fasteners. The design of these hinges can be seen in Appendix B and the result is shown in figure 3.3.

Figure 3.3: 3D printed hinges to move the skin layer and expose the underlying structure.

This setup also provides the possibility to have easy access to the underlying layers, making them accessible for maintenance or alterations to the setup. Optional the layer can be partly covered with surgical cloth to hide the trestle frame, making the model appear more realistic.

Fat

From literature is concluded that the thickness of the fat layer has an average of around 24 [mm]. [36] During pregnancy the fat layer is stretched, however around 20 weeks this thickness should still be representative and therefore this dimension is persisted throughout this model. It is also found that the shear modulus varies between 1.9 - 31.9 [kPa].[39–42] In that same literature a substitute material is examined and proved suitable for simulations. This material is a silicone rubber compound called the Ecoflex 00-10. It is manufactured by a company called Smooth-On, which is specialized in rubber and silicone molding.[2]

The Ecoflex 00-10, is a two component silicone rubber, which has a compound ratio of 1A:1B. After the two components are mixed and stirred thoroughly, it is cast into a mold, in this case a

[2] https://www.smooth-on.com/

Tupperware box was used. The mold was filled up to a thickness of 24 [mm] and lay to dry overnight. When the material was settled, it was removed from the mold and cut into a rectangle. Technical specifications of the material can be found in Appendix D.

Muscle

According to literature the muscle tissue layer in the abdomen has an average thickness of 7.4 [mm].[36] As can be seen in chapter 1.3, this thickness varies across the abdominal wall depending on the location of the cut-section. However, in this study the average thickness of 7.4 [mm] is persisted. According to sources, the shear modulus of this muscle tissue in relaxed condition is 4.6 - 23.8 [kPa].[40, 43–45] To mimic the muscle layer, a type of silicon rubber named Dragon Skin 10 Medium can be used since its relevant mechanical properties are comparable to those of real muscle tissue.[39] This type of silicone is tougher than the previously mentioned Ecoflex 00-10 which is used for the fat layer, but is molded with the same procedure. More information of this material can be found in the data sheets gathered in Appendix D. Two components are cast with a compound ratio of 1A:1B into a square box. The aim was to achieve a thickness of the earlier mentioned 7.4 [mm] but because of the higher viscosity of the Dragon Skin 10 Medium compared to the EcoFlex, it proved more challenging to achieve this goal, and after the material settled it achieved a thickness of around 8 [mm]. This value differs from the initial 7.4 [mm], however differences in anatomy per patient and variable wall thickness depending on the location of perforation through the abdominal wall cause variations of this value in reality, therefore the value of 8 [mm] was judged acceptable.

3.1.2. Uterus

Other than a standard abdominal model like a box trainer, the maternal phantom model includes an extra layer, representing the artificial uterus. Since the uterus is in fact a smooth muscle a material with mechanical behaviour comparable to muscle tissue is used.[31] Therefore, the same silicon, Dragon Skin 10 Medium is chosen as for the muscle layer to represent this layer in the maternal model. The thickness of a uterus during labour is around 6 [mm].[34] This dimension is maintained during fabrication of this layer. However, the same issue with molding the previous muscle layer happened with this mold. Due to the difficulties with casting caused by the high viscosity of the unsettled silicon, the thickness ended up around 8 [mm]. Since 8 [mm] is still a realistic value for a uterus wall thickness, this cast was used in the phantom model nonetheless.

3.1.3. Amniotic sac

Finding artificial material for mimicking the amniotic sac proved more challenging than the other layers. This is caused by the fact that little is published about the mechanical properties of the amniotic sac. However to make a justified choice of materials for this component of the artificial maternal model, tests need to be performed to learn more of this material. Therefore this section elaborates on a small study performed to attempt to motivate the choice of material to represent the amniotic sac.

To understand how the amniotic sac behaves during fetal surgery, material tests need to be conducted to determine this behavior. One way to do this is by determining relevant mechanical properties of the material and finding material with corresponding mechanical properties. Relevant properties are shear- and Young's moduli, properties which other studies have examined for finding artificial substitutes for fat and muscle tissue.[36, 39] Guidelines are composed for determining these mechanical properties of living tissues and are explained in Y.C. Fung 's book Bio-mechanics.[47] However, most of the tests described by Fung are very elaborate and specific. Therefore it is decided that such a test is too comprehensive to perform in the process of this particular graduate thesis, which has the ultimate goal of producing a physical phantom model. Nevertheless a material needed to be found which resembles the mechanical behavior of the amniotic sac. In order to do so, a simpler method is chosen to give insights in the mechanical behaviour of the tissue. These simpler tests would also be applicable to other materials of which the properties are unknown to find a material which would realistically represent the amniotic tissue.

The amniotic sac is described to have a low Young's modulus since it is referred to as flexible.[31] A silicone rubber is expected to approach the elastic behaviour of the amnion since rubber and silicone have a low shear and Young's modulus as well. Furthermore silicone rubbers come in a wide variety of stiffness and strengths making it more likely to find a specific compound which approaches the amniotic tissue. To maintain a guideline throughout these experiments, the ISO 37 standard is chosen. In ISO 37 is described how to perform a tensile test to determine the tensile strength of vulcanized and thermoplastic rubber. For the experiment this standard is followed where

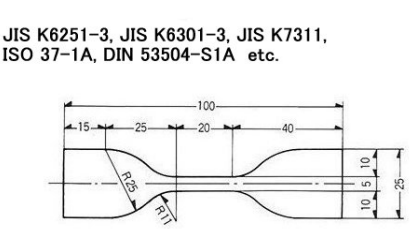


Figure 3.4: Technical drawing of the in ISO 37-1A specified test specimen.

possible.

In the ISO 37 standard the dimensions of a sample are specified, these dimensions can be seen in figure 3.4. To cut the samples in these dimensions for the experiment a pneumatic press with a stamp was used as shown in figure 3.5. Because the amniotic material was too fragile, the ISO 37 stamp was somewhat altered. Normally the stamp presses down the material before cutting its silhouette, to strike out the material after pressing. However it was observed that pressing down on the tissue would weaken the material and make it useless. Therefore the stamp is altered to cut without pressing it on the pressing bed.

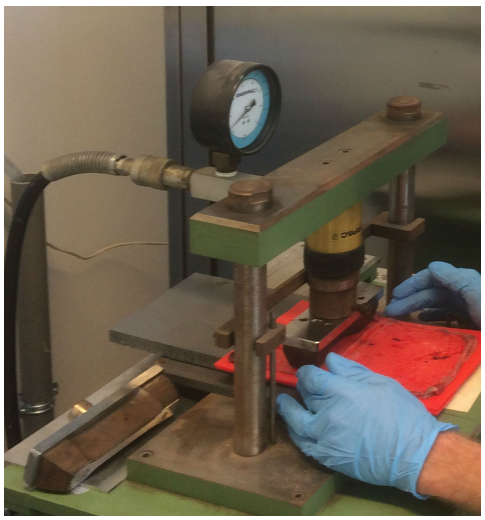


Figure 3.5: The process of die cutting the amnion.

The amniotic tissue was obtained from the obstetric department of the Leiden University Medical Centre (LUMC). There it was cut from the afterbirth, right after delivery and placed in a plastic container. It was die-cut into the specimen size within three days of delivery. In that period it was being cooled, but not frozen, to preserve the properties of the material.

The result is shown in figure 3.6. From two grafts of amniotic tissue, which also came from

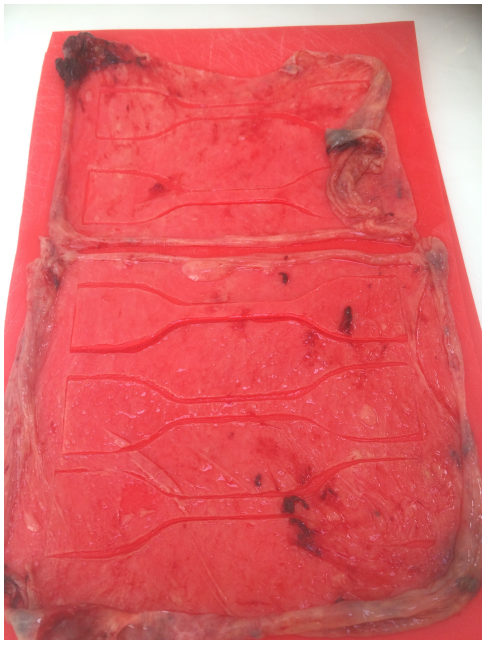


Figure 3.6: Samples of amniotic sac die-cut with a pneumatic press.

two different deliveries, a total of five tissue strips were retrieved, of which four were usable for testing; two of each graft because one of the samples was damaged too much during the cutting procedure. The four samples were placed in a layer of clinical solution. To create this solution Phosphor Buffered Saline (PBS) tablets from AppliChem Panreac were used. These tablets can be dissolved in demineralised water to create a clinical solution with a pH of 7.4 and the same osmolarity and ion-concentration as found in the human body. From the tray, the four samples were mounted in a linear stage. A schematic overview of this linear stage can be seen in figure 3.7

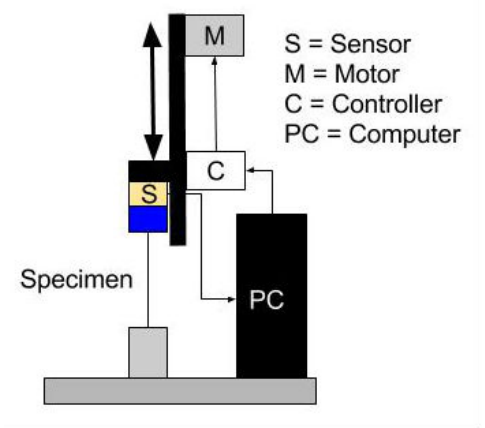


Figure 3.7: Schematic overview of the linear stage used for this experiment.

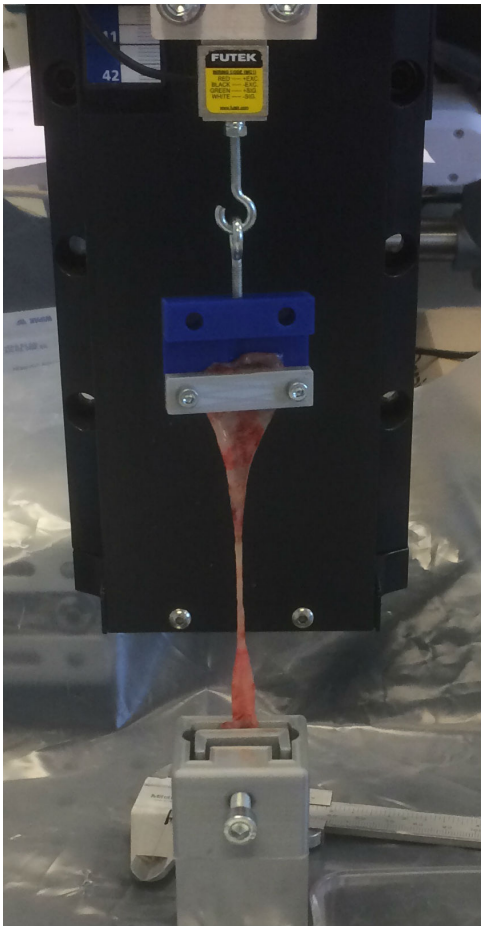


Figure 3.8: Picture of the tensile test of amniotic tissue.

Materials used in tensile test.(figure 3.8)

- Linear stage Aerotech, US PRO-115
- Futek 2,5 [N] Loadcel, LSB200 S-Beam
- Restraining components, 3D printed (for technical drawings see Appendix B
- 2x Bolt M3x16 Hex
- Bolt M6x30 Hex
- Bolt M3x20 Hook
- 2x M3 nut

As described in ISO 37 the specimen is elongated with 3 [mm/s].

