REVIEW ARTICLE

Use of Oxidized Regenerated Cellulose in Vaginoplasty Surgeries: Review of Safety, Vaginal Epithelization, and Sexual Satisfaction

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Abstract

Introduction: Vaginal agenesis is an uncommon condition. This may occur as an isolated developmental anomaly or may be associated with other anomalies. Vaginal agenesis can impose immense psychological stress on a woman. The aim of vaginoplasty is to create a neovagina that has a satisfactory appearance, function, and feeling. A perineal approach with various surgical modifications is the most commonly performed technique. However, the material of graft varied from bowel transplants, thigh or subcutaneous abdominal flaps, split-thickness skin grafts, amnion, and oxidized regenerated cellulose etc. among various studies.

Review: The electronic databases (PubMed, Google Scholar) were searched using a combination of the following search terms "Vaginoplasty", "Neovagina", and "oxidized regenerated cellulose". The thirteen full-text case reports/series on epithelization of a neovagina using oxidized regenerated cellulose in vaginoplasty surgeries were reviewed.

Discussion: The use of oxidized regenerated cellulose during vaginoplasty as a graft substitute can provide good surgical results such as epithelization of a neovagina, vaginal length achieved, and satisfactory sexual intercourse after surgery, without increasing the risk of operative complications and late post-operative complications.

Conclusion: Vaginal reconstructive surgery using oxidized regenerated cellulose for epithelization is a simple, safe, and effective technique with promising results in terms of epithelization, achieving adequate vaginal length, and satisfactory sexual intercourse.

Keywords: Neovagina, Oxidized regenerated cellulose, Vaginoplasty.

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Introduction

Oxidized regenerated cellulose (ORC) is an absorbable plant-based product. It forms a matrix for platelet aggregation by melting into the tissue, and it also has antimicrobial properties against a wide range of microorganisms.[1] Oxidized regenerated cellulose (commercial names: Surgicel®, Surgicel Nu-Knit®, Surgicel Fibrillar®, Interceed®, and Gelitacel®) has been used as a topical hemostatic agent in various surgeries like intrathoracic surgeries[2] and pelvic surgeries[3] to prevent adhesions, in wound dressings[4] as well as used as filling biomaterial in breast-conserving surgery.[5] Oxidized regenerated cellulose was the first tested synthetic mechanical adhesion barrier agent to cover traumatized peritoneum in the pelvis. This was approved by the US Food and Drug Administration in 1989 for use during abdominal and pelvic surgery. Cotton fabric is interwoven with pure cellulose and later oxidized for manufacturing ORC. It is bioabsorbable and can be used as a mesh or swab. When used as a support matrix, it helps in clot formation as well as lowers the local pH.[6] This property of lowering the pH explains the antimicrobial properties of ORC. This review is focused on the use of ORC in vaginoplasty surgeries and common indications are vaginal agenesis [Mayer–Rokitansky–Küster–Hauser syndrome (MRKH), androgen insensitivity syndrome (AIS), and cervicovaginal agenesis (CVA)] and vaginal atresia as a consequence of trauma, surgery, chemical treatment, or radiation. The principal aim of vaginoplasty surgeries is to create a potential space between the rectum and the urinary bladder. Various surgical techniques using different approach such as laparoscopic, laparotomic, perineal, or combined procedures have been described. A perineal approach using the Abbe Wharton McIndoe technique is the most commonly performed vaginoplasty surgery with various modifications. However, the material of graft varied from bowel transplants, thigh, or subcutaneous abdominal flaps, split-thickness skin grafts, etc., among various studies.[7] Amnion grafts became popular in 1984 as there was no need for laparotomy or graft harvesting surgery.[8] The first use of ORC in 1994 during vaginoplasty was incidental as the amnion prepared for the surgery got contaminated accidentally and surgeons used the ORC absorbable adhesion barrier to cover the inflatable stent that was placed within the neovagina.[9] Since then, there are various studies on the use of ORC during vaginoplasty/

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Table 1: Baseline characteristics of patients in the included studies

