A training phantom for a vesicovaginal fistula repair with the transvaginal approach

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***Abstract*—*Background*: In Africa, many women suffer from vesicovaginal fistulas. In this study, a phantom model for a vesicovaginal fistula repair was developed that can be produced and used in Africa, to train medical doctors in the treatment of simple fistulas by the transvaginal approach.**
***Method of production*: The phantom consists out of 3D printed PLA parts and silicone parts. The framework and the moulds for the required organs were 3D printed with PLA, and silicone was then poured into the moulds. To determine which tissue-mimicking silicone material to use, a test focused on the tendency to rupture, and a tensile test were performed. It followed that to mimic the vaginal tissue, Dragon Skin 10 with 11% silicone oil was most suitable. To mimic the bladder tissue both Dragon Skin 10 with 11% silicone oil and Dragon Skin 10 with Slacker could be suitable. Therefore, two bladders with both materials were made. The cervix, the vulva, and a plate that closes off the bladder were all made with Dragon Skin 10 without an additive. To mimic the urethra a tube of natural rubber was used, and to mimic the connecting fascia between the bladder and vagina and to connect the organs silicone glue was used.**
***Testing results*: A clinical validation test was performed by two dutch gynaecologists to validate the overall initial model, the representation of the materials, and whether the procedural steps of excising, dissecting, and suturing of the tissue could be performed. The water-tightness was not tested in this stage yet. It mainly followed that the angle of the model should be adjusted to the Trendelenburg position and that the working space should be broadened. Both improvements were processed in an updated final model, on which a secondary test was performed by a pelvic surgeon. In this stage also a water-tightness test was performed, from which it followed that the bladder with Slacker became watertight after suturing, the bladder with silicone oil, however, did not. Therefore, Dragon Skin 10 with Slacker is most suitable for mimicking the bladder tissue. The material costs for the permanent parts of the final phantom model are €14,23 and for the replaceable parts, the material costs are €5,38.**
***Conclusion*: All procedural steps could be performed on the final phantom model without any problems. And, the model can be produced locally, while keeping the costs low. Overall, the model is suitable to be used as a phantom to train medical doctors in the treatment of a simple vesicovaginal fistula repair with the transvaginal approach.**

***Index Terms*—Vesicovaginal fistula, transvaginal approach, phantom, suturing, tissue-mimicking material, silicone, 3D printing**

I. Introduction

It is estimated that in Africa 30.000 to 130.000 new cases arise annually and a total of 3 million women suffer from untreated vesicovaginal fistulas in low resource countries worldwide [1, 2, 3, 4]. A vesicovaginal fistula is an abnormal communication between the bladder and vagina (see figure 1), that can result in urine leakage through the vagina. This does not only lead to physical but also psychological problems [1, 2, 3, 4, 5, 6]. In developing countries, the most common cause of a vesicovaginal fistula is obstructed labour [1, 2, 3, 4]. During obstructed labour the pressure of the baby's head can obstruct the blood flow in the tissue between the vagina and bladder, which results in oxygen shortage leading to the tissue dying away, leaving a hole between these cavities [1, 2, 7]. Factors that impact the high rate of cases in low resource countries are early childbearing (before full pelvic growth is achieved), poor socioeconomic status, low literacy rate, malnourishment, inadequately developed infrastructure for health care for pregnant women and lack of access to emergency obstetric services [1, 3, 4, 5, 6]. Some consequences of obstructed labour are stigmatization and social isolation because it is often seen as a punishment from God and patients are abandoned by their families because of the smell of urine [1, 5, 7].

Figure 1: *Vesicovaginal fistula [8].*

The majority of vesicovaginal fistulas require surgery [2, 3]. To improve the outcome of the surgery, the doctors performing the procedures must be well trained. In Africa where the condition is most common, a lot of medical doctors are not familiar with this procedure, causing patients suffering from a vesicovaginal fistula to have to travel to specialised clinics to receive treatment. While 25% of patients with a vesicovaginal fistula could easily be cured with a near 100% success rate [9]. In this study, we developed a phantom model for a vesicovaginal fistula repair that can be produced and used in Africa to train medical doctors in the treatment of simple fistulas.

Structure

Subsequent to the introduction some background is given on phantom models, and simple fistulas and the transvaginal approach are explained (section II). Moreover, the requirements for the phantom model are stated. Thereafter, the method of production of the phantom model is addressed in three sub chapters (section III). Firstly, the development of the 3D printed moulds and parts are presented (section III-A). Secondly, the results of material tests on different silicone materials are presented to explain the choice of the material combination for mimicking the tissues (section III-B). Lastly, the fabrication steps of the initial model are described (section III-C). Afterward, the methodology and results of a clinical validation test, performed with two experienced gynaecologists on the initial model, is described in section IV. This resulted in some improvements which are presented and processed in a final model (section V). This final model is tested by a pelvic surgeon in a secondary test, of which the methodology and results are presented in section VI. Next to the secondary test, the costs of the initial model and final model are determined and compared (section VII). After that, an additional material test is performed on the difference in tendency to rupture between samples with continuous and interrupted sutures (section VIII). The phantom model is then discussed (section IX), after which a short conclusion follows (section X).

II. Background

Phantoms are artificial models that represent anatomical structures of parts of the body with tissue-mimicking materials that can be used in medical research or training [10, 11]. Most phantoms of the female pelvis are focused on imaging, for example a study by Kadoya et al. involving CT images of all pelvic organs, or the studies of Choi et al. and Lurie et al. involving the endoscopic view of the bladder [12, 13, 14]. A few researches looked at needle insertion [10, 15, 16], but sutures were rarely used, only by Nattagh et al. [11]. The phantom made in this current study is unique because it involves suturing and addresses the transvaginal approach of the vesicovaginal fistula repair, which is not done before. This phantom model is focused on the treatment of simple fistulas, which are classified as singular, under 4 cm in diameter, without urethral involvement, without scarring of vaginal tissue, and not circumferential [17].

In low resource countries, the majority of fistulas are treated with the transvaginal approach [5]. This is most preferred, because of its simplicity and efficacy and it minimises the operative complications, the hospital stay, the blood loss, and the pain following the procedure while achieving equal success rates [3, 4, 5, 18, 19, 20, 21]. Table I provides a short overview of the basic transvaginal approach (see Appendix A for a more detailed description of the procedural steps of the approach).

Table I: Procedural steps of the basic transvaginal approach [22].

Step 1: Exposure of fistula, ensure no other fistula is present.
Step 2: Mobilize the bladder and excise scar tissue around the fistula tract i.e. dissect the vagina of the endopelvic fascia and bladder.
Step 3: Close the bladder watertight without tension and then do a dye test to confirm closure and then decompress the bladder with a catheter.
Step 4: Closure of the vagina and ensure good haemostasis.

Important requirements for the phantom model, that followed from the procedural steps, are:
- that the scar tissue of the fistula should be mimicked;
- that forceps should be able to be used on the materials mimicking the vagina;
- that the vaginal wall should be able to be incised by a scalpel;
- that the wall of the bladder and the vagina should be connected by a thin layer and that the vaginal wall can be dissected away from the bladder wall;
- that the material for the bladder should be able to become watertight by suturing;
- and that the bladder should be able to be filled with liquid to test this water-tightness.

Another important requirement is that it should be possible to produce the phantom model locally.

III. Method of the phantom production

A. 3D printing

The CAD software SolidWorks was used to design different moulds for each part of the phantom model. The moulds were 3D printed with PLA in an Ultimaker 2+. PLA was chosen due to its high printability and low price [23]. Since 3D printers are available in low resource settings, using this method makes it possible to produce the model locally. Furthermore, a package with the CAD models and a short instruction can easily be transferred so that it can be reproduced locally.

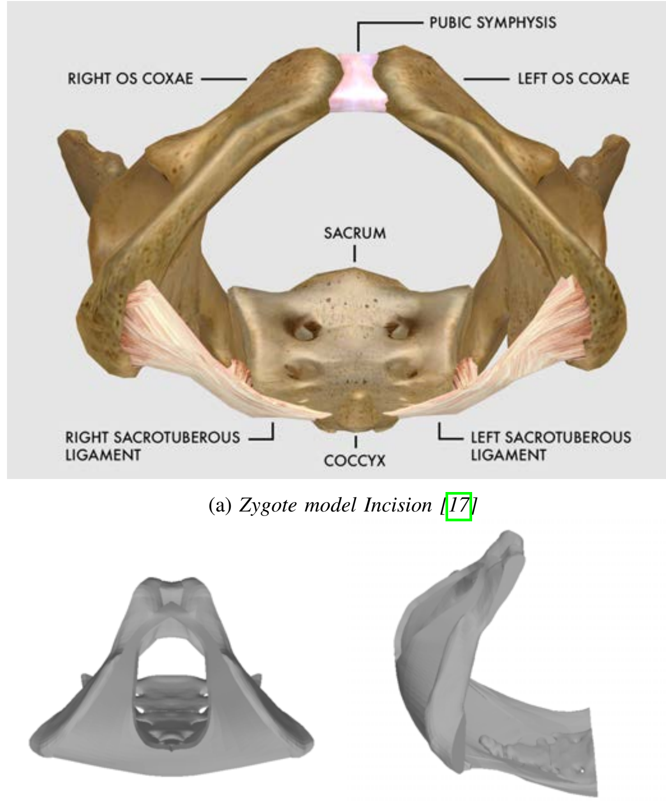
For a *bladder* of about 180 mL and 3 mm thickness a mould consisting of two parts was designed, including a hole of 8 mm for the urethra and a hole of 13 mm to connect the bladder to the fistula. The volume of the bladder was chosen because it should be possible to fill the bladder up to about 180 mL in order to perform a dye test [9, 22, 24]. Moreover, the thickness corresponds to real bladder tissue [25]. A different mould, consisting of two parts, was designed for a circular plate of 3 mm to close the bladder off (see Appendix B-A for a depiction and technical drawing of the moulds for the bladder).

Moreover, a mould, consisting of four parts, was designed to produce a *vagina* of 2 mm thickness with an inner diameter of 5 cm including a hole of 11 mm with a thickened edge at both sides to represent the fistula. This thickened edge increases the stiffness of the material and thereby mimics the scar tissue of the *fistula*. The thickness and diameter of the vagina were determined based on the dimensions of real vaginal tissue [26, 27]. The length of the vagina is 11 cm, which is slightly longer than the found values in literature of 8-10 cm [28, 29] because the cervix will hang about 12 mm in the vagina, and an extra margin is added so that it can be secured to the frame (see Appendix B-B for a depiction and technical drawing).

Moulds for the *cervix* and for the *vulva*, each consisting of two parts, were also designed to make the appearance inside and outside the vagina more realistic (see Appendix B-C and B-D for a depiction and technical drawing of the moulds). The vulva was simplified and designed in a distended position, so the vagina could still be entered easily.

Each mould had a hole at the bottom to clamp in the syringe and a smaller hole inside this hole to inject the silicone, furthermore, air holes were made on top. The hole for the syringe was placed at the bottom so the silicone evenly levels up and any trapped air would move up to the air holes on top. Each mould had a small 3D printed pin to close off the hole of the syringe. For the bladder, this hole was closed off by a larger pin that matches the shape of the inner mould of the bladder at the tip, to leave a hole for the urethra (see Appendix B-A).

A zygote model of a female with realistic measurements made by the company Incision was used to export a model of the female pelvis with realistic size and shape of (parts of) the left and right os coxae, the sacrum, the coccyx, the pubic symphysis and the left and right sacrotuberous ligaments, with a layer of skin to fill the gap (see figure 2). It was chosen to leave an opening of about 75x45 mm for the vagina in the skin, over which the vulva could be secured. The model was 3D printed with PLA in an Ultimaker 2+ and a frame was built around it in SolidWorks and also 3D printed with PLA, to secure the organs inside the model (see appendix B-E for a depiction and technical drawing of the framework). It was chosen to place the sacrum more or less parallel to the table with the lithotomy position of the patient in mind [9, 24]. The angle of the framework where the bladder is placed was determined at 30 degrees. This way, the vagina that is attached to the bladder is parallel to the sacrotuberous ligaments and the coccyx. The 3D printed parts of the frame were connected with hard PVC glue [30].



(a) *Zygote model Incision [17]*

(b) *Front view of exported model with skin*

(c) *Side view of exported model with skin*

Figure 2: *Exported zygote model.*

B. Silicone materials

The tissue-mimicking material representing the bladder and vagina was chosen after a previously performed experimental study on suitable materials (see Appendix C for an elaborated description of this study). In this study, the tendency to rupture of different materials was tested. Samples of 50x50x2 mm, with a sutured hole in the middle representing the fistula, were placed in a linear stage actuator with a stepper motor. The stage slid up until 62.5 mm extending the silicone sample at a rate of 1.65 mm/s. The force acting on the sample during this extension was measured by a load cell over a loop time of 100 ms. A video was made aligning the graph and the top view of the sample in the stage. This way, it could be determined at which time and force the suture started to rupture. From the test on the two material combinations with the highest potential, it followed that Dragon Skin with Slacker took significantly longer to start to rupture than Dragon Skin with 11% silicone oil (mean = 12892 vs 8427 ms, $P = 0.002253$) (see figure 3). This indicates that Dragon Skin with Slacker will stay watertight when under tension longer than Dragon Skin with silicone oil.

Furthermore, tests were performed on a tensile machine to determine the stress-strain curve and thereby the E-modulus, by calculating the slope of the curve from 1% to 5% strain, of the two material combinations (see figure 4) (see Appendix C for an elaborated description of this experiment). The E-modulus of the sample of Dragon Skin with silicone oil (0.1967 MPa) was closest to the E-modulus of real bladder tissue (0.25 and 2.1 MPa [31, 32]). However, the E-modulus

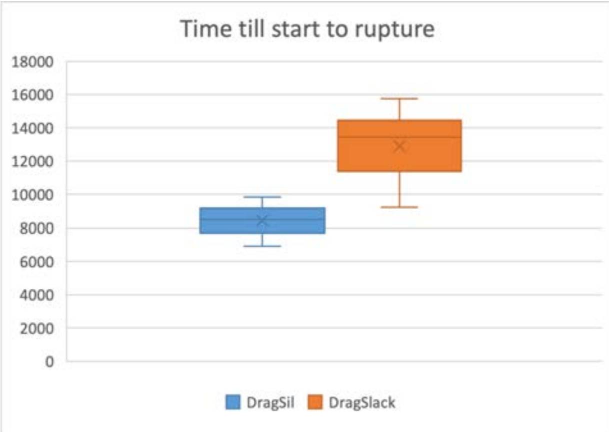
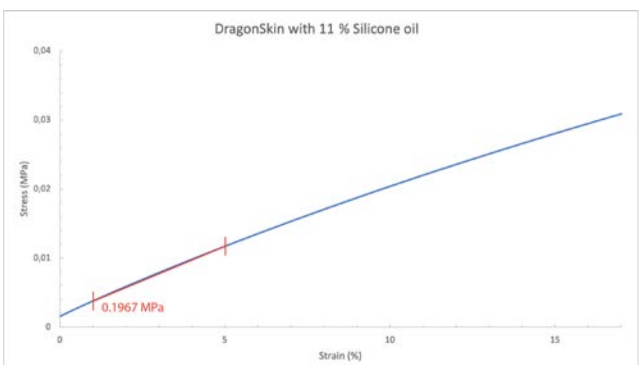
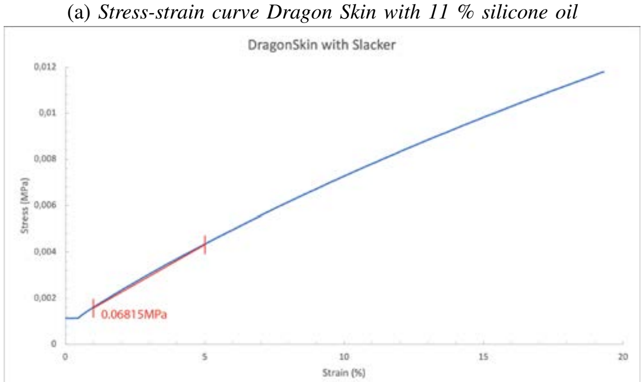


Figure 3: *Box plot presenting the scatter of the time rupture starts of Dragon with silicone (DragSil) and Dragon with Slacker (DragSlack).*

of the sample with Slacker (0.06815 MPa) was closest to the slope of the stress-strain curve of bladder tissue at small deformations (0.04 MPa [33]). Therefore, both materials might be suitable to mimic the bladder tissue. To make a definitive decision on the most suitable material, a water-tightness test will be performed later in the process. For the vaginal tissue, the E-modulus of the sample with silicone oil (0.1967 MPa) was closest to the slope of the stress-strain curve at small deformations (0.10 and 0.50 MPa [33, 34]). Therefore, this material is most suitable to mimic vaginal tissue.



(a) *Stress-strain curve Dragon Skin with 11 % silicone oil*



(b) *Stress-strain curve Dragon Skin with Slacker*

Figure 4: *Determination of E-modulus from stress-strain curves*

Based on the material test, it was chosen to use Dragon Skin 10 with 11% silicone oil to represent the *vaginal tissue*, and a mauve liquid silicone pigment was added. For the *bladder tissue*, it was chosen to make two models. In one model Dragon Skin 10 with 11% silicone oil was used and in the other model Dragon Skin 10 with Slacker was used, and a yellow liquid silicone pigment was added to both. For the *vulva*, *cervix* and the plate that closes off the bladder, Dragon Skin 10 was used without an additive, only brown, mauve and yellow liquid silicone pigments were added, respectively. No additive was added because the feeling of these parts is of less importance because they are not involved in the procedure, and adding an additive is more expensive.

To mimic the *urethra* a tube of yellow natural rubber with an inner diameter of 6 mm and an outer diameter of 10 mm was used. This size was chosen because a catheter of 16 Fr must be able to enter the urethra and it matches the diameter and wall thickness of the female urethra [35, 36]. The length of the urethra was about 4 cm long, corresponding to the 3-4 cm in reality [28, 37].

C. *Fabrication of the phantom model*

To fabricate the model, the silicone parts were made in the moulds. Release agent was sprayed on the separate parts of the moulds and dried for a few minutes at room temperature, then the parts were connected by bolts and nuts. The silicone was mixed in a paper cup with a wooden spatula to the required ratio and poured into the syringe. After vacuum was applied in the syringe, as similarly done in Appendix C, silicone was injected into the mould. After pounding the bottom of the mould at the table a few times to release the air bubbles, the silicone cured for at least eight hours.

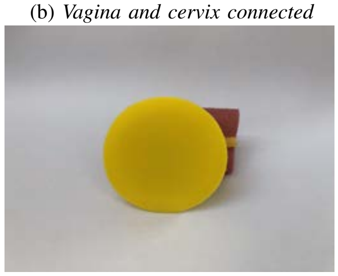
To connect the plate to the bladder, the bladder with the urethra and the vagina with the cervix, the surfaces were degreased with alcohol and a silicone glue, Elastosil E43, was used [38]. This was also used to mimic the connecting fascia between the bladder and the vagina and to connect the bladder to the fistula. After applying glue to the vagina about 2 cm around the fistula's hole, the bladder's hole was stretched over the thickened edge of the fistula in the vagina. Pressure was then applied for at least 10 hours by wrapping an elastic band around the glued area with a hard tube inside the vagina to maintain the shape. Figure 5 depicts the intermediate stages in connecting the silicone parts.

