BioXclude®

Non-Surgical Periodontal Therapy Adjunct

EASY • SAFE • EFFECTIVE

Handling Guide

BioXclude is intended for use after standard root planing and scaling procedures, for periodontal pocket depths ≤ 5 mm. Clinicians generally have an algorithm related to when they choose to employ a locally applied non-surgical scaling and root planing adjunct.

The following protocol belongs to Dr. Mark Lucas, DDS, MS, and has been utilized in our initial trials. The protocol reserves said therapies for periodontal defects which presented at the phase I periodontal reevaluation appointment as significantly improved but not quite into the predictably maintainable zone of ≤ 4 mm. Also, periodontal maintenance patients exhibiting some site-specific breakdown could be candidates for local ScRP and locally applied adjunct.

Non-surgical periodontal therapy adjunct recommended dose size: 8x8 mm per site

Post-Operative Instructions

- No eating or drinking for 30 minutes following treatment
- Avoid touching the treated areas.
- Wait 12 hours after your treatment before brushing teeth.
- Wait 10 days before using floss, toothpicks, or other devices designed to clean between the treated teeth.
- Avoid foods for 1 week that could hurt your gums (popcorn, chips).
- Don't chew gum or eat sticky foods.

After 10 days, resume cleaning between the treated teeth on a daily basis.

Handling Instructions

Perform standard scaling and root planing procedure

Pressure gauze to decrease bleeding from treated site

Use BioXclude in 3 Simple Steps

STEP 1:

- Pick up the dry membrane with dry forceps and hydrate it by immersing in sterile saline or sterile water until the membrane is pliable (Approximately 30 seconds)

STEP 2:

- Wetted membrane is initially introduced to the pocket with cotton forceps and the other instrument (probe or cord packer) is used to drive the membrane into the pocket

STEP 3:

- Exchange the forceps for a second cord packer or probe
- Alternate one instrument to stabilize the membrane while the other instrument drives it into the pocket, continuing until the membrane is condensed to the bottom of the pocket

Better results, backed by research.

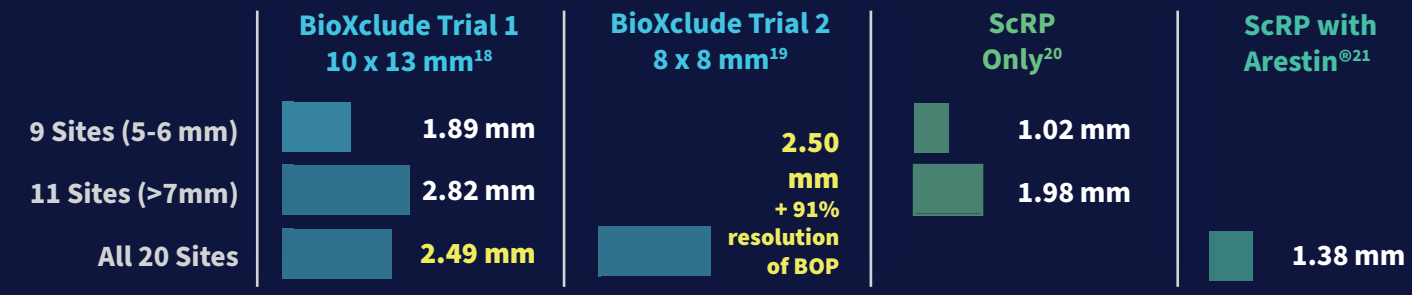
The basic scientific evidence related to dehydrated human deepithialized amnion-chorion membrane (dDACM) demonstrates increased hematopoetic and mesenchymal stem cell recruitment to the membrane secondary to chemotactic proteins inherent in the membrane offers the invaluable attributes of increased blood supply and modulated inflammatory response within the site. The main structural collage is Type I with various other structural proteins which, combined with the growth factors and other signaling molecules present in the membrane, could affect the rate of healing in a treated periodontal defect. In the medical arena, dDACM is the new standard of care in the treatment of chronic wounds such as chronic diabetic ulcers. Although the diseased periodontal defect is a different entity in many respects, it still shares some chronic wound characteristics.

