



Original article

Simple neovaginoplasty using spontaneous regeneration ability of labial and vestibular flap in patients with Müllerian agenesis

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ARTICLE INFO

Article history:

Received 23 January 2017

Received in revised form

29 May 2017

Accepted 1 June 2017

Available online 1 July 2017

Keywords:

Labial advancement flaps

Müllerian agenesis

Neovagina

Vaginoplasty

ABSTRACT

Objectives: This study is aimed to introduce a simple neovaginoplasty procedure without significant complications using the spontaneous regenerative ability of labial and vestibular advancement flaps in patients with Müllerian agenesis.

Materials and methods: Prospectively collected data of 5 patients with vaginal agenesis due to Müllerian duct abnormality who underwent neovaginoplasty using labial and vestibular advancement flaps were retrospectively reviewed. Operative details, perioperative outcome, complications, length and width of the neovagina, and the postoperative sexual activity were evaluated.

Results: The mean operation time was 48 min (range 30–60 min) and the duration of follow-up ranged from 7 to 50 months. The mean length of the neovagina was 9.6 cm × 3.5 cm and 10.8 cm × 3.5 cm at hospital discharge and at final follow-up, respectively. No significant complications occurred during or after surgery. Epithelialization was completed by 8–20 months and the time to first sexual intercourse ranged from 3 weeks to 27 months and none of the patients experienced any intercourse-related difficulties.

Conclusion: Our neovaginoplasty technique using labial and vestibular advancement flap is simple, safe, minimally invasive and effective while avoiding the morbidity associated with other grafting techniques.

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Background/Introduction

Müllerian agenesis, also known as Mayer–Rokitanski–Kuster–Hauser (MRKH) syndrome is a rare congenital anomaly of the female genital tract with a reported incidence of 1:5000–10,000 in female infants.^{1,2} With the congenital absence of vagina and uterus, affected individuals have normal 46XX female karyotype, functional ovaries and normal development of secondary sexual characteristics. It accounts for approximately 10% of primary amenorrhea.³

Conflicts of interest: The authors have no conflict of interest relevant to this article.

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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Both surgical and non-surgical techniques have been suggested over the years for neovagina formation in patients with Müllerian agenesis.^{4–6} The most widely used non-surgical techniques are the Frank technique⁷ and its modification by Ingram⁸ which are both accomplished by applying constant pressure to the perineum using specially designed dilators.

Surgical techniques include vaginoplasty using various intestinal segments such as the rectum, ileum and sigmoid.^{9–11} Davydov procedure which can be performed either conventionally¹² or laparoscopically¹³ brings down the peritoneum of Douglas pouch into the vaginal cavity whereas laparoscopic Vecchietti procedure involves an acrylic sphere in the perineum connected to an abdominal traction device through the abdomen.^{14,15}

McIndoe operation which is the most widely used method uses a split thickness skin graft over a mold to create a new vagina.¹⁶ To prevent contracture that can occur with the shrinkage of graft, full thickness skin grafts¹⁷ and vaginoplasty using skin flaps from labia minora,^{18,19} inner thigh²⁰ and myocutaneous flaps using gracilis

<http://dx.doi.org/10.1016/j.gmit.2017.06.004>

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muscle^{21,22} and rectus abdominis muscle²³ have also been attempted and reported.

However, each method has its own shortcomings including unsatisfactory cosmetic appearance, extensive operation time, high risk of postoperative complications, invasiveness as well as discomfort,²⁴ and no consensus over the best therapeutic approach has been reached.

Purpose/Aim

The primary goal of the treatment of vaginal agenesis is to construct a physiological vagina to enable normal sexual intercourse with minimal procedure-related morbidity. Therefore, this study was aimed to introduce a simple and safe neovaginoplasty using spontaneous regeneration ability of labial and vestibular advancement flaps in five patients with Müllerian agenesis.

Materials and methods

Between July 2011 and June 2014, 5 patients with vaginal agenesis due to Müllerian duct agenesis underwent neovaginoplasty using labial and vestibular advancement flaps at the Center for Minimally Invasive Surgery and Treatment, Department of Obstetrics and Gynecology in Good Moonhwa Hospital. This study was approved by the Institutional Review Board of Good Moonhwa Hospital (#2011-03).

Patients

All patients had primary amenorrhea and were aware of the absent vagina and uterus upon first visit to our hospital. Secondary sexual characteristics including breast development, axillary and pubic hair, and appearance of external genitalia were normal.

