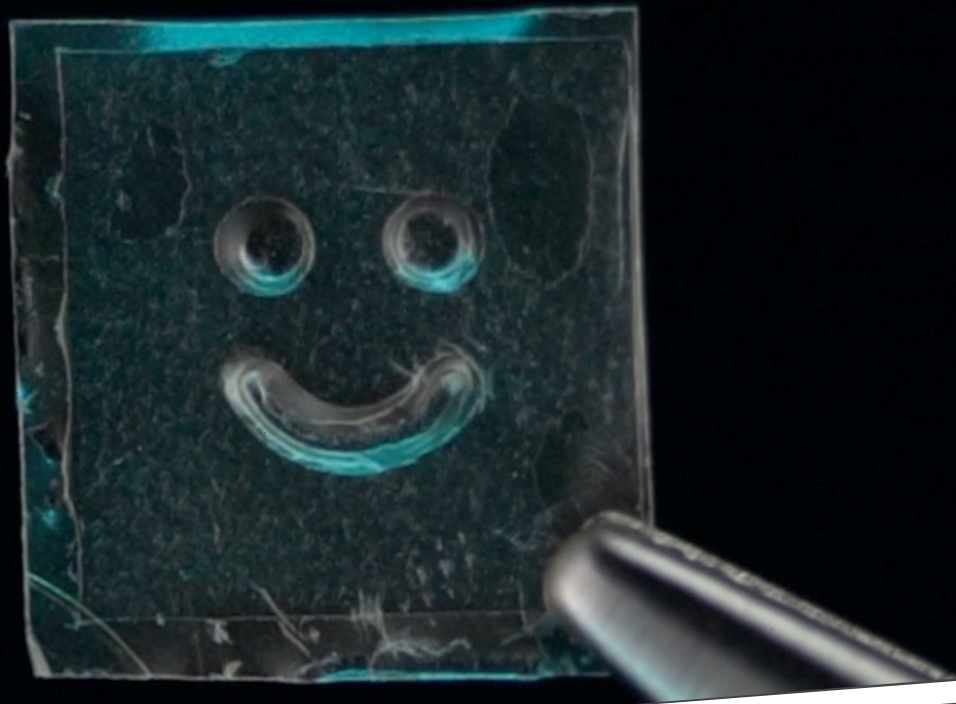


BioXclude®

AMNION-CHORION ALLOGRAFT

**RESORBABLE BARRIER MEMBRANE
+
GROWTH FACTORS**

(It's a barrier AND a carrier in one!)



**ANTI-INFLAMMATORY
ANTI-MICROBIAL
ACCELERATED HEALING
IMMUNOPRIVILEGED
LEAVE IT EXPOSED
SAFE TO TOUCH TOOTH SURFACES**

What is BioXclude®



BioXclude® is the only minimally manipulated dehydrated human deepithelialized amnion-chorion membrane available for use in a variety of dental, endodontic, oral maxillofacial, and periodontal regenerative procedures as a barrier, conduit, connector or cushion. Amnion-chorion tissue contains biological factors which aid in healing, promote angiogenesis, reduce inflammation and accelerate flap reattachment. It also possesses inherent anti-bacterial properties and the tissue is non-immunogenic. ^(1-4, 7, 8, 16)

The Bioactive Advantage

Over 280 preserved growth factors, cytokines and chemokines have been identified within BioXclude®. The complex extracellular matrix composition combined with these retained biological factors offer critical advantages over other membrane materials, demonstrated in-vitro and in-vivo. ^(1-3, 5, 7, 8, 11-14, 16)

- Safely Exposed to the Oral Environment
- Cell Occlusive Barrier
- Growth Factors
- Anti-inflammatory
- Decreased Post-Operative Pain
- Facilitates Rapid Vascular Growth
- Recruits Mesenchymal and Hematopoietic Stem Cells
- Hastened Epithelialization
- Hastened Flap Reattachment
- More Keratinized Tissue
- Stem Cell Magnet
- Anti-Microbial
- Angiogenic

Composition

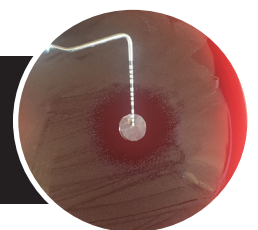
BioXclude® is composed of allograft amnion and chorion tissue. These layers represent the inner and outermost layers of the amniotic membrane, the only barrier between the mother and fetus, protecting both from each another's immune system and infection. It also serves as a shock absorber, prevents adhesion and regulates fetal temperature. Chorion tissue consists of a reticular layer, a basement membrane containing a layer of dense connective tissue and a trophoblast layer.

