

# Evaluation of amnion in creation of neovagina in women with Mayer-Rokitansky-Kuster-Hauser syndrome

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**Objective:** To assess the outcome of amnion vaginoplasty in cases of vaginal agenesis due to Mayer-Rokitansky-Kuster-Hauser (MRKH) syndrome managed at the authors' institution.

**Design:** Retrospective study.

**Setting:** Tertiary care hospital.

**Patient(s):** Fifty women with MRKH who underwent neovaginoplasty.

**Intervention(s):** Modified McIndoe's vaginoplasty was done in all the patients, using human amnion graft.

**Main Outcome Measure(s):** Functional status assessed by Female Sexual Function Index, anatomic status (length and width of neovagina), and epithelialization of vagina.

**Result(s):** Mean ( $\pm$ SD) vaginal length after surgery was  $8.2 \pm 1$  cm. Mean vaginal length at 6-month follow-up in sexually active patients was significantly longer as compared with the patients who were not sexually active after surgery ( $8.4 \pm 1.04$  cm vs.  $6.6 \pm 2.4$  cm). Mean Female Sexual Function Index score was  $30.8 \pm 2.1$ . Vaginal biopsy showed complete epithelialization of vaginal mucosa.

**Conclusion(s):** In a developing nation like India, McIndoe's method with amnion graft seems to be a promising option owing to its low cost, easy availability, and safety, ease of the procedure not requiring any special instrument, physiologic outcome with respect to epithelialization of the vagina without hair growth, and satisfying functional outcome. (Fertil Steril® 2017; ■:■-■. ©2017 by American Society for Reproductive Medicine.)

**Key Words:** Amnion, MRKH, neovagina, vaginal agenesis, vaginoplasty

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**M**ayer-Rokitansky-Kuster-Hauser (MRKH) syndrome is a rare congenital malformation affecting 1 in 4,000–5,000 females (1). It is characterized by congenital absence of müllerian structures (uterus and vagina) with normal female (46XX) karyotype. Ovarian function is normal, resulting in normal secondary sexual characteristics. Various other

anomalies have been found to be associated with MRKH, such as renal anomalies (single, horseshoe, and pelvic kidney) in 40% and skeletal anomalies in 10%–15% of cases (2–4). Girls usually present at approximately 15 to 16 years of age with primary amenorrhea. Some might present after marriage with complaint of dyspareunia. Vaginal agenesis

hampers the sexual activity of women, which has great impact on psychological health. Vaginoplasty improves their sexual function, resulting in increased self-confidence and psychological well-being.

People have used various methods for vaginal agenesis, both nonsurgical like Frank and Ingram and surgical like McIndoe, William, Vecchietti, and Davydov. However, the best method among these is a debatable topic. To cover the neovagina, various materials like amnion, peritoneum, skin, and oxidized regenerated cellulose can be used. A problem with skin graft is the additional scar to patients for graft retrieval. The advantages of amnion are its easy availability and that it has

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no cost, is more physiologic, and does not require additional scar as in case of vaginoplasty with skin graft. This study discusses the outcomes of amnion vaginoplasty in cases of vaginal agenesis due to MRKH managed at our institution.

## MATERIALS AND METHODS

This was a retrospective study conducted at the Department of Obstetrics and Gynaecology, All India Institute of Medical Sciences, New Delhi over a period of 6.5 years from January 2010 to July 2016. Approval from the institute review board was obtained. The study included 50 females with MRKH who underwent neovaginoplasty by modified McIndoe's technique using human amnion graft. Only females who were married or planned for marriage in the near future were chosen for vaginoplasty because of the existing social setup in our country. In case of young females not planned for marriage, the surgery was delayed because of high noncompliance rates for long-term use of the vaginal mold after the procedure. The diagnosis of MRKH was made on the basis of history of amenorrhea, presence of secondary sexual characteristics, and absence of uterus and vagina on examination. Before the procedure all patients underwent ultrasonography of the kidneys and pelvis, X-ray of the lumbosacral spine, and karyotype. After confirmation of the diagnosis, counseling of the patient and her family was done for implications of the condition, management options, and fertility concerns. Informed, written consent was obtained from all patients. The procedure was done under spinal anesthesia in the lithotomy position. After per-urethral catheterization the vaginal dimples were identified and serial dilatation was done with Hegar's dilators (Fig. 1). The median raphe was divided, and the space between bladder and rectum was dissected as high as possible, taking care not to enter the peritoneal cavity. Hemostasis was ensured because the vaginal cavity should be dry to prevent failure of the amnion graft. The vaginal mold was prepared with presterilized foam covered with a condom, over which amnion was wrapped and fixed with 2-0 catgut (Fig. 1). After insertion of the mold, labia minora was approximated at midline, with sutures to secure the mold. Amnion was taken from the placenta after delivery by elective cesarean section in properly screened females with

