Long Term Anatomical and Functional Results of Modified McIndoe Vaginoplasty with Amnion Graft in Patients with Congenital Vaginal Aplasia Compared with a Control Group

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Abstract

Background: Vaginal aplasia is a rare congenital anomaly with different surgical techniques suggested for vaginal reconstruction. McIndoe vaginoplasty is an easy one of these surgical methods with a low morbidity rate, but its long-term results need to be further investigated. Therefore, the female genital anatomy and sexual function was examined after performing McIndoe vaginoplasty in patients with müllerian anomaly or androgen insensitivity syndrome.

Materials and Methods: In this historical cohort study, the data of 25 patients undergoing McIndoe vaginoplasty with amniotic graft from 2006 to 2017 at four selected hospitals of Shiraz affiliated with Shiraz University of Medical Sciences in Iran were extracted from medical records. Then, the patients were called to refer for physical examination and fill the Female Sexual Function Index (FSFI) questionnaire. In addition, 31 women of the same age range and without a sexual problem, vaginal surgery, or delivery were selected as the control group. Finally, the results of vaginal measurements and FSFI scores of the two groups were compared together.

Results: The average vaginal length of the case and control groups were 5.60±2.38 and 8.47±1.31 cm, respectively. Furthermore, the mean proximal vaginal diameter in case and control groups were measured 2.94±0.92, and 4.12±0.70 cm, respectively (P<0.001). The mean FSFI score of the case group was 12.81±7.87, and 24.19±2.90 for the control group (P<0.001). The vaginal indices and FSFI of the patients using mold routinely were still lower than the control group (P<0.05) although theyhad a larger vagina (P<0.001).

Conclusion: Vaginal reconstruction using McIndoe vaginoplasty with amniotic graft failed to provide normal vagina function and anatomy for patients with congenital vaginal aplasia in long-term follow-up.

Key Words: Congenital, Reconstructive Surgical Procedures, Vagina.

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1- INTRODUCTION

Defects in the development of female genital tract during embryogenesis can result in various congenital anomalies such as uterovaginal aplasia. In this regard, Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome, also known as müllerian or vaginal agenesis, is the most common form of uterovaginal aplasia which includes congenital aplasia of the uterus and upper vagina (1, 2). Moreover, there are other syndromes that can result in vaginal agenesis (e.g., androgen insensitivity syndrome or testicular feminization in which the female individual has XY karyotype and testes) (3). Individuals with an absent vagina have similar sexual problems and perceived stress but different pathogeneses (4). The primary challenge in patients with vaginal aplasia is the diagnosis since they may remain undiagnosed due to their normal external genitalia until adolescence, when they develop primary amenorrhea or cyclic abdominal pain (5).

Imaging investigations is strongly suggested for diagnosing the exact anomalies in the genital tract, ovaries, and uterus, as well as the associated organs such as urinary tract according to which the treatments are scheduled (6, 7). On the other hand, the lack of vagina causes a great distress for the patient and makes her feel different from others. Therefore, creating a functional neovagina is one of the essential treatments primarily achieved using vaginal dilators routinely, followed by a surgery which also requires maintenance by using dilators or frequent intercourse is (8). The surgical techniques introduced for making a neovagina include traction methods such as Vechietti, graft-based methods such as Abbe-McIndoe, and Davydov methods. On the other hand, various tissues such as skin, peritoneum, amnion, and bioengineering tissues are suggested to be applied as a graft such as skin, peritoneum, amnion, and bioengineering tissues (9). Furthermore, the Modified McIndoe technique is considered as a simple method with low risk of morbidity as it needs no laparotomy, while other techniques are reported to be complex (10, 11). Hence, selecting the surgical method and graft tissue used for the patients is mainly based on the surgeon's preference, and availability of materials and instruments (12). The individual's sexual function is another important aspect neglected by the researches reporting the surgical success, because they have mainly focused on the vaginal anatomy. However, providing the individual a normal sexual function is the main aim of the treatment which needs more long-term assessments (13). The anatomical and functional results of amnion graft is only studied in a few patients (14).Therefore, evaluating the long-term surgical outcome of the amnion graft is necessary. Accordingly, the present study aimed to investigate the vaginal anatomical and sexual function in female patients with müllerian anomaly or androgen insensitivity syndrome after McIndoe vaginoplasty.

