# **ORIGINAL ARTICLE**

# Comparative Study of Creation of Neovagina Using Skin Graft and Interceed in Mayer–Rokitansky–Küster–Hauser Syndrome

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## **A**BSTRACT

**Objective:** This study compared and evaluated the outcomes of using Interceed and skin graft in vaginoplasty for women with Mayer–Rokitansky–Kuster–Hauser (MRKH) syndrome on the basis of vaginal length (neovagina), procedure safety, patient satisfaction (sexual) after marriage, ease of procedure, procedure time, and morbidity.

Materials and Method: Over the course of 18 months, this hospital-based randomized controlled trial was conducted at a tertiary care center. There were 17 women with primary amenorrhea and MRKH syndrome who had undergone vaginoplasty and met the inclusion and exclusion criteria. Nine women received vaginoplasty with Interceed and eight women got vaginoplasty with skin graft, and they were monitored for 6 months postmarriage using a computerized block randomization system. Anatomical and functional outcomes were assessed in these women. The percentage, mean, and standard deviation (SD) were calculated using Epi Info program. For the analysis, the Mann–Whitney and Fischer tests were used.

**Observations:** Women in group A (Interceed) were  $22.322 \pm 1.59$  years old, whereas those in group B (split-thickness skin transplant) were  $23.85 \pm 1.83$  years old.

On day 8, the length of the vagina in women who had vaginoplasty with Interceed (Group A) was 8.8330.4153 cm, which was longer than  $8.413 \pm 0.4190$  cm in women who had split-thickness skin transplant (Group B). The vaginal width was determined to be two-finger breadth in both groups.

The duration of surgery in women undergoing vaginoplasty with Interceed (Group A) was  $32 \pm 4.243$  minutes as compared to split-thickness skin graft (Group B) where it was  $61.38 \pm 8.634$  minutes. This difference is statistically significant.

The functional outcome in relation to sexual satisfaction (lubrication, orgasm, satisfaction, and pain) in women undergoing vaginoplasty with Interceed was 77.8% as compared to 37.5% with Split-thickness skin graft.

**Conclusion:** By using Interceed for vaginoplasty, gynecologist is independent and no separate procedure is required for graft. It is safe, easy, effective, less time-consuming and patient satisfaction with anatomical and functional outcome is good due to squamous epithelization. Hence, is a potential alternative for vaginal agenesis.

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## Introduction

Vaginal agenesis, MRKH syndrome, a congenital absence of the vagina, commonly manifests as primary amenorrhea. The most important goal of treatment is to create a sexually functioning neovagina. Thus, solving problems of sexual life. Vaginoplasty is a type of genitoplasty where a potential space is created in rectovesical space of adequate length, width and is esthetically accepted for penetrative intercourse.

There is currently no consensus on the optimum method for achieving this goal. The American Congress of Obstetricians and Gynecologists advocates non-surgical self-dilatation with progressive perineal dilatation as first-line therapy because it is minimally invasive. <sup>1,2</sup> Surgery to establish a neovagina is advised for the patients who have failed to respond to non-surgical treatment.

The vaginal approach is used in the McIndoe treatment to prepare a neovagina. Autologous skin grafts, typically from the buttocks or thigh,<sup>3</sup> amnion,<sup>4–6</sup> Interceed (Ethicon Inc., Somerville, NJ),<sup>7</sup> peritoneum (Davydoy procedure),<sup>8–11</sup> autologous *in vitro* 

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cultured vaginal tissue, <sup>12</sup> and labial or gracilis flaps <sup>13–16</sup> have all been used for the McIndoe procedure.

Split-thickness skin grafts obtained from the buttocks or thigh area are the most widely used graft material for the McIndoe surgery. 17,18 Scarring and contracture of the graft material, pigmentation and presence of hair in the vaginal graft tissue, and poor physical appearance of the donor site are all risks associated with this operation. Hence, to reduce such complications, the alternative graft materials are needed.

Interceed is an absorbable adhesion barrier manufactured from oxidized, regenerated cellulose which meant to minimize occurrence of postsurgical adhesions. It can prevent all issues such as scarring and contractures.

# **Study Objective**

This study compared and evaluated the anatomical and functional outcomes of using Interceed and skin graft in vaginoplasty for women with MRKH syndrome in terms of vaginal length, procedure safety, patient satisfaction (sexual) after marriage, ease of procedure, procedure time, and morbidity.

