A Prospective Study Investigating Fistula Rate Following Primary Palatoplasty Using Acellular Dermal Matrix

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Background: Acellular dermal matrix (ADM) has been described as an adjunct in primary cleft palate repair to reduce the fistula rate in several retrospective studies (level III or lower); however, current data are insufficient to definitively conclude its efficacy for this purpose. The goal of the present study was to provide prospective, higher level of evidence data investigating the effect of ADM on fistula rate following primary palatoplasty.

Methods: A prospective clinical trial was conducted in which ADM was used uniformly in all primary cleft palate repairs that met inclusion criteria. For comparison, a matched control group was identified (retrospectively) from the same center/surgeon's database. Primary outcome was the rate of palatal fistula formation. Secondary outcomes included bleeding, infection, and delayed healing.

Results: A total of 130 patients were included in the analysis consisting of 65 in both the study and control groups. There were no statistically significant differences in patient demographics or cleft /surgical characteristics. The results demonstrated a fistula rate of 1.5% in the study group versus 12.3% in the control group ($P = 0.03$). The other complications (infection, bleeding, delayed healing) were similar between the groups.

Conclusion: The study provides the highest level of evidence currently available (level II, prospective data) investigating the effect of ADM on fistula rate following primary palatoplasty. The results demonstrate a low overall fistula rate (1.5%) and suggest there may be a clinically significant reduction in fistula formation associated with the routine use of ADM in all primary palate repairs. *(Plast Reconstr Surg Glob Open 2018;6:e1826; doi: 10.1097/GOX.0000000000001826; Published online 15 June 2018.)*

INTRODUCTION

Palatal fistula formation remains one of the most cumbersome complications following primary palatoplasty, representing a significant challenge to the cleft surgeon.

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Due to the variability of operative techniques and documentation of fistula occurrence and location, the reported incidence of fistula rates following primary cleft palate repair is highly variable, ranging from 0% to 76%.[1] However, a recent systematic review of 9,294 patients from 44 studies demonstrated fistula rates of 5.4% and 17.9% among patients with Veau I/II and Veau III/IV cleft palates, respectively.[2]

Oronasal fistulas may occur at any location along the repair including the hard palate, junction of the hard and soft palate and the soft palate. Although multifactorial in etiology, tension at the site of the repair resulting from

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cleft width and/or shortage of local tissues is considered by most to be the main factor contributing to fistula formation. The highest frequency of postoperative fistulas can be observed at the junction of the hard and soft palate, where cleft width is widest and tension on the repair is the greatest.[3] Other patient-specific and surgery-specific factors such as cleft type, cleft width, mucosal tears, damage to the vascular pedicle, postoperative hemorrhage, infection, and surgeon experience may also play a role.[4]

Once formed, palatal fistulas are notoriously difficult to repair due to the compromised vascularity, inherent fibrosis, and limited mobility of palatal tissues, leading to particularly high rates of recurrence ranging between 30% and 65% and subsequent need for additional reoperations.[5,6] Given the significant morbidity to the patient and important cost to the medical system associated with revisional surgeries, many techniques have been described in an effort to decrease the risk of fistula formation following primary palatoplasty. One such technique has been the addition of acellular dermal matrix (ADM) to the repair site. ADM is commonly used in prosthetic breast reconstruction to bolster tenuous mastectomy flaps, but has also been described in cleft palate surgery as a prophylactic adjunct for primary repair and revisional fistula surgeries.[1,7] Although initial studies reported a potential benefit of ADM in lowering fistula rates, a subsequently published meta-analysis demonstrated that there was insufficient evidence (prospective data, level II, or higher) to confirm a definitive decrease in fistula rates associated with its use in primary cleft repairs.[8] To that end, the objective of the current study was to provide prospective data to help determine whether the routine use of ADM in primary palatoplasty reduces the incidence of palatal fistulas.