2- MATERIALS AND METHODS

In this historical cohort study, all the patients with müllerian anomaly or androgen insensitivity syndrome admitted to Shiraz University of Medical Sciences affiliated hospitals (i.e., Faghihi, Zaiynabiye, and Ghadir Mother and Child) between 2006 and 2017 and subjected to the vaginal reconstruction surgery using McIndoe technique with amniotic graft were considered as the study population. In addition, their surgical procedure was the sameand they were advised to use molds routinely after the surgery. The patients' McIndoe vaginoplasty was initiated via a transverse incision in the apex of the vaginal dimple. Secondly, the space between the bladder and the urethra in anterior and rectum in posterior was dissected up to the peritoneal surface.

Furthermore, the puborectalis muscles were incised bilaterally in patients with androgen insensitivity syndrome followed by placing a 9×4 cm sterilized hand-made mold in the neovagina. The mold was composed of a sponge wrapped around a hard core (syringe barrel), and covered by two layers of condom, and an amnion graft sewn over its ending. It was kept in place for 10 days and after its removal, the neovagina was irrigated and inspected carefully for any sign of excessive pressure or graft rejection. Accordingly, the patients were instructed to use the mold continuously for 6 weeks and remove it only for urinating and defecating.

After 6 weeks, an appropriate-sized silicone dilator (CooperSurgical Inc. United States) was selected, and the patient was informed to nightly use it for 12 months and occasionally thereafter in case of having irregular intercourse. In addition, they were visited regularly during the first year of post-operation period. However, visiting was afterwards limited to annual gynecological exams or any new complaints. The contact information of eligible patients was extracted from the medical records of the hospitals using the consensus method (n=25). Then, the researcher called them, obtained their consent to participate in the study, and referred them to the selected center for physical examination and questionnaire completion. 31 sexually active women of the same age range (among the patients attended the gynecology clinic of the same hospitals), without any disease (such as diabetes mellitus, hypertension, chronic inflammatory diseases, and depression), and medications use affecting their sexual function, and history of vaginal delivery or surgery were afterwards selected as the control group. Subsequently, the researcher explained the study objectives to them and asked them to read and sign the written informed consent form for their participation in the study. All the participants were examined by a single gynecologist who performed the two-finger vaginal examination and recorded the patients' vaginal parameters using a 1-1.5×6-inch vaginal dilator (Venus brand, made in Iran) made of paraffin. The diameter and length of the dilator inserted without pressure or pain were considered for measuring the vaginal diameter and length by marking the exiting site of the dilator from introitus and measuring its distance from the dilator's apex placed in the fornix. The Female Sexual Function Index (FSFI) was developed by Rosen et al. to assess female sexual function during a four-week time frame (12).

In this regard, the domains and selected items reflect the American Foundation for Urological Disease (AFUD) classification system for Female sexual dysfunction (FSD). The 19 questionnaire items are summarized into six subscales including sexual desire (two items), arousal (four items), lubrication (four items), orgasm (three items), satisfaction (three items), and pain (three items). The subscales range from zero (or one) to five, in which higher scores indicate better sexual function. To measure the participants' sexual function using the FSFI, the researcher explained to the participants how to complete the questionnaire and stayed with them to answer their questions during its fulfillment. On the other hand, the questionnaire evaluated the participants' sexual function in six domains, including sexual desire (two items), arousal (four items), lubrication (four items), orgasm (three items), satisfaction (three items), and pain (three items). In addition, it totally had 19 items with multiple choices, and the subscales ranged from zero (or one) to five where higher scores implied better sexual function (15). It is worth noting that the persian version of this questionnaire was used in this study (16, 17). The patients' ages at the time of surgery and follow-up were collected from

