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Effects of different vaginal mould use approaches after vaginoplasty with artificial dermis in patients with Mayer–Rokitansky–Küster–Hauser syndrome

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Abstract

Objective: To assess the therapeutic effects of different vaginal mould use approaches after vaginoplasty in patients with Mayer–Rokitansky–Küster–Hauser (MRKH) syndrome.

Methods: Patients with MRKH syndrome who underwent surgery from 2010 to 2015 in our hospital were retrospectively evaluated. Vaginoplasty was performed with artificial dermis, and vaginal moulds were used for 6 months postoperatively. The patients were divided into an intermittent group and continuous group according to the vaginal mould approach.

Results: Thirty-five patients were evaluated (intermittent group, 19 patients; continuous group, 16 patients). One month postoperatively, the mean vaginal length and width in the intermittent group were 9.26 ± 0.56 and 3.82 ± 0.25 cm, respectively, and those in the continuous group were 9.44 ± 0.51 and 3.86 ± 0.22 cm, respectively. Six months postoperatively, the mean vaginal length and width in the intermittent group were 8.94 ± 0.71 and 3.76 ± 0.26 cm, respectively, and those in the continuous group were 8.69 ± 0.48 and 3.65 ± 0.30 cm, respectively. The mean Female Sexual Function Index scores in the intermittent and continuous groups were 28.61 ± 0.71 and 28.4 80 ± 0.79 respectively, after normal sexual life.

Conclusion: Both intermittent and continuous use of postoperative vaginal moulds may be effective.

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Introduction

Mayer–Rokitansky–Küster–Hauser (MRKH) syndrome is characterized by congenital aplasia of the uterus and upper two-thirds of the vagina in female individuals with normal development of secondary sexual characteristics and a normal 46, XX karyotype.[1] The common signs of MRKH syndrome include vaginal agenesis and primary amenorrhea, and its estimated incidence is 1 in 4500 to 5000 female births.[2]

Because of unaltered ovarian function, most patients exhibit normal secondary sexual characteristics other than lack of menstruation in the early teenage years.[3,4] Affected patients have normal sexual psychology without a vagina; therefore, vaginal reconstruction (creation of a neovagina of appropriate size allowing for sexual intercourse) is a major therapeutic goal in patients with MRKH syndrome.[5,6]

Many methods of vaginoplasty are available, including the Abbè–McIndoe procedure and its subsequent modifications such as the Vecchietti operation, the Davydov procedure, sigmoidal coloplasty, and further methods using the buccal mucosa, amnion, or other allografts.[6–9]

Postoperative problems associated with vaginoplasty include potential intestinal complications, malodourous secretions, and vaginal prolapse and stenosis[10,11] that affect the patient's sexual life. Therefore, a vaginal mould (dilator device) can be introduced by the physician to alleviate stenosis.[12] However, whether continuous or intermittent use of a vaginal mould after vaginoplasty is more beneficial remains unknown. Therefore, this study was performed to evaluate the therapeutic effects of different vaginal mould use approaches after vaginoplasty in patients with MRKH syndrome.

Materials and methods

Patients

This retrospective study included patients with MRKH syndrome who underwent vaginoplasty with artificial dermis in Beijing Obstetrics and Gynecology Hospital affiliated with the Capital University of Medical Sciences from January 2010 to December 2015. The inclusion criteria were (1) primary amenorrhea; (2) well-developed secondary sexual characteristics, a well-developed vulva, and a vaginal vestibular recess depth of 0.5 to 1.0 cm; (3) preoperative ultrasound and pelvic magnetic resonance imaging findings indicating the lack of a normal uterus in the pelvic cavity; (4) chromosome karyotype analysis indicating 46, XX; (5) sex hormone levels within the reference ranges; and (6) the presence of a male or female partner and sexual and surgical requirements. The exclusion criteria were (1) endometrium within the uterine cavity showing blood retention and (2) preoperative chronic pelvic pain that continued to impact postoperative sexual satisfaction.