Results

During handling and preparing of the amniotic material it showed that the amniotic material was weaker than expected. During preparation of the specimen test strips, the first strip was already succumbed to the load applied by the ejector plate of the stamp. Alterations had to be made to successfully cut the specimen strips. Where silicone was expected to approach the mechanic properties of the amniotic sac it appeared that the magnitude of mechanical properties was of an other order. During the test with the amniotic tissue, the 2.5 [N] force sensor was used, where in testing the stage with silicone material, a 12.5 [N] force sensor would barely be able to measure the force since it almost exceeded its limit.

To transfer from the voltage and displacement data retrieved from the linear stage, the following formulas are used.

$$\sigma = \frac{F}{A} = \frac{Vk}{bh} \quad \text{and} \quad \epsilon = \frac{\Delta L}{L}$$

In the first formula, F is the force in Newtons, calculated when the voltage V measured in [mV] is multiplied by a factor k This factor k is dimensionless and is found by calibrating the force sensor with calibrating weights. This way the voltage of the sensor can be converted into force. Besides determining this factor k, the restraints and samples were also weighed and this voltage was subtracted from the voltage during the measurements to purely measure the reaction force of the material. This is divided by the thickness and width of the sample in [mm], the cross sectional area A, to get the stress, σ.

In figure 3.9 the results are shown in the form of a stress strain curve. It can be observed that the material behaves in a non-linear fashion and the behaviour of the different specimen strips lies close to each other.

Specimen	Thickness [mm]	Weight [g]	σ_y [MPa]
Sample 1	0.63	1.20	0.28
Sample 2	0.60	0.85	0.28
Sample 3	0.60	0.78	0.21
Sample 4	0.60	1.30	0.18

Table 3.1: Thickness, weight and yield strength of four samples. Thickness is determined by measuring at three locations of the material and taking the average of those measurements.

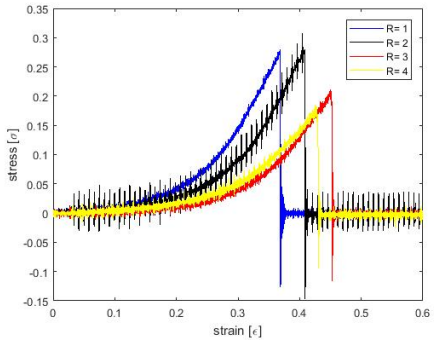


Figure 3.9: Graphs of the different stress /strain curves of the amniotic tissue.

Since this material is non-linear, there is not a single value for the Young's modulus. The Young's modulus can be calculated by calculating the slope at a certain point in the stress/strain curve. After the first results it is found that the material has a very low elastic resistance and is expected to have a very low Young's modulus. For this study the maximum movements of the amnion are established at 10 [mm]. Therefore the Young's modulus of amniotic tissue at a 10 [mm] elongation is calculated.

Specimen	E at 10 [mm] [MPa]
Sample 1	2.1E-4
Sample 2	8E-3
Sample 3	2.0E-4
Sample 4	1.2E-4

Table 3.2: Youngs modulus at 10 [mm] elongation.

Discussion

Since there are only four samples, the sample size is quite limited. However, the results per sample are comparable. This test has a number of limitations. Firstly the noise which can be seen in the stress strain curves, figure 3.9, is caused by the movement of the linear stage. For the measurement of small forces they contribute to quite an error.

Secondly, the amnion was at 36 weeks of gestation, then was cooled for three days after birth before it was subjected to these tests. It is probable that the amnion has different properties because of this process compared to an amnion at 16 - 20 weeks of gestation.

Thirdly, pressing the amnion while die cutting it proved to render the material useless, the material was die-cut while spread out on a plastic sheet. This would make the specimen prone to irregularities, as the pressing down would flatten the material. On the other hand, the weight of the specimen varied very little, as well as the diameter at different location of the different specimen. These differences in specimen weight could also be caused by the amount of clinical solution covering the specimen, as the samples were kept in a layer of this fluid to prevent dehydration. This is backed up by the observation that an increased weight does not correlate with an increased yield strength.

A fourth limitation was that the material would have the tendency to curl up. This made it impossible to measure the changing cut section dimensions during the stretching of the material.

Conclusion

From these tests is concluded that the Young's modulus of the amniotic sac is lower than 21 [kPa] within a 10 [mm] movement. Concludes it is a material which is very unresistant to stretching compared to silicone rubber which has a Young's modulus varying between 1000 - 50000 [kPa].[3] Since the material properties of amniotic sac approach that of gels and liquids, a material needs to be found that has the same characteristics. However, when compared to the other layers the contribution of an artificial amnion with those mechanical properties can be regarded low enough to be ignored, or other wise be measurable.

As for the amount of trauma that is inflicted on the amnion during surgery via movement of the instruments through the trocar, the displacements at the point of intersection between the trocar and the amnion is the only reference that can be measured properly.

3.1.4. Trestle frame

The main material for the mount is acrylic glass for its translucent properties, providing visual information of what is inside the trestle frame. Four aluminum extruded profiles provide stiffness for the trestle frame as well as provide mounting options for the artificial abdominal wall. A mounting plate keeps the trestle frame in place and in a fixed position regarding the Aurora measurement system.

The trestle frame is composed of two identical laser cut acrylic glass profiles. Acrylic glass is chosen on behalf of the requirement of transparency. The two profiles are connected with four aluminum extruded profiles to provide rigidity. The choice for these profiles comes from the fact that these profiles provide a wide variety of attachment possibilities due to their counterdraft grooves. The 3D printed hinges described under section 3.1.1, fit inside these counterdraft grooves.

[3] https://www.azom.com/

Trestle frame specifications

- 4 x 280 [mm] Rose-Krieger BLOCAN Profile 30 x 30 [mm]
- 2x Laser-cut 8 [mm] Acrylic trestles.
- 4x RVS Lever Hook, RoHS compliance.
- 4x RVS Lever Bracket, RoHS compliance.

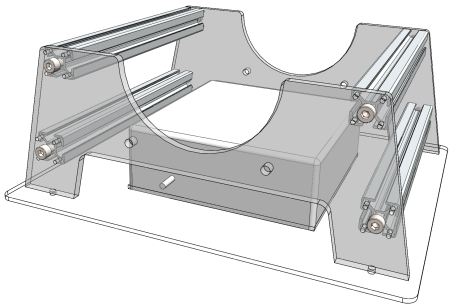


Figure 3.10: Sub-assembly of the trestle frame, including the aurora measurement system.

The trestle frame is bolted onto a large 350x400 [mm] base plate of acrylic glass with a thickness of 4 [mm]. In the center of this plate, a square is cut out in the exact size of the aurora measuring system. The aurora measurement system can be pressed into this shape causing it to get logged into place without the need for tools. Further details of the aurora measurement system can be read in section 3.1.6 of this chapter.

3.1.5. Uterine cavity

The material for fabrication of the abdominal cavity is transparent. Reasoning behind this is to be able to see what is happening inside the model during testing. It also provides good visual feedback if the model would show any signs of leakage. The Uterine cavity is constructed with an extruded acrylic pipe with an outer diameter of 150 [mm] and a 5 [mm] wall thickness. In the top of the pipe an entry location has been opened. This is a lengthwise 80x50 [mm] milled opening with a cutter radius of 5 [mm]. This provides a location for instrumentation to enter the cavity.

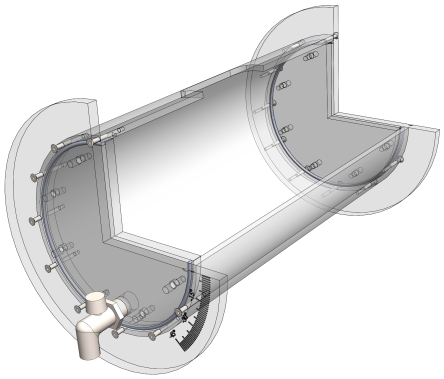


Figure 3.11: Cut-section of the 3D CAD model of the Uterine Cavity.

Uterine cavity specifications:

- Laser-cut 4 [mm] Acrylic glass
- O-ring FKM 75 shore - General use (Inside Ø=135 Cable Ø=3)
- Acrylic tube, 150 x 140 [mm], extruded - Clear plastic length: 300 [mm].

To maintain water tightness this pipe is sealed on both ends with a flange. These flanges are composed of three laser cut acrylic glass round plates. Two of these plates fit tightly within an end of the pipe. This tightness is achieved by surrounding one round plate with an o-ring. This o-ring has an outer diameter of 141 [mm]. On top of these rounds, a larger round cover plate is attached. These cover plates are tightly bolted onto the sides of the pipe. This sub-assembly can be seen in figure 3.11. The pipe is sunken onto the trestle frame. Where it is fixated using an adjustment bolt. The outer plate is fitted with a 3/5 [inch] hole, in which a standard faucet can be placed. On this faucet, using an adapter, a garden hose can be attached. This provides a filling as well as an emptying location for the liquids in the phantom model. Since the uterine cavity can be rotated in the trestle, a protractor is outlined with a laser cutter into one of the outer plates. The lines of the protractor align with the top trestle frame showing at what angle the entry location is positioned.

3.1.6. Measurement system

The aurora real-time electromagnetic tracking solution by northern digital with the planar field generator was selected as measurement system . This measurement system is specialized for tracking medical devices during a procedure.[4] It should meet the requirements formulated in chapter 2 regarding degrees of freedom and accuracy. This system can track the location of multiple sensors in a volume in front of a 200 x 200 [mm] real time electromagnetic tracking device.

[4]https://www.ndigital.com/msci/products/aurora/

Aurora v3 system specifications

- Aurora field generator planar 20-20 V2/V3 Dome volume.
  - Calibrated working volume: Dome shape with cylinder diameter 960 [mm], cylinder height 400 [mm] maximum dome height 660 [mm]
  - Dimensions (LxWxH): 200 x 200 x 70 [mm]
  - Weight: 2.6 [kg]
  - Cable length: 4.5 [m]
- Aurora System Control Unit V3 - CR13
  - Two isolated SIU ports for V3 SIU
  - USB and RS422 interface
  - Sync port
  - Power input: 110-240 VAC, 50/60 [Hz]
  - Dimensions (LxWxH): 230 x 172 x 84 [mm]
- Aurora 4-Port Sensor Interface Unit V3-4P FW 3.002
- Aurora SCU / SIU Connection Cable 4.5 [m]
- USB cable 5 [m] with ferrites for hybrid Polaris Spectra & Aurora
- System Documentation & Software Aurora V3
- 3x Aurora 5DOF Sensor, 0.8 x 11 [mm], 2.5 [m] lead wires
  - 0.8 [mm] x 11 [mm] (diameter x length)
  - Twisted-pair lead wires 2.5 [m]
  - Sensor protected by coating (no sleeve)

To measure the translations in the amnion, a trocar port is fitted with two sensors. One on the outside of the artificial abdominal wall and one inside the artificial uterus. They are held in place and protected by heat shrink tubing. These sensors can be seen real time in a 3D environment. These two coordinates show the position and the angle of the trocar. To get a reference point, a third sensor is added on the rigid outside part of the uterus. A schematic overview of the sensor locations can be seen in figure 3.12

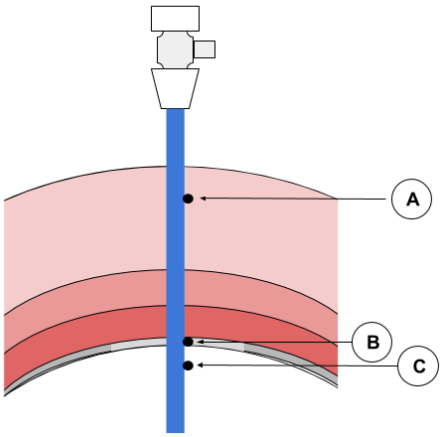


Figure 3.12: Schematic of the locations of the sensors in a cut-section of the abdominal wall. A: Top sensor, B: Reference at amnion location, C: Inner sensor.

