Archives of Aesthetic Plastic Surgery
Vol. 18, No. 2, 133-137, 2012

보형물을 이용한 유방재건술에서 새롭게 개발된 무세포 동종사체진피(CG Derm™)사용의 유용성에 대한 전향적 연구

김영석 · 정보람 · 홍종원 · 노태석 · 나동균

연세대학교 의과대학 강남세브란스병원 성형외과학교실-인체조직복원연구소

Application of Newly Developed Acellular Dermal Matrix Allograft (CG DermTM) in Breast Reconstruction with the Implant: The Prospective Study

Young Seok Kim, M.D., Bo Rham Jeong, M.D., Jong Won Hong, M.D., Tai Suk Roh, M.D., Dong Kyun Rah, M.D.

Institute for Human Tissue Restoration, Department of Plastic & Reconstructive Surgery, Gangnam Severance Hospital, Yonsei University College of Medicine, Seoul, Korea

Several freeze-dried human acellular dermal matrix have been introduced and they helped to facilitate implant based breast reconstruction by providing support to the breast lower pole, firm fixation of inframammary fold, and simple operation procedure. We evaluated clinical outcomes of recently produced human acellular dermal matrix, CG Derm™, prospectively. CG Derm™ was used in six patients and eight breasts for implant breast reconstruction. Complete blood cell count test, rountine chemisty(including ESR) test, and CRP test were performed before and after the surgery. Postoperative complication was evaluated including infection, seroma, implant malpostion, rippling deformity, and capsular contracture. Randomly selected two patients underwent breast MRI after reconstruction. Finally we examine patients' satisfaction survey and plastic surgeons' evaluation. Satisfactory breast lower pole fullness, symmetric inframammary folds and breast shapes were achieved in most patients. Overall, patients had sufficient aesthetic satisfaction and surgeon's evaluation was also good. There was no major complication except four cases of seroma which healed with conservative management. Implant breast reconstruction using CG Derm™ was safe and obtain good aesthetic results. But further and larger scale study should be performed to reveal out the relatively high risk of seroma.

(Archives of Aesthetic Plastic Surgery 18: 133, 2012)

Key Words: Breast reconstruction, Breast implant, Allograft, Skin substitutes

I. INTRODUCTION

Since Breuing et al.[1] introduced the insertion of implant into the dual plane subpectoralis major muscle-sub-AlloDerm (Allogenic acellular dermal matrix, LifeCell Corp., Branchburg, NJ) for patients who had received mastectomy for breast cancer and then were receiving implant breast reconstruction in 2005, studies on surgery by similar methods have reported good results,[2-7] and we also reported its usefulness through 'A Study on Breast Implant Reconstruction Using AlloDerm® Sling Technique: Effects on Clinical Course and Encapsulation' in 2009 (Journal of the Korean Society of Plastic and Reconstructive Surgeons Vol. 36, No. 6, 755-760).[8]

CG Derm™ (CG Bio Corp., Seoul, Korea) is allogenic acelluar dermal matrix for grafting made by processing human skin tissue obtained from domestic donors. CG Derm™ is for treating soft tissue defect in burns, abdominal wall reconstruction to treat hernia, and a product for above-mentioned breast reconstruction using implant has also been commercialized at Korea and is being used in surgery. However, no study has been reported on the clinical course after surgery that applied the

Received October 4, 2012
Revised October 12, 2012
Accepted October 15, 2012

Address Correspondence: Tai Suk Roh, M.D., Ph.D., Department of Plastic & Reconstructive Surgery, Gangnam Severance Hospital, Yonsei University College of Medicine, Seoul 135-720, Korea.
Tel: +82-2-2019-3420, Fax: +82-2-3463-4914, E-mail: rohts@yuhs.ac

*본 연구는 대웅바이오㈜(Daewoong Bio Incorp., Seoul, Korea)연구비 지원에 의하여 이루어졌음.

product to the implant based breast reconstruction.