This study was approved by the ethics committee of Beijing Obstetrics and

Gynecology Hospital affiliated with the Capital University of Medical Sciences. The requirement for informed consent was waived because of the retrospective design. The ethics/review board attested that the patients had provided written informed consent before the operation.

Surgical procedure

All patients underwent vaginoplasty by the same surgical team under general anesthesia in the lithotomy position. A neovagina that was about 10 cm long and 3 to 4 cm wide was created between the bladder and rectum. An artificial dermis (C-IHM-10 × 15; Cook Biotech, West Lafayette, IN, USA) was made into a 10-cm cylinder with one end closed and the other open and was then sutured in the artificial vagina using 3-0 suture (Vicryl Plus; Johnson & Johnson, New Brunswick, NJ, USA). A vaginal mould (Hangzhou Kangji Medical Instrument Co., Ltd., Hangzhou, China) with a drainage hole (10 cm in length, 4 cm in diameter) was placed in the neovagina after the operation (Figure 1) and removed 14 days later. The patients were kept in the hospital for the entire 14 days to ensure that the mould remained in place.

Surgical success was assessed according to the criteria established by Callens et al.,[13] who summarized 190 studies published in the English language on PubMed from 1898 to 2013. A successful operation was defined as a >7 cm anatomical depth of the vagina and functional sexual intercourse.

Grouping and postoperative care

The patients were grouped into an intermittent group and continuous group according to the use of the vaginal mould after surgery. In all patients, a vaginal silicone mould (4 cm in diameter, 10 cm in length) was used to dilate the neovagina according to the patient's life and work schedule after surgery. The patients were instructed to abstain from sexual activity for 6 months after surgery. The vaginal mould was used for 6 months to prevent contraction of the neovagina. In the intermittent group, the patients used the vaginal mould three times a day for 30 minutes each. In the continuous group, the patients wore the mould continuously for more than 8 hours every night.

The vaginal mould could be cleaned by a simple flush with an iodophor and running water daily. All patients started normal sexual life after 6 months of vaginal mould use.

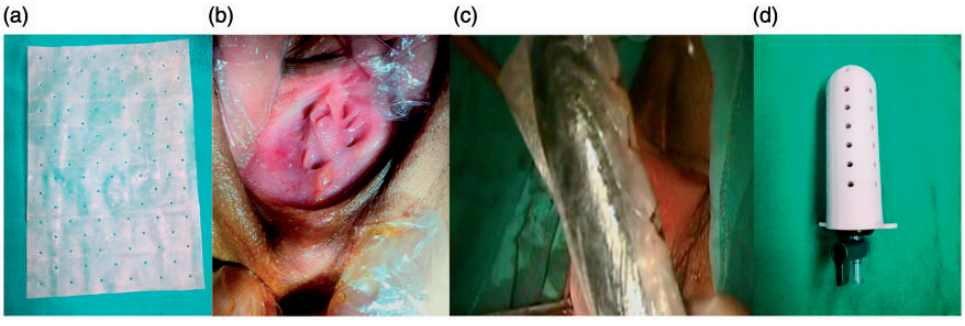

Figure 1. Materials for the surgical procedure and perineal appearance in patients with Mayer–Rokitansky–Küster–Hauser (MRKH) syndrome. (a) Vaginal mould. (b) Perineal appearance in a representative patient with MRKH syndrome. (c) Artificial dermis. (d) Vaginal mould.

Data collection and follow-up

The patients' general information was collected from the medical records. In the outpatient clinic, we used a speculum to expose the new vagina and employed a ruler to measure the vaginal length and width. Anatomical data included the vaginal length, width, and epithelialization obtained at 1 and 6 months after surgery. The Female Sexual Function Index (FSFI)[14] was used to assess satisfaction with sexual life based on telephone or medical records 12 months postoperatively. Sexual function was classified as excellent (FSFI score of 30–35 points), good (FSFI score of 22–29 points), or poor (FSFI score of <22 points).[14]

Outpatient follow-up was performed by telephone at 1 and 6 months after surgery and yearly thereafter. The last follow-up date was 31 December 2018. FSFI assessment was performed during follow-up.