This construction provides the measurement of rotations and translations of the trocar in respect to the amnion. To place the trocar inside the abdominal wall it is covered with soap to facilitate entry to the cavity without damaging the sensors on the trocar. The locations of the sensors influence the accuracy of the measurement of the translations of the amnion. When the sensors are placed further from the point of rotation the more accurate the angle as well as the translations of the perforation point through the amnion can be measured. On the contrary, when the sensors are further from the point of rotation the error due to bending of the trocar increases. To measure the translations of the perforation point through the amnion, at least one sensor on the trocar should correspond with the location of the amnion.

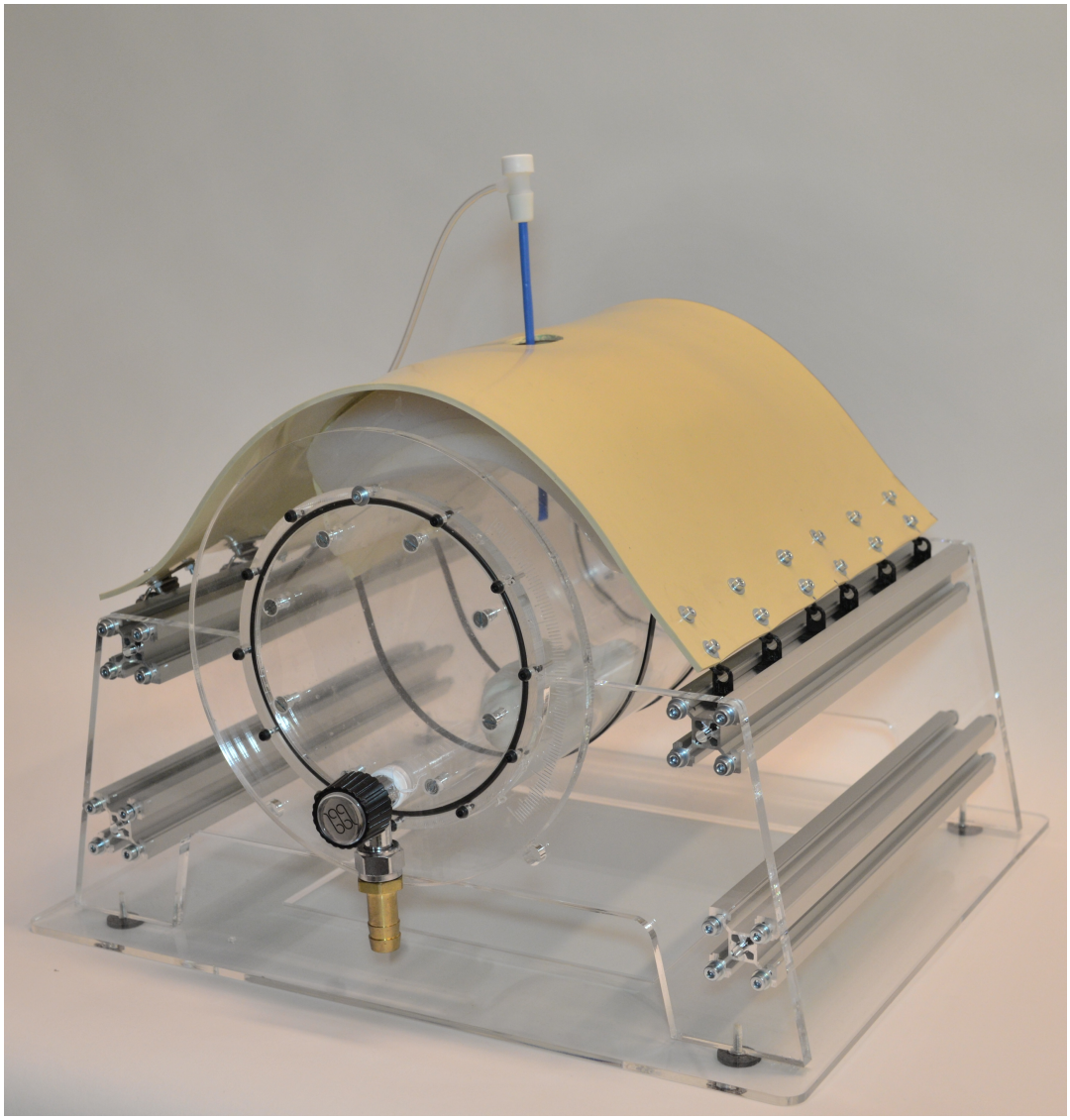


Figure 3.13: Photo of the phantom model without the measuring system and laptop.

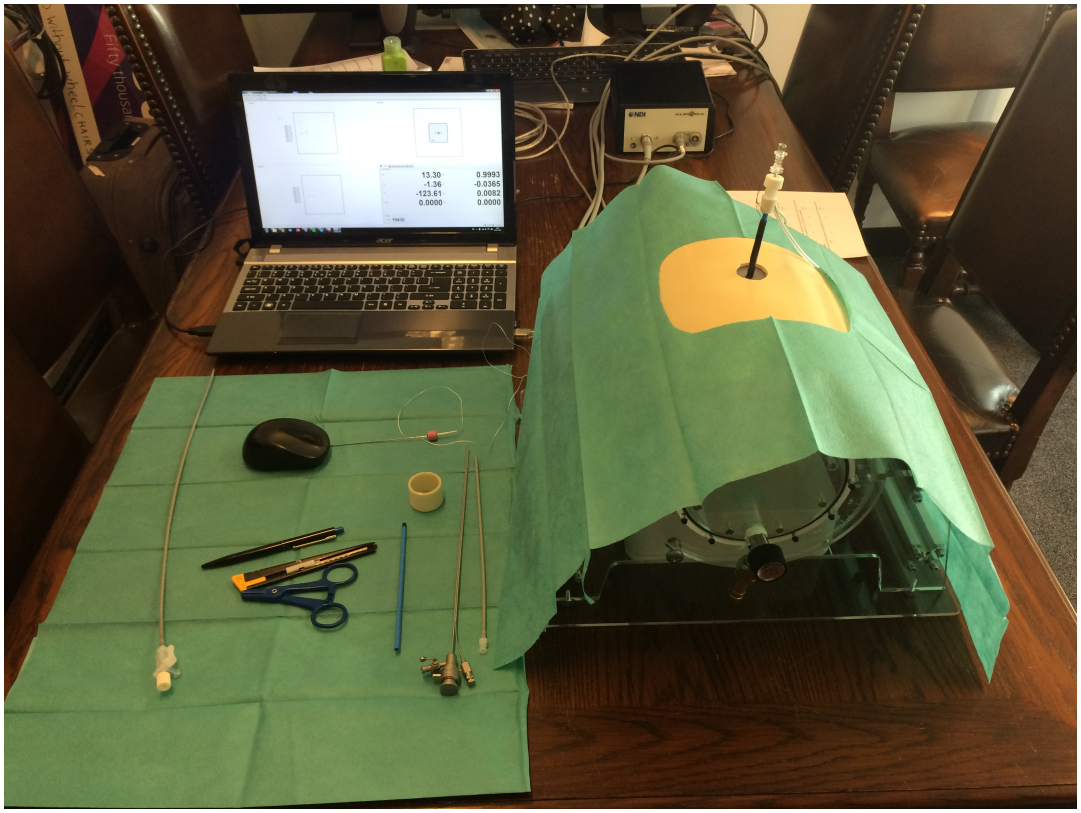


Figure 3.14: Photo of the experimental setup as performed in the Leiden University Medical Centre.

3.2. User evaluation

The experimental setup was assembled in an office at the Leiden University Medical Centre for the evaluation of the model. It was placed on top of a wooden table, because a table with a steel frame would possibly influence the accuracy of the measurements due to magnetic distortion of the aurora measuring system. The medical specialists were invited to come to this office where the model would be demonstrated. Afterwards, they were requested to fill in a questionnaire which asked their opinion about the phantom model, which can be found in Appendix C. This setup can be seen in figure 3.14. When a participant would come into the office, the following procedure would be followed:

1. Introduction
2. Explanation of the goal of this study
3. Invitation to play with and examine the phantom model
4. The request to fill out a questionnaire.
5. A short interview
6. Registration of contact information.

During an introduction the goal of the study was explained as well as the goal of this user test. This was followed by the opportunity for the medical specialists to test and try out the phantom model, move the trocar and see the corresponding readouts on the monitor and feel the different abdominal layers. The session was continued with the request to fill out a questionnaire and the session ended with a short interview to learn more about their opinion about the phantom model. During this interview following the questionnaire, questions focused on what could be improved on the phantom model and in which applications would this model be useful. The questionnaire was designed to push the participants in having an opinion about a number of aspects. These aspects were explained shortly and could be judged in 5 gradations, 1 being ”poor” and 5 being ”good”. These aspects were:

- Ease of Use - Do you think this setup can be used without elaborate instructions?
- Functionality This model provides a testing environment to track tools, do you think this is useful?
- Performance - This model can measure in hundreds of [mm], what do yo think of this

performance?

- Costs - This model can be produced for around 400 - 500 euro's (apart from the measuring system and laptop). What do you think about this price range?
- Look and Feel - When you see and touch the model what do you think about the aesthetics of the model?
- Realism - The properties of the layers that compose the artificial abdominal wall approach the properties of the actual situation. In your experience, do you think this is accomplished?
- Added value - Do you think this model contributes to the development of instruments for fetoscopic surgery?

The price range of 400 - 500 euro was based on the amount of material costs of 200 euro's in combination 10 hours of production and assembly time.

On the other side of the questionnaire the following three open questions were formulated, to spark the conversation.

- What do you miss in the model?
- What can be improved?
- Do you think there are other fields of medicine where this model can be useful?

The questionnaire was limited to this double sided document to reserve more time for further conversation about the model. This was done because the amount of time each fetal surgeon had for this evaluation was unclear and in this format it was an accessible setup were surgeons could stop by or take more time to comment on the model.

4

Results

In this chapter the results are gathered from building and validating the designed phantom model. This chapter begins with a section in which the phantom model is compared to the earlier described requirements. This is followed by the results from a validation study with the experimental setup described in section 3.2. In this validation study at Leiden University Medical Centre, as can be seen in progress in figure 4.3, the participants were asked to fill in the questionnaire followed by a short interview. These results are gathered in section 4.2.

4.1. Requirements verification test

To explore if the designed phantom model accomplishes the design goal, it is verified with the earlier described requirements in chapter 2.1. Weather the model meets the demands is discussed per category.

4.1.1. Dimensional

The artificial abdominal wall of the model includes the layers described in the requirements, respectively the uterus, muscle, fat and skin layer. However, layers like the peritoneum and amniotic sac are excluded due to their marginal contribution to the mechanical properties of the collective layer buildup. The mechanical properties of the skin layer and fat layer are integrated and simulated as one homogeneous layer. This corresponds with the anatomical configuration where the bottom layer of the skin, the hypo-dermis, transitions smoothly into the subcutaneous fat as explained in section 1.3. The muscle is constructed as a single homogeneous layer, which in reality consists of multiple muscle groups and tendons. The relevant mechanical properties of the fat and muscle layers correspond with those of the artificial tissue found in literature. The thickness of the layers is of a realistic magnitude as well as can be seen in table 4.1. Regarding scale the model meets the requirements, as it has the same instrument to body ratio as an actual human abdomen, however it is simplified to a cylindrical shape. Due to that shape the model can contain more liquid that the required volume of 1 [L]. The global dimensions of the model are 400 x 350 x 260 [mm] this exceeds the height limit formulated in the requirements. However, the model can be taken apart in subassemblies and in that configuration the height is reduced to 200 [mm].

Layer	In literature [mm]	In model [mm]
Uterus	7-21[33]	8
Muscle	7.7[36]	8
Fat	24[36]	24.8

Table 4.1: Thickness of the abdominal layers in the model compared to the anatomically corresponding thickness found in literature.