A Paradigm Shift In Resorption Kinetics

BioXclude® jump starts the natural wound healing process. It allows for rapid gingival epithelial cell migration and promotes neovascularization, enabling the rapid establishment of blood supply by activating the migration of human mesenchymal and hematopoietic stem cells. BioXclude® stimulates the proliferation and migration of human microvascular endothelial cells and causes these cells to produce and release angiogenic growth factors. The high concentration of Laminin-5 provides an ideal substrate for the attachment of gingival epithelial cells and Directly Attached Tooth cells (DAT cells), which supports why BioXclude® may be placed over exposed roots and is safe to leave exposed. **BioXclude® resorbs in 8-12 weeks** as demonstrated with histology.¹⁷ BioXclude® is truly a paradigm shift in resorption kinetics. It is a bioactive barrier, recruiting mesenchymal stem cells to the site, which differentiate between hard and soft tissues before the matrix resorbs. Once this process begins, it's faster resorption profile is ideal, allowing the periosteum to take over. This process challenges the established theories regarding barrier membrane characteristics which have been based solely on an inert scaffold model. ^(2, 5, 6, 10-12, 13-15)

Proven Bactericidal

Placental tissues are inherently antibacterial, offering a safer, superior material to leave exposed to the oral environment and placed in the maxillary sinus. In two separate studies, BioXclude® was proven bactericidal, in contrast to porcine collagen, which promoted bacterial growth, and porcine pericardium demonstrating no anti-microbial activity. ^(7,8)



Aggregatibacter actinomycetemcomitans • Note the zone of inhibition around the BioXclude® disc

One Product. Simple. VERSATILE.

SOCKET PRESERVATION

IMPLANTS

PERI-IMPLANTITIS

GUIDED TISSUE REGENERATION

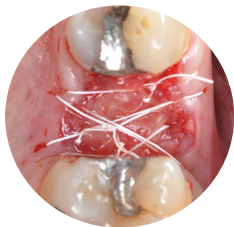
SINUS / FLAP PERFORATION REPAIR

NEURAL PROTECTION / REGENERATION

ADHESION BARRIER

ORAL WOUNDS

NON-SURGICAL PERIODONTAL THERAPY

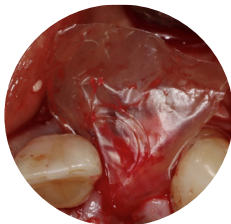


KEEP IT MINIMALLY INVASIVE

- No flap elevation required
- Simply tuck BioXclude® 1mm under gingival margin
- Easily achieved with a reverse (inverted) suturing technique

NO NEED TO TRIM

- Allow BioXclude® to drape and adhere
- This allows a larger piece to bunch up between the teeth adjacent to the site, while also extending over the buccal portion of the graft, and onto native bone



NO NEED TO FIXATE

- BioXclude® will stick to any hydrated surface
- Place dry and allow it to hydrate to the site, or hydrate over the top with sterile saline
- BioXclude® adheres like shrink wrap

UNMATCHED ADHESION

- No other product adheres to the Schneiderian membrane like BioXclude®
- Easily applied dry, naturally hydrates and seals the perforation like a patch
- No need for further fixation



BioXclude® Reinvents the Membrane “Rules”

The physical properties of BioXclude® allow clinicians to avoid many of the drawbacks associated with traditional collagen and synthetic membranes. This allows for a simplified, less invasive procedure resulting in less chair time.

