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

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Introduction

It is estimated that in Africa 30,000-130,000 new cases arise annually and a total of 3 million women suffer from untreated vesicovaginal fistulas (VVFs) in Low- and Middle-Income Countries (LMICs) worldwide.[1,2,3,4] A VVF is an abnormal communication between the bladder and vagina that can result in urine leakage through the vagina. This does not only lead to physical but also psychological problems.[1-6] In LIMCs, the most common cause of a VVF is obstructed labour.[1,2,3,4] 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 are factors that impact the high rate of cases in LIMCs.[1,3,4,5,6] Some of the consequences are stigmatization and social isolation, because obstructed labour is often seen as a punishment from God and patients are abandoned by their families because of the smell of urine.[1,5,7]

To treat a vesicovaginal fistula the approach can either be abdominal (open or laparoscopic) or transvaginal, depending on the severity of the fistula and the surgeon's experience.[3,4,6] In general, complex fistulas are approached transabdominal, and simple fistulas are approached transvaginal.[3,4,6,8] Simple fistulas are classified as singular, when under 4 cm in diameter, without urethral involvement, without scarring of vaginal tissue, and not circumferential.[9] An example of a complex fistula can be when the fistula is highly retracted with a narrow vagina or when other pelvic structures are involved.[3,4,6] Sometimes interposition flaps are used between the bladder and the vagina at complex fistulas, to improve healing and reduce the chances of re-

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currence.[4,5,6,10,11] The laparoscopic approach can be used in the same cases as the transabdominal approach; however, it is not widely used due to the costs and lack of skilled surgeons.[3,4] In simple fistulas the most preferred approach is transvaginal, because of its simplicity and efficacy and it minimises the postoperative complications, the hospital stay, the blood loss, and the pain following the procedure while achieving equal success rates.[3,4,5,8,10,11,12] Most fistulas in LMICs are treated with this approach.[5]

To increase access to VVFs and to improve the outcome of surgery, the surgeons performing the procedures must be well-trained. In Sub-Saharan Africa where the condition is most common, a lot of surgeons are not familiar with this procedure, therefore, patients suffering from a vesicovaginal fistula must travel to specialised clinics to receive treatment. To increase the access to training, phantoms can be used.[13,14] Most phantoms of the female pelvis are focused on testing and user-training of imaging devices, as done in a study by Kadoya et al.[15,16,17] involving CT images of all pelvic organs, or in the studies of Choi et al. and Lurie et al. involving the endoscopic view of the bladder. A few researchers developed phantoms that are used to test/train needle insertion,[13,18,19] but phantoms that facilitate performing sutures were used rarely, e.g., by Nattagh et al.[14]

Therefore, this paper presents the development of a training phantom model for a transvaginal vesicovaginal fistula repair. The model focuses 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.[9] The phantom (frame and moulds) can be easily produced (both the model and the elements that needs to be replaced every time after a training) using 3D printing with the widely available 3D-print material PLA and silicone for the soft parts in LMICs. The model in this study can be used for the training of medical doctors and gynaecologists not (yet) familiar with the procedure. It includes both dissection of the fistula and repair in layers. The development of the training phantom in 2 iterations and evaluations done by gynaecologists working in the Netherlands and residents in gynaecology in Kenya will be described in detail.

Methods

This study consists of several phases, first, the design requirements for the phantom were established based on the procedural steps as well as on the context of manufacturing in LMICs. Secondly, the first iteration of the phantom was produced by 3D printing and silicone materials representing the bladder and vagina. Additionally, this first phantom was evaluated by 2 gynaecologists with experience in the treatment of vesicovaginal fistulas. A second iteration of the prototype was developed incorporating the feedback from the gynaecologists and the improved design was evaluated by 5 residents in gynaecology in Kenya. The study has been approved by the Human Resource Ethical Committee of the TU Delft (HREC 2388).

