DOI: 10.7860/JCDR/2025/77461.21696

Review Article

Obstetrics and Gynaecology Section

Different Methods of Customised Vaginal Stent Fabrication in Vaginoplasty: A Comprehensive Review

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ABSTRACT

The non formation of the vagina, known as vaginal agenesis, impacts patients' psychological health in addition to being a congenital defect. Vaginal agenesis affects one in every 4,000 to 10,000 females. Despite presenting with primary amenorrhoea, patients with vaginal agenesis appear physically normal, with normal height, breast development, body hair and external genitalia. The care of patients with vaginal agenesis involves psychosocial counselling in addition to addressing the physical anomalies. The anatomical anomaly can be treated surgically by elongating the vagina and creating a neovagina. The procedure for creating a neovagina is called vaginoplasty and the McIndoe technique is often used to establish a vaginal canal prior to graft stabilisation of the neovagina. Vaginal stenosis following the surgery is the most common complication observed. Patency maintenance is key to a successful surgery; therefore, vaginal stents are fabricated. They not only serve as a haemostat but also as a graft stabiliser and prevent the shrinking or contraction of the neovagina. This review outlines and describes various methods for fabricating customised vaginal stents. It aims to provide readers with an overview of both old and new innovations employed in the fabrication of vaginal stents/vaginal dilators, taking both anatomical and psychological effects into consideration.

Keywords: Mayer Rokitansky Küster Hauser syndrome, Neovagina, Vaginal agenesis

INTRODUCTION

Vaginal agenesis occurs in one out of every 4,000 to 10,000 females [1]. Diagnosis follows laboratory investigations (testosterone and Follicular Stimulating Hormone (FSH) levels), Magnetic Resonance Imaging (MRI) and Ultrasound Sonography (USG). The vagina may be present and can appear as a prolonged vaginal apex without a cervix or as a small flush dimple [2]. Additionally, psychological counselling is offered to the patients. Many patients lament their infertility, struggle with anxiety and despair and question their femininity [3].

Vaginal stenosis following vaginoplasty is the most common complication encountered. Patency maintenance is crucial for successful surgery; therefore, vaginal stents are fabricated. They work as both a haemostat and a graft stabiliser while preventing the shrinking or contraction of the neovagina. This literature review outlines and describes various methods to fabricate customised vaginal stents.

DISCUSSION

Vaginoplasty

Vaginoplasty refers to any surgical operation that creates or reconstructs the vagina. Females with congenital vaginal hypoplasia or absence are candidates for vaginoplasty. This condition may occur alone, as seen in Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome, or it may be associated with other abnormalities such as cloacal malformation and significant genitourinary anomalies like disorders of sex development [4].

Various non surgical and surgical techniques have been employed for vaginoplasty. Non surgical methods include vaginal dilation, as described by Damast S in 2019 [5]. This method aims to create a vagina or enlarge an existing structure that is insufficient for sexual activity using graded vaginal dilators. Among surgical techniques, one of the most frequently discussed vaginoplasty procedures in the literature is the McIndoe (Abbe-McIndoe-Reed) approach [4]. Blunt dissection of the area formed between the rectum and bladder creates a potential vaginal gap. A split-thickness skin graft is harvested from the buttock, abdomen, or thigh, placed on a mold, and incubated for seven days in the vaginal area. After this time, the graft will epithelialise and line the vaginal opening. Following the operation, the patient must continue to maintain her neovagina using vaginal stents or dilators [4].

