Outcomes of Porcine Acellular Dermal Matrix in Patients with Extensive Burn Scars

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Background: *Scar excision and wound coverage with skin graft is one of the standard techniques for treatment of burn scar contracture. However, patients with extensive burn scars might have limited donor areas for split thickness skin grafts. In the past 20 years, there have been many clinical innovations over the use of dermal regeneration template. But there were limited clinical studies of porcine acellular dermal matrix, especially in extensive burn scars.*
Objective: *This study was design to evaluate the outcomes of porcine acellular dermal matrix in patients with extensive burn scars.*
Material and Method: *Patients with more than 40% burn area that were admitted and received debridement and coverage with Pelnac® dermal substitute since January to December 2012 were enrolled in this study.*
Results: *8 extensive burns (9 burn areas) with a mean age of 25.5±10.26 years underwent debridement and coverage with Pelnac® dermal substitute. 4 patients (44.4%) were male and 4 patients (44.4%) were female. The mean burn percentage was 64.6±16.59% (range, 40 to 92%). The Vancouver scar scales at 3, 6 and 12 months of 8 patients and 9 burn areas had significant improvement after treatment (p-value ≤0.05). There was no infectious complication in this study.*
Conclusion: *The porcine acellular dermal matrix demonstrated the effective treatment outcomes in extensive burn patients with limited area of donor sites for skin graft.*

Keywords: *Porcine, Acellular dermal matrix, Post-burn scar, Scar treatment, Extensive burns*

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The previous literature had been reported that the incidence of burn injury from any cause was 7.1 per 100,000 cases/year[1]. The overall mortality rate was 4.4% and increased with burn size[2]. The current gold standard for deep burns treatment is surgical debridement and closure with autologous split thickness skin grafts or "STSG" (epidermis plus a thin layer of dermis). Nevertheless, donor areas are limited in extensive burns, and the residual scars are remained unsatisfied due to the lack of dermis[3-6]. An artificial skin system, composed of dermal and epidermal analogs designed to match with the goal to provide early wound coverage and minimize the need for autograft dermis, was developed from bovine collagen and approved by the Food and Drug Administration (FDA) of US government in March 1996 for use in acute burn injury[7]. The artificial dermis helped to decrease length of stay in two or more risk factor group[7], allowed more rapid wound closure with less contraction when applied with meshed split thickness skin graft[8]. Using split thickness skin autograft alone for releasing of contracture followed by resurfacing of tight, painful of keloid scars; unaesthetic scars[9-12]. In March 1996, there was reports of 10 human cases of a novel form of Creutzfeldt-Jakob disease in the United Kingdom, and its possible link to the agent that causes bovine spongiform encephalopathy (BSE) caused a major loss of confidence and disruption of trade in cattle and bovine products from the United Kingdom as well as in other countries where bovine spongiform encephalopathy (BSE) had been reported[13]. The religious and cultural differences need to be considered when using bovine tissues[3].

Within the past 20 years, there has been a large amount of clinical innovation over the use of dermal regeneration template. Evidence-based data suggests that this technology has great potential to

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simplify our reconstructive procedures and provide a durable and aesthetic reconstruction of human skin. But most of them were studied in animals and there were few studies on extensive burn patients[14-21]. There were many quantitative and qualitative measurement modalities to effectively evaluate and monitor treatments. The Vancouver scar scale remains widely applicable to evaluate therapy and as a measure of outcome in burn studies[22,23].

In this study, we evaluated the outcomes of porcine acellular dermal matrix in patients with extensive burn scars, assessed by the Vancouver scar scale. Furthermore, we assessed graft take rate, infection rate and patient satisfaction.

Material and Method

Authors performed a prospective study of 18 to 70 years old patients with extensive burn >40% total body surface area (TBSA) who had been treated in Siriraj burn unit between January to December 2012. Patients with chronic skin disease, diabetes mellitus, steroid usage, history of keloid scars and allergy to component of products were excluded. The study had been approved by the Institutional review board (IRB) of Siriraj Hospital. The surgical technique operation was done into 2 stages. The first stage operation, burn scars were excised deep into normal subcutaneous tissue in order to release the scar. The porcine artificial skin (Pelnac® as in Fig. 1) was tailored to fit the excised open wounds. It was sutured in place to the wound base with staples. It was compressed lightly with paraffin gauzes then thick gauze was covered as top dressing. The second stage operation was done at approximately 14 to 21 days after first operation in order to wait for neodermis formation. The silicone sheet on top of porcine artificial skin was peeled off then the harvested autologous thin 0.006 inches split thickness skin grafts were applied on the neodermal area. The thin split thickness grafts were fixed to the surrounding skin with staples.