S. No.	*Study*	*Number of participants*	*Age in years*	*Cause of vaginal agenesis*	*Associated developmental anomalies*
1.	Jackson et al.[9]	4 (2+2*)	18–34	MRKH	Not mentioned
2.	Motoyama et al.[17]	10	14–25	MRKH (8) CVA (2)	Left renal agenesis with ectopic right horse shoe shape kidney (1)
3.	Sharma et al.[12]	10	17–22	MRKH	Unilateral renal agenesis (1) Scoliosis (1) Spina bifida with absent 12th rib (1)
4.	Deka et al.[18]	1	16	MRKH	Leiomyoma
5.	Frigerio et al.[15]	1	15	Cervical fibrous cord with vaginal agenesis	None
6.	Dadhwal et al.[14]	10	17–25	MRKH	Spina bifida (2) Associated renal anomaly (2)
7.	Dorneles et al.[13]	11	18–26	MRKH (8) CVA (3)	Unilateral kidney (2) Solitary pelvic kidney (1) Multiple skeletal malformation (1)
8.	Kajikawa et al.[19]	8	18–27	MRKH	Absent right kidney (2)
9.	Crema et al.[16]	10	12–26	Vaginal agenesis (7) Vaginal atresia with functional uterus (3)	Unilateral renal agenesis (2) Hypospadias (1)
10.	Kalpdev et al.[20]	6	23–26	MRKH	Not mentioned
11.	Anagani et al.[21]	52	18–34	MRKH (48) AIS (4) (Gonadectomized)	Not mentioned
12.	Acièn et al.[10]	7	17.9–24.1	MRKH (6) Morris syndrome (1) (Gonadectomized)	Cat eye syndrome (1) Renal hypoplasia (1) Scoliosis (2)
13.	Leite et al.[21]	1	17	MRKH	None

The symbol "*" denotes patients who had history of vaginal surgery in the past

cervicovaginoplasty surgeries. The review aims to make a consensus about the use of ORC during vaginoplasty as a graft and its efficacy in the epithelization process and surgery outcomes.

Methods

The Electronic database (PubMed, Google Scholar, Scopus, and Embase) were searched in January 2022 using the following terms "vaginoplasty," "neovagina," and "oxidized regenerated cellulose" to identify the relevant studies. Full-text studies available in the English language were included in this review. Studies where full text was not available or available in language other than English were excluded. Thirteen studies during 1994–2021 on epithelization of a neovagina using ORC in vaginoplasty surgeries were included after applying the inclusion and exclusion criteria mentioned above and reviewed.

Results

The baseline characteristics of the patients are summarized in Table 1. The most common indication for vaginoplasty was MRKH followed by CVA and AIS, etc., in all the included articles. The most common associated anomaly was unilateral renal agenesis and spina bifida.[9–21] Chromosomal abnormality was detected in only one patient among all patients of all studies.[10] The patient's karyotype revealed 47 XX + mar [18], partial trisomy 22q11.2 in mosaic. The age of the patients varied from 14 to 34 years in all the included articles. The type of mold, type of ORC used as a graft, and various outcomes related to surgery are summarized in Table 2.[9–21] Vaginoplasty was performed by a perineal approach using the varied surgical technique. A variety of molds were used such as foam molds, silicone molds, disposable syringes, mold made up of sterile gloves, inflatable stents, etc. The bladder catheter was kept *in situ* till mold removal/replacement for a variable period of time.

All the patients received antibiotics in the postoperative period. After 2–10 days of surgery, the labial sutures were cut, vaginal mold was taken out, and neovagina was inspected and irrigated with normal saline. After that, the same/similar/different mold was inserted depending upon the study and subsequently, the patients were taught how to insert the mold and were encouraged to keep the mold inside the neovagina except during urination/defecation. However, in one study mold was not reinserted after the first mold removal on postoperative day 7. Rather, the patients were advised to do vaginal dilatation themselves using plastic dilators twice daily for 8 weeks and then once daily for 10 months.[11] The final vaginal length achieved in most studies was 7–12 cm except for 1 patient, where the length of neovagina was <4 cm.[12]

Complications

Vaginoplasty surgeries involve dissection in fibroareolar tissue between the urinary bladder anteriorly and the rectum posteriorly. Injury to such vital structures has to be avoided during the dissection.

Table 2: Type of mold, type of ORC used as graft, and various outcomes related to surgery

