Three-Dimensional–Printed Vaginal Molds for Use After McIndoe Neovagina Creation

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BACKGROUND: Surgical vaginoplasty is a highly successful treatment for congenital absence of the vagina. One key to long-term success is the use of an appropriate vaginal mold in the immediate postoperative period. We present the use of a three-dimensional (3D)–printed vaginal mold, customizable to the anatomy of individual patients.

TECHNIQUE: Vaginal molds were designed using a 3D modeling software program. The design included narrowing around the urethra, holes for egress of secretions, and a knob for insertion and removal. Dental resin was 3D-printed into various-sized vaginal molds, and post-processing was performed.

EXPERIENCE: We present the use of the 3D-printed mold for a patient with a history of cloacal exstrophy and a unique pelvic shape. Two prior neovagina surgeries in this patient had been unsuccessful due to ineffective handheld dilator use; the patient experienced success with the 3D-printed intravaginal mold.

CONCLUSION: The use of the 3D-printed vaginal mold is an alternative to the limited commercially available models today and allows for customization to user anatomy. With 3D printers becoming more widely accessible, we believe this method could become universally accepted, with hopes of contributing to increased patient satisfaction and decreased complications.

(Obstet Gynecol 2022;140:311–5)
DOI: 10.1097/AOG.0000000000004861

Congenital absence of the vagina and uterus is present in 0.2–0.7% of females.[1] Although many of these conditions are diagnosed around the time of puberty, the psychological effects that accompany them can be lifelong. Surgical vaginoplasty is the preferred method of treatment when vaginal dilation is not an option due to patient discomfort or preference or when previous dilator treatment has been unsuccessful. The most performed vaginoplasty procedure is the McIndoe procedure.[1] Traditionally, this involves creation of a neovaginal orifice followed by placement of a split-thickness skin graft and insertion of a vaginal mold to maintain patency.

Overall, the procedure is highly effective, with up to a 79% satisfaction rate.[2] This reconstruction is not without risks, however, with complications reported in up to 10% of cases.[2] Risks associated include fistula formation (1%), graft site infection (5.5%), contractures (variable with mold compliance), and graft detachment.[1] The development of these complications is associated with a combination of factors, including anatomic variances and patient compliance with mold placement.[1]

One key to long-term success of the McIndoe procedure is the use of an appropriate vaginal mold. An unsuitable mold could result in inappropriate drainage, detachment of the graft, fistulization, and loss of the surgically created space. A mold that is not conducive to patient self-application could lead to increased risk of contracture from insufficient use. A number of studies have been performed attempting to find the ideal mold, each with its own risks and benefits.[3–6] Of the small number of commercially available molds today, each is limited by standardized

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Each author has confirmed compliance with the journal's requirements for authorship.

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Financial Disclosure
The three-dimensional–printed vaginal mold is not labelled and not yet FDA-approved for the indication discussed in this article. John B. Gebhart has received royalties from Urocure, UpToDate, and Elsevier. The other authors did not report any potential conflicts of interest.

ISSN: 0029-7844/22

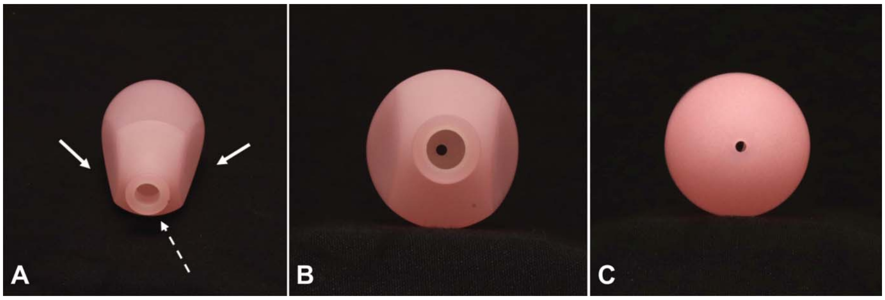

Fig. 1. A. Inferior view of the three-dimensional–printed vaginal dilator showing distal tapering (*solid arrows*) and the knob for removal and egress of vaginal secretions (*dashed arrow*). **B.** Vaginal dilator viewed from the most inferior portion. Through the opening of the distal knob, the hole at the vaginal apex can be visualized. **C.** Superior view of vaginal mold, with a hole to allow for vaginal secretion egress.

