Neovagina creation methods and their potential impact on subsequent uterus transplantation: a review

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Congenital uterovaginal aplasia commonly occurs in Mayer–Rokitansky–Küster–Hauser syndrome. Various methods of neovagina creation exist, including nonsurgical self-dilation, surgical dilation, and surgical procedures involving skin or intestinal transplants. Subsequent uterus transplantation is necessary to enable pregnancy. We review the main characteristics, advantages, and disadvantages of established neovagina creation methods and discuss their suitability regarding subsequent uterus transplantation. Suitability criteria include sufficient vaginal length, absence of previous major intra-abdominal surgery, a natural vaginal axis, and a natural vaginal epithelium. In conclusion, Vecchietti-based laparoscopically assisted neovagina creation provides ideal functional conditions for uterus transplantation. Nonsurgical self-dilation and Wharton–Sheares–George vaginoplasty may also be suitable.

Keywords  
Frank’s vaginal self-dilation, laparoscopic Vecchietti neovagina, MRKH syndrome, neovagina creation, uterus transplantation, vaginoplasty, Wharton–Sheares–George vaginoplasty.

Tweetable abstract  
This review discusses the main advantages and disadvantages of neovagina creation methods with regard to subsequent uterus transplantation.

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Background

Uterus transplantation, a surgical achievement of recent years, is increasingly offering women with Müllerian agenesis, or Mayer–Rokitansky–Küster–Hauser syndrome (MRKHS), the unique chance to experience pregnancy and the delivery of their own genetically related children. MRKHS occurs at an incidence of 1 per 4000–5000 in the female population. The first human living donor uterus transplantation in Germany was performed at Tübingen University Hospital in 2016, in close collaboration with Matts Brännström’s team from the University of Gothenburg, Sweden. Whereas in the past the primary goal in the treatment of patients with MRKHS was to create a functional neovagina with low short- and long-term morbidity, the increasing availability of human uterus transplantation now raises the question as to the suitability of the various methods of neovagina creation with regard to subsequent transplantation, and whether this calls for new requirements regarding the optimal method for creating a neovagina. In our experience, the technique of neovagina creation is crucial to the surgical success of subsequent uterus transplantation. As there are numerous techniques for neovagina creation, which differ significantly with respect to surgical invasiveness, use of auto- or allogenic transplants, and anatomical outcome, this review focuses on the best preconditions for uterus transplant surgery. Determining aspects include having had only a small number of previous surgeries, with few intra-abdominal adhesions, and having a neovagina of high elasticity with a natural anatomical axis. The aim is to create a neovagina of sufficient length (≥8 cm) and width (≥2 cm), lined with natural epithelium, and without the need for lifelong dilation. During uterus transplantation, the recipient’s vaginal vault is dissected free from the rectum and bladder and opened according to the size of the uterine cervix and the vaginal rim of the uterus, which is anastomosed. The first months after surgery appear to be crucial concerning the development of a stenosis of the uterovaginal anastomosis so that a wide and flexible neovagina is essential to the...
success of uterus transplantation surgery. Moreover, a sufficient width of the uterovaginal anastomosis is important for both the cervical biopsies necessary to monitor the immunosuppressive therapy and the subsequent in vitro fertilisation procedures. As MRKHS is associated with a high incidence of concomitant urinary tract malformations, it is critical to avoid surgical trauma of these organs during neovagina creation. Subsequent uterus transplantation necessitates temporary immunosuppression, and therefore the procedure should not involve allografts with a high risk of perioperative infections. Our objective was to analyse the specific advantages and disadvantages of the most widespread methods of neovagina creation to assess their suitability with regard to subsequent uterus transplantation and their potential impact on transplant success. To this end, we retrospectively reviewed the existing literature, focusing on the advantages and disadvantages of established neovaginal reconstruction methods with regard to specific anatomical criteria considered essential to the success of subsequent uterus transplantation.

Methods

We conducted PubMed and Cochrane Library searches for English-language publications from 2001 to 2019, focusing on the short- and long-term outcomes obtained with different methods of neovagina creation. A total of 44 qualitative and quantitative studies, mostly in MRKHS patients, were included in our analysis. Inclusion was based on whether studies reported data on anatomical success in terms of neovaginal length (≥8–9 cm) and width (≥2 cm), a natural anatomical axis, and the formation of a functional vaginal epithelium. Furthermore, a qualitative risk/efficacy profile was established in order to identify techniques offering low invasiveness paired with high success rates and low complication rates during long-term follow-up.