## MATERIALS AND METHODS

After receiving ethics committee approval, this hospital-based randomized controlled experiment was conducted over 18 months in a tertiary care hospital.

## Criteria for Inclusion

- Vaginal agenesis caused by the MRKH condition in women willing to undergo neovagina formation surgery (McIndoe's procedure).
- A woman who is about to marry in 4–6 months.

## **Criteria for Exclusion**

- The presence of a medical condition that prevents surgery or jeopardizes the surgical outcome.
- · The previous attempt at neovaginal surgery.

## Sample Size

Due to the low occurrence of MRKH syndrome, a time-limited research with 17 women with MRKH presenting as primary amenorrhea was conducted over an 18-month period.

## **Evaluation**

All the women attending gynecology outpatient department presenting with primary amenorrhea and diagnosed to have MRKH syndrome and about to get married in 4–6 months were enrolled in study.

Women were subjected to detailed history, history of instrumentation, menstrual history, and family history. A careful local examination was performed after a thorough general examination, breast assessment, per abdomen, cardiovascular system, and respiratory system examination, to determine the length of vagina. They were tested by karyotyping, evaluation of hormones and ultrasound examination for the uterus, kidneys followed by computed tomography or magnetic resonance imaging before surgery. Before surgery, the diagnosis of MRKH syndrome-related vaginal agenesis was verified.

## Randomization

Block randomization was used to determine whether Interceed or split-thickness skin grafts should be used for women undergoing vaginoplasty (computerized sheet). A total of 18 women underwent vaginoplasty, with nine undergoing the procedure using Interceed and eight undergoing the procedure with split-thickness skin grafting. The procedure was performed by the same surgeon, who was skilled and experienced.

# Counseling

It is an important component of preoperative preparation. Women were counselled for psychosocial adjustment to anomaly, menstruation, reproduction, cooperation for postoperative dilatation and use of vaginal mould.

Two groups of women were formed.

- Women in group A who had vaginoplasty with Interceed.
- Women in group B who had a vaginoplasty using a splitthickness type of skin graft.

# Steps of Vaginoplasty

Hydrodissection with 100 cc of Adrenaline with Saline, Cruciate Incision on Vaginal Dimple, Creation of Rectovesical Space

After Foley catheter implantation and meticulous evaluation of the perineum and rectum a 2 cm cruciate incision between the rectum and vagina was made with a knife. Using meticulous, slow, and painful blunt dissection and intermittent rectal inspections to pinpoint the site of the rectum and avoiding damage to rectal tissue, a neovaginal region was created without causing harm to the rectum or bladder. Packing and sutures, if necessary, were used to ensure hemostasis.

Preparation of Mould or Form, Soft Mould Insertion with Decompression, Decompression so that Form takes Form of Neovagina, Tight Crossed Strapping to Fasten Mould to Skin Soft mould (a form was made of foam 10 cm length and 4 cm width wound over mallecots catheter covered with condom and tied at base). This was covered with either skin graft or by Interceed. Then it was connected to a suction machine to shrink in size before insertion and was deflated once the form was inserted in the neovagina so that it takes the form of the neovagina, and strapping was done. Extra length of the mallecots catheter was cut.

Mould was kept for 7 days. Catheter was kept for 7 days.

On seventh day under sedation the soft mould was removed and betadine cleaning of neovagina was done. The length of neovagina was assessed by calibrated Ayre's spatula. A plastic mould lubricated with soframycin cream was inserted. Patients were told to use it for 6 months or until they had repeated sexual intercourse for a decreasing number of hours (from 20 hours per day at the start to 6–8 hours per night after 4 months), and the lady and her spouse were asked about their sexual experience.

## Interventions

Creation of potential rectovesical space of adequate length, width and is esthetically accepted for penetrative intercourse and insertion of soft mould covered with either skin graft or Interceed. After 8 days, the soft mould was replaced by plastic mould.



**Table 1:** Distribution of women undergoing vaginoplasty with Interceed and split-thickness skin graft

Group	Ν	Mean	SD
Interceed	9	22.322	1.5928
Skin	8	23.850	1.8385
Total	17	23.041	1.8344

Mann–Whitney U test, p = 0.093

Table 2: Length of vagina (in cm) postoperatively

Group	N	Mean	SD
Interceed	9	8.833	0.4153
Skin	8	8.413	0.4190
Total	17	8.635	0.4582

Mann–Whitney U test, p = 0.074

Table 3: Duration of surgery (in min)

Group	N	Mean	SD
Interceed	9	32.00	4.243
Skin	8	61.38	8.634
Total	17	45.82	16.433

Mann-Whitney U test, p < 0.001

#### **Outcomes**

## **Primary Endpoints**

- To achieve optimal neovagina in terms of esthetics and function (anatomical and functional outcome).
- Sexual intercourse satisfaction (lubrication, orgasm, satisfaction, and pain).