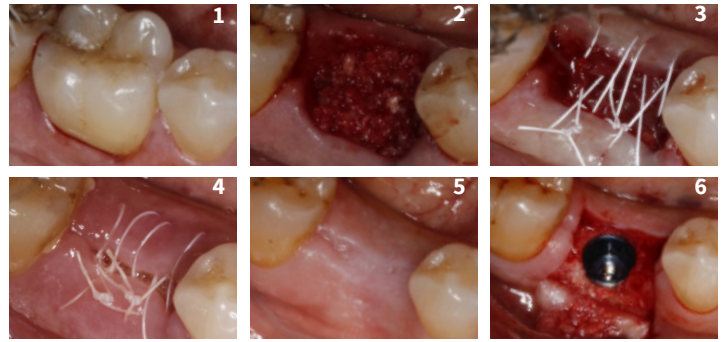
Witness the unique and beneficial handling characteristics that make BioXclude® more efficient and effective.

- **NO NEED TO TRIM - LET BIOXCLUDE® TOUCH ADJACENT TEETH**
- **NO ORIENTATION - PLACE UP OR DOWN, FOLD IT, ALLOW TO “BUNCH” UP**
- **SAFELY TOUCH ROOT SURFACES**
- **SAFELY TOUCH IMPLANT SURFACES**
- **PLACE OVER OR UNDER OTHER MEMBRANES, MESH OR PALATAL TISSUE**
- **LACKS RIGIDITY, EASILY ADAPTS AND ADHERES**
- **NO NEED TO TACK OR SUTURE**
- **THIN PROFILE - EASIER TO OBTAIN PRIMARY CLOSURE**
- **NO PRE-HYDRATION NECESSARY**
- **NO RETRIEVAL - FULLY RESORBS IN 8-12 WEEKS**
- **STORES AT AMBIENT CONDITIONS WITH A 5 YEAR SHELF LIFE**

Clinical Cases

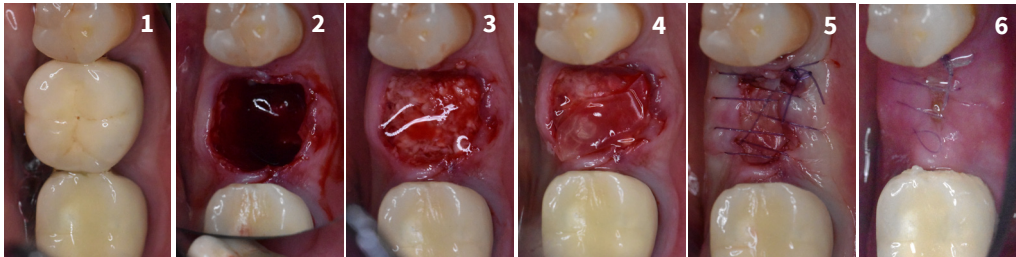
Anterior Socket Preservation: Minimally-Invasive

1. Pre-op PA
2. FDBA + BioXclude®
3. (2) Reverse figure-eight sutures
4. 10-day post-op
5. 6 month post-op
6. Implant placement



Dan Cullum, DDS, Coeur D'Alene, ID

Posterior Socket Preservation: Minimally-Invasive

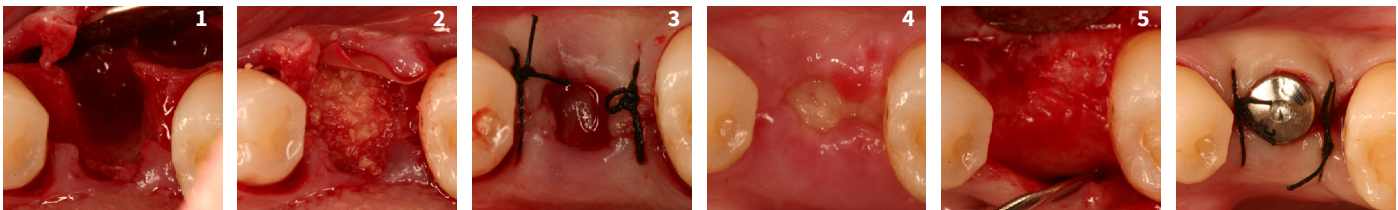


1. Hopeless tooth #4.6
2. Atraumatic extraction
3. FDBA
4. BioXclude®
5. Stabilizing suture 5.0 Monocryl
6. 12-day post-op

