



# **Case Report** Customised vaginal dilator: A case report

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#### ABSTRACT

Vaginal agenesis, which occurs in approximately 1 in every 5,000 to 7,000 female births. In place of the vagina, there is typically a small pouch or dimple that is 1 to 4 cm in depth. The treatment may either be a surgical or non-surgical method, but the chosen method needs to be tailored to the individual's needs. The non-surgical creation involves the dilator expansion methods that have been in use for decades. This involves the use of graduated dilators to gradually increase the caliber to a predetermined size.

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#### 1. Introduction

According to Foley, Sallie and George W. Morley, approximately one in every five thousand to seven thousand female births vaginal agenesis occurs.<sup>1</sup> The external genitalia in these patients is not normal. There is typically a little invagination, a small pouch or a dimpling that is usually about 1 to 4 cm in depth in the place of the vagina. The treatment options include either a surgical or a nonsurgical approach, based on the patient's requirements. The primary procedure usually involves the formation of a new canal either by a surgical or a non-surgical method. The creation of a vagina within a pre-existing canal is done in the second method. The non-surgical procedure is more commonly done using the dilator expansion method.

### 2. Case Report

A 20-year-old female was referred from the Department of Obstetrics and Gynaecology with a complaint of a blind vaginal pouch and primary amenorrhoea for fabrication of a vaginal dilating prosthesis. Initially, a customised primary

dilator with its head confirming to the size of a No:12 Hegars dilator was made in consultation with the treating Gynaecologist. A wax pattern measuring approximately 4 cm in length and about 1 cm in diameter was carved which was then processed in heat cure acrylic resin using the conventional laboratory procedures. The customised prosthesis was cylindrical but gradually narrowing towards the tip and with a small handle to allow ease of insertion and retrieval. The prosthesis after acrylisation was accurately finished and well polished to ensure a smooth and even surface (Figure 1). The finished prosthesis was left overnight in 100% glutaraldehyde disinfecting solution.

The patient was operated under general anaesthesia after thorough evaluation for vaginoplasty. A total abdominal hysterectomy with vaginoplasty was carried out. The customised primary vaginal dilator was covered with an amniotic membrane and inserted into the vagina after freshening the vaginal pouch mucosa. The mould and surgical dressing was removed on the  $5^{th}$  postoperative day.

The patient was under review at the Department of Obstetrics and Gynaecology for a month after which she was referred back for vaginal dilators of sequential dilations starting once again from the size of the head of a Hegars

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no:12 dilator. The size of the forceps was determined and a wax pattern having a diameter of about 1.5 cm at the apex a gradually increasing diameter of about 2cm to the base and a length of about 3.5 cm was made using modelling wax (Hindustan Modelling Wax, India). A series of wax patterns in gradually increasing diameter and length varying from 6cm to 8cm was then fabricated with a handle at the broad end for easy placement and removal. The length of the last wax pattern was about 3.5cm (Figure 2). The wax patterns were invested and packed using heat polymerising acrylic resin. (DPI, Heat cure, Clear). The sequentially sized patterns were acrylised, retrieved, trimmed, polished and left overnight in a glutaraldehyde disinfecting solution before being handed over to the patient (Figure 3).



Figure 1: Primary customised vaginal dilator



Figure 2: Wax pattern showing size of the largest dilator

In consultation with the Gynaecologist, the patient was advised to place the vaginal dilators along with the application of 2% xylocaine jelly into the prepared vaginal pouch. The patient was advised to report back to the Gynaecologist every 2 weeks before changing over to the dilator of the next incremental size. Four months following the use of the vaginal dilators, the patient was comfortable using the dilator of the largest size without any bleeding and achieving the required vaginal opening as planned by



Figure 3: Vaginal dilators of increasing sizes

the Gynaecologist. During the 01 year follow-up review, the patient was comfortable using the largest size.

#### 3. Discussion

The vagina is a muscular and elastic organ which is a part of the female genital tract leading from the external genitals to the cervix of the uterus. Various malformations can occur in the female genital organ, one among them being Mullerian Agenesis. Mullerian Agenesis is also referred to as Vaginal Agenesis, Congenital Absence of Uterus and Vagina (CAUV), Mullerian Aplasia, Mayer-Rokitansky-Kuster-Hauser-Syndrome (MRKH Syndrome), Genital Renal Ear Syndrome (GRES).<sup>2</sup>

Foley, Sallie, and George W. Morley have stated that "vaginal agenesis involves issues of physical abnormality, body image, sexual identity, and sexual/reproductive that require long-term medical functioning and psychological management".<sup>2</sup> They also said that vaginal agenesis, which occurs in approximately 1 in every five thousand to seven thousand female births, is a significant threat to the mental health and well-being of an otherwise normal, healthy young woman.<sup>1</sup> More than 90% of patients with vaginal agenesis fulfil the criteria of Rokitansky-Kuster- Hauser syndrome-ie, 46, XX karyotype with normal, functioning ovaries. Only 5% of these patients have a uterus.<sup>2</sup>In most of these patients, instead of a vagina, there is usually an invagination or a dimpling that may vary from about 1 cm to 4 cm in depth.