4.1.2. Ergonomical

Filling of the model can be performed using a standard 1/2 [inch] water hose. This means it can be connected to a wide set of faucets and even provides filling with a funnel. All containing components of the model are made with acrylic glass to provide transparency and the ability to be rinsed after use. The model can be assembled and taken apart, however multiple tools are needed to perform this procedure. Therefore the requirements that the model can be assembled and disassembled with only one type of tool is not accomplished. This is due to the availability of certain standard components like nuts and bolts in the environment this model was created and assembled in. However, with some design adjustments with this particular part of the requirements these goals could be met. The opening, closing and mounting the artificial abdominal layers is quite laborious as well. After the first assembly the model was tested for leakage by filling it to the brim with water as can be seen in figure 4.1. The phantom showed some

leakage at the locations where bolts connect the sub-assembly that seal the acrylic tube as well as the bolts that hold these sub-assemblies together. This leakage was stopped by tightening the bolts. The model could be assembled within half an hour, from unpacking the suitcase to tracking the movements of the trocar. This excludes filling the model, of which the time depends on the availability of a water supply.

4.1.3. Experimental

The models uterine cavity has a volume capacity of around 4,5 [L]. This means the inserts described in the set of requirements, like the placenta, and one or two fetuses can fit inside the cavity. The setup provides entry of varying diameters of instruments. All tools currently used transabdominal in fetal procedures can also be used in the phantom model. Since the uterine cavity can be rotated in the trestle frame, the requirement of entering the cavity from multiple angles is achieved.

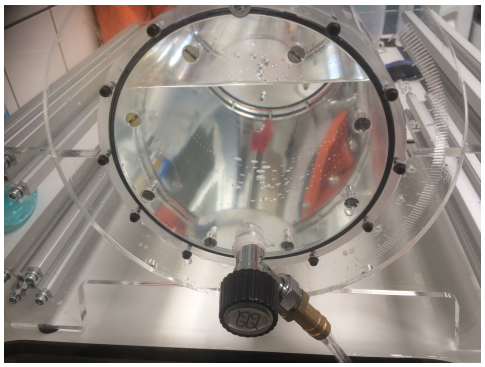


Figure 4.1: A photo of the testing of the model for water tightness.

4.1.4. Technical

The shear modulus of muscle and fat tissue is comparable of that of the corresponding silicone layers found in literature.[39–42] The thickness of the layers in the model meet the required averages determined in the list of requirements as well. However, due to the way it is fixated upon the frame the material layers are somewhat stretched and flattened underneath the straps and bulge in other places causing irregular thickness across the model. Even though these irregularities cause a discrepancy between the aimed thickness and the achieved thickness, it is within the limits of what is realistic.
The predetermined translations and rotations of the trocar through the amnion are possible. However, to achieve the maximum rotations of 60° and maximum translations of 10 [mm] needs a lot of effort.

4.1.5. Measuring system

The chosen aurora measuring system meets the set of requirements regarding the degrees of freedom in translations and rotations. The location of a sensor placed on the trocar can be measured in hundreds of [mm]. In resting state, meaning none of the sensors are perturbed, these coordinates are expressed in values with a 0,03 [mm] accuracy. This may be due to noise of interference of metal objects around the setup as well as small vibrations. According to the data sheet the aurora can measure with an accuracy of 0.48 [mm] This is on the edge of the acceptable limit at 0.5 [mm], mentioned in the list of requirements. The aurora fits inside an acrylic plate and is therefore removable without the use of instruments. Due to interference with metal objects, the parts that originally held the abdominal layers in place had to be replaced with plastic tie-raps.

4.1.6. Wishes

The wish of being able to enter with multiple devices is met and is provided with an entry area of 50 x 80 [mm]. It is not possible to enter the model from multiple angles at the same time, since this is the only location for entry. The wish for the intra-abdominal pressure to measurable is not met. The model is however adjustable to simulate other procedures, although these adjustments would need some tooling.

4.2. User experience test

The User Experience test consists of two parts, a survey and an interview. This section starts with the survey and then continues with the results from the interviews. This section ends with other noticeable remarks that resulted from the user validation study. The study was conducted with four participants (n=4). All participants were medical specialists who perform fetal surgeries.

4.2.1. User evaluation survey

The survey consisted of seven aspects which could be rated between 1 being poor up to 5 being good. Each aspect was explained with a question. Per aspect the rating is given, followed by the remarks of the participants.

Ease of use

The ease of use was rated 4,75 out of a maximum of 5. One remark was that when an assignment would be performed some explanation would be needed. The overall opinion was that medical staff would know how to work with this setup, since it approaches a realistic situation.

Functionality

The functionality of the model was rated 4,75 out of a maximum of 5. The function of the phantom model, the measurements of the translations of tools, was overall judged as useful. It could have applications in medical research as well as training facilities.

Performance

Accuracy performed by the Aurora was rated 4 out of 5. This seems a high rating, however one medical specialist rated this aspect 2 out of 5. The argument for this relatively low rating was that the accuracy of the system would not have the need to be lower than an estimated 0,1 [mm] and the changes in movement direction were more relevant.

Costs

The production costs of the phantom model, measurement system and laptop excluded) ranging between 400 - 500 euro's was rated an average of 4,75 out of 5. Unanimously the medical specialist stated that such a price range is acceptable regarding the price range of the current phantom models.

Look and feel

Look and feel scored the lowest with an average of 3,5 out of 5. Remarks were that the skin could be softer to approach a more realistic situation. Also the abdominal wall felt too stiff. In one survey a participant made the comparison with the model of surgical touch, where that phantom model was judged to be more lifelike. However, the wall on the maternal phantom model from this study was judged stiffer, it approached a more realistic feel than the phantom model of surgical touch.

Realism

The aspect of realism scored a 4 out of 5. In two of the surveys comments were that the uterus wall felt too stiff. Especially with big deflections of more than 45° the comment was that a real abdominal wall would be more compliant in that situation.

Added value

Added value scored the highest with a maximum score of 5 out of 5. The interviewed medical specialists unanimously stated that this phantom model would contribute to the development of fetoscopic instruments and the optimization of fetoscopic procedures.

4.2.2. Debatable questions

The survey was followed by three debatable questions. Answering these questions resulted in the following remarks.

What do you miss in the model?

- The option to vary the size/thickness of fat.
- An artificial placenta.
- An assignment like "laser" the placenta, measuring deflections and directional changes.
- A more realistic appearance.

What can be improved?

- Instead of the translations in the horizontal plane, include measurements in the vertical axis. Movements of the trocar through the abdominal wall.
- Thickness and stiffness of uterus wall.
- In the case of thinner material (diameter of measuring instrument), testing in patients would be the next step. (for now the diameter is too large).
- Quality of the skin.
- Smoothness of movement in the max of deflection amplitude.
- Incorporate ultrasound possibilities.

Do you think there are other field of medicine where this model can be useful?

- All Endoscopy procedures.
- Laparoscopy.
- Measuring experience in other fields.
- Training (Also Amniocentesis).
- Planning of fetal surgery in extreme obese women.

Other remarks

- Good setup and execution, a lot of experiments imagine-able.
- A commercial future?
- Sensor on the tip of the trocar or at the end of a scope.

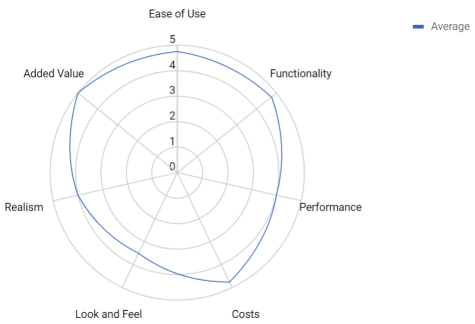


Figure 4.2: The results of the survey gathered in one diagram.

Figure 4.3: Photo of the experimental setup being examined by Resident dr. F. Slaghekke.

4.2.3. Other interesting remarks

During and after answering the questionnaire and the debatable questions, there was room for remarks and further conversations with the medical specialists. From feedback received by these participants, some other noteworthy items came up. In this section these remarks are gathered and explained.

- The thickness and stiffness of the uterus wall was considered too stiff and perhaps too thick during the questionnaire. However, in this conversation this aspect was compared to the current model of surgical touch that is being used. In that conversation it was remarked that the surgical touch models often have a too flexible abdominal wall.
- Participants noted that the magnitude of deflection during FLC is often determined by the location of the placenta. When the placenta is more anterior located, these movements increase to reach these positions. In a training scenario therefore the amount of deflection would not be the benchmark for the skill of a surgeon. Instead, a skillful surgeon would have a decreased amount of directional changes compared to an unskilled surgeon. Therefore it would also be interesting to measure the amount of movements instead of the magnitude of movements.
- Another remark that was not expected was that surgeons missed a monitor displaying the inside of the uterus. Normally the surgeons look at a monitor while performing surgery, instead of the model.
- In the Netherlands, knowledge transition is quite elaborate, however in the Baltic states a lot of experienced medical specialists go to private clinics creating a knowledge gap with the remaining doctors. Therefore there is a large demand for affordable trainers which provide training in for example amniocentesis.
- An interesting study would be to vary the thickness of the fat and muscle layers to train for procedures. Especially for amniocentesis this is a challenging procedure.
- During a real procedure the magnitude of movement of the instruments is in reality greater more around 60 - 70 degrees. The abdominal wall is more compliant in the in vivo situation, facilitating these movements.

5

Discussion

In chapter 1 it was mentioned that the aim of this study is to develop a phantom maternal model which is specialized for testing and development of fetoscopic instruments and measuring stress in the amnion. In this chapter is discussed if this study was successful in fulfilling this goal. This discussion is divided in different sections. It starts with discussing the comparison with requirements from section 4.1 followed by a discussion of the user experience test. The recommendations are split up in different sections as well, respectively improvements of the phantom model, societal relevance, future research and commercial purpose. This chapter and also this study ends with a conclusion in which the accomplishment of the study goal is discussed. This study goal is to create a phantom model, which is specialized for testing and development of fetoscopic instruments and measuring the stress on the amnion. By determining these stresses, it is possible to indicate the trauma caused by movements performed in certain procedures or by the use of certain instruments. In addition this trauma indication can be used to optimize currently used, or for the development of new, instruments and procedures.

5.1. Comparison with requirements

From the comparison with the list of requirements in chapter 4.1 it appears that most requirements are met. The phantom model has realistic dimensions and can be used for the intended purposes regarding the execution of different experiments. The choices in shape and modular assembly proved to benefit the design of the phantom model as well.

However, it also shows that regarding ergonomics, progress can be made in the phantom model. Assembly of the model is quite laborious because of the many bolts which need to be screwed in order to achieve water tightness of the uterine cavity. These locations are also prone to leakage when the bolts are not screwed tight enough. In an improved design this construction should be altered to improve assembly time and water tightness. During the production of the model, drilling and milling the acrylic glass proved to be very difficult, since the material was prone to cracking and melting under the heat of the tools. Perhaps bolting the side plates to close the uterine cavity can be improved by sealing the ends with a different method. For example an expanding ring which seals both ends of the cavity.

5.2. Evaluation of user experience test

The user experience test gave a lot of new insights even though it was limited to a feedback round of the medical specialists. However, more could have been achieved when the medical specialists had been given an assignment, or a challenge to complete by operating the experimental setup. At the time it was unclear how many medical specialists would evaluate the model and how much time they had available. Therefore the test was kept accessible and flexible depending on these parameters and an assignment was reasoned to be a bridge too far. For future experience tests this is something that can be taken into account. Important to note is that the time of medical specialists is very scarce, so clear communication is key for success with such a kind of test.

5.3. Improvements of the phantom maternal model

From the user experience test and the comparison with the requirements a number of limitations came to light. These limitations lead to improvements regarding the phantom model. On point of improvement is that the maternal model is constructed in a way that it facilitates fetoscopic en-

try. However, there are procedures or parts of procedures where instead of endoscopes, ultrasound is used. The maternal model has a hard acrylic wall which reflects the sound waves of ultrasound, prohibiting the use of this technique. For a wider variety of applications it is interesting to alter the model in a way that it would allow for the use of ultrasound technology.