Thus, we purposed to examine the clinical course of breast implant reconstruction using newly developed allogenic acellular dermal matrix CG Derm™ through a prospective study.

II. MATERIALS AND METHODS

A. Subject and material

The subjects of this study were six patients (eight cases of breast) who wanted breast reconstruction after mastectomy and gave an informed consent to the clinical experiment before surgery.

We excluded those who planned or had already had radiotherapy after mastectomy, those for whom implant insertion was impossible due to surgical site infection, and those suspected to have inflammation or systemic infection in preoperative examination (ESR>20mm/hr and CRP>6.0mg/L).

Tissue expander insertion and breast implant insertion using CG Derm™ were performed from June 2010 to December 2011. Three patients (3 cases of breast) had immediate reconstruction, and the other three patients (5 cases of breast) had delayed reconstruction. The mean age was 54.3 (48-61) and the mean BMI was 21.83 kg/m^2 (±1.08 kg/m2). The follow-up period ranged from 18 to 24 months and the mean follow-up period was 20.7 months. The cause of mastectomy was stage-0 breast cancer in two patients, stage-I breast cancer in three, and stage-II breast cancer in one, and all of them received total mastectomy.

Tissue expander used in the 1st operation was 350cc in seven cases, and 450cc in one case, and the mean inflation volume at the operating room was 122.5cc. For CG Derm™, we used one 1.04- 2.29mm in thickness and 13 x 4.75cm in the mean size. The period taken for tissue expansion was 5.3 months on the average, and the average volume after expansion was 300.6cc.

2nd operation(permanent breast implant insertion) was performed after 6 months on the average from the insertion of tissue expander. The used permanent breast implant was 275cc smooth round shape cohesive gel in four cases of breast, 325cc textured round shape cohesive gel in three cases, and 225cc textured round shape cohesive gel in one case(Table 1). None of the patients received radiotherapy after the surgery, and one patient (one case of breast) received chemotherapy.

B. Operation method

In case of immediate reconstruction, just after total mastectomy we used the incision line made in the mastectomy. And in case of delayed reconstruction, we incised over the scar left by the previous mastectomy.

The surgical procedure was the same as that described in the paper[8] that the present researchers published earlier, and the only difference was that the material was switched from AlloDerm® to CG Derm™.

After the surgical procedure was completed, CG Derm™ was fixed on the inferior margin of the origin of the separated pectoralis major muscle on the superior side, to the serratus anterior muscle on the lateral side, and to the chest wall on the medial and inferior side(Fig. 1). Before suture, we resected all wound margins suspected to have the possibility of necrosis because of congestion or inadequate perfusion during operation, and inserted a drain tube under the subcutaneous at the inframammary fold above CG Derm™. The drain tube was maintained until daily drainage became less than 30cc, and during the admission period the patient was received with venous or oral antibiotics.

C. Evaluation

To evaluate safety of CG Derm™ all patient examed complete blood cell count test, rountine chemisty(including ESR)

Table 1. Summary of Patients

Case	Age (Year)	Follow up (Month)	Diagnosis	BMI (kg/m^2)	Material (size: cm/Thickness: mm)	T/E (cc)	Initial inflation(cc)	Total inflation(cc)	Site	Timing	Breast Implant(cc)
Patient 1	50	24	IDC, stage I	23.44	4×14/1.04~2.29	450	100	360	Lt.	I	275, R,S
Patient 2	48	22	Mucinous carcinoma, stage I	21.1	5×14/1.04~2.29	350	200	310	Rt.	I	325, R,S
Patient 3	61	21	DCIS	21.69	4×13/1.04~2.29	350	100	265	Rt.	D	275, R,S
Patient 3	61	21	DCIS	21.69	5×13/1.04~2.29	350	100	255	Lt.	D	275, R,S
Patient 4	60	20	Mucinous carcinoma, stage I	22.03	6×12/1.04~2.29	350	100	250	Rt.	D	225, R,T
Patient 5	52	20	IDC, stage IIA	20.31	5×12/1.04~2.29	350	100	320	Rt.	D	325, R,S
Patient 5	52	20	ADH	20.31	5×12/1.04~2.29	350	100	290	Lt.	D	325, R,S
Patient 6	55	18	DCIS	22.43	4×14/1.04~2.29	350	180	355	Lt.	I	275, R,S
Mean	54.3	20.7		21.83	4.75×13/1.04~2.29	363	122.5	300.6			287.5