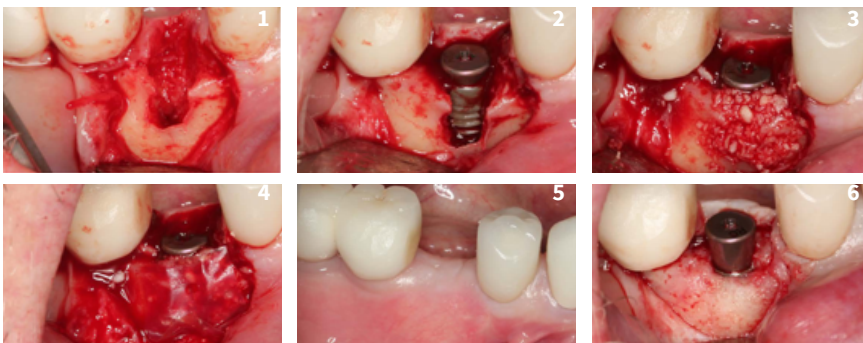
Vinay Bhide, DDS, MSc, Toronto, ON

Socket Preservation: Significant Bony Defect

1. Buccal defect
2. FDBA + BioXclude®
3. Site left exposed
4. 10-day healing
5. 3-month re-entry
6. Implant placement



Dan Holtzclaw, DDS, MS, Austin, TX



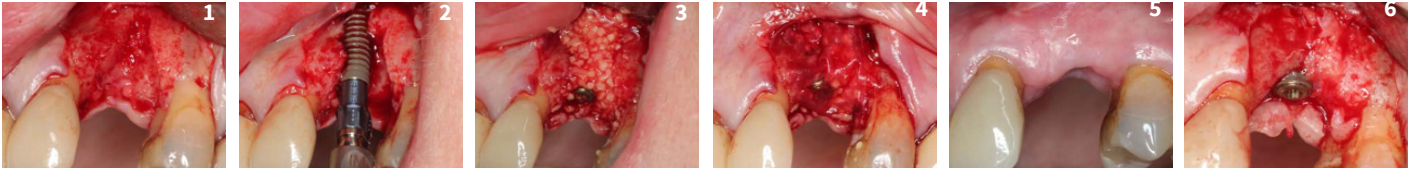
Immediate Implant

1. Failed implant removal
2. Implant placement
3. Bone graft placement
4. BioXclude® placement
5. Post-op view
6. Re-entry

Robert Miller, DMD, Plantation, FL

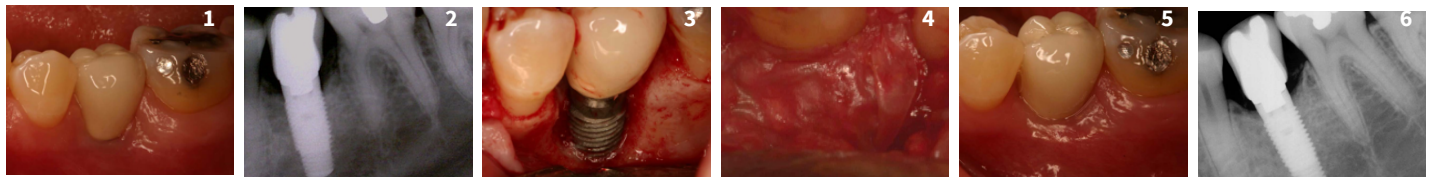
Immediate Implant: Moderate Facial Defect

1. Buccal defect
2. Implant placement
3. Bone graft placement
4. BioXclude® placement
5. Post-op view
6. Re-entry



Robert Miller, DMD, Plantation, FL

1. Pre-op implant #4.6
2. Pre-op PA
3. Defect
4. BioXclude® in place (Grafted with Bone Putty)
5. 12-month post-op
6. 12-month PA