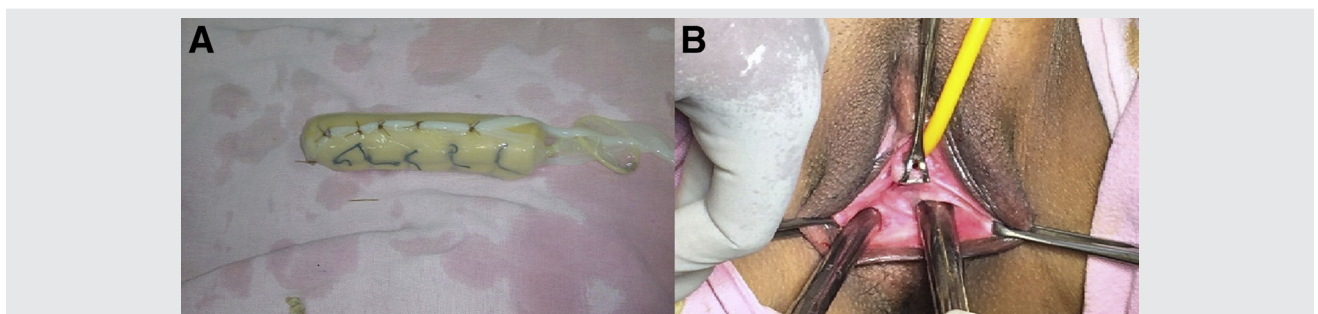
no risk factor for human immunodeficiency virus and hepatitis B. Screening was done for human immunodeficiency virus, hepatitis B surface antigen, and hepatitis C virus. Broad spectrum IV antibiotics were given in the postoperative period. Foley's catheter was kept for 7 days and removed at the time of mold change. The vaginal mold was changed on the seventh postoperative day. A glass mold was used according to the size of the created neovagina. Patients were instructed to use the glass mold throughout the day and night for 1.5 months. Later, if patients had regular sexual intercourse, the vaginal mold was used only at night. The outcome measures were functional status (sexual function), anatomic status (length and width of neovagina), and epithelialization of vagina. Follow-up was done at 1 month, 3 months, and 6 months by gynecologic examination (Fig. 2). Vaginal biopsy was obtained to look for epithelialization in the patients who gave consent for the same. Functional status in sexually active females was assessed by overall sexual satisfaction using the Female Sexual Function Index (FSFI), a 19-item questionnaire (5).

Data analysis was done using SPSS software, version 20.0 (IBM). Descriptive statistics such as mean, SD, and range were calculated for continuous variables. The mean values of vaginal length between the sexually active and inactive groups were compared using Student's independent *t* test. A probability of  $P < .05$  was considered statistically significant.

## RESULTS

A total of 50 patients were included in the study. The mean ( $\pm$ SD) age of these patients was  $22.84 \pm 5.2$  years, ranging from 17 to 37 years. Of the 50 patients 14 (28%) were married and 36 (72%) were unmarried. These unmarried patients were planning for marriage, and surgery was done approximately 3 months before marriage. The main presenting complaint was primary amenorrhea for unmarried patients and primary amenorrhea along with dyspareunia in married females. On examination secondary sexual characteristics were normal in all the patients, and the vagina was either absent in 36 patients (72%) or short and blind, ranging from 1 to 4 cm, in 14 patients (28%). On workup renal abnormality was detected in 6 patients (12%), all of whom had a single kidney. Skeletal

**FIGURE 1**



(A) Vaginal mold covered by condom and wrapped with fresh amnion, ready for insertion into neovagina. (B) Serial dilatation of vaginal dimples.

Vatsa. Amnion vaginoplasty in MRKH patients. *Fertil Steril* 2017.

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