

돼지진피조직 (Porcine Dermal Matrix, Permacol[®])을 이용한 보형물 유방재건술: 무세포성 사체 진피 (Acellular Cadaveric Dermis, AlloDerm[®])와 비교연구

정보람 · 노태석 · 김영석 · 홍종원 · 나동균

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Implant Breast Reconstruction Using Porcine Dermal Matrix (Permacol[®]): A Comparative Study with Acellular Cadaveric Dermis (AlloDerm[®])

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Purpose: The use of tissue expander/implant in breast reconstruction using tissue expander-implant is one of the most common surgical procedures. The use of AlloDerm as a sling to reestablish the lower pole of the pectoralis major muscle results a decrease in morbidity compared with more invasive procedures. However the use of AlloDerm is more expensive than other options. We decided to compare AlloDerm with Permacol, which has been safely used in human body reconstruction and is less costly than AlloDerm.

Methods: After mastectomy, the inferolateral origin of the pectoralis major muscle was elevated. Either AlloDerm or Permacol was sutured to the chest wall at the level of the previously marked inframammary fold. The lower border of the pectoralis major muscle and the upper portion of the crescent-shaped piece of either AlloDerm or Permacol was sutured together using a tension free technique, and a tissue expander was subsequently inserted into the subpectoral-subAlloDerm (or Permacol) dual pocket.

Results: AlloDerm was used in twenty-one patients (28 breasts) and Permacol was used in six patients (11 breasts) for tissue expander-implant breast reconstruction. During the mean follow-up period of 17 months (8~25 months). Two infections (7%) occurred in AlloDerm cases

and four infections (36%) occurred in Permacol cases.

Conclusion: This study is the first comparison of tissue expander/implant breast reconstruction using AlloDerm and Permacol. The use of Permacol resulted in more post-operative infection compared with the use of AlloDerm. This report is still limited with the small number of cases studied.

Key Words: Breast reconstruction, Permacol, AlloDerm, Tissue expansion

I. INTRODUCTION

There are two principle methods of breast reconstruction following mastectomy for the treatment of breast cancer: the use of autologous tissue or prosthetic devices. Implant-based breast reconstruction methods have been subject of many studies. A autologous breast reconstruction is the most frequently used method. The tissue expander/implant method requires the insertion of a tissue expander after mastectomy, subsequent gradual saline injection expanding the surrounding tissues, and substitution with permanent implants after several weeks. This method has a number of advantages over autologous tissue reconstruction in that it results in texture, color and sensation similar to that of the adjacent tissue, shorter operation time, minimal scarring, faster recovery, and avoidance of donor site morbidity.¹ Tissue expanders are inserted under the pectoralis major muscle by lifting the inferiolateral portion of the muscle. However, complete coverage of the expanders by the muscle is often difficult to achieve. This could result in a number of complications, including capsular contracture and expander/implant exposure or extrusion. Having a portion of the expander/implant covered only by a skin-subcutaneous tissue flap, and not by muscle, leads to thinning of the soft tissues of the inferior pole of the breast.^{1,2} In order to prevent this side effect, a method for creating inducing a complete submuscular pocket by elevating both the pectoralis major and the anterior serratus muscle was developed. However, this method

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could lead to malpositioning of the implants above the inframammary fold.² In 2005, Breuning et al. developed the AlloDerm-Sling technique in which they created a subpectoral-subAlloDerm pocket using AlloDerm[®] of 0.79~1.78 mm thickness, which was originally developed for breast reconstruction since 2004, and firmly secured in the position of the inframammary fold. This technique is performed in order to reduce thinning of soft tissues after tissue expansion and to achieve satisfactory lower-pole fullness.¹ Subsequent studies by Gamboa-Bobadilla, Salzberg, Bindingnavele and others have also documented aesthetically satisfying results using AlloDerm[®] in breast reconstruction.³⁻⁵ In addition, Preminger et al. no difference in the rate of postoperative complications such as seroma (6.7%), hematoma (6.7%), infection (2.2%) between AlloDerm-sling technique and older methods using tissue expanders and implants.⁶ Although this method is safe and result in excellent outcomes, AlloDerm-sling technique has its limitations of raising the cost of treatment 33%.