Dan Holtzclaw, DDS, MS, Austin, TX

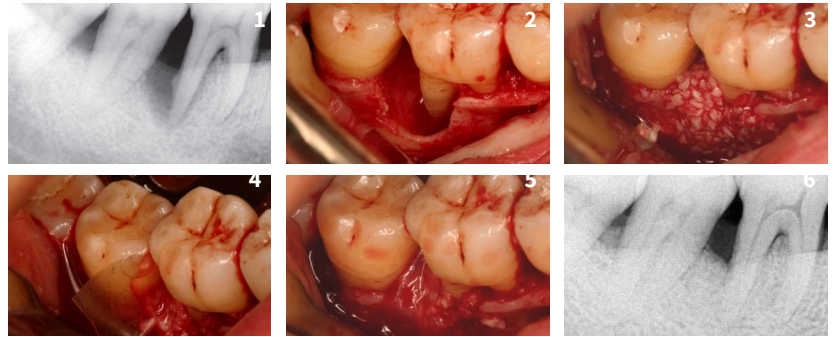
Implant Repair: Peri-implantitis

Guided Tissue Regeneration

1. Pre-op #4.6
2. Defect
3. Grafted with FDBA
4. BioXclude® placed interproximally - can flash hydrate
5. BioXclude® hydrated
6. 16-month post-op

Probing Depth

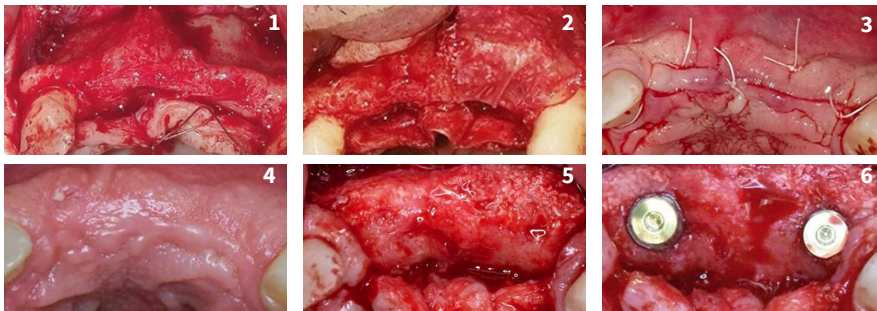
Pre-Op = 12mm
3 Mos = 3mm



Dan Holtzclaw, DDS, MS, Austin, TX

Guided Bone Regeneration: BioXclude® Only

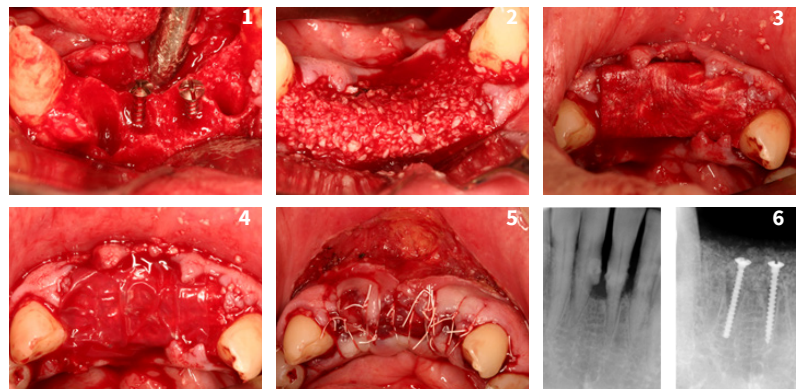
1. Pre-op defect
2. Autogenous scrapings / xenograft bone, BioXclude® placed
3. Primary closure with PTFE
4. 8-month healing
5. 8-month re-entry
6. Implants placed



Vinay Bhide, DDS, MSc, Toronto, ON

Guided Bone Regeneration: Double Membrane

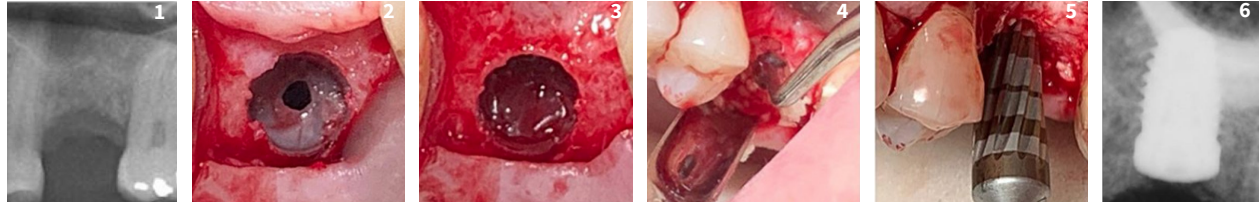
1. Extraction #3.2-4.2; tenting screws placed
2. Grafted w/FDBA
3. Collagen membrane placed
4. BioXclude® placed OVER collagen
5. Non-primary closure (vestibular dissection into chin performed to close the site).
6. Pre-op/post-op PA