Another point of improvement of the phantom model is that the abdominal layers get a lot of stiffness from the underlying construction. This possibly causes the observation, that the uterus layer is in the real situation more compliant. Eliminating the mechanical contribution of the acrylic glass to the artificial abdominal wall or integrating it to the collective stiffness of the abdominal wall would improve the realism factor of the model.

The skin layer was found to be too stiff compared to a real skin. Finding a more suitable material for this element would improve the look and feel of the model. Another option would be to integrate the skin layer and fat layer not only on a mechanical but also an aesthetic point of view. Making the fat layer the outer layer with skin tone and feel of real skin. Another benefit from this integration would be that since the fat layer is cast in a mold, the mold could include a navel and relief corresponding to the anatomical wall creating the look of muscle groups. This would give the phantom model a more realistic appearance. The same can be said about the muscle layer where specially designed molds could simulate the different muscle groups. This would make the point of trocar insertion relevant to the mechanical behaviour of said port.

In the current situation, moving the trocar through the abdominal wall is measured with three sensors, two on the trocar to measure its position and one sensor as a reference point. This configuration regards the trocar as a stiff component. However, realistically the trocar bends when being rotated through the abdominal wall. To get an accurate measurement of the movements, there should be a third sensor added to the trocar, to map the magnitude of this curvature.

5.4. Societal relevance

In chapter 1 it is found that an increase in the detection of congenital anomalies, the need for fetal procedures increases. To develop these procedures, a phantom model is needed that can be used in a experimental setup. The currently used phantom models from surgical touch do not facilitate the variability of tissue layers, the tracking of tools and are easily damaged and therefor not suitable for experimental setups. The phantom model developed in this study however would fill in that gap. Making it a stepping stone for instruments and procedures that could be developed in the future. In the questionnaire of the user experience test the phantom model was rated a maximum score on the aspect of added value. This feedback form medical specialists confirms the earlier stated societal relevance.

5.5. Future research

Parallel to this study, a co-graduate student Joe Juffermans, composed a mathematical model of the uterus in which the movements of instruments could be registered. It would be interesting to compare the theoretical aspect of his study with the practical aspect of this study.
Another direction for future research would be to research the trajectory of a trocar through the multiple abdominal and uterus layers. From the beginning of this study, There is a starting point where a trocar is already perforated through all abdominal layers into the uterus. However, puncturing these layers would bring up some interesting questions. For example where in this case the amnion seemed irrelevant in regard to the movements of the trocar, perhaps it plays a greater role in probing the uterus. Unknown factors that could be examined would be the magnitude of force needed to perforate these layers, the effect of the preload on the amnion or what happens to the intrauterine pressure while perforating all layers. When researching these kinds of topics, using a real amnion might be a possibility. The model is designed in such a way that an actual amnion retrieved after birth can be implemented in the abdominal wall. By using an actual amnion and performing experiments with it, afterwards one can examine under a microscope what damage is inflicted to the amnion.

For future research, more in the line of this study it would be interesting to examine a number of variables the phantom model from this study is suitable for.

- Translucence of amniotic fluids. How do laser tools behave in different degrees of turbidity?
- By varying the thickness of the fat and muscle layers, differences can be examined between obese or muscular patients and its effect on the quality and safety of procedures.
- Fetal- and placental orientation. What are the effects of a anterior located placenta?

- Instrument comparison. How do newly developed instruments hold against the established order of instruments? For example steerable versus non-steerable instuments.

Since the phantom model can provide laparoscopic surgical simulation in a closed environment, gases created by cutting tissue can be measured. This could also be applied for the purpose of measuring the amount debris from morcellation.

5.6. Commercial purpose

The phantom model developed in this study, can replace an existing commercial model in a number of specific setups in scientific research. The market for scientific research, which the phantom model in this study focused on, is often looking for specific tailored solutions like this. It is therefore by definition not a big market to focus on. In the user experience test came to light that the medical knowledge transition in the lesser developed countries of the European Union, like the Baltic states, is poorer compared to that of countries like the Netherlands. In those countries there is a high need for training methods. This phantom model could be adapted to this purpose. In combination with the comparably low production costs, this makes for a commercial opportunity where the market would be medical training's centres in eastern Europe. For expanding the commercial purpose, the phantom model could also be adapted for other laparoscopic procedures.

5.7. Conclusion

In this study the goal to develop a phantom maternal model which is specialized for testing and development of fetoscopic instruments and measuring stress on the amnion is partially succeeded. The phantom model does achieve a test and develop environment for fetoscopic instruments, with representative tissue layers. In this environment the movements of a trocar can be measured which can be used to determine the quality of a procedure. The goal to measure stress in the amnion in not achieved. The amnion was judged too fragile to make a relevant translation between the movements and the stresses in this tissue layer. However, the translations can be used as a measure of trauma inflicted on the amnion. The model showed to have potential as a training environment for fetoscopic procedures although design changes need to be made with that goal in mind. As a training tool this direction in phantom models could also have a commercial purpose, improving the quality of surgery by increasing the skill of the surgeons. Future research should focus on making the link between an artificial model, physical or mathematical, and the real situation.

A

Appendix A: Fetoscopic procedures

A.1. Prenatal Surgeries

First step in developing this female abdominal model is to map out what kind of fetal procedures are presently performed. In this section these procedures are explained.

A.1.1. Twin-to-twin transfusion syndrome (TTTS)

Twin-to-twin transfusion syndrome (TTTS) is one of the most challenging complications, which occurs in 10% to 20% of monozygous twin gestations (0.4% of total gestations) and if untreated leads to mortality approaching 80% - 100%. [7, 8] The twins share blood vessels through the placenta which is a problem when this blood flow is out of balance and one twin receives more blood (recipient) than the other (the donor). Treatment of TTTS depends on the severity of the illness. In minor cases TTTS is treated by decreasing the amount of amniotic fluid to reduce the pressure on the placental surface, providing better hemodynamics, and to prevent a preterm delivery. Survival rates vary from 13% to 87% with neurological complications ranging from 5% to 58%. [25] It is performed with the use of a 18-gauge needle with a 1.270 mm outer needle diameter. In the more complex cases fetoscopic laser coagulation (FLC) is performed to coagulate the shared blood vessels in the placenta. (Figure A.1) During this procedure a 3.3 mm trocar is percutaneously inserted into the amniotic sac. Through this trocar a 2 mm endoscope is fitted to provide visual feedback and a 0.4 mm diode laser fiber for coagulation of the inter twin vascular anastomoses.[25, 48] This procedure results in survival rates varying from 53% to 69% with neurological complaints ranging from 4% to 11%.[49–54]

Cases occur where the placenta is in an unfavorable position. Worst case is the complete anterior placenta where the placenta is located on the anterior wall of the amniotic sac.[29] In this configuration the placenta is hard to reach with the fetocscope. One study reports that the use of a 30°fetoscope improves the accessibility of the area of the communicating vessels. [55] Other studies show the possibility of laparoscopic assisted flc, where 3 mm trocar is placed from a dorsolateral position under laparoscopic guidance to provide access to the communicating vessels in the placenta. [28, 38]

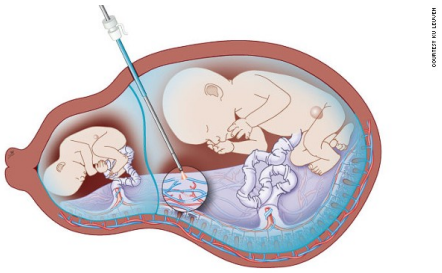


Figure A.1: Cut-section of the FLC procedure [1]

A.1.2. Twin reversed arterial perfusion sequence

The twin reversed arterial perfusion (TRAP) sequence is a syndrome in witch the blood circulation of the twins are connected instead of independent. One of the twins has a deformed or lacks a heart and is called the acardiac- or TRAP twin. The other twin is normal and called the pump twin, because it pumps blood through both fetuses. Because the blood flow in the TRAP twin is reversed, this syndrome is called reversed arterial perfusion. The TRAP sequence occurs about 1 in 200 twin pregnancies or 1 in 35000 (0.003%) pregnancies overall. It is comparable to the TTTS, however the acardiac twin is not viable. [9, 10] In a study where 49 TRAP cases were examined, the mortality rate 51% mortality when left untreated with surgery. Only 24% of the deliveries in this group occurred after 36 weeks of gestation.[26] In a study by Hecher et al. in 2006 60 pregnant women were treated with FLC in either the placenta (n=18) or the umbilical cord (n=42). The overall survival rate

was 80% with no difference between the umbilical and placental group. In 11 (18%) cases, PPROM occurred before 34 weeks of gestation. In 9 cases a second port was used during the FLC, with two of these (22%) lead to (PPROM). [9]

A.1.3. Spina bifida

Spina Bifida, or myelomeningocele, is one of the most common types of neural tube defects. It occurs in the U.S. in 0,34% of live births and has a death rate of around 10%.[11] With spina bifida, or myelomeningocele, the neural tube is not fully closed causing spinal fluid to leak from and amniotic fluid towards the spinal chord. This causes infections which in turn cause severe malformations.

In a study by Adzick et al. in 2013, fetuses with spina bifida who were treated prenatally had an average gestational age (GA) of 34.1 weeks and 13% premature births (GA<30 weeks) where post natal treatment lead to an average GA of 37.3 weeks with no cases of a premature delivery. [27] This difference confirmed an earlier study by Verbeek et al. in which a GA median of 32 weeks in a fetally operated group was compared to a GA median of 39 weeks in the neonatally operated group. [12]

Spina bifida can be treated by closing the neural tube with a patch or with stitches. Stitching the opening is done by performing multiport surgery with 1x5mm 2x 3mm trocar ports[13] Within the department of biomedical engineering at the TU Delft a new method is being developed for treating myelomeningocele

A.1.4. Congenital diaphragmatic hernia

Congenital Diaphragmatic Hernia (CDH) is a defect of the diaphragm, where the upper intestines protrude in the thoracic cavity and pressurize the lungs causing pulmonary arterial hypertension and pulmonary hypoplasia. This syndrome occurs in 0.02%-0.04% of pregnancies.[56, 57] The survival rate of CDH is 50% with post-natal care, but an adverse lung-to-head ratio or a liver herniation would worsen that outcome. [14–16] CDH can be treated prenatally with fetoscopic tracheal occlusion (FETO) therapy, a procedure where a balloon is placed inside the fetus' trachea to restore the pressure in the lungs as can be seen in figure A.2 Entrance to the amniotic sac is provided by a 3.3 mm trocar port [16]

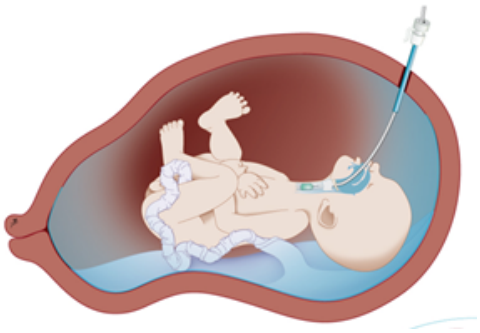


Figure A.2: Cutsection of FETO Therapy[2]

A.1.5. Aortic stenosis, pulmonary stenosis

Aortic or pulmonary stenosis is a condition in which an artery or pulmonary duct is narrowed in a way that it compromises the health of the fetus. In a study by Stagnati et al. in 2015 the prevalence of pulmonary stenosis was estimated at 1.15% in monochronic twin pregnancies.[58] With the use of balloons and stents the blood vessels the ducts can be opened. [17–20] Entry to the amniotic sac is provided by needles ranging from gauge 19 to gauge 16 (1.067 mm - 1.651mm)

A.1.6. Bilateral lower urinary tract obstruction (LUTO)

Lower urinary tract obstruction can be treated by shunting the bladder of the unborn infant. LUTO is seen in 1% of all pregnancies, however they are only problematic in around 0,2% of the cases.[21–23] Figure A.3