Permacol[®], developed in the United Kingdom in 1998, is an acellular dermis extracted from porcine skin, made to resist biodegradation by removing cellular and noncollagenous debris.⁷ Permacol[®] has been reported to be safe when applied to various parts of the body and to have similar efficacy of AlloDerm[®] in abdominal wall reconstruction.^{8,9} The goal of this study was to compare the efficacy and safety of Permacol[®], which is 50% less expensive than AlloDerm[®], with that of a similar thickness of AlloDerm[®], in tissue expander/implant breast reconstruction.

II. MATERIALS AND METHODS

A. Subject

Patients who underwent total mastectomy due to breast cancer at Gangnam Severance Hospital from January 2008 to June 2010 were included in this retrospective study. A total of 27 patients underwent surgery; 21 with AlloDerm[®] (LifeCell Corporation, Woodlands, TX) and 6 with Permacol[®] (Tissue Science Laboratories, Inc., Andover, MA). Thirty-nine breasts were studied; 28 cases of AlloDerm[®] and 11 cases of Permacol[®] (Table I). Mean age, mean BMI, mean duration of follow up, mean size of tissue expanders (cc), and mean volume of tissue expansion were recorded. AlloDerm[®], with an average thickness of 0.71~1.66 mm, and Permacol[®], with an average thickness of 1.5 mm, were used. Tissue expanders (textured, contour profile; Mentor Co. U.S.A) with an insertion port on the anterior surface were used in all

patients. Postoperative complications including infection, hematoma, seroma, and implant exposure were compared between the two groups. AlloDerm[®] and Permacol[®] were sampled on 7 days after operation to compare collagen structure (Masson's trichrome stain), cellular infiltration (hematoxylin and eosin stain), and neovascularization (CD31 immuno stain). AlloDerm[®] sample was obtained from the patient without infection by lateral small incision on the local anesthesia. Permacol[®] sample was obtained from the patient who had symptoms of infection sign when the wound irrigation with saline. All samples obtained after receiving informed consent.

B. Operation method

The pectoralis major muscle was approached through the incision and the muscle origin was elevated from the chest wall. Previously measured tissue expanders were inserted under the pectoralis major muscle and either AlloDerm[®] or Permacol[®] was trimmed to an appropriate size in order to match the area of expander not covered by the muscle. Using #3 absorbable suture material (Polysorb, United States Surgical Corp.), the prepared material was continually sutured to the inferior border of the dissected pectoralis major muscle superiorly, the superior border of the serratus anterior muscle laterally, and to the chest wall on the same level as the contralateral inframammary fold inferiorly. The patient was positioned to sit up at 90 degree angle in order to ensure symmetry with the contralateral inframammary fold and to appropriately adjust the position of the AlloDerm[®] or Permacol[®] before anchoring it. Subsequently, an appropriate amount of saline that would not exert tension on the skin flaps was injected into the tissue expanders in order to prevent translocation and complications including seroma. One drain was placed and antibiotics were used for 7 to 10 days after the operation in order to prevent postoperative infection. Tissue expansion by saline injection began from the 10 to 14 days after operation, and tissue expanders were replaced with permanent implants six months later.

C. Statistical Analysis

SPSS (version 18.0) was used for statistical analysis, and all mean values were presented as mean \pm standard deviation. The Kolmogorov-Smirnov test was used for normality test of all variables of the two groups. In order to check out that there is no difference between the subjects of the AlloDerm[®] and the Permacol[®] groups, pairwise comparisons were performed using the inde

