



# **IDEAS AND INNOVATIONS**

Pediatric/Craniofacial

# Cleft Palate Fistula Closure Utilizing Acellular Dermal Matrix

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**Summary:** Fistulas represent failure of cleft palate repair. Secondary and tertiary fistula repair is challenging, with high recurrence rates. In the present retrospective study, we review the efficacy of using acellular dermal matrix as an interposition layer for cleft palate fistula closure in 20 consecutive patients between 2013 and 2016. Complete fistula closure was obtained in 16 patients; 1 patient had asymptomatic recurrent fistula; 2 patients had partial closure with reduction of fistula size and minimal nasal regurgitation; 1 patient developed a recurrent fistula without changes in symptoms (success rate of 85%). We conclude that utilizing acellular dermal matrix for cleft palate fistula repair is safe and simple with a high success rate. (*Plast Reconstr Surg Glob Open 2018;6:e1682; doi: 10.1097/GOX.000000000001682; Published online 13 March 2018.*)

### **INTRODUCTION**

Postoperative presence of a fistula represents failure of cleft palate repair. The major symptoms associated with fistulas are nasal regurgitation and speech problems. The incidence of postoperative fistula following primary cleft palate repair ranges from 0% to 58%,<sup>1</sup> but at leading centers is expected to be under 10%.<sup>2</sup>

Fistula formation is associated with reduced vascularity and scar tissue; even areas at a distance from the repair, though not burdened with a scar, may still have restricted motility, making tension-free closure, the hallmark of effective palate repair, challenging at best and impossible in certain cases.<sup>3,4</sup> As a result, the prognosis for successful fistula closure declines with each added attempt at the repair site.<sup>5–8</sup>

To close secondary and tertiary palatal fistulas, the surgeon needs to perform a 3-layered, tension-free closure.

From the \*Department of Oral and Maxillofacial Surgery, Rambam Health Care Campus, Haifa, Israel; †Bruce Rappaport Faculty of Medicine, Technion - Israel Institute of Technology, Haifa, Israel; ‡Division of Pediatric Plastic Surgery, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio; and \$Department of Orthodontics, Rambam Health Care Campus, Haifa, Israel.

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The name of the trial registry and the registration number: Cleft Fistula Closure Using Dermal Graft. 0672-15-RMB.

Copyright © 2018 The Authors. Published by Wolters Kluwer Health, Inc. on behalf of The American Society of Plastic Surgeons. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal. DOI: 10.1097/GOX.00000000001682 Often this is achieved by interposing grafts of bone, cartilage, fascia, and fat.<sup>9-12</sup> This additional tissue provides a mechanism for tension-free closure and is a safety net against a possible oral layer breakdown of the closure. However, tissue grafts also result in donor-site morbidity with potential cosmetic problems. Allograft material, such as acellular dermal matrix (ADM), resolves these potential complications. In the present study, we retrospectively review the efficacy of using ADM for cleft palate fistula closure.

# **MATERIALS AND METHODS**

Twenty consecutive patients underwent palate fistula closure utilizing ADM from 2013 to 2016; each patient was assigned a Veau palate designation and a Pittsburgh fistula classification.

All patients were treated under general anesthesia using the following techniques depending on the size (large > 10 mm, medium 5–10 mm, and small < 5 mm) and location of the fistula: two-flap palatoplasty, von Langenbeck, or rotational flaps. ADM was shaped according to the fistula size, then firmly sutured to the nasal layer, followed by closure of the oral layer in a tension-free manner. Postoperatively, patients were seen regularly for at least 6 months and assessed with respect to infection, dehiscence, graft rejection, and fistula recurrence.

#### RESULTS

Table 1 presents a summary of the results for the 20 patients studied, including 11 females and 9 males. Mean patient age was 13.9 years, ranging from 2 to 43 years. The mean length of follow-up was 9.7 months. The initial

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Table 1. Patients Demographic Data and Outcome

Patient Number	Sex	Type of Original Cleft	Veau Classification	Pittsburgh Fistula Classification	Fistula Size	Age at ADM (y)	Fistula Repair Technique	Follow-up (mo)	Outcome
1	М	BLCLP	IV	IV	Large	12	А	23	Complete closure
2	Μ	BLCLP	IV	III	Small	24	С	12	Complete closure
3	F	BLCLP	IV	III	Large	22	В	17	Complete closure*
4	F	BLCLP	IV	V	Large	9	А	13	Recurrence
5	F	BLCLP	IV	V	Medium	4	А	11	Complete closure
6	F	BLCLP	IV	V	Large	43	А	11	Complete closure
7	F	ULCLP	III	IV	Large	11	А	6	Complete closure
8	Μ	BLCLP	IV	V	Large	9	Α	6	Complete closure*
9	F	BLCLP	IV	III	Medium	9	Α	6	Complete closure
10	F	SHP	II	III	Large	19	Α	6	Complete closure
11	Μ	ULCLP	III	IV	Large	16	Α	6	Partial closure
12	Μ	BLCLP	IV	IV	Large	20	А	7	Partial closure
13	F	BLCLP	IV	V	Large	8	А	7	Complete closure
14	F	BLCLP	IV	V	Large	17	А	6	Complete closure
15	F	SHP	II	III	Medium	3	В	6	Complete closure
16	Μ	BLCLP	IV	III	Small	20	С	21	Partial closure†
17	М	BLCLP	IV	IV	Medium	16	А	11	Complete closure
18	Μ	ULCLP	III	V	Medium	17	А	6	Complete closure
19	Μ	ULCLP	III	III	Large	6	В	7	Complete closure
20	F	ULCLP	III	IV	Large	2	А	6	Complete closure

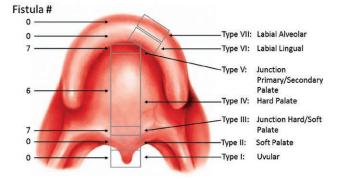
\*Oral dehiscence.