METHODS

Study Design

The clinical trial was conducted at the H.B Williams Craniofacial and Cleft Surgery Unit of the Montreal Children's Hospital and received IRB approval from the McGill University Health Center. The study was also registered as a prospective trial on clinicaltrials.gov (identifier: NCT01867632). From 2012 to 2016, primary cleft palate patients were prospectively enrolled into the single-arm study group that would uniformly have ADM incorporated into their palatal repair. Inclusion criteria were patients who presented for primary cleft palate repair before the age of 3 (including adopted and syndromic cleft palate patients). Exclusion criteria were patients diagnosed with known healing issues, Veau type I cleft palates (as these involve only the soft-palate and its musculature where ADM is not employed), patients with less than 6 months follow-up, patients with previous palatal surgery or whose family did not consent to be included in the study. Informed consent was obtained from parents or legal guardians of all eligible candidates after a detailed discussion regarding potential risks of using ADM. All surgeries were performed by a single surgeon (senior author, M.G.) using either a modified Furlow palatoplasty or intravelar velo-plasty (IVVP) with relaxing incisions, as described below. Patients were randomized to either technique using a coin toss to allow for even distribution of both repair types employed at our center. The study adheres to the STROBE guidelines for cohort studies.

For purposes of comparison, a "control" group of cleft palate patients (in which ADM was not uniformly used) was identified from our center's patient database. Patients included in the control group were selected from outside of the prospective study cohort period with matching inclusion/exclusion criteria (ie, Veau cleft classifications, age, primary repairs, and so on). Before initiating the prospective trial, our center's treatment algorithm was to employ ADM in select cleft repairs with tight or tenuous nasal repairs, as previously reported by Losee et al.[1] Thus, palate repairs that had ADM selectively used as part of their surgery were included in the control group to avoid biasing this group toward less difficult repairs and a lower than expected fistula rate (caused by systematically eliminating repairs that had a tenuous nasal layer repair and therefore received ADM as part of the surgery). To minimize the possibility that evolving surgical experience affected the documented fistula rates in the prospective group, care was taken to include in the control group patients repaired both before beginning (2012) and after completing (2016) the prospective study period.

To ensure the study would be adequately powered to capture a change in fistula rates as a result of the intervention (uniform ADM use), a sample size calculation was performed *a priori*. Using a 2-tailed test with an alpha level of 0.05 and a statistical power of 0.8, a sample size of 65 patients was determined to be required for each group.

The primary outcome of the study was the rate of palatal fistula formation. Other complication outcomes investigated included bleeding, infection, and delayed healing (defined as temporary, partial oral layer dehiscence, which spontaneously healed without intervention). For the purpose of this study, a palatal fistula was defined as a full-thickness communication between the oral and nasal cavities occurring in any location in the palate posterior to the alveolus.

Surgical Technique

All cleft palates were repaired with either the Children's Hospital of Philadelphia modification of a Furlow double-opposing Z-plasty[9] or an IVVP with relaxing incisions (von Langenbeck, hybrid, or Bardach style) as described previously in the literature. Nasal mucosa was mobilized to allow primary closure without vomer flaps.