Initial trials demonstrate better results with SRP including **BioXclude application**, than SRP alone, or SRP with Arestin.

Non-Surgical Periodontal Therapy Adjunct Studies

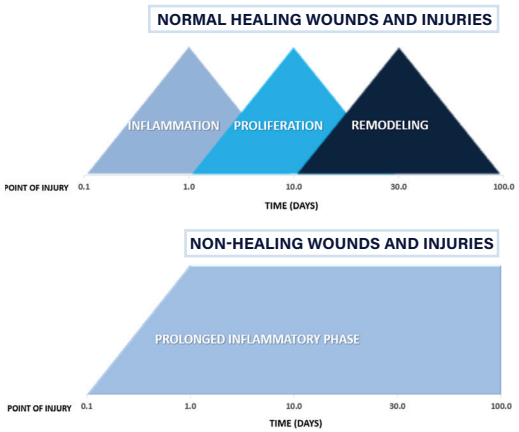
These studies followed patients at 5-12 week re-evaluation of probing depth following ScRP with BioXclude condensed into periodontal pockets of 5mm of greater. **Note the consistent improvement achieved with BioXclude regardless of the change in graft size.**

MEAN PROBING DEPTH IMPROVEMENT



[18] Schwab M. Innovative addition of dehydrated human amnion-chorion membrane during scaling & root planing. Private Practice Clinic (Denver, CO). Snoasis Medical Report Data on File 2016. [19] Dodge J, Rademacher A. Dehydrated human amnion-chorion product as an adjunct to scaling & root planning in maintenance patients: A pilot study. Private Practice Clinic (Boulder, CO). Submitted for Publication. [20] Hung H, Douglas C. Meta-analysis of the effort of scaling and root planning, surgical treatment and antibiotic therapies on periodontal probing depth and attachment loss. J Clin Perio 2002; 29: 975-986 [21] G. Minocycline HCl microspheres reduce red-complex bacteria in periodontal disease therapy. Goodson J, Gunsolley J, et al. J Perio 2007; 78 (8): 1568-1579.

Anti-Inflammatory



Additionally, dDACM offers the invaluable attributes of **increased blood supply** and **modulated inflammatory response** within the site. Although inflammation is a necessary step in the healing process, it is known that a prolonged inflammatory phase coincides with chronic non-healing wounds, including periodontitis.

REGULATORS OF WOUND HEALING IN AMNION-CHORION	**CYTOKINES**	Ang, ANG-2, bFGF, BMP-5, BDNF, EG-VEGF, EGF, FGF-4, KGF; FGF-7, GH, HB-EGF, HGF, IGF-1, IGFBP-1, IGFBP-2, IGFBP-3, IGFBP-4, IGFBP-5, IGFBP-6, β-NGF, PIGF, PDGF-AA, PDGF-BB, TGF-α, TGF-β1, VEGF, TIMP-1, TIMP-2, TIMP-4
REGULATORS OF INFLAMMATION IN AMNION-CHORION	**CYTOKINES**	GCSF, GM-CSF, GDF-15, IFNɣ, IL-1α, IL-1β, IL-1ra, IL-4,5,6,7,10, IL-12p40, IL-12p70, IL-15, IL-17, MCSG, OPG
	CHEMOKINES	BLC, Eotaxin-2, I-309, IL-8, IL-16, MCP-1, MIG, MIP-1α, MIP-1β, MIP-1δ, RANTES

Antibacterial

Finally, dHACM possesses **innate antimicrobial proteins** with research from both the **University of Colorado School of Dental Medicine Graduate Periodontics Department** as well as ongoing research at **UT Health Houston Graduate Periodontics Department** showing the potential of the dHACM **membrane's ability to kill various species of bacteria**, including important periodontal pathogens such as *A. actinomycetemcomitans*, *P. gingivalis* and *P. intermedia*. Current mass spectrometry works underway at UT Health Houston to determine the potential antimicrobial proteins. Historically, the Ob/Gyn medical literature describes Human Beta Defensins, elafin and others as constituent antimicrobial proteins within amnion-chorion.