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(Citation)

The Kobe journal of the medical sciences, 58(5):138-144

(Issue Date)

2012

(Resource Type)

departmental bulletin paper

(Version)

Version of Record

(JaLCD0I)

<https://doi.org/10.24546/81005038>

(URL)

<https://hdl.handle.net/20.500.14094/81005038>



Less Invasive New Vaginoplasty Using Laparoscopy, Atelocollagen Sponge, and Hand-Made Mould

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Received 31 July 2012 / Accepted 20 December 2012

Key Words: Mayer–Rokitansky–Küster–Hauser (MRKH) syndrome, vaginoplasty, atelocollagen sponge, hand-made mould, laparoscopy

ABSTRACT

OBJECTIVE: The purpose of this study was to validate the therapeutic efficacy of the innovative surgical approach using laparoscopy, atelocollagen sponge, and hand-made mould on the achievement of a satisfactory neovagina in patients with vaginal agenesis.

STUDY DESIGN: The current study involved four patients diagnosed as having Mayer–Rokitansky–Küster–Hauser syndrome. After creating a vaginal tunnel, the mould wrapped with atelocollagen sponge was placed within the neovagina. The hand-made mould made of expanded polystyrene was started to insert into the neovagina at 7 days after operation. Since this mould is lighter and easier to adjust compared with the previous commercialized ones, it was less stressful for the patients to master the procedure than previous methods.

RESULTS: Average operation time was 124 minutes with average blood loss being 45 ml. Average hospital stay was 23 days. The mean length of the neovagina one week postoperation was 8 cm with two fingers in width in all patients. No remarkable postoperative complications were noted. At two months after surgery, the neovagina was confirmed to be completely epithelialized in all patients, assessed by Schiller's test.

CONCLUSIONS: This innovative surgical procedure using a mould wrapped with atelocollagen sponge may be a more useful approach for the treatment of vaginal agenesis.

INTRODUCTION

Mayer–Rokitansky–Küster–Hauser (MRKH) syndrome is a clinical entity characterized by congenital agenesis of the vagina, a rudimentary uterus, and normal fallopian tubes and ovaries. It occurs in one out of 4,000 - 10,000 female births (1). Numerous techniques have been reported for the creation of a neovagina, including non-invasive and invasive methods. Wharton simply recommended to place a condom-covered mould in the neovagina to allow the vaginal granulation tissues to be epithelialized quickly (2). However, this method fell out of favor because of the complaints of prolonged bloody vaginal discharge from the granulation tissues.

LESS INVASIVE NEW VAGINOPLASTY

We have reported a successful creation of a neovagina in a patient with MRKH syndrome using a modified McIndoe's procedure with oxidized regenerated cellulose to solve the problems associated with the original procedure (3, 4). However, we have experienced the difficulty in inserting the commercially-available mould made of acrylic resin due to the patients' pains and spontaneous falling of the mould from the neovagina due to its heaviness. Thus, the use of previous moulds causes the physical and mental stresses on patients, resulting in the failure of self-management. To solve this problem, we devised a mould that is made of expanded polystyrene. This light and small-sized mould enabled the patients to make an easy self-control.

Herein, we report an innovative vaginoplasty and postoperative management in the treatment of the patients with MRKH syndrome.

MATERIAL AND METHODS

Patients and Preoperative care

Four patients were referred to our hospital with a complaint of primary amenorrhoea. The diagnosis of MRKH syndrome was made with the comprehensive clinical procedure involving the physical examination, ultrasound of the pelvis, hormonal profile, intravenous pyelography, magnetic resonance imaging, and chromosomal analysis. Patients and their parents requested vaginal reconstruction. After obtaining the consent regarding the surgical approach and complications associated with the procedures, it was decided to carry out the modified McIndoe's method using artificial dermis and laparoscopy for vaginal reconstruction.