# Secondary Endpoints

- Hospitalization period.
- Operative time, bleeding, and complications.

# Safety and Adverse Effects

#### Adverse Effects

- Stenosis caused by retraction of neovaginal wall, resulting in painful mould introduction.
- Fistulization between vagina, rectum, and urethra. Discharge owing to necrosis caused by vaginal wall compression.

# **Statistical Analysis**

Epi Info (Centers for Disease Control and Prevention in Atlanta, Georgia, USA) software was used to introduce and evaluate all of the data. Because there were fewer cases, the data was presented explicitly including the qualitative and quantitative variables, in the tables, and the data was expressed as percentages, means, standard deviations. The Epi Info Mann–Whitney test, as well as the Fischer test were applied for analysis.

## Observations

The study comprised of 17 women with vaginal agenesis who met the study's inclusion and exclusion criteria, 17 of them were diagnosed with MRKH syndrome and are described in Table 1.

The mean age of the women was  $22.322 \pm 1.59$  years in group A (Interceed) and  $23.85 \pm 1.83$  years in group B (split-thickness skin graft) and the groups were comparable.

**Table 4:** Complications in women undergoing vaginoplasty with Interceed and split-thickness skin graft

Complications	Yes/No	Count/ Percentage	Interceed	Skin	Total
Discharge, painful insertion of mould	n	Count %	7	1	8
		(within group)	77.8	12.5	47.1
	у	Count %	2	7	9
		(within group)	22.2	87.5	52.9
Total		Count %	9	8	17
		(within group)	100.0	100.0	100.0

Fisher exact test, p = 0.012

Table 5: Functional outcome as sexual satisfaction

Functional outcome	Yes/ No	Count/ Percentage	Interceed	Skin	Total
Functional sexual satisfaction (lubrication, orgasm, satisfaction, and pain)	n	Count %	2	5	7
		(within group)	22.2	62.5	41.2
	у	Count %	7	3	9
		(within group)	77.8	37.5	58.8
Total		Count %	9	8	17
		(within group)	100.0	100.0	100.0

Fisher exact test, p = 0.117

Table 2 comprises the length of vagina (in cm) on day 8 in women undergoing vaginoplasty with Interceed and split-thickness skin graft.

As described in Table 2, the length of vagina on day 8 in women undergoing vaginoplasty with Interceed (Group A) was 8.833  $\pm$  0.4153 cm which was longer as compared to 8.413  $\pm$  0.4190 cm with split-thickness skin graft (Group B). In both groups, the vaginal width was found to be two-finger breadth.

Our findings suggest that neovaginal development and epidermization of neovagina without the use of skin grafts can be accomplished with satisfactory anatomic outcomes using McIndoe's approach.

Table 3 comprises the duration of surgery in women undergoing vaginoplasty with Interceed and split-thickness skin graft.

The operative duration in women undergoing vaginoplasty with Interceed (Group A) was 32  $\pm$  4.243 minutes as compared to split-thickness skin graft (Group B) where it was 61.38  $\pm$  8.634 minutes which is shown in Table 3. This difference is statistically significant.

Table 4 comprises the complications in women undergoing vaginoplasty with Interceed and split-thickness skin graft.

Table 4 mentions the complications in terms of discharge and painful insertion of mould. The complications among women in the form of discharge and painful insertion of mould was 22.2% (Group A) in women undergoing vaginoplasty with Interceed compared to 87.5% with split-thickness skin graft (Group B). This was statistically significant. During hydrodissection, one girl had hypotension and ventricular tachycardia and required resuscitation. This was due to

use of adrenaline with saline for hydrodissection. Later, we resorted to use of only saline for hydrodissection.

None of the women undergoing vaginoplasty had fistulae.

Table 5 comprises the functional outcome as sexual satisfaction (lubrication, orgasm, satisfaction, and pain) in women undergoing vaginoplasty with Interceed and Split-thickness skin graft.

