CLINICAL EVALUATION OF A NEW BILAYER ARTIFICIAL DERMIS FOR REPAIR OF ORAL MUCOSAL DEFECTS: REPORT OF TWO CASES

Chun-Ming Chen, Chia-Fu Yang, I-Yueh Huang, Yee-Shyong Shen, Tien-Yu Shieh, Chung-Ho Chen, and Huey-Er Lee

Department of Oral Maxillofacial Surgery and ¹School of Dentistry, Kaohsiung Medical University, Kaohsiung, Taiwan.

Free mucosal grafts or split-thickness skin grafts have been used in patients undergoing repair procedures for oral mucosal defects. Conventional methods require the creation of second surgical wounds for use as donor sites. We applied two bilayers of artificial dermis to repair a buccal mucosal defect in one case and vestibular extension in another case. After removal of the sutures, no infection, pain, or hemorrhage developed in these patients. The results of granulation and epithelialization were good. Satisfactory appearance and function were achieved in both cases. Therefore, bilayer artificial dermis may be recommended for the repair of oral mucosal defects.

Key Words: artificial dermis

Collagen is considered one of the most suitable materials for constructing artificial substitutes for diseased or damaged tissues and organs. Collagen-based grafts have often been used as major components of artificial tissue substitutes [1]. Yannas and Burke first developed an artificial dermis, which seemed unique because of its ability to induce a dermis-like tissue layer, and seemed to have advantages over previous similar membranes, which served merely as a temporary skin cover [2]. The bilayer artificial skin consisted of a complex of collagen and chondroitin sulfuric acid (a glucosaminoglycan, GAG) with a silicone membrane. Since then, extensive research on various modifications have shown that the spongy collagen matrix is gradually replaced by host tissue [3,4]. Terudermis™ (Terumo Corp, Tokyo, Japan) is a bilayer artificial graft for patients with dermal defects [1,5]. It is similar to the collagen-GAG/silastic bilayer membrane developed by Yannas and Burke [2], but its antigenicity has been modified in order to reduce the inflammatory response and increase cellular affinity. It is composed of an outer layer of silicone and an inner spongy layer of collagen (Figure 1).

Figure 1. Bilayer artificial dermis: superior layer of silicone membrane (about 100 µm) and inferior collagen sponge layer (3 mm).
There are few reports of the application of Terudermis™ in Taiwan. The purpose of this report was to evaluate the usefulness of artificial dermis grafts for oral mucosal defects.

**Case Presentation**

**Case 1**
A 51-year-old male complained of a white lesion over the left buccal mucosa for an unknown duration. Oral examination showed a 20 × 15 mm whitish exophytic and rough surface lesion, which could not be rubbed off, on the left buccal mucosa. Pan-oral fibrous bands prevented the mouth from opening beyond 30 mm from the incisal edge of tooth 8 to tooth 25. Biopsy showed verrucous hyperplasia with submucosal fibrosis of the left buccal mucosa. Under general anesthesia, the lesion was excised to about 25 × 20 × 15 mm (Figure 2), and an appropriate-sized piece of Terudermis™ was placed directly on the wound (Figure 3). A transkin fixation technique was used to hold the graft firmly to its bed. During the operation, maximum mouth opening was increased to 37 mm. The postoperative course was unremarkable. The sutures and silicone membrane were removed on the seventh postoperative day, when the surface of the left buccal mucosal wound was covered with granulation tissue. Re-epithelialization proceeded with minimal contraction of the wound. Lack of jaw-opening exercise was believed to be responsible for relapse. Therefore, long-term postoperative care with mouth-opening exercises was necessary. Follow-up for 14 months showed no evidence of recurrence. Maximum mouth opening was slightly increased to 38 mm (Figure 4).

**Case 2**
A 66-year-old male presented with inflammatory hyperplastic tissue along the margins of an ill-fitting maxillary long-span bridge, due to irritation by the ill-fitting edge of the bridge that extended from the left maxillary molar to the premolar area (Figure 5). There was extensive loss of the vestibule in the posterior area of the left edentulous maxilla. An incision was made in the mucosa at the gingivobuccal fold, and care was taken to cut only through the mucosa, not through the periosteum. The mucosa was supraperiosteally dissected upward, and the vestibule was adequately extended. Terudermis™ was cut to fit the extension area and reflected area (about 15 × 20 mm), placed directly on the wound, and sutured into place as a mucosal substitute. A tie-over bolus dressing and transkin sutures were used to hold the graft firmly to its bed. The transkin sutures and silicone membrane were removed on the seventh postoperative day, when the surface of the left buccal mucosal wound was covered with granulation tissue. Re-epithelialization proceeded with minimal contraction of the wound. Lack of jaw-opening exercise was believed to be responsible for relapse. Therefore, long-term postoperative care with mouth-opening exercises was necessary. Follow-up for 14 months showed no evidence of recurrence. Maximum mouth opening was slightly increased to 38 mm (Figure 4).
postoperative day. Granulation and epithelialization were good in the entire wound. The patient was followed for 6 months with little relapse, and 10 mm of vestibular depth was created (Figure 6).