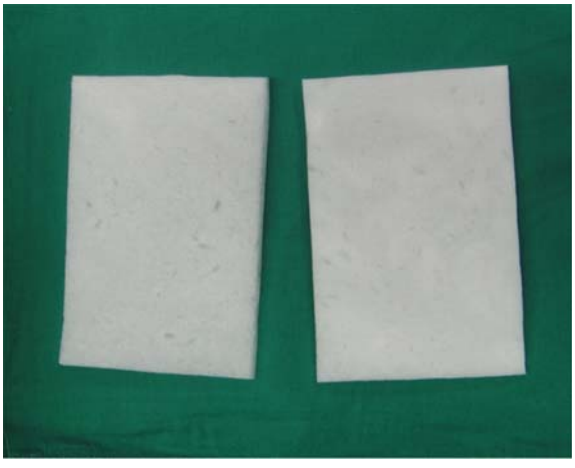

Fig. 1 Artificial skin sheet.

Data collection

After the first stage operation, the dermal matrix take rates were recorded. The split thickness skin graft take rates and infection rates were recorded at 2 weeks after the second stage operation. The Vancouver scar scales were recorded at 3 months, 6 months and 12 months after the second stage operations.

Statistical analysis

Data was analyzed by SPSS version 11.05. The paired Student's t-test and ANOVA were used to compare Vancouver scar scales of the preoperative scores with 3-month, 6-month and 12-month postoperative conditions. Statistical significance was determined by *p*-value less than 0.05. Mean and standard deviation were used for comparisons of percentage of dermal matrix take, skin graft take, infection rate, and patient satisfaction.

Results

There were 8 patients in this study and one of the patients had 2 areas of burn scars, so the number included in the study to analyze was 9 burn areas. The demographic data of this study were demonstrated in Table 1. Vancouver scar scales at the pre-operative and post-operative periods 3-month, 6-month and 12-month were analyzed with paired t-test and ANOVA as shown in the Table 2-4. The graph in the Fig. 2 demonstrated the reduction in mean VSS after treatment with the passing of time.

In the Table 3, the difference of VSS at 3, 6 and 12 months from the preoperative value were statistically significant (p-value ≤ 0.05).

The VSS were further analyzed with ANOVA and there also showed significant in statistics of VSS (p-value ≤ 0.05) as shown in the Table 4.

The secondary outcomes in this study, the mean of porcine dermal matrix take rate was 97.22 ± 1.92, the mean of split thickness skin graft take rate was 96.11 ± 4.43 and the mean of patient satisfaction score was 8.12 ± 0.64. There was no wound infection in the study.

Discussion

The porcine acellular dermal matrix used in this study improved the Vancouver scar scale significantly after treatment with the passing time. The result may explained from more physiologic like arrangement pattern of subcutaneous collagen fiber in the excision site if it was compared with the general scar excision site that covered only with more thickness of autologous skin graft. From more physiologic like pattern that created from artificial acellular matrix creation can make the scar after reconstruction more soft and flexible that expressed in the statistic significant

Table 1. Demographic data of the patients

Demographic data	Mean ± SD
Age (years)	25.5±10.26 (19-50)
Gender (male: female) (%)	44.4:44.4
Length of stay (days)	19.0±1.60 (17-22)
Percentage of burn area (%)	64.6±16.59 (40-92)

Table 2. Vancouver scar scales (VSS) at each time point

Vancouver scar scales	Mean ± SD
Preoperative	10.44±1.13
At 3 month	8.0±1.58
At 6 month	5.22±1.39
At 12 month	3.88±1.36

Table 3. Paired t-test of Vancouver scar scales

	Paired differences 95% confidence interval of the difference		t	df	*p*-value
	Lower	Upper			
Pair 1 VSS_0 to VSS_3	1.57555	3.31334	6.487	8	0.000
Pair 2 VSS_0 to VSS_6	4.29840	6.14605	13.035	8	0.000
Pair 3 VSS_0 to VSS_12	5.53066	7.58045	14.750	8	0.000

* VSS_0 mean pre-operative VSS, VSS_3 mean post-operative 3-month VSS, VSS_6 mean post-operative 6-month VSS, VSS_12 mean post-operative 12-month

Table 4. ANOVA analysis of the Vancouver scar scales at different times

(I) VSS	(J) VSS	Mean difference (I-J)	Std. error	*p*-value	65% confidence interval for difference	
					Lower bound	Upper bound
1	2	2.444	0.377	0.001	1.134	3.755
	3	5.222	0.401	0.000	3.829	6.616
	4	6.556	0.444	0.000	5.009	8.102
2	1	-2.444	0.377	0.001	-3.755	-1.134
	3	2.778	0.434	0.001	1.268	4.287
	4	4.111	0.351	0.000	2.889	5.333
3	1	-5.222	0.401	0.000	-6.616	-3.829
	2	-2.778	0.434	0.001	-4.287	-1.268
	4	1.333	0.333	0.024	0.174	2.493
4	1	-6.556	0.444	0.000	-8.102	-5.009
	2	-4.111	0.351	0.000	-5.333	-2.889
	3	-1.333	0.333	0.024	-2.493	-0.174

VSS mean Vancouver scar scales, VSS 1 mean pre-operative VSS, VSS 2 mean 3-month VSS, VSS 3 mean 6-month VSS, VSS 4 mean 12-month VSS

decrease of passing time Vancouver Scar Scale (VSS).