Dan Holtzclaw, DDS, MS, Austin, TX

Perforation Repair: Crestal Sinus Lift

1. Pre-op PA
2. Sinus perforation
3. BioXclude® in place
4. FDDB
5. Implant placed
6. Immediate post-op PA



Anthony Del Vecchio, DDS, Yorktown Heights, NY

1. Sinus membrane perforation
2. BioXclude® placed dry
3. BioXclude® adheres to sinus and seals perforation
4. FDDB placed
5. Lateral sinus window covered with BioXclude®

Perforation Repair: Lateral Sinus Lift

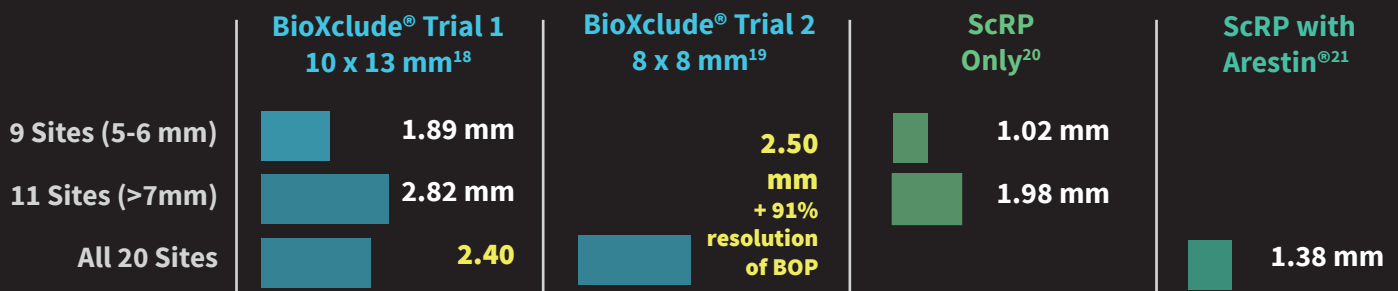


Dan Holtzclaw, DDS, MS, Austin, TX

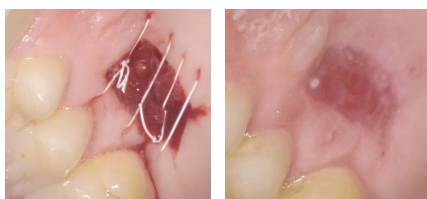
Non-Surgical Periodontal Therapy Adjunct

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



Soft Tissue Donor Site Application

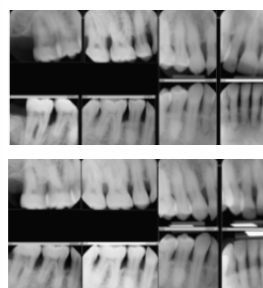


Initial 1 Week Post-Op

Decreased post-op pain and inflammation + accelerated healing

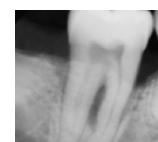
Nicholas Poulos, DDS, MS, Denver, CO

Periodontal Laser Therapy + BioXclude® Adjunct

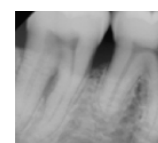


Pre-Op

Post-Op



Initial PD
Average: **4.99 mm**



Post-Op PD
Average: **3.03mm**

Post-Op PD Improvement
Average: **1.96mm**

Nicholas Poulos, DDS, MS, Denver, CO

Safety, Procurement and Processing

The placental tissue is sourced in the United States with informed consent from pre-screened mothers following elective cesarean section deliveries only. The tissue is procured, processed, and distributed according to standards and regulations established by the American Association of Tissue Banks and the United States Food & Drug Administration.