In cases where ADM was utilized, a 2×4 cm ultra-thin sheet (0.3–0.4 mm thickness) of ADM (DermaMatrix, Synthes CMF, West Chester, Pa.) was trimmed and placed between the oral and nasal tissue layers, starting just anterior to the muscle repair and extending to the anterior border of the cleft (or to the junction of the hard palate and alveolus in Veau III or IV palates). The ADM is tailored to overlap the nasal suture line and areas where nasal repair is tenuous by 3–4 mm on each side, usually measuring about 7–12 mm in total width tapering anteriorly if needed, similar to the technique described by Losee et al.[1] (Figs. 1, 2). The ADM is positioned once the nasal layer
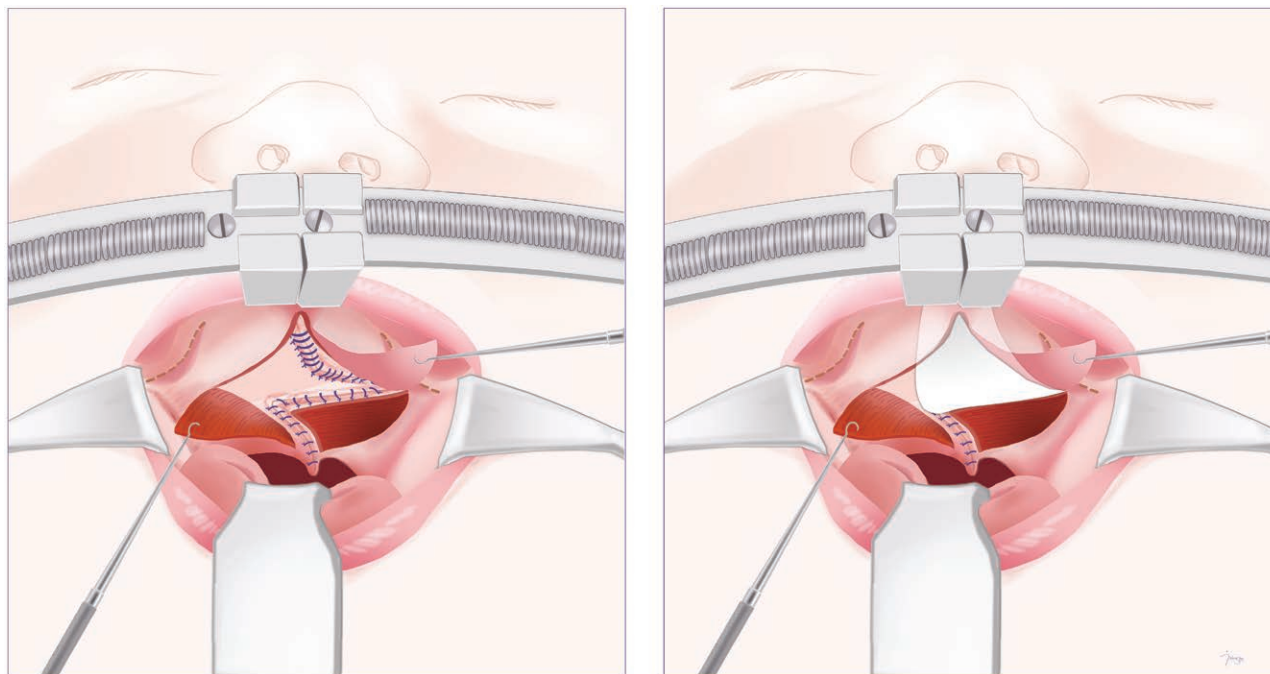
Fig. 1. Schematic representation of the placement of the ADM in the modified Furlow palatoplasty technique. The left image demonstrates the nasal mucosal repair and nasal Furlow flap transpositions completed. The image on the right demonstrates the placement of the ADM (white) starting just anterior to the muscle repair, tailored to overlap the nasal suture line and areas where nasal repair is tenuous by 3–4 mm on each side, usually measuring about 7–12 mm in total width and tapering anteriorly as needed. Translucent areas are to demonstrate where ADM is placed underneath the oral mucosa.

and muscle repairs are complete and tacked with a single 4.0 Vicryl suture (Ethicon, New Jersey, N.J.) to the nasal layer (**see** video, Supplemental Digital Content 1, which displays intraoperative demonstration of the placement and tailoring of ADM during a Veau II cleft palate repair using an IVVP technique with von Langenbeck relaxing incisions. This video is available in the "Related Videos" section of PRSGlobalOpen.com or at ***http://links.lww.com/PRSGO/A791***). The oral layer was then closed as usual using simple interrupted sutures in the soft palate and horizontal mattress sutures in the hard palate. 4.0 Vicryl was used for all mucosal and muscle repairs.

Data Collection and Analysis

Data were collected from paper and electronic patient charts using a standardized data extraction sheet developed for this review. Recorded patient characteristics included sex, age at operation, presence of associated syndromes, adoption status, type of cleft (Veau classification), and cleft width. Recorded procedure-specific characteristics included technique used, use of ADM, closure of nasal mucosa, length of operating time, duration of hospital stay, and complications (bleeding, delayed healing, infection, and palatal fistula). Comparisons between groups were tested with Chi-square test, Fisher exact test, or *t* test.[10] All the analyses were performed with SAS version 9.4.