†Asymptomatic fistula.

A, two-flap palatoplasty; B, von Langenbeck; BLCLP, bilateral cleft lip and palate; C, rotational technique; F, female; M, male; SHP, soft and hard palate cleft; ULCLP, unilateral cleft lip and palate.

Veau classification diagnosis for these patients included 13 with Veau IV clefts (65%), 5 type III (25%), and 2 type II (10%). Pittsburgh fistula designation included 7 type III (junction of hard and soft palate), 6 type IV (within the hard palate), and 7 type V (at the junction of the primary and secondary palates; Fig. 1). Most of the fistulas were larger than 10 mm (65%).

The two-flap palatoplasty was predominantly utilized for fistula repairs (15 of 20). Pittsburgh type IV and V fistulas were repaired exclusively by two-flap palatoplasty technique; Pittsburgh type III were repaired utilizing the von Langenbeck (3), two-flap palatoplasty (2), and rotational (in 2 small fistulas) techniques. Complete fistula closure was obtained in 16 patients (80%; Fig. 2); 2 of whom had temporary dehiscence of the oral mucosal layer that subsequently healed without evidence of fistula. Three patients (15%) had partial closure with reduction of the fistula size and minimization of symptoms; 1 of these 3 patients had significant reduction in fistula size and was no longer symptomatic. One patient (5%) had recurrent fistula without improvement in size or



**Fig. 1.** Location-based fistula Pittsburgh classification before fistula repair with ADM.

extent of nasal regurgitation. The recurrent fistula locations included 1 at the junction of the primary and secondary palates (type V), 2 in the hard palate (IV), and 1 at the junction of the hard and soft palate (III).

#### DISCUSSION

Indications for fistula repair are generally related to the symptomatic presentation including hypernasality and nasal regurgitation of oral contents. Although fistula repair has been demonstrated to improve these symptoms,<sup>13</sup> often these fistulas are simply not repaired. The patient and family "make their peace with the fistula" or may opt for a palatal appliance that covers the fistula.<sup>14,15</sup> However, an obturator is associated with low patient compliance and often provides an insufficient seal, especially as the patient ages.<sup>16</sup> Consequently, surgical treatment continues to be the most advocated and effective method for fistula closure.<sup>17</sup>

Following the initial report by Clark et al.<sup>18</sup> of ADM utilized to close a palatal fistula in a single patient, several studies have been published.<sup>19-24</sup> ADM, derived from human skin, is devoid of antigenic factors, but preserves dermal elements. Following implantation, cellular components from the host migrate into the ADM without immune rejection.<sup>25</sup>

In this study, we used the two-flap palatoplasty technique for type IV and V fistulas. For type III fistulas, we used all 3 techniques, depending on the fistula size. Rotational flap techniques were used in smaller fistulas.

The site most likely for fistula recurrence following fistula repair is generally at the junction of the primary and secondary palate (type V)<sup>26</sup>; however, in our study, similarly to Landheer et al.<sup>27</sup> 2 fistulas were present within the hard palate (type IV), 1 at the junction of hard and soft palate (type III), and 1 at the junction of the primary and secondary palate (type V). In this series, we achieved complete fis-

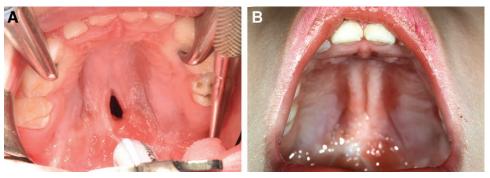


Fig. 2. A, Clinical photograph showing cleft palate fistula before repair with ADM. B, Two months postoperatively showing complete fistula closure.

tula closure in 16 of 20 patients. Of the 4 patients with fistula recurrence, 1 repair failed and was repaired using a tongue flap. Overall, we had 3 symptomatic fistulas (15%) and a success rate of 85%, with fistula distributions by Pittsburgh classification similar to those seen in other publications. These results are favorable compared with both non-ADM fistula repair recurrence rates (33–37%),<sup>19,28</sup> and the most recent reports of fistula repair with ADM (20–33%).<sup>26,29</sup>

In addition to the tension-free closure achieved by interposing autografts, the ADM provides a scaffold for tissue ingrowth, revascularization, and mucosal epithelialization without any evidence of donor-site morbidity or immunologic rejection and the expense of additional surgery time.

# **CONCLUSIONS**

Utilizing ADM for cleft palate fistula repair as an interposition layer is a safe and simple procedure that reduces fistula recurrence compared with closures without ADM. A larger, prospective, randomized trial is required for determining efficacy in secondary and tertiary fistula repairs.

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