Statistical analysis

SPSS for Windows, Version 16.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Continuous data were evaluated by the Kolmogorov–Smirnov test for normality. Normally distributed continuous data are presented as mean ± standard deviation, and non-normally distributed data are expressed as median (range). Student's independent t test was performed for comparisons. A P value of <0.05 was considered statistically significant.

Results

Baseline patient characteristics

Vaginoplasty was successfully performed in 39 patients without bladder, urethral, or rectal injuries. However, the data of four patients were not fully available. Therefore, 35 patients ranging in age from 20 to 30 years were assessed (intermittent group, 19 patients; continuous group, 16 patients). The patient's mean age, surgery duration, and perioperative blood loss in the intermittent group were 23.89 ± 2.56 years, 66.84 ± 20.01 minutes, and 38.42 ± 17.08 mL, respectively, and those in the continuous group were 24.06 ± 2.82 years, 63.75 ± 14.66 minutes, and 44.44 ± 21.50 mL, respectively (Table 1). There were no significant differences in age, operation time, or blood loss between the two groups.

Anatomical and sexual outcomes

One month after surgery, the mean vaginal length and width in the intermittent group were 9.26 ± 0.56 and 3.82 ± 0.25 cm, respectively, and those in the continuous group

Table 1. Baseline features of patients with Mayer–Rokitansky–Küster–Hauser syndrome.

	Intermittent group (n = 19)	Continuous group (n = 16)	*P*
Age, years	23.89 ± 2.56 (20–28)	22.87 ± 2.39 (20–30)	0.85
Disease course, years	6 (2–14)	4 (1–10)	0.10
Associated malformations			
Ovarian	0 (0.00)	1 (6.25)	
Renal	0 (0.00)	2 (12.5)	
Skeletal	0 (0.00)	1 (6.25)	
Duration of surgery, minutes	66.84 ± 20.01 (40–120)	63.75 ± 14.66 (40–100)	0.61
Blood loss, mL	38.42 ± 17.08 (20–80)	44.44 ± 21.50 (20–90)	0.45
Follow-up, years	6 (3–8)	7 (4–8)	0.12

Data are presented as mean ± standard deviation (range), n (%), or median (range).

were 9.44 ± 0.51 and 3.86 ± 0.22 cm, respectively (Table 2). Epithelialization of the vaginal mucosa was found 6 months postoperatively in both groups (Figure 2). Six months after surgery, the mean vaginal length and width in the intermittent group were 8.94 ± 0.71 and 3.76 ± 0.26 cm, respectively, and those in the continuous group were 8.69 ± 0.48 and 3.65 ± 0.30 cm, respectively (Table 2). The mean FSFI scores at 6 months postoperatively were 28.61 ± 0.71 and 28.48 ± 0.79, indicating a successful sexual life (Table 2). There were no significant differences between the two groups.

Long-term patient outcomes

All 35 patients were followed up for 3 to 8 years, and 34 were satisfied with their sexual life via FSFI assessment. One patient broke up with her boyfriend 2 years after surgery; she stopped wearing the mould and showed a vaginal depth of 5 cm with a width of 3 cm at 3 years postoperatively because of the lack of sexual activity.

Table 2. Anatomical and sexual outcomes of patients with Mayer–Rokitansky–Küster–Hauser syndrome after vaginal mould use.

	Intermittent group (n = 19)	Continuous group (n = 16)	*P*
Vaginal length, cm			
1 month post-surgery	9.26 ± 0.56 (8–10)	9.44 ± 0.51 (8–10)	0.35
6 months post-surgery	8.94 ± 0.71 (8–10)	8.69 ± 0.48 (8–10)	0.22
Vaginal width, cm			
1 month post-surgery	3.82 ± 0.25 (3–4)	3.86 ± 0.22 (3–4)	0.47
6 months post-surgery	3.76 ± 0.26 (3–4)	3.65 ± 0.30 (3–4)	0.26
FSFI 12 months post-surgery	28.61 ± 0.71 (27.6–29.1)	28.48 ± 0.79 (26.9–29.5)	0.61

Data are presented as mean ± standard deviation (range).
FSFI, Female Sexual Function Index.