The holes in the 3D printed framework where the vulva and vagina are secured were made with a hand drill size 4 mm. The vulva was attached to the framework with eight bolts and nuts size M3 and length of 16 mm, with a sheet-metal ring on each side. After the vagina was attached to the bladder, it was secured at the back of the two bolts at the bottom and the two bolts at the top. The holes in the silicone of the vagina were made using a revolving hole punch. Figure 6 depicts the total assembled model.

(a) *Bladder and urethra connected*

(b) *Vagina and cervix connected*

(c) *Bladder and vagina connected*

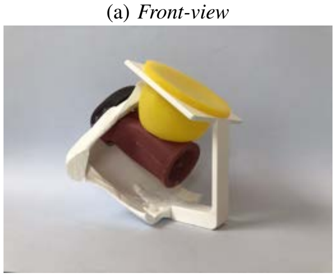


(d) *Bladder plate connected and urethra cut to the correct length*

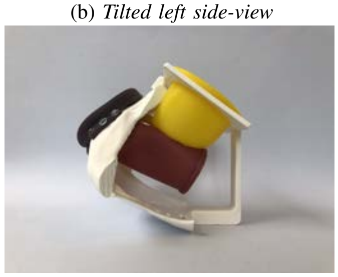
Figure 5: *Intermediate stages in connecting the silicone parts.*

(a) *Front-view*

(b) *Tilted left side-view*



(c) *Tilted right side-view*



(d) *Side-view*

Figure 6: *Total assembled model.*

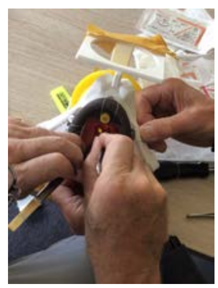
IV. Clinical validation test with the initial model

A. Test methodology

To determine whether the phantom model can be used as a training model, which adjustments are necessary and which material represents the bladder best, a qualitative test was performed. Two dutch gynaecologists, who performed many vesicovaginal fistula repairs, were asked to perform the procedure of the vaginal approach for a vesicovaginal fistula repair on the phantom model. They were asked to verbally comment on their findings while performing the procedure. Afterwards, a questionnaire with a Likert scale from one to five (strongly disagree to strongly agree) was used to map out their opinions in a nuanced way [39] (Appendix D). In this test the main focus was to validate the overall initial model, the representation of the materials, and whether the procedural steps of excising, dissecting, and suturing of the tissue could be performed. The water-tightness of the sutures in the bladder was not tested in this stage yet.

B. Test results

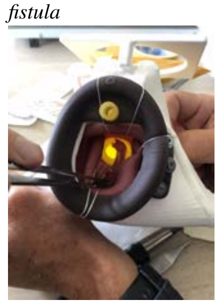
Both gynaecologists performed the procedure in their own manner. The first gynaecologist started by incising the vaginal tissue about 2 cm away from the bladder, then separating the bladder and the vagina wall by dissecting the vagina from the fascia and then cutting away the fibrous ring (see figure 7). While the second gynaecologist first removed the fibrous ring and then separated the walls by dissecting the vagina from the fascia. They both used a continuous suture to close the bladder and the vagina. Table II provides an overview of the scores on realistic anatomical properties and feeling of the organs given by the first and second gynaecologist, respectively. Table III provides an overview of the scores on the procedural steps, given by the first and second gynaecologist, respectively.



(a) *Incising around the fistula*

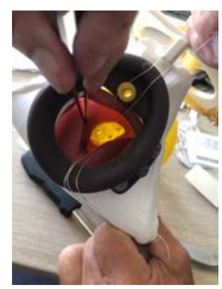
(b) *Preparing the walls*

(c) *Preparing the walls*



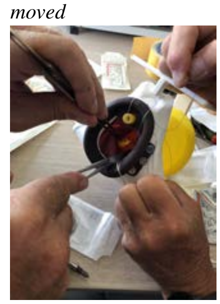
(d) *Cutting away fibrous ring*

(e) *Fibrous tissue removed*

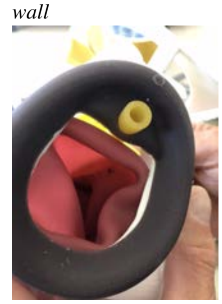


(f) *Suturing bladder wall*

(g) *Bladder wall closed*



(h) *Suturing vaginal wall*



(i) *Vaginal wall closed*

Figure 7: *Pictures of the procedure performed on the phantom model.*

Table II: Scores of the two gynaecologists on the realistic anatomical properties and feeling of the organs.

	Bladder (Slacker/silicone oil)	Vagina	Urethra	Cervix	Vulva	Fistula
Realistic anatomical properties	4/4 – 4/4	4 – 4	5 – 4	5 – 5	4 – 2	5 – 5
Realistic feeling	4/4 – 4/4	4 – 4	5 – 4	5 – 5	4 – 1	5 – 4

Table III: Scores of the two gynaecologists on the procedural steps.

Procedural step	**Scores**
Locating the fistula is realistic	4 – 4
Exposing the fistula is realistic	4 – 3
Incising the vaginal tissue is realistic	4 – 4
Incising the bladder tissue is realistic	4 – 4
Separating the bladder tissue from the vaginal tissue is realistic	4 – 2
Suturing the bladder tissue is realistic	4 – 4
Suturing the vaginal tissue is realistic	4 – 4
The phantom model is suited to be used for training purposes	4 – 4

1) First gynaecologist

The first gynaecologist was asked to perform the entire procedure on the model with the bladder made out of Dragon Skin with Slacker. Due to time management only the suturing was tested on the model with the bladder made out of Dragon Skin with silicone oil, since the rest of the procedural steps are the same.

The first score in each column in table II presents the given score of the first gynaecologist based on realistic anatomical properties and feeling of the organs. And the first score in each row in the scores column in table III presents the given score of the first gynaecologist based on the realistic performance of the procedural steps. These findings are strengthened by the comment that incising and suturing the tissue feels realistic and the ring that represents the fistula feels realistic. During and after the experiment some comments were given regarding the model, which are presented in this paragraph. Firstly, the angle from which you look in the model should be more tilted like the Trendelenburg position. Moreover, the bladder can be pulled through the frame, however, this is not a problem. In reality, it can also be pulled down, some fistula surgeons even pull the bladder out entirely. In addition, it would be valuable if the pelvis can move around a bit because, in reality, you can also move the patient. Furthermore, traction sutures were used to pull the vaginal wall out more and expose the fistula, it would be beneficial to be able to secure these to the model. Additionally, preparing the wall by incising around the fistula and separating the walls of the bladder and vagina takes some getting used to, but in real life, there are also more difficult and more easy parts. It usually is a bit easier to pull the fistula towards you when it is incised and then the fascia becomes easier to cut. Nevertheless, cutting the fistula loose entirely feels like real life. Lastly, the bladder could be closed without tension, closing the vagina without tension was a bit more difficult, however, after preparing the wall broader, this could also be done.

2) Second gynaecologist

The second gynaecologist was asked to perform the procedure on the model with the bladder made out of Dragon Skin with silicone oil. Due to time management only the suturing was tested on the model with the bladder made out of Dragon Skin with Slacker, since the rest of the procedural steps are the same. For testing the model with the second gynaecologist, we adjusted the angle of the framework in the Trendelenburg position by adding a block underneath.

The second score in each column in table II presents the given score of the second gynaecologist based on realistic anatomical properties and feeling of the organs. The vulva scored a two based on realistic anatomical properties and a one on realistic feeling because the edge was too stiff, which limits the working area. The second score in each row in the scores column in table III presents the given score of the second gynaecologist based on the realistic performance of the procedural steps. Separating the bladder tissue from the vaginal tissue scored a two, because the walls were too difficult to separate from each other. However, suturing the tissue feels realistic. During and after the experiment some comments were given regarding the model, which are presented in this paragraph. Firstly, the angle of the model is good. However, the angle that the forceps have to make to work around the fistula is difficult, using traction sutures helps a bit, but the sides of the model are not able to broaden. This stiffness limits the working area, normally you can push the vulva to the sides more. Moreover, the width of the connecting fascia may be a bit more broadened and less strongly connected for preparing the tissue. Furthermore, while pulling the bladder down, the urethra became loose. In addition, the walls of the vagina are a bit stiff, so sometimes the folds limit the vision. The size of the fistula may be a bit smaller, but not so small that it only needs a few sutures. Overall, the model does approach reality.

V. Processed improvements in a final model

After the tests performed with the gynaecologists, there were some points, that could be altered for improvement. To start with, regarding the framework, the angle should be adjusted to a Trendelenburg position to get the correct angle to perform the procedure, as also explained in the book by Campbell [24]. In the final model this angle was adjusted to 65 degrees, and the bladder was placed a bit lower to be able to pull it down better (see appendix E for a depiction and technical drawing of the updated framework). Furthermore, the working space in the initial model was limited due to the hard 3D printed skin of PLA. In addition, the vulva was too stiff also limiting the working space. To improve this, in the final model the gap in the 3D printed model was broadened. This gap was filled by a new version of the vulva with thinner labia and more silicone on the sides, representing skin (see appendix E for a depiction and technical drawing of the updated mould for the vulva).

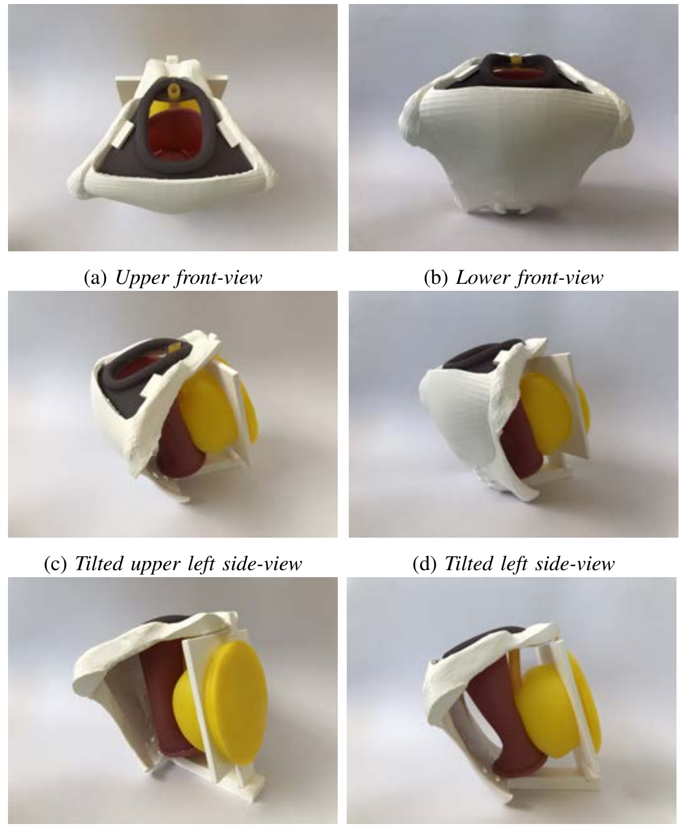
Regarding the procedure there were also some improvement suggestions. Separating the bladder wall from the vaginal wall was too difficult in the model tested with the second gynaecologist, because the layer of silicone glue that represents the fascia was too thick. During the fabrication of this model, there were some struggles with connecting the bladder to the vagina which led to an extra layer of glue. In the final model, the layer of silicone glue representing the fascia was spread thinner and more even.

As followed from the test the silicone glue does not attach that well to the urethra, made out of natural rubber, leading to loosening of the urethra from the bladder. To overcome this problem the hole in the bladder can be made smaller to clamp in the urethra more, another glue, such as cyanoacrylate glue, can be used, or a texture could be created on the urethra to increase the adhesive surface. In the final model, the urethra was fixed to the bladder with cyanoacrylate glue, afterwards, a layer of silicone glue was added to seal the edges.

To expose the fistula more, often traction sutures are used, normally you can suture these in the skin of the patient. However, because the model is made out of PLA this was not possible. In the final model the traction sutures could be secured at the top and bottom of the 3D printed model and on the sides by surgical clamps.

To gain a more realistic look, the vulva was glued with cyanoacrylate glue to the framework instead of fixed with bolts and nuts. Also, the vagina was glued to the vulva. Figure 8 depicts the total assembled final version of the model.

In reality, the patient can be moved around a bit, therefore in a future model, it would be valuable if this is possible. A possibility is to use a ball joint vice to clamp in the model at the table [40]. However, this was not implemented in the final model since it is not certain that these are available in Africa.



(a) *Upper front-view* (b) *Lower front-view* (c) *Tilted upper left side-view* (d) *Tilted left side-view* (e) *Tilted right side-view* (f) *Side-view*

Figure 8: *Total assembled final model.*

VI. Secondary validation test with the final model

A. Test methodology

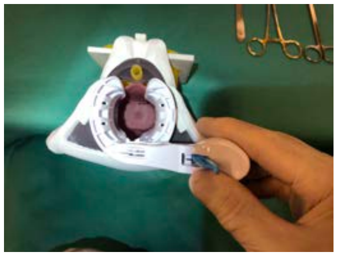
A pelvic surgeon was asked to perform all procedural steps on the final model. The surgeon used continuous sutures. In this stage, also a test was performed on the water-tightness of the two materials for the bladder. This was done by filling the bladder with brown-coloured liquid via the urethra after the bladder was sutured and checking for any leakage by holding a gauze against the suture (see figure 9l and 9m). It was chosen to do a gravity test to check for leakage [22]. During this test, only the barrel of the syringe is used, attached to the Foley catheter. Then the Foley catheter is pinched as the syringe is filled so the amount of liquid that goes into the syringe can be measured [22]. The syringe barrel is held about 20 cm above the urethral level and the liquid flows in by gravity. The syringe is continued to be filled until the liquid no longer flows [22]. In practice, this method is mainly used when it is expected that the bladder is small [22].

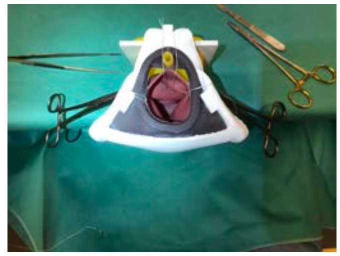
B. Test results

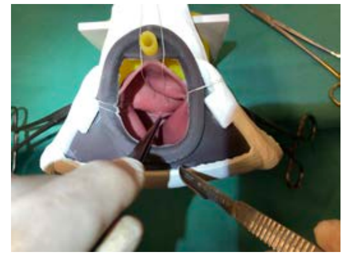
From this gravity test, it followed that the bladder made out of Dragon Skin with Slacker did not show any leakage. However, the bladder made out of Dragon Skin with 11% silicone oil did show leakage, mostly at the insertion points of the sutures (see figure 10). This indicates that Dragon Skin with Slacker is the most suitable material to mimic the bladder.

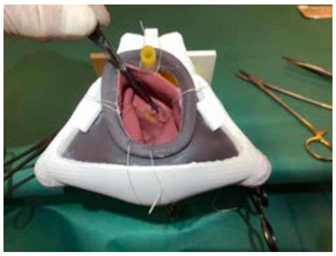
An overview of the procedural steps performed on the updated final phantom model is depicted in figure 9. After the steps were performed by the pelvic surgeon, it followed that the adjustments to the framework and vulva indeed led to more freedom in movement. Moreover, the traction sutures could easily be secured at the top and bottom of the 3D printed model and on the sides by surgical clamps (see figure 9c). All procedural steps could be performed on the final model without any problems.

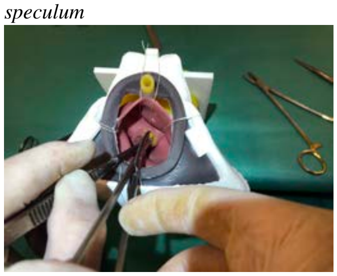

(a) *Required instruments*

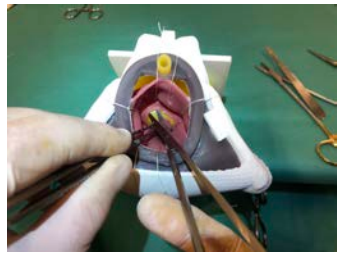

(b) *Fistula identification using a speculum*

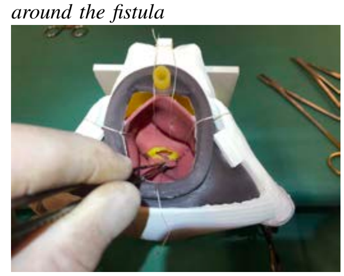

(c) *Fistula exposure using traction sutures*

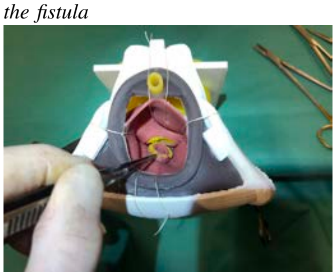

(d) *Ventral incision vagina wall around the fistula*


(e) *Dorsal incision vagina wall around the fistula*

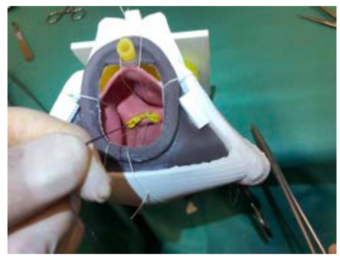

(f) *Dissection between the vaginal and bladder wall*

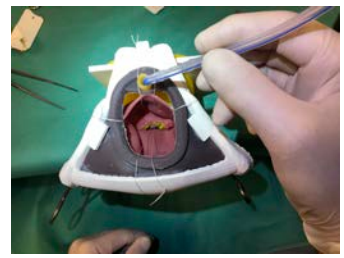

(g) *Dissection between the vaginal and bladder wall*

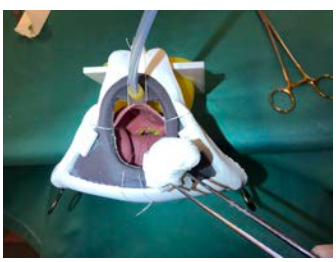

(h) *Excision of the fistula*

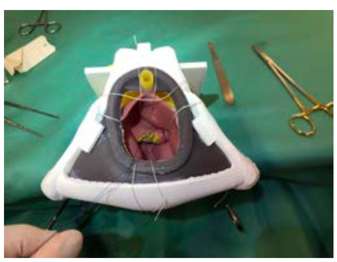

(i) *Excision of the fistula*

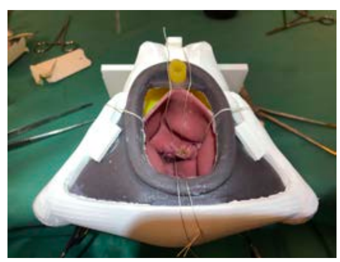

(j) *Bladder wall repair*


(k) *Bladder wall repair*


(l) *Inserting the catheter for the water-tigthness test*


(m) *Checking for leakage by filling the bladder with liquid and holding a gauze against the sutures*


(n) *Vaginal wall repair*


(o) *Vaginal wall repair*

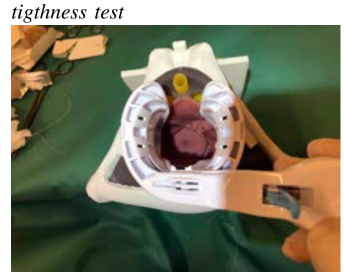

(p) *End result*

Figure 9: *Procedural steps performed on the phantom model.*


Figure 10: *Leakage at insertion points of the sutures in the bladder made out of Dragon Skin with 11% silicone oil.*

VII. Costs

Since the model will be made for low resource countries, it is desired to keep the costs low. Table IV and table V provide an overview of the material costs of the initial model for the replaceable and permanent parts separately. The costs for the needed, syringes, cups and stirring spatulas are not taken into account. The required amount of filament was estimated by the 3D printing software Cura.