Table I. Summary of Patients

Case	Age (Year)	Follow up (Month)	Diagnosis	BMI (kg/m ²)		Material (size: cm/Thickness: mm)	T/E (cc)	Total inflation(cc)	Site	Timing
1	28	25	DCIS	18.83	A	5*15/ 0.53-0.76	350	320	U	I
2	35	25	DCIS	22.5	A	5*13/0.53-0.76	300	400	U	I
3	44	22	DCIS	22.24	A	8*15/0.53-0.76	350	300	U	I
4	44	20	DEH	20.57	A	5*13/0.53-0.76	350	260	U	D
5	59	18	IDC	24.3	A	4*19/0.53-0.76	450	210	U	I
6	54	19	Lt.: CCH Rt.: DCIS	25.18	A	8*15/0.53-0.76	350	390	B	I
7	42	16	DCIS	21.83	A	6*11/0.53-0.76	450	400	U	I
8	25	16	IDC	18.08	A	4*16/0.79-2.03	350	380	U	I
9	41	20	Lt.: FAH Rt.: DCIS	19.03	A	4*16/0.79-2.03	350	355	B	I
10	39	12	DCIS	21.17	A	4*16/0.79-2.03	350	350	B	I
11	36	19	DCIS	17.3	A	4*16/0.79-2.03	350	100	U	I
12	40	22	Lt.: DCIS Rt.: FD	16.89	A	4*16/0.79-2.03	350	280	B	I
13	37	13	IDC	24.36	A	4*16/0.79-2.03	550	520	U	I
14	44	8	Lt.: DCIS Rt.: ADH	22.27	A	Lt.: 4*12/0.79-2.03 Rt.: 4*16/0.79-2.03	350	390	B	I
15	35	13	Lt.: ILC Rt.: ADH	17.09	A	Lt.: 4*12/0.79-2.03 Rt.: 4*16/0.79-2.03	350	270	B	D
16	32	10	IDC	18.81	A	4*16/0.79-2.03	350	310	U	I
17	37	25	PT	22.15	A	4*16/0.79-2.03	450	480	U	I
18	46	15	TC	25.39	A	4*16/0.79-2.03	450	420	U	I
19	32	12	FD	20.83	A	4*16/0.79-2.03	450	430	U	D
20	31	20	IDC'	22.64	A	8*14/0.79-2.03	450	430	U	I
21	36	21	IDC	22.04	A	Lt.: 4*16/0.79-2.03 Rt.: 4*12/0.79-2.03	Lt: 350 Rt.:450	Lt.:450 Rt.:380	B	Lt: I Rt.: D
22	35	18	DCIS	19.33	P	10*15/1.5	350	380	U	I
23	33	12	DCIS	21.05	P	10*15/1.5	350	360	B	I
24	45	17	Lt.: IP Rt.: DCIS	20.83	P	10*15/1.5	350	330	B	I
25	38	15	Lt.: DCIS Rt.: FAH	22.83	P	10*15/1.5	350	380	B	I
26	34	17	DCIS	19.04	P	10*15/1.5	350	355	B	I
27	48	19	IP	22.97	P	5*7.5/1.5	450	Lt.:380 Rt.:375	B	I

DCIS, Ductal carcinoma in situ; DEH, Ductal epithelial hyperplasia; IDC, Invasive ductal carcinoma; CCH, Columnar cell hyperplasia; FAH, Fibroadeomatoid hyperplasia; FD, Fibrocystic disease; ADH, Atypical ductal hyperplasia; ILC, Invasive lobular carcinoma; PT, Phyllodes tumor; TC, Tubular carcinoma; IDC, Infiltrating ductal carcinoma; IP, Intraductal papilloma; A, AlloDerm; P, Permacol; T/E, Tissue expander; U, Unilateral; B, Bilateral; I, Immediate; D, Delayed.

pendent T-test for continuous variables. For compare of the complications of the AlloDerm[®] and the Permacol[®] groups, the Chi-square test was used for categorical variables. And a *p*-value less than 0.005 was defined as statistically significant.

III. RESULTS

A mean age of 39.5 (\pm 7.78) years, average follow up period of 17.6 (\pm 5.01) months, average BMI of 20.9 (\pm 2.73) kg/m², average tissue expander size of 381.5 (\pm 57.4) cc and average volume of expansion of 352.2 (\pm 88.7) cc were noted in the AlloDerm[®] group. For the Permacol[®] group, an average age of 40.4 (\pm 6.06) years, average follow-up period of 16.6 (\pm 2.21) months, average BMI of 21.4 (\pm 1.56) kg/m², average tissue expander size of 372.2 (\pm 44.1) cc and average volume of expansion of 363.3 (\pm 21.2) cc were recorded. So significant differences between the two groups in these parameters were not detected, except for the mean follow up period (Table II).

