

Acellular dermal matrix allograft: An effective adjunct to oronasal fistula repair in patients with cleft palate

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Marwa AbdElWahhab El-Kassaby, Mosaad Abd Al-Jawwad Khalifah,
Salah Abdelfattah Metwally, Khaled Abd Elmonaem Abd Elkader

Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Ain Shams University, Cairo, Egypt

Address for correspondence:

Dr. Mosaad A Khalifah, Street, No. 6, Al-Shona, Hosh Isa, Al-Behera, Postal Code - 22728, Egypt.
E-mail: mosaad78@hotmail.com

ABSTRACT

Context: Oronasal fistula (ONF) following cleft palate (CP) repair are a challenging problem associated with high recurrent rates. Acellular dermal matrix allograft is an available tissue substitute. **Aims:** The aim of this study was to evaluate the effectiveness of acellular dermal matrix in the repair of ONF associated with CP that is recurrent or larger than 15 mm in any dimension. **Settings and Design:** This is a prospective study where 12 patients with repaired CP suffering from ONF of the hard palate >15 mm in diameter were included. **Materials and Methods:** Age ranged from 12 to 25 years. Acellular dermal matrix was firmly secured between repaired oral and nasal mucosal layers. Patients were clinically followed-up for 6 months postoperatively to assess total time for complete healing, dehiscence and/or refistulization. **Statistical Analysis Used:** Fisher's exact test. **Results:** Acellular dermal matrix was integrated with successful fistula closure in all except 1 patient where failure of graft integration was noticed early postoperatively. In 6 patients, the oral mucosal layer showed dehiscence, through which the graft was exposed. Graft integration extended from 4 to 12 weeks postoperatively during which patients were instructed to follow a soft diet and meticulous oral hygiene measures. **Conclusions:** Acellular dermal matrix allografts are safe and effective adjuncts for use in closure of ONF in the hard palate that is recurrent or larger than 15 mm in any dimension.

Keywords: Acellular dermal matrix allograft, cleft palate, oronasal fistula

INTRODUCTION

Oronasal fistula (ONF) is a complication of palatoplasty procedure which can have significant functional sequelae^[1,2] including nasal regurgitation of food or liquid, fetor or is, chronic inflammation, and hearing loss.^[3] In addition to speech symptoms include nasal escape, hypernasality, and velopharyngeal incompetence.^[2] A variety of factors have been reported to increase the incidence of ONF, including tension along the palate repair, hemorrhage, upper respiratory infection, absence of multilayer closure, increasing cleft severity, and technique of repair.^[2-6]

Oronasal fistula are difficult to repair.^[7-9] The repair of a recurrent ONF is much more difficult than it seems where a small defect often requires an extensive operation to repair.^[10,11] The frequently disappointing results of some conventional methods of repair are

evidenced by the multiplicity of techniques for fistula closure^[8] and the importance of fistula prevention is reflected in the difficulty in attempts at repair and the typically high recurrence rates.^[7,9] In situations where there is a defect larger than 15 mm, successful closure may dictate utilization of additional soft tissue using a regional flap and or grafts.^[12] Acellular dermal matrix provides a scaffold for tissue ingrowth, revascularization, and mucosal epithelialization. Acellular dermal matrix is safe, easy to use, widely available, strong, and resistant to infection and rejection, avoids a donor site surgery and associated morbidity, and permits a good healing with no functional deficit as contracture, contour deformity as depression or hypertrophy, or postoperative adhesion. The main disadvantage of its use is the associated relatively high cost.^[7,13-16]

Acellular dermal matrix has been successfully applied in the treatment of ONF especially if recurrent or refractory.^[8,17,18]

Hence; the aim of the current study was to evaluate the effectiveness of acellular dermal matrix in ONF repair associated with cleft palate (CP) that is recurrent or larger than 15 mm in any dimension.

MATERIALS AND METHODS

This prospective study follows the Declaration of Helsinki on medical protocol and ethics and an approval from the Ethical Committee of Ain Shams University, Egypt as an institutional review board has been gained before commencing the study.

This prospective study was conducted on 12 patients with ONF secondary to CP repair selected from the Cleft Care Clinic affiliated to the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Ain Shams University. This research was conducted after approval of Research Ethics Committee, Faculty of Dentistry, Ain Shams University.

