Modifications and innovations in mc indoe vaginoplasty for better outcomes

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Abstract
Vaginal agenesis is one of the most common female genital disorders. It may be an isolated problem or part of a syndrome. Diagnosed late and having complex psychological issues, the reconstruction to provide a normal functioning vagina is a challenge. Although numerous techniques are described, there appears to be no consensus on which is the ideal one. Nor is there one opinion on when the reconstruction should be taken up. The McIndoe technique 22,26,27, has been used over the ages with success. Many modifications 43,45 have been described. The present paper describes some modifications with which better results can be achieved consistently with this technique.

Keywords: Vagina and neovagina, Vaginoplasty, Agenesis, Syndrome, MRKH, McIndoe, condom, Foam, Amniotic membrane, Paraffin gauze, Negative pressure.

Introduction
Vaginal agenesis is one of the most psychologically traumatic congenital anomalies of the female reproductive tract. As a newborn or child cannot understand it, the mental trauma is borne by the parents. The incidence is estimated at 1 in 4,000-5,000 live female births. Vaginal agenesis occurs either as an isolated developmental defect or within a complex of more extensive anomalies, most commonly associated with Mayer-Rokitansky-Küster-Hauser syndrome (Mullerian agenesis) 20,24,38,. MRKH is described as congenital vaginal agenesis in an individual with normal female genotype, phenotype and normal endocrine status. Type I MRKH syndrome 50,53 is characterized by an isolated absence of the proximal two-thirds of the vagina, whereas Type II is marked by other malformations- vertebral, cardiac, urologic and ontological anomalies: Renal (34%) and the skeletal (12%). The ovarian function in these patients is usually normal.

Apart from patients of vaginal agenesis, patients with complete or partial androgen insensitivity, transsexuals and patients with acquired defects following trauma, resection of pelvic tumour or radiotherapy may present for treatment. Gender reassignment has come up as a modern fad. Apart from the physical issue, it is a major psychological problem.

Patients with vaginal agenesis are often diagnosed late if antenatal scans don’t pick it (Transvaginal scans are not done routinely in pregnancy). The pediatricians or Obstetricians miss it at Childbirth, then they usually present with primary amenorrhea, failure of consummation of marriage or with infertility. Left untreated, vaginal agenesis can result in devastating repercussions on fertility, sexual function and psychology. Inadequate correction can result in a major liability.

Creating a functional neo vagina is a challenge, the aim being to provide a vagina of an appropriate length, adequate caliber and with aesthetic acceptance10. There are several non surgical and surgical techniques described in literature 1,2,7,11,12,13. The very fact that there are so many described techniques attests to the fact that no single technique is the perfect answer to this complex problem.

The timing of surgery depends on the patient's anatomic configuration and on the presence or absence of functional endometrial tissue. Opinion varies as to when this correction should be taken up.

Aims and Objectives
The author has undertaken different vaginal reconstructive procedures for over 29 years. The present series is the use of McIndoe technique, with
some modifications 28,29,35. The aim of this article is to present these adaptations and modifications to the McIndoe Vaginoplasty 41,43,45 to simplify the procedure so that we can achieve consistently acceptable results.

The important steps include
1. Creating an adequate space for the neo vagina.
2. Decreasing the possibility of injury to the bladder and rectum.
3. Achieving haemostasis to ensure proper resurfacing.
4. Use of amnion to avoid donor site morbidity 54.
5. Using a suitable and easily available mould post operatively and ensuring the stability of graft when the mould is changed for dressing.
6. Providing sensation at the proximal part of the neo vagina.

Materials and Methods
This study has been undertaken in 11 cases of vaginal reconstructions from 2005 to 2012 with an average follow up of 5-8 years. All the cases selected were of primary agenesis where no procedure had been tried earlier. None of these patients had functioning endometrial tissue or a normal uterus.