Requirements

Important requirements for the VVF phantom model, that follow from the procedural steps are:

- The scar tissue of the fistula should be mimicked.
- A forceps should be able to be used on the materials mimicking the vagina.
- The vaginal wall should be able to be incised by a scalpel.
- 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.
- The material for the bladder should be able to become watertight by suturing.
- The bladder should be able to be filled with liquid to test this water-tightness.
- Reuse of parts as much as possible.

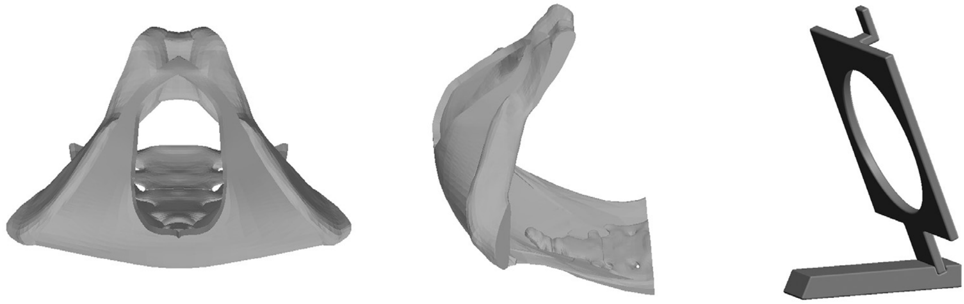

Fig. 1. SolidWorks images of the frame. Left: front view of the anatomical frame. Middle: side view of the anatomical frame. Right: base Frame to connect parts.

Requirements that follow from the context of manufacturing in LMICs:

- Use of materials for 3D printing that are available in many LMICs.
- Use of standard 3D printers (e.g., Ultimaker etc.)
  - 3D printing with PLA for the bony elements, holder, and the moulds.
- Use of off-the-shelf materials for the soft tissues
  - silicon and additives, silicon glue, cyanoacrylate glue, a natural rubber tube.
- Use of a low-costs urine catheter (below 25 Euro).
- Overall costs of the materials for 1 single model below 25 Euro.
- Costs of the single-use parts below 10 Euro.

Phantom design and production (first generation)

The phantom was designed using 3D-printed PLA parts for the bony structures, the frame, and moulds to prepare the silicone parts mimicking soft tissues.

The tissue-mimicking material representing the bladder and vagina was chosen after performing experiments on potentially suitable materials see Supplementary material I for tests of different tissue materials for vagina and bladder.

Printing of base and anatomical frame

A frame is used to connect the model parts and to secure the organs inside (Fig. 1, Supplementary Material II). The base and anatomical frames were 3D printed with PLA in an Ultimaker 2+. PLA was chosen due to its high printability and low price.[20] A model of a female with realistic measurements was used to export a model of the female pelvis with realistic size and shape. An opening of about 75×45 mm for the vagina was used to secure the vulva. The sacrum was placed more or less parallel to the table with the lithotomy position of the patient in mind.[21] 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.

Soft materials

The silicone parts for the soft materials were made using moulds. 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+. See Supplemental Material II and III for details on producing the moulds and tissue fabrication. The silicone was cured in the moulds for at least 8 hours. For the tissue-mimicking silicone material, Dragon Skin 10 and 2 different additives, 11% silicone oil (bladder) and Slacker (vaginal tissue), were used. The cervix, the vulva, and a plate that closes off the bladder were all made with Dragon Skin 10 without an additive.

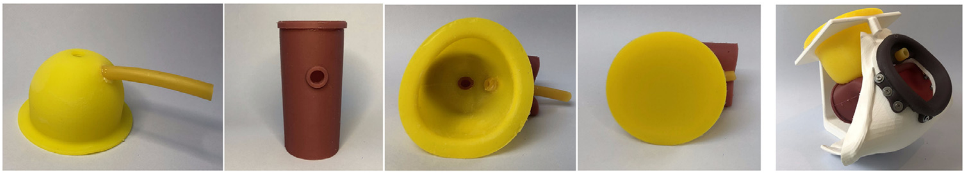

Fig. 2. Intermediate stages in connecting the silicone parts. From left to right: Bladder and urethra connected. Vagina and cervix connected. Bladder, bladder cover, and vagina connected. Most Right: Total assembled first prototype.