Neovaginal construction methods

The methods of neovagina creation used in the treatment of vaginal aplasia can be divided into two groups: nonsurgical and surgical techniques. Whereas nonsurgical techniques are based on mechanical dilation, surgical methods involve intra-abdominal traction or the use of allogenic or autogenic transplants. To date, no randomised controlled trials have been conducted to evaluate and compare the long-term results of the various neovaginal construction methods with regard to subsequent uterus transplantation. Tables 1–3 summarise the established neovagina creation procedures discussed below, their general advantages and disadvantages and their suitability with regard to subsequent uterus transplantation.

Nonsurgical method: vaginal self-dilation

Nonsurgical progressive vaginal self-dilation (see Table 1), known as Frank’s method, involves the use of vaginal dilators of increasing size that are inserted into the vaginal dimple, with pressure applied over several months, thus gradually increasing the vaginal length. This procedure is reported by patients as being tedious and painful, and hence requires a high level of motivation on the part of the patient.

Reported complications of Frank’s method include secondary vaginal shrinkage or prolapse and accidental urethral dilation. Self-dilation yields a comparatively short vagina with an average length of 6.65 cm. Moreover, progressive self-dilation provides a noninvasive technique without any surgical risks, offers a high success rate of 69–95%, and is cost-effective. With regard to subsequent uterus transplantation, Frank’s method can be considered an option, provided an adequate vaginal length is achieved.

Surgical method using autogenic transplants: McIndoe vaginoplasty

The McIndoe vaginoplasty (see Table 2) involves surgical tunnelling of the vesicorectal space to the pouch of Douglas peritoneum, followed by the insertion of an autogenic split-thickness skin graft on a vaginal dummy, which is removed after a few days. High rates of anatomical and functional success (83–96%) are reported. Nonabdominal access and the relatively simple technique used are the main advantages of this procedure. Disadvantages include the risk of fistulas (2.4%), the growth of hair on the skin transplant, transplant rejection (<1%), secondary stenosis (4.9%), and rare cases of squamous cell carcinoma. Compared with other surgical techniques the McIndoe neovagina shows the highest rate of reoperations and infections (7.3%). Given the risk of transplant rejection and high infection rates, the McIndoe technique cannot be considered a suitable first-line treatment before uterus transplantation, considering the mandatory immunosuppression that uterus transplantation involves.

Surgical method using autogenic transplants: Davydov vaginoplasty

A combination of vesicorectal tunnelling and autogenic tissue transplantation, the Davydov technique (see Table 2) is now performed laparoscopically. After the vesicorectal space is dissected, the pouch of Douglas peritoneum is mobilised and fashioned to form the future neovagina. Functional success rates are reported as 92–93%, with a vaginal length of about 8.5 ± 1.6 cm and low intra- and postoperative risks. After 6 months, vaginoscopy and biopsy results demonstrated the presence of iodine-positive vaginal epithelium, however, there is an increased risk of...
bladder or intestinal injury (3.8%), postoperative infections, and vaginal prolapse. Further potential complications include a high rate of postoperative vaginal vault granulation (8.7%) and the risk of vaginal stenosis (5.1%).

With regard to later uterus transplantation, the suitability of the Davydov method is limited. In the case of postoperative failure, reoperations are difficult and are associated with intra-abdominal adhesions. The feasibility of uterus transplantation may be impaired by the altered pelvic anatomical structures.

Surgical methods using autogenic transplants: skin-flap vaginoplasty techniques
Vaginoplasty techniques using full skin transplants, like gracilis, gluteal, or vulvoperineal flaps (see Table 2), show a low rate of postoperative shrinkage but an increased risk of scarring (5.8%), intravaginal hair growth (5.8%), necrosis, dehiscence, or dyspareunia, as well as the risk of developing squamous cell carcinoma. The Williams vulvovaginoplasty is a procedure in which the extended labia majora are sutured into a perineal pouch, forming a neovagina with a vertical axis that subsequently requires regular dilation or frequent sexual intercourse. The unnatural axis and the aforementioned complications associated with natural skin grafts (Table 2) render these techniques unsuitable for subsequent uterus transplantation, however.