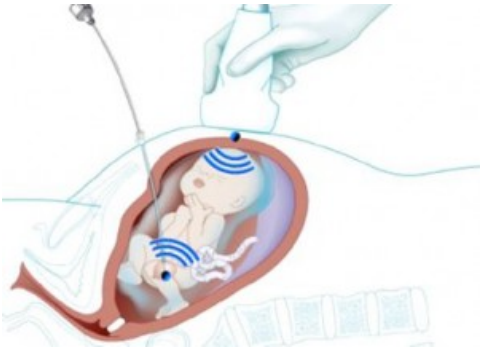


Figure A.3: Cutsetcion of LUTO Therapy[3]

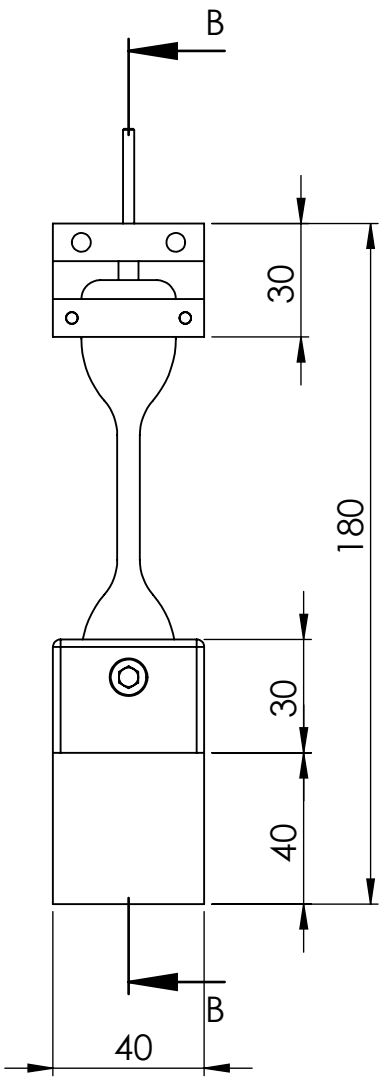
[1] http://www.gift-surg.ac.uk/project/medical-conditions/FLC
[2] http://www.gift-surg.ac.uk/project/medical-conditions/FETO
[3] http://www.gift-surg.ac.uk/project/medical-conditions/LUTO

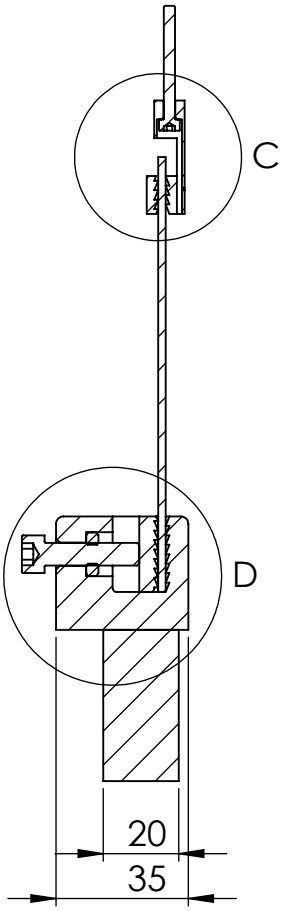
A.1.7. Congenital cystic adenomatomoid malformation, pulmonary sequestration

Congenital cystic adenomatomoid malformations and pulmonary sequestrations are syndromes which prevent the optimal blood flow through the infants lungs. These are the most common micro cystic or solid-looking fetal lung lesions associated with hydrops which lead to a high mortality rate.[24] With open fetal surgery these lesions can be treated however new developments explore minimal invasive approaches.

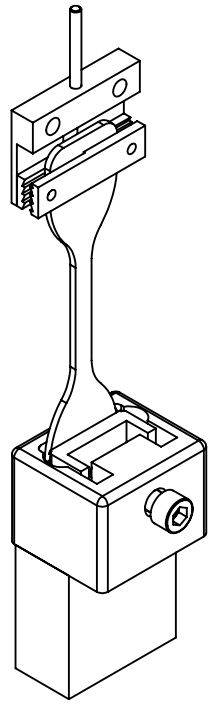
B

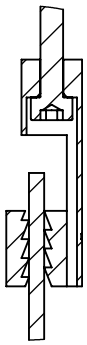
Appendix B: Technical drawings



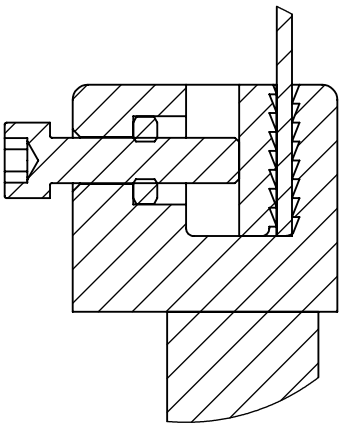


SECTION B-B



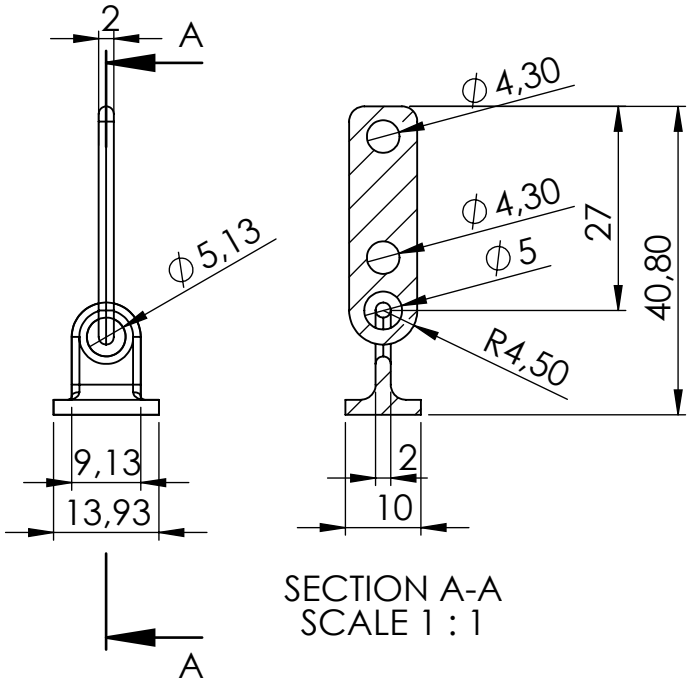


DETAIL C
SCALE 1 : 1

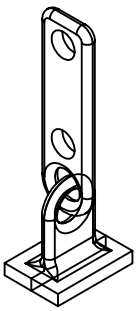


DETAIL D
SCALE 1 : 1

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS SURFACE FINISH: TOLERANCES: LINEAR: ANGULAR:		FINISH:			DEBURR AND BREAK SHARP EDGES	DO NOT SCALE DRAWING	REVISION
	NAME	SIGNATURE	DATE			TITLE:	
DRAWN							
CHK'D							
APPV'D							
MFG							
Q.A				MATERIAL:		DWG NO.	A4
						Assem_testopstelling2	
				WEIGHT:		SCALE:1:2	SHEET 1 OF 1



SECTION A-A
SCALE 1 : 1



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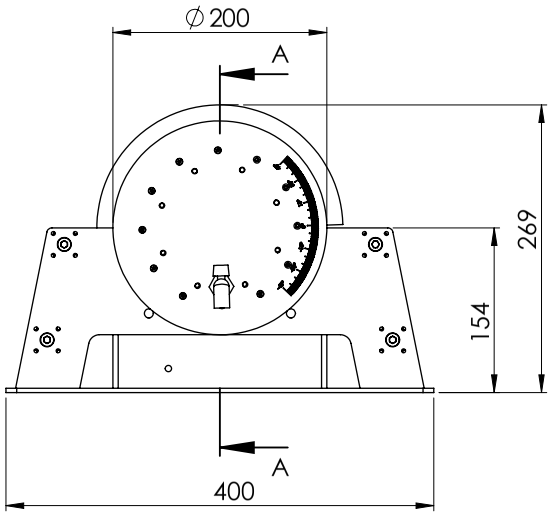
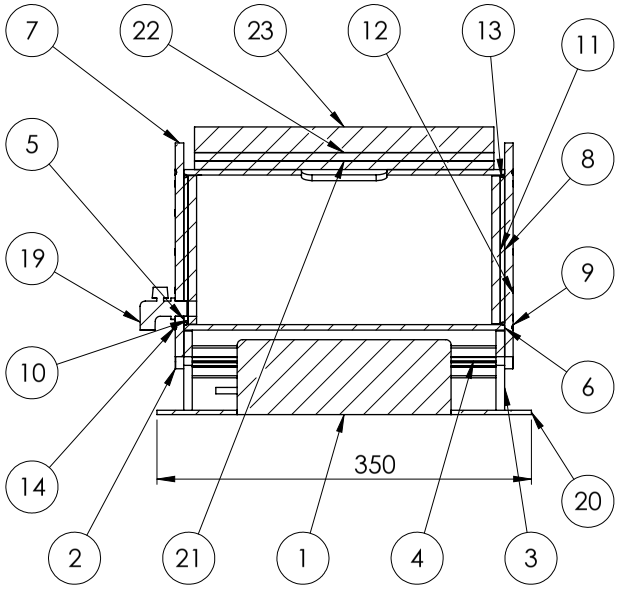
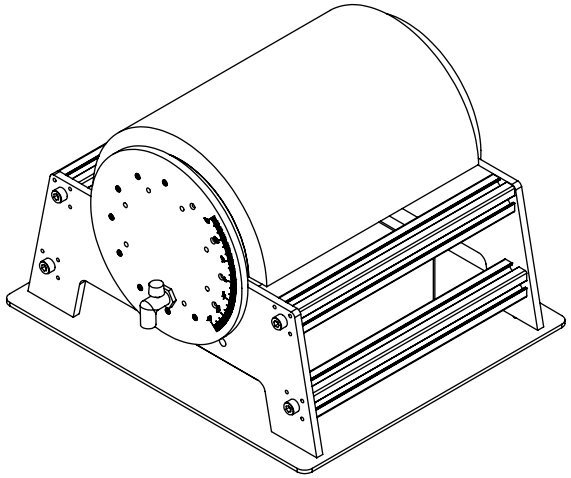
	NAME	SIGNATURE	DATE		TITLE:	
DRAWN	Jochem van Leijsen				Hinge	
CHK'D						
APPV'D						
MFG						
Q.A				MATERIAL: PLA	DWG NO.	A4
				WEIGHT:	SCALE:1:1	SHEET 1 OF 1





SECTION A-A



ITEM NO.	PART Name	QTY.
1	Aurora	1
2	ISO 4762 M8 x 25 - 25N	8
3	Perspex_mount_c11	2
4	3 842 990 720/50mm	4
5	Perspex_eindstop	1
6	Tube	1
7	Draaiplaat	1
8	Perspex_eindstop_dicht	1
9	Afdekplaat	1
10	Stop_open_binnen	1
11	Stop_dicht_binnen	1
12	ISO 10642 - M3 x 20 - 20N	8
13	O-Ring_135_d3	2
14	ISO 10642 - M3 x 16 - 16N	8
15	ball valve_body	1
16	ball_in	1
17	seal	2
18	hand	1
19	C11_Faucet	1
20	C11_Groundplate	1
21	C11_AB_Uterus_8mm	1
22	C11_AB_Muscle_8mm	1
23	C11_AB_Fat_24mm	1

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN MILLIMETERS
SURFACE FINISH:
TOLERANCES:
LINEAR:
ANGULAR:

FINISH:

DEBURR AND BREAK SHARP EDGES

DO NOT SCALE DRAWING | REVISION

	NAME	SIGNATURE	DATE
DRAWN			
CHK'D			
APPV'D			
MFG			
Q.A			

MATERIAL:

WEIGHT:

TITLE:

DWG NO. Assembly_C11

A3

SCALE:1:5

SHEET 1 OF 1

C

Appendix C: Questionnaire for model evaluation

f.slaghekke@lumc.nl.

Questionnaire Phantom Maternal Model

Name: Femke Slaghekke
Function: gynaecology, fellow perinatologie & foetale therapie

Ease of use
Do you think this setup can be used without elaborate instructions? — with an challenge

Poor				Good
0	0	0	0	~~0~~

Functionality
This model provides a testing environment to track tools, do you think this is useful?