Operative techniques

Under general anesthesia, the patients were placed in the dorsal lithotomy position. Pneumoperitoneum was established after insertion of a trocar through the umbilicus with 15 mmHg of CO₂. A 10 mm cannula was inserted, and the laparoscope was inserted through it, and subsequently both 10 and 5 mm cannulas were inserted into the pelvic cavity through the

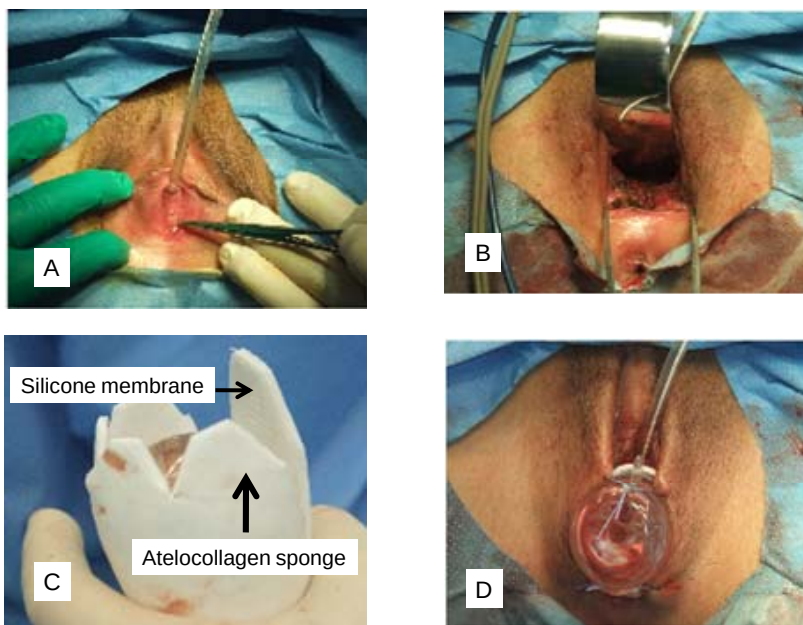


Figure 1.
Surgical approaches. An incision was made in the vestibular part of the vagina. (B) The space between the rectum and the urethra and bladder, was dissected up to reaching the Douglas pouch. (C) The mould was wrapped with the artificial dermis. Inside: silicone membrane. Outside: atelocollagen sponge. (D) The mould was inserted into newly created vaginal space, and the labia were sutured together over the mould.

incisions that were made bilaterally 5 cm from the right and left anterosuperior iliac spine at the level of umbilicus. An exploration of the pelvic and abdominal organs was performed carefully.

A transverse incision was made at the vestibular part of the vagina (Fig. 1A), and with two fingers, the space was dissected between the rectum and the urethra and bladder, up to reaching the Douglas pouch (Fig. 1B). At this time, the damage to the bladder and rectum could be prevented by the goal of the laparoscopic light source. The mould made of acrylic resin was wrapped with the artificial dermis (Terudermis^R, Terumo Co. Ltd, Tokyo, Japan) (Fig. 1C). The mould was then inserted into the newly created cavity, and the artificial dermis was fixed to the newly created vaginal space (5). The labia minora was sutured together over the mould (Fig. 1D).

Postoperative care

A Foley catheter was maintained for one week to avoid the post-operative urine retention and contamination of the external genitalia by urine. The intra-vaginal mould was removed 7 days after surgery without bleeding or foul discharge. The neovagina was irrigated daily with sterile saline solution. Squamous epithelialization of the neovagina was confirmed by Schiller's test without performing traumatic punch biopsy.

Patients were encouraged to practice the daily removal and insertion of the hand-made mould. Because our hand-made mould was made of expanded polystyrene covered with condom (Fig. 2), it was very light and easy for patients to process according to the size of

