

Case Report

Acellular Fish Skin Graft as a Possible Alternative to Autogenous Tissue in Vestibuloplasty for Bilateral Cleft Lip and Palate: A Case Report

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Abstract

Objective: Bilateral cleft lip and palate (BCLP) is a craniofacial malformation often associated with anatomical and functional impairments, including a shallow oral vestibule in the premaxillary region. This condition requires a vestibuloplasty to restore the space between the teeth and upper lip, also improving aesthetics. Traditional techniques frequently require autologous grafts, leading to increased morbidity. Tissue bioengineering provides suitable alternatives. **Methods:** We present the case of a 19-year-old female, who had undergone several surgeries for BCLP management, complaining of a lack of upper lip projection and an insufficient vestibular dept in the premaxilla region. We reported short-term follow-up using Acellular Fish Skin Graft (AFSG, Kerecis™) as a substitute to autologous graft to perform a vestibuloplasty. Outcome assessment was based on clinical measurements. **Results:** The graft showed early signs of vascularization. Clinical outcomes included improved vestibular depth, from 1 mm preoperatively to 8 mm, upper lip projection, and functional mobility after a six-month follow-up period. The patient experienced an uneventful recovery and was satisfied with the aesthetic result. **Conclusions:** This case, presenting the first application of AFSG in vestibuloplasty, tends to reassure us about its safety. AFSG might be an effective biocompatible alternative to autologous grafts in vestibuloplasty, offering promising results in mucogingival reconstruction. Further studies are needed to confirm long-term stability and integration in oral tissues.

Keywords: bilateral cleft lip and palate; acellular dermal matrix; vestibuloplasty; mucogingival surgery; oral surgery



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1. Introduction

Cleft lip and palate (CLP) is one of the most common congenital craniofacial anomalies, resulting from incomplete fusion of facial structures during early embryonic development. It is characterized by a rift in the lip, the palate, or both which can vary in severity, often associated with significant anatomical and functional impairments, therefore requiring multidisciplinary care [1]. In bilateral cleft lip and palate (BCLP), one of the issues is a shallow oral vestibule in the premaxilla area. This condition is due to embryonic development but also to surgical management. The upper lip adheres frequently to the premaxilla through scar tissues formed during labioplasty or after bone grafting procedures. This can consequently lead to articulation disorders, a lack of lip mobility, and upper lip projection,

and as there are also problems with general hygiene and local immunity, periodontal hygiene might be affected [2,3].

Vestibuloplasty is needed to deepen the premaxilla vestibule by creating a space between the teeth and the lip. Soft tissue grafting vestibuloplasty is traditionally performed with oral mucosal, in connection with donor-site morbidity and increased operative time [4,5]. To address these limitations, various engineered tissue replacements have been explored in the past decades. These materials aim to replicate the structural, mechanical, and biological characteristics of native gingival tissue. Among them, bovine and porcine collagen-based materials have shown promises due to their biocompatibility and ability to support wound healing without the drawbacks of autologous grafts [6].

Acellular fish skin graft (AFSG), a novel xenograft derived from the skin of the Atlantic cod (*Gadus morhua*), has emerged as a suitable class of biomaterials leading to good results. It is currently being used, after FDA approval, as a wound treatment product under the brand name Kerecis™ Omega3 [7]. The structure of the piscine matrix, as well as bioactive properties, respected by minimally processing the skin of the Atlantic cod, promote tissue regeneration. Fish skin grafts have shown superior three-dimensional cellular ingrowth, given their biochemical composition comprising omega-3-fatty acids, compared with bovine and porcine collagen-based materials, and may act as a bacterial barrier for 24–48 h [8,9]. Omega-3-fatty acids may accelerate tissue regeneration through rapid migration and proliferation of fibroblasts, keratinocytes, and endothelial cells. Homogeneous scaffolds further facilitate angiogenesis [10]. Traditionally used for the management of complex wounds, such as burns and diabetic foot ulcers, its scope of indications has recently been enlarged to include abdominal closure management [11] and repair of defects after excision of squamous cell carcinoma on the eyelid [12]. To our knowledge, the first application in the oral cavity was realized in 2018 [13] in over six subjects in order to correct mucogingival recession around teeth: the results showed long-term gain in keratinized tissue width. The AFSG was incorporated into the host area and infiltrated by autologous cells, while the graft slowly broke down.

We report a case of vestibuloplasty, using AFSG as an alternative to an autograft or mammalian-based material, in a 19-year-old female born with BCLP. The aim of this report is to reveal the efficiency of AFSG in mucogingival management and promote its use as a suitable alternative to mucosal autografts, achieving favorable functional and aesthetic outcomes.

2. Case Presentation

In adherence with national guidelines, Ethics Committee approval was not required, but the consent form was signed by the patient in accordance with the principles outlined in the Declaration of Helsinki (1975, revised in 2013).