Transrectal ultrasound was initially performed to confirm absence of uterus and the presence of ovaries.

All patients were submitted to preoperative assessments including physical examination, chromosomal studies, either abdomino-pelvic magnetic resonance imaging (MRI) or computed tomography (CT) to assess the Müllerian anomaly as well as the presence of renal anomalies, and counseling on advantages and disadvantages of non-surgical and surgical techniques.

Preoperative treatment

All women were encouraged to try Frank's method preoperatively using Vaginal Dilator Set (Vaginismus.com, USA) and all were compliant to self perineal pressure application. The duration of preoperative treatment ranged between 14 days and 15 months depending on the time until individually desired operation schedule.

Operative technique

Under general anesthesia, the patient was placed in lithotomy position and a 16 Fr urethral Foley catheter was placed. The posterior portions of both labia minora were grasped with Allis clamps (Fig. 1A), and a midline incision was made in the perineum from the fourchette (Fig. 1B). Starting from this incision, a tunnel between the bladder and rectum was created by blunt and sharp dissections in the upward direction. Through blunt dissection the risk of rectal perforation and urethral injury can be minimized. This blunt dissection is continued until a 3.5 cm wide, 10 cm lengthened tunnel is obtained (Fig. 1C). Fibrous tissue encountered during dissection between the bladder and rectum was cut using unipolar electrocautery or metzenbaum scissors. The epithelial layer of redundant labia minora and vestibulum were dissected from the underlying tissue (Fig. 1D and E).

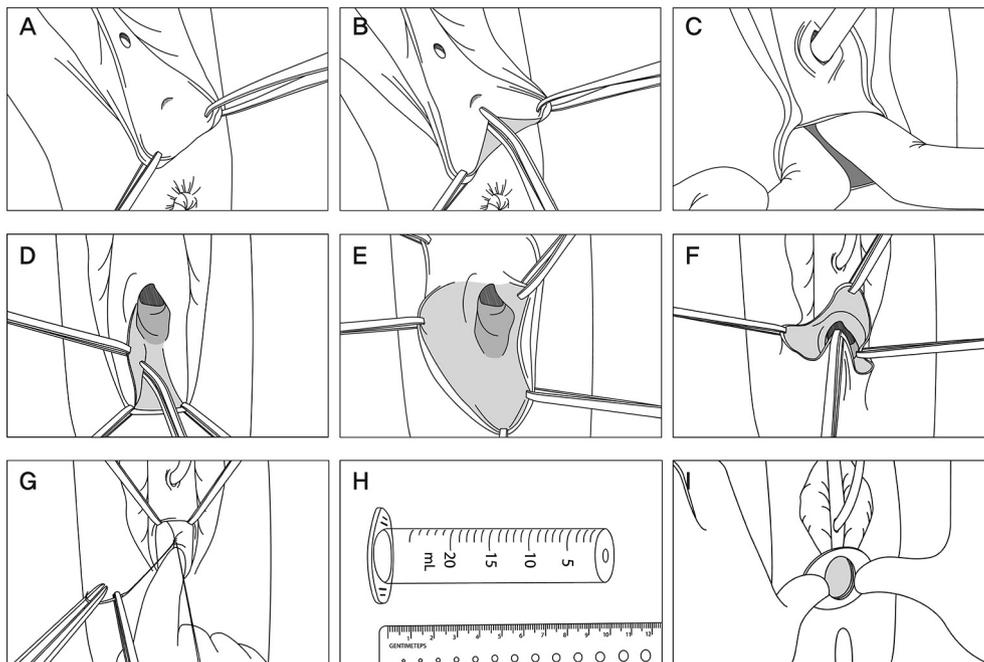


Fig. 1. Operative procedures of Neovaginoplasty using labial flap. (A) Posterior portions of both labia minora were grasped with Allis clamps. (B) A midline incision is made in the perineum from the fourchette. (C) A tunnel between the bladder and rectum is created by blunt and sharp dissections in the upward direction. (D, E) The epithelial layer of redundant labia minora and vestibulum are dissected from the underlying tissue. (F) The mobilized skin and mucosa were then moved into the created tunnel as deeply as possible but without tension of the flap. (G) The mobilized skin and mucosa are sutured to the wall of the tunnel with interrupted #3-0 polysorb sutures. (H) The adaptor is cut off from a 20 plastic syringe. (I) The trimmed syringe was placed in the vaginal cavity after surgery.