Postoperative Care

Postoperative care was identical in all cases and followed our institutional protocol for cleft palate surgery. Patients were hospitalized for a minimum of 1 night,

received oral antibiotics for a total of 5 days, and were orally fed using a syringe to minimize palatal trauma for 10 days following the surgery. Routine surveillance for fistula formation was conducted for a minimum of 6 months postoperatively.

RESULTS

Table 1 summarizes patient characteristics, including demographics, cleft, and surgical details of patients in the study (prospective cohort) and control groups. There were no statistically significant differences in patient demographics including age at operation, sex, adoption or syndromic status, or hospital stay. Both groups had similar cleft and surgical characteristics with no statistically significant differences in distribution of Veau palatal types, cleft widths, repair techniques used and operative times (Table 1).

Fistula rate, the primary study outcome, was statistically significantly lower in the study group (1.5%) versus the control group (12.3%, *P* = 0.03). The other complications including infection and bleeding were similar between the groups. Cases with delayed healing were more common in the study group but the difference was not found to be statistically significant. Complications are summarized in Table 2.

DISCUSSION

Despite early promising reports, evidence to date supporting the role of ADM in reducing the fistula rate following primary palatoplasty has been retrospective, level III, or lower.[1,7,8,11] In determining the efficacy of a novel
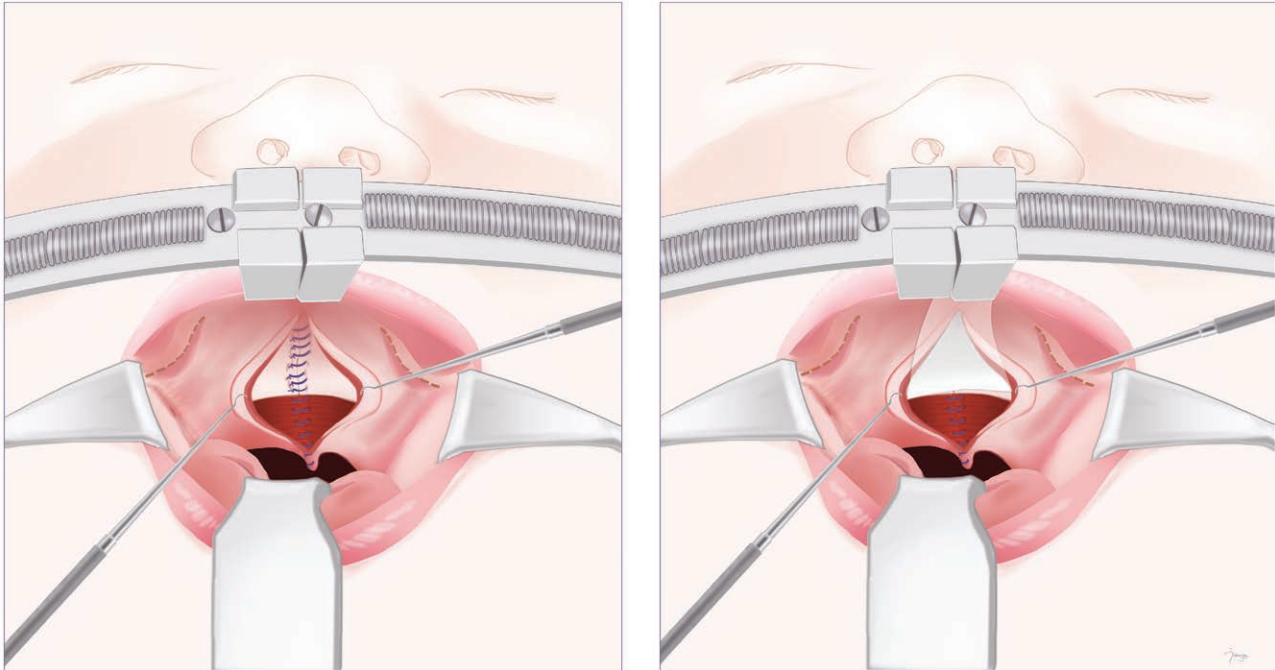
Fig. 2. Schematic representation of the placement of the ADM in the IVVP palatoplasty technique. The left image demonstrates the nasal mucosal repair and intravelar veloplasty completed. The image on the right demonstrates the placement of the ADM (white) starting just anterior to the muscle repair, tailored to overlap the nasal suture line and areas where nasal repair is tenuous by 3–4 mm on each side, usually measuring about 7–12 mm in total width and tapering anteriorly as needed. Translucent areas are to demonstrate where ADM is placed underneath the oral mucosa.
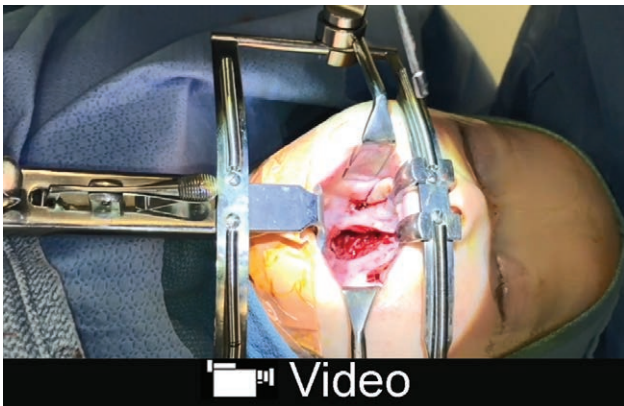
Video Graphic 1. See video, Supplemental Digital Content 1, which displays intraoperative demonstration of the placement and tailoring of ADM during a Veau II cleft palate repair using an IVVP technique with von Langenbeck relaxing incisions. This video is available in the "Related Videos" section of PRSGlobalOpen.com or at *http:// links.lww.com/PRSGO/A791*.