DCIS, Ductal carcinoma in situ; IDC, Invasive ductal carcinoma; ADH, Atypical ductal hyperplasia; T/E, Tissue expander; I, Immediate; D, Delayed; R, Round; S, Smooth; T, Textured.

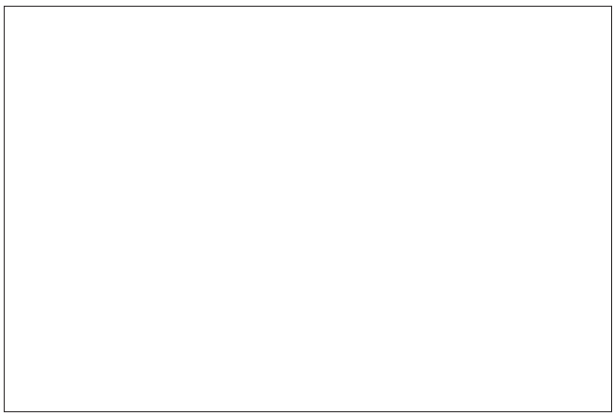

Fig. 1. Intraop (Tissue expander insertion) Implant was inserted beneath subpectoal-subAlloDerm dual-plane.

test, CRP test before the first surgical treatment, right before discharge and four weeks later of surgery. After first surgery, drain was checked every day. We defined seroma as over 30cc of drainage at a day after 10th postoperative day. Through all follow up period complications including infection, seroma, implant malpostion, inframammary fold asymmetry, rippling deformity, and capsular contracture were checked.

On patients' last outpatient visit, we conducted a questionnaire survey on the patients' subjective satisfaction with the shape of breast mound, overall satisfaction, and their intention to recommend to others, giving full score 10 for 'Very satisfied.' In addition, two different plastic surgeons made finial objective evaluation on breast mound shape, the presence of breast mound displacement (high score for less displacement), symmetry, the position of inflamammary fold, touch, rippling deformity, capsular contracture, overall progress, and general evaluation.

D. Magnetic resonance image examination

Selecting two out of the six patients at random, we took breast MRI after three month from the 2nd operation and confirmed that CG Derm™ was supporting the soft tissue of lower pole of reconstructed breast and that there was no capsular contracture or implant displacement.

Ⅲ. RESULTS

After the insertion of tissue expander, none of the eight cases of breast showed side effects such as wound infection at the surgical site, systemic infection, hypersensitivity, immunologic response, wound dehiscence at the surgical site, and any significant hematologic or serologic abnormal value, but four cases of breast in three patients showed seroma having over 30cc of daily drainage even after 10 days from the surgery and they were cured completely through conservative treatment.

In the interim evaluation of reconstructed breast conducted just before the insertion of permanent breast implant, the displacement of tissue expander was not observed but inflamammary fold was slightly asymmetric in two patients (two cases of breast), so it was corrected through inframammary fold repositioning during the 2nd operation. None of the cases had capsular contracture.

In the patients' subjective satisfaction surveyed on their last outpatient visit, the satisfaction level was 7.87 for mound shape, 7.4 for intention to recommend to others, and 7.4 for overall satisfaction(Table 2). The results of final evaluation by plastic surgeons were 8.25 for reconstructed breast mound shape, 8.63 for the displacement of reconstructed breast mound, 8.63 for the symmetry of reconstructed breast, and 8.25 for the position of inframammary fold. Touch of reconstructed breast was 8.38 out of 10, and rippling deformity and capsular contracture were not observed. The course evaluation was 8.63, and general evaluation 8.63(Table 3).