In the AlloDerm[®] group, there were five cases (17%) of postoperative complications; two cases of infection

(7%), one case of hematoma (2.7%), one case of seroma (3.7%), one case of implant exposure (3.7%), among which infection and implant exposure occurred concurrently in one breast. In the infected case, breast reconstruction was completed by irrigating the subpectoral-sub-AlloDerm[®] pocket with saline, replacing the infected tissue expander with a new expander and continuing expansion. In the Permacol[®] group, there were five cases in which complications including four cases of infection (36%), one case of seroma (9%) and one case of implant exposure (9%). One case of seroma and infection occurred in one breast, and one case of implant exposure and infection occurred in one breast (Table III). Significant differences were detected between the two groups in infection occurrence (*p*=0.02) and total complication occurrence (*p*=0.01). One case of infection was treated with antibiotics and normal saline irrigation alone, while two cases required replacement of infected tissue expanders to complete breast reconstruction.

Histologic comparison of samples collected on the seventh postoperative day revealed thicker, coarser collagen fiber structures in the Permacol[®] group (Fig. 1)

Table II. Matching with AlloDerm and Permacol

	Total (n = 39)	AlloDerm (n = 28)	Permacol (n = 11)	<i>p</i> -value
Mean Age (Year)	39.8 (\pm 7.32)	39.5 (\pm 7.78)	40.4 (\pm 6.06)	0.78
Mean Follow up (Month)	17.3 (\pm 4.48)	17.6 (\pm 5.01)	16.6 (\pm 2.21)	0.008
Mean BMI (kg/m ²)	21.1 (\pm 2.48)	20.9 (\pm 2.73)	21.4 (\pm 1.56)	0.53
Mean tissue expander size (cc)	379.17 (\pm 53.95)	381.48 (\pm 57.42)	372.2 (\pm 44.09)	0.45
Mean volume of inflation(cc)	355 (\pm 77.23)	352.22 (\pm 88.67)	363.3 (\pm 21.06)	0.80

Values are mean \pm standard deviation.

The independent T-test was used for statistical analysis.

*: *p*-value > 0.05

†: *p*-value < 0.05

Table III. Complications after AlloDerm and Permacol

	AlloDerm (n = 29)	Permacol (n = 11)	<i>p</i> -value
Infection	2 (7%)	4 (36%)	0.02
Hematoma	1 (3.7%)	0 (0%)	> 0.99
Seroma	1 (3.7%)	1 (9%)	> 0.99
Implant exposure	1 (3.7%)	1 (9%)	> 0.99
Total	5 (17.2%)	6 (54.5%)	0.01

The Chi-square test was used for statistical analysis.

*: *p*-value > 0.05

†: *p*-value < 0.05

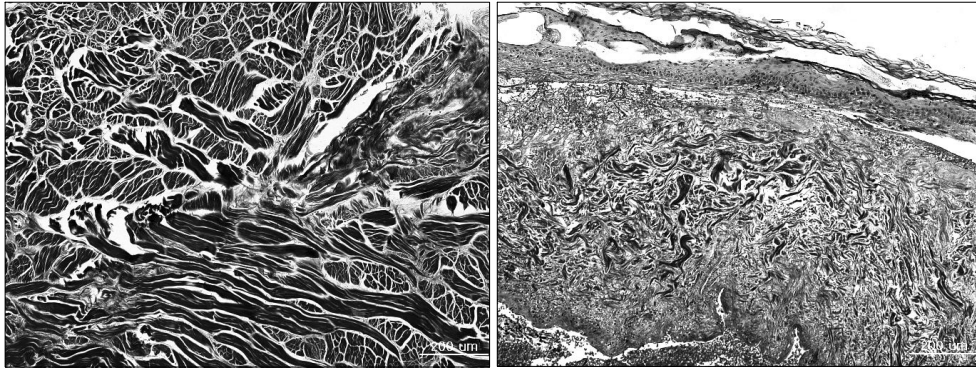


Fig. 1. Histologic analysis demonstrated more thick and coarse collagen fiber in Permacol (Right) than AlloDerm (Left) 1 week after operation (Masson's trichrome, $\times 100$).