As indicated in table IV the material costs for the bladder with Slacker are €0,67 higher than the material costs for the bladder with silicone oil.

Adjusting the model led to different permanent costs. Table

VI provides an overview of the new material costs of the permanent parts. The adjustments decreased the material costs of the permanent parts by €1,66.

Table IV: Cost overview replaceable parts of the initial model

Part	Material	Needed amount	Costs
Bladder	Dragon Skin 10, Slacker and yellow pigment	36 g of part A and B, 18 g Slacker and 0.1 g pigment	€1,36+€1,12+ €0,03 = €2,51 [41, 42, 43]
Bladder	Dragon Skin 10, silicone oil and yellow pigment	41 g of part A and B, 9.02 g silicone oil and 0.1 g pigment	€1,56+€0,25+ €0,03 = €1,84 [41, 43, 44]
Bladder top	Dragon skin 10 and yellow pigment	20 g of part A and B and 0.07 g pigment	€0,76+€0,02 = €0,78 [41, 43]
Vagina	Dragon Skin 10, silicone oil and mauve pigment	25 g of part A and B and 5.5 g silicone oil 0.1 g pigment	€0,96+€0,16+ €0,03 = €1,15 [41, 43, 44]
Cervix	Dragon Skin 10 and mauve pigment	5.5 g of part A and B and 0.4 g pigment	€0,21+€0,01 = €0.22 [41, 43]
Urethra	Natural rubber	5 cm	€0,09 [45]
Fascia and connections	Elastosil E43	app. 7.5 mL	€0,72 [38]
Total		**€5,38** (bladder with slacker) or **€4,71** (bladder with silicone oil)	

Table V: Cost overview permanent parts of the initial model

Part	Material	Needed amount	Costs
Vulva	Dragon Skin 10 + brown pigment	28 g of part A and B and 0.1 g pigment	€1,07+€0,03 = €1,10 [41, 43]
Bladder moulds	PLA filament	51.49 m	€2,93 [46]
Vagina mould	PLA filament	26,01 m	€1,48 [46]
Cervix mould	PLA filament	5.84 m	€0,33 [46]
Vulva mould	PLA filament	13.30 m	€0,76 [46]
Framework	PLA filament	31.06 m	€1,76 [46]
Connection of frame	Hard PVC glue	app. 1 mL	€0,03 [30]
Bolts and nuts for moulds	Metal	12 bolts M4, 12 nuts M4, 24 sheet metal rings M4, 30 bolts M3, 30 nuts M3, 60 sheet metal rings M3	€6,30 [47]
Bolts and nuts for framework	Metal	8 bolts M3 length 16 mm, 8 nuts M3, 16 sheet metal rings M3	€1,20 [47]
Total			**€15,89**

VIII. Material test on suture type

It differs per surgeon what type of suture is preferred, there are some clinical and experimental studies on the type of sutures but they have not concluded that one technique is superior to the other [49, 50]. For the closure of a vesicovaginal

Table VI: Cost overview permanent parts after processed improvements

Part	Material	Needed amount	Costs
Vulva	Dragon Skin 10 + brown pigment	25 g of part A and B and 0.1 g pigment	€0,96+€0,03 = €0,99 [41, 43]
Bladder moulds	PLA filament	51.49 m	€2,93 [46]
Vagina mould	PLA filament	26,01 m	€1,48 [46]
Cervix mould	PLA filament	5.84 m	€0,33 [46]
Vulva mould	PLA filament	11.85 m	€0,68 [46]
Framework	PLA filament	24.64 m 31.06 m	€1,40 [46]
Connection of frame	Hard PVC glue	app. 1 mL	€0,03 [30]
Bolts and nuts for moulds	Metal	12 bolts M4, 12 nuts M4, 24 sheet metal rings M4, 30 bolts M3, 30 nuts M3, 60 sheet metal rings M3	€6,30 [47]
Connection silicone parts	Cyanoacrylate glue	app. 1 g	€0,09 [48]
Total			**€14.23**

fistula, the standard is to use interrupted sutures, because this method may reduce the odds of dehiscence compared to a continuous suture [51, 52, 53]. However, the amount of suture material, the operative time and the effort of the surgeon are reduced when using continuous sutures [52]. To be able to give an advice on what type of suture to use, a test in the linear stage actuator with a stepper motor was performed, in the same way as in section III-B, to compare the effect of a continuous suture or interrupted sutures on samples of Dragon Skin with Slacker (see Appendix C for an elaborated description of this test in the experimental study on suitable materials).

(a) *The scatter of the time till rupture starts of 2 mm thick Dragon Skin with Slacker plates with interrupted and continuous sutures.*

(b) *The scatter of the time till rupture starts of 3 mm thick Dragon Skin with Slacker plates with interrupted and continuous sutures.*

Figure 11: *Box plots comparing the time till rupture starts of samples with interrupted (DragSlackInt) and continuous sutures (DragSlackCont).*

For both 2 mm and 3 mm thickness the samples with a continuous suture took significantly longer to start to rupture (for 2 mm, mean = 16227 vs 12892, P = 0.02274 and for 3 mm, mean = 17030 vs 13038, P = 0.02329) (see figure 11). This indicates that closure with a continuous suture holds longer when under tension. The scatter of the box plot of the continuous suture is smaller, implying that using a continuous suture leads to more steady repetitive results.

IX. Discussion

A training phantom for a vesicovaginal fistula repair with the transvaginal approach involving simple fistulas was presented. The materials were chosen based on literature and material tests, and their mechanical properties were compared to real tissue. The vaginal tissue was mimicked by Dragon Skin 10 with 11% silicone oil based on the slope of the stress-strain curve at small deformations. Two materials were tested to mimic the bladder tissue. Although the costs for the model with silicone oil are lower, a water-tightness test on these two materials showed that the model with silicone oil was not watertight at the sutures. Since the bladder has to become watertight after suturing, the model with Slacker is most suitable for mimicking the bladder tissue. The procedural steps could be performed on the phantom model without any problems after the suggestions of the gynaecologists to broaden the working space and to adjust the angle of the model to the Trendelenburg position were processed in an updated final model. The thickened edge in the vagina that represented the fistula realistically mimicked the scar tissue of the fistula. The vaginal wall could be incised and dissected away from the bladder wall, and the fistula could be excised. The bladder tissue could be repaired with sutures and a dye test with the use of a catheter could be performed to check the water-tightness of the bladder. Lastly, the vaginal tissue could be repaired to complete the procedure. The material costs could be kept low, for the permanent parts of the final phantom model the costs are €14,23 and for the replaceable parts, the material costs are €5,38. It is advised to use a continuous suture since it starts to rupture when under tension later than an interrupted suture, and it shows more steady repetitive results.

As stated before, in previous works, most phantoms of the female pelvis are focused on imaging [12, 13, 14]. Only a few researches looked at needle insertion, but sutures were rarely used [10, 11, 15, 16]. Furthermore, no previous phantom models focused on the transvaginal approach of the vesicovaginal fistula repair. The phantom made in this study is unique because it does involve suturing and is focused on this procedure. Some aspects of the fabrication of previous made phantom models, however, were similar to the production of the model in this current study.

To start with, the base materials that were tested in this study, were used in the production of other phantom models [13, 54, 55, 56]. The additives silicone oil and Slacker that were used to tune the mechanical properties of the silicone were not used in these other models. Pacioni et al., however, did use Slacker in combination with silicone and stated that it gave the silicone a human tissue-like self-sealing property, meaning the ability to close again after needle insertion [57]. The same result followed from the water-tightness test in this study, where the model of Dragon Skin with Slacker was able to become watertight after suturing. In several studies, oil is also used to alter the E-modulus and the tactile properties of the tissue-mimicking silicone material [10, 58, 59]. This study was the first to use Dragon Skin (in combination with the additives) to mimic the bladder and vaginal tissue, and the cervix and vulva.

Furthermore, moulds made by 3D printing are widely used in the production of other phantom models, since it offers an accurate and reproducible way to build soft organ models [12, 13, 14, 54, 55, 60, 61, 62]. The silicone parts that are produced by the 3D printed moulds in this study also experience a high reproducibility, regarding shape, colour and feeling. The same accounts for the 3D printed parts for the framework. Since complicated 3D shapes can easily be produced, 3D printing is proven to be a suitable method to mimic the bones in the framework.

To spare material and thereby costs, it would be valuable if the replaceable parts of the silicone could be recycled. The recycling process of silicone is mostly done by specialised recycling companies that downcycle it into silicone oil, that can be reused [63]. However, since this is not a possibility in Africa, other methods should be explored. It is possible to granulate the silicone into small particles and mix this with new silicone [63]. Since the materials include different additives and pigments they should be separated first to avoid a direct effect on the visual and mechanical properties. Ghosh et al. tested the addition of silicone rubber vulcanizate powder (SVP) with a particle size from 2 μm to 110 μm and an average of 33 μm, obtained from silicone rubber by mechanical grinding, in silicone rubber [64]. They observed that on incorporation of even a high loading of SVP (60 parts per hundred) the tensile and tear strength of the silicone rubber are decreased by only about 20% [64]. The modulus was reduced by 15%, while the hardness, tension set and hysteresis loss undergo marginal changes and compression stress-relaxation is not significantly changed [64]. To determine whether this is a possibility to apply to the parts of the phantom model, further tests are necessary. It should be determined to what size it is possible to granulate the silicone into in Africa, and when mixed with new silicone what the effects on the mechanical and visual properties are. Furthermore, it should be determined how often the material can be recycled, until the loss in properties is unacceptable.

This study showed that a phantom model for a vesicovaginal fistula repair of a simple fistula with the transvaginal approach was made on which all procedural steps realistically could be performed. The material costs are kept low, and locally available materials are used so that the model can be produced in Africa. Furthermore, a package will be provided with an instruction manual (see Appendix F for the manual) and the CAD files for the moulds to transfer the fabrication steps, so that the production can be implemented locally.

Limitations

As indicated, the model is focused on the treatment of simple fistulas, which is only a limited number of fistulas. Therefore, the training model is not applicable for training purposes for all types of fistula.

Since obstetric vesicovaginal fistulas do not occur in western countries, only a few gynaecologists that operated as tropical doctors could be contacted to test the phantom model. Therefore, we could only receive feedback on the initial phantom model from two experienced gynaecologists. Due to time limitations, the final model was only tested with a pelvic surgeon. For a broader analysis, it would be valuable to test the model with a larger number of experienced doctors but also with residents without experience to test whether the model is beneficial for learning purposes.

In the cost estimations, only the material costs were taken into account, because the production costs were hard to estimate. This was due to the availability of a free 3D printer and because we produced and assembled the silicone parts ourselves, without any labour costs.

In the final model it was decided to glue the vulva to the framework instead of fixing it with bolts and nuts to gain a more realistic look. Due to time limitations it was not tested how long this glue holds for these permanent parts. Also, the vagina was glued to the vulva, however, it was not tested whether this glue could be removed afterwards. These aspects should be tested to determine whether this method is superior to using bolts and nuts.

The sutures for the test on the effect of continuous and interrupted sutures were placed by one surgeon. The consistency of the surgeon could have led to the small scatter of the continuous suture. Furthermore, a small number of samples were tested. To get a more conclusive result more samples should be tested and different surgeons should place the sutures to determine whether the small scatter is a result of the used technique or of the consistency of the surgeon. Also, the small scatter could be an effect of the fact the silicone material is more uniform than real human tissue. However, this would not explain the difference between the samples with interrupted sutures and the samples with a continuous suture. Further research is needed to be able to conclude whether one technique is superior to the other.

Some tests were performed on the tendency to rupture and the stress-strain curve of a small deformation was determined to calculate the E-modulus. This way, the values of the tissue-mimicking material could be compared with the values of real tissue. However, more mechanical properties of the tissue-mimicking material can be compared to the values of real tissue. Therefore, in future research more tests should be performed on other mechanical properties of the tissue-mimicking materials, such as the maximal stress and strain at rupture.

X. Conclusion

In conclusion, a phantom model was developed and successfully tested by two gynaecologists and a pelvic surgeon. The scar tissue of the fistula is realistically mimicked by a thickened edge. Forceps could be used on the tissue-mimicking material for the vaginal wall and it could successfully be incised and dissected away from the bladder wall. The tissue-mimicking material for the bladder wall could be repaired water-tightly with sutures and a dye test with the use of a catheter could be performed. Moreover, the model can be produced locally, while keeping the costs low. Overall, the model is suitable to be used as a phantom to train medical doctors in the treatment of a simple vesicovaginal fistula repair with the transvaginal approach.

Acknowledgments

I would like to thank Toon Koebrugge for providing a CAD file of the female pelvis, that could be used as a framework for the phantom model. As well as Jules Schagen van Leeuwen and Heleen van Beekhuizen for providing feedback on the initial phantom model. Along with Theo Wiggers for performing the secondary test and for his guidance throughout the study. And also Jenny Dankelman for supervising the project from the side of TU Delft.

Ethics

The clinical validation test has been approved by The Human Research Ethics Committee (HREC) of Delft University of Technology.

References

[1] L Lewis Wall. "Obstetric vesicovaginal fistula as an international public-health problem". In: *Lancet* 368 (2006), pp. 1201–1210. DOI: 10.1016/S0140-6736(06)69476-2. URL: www.thelancet.com.

[2] Haley Medlen and Heather Barbier. "Vesicovaginal Fistula". In: (Nov. 2021). URL: https://www.ncbi.nlm.nih.gov/books/NBK564389/.

[3] Michael Stamatakos et al. "Vesicovaginal Fistula: Diagnosis and Management". In: *The Indian Journal of Surgery* 76.2 (2014), p. 131. ISSN: 09739793. DOI: 10.1007/S12262-012-0787-Y. URL: /pmc/articles/PMC4039689//pmc/articles/PMC4039689/?report=abstracthttps://www.ncbi.nlm.nih.gov/pmc/articles/PMC4039689/.

[4] Muhammad A. Malik et al. "Changing trends in the etiology and management of vesicovaginal fistula". In: *International journal of urology : official journal of the Japanese Urological Association* 25.1 (Jan. 2018), pp. 25–29. ISSN: 1442-2042. DOI: 10.1111/IJU.13419. URL: https://pubmed.ncbi.nlm.nih.gov/28762575/.

[5] Rachel A. Moses and E. Ann Gormley. "State of the Art for Treatment of Vesicovaginal Fistula". In: *Current urology reports* 18.8 (Aug. 2017). ISSN: 1534-6285. DOI: 10.1007/S11934-017-0708-5. URL: https://pubmed.ncbi.nlm.nih.gov/28656520/.

[6] Shanmugasundaram Rajaian, Murugavaithianathan Pragatheeswarane, and Arabind Panda. "Vesicovaginal fistula: Review and recent trends". In: *Indian Journal of Urology : IJU : Journal of the Urological Society of India* 35.4 (2019), p. 250. ISSN: 0970-1591. DOI: 10.4103/IJU.IJU{_}147{_}19. URL: /pmc/articles/PMC6792412//pmc/articles/PMC6792412/?report=abstracthttps://www.ncbi.nlm.nih.gov/pmc/articles/PMC6792412/.

[7] Denis Mukwege. *De kracht van vrouwen*. 2nd ed. Amsterdam: De Bezige Bij, 2021. ISBN: ISBN9789403154817.

[8] *Vesicovaginal Fistula*. URL: https://www.drugs.com/cg/vesicovaginal-fistula-repair.html.

[9] Brian Hancock. "First Steps in Vesico-Vaginal Fistula Repair". In: *The Royal Society of Medicine Press Limited* (2005).

[10] Pan Li, Zhiyong Yang, and Shan Jiang. "Tissue mimicking materials in image-guided needle-based interventions: A review". In: *Materials science & engineering. C, Materials for biological applications* 93 (Dec. 2018), pp. 1116–1131. ISSN: 1873-0191. DOI: 10.1016/J.MSEC.2018.09.028. URL: https://pubmed.ncbi.nlm.nih.gov/30274042/.

[11] Khashayar Nattagh et al. "A training phantom for ultrasound-guided needle insertion and suturing". In: *Brachytherapy* 13.4 (2014), pp. 413–419. ISSN: 18731449. DOI: 10.1016/J.BRACHY.2014.01.003.

[12] Noriyuki Kadoya et al. "Evaluation of deformable image registration between external beam radiotherapy and HDR brachytherapy for cervical cancer with a 3D-printed deformable pelvis phantom:" in: *Medical Physics* 44.4 (Apr. 2017), pp. 1445–1455. ISSN: 00942405. DOI: 10.1002/MP.12168.

[13] Eunjin Choi et al. "Soft Urinary Bladder Phantom for Endoscopic Training". In: *Annals of Biomedical Engineering* 49.9 (Sept. 2021), pp. 2412–2420. ISSN: 15739686. DOI: 10.1007/S10439-021-02793-0.

[14] Kristen L. Lurie et al. "Three-dimensional, distendable bladder phantom for optical coherence tomography and white light cystoscopy". In: *Journal of Biomedical Optics* 19.03 (Mar. 2014), p. 1. ISSN: 1083-3668. DOI: 10.1117/1.JBO.19.3.036009.

[15] Tonke L. de Jong et al. "PVA matches human liver in needle-tissue interaction". In: *Journal of the Mechanical Behavior of Biomedical Materials* 69 (May 2017), pp. 223–228. ISSN: 18780180. DOI: 10.1016/J.JMBBM.2017.01.014.

[16] Yancheng Wang et al. "Silicone-based tissue-mimicking phantom for needle insertion simulation". In: *Journal of Medical Devices, Transactions of the ASME* 8.2 (2014). ISSN: 1932619X. DOI: 10.1115/1.4026508.

[17] *Incision Academy: Vesicovaginal Fistula Repair*. URL: https://academy.incision.care/courses/vesicovaginal-fistula-repair/steps/1/sub/1.

[18] Abdullah Gedik et al. "Which Surgical Technique Should be Preferred to Repair Benign, Primary Vesicovaginal Fistulas?" In: *Urology Journal* 12.6 (Dec. 2015), pp. 2422–2427. ISSN: 1735-546X. DOI: 10.22037/UJ.V12I6.3061. URL: https://journals.sbmu.ac.ir/urolj/index.php/uj/article/view/3061.

