A novel dehydrated amnion allograft for use in the treatment of gingival recession: An observational case series.

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Abstract

Background: Autograft tissue currently remains the "gold standard" of periodontal plastic surgery. It provides excellent predictability, improved long-term root coverage, and superior esthetics over other treatment options. Unfortunately, autogenous graft tissue is limited in supply and significantly increases patient morbidity. For these reasons, the dental profession continues to search for an effective and easy to use alternative.

Methods: A novel allograft composed of amnion tissue has recently been introduced for use in periodontal plastic surgery. The aim of this five patient observational case series was to document the use of allograft amnion in the treatment of shallow-to-moderate recession defects at three months.

Results: The average age of the five patients was 46 years with the youngest being 30 and the oldest 65 years of age. The average mucogingival defect size was 3.3mm (±0.84). At three months after surgery, there was an average increase of 3.2mm (±1.71) of new gingival tissue representing 97% (±0.5) defect coverage.

Conclusion: Based on the data collected in this cases series, processed dehydrated allograft amnion may provide an effective alternative to autograft tissue in the treatment of shallow-to-moderate Miller Class I and II recession defects. Additionally, the self-adherent nature of the amnion allograft significantly reduces surgical time and makes the procedure easier to perform relative to techniques involving the use of autograft or allograft dermis tissue.

KEY WORDS: Gingival recession, gingiva/surgery, allograft, amnion

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Background

Approximately one-quarter of the United States adult population possesses gingival recession defects.[1] This loss of gingival tissue can result in dental hypersensitivity, difficult plaque control, root caries, bone loss, and impaired aesthetics. From a scientific and clinical perspective, covering an exposed root surface with new gingival tissue presents one of the most challenging scenarios for regeneration of new tissue in the entire body. The avascular and microbiologically affected nature of the root surface acts as a barrier to regenerative efforts. Additionally, newly formed tissue must withstand the physical forces of mastication, speaking, and oral hygiene.

Various surgical approaches and materials have been employed for the treatment of gingival recession.[2,3,4,5,6,7,8] In most of these approaches, the exposed root surface is cleansed of bacterial endotoxins and regenerative material is placed over the defect. The materials used in these procedures include autogenous free gingival grafts,[9] autogenous connective tissue grafts,[6] and allograft dermis tissue.[10] Additionally, biologic mediators such as enamel matrix derivative, platelet-rich plasma, and recombinant platelet derived growth factor have been introduced into surgical protocols with the intent of accelerating and directing the wound healing.[11,12,13] Despite the introduction of allograft dermis tissue products and biologic mediators, autograft tissue remains the "gold standard" of periodontal plastic surgery as it provides excellent predictability, improved long-term root coverage, and superior esthetics over other treatment options.[14] Despite these clinical outcomes, the use of autograft tissue has drawbacks. Autogenous graft tissue is limited in supply and its procurement significantly increases patient morbidity while also lengthening the duration of surgery. Considering these pitfalls, many patients have an aversion to periodontal plastic procedures and delay or completely forgo treatment. Ultimately, this may cause the condition to worsen and possibly decrease the probability of successful outcomes when eventually treated. For these reasons, the dental profession has continued to search for an alternative soft tissue graft material that is effective and easy to use.

Recently, allograft alternatives to autogenous tissue grafts have been introduced in the form of allograft dermis tissue products (Puros® Dermis, Zimmer Dental, Warsaw, IN, USA and Alloderm®, LifeCell Corporation, Branchburg, NJ, USA). An additional allograft of alternative origin is derived from human amnion tissue (BioCover™, Snoasis Medical, Denver, CO, USA). This novel soft tissue allograft is composed of multiple layers of dehydrated human amnion tissue processed via Purion™, a proprietary tissue processing technology that preserves the inherent structure of amnion while cleansing and fusing its layers together.

To demonstrate the viability this allograft for the treatment of mucogingival defects, the aim of this five patient observational case series was to record the use of processed dehydrated allograft amnion in the treatment of shallow-to-moderate gingival recession defects.

