Original Article

Creation and evaluation of a three-dimensional-printed synthetic vas deferens for microsurgical training

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ABSTRACT

Introduction: Individuals choose to undergo vasectomy reversal for a variety of reasons, including remarriage or due to the death of a child. To be proficient in this procedure, the surgeons need to be high volume and the trainees require a safe environment to develop their microsurgical skills. To overcome this challenge, we used three-dimensional (3D) printing to create a synthetic model of the vas deferens with properties similar to the human vas deferens. We distributed this model to experienced microsurgeons for evaluation.

Methods: The vas deferens model was created using thermoplastic polyurethane filament. The filament was then infused with a foaming agent to allow for temperature-dependent tuning of the material's stiffness. The model's outer diameter was 1 mm and the inner lumen was 0.5 mm. Fellowship-trained male reproductive urologists were recruited from the Society for the Study of Male Reproduction website. They used our model and judged it on several factors by completing a 13-question survey.

Results: We received completed evaluations from five microsurgeons. Eighty percent of the surgeons were able to complete a full anastomosis on the model using 9-0 and 10-0 sutures. The majority of the completed anastomoses were performed using the one-layer technique. The average responses for the model's usefulness as a practice tool, a training tool, and overall assessment ranged from 72 to 79 out of 100. Comments for the improvement included the need for a more flexible and softer model.

Conclusions: We created a 3D-printed synthetic vas deferens that serves as a valuable training and practice tool.

INTRODUCTION

A small percentage of men, despite willingly and often enthusiastically undergoing the vasectomy, change their minds and choose to restore fertility later in their lives, and opt to undergo the vasectomy reversal surgery.[1] Some highlighted reasons for which an individual may choose to undergo a vasectomy reversal include the death of a child, change in financial situation, divorce and/or remarriage, or as a treatment for the post-vasectomy pain syndrome.[2,3] Vasectomy reversal is a technically challenging surgery and requires a considerable amount of microsurgical expertise to achieve a high rate of success.[4] Such skills are difficult to learn and must be maintained through frequent practice. Unfortunately, for the urologists who like to perform vasectomy reversals and for trainees who want to learn how to perform them, the vasectomy reversal surgery is currently being performed less often than in the past. In fact, the frequency of vasectomy reversal surgery has been on a decline for the past few decades. Why is this so? This may be due to several reasons including the costs associated with the surgery, the availability of sperm retrieval techniques coupled with advancement in the reproduction technologies for women, and the couple and the surgeon preference.

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Currently, the data suggest that the surgeons who perform the vast majority of the vasectomy reversals perform an average of only three vasectomy reversals over a period of 6-years.[5] Some "high volume" teaching centers perform only 10 or so vasectomy reversals per year and only a handful of centers nationally and internationally perform more than 50 per year.

The infrequency with which these procedures are performed limits the opportunities for the experienced surgeons to improve their skills – or even to maintain them – and for trainees to develop their microsurgical skills. High-volume surgeons have been shown to have outcomes that are comparable to the previously published contemporary series with one article defining "high volume" as an average of 37 cases for faculty microsurgeons.[6] The issue lies at centers or training programs that are not considered to be high-volume. Vasectomy reversal is a challenging procedure due to the small size of the structures involved and requires a sufficient number of repetitions to refine and maintain the skills needed to successfully perform the procedure. At our program, we believe that acquiring the microsurgery skill is as important as any other skill set in urology. Thus, we developed a curriculum for microsurgery education that uses, among other things, a three-dimensional (3D)-printed vas deferens model to teach the microsurgical skills such as suture placement and needle handling.

We internally validated our model through an iterative process of development and testing. Now, that we have developed the model to our own specific needs, we decided to let others, outside of our own institution, test it, and determine if it is useful for their educational needs.

MATERIALS AND METHODS

Approval from our Institutional Review Board was obtained for this study on February 3, 2023, as an exempt study. Informed consent was obtained from all the participants. The procedures of the study adhered to the ethical guidelines of the Declaration of Helsinki and its amendments. The study's approval number was i23-00076. The authors confirm the availability of, and the access to, all the original data reported in this study.