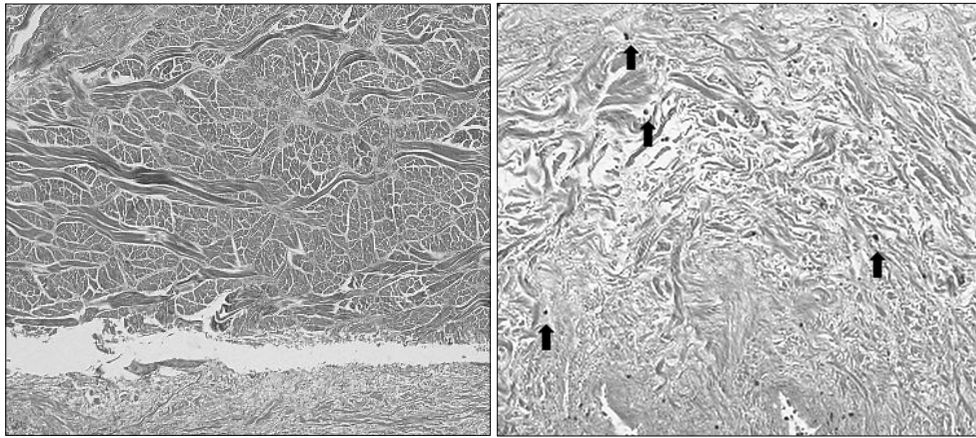


Fig. 2. Histologic analysis demonstrated more cell infiltration (arrow) in AlloDerm (Left) than Permacol (Right) 1 week after operation (H & E, $\times 100$).

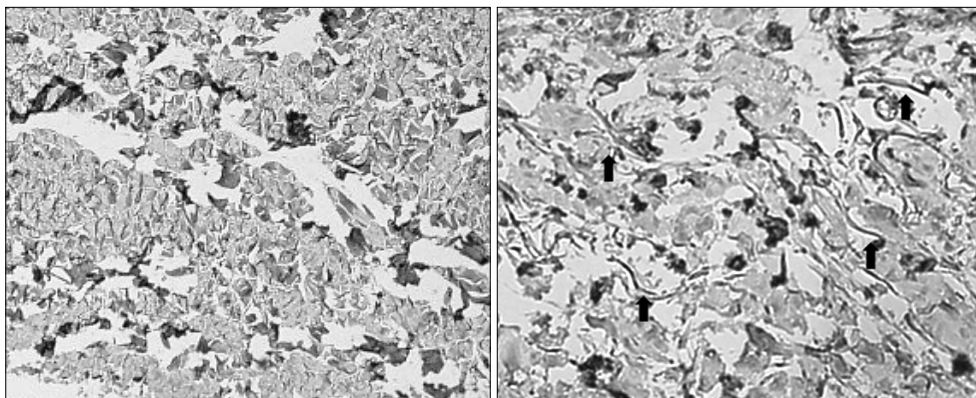


Fig. 3. Histologic analysis demonstrated more endothelial cell ingrowth (arrow) in AlloDerm (Left) than Permacol (Right) 1 week after operation (CD31, $\times 100$).

analysis of Masson's trichrome staining. Cellular infiltration on hematoxylin and eosin staining (Fig. 2) and endothelial cell proliferation evidenced by CD31 immunostaining (Fig. 3) appeared only the AlloDerm[®] group.

Case 1

A 47 year old female was admitted for bilateral breast cancer. After bilateral total mastectomy, a subpectoral- subPermacol[®] pocket was created using a 1.5-mm-thick, 10 \times 15 cm² piece of Permacol[®], 350 cc tissue expanders were inserted, and 130



Fig. 4. (Left) Preoperative view. (Right) One year after tissue expander removal and change with smooth cohesive gel mammary implant.