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length, girth, and shape. They are often difficult to place and remove. The majority lack fenestration, hindering the egress of vaginal secretions. This combination of factors contributes to decreased patient comfort and, therefore, compliance and possibly an increased complication rate. We present the use of a customizable three-dimensional (3D)–printed vaginal mold.

TECHNIQUE

This project was reviewed by the Mayo Clinic Institutional Review Board and was found to be exempt. To design the mold, 3D anatomical measurements of the planned neovaginal space were collected from volumetric computed tomography imaging. Using both these measurements and surgeon input, the mold design was created using a primary superior

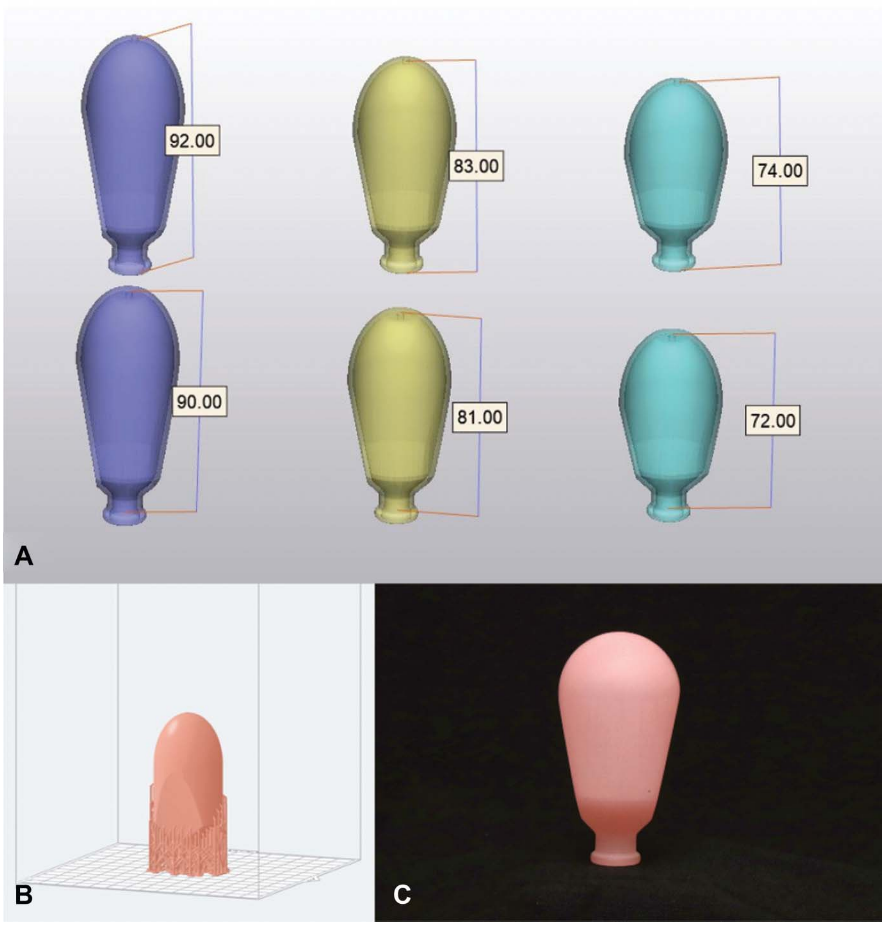

Fig. 2. Three-dimensional printing steps: design, printing, postprocessing. **A.** Various-sized (in mm) vaginal molds with a spherical superior aspect (*upper row*) or superior plateau (*lower row*). **B.** Mold design using PreForm build preparation software. **C.** Mold after postprocessing. Note the smoothed edges and polished surface. Images created by Joel Pino. Used with permission.

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Video 1. Time lapse of a mold being printed three dimensionally. The video demonstrates three-dimensional printing of three molds, using dental resin, simultaneously over 9 hours. The molds are printed upside down, starting at the distal knob. Scaffolding is printed simultaneously to allow for stability, and is removed during postprocessing. The printing process begins with the build platform in the starting (lowered) position; this platform rises as the printing project progresses. Video created by Joel Pino, Amy Alexander, Eric Erie. Used with permission.

sphere, two cylinders (one larger main superior cylinder and a smaller inferior drain conduit cylinder), and a torus ring. Lofting was used to connect the main cylinder to the drain cylinder. Parallel oblique sketch planes from the tangent of the main cylinder were used to trim the anterior and posterior aspects of the mold. A 2-mm wall created through an internal hollow function and a 3-mm cylindrical egress hole was made at the axis of the superior sphere to facilitate drainage through the mold (Fig. 1). Three different sizes, with total lengths of 92 mm, 83 mm, and 74 mm, were provided as options for use (Fig. 2A). Additionally, a 2-mm plateau was created on the cephalad (adjacent to the neovaginal apex) portion of each of the three sizes to produce an additional three options for fitting. All design work was original and produced using a 3D modeling software program called Materialise 3-matic Medical 16.0.