To mimic the urethra a tube of natural rubber was used, and finally silicone glue was used to mimic the connecting fascia between the bladder and vagina and to connect the organs. A hole of 11 mm with a thickened edge with increased stiffness at 1 side represents the scar tissue of the fistula.

Fabrication of the VVF phantom model

The 3D printed parts of the frame were fixed together using glues. See Supplementary materials III for details. Figure 2 depicts the intermediate stages in connecting the silicone parts. Holes in the 3D printed framework were made to secure the vulva and vagina. The vulva was attached to the framework using bolts and nuts and the vagina was attached to the bladder. Figure 2 (right) depicts the total assembled model.

The CAD files for the model and the models are available online through an open access link with an instruction manual (https://doi.org/10.4121/f487e16e-c4f5-4f62-84a8-4650807c9004).

Evaluation of the first iteration of the phantom

To validate the first prototype, 2 Dutch gynaecologists, who performed many vesicovaginal fistula repairs, were asked to comment on their findings while performing the procedure. Most aspects scored by the expert gynaecologists received a Likert scale 4 or 5 (see Table A1 and A2, Appendix A). Feedback on lower-scoring parts were used to improve the phantom. The following feedback was given by the gynaecologists and incorporated in the second iteration of the prototype (final prototype)

1. In the final model, the angle of the anatomical frame was adjusted to 65 degrees to get the correct angle to perform the procedure, and the bladder was placed a bit lower to be able to pull it down better.
2. The working space in the initial model was limited, therefore, the gap in the 3D printed model was broadened and more silicone was added on the sides, representing skin.
3. Some suggestions were made to improve the procedure. Separating the bladder wall from the vaginal wall was too difficult. In the final model, the layer of silicone glue representing the fascia was spread thinner and more even. To gain a more realistic look, the vulva was glued with cyanoacrylate glue to the frame instead of using bolts and nuts. The vagina was sutured to the vulva, to create a strong fixation.

Evaluation of the second iteration of the phantom

The improved model was tested by 5 residents in obstetrics and gynaecology from Kenyatta Hospital in Nairobi Kenya using the same Likert scale (Table A3, Appendix A) with as main categories: anatomy, tissue feeling and execution of the procedure. Moreover, surgeon TW performed the procedure after which the watertightness was tested.[22] This was done by filling the bladder with coloured liquid via the urethra using the barrel of the syringe attached to a Foley

Fig. 3. Total assembled final model. Upper: tilted upper left side-view. Left: upper front-view. Right: tilted right side-view.

catheter. The syringe barrel is held 20 cm above the urethral level and the liquid flows in by gravity. Leakage was checked by putting a gauze against the suture location.

Results

The final prototype is depicted in Figure 3. An overview of the procedural steps performed on the updated final phantom model is depicted in Figure 4. After the steps were performed by the surgeon, it followed that the adjustments to the framework and vulva indeed led to more freedom of movement. Moreover, the traction sutures could easily be secured to the 3D-printed model. All procedural steps could be performed on the final model without any problems. From the gravity test, it followed that the bladder made of Dragon Skin with Slacker did not show any leakage, indicating that Dragon Skin with Slacker is a suitable material to mimic the bladder.