Materials and Methods

The aim of this five patient observational case series was to record the use of processed dehydrated allograft amnion in the treatment of shallow-to-moderate recession defects defined as ≤3 mm of recession when there was no attached gingiva and or a lack of keratinized tissue around the defect and ≥ 3 mm of recession when the defect was surrounded by healthy tissue. In all cases, only one tooth was treated and all patients met the inclusion and exclusion criteria. All patients were treated using the following surgical protocol: 1) 60-second pre-operative rinse with 0.12% Chlorhexidine and local administration of 2% xylocaine with epinephrine, 1:100,000. 2) Measurement of gingival recession defect. A standard periodontal probe was used to measure from the cementoenamel junction (CEJ) to the apical extent of the gingival margin in the recession defect. 3) Preparation of exposed root surfaces which involved minimal flattening with hand instrumentation. 4) 2-minute application of tetracycline solution followed by saline rinse. 5) Intrasulcular incisions at the buccal margin of treated tooth and extending to the adjacent tooth to include the papillae with horizontal incisions made at right angles to the adjacent interdental papillae, at the level of the CEJ. Two oblique vertical incisions along the adjacent teeth were extended beyond the mucogingival junction (MGJ) and a trapezoidal mucoperiosteal flap was raised to the point of the MGJ. 6) Split thickness dissection allowing for coronal positioning of the flap. 7) De-epithelialization of adjacent papilla. 8) The processed dehydrated allograft was placed onto the exposed root surface and proximal bone with the embossed side facing outward away from the tooth (figure 1). Upon placement, the processed dehydrated amnion allograft becomes hydrated and self-adheres to the exposed root and proximal bone, thus eliminating the need for suture techniques (figure 2). 9) Immediately after placing the membrane, the reflected flap was coronal positioned over the processed dehydrated amnion allograft and secured with either an interrupted or sling suture technique. Care was taken not to move the allograft after placement and during flap closure.

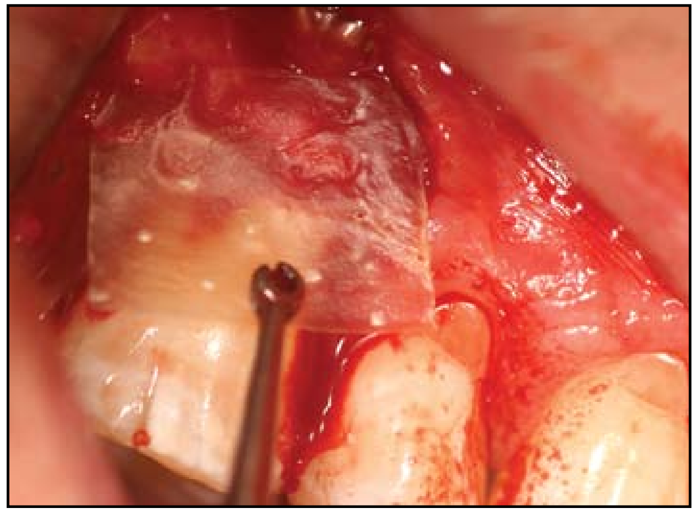

Figure 1: Amnion allograft being placed over the defect site.

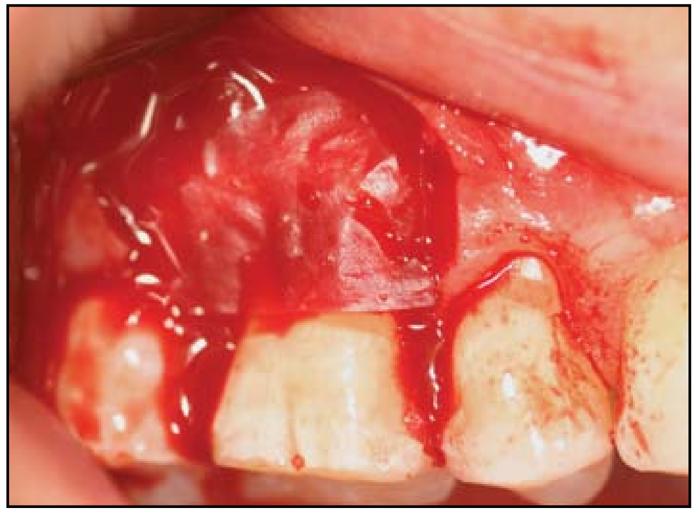

Figure 2: Rehydrated allograft secured over the defect site.