[19] Lauren Wood Thum et al. "Vaginal Fistula Repairs". In: *Female Pelvic Surgery, Second Edition* (Jan. 2020), pp. 139–163. DOI: 10.1007/978-3-030-28319-3{_}10. URL: https://link.springer.com/chapter/10.1007/978-3-030-28319-3_10.

[20] Dominic Lee and Philippe Zimmern. "Vaginal Approach to Vesicovaginal Fistula". In: *The Urologic clinics of North America* 46.1 (Feb. 2019), pp. 123–133. ISSN: 1558-318X. DOI: 10.1016/J.UCL.2018.08.010. URL: https://pubmed.ncbi.nlm.nih.gov/30466697/.

[21] Roberto Angioli et al. "Guidelines of how to manage vesicovaginal fistula". In: *Critical Reviews in Oncology/Hematology* 48 (2003), pp. 295–304. DOI: 10.1016/S1040-8428(03)00123-9.

[22] Michael Breen. "Manual of Obstetric Fistula Surgery". In: The Global Library of Women's Medicine, 2019. ISBN: 978-0-9927545-7-0.

[23] *Ultimate 3D Printing Material Properties Table*. URL: https://www.simplify3d.com/support/materials-guide/properties-table/.

[24] Ishbel Marion Campbell and Ian Shane Asiimwe. *Nursing Care For Women With Childbirth Injuries Ishbel Marion Campbell*. 2021. ISBN: 9780992754594. URL: www.ucif.co.uk/.

[25] Jenn Ming Yang and Wen Chen Huang. "Bladder Wall Thickness on Ultrasonographic Cystourethrography". In: *Journal of Ultrasound in Medicine* 22.8 (Aug. 2003), pp. 777–782. ISSN: 1550-9613. DOI: 10.7863/JUM.2003.22.8.777. URL: https://onlinelibrary.wiley.com/doi/full/10.7863/jum.2003.22.8.777https://onlinelibrary.wiley.com/doi/abs/10.7863/jum.2003.22.8.777https://onlinelibrary.wiley.com/doi/10.7863/jum.2003.22.8.777.

[26] Lúcia Alves Da Silva Lara et al. "Menopause leading to increased vaginal wall thickness in women with genital prolapse: Impact on sexual response". In: *Journal of Sexual Medicine* 6.11 (2009), pp. 3097–3110. ISSN: 17436109. DOI: 10.1111/J.1743-6109.2009.01407.X. URL: https://www.researchgate.net/publication/26718460_Menopause_Leading_to_Increased_Vaginal_Wall_Thickness_in_Women_with_Genital_Prolapse_Impact_on_Sexual_Response.

[27] Paula B. Pendergrass et al. "The Shape and Dimensions of the Human Vagina as Seen in Three-Dimensional Vinyl Polysiloxane Casts". In: *Gynecologic and Obstetric Investigation* 42.3 (Jan. 1996), pp. 178–182. ISSN: 0378-7346. DOI: 10.1159/000291946. URL: https://www.karger.com/Article/FullText/291946https://www.karger.com/Article/Abstract/291946.

[28] Elaine N Marieb, Katja Hoehn, and Marieb Hoehn. *Global edition Human anatomy & Physiology tenth edition Human anatomy & Physiology*. ISBN: 1-292-09697-7.

[29] Adwoa Baah-Dwomoh et al. "Mechanical Properties of Female Reproductive Organs and Supporting Con-

nective Tissues: A Review of the Current State of Knowledge”. In: *Applied Mechanics Reviews* 68.6 (Nov. 2016). ISSN: 00036900. DOI: 10.1115/1.4034442.

[30] *Bison PVC lijm hard 100ml*. URL: https://www.praxis.nl/bouwmaterialen/bouwbenodigdheden/tape-lijm/kit-lijmen/bison-pvc-lijm-hard-100ml/3604100?channable=02490e6964003336303431303039&gclid=Cj0KCQjwio6XBhCMARIsAC0u9aEnICVC78IDCOgj5mgQgplCZSKpihXN-KBdZGHiRKSDNV4nMW2iOXEaAnynEALw_wcB.

[31] S. E. Dahms et al. “Composition and biomechanical properties of the bladder acellular matrix graft: Comparative analysis in rat, pig and human”. In: *British Journal of Urology* 82.3 (1998), pp. 411–419. ISSN: 00071331. DOI: 10.1046/J.1464-410X.1998.00748.X.

[32] Pedro A.L.S. Martins et al. “Uniaxial mechanical behavior of the human female bladder”. In: *International Urogynecology Journal* 22.8 (2011), pp. 991–995. ISSN: 14333023. DOI: 10.1007/S00192-011-1409-0.

[33] P. Chantereau et al. “Mechanical properties of pelvic soft tissue of young women and impact of aging”. In: *International Urogynecology Journal* 25.11 (Oct. 2014), pp. 1547–1553. ISSN: 14333023. DOI: 10.1007/S00192-014-2439-1.

[34] Clay Jean-Charles et al. “Biomechanical properties of prolapsed or non-prolapsed vaginal tissue: Impact on genital prolapse surgery”. In: *International Urogynecology Journal* 21.12 (2010), pp. 1535–1538. ISSN: 09373462. DOI: 10.1007/S00192-010-1208-Z.

[35] Donna Mazloomdoost et al. “Histologic Anatomy of the Anterior Vagina and Urethra”. In: *Female pelvic medicine & reconstructive surgery* 23.5 (Sept. 2017), pp. 329–335. ISSN: 2154-4212. DOI: 10.1097/SPV.0000000000000387. URL: https://pubmed.ncbi.nlm.nih.gov/28118170/.

[36] By F Robert Zacharin. *The suspensory mechanism of the female urethra*. Tech. rep. 3. 1963, pp. 423–427.

[37] Benjamin Abelson et al. “Sex differences in lower urinary tract biology and physiology”. In: *Biology of Sex Differences* 9.1 (Oct. 2018). ISSN: 20426410. DOI: 10.1186/S13293-018-0204-8.

[38] *Wacker Elastosil E43 transparant - Siliconesandmore.com*. URL: https://www.siliconesandmore.com/nl/elastosil-e43.html?id=143556947&gclid=CjwKCAjw9-KTBhBcEiwAr19ig2HnFQ_pasAtbiRPN1mujRC2Dnwwi5XVydzrrpyH3uIFY-wuDMfbeBoCxIkQAvD_BwE.

[39] *Likert Scale Definition, Examples and Analysis — Simply Psychology*. URL: https://www.simplypsychology.org/likert-scale.html.

[40] *Stanley 360° multifunctionele kogelgewricht bankschroef - Baptist*. URL: https://baptist.nl/klemmen-en-lijmen/meubelmakersbankschroeven-en-werkbankspindels/stanley-360-multifunctionele-boorklem.

[41] *FormX Home*. URL: https://www.formx.nl/products/silicone1/dragon-skin-series/dragon-skin-10-medium---3628-kg.php.

[42] *FormX Home*. URL: https://formx.nl/accessories/silicon-miscellaneous/slacker/slacker-1--gallon-363-kg.php.

[43] *FormX Home*. URL: https://www.formx.nl/pigments/siltoneflock/index.php.

[44] *Siliconenolie 50 cSt - Siliconesandmore.com*. URL: https://www.siliconesandmore.com/nl/siliconenolie-50-cst.html?id=60394685.

[45] *Natuur Latex Rubber Slangen 1.6 2 3 4 5 6 7 9 10 12 14 17Mm Hoge Veerkrachtig Elastische Chirurgische Medische Buis Slingshot Catapult— — - AliExpress*. URL: https://nl.aliexpress.com/item/1005003814027710.html?spm=a2g0o.order_detail.0.0.647f6d76nkRaD4&gatewayAdapt=glo2nld.

[46] *RepRapFilament PLA—Wit 1.75 mm / 1 kg — 3D print experts — ReprapWorld NL*. URL: https://reprapworld.nl/3d-filament/pla/1-75-reprap-filament-pla-wit-1kg/&f=gs?f=gs&mkwid=slUDPvi4d_dc|pcrid|562691590457|pkw||pmt||slid||prid|PF_1733_8719345005596_RRFPLAWHITE1000MM175&pgrid=127229392302&ptaid=pla-1468634505332&gclid=Cj0KCQjwxb2XBhDBARIsAOjDZ36XDJinBzvMsMjwKUsbitPV8 JXwNA9AdXsCoemKMIaAtTvEALw_wcB.

[47] *GAMMA bouwmarkten - doe het zelf bouwmarkt*. URL: https://www.gamma.nl/.

[48] *Everbuild secondelijm medium viscositeit—Toolstation.nl*. URL: https://www.toolstation.nl/everbuild-secondelijm-medium-viscositeit/p16435?_gl=1*fw411h*_up*MQ..&gclid=CjwKCAjw3qGYBhBSEiwAcnTRLlTznjPTAi0qbJOflRO2u9lndCJ qOtZ6cpoFcQE-090hoCBsMQAvD_BwE.

[49] Juliette C. Slieker et al. “Systematic Review of the Technique of Colorectal Anastomosis”. In: *JAMA Surgery* 148.2 (Feb. 2013), pp. 190–201. ISSN: 2168-6254. DOI: 10.1001/2013.JAMASURG.33. URL: https://jamanetwork.com/journals/jamasurgery/fullarticle/1654856.

[50] Roman Eickhoff et al. “Influence of suture technique on anastomotic leakage rate-a retrospective analyses comparing interrupted-versus continuous-sutures”. In: *International journal of colorectal disease* 34.1 (Jan. 2019), pp. 55–61. ISSN: 1432-1262. DOI: 10.1007/S00384-018-3168-6. URL: https://pubmed.ncbi.nlm.nih.gov/30250969/.

[51] Himanshu Gupta et al. “Comparison of interrupted versus continuous closure in abdominal wound repair: A meta-analysis of 23 trials”. In: *Asian Journal of Surgery* 31.3 (2008), pp. 115–123. ISSN: 02193108. DOI: 10.1016/S1015-9584(08)60069-X.

[52] Owais Ahmed et al. “Comparison of the Interrupted and Continuous Suture Techniques for the Closure of Oral and Nasal Mucosal Layers in Cleft Palate Surgery”. In: *Cureus* 13.12 (Dec. 2021). DOI: 10.7759/CUREUS.20779. URL: /pmc/articles/PMC8793892//pmc/articles/PMC8793892/?report=abstracthttps://www.ncbi.nlm.nih.gov/pmc/articles/PMC8793892/.

[53] Ashwani Kumar et al. “Comparison of Continuous vs Interrupted abdominal Fascial Closure in Patients

with Peritonitis." In: *Journal International Medical Sciences Academy* 33.3 (July 2020), pp. 138–142. ISSN: 0971071X.

[54] Xiangzhou Tan et al. "Soft Liver Phantom with a Hollow Biliary System". In: *Annals of Biomedical Engineering* 49.9 (Sept. 2021), pp. 2139–2149. ISSN: 15739686. DOI: 10.1007/S10439-021-02726-X.

[55] Fabian Adams et al. "Soft 3D-Printed Phantom of the Human Kidney with Collecting System". In: *Annals of Biomedical Engineering* 45.4 (Apr. 2017), pp. 963–972. ISSN: 15739686. DOI: 10.1007/S10439-016-1757-5.

[56] Stefanie Ehrbar et al. "ELPHA: Dynamically deformable liver phantom for real-time motion-adaptive radiotherapy treatments". In: *Medical Physics* 46.2 (Feb. 2019), pp. 839–850. ISSN: 00942405. DOI: 10.1002/MP.13359.

[57] Alessia Pacioni et al. "Patient-specific ultrasound liver phantom: materials and fabrication method". In: *International Journal of Computer Assisted Radiology and Surgery* 10.7 (July 2015), pp. 1065–1075. ISSN: 18616429. DOI: 10.1007/S11548-014-1120-Y/TABLES/2. URL: https://link.springer.com/article/10.1007/s11548-014-1120-y.

[58] S. Y. Ng and C. L. Lin. "Tunability of Acoustic and Mechanical Behaviors in Breast Tissue Mimicking Materials". In: *Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Annual International Conference* 2019 (July 2019), pp. 1998–2002. ISSN: 2694-0604. DOI: 10.1109/EMBC.2019.8857843. URL: https://pubmed.ncbi.nlm.nih.gov/31946292/.

[59] Burcin Ustbas et al. "Silicone-based composite materials simulate breast tissue to be used as ultrasonography training phantoms". In: *Ultrasonics* 88 (Aug. 2018), pp. 9–15. ISSN: 1874-9968. DOI: 10.1016/J.ULTRAS.2018.03.001. URL: https://pubmed.ncbi.nlm.nih.gov/29525227/.

[60] Philip C Somerwil et al. "An anthropomorphic deformable phantom of the vaginal wall and cavity". In: (2021). DOI: 10.1088/2057-1976/ac1780. URL: https://doi.org/10.1088/2057-1976/ac1780.

[61] Dandan Li et al. "Soft Phantom for the Training of Renal Calculi Diagnostics and Lithotripsy". In: *Annual International Conference of the IEEE Engineering in Medicine and Biology Society. IEEE Engineering in Medicine and Biology Society. Annual International Conference* 2019 (July 2019), pp. 3716–3719. ISSN: 2694-0604. DOI: 10.1109/EMBC.2019.8856426. URL: https://pubmed.ncbi.nlm.nih.gov/31946682/.

[62] Eunjin Choi et al. "A High-Fidelity Phantom for the Simulation and Quantitative Evaluation of Transurethral Resection of the Prostate". In: *Annals of Biomedical Engineering* 48.1 (Jan. 2020), pp. 437–446. ISSN: 15739686. DOI: 10.1007/S10439-019-02361-7.

[63] Andrew Krosofsky. *Is Silicone Recyclable?* June 2021. URL: https://www.greenmatters.com/p/is-silicone-recyclable.

[64] Arun Ghosh et al. "Recycling of silicone rubber waste: Effect of ground silicone rubber vulcanizate powder on the properties of silicone rubber". In: *Polymer Engineering & Science* 43.2 (Feb. 2003), pp. 279–296. ISSN: 1548-2634. DOI: 10.1002/PEN.10024. URL: https://onlinelibrary.wiley.com/doi/full/10.1002/pen.10024https://onlinelibrary.wiley.com/doi/abs/10.1002/pen.10024https://onlinelibrary.wiley.com/doi/10.1002/pen.10024.

[65] Gwyneth Lewis and Luc de Bernis. *Obstetric fistula: Guiding principles for clinical management and programme development*. Tech. rep. World Health Organization.

[66] Sanaz Mosafer Khoorjestan, Gholamreza Rouhi, and Karamollah Toolabi. "An investigation of the effects of suture patterns on mechanical strength of intestinal anastomosis: an experimental study: Suture patterns and material for intestinal anastomosis". In: *Biomedizinische Technik* 62.4 (Aug. 2017), pp. 429–437. ISSN: 00135585. DOI: 10.1515/BMT-2016-0103/PDF. URL: https://www.degruyter.com/document/doi/10.1515/bmt-2016-0103/html?lang=de.

[67] Nick Marsidi et al. "Measuring Forces in Suture Techniques for Wound Closure". In: *Journal of Surgical Research* 255 (Nov. 2020), pp. 135–143. ISSN: 0022-4804. DOI: 10.1016/J.JSS.2020.05.033.

[68] Thomas H. Witte et al. "A transducer for measuring force on surgical sutures". In: *Canadian Journal of Veterinary Research* 74.4 (2010), p. 299. ISSN: 08309000. URL: /pmc/articles/PMC2949343//pmc/articles/PMC2949343/?report=abstracthttps://www.ncbi.nlm.nih.gov/pmc/articles/PMC2949343/.

[69] Tim Horeman et al. "Force sensing in surgical sutures". In: *PloS one* 8.12 (Dec. 2013). ISSN: 1932-6203. DOI: 10.1371/JOURNAL.PONE.0084466. URL: https://pubmed.ncbi.nlm.nih.gov/24376812/.

[70] Tim Horeman et al. "Visual Force Feedback Improves Knot-Tying Security". In: *Journal of Surgical Education* 71.1 (Jan. 2014), pp. 133–141. ISSN: 1931-7204. DOI: 10.1016/J.JSURG.2013.06.021.

[71] Boris Gabriel et al. "Vagina, abdominal skin, and aponeurosis: do they have similar biomechanical properties?" In: *International urogynecology journal* 22.1 (2011), pp. 23–27. ISSN: 1433-3023. DOI: 10.1007/S00192-010-1237-7. URL: https://pubmed.ncbi.nlm.nih.gov/20798926/.

Appendix A
Elaborate description transvaginal approach

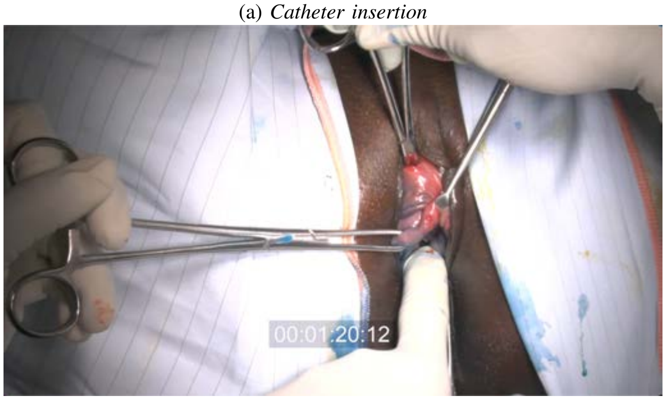
The description in the next four paragraphs is given by a training video of Incision and explains the basic transvaginal approach in detail [17]. During the whole procedure the patient is placed in the lithotomy position, which is most common for the transvaginal approach [65].

Fistula exposure

"The first step is the fistula exposure. An indwelling catheter is introduced into the urethra (figure 12a) and the bladder is filled with diluted methylene blue, forceps may be used to pull the vaginal mucosa interiorly in order to visualise the fistula opening (figure 12b). Once the leakage is confirmed, the catheter is removed, after which a pair of forceps is introduced into the urethra and the tip is guided to the fistula in order to measure the length between the urethral opening and the fistula opening, a finger may be used to guide the tip to the opening (figure 12c). The vaginal mucosa is then lifted using Allis forceps approximately 2 to 3 cm from the lateral margins of the fistula, for better exposure of the fistula before the infiltration can commence (figure 12d)."