For three cases of breast in two patients, we took MRI after three month from the 2nd operation. Even though we could not figure out CG Derm™ exactly with MRI image, we observed sufficient breast lower pole soft tissue, not distorted implant shape and position, and normal capsule around implant in the mid clavicle sagittal view (Fig. 2).

Ⅳ. DISCUSSION

With the recently increasing incidence of breast cancer among young women in Korea, breast reconstruction using implant is spotlighted because it does not leave a scar in the donor site and its surgical procedure is simple. It is conducted usually through two stages, inserting tissue expander to expand insufficient skin tissue in the 1st operation and inserting implant

Table 2. Patients' Subjective Satisfaction Survey

Case	Mound shape	Intention to recommend to others	Overall satisfaction
Patient 1	8	7	7
Patient 2	9	8	8
Patient 3 (Rt.)	7	7	7
Patient 3 (Lt.)	8	7	7
Patient 4	7	7	7
Patient 5 (Rt.)	8	8	8
Patient 5 (Lt.)	8	8	8
Patient 6	8	7	7
Mean	7.87	7.4	7.4

Table 3. Evaluation by Plastic Surgen

Case	Mound shape	Displacement of reconstructed breast mound	Symmetry of reconstructed breast	Position of inframammary fold	Touch of reconstructed breast	The course evaluation	General evaluation
Patient 1	8	9	9	9	8	9	9
Patient 2	9	9	9	9	9	9	9
Patient 3 (Rt.)	7	8	8	7	8	8	8
Patient 3 (Lt.)	8	8	8	8	8	8	8
Patient 4	8	9	9	8	8	8	8
Patient 5 (Rt.)	9	9	9	8	9	9	9
Patient 5 (Lt.)	9	9	9	8	9	9	9
Patient 6	8	8	8	9	8	9	9
Mean	8.25	8.63	8.63	8.25	8.38	8.63	8.63

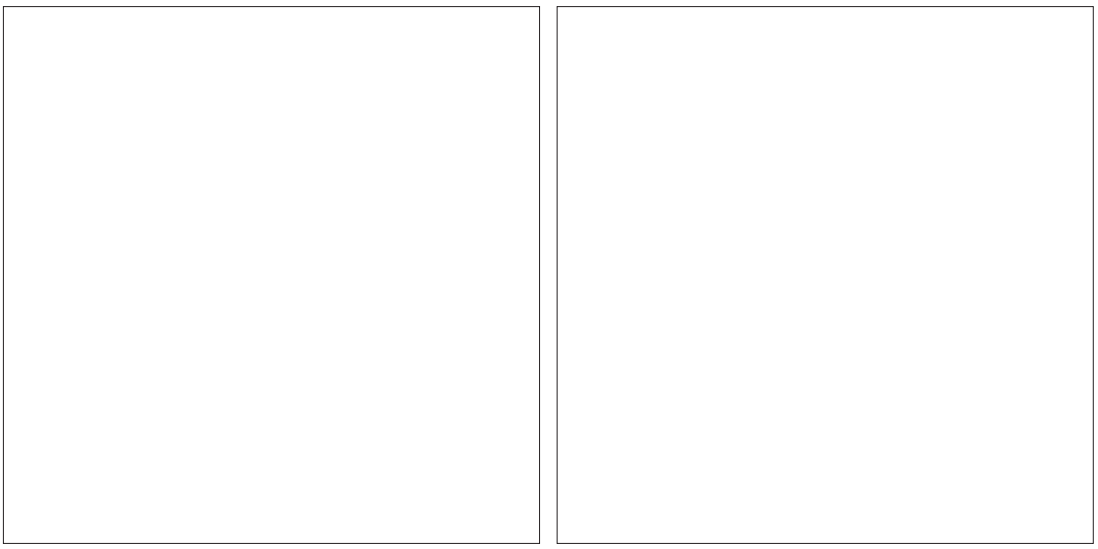

Fig. 2. 48/F patient. Comparison between preop (Left), 1st stage postop (5 month after Tissue expander insertion)(Right).

in the 2nd operation. In general, the superior part of tissue expander is placed below the pectoralis major muscle and its inferior part on the dual plane below the subcutaneous tissue. But Asian women have thin skin and subcutaneous tissue, the skin may be perforated while the tissue expander expands and, as a result, the implant can be exposed or bottoming out deformity can take place, and later when permanent implant is inserted it can be followed by complications such as rippling deformity.