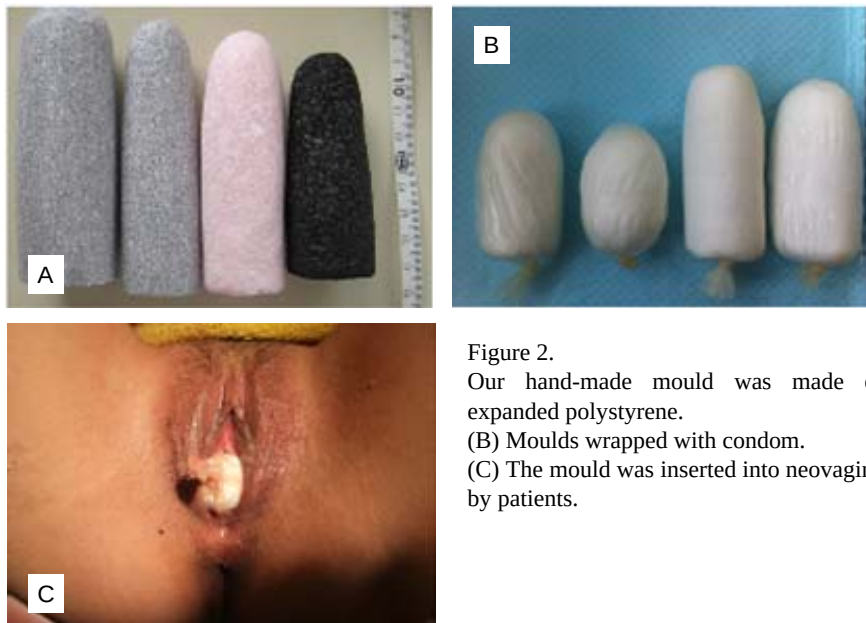


Figure 2.
Our hand-made mould was made of expanded polystyrene.
(B) Moulds wrapped with condom.
(C) The mould was inserted into neovagina by patients.

neovagina. Gentamycin cream was applied to the mould before insertion. The patient discharges it by themselves when they can control the insertion without any help. Patients were advised to keep the mould in the neovagina all times during the first three months after surgery. When the patients have regular sexual intercourse three months after surgery, the mould was removed; otherwise, the mould should be kept in the neovagina. Follow-up examinations were performed monthly for 6 months. At each visit, the vaginal depth and the degree of epithelialization were observed to assess the functional length of the neovagina.

RESULTS

From November 2010 to August 2011, four women were diagnosed as having MRKH syndrome before surgery. All patients showed amenorrhea, but had normal female karyotype and normal secondary sexual characteristics with normal bilateral ovaries, a rudimentary uterus, and an absence of vagina (Table I). All patients had a normal ovarian

Table I. Patient profiles

Case	Age(y)	Secondary sex characteristics	Chromosomal abnormality	Urogenital anomaly	Ovarian morphology and functions
1	16	Normal	None	None	Normal
2	20	Normal	None	None	Normal
3	23	Normal	None	None	Normal
4	43	Normal	None	None	Normal

function by a hormone level and secondary sexual characteristics. They underwent the vaginoplasty with laparoscopy, atelocollagen sponge, and hand-made mould at Kobe University Hospital. Average operation time was 124 minutes (range 95 - 172 minutes). Average blood loss amounted to 45 ml (range 15 - 130 ml). Average hospital period was 23 days (range 21 - 26 days). The silicone membrane was removed spontaneously from the neovagina on 7 to 10 days after surgery. At that time, the neovagina was found to be covered by a very thin epithelium-like layer with neovascularization. A quarter of the neovagina was completely epithelialized like normal vaginal mucosa.

The mean length of the neovagina one week after surgery was 8 cm (range 7 - 9) with two fingers in width in all patients. Because the ready-made moulds were not sufficiently fitted to the neovagina in the patients, the moulds were newly made by us during hospitalization. The average number of moulds that were used amounted to was 4 (range 2 to 7) for each patient. At two months after operation, the neovagina was noted to be completely epithelialized in all patients when assessed by Schiller's test. One patient could successfully engage in sexual intercourse three months after surgery with no feelings of discomfort or any use of Lubricant. For the patients without having sexual partner, no problems has been reported about the compliance in the use of hand-made mould. All patients maintained a well-formed neovagina of 8 cm in average length and two fingers in width at six months follow-up after surgery (Table II).

Among the four cases presented here, we explain the last patient with the oldest age of 42. This patient had visited a hospital with a complaint of primary amenorrhea at the age of 17, but had been told of no therapy for this disease. She had spent her life for 25 years since then with a huge mental distress. She has recently been diagnosed as having MRKH syndrome and known that vaginoplasty may make it possible to have sexual intercourse.

Table II. Anatomical results after surgery

Case	Two months after operation		Six months after operation	
	Length of neovagina (cm)	Epithelialization	Length of neovagina (cm)	Condition of neovagina
1	7	completed	8	good
2	9	completed	8	good
3	8	completed	9	good
4	8	completed	7	good

DISCUSSION

This appears to be the first report to demonstrate the creation of a neovagina that uses atelocollagen sponge and hand-made mould. Numerous methods have been reported regarding the creation of a neovagina in patients with MRKH syndrome, including the non-surgical techniques and surgical techniques such as Vecchietti's procedure, McIndoe's procedure, Williams's procedure, and their modifications (6-10). The ideal time for intervention is at or after adolescence, when woman has reached the physical and psychological maturity. Surgical treatment should be performed in adolescence before sexual intercourse (11).