their medical records via personal communication, respectively. All the patients in the case and control groups were married women with active sexual lives. Furthermore, the patients in the case group were asked if they utilized the mold routinely as prescribed and accordingly categorized into two groups. Finally, the patients in the case group with a minimum vaginal length of 6 cm and diameter of 3 cm were considered as having a normal vaginal anatomy. In the first place, the normal distribution of numeric variables was assessed for statistical analysis using the Shapiro-Wilk test and showed a normal distribution. Accordingly, the descriptive results of numeric variables were presented by mean±standard deviation (SD), and compared between the two groups using independent samples t test. Then, the mean duration from the time of surgery was compared between the groups with normal and abnormal vaginal indices using Chi-square test to study the effect of the time elapsed from surgery on the results. Furthermore, the statistical software IBM SPSS Statistics for Windows version 21.0 (IBM Corp. 2012. Armonk, NY: IBM Corp.), was used for statistical analysis and the p-values of 0.05 or less were considered statistically significant.

3- RESULTS

19 out of 25 patients included in the case group had Mullerian anomaly and the six remaining patients had androgen insensitivity syndrome. The results of imaging findings (recorded from patients' medical records) revealed that of 19 patients with Müllerian anomaly, 12 had müllerian agenesis and 7 had rudimentary tissues. In addition, all the patients with androgen insensitivity syndrome had undergone gonadectomy. On the other hand, two patients with Müllerian anomaly had associated anomalies, including renal agenesis and incorrect urethral path. Furthermore, the upper 2/3 of these 25

patients' vagina was absent and there was only vaginal dimple remaining (with an approximate depth of 1-2 cm). Moreover, the recorded intra-operative complications included one case of rectal tearing which was primarily repaired. There was no case of postoperative complications such as fistula, infection, or hemorrhage. However, there were two cases of re-stenosis after surgery, one of whom underwent re-operation despite her regular use of mold, whose re-operation data were considered in the research, while the other one did not follow her problem. The mean age of the patients included in the case group was 25.35 years at the time of surgery and 31.03 years at follow-up, while that of the control group was 28.77 years.

On the other hand, the average vaginal length in the case group was reported to be 5.60±2.38 cm which was significantly lower than that of the control group (8.47±1.31 cm) (P<0.001). In addition, the average vaginal diameter in the case group was significantly lower than that of the control group (2.94±0.92 vs. 4.12±0.70 cm, respectively; P<0.001). The mean total FSFI scores and also all of the domains were significantly lower in the case group compared with the control group (all P<0.001). However, as shown in **Table.1**, the mean score of desire was similar between the groups (P=0.36).

17 out of 25 patients in the case group used mold. In addition, studies on anatomy and functionality based on using molds demonstrated a significant difference between the two groups, including the patients who had used molds and those who refused to use it, in terms of the average vaginal length (6.88±1.40 vs. 2.87±1.55 cm), vaginal diameter (3.35±0.58 vs. 2.06±0.94 cm), and total FSFI scores (17.21±5.32 vs. 3.45±0.62, respectively; all P<0.001). Therefore, the values related to the group of using mold patients were compared with those of the control group. The results showed that the

control group had a larger vagina and better FSFI score in all domains (P<0.05), except desire (P=0.748), compared to the case group who had used molds (**Table.2**). The mean duration passed from the time of surgery was 48.8 months (minimum of 12 and maximum of 115 months). Furthermore, the patients of the case group were divided into groups with normal (14 patients) and abnormal vaginal anatomy (9 patients), but the mean duration of follow-up was similar in both groups.

Table-1: Comparing mean FSFI scores of the case and control group.

Variables	Case group (n=25)	Control group (n=31)	P- value[*]
Desire	3.72±0.91	3.93±0.83	0.36
Arousal	2.09±1.79	4.03±0.72	<0.001
Lubrication	2.14±1.85	4.49±0.73	<0.001
Orgasm	1.13±1.00	2.81±0.53	<0.001
Satisfaction	1.77±1.63	3.76±0.50	<0.001
Pain	1.93±1.68	5.14±0.60	<0.001
Total FSFI score	12.81±7.87	24.19±2.90	<0.001

[*]The results of independent samples *t* test, considered significant at values <0.05; all values are reported as mean ± standard deviation. FSFI: Female Sexual Function Index.