(a) *Catheter insertion*

(b) *Visualisation of the fistula opening*



(c) *Forceps in urethra*

(d) *Vaginal mucosa lifted*

Figure 12: *Fistula exposure [17].*

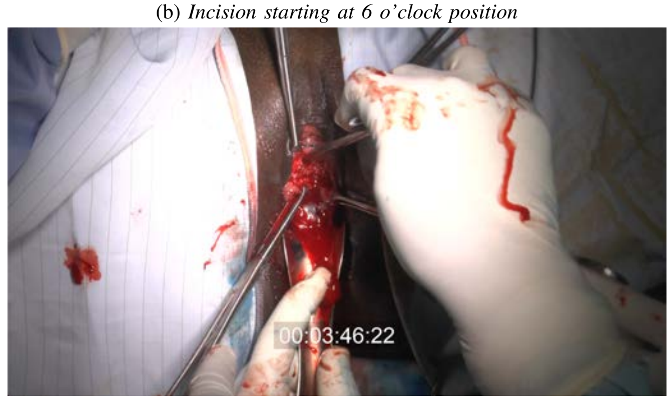
Fistula dissection

"The next step is the fistula dissection. The vaginal mucosa is infiltrated using a 1:200000 adrenaline solution for hydrodissection, which develops a plane between the tissue that will aid in the incision of the fistula later. The plunger should first be pulled back to make sure that a vessel is not entered. Moreover, the needle used has been bent at an angle to facilitate the injection into the submucosal layer (figure 13a). The use of an adrenaline solution will minimise bleeding so visualisation of the operating field is not tempered. The vaginal mucosa is incised circumferentially around the edge of the fistula using a scalpel. If the visualisation of the fistula is not clear the forceps may be reapplied on the vaginal mucosa, or the edge of the fistula may be grasped and lifted for better exposure. It is advised to start the incision of the fistula at the six o'clock position so bleeding of the tissue will not hamper visualisation (figure 13b). After the circumferential incision of the fistula, the vaginal mucosa is dissected away from the bladder tissue for about 2 cm from the fistula edge, using curved scissors (figure 13c). It is advised to perform only as much dissection around the fistula that is needed to avoid damage to the ureters and possible denervation of the bladder neck. The use of curved scissors will facilitate the dissection of the tissue because of the curved angle of its tip. A pair of forceps is now inserted into the fistula opening in order to estimate the free margin of the bladder after the dissection (figure 13d)."

(a) *Adrenaline infiltration*

(b) *Incision starting at 6 o'clock position*

(c) *Curved scissors for dissection of the tissue*



(d) *Estimate free margin*

Figure 13: *Fistula dissection [17].*

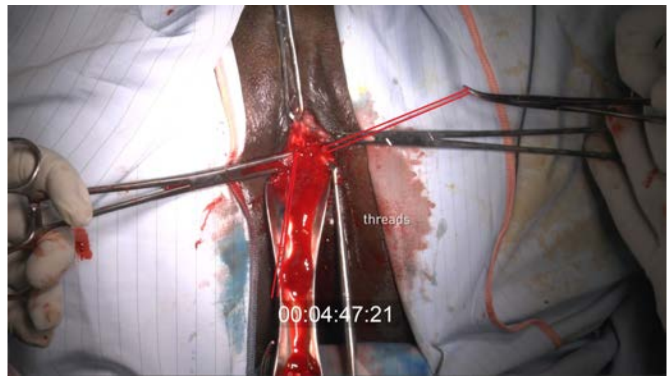
Bladder wall closure

"The following step is the closure of the bladder (figure 14a), this is done using transverse absorbable interrupted sutures. The closure of the opening should start on either apex of the opening first to make sure that the corners are included, and the opening is properly closed. The threads are then secured. The centre portion of the opening in the bladder is now closed using a transverse absorbable suture in a similar manner. The threads are then secured and cut. The threads of the corner sutures, however, are not cut at this stage as they facilitate the retraction and handling of the tissue and will be cut later (figure 14b). After the surgeon is happy with the closure of the fistula opening on the bladder wall, a catheter is once again inserted into the urethra for the insertion of methylene blue dye to check for a watertight compartment on closure (figure 14c). A piece of gauze is applied below the urethra and catheter to identify the spot of a possible dye leakage in case the closure was not watertight without staining the surrounding tissue (figure 14d)."

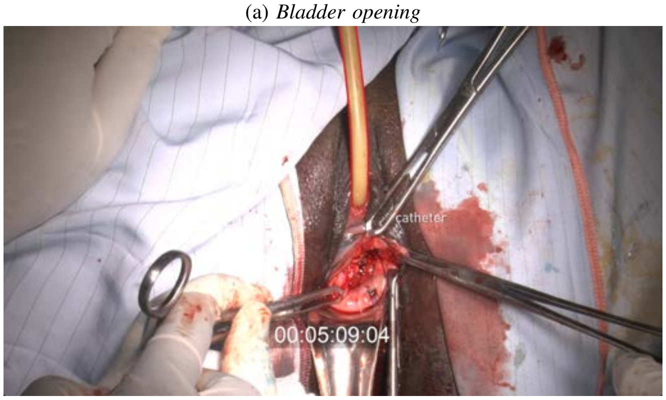
Vaginal wall closure

"The last step is to close the vaginal opening where the fistula was located, transversely with interrupted absorbable sutures. A number of sutures may be applied until the surgeon is happy with the closure of the vaginal mucosa. The closure is then inspected, and hemostasis is confirmed. A catheter is left in the bladder for seven to ten days postoperatively for continuous drainage."