Surgical method using autogenic transplants: intestinal vaginoplasty
Neovagina creation from bowel segments commonly uses the sigmoid colon (see Table 2). After tunnelling the vesicorectal space, the separated sigmoid transplant is inserted and fixed at the introitus. Intraoperative complications include bleeding and injury of the rectum or other bowel parts, with a risk of re-laparotomy (<1%). Extensive discharge (2.9%), neovaginal shrinkage (17%), anastomosis insufficiency, and bowel necrosis (<1%) are reported as postoperative complications. There are also case reports of neovaginal prolapse (3.5%), adenocarcinoma development, and ulcerating colitis (2.3%) after sigmoid neovagina surgery. Despite the high reported success rates of 77–90%, the incidence of complications, particularly the rate of secondary neovaginal stenosis (9.5%) and the high risk of infections from intestinal flora under immunosuppressive therapy, with potential endomyometritis or thrombosis, seem valid reasons to exclude sigmoid vaginoplasty in patients wishing to undergo uterus transplantation at a later stage.

Surgical method without transplants: Wharton–Sheares–George vaginoplasty
The Wharton–Sheares–George vaginoplasty procedure creates a neovagina by surgically dissecting the vesicorectal space without using a transplant (see Table 3). After probing the obliterated Müllerian ducts, a vaginal dummy covered with oestrogen cream is inserted daily by the patient and left in place for 3 months. Long-term follow-up shows physiological epithelialisation of the neovagina (80%), a persisting sufficient vaginal depth (96%), and the absence of contractions (91%) in patients receiving this treatment. The need for lifelong dilation to avoid secondary stenosis and the risk of rectoceles and cystoceles constitute disadvantages of this method. With regard to subsequent uterus transplantation, the Wharton–Sheares–George technique appears suitable, particularly because it creates a natural neovaginal axis and obviates the need for tissue transplantation.

Surgical method without transplants: laparoscopic Vecchietti method
The method developed by Vecchietti (see Table 3) in the 1960s is based on stretching the vaginal dimple intra-
## Table 2. Surgical neovagina creation with autogenic tissue transplants: characteristics relevant to subsequent uterus transplantation

| Technique; total patients reported (References) | Neovaginal length/width | Functional epithelium | Anatomical axis | Advantages | Disadvantages |
|------------------------------------------------|-------------------------|-----------------------|-----------------|------------|--------------|
| McIndoe neovagina; 103<sup>35–37</sup> | Mean length 8–12 cm and width 3–4.5 cm | Unnatural epithelium/ split-thickness graft | Natural | Good vaginal length and width | Invasive method |
| | | | | Nonabdominal access | Anatomical success rate of only 83% |
| | | | | Low rate of contractures | Risk of intraoperative haemorrhage (<1%), rectal perforation (<1%) |
| | | | | 96% successful take of the graft | Postoperative vaginal, urinary tract, and graft infections (7.3%) |
| | | | | | Risk of strictures and contractures (4.9%) |
| | | | | | Risk of postoperative fistulas (2.4%) |
| | | | | | Partial or total graft rejection, vaginal prolapse (<1%) |
| | | | | | Growing hair on skin transplant |
| | Mean vaginal length ≥6.3–13 cm, width 2.8–3.5 cm | Iodine-positive vaginal epithelium after 6 months | No data | No shrinkage risk | Risk of squamous cell carcinoma |
| | | | | | Complete epithelialisation of the vagina (100%) |
| Davydov neovagina; 165<sup>11,12,38–40</sup> | Mean vaginal length 9.2–10.5 cm and width of 4.3–4.5 cm | Squamous cornified epithelium | Unnatural | No major intraoperative risks reported | Invasive method |
| | | | | Low rate of postoperative shrinking | Postoperative scar and stenosis (5.8%) |
| | | | | No scar or granulation tissue (63–92%) | Intravaginal hair growth (5.8%) |
| | | | | | Risk of fistulas (2.3%) |
| Skin-flap vaginoplasty; 47<sup>41–43</sup> | Mean vaginal length ≥7–15 cm, mean width 4 cm | Intestinal mucosa | Natural | Natural lubrication | Invasive method |
| | | | | | Highest vaginal length |
| | | | | | Postoperative shrinking (17%), vaginal stenosis (10.5%) |
| | | | | | Intraoperative rectal, urethral, or bowel injury (<1%) |
| | | | | | Intraoperative haemorrhage (<1%) |
| | | | | | Postoperative stenosis of the introitus (9.5%) |
| | | | | | Vaginal prolapse (3.5%) |
| | | | | | Vaginal discharge (2.9%) |
| | | | | | Risk of infection (2.3%) |
| | | | | | Risk of necrosis, colitis, ileus, fistulae, and abscess (<1%) |
| | | | | | Risk of anastomosis insufficiency |