therapeutic intervention (such as the addition of ADM to palate surgery), prospective data are preferred due to its ability to render more precise estimates of the incidence of an outcome (fistula formation, in this case) and is associated with less risk of bias and confounding than retrospective study designs. To that end, the present study provides the first prospective (level II) data investigating the effect of ADM on primary palatoplasty fistula rate, demonstrating a 1.5% fistula rate in a cohort of 65 primary Veau II-IV cleft palate repairs. The reported study group fistula rate is significantly lower ($P = 0.03$) than that of a matched control group of 65 primary palate repairs performed by the same surgeon, suggesting a beneficial effect of routine ADM use on primary cleft palate repair fistula rates.

Although there is significant variability in published literature fistula rates ranging from 0% to 76%, the fistula rate from the present study (1.5%) is comparable, if not favorable, to more updated literature values. In their systematic review, Timbang et al.[12] reported an overall fistula rate ranging from 7.87% to 9.81%, compared with the 8.6% overall fistula rate reported by Hardwicke et al.[2] in their analysis of 9,294 cleft palate repairs from 44 studies. Importantly, the fistula rate was significantly affected by cleft severity (and therefore the distribution of Veau types) with 5.4% and 17.9% fistula rates reported for Veau I/II and Veau III/IV cleft palates, respectively.[2] In the present study, the control group fistula rate (12.3%) was well within the reported range although being slightly higher than the overall average fistula rates from the aforementioned systematic reviews. This can be attributed to the fact that Veau type I palates were not included in the clinical trial as they involve only the soft palate and its musculature where ADM is not utilized, resulting in a higher relative proportion of Veau III and IV type palates in the groups analyzed. As such, the overall average fistula rates (study and control groups) were increased toward the higher fistula incidence associated with Veau III/IV palate repairs (17.9%) demonstrated in the systematic review by Hardwicke et al.[2]

Variability in included cleft populations has also been previously noted to affect reported fistula rates.[13] As an ex-