All patients underwent routine investigations including USG (KUB) to rule out major renal anomalies. The surgical team consisted of a plastic surgeon and a gynecologist. Before starting the surgery for stage I, Inj. Amoxycilav 1.2 was administered as a prophylactic antibiotic on the night before and one hour before surgery. Local Hygiene and cleaning the perianal area with betascrub for 3 days prior to surgery was undertaken with liquid diet for the same duration with standard PEGLAC solution from 4 pm to 10 pm a day before stage I surgery.

The surgery was done in two stages.
Stage I: Creating a space for the neo vagina.
Stage II: Insertion of mould with amniotic membrane graft.

For stage I all the patients were operated under spinal anaesthesia in the lithotomy position with urethral catheterization. An X-shaped incision is given in the perineum at the dimple or existing depression. The lateral part of the X flaps were dissected so that they could be advanced into the neo vagina. Then a vesico-rectal space was created by blunt dissection between the urethra, bladder and the rectum reaching up to the pouch of Douglas. The assistant kept her middle finger in the rectum guiding the dissection. The cavity was packed with roll gauze which was removed after 10 mins to ensure haemostasis. The cavity was packed post operatively with betadine lotion soaked roll gauze and patient was transferred to post op. Stage II was taken up on the next day. A mould was created using a condom stuffed with betadine lotion soaked roll gauze (Fig.1). The amniotic membrane was harvested from a sero negative donor undergoing C-section. It is cleaned and banked in normal saline. It was stitched over the condom-mould covered with paraffin gauze.

The patient was placed in lithotomy again under sedation. The pack is removed providing a dry space for the graft which ensures a good uptake. The condom mould with the graft is inserted. The edges of the amniotic membrane graft 3,9,15,40,54 are stitched to the X flap tips which drew the flaps in when dressing pressure was applied. A dressing pad was placed over it and the labia are loosely stitched together using silk sutures to retain it in place. A T-bandage was applied. In three cases we used a 40 density foam splint rolled on itself and in one a splint cut out from a foam block covered with a condom.

The patient was advised to keep her thighs in adduction. The Foley catheter was maintained for 1 week. All patients urinated smoothly and no fistulae were found. In one case where there was a doubt of bladder injury, catheterization was maintained for 14 days. All the patients were placed on a liquid diet on the second day after stage II and a normal diet after a week. Antibiotic was given for a week post operatively.

The mould was removed on the fourth day with thighs in abduction and by cutting the labial stitches, softly pulling out the roll gauze followed by the condom and paraffin gauze. In cases where foam splint was used, it was deflated with negative pressure to help in change/removal. The newly created vagina was irrigated with diluted (1%) povidone-iodine solution and normal saline. A new condom wrapped with paraffin gauze was placed and stuffed with roll gauze soaked in betadine lotion. After 4-5 days it was removed and the neo vagina irrigated in the same
manner. A prosthetic mould was placed in the neo vagina covered with a condom and the patient educated in its removal and reinsertion. A mould made from a candle or dental compound was given to the patient to use.

The patients were allowed to engage in sexual intercourse after 3 months (if they were married or had a companion) after joint consulting of both the partners. The mould use was incrementally decreased over the next 2-3 months until the patient kept the mould in the new vaginal cavity for only a short time each day. Six months after the surgery, if the patient engaged in regular sexual intercourse, the frequency of the mould use was left to the patient.

![Fig 1:](image1.png) Condom stuffed with roll gauze soaked in betadine lotion to use as a prosthesis.

![Fig 2:](image2.png) Condom covering foam piece with negative pressure apparatus.

