In vivo Durability and Safety of Rolled Acellular Dermis in a Submucosal Pocket in Pigs

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BACKGROUND

Velopharyngeal insufficiency (VPI) is a common disorder in children with cleft lip and palate, and can also be seen in children with submucous clefting or prior adenoidectomy surgery. VPI results from failure of the soft palate to effectively contact the posterior pharyngeal wall causing difficulties with speech and swallowing. Effective, long lasting correction is currently limited mainly to sphincter pharyngoplasty and posterior pharyngeal flap closure. These are more complicated and lengthy surgeries, which can lead to development of sleep disordered breathing or frank obstructive sleep apnea. An alternate, minimally invasive surgical option with reduced surgical morbidity is posterior nasopharyngeal augmentation with autologous or exogenous materials. Various alloplastic implants and injections have been studied for posterior pharyngeal augmentation, including Teflon, fat, Cymetra, Zyplast, and calcium hydroxyapatite, but none have shown satisfactory, long lasting results. Acellular dermal matrix sheeting (AlloDerm or Strattice, LifeCell Corp., Branchburg, NJ) is a commercial, soft tissue product demonstrating non-inflammatory properties with good durability and tissue ingrowth. The aim of the current study is to build on past investigations of pharyngeal augmentation and dermal matrix longevity to assess this product in a submucosal location.

METHODS

For this study, twelve domestic piglets were implanted at five weeks of age with a standardized rolled acellular dermal matrix (Strattice©) implant (Figure 1). A transverse submucosal tunnel was created in the soft palate, the implant was placed, and the lateral incisions were closed with dissolvable suture (Figure 2). A control group of three piglets underwent sham operations with creation of submucosal pockets but no implant. Pre and post operative photographs were taken and measurements of implant bulk were obtained. After a period of observation for 90 days without further intervention, the animals were sacrificed and the palates were harvested for examination (Figure 3). Histopathologic analysis was performed on the harvested palates, specifically looking at the implant site for microscopic evidence of matrix persistence, host inflammatory response and/or rejection of the implanted material. Immunohistochemical stains using antibodies directed against Leukocyte Common Antigen (Dako, Glostrup, Denmark) and Collagen IV (Dako, Glostrup, Denmark) and histochemical stains for Verhoeff’s Elastic Van Gieson (Dako, Glostrup, Denmark) and Masson’s Trichrome were performed.

RESULTS

All animals tolerated the surgical procedure well and thrived for the planned 90 day period of observation without surgical or medical complication. Following this period, the palates were harvested, photographs were taken (Figure 3) and gross measurements of the height of the soft palate at the site of the prior implant were taken (Table 1). The average height of the implanted pigs’ palates was 5.25mm compared to the control group average of 5.33mm. This was not a statistically significant difference. All of the surgical sites healed without complication or exposure of the implant. Histologic analysis showed sections of the acellular dermal matrix to have a characteristic appearance using polarized light (Figure 4a). Upon careful analysis of the entire submucosal surgical plane microscopically, essentially no difference between the sham and the implanted pigs was observed. More specifically, there was no appreciable difference in lymphocytic infiltration or collagen and elastin deposition. No granulomas or areas of necrosis were noted. Importantly, little to no acellular dermal matrix bearing the characteristic features under polarized light could be appreciated in either study population (Figure 4b).

CONCLUSIONS

Based on both the gross and histologic findings of implanted and sham pig palates, we conclude that there is minimal, if any, persistence of a rolled implant of acellular dermal matrix when placed in a piglet soft palate submucosal pocket after 90 days. The implant does appear safe, with no noted shifting, extrusion, or exposure of the material and no inflammatory response generated in the host. Confounding factors in this animal model include the close proximity of a rich population of lymphoid and antigen presenting cells in the pig palate, which may serve to speed resorption of the implant. Another consideration is the extreme growth of the animals over the chosen observation period, as they grew from an average of 6.5kg at implant to an average of 57.3kg at the time of sacrifice. This extreme growth of the palate size would tend to overcome any expected bulk from the initial, relatively small implant.

REFERENCES