Table 5 compares the functional outcomes in both groups. The functional outcome in relation to sexual satisfaction (lubrication, orgasm, satisfaction, and pain) in women undergoing vaginoplasty with Interceed was 77.8% as compared to 37.5% with split-thickness skin graft.

## Discussion

The second most prevalent cause of primary amenorrhea is the MRKH syndrome.

About one in every 4,000–5,000 live female births is affected. The MURCS association, which is anacronym for (MU)llerian, (R)enal, (C)ervicothoracic (S)omite abnormalities and is a developmental condition that mostly affects the urogenital system, is seen in 47% of the patients, the atypical form in 21%, and the most severe form in 32%. <sup>10</sup> Wnt family member 4 (Wnt4) mutation is linked to MRKH syndrome. <sup>19</sup>

Frank's graded hard glass dilators and Ingram's (1981) dilators attached to a bicycle seat mounted on a stool were recommended for non-surgical management. Vaginal dilation can create a negative emotional impact on women; hence, a proper counselling and a psychological consultation may be required prior to achieving maximum efficacy.<sup>20</sup>

The surgical development of a neovagina has been attempted for a long time, with varied degrees of success. In 1559, Columbus was the first to describe the congenital absence of vagina. To maintain vaginal patency, Dupuytren's first described vaginoplasty with tampons. Abbas used split-thickness skin graft to cover the mould.

Abbe–Wharton–McIndoe was the first to create a gap between the rectum and the bladder in 1938. To maintain the space sealed, a balsa mould was utilized, although this resulted in recurrent granulation tissue and scarring. Then, in England, Sir Archibald McIndoe employed a split-thickness skin transplant in conjunction with continuous and sustained postoperative dilation.<sup>21</sup>

Intermittent vaginal dilatations (non-surgical procedures) or vaginoplasty can be used to create a new vagina (surgical method). In some situations of the primary vaginal atresia, the non-surgical technique may be useful. The majority of women, however, will require vaginal reconstruction.

The patient's cooperation is critical in vaginoplasty because maintaining the vaginal space throughout the contraction period of wound healing is critical, and this may be accomplished efficiently with moulds/stents. Congenital vaginal absence MRKH syndrome is one of the most common reasons for vaginal reconstruction.

Thigh flaps, fasciocutaneous flaps, gracilis flaps, labia minora flaps, peritoneum, amnion, the Interceed adhesion barrier, and autologous buccal mucosa are some of the other surgical options. For similar reconstructions, the recombinant basic fibroblast growth factor and artificial dermis have recently been used.

Use of split-thickness graft requires help of a plastic surgeon, it takes longer time, is associated with morbidity. Split-thickness skin grafts resulted in a decreased vaginal length and a substantial amount of blood loss throughout the treatment. However, downsides include a thigh scar that requires dressing, dry dyspareunia, the possibility of hair development in the graft, and

the requirement for a postoperative mould. Interceed was better taken than skin graft. It took less operative time, the morbidity was less and the anatomical and functional outcome was comparable with studies by Jackson and Rosenblatt, where the sample size was four women who underwent vaginoplasty using Interceed. These were followed up for 3–6 months and had no complications with good outcome. <sup>22</sup>

Motoyama et al. studied two cases with favorable clinical outcome, and the stay in hospital was for 2 days only.<sup>23</sup>

A large Indian study by Anagani et al. over 8 years with 52 women with MRKH showed operative time of 35 min, and neovaginal length of average 8.4 cm, which is comparable with our study.<sup>24</sup>

It is not only the length of neovagina that is important but the function also plays a major role in sexual satisfaction and with Interceed the epithelization takes place within 3 months.

## LIMITATIONS

As the incidence of vaginal genesis is low, the sample size is less and the follow-up is for 6 months.

# Conclusion

- By using Interceed for vaginoplasty gynecologist is independent, no separate procedure is required for graft. It is safe, easy, effective, less time consuming and the patient satisfaction with anatomical and functional outcome is good due to squamous epithelization. Hence is a potential alternative for vaginal agenesis.
- The successful outcomes of this procedure majorly depend on thorough knowledge of the surgical anatomy and a meticulous dissection.
- The patient and her parents need to be counseled regarding her modified marital prospects about sexuality, difficult child bearing, social, and financial self-sufficiency.
- However, a proper surgical technique and hemostasis, as well as postoperative assistance, are essential.
- Meticulous patient selection thorough counseling and education, clear recommendations regarding self-replacement, and psychological support is critical to success.

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