A healthy 19-year-old female patient, born with a BCLP, was suffering from insufficient upper lip projection. She had undergone cheiloplasty and palatoplasty in India during childhood, followed by alveolar bone grafting at the age of nine. A Le Fort I osteotomy was performed at age 17, and a rhinoplasty one year later.

Clinical examination showed a shallow upper anterior vestibule in the premaxillary region (Figures 1A and 2A). She had a deficiency of the upper lip projection, associated with limited lip mobility; several treatment options were discussed, namely, vestibuloplasty using mucosal free grafting, mammalian matrix, or an acellular fish skin graft (AFSG), which the patient chose. The choice was guided by lower morbidity, having no donor site, and the anti-inflammatory properties of AFSG, since she has no fish allergy. No imaging was needed to support the choice of treatment plan.

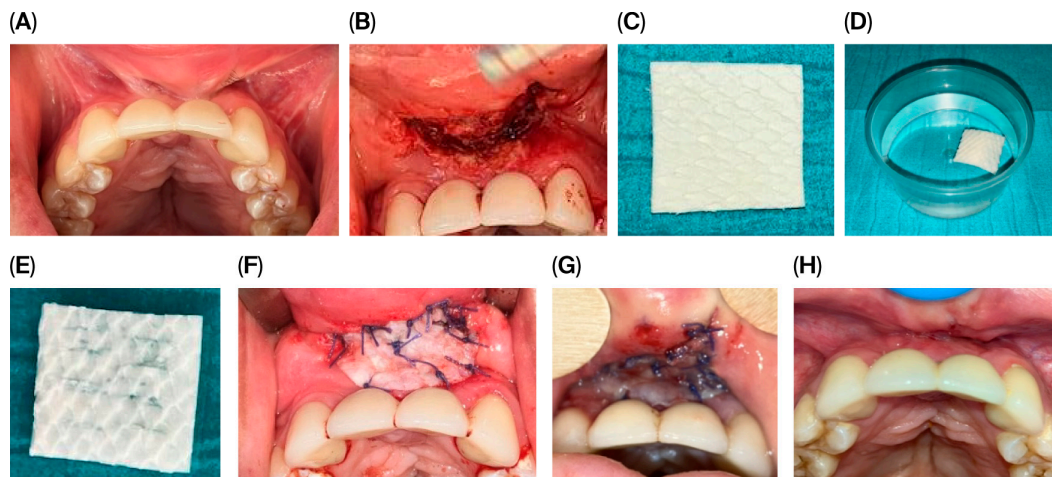


Figure 1. (A): Shallow vestibule in the premaxillary area. (B): V-shaped incision. (C): Acellular fish skin graft (AFSG) with the side bearing the scale imprint. (D): AFSG in saline solution. (E): AFSG meshed. (F): The AFSG sutured to the surrounding mucosa and periosteum. (G): On postoperative day three, satisfactory integration of the AFSG. (H): One month after surgery, full integration of the graft and vestibular depth in the incisal region had increased.

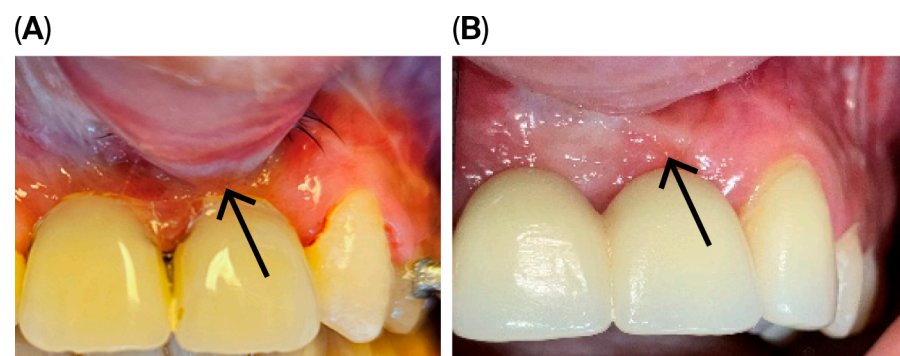


Figure 2. (A). Shallow vestibule in the premaxillary area with a gingivitis reflecting difficulties in maintaining good oral hygiene in the area. (B). Six months after the surgery, the vestibular depth in the incisal region had increased and the gingiva was healthy. Arrows: the lowest gingival height.

The surgical procedure was performed under general anesthesia, orotracheally. The patient received amoxicillin-clavulanate for prophylaxis at induction (intravenous, 2.2 g), continued postoperatively (oral administration, 1 g) for five days, twice daily.