Roszaman Ramli and Ghazali Ismail in their article "Vaginal and Cervical Agenesis: Hysterectomy in a Young Girl" said that "amenorrhea, may be temporary or permanent".<sup>2</sup> They further classified it as primary and secondary amenorrhea. Primary amenorrhea is the absence of menarche up to the age of 16 years while secondary amenorrhea refers to the absence of more than 3 menstrual cycles.<sup>3</sup> It is also important that both the patient and her family are well-counselled and motivated for treatment. The procedure includes the correction of vaginal aplasia which can either be achieved either surgically or by nonsurgical techniques, which is decided on a case-to-case basis depending on the individual needs of the patient.

Frank RT in his article on "The formation of an artificial vagina without an operation".<sup>4</sup> describes that the procedure primarily consists of the creation of a new cavity by a surgical or non-surgical method. He suggested vaginal replacement with a pre-existing canal lined with a mucous membrane such as a segment of the bowel. The nonsurgical procedure commonly involves the dilator expansion methods among which the nonsurgical "Frank Procedure" which was initially described in 1938 is the most popular method for creating a vagina. The goal primarily is to widen the diameter the increase the length of the vagina by using a series of graduated dilators so that surgical intervention can be avoided. Previously, patients were advised to sit on a hard stool or a firm chair with the tip of the dilator inserted through the hymenal ring into the vaginal dimple or pouch. The reason for the failure of this method is not understood.

The modification of the Frank procedure was the Ingram "bicycle seat" as described by Ingram JIM.<sup>4</sup> This racingtype bicycle seat as described by Ingram was positioned between the buttocks and therefore ensured better contact with the perineum and provided direct pressure from the graduated dilator onto the incompletely formed vagina.<sup>5</sup> In the year 2006, Mee-Hwa Lee further modified Ingram's technique by using an ordinary chair as a modification of Frank's handheld method. Here, the acrylic resin was used for the fabrication of the dilator which allowed relining as and when required for size modifications when compared to Pyrex that was used by Frank. Another modification of this technique was the use of tight underwear to apply firm, continuous and constant pressure on the vaginal tissue without the need to use the patient's hand. This non-surgical method for the creation of a new vagina with the help of custom-fabricated vaginal dilators is usually the treatment of choice if suitable and often helpful in widening a narrow vagina. It is also a preferred and more affordable method. Also, according to Mee-Hwa Lee "Compared to the surgical methods, non-surgical vaginal dilation has the advantage of low morbidity, and no surgical scarring".<sup>6</sup> The vaginal tissues over a period of time become softer and more pliable by gradually developing in regions previously undeveloped or narrow.

The other surgical methods for a neovagina creation include the Abbe-McIndoe operation, the Vecchietti operation and the sigmoidal coloplasty.<sup>7,8</sup> Surgical procedures however can lead to stricture leading to further reduction in the opening.

Prosthesis made with silicone material are soft and more flexible which may lead to failure in achieving the desired size of the vagina. It can also deteriorate and tear in longterm use. Acrylic material is economical when compared with silicone. It is less tedious and can be easily relined. It is also easy to keep it clean, preventing any deposition, and

#### allowing for better hygiene.<sup>9</sup>

These dilators are very important for the success of the treatment and a maxillofacial Prosthodontist plays a pivotal role in the fabrication of the prosthesis. Failure to wear these stents is one of the major causes of treatment failure. If not properly constructed it can lead to graft maceration, sloughing and graft detachment.<sup>10</sup>

Although the use of conventional solid rigid acrylic dilators has proved to be successful, they may cause complications such as urethritis, cystitis, vesical or rectovaginal fistula, secondary genital prolapse, and even vaginal necrosis. These complications are commonly witnessed when the dilators are not used sequentially and recall and reviews have not been performed. A lack of compliance to wear a dilator, even if it is inconvenient, is known to be the main cause of failure. A common reason stated by patients is pain and discomfort from solid acrylic dilator therapy.<sup>11</sup>

Use of vaginal stents in radiotherapy is well known. During radiation therapy treatment, healthy vaginal tissue can get irritated and sore. As the tissue heals it can cause scar tissue to form in your vagina. This can cause changes to your vagina like vaginal dryness, narrowing, or shortening. These changes can make vaginal exams and sexual intercourse uncomfortable. Using a vaginal dilator can prevent or treat these changes by preventing scar tissue from forming, helping break down the scar tissue that has formed and Increasing blood flow to the area. The purpose of dilator therapy in the early response phases post radiotherapy is to separate and prevent the formation of early adhesions between the walls of the mucosa. The secondary purpose of the dilator is to counteract the late effects in the submucosa including elastosis and circumferential fibrosis of the vaginal canal by stretching the vaginal tissue and promoting epithelial cell growth. Several studies have found significant associations between preventive dilation use and lower risk of vaginal stenosis following radiotherapy. It is commonly accepted that dilator therapy safely delays or prevents vaginal stenosis and is considered "best practice" in an international guidelines statement.12

#### 4. Conclusion

The use of inexpensive and easily accessible acrylic vaginal dilators may be an effective and non-invasive alternative with few side effects for women with vaginal agenesis, particularly in the developing countries. Despite the good results of dilation therapy reported since the 1930s, surgeons are still looking for the best surgical technique. Efforts should be made to improve results with the development of validated dilation programs and therapeutic education by multidisciplinary experienced teams, in association with the patients.

#### 5. Source of Funding

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#### 6. Conflict of Interest

None.

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