Table-2: Comparing mean vaginal indices and FSFI scores between the control group and the patients in the case group who used mold.

Variables	Case group (n=25)	Control group (n=31)	P-value[*]
Vaginal length	6.88±1.40	8.47±1.31	<0.001
Vaginal diameter	3.35±0.58	4.12±0.70	<0.001
Desire	3.84±1.01	3.93±0.83	0.748
Arousal	3.08±1.26	4.03±0.72	0.02
Lubrication	3.15±1.33	4.49±0.73	<0.001
Orgasm	1.67±0.75	2.81±0.53	<0.001
Satisfaction	2.61±1.29	3.76±0.50	<0.001
Pain	2.84±1.22	5.14±0.60	<0.001
Total FSFI score	17.21±5.32	24.19±2.90	<0.001

[*]The results of independent samples *t* test, considered significant at values <0.05; all values are reported as mean ± standard deviation. FSFI: Female Sexual Function Index.

4- DISCUSSION

The present study aimed to investigate female vaginal anatomical and sexual function after McIndoe vaginoplasty in patients with Müllerian anomaly or androgen insensitivity syndrome. The results showed that 56% of patients with Müllerian anomaly or androgen insensitivity syndrome had normal vaginal anatomy at the time of follow-up, indicating the success rate of this surgical technique. However, the comparison between the vagina anatomical indices and the sexual function scores with an age-matched control group revealed that the

patients had a significantly smaller vagina and lower FSFI scores. In addition, the results showed that this type of surgery could not provide a normal functional vagina for the patients in a mean follow-up of 48.8 months (the range of 12 to 115 months). To the best of the authors' knowledge, the present study is the first report of the anatomical and functional outcome of McIndoe surgery with amnion graft, compared with a normal control group, since most studies regarded the surgical outcome using before-after assessments and only performed subgroup analyses (10, 14, 18).

In a study conducted by Bastu et al., the follow-up of 23 patients aged 13 to 26 years who underwent modified McIndoe with skin graft indicated a postoperative vaginal length of 4-11 cm (average length of 7.8 cm) after a mean of 60 months (18-118 months) (10). In this regard, the average vaginal length of the case group in our research (6.88 cm) was shorter than that reported by Batsu et al. (10), with the same surgical technique and a different used graftwhich could be due to the different frequency of the patients' mold usage. In fact, 17 out of 25 patients (68%) used mold in this study, while of 23 patients, 19 (83%) used mold in Bastu et al.'s reports (10).

According to the evidences, the routine use of vaginal dilator is considered as an important stage of treatment (19) which is confirmed by the results of the present study, indicating that the patients using mold routinely had a significantly larger vagina and better FSFI scores compared to those who refused to use mold routinely. Therefore, the success rate after surgery may vary based on routine mold use, as well as the difference in the details of the surgical technique. Some studies have also suggested that vaginal dilators can be used as an effective first-line treatment with low complications (12, 19), which is consistent with the results of the present research

regarding the significant effect of mold use. Using different molds (e.g., inflatable soft molds with or without suction, silicon or acrylic-based rigid molds) which after the Abbe-McIndoe procedure was suggested in the present research (20, 21). However, these molds fail to drain uterine secretions for better graft uptake and hence, may have the risk of rectovaginal fistulae, obstructive uropathy in rigid molds, and the risk of graft rejection in soft ones. Therefore, some people have initiated producing other vaginal mold types such as the mold over the syringe barrel which has had favorable results regarding appropriate uterine drainage, satisfactory graft uptake, reduced cavity contracture, and acceptable patient compliance (22).

In this paper, the use of mold resulted in significant improvement of sexual function (higher FSFI scores in total scores and all of the domains), and vaginal anatomical indices. Thus, it is strongly recommended to instruct patients the appropriate use of mold after surgery. In a recent study by Fotopoulou et al., seven patients with congenital vaginal aplasia and a mean age of 20.86 underwent modified McIndoe procedure using human freeze-dried amniotic membranes. The results implied that the mean FSFI score and vaginal length was 30 and 9.3 cm, respectivey, after a 1.5-year follow-up (14).