In 2005, Breuning[1] introduced the AlloDerm sling technique that grafts AlloDerm on the inferior of pectoralis major muscle and then inserts implant into the pocket sub-pectoralis major muscle-subAlloDerm plane and, by doing so, fixes the position of inframammary fold firmly and obtains satisfactory reconstructed breast lower pole fullness. Since then, several studies reported cosmetically superior results without increasing other complications,[9,10] and according to a survey in the U.S. in 2010, 50% of implant breast reconstruction patients were operated by the AlloDerm sling technique.[11]

As pointed out by the authors[8] and de Blacam C et al.,[12] however, the high cost of AlloDerm increases the expense of implant breast reconstruction. Allogenic acelluar dermal matrix CG Derm™, which began to be produced in Korea in 2010 and is used in skin graft for burns and other skin wounds, is about 20% cheaper in unit price than AlloDerm. What is more, because it is thicker than AlloDerm (1.04~2.29 mm vs. 0.79~2.03 mm) its effect of soft tissue reinforcement is higher.

CG Derm™ is thicker than AlloDerm, it may takes a longer time for engraftment and the risk of failure in engraftment is higher, but in this study we observed grossly in the 2nd operation that CG Derm™ had been engrafted properly. And during clinical courses, hematologic or serologic problem was not occurred. In addition, there were no side effects such as the thinning and perforation of skin during tissue expansion, the downward displacement of the inframammary fold, the rippling deformity, and the capsular contracture, and these results correspond to the advantages of the AlloDerm sling technique (Fig. 3).

In the MRI of three cases of breasts taken after three month from the 2nd operation, the mid clavicle sagittal view showed that the superior part of the implant was covered with pectoralis major muscle and the inferior part was reinforced firmly with capsule formed with CG Derm™. The implant shape was not distorted and its' position was proper. With these results, surgeons gave 8.63 out of 10, which is a relatively high score, in their final evaluation, but the patients' subjective satisfaction in the questionnaire survey was 7.4, somewhat lower than the surgeons' evaluation. This is probably because patients' expectation for breast reconstruction is usually higher than surgeons' therefore it may be necessary to lower patients' excessively high expectation through giving a sufficient explanation before surgery.

In the results of this study, seroma occurred in four out of the eight cases of breast and this incidence is higher than that in other studies with AlloDerm (2.3~14.6%).[13] What is more, seroma was cured through conservative treatment without other complications, but considering that two cases of them received inframammary fold repositioning and one received capsulectomy in the 2nd operation, we cannot exclude the possibility that seroma might have a negative effect on the cosmetic outcome. Because the sample size was small, however, further larger-scale research may be necessary on how the incidence of seroma affects cosmetic outcomes in the use of CG Derm™.