Survey instrument and subject recruitment

Using publicly available information on the "Find a Society for the Study of Male Reproduction (SSMR) Doctor" section of the SSMR website, we obtained the e-mail addresses of fellowship-trained male reproductive urologists and recruited them to test our model. Other individuals were recruited through personal invitation. When participants enrolled in the study, we sent the model by US mail and followed up with an anonymous 13-question survey sent through Qualtrics. We asked participants to attempt an anastomosis of their choice, either 1 or 2-layer, and judge our model on a variety of factors such as similarity to the native vas deferens, ease in placing the sutures, and usefulness as a training tool, among others; [Appendix A]. All the participating testers were contacted a total of 3 times to ensure completion of the survey.

Three-dimensional model design

The synthetic vas deferens model was designed using the SolidWorks CAD software (Dassault Systèmes SolidWorks Corporation, Waltham, MA) and the model was printed with commercially available, off-the-shelf filament material selected to give the model similar physical characteristics to the native, biological vas deferens. The model's outer diameter was 1 mm and the inner lumen of the model was 0.5 mm. For additional technical information regarding the 3D printing process, please refer to [Appendix B].

RESULTS

We received a total of 15 responses from the surgeons who agreed to participate in our study. Fifteen models were then mailed to the participating surgeons. We received the completed model evaluations from five male reproductive urologists. Their impression of the quality of the model is shown in Table 1. The surgeons were able to use 9-0 and 10-0 sutures and 80% were able to complete a full anastomosis with the model [Figure 1]. Two survey participants relayed that the lumen was too large for a two-layer anastomosis and was more feasible for a one-layer anastomosis. Regarding the similarity to and the usefulness of the model, we asked the participants to rate tactile similarity to the vas deferens, axial flexibility, sturdiness, ease to place the sutures, usefulness as a practice tool, usefulness as a training tool, and overall assessment from 0 to 100. We collected average results for each of these seven variables [Figure 2]. Average responses for usefulness as a practice tool, a training tool, and overall assessment ranged from 72 to 79 out of 100. In terms of

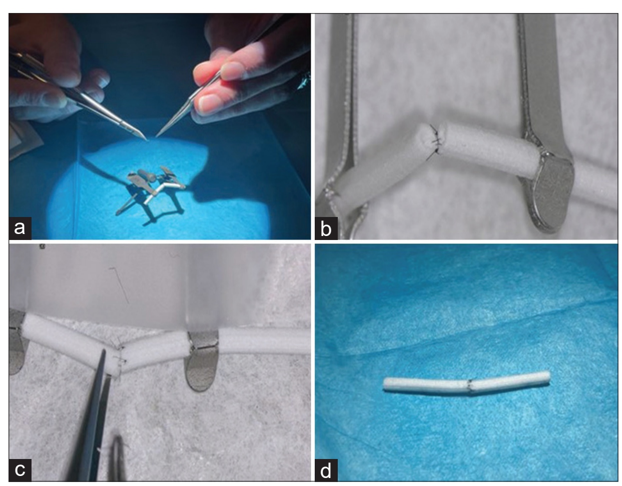

Figure 1: Synthetic Vas Model. (a) Vas model within microspike approximator. (b) Beginning of anastomosis. (c) Anastomosis of the posterior wall. (d) Completed anastomosis

Table 1: Survey responses by participant regarding use of the model

Participants	Suture and anastomosis type	Complete?	If incomplete, why?	Comments
One	9-0, modified two-layer	No	Difficulty stabilizing	1. Stability, 2. Wider lumen to ease practice, 3. Different colors to serosal + luminal layer to differentiate when placing sutures
Two	9-0, one-layer	Yes	N/A	A little more flexibility
Three	9-0, one-layer	Yes	N/A	In my honest opinion, this model would be better with a softer, more compressible material
Four	10-0, two-layer	Yes	N/A	
Five	10-0, one-layer	Yes	N/A	Slightly too firm, lumen too large, and muscularis too thin. As a training device, it would be nice to have it come in two pieces with weighted ends because it moves around a lot since the ends are free and not fixed like in a real patient. It's great for training - I used it with my physician assistant to show her some basic microsurgical suturing techniques. Would like to have been able to do a two-layer anastomosis