The applied surgical techniquewas similar to that in the present research, while the number of patients in the aforementioned study was low. Comparing the results of anatomical and functional outcomes between the two studies indicates that the average vaginal length (6.8 cm), and FSFI score (12.81) reported by Fotopoulou et al. (14), is higher than that of the present study. The difference between the FSFI scores of the case group in the present paper and that reported by Fotopoulou et al. (14) may be representative of the fact that the individuals' sexual function

depends on their religious, cultural, and social background (23, 24). In addition, the total FSFI score reported by Fotopoulou et al. (14) is even higher compared to that in the control group of this study. Meanwhile, the mean FSFI score is lower than the cut-off point of sexual dysfunction in the control group of this paper (<28), indicating the presence of sexual dysfunction in the control group. Since there are religious and legal boundariesin Iran regarding women's sexual relationships and the matter of sex is considered as a social taboo, the issue of sexual function in Iran is different from other countries. Therefore, education on sexual relationships is not given at school and the social-sex development fails to occur in most individuals (25, 26).

Subsequently, many individuals with sexual dysfunction remain undiagnosed, as they feel ashamed to refer to a physician for this issue or talk about their sexual problem (27, 28). Therefore, the issue of sexual dysfunction is of great importance in Iran. Furthermore, physicians should investigate their patients' sexual life for appropriate diagnosis and management, especially in patients with neovagina who are at a greater risk of sexual problems due to the complicated course of creating a new vagina for them (29, 30).

According to the findings of the present study, the patients who used mold routinely after surgery had a better anatomical and functional outcome, compared with those who refused to use mold. However, they had a smaller vagina and worse sexual function than the control group, considering the fact that the desire domain of the questionnaire was the same in all groups. Therefore, these results indicate that women with vaginal agenesis have normal sexual desires but impaired sexual functions, including arousal, orgasm, lubrication, satisfaction, and pain, even when using mold routinely after surgery. Which implies the necessity of

paying greater attention to their treatment efficacy to maintain their normal sexual function. Furthermore, these results confirm those of previous studies, indicating sexual disorders in patients with Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome who underwent other types of surgery for creating a neovagina (29, 30) although they were not compared with a control group. The present study indicated the long-term outcome of anatomical vaginal indices in the patients who underwent McIndoe surgery with amnion graft, using an accurate physical examination. A single gynecologist conducted these examinations, assessed the patients' sexual function by a valid questionnaire, and compared them with an age-matched control group.

However, this research had some limitations. Firstly, some parts of the data were collected retrospectively and any bias in the data collection and record at that time could lead to the bias in the results. Secondly, a minimum of the duration passed from surgery was not specified and the wide range of follow-up duration (12 to 115 months) could influence the results of this study. In addition, this study evaluated the surgical outcome of one surgical technique (McIndoe technique with amnion graft) in a sample of Iranian women selected from one city. Therefore, the results may not be generalizable to all the women suffering from this disease or undergoing other types of surgeries for creating a neovagina. Moreover, his small size of the subgroups was another limitation of this research.

5- CONCLUSION

Contrary to the results of previous studies that showed favorable results for surgery with amnion graft, the results of the present study demonstrated that the McIndoe technique failed to create a normal vaginal anatomy or sexual function in all women with MRKH or androgen

insensitivity syndrome who underwent the surgery for creating a neovagina, orthose who used mold routinely. These results were inconsistent with those of the previous studies which indicated that the McIndoe surgery with amnion graft was favourable. This contradiction may be mainly due to the fact that the previous researches failed to compare their results with a control group comprising normal women. In addition, the positive effect of mold use after surgery was the other finding of the present research which is in line with the results of previous papers. Therefore, it is strongly suggested to use mold routinely after surgery. Meanwhile, additional strategies are required for improving the sexual function in such patients. Last of all, comparing the results of different surgical techniques used for such patients may be helpful for providing surgeons a wider perspective for choosing the most appropriate one with the best long-term outcomes on the women's vaginal size and sexual function.

6- CONFLICT OF INTEREST: None.

7- ACKNOWLEDGEMENTS

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