Poor				Good
0	0	0	0	~~0~~

Performance
This model can measure in hundreds of mm, what do you think about this performance?

Poor				Good
0	0	0	~~0~~	~~0~~

Costs
This model can be produced for around 400 - 500 euro's, (apart from the measuring system and laptop). What do you think about this price range?

Poor				Good
0	0	0	~~0~~	0

Look and feel
When you see and touch the model what do you think about the aesthetics of the model?

Poor				Good
0	0	0	~~0~~	0

aesthetics good feels to stiff.

Realism
The properties of the layers that compose the artificial abdominal wall approach the properties of the actual situation. In your experience, do you think this is accomplished?

Poor				Good
0	0	~~0~~	0	0

uterus wall stiff.

Added value
Do you think this model contributes to the development of instruments for fetoscopic surgery?

Poor				Good
0	0	0	0	~~0~~

What do you miss in the model?

* placenta
* opdracht → "take the placenta" → multi cut layer ↓ freq.

What can be improved?

1. thickness and stiffness of uterus wall
2. indien dunner materiaal → goed om te testen in patiënten (nu diameter te groot)

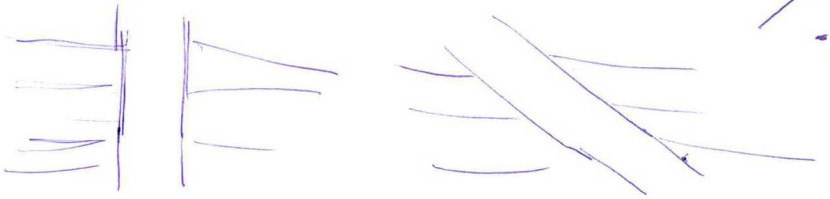
Do you think there are other fields of medicine where this model can be useful?

meaning experience in other fields

Other remarks:

* sensor op tip of op uiteinde van scoop

- hoger bereik / hue groot uitleg.
- maar ook hoe raak



Questionnaire Phantom Maternal Model

Name: Monique Haak
Function: Fetal Surgeon

Ease of use
Do you think this setup can be used without elaborate instructions?

Poor				Good
0	0	0	0	X

Functionality
This model provides a testing environment to track tools, do you think this is useful?

Poor				Good
0	0	0	0	X

Performance
This model can measure in hundreds of mm, what do you think about this performance?

Poor				Good
0	0	0	0	X

But I think it is not necessary to measure more > 0,1 mm

Costs
This model can be produced for around 400 - 500 euro's, (apart from the measuring system and laptop). What do you think about this price range?

Poor				Good
0	0	0	0	X

Look and feel
When you see and touch the model what do you think about the aesthetics of the model?

Poor				Good
0	0	X	0	0

skin could be a little softer

Realism
The properties of the layers that compose the artificial abdominal wall approach the properties of the actual situation. In your experience, do you think this is accomplished?

Poor				Good
0	0	0	0	X

Added value
Do you think this model contributes to the development of instruments for fetoscopic surgery?

Poor				Good
0	0	0	0	X

Additional comment:
produces different models with different sizes of subcutaneous tissue.

What do you miss in the model?

2 or → different size (thickness) of "flat"

What can be improved?

- skin, smoothness of movement in the max of amplitude
- US possibility

Do you think there are other fields of medicine where this model can be useful?

- training (also amnio centesis)
- planning of fetal surgery in extreme obese women

Other remarks:

Questionnaire Phantom Maternal Model

Name: Annemieke Middeldorp

Function: gynaecoloog
foetaal behandelaar

Ease of use

Do you think this setup can be used without elaborate instructions?

Poor				Good
0	0	0	0	0

Functionality

This model provides a testing environment to track tools, do you think this is useful?

Poor				Good
0	0	0	0	0

Performance

This model can measure in hundreds of mm, what do you think about this performance?

Poor				Good
0	0	0	0	0

Costs

This model can be produced for around 400 - 500 euro's, (apart from the measuring system and laptop). What do you think about this price range?

Poor				Good
0	0	0	0	0

Look and feel

When you see and touch the model what do you think about the aesthetics of the model?

Poor				Good
0	0	X	0	0

Realism

The properties of the layers that compose the artificial abdominal wall approach the properties of the actual situation. In your experience, do you think this is accomplished?

Poor				Good
0	0	0	0	0

afh. van grootte van incisies

Added value

Do you think this model contributes to the development of instruments for fetoscopic surgery?

Poor				Good
0	0	0	0	0

voor kleine wel

What do you miss in the model?

registratie op de heer bewegingen

What can be improved?

Do you think there are other fields of medicine where this model can be useful?

laparoscopy ???

Other remarks:

Questionnaire Phantom Maternal Model

Name: D. Oepkes
Function: Gynaecology

Ease of use
Do you think this setup can be used without elaborate instructions?

Poor				Good
0	0	0	X	0

Functionality
This model provides a testing environment to track tools, do you think this is useful?

Poor				Good
0	0	0	0	X

Performance
This model can measure in hundreds of mm, what do you think about this performance?

Poor				Good
0	0	0	0	X

Costs
This model can be produced for around 400 - 500 euro's, (apart from the measuring system and laptop). What do you think about this price range?

Poor				Good
0	0	0	0	X

Look and feel
When you see and touch the model what do you think about the aesthetics of the model?

Poor				Good
0	0	X	0	0

Realism
The properties of the layers that compose the artificial abdominal wall approach the properties of the actual situation. In your experience, do you think this is accomplished?

Poor				Good
0	0	0	0	X

Added value
Do you think this model contributes to the development of instruments for fetoscopic surgery?

Poor				Good
0	0	0	0	X

What do you miss in the model? nog realistische huiteffect

What can be improved? ook verticale bewegingen ?

Do you think there are other fields of medicine where this model can be useful? all endoscopy procedures

Other remarks:

- mooie opzet en uitwerking
veel mentige experimenten mee te bedenken
- toekomst: commercieel ?

D

Appendix D: Data sheets silicone rubbers

Ecoflex® Series

Super-Soft, Addition Cure Silicone Rubbers

Cured Material Certified Skin Safe!

www.smooth-on.com

PRODUCT OVERVIEW

Ecoflex® rubbers are platinum-catalyzed silicones that are versatile and easy to use. **Ecoflex®** rubbers are mixed 1A:1B by weight or volume and cured at room temperature with negligible shrinkage. Low viscosity ensures easy mixing and de-airing, or you can choose to mix and dispense using our convenient dispensing cartridges. Cured material is skin safe and certified by an independent laboratory to ISO 10993-10, Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization.

Cured rubber is very soft, very strong and very "stretchy", stretching many times its original size without tearing and will rebound to its original form without distortion. **Ecoflex®** rubbers are water white translucent and can be color pigmented with Silc Pig® pigments for creating a variety of color effects. You can also add Smooth-On's Silicone Thinner® to further lower the viscosity. THI-VEX® silicone thickener can be added by weight to Ecoflex® silicones for brushable aplications.

Soft, Softer, Softest . . . **Ecoflex®** rubbers are based on Smooth-On's Dragon Skin® technology and are currently available in four different hardness': Shore A-5, Shore 00-10, 00-20, 00-30 and 00-50. They are suitable for a variety of applications including making prosthetic appliances, cushioning for orthotics and special effects applications (especially in animatronics where repetitive motion is required). **Ecoflex® 5** has a pot life of 1 minute and a demold time of 5 minutes – Available only in dispensing cartridges.

Note: Ecoflex® 00-10 cures with a "tacky" surface.

TECHNICAL OVERVIEW

	Mixed Viscosity (ASTM D-2393)	Specific Gravity (g/cc) (ASTM D-1475)	Specific Volume (cu. in./lb.) (ASTM D-1475)	Pot Life (ASTM D-2471)	Cure Time	Shore Hardness (ASTM D-2240)	Tensile Strength (ASTM D-412)	100% Modulus (ASTM D-412)	Elongation at Break % (ASTM D-412)	Die B Tear Strength (ASTM D-624)	Shrinkage (in./in.) (ASTM D-2566)
Ecoflex® 5	13,000 cps	1.07	25.8	1 min.	5 min.	5A	350 psi	15 psi	1000%	75 pli	< .001 in./in.
Ecoflex® 00-50	8,000 cps	1.07	25.9	18 min.	3 hours	00-50	315 psi	12 psi	980%	50 pli	< .001 in./in.
Ecoflex® 00-30	3,000 cps	1.07	26.0	45 min.	4 hours	00-30	200 psi	10 psi	900%	38 pli	< .001 in./in.
Ecoflex® 00-20	3,000 cps	1.07	26.0	30 min.	4 hours	00-20	160 psi	8 psi	845%	30 pli	< .001 in./in.
Ecoflex® 00-10	14,000 cps	1.04	26.6	30 min.	4 hours	00-10	120 psi	8 psi	800%	22 pli	< .001 in./in.

*All values measured after 7 days at 73°F/23°C

Mix Ratio: 1A:1B by volume or weight
Color: Translucent

Useful Temperature Range: -65°F to 450°F (-53°C to 232°C)
Dielectric Strength (ASTM D-147-97a)***:*** >350 volts/mil

PROCESSING RECOMMENDATIONS

PREPARATION... Safety – Use in a properly ventilated area ("room size" ventilation). Wear safety glasses, long sleeves and rubber gloves to minimize contamination risk. Wear vinyl gloves only. Latex gloves will inhibit the cure of the rubber.

Store and use material at room temperature (73°F/23°C). Warmer temperatures will drastically reduce working time and cure time. Storing material at warmer temperatures will also reduce the usable shelf life of unused material. These products have a limited shelf life and should be used as soon as possible.

Cure Inhibition – Addition-cure silicone rubber may be inhibited by certain contaminants in or on the pattern to be molded resulting in tackiness at the pattern interface or a total lack of cure throughout the mold. Latex, tin-cure silicone, sulfur clays, certain wood surfaces, newly cast polyester, epoxy, tin cure silicone rubber or urethane rubber may cause inhibition. If compatibility between the rubber and the surface is a concern, a small-scale test is recommended. Apply a small amount of rubber onto a non-critical area of the pattern. Inhibition has occurred if the rubber is gummy or uncured after the recommended cure time has passed.

Because no two applications are quite the same, a small test application to determine suitability for your project is recommended if performance of this material is in question.

To prevent inhibition, one or more coatings of a clear acrylic lacquer applied to the model surface is usually effective. Allow any sealer to thoroughly dry before applying rubber. Note: Even with a sealer, platinum silicones will not work with modeling clays containing heavy amounts of sulfur. Do a small scale test for compatibility before using on your project.

Safety First!

The Material Safety Data Sheet (MSDS) for this or any Smooth-On product should be read prior to use and is available upon request from Smooth-On. All Smooth-On products are safe to use if directions are read and followed carefully.

Keep Out of Reach of Children

Be careful. Use only with adequate ventilation. Contact with skin and eyes may cause irritation. Flush eyes with water for 15 minutes and seek immediate medical attention. Remove from skin with waterless hand cleaner followed by soap and water.

Important: The information contained in this bulletin is considered accurate. However, no warranty is expressed or implied regarding the accuracy of the data, the results to be obtained from the use thereof, or that any such use will not infringe upon a patent. User shall determine the suitability of the product for the intended application and assume all risk and liability whatsoever in connection therewith.

Applying A Release Agent - Although not usually necessary, a release agent will make demolding easier when pouring into or over most surfaces. Ease Release® 200 is a proven release agent for use with silicone rubber. Mann Ease Release® products are available from Smooth-On or your Smooth-On distributor.

IMPORTANT: To ensure thorough coverage, lightly brush the release agent with a soft brush over all surfaces of the model. Follow with a light mist coating and let the release agent dry for 30 minutes.

If there is any question about the effectiveness of a sealer/release agent combination, a small-scale test should be made on an identical surface for trial.

MEASURING & MIXING...