NA=Not available

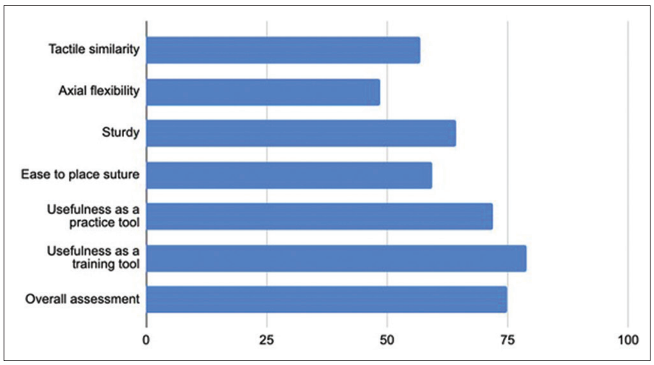

Figure 2: Average similarity to and usefulness of the model, n = 5

similarity to the vas deferens itself, the respondents found the model to be stiffer, as the axial flexibility received an average score of 48 out of 100.

General comments highlighted the need for the model to be more flexible, softer and to come with weighted, fixed ends to make it more similar to the vas deferens. However, the general consensus was that our model, although not perfect, was valuable as a training and practice tool.

DISCUSSION

Our model was created using 3D printing – a technology now available to the masses – and is cheap, durable, reproducible, and based on the results of this study, acceptable for a microsurgery training and practice tool. The overall assessment score was 75 out of 100 regarding the similarity and the usefulness of the model. Survey respondents stated that, on an average, the tactile similarity to a human vas deferens was 55 out of 100 and the ease of placement of sutures was 55 out of 100. Most of the participants were able to complete a one-layer anastomosis and one participant was able to complete a two-layer anastomosis. One participant was unable to complete a two-layer anastomosis secondary to issues related to the stability of the model. Previous comparisons of outcomes between modified one-layer and two-layer vasovasostomy techniques have shown equal patency rates.[7,8] Some criticisms include the lack of stability of the model within the microspike approximator, the need for softer material, larger lumen, and the lack of color to differentiate between the serosal and the luminal layers. These criticisms have simple corrections and the remedial measures can be performed in a low-cost and efficient manner. Our foaming agent allows us to fine-tune the stiffness of our model which can be easily be reprinted to be less firm. We can also address the lack of stability by printing longer segments and use tapes to hold the segments in place. Finally, we can modify the color of the inner lumen by simply injecting a dye using a fine gauge needle. With these remedial measures, we will thus increase the stability of the model and modify the color of the inner lumen. These changes will serve to make the two-layered anastomosis more feasible. While creating future iterations of this model, we will take these considerations into account and apply these changes.

To improve a skill set, one must learn the right technique and practice repeatedly. The use of simulation within urology has become increasingly popular as it allows for the surgical skills to be practiced in a safe low-pressure environment.[9] Within the UK, a simulation course for junior urology residents has been developed that has led to an increase in the level of knowledge, increased operative competency, and operative confidence.[10] We believe that this is applicable to the microsurgical training as well. Essential microsurgical skills include the correct handling of the instruments, improving dexterity, the ability to load the needle, and knot tying.[11] A variety of studies have shown that completion and regular interim practice using simulation-based training programs makes the trainee better at microsurgery, with associated better outcomes.[12-14] Accordingly, our model will serve to help the trainees acquire essential microsurgical skills. The model has tactile similarity to a human vas deferens which can help trainees develop a feel for how the needle will pass through the actual tissues. The model also helps develop skills such as needle loading in between the throws and knot tying to complete an anastomosis. Given that 80% of the US-based urology residency programs have a fellowship-trained microsurgeon on faculty, this training tool can be widely beneficial.[15] Our model will allow trainees to hone their skills and thus have the confidence to become more involved in microsurgery cases at their institutions.

Most simulated vasectomy reversal training is undertaken on the animal models, such as the femoral arteries of the chicken thigh, the rat vas deferens, the canine postneuter specimens, and the bull vas deferens.[16-18] These models, while excellent in their own ways, are not ideal. They are neither readily available or durable, and are not cost-effective.[16,19] In addition, these models are not anatomically similar to a human vas deferens. Other models have also been descried which use silicone tubing. When tested on trainees in a controlled environment, the silicone tubing was as effective as the live animal vas deferens for microsurgical education.[13] Despite the efficacy of silicone tubing as a training model, there remains a need for a synthetic alternative that more closely resembles the physical properties of a human vas deferens.[20]