A commonly used dental resin (Denture Base) was chosen for the material of the mold. This material was chosen given its long-standing safety profile in the oral cavity. Furthermore, dental resin is lightweight, nonporous, and nonabrasive. The molds were printed in duplicate on a Formlabs Form 3B vat photopolymerization 3D printer (Fig. 2B). The orientation and support of the structures was determined and performed by a member of the Anatomic Modeling Unit's Healthcare Technology Management staff to optimize 3D printing performance and part quality; internal supports were not feasible in this printing process due to the inability to remove them postprinting, so the build setup was not trivial. In this optimized orientation, print time for one mold was approximately 9 hours (Video 1).

When printing was complete, parts were removed from the build platforms and soaked in 99.0% isopropyl alcohol for 20 minutes. Supports were then carefully detached from the molds. At the juncture between mold and supports, a wet-sanding technique was used to smooth the surface. The sequence of sanding was as follows: 600-grit paper to sand the entire surface until layer lines were smooth, followed by 2,500-grit paper until audible scratching no longer occurred, and, finally, a 3M micro-fine pad was used in a dry-sanding technique to remove any remaining tactile deformities on the surface of the mold (Fig. 2C). Various-sized molds can be brought to the operating room (Fig. 3), and, once the vaginal topography is evaluated, a specific mold can be sterilized before use per Formlabs Denture Base recommendations.

Scan this image to view Video 1 on your smartphone.

EXPERIENCE

We present the use of the 3D-printed vaginal mold in a 29-year-old woman who was born with cloacal exstrophy. Patients with this condition have often had multiple surgeries to correct genitourinary, gastrointestinal, and orthopedic anomalies. The pelvis has a platypelloid-type shape with a reduced anterior–posterior diameter and nonunion of the symphysis; this topography precludes the use of standard vaginal molds. The anatomy of our patient was also notable for a shortened anterior–posterior pelvic diameter, nonunion of the symphysis pubis, prior bladder neck closure and creation of a neobladder and continent catheterizable channel, and anal atresia with the presence of an end colostomy. Our patient had undergone two prior neovagina creation attempts but was unable to maintain patency (Fig. 4A). We performed a repeat procedure using a 3D-printed mold that was custom made for the patient's anatomy (Fig. 4B and C). She demonstrated ease with removal and maintenance of the 3D-printed mold and, 1 year after surgery, maintains a patent neovagina with a normal total vaginal length.

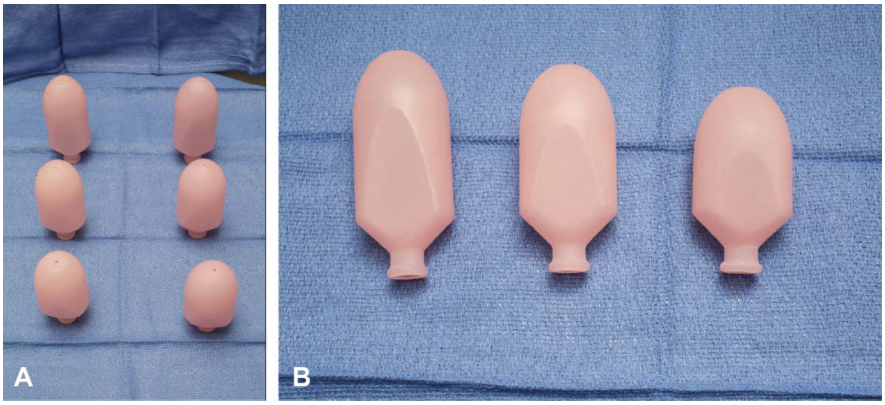

Fig. 3. Final product: three-dimensional–printed vaginal molds of various sizes available in the surgical suite. Top view (**A**); side view (**B**).