Before you begin, pre-mix Part B thoroughly. After dispensing required amounts of Parts A and B into mixing container (1A:1B by volume or weight), **mix thoroughly for 3 minutes making sure that you scrape the sides and bottom of the mixing container several times.** After mixing parts A and B, vacuum degassing is recommended to eliminate any entrapped air. Vacuum material for 2-3 minutes (29 inches of mercury), making sure that you leave enough room in container for product volume expansion.

POURING, CURING & MOLD PERFORMANCE...

For best results, pour your mixture in a single spot at the lowest point of the containment field. Let the rubber seek its level up and over the model. **A uniform flow will help minimize entrapped air.** The liquid rubber should level off at least 1/2" (1.3 cm) over the highest point of the model surface.

Curing / Post Curing - Allow rubber to cure as prescribed at room temperature (73°F/23°C) before demolding. Do not cure rubber where temperature is less than 65°F/18°C. **Optional:** Post curing the mold will aid in quickly attaining maximum physical and performance properties. After curing at room temperature, expose the rubber to 176°F/80°C for 2 hours and 212°F/100°C for one hour. Allow mold to cool to room temperature before using.

If Using As A Mold - When first cast, silicone rubber molds exhibit natural release characteristics. Depending on what is being cast into the mold, mold lubricity may be depleted over time and parts will begin to stick. No release agent is necessary when casting wax or gypsum. Applying a release agent such as Ease Release® 200 (available from Smooth-On) prior to casting polyurethane, polyester and epoxy resins is recommended to prevent mold degradation.

Thickening Ecoflex® Silicones - **THI-VEX®** is made especially for thickening Smooth-On's silicones for vertical surface application (making brush-on molds). Different viscosities can be attained by varying the amount of THI-VEX®. See the **THI-VEX® technical bulletin** (available from Smooth-On or your Smooth-On distributor) for full details.

Thinning Ecoflex® Silicones - Smooth-On's Silicone Thinner® will lower the viscosity of Ecoflex® silicones for easier pouring and vacuum degassing. A **disadvantage** is that ultimate tear and tensile are reduced in proportion to the amount of Silicone Thinner® added. ***It is not recommended to exceed 10% by weight of total system (A+B).*** See the Silicone Thinner® technical bulletin (available from Smooth-On or your Smooth-On distributor) for full details.

Mold Performance & Storage - The physical life of the mold depends on how you use it (materials cast, frequency, etc.). Casting abrasive materials such as concrete can quickly erode mold detail, while casting non-abrasive materials (wax) will not affect mold detail. Before storing, the mold should be cleaned with a soap solution and wiped fully dry. Two part (or more) molds should be assembled. Molds should be stored on a level surface in a cool, dry environment.

Call Us Anytime With Questions About Your Application.

Toll-free: **(800) 381-1733** Fax: **(610) 252-6200**

The new **www.smooth-on.com** is loaded with information about mold making, casting and more.

Dragon Skin® Series

Addition Cure Silicone Rubber Compounds

Cured Material Certified Skin Safe!

www.smooth-on.com

PRODUCT OVERVIEW

Dragon Skin® silicones are high performance platinum cure liquid silicone compounds that are used for a variety of applications ranging from creating skin effects and other movie special effects to making production molds for casting a variety of materials. Because of the **superior physical properties** and flexibility of Dragon Skin® rubbers, they are also used for medical prosthetics and cushioning applications. Dragon Skin® rubbers are also used for a variety of industrial applications and have a service temperature range of a constant -65°F to +450°F (-53°C to +232°C).

Great for Making Molds for a Variety of Applications - Available in **Shore 10A, 20A and 30A**, Dragon Skin® silicones can be used to make exceptionally strong and tear resistant molds for casting plaster, wax, concrete (limited production run), resins and other materials.

Time Tested, Versatile Special Effects Material – Soft, super-strong and stretchy, Dragon Skin® 10 (**Very Fast, Fast, Medium and Slow speeds**) is used around the world to make spectacular skin and creature effects. An infinite number of color effects can be achieved by adding Silc Pig® silicone pigments or Cast Magic® effects powders. Cured rubber can also be painted with the Psycho Paint® system. Cured material is skin safe and certified by an independent laboratory to ISO 10993-10, Biological evaluation of medical devices, Part 10: Tests for irritation and skin sensitization.

Easy To Use – Dragon Skin® silicones are mixed 1A:1B by weight or volume. Liquid rubber can be thinned with Silicone Thinner® or thickened with THI-VEX®. Rubber cures at room temperature (73°F/23°C) with negligible shrinkage. ***Vacuum degassing is recommended to minimize air bubbles in cured rubber.***

TECHNICAL OVERVIEW

	Mixed Viscosity (ASTM D-2393)	Specific Gravity (g/cc) (ASTM D-1475)	Specific Volume (cu. in./lb.) (ASTM D-1475)	Pot Life (ASTM D-2471)	Cure Time	Shore A Hardness (ASTM D-2240)	Tensile Strength (ASTM D-412)	100% Modulus (ASTM D-412)	Elongation at Break % (ASTM D-412)	Die B Tear Strength (ASTM D-624)	Shrinkage (in./in.) (ASTM D-2566)
Dragon Skin® 10 Very Fast	23,000 cps	1.07	25.8	4 min.	30 min.	10A	475 psi	22 psi	1000%	102 pli	< .001 in./in.
Dragon Skin® 10 Fast	23,000 cps	1.07	25.8	8 min.	75 min.	10A	475 psi	22 psi	1000%	102 pli	< .001 in./in.
Dragon Skin® 10 Medium	23,000 cps	1.07	25.8	20 min.	5 hours	10A	475 psi	22 psi	1000%	102 pli	< .001 in./in.
Dragon Skin® 10 Slow	23,000 cps	1.07	25.8	45 min.	7 hours	10A	475 psi	22 psi	1000%	102 pli	< .001 in./in.
Dragon Skin® 20	20,000 cps	1.08	25.6	25 min.	4 hours	20A	550 psi	49 psi	620%	120 pli	< .001 in./in.
Dragon Skin® 30	30,000 cps	1.08	25.7	45 min.	16 hours	30A	500 psi	86 psi	364%	108 pli	< .001 in./in.

Mix Ratio: 1A:1B by volume or weight
Color: Translucent
Useful Temperature Range: -65°F to +450°F (-53°C to +232°C)
Dielectric Strength (ASTM D-147-97a)**:** >350 volts/mil

*All values measured after 7 days at 73°F/23°C

PROCESSING RECOMMENDATIONS

PREPARATION... Safety – Use in a properly ventilated area ("room size" ventilation). Wear safety glasses, long sleeves and rubber gloves to minimize contamination risk. Wear vinyl gloves only. Latex gloves will inhibit the cure of the rubber.

Store and use material at room temperature (73°F/23°C). Warmer temperatures will drastically reduce working time and cure time. Storing material at warmer temperatures will also reduce the usable shelf life of unused material. These products have a limited shelf life and should be used as soon as possible.

Cure Inhibition – Addition-cure silicone rubber may be inhibited by certain contaminants in or on the pattern to be molded resulting in tackiness at the pattern interface or a total lack of cure throughout the mold. Latex, tin-cure silicone, sulfur clays, certain wood surfaces, newly cast polyester, epoxy, tin cure silicone rubber or urethane rubber may cause inhibition. If compatibility between the rubber and the surface is a concern, a small-scale test is recommended. Apply a small amount of rubber onto a non-critical area of the pattern. Inhibition has occurred if the rubber is gummy or uncured after the recommended cure time has passed.

Because no two applications are quite the same, a small test application to determine suitability for your project is recommended if performance of this material is in question.

Safety First!

The Material Safety Data Sheet (MSDS) for this or any Smooth-On product should be read prior to use and is available upon request from Smooth-On. All Smooth-On products are safe to use if directions are read and followed carefully.

Keep Out of Reach of Children

Be careful. Use only with adequate ventilation. Contact with skin and eyes may cause irritation. Flush eyes with water for 15 minutes and seek immediate medical attention. Remove from skin with waterless hand cleaner followed by soap and water.

Important: The information contained in this bulletin is considered accurate. However, no warranty is expressed or implied regarding the accuracy of the data, the results to be obtained from the use thereof, or that any such use will not infringe upon a patent. User shall determine the suitability of the product for the intended application and assume all risk and liability whatsoever in connection therewith.

Cure Inhibition – To prevent inhibition, one or more coatings of a clear acrylic lacquer applied to the model surface is usually effective. Allow any sealer to thoroughly dry before applying rubber. Note: Even with a sealer, platinum silicones will not work with modeling clays containing heavy amounts of sulfur. Do a small scale test for compatibility before using on your project.

Applying A Release Agent - Although not usually necessary, a release agent will make demolding easier when pouring into or over most surfaces. Ease Release® 200 is a proven release agent for making molds with silicone rubber. Mann Ease Release® products are available from Smooth-On or your Smooth-On distributor.

IMPORTANT: To ensure thorough coverage, lightly brush the release agent with a soft brush over all surfaces of the model. Follow with a light mist coating and let the release agent dry for 30 minutes.

If there is any question about the effectiveness of a sealer/release agent combination, a small-scale test should be made on an identical surface for trial.

MEASURING & MIXING...

Before you begin, pre-mix Part B thoroughly. After dispensing required amounts of Parts A and B into mixing container (1A:1B by volume or weight), **mix thoroughly for 3 minutes making sure that you scrape the sides and bottom of the mixing container several times.** After mixing parts A and B, vacuum degassing is recommended to eliminate any entrapped air. Vacuum material for 2-3 minutes (29 inches of mercury), making sure that you leave enough room in container for product volume expansion.

POURING, CURING & MOLD PERFORMANCE...

For best results, pour your mixture in a single spot at the lowest point of the containment field. Let the rubber seek its level up and over the model. **A uniform flow will help minimize entrapped air.** The liquid rubber should level off at least 1/2" (1.3 cm) over the highest point of the model surface.

Curing / Post Curing - Allow rubber to cure as prescribed at room temperature (73°F/23°C) before demolding. Do not cure rubber where temperature is less than 65°F/18°C. **Optional:** Post curing the mold will aid in quickly attaining maximum physical and performance properties. After curing at room temperature, expose the rubber to 176°F/80°C for 2 hours and 212°F/100°C for one hour. Allow mold to cool to room temperature before using.

If Using As A Mold - When first cast, silicone rubber molds exhibit natural release characteristics. Depending on what is being cast into the mold, mold lubricity may be depleted over time and parts will begin to stick. No release agent is necessary when casting wax or gypsum. Applying a release agent such as Ease Release® 200 (available from Smooth-On) prior to casting polyurethane, polyester and epoxy resins is recommended to prevent mold degradation.

Thickening Dragon Skin® Silicones - **THI-VEX®** is made especially for thickening Smooth-On's silicones for vertical surface application (making brush-on molds). Different viscosities can be attained by varying the amount of THI-VEX®. See the **THI-VEX® technical bulletin** (available from Smooth-On or your Smooth-On distributor) for full details.

Thinning Dragon Skin® Silicones - Smooth-On's **Silicone Thinner®** will lower the viscosity of Dragon Skin® for easier pouring and vacuum degassing. **A disadvantage** is that ultimate tear and tensile are reduced in proportion to the amount of **Silicone Thinner®** added. ***It is not recommended to exceed 10% by weight of total system (A+B).*** See the **Silicone Thinner® technical bulletin** (available from Smooth-On or your Smooth-On distributor) for full details.

Mold Performance & Storage - The physical life of the mold depends on how you use it (materials cast, frequency, etc.). Casting abrasive materials such as concrete can quickly erode mold detail, while casting non-abrasive materials (wax) will not affect mold detail. Before storing, the mold should be cleaned with a soap solution and wiped fully dry. Two part (or more) molds should be assembled. Molds should be stored on a level surface in a cool, dry environment.

Call Us Anytime With Questions About Your Application.

Toll-free: **(800) 381-1733** Fax: **(610) 252-6200**

The new **www.smooth-on.com** is loaded with information about mold making, casting and more.

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