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# The use of heterogeneous acellular dermal matrix in the closure of hard palatal fistula



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ABSTRACT

*Objective:* The aim of this study was to evaluate the efficacy of closure of hard palatal fistula using Heal-All<sup>®</sup> Oral Biofilm, a heterogeneous acellular dermal matrix graft.

*Patients and methods:* Superior lip mucosal or myomucosal flap and buccal myomucosal flap were used in 20 patients (group 1) (2000–2005); whereas, heterogeneous acellular dermal matrix graft was performed in 18 patients (group 2) (2005–2013). The recurrence in the closed fistula and the obliteration of gingivolabial and gingivobuccal sulci were seen postoperatively with follow-up appointments at 1–3 months for all cases.

*Results:* The recurrence rate of hard palatal fistula has been reduced from 25 to 11.1% with the use of heterogeneous acellular dermal matrix graft, and the rate of the obliteration of gingivolabial and gingivobuccal sulci has been decreased from 90 to 5.5%.

*Conclusions:* Closure of hard palatal fistula using Heal-All<sup>®</sup> Oral Biofilm graft is a useful method with high success rate. It is a day-case procedure especially to avoid dividing the pedical of the flap after follow-up, and the gingivolabial and gingivobuccal sulci do not need further procedures to deep with follow-up. © 2013 Elsevier Ireland Ltd. All rights reserved.

#### 1. Introduction

The hard palatal fistula often occurs after the primary palatoplasty and the resection of palatal tumours at the hard palate such as cystic defects of maxillary. It is a clinical common postoperative complication [1]. It has a very serious influence to the patient's eating and pronunciation which seriously impacts the quality of life of the patient [1].

The incidence of fistula occurrence after palatoplasty has been reported to range from 10 to 20% [2]. The incidence of palatal fistula after cleft palate repair in our cleft palate population was about 2.33% [3]. There were very few reports in the literature about the incidence of hard palatal fistula following the resection of tumours; however, in the oral and maxillofacial surgical practice, the case of palatal fistula occurs frequently, the clinical presentation usually opens to the maxillary sinus. Therefore, it makes the repairing more difficult. Several techniques have been described to treat the hard palatal fistula with good results such as a local mucoperiosteal flap [4], V-Y two-layer repair [5], superior lip mucosal or myomucosal flap [6], buccal myomucosal flap [7,8], superiorly based facial artery muscolomucosal flap [9], tongue flap and free flap (such as a folded radial forearm free flap) [10,11].

Heterogeneous Acellular Dermal Matrix (Heal-All<sup>®</sup> Oral Biofilm, Zhenghai Biological Technology Co. Ltd., Yantai, China) has been utilized extensively in repairing oral mucosa and soft tissues defects [12,13], in dental implant as guided bone regeneration materials [14], in good ossification with an ability of anti-infection and in reducing incidence of Frey syndrome [15,16]. We have used Heal-All<sup>®</sup> Oral Biofilm graft for closure of hard palatal fistula since Janurary 2005. The purpose of this study was to evaluate the efficacy of closure of hard palatal fistula using Heal-All<sup>®</sup> Oral Biofilm graft, a heterogeneous acellular dermal matrix graft.

#### 2. Patients and methods

#### 2.1. Patients

This study was conducted on 38 patients who had hard palatal fistula for more than six months after repair of cleft palate or the resection of tumour at the hard palate. Their ages ranged from 2 to 69 years with a mean age of 15 years and 8 months; 22 patients were males and 16 patients were females. All cases were collected from the oral and maxcillofacial surgery outpatient clinic of the Hunan Provincial People's Hospital in the period from January 2000 to January 2013. The original defects in our patients included 36 children as a complication for cleft palate repair and 2 adults' cases for resection of the hard palatal tumour. Patients with history of previous radiation were excluded. The length of hard palatal fistula ranged from 5 to 18 mm. The charts of all cases were

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reviewed. In group 1, twenty patients underwent hard palatal fistula repair using superior lip mucosal or myomucosal flap and buccal myomucosal flap between January 2000 and January 2005. In group 2, eighteen patients were closed by using Heal-All<sup>®</sup> Oral Biofilm graft (heterogeneous acellular dermal matrix) between January 2005 and January 2013. Two groups of patients in age, gender and the length of fistula had no statistically significant differences (P > 0.05). The study was approved by the Institutional Review Board of Hunan Provincial People's Hospital; and, informed consents were obtained from the parents of the minor patients and agreed by the adult patients.

#### 2.2. Materials

Heterogeneous acellular dermal matrix graft (Heal-All<sup>®</sup> Oral Biofilm, Zhenghai Biological Technology Co. Ltd., Yantai, China) was chosen. All biofilm grafts are B type with thicknesses ranging from 0.30 to 0.69 mm and stripping formers being sterile products. There is an UP surface which is a layer of basement membrane for all biofilm grafts. Different specifications of the biofilm graft were selected according to the size of fistula. Commonly used sizes were  $2 \times 2.5$  cm and  $3 \times 4$  cm. The length and width of biofilm graft were tailored according to the size of fistula during the operation.

#### 2.3. Operation methods

There were no upper respiratory tract infection and no ulcer at the hard palatal mucosa for all patients (Fig. 1). Most of the patients



Fig. 1. The hard palatal fistula follow-up with the resection of palatal tumours.

were subjected to closure of the fistula under general anesthesia with oral endotracheal intubation. One of the adult patients was under local annesthesia. A Dingmans mouth gag was introduced during this process. In group 2, the closure of fistula was carried out in 3 layers. The first layer was the mucoperiosteal flap around the fistula which was elevated as bilateral hinge flaps. Both flaps were inverted so that the mucosal surface faced the nasal cavity and



Fig. 2. Steps of the operation. (A) The mucoperiosteal flap was elevated and inverted covering the nasal side of the fistula. (B) The bilateral hinge flaps were sutured together using 4-0 Vicryl. (C) Oral Biofilm graft covering the surface of the first layer. (D) The oral mucoperiosteal flap was elevated from the side of fistula and transposed to cover Oral Biofilm graft.

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