(a) *Bladder opening*



(b) *Threads of the corner sutures not cut*



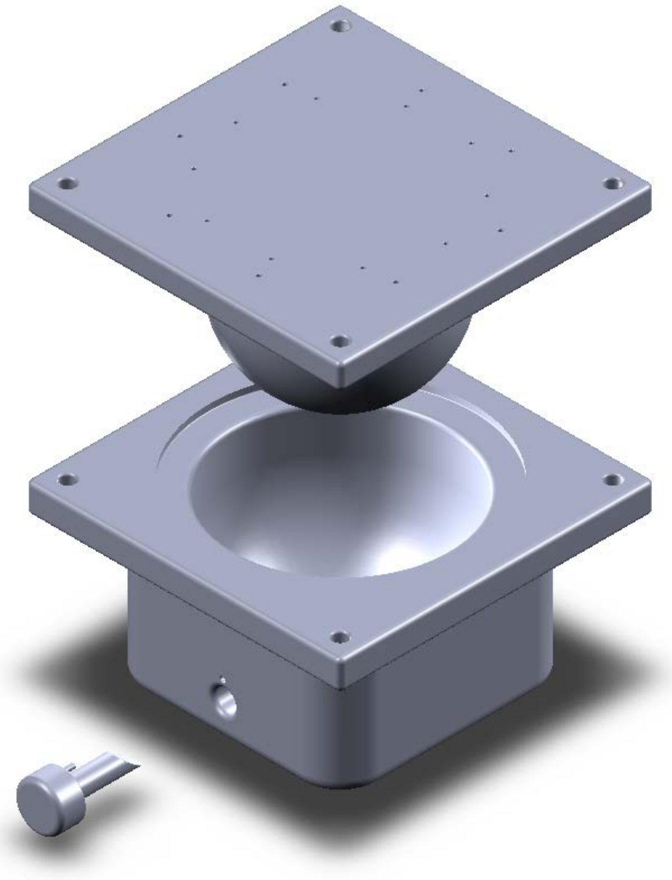
(c) *Catheter introduced in urethra*

(d) *Gauze used to check if closure is watertight*

Figure 14: *Bladder closure [17].*

APPENDIX B
DETAILED DEPICTION OF THE MOULDS

A. Bladder



(a) *Exploded view mould bladder*

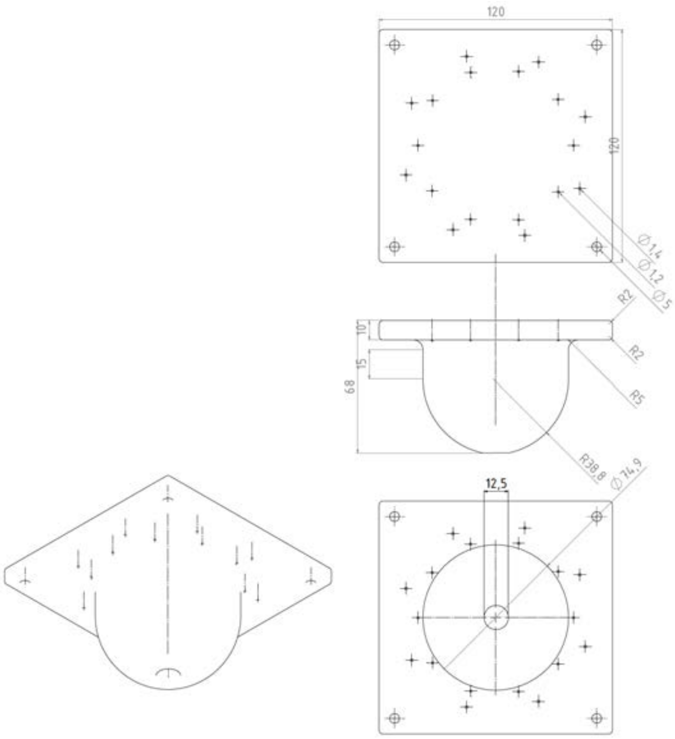
(b) *Inner mould bladder*

(c) *Outer mould bladder*

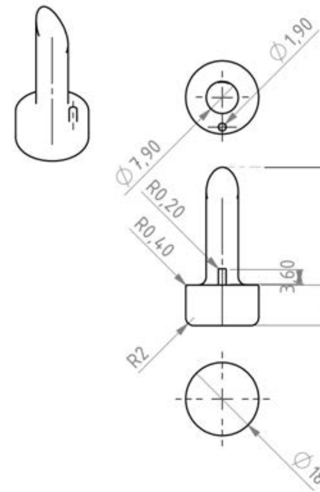
(d) *Urethra pin*

Figure 15: *Parts mould bladder.*

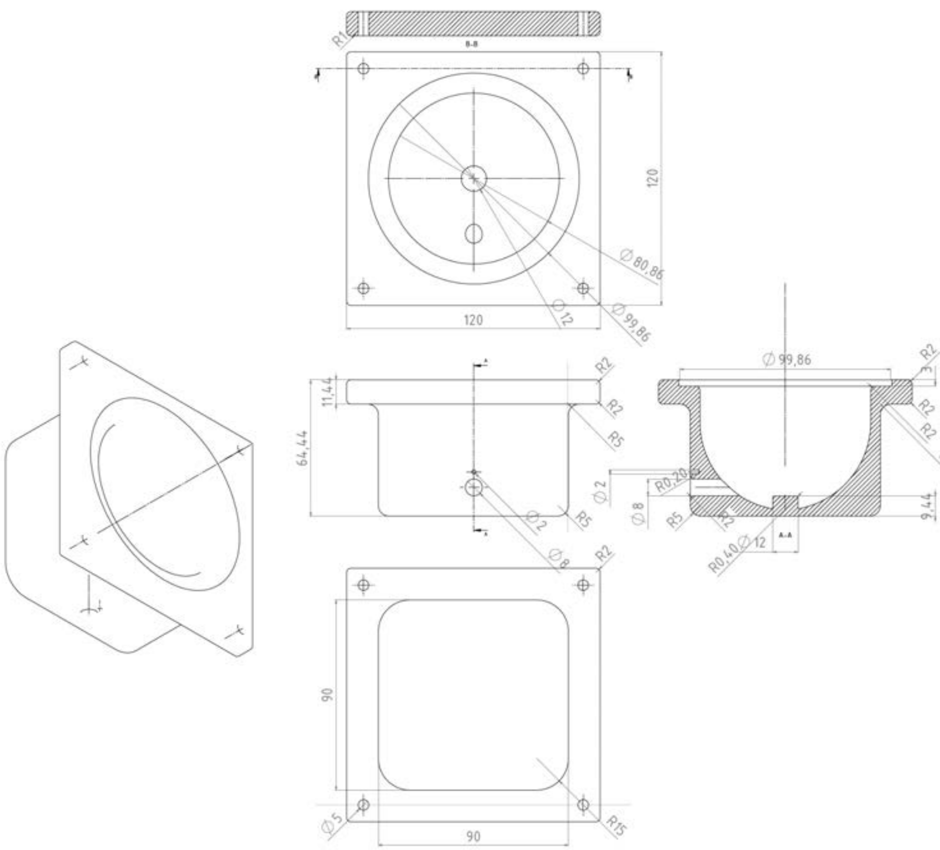
Figure 16: *Bladder top mould.*



(a) *Inner mould bladder*

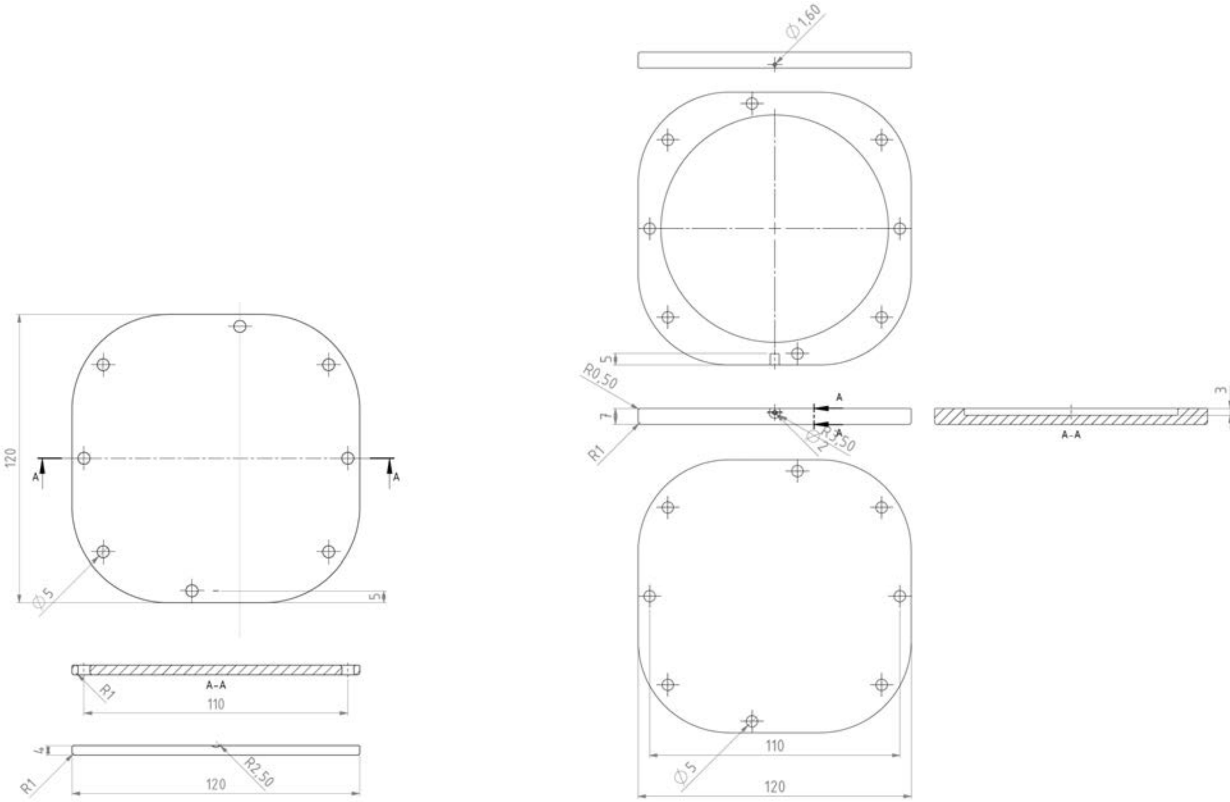


(b) *Urethra pin*



(c) *Outer mould bladder*

Figure 17: *Technical drawings parts mould for the bladder in mm.*

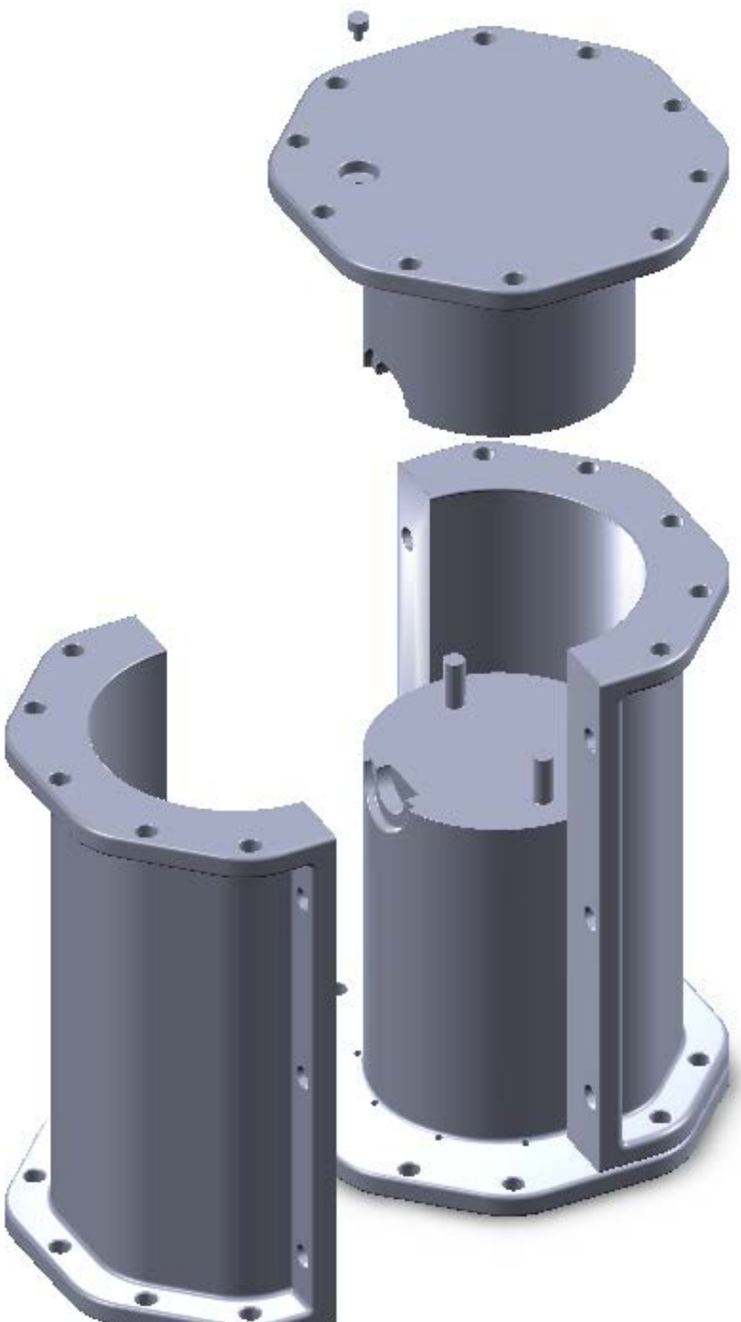


(a) *Bladder top mould part one*

(b) *Bladder top mould part two*

Figure 18: *Technical drawings parts mould for the bladder top in mm.*

B. Vagina



(a) *Exploded view mould vagina*

(b) *Inner mould vagina part one*

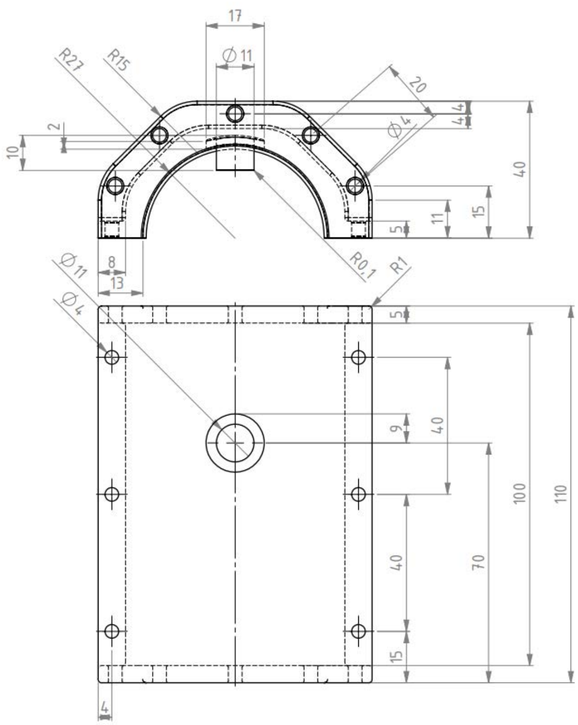
(c) *Inner mould vagina part two*

(d) *Outer mould vagina part one*

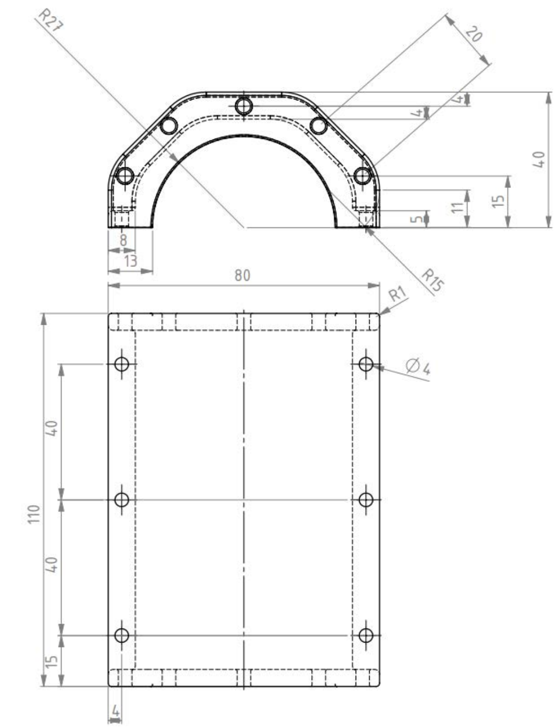
(e) *Outer mould vagina part two*

(f) *Vagina close-off pin*

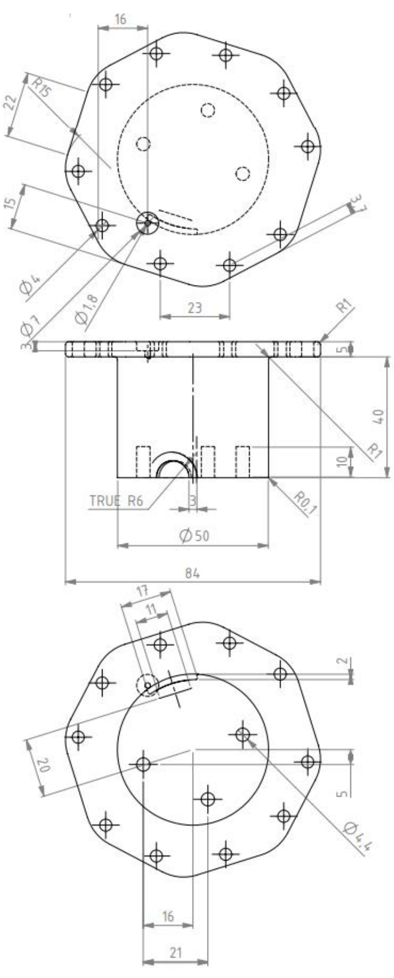
Figure 19: *Parts mould vagina.*



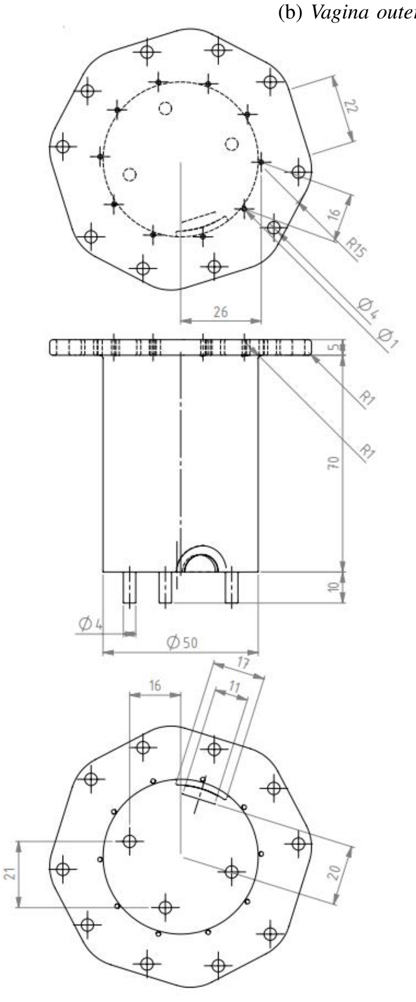
(a) *Vagina outer mould part one*



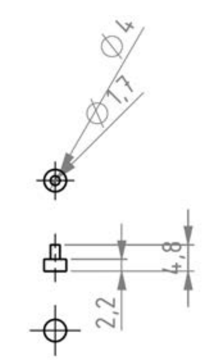
(b) *Vagina outer mould part two*



(c) *Vagina inner mould part one*



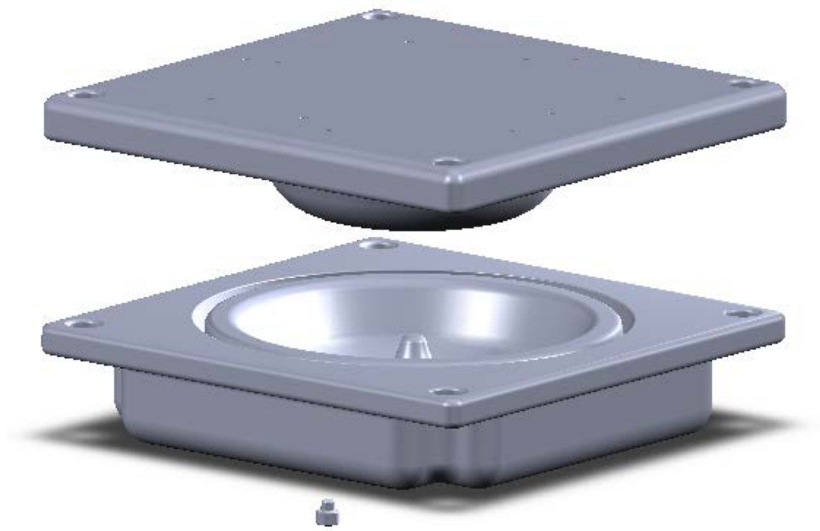
(d) *Vagina inner mould part two*



(e) *Vagina close-off pin*

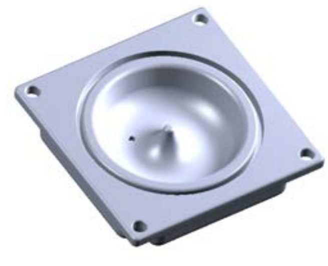
Figure 20: *Technical drawings parts mould for the vagina in mm.*

C. Cervix



(a) *Exploded view mould cervix*

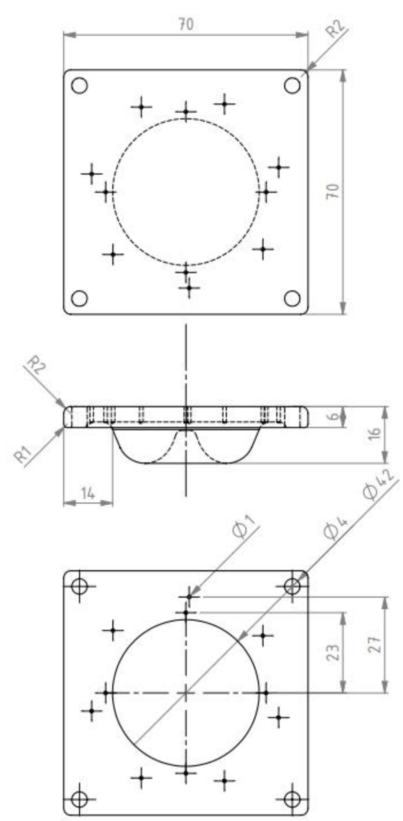
(b) *Inner mould cervix*



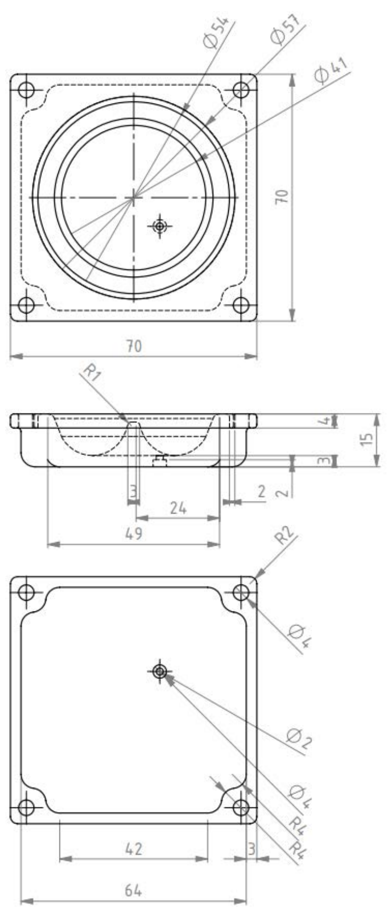
(c) *Outer mould cervix*

(d) *Cervix close-off pin*

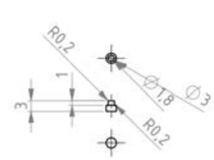
Figure 21: *Parts mould cervix.*



(a) *Inner mould cervix*



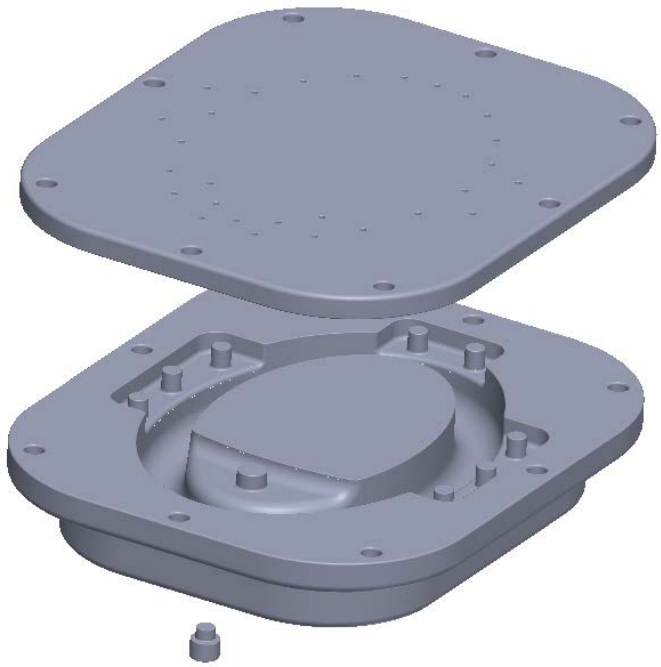
(b) *Outer mould cervix*



(c) *Cervix close-off pin*

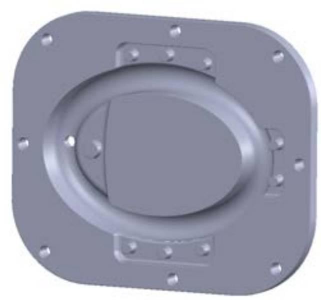
Figure 22: *Technical drawings parts mould for the cervix in mm.*

D. Vulva



(a) *Exploded view mould vulva*

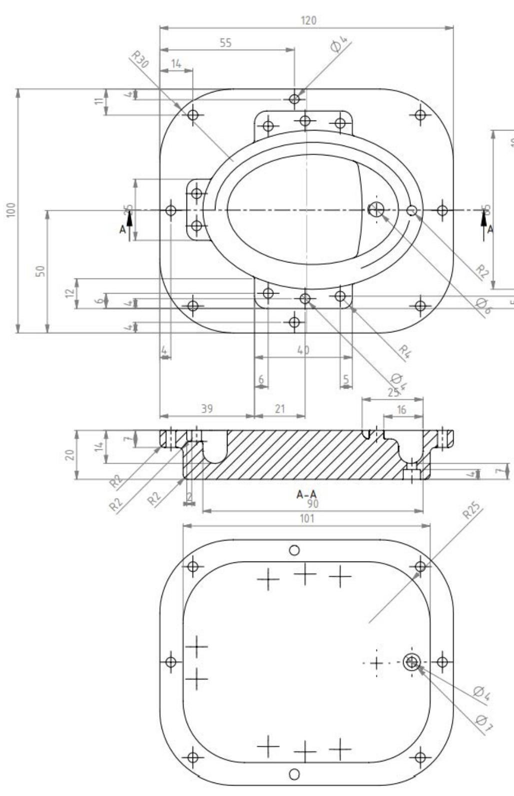
(b) *Mould vulva part one*



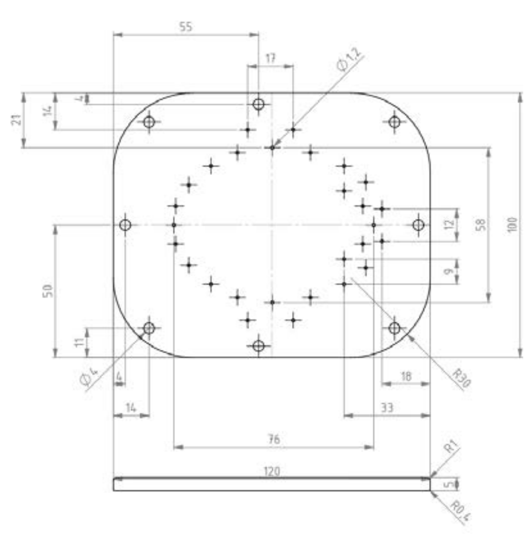
(c) *Mould vulva part two*

(d) *Vulva close-off pin*

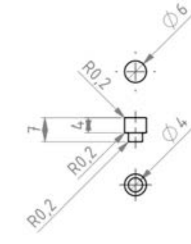
Figure 23: *Parts mould vulva.*



(a) *Mould vulva part one*



(b) *Mould vulva part two*



(c) *Vulva close-off pin*

Figure 24: *Technical drawings parts mould for the vulva in mm.*

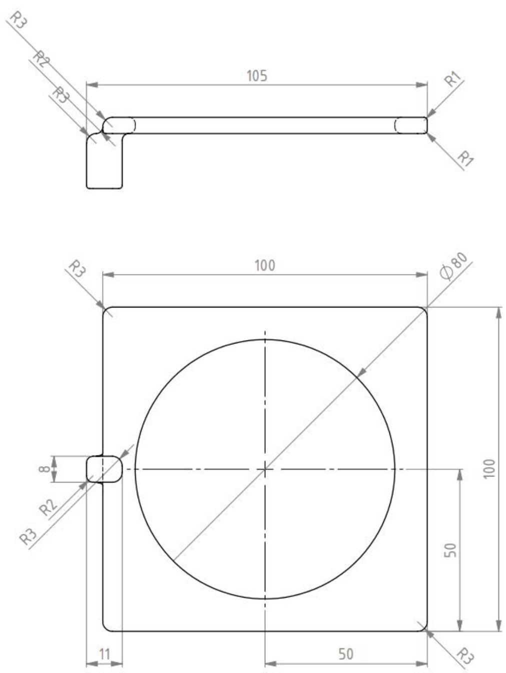
E. Framework

(a) *Framework assembled*

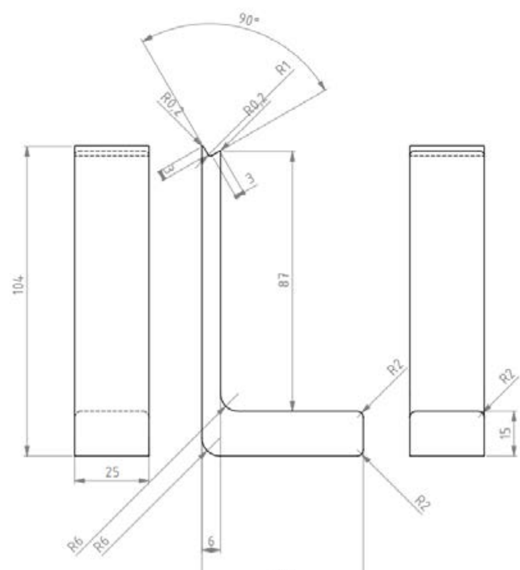
(b) *Framework part one*

(c) *Framework part two*

Figure 25: *Framework.*



(a) *Framework part one*



(b) *Framework part two*

Figure 26: *Technical drawings parts framework in mm.*

Appendix C
Tensile tests on different tissue-mimicking silicone materials for the bladder and vaginal tissue.

***Abstract* - The aim of this research is to find suitable materials for the development of a phantom model for a vesicovaginal fistula repair. Important is that the tissue-mimicking material for the bladder is watertight after suturing. Therefore, the tendency to rupture of different materials is tested in this study by placing the samples in a linear stage actuator with a stepper motor. The materials tested are Dragon skin 10 with 11% silicone oil, Dragon skin 10 with Slacker, EcoFlex 00-20, each with a hole that represented the fistula. It followed that EcoFlex could be ruled out, due to its tendency to tear faster while inserting the needle and its tendency to rupture at a lower force and shorter amount of time. From further tests, it followed that Dragon Skin combined with Slacker took significantly longer to start to rupture than the Dragon Skin combined with silicone oil (mean = 12892 vs 8427 ms, P = 0.002253). This indicates that Dragon Skin with Slacker will stay watertight when under tension longer than Dragon Skin with silicone oil. Furthermore, tests were performed on the difference between interrupted and continuous sutures. It followed that for both 2 mm and 3 mm thickness the Dragon Skin with Slacker samples with a continuous suture took significantly longer to start to rupture (for 2 mm, mean = 16227 vs 12892, P = 0.02274 and for 3 mm, mean = 17030 vs 13038, P = 0.02329). Lastly, the stress-strain curve and thereby the E-modulus were obtained by a tensile machine. The E-modulus of the sample of Dragon Skin with silicone oil (0.1967 MPa) was closest to the E-modulus of real bladder tissue. However, the E-modulus of the sample with Slacker (0.06815 MPa) was closest to the slope of the stress-strain curve of bladder tissue at small deformations. Therefore, both materials might be suitable to mimic the bladder tissue. Further tests are needed on the water-tightness to conclude which material is most suitable. The E-modulus of the sample with silicone oil was closest to the slope of the stress-strain curve of vaginal tissue at small deformations, therefore this material is most suitable to mimic vaginal tissue.**

I. Introduction

In Africa, many women suffer from vesicovaginal fistulas. To train medical doctors in the treatment of simple fistulas by the transvaginal approach, the aim of this research is to find suitable materials for the development of a phantom model for a vesicovaginal fistula repair.