Table 1. Patient Characteristics

Demographics	Study Group (n = 65)	Control Group (n = 65)	P
Age at operation (mo), mean (SD)	13.7 (5.8)	15.4 (6.3)	0.11
Sex, n (%)			
Male	32 (49.2)	30 (46.2)	0.67
Female	33 (50.8)	35 (53.8)	
Adopted, n (%)			
Yes	7 (10.8)	9 (13.8)	0.62
No	58 (89.2)	56 (86.2)	
Associated syndromes, n (%)			
Yes	11 (16.9)	16 (24.6)	0.3
No	54 (83.1)	49 (75.4)	
Hospital Stay (d), mean (SD)	1.6 (1.3)	1.9 (1.3)	0.24
Cleft characteristics			
Veau classification, n (%)			
II	35 (53.8)	32 (49.2)	0.77
III	18 (27.7)	21 (32.3)	
IV	12 (18.5)	12 (18.5)	
Cleft width (mm), mean (SD)	12.6 (1.9)	12.4 (1.7)	0.42
Surgery characteristics			
Operating time (min), mean (SD)	128.2 (33.9)	125.3 (35.0)	0.66
Surgical technique			
Modified Furlow palatoplasty	34 (52.3)	35 (53.8)	0.93
Intra-velar veloplasty	31 (47.7)	30 (46.2)	
ADM use, n (%)			
Yes	65 (100)	20 (30.8)	< 0.001
No	0 (0)	45 (69.2)	

Table 2. Complications

Complications	Study Group (n = 65)	Control Group (n = 65)	P
Overall complications, n (%)	7 (10.8)	10 (15.1)	0.46
Fistula, n (%)			
Yes	1 (1.5)	8 (12.3)	0.03
No	64 (98.5)	57 (87.7)	
Bleeding, n (%)			
Yes	2 (3.1)	0 (0)	0.24
No	63 (96.9)	65 (100)	
Delayed healing, n (%)			
Yes	4 (6.2)	2 (3.1)	0.44
No	61 (93.8)	63 (96.9)	
Infection, n (%)			
Yes	0 (0)	0 (0)	
No	65 (100)	65 (100)	

ample, adopted patients with delayed repairs have been identified as a subgroup associated with higher complication and fistula rates.[14,15] Adopted patients were included in the present study and accounted for a slightly larger proportion of patients in the control group (n = 9, 13.8%) and than the study group (n = 7, 10.8%). Thus, although this small difference in distribution of adopted patients may have raised the fistula rate in a more impactful way in the control cohort, its effect was not statistically different between the groups (ie, the groups were demographically identical from a statistical perspective).

Careful consideration was given to the present study design, based on the limitations identified in the existing data outlined in the published meta-analysis on the subject.[8] In addition to well-matched groups for comparison (patient demographics, cleft type distribution, and so on) and sufficient numbers to provide reliable estimates of fistula rate, an additional key consideration was the statistical power of the study and hence the ability to detect a difference in fistula rates between the 2 differing palate repair techniques (study and control cohorts). Determined by both the selected power threshold and the relative

incidence of the outcome (in this case, fistula rate), an *a priori* power calculation determined that a sample size of 65 patients per group would be required to power the study at an 80% threshold that is considered standard in such therapeutic studies. Based on most high-volume cleft surgeons' caseload, a single-surgeon randomized, prospective clinical trial (level I evidence) requiring the enrolment of 130 patients (2 groups of 65) would have taken 6–10 years taking into account families that refuse to be part of the study and/or are lost to follow-up. To that end, a multi-surgeon/multi-center trial was contemplated to shorten the study time frame; however, the significant inherent variability between surgeons performing the palatal repairs (technique, postoperative care, experience, reporting of fistulas, and so on) would have introduced significant additional bias and, thus, similar challenges to data interpretation.

The utilized study design (a prospective study cohort with a demographically and cleft characteristics-matched (retrospective) control cohort from a single surgeon/center) was thus selected as the most reasonable compromise and alternative to a prospective randomized trial. Al-

though this study design is subject to a time bias associated with the nonsimultaneous chronology of the 2 groups that cannot be eliminated, every effort was made to limit the bias associated with evolving skill level over the study period by including palate repairs in the control group performed before, during (patients excluded from the study cohort due to family refusal to participate) and after the prospective collection period. Care was also taken to exclude from the control pool all palate repairs performed in the first 2 years of the study surgeon's clinical practice to minimize differences in technical skill between the groups. Nevertheless, the authors cannot completely remove the potential bias related to a comparison of the chronologically separated study and control groups and consider this a limitation of the study.