SynVas, (SynDaver Inc), is a commercially available silicone product that is promoted for anastomosis training. The biggest disadvantage of the SynVas is its high cost. A set of 3 SynVas models costs $167.45. Moreover, SynVas's utility as a training tool has never been studied or validated.[21] The total cost of research and the development of our model was under $70, including the materials. On a per-model basis, each 2 cm segment of the model costs pennies, not dollars, and certainly not hundreds of dollars, to produce. Our model can be easily reproduced by other centers by providing them with a list of materials required for the production and the Standard Triangle Language file (.STL) needed for the 3D printing process. One limitation for model reproduction may include the lack of access to a 3D printer which may be due to the financial or technological constraints in some regions. A potential solution to this limitation may include shipping of the completed models to these regions at a low cost.[22]

Our group certainly is not the first to create a 3D-printed model of vas deferens. Tradewell *et al.* produced a 3D-printed vas model of deferens for vasovasostomy training. Their model was a bit too stiff, besides that, the model yielded similar results as far as the ability of the surgeons to successfully suture one end to the other with fine suture material was concerned.[23] The 3D-printed vas deferens models do not require a mold – an advantage over the silicone models. Furthermore, the 3D printing allows to fine-tune the geometry of the print, which means that the models can be created with varying size dimensions and physical properties to mimic a variety of different clinical scenarios, such as the commonly encountered discrepancy in the vasal diameter between the testicular and abdominal ends following a prolonged obstructive interval.

CONCLUSIONS

We developed an affordable and readily available 3D-printed vas deferens model that we use presently to train residents in vasal microsurgery techniques. This study illustrates that the experienced urologic microsurgeons agree that this model is a valuable training and practice tool. Given the findings of this study, we encourage other programs to adopt our model and use it to teach and practice microsurgery. We will continue to develop and refine our model based on the feedback of the experts.

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APPENDICES

Appendix A: *Survey Instrument*

Q1: Suture type used?
  7-0, 8-0, 9-0, 10-0
Q2: Was Anastomosis completed, attempted but not completed, Not attempted?
  Anastomosis Completed, Anastomosis attempted but not completed, Attempt but not completed
Q3: If anastomosis was attempted but not completed or not attempted. Please explain why?
Q4: What type of anastomosis was completed or attempted but not completed?
  One-layer anastomosis, Two-layer anastomosis
Q5: Please explain why you choose to do a one-layer anastomosis or two-layer anastomosis
Q6: Tactile similarity to native vas deferens (0-not at all, 100-identical)
Q7: Axial rigidity (0-too stiff, 100-identical)
Q8: Friability (0-too friable, 100-identical)
Q9: Hardness (ease/difficulty to place suture) (0-too hard, 100-identical)
Q10: Usefulness as a practice tool (0-not at all, 100-amazing)
Q11: Usefulness as a training tool (0-not at all, 100-amazing)
Q12: Overall assessment of model (0-worst, 100-best)
Q13: Please tell us what you think works well for the existing model and what aspects should be improved upon

Appendix B: *Technical information*

The synthetic vas deferens model was designed in SolidWorks CAD software (Dassault Systèmes SolidWorks Corporation, Waltham, MA) as a cylinder with the following dimensions: 1 mm diameter with 0.5 mm inner lumen. Models were prepared for printing using Simplify3D slicing software (Simplify3D, Cincinnati OH).

The optimal printer temperature was determined by our needs for flexibility and hardness of the model. For printing the model, we selected a commercially available thermoplastic polyurethane (TPU) filament infused with a foaming agent that allows for temperature-dependent tuning of material stiffness (Varioshore TPU, colorFabb B. V., Belfeld, The Netherlands). We selected TPU because it is a flexible filament and its moduli can be adjusted depending on the printing temperatures.

At higher printing temperatures, the foaming agent expands more during printing resulting in a higher void fraction/softer material. We tuned the printing temperature and extrusion multiplier in the slicer software to maintain the nominal dimensions of the vas tube while adjusting the void fraction of the TPU (i.e., the flow rate is reduced at higher temperatures in an attempt to keep the printing volume constant). Models were printed on an AON M2 fused deposition modeling (FDM) 3D printer (AON3D, Montreal, QC) using 0.1 mm layer height.

The models were printed as one unit attached to a base; rectangular anchors at each end. Since the vas models have a very small direct contact area with the build plate, the anchors help maintain adhesion without using rafts (which can tear away the thin wall of the vas upon removal) and allow for continuous extrusion of the soft flexible filament during printing to avoid the need for retraction and improve print quality.