Purion® Process

This proprietary process safely and gently separates placental tissues, cleans and reassembles layers, and then dehydrates the tissue to preserve the key elements associated with healing. The Purion® process removes blood components while protecting the delicate scaffold of the tissues, leaving an intact extracellular matrix. Following processing, the allografts are terminally sterilized (SAL 10⁻⁶)



CHOOSING THE RIGHT SIZE:

No flap elevation:

Tuck 1mm under gingival margin

Flap Elevation:

Cover all graft material; extend onto native bone 3mm

Sinus Perforation:

Extend 5mm past edge of perforation

Size Choices



Innovation Supported By Research

Pioneering Placental Tissue Science and Regenerative Biomaterials

Snoasis Medical has pioneered the development and use of placental tissue products for tissue repair and regeneration in dental-oral maxillofacial surgery for over 10 years. For more information, review this sample of our **scientific** and **clinical studies**:

- Ashraf H, Font K, Powell C, et al. "Anti-microbial Activity of an Amnion-Chorion Membrane to Oral Microbes", *International Journal of Dentistry*, vol. 2019, Article ID 1269534, 7 pages, 2019.
- De Angelis N, Kassim ZH, Frosecchi M, et al. "Expansion of the zone of keratinized tissue for healthy implant abutment interface using de-epithelialized amnion/chorion allograft." *Int J Periodontics Restorative Dent* 2019; 39: e83-e88. Doi: 10.11607/prd.3757.
- Cullum D, Lucas M. "Minimally invasive extraction site management with dehydrated amnion/chorion membrane (dHACM): Open-socket grafting." *Compendium* 2019; 40(3):178-183.
- Temraz A, Ghallab H, Hamdy R, et al. "Clinical and radiographic evaluation of amnion-chorion membrane and demineralized bone matrix putty allograft for management of periodontal intrabony defects: a randomized clinical trial." *Cell Tissue Bank* 2019;
- Taalab M, Gamal R. "The effect of amniotic chorion membrane on tissue biotype, wound healing and periodontal regeneration." *IOSR J Dent Med Sciences* 2018; 17(12):61-69.
- Solomon C, Kim M, Volk D, Kellert M. "The use of bioactive membranes to enhance endodontic surgical and regenerative outcomes." *New York St Dent J* 2018; 11:26-30.
- Maksoud M., Guze K., "Tissue expansion of dental extraction sockets using dehydrated human amnion/chorion membrane: Case series." *Clin Adv Periodontics* 2018, 8:111-114.
- Holtzclaw D. "Repair of Dental Implant Induced Inferior Alveolar Nerve Injuries with Dehydrated Human Amnion-Chorion Membranes: A Case Series." *Imp Adv Clin Dent* 2018; 10(6):16-28.
- Hassan M, Prakasam S, et al. "A randomized split-mouth clinical trial on effectiveness of amnion-chorion membranes in alveolar ridge preservation: A clinical, radiologic, and morphometric study." *Int J Oral Maxillofac Implants* 2017; 32:1389-1398.
- Prakasam S. "Dehydrated amnion-chorion membranes for periodontal and alveolar regeneration." *Decis Dent* 2017; 3(8): 21-25.
- Holtzclaw D, Tofe R. "An updated primer on the utilization of amnion-chorion allografts in dental procedures." *J Imp Adv Clin Dent* 2017; 2(9):16-37.
- Nevins M, Aimetti M, Benfenati SP et al. "Treatment of moderate to severe buccal gingival recession defects with placental allografts." *Int J Periodontics Restorative Dent* 2016; 36:171-177
- Holtzclaw D. "Dehydrated human amnion-chorion barrier used to assist mucogingival coverage of titanium mesh and rhBMP-2 augmentation of severe maxillary alveolar ridge defect: A case report." *J Imp Adv Clin Dent* 2016; 8(4): 6-16.
- Holtzclaw D. "Maxillary sinus membrane repair with amnion-chorion barriers: A retrospective case series." *J Perio* 2015; 86(8):936-940.
- Masse M, Chinn K, Lei J et al. "Dehydrated human amnion/chorion membrane regulates stem cell activity in vitro" *J Biomed Mater Res Part B* 2015:00B:000-00.