Different techniques of vaginoplasty have various advantages and disadvantages. Intestinal vaginoplasty using the intestinal segments is a major operation, but poses a considerable risk to the patients with a frequent incidence of foul-smelling vaginal discharge. Vaginoplasty using either amnion grafts, skin, or mucosal tissues may result in relatively poor sexual function (12). While Vecchietti's procedure requires a special traction device, McIndoe's procedure needs the common step in vaginoplasty of tissue dissection between urinary tract and rectum without requiring special device. (13). The most common surgical approach is the McIndoe's procedure to date. However, the McIndoe's procedure is accompanied by the formation of visible scars at the origin of the skin graft site, which is usually unacceptable to young patients (14). Our colleagues, Motoyama *et al.* have reported 10 cases of vaginoplasty with the modified McIndoe's method using an InterceedTM (Johnson & Johnson Co. Ltd, Tokyo, Japan) absorbable adhesion barrier (3, 4). This method was easy and less invasive compared with the McIndoe's method. However, our new method presented here can be performed more safely, reliably, and simply compared with the Motoyama's method using InterceedTM. The points of our new method can be summarized as follows:

1. Laparoscopy; in our current method, the damage of bladder and rectum during the transvaginal approach can be prevented by using the light source of laparoscopy as an index.
2. Atelocollagen sponge; the artificial dermis is a collagen sponge composed of fibrillar atelocollagen and heat-denatured atelocollagen cross-linked dehydrothermally (15). After

grafted onto a living subject, endothelial cells and fibroblasts were shown to introduce into the collagen matrix, which was gradually replaced by host tissues (15). Artificial dermis was reported to be useful for treating full-thickness skin defects and oral vestibular extension (16). In addition, Noguchi *et al.* reported that the combination of atelocollagen sponge and bFGF for vaginoplasty accelerated the epithelialization in the neovagina and reduced the amount of bloody vaginal discharge from the granulation tissues (5). In this context, it seems likely that the atelocollagen sponge is superior to Interceed^R.

3. Hand-made mould made of expanded polystyrene; since the commercialized, ready-made moulds composed of acrylic resin are very hard, keeping it long in the vagina often causes the physical and mental stresses in patients. However, our hand-made mould made of expanded polystyrene is easy to adjust to the neovagina and bring less pains to the patients. It costs cheaper than previous methods. Furthermore, the patients can make the mould by themselves, making their long-time-self control easier. Thus, it is likely that our new method of vaginoplasty is a safe and reasonable choice for patients with vaginal agenesis which produces satisfactory results.

With regards to the laparoscopic vaginoplasty in our cases, the operating time ranged from 60 to 150 minutes, and intraoperative hemorrhage volume did from 50 to 200 ml (11, 17-21). Our results are in agreement with the previously published ones (11, 17-21). However, the length of hospitalization for our patients was longer compared with reported ones (11, 17-21), because our procedure required the close physical and mental care in the practice of the removal and insertion of our hand-made mould by patients.

Noguchi *et al.* described that the complete epithelialization of the neovagina occurred starting from the entrance of the neovagina toward the vaginal cuff, and the host cells such as fibroblasts and endothelial cells invaded the atelocollagen sponge from the basement. Then, these cells proliferated, forming the new capillaries, and were differentiated to the epithelium (5). In our experiences, the neovagina was found to be covered by epithelium-like layer with neovascularization seven days after surgery. And two months after operation, the epithelization of neovagina became complete in all patients. The neovagina created with our present technique was epithelialized more quickly than the McIndoe's method (13, 14). These findings support a notion that the atelocollagen sponge is superior to InterceedTM in epithelialization (3, 4). Vaginal agenesis remains a rare condition, and surgical decision making is highly complex.

In the treatment of vaginal defect, a multidisciplinary team comprising of well-experienced gynecologists, nurses, and psychological counselors is required to be responsible to manage the patients. The best therapeutic procedure and good postoperative management would bring them long-term satisfaction.

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