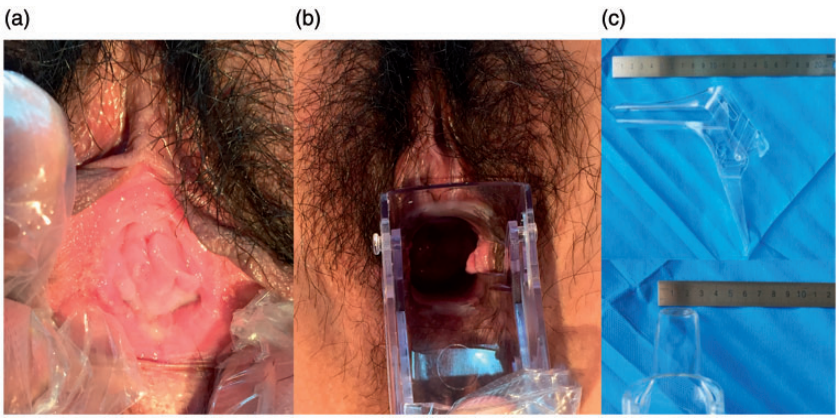

Figure 2. Vaginal examination. (a) Neovagina of a representative patient with Mayer–Rokitansky–Küster–Hauser syndrome. (b) A vaginal speculum was used to examine the patient's new vagina 6 months after the operation. (c) A speculum was used to expose the neovagina of the patient, and the vaginal length and width were measured with a ruler.

This patient developed vaginal stenosis and was ultimately unable to have sex.

Discussion

In this retrospective study, both intermittent and continuous mould use approaches after surgery were effective, resulting in satisfactory anatomical features and allowing an active sexual life in the patients. Patients with MRKH syndrome show dysplasia of the Müllerian canal, including no vagina and no uterus or only a primordial uterus. MRKH syndrome is mostly diagnosed by the presence of primary amenorrhea (85.3%), lower abdominal pain (4.5%), and difficulty in sexual intercourse (3.8%).[2,15] The age at diagnosis of MRKH syndrome is 15 to 18 years,[16] whereas the age at treatment is mostly related to the patient's sexual needs and often lags behind the age at first diagnosis.

Congenital vaginal ailments can be treated nonsurgically; e.g., using vaginal dilators.[17] Nonsurgical treatment is best for patients with acceptable vestibular dimples and depressions of >3 cm, but such treatment may cause long-term pain and embarrassment with poor treatment adherence. In addition, vaginal prolapse occurs in some patients during nonsurgical procedures, necessitating surgery.[18] Surgical treatment is performed by artificial vaginoplasty. Biomembrane tissue engineering has been successfully applied for the reconstruction of multiple organs, and various types of biofilms have good histocompatibility, strong applicability, and the ability to withstand infection. Moreover, there is no risk of potential malignant transformation of an artificial dermis; therefore, artificial vaginoplasty has become the first choice for patients with MRKH syndrome.[19] Callens et al.[13] indicated that an anatomical vaginal depth of >7 cm and functional sexual intercourse reflect a successful operation; based on these criteria, vaginoplasty has a higher success rate than nonsurgical methods (90% versus 75%). However, the artificial vagina has no muscle fibers, and patients are at risk of vaginal stenosis or contracture after vaginoplasty.[20]