The mobilized skin and mucosa were then moved into the created tunnel as deeply as possible but without tension of the flap (Fig. 1F), and sutured to the wall of the tunnel with interrupted #3-0 polysorb sutures to lead further epithelialization of the remnant raw neovaginal wall (Fig. 1G). Rectal examination confirmed intact rectal mucosa without penetration of the sutures. A dilating device was made by cutting the adaptor off a 20 plastic syringe (Fig. 1H) and it was placed in the vaginal cavity after surgery to maintain the newly created space (Fig. 1I). The neovaginal cavity was irrigated daily with normal saline followed by intravaginal placement of antiseptic tablet and estriol vaginal suppository (Ovestin[®], Organon, Netherlands). Daily vaginal insertion of an antiseptic vaginal tablet (Cenasert[™], Alvogen Korea) and estriol 0.5 mg vaginal suppository (Ovestin[®], Organon, Netherlands) was done until discharged from hospital and time of discharge depended upon the surgeon's decision according to individual patient's healing process. The 20 cc trimmed syringe was exchanged daily and the patients were advised to keep it in the neovagina at all times during the hospital stay and until first outpatient visit at 1 week after discharge.

Follow-up

Follow up was performed weekly for 1 month, biweekly until 3 months and monthly until 6 months postoperation and the length, diameter and epithelialization status of the neovagina were assessed on each visit. The patients were recommended to keep the trimmed syringe inside the vagina at all times during 1 month following operation. After that, patients were advised to keep the homemade dilating device daily for variable hours according to the epithelialization status and vaginal length/width (20, 15, 12 h in 50%, 70%, 90% epithelialization, respectively). Once the vagina was at least 70% epithelialized, patients were encouraged to start intercourse if desired, and if the patient was not having regular sexual intercourse, the 20 cc syringe was kept daily during sleep. After 6 months, follow up was done every 3 months until 1 year, and every 6 months thereafter.

Results

The age of the patients ranged from 18 to 47 years. Of the 5 patients, 1 woman had been married for 23 years, 1 patient was

engaged and the other 3 were unmarried. Serum FSH and E₂ levels checked upon first visit were within normal limit in all. On physical examination, all patients had well-developed secondary sexual characteristics and a small blind-ending vaginal dimple. Transrectal ultrasound and MRI/CT showed the absence of uterus while both ovaries were normally identified. One patient had unilateral renal agenesis. The clinical characteristics and postoperative outcomes of patients are shown in Table 1.

The duration of preoperative treatment ranged from 14 days to 15 months depending on the desired operation date of each patient and all patients were recommended to use the Vaginal Dilator Set right after the first visit until surgery. The mean operation time was 48 min (range 30–60 min), and the mean hospital stay was 23.4 days (range 9–30 days). The duration of follow-up ranged from 7 to 50 months. The mean length of the neovagina was 9.6 cm × 3.5 cm and 10.8 cm × 3.5 cm at hospital discharge and at final follow-up, respectively. No significant complications occurred during or after surgery. Epithelialization was completed by 8–20 months depending on the amount of well-developed labial and vestibular tissue available at the time of surgery. The time to first sexual intercourse ranged from 3 weeks to 27 months and none of the patients experienced any intercourse-related difficulties. Full epithelialization was not a prerequisite to starting sexual intercourse (Table 2).

Discussion

The most important thing in neovaginoplasty is the creation of a new vagina of sufficient length that does not narrow over time in addition to providing a satisfactory cosmetic result while leaving the external genitalia intact.¹⁵ Frank's method used dilation for approximately 30 min per day with a gradual increase in the size of glass dilators. The McIndoe procedure used a skin graft between the bladder and the rectum, and creates vaginal canal.¹⁶ However, the dilators are uncomfortable, unpleasant, and act as a constant reminder of the abnormality.²⁵ The skin graft is usually held in place within the neovagina with some sort of space-occupying vaginal stent. McIndoe technique also has a major disadvantage with the formation of visible scars at the origin of the skin graft site, resulting in an unsatisfactory cosmetic appearance, dry vagina and vaginal stenosis. The colon segment has been used as a substitute of skin graft, but in spite of advantages of reduced risk of stricture and natural lubrication, several problems such as excessive mucous

Table 1
Clinical characteristics of the 5 patients.

