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

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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 refistulaization. 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 including nasal regurgitation of food or liquid, fetor oris, chronic inflammation, and hearing loss. In addition to speech symptoms include nasal escape, hypernasality, and velopharyngeal incompetence. 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 multiclayer closure, increasing cleft severity, and technique of repair.

Oronasal fistula are difficult to repair. The repair of a recurrent ONF is much more difficult than it seems where a small defect often requires an extensive operation to repair. The frequently disappointing results of some conventional methods of repair are evidenced by the multiplicity of techniques for fistula closure and the importance of fistula prevention is reflected in the difficulty in attempts at repair and the typically high recurrence rates. 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. 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.

Acellular dermal matrix has been successfully applied in the treatment of ONF especially if recurrent or refractory.
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
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                         | 6              | P=0.0063            | 1       | Significant  |
| Dehiscence                         | 5              | 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) | Number of cases | Mean period=8.82 week |
|---------------------------|-----------------|-----------------------|
| 4                         | 2               | 8.82 week             |
| 5                         | 1               |                       |
| 8                         | 3               |                       |
| 12                        | 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.16-18

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;17-18 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, 2006.18

None of the cases exhibited contracture since acellular dermal matrix provided a matrix that was truly capable of preventing the contraction due to the granted nature of being a matrix of the dermis that can readily forms neo dermis, that confirms the results of Clark et al., 2003;17 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;18 Cole et al., 2006;15 Steele and Seagle, 2006.18

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.

REFERENCES

1. Witt PD, Marsh JL. Advances in assessing outcome of surgical repair of cleft lip and cleft palate. Plast Reconstr Surg 1997;100:1907-17.
2. Wilhelm BJ, Appelt EA, Hill L, Blackwell SJ. Palatal fistulas: Rare with the two-flap palatoplasty repair. Plast Reconstr Surg 2001;107:315-8.
3. Jeffery SL, Boorman JG, Dive DC. Use of cartilage grafts for closure of cleft palate fistulae. Br J Plast Surg 2000;53:551-4.
4. Posnick JC. The staging of cleft lip and palate reconstruction: Infancy through adolescence. In: Posnick JC, editor. Craniofacial and Maxillofacial Surgery in Children and Young Adults. Philadelphia (PA): W.B. Saunders; 2000. p. 785-826.
5. Agrawal K. Cleft palate repair and variations. Indian J Plast Surg 2009;42 Suppl: S102-9.
6. Rennie A, Treharne LJ, Richard B. Throat swabs taken on the operating table prior to cleft palate repair and their relevance to outcome: A prospective study. Cleft Palate Craniofac J 2009;46:275-9.
7. Clark JM, Safiodh SH, Israel JM. Decellularized dermal grafting in cleft palate repair. Arch Facial Plast Surg 2003;5:40-4.
8. Steele MH, Seagle MB. Palatal fistula repair using acellular dermal matrix: The University of Florida experience. Ann Plast Surg 2006;56:50-3.
9. Smith DM, Vecchione I, Jiang S, Ford M, Deleyiannis FW, Haralama MA, et al. The Pittsburgh fistula classification system: A standardized scheme for the description of palatal fistulas. Cleft Palate Craniofac J 2007;44:590-4.
10. Pigott RW, Rieger FW, Moodie AF. Tongue flap repair of cleft palate fistulae. Br J Plast Surg 1984;37:285-93.
11. Ogle KE. The management of oronasal fistulas in the cleft palate patient. Oral Maxillofac Surg Clin North Am 2002;14:533-62.
12. Ruiz RL, Costello BJ. Reconstruction of cleft lip and palate: Secondary procedures. In: Miloro M, editor. Peterson’s Principles of Oral and Maxillofacial Surgery. 2nd ed. London: BC Decker Inc.; 2004. p. 871-8.
13. Schafani AP, Romo T3, Jacoно AA, McCormick S, Cocker R, Parker A. Evaluation of acellular dermal graft in sheet (AlloDerm) and injectable (micronized AlloDerm) forms for soft tissue augmentation. Clinical observations and histological analysis. Arch Facial Plast Surg 2000;2:130-6.
14. Lee GN, Kang SY, Park J, Cho SH. Reconstruction of soft tissue defects using multilayer of acellular human dermal allograft and terudermis. J Korean Soc Plast Reconstr Surg 2009;42 Suppl: S102-9.
15. Kolker AR, Brown DJ, Redstone JS, Scarpinato VM, Wallack MK. Multilayer reconstruction of abdominal wall defects with acellular dermal allograft (AlloDerm) and component separation. Ann Plast Surg 2005;55:36-41.
16. Yim H, Cho YS, Seo CH, Lee BC, Ko JH, Kim D, et al. The use of AlloDerm on major burn patients: AlloDerm prevents post-burn joint contracture. Burns 2010;36:322-8.
17. Cole P, Horn TW, Thaller S. The use of decellularized dermal grafting (AlloDerm) in persistent oro-nasal fistulas after tertiary cleft palate repair. J Craniofac Surg 2006;17:836-41.
18. Kirschner RE, Cabling DS, Slepman AE, Siddiqui F, LaRossa DD, Losee JE. Repair of oronasal fistulae with acellular dermal matrices. Plast Reconstr Surg 2006;118:1431-40.