Inclusion criteria

Patients have an ONF that is recurrent or larger than 15 mm in any dimension and located anywhere in the hard palate suffering from

its effects as: Nasal regurgitation during feeding and hypernasality within an age range of 12-25 years.

Exclusion criteria

Patients who had any medical problem that would contraindicate surgical intervention or affect the healing of the surgical wound, did not satisfy any of afore mentioned criteria, uncooperative, with poor oral hygiene, and or refused participation in the study.

Standard operative procedures

Patients underwent closure of ONF under general anesthesia where, nasal side closure of the fistulous defect was performed using available adequately released turnover flaps using multiple interrupted absorbable sutures. For oral layer closure; an incision was created just palatal to the upper dentition. The oral mucoperiosteum was elevated around the fistula for adequate exposure. The acellular dermal matrix (Porous® Dermis Allograft Tissue Matrix, Tutogen Biologics company, Industriestraß 6, 91077 Neunkirchen a. Br., Germany) as shown on Figure 1 was hydrated for 30 min in two successive sterile saline dishes and firmly secured and sutured over the repaired nasal mucosal layer. The oral mucoperiosteum was repositioned and sutured to cover the majority of the graft. This is demonstrated in Figures 2-7.

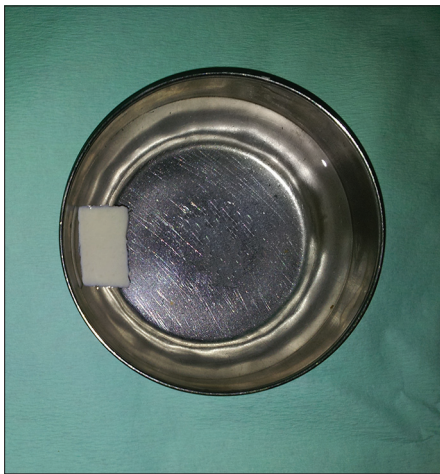


Figure 1: Acellular dermal matrix within the saline dish

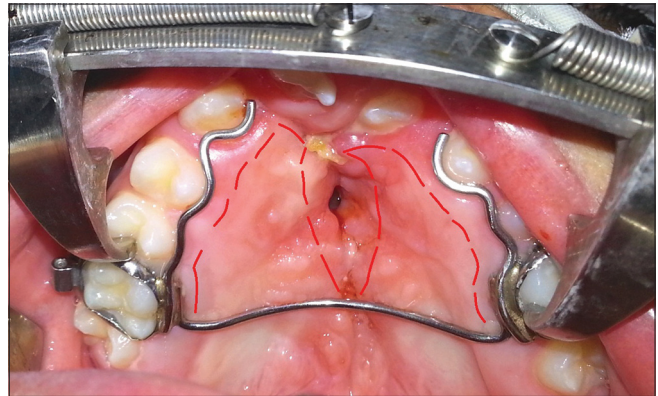


Figure 2: Preoperative photograph shows a recurrent case (had eight previous failed attempts for repair elsewhere). Dashed lines demonstrate the markings for the incisions



Figure 3: Intraoperative photograph showing the repaired nasal layer using turnover flap

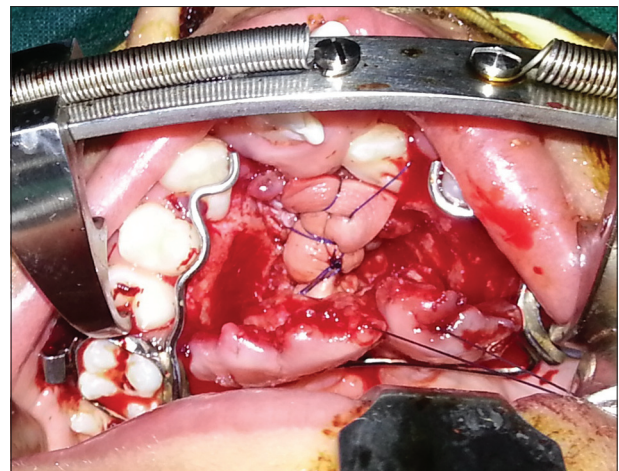


Figure 4: Intraoperative photograph showing acellular dermal matrix wrapped around the repaired nasal layer