| Patient | Age (years) | Married | Secondary sexual characteristics | Serum level | | Karyotype |
|---------|-------------|---------|----------------------------------|--------------|------------------------|-----------|
| | | | | FSH (mIU/ml) | E ₂ (µg/ml) | |
| 1 | 18 | No | Normal | 5.92 | 58.0 | 46 XX |
| 2 | 34 | No | Normal | 5.38 | 87.5 | 46 XX |
| 3 | 23 | No | Normal | 1.70 | 287.0 | 46 XX |
| 4 | 47 | Yes | Normal | 3.82 | 212.1 | 46 XX |
| 5 | 21 | No | Normal | 2.54 | 63.5 | 46 XX |

Table 2
Operative outcomes.

| Patient | Operating time (min) | Hospital stay (days) | Duration of follow-up (months) | Vagina: length (cm) | | Time to epithelialization (months) | Time to the first intercourse (months) |
|---------|----------------------|----------------------|--------------------------------|-----------------------|--------------------|------------------------------------|--|
| | | | | At hospital discharge | At final follow-up | | |
| 1 | 30 | 30 | 50 | 9 | 9 | 8 | 27 |
| 2 | 40 | 22 | 25 | 9 | 13 | 20 | 19 |
| 3 | 60 | 14 | 15 | 10 | 12 | 15 | 4 |
| 4 | 50 | 10 | 7 | 10 | 10 | 10 ^a | 3 weeks |
| 5 | 60 | 9 | 21 | 10 | 10 | 15 | 19 |

^a This patient shows 80% epithelialization at postoperative 10 months.

discharge and foul odor, bowel obstruction and peritonitis have been reported.²⁶ Our present study shows that our technique using labial and vestibular advancement flaps in neovaginoplasty provides a sufficient sized vagina to enable normal sexual intercourse while avoiding the complications and disadvantages associated with other grafting technique used in practice. This result suggests that our method is simple, safe, minimally invasive, and an effective alternative approach for vaginal agenesis.

In this respect, another important factor in the outcome of neovaginoplasty is obtaining healthy tissue to cover the newly created vagina. If available, utilization of a local flap would be preferable than grafts in terms of vascularization given that morbidity of the donor site is minimal. Rotational flaps can be applied if there is sufficient amount of local tissue available. Vaginoplasty utilizing myocutaneous flaps such as pudendal thigh and gracilis as well as other fasciocutaneous rotational flaps have been reported. However, the use of them was limited due to resultant extensive donor site scarring.^{22,27} Advancement flaps can be also considered when adjacent skin with laxity is available. Previously, two groups have reported their experience with labia minora flaps in neovaginoplasty.^{19,28} Our present study also used advancement flap of labial and vestibular tissue.

The use of labial advancement flap has several advantages. The first is proximity to the recipient site, relative laxity and minimal donor site morbidity. The second is that labial flap has great regenerative ability, but with no or minimal danger of flap necrosis or donor site scarring, providing a good cosmetic appearance which is a very important factor for women. Finally, our labial flap use did not require the amount of tissue to cover the entire lining surface of the newly created vagina but just enough to serve as a guide for epithelialization of the uncovered vaginal surface unlike the other conventional vaginoplasties which required full coverage of vaginal surface.^{16,26}

In neovaginoplasty using labial flap, we were very careful in two ways. One is that we did not try to cover the whole surface of the vagina but fixed whatever sized flap we could dissect from the labia minora and vestibulum at a point it could reach without tension. As a result, our method did not require a wide dissection because even a small sized flap was enough to lead natural epithelialization of the raw surface over time due to their spontaneous regeneration ability. Hwang et al had used a split thickness skin graft if labia minora were underdeveloped and not enough to completely cover the vaginal lining, in which case donor site scarring would have been inevitable.¹⁹ The other is that our method involves placement of 20 cc trimmed syringe in the vaginal cavity from the day of operation to maintain the newly created space. The hole which appears at the tip of the syringe serves as a drainage channel for whatever discharge that might otherwise pool in the vaginal cavity, thus minimizing the chance of postoperative infection. Moreover, the smooth slippery surface of the plastic syringe makes it ideal for easy insertion and removal, sparing the unnecessary hassle of becoming attached to the vaginal surface which is frequently encountered with molds. Flack et al created a conical pocket with the labial flaps and placed it in the vaginal cavity in which a finger cot packed with antibiotic impregnated gauze is placed for 5 days postoperatively.²⁸ However, the use of a packed finger cot would not have been ideal for the postoperative use by patients at home in terms of preparation and handling.

