Instruments & Methods

VAGINOPLASTY USING AMNION

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Fifteen patients with various developmental and acquired abnormalities of the vagina were treated by the application of human amnion over a mold after surgical dissection of a space for the new vagina or enlargement of an existing but strictured one. Excellent results were achieved in cases of complete and partial vaginal agenesis, and there was improvement in all of the patients with vaginal strictures. ***(Obstet Gynecol 67:443, 1986)***

Malformations of the vagina are an uncommon but serious problem. Their severity ranges from complete vaginal agenesis to vaginal shortening, as is observed in patients with androgen insensitivity. More complicated abnormalities are found in the masculinized female, and vaginal strictures, often secondary to vaginal surgery, can be a major problem. All these abnormalities make coitus difficult or impossible and, if a functioning uterus is present, hematometra or hematocolpos may complicate further the situation.

Various treatments have been described for vaginal agenesis. Frank's[1] method of graduated vaginal dilatation has given good results in the present authors' patients, 50% of them requiring no surgical treatment.

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For those requiring surgery, the Williams vulvovaginoplasty[2] uses the labia to create a perineal pouch. This produces a posteriorally directed vagina whose length may be limited by the length of the perineum, but in many instances, satisfactory results have been reported.[3] McIndoe and Bannister[4] described the use of a split-skin graft to line a normally situated, surgically dissected vagina. The patient suffers considerable discomfort from the donor skin site, which may remain unsightly while complications such as persistent granulation tissue and even fistula formation due to prolonged use of a vaginal mold, are sometimes seen.[5] Vaginal strictures, whatever their etiology, respond poorly to excision as new fibrous tissue often leads to recurrent contraction. Amnion is being used increasingly as a biologic skin dressing[6] and has been used to line an artificially constructed vagina.[7,8] The authors report herein their experience with the use of amnion.

Patients and Methods

Between August 1983 and July 1984, amnion was used in 15 patients undergoing various forms of vaginoplasty. The age of the patients ranged between 14 and 28 years (mean 19.3 years). The three youngest patients (two aged 14 years and one aged 15 years) required surgery primarily to facilitate menstrual drainage. The types of vaginal abnormality are shown in Table 1. The nine patients with a congenitally absent vagina or a short vagina secondary to androgen insensitivity had been using Frank's[1] method of vaginal dilatation for some time without complete success. Three of these nine patients also had undergone a Williams vulvovaginoplasty, which had been unsatisfactory. Two of the three patients with vaginal strictures had had repeated operations all followed by recurrent contraction.

Under general anesthesia, the patient was placed in the lithotomy position and the vaginal dissection was performed. In those cases of complete or partial vaginal agensis, the vault was incised transversely and a vaginal pouch was created by blunt dissection. In cases of vaginal stricturing, scar tissue was incised longitudinally to widen the vagina; deep and multiple incisions were required to obtain a vagina of normal caliber. When hemostasis had been achieved, a vaginal mold of dental stent was selected of a size just large enough to ensure firm application of the amnion, with which it was covered, to the vaginal wall without undue pressure on the rectum or urethra. The labia majora were approximated with silk sutures to keep the mold in place. A Foley catheter was inserted for 48 hours in the first four patients, then it was decided that the catheter was unnecessary.

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Table 1. Type of Vaginal Abnormalities and Postoperative Functional Results

Type of abnormality	No. of patients	Preoperative vaginal length	Postoperative vaginal length (4 wk)	Functional result
Congenital absence of vagina	7	1.5–5 cm (mean = 3.7 cm)	6–10 cm (mean = 8.4 cm)	1 patient sexually active 5 patients using no. 5 dilator to full length 1 patient using no. 4 dilator to full length
Androgen insensitivity: short vagina	2	6 cm	10 cm	Both sexually active
Partial vaginal agenesis with proximal hematocolpos	2			Effective drainage achieved. Both patients using no. 4 dilator
Proximal vaginal agenesis and cervical agenesis with haematometra	1			Cervical canalization failed. Hysterectomy performed. 8-cm vagina using no. 4 dilator
Previous vaginal surgery				
Vaginal strictures				
Distal vaginal agenesis treated by vaginal advancement procedure	1			Coital function much improved. Mild residual stricturing
Sacral agenesis with absent proximal vagina: previous hysterectomy	1			Improved coital function. Moderate recurrent stricturing
Sarcoma botyroides treated by hysterectomy and anterior extentoration	1			Excellent result with minimal recurrent stricturing. Coital function normal.
Total no. of patients	15			