<sup>a</sup>Requirements/definition of anatomical success: vaginal length of ≥8 cm and width of ≥2 cm, with no contracture or shrinking; functional noncornified squamous epithelium; natural anatomical axis between bladder and rectum.
abdominally after abdominovaginal dissection of the vesico-rectal space. Via a pluggable segmented dummy, which is connected to two threads, pressure is continuously exerted on the vaginal dimple, thus creating a neovagina within a matter of days. In 1992, a Vecchietti-based laparoscopically assisted technique was established at Heidelberg University Hospital in Germany and subsequently optimised at the Department of Obstetrics and Gynaecology at Tübingen University Hospital, Germany (see Figure 1). Major advantages of Vecchietti-based methods include that they create a neovagina with normal anatomy, histomorphology, and functionality. Moreover, they obviate the need for extraneous tissues, such as skin, peritoneum, or intestine, and plastic surgery, which causes visible scars. Most importantly, functional vaginal lengths of 10–12 cm are achieved very quickly within days. Significant advantages over other neovaginal procedures, e.g. the McIndoe technique, include the absence of major scarring from skin grafting. The Vecchietti method offers good functional results because the neovagina soon becomes lined with the typical vaginal epithelium. Moreover, with an anatomical success rate of 97–99%, the neovagina retains an adequate size even in the absence of regular sexual intercourse, and there is no need for long-term dilation. The procedure is fast, effective, and minimally traumatic, with low rates of long-term complications (1–1.8%) even in the presence of urinary tract malformations such as pelvic kidney. Surgical vesicorectal tunnelling is not required and the use of vaginoabdominal blunt perforation of the vaginal dimple is not associated with high complication rates or poor functional outcome. This low-risk procedure creates a vaginal canal in the correct axis that provides an adequate size and secretory capacity for vaginal intercourse without the need for continual postoperative dilation, and therefore requires minimal care to maintain the long-term benefits of the procedure.

### Conclusions and future perspectives

The preoperative selection process including, amongst others, meticulous physical examinations and psychological assessments, imaging, and immunological testing, is of great importance to ensure both donor and recipient safety and the success of uterus transplantation. During uterus transplantation surgery, the vaginal vault is dissected free from the bladder and rectum and, in the case of patients with MRKHS, the uterine rudiment needs to be cleaved to reach the top of the vagina. Sutures for subsequent organ fixation are attached to the round ligaments, the sacrouterine ligaments, and the two lateralised parts of the uterine rudiments in patients with MRKHS. The cranial portion of the recipient’s vaginal vault is opened by

| Technique; total patients reported (References) | Anatomical successa | Advantages | Disadvantages |
|-----------------------------------------------|---------------------|------------|---------------|
| Traction vaginoplasty: Vecchietti; 566,11,20,24,48–50 | Mean vaginal length ≥6–10 cm; width 2.0–2.8 cm Natural noncornified squamous vaginal epithelium Natural | Low intraoperative complications rate (1–1.8%) Anatomical success rate 97–99% Absence of major scarring Fast and effective No long-term dilation needed Leaves pelvic anatomy intact | Invasive method Risk of intraoperative ureter, rectum, or bladder lesions (1–1.8%) |
| Wharton-Sheares –George; 58,16,17,51,52 | Mean vaginal length 7–12 cm and width 1.5–3.8 cm Natural noncornified squamous vaginal epithelium Natural | Anatomical success rate 93% Low complication rate or complications only reported after a previous procedure No contractures (91%) Normal vaginal depth ≥7 cm (96%) | Invasive method Intraoperative haemorrhage (1.9%) Bowel injury (<1%) Risk of intraoperative ureter, rectum, or bladder lesions Risk of secondary stenosis, contractures (8.6%) Risk of cystoceles and rectoceles Long-term dilation needed |

*Requirements/definition of anatomical success: vaginal length of ≥8 cm and width of ≥2 cm, with no contracture or shrinking; functional noncornified squamous epithelium; natural anatomical axis between bladder and rectum.*

Table 3. Surgical neovagina creation without tissue transplants: characteristics relevant to subsequent uterus transplantation

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means of a longitudinal incision of 40 mm and then anas-

tomosed to the donor’s uterus.