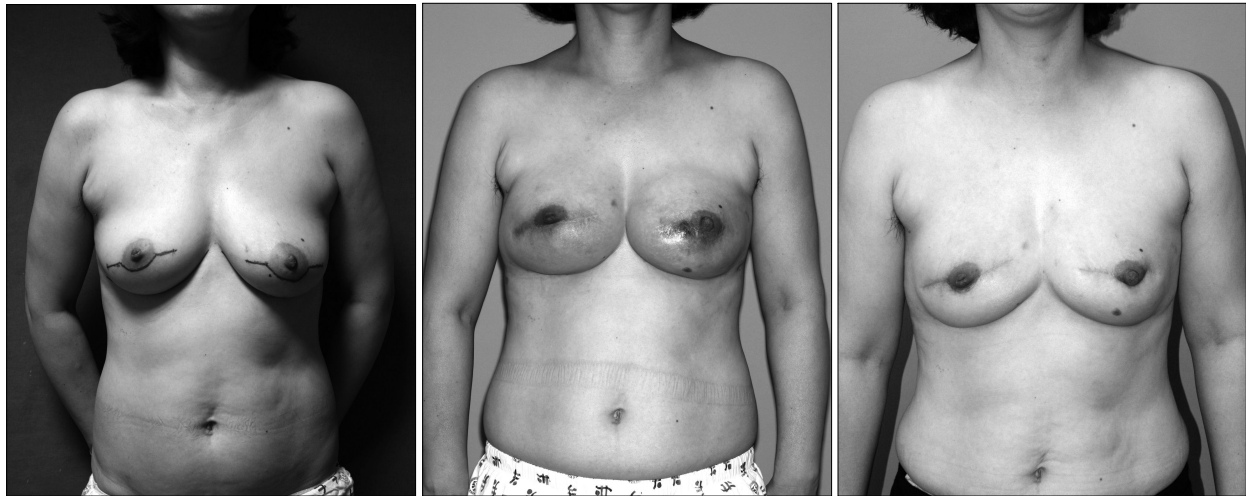


Fig. 5. (Left) Preoperative view. (Center) Three month after tissue expander insertion. (Right) Three month after tissue expander removal and change with smooth cohesive gel mammary Implant.

cc of saline was subsequently injected. A microbial culture study at the time of drain removal on the right breast revealed *Pseudomonas aeruginosa*. Infection was controlled with antibiotics and saline irrigation and tissue expansion was continued without replacement of tissue expanders. Since subsequent culture studies during tissue expansion were negative for microbial growth and there were no clinical symptoms of mastitis, tissue expanders filled to 330 cc were replaced with 220 cc cohesive-gel prosthetic breast implants (Fig. 4).

Case 2

A 50-year-old female was admitted for bilateral breast cancer. After bilateral total mastectomy, a subpectoral-sub-Permacol[®] pocket was created using a 1.5-mm-thick, 5 × 7.5

cm² piece of Permacol[®], 450 cc tissue expanders were inserted, and 200 cc of saline was subsequently injected. Symptoms of mastitis manifested in the right breast, which was treated with antibiotics and saline irrigation. Later, exudate appeared at the incision site on the left breast, which was treated with antibiotics, saline irrigation, and tissue expander replacement. As there was no subsequent mastitis and tissue expansion was safely completed, tissue expanders were replaced with cohesive-gel prosthetic breast implants (Fig. 5).

IV. DISCUSSION

Two-stage breast reconstruction using tissue expander/

implants is a frequently used method of bilateral reconstruction as there is no loss of donor site tissue. Complications such as implant exposure, capsular contracture and extrusion of the tissue expander due to skin necrosis are generally prevented by completely enclosing the tissue expanders within the submuscular pocket.¹⁰ However, even if complete coverage is possible, the possibility of side effects due to the high riding of the implant over the inframammary fold still remains.⁴ In order to address tigus complication, Breuing et al. developed tissue expander/implant breast reconstruction method using AlloDerm[®] instead of the anterior serratus muscle to cover up the inferior portion of the tissue expanders, which provides support to the soft tissues in the lower pole of the breast.¹ This technique reduces complications including both implant exposure or extrusion, and capsular contracture and upward deviation of the implants.¹ Preminger⁶ et al. reported that tissue expander/implant breast reconstruction using AlloDerm[®] does not increase the risk of postoperative complications compared with conventional methods. Yoon JH et al.⁹ reported similar results when the AlloDerm[®] sling operation was used Asian women. Despite its efficacy and safety, a significant amount of AlloDerm[®] is needed to cover up the inferior portion of the tissue expanders, thereby raising operation costs by 33%. For this reason, this study examined the use of Permicol[®] as a dermal substitute, Permicol[®] is 50% less expensive than AlloDerm[®] and has been used safely in reconstructive surgery.