Two patients with distal vaginal agenesis had undergone vaginal advancement operations[9] that had strictured, resulting in the development of proximal hematocolpos. The patient with cervical dysgenesis had a hematometra. In these three patients menstrual blood was drained before the amnion insertion and further menstruation was prevented by continuous use of a combined oral contraceptive pill.

The amnion had been collected immediately after delivery, one to six days before its use. Ideally, delivery was by elective cesarean section, but on several occasions amnion from an emergency cesarean section or a vaginal delivery was used provided the membranes had been ruptured for less than 12 hours. After collection, the amnion was stripped from the chorion, apart from a small piece of the latter left as a marker, rinsed several times in normal saline to remove all of the blood, and then stored at 4C in a solution of crystalline penicillin, 50,000 U per 100 mL of saline. Before insertion the amnion was rinsed in normal saline and a swab was taken to culture for any contamination. Using the chorion marker as a guide, the amnion was draped over the mold with the mesenchymal surface outermost to apply against the vaginal surface. The mold was removed under general anesthesia five to seven days later, usually the latter, and discharge that had accumulated behind the mold was removed with normal saline. A vaginal swab was taken. A clean mold was inserted covered with a further piece of amnion and again the labia was approximated with silk sutures. After a further five to seven days the second mold was removed under general anesthesia or, as in two patients, light sedation. In two patients in whom the graft had been changed at five days and the mold removed after five days, a third application of amnion was used. A third amnion application also was used in one patient who bled excessively after the first operation, necessitating removal of the mold and vaginal packing for 48 hours.

After removal of the final mold, the patient was instructed in how to use a glass vaginal dilator of appropriate size and was asked to insert this three times a day for at least 15 minutes. Dienestrol cream was used as a lubricant. Two weeks later, the patient was encouraged to have intercourse, if appropriate, or to continue with the dilator. All patients were reviewed one month postoperatively and then at three monthly intervals. Blood was taken preoperatively and three months postoperatively to test for the development of red blood cell antibodies.

Results

At the first mold change, the amnion could be seen as a distinct layer applied to the vaginal wall. On removal of the second mold the amnion covering appeared to be complete in all but two patients in whom a further amnion graft was inserted. By the fourth week postoperatively, healthy pink vaginal epithelium was visible with, in some cases, only small areas of granulation tissue. Initial epithelialization was excellent.

At the first and second mold changes a profuse and often offensive discharge was found. Table 2 summarizes the results of bacterial swabs taken from the

Table 2. Results of Bacterial Swabs Taken From the Amnion Specimens and at Mold Removal

	No.	No. with organisms	Type (no.)	Storage times
Amnion culture Source				
Elect CS	19	2	*E coli* & *S albus* (1)	1 d
			Strept group B (1)	1 d
Emerg CS or VD	14	2	Strept group B	3 d
			Strept group D & Bacteroides	2 d
Organisms 1st mold change	15	7	Mixed coliform & strepts (4)	
			Klebsiella & Gardnerella (1)	
			Bacteroides & strepts (1)	
			Proteus & *E coli* (1)	
Organisms 2nd mold change	15	5	Klebsiella & Gardnerella & strepts (1)	
			Strept faecalis (1)	
			Pseudomonas (1)	
			E coli, proteus & strepts (1)	
			Proteus & *E coli*	

Elect CS = elective cesarean section; Emerg CS = emergency cesarean section; VD = vaginal delivery; *E coli* = *Escherichia coli*; *S albus* = *staphylococcus albus*; Strept = streptococcus.

amnion specimens just before vaginal application and vaginal discharge at the time of mold removal. It was surprising that, despite the addition of crystalline penicillin to the storage solution, streptococci were the predominant organisms grown from the amnion. The route of delivery and the storage time of the amnion had no obvious effects on the incidence of positive amnion swabs, nor positive vaginal cultures. No patient received prophylactic antibiotics, except one patient with persistent bleeding, who was treated from the first postoperative day with amoxicillin and metronidazole, and a further patient with heavy discharge was treated with cotrimoxazole and metronidazole from the third postoperative day. Positive vaginal cultures were not treated with antibiotics as they were never accompanied by signs of systemic infection. The presence or absence of vaginal cultures appeared to have no bearing on the eventual outcome.

All patients found the molds uncomfortable postoperatively, but all were mobile and required mild analgesia only. Routine urinary catheter insertion was abandoned early on, although one of the later patients required suprapubic catheterization for urinary retention. Most patients noticed postoperative discharge and slight bleeding for 48 hours. One patient bled persistently, requiring removal of the mold and vaginal packing for 48 hours. The rectum was entered in one patient during vaginal dissection, and immediately repaired. Subsequent surgery three months later was uncomplicated. One patient developed a urinary tract infection.

The anatomic and functional results in the different abnormality groups are summarized in Table 1. All patients had greatly improved vaginal length and capacity as a result of this treatment. Excellent results were achieved in patients with complete or partial vaginal agenesis. The ultimate result was directly related to the motivation of the patient and her dedication to postoperative dilatation. The vaginal tissues remained supple with no evidence of fibrous tissue formation. One unfortunate patient dislocated her knee shortly after discharge from hospital and was unable to use the vaginal dilators effectively for three weeks. The result in this patient was understandably poor with a vaginal length of 6 cm one month postoperatively.

There was improvement in all patients with vaginal strictures, however, some contraction was present by three months postoperatively. Menstrual drainage was secured in the two young patients with partial vaginal agenesis and proximal hematocolpos. Cervical canalization was attempted in the patient with cervical agenesis and hematometra, but was unsuccessful. This patient underwent a hysterectomy.

No long-term complications have been observed so far. Follow-up ranges from three to 12 months. In particular, chronic granulation tissue has not been observed and, as long as dilatation has been maintained, vaginal shrinkage has not occurred. No patient developed new red cell antibodies.

Discussion

Human amnion is a readily available, cost-free protective biologic dressing and is thought to promote re-epithelialization. Faulk et al[10] have demonstrated microscopic evidence of new vessel formation and proposed that an angiogenic factor is produced by amnion. There is no problem with immune rejection because amnion does not express histocompatibility antigens and Akle et al[11] found no evidence of tissue rejection when amnion was implanted subcutaneously in volunteers. Amnion appears to have an antibacterial effect, possibly by achieving cover and closure of the wound. Enzymes, such as lysozyme, produced by the amnion, may be bactericidal. Although a purulent discharge was found frequently between the amnion and the mound, an organism was cultured from less than half of the patients.

Amnion has been stored in a solution of sodium hypochlorite, penicillin, streptomycin, and some workers have added antifungal agents. Dino et al[12] have kept membranes sterile for at least 30 days and have set up an amnion bank to ensure a regular

supply. It also may be maintained in tissue culture or stored dry. Access to a fresh supply is usually simple and therefore it does not need to be stored for more than a few days. A growth of organisms on four of the 33 specimens used was found and in only one patient was a similar organism later cultured from a vaginal swab. Nevertheless, the amnion should be as fresh as possible.

Tancer et al[7] have described four cases in which they used amnion as a graft on vaginoplasties. Dhall[8] has reported more recently five cases from whom vaginal biopsy specimens were taken at follow-up visits, which showed a vaginal epithelium was present by eight to ten weeks. The present authors add a further 15 patients in whom amnion has been used with great success in those patients with vaginal agenesis and with benefit to patients with vaginal strictures.

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