In the first clinical uterus transplantation trial, the nine
organ recipients had four different types of vagina: one had a
normal vagina, three had a neovagina created by self-di-
alation (Frank’s method), four had skin-graft neovaginas, and
one had a surgically dilated vagina. Two recipients experi-
enced severe complications that resulted in the surgical
removal of the graft, one for a severe intrauterine abscess
and the other because of uterine vessel thrombosis resulting
in graft necrosis.28,29

A uterus transplantation from a living donor was per-
formed by Fageeh et al. for a woman with a normal vagina
who had lost her uterus in the context of an obstetric
emergency.30 A transplantation from a deceased donor was
conducted in Turkey in 2013 for a patient with MRKHS
who had undergone vaginal construction with a free jej-
unum segment 2 years earlier, but no successful pregnancy
has been reported so far.31

Chmel et al.3 reported seven cases of surgically successful
uterine grafts from four living and three deceased donors.
Of the uterus recipients from living donors, three had
undergone laparoscopic Vecchietti neovagina creation,
whereas one had an anatomically normal vagina. Of the
uterus recipients from deceased donors, one had a laparo-
scopic Vecchietti neovagina, one had been born with a nor-
mal vagina, and one had created a neovagina by self-
dilation. Partial postoperative stenosis of the uterovaginal
anastomosis developed in three recipients: two recipients
from living donors and one recipient from a deceased
donor. One of the two uterus recipients from living donors
had been born with a normal vagina, the other had a Vec-
chietti neovagina. In the case of recipients from deceased
donors, partial thrombosis of the uterovaginal anastomosis
was seen in one patient with a neovagina created by self-di-
alation. The anastomosis constrictions occurred between
the first and second months after transplantation, and the
recipient from a living donor who had been born with a
normal vagina required two transvaginal surgical incisions
that caused bladder injury and the postoperative develop-
ment of a vesicovaginal fistula. A main cause of vaginal
stenosis was seen in the discrepancy between the large uter-
ine cervix and the narrow and tough vaginal vault.3

At our institution, the eligibility criteria for uterus recip-
ients include, amongst others, that candidates must not
previously have undergone major intra-abdominal surgery
or intestinal neovagina creation, and must have normal
ovaries with good ovarian reserve.26 In our observation,
(neo)vaginal anatomy must meet the following require-
ments to ensure successful uterus transplantation: (i) a
minimum length of 8–9 cm; (ii) an adequate width of at
least 2 cm; (iii) a functional vaginal epithelium; and (iv) a
natural anatomical axis. The correct width of the uterovagi-
mal anastomosis is important with regard to post-transplan-
tation cervical biopsies and frozen-embryo transfers.3 Two
successful and one aborted attempt of uterus transplanta-
tions from living donors were performed at Tübingen
University Hospital, Tübingen, Germany, in 2016 and
2017, in close collaboration with the Department of Obstet-
rics and Gynaecology of the University of Gothenburg,
Sweden, with all three recipients being women with uterine
agenesis (MRKHS).2 One recipient had undergone laparo-
sopic Vecchietti-based neovagina creation and one had
performed vaginal self-dilation, both with sufficient vaginal
length and width and a normal vaginal epithelium, provid-
ing optimum conditions for subsequent uterus transplanta-
tion surgery.20 There is as yet no consensus in the medical
literature as to which of the surgical options for the cre-
ation of a neovagina provides the best uterus transplanta-
tion results. Clearly, all described procedures should be
performed by surgeons with extensive experience in vaginal
reconstruction and laparoscopic surgery. To conclude, and
in light of the current literature and our own experience,
the Vecchietti-based laparoscopically assisted method of
neovagina creation provides ideal functional conditions for
later uterus transplantation. Frank’s nonsurgical self-

**Figure 1.** Vecchietti-based laparoscopically assisted neovagina creation
without vesicorectal tunnelling: drawing of the immediate postoperative
situation (as viewed from above). About one segment of the pluggable
vaginal dummy (a) is inserted in the vaginal dimple. The top of the
dummy is attached via retroperitoneal threads (b) to the purpose-
designed traction device (c) on the surface of the abdomen, allowing
the neovagina to be formed by slow, continuous stretching under close
monitoring of the tension. Reproduced with permission.53
dilation method and the Wharton–Sheares–George vaginoplasty appear to provide further suitable options for neovagina creation prior to uterus transplantation.

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SYB reports speaker and consultancy honoraria from Karl Storz SE & Co. KG, Tuttingen, Germany. No interests declared by all other authors. Completed disclosure of interests form available to view online as supporting information.

Contribution to authorship
AK conducted the literature searches, participated in data analysis, and wrote the initial draft. FAT, KR, and DS participated in data analysis and revised the draft manuscript for intellectual content. DW and SYB conceived and participated in the literature searches, participated in data analysis, and wrote the initial draft. FAT, KR, and DS participated in the literature searches, participated in data analysis, and revised the draft manuscript for intellectual content.

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