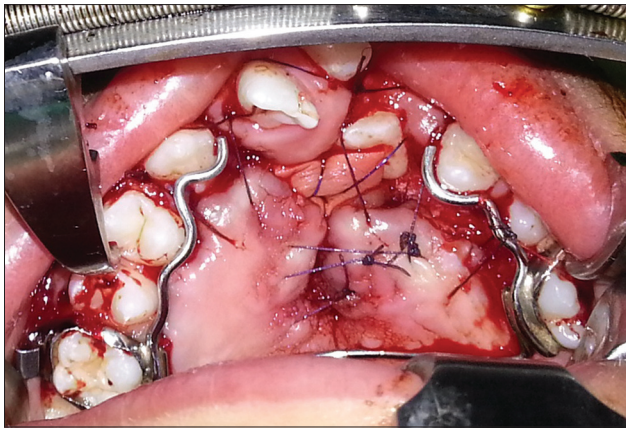


Figure 5: Intraoperative photograph showing the case after suturing the oral mucosa

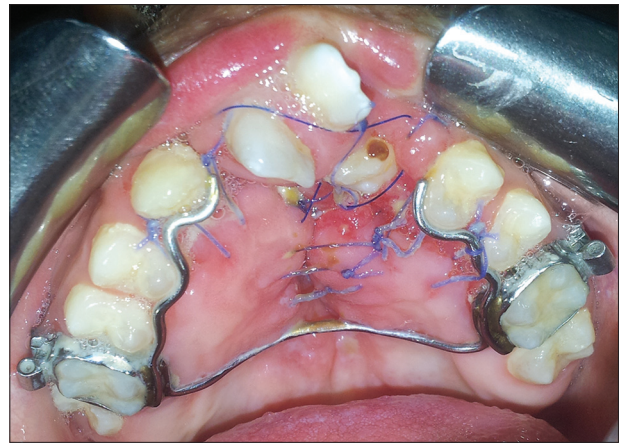


Figure 6: Postoperative photograph after 1 week



Figure 7: Postoperative photograph after 3 months

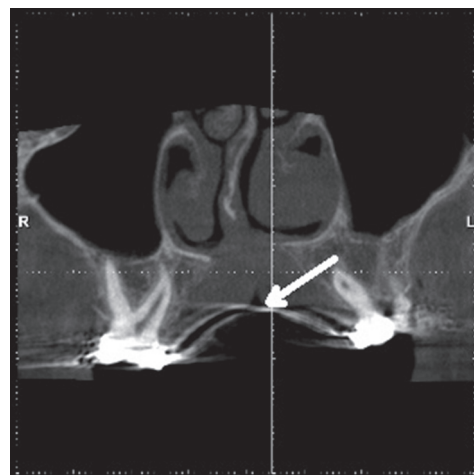


Figure 8: Postoperative cone beam coronal computed tomography after 3 months demonstrating a cul-de-sac depression (white arrow)

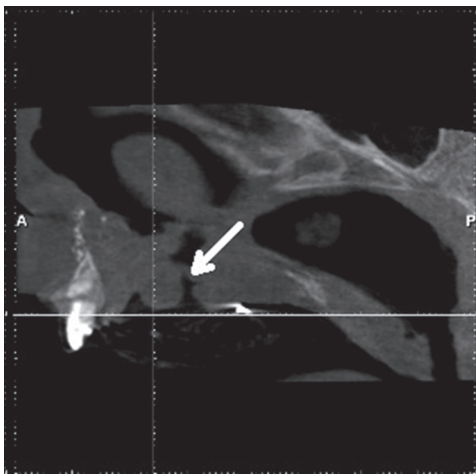


Figure 9: Postoperative cone beam sagittal computed tomography after 3 months demonstrating a cul-de-sac depression (white arrow)

Postoperative follow-up was performed at 2 weeks and at 1, 2, 3 and 6 months for assessment of failure of closure as manifested in recurrence of fistula with oronasal regurgitation, total time for complete healing, rejection of the acellular dermal matrix from the site of surgical repair, and for assessment of the presence of contracture, dehiscence or contour deformity as depression or hypertrophy. A cone beam CT was done at three months

postoperatively [Figures 8 and 9]. Soft diet of various nutrients and meticulous oral hygiene measured were overemphasized on for patients during the entire follow-up period.