Statistical analysis of patient characteristics in the 2 groups included in the study demonstrated no statistical differences in demographics including distribution of sex, age at repair, complexity of cleft (Veau classification), cleft widths, type of repair (modified Furlow palatoplasty versus IVVP with relaxing incisions), surgical time, length of hospital stay, adoption, or syndromic status. The occurrence of complications (other than fistula formation) including infection, delayed healing, and bleeding were also statistically similar between the 2 study arms. Hence, potential demographic confounders were unlikely in the study groups as both groups were statistically matched.

From a technical perspective, ADM is easy to use and adds less than 5 minutes to the total operative time. As ADM is commercially prepared, it is not associated with any donor-site morbidity and is more rapid than autologous flap options. Although the exact mechanism by which it reduces fistula formation is not clear, we hypothesize that it becomes rapidly incorporated and serves as an "additional" layer of closure should there be either a dehiscence of the oral or nasal layers. To that end, the authors suggest the thinnest piece of ADM available for this indication (0.3–0.4 mm) to facilitate rapid vascular ingrowth and incorporation. In our experience, fistula formation often becomes apparent between 5 and 10 days postrepair, by which time the ADM is firmly adherent and may serve as a hermetic boundary to prevent flow through of saliva and progression to full-thickness fistulization. Indeed, in 4 cases in the study group, we witnessed delayed healing with partial oral layer dehiscence and exposure of the ADM at the 1-week visit, all of which progressed to heal spontaneously without intervention by the 3-week follow-up visit. Clark et al.[7] noted a similar effect in their report of a cleft repair where total oral mucosal closure was not possible and a small defect with exposed ADM went on to spontaneously close. We postulate that there is a similar rate of nasal layer dehiscence in routine palatal repairs that is not visible to the surgeon on oral examination, but leaves repairs without ADM with only the oral layer closure to maintain the integrity of the repair that may breakdown and form a fistula in certain cases.

Although a formal cost-effectiveness analysis is forthcoming, the additional 5 minutes of operative time and expense of a 2×4 cm piece of ultra-thin ADM (approximately $150) seems to be justifiable for a significant reduction in fistula rate and costs associated with this outcome (revisional surgery, increased follow-up, and speech therapy services). Analyzed differently, the results suggest that for every 9.4 cases ($1,410), the routine application of ADM can prevent the formation of 1 palatal fistula when compared with the control treatment protocol (use of ADM only in tenuous mucosal repairs).

The effect of ADM on speech is also under investigation at our center. Care is taken in our described technique to place the ADM anterior to the muscle repair to minimize any effect on its function; however, further longitudinal studies to evaluate its impact on speech outcomes are warranted.

Limitations of the study include the previously discussed, nonrandomized nature of the clinical trial. This limitation, and measures taken to minimize the bias associated with the sequential (nonsimultaneous) timing of the groups were discussed earlier. In addition, although the decision to carry out the trial as single surgeon study design has significant advantages in limiting technical factors that may confound data analysis, it may also limit the generalizability of the results (ie, results limited to a particular skill set or operator).

Limitations associated with interpretation of the data include the retrospective nature of the control group (more prone to bias and confounding than the prospective study cohort) and the understanding that select cases in the control group had ADM used during the palate surgery, as discussed earlier for cases with tenuous nasal repairs. The exclusion of these cases would have resulted in a significant selection bias by removing a number of complex repairs (mostly Veau type III and IV palates) preferentially from the control group. An analysis of our control group revealed that ADM was used in 30.8% of control group cases, a rate roughly in keeping with that described by Losee et al.[1] in their study in which 34% of patients had ADM used in their repair for difficult cases. Thus, based on the fact that the 2 groups were identically matched (demographics, cleft type distribution) except for the use of ADM which was 30% of cases in the control cohort and 100% of surgeries in the study arm, the statistical analysis suggests that the routine use of ADM decreased the fistula rate compared with its intermittent or selective use alone. Unfortunately, the investigators cannot identify at this time if the use of ADM is more beneficial for particular cleft types, characteristics, or subpopulations (eg, adopted or syndromic patients).