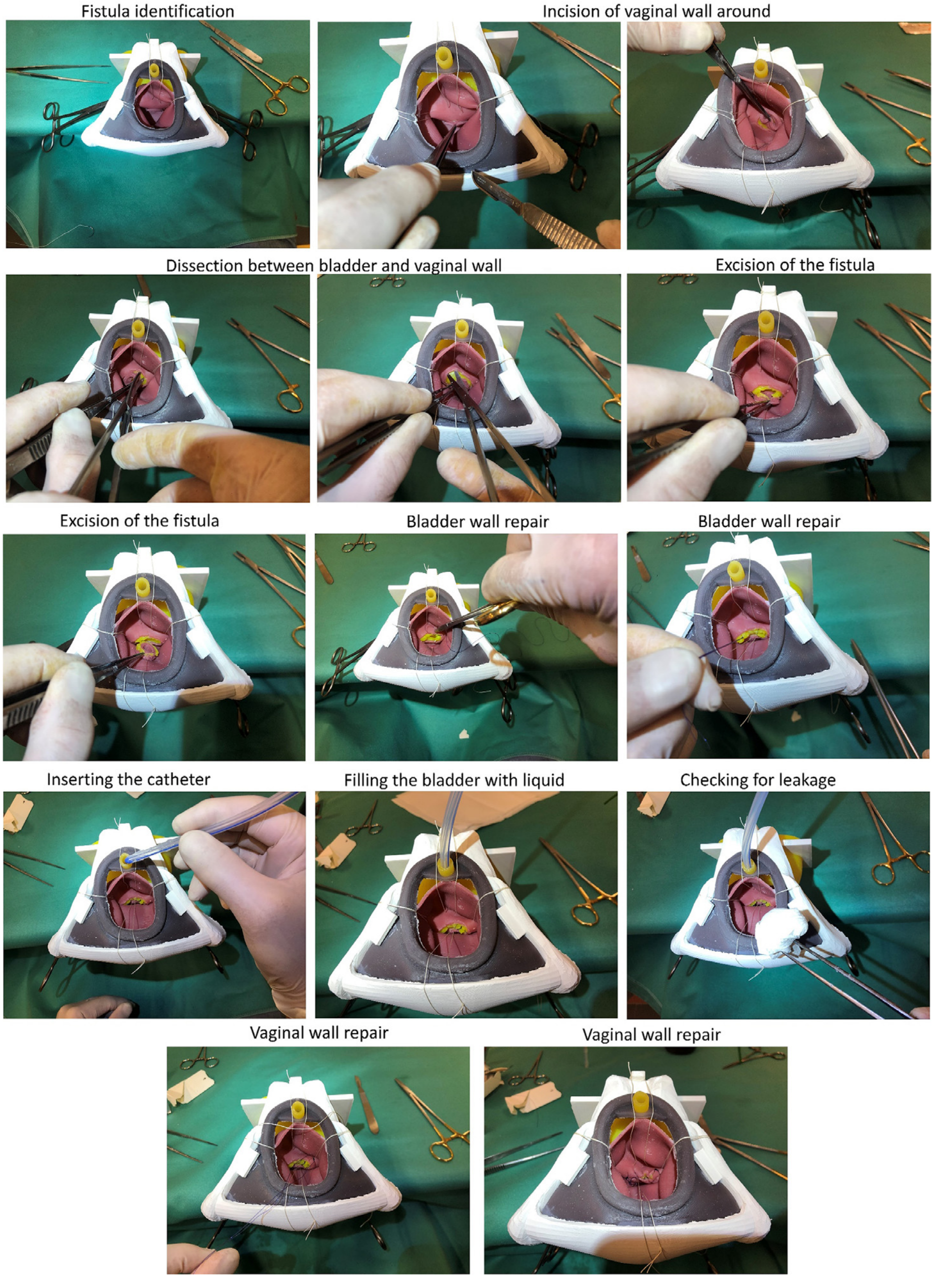

Fig. 4. The procedural steps performed on the phantom model.

Evaluation of the final prototype in Kenya

The results of the evaluation by the 5 residents of the improved model can be found in Table A3, Appendix A. It shows the Likert score of the 3 main categories: anatomy, tissue feeling, and execution of the procedure, and the score of the suitability of the phantom for training purposes. The anatomical properties of the model (bladder, vagina, urethra, vulva and location and size of the fistula scored on average a 3.5, feeling of tissues (bladder, vaginal, urethra, cervix, vulva fistula) scored a 3.4, and the procedural steps (locating exposing incising, separating, suturing) a 3.4. The overall score for suitability for training purposes was 3.8. Improvement could be achieved in the laxity of the vaginal wall and less stiffness of the pelvic floor.