				Complications						*Sexual satisfaction*		*Epithelization*			
S. No.	*Study*	*Type of mold*	*Type of ORC used*	*Intraoperative*	*Early postoperative*	*Late postoperative*	*Achieved Vaginal length*	*Follow-up duration (months)*	*Mold removal/ replacement*	*Satisfactory*	*Unsatisfactory/ Dyspareunia*	*Clinical examination*	*Schiller's test*	*Biopsy*	*Completed by*
1.	Jackson et al.[9]	Heyer-Schulte inflatable stent	Interceed	No	UTI: 1	No	6–12	4–18 months	After 4–6 days Replaced by similar mold covered with estrogen cream Again, changed after 4–5 days At 6 months replaced by solid acrylic mold	3 out of 4	1 out of 4	Monthly for 6 months	*	*	6 months
2.	Motoyama et al.[17]	Synthetic resin covered by antibiotics and steroid cream	Interceed	No	–	–	8–10	6 months	After 2 days Replaced by similar mold	All who were sexually active		–	1 month	Taken twice at 1 month and 2 months	4 months
3.	Sharma et al.[12]	Foam mold covered with condom	Surgicel	No	UTI: 2	–	<4–10	12 months	After 7 days Replaced by glass mold	8 out of 10	1 out of 10 1: lost to follow-up	Done	*	Done but result not mentioned	Not mentioned
4.	Deka et al.[18]	Foam mold	Surgicel	No	–	–	–	4 months	After 5 days	–	–	–	–	–	–
5.	Frigerio et al.[15]	Material of mold not mentioned	Interceed	–	–	No	7	Approximately 3 years	After 5 days Replaced by similar mold	Only 1 patient (Case report) Had satisfactory intercourse after surgery		After 15 days	*	*	6 months
6.	Dadhwal et al.[14]	Foam mold covered with condom	Surgicel	No	–	Partial vaginal stenosis: 1	7–10	6 months	After 8–10 days Replaced by glass mold	No comment	1: due to extensive granulation tissue	-	*	At 2 and 6 months	5 months
7.	Dorneles et al.[13]	Silicon mold	Oxidized cellulose	No	Died due to sudden cardiac arrest: 1	Vaginal stenosis-2 (CVA)	7–12	6–24 months	After 3 days	All who were sexually active (7 out of 10+1) FSFI score was used (Mean 32.5 + – 1.1)		-	*	4 times Intraoperative 1 month With 5 months After >6 months (compared with control 8 group)	6 months

8.	Kajikawa et al.[19]	Not mentioned	ORC	No	No	No	8–18	3–16 months	4–7 days	No comment	No comment	–	–	Three times from 2 to 16 Months	6–16 months
9.	Crema et al.[16]	Silimed (inflatable and malleable mold with drainage system)	Interceed	1: Hysterectomy in patient with vaginal atresia with functional uterus	–	–	10	>9 months	On postoperative day 7	No comment	No comment	–	*	Four times at 1, 2, 3, and 9 months	9 months
10.	Kalpdev et al.[20]	20 cc disposable syringe	Interceed	–	No	No	7–9	12 months	After 7 days Replaced by freshly made mold without Interceed	All who were sexually active		–	7 days, 2–3 months	1 month	3 months
11.	Anagani et al.[11]	Glove with nonadherent petroleum gauze filled inside and covered with condom	Interceed	No	No	No	8.1–8.6 (6 weeks)	5 years	On postoperative day 7 Advised to vaginal dilatation using plastic dilators twice daily for 8 weeks then once daily for 10 months	All who were sexually active (11 out of 52)		Done	1 month 3–4 months 6 months	6 months	6 months
12.	Acièn et al.[10]	Paciena	Interceed	–	Pelvic hematoma: 1 Moderate blood loss: 1 Postoperative discomfort: 1 Postoperative denial: 1 Vaginal infection (Pseudomonas): 2	–	8–10	–	After 12 days By similar mold of smaller caliber	All who were sexually active (2 out of 6) FSFI score was used 1-refused to participate in follow-up			1 month 3–4 months 6 months	6 months Biopsy was done only in 2 patients	1 year
13.	Leite et al.[21]	Silicon	Interceed	–	–	–	8–9	4 years	After 5 days Then used only at night	Not initiated sexual intercourse		Done	*	*	1 year

"–" denotes these reports are not mentioned. "*" denotes not done findings. UTI, urinary tract infection

Vaginoplasty surgeries have associated risks of the urinary bladder, urethral, and rectal injuries. However, no such major intraoperative complications were reported in any of these case reports/series. Though few patients developed urinary tract infections (UTIs) in the immediate postoperative period (one patient in Jackson et al.'s study and two patients in Sharma et al.'s study).[9,12] Only one article reported mortality in their series, where the patient expired after 8 days of surgical procedure due to pulmonary embolism.[13] Acién et al. reported complications like pelvic hematoma and a moderate degree of blood loss during surgery, postoperative discomfort, vaginal infections, and postoperative denial in their case series.[10] Three patients among all the included patients in this review had late postoperative complications in form of vaginal stenosis. Two of them had undergone cervicovaginoplasty and one had vaginoplasty.[13,14]