All patients were prescribed Lortab 5.0 and over-the-counter ibuprofen pain medication. Oral hygiene instructions included discontinuing tooth brushing near the surgical site and to use a 0.12% Chlorhexidine rinse twice a day until instructed by the clinician to do otherwise. Sutures were removed at two weeks after surgery. Patients were seen two, four, and twelve weeks following surgery. At 12 weeks, grafted defect sites were


Figure 3: Patient 1 before treatment.


Figure 4: Patient 1 three months after treatment.

re-measured with a standard periodontal probe from the CEJ to the apical extent of the gingival margin. Gingivoplasty was not utilized in any case to smooth newly formed tissue.

Results

Patient 1 was a 34 year old female, non-smoker with a 2 mm recession defect on tooth #11 with no attached gingiva present. Figures 3 and 4, respectively, show the pre and post operative (3 months) photos. Patient 2 was a 30 year old female, non-smoker with a 4 mm recession defect on tooth #27. Figures 5 and 6, respectively,

Table 1: Summary of defect coverage

Patient	Defect Size	Residual Defect	Percent Coverage
1	2mm	0mm	100%
2	4mm	0mm	100%
3	3mm	0mm	100%
4	4mm	0mm	100%
5	3.5mm	0.5mm	88%

recession defect on tooth #6. Figures 9 and 10, respectively, show the pre and post operative (3 months). Patient 5 was a 49 year old female, non-smoker, with a 3.5 mm recession defect on tooth #5. Figures 11 and 12, respectively, show the pre and post operative (3 months) photos.

The average age of the five patients was 46 years with the youngest being 30 and the oldest 65 years of age. The average defect size treated was 3.3mm (± 0.84). At three month there was an average increase of 3.2 mm (±1.71) of new gingival tissue representing 97% (± 0.5) root coverage. A summary of the results in terms of root coverage is provided in Table 1.

Discussion

The amniotic sac encloses the developing fetus through gestation and is composed of amnion and chorion tissue. Amnion lines the inner most portion of the amniotic sac and consists of a single layer of epithelium cells, thin reticular fibers (basement membrane), a thick compact layer, and a fibroblast layer (figure 13). The basement membrane contains

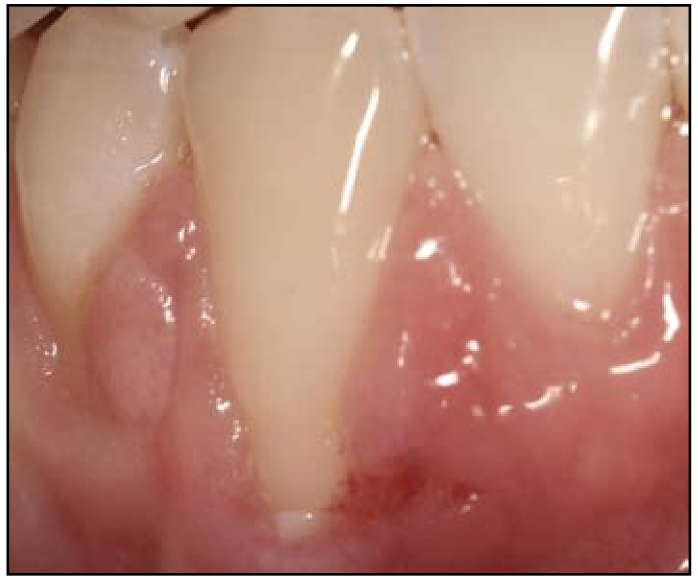
Figure 5: Patient 2 before treatment. .


Figure 6: Patient 2 three months after treatment.


Figure 7: Patient 3 before treatment.


Figure 8: Patient 3 three months after treatment.

collagen types III, IV, and V and cell-adhesion bioactive factors including fibronectin and laminins.