Material costs

Since the model is meant to be made for low-resource countries, it is desired to keep the costs low. The material costs for the permanent parts were about €15. The moulds and frame made from PLA filament (~120 m) cost ~€ 7, and the vulva and Dragon Skin 10 with brown pigment ~€ 1, and glues, bolts, nuts, and rings ~ € 7. The material costs for the replaceable parts are ~€ 6. This includes the bladder and top with yellow pigment, the vagina and cervix with mauve pigment, natural rubber (5 cm) for the urethra, fascia, and connections. Labor hours are not considered.

Discussion

A training phantom for a vesicovaginal fistula repair with the transvaginal approach involving simple fistulas was presented. The evaluation of the first and second iterations of the prototype showed that the procedural steps could be performed on the phantom model without any problems after implementing the suggestions of the experts to broaden the working space and to adjust the angle of the model to the Trendelenburg position. The thickened edge of the vagina 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. It was possible to repair the bladder tissue with sutures and the dye test could be performed to check the watertightness of the bladder. Lastly, the vaginal tissue could be repaired to complete the procedure.

Phantom development

As stated before, in previous works, most phantoms of the female pelvis are focused on testing/training imaging modalities.[15,16,17] Only a few researchers looked at phantoms to facilitate needle insertion, but phantoms to facilitate sutures, such as described in this research, are rarely used.[13,14,18,19] Recently Kent et al. published about a low fidelity model[23] (ahead of print). Details are lacking, but the model allows for suturing to be practiced, however bladder filling to check watertightness in contrast to the presented model does not seem to be possible in this model Other studies report about standardized animal models, involving dogs, pigs and sheep.[24-26] These animal models come with high costs, the necessity of an extra operation to create the fistula, and show inconsistent success percentage of fistula formation. The phantom made in this study is unique because it does involve suturing and testing of watertight bladder closure and is specifically tailored to manufacturing in LMICs.

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.[15,16,17,24,27-31] 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 anatomical frame. Additionally, 3D printing is rapidly becoming more widely available in many LMICs contributing to the widespread implementation of training phantoms as presented in this paper.

The materials used to mimic soft tissue that were tested in this study, are already used in the production of, for example, a liver phantom.[13,27,28,32] However, additives such as silicone oil and Slacker that are used to tune the mechanical properties of the silicone were not used in previous 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.[33] The same result followed from the water-tightness test in this study. 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.[10,34,35] As far as we know 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.

The combination of 3D printing and the use of silicone with off-the-shelf additives for reasonable prices tailors to goal of this training phantom to be produced in LMICs. In order to facilitate the widespread implementation of this training model we have shared our files and a manual open access.

Evaluation

The material costs could be kept low. To spare material and thereby costs, it would be valuable if the replaceable parts of the silicone could be recycled as well.[36] 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.[37] They observed that with the 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%.[37] The modulus was reduced by 15%, while the hardness, tension set, and hysteresis loss underwent marginal changes and compression stress-relaxation are not significantly changed.[37] To determine whether this is a possibility to apply to the parts of the phantom model, further tests are necessary.

The feedback of the experts showed that a phantom model was made on which all procedural steps of the repair of a simple fistula with the transvaginal approach could be performed. Interestingly is that the novice residents scored several aspects such as locating the fistulae, lower on the questionnaire (Table A3, Appendix A), despite the improvements made after incorporating the feedback of the experts. That novices scored lower might be due to the fact that they are not experienced enough with this difficult procedure and that they experienced the procedure more difficult than expected.

Next steps in validation of the model includes finding partners in LIMCs to produce the model. This can be small 3D print companies as well as hospitals of universities willing to take up the challenge of using 3D printing. We will investigate whether the provided online instruction material is sufficient, and adapt the online instructions when necessary.

Limitations

The model is focused on the treatment of simple fistulas. The training model is not applicable for training purposes for more complex types of fistulas. Only a few surgeons were contacted to test the phantom model. For a broader analysis, it would be valuable to test the model with a larger number of experienced surgeons, but also with residents without experience to test whether the model is beneficial for learning purposes.