Epithelization

The status of epithelization has been monitored by various means like clinical observation, Schiller's test, and histopathological confirmation. The clinical examination only was used in studies by Jackson et al. and Frigerio et al.[9,15] The epithelization was found to be completed in a 6-month duration. The duration was found to be prolonged in cases having granulation tissue. In one of the cases, good epithelization was observed as early as the 15th postoperative day.[15]

The histopathological examination has also been used in conjunction with Schiller's test to confirm epithelization at various time points (biopsy 1–4 times between duration 1 and 9 months). Crema et al. found granulation tissue, isolated or grouped cells of epithelial type at the one-month postoperative stage.[16] At 2 months after the surgery, the presence of granulated tissue was noted along with epithelioid cells. They were seen to form layers and islands. By the third month, layers of well-defined stratified epithelial tissue on the free surface along with granulation tissue could be identified. The surgeons found the epithelization to be completed by the median of 6 months (range 3–9 months).

The amount of collagen content as estimated by Dornelas et al. by image processing tools on Picrosirius stain biopsy sections was found comparable to that of a normal vagina.[13] In the presence of surgical site infection, epithelization was delayed but was found to be completed by 6 months by Acién et al.[10]

Sexual Satisfaction after Surgery

The patients were followed up for a variable time after surgery ranging from 4 months to 5 years. After completion of epithelization, patients with a sexual partner were encouraged for vaginal sexual intercourse whereas the patients with no sexual partner were instructed to use the mold daily for a variable period. Two studies used Female Sexual Function Index (FSFI) to categorize sexual satisfaction after surgery.[10,13] They stated that all the women were satisfied with the outcome of the procedure. Most of the patients who were sexually active after the surgery had a satisfactory sexual experience in all the included studies. They did not report any kind of discomfort during vaginal intercourse and need for any kind of lubricant or dilators.

Discussion

A successful vaginal reconstructive procedure should result in good vaginal length, minimal dilatation, and should provide acceptable physiological and sexual satisfaction. A graft used in various studies of vaginoplasty varied from bowel transplants, thigh or subcutaneous abdominal flaps, split-thickness skin grafts, etc. Amnion grafts became popular in 1984 over other grafts used as there was no need for laparotomy or graft harvesting surgery.[8] The problem with amnion graft is that it requires the selection, acquisition, and preservation of the amniotic membrane and there is a risk of infection transmission through the graft. In vaginoplasty surgeries, the use of split-thickness skin grafts leaves a scar at the site of skin harvest.

The use of ORC as a graft in vaginoplasty overcame many problems faced in other grafts such as the need for prior laparotomy for bowel harvest for grafting or scar formation in split-thickness skin grafts or risk of infection transmission in amnion grafts.

Oxidized regenerated cellulose is applied over raw tissue surfaces at the last stage of surgery after meticulous hemostasis has been achieved, and it is designed to form a gelatinous protective layer between raw surfaces within 8 hours of application. Following this, it is broken down into its monosaccharide constituents and is designed to be absorbed within 2 weeks.

The oxidized cellulose acts as a protective coating on the denuded neovaginal surface and allows vaginal granulation tissue to epithelize. Cellulose due to its nonadherent nature provides space between mold and neovagina and allows epithelization to take place. Oxidized regenerated cellulose is an interesting alternative material with excellent results. Moreover, it does not involve any additional surgical steps and it does not expose the patient to the risk of infection from transmitted viruses. As there are studies that have proved the presence of the hepatitis C virus in a donor's amniotic membrane, who had a negative serology report.[16] Also, the results obtained with the use of ORC as a graft are comparable to the studies where amnion was used as a graft for neovaginal epithelization.[22,23]

Oxidized regenerated cellulose satisfies the safety criterias as there were no major intraoperative complications observed in any of the 13 studies where it was used in vaginoplasty as well. The patients had a timely postoperative recovery without any risk of infection transmission. The efficacy of ORC in vaginoplasty was measured by monitoring the epithelization process of the neovagina in the quoted studies where it was completed by 4–6 months in most of the studies with some variation in the timing of epithelization in other studies. The functional success of ORC in vaginoplasty was measured by the sexual satisfaction of the patients in follow-up which was satisfactory in the majority of the patients.

Conclusion

Vaginoplasty using ORC as a graft material for epithelization is a simple, safe, and effective technique with promising results in terms of epithelization, achieving adequate vaginal length, and satisfactory sexual intercourse. The use of ORC provides support in achieving hemostasis, minimal chance of postoperative infection due to its antimicrobial property, and good postoperative recovery and neovagina epithelization.

Precis

We reviewed cases of vaginoplasty surgeries in which ORC was used as graft and showed good surgical outcomes.

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