In the present study, patients were advised to keep the trimmed syringe at home daily for variable hours according to the epithelialization status and vaginal length/width. Since our method left a significant portion of the vaginal cavity raw without covering epithelium, our present study used antiseptic and estriol (Ovestin[®]) vaginal suppository postoperatively until sufficient epithelialization was observed. The suppositories not only provide a moist intra-vaginal environment, but also promote epithelialization.

Liu et al reported that decrease of neovaginal length in almost all patients after the laparoscopic peritoneal vaginoplasty surgery (median decrease 2 cm, range 0–5.5 cm) was noticed. They also suggested that a neovagina of adequate length, likely to be no less than 7 cm, should provide adequate hardware for a successful and satisfying sexual activity, although satisfactory and gratifying sexual activities certainly involve many factors.²⁹ In the present study, the neovagina continued to epithelialize at a rate of approximately 1 cm per month and the neovagina became completely epithelialized by 15 months post-surgery in most cases except for one case (#4) who showed 80% epithelialization at 10 months but was lost to follow up due to relocation to a different region. The mean length × diameter of the neovagina at hospital discharge after surgery was 9.6 cm × 2FB and 10.8 cm × 2FB at last follow up. However, none of the patients experienced any difficulties in having sexual intercourse. In case 4, the patient had been married for 23 years on first outpatient visit and a 3 cm vaginal dimple was noted initially with sufficient healthy labial tissue. A 10 cm-deep vaginal canal fully covered with healthy labial tissue except for the proximal end was obtained by 2 weeks postoperation and the patient was allowed to resume intercourse if desired. Once the flap was securely attached, early intercourse was recommended to maintain the vaginal length. The time of first intercourse would vary among patients greatly according to the epithelialization process as well as the presence of a sexual partner.

The operation time usually depends on the type of procedure. The operation time have been reported to be around 120 min in laparoscopic Davydov procedure,^{13,30} average 72.2 min in one-stage transvestibular vaginoplasty with pelvic peritoneum,²⁴ ranged from 45 min to 80 min in Vecchiatti's operation.³¹ Compared with these procedures, our procedure could be performed in less than 60 min with no significant intraoperative blood loss or postoperative vaginal bleeding. In addition, none of the 5 patients in our study experienced complications of any sort, whereas most studies have reported various complications including the risk of rectovaginal fistula^{24,32} and wound dehiscence.³³

Time to epithelialization depends on the size of obtained labial flap. In this respect, a potential limitation of our technique may be that time to epithelialization took more than 6 months when the length of flap was short (patient #3). However, the patient did not experience any discomfort or difficulty during sexual intercourse even if the vagina was not fully epithelialized.

One of the limitations in the present study is the rather extensive hospital stay, 30 days in the longest and this is mainly because the postoperative epithelialization process had to be monitored by the surgeon since this was her first case using this approach. In addition, the medical cost for hospital stay in Korea is low so usually the cost alone is not a problem when the surgeon decides inpatient observation is needed and the patient fully understands and agrees. Fortunately, the length of stay continued to decrease with the increasing number of cases. Another limitation of our study is a small number of cases. Further study with a greater number of subjects and long term follow up is warranted to identify long term complications related to the procedure.

We attempted this technique in effort to avoid the problems associated with various grafting techniques such as unsatisfactory cosmetic appearance mostly due to donor site scarring, extensive operation time, high risk of postoperative complications and invasiveness. Although it is difficult to provide a matched comparison in the present study, our technique yielded good epithelialization enabling early intercourse. Our mean operation time was 48 min whereas conventional grafting techniques required 60–120 min.^{13,24,30,31} In this respect, the present study has concluded that our technique of neovaginoplasty using labial and vestibular advancement flap is safe, minimally invasive and

effective compared to other techniques. We consider that the three following steps are the key to maintaining the vaginal length and width initially created at the time of surgery throughout follow up: 1) sufficient dissection of the vaginal space, 2) keeping the syringe so that whatever discharge that is produced from the raw surface of newly created vagina can be drained through the hole and lowering the chance of infection, 3) application of antiseptic intravaginal tablet and estriol suppository (Ovestin®) to reduce infection and promote epithelialization.

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