In the final model, it was decided to suture the vulva to the frame after holes were incorporated in the bony part. The vagina was sutured to the vulva. This connection is strong but needs to be repeated for every procedure. More tests are needed if with the widened vulvar access, repair is now more mimicking the clinical situation.

Future research could focus on developing a training for more complex types of fistulas. However, development of a model, both animal or low fidelity, for complex fistulas will require a lot of effort and include higher costs, since many different types of obstetric fistulas exists.[38] A low fidelity trainer for complex fistulas might be unrealistic. Hence, the developed fistula trainer aims to provide gynaecologist a training solution as an initial step in the training of most of the simple fistulas, leaving the complex fistulas for referring to a specialized centre.

Conclusion

In conclusion, a phantom model was developed and successfully tested by experienced surgeons and gynaecological residents. The scar tissue of the fistula is realistically mimicked by a thickened edge and it could successfully be incised and dissected away from the bladder wall. Forceps could be used on the tissue-mimicking material for the vaginal wall but in a new version more laxity is necessary. 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 by the use of 3D-Printing, 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. However, more research is needed to investigate the effectiveness of training on the vesicovaginal fistula repair phantom on the learning curve of resident surgeons and gynaecologists. At this moment only a few versions of the phantom model are available. In order to facilitate research with this training model, as well as further implementation, we have shared our files and the manual as open access.

Declaration of competing interest

T. Wiggers reports a relationship with Incision that includes: consulting or advisory and equity or stocks. The other authors declare that they have no known competing financial interests or personal relationships that could influence the work reported in this paper.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.cpsurg.2024.101550.

Appendix A - Likert scale questionnaire and the scores of expert gynaecologists and resident surgeons

Table A1
Scores of the 2 expert 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 A2
Scores of the 2 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

Table A3
Scores of the residents surgeons.

	Strongly disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly agree (5)	Comments
Anatomy	Number of residents					
The anatomical properties of the bladder are realistic			1	4		
The anatomical properties of the vagina are realistic				5		
The anatomical properties of the urethra are realistic			4	1		
The anatomical properties of the cervix are realistic			1	4		
The anatomical properties of the vulva are realistic			1	3		1 missing
The anatomical properties (shape, diameter) of the fistula are realistic				3	2	
Feeling						
The feeling of the bladder tissue is realistic (first model, slacker)		1	2	2		
The feeling of the bladder tissue is realistic (first model, silicone oil)		1	2	2		
The feeling of the vaginal tissue is realistic			1	4		
The feeling of the urethra tissue is realistic		3	1	1		
The feeling of the cervix tissue is realistic		1	1	2	1	
The feeling of the vulva tissue is realistic		2	2	1		
The feeling of the fistula tissue is realistic			1	4		
Procedure						
Locating the fistula is realistic				3	2	
Exposing the fistula is realistic				3	2	
Incising the vaginal tissue is realistic		3		2		

(*continued on next page*)

Table A3 (*continued*)

	Strongly disagree (1)	Disagree (2)	Undecided (3)	Agree (4)	Strongly agree (5)	Comments
Incising the bladder tissue is realistic	1	1	1	2		
Separating the bladder tissue from the vaginal tissue is realistic	1		1	3		
Suturing the bladder tissue is realistic		1		4		
Suturing the vaginal tissue is realistic			1	4		
Total phantom						
The phantom model is suited to be used for training purposes			2	2	1	

CRediT authorship contribution statement

Tink Voskamp: Conceptualization, Writing – original draft, Methodology, Software, Investigation, Visualization, Writing – review & editing. **Weston Wakasiaka Khisa:** Investigation. **Roos M. Oosting:** Writing – review & editing, Data curation. **Theo Wiggers:** Conceptualization, Methodology, Investigation, Writing – review & editing, Supervision. **Jenny Dankelman:** Conceptualization, Methodology, Writing – original draft, Writing – review & editing, Supervision.

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