Epithelization of the neovagina requires 3 to 6 months after vaginoplasty using artificial dermis.[21] To ensure a normal sexual life, it is necessary to maintain the length and width of the neovagina with regular use of a vaginal mould or dilator after surgery.[22] Because the treatment schedule of the vaginal mould involves all aspects of the patient's life and work time, investigation is needed regarding how to properly coordinate life, work, and treatment schedules; improve patient compliance; and ensure therapeutic efficacy. Most experts advocate that dilation occurs as often as the patient is able to comply, but wide variability exists among patients in terms of how often to dilate. Nonetheless, many agree that 10 to 30 minutes of daily use is beneficial, and a 10- to 20-minute cycle can be repeated three times daily for optimal results.[23,24] In one study, patients who underwent the laparoscopic Vecchietti modified technique were instructed to use vaginal dilators after device removal, starting with the smallest dilator and keeping it inserted in the neovagina for approximately 8 to 10 hours daily in the first postoperative month.[25] No unified recommendations regarding the specific use of vaginal moulds after vaginoplasty have been established. Large-scale prospective studies cannot be conducted because of the small number of clinical cases compounded with the different living habits and sexual needs of the patients. Therefore, we retrospectively analyzed the data of patients with different mould use approaches and found that both continuous and intermittent use resulted in continuous vaginal expansion after surgery as well as a satisfactory sexual life. The FSFI scores of the patients in this study were within a satisfactory

range. Additionally, 6 months after the operation, the vaginal mucosa was smooth and ruddy with good elasticity for intercourse. Such outcomes greatly improve patients' quality of daily life and build confidence. According to the above findings, patients should choose between intermittent and continuous use of vaginal moulds based on their individual working and living conditions. This would improve compliance, thereby maintaining the effectiveness of vaginoplasty.

This study had several limitations. First, in terms of postoperative follow-up, the patients' spouses' satisfaction with their sexual life was not assessed because of patient privacy and cultural habits. Second, this was a single-center study with a relatively small sample size. Third, because some patients did not have the time and/or a place to complete the treatment three times a day, they were required to wear the mould at night. Finally, the patients had a choice between intermittent or continuous treatment. This was not a randomized double-blind trial, which is another limitation of our study. Therefore, large multicenter trials with a prospective design are warranted to confirm these findings.

In conclusion, this retrospective study of 35 patients demonstrated that both intermittent and continuous vaginal mould use after vaginoplasty are comparable in providing satisfactory anatomical features and allowing an active sexual life. These findings suggest that individuals may be free to choose a vaginal mould use approach (intermittent or continuous) based on their working and living conditions.

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Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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References

1. Morcel K, Camborieux L and Guerrier D. Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome. *Orphanet J Rare Dis* 2007; 2: 13.
2. Herlin M, Bjørn AM, Rasmussen M, et al. Prevalence and patient characteristics of Mayer-Rokitansky-Küster-Hauser syndrome: a nationwide registry-based study. *Hum Reprod* 2016; 31: 2384–2390.
3. Pastor Z, Froněk J, Nováčková M, et al. Sexual life of women with Mayer-Rokitansky-Küster-Hauser syndrome after laparoscopic Vecchietti vaginoplasty. *Sex Med* 2017; 5: e106–e113.
4. Both S, Kluivers K, Ten Kate-Booij M, et al. Sexual response in women with Mayer-Rokitansky-Küster-Hauser syndrome with a nonsurgical neovagina. *Am J Obstet Gynecol* 2018; 219: 283.e1-e8.
5. Ding JX, Chen LM, Zhang XY, et al. Sexual and functional outcomes of vaginoplasty using acellular porcine small intestinal submucosa graft or laparoscopic peritoneal vaginoplasty: a comparative study. *Hum Reprod* 2015; 30: 581–589.
6. Leithner K, Naderer A, Hartung D, et al. Sexual and psychosocial functioning in women with MRKHS after neovaginoplasty according to Wharton-Sheares-George: a case control study. *PloS One* 2015; 10: e0124604.
7. Kuessel L, Wenzl R, Marschalek ML, et al. Using the Wharton-Sheares-George method to create a neovagina in patients with Mayer-Rokitansky-Küster-Hauser