Hypertrophic scarring following burn injuries is a great concern for patients with deep burn injuries characterized as a raised scar above the skin level[28].This may cause significant functional and cosmetic impairments including symptoms of pruritus and pain, which are all responsible for a decrease in quality of life[29,30]. Previous studies reported diverging incidences of hypertrophic scarring. Incidence rate of scars is over 70% following burns and 40% with hypertrophic scars[31]. Using skin grafts and flaps in the reconstruction of movement functions is one of methods to treat post burn hypertrophic scars. Artificial dermis is a new modality to solve this problem especially in patient with large full thickness burn wounds and do not have enough healthy skin for donor site skin grafts[32-33].

Pelnac®, an artificial dermis, is made up of an outer silicone layer and inner porcine at elocollagen sponge layer. After the implantation of Pelnac® on to the wound, fibroblasts start to infiltrate into the inner collagen pores and new capillaries are formed within 2-3 weeks[33]. After this new dermal layer (neodermis) is formed with a new extracellular matrix, the outer silicone layer can be removed (after 2 to 3 weeks). This is then followed by ultra-thin split thickness skin graft implantation on top of the neodermal layer. The limited donor site can be harvested many times within a shorter period compared to regular split thickness skin graft because the harvested split thickness skin graft is ultra-thin. This material is very useful to surgeons for their surgical procedures in improving hypertrophic scars.

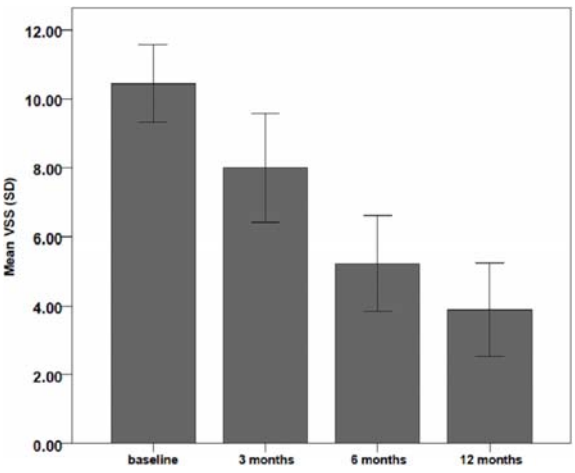

Fig. 2 The graph demonstrated the reduction of mean of Vancouver scar scales after treatment.

In this case report, we describe our experience in the reconstruction of scar contracture using artificial dermis (porcine collagen sponge) in a post burn patient with hypertrophic scar.

Scar contracture is the crucial problem after burn injuries. This problem is always challenging to the physicians taking care of these patients. Generally, there are various methods to prevent and treat hypertrophic scar such as topical agents, steroid injection, pressure garment and surgery. The proper treatment of severe scar contracture is by surgical procedure in order to release the skin tension and sometimes correct limitation of joint movement that can improve functions at last.

Artificial bilayer dermis (graft for dermal defect) "Pelnac®" is composed of an inner sponge layer of atelo-collagen and an outer layer of silicone. It can be used in acute burn treatment and burn reconstruction procedures, or used as a single layer in trauma cases and other skin loss areas after surgery in tumor or nevus removal. Previous literatures had reported that it is very effective in both functional and cosmetic benefits[34-36]. The contracture of defects is found to be insignificant[26]. In this our studies showed much benefit to improve joint range of motion especially in hands and feet as 2 cases demonstrated in Fig. 3, 4. We have shown that Pelnac® is beneficial for scar reconstruction especially when patients have a large burn area and do not have enough healthy skin graft area for application to the wound after scar excision.

Conclusion

The porcine acellular dermal matrix had the effective treatment outcomes in extensive burn patients with limited area of donor sites for skin graft.

What is already known on this topic?

Extensive burn injury patient faced problem with the shortage of healthy donor sites skin graft to coverage the wounds.

What this study adds?

The porcine cellular dermal matrix was a one of the effective option in extensive burn treatment that had limited area of donor sites skin graft.

Potential conflicts of interest

None.