**Table 1:** Characteristics of patients who underwent modified McIndoe vaginoplasty

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age at surgery in years</th>
<th>Other abnormalities</th>
<th>Operating time stage I</th>
<th>Operating time stage 2</th>
<th>Hospitalisation in days</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>18</td>
<td>Nil</td>
<td>22 min</td>
<td>10 min</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>17</td>
<td>Nil</td>
<td>30 min</td>
<td>08 min</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>21</td>
<td>Nil</td>
<td>20 min</td>
<td>11 min</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>23</td>
<td>Nil</td>
<td>25 min</td>
<td>10 min</td>
<td>10 days</td>
<td>Bleeding</td>
</tr>
<tr>
<td>5</td>
<td>17</td>
<td>Nil</td>
<td>22 min</td>
<td>10 min</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>18</td>
<td>Nil</td>
<td>25 min</td>
<td>12 min</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>17</td>
<td>Nil</td>
<td>28 min</td>
<td>08 min</td>
<td>14 days</td>
<td>Suspected bladder injury</td>
</tr>
<tr>
<td>8</td>
<td>15</td>
<td>Nil</td>
<td>22 min</td>
<td>09 min</td>
<td>7 days</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>19</td>
<td>Nil</td>
<td>20 min</td>
<td>08 min</td>
<td>7 days</td>
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<tr>
<td>10</td>
<td>19</td>
<td>Nil</td>
<td>22 min</td>
<td>10 min</td>
<td>7 days</td>
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</tr>
<tr>
<td>11</td>
<td>16</td>
<td>Nil</td>
<td>18 min</td>
<td>08 min</td>
<td>7 days</td>
<td></td>
</tr>
</tbody>
</table>
Discussion

The confirmation of the diagnosis is inevitably a psychological shock for the patient and her family. The absence of a vagina has a profound impact on the young woman’s sense of femininity. Aesthetically and functionally inadequate correction can result in major psychological problems in adolescent age and even result in marital disputes. Counselling the parents and making them a part of the treatment team helps in promoting long term satisfaction. The treating surgeon must keep in mind to be practical and not give too many assurances to the patient and family.

Vaginoplasty is considered as the major therapeutic strategy for these patients. The main reason for the creation of a neo vagina in is to make sexual intercourse possible for these patients. Ideally, the creation of a neo vagina should be simple, safe, and most importantly, should allow for satisfactory sexual intercourse. In some cases with a normal uterus it might even be possible to have a child.

The McIndoe technique was first described in 1938 by Bainster and McIndoe. Despite the existence of several alternative methods, there is still no consensus regarding the best option for surgical correction. As with the majority of surgical procedures, the first operation is likely to be the most successful.17 In a fresh case it is relatively easy to create a proper space and maintain it post operatively with a cooperative patient.

Decreasing the possibility of injury to the bladder by use of catheter and to the rectum by the assistant placing a finger in the rectum is very practical. There has been the use of rectal tube for this purpose but a finger is live and responsive and can actually guide the dissection.

Staging of the procedure produces a satisfactory haemostasis which is essential for membrane uptake. We have found this extremely useful even in cases where we used STSG. We have never used cultured epidermal cells at our centre.

Using a suitable and easily available mould gives satisfactory pressure and avoids the traction on the membrane during dressing change. The betadine lotion soaked roll gauze mould gives the advantage of removal of the roll gauze and then the condom and paraffin gauze at the first dressing causing no traction on the
amnion. In four cases we used a condom filled with foam and collapsed it with negative pressure (Fig 2). After insertion the negative pressure was released so that the foam swelled up to provide pressure in the neo vagina (Fig 3). The removal was done with again applying negative pressure to collapse the mould. The use of a condom mould post operatively and using a condom to cover the stents during follow up provide a cheap and readily available method of ensuring hygiene and prevent infection. The results with use of condom packed with betadine gauze and foam were comparable.

The insertion of the dissected flaps prevents stenosis and provides sensation at the proximal part of the neo vagina 17,25,33. We have been using STSG 5,19 as well as buccal mucosa prior to this series but prefer amnion as there is no donor site morbidity. The donor scars in asian skin are likely to undergo hypertrophy. In cases where we did use STSG 44 earlier, the graft was taken from the posterior surface of the thigh so that the patients could not easily see the donor site.

We have no experience with the use of tissue-engineered biological mesh. Adjuvant therapy such as post operative vaginal dilation treatment and psychological support can influence outcome and satisfaction of the patient.

The ideal time for intervention is after adolescence, when the woman has reached physical and psychological maturity. In the past, vaginal reconstruction procedures using pudendal and gracilis flaps 36,37,42 were performed on infants and pre pubertal girls in our centre. The concept was that a child with a normal uterus could be spared the trauma of discovering her deformity on attaining puberty. But surgical revisions were almost always needed in adolescence thus defeating the purpose of this early intervention. Deferring the treatment allows the woman herself to be involved in the decision making but also increases compliance with adjuvant dilation therapy.