**DISCUSSION**

When a small oral mucosal defect needs to be repaired, the first choice of procedure should be one where the neighboring mucosa can be advanced to the defect. A large oral mucosal wound is difficult to cover using the primary closure method because it may result in limitation of mouth opening. Autogenous skin graft is widely used in reconstructive surgery and usually produces good results. However, this method involves secondary damage to the donor site, so various biomaterials have been developed to satisfy patient choice or resolve problems with potential donor sites.

A new type of collagen-based artificial dermis (Terudermis™) is produced by physicochemical modification of collagen to increase cellular affinity. Matsui et al reported the histologic evaluation of skin reconstruction in rats using Terudermis™ [6]. They found that collagenous material composed of fibrillar collagen and heat-denatured collagen with dehydrothermal cross-linking produced remarkably enhanced infiltration of fibroblasts and capillaries in the early stages, and as a result, promoted the reconstruction of connective tissue. Omura et al reported the effective repair of oral mucosal defects using Terudermis™ after operations for cancer in five patients [7]. In our Case 1, repair was effective, and the postoperative mouth-opening exercise program proved important as a means of maintaining or increasing mouth-opening capacity.

Various techniques of vestibuloplasty have been used to extend the labiobuccal vestibule to provide sufficient soft-tissue covering for the residual ridge [8]. These include submucosal advancement vestibuloplasty, secondary epithelialization (re-epithelialization) vestibuloplasty, and grafting vestibuloplasty. The disadvantages of submucosal advancement vestibuloplasty and secondary epithelialization vestibuloplasty, including unpredictability of the amount of relapse of the vestibular depth, scarring in the depth of the vestibule, and discomfort, occur with longer healing times. Free palatal grafts or split-thickness skin grafts have conventionally been used for vestibular extension. The main disadvantage of autogenous grafting is the necessity of a second wound at the donor site and the discomfort that can occur during the postoperative period. Bessho et al used Terudermis™ for oral vestibular extension in 50 patients [5]. No side effects were reported by any patients, possibly because atelocollagen was used, which has shown reduced antigenicity compared with conventional insoluble collagen. The investigators found that the degree of contracture was similar to that seen with autogenous mucosa or free skin grafts. Therefore, Terudermis™ might be an alternative artificial graft for vestibular extensions. The result in Case 2 was similar to Bessho et al’s report. However, the non-keratinized epithelium that grows over Terudermis™ cannot be keratinized. Keratinized mucosa can more readily withstand the rigors of mastication.

In conclusion, the new bilayer artificial dermis originally developed to cover dermal defects in patients undergoing

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**Figure 5.** Multiple fissured masses of inflammatory hyperplastic tissue in the left posterior maxillary vestibule.

**Figure 6.** At the follow-up appointment 6 months postoperatively, the wound has healed with little relapse and there is 10 mm of vestibular depth.
plastic surgery has recently been evaluated for its application in oral surgery. In our two cases, there was no evidence of partial necrosis, wound infection, or mouth-opening limitation. The postoperative course was unremarkable and the repair was effective. Thus, Terudermis™ is an alternative to free mucosal grafts or split-thickness skin grafts in the repair of oral mucosal defects.

REFERENCES

新型雙層人工真皮修補口腔黏膜缺損之臨床評估的修補 — 2 病例報告

陳俊明¹ 杨家福¹ 黄逸岳¹ 沈兆雄¹ 謝天瑜¹ 陳中和¹ 李惠娥²
高雄医学大学 ¹口腔颚面外科 ²牙醫學系

針對手術後口腔黏膜的缺損，傳統的方法是利用口腔黏膜移植片，或是裂層皮膚移植片，來做為缺損處的修補，但是這些方法都需要有採取組織的供給部位，因而產生第二個手術的傷口，而且手術時間也會延長。膠原組織是一種很合適的生物性材料，已經在臨床上廣泛做為修補受損組織和器官的一種人工替代物。本篇提出一種新型人工真皮，它是以膠原組織為主要的支架，透過生化技術的改良，降低抗原反應以及增進細胞長入膠原組織的能力，進而引導軟組織的生長。本篇提出二例使用人工真皮，用來修補口腔黏膜手術後的缺損，其中一例是用在修補口腔黏膜良性上皮病變切除後的缺損，另一例是用在口腔前庭加深的術後，這二位病人經過術後的定期追蹤，我們發現修補後其口腔黏膜的功能與美觀，均有不錯的效果，因此我們認為此種新型的人工真皮，是可用在修補手術後口腔黏膜缺損的一種組織替代物。

關鍵詞：人工真皮
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通訊作者：陳俊明醫師
高雄醫學大學口腔顱面外科
高雄市 807 三民區十全一路 100 號