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Fig. 3 A 17-year old girl got burn total 70% TBSA at trunk and both legs and feet 3 years ago. She got scar contracture at both feet that limit her walking and difficulty for wearing shoes. A) Pre-operative status, B) After first operation; Pelnac® placement (right foot), C) After second operation; thin skin graft (right foot), D) After second operation; thin skin graft, E) 3 month follow-up, she can walk and wear shoes comfortably.

Fig. 4 A 40-year old man got burn total 47% TBSA at trunk both arms and both legs. 2 years later he got scar contracture at right knee that limit his walking and right knee extension. A) Scar contracture at right popliteal area that limit knee extension, B) After scar excision, C) After Pelnac® placement.

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ผลการรักษาผู้ป่วยที่มีแผลเป็นขนาดใหญ่จากการถูกไฟไหม้ด้วยการใช้ผิวหนังสังเคราะห์จากเนื้อเยื่อหมู

พรพรหม เมืองแมน, เจษฎา เวชวิทยานุกูล, กุสุมา ชินอรุณชัย, เลิศพงศ์ สมจริต, จตุพร ศิริกุล, เรวัต ชุณหสุวรรณกุล

ภูมิหลัง: *การผ่าตัดแผลเป็นปลูกถ่ายผิวหนังเป็นการรักษาวิธีมาตรฐานวิธีหนึ่งในการรักษาแผลเป็นหดรั้งที่เกิดหลังไฟไหม้ แต่ปัญหาที่พบในผู้ป่วยแผลไหม้ที่มีการบาดเจ็บขนาดใหญ่คือไม่สามารถหาบริเวณของผิวหนังปกติที่จะสามารถนำมารักษาปลูกถ่ายได้ วิทยาการเพื่อพัฒนาการรักษาด้วยการใช้ผิวหนังสังเคราะห์มีการพัฒนาและศึกษามาตลอดระยะเวลา 20 ปี แต่ข้อมูลดังกล่าวยังค่อนข้างจำกัดสำหรับกลุ่มผู้ป่วยแผลเป็นเกิดหลังแผลไหม้ที่มีการบาดเจ็บขนาดใหญ่*

วัตถุประสงค์: *การศึกษานี้ถูกออกแบบมาเพื่อประเมินผลการรักษาผู้ป่วยแผลเป็นเกิดหลังแผลไหม้ที่มีการบาดเจ็บขนาดใหญ่ ด้วยการผ่าตัดใช้ผิวหนังสังเคราะห์จากเนื้อหมู*

วัสดุและวิธีการ: *ศึกษาถึง Vancouver scar scales ก่อนทำการผ่าตัด หลังการผ่าตัดที่ 3, 6 และ 12 เดือน ของผู้ป่วยแผลไหม้ที่มีขนาดการบาดเจ็บมากกว่า 40 เปอร์เซนต์ของพื้นที่ผิวร่างกายที่มารักษาตัวในหอผู้ป่วย Burn Unit โรงพยาบาลศิริราชตั้งแต่ เดือนมกราคม ถึง เดือนธันวาคม พ.ศ. 2555 ที่ได้รับการผ่าตัดปิดแผลด้วยการใช้ผิวหนัง สังเคราะห์จากเนื้อหมู (Pelnac®)*

ผลการศึกษา: *ผู้ป่วยแผลไหม้ที่มีขนาดการบาดเจ็บมากกว่า 40 เปอร์เซนต์ของพื้นที่ผิวร่างกายจำนวน 8 ราย เป็นจำนวนแผลไหม้ 9 แผลเป็นกลุ่มตัวอย่างในการศึกษา เป็นผู้ป่วยชาย 4 ราย (44.4%) และผู้ป่วยหญิง 4 ราย (44.4%) อายุเฉลี่ยของกลุ่มตัวอย่างมีค่า 25.5±10.26 ปี ขนาดแผลไหม้โดยเฉลี่ย 64.6±16.59 เปอร์เซนต์ ของพื้นที่ผิวร่างกาย (40 ถึง 92%) ผู้ป่วยได้รับการผ่าตัดแก้ไขแผลเป็น ปิดแผลด้วยการใช้ผิวหนังสังเคราะห์จากเนื้อหมู (Pelnac®) ผลการรักษาดีอย่างมีนัยสำคัญทางสถิติจากการประเมินด้วย Vancouver scar scales ที่ 3, 6 และ 12 เดือน (p-value ≤0.05) โดยไม่พบภาวะติดเชื้อ*

สรุป: *การรักษาผู้ป่วยแผลเป็นเกิดหลังแผลไหม้ที่มีการบาดเจ็บขนาดใหญ่ที่มีปัญหาขาดแคลนผิวหนังในการปลูกถ่ายด้วยการผ่าตัดใช้ผิวหนังสังเคราะห์จากเนื้อหมูให้ผลการรักษาที่ดี*