A final limitation worth noting was that the rate of transmitted infection associated with the use of ADM was not examined in this study, although patients were informed of this potential risk during the consent process. These risks are reported to be negligible with the current processing techniques although a finite risk cannot be excluded.

CONCLUSIONS

This study provides the highest level of evidence currently available (level II, prospective cohort) investigating the utility of ADM in cleft palate surgery. The results demonstrate that the routine application of ADM was associ-

ated with a 1.5% fistula rate following primary palatoplasty and a statistically significant reduction in fistula rate in Veau II-IV cleft palate repairs compared with a matched, retrospective control group. The routine use of ADM in primary cleft plate repairs is rapid, simple, and relatively inexpensive, and may decrease morbidity and revisional surgeries associated with palatal fistulas.

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REFERENCES

1. Losee JE, Smith DM, Afifi AM, et al. A successful algorithm for limiting postoperative fistulae following palatal procedures in the patient with orofacial clefting. *Plast Reconstr Surg.* 2008;122:544–554.
2. Hardwicke JT, Landini G, Richard BM. Fistula incidence after primary cleft palate repair: a systematic review of the literature. *Plast Reconstr Surg.* 2014;134:618e–627e.
3. Amaratunga NA. Occurrence of oronasal fistulas in operated cleft palate patients. *J Oral Maxillofac Surg.* 1988;46:834–838.
4. de Agostino Biella Passos V, de Carvalho Carrara CF, da Silva Dalben G, et al. Prevalence, cause, and location of palatal fistula in operated complete unilateral cleft lip and palate: retrospective study. *Cleft Palate Craniofac J.* 2014;51:158–164.
5. Schultz RC. Management and timing of cleft palate fistula repair. *Plast Reconstr Surg.* 1986;78:739–747.
6. Cohen SR, Kalinowski J, LaRossa D, et al. Cleft palate fistulas: a multivariate statistical analysis of prevalence, etiology, and surgical management. *Plast Reconstr Surg.* 1991;87:1041–1047.
7. Clark JM, Saffold SH, Israel JM. Decellularized dermal grafting in cleft palate repair. *Arch Facial Plast Surg.* 2003;5:40–44; discussion 45.
8. Aldekhayel SA, Sinno H, Gilardino MS. Acellular dermal matrix in cleft palate repair: an evidence-based review. *Plast Reconstr Surg.* 2012;130:177–182.
9. Kirschner RE, Wang P, Jawad AF, et al. Cleft-palate repair by modified Furlow double-opposing Z-plasty: the Children's Hospital of Philadelphia experience. *Plast Reconstr Surg.* 1999;104:1998–2010; discussion 2011.
10. Sheskin DJ. *Handbook of Parametric and Nonparametric Statistical Procedures.* Boca Raton, Fla.: CRC Press; 2003.
11. Helling ER, Dev VR, Garza J, et al. Low fistula rate in palatal clefts closed with the Furlow technique using decellularized dermis. *Plast Reconstr Surg.* 2006;117:2361–2365.
12. Timbang MR, Gharb BB, Rampazzo A, et al. A systematic review comparing Furlow double-opposing Z-plasty and straight-line intravelar veloplasty methods of cleft palate repair. *Plast Reconstr Surg.* 2014;134:1014–1022.
13. Bykowski MR, Naran S, Winger DF, et al. Abstract 116: the rate of oronasal fistula formation following primary cleft palate surgery: a meta-analysis. *Plast Reconstr Surg.* 2014;133:132–133.
14. Shay PL, Goldstein JA, Wink JD, et al. International adoptees with cleft lip and/or palate: lessons learned from a growing population. *Ann Plast Surg.* 2016;77:377–382.
15. Swanson JW, Smartt JM Jr, Saltzman BS, et al. Adopted children with cleft lip and/or palate: a unique and growing population. *Plast Reconstr Surg.* 2014;134:283e–293e.