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DISCUSSION

Optimizing vaginal molds after neovaginal surgeries is not a new concept, but one that has been studied for years. Classically, McIndoe procedural texts describe the use of a rigid solid cylinder mold for the first week after surgery, which is then replaced by a soft mold.[1] Since its original documentation, many modifications of molds have been studied, from material to shape.

As far as rigid molds, silicone dilators are firm and often more comfortable; however, they have a tendency to collect debris on their rough surface. Acrylic, which is less giving in nature, is effective in maintaining the vaginal contour; however, it applies more pressure to the vaginal walls and underlying organs, risking tissue necrosis and fistulization.[3] The idea of a soft mold was studied by Concannon et al,[4] who suggest filling a condom with a polyester fiber. This mold could be compressed of all air before insertion and then "inflated" to accommodate the user's anatomy once in place. Although the technique was successful in all four cases studied, no mention was made of after care and long-term outcomes.

Wiser and Bates focused on shape when they created a polystyrene mold with a shortened and rounded base caudally to fit atop the perineal floor and anterior groove to accommodate the urethra.[5] Hollow dilators have been suggested to aid in efflux of vaginal secretions, along with decreased weight for patient comfort.[7]

The use of the presented 3D-printed vaginal mold combines all of these efforts to create the optimal vaginal mold. The use of the 3D printer for customizable vaginal molds opens the door not only to increased patient satisfaction, but also the possibility of decreased complications. Most significantly, these models can be customized to the unique anatomy of their users. This aspect will hold utmost significance in patients with a history of prior pelvic radiation, surgery, or other anatomic irregularities, as with the case we presented.

The 3D-printed molds come with a patient-friendly knob on the distal end. This allows for increased ease in placement and removal, which

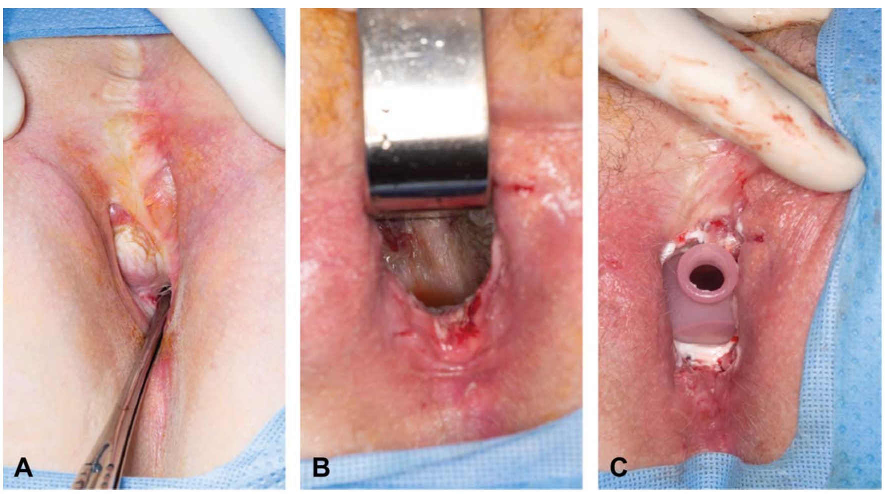

Fig. 4. Use of the three-dimensional–printed mold in a patient with cloacal exstrophy and two prior unsuccessful neovagina attempts. **A.** Before the procedure, the patient's anatomy was notable for a distorted introitus and a vaginal canal with significant scarring, foreshortened to 2 cm. **B.** After the neovagina surgery (postoperative day 10), the patient had excellent graft uptake and a total vaginal length of 10 cm. **C.** The three-dimensional–printed vaginal mold displayed in situ.

Kisby. Three-Dimensional Vaginal Molds. Obstet Gynecol 2022.

would increase compliance. Holes along the proximal and distal ends of the mold allow for vaginal secretion egress, theoretically lowering the risk of infection and contained seroma or hematoma. The narrowing at the area of the urethra helps to prevent obstructed urination, theoretically decreasing the risk of fistulization.

Overall, we believe the 3D-printed vaginal molds to be more anatomic than the alternative models commercially available today. Based on our institution's experience, patients report that the molds are comfortable and user-friendly. With 3D printers becoming more widely accessible, we believe this method could become universally accepted and hopefully contribute to increased patient satisfaction and decreased complication rate after neovaginal surgery.

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PEER REVIEW HISTORY

Received January 28, 2022. Received in revised form March 25, 2022. Accepted March 31, 2022. Peer reviews and author correspondence are available at http://links.lww.com/AOG/C774.