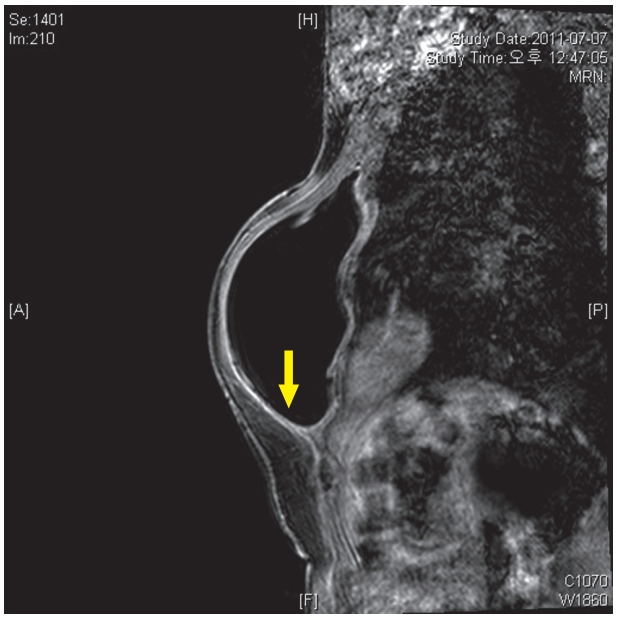

Fig. 3. 52/F patient's MRI mid clavicle saggital view. The upper part of breast implant coverd with pectoralis major muscle(*) and lower part of breast supported by capule consisted with CG DermTMTM (arrow). There is no capsular contracture or implant distortion. Sufficient breast lower pole thickness observed.

V. CONCLUSION

In implant breast reconstruction with CG Derm™, it was safe and simple procedure, its' aesthetic result was good, so it could another good choice in implant breast reconstruction. But in our study seroma formation was higher than previous report using AlloDerm, so it is need to more lager study require.

REFERENCES

1. Breuning KH, Warren SM: Immediate Bilateral Breast Reconstruction With Implants and Inferolateral AlloDerm Slings. *Ann Plast Surg* 55: 232, 2005
2. Gamboa-Bobadilla GM: Implant Breast Reconstruction Using Acellular Dermal Matrix. *Ann Plast Surg* 56: 22, 2006
3. Salzberg CA: Nonexpansive Immediate Breast Reconstruction Using Human Acellular Tissue Matrix Graft (AlloDerm). *Ann Plast Surg* 57: 1, 2006
4. Bindingnavele V, Gaon M, Ota KS, Kulber DA, Lee DJ: Use of acellular cadaveric dermis and tissue expansion in postmastectomy breast reconstruction. *Plast Reconstr Surg* 60: 1214, 2007
5. Breuing KH and Colwell AS: Inferolateral AlloDerm Hammock for Implant Coverage in Breast Reconstruction. *Ann Plast Surg* 59: 250, 2007
6. Zienowicz RJ, Karacaoglu E: Implant-Based Breast Reconstruction with Allograft. *Plast Reconstr Surg* 120: 373, 2007
7. Spear SL, Parikh PM, Reisin E, Menon NG: Acellular Dermis-Assisted Breast Reconstruction. *Ann Plast Surg* 59: 250, 2008
8. Yoon JH, Kim YS, Roh TS, Rah DK: Implant Breast Reconstruction using AlloDerm Sling; Clinical Outcomes and Effect to Capsular Formation. *J Korean Soc Plast Reconstr Surg* 36(6): 755-760, 2009
9. Preminger BA, McCarthy CM, Hu QY, Mehrara BJ, Disa JJ: The Influence of AlloDerm on Expander Dynamics and Complications in the Setting of Immediate Tissue Expander/Implant Reconstruction. A Matched-Cohort Study. *Ann Plast Surg* 60: 510, 2008
10. Vardanian AJ, Clayton JL, Roostaeian J, Shirvanian V, Da Lio A, Lipa JE, Crisera C, Festekjian JH: Comparison of implant-based immediate breast reconstruction with and without acellular dermal matrix. *Plast Reconstr Surg* 128(5): 403e-410e
11. Gurunluoglu R, Gurunluoglu A, Williams SA, Tebockhorst S: Current Trends in Breast Reconstruction: Survey of American Society of Plastic Surgeons 2010. *Ann Plast Surg* 22: 2011 [Epub ahead of print]
12. de Blacam C, Momoh AO, Colakoglu S, Slavin SA, Tobias AM, Lee BT: Cost Analysis of Implant-Based Breast Reconstruction With Acellular Dermal Matrix. *Ann Plast Surg* 16: 2011[Epub ahead of print]
13. Sbitany H, Serletti JM: Acellular dermis-assisted prosthetic breast reconstruction: a systematic and critical review of efficacy and associated morbidity. *Plast Reconstr Surg* 128(6): 1162-9, 2011