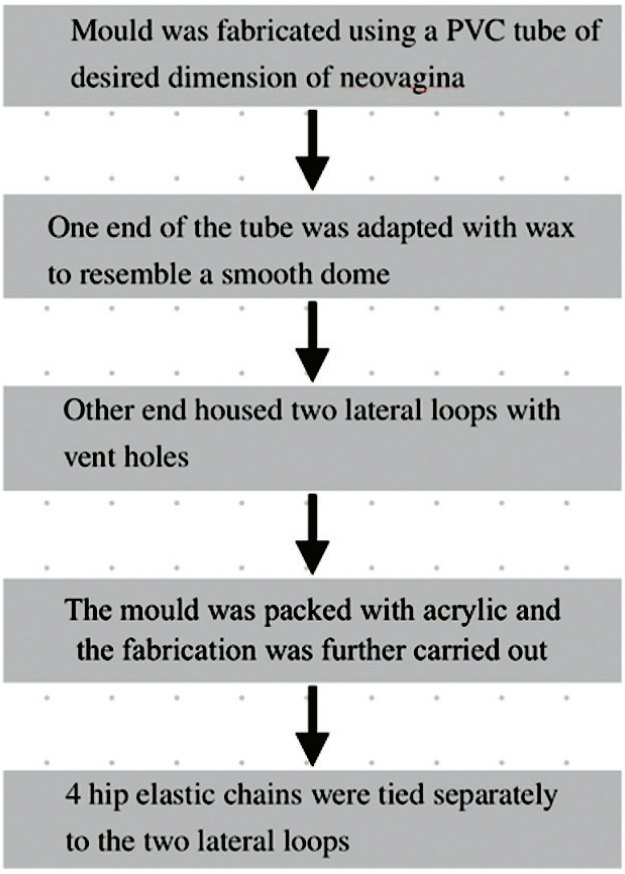
Vaginal Stent

When patients require vaginoplasty for vaginal abnormalities and strictures, vaginal stents are utilised to prevent vaginal stenosis. Several prefabricated or customised stents, including tissue expanders, vacuum-expandable condom molds, ORFIT "S" vaginal stents, inflated stents and acrylic, basic syringe, hollow acrylic, or silicone-coated acrylic stents, have been reported for patency maintenance following vaginoplasty. With changing times, there has been a preference for customised vaginal stents, which are fabricated after measuring the dimensions of the newly constructed vagina, also called the neovagina. These stents are tailor-made to fit the patient's needs and provide comfort and ease of use [6].

1. **Customised silicone vaginal stent:** Kamalakannan J et al., used putty-consistency addition silicone to create an impression on the handle of an autoclaved mouth mirror by applying Vaseline on the inner surface of the neovagina. The impression was invested to form a mold. Maxillofacial silicone was then utilised to fabricate the stent using the acquired mold. The patient had the vaginal stent implanted for two weeks. She was instructed to use the prosthesis for four to five hours a day while using a lubricant anaesthetic jelly to facilitate simple and painless insertion. Tight pants were suggested to apply and sustain pressure. The patient received instructions on how to maintain her personal hygiene and the cleanliness of the stent. To avoid fungal growth, the patient was advised to thoroughly wash the stent under running water and to cleanse

it with a gentle vaginal wash both before and after use. Due to its softness, lightweight nature, and smooth texture, the silicone prosthesis was found to be comfortable, enhancing the patient's overall quality of life [7].

2. **Self-made inflatable vaginal dilator:** A long Kelly, a vaginal prep kit with sterile foam sponges, a 60-cc catheter tip syringe, a radio-opaque sterile sponge, a ruler, a sterile vaginal ultrasound probe cover, sterile gloves, scissors and a 0-vicryl suture were used to create a custom-inflated vaginal stent. Its deflatable nature prevents damage to or interference with the delicate tissue transplant during insertion, removal, or repositioning. Made of surgical materials and being radio-opaque, it complies with operating room protocols and regulations. It effectively applies circumferential pressure for graft adhesion and offers a substantial adjusting range [8].
3. **Acrylic stent with attached waist retentive loops:** A Polyvinyl Chloride (PVC) tube-invested mold was created. Wax was used to build a smooth dome on one end of the tube and a wax closure on the other to form the base. The stent was held in place by elastics secured to the patient's hips through two lateral loops tied at the vent holes located in the base. An elastomeric imprint substance with a putty consistency preserved the loop's patency during the processing step. To prevent stent misalignment and lateral movement at the surgical site, the four hip elastic chains and the two lateral loops were connected independently. Four elastics were linked to the two loops on the stent, which were secured around the hips to avoid dislodgement during functional activity [Table/Fig-1]. Additionally, the loops helped maintain parallelism to the vaginal axis, preventing excessive pressure and any resulting postoperative meatal or urethral necrosis [9].



[Table/Fig-1]: Acrylic stent with attached waist retentive loops.

4. **Tissue conditioner coated hollow acrylic vaginal stent:** After creating a wax scaffold, a rigid layer of acrylic resin with a thickness of 2 mm was applied, followed by adding a robust tissue conditioner stuffed inside a putty mold. The wax scaffold is later removed to create a hollow passage for any neovaginal discharge. The customised vaginal stent's hollowed design allows secretions and tissue fluids to exit. The vaginal stent is made from a variety of materials. By utilising a stiff acrylic resin core on the inside and a soft-tissue conditioner layer on the outside, the disadvantages of both rigid and resilient stents are mitigated. This design provides the stent with sufficient resilience from the outer layer to ensure patient comfort, while the acrylic section offers enough strength to maintain the newly created vagina [10].
5. **Hollow lightweight acrylic vaginal stent:** A scaffold was constructed in a modelling compound. Orientation grooves were created on a two-piece mold. By softening the modelling wax, molding it and sealing it onto the mold walls, a hollow wax pattern for the stent was created. Using a syringe, water was pumped into the wax pattern, resulting in a cylindrical block of ice that was frozen upright. After mixing and pouring heat-cure acrylic resin into the two halves, the cylindrical ice block was positioned between the molds packed with resin and allowed to cure. Once cured, the stent was removed and a hole was drilled to drain the water. The hole was sealed with self-curing acrylic resin. The acrylic hollow stent provides the benefit of being rigid while remaining lightweight. Ice, used to create the hollowness, is readily available and easy to remove postfabrication from the stent [11].
6. **Hollow vaginal stents made from acrylic with frozen coconut oil:** The first step in the procedure involves taking a neovaginal imprint to gather relevant information. Next, type III dental stone is used to create a cast or mold based on this impression. The initial stent is then created using a wax template. To ensure accuracy, the handle-equipped modelling wax pattern is meticulously checked against the cast. The final step involves flasking, which entails placing the wax design into a flask in preparation for the subsequent steps. A mold made of frozen coconut oil was used to create a second wax pattern replica, allowing for the construction of a hollow stent that precisely matches the original wax template. After dewaxing the flask and applying separating media to both sides, the stent was created by sandwiching it between two layers of transparent heat-cure acrylic resin while filling it with frozen coconut oil during packing. The two halves of the mold were filled and mixed with heat-cure acrylic resin. The flasks were then sealed and short curing cycles were completed. A cylindrical frozen coconut oil block was placed between the two sections of the mold [Table/Fig-2]. To ensure a proper fit, the vaginal stent was carefully placed in the neovagina [12].
7. **Digitally fabricated vaginal stent:** A meticulously designed hollow acrylic vaginal stent was produced during the stent creation process. These specific measurements were based on the thickness of tissue between the pelvic peritoneum and perineum, as measured by a gynaecologist using MRI. Following impression and compound impression, the cast was fabricated and the resulting Standard Tessellation Language (STL) file was scanned using an EOS X 5 3D printer. The initial stent was created using the resin material Creality 3D LD-002R LCD Resin 3D Printer. The personalised stent was fabricated using a faster and more efficient digital workflow [13].
8. **Silicone-coated acrylic vaginal stent:** The stent consists of three parts: an outer silicone layer, an inner acrylic layer and a plastic piece that is fixed perpendicularly and has holes in it. The main body is made of solid acrylic material and is shaped like a syringe from the inside out. After preparing the three parts individually, they are combined to create a small unit and heated to between 80 and 90° Celsius for five minutes. For surgical use, the stent is sterilised using ethylene oxide. The holes in the plastic component are designed to secure the