Permicol[®] is an acellular dermis extracted from porcine skin from which cellular and noncollagenous debris known to cause immunologic reactions, have been removed.⁷ Animal studies have shown that the use of permacol does not lead to allergic reaction, cytotoxicity, mutation induction capability, systemic reaction, or intradermal reaction. Permicol[®] has attained CE (Conformite Europea) Mark Class III and can be safely used in all parts of the human body. Its use in abdominal wall reconstruction has been approved by the United States FDA. Permacol[®] transplanted on the abdominal wall maintains its innate strength while inducing the growth of surrounding fibroblasts and neovascularization, eventually leading to permanent integration into the patient's tissue.⁸ Permacol[®] is mostly composed of type I collagen (93~95%) and small amount of elastin and type III collagen, and its chemically assembled three dimensional structure renders it resistant to biodegradation as opposed to AlloDerm[®] which has non cross-linked collagen structure.¹¹ Patrick et al published that Permacol[®] can be a reasonable alternative to AlloDerm[®] in that

it provides similar tensile strength, induces intracellular growth and neovascularization, does not need to be removed when used on contaminated surface during reconstruction, and is 50% less expensive than the same sized AlloDerm[®].⁸ Additionally, Permacol[®] has an advantage of easier manipulation. AlloDerm[®] is divided into dermis and basement membrane, and intracellular growth and neovascularization occurs better in the dermis. Therefore, when using AlloDerm[®] for implant breast reconstruction, smooth, shiny, well-blood absorptive dermal surface has to face the subcutaneous tissue side, while the opposite basement membrane side needs to face the tissue expanders. Permacol[®], on the other hand, can be easily transplanted without discriminating sides and orientation.

As for this reason, this study aimed at comparing the use of safe, cost-competitive, and easily manipulative Permacol[®] in tissue expander-implant breast reconstruction with the original AlloDerm[®] sling operation. Both the AlloDerm[®] group and Permacol[®] group achieved natural looking lower-pole fullness and symmetric inframammary fold, but the rate of complication varied between the two groups. The rate of complications in the AlloDerm[®] group including infection (7%), hematoma (3.7%), seroma (3.7%), and implant exposure (3.7%) corresponded with outcomes documented from previous studies. Complications that occurred in the Permacol[®] group were infection (36%), seroma (9%), and implant exposure (9%), disclosing higher infection rate.

In investigation for the reason for such higher infection rate, precedent studies were considered. Melman et al. published a study comparing AlloDerm[®] and Permacol[®] in porcine hernia model. Both materials maintained similar tensile strength regardless of transplantation period of 1~12 months, but biopsy results after 1 month of transplantation revealed statistically significant result of more neovascularization and intracellular proliferation in AlloDerm[®] than Permacol[®], whereas there were no significant difference between the two groups after 12 months.¹² This outcome indicates that neovascularization and intracellular proliferation occurs more slowly in cross-linked three dimensionally structured Permacol[®] than non cross-linked AlloDerm[®]. It has also been confirmed in this study that endothelial cell proliferation was present only in AlloDerm[®] in histological analysis of the samples acquired on the 7th postoperative day.

In this study, only one surface of Permacol[®] was in contact with the tissue since it encloses the tissue expander, allowing only that surface available for neovascularization and intracellular proliferation. This

was the same case for AlloDerm[®], but it was less affected by the reduced surface area as the dermis which is more advantageous in angiogenesis and intracellular growth faces the tissue. As reflected in Melman's study, there is a possibility that Permacol[®] with slower rate of neovascularization and intracellular proliferation will take even longer with reduced surface contact in comparison to transplantation into the abdominal wall.¹⁰ In addition, the skin flap in contact with Permacol[®] is usually given tension and the subcutaneous layer is often damaged by continuous traction during mastectomy, further delaying the process. It can be assumed that such factors may have lead to increased rate of postoperative infection in the Permacol[®] group. However, the small number of cases and relatively short follow-up period has limitations in drawing conclusions that Permacol[®] increased infection rate.

Nonetheless, given that there are only a few reports on the use of Permacol[®] in breast reconstruction yet many Korean surgeons in local clinics are using Permacol[®] to provide support for the soft tissue defect after breast augmentation, and considering the cost-effectiveness and lack of complications such as translocation or exposure of implants and capsular contracture, Permacol[®] will prove efficacious in plastic surgery of the breasts with the support of more future studies.

V. CONCLUSION

This study revealed that tissue expander-implant breast reconstruction using Permacol[®] is cost-effective, yet holds higher risk of infection in comparison to AlloDerm[®]. But limitation of this study is a small number of cases. Nevertheless, study on Permacol[®] is only at its beginning stage at the moment, requiring more cases and studies to affirm its already established efficacy in breast reconstructive surgery.

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