The procedure consisted of a standard apically repositioned flap followed by placement of the AFSG after releasing scar tissue in the upper lip. A V-shaped incision (Figure 1B) was made 1 mm apical to the mucogingival junction which was next to the alveolar crest. The incision extended bilaterally to a total length of 5 cm. Muscle fibers and fibrous bands attached to the area were dissected from the periosteum and released to deepen the vestibule.

The AFSG was trimmed to fit the dimensions of the recipient site and placed in a sterile 0.9% saline solution at room temperature for three minutes (Figure 1C,D). Then, the graft was meshed (Figure 1E) and applied to the exposed area in the vestibule, with the side bearing the scale imprint facing the surgeon to respect the physiologic position of the basement membrane, then sutured to the surrounding mucosa and periosteum using 4–0 resorbable (Vycril) sutures (Figure 1F) to minimize shear forces and dead spaces. Opting for absorbable sutures avoided discomfort of suture removal.

The exposed portion of the graft was covered with paraffin-impregnated gauze, which was also sutured to the mucosal margins. We recommended that the patient brush her teeth

with a soft toothbrush in the surgical area with usual toothpaste and a normal toothbrush in the other areas, and perform 0.1% chlorhexidine mouthwashes three times daily, for two weeks. Perioperative analgesia and antiseptic protocols followed institutional standards. The protocol was observed by the patient. On postoperative day three, the gauze was removed without anesthesia, revealing satisfactory integration of the AFSG (Figure 1G). The patient was instructed to apply a non-sutured dressing for an additional three days and to begin massage of the area at three weeks postoperatively; however, she did not adhere to this recommendation.

The postoperative course was uneventful, with no edema or hematoma recorded. The pain was well-controlled with paracetamol and ibuprofen. One month after surgery, the graft was fully integrated, and vestibular depth in the incisal region had increased (Figure 1H) from 1 mm to 10 mm, measured with a millimeter caliper from the neck of the maxillary left central incisor to the gingivobuccal sulcus. This location represented the narrowest portion of the vestibule. Measurements were blinded, taken three times by the operator and the same dental assistant, not involved in the surgery, during the same session. The mean value of the three measurements of each observer was reported. At six months, vestibular depth measured 8 mm (Figure 2B) over a homogenous colored gingiva, presenting a satisfying elasticity. No standardized patient-reported or functional outcome measures were used. Outcomes were primarily clinician-based and were functionally and aesthetically satisfactory, with improved upper lip projection (Figures 3–5) and a good gingival color match. The patient was satisfied with the results.

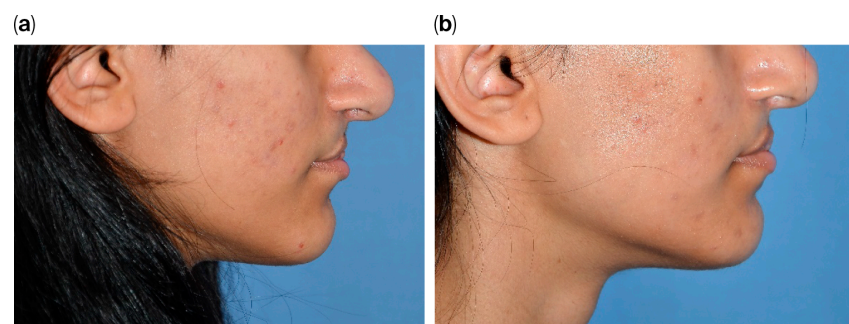


Figure 3. Lateral view of the lips preoperatively (a) and at six-month follow-up (b).

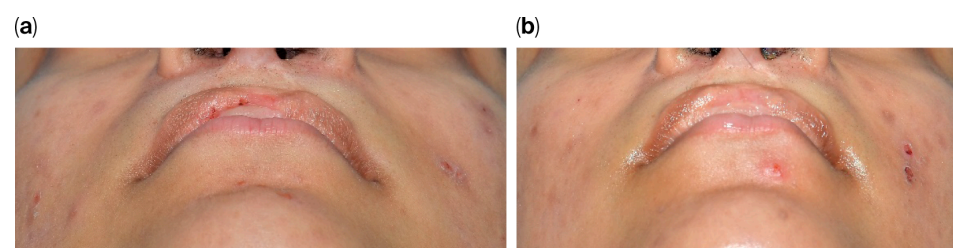


Figure 4. Inferior view of the lips preoperatively (a) and at six-month postoperative follow-up (b).

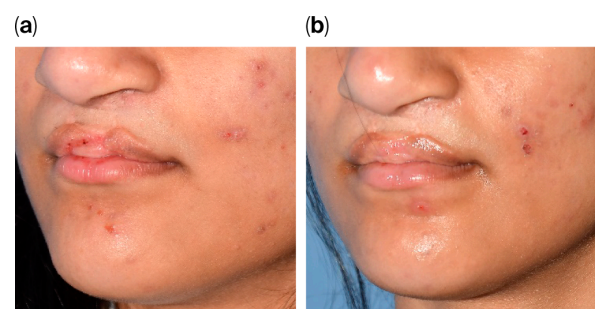


Figure 5. Three-quarter view of the lips preoperatively (a) and at six-month follow-up (b).