Data suggests the amnion basement membrane closely mimics the basement membrane of human oral mucosa.[15] Of particular interest is the fact that this amnion layer possesses several types of laminins, with Laminin-5 being the most prevalent. Laminin-5 plays a role in the cellular adhesion of gingival cells

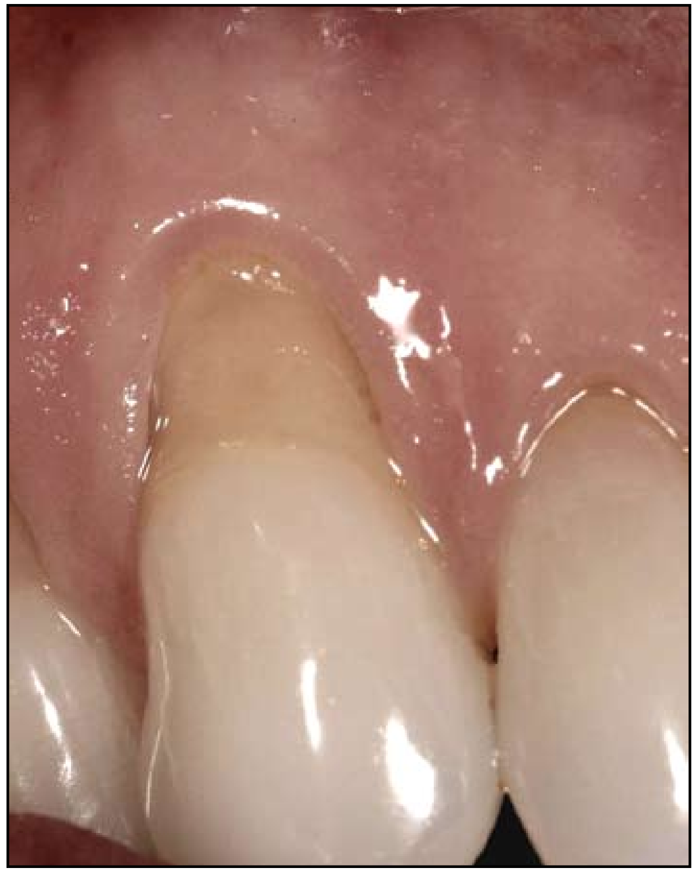

Figure 9: Patient 4 before treatment.

Figure 10: Patient 4 three months after treatment.

and concentrations of this glycoprotein in amniotic allograft may be useful for periodontal grafting procedures.[16]

Amnion tissue contains growth factors that may aid in the formation of granulation tissue by stimulating fibroblast growth and neovascularization.[17] Additionally, the cells found within tissue exhibit characteristics associated with stem cells and may enhance clinical outcomes[18]. Amnion has shown an ability to form an early physiologic "seal" with the host tissue precluding bacterial contamination[19] and multiple studies support amnion's ability to decrease the host immunologic response via mechanisms such as localized suppression of polymorphonuclear cell migration.[20]

Amniotic tissue has been used since the early 1900s for skin grafts, treatment of burns, and treatment of ulcerated skin conditions. More recently it has been used for temporary biologic dressings for full-thickness wounds,[21] reconstruction of damaged or malformed organs,[22] and prevention of tissue adhesion.[23] Additionally, use of amniotic tissue has been reported to decrease post-operative pain when used as a wound dressing.21 Amnion tissue grafts have also been routinely used for the past decade in ophthalmologic surgery. Cryo-preserved amnion[24] and dehydrated amnion[25] have demonstrated equivalent results to conjunctive autograft tissue in ocular reconstruction procedures.

In the production of the amnion allograft used in this study, pre-screened, consenting mothers donate the amnion and associated tissues during elective cesarean section surgery. All donated tissue follows strict guidelines for procurement, processing, and distribution, as dictated by the United States Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB). These safety measures include testing for serological infectious diseases such as human immunodeficiency virus (HIV) type 1 and 2 antibodies, human T-lymphotropic virus (HTLV) type 1 and 2 antibodies, Hepatitis C antibody, Hepatitis B surface antigen, Hepatitis B core total antibody, serological test for Syphilis, HIV type 1 nucleic acid test, and Hepatitis C virus nucleic acid test. Upon collection of the maternal tissue, the amnion and chorion tissues are carefully separated and the amnion is cleansed prior to processing. The allograft is terminally sterilized, dehydrated and embossed with the letters "SM" to allow for proper orientation during placement (figure 14), perforated, and terminally sterilized (SAL 10-6). Figure 15 shows separation of the amnion from the chorion while figure 16 demonstrates amnion tissue prior to processing.