syndrome: a step-by-step video tutorial. *Fertil Steril* 2016; 106: e20–e21.
8. Lesavoy MA. Vaginal reconstruction. *Clin Obstet Gynaecol* 1985; 12: 515–525.
9. Sabatucci I, Palaia I, Marchese C, et al. Treatment of the Mayer-Rokitansky-Küster-Hauser syndrome with autologous in vitro cultured vaginal tissue: descriptive study of long-term results and patient outcomes. *BJOG* 2019; 126: 123–127.
10. Mungadi IA, Ahmad Y, Yunusa GH, et al. Mayer-Rokitansky-Kuster-Hauser syndrome: surgical management of two cases. *J Surg Tech Case Rep* 2010; 2: 39–43.
11. Le A, Wang Z, Shan L, et al. Retraction note to: peritoneal vaginoplasty by Luohu I and Luohu II technique: a comparative study of the outcomes. *Eur J Med Res* 2017; 22: 26.
12. Londra L, Chuong FS and Kolp L. Mayer-Rokitansky-Kuster-Hauser syndrome: a review. *Int J Womens Health* 2015; 7: 865–870.
13. Callens N, De Cuypere G, De Sutter P, et al. An update on surgical and non-surgical treatments for vaginal hypoplasia. *Hum Reprod Update* 2014; 20: 775–801.
14. Meston CM, Freihart BK, Handy AB, et al. Scoring and interpretation of the FSFI: what can be learned from 20 years of use? *J Sex Med* 2020; 17: 17–25.
15. Wagner A, Brucker SY, Ueding E, et al. Treatment management during the adolescent transition period of girls and young women with Mayer-Rokitansky-Küster-Hauser syndrome (MRKHS): a systematic literature review. *Orphanet J Rare Dis* 2016; 11: 152.
16. Govindarajan M, Rajan RS, Kalyanpur A, et al. Magnetic resonance imaging diagnosis of Mayer-Rokitansky-Kuster-Hauser syndrome. *J Hum Reprod Sci* 2008; 1: 83–85.
17. Dabaghi S, Zandi M and Ilkhani M. Sexual satisfaction in patients with Mayer-Rokitansky-Küster-Hauser syndrome after surgical and non-surgical techniques: a systematic review. *Int Urogynecol J* 2019; 30: 353–362.
18. Walch K, Kowarik E, Leithner K, et al. Functional and anatomic results after creation of a neovagina according to Wharton-Sheares-George in patients with Mayer-Rokitansky-Küster-Hauser syndrome-long-term follow-up. *Fertil Steril* 2011; 96: 492–497.e1.
19. Dias M, Bilhar APM, Rios LC, et al. Neovaginoplasty using Nile tilapia fish skin as a new biologic graft in patients with Mayer-Rokitansky-Küster-Hauser syndrome. *J Minim Invasive Gynecol* 2020; 27: 966–972.
20. McQuillan SK and Grover SR. Systematic review of sexual function and satisfaction following the management of vaginal agenesis. *Int Urogynecol J* 2014; 25: 1313–1320.
21. Bianchi S, Frontino G, Ciappina N, et al. Creation of a neovagina in Rokitansky syndrome: comparison between two laparoscopic techniques. *Fertil Steril* 2011; 95: 1098–100.e1-3.
22. Bastu E, Akhan SE, Mutlu MF, et al. Treatment of vaginal agenesis using a modified McIndoe technique: long-term follow-up of 23 patients and a literature review. *Can J Plast Surg* 2012; 20: 241–244.
23. Rock JA, Reeves LA, Retto H, et al. Success following vaginal creation for Müllerian agenesis. *Fertil Steril* 1983; 39: 809–813.
24. Edmonds DK, Rose GL, Lipton MG, et al. Mayer-Rokitansky-Küster-Hauser syndrome: a review of 245 consecutive cases managed by a multidisciplinary approach with vaginal dilators. *Fertil Steril* 2012; 97: 686–690.
25. Fedele L, Bianchi S, Frontino G, et al. The laparoscopic Vecchietti's modified technique in Rokitansky syndrome: anatomic, functional, and sexual long-term results. *Am J Obstet Gynecol* 2008; 198: 377.e1-6.