RESULTS

Regarding the recurrence of the fistula with oronasal regurgitation, 1 case of recurrence was recorded out of the 12 cases of the study with success rate of 91.7%. Oral mucosal layer dehiscence has been reported in 6 cases leading to dehiscence followed in 5 cases by reepithelialization over the integrated graft and otherwise uneventful complete healing by the period of 3 months. The failed case did not show reepithelialization or graft integration, thus closure was not amenable and oronasal regurgitation was, unfortunately, encountered. No contracture or contour deformity was observed in any of the study cases. None of the cases showed rejection of acellular dermal matrix. Data regarding those parameters are showed in Table 1. Total time of complete healing for successful cases is demonstrated in Table 2.

DISCUSSION

Oronasal fistula is a very difficult problem (particularly if recurrent or refractory) facing the caring team and the suffering patient.

Table 1: Results regarding recurrence, dehiscence, contracture, contour deformity, rejection of acellular dermal matrix and succeeded cases

Item	Number of cases	Fisher's exact test	α level %	Significance
Recurrence	1	$P=0.0063$	1	Significant
Dehiscence	6	$P=1.2256$	5	Insignificant
Contracture	0	$P=0.0004$	1	Significant
Deformity	0	$P=0.0004$	1	Significant
Acellular dermal matrix rejection	0	$P=0.0004$	1	Significant
Succeeded cases	11	$P=0.0063$	1	Significant

Table 2: Demonstrates healing periods recorded

Healing period of (weeks)	4	5	8	12	Mean period=8.82 week
Number of cases	2	1	3	5	

Occurrence of functioning ONF declares in most circumstances the existence of a vicious circle of failure. The repair of a recurrent ONF is much more difficult than it seems, and most fistulae present a problem in which an extensive operation is needed to resolve a small defect.^[10,11]

In our prospective clinical study, acellular dermal matrix was firmly secured and sutured over the repaired nasal layer. One out of 12 cases showed ONF recurrence. That success might be attributed to the well wrapping of the acellular dermal matrix to the repaired nasal layer that fixed it in place until integration of the graft takes place. However, failure of closure in the case of recurrence did not seem to be the result of rejection since there were no signs of inflammation or grave host immune response. Nevertheless, simple wound breakdown on the oral side appeared to be the cause. That mucosal dehiscence has been reported in our study and elsewhere by > 1 author;^[7,18] however, those followed by acellular dermal matrix mucosalization and complete healing.^[7,18] Unfortunately, that was not the scenario met by us for the only failing case where failure of the graft revascularization, integration and uptake was due to extensive dehiscence of the oral layer that hindered the graft to function as a scaffold graft. As well, acellular dermal matrix functioning as a barrier did not seem to resist that failure. Regardless of that, acellular dermal matrix success was confirmed and that went in agree with the results of Cole *et al.*, 2006;^[17] Kirschner *et al.*, 2006;^[18] and Steele and Seagle, 2006.^[8]

None of the cases exhibited contracture since acellular dermal matrix provided a matrix that was truly capable of preventing the contracture due to the granted nature of being a matrix of the dermis that can readily forms neodermis, that confirms the results of Clark *et al.*, 2003;^[7] and goes in the same context with the findings of Lee *et al.*, 2001.^[14]

Considering contour deformity, all the cases showed no contour deformity. That might be due to the relatively comparable thickness of acellular dermal matrix with the oral mucosa. Acellular dermal matrix has not been rejected in any of the cases. These results are in agree with those of Clark *et al.*, 2003;^[7] Cole *et al.*, 2006;^[17] Steele and Seagle, 2006.^[8]

CONCLUSION

Acellular dermal matrix is an easy technique, obviates the need for donor site surgery and in turn no donor site morbidity, does not lead to contour deformity, does not necessitate second surgery, in addition to the relative availability of the material. Acellular dermal matrix allografts are safe and effective adjuncts for use in closure of ONF in the hard palate that is recurrent or larger than 15 mm in any dimension.

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