Figure 11: Patient 5 before treatment.

Figure 12: Patient 5 three months after treatment.

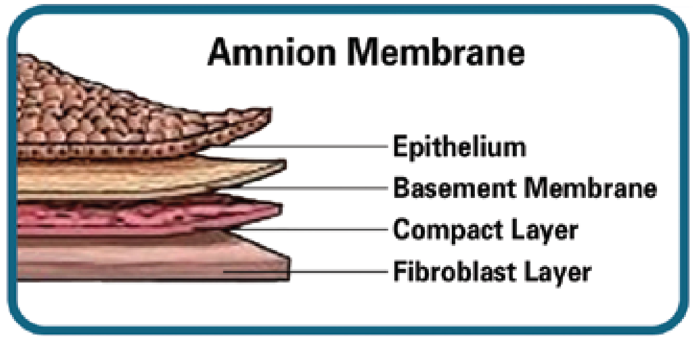

Figure 13: The structure of amnion tissue.

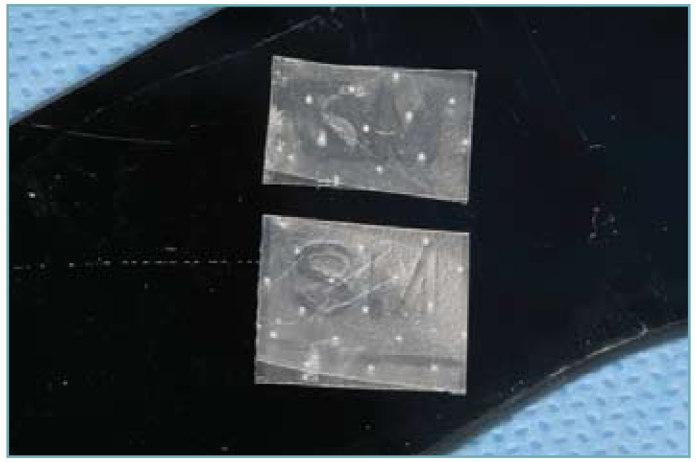

Figure 14: Amniotic allograft with embossed markings. Note processed perforations for improved vascularization.

Figure 15: Amnion and chorion tissues being separated.

Figure 16: Amnion tissue is cleansed before processing.

The aim of this observational case series was to document the use of processed dehydrated allograft amnion in the treatment of shallow-to-moderate mucogingival recession defects. Collected data and subjective observation by the authors indicates that the use of processed dehydrated allograft amnion provides good results in terms of root coverage, increased tissue thickness, and increased attached gingival tissue. Although not specifically recorded during this study, processed dehydrated allograft amnion demonstrated excellent esthetic results in terms of texture and color match. There were no adverse reactions during the course of this study and patients reported relatively little post-operative discomfort. The ability of processed dehydrated allograft amnion to self-adhere eliminates the need for sutures, making the procedure less technically demanding and significantly decreasing surgical time. The ability to self-adhere makes processed dehydrated allograft amnion an attractive option for multi-teeth procedures and recession defects in particularly hard to reach areas such as the molar region.

Conclusion

Based on the data collected in this cases series, processed dehydrated allograft amnion may provide an effective alternative to autograft tissue in the treatment of shallow-to-moderate Miller Class I and II recession defects. Additionally, the self-adherent nature of the amnion allograft significantly reduced surgical time and made the procedure easier to perform relative to techniques involving the use of autograft or allograft dermis tissue. Although this case series provides initially promising results for utilization of processed dehydrated allograft amnion in particular mucogingival defects, the limited number of patients, lack of controls, and short duration of this study warrants additional research be conducted to confirm the results of this study.

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Disclosure
Dr. Gurinsky serves on the Clinical Advisory Board for Snoasis Medical, Inc. and has a financial interest in the company.

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