Phantoms are artificial models that represent anatomical structures of parts of the body with tissue-mimicking materials that can be used in medical research or training [10, 11]. To mimic human tissue, silicone is most widely used (unpublished results from my literature study). In this study, two silicone materials were tested to mimic the bladder and vaginal tissue, namely Ecoflex 00-20 used by Choi et al., Tan et al., Adams et al. and Ehrbar et al., and Dragon Skin also used by Ehrbar et al. and Tan et al. [13, 54, 55, 56]. The materials were also tested with two additives, silicone oil and Slacker to tune the mechanical properties [10, 58].

Important is that the tissue-mimicking material for the bladder is watertight after suturing. Therefore, the tendency to rupture of the different materials is tested in this study.

II. Method

Moulds

To produce silicone plates that can be tested for the material selection, moulds were designed in the CAD software SolidWorks and 3D printed with PLA in an Ultimaker 2+. The moulds consisted of two halves that were connected to each other by eight bolts and nuts (size M4), on top there were four air holes with a diameter of 1 mm. At the bottom was a hole with a diameter of 4 mm up to a depth of 4 mm to clamp in the syringe, inside this hole was another hole of 2 mm to inject the silicone into the mould. The dimensions of the silicone plates that were created by these moulds are 100x50x3 mm and 100x50x2 mm. A release agent was sprayed on the two halves of the mould before connecting them.

(a) *Pouring required ratio of silicone in a paper cup*

(b) *Stirring silicone with a wooden spatula*

(c) *Pour silicone into the syringe and apply vacuum to remove bubbles*

(d) *Inject silicone into the connected mould*

(e) *Put a nail in the hole for the syringe to close off*

Figure 27: *Producing silicone plates by use of the 3D printed mould.*

Figure 27 provides an overview of the production steps of the silicone plates. After mixing the silicone in the required ratio (figure 27a and 27b), it was poured into the syringe. Vacuum was then applied to the syringe (figure 27c), and the silicone was injected at the bottom of the mould (figure 27d) so that the trapped air in the mould would be pushed up to the air holes. To close the hole of the syringe after injecting the silicone, a nail was used (figure 27e). The silicone was cured for at least eight hours at room temperature.

In the first version, no vacuum was applied, resulting in a plate with many bubbles (figure 28). To improve this in the second version an electrical toothbrush was held against the mould after the silicone was injected, to create vibrations so that the bubbles would move up. This improved the plate a bit, however, there were still many bubbles present (figure 28). In the third version, vacuum was applied to the syringe before injecting it into the mould. This was done by keeping the syringe upright and putting one finger on top of the tip while pulling the plunger down (figure 27c). The plunger was released slowly so that the air would move up, this was repeated like a pumping motion until most bubbles were gone, and the air was then released out of the syringe. This action was repeated if many bubbles were still present. After injecting the silicone into the mould, an electrical toothbrush was held against the mould. Afterwards, no bubbles were present in the silicone sample (figure 28).

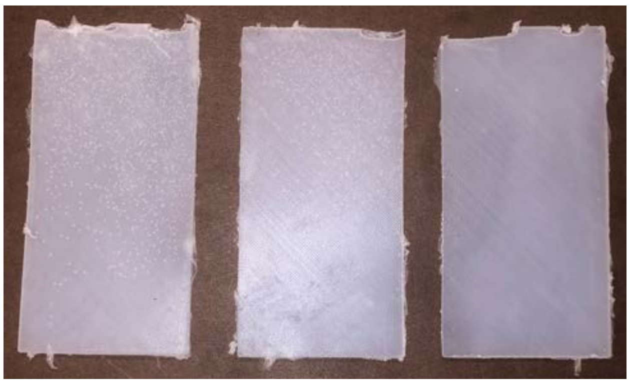


Figure 28: *Showing bubbles in the first, second and third versions of silicone plates, respectively.*

Silicone materials

To start, six different material combinations were made: Dragon skin 10, Dragon skin 10 with silicone oil, Dragon skin 10 with Slacker, EcoFlex 00-20, EcoFlex 00-20 with silicone oil and EcoFlex 00-20 with Slacker. It was determined that Dragon skin 10 alone was too stiff to suture, and the EcoFlex 00-20 plates with the two additives were too flexible and sticky to suture. Therefore, the materials used in the test were EcoFlex 00-20, Dragon skin 10 with 11% silicone oil and Dragon skin 10 with 0.5 part Slacker. The ratios of the additives were determined by trial and error (of stickiness and feel) and based on the advice in the instruction manual of the materials.

Approach

The approach was to measure the time and force until rupture of the silicone samples at the suture. Instead of pulling at the sutures as done by Khoorjestan et al. [66] or measuring the forces on the suture and/or tissue during suturing as done by Marside et al., Witte et al. and Horeman et al. [67, 68, 69, 70], it was decided to suture a hole, representing the fistula, in the middle of the silicone sample and clamp the silicone plate at each end (figure 29). This was done because it is more likely for the tissue to rupture due to tension on the suture afterwards than during suturing. Each silicone plate was cut into plates of 50x50x2 mm. Each hole was sutured with five interrupted sutures of about 2 mm from the edge and 4 mm in between the sutures (sometimes the distances were 3 or 5 mm), each containing six knots. The

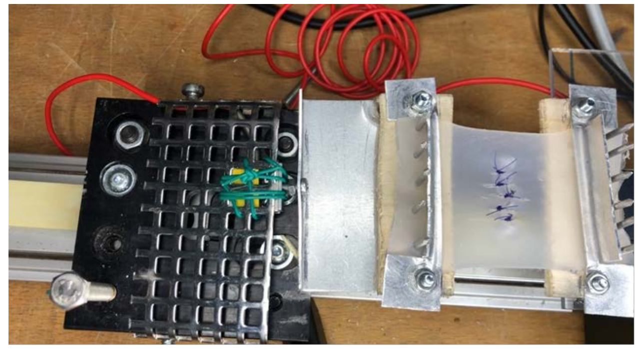


Figure 29: *Silicone plate clamped in the stage.*

needle used was DR26 3/8c 26 mm Taper and a Monosyn 3/0 metric 2 glyconate monofilament absorbable suture was used. After the sample was placed in the linear stage actuator with a stepper motor (figure 29), the stage slid up until 62.5 mm extending the silicone sample at a rate of 1.65 mm/s. The force acting on the sample during this extension was measured by a load cell over a loop time of 100 ms. A video was made aligning the graph and the top view of the sample in the stage. This way, it could be determined at which time and force the suture started to rupture and fully ruptured. When the material started to rupture about 2 mm on the video, the corresponding peak in the graph was taken as the matching value. For full rupture, the same was done.

a) First test

The hole that represented the fistula was either a circle of 13 mm, a common size for a simple fistula, or a straight cut of 20 mm, this value was chosen because when stretched into a circle it corresponds to the 13 mm of the circle. Of each material, two samples with a circular hole and two samples with a straight cut were tested. The circular hole was made using a mould so that each hole would be the same.

b) Second test

Additional tests were performed in the same manner as the first test on four 2 mm Dragon Skin with Slacker plates and four 2 mm Dragon Skin with silicone oil plates, this time only with the circular hole since this represents the fistula best.

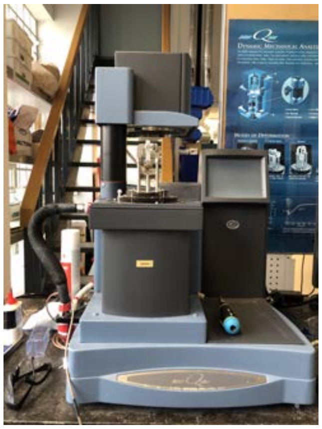
c) Third test

Furthermore, next to the different materials, tests were performed on the effect of a continuous suture or interrupted sutures on both 2 mm thickness and 3 mm thickness of the Dragon Skin with Slacker with a circular hole. The test was performed in the same manner as the previous ones. Four tests were performed per type and for the 2 mm plates with interrupted sutures, the values of the previous tests were used.

d) Fourth test

New moulds were designed, 3D printed and assembled in the same manner as before to produce small strips of 40x8x2.20 mm. A tensile testing machine (TA Instruments Q800 Dynamic Mechanical Analyzer 1) (figure 30) was used to obtain the stress-strain curve up to a ramp displacement of

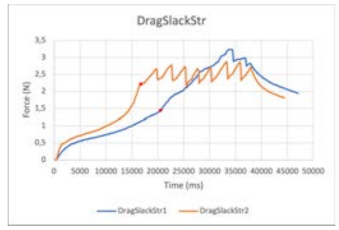
2000.00 µm/min to 4000.00 µm/min from a Dragon Skin with 11% silicone oil plate with the dimensions of 22.77x8.00x2.20 mm, and a Dragon Skin with Slacker plate with the dimensions 25.10x8.00x2.20 mm. The length was determined while the plates were clamped in the machine. The E-modulus was then determined by calculating the slope of the curve from 1% to 5% strain.



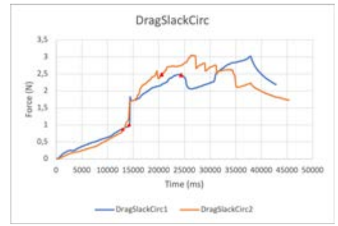
(a) *TA Instruments Q800 Dynamic Mechanical Analyzer 1*

(b) *Plate clamped in a tensile machine*

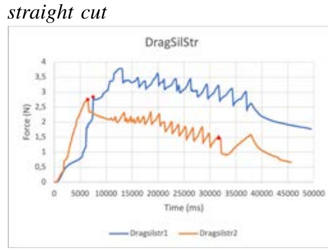
Figure 30: *Tensile machine*



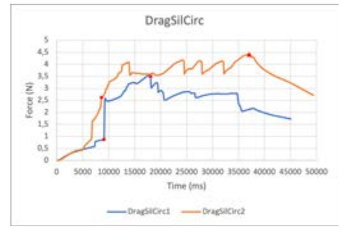
(a) *Dragon Skin with Slacker and a straight cut*



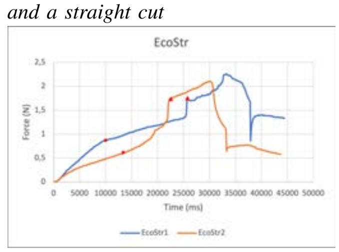
(b) *Dragon Skin with Slacker and a circular hole*



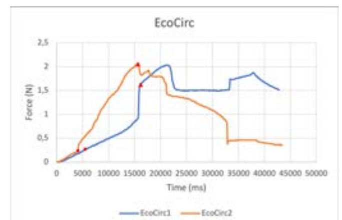
(c) *Dragon Skin with 11% silicone oil and a straight cut*



(d) *Dragon Skin with 11% silicone oil and a circular hole*



(e) *Ecoflex 00-20 with a straight cut*



(f) *Ecoflex 00-20 with a circular hole*

Figure 31: *Graph showing force against time of all 2 mm thickness samples with an interrupted suture and either a circular hole or straight cut. Presenting the start of rupture by the red dot and full rupture by the red triangle.*

III. RESULTS

a) First Test

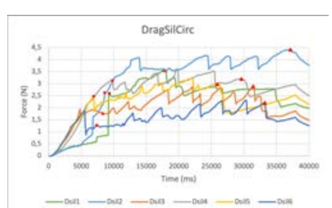
It was found that inserting the needle in the EcoFlex 00-20 material had to be done more carefully since it had the tendency to tear faster than the other materials. The sample with silicone oil was easy to suture, and the feeling during suturing was realistic. The sample with Slacker was a bit harder to suture because it moved more when pulling at the suture, but the feeling was still realistic.

The samples with Dragon Skin and Slacker with the straight cut did not fully rupture (figure 31a). From the Dragon Skin with silicone oil and the straight cut also one sample did not fully rupture (31c). Overall, the samples with the straight cut ruptured after a longer amount of time (figure 31). All samples with the circular hole started to rupture at the sutures in the middle and then outwards. This can be explained by the fact that the distance between the material the sutures have to hold together is biggest in the middle, meaning the tension in the suture is highest there.

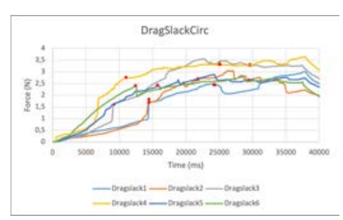
Moreover, the samples of EcoFlex 00-20 started to rupture at a lower force than the other samples (figure 31). For the circular hole, which represents the fistula best, the time before the sample started to rupture was shorter (figure 31f).

b) Second Test

From the additional tests performed on Dragon Skin with Slacker and Dragon Skin with 11% silicone oil with the circular hole (figure 32), it followed that Dragon Skin combined with Slacker took significantly longer to start to rupture than the Dragon Skin combined with silicone oil (mean = 12892 vs 8427 ms, P = 0.002253) (figure 33a). The time difference between starting to rupture and full rupture for Dragon Skin with silicone oil and Dragon Skin with Slacker was not significant (mean = 20748 vs 18791, P = 0.7780) (figure 33b). Again the samples started to rupture at the sutures in the middle and then outwards.

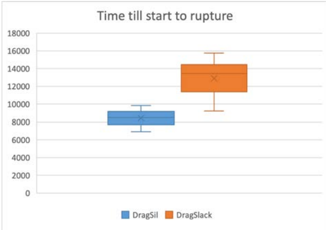


(a) *Dragon Skin with 11% silicone oil*

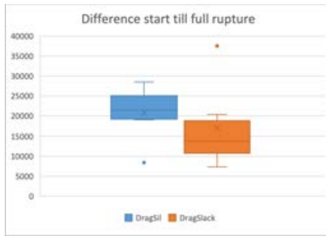


(b) *Dragon Skin with Slacker*

Figure 32: *Graph showing force against time of the samples of Dragon Skin with Slacker and Silicone oil with the circular hole and interrupted suture. Presenting the start of rupture by the red dot and full rupture by the red triangle.*



(a) *The scatter of the time till rupture starts of Dragon with silicone (DragSil) and Dragon with Slacker (DragSlack)*

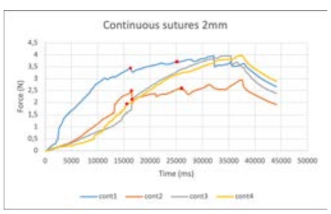


(b) *The scatter of the difference between the start and full rupture time of Dragon with silicone (DragSil) and Dragon with Slacker (DragSlack).*

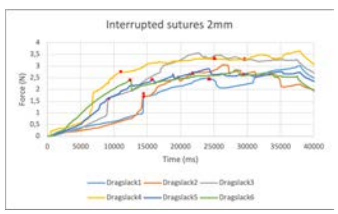
Figure 33: *Box plots comparing Dragon Skin with silicone oil and Slacker.*

c) Third Test

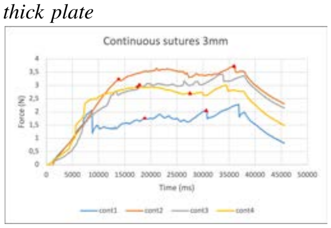
In this test the time to rupture of continuous and interrupted sutures were compared for Dragon Skin combined with Slacker of 2 mm thickness and 3 mm thickness (figure 34). For both thicknesses the samples with a continuous suture took significantly longer to start to rupture (for 2 mm, mean = 16227 vs 12892, P = 0.02274 and for 3 mm, mean = 17030 vs 13038, P = 0.02329) (figure 35). Furthermore, the scatter of the box plot of the continuous suture is smaller (figure 35).



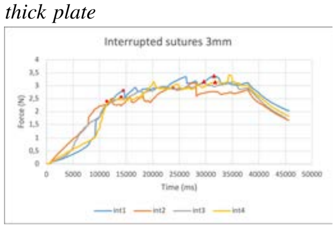
(a) *Continuous sutures on a 2 mm thick plate*



(b) *Interrupted sutures on a 2 mm thick plate*



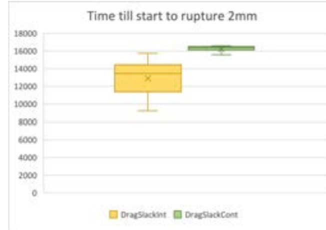
(c) *Continuous sutures on a 3 mm thick plate*



(d) *Interrupted sutures on a3 mm thick plate*

Figure 34: *Graph showing force against time of the 2 mm and 3 mm samples of Dragon Skin with Slacker with either an interrupted or continuous suture. Presenting the start of rupture by the red dot and full rupture by the red triangle.*

The samples still started to rupture in the middle for each type of suture and thickness of the material. However, with the continuous sutures, not all samples ruptured completely (figure 34). Moreover, it could be noticed during the experiment that the holes at the suture ruptured more gradually with the continuous suture.



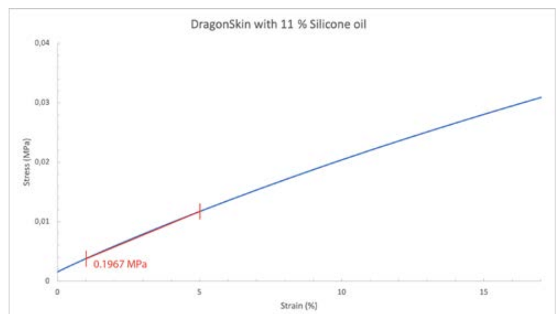
(a) *The scatter of the time till rupture starts of 2 mm thick Dragon Skin with Slacker plates with interrupted and continuous sutures.*

(b) *The scatter of the time till rupture starts of 3 mm thick Dragon Skin with Slacker plates with interrupted and continuous sutures.*

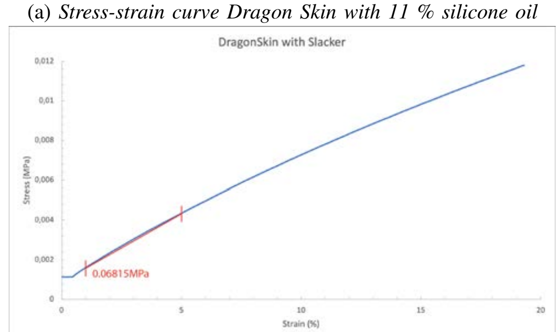
Figure 35: *Box plots comparing the time till rupture starts of samples with interrupted (DragSlackInt) and continuous sutures (DragSlackCont).*

d) Fourth test

Figure 36 presents the stress-strain curve of the Dragon Skin with 11% silicone oil plate and of the Dragon Skin with Slacker plate generated by the tensile machine, with the determination of the E-modulus. This resulted in an E-modulus of 0.1967 MPa and 0.06815 MPa, respectively for the two materials.