[Table/Fig-2]: Hollow vaginal stents out of acrylic with frozen coconut oil.
Image source- Author's case image

stent to the body. Just before the heating process that turns the liquid silicone into solid silicone, the silicone is sprayed onto the exterior of the acrylic stent. The silicone-coated acrylic stent provides rigidity through the acrylic part, while the silicone layer aids in graft stabilisation [14].

9. **Vacuum expandable condom mold:** Polyurethane foam with an open-cell structure is used to create the vaginal stent. The foam is cut to the desired length and rolled longitudinally like a cigar. Next, a latex condom is placed over it, and the tube used for aspiration is removed through the open end of the condom. To create an airtight stent, the condom is wrapped around the aspiration tubing using a 0-silk tie. Suction is applied to the aspiration tubing and it is clamped to maintain a vacuum. With minimal tension, the edges of the skin graft are stitched longitudinally around the deflated stent. After dissecting the vaginal canal, the skin graft sleeve and deflated stent are positioned. Upon unclamping the aspiration tube, a vacuum is created inside the stent, allowing the foam to expand and fill the entire vaginal area. This vaginal stent enhances graft retention with minimal discomfort for the patient and is simple, cost-effective and time-efficient to manufacture. The components are easily assembled, sterile, processed by the manufacturer and readily available [15].
10. **Silicone-based vaginal mold using a condom:** To create a vaginal mold, one part of 80 mL of liquid silicone and one part of 20 mL of liquid silicone activator were thoroughly mixed and placed inside a condom. The mold was then left in the warm sun. After four hours, the condom was punctured multiple times with a needle to allow air to escape and accelerate the molding process. The condom was removed and the mold was prepared for use after 48 hours. The primary concern when using a vaginal stent is the resistance caused by the blunt tip of the mold at the neo introitus entrance. The prepared mold is easy to use, as its tip is soft, sharp and slim [16].
11. **Simple syringe as a stent:** Different-sized syringes are used, and they are wrapped in gauze and non adhesive material in several layers. The toll (Jelonet) surrounding the syringe body provides strong, pliable support for the skin graft. The gauze layers hold the graft in place and absorb any vaginal discharge while maintaining close proximity to the walls of the vagina. The sturdy wall of the syringe reduces the tendency for the vaginal wall and graft to shrink. Additionally, the nozzle of the syringe can serve as a conduit for draining any uterine fluids. The syringe stent is an affordable, practical and effective method for stent placement. Syringes are available in various sizes suitable for different restorative scenarios [17].

CONCLUSION(S)

Vaginal stenosis, or the relapse of the neovagina following vaginoplasty surgery, has been the most frequent cause of failure. Vaginal stents, also referred to as vaginal dilators, are the ideal choice for maintaining patency. The stents can be either rigid or flexible, hollow for lightweightness, or acrylic with a passage for vaginal fluid discharge. They can be economical, sterile, customised using surgical supplies, or made from easily available materials. Rehabilitating the patient through surgery followed by regular use of dilators can significantly impact the patient's psychological health and compliance. Therefore, it is essential that the stent is tailored to meet the specific needs of the patients.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Dec 26, 2024
- Manual Googling: Apr 12, 2025
- iThenticate Software: Apr 15, 2025 (7%)

ETYMOLOGY: Author Origin

EMENDATIONS: 6

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was informed consent obtained from the subjects involved in the study? NA
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **Dec 23, 2024**
Date of Peer Review: **Feb 17, 2025**
Date of Acceptance: **Apr 17, 2025**
Date of Publishing: **Oct 01, 2025**