3. Discussion

The management of vestibuloplasty in patients with bilateral cleft lip and palate (BCLP) remains a significant clinical challenge, particularly with respect to restoring a functional oral vestibule and enhancing labial aesthetics and mobility [2,7,14]. Sindet-Pedersen et al. [14] and others have reported that scar bands can impair facial growth, contribute to articulation disorders, and promote resorption of transplanted bone. Consequently, several authors recommend restoring vestibular depth before school age in cases of complete bilateral clefts [3,15]. Traditionally, reconstruction relies on autologous grafts, such as oral mucosal or full-thickness skin grafts. Although effective, these procedures are associated with donor-site morbidity, increased operative time, and additional scarring [4,5]. The present case highlights the effectiveness of an acellular fish skin graft (AFSG, Kerecis™) as a promising alternative for vestibuloplasty in this complex clinical setting.

In this case, use of AFSG had produced an increase in vestibular depth—from 1 mm preoperatively to 10 mm at one month—followed by stable maintenance at 8 mm at six months postoperatively. Graft integration was excellent, with no signs of excessive inflammation. Sharing the advantage of no donor site with allografts or xenografts [4–6], AFSG allows a color and texture match with them [6].

A key advantage of AFSG might be its composition. First, the microscopic architecture of fish skin is similar to the human extracellular matrix. More precisely, the epidermidis of fish is a multi-layered tissue, separated from the dermis by a basement membrane. An acellular dermal matrix is derived from decellularized codfish skin. While immunogenicity of mammalian-derived matrices has been described as moderated, depending on the processing, that of AFSG might be low, since it contains few mammalian antigens [8,16]. Indeed, mammalian-derived matrices require extensive chemical processing to reduce immunogenicity, while Atlantic cod skin undergoes minimal processing due to the absence of documented viral transmission to humans as swine influenza or bovine spongiform encephalopathy. As a result, AFSG preserves its native three-dimensional architecture, lipid content, and bioactive components, including type I collagen, fibrin, proteoglycans, and omega-3 polyunsaturated fatty acids as docosahexaenoic acid (DHA) [8,10,16]. These elements not only provide a structural scaffold but also actively promote revascularization, fibroblast and endothelial cell proliferation, and wound remodeling. Moreover, DHA is known to exhibit antibacterial effects by disrupting microbial cells membranes, modulating response and reducing the expression of proinflammatory cytokines [17]. Consequently, AFSG may act as a dermal matrix, as well as an active biological dressing, accelerating healing and potentially reducing antibiotic requirements through its barrier and antibacterial properties [18,19].

The patient demonstrated notable functional and aesthetic improvements, including enhanced upper lip projection and increased mobility, contributing to satisfaction. The maintenance of an adequate periodontal profile and the absence of discernible differences in color or texture relative to the adjacent mucosa further underscore the harmonious integration of the graft. Although a minor reduction in vestibular depth occurred (from 10 mm to 8 mm), such regression is a known limitation of vestibuloplasty procedures. The literature emphasizes the role of retention devices—such as sutured paraffin-impregnated gauze or removable splints—in mitigating this recurrence [2]. In this case, the use of paraffin-impregnated gauze likely contributed to the stability of the outcome, despite partial non-adherence to postoperative massage instructions. Massage might have softened the scar, leading to an increased vestibule depth. Yet, evidence for the use of scar massage is weak [20]. Although no specific concerns were raised by the patient, this feature may facilitate wider clinical adoption across diverse populations.

Within the limitations of this reported case, it is important to note the need for caution in individuals with fish allergies. Plus, metric outcomes were subjective, with the absence of standardized assessment and a validated patient form. In addition, the number of patients treated with this type of graft remains limited; therefore, caution is warranted. Further use in a larger patient population with a comparative control and a longer follow-up with standardized outcome scales, particularly for oral applications integrating histologic assessment, is necessary. Those will provide more robust conclusions. Even though clinical integration was excellent in this case, long-term studies are required to confirm reproducibility, persistence of tissue integration, and neovascularization.

4. Conclusions

This case report demonstrates a successful use of AFSG. Despite the inherent limitations of a single exploratory case, AFSG may be considered a potential alternative to autologous grafts for vestibuloplasty in patients with BCLP. Owing to its bioactive properties, AFSG could represent a valuable option for mucogingival reconstruction in complex clinical situations. Nevertheless, further investigations, including larger patient cohorts and long-term follow-up studies, are necessary to confirm these preliminary findings and to evaluate long-term aesthetic and functional outcomes, thereby strengthening its clinical relevance.

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