Immediate complications generally are haemorrhage and haematoma formation. These were avoided by the two stage technique. The packing provides a natural method of producing haemostasis without any cautery. Pain and scarring and hypertrophy at the donor site seen if STSG44 is used was avoided by uses of amnion. Careful dissection prevents bladder or rectal injury. The use of the assistants finger in the rectum is live and responsive in the dissection.

The malodorous mucoid discharge seen with the sigmoid or intestinal reconstruction is not seen with this technique. Complications like prolonged non-infective discharge, recto vaginal fistula, vesico vaginal fistula, failure of membrane uptake were not seen in this study. No serious complication occurred during the peri or post operative period. Many cases with STSG have had incidence of Squamours cell carcinoma 4,23,46 which have not been seen with amniotic membrane.

We have not undertaken any studies to evaluate the functional sexual outcomes after the creation of a neo vagina by this or other surgical techniques. We plan to start assessing the sexual functional results using a FSFI (female sexual function index) standardized questionnaire.

There are limitations in our study. First is the relatively small sample size and the other is the absence of a control group. However, all the included cases are consecutively and contemporarily collected. Second no study was done about the flora of the neo vaginal microecology after vaginoplasty. Thirdly no histo pathological samples were taken from the neo vagina for analysis.

### Table 2: Advantages and disadvantages of this technique.

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
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<tbody>
<tr>
<td>Does not require abdominal surgical entry</td>
<td>Vaginal dryness</td>
</tr>
<tr>
<td>Use of amnion prevents donor site morbidity</td>
<td>Post operative dilation or sexual intercourse is required</td>
</tr>
<tr>
<td>No risk of hypertrophic scarring</td>
<td>Potential risk of disease transmission</td>
</tr>
<tr>
<td>No change in vaginal flora</td>
<td>Stricture formation</td>
</tr>
<tr>
<td>Quicker and complete procedure than dilatation</td>
<td>Use of STSG can produce hair in the neo vagina</td>
</tr>
<tr>
<td>There is less emotional stress</td>
<td>There is a reported risk of squamous cell carcinoma</td>
</tr>
</tbody>
</table>
Results
A successful surgical intervention is creating a new vagina with adequate length that is functional and sensitive, but not limited only to the length and dimensions. Therefore, successful metaplasia in the membrane also plays an important role in the sensitivity and elasticity of the newly created vagina. The final results were excellent in all the cases with complete graft take, satisfactory dimensions of the neovagina and no stenosis or fistulas. One patient however had minimal bleeding during mould insertion after 2 weeks which subsided with the conservative management. All the patients came for regular follow-up except one. All patients who underwent this surgery were compliant with postoperative vaginal mould use.

The psychological outcome was also very encouraging. Consuling was also provided to the husbands/partners of these patients. For the unmarried patients, the mothers were consulted. Most of the patients who came for follow-up after the marriage reported satisfactory sexual relationships and were satisfied with the vaginal depth.

Conclusion
Vaginal agenesis is complex situation and making a surgical decision making is a highly testing matter. As surgical skills and technologies become more advanced, surgeons are extending them to neo vaginal construction. Laparoscopic techniques do have a small role in treating women who have failed vaginal dilation or attempted surgery. Newer techniques using autologous vaginal tissue may in the future increase the armamentarium available to clinicians dealing with these rare conditions. These women should be only managed in specialist centres by a multidisciplinary team with psychological support. Specialist units should be able to offer all treatment options and also have a duty to provide long-term outcome data.

To optimize sexual comfort, the clinical management of women with vaginal agenesis must be multidisciplinary and individually tailored. Our findings suggest that the modified McIndoe technique is a simple, effective procedure for the treatment of vaginal agenesis, but proper mould usage after surgery remains the cornerstone of the treatment. Further research is needed to prospectively evaluate the clinical success of different surgical techniques.

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Conflict of Interest
None.

References