(a) *Stress-strain curve Dragon Skin with 11 % silicone oil*



(b) *Stress-strain curve Dragon Skin with Slacker*

Figure 36: *Determination of E-modulus from stress-strain curves*

IV. Discussion

a) First test

From the first test, it followed that Ecoflex 00-20 can be ruled out due to its tendency to tear faster while inserting the needle and its tendency to rupture at a lower force, and for the circular hole after a shorter amount of time, when placed in the stage. This is not desirable since it indicates that the sutures will not be watertight while under tension.

b) Second test

From the second test, it followed that the sample of Dragon Skin with Slacker took significantly longer to start to rupture than the sample with silicone oil. This indicates that Dragon Skin with Slacker will stay watertight when under tension longer than Dragon Skin with silicone oil. Meaning that Dragon Skin with Slacker might be most suitable to mimic the bladder tissue.

c) Third test

It differs per surgeon what type of suture is preferred, there are some clinical and experimental studies on the type of sutures but they have not concluded that one technique is superior to the other [49, 50]. For the closure of a vesicovaginal fistula, the standard is to use interrupted sutures, because this method may reduce the odds of dehiscence compared to a continuous suture [51, 52, 53]. However, the amount of suture material, the operative time and the effort of the surgeon are reduced when using continuous sutures [52]. From this study, it followed that the samples with the continuous suture took significantly longer to start to rupture than the samples with the interrupted sutures. This is opposed to the implication that the odds of dehiscence are higher for continuous sutures. Furthermore, the scatter of the box plot of the continuous suture is smaller, implying that using a continuous suture leads to more steady repetitive results. However, this is also influenced by the fact that one surgeon placed all sutures. In this study, a small number of samples were tested. Therefore, further research is needed on the effect of interrupted and continuous sutures to be able to conclude whether one technique is superior to the other.

It should be noted that during the first, second and third experiments, the silicone samples were clamped in the stage in combination with nails to prevent slippage. It could be noticed during the experiments that the sample started to rupture at the suture before rupturing at the nails, however, small slippage and ruptures could have had an effect on the results of the measurements.

After these experiments the values at which the material started to rupture were determined by looking at the video of the sample in the stage and the corresponding graph. When the material started to rupture about 2 mm on the video, the corresponding peak in the graph was taken as the matching value. Although in most cases it could clearly be seen in the graph as well that this was the starting point, there might be some deviations here since it was determined by eye.

d) Fourth test

The E-modulus for the bladder varies around 0.25 and 2.1 MPa [31, 32]. The E-modulus of the sample of Dragon Skin with silicone oil (0.1967 MPa) was closest to this value. The slope of the stress-strain curve of bladder tissue at small deformations is about 0.04 MPa [33]. The E-modulus of the sample of Dragon Skin with Slacker was closest to this value (0.06815 MPa).

The slope of the stress-strain curve of (non-prolapsed) vaginal tissue at small deformations varied more or less between 0.10 and 0.50 MPa [33, 34, 71]. The E-modulus of the sample of Dragon Skin with silicone oil, which was also calculated at a small deformation, was closest to this value.

This indicates that to mimic the bladder tissue, both Dragon Skin 10 with silicone oil and Dragon Skin with Slacker might be suited. To mimic the vaginal tissue Dragon Skin 10 with 11% silicone oil is most suited.

Silicone oil is needed to a much lesser extent than Slacker (11% vs 25%). Furthermore, the price of silicone oil is 28.55 euro per kg [44], while the price of Slacker is 47.99 euro per kg [42]. Therefore, it is much cheaper to use silicone oil than Slacker so it might be preferable. Further tests are needed on the water-tightness of both materials to conclude which material is most suitable.

Due to time limitation a selection was made in the materials that were tested. Although the indications are that these materials are suitable, a broader material research could have led to a different outcome.

V. CONCLUSION

From a test on the difference of continuous and interrupted sutures it followed that the samples with a continuous suture significantly started to rupture after a longer amount of time than the samples with an interrupted suture. Moreover, it followed that silicone oil is cheaper than Slacker and the E-modulus of Dragon Skin with silicone oil is nearer to the E-modulus of the bladder in comparison to Dragon Skin with Slacker. However, for small deformations, the slope of the stress-strain curve for Dragon Skin with Slacker was closest to that of the bladder and the sample with Slacker took significantly longer to start to rupture than the sample with silicone oil. Therefore, both materials might be considered to mimic the bladder tissue and further tests are needed on the water-tightness to conclude which material is most suitable. Furthermore, to mimic the vaginal tissue, Dragon skin with 11% silicone oil is most suitable, because the sutures in the vagina do not have to be watertight, because the slope of the stress-strain curve of Dragon Skin with silicone oil is closest to that of the vaginal tissue for small deformations, and because it is cheaper than Dragon Skin with Slacker.

APPENDIX D
LIKERT SCALE QUESTIONNAIRE

	Strongly disagree	Disagree	Undecided	Agree	Strongly agree	Comments:
Anatomy						
The anatomical properties of the bladder are realistic						
The anatomical properties of the vagina are realistic						
The anatomical properties of the urethra are realistic						
The anatomical properties of the cervix are realistic						
The anatomical properties of the vulva are realistic						
The anatomical properties (shape, diameter) of the fistula are realistic						
Feeling						
The feeling of the bladder tissue is realistic (first model, Slacker)						
The feeling of the bladder tissue is realistic (first model, silicone oil)						
The feeling of the vaginal tissue is realistic						
The feeling of the urethra is realistic						
The feeling of the cervix is realistic						
The feeling of the vulva is realistic						
The feeling of the fistula is realistic						
Procedure						
Locating the fistula is realistic						
Exposing the fistula is realistic						
Incising the vaginal tissue is realistic						
Incising the bladder tissue is realistic						
Separating the bladder tissue from the vaginal tissue is realistic						
Suturing the bladder tissue is realistic						
Suturing the vaginal tissue is realistic						
Total phantom						
The phantom model is suited to be used for training purposes						

Other comments (suggested improvements, pros and cons, etc.):

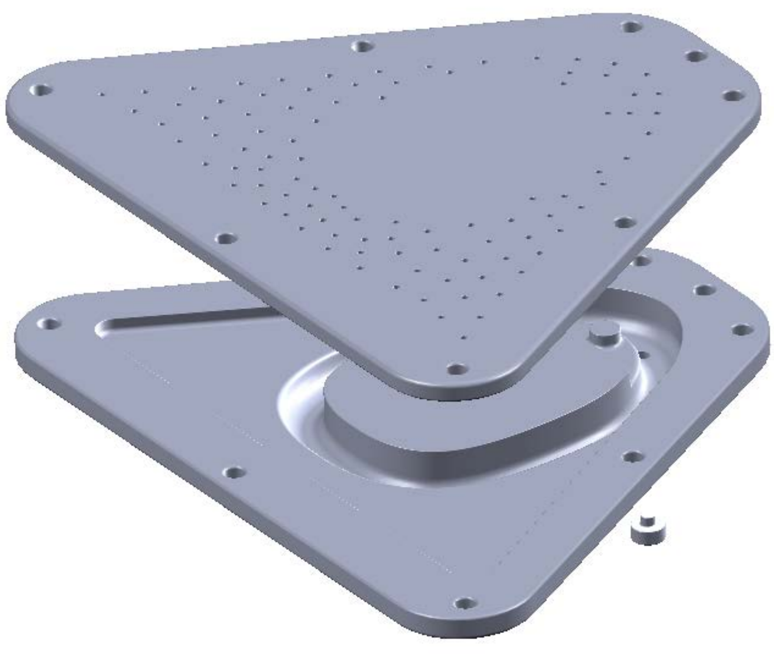
Appendix E
Detailed depiction of the updated framework and the updated mould for the vulva

(a) *Framework assembled*

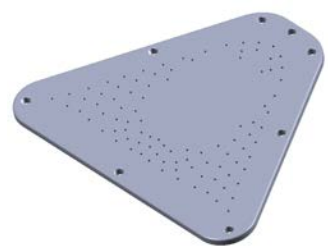
(b) *Framework part one*

(c) *Framework part two*

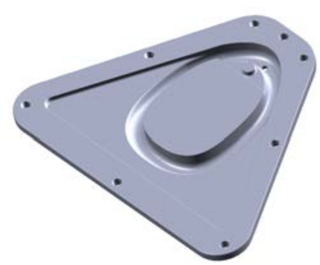
Figure 37: *Updated framework.*



(a) *Exploded view mould vulva*



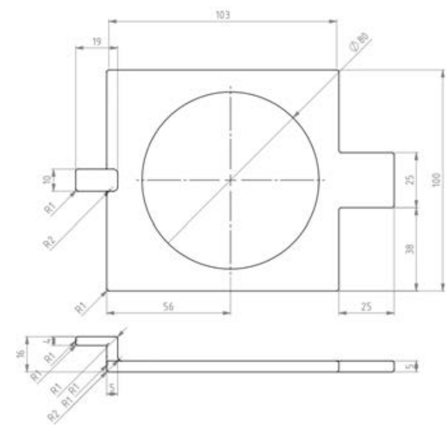
(b) *Mould vulva part one*



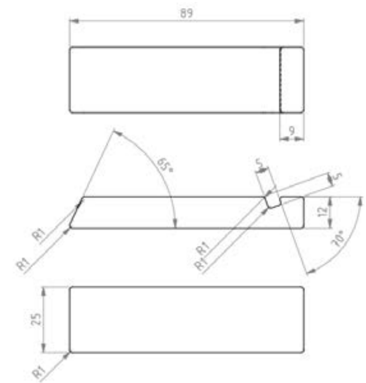
(c) *Mould vulva part two*

(d) *Vulva close-off pin*

Figure 38: *Parts updated mould vulva.*

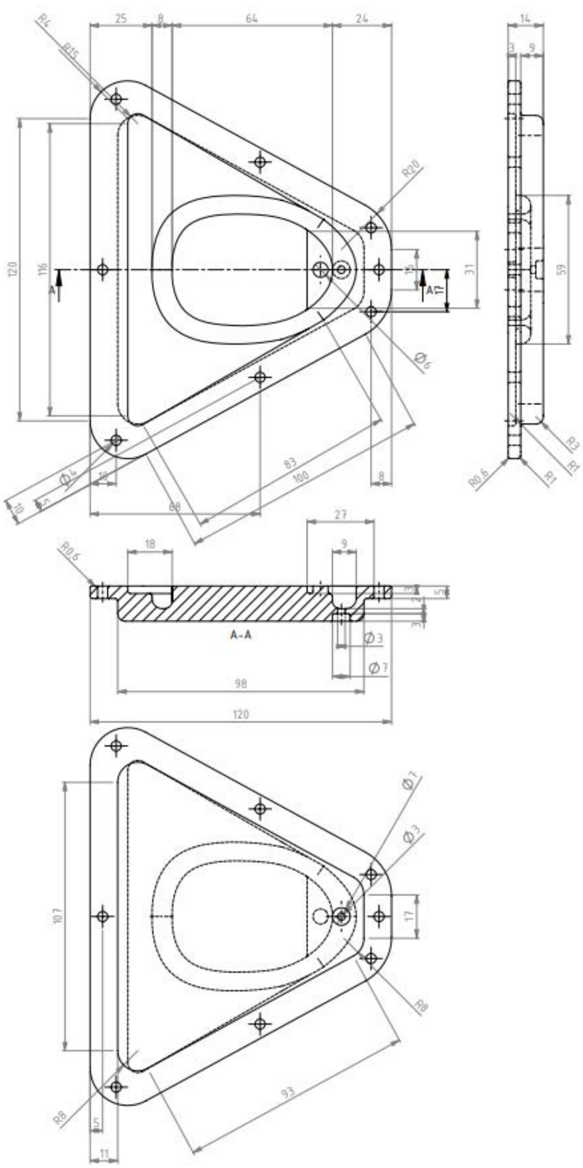


(a) *Framework part one*

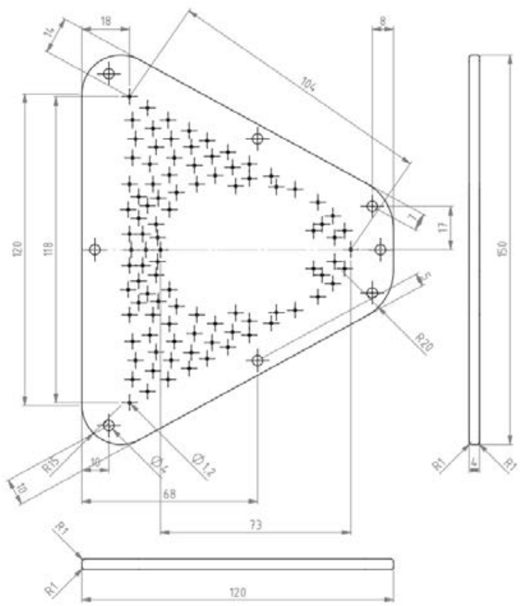


(b) *Framework part two*

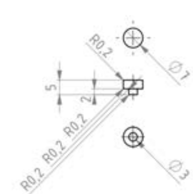
Figure 39: *Technical drawings parts for the updated framework in mm.*



(a) *Mould vulva part two*



(b) *Mould vulva part one*



(c) *Close-off pin vulva*

Figure 40: *Technical drawings parts mould for the updated vulva in mm.*

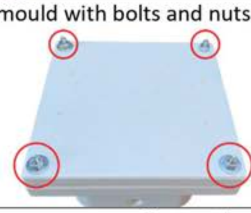
APPENDIX F
INSTRUCTION MANUAL PHANTOM MODEL

MOULDING STEPS

Step 1: Make sure the parts of the mould are clean. If not, clean with soap and let it dry.

Step 2: Spray release agent on the surfaces that will be in contact with the silicone.

Step 3: Connect the parts of the mould with bolts and nuts.



Step 4: Pour the silicone in the paper cup according to the required ratio and amount as given in the table.

Part	Amount
Bladder	36 g Dragon Skin 10 part A 36 g Dragon Skin 10 part B 18 g Slacker App. 6 drops of yellow liquid pigment
Bladder plate	20 g Dragon Skin 10 part A 20 g Dragon Skin 10 part B App. 4 drops of yellow liquid pigment
Vagina	25 g Dragon Skin 10 part A 25 g Dragon Skin 10 part B 5.5 g silicone oil App. 6 drops of mauve liquid pigment
Cervix	5.5 g Dragon Skin 10 part A 5.5 g Dragon Skin 10 part B App. 1 drop of mauve liquid pigment
Vulva	25 g Dragon Skin 10 part A 25 g Dragon Skin 10 part B App. 6 drops of brown liquid pigment

NOTE: For the vagina, first stir the A and B parts a few times before adding the silicone oil and the colour pigment.

Step 5: Stir the silicone mixture for about 2-3 minutes.

Step 6: Pull the plunger out of the syringe and close off the hub of the barrel, then fill the syringe with the silicone mixture where the plunger is normally placed. The table provides an overview of the used syringe for each mould.

Part	Used syringe
Bladder	50 mL catheter tip (tip diameter about 7 mm)
Bladder plate	50 mL catheter tip (tip diameter about 7 mm)
Vagina	50 mL catheter tip (tip diameter about 7 mm)
Cervix	20 mL luer tip (tip diameter about 4 mm)
Vulva	50 mL catheter tip (tip diameter about 7 mm)

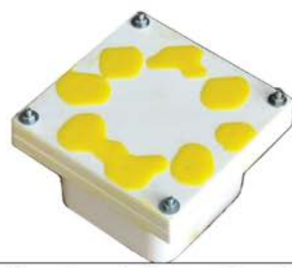
NOTE: For the bladder, first fill the syringe with halve of the silicone mixture, perform step 7, 8 and 9 and repeat when the syringe is empty with the other halve of the mixture. For the cervix, if there are multiple moulds available and step 1 to 3 are performed on all moulds, it is easier to mix the amount for 2, 3 or 4 cervixes at the same time, this amount still fits in the syringe.

Step 7: Put the plunger back in, turn the syringe upside down and open the hub of the barrel. Release the air and then put your finger on the tip (hub) of the barrel and apply vacuum by pulling the plunger down in a pumping motion, until most bubbles are gone.

Step 8: Remove the finger and release the air out of syringe by pushing the plunger.

Step 9: Put the syringe in the indicated hole in the mould and slowly push the plunger to fill the mould with silicone.

Step 10: Make sure to fill the mould entirely, keep pushing after the silicone comes out of the air holes, to make sure when trapped air is released there is still enough silicone inside the mould, so there will be no air bubbles present in the silicone.



Step 11: Close off the hole for the syringe in the mould and pound the bottom of the mould on the table a few times to release air bubbles.

Step 12: Let the silicone cure for at least 8 hours and release the silicone parts out of the moulds.

FABRICATION STEPS SILICONE PARTS

Step 1: Apply silicone glue in the edge of the cervix and place the vagina in the edge. Let it dry for a few hours.

Step 2: Cut the urethra to 5 cm and apply a layer of cyanoacrylate glue around it, then place in the indicated location in the bladder. Add a bit more glue around the inner and outer edges, and let it dry for 10 minutes.

Step 3: Add silicone glue in the inner and outer edges to seal it off. Let it dry for a few hours.

Step 4: Put a hard tube inside the vagina and apply a thin layer of silicone glue over the entire area about 2 cm around the fistulas hole, at the thickened edge the glue layer must be a bit thicker.

Step 5: Stretch the bladder's hole for the fistula over the thickened edge of the vagina and apply pressure.

Step 6: Wrap a layer of plastic foil over the glued area and around the tube. Then wrap an elastic band around it to maintain pressure. Leave it like this for about 10 hours.

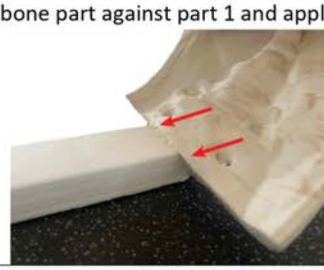
Step 7: Remove the elastic band and the foil and reshape the bladder.

Step 8: Apply glue on the circular edge of the bladder, place the bladder plate on top of this and lay it flat on the side of the plate to be able to apply pressure for about 10 minutes. Let it dry for a few hours.

FABRICATION STEPS FRAMEWORK

Step 1: Clamp part 1 of the framework at the table and apply hard PVC glue.

Step 2: Push the 3D printed bone part against part 1 and apply pressure for 10 minutes.



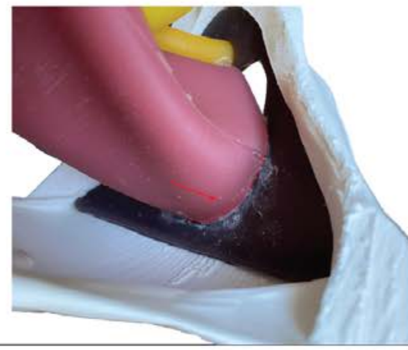
Step 3: Apply glue in the edge of part 1 and slide in part 2. Apply glue on top of part 2 where it touches the 3D printed bone part. Let it all dry for half an hour.

Step 4: Apply cyanoacrylate glue to the edges of the silicone around the vulva at the indicated location and push against the framework, hold for a few minutes until it is dry.

PLACING SILICONE PARTS IN FRAMEWORK

Step 1: Place the bladder with the urethra and vagina in the framework and push the urethra through the indicated hole in the vulva.

Step 2: Apply glue on the edge of the vagina and push against the vulva. Let it dry for a few minutes.



END RESULT: