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GENERAL GYNECOLOGY

Comparison of neovaginoplasty using acellular porcine small intestinal submucosa graft or Interceed in patients with Mayer–Rokitansky–Küster–Hauser syndrome

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Abstract

Objective To compare using the acellular porcine small intestinal submucosa (SIS) graft or the Interceed in patients with MRKH syndrome undergoing creation of a neovagina.

Methods In this retrospective study, patients with MRKH syndrome undergoing creation of a neovagina from 2016 to 2018 were retrospectively investigated. Wharton–Sheares–George neovaginoplasty was performed using the acellular porcine SIS graft or the Interceed.

Results Overall, 67 patients were included for analysis. The operating time, the estimated blood loss and return of bowel activity were similar between the two groups. However, the total cost in the SIS group was significantly higher than that in the Interceed group due to the cost of the SIS graft. The mean length and width of the neovagina were similar between the two groups. However, the incidence of granulation in vaginal apex was higher in the SIS graft group than that in the Interceed group. There was no statistically significant difference in the total FSFI scores between the two groups who became sexually active postoperatively.

Conclusions Our results demonstrated that Wharton–Sheares–George method provided the patients to have satisfactory sexual intercourse. The Interceed played a role in the reconstruction of neovagina no less than the SIS graft.

Keywords MRKH syndrome · Acellular porcine small intestinal submucosa graft · Neovagina

Introduction

Mayer–Rokitansky–Küster–Hauser (MRKH) syndrome is a rare abnormality. The incidence was about 1 in 5000 newborn girls. The clinical symptoms included complete or partial agenesis of the vagina, possible associated renal (40%), skeletal (10–12%), auditory (4.5%) abnormalities and others [1]. And it remains the second most common reason of primary amenorrhea. The cause of the disease was unclear; perhaps hereditary and environmental factors played a part in it. The development of adolescent progress and secondary sexual characteristics is always normal, due to the normal female 46,XX karyotype and ovarian hormonal function [2].

The most significant therapy for MRKH syndrome was the creation of a neovagina. And the patients had the chances of satisfactory sexual intercourse and well-being [3]. In recent years, we performed neovaginoplasty according to Wharton–Sheares–George method. In our published data, we reported an acellular porcine small intestinal submucosa (SIS) graft for reconstruction of the vagina [4, 5]. On the other hand, as a new method, the Interceed was initially used in the vaginoplasty in 1994 [6].

In this retrospective study, we compared the application of the acellular porcine small intestinal submucosa (SIS) graft or the Interceed in patients with MRKH syndrome undergoing creation of a neovagina.

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Methods

It was a retrospective study. The study design and protocol were approved by the Institutional Review Board of the Obstetrics and Gynecology Hospital of Fudan University, Shanghai, P. R. China. Patients with MRKH syndrome undergoing creation of a neovagina from January 2015 to December 2017 were retrospectively investigated. Diagnosis of MRKH was based on clinical examination, sex steroid hormone levels, chromosomal analysis, pelvic and kidney ultrasonography in our hospital.

Surgical procedures were as follows. All patients were given their informed consent before the surgical intervention. Under general anesthesia and catheterized bladder, the patient was in the lithotomy position. In the connective tissue plane between the bladder and rectum, the vestiges of the müllerian ducts were identified. With the index finger in the rectum as a direction and protection, Hegar's dilators of increasing size (4.5–10) were pushed through the dimples gently. After that, a double-barreled canal appeared. Then, the raphe between the canals was incised. The neovagina was created. The selection of SIS or Interceed was decided upon following the patients' own choice. A vaginal mold wrapped with SIS (20 * 7 cm, Surgisis®, Cook Medical, Bloomington, IN, USA) or Interceed (7.6 * 10.2 cm, Ethicon Division, Johnson & Johnson, Cornelia, GA) was placed in the neovagina for 6 months. The patients were suggested to wear the vaginal mold continuously over the following 6 months. After that, they were allowed to have the first sexual intercourse. Otherwise, the mold wearing time was 1 h daily, until they had sexual activity at least twice a week.

All the cases were followed up at 6 and 12 months after the treatments. If the patients had sexual activity, the sexual function of the patients was evaluated by the FSFI questionnaire at 7 months after the treatments, which contains 19 self-report questions and categorizes sexual dysfunction in six domains as follows: desire, arousal, lubrication, orgasm, satisfaction and pain. The full scale score ranges from 2.0 to 36.0. The greater the score, the better the result.

Statistical analyses were performed using SPSS 16.0 software (SPSS, Inc., Chicago, IL, USA). Data are expressed as the mean ± standard deviation (SD). A Mann–Whitney U test was performed to compare quantitative variables. A P value of 0.05 was considered significant for all tests.

Results

Overall, 67 patients were included (24 for the SIS graft, 43 for the Interceed) for analysis. All patients had the symptom of primary amenorrhea, and they all had the normal secondary sex characteristics.

No chromosomal abnormality was noted in all the subjects. Elevated androgen was detected in 50 cases. One renal agenesis appeared in 48 cases.

The operating time, the estimated blood loss and return of bowel activity in the SIS graft group were similar with that in the Interceed group. However, the total cost in the SIS group was significantly higher than that in the Interceed group due to the cost of the SIS graft ($2570 per graft). There were no intraoperative and postoperative complications in both groups except that five cases had a fever in the SIS group (Table 1).

All patients had a continuous mold wearing time for 6 months postoperatively and then returned for their follow-up at 6 and 12 months after treatments. The mean length and width of the neovagina in the SIS graft group were similar with the Interceed group (7.0 ± 0.6 cm vs. 7.1 ± 0.8 cm, $P = .54$, 2.8 ± 0.3 cm vs. 2.7 ± 0.5 cm, $P = .74$, respectively) at 6 months after treatments. However, the incidence of inflammatory granulation at the vaginal apex was higher in the SIS graft group than that in the Interceed group (6/24 vs. 4/43, $P < .001$) 1 month after operation. The situation was resolved with the use of metronidazole suppositories quaque nocte consecutively. Sixteen (66.7%) patients in the SIS group and 31 (72.1%) in the Interceed group subsequently had a sexual partner and became sexually active. The mean length and width of the neovagina in the SIS graft group were similar with the Interceed group (7.6 ± 0.8 cm vs. 7.5 ± 0.5 cm, $P = .65$, 2.9 ± 0.4 cm vs. 2.9 ± 0.6 cm, $P = .88$, respectively) at 12 months after treatments in the cases who had sexual activity at least twice a week. And the lengths of these cases at 12 months after treatments were longer than the lengths at 6 months (7.6 ± 0.8 cm vs. 7.0 ± 0.6 cm, $P = .015$, 7.5 ± 0.5 cm vs. 7.1 ± 0.8 cm, $P = .027$, respectively). There was no statistically significant difference in the total FSFI scores and the scores of all six domains

Table 1 Clinical characteristics of SIS and Interceed groups

Parameter	SIS group	Interceed group	P
Age (years)	22.7 ± 4.1	21.3 ± 3.7	0.80
Operating time (minutes)	26.4 ± 9.8	29.1 ± 8.1	0.75
Estimated blood loss (ml)	10.2 ± 1.4	12.3 ± 2.3	0.67
Return of bowel activity (hours)	20.3 ± 5.2	21.4 ± 4.6	0.55
Total cost ($)	5612 ± 654	2439 ± 435	< .001

Table 2 Characteristics and results of anatomical outcomes and sexual functional outcomes of SIS and Interceed groups at 6 and 7 months after treatments

Parameter	SIS group	Interceed group	*P*
Neovagina			
Length (cm)	7.0 ± 0.6	7.1 ± 0.8	.54
Width (cm)	2.8 ± 0.3	2.7 ± 0.5	.74
Inflammatory granulation (*n*)	6	4	< .001
The total FSFI scores	26.54 ± 4.50	26.81 ± 3.21	.71
Desire score	3.82 ± 0.65	3.73 ± 0.71	.86
Arousal score	4.36 ± 0.48	4.51 ± 0.90	.61
Lubrication score	4.78 ± 0.93	4.56 ± 0.47	.49
Orgasm score	4.51 ± 0.88	4.63 ± 0.69	.68
Satisfaction score	4.45 ± 0.71	4.54 ± 0.81	.74
Comfort score	4.62 ± 0.68	4.84 ± 0.74	.66

Table 3 Characteristics and results of anatomical outcomes and sexual functional outcomes of SIS and Interceed groups at 12 months after treatments

Parameter	SIS group	Interceed group	*P*
Neovagina			
Length (cm)	7.6 ± 0.8	7.5 ± 0.5	.65
Width (cm)	2.9 ± 0.4	2.9 ± 0.6	.88
The total FSFI scores	32.18 ± 2.21	31.66 ± 3.42	.68
Desire score	4.74 ± 0.71	4.68 ± 0.42	.71
Arousal score	5.10 ± 0.65	5.46 ± 0.21	.78
Lubrication score	5.55 ± 0.38	5.32 ± 0.55	.66
Orgasm score	5.37 ± 0.53	5.40 ± 0.53	.82
Satisfaction score	5.74 ± 0.60	5.28 ± 0.33	.69
Comfort score	5.68 ± 0.47	5.52 ± 0.38	.80

of the FSFI between the two groups at 7 and 12 months after the treatments (26.54 ± 4.50 vs. 26.81 ± 3.21, $P = .71$, 32.18 ± 2.21 vs. 31.66 ± 3.42, $P = .68$, respectively) (Tables 2, 3). And the total FSFI scores of these cases at 12 months after treatments were greater than the scores at 7 months (32.18 ± 2.21 cm vs. 26.54 ± 4.50 cm, $P = .008$, 31.66 ± 3.42 cm vs. 26.81 ± 3.21 cm, $P = .007$, respectively).

Discussion

As a novel bioactive material for tissue graft, SIS provided scaffold for the remodeling tissues. It was reported that myringoplasty by using SIS yielded reduced surgical time and no adverse reaction, compared with autologous temporalis fascia repair in children. And the audiometric tests showed the good effect [7, 8].

To our knowledge, we initially applied the SIS in the reconstruction of female reproductive tract abnormalities [4]. A combined laparoscopic and vaginal cervicovaginal reconstruction with an SIS graft was performed to resolve the dysgenesis of uterine cervix and vagina. Fortunately, resumption of menstruation appeared in all the cases. And no case had cervical or vaginal stenosis in the follow-up [9]. We also compared the laparoscopic Davydov procedure with the vaginoplasty using SIS graft. The SIS graft group had the shorter operating time, less estimated blood loss, an earlier return of bowel activity and an earlier return to work [10].

However, the length of the neovagina in the SIS group seemed to be improved in the two studies due to the operation method [11]. It was reported that neovagina performed by Wharton–Sheares–George method had a satisfactory length and width. And it provided the patient the possibility to have satisfactory sexual intercourse [12]. Our results were similar with them.

Furthermore, we revealed that the lengths of the neovagina in cases who had regular at 12 months after treatments were longer than the lengths at 6 months. And the total FSFI scores of these cases at 12 months after treatments were greater than the scores at 7 months. Perhaps initially a few patients were in fear of the new sexual intercourse. Then the relative frequency of sexual intercourse increased through continuous attempt. So we considered that the flexibility of the neovagina could be enhanced by the regular sexual intercourse and then the length was increased. As a result, the total FSFI scores improved. And we investigated the cost. The Interceed was much cheaper than the SIS, and it reduced the cost for the patients MRKH syndrome in the developing country.

As an absorbable oxidized regenerated cellulose, the Interceed was used intraoperatively to reduce and prevent adhesion formation by forming a gelatinous layer between raw areas [13, 14]. Lee used an absorbable Interceed pouch with double-layer skin closure for a remnant defect in the breast cancer surgery. And the cosmetic outcomes were self-reported to be excellent and good in 90.7% (39/43) cases [15].

In the initial research, the Interceed was used to prevent the adhesion between the stent and the raw surfaces in the dissection of the neovaginal tunnel, though the sample size was small. In the study, 10 patients were performed the vaginoplasty. Inflammatory granulation at the apex of the neovagina was also detected in five cases postoperatively and electrocautery was performed [16]. However, in our study, we did not use electrocautery. We considered that sterile environment was more important for the treatment of inflammatory granulation. And it was proved the Metronidazole Suppositories were effective. The incidence of inflammatory granulation seemed higher in the SIS group than the

Interceed group. We considered that perhaps the bioactive material was more irritative than the Interceed. In another two small sample size studies, seven cases of MRKH syndrome were performed vaginoplasty with the Interceed and the neovagina was satisfactory [6, 17].

In the previous study, we tried to combine laparoscopic and Wharton–Sheares–George cervicovaginal reconstruction using an SIS graft for a young patient with MRKH syndrome with a rudimentary cavity. And it resulted in favorable outcome with functional and anatomic satisfaction [18]. In the future, we plan to perform the cervicovaginal reconstruction with the Interceed.

In conclusion, our results demonstrated that Wharton–Sheares–George method provided a perfect alternative to the management of MRKH syndrome. The Interceed played a great role in the reconstruction of neovagina no less than the SIS graft. Compared with the SIS, the use of the Interceed may reduce the cost and the incidence of inflammatory granulation. However, neither SIS graft or Interceed needed a longer mold use time than other methods. And compared to other methods, the smaller neovaginal lengths should be improved in the future.

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Authors' contribution KH, JD contributed to the design of the manuscript. XZ, JD helped in writing the manuscript. JQ contributed to the statistics.

Compliance with ethical standards

Conflict of interest The authors declared that they have no conflict of interest.

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