- Maan Z, Rennert R, Koob T et al. "Cell recruitment by amnion chorion grafts promotes neovascularization." *J Surgical Res* 2015; 193(2): 953-962.
- Chi S, Andrade D, Kim M, Solomon C. "Guided tissue regeneration in endodontic surgery by using a bioactive resorbable membrane." *J Endod* 2015; 41:559-562. April
- Rosen P, Froum S, Cohen W. "Consecutive case series using a composite allograft containing mesenchymal cells with an amnion-chorion barrier to treat mandibular Class III/IV furcations." *Int J Perio Rest Dent* 2015; 35:561-569
- Holtzclaw D. "Open sinus healing comparison between non-perforated Schneiderian membrane and a perforated Schneiderian membrane repaired with amnion-chorion allograft barrier: A controlled, split mouth case report." *J Imp Adv Clin Dent* 2014; 6(8):11-21.
- Prakasam S. "Dehydrated amnion-chorion membranes for periodontal and alveolar regeneration." *Decis Dent* 2017; 3(8): 21-25.
- Koob T, Lim J, Zabek N et al. "Cytokines in single layer amnion allografts compared to multi-layer amnion/chorion allografts for wound healing." *J Biomed Mater Res B* 2014: DOI: 10.1002/jbm.b.33265.
- Koob T, Lim J, Masee M et al. "Angiogenic properties of dehydrated human amnion/chorion allografts: Therapeutic potential for soft tissue repair and regeneration." *Vas Cell* 2014; 4(10): doi: 10.1186/2045-824X-6-10.
- Koob T, Lim J, Masee M et al. "Properties of dehydrated human amnion/chorion composite grafts: Implications for wound repair and soft tissue regeneration." *J BioMed Mater Res Part B* 2014:00B:000-000.
- Holtzclaw D, Cobb C. "Extraction site preservation using new graft material that combines mineralized and demineralized allograft bone: A case series report with histology." *Compendium* 2014; 2 (35):107-112.
- Holtzclaw D, Toscano N. "Amnion-chorion allograft barrier used for guided tissue regeneration treatment of periodontal intrabony defects: A retrospective observational report." *Clin Adv Perio* 2013; 3(3):131-137.
- Koob T, Rennert R, Zabek N et al. "Biological properties of dehydrated human amnion/chorion composite graft: implications for chronic wound healing." *Int Wound J* 2013; 10(5):493-500.
- Rosen P. "A case report on combination therapy using a composite allograft containing mesenchymal cells with an amnion-chorion barrier to treat a mandibular Class III furcation." *Clin Adv Perio* 2013; 3(2):64-69.
- Holtzclaw D, Hinze F, Toscano N. "Gingival flap attachment healing with amnion-chorion allograft membrane: A controlled, split mouth case report replication of the classic 1968 Hiatt study." *J Imp Adv Clin Dent* 2012; 4(5):19-25.
- Rosen P. "Comprehensive periodontal regenerative care: Combination therapy involving bone allograft, a biologic, a barrier, and a subepithelial connective tissue graft to correct hard- and soft-tissue deformities." *Clin Adv Perio* 2011; 1(2):154-159.
- Holtzclaw D, Toscano N. "BioClude® placental allograft tissue membrane in combination with bone allograft for site preservation: A Case Series." *J Imp Adv Clin Dent* 2011; 3(3):35-50.

REFERENCES: [1] Koob T, Rennert R, Zabek N, et al. Biological properties of dehydrated human amnion/chorion composite graft: implications for chronic wound healing. *Int Wound J* 2013; doi: 10.1111/ijw.12140. [2] Koob T, Li W, Gurtner G et al. Angiogenic properties of dehydrated human amnion/chorion allografts: therapeutic potential for soft tissue repair and regeneration. *Vas Cell* 2014; 4(10): doi:10.1186/2045-824X-6-10. [3] Koob T, Zabek N, Masee N, et al. Properties of dehydrated human amnion/chorion composite grafts: implications for wound repair and soft tissue regeneration. *J BioMed Mater Res Part B* 2014:00B:000-000. [4] Xenouli P, Lucas M, Chlipala E, et al. Comparison of porcine and amniotic resorbable collagen membranes using H&E staining and immunohistochemistry. Manuscript in Preparation. Data on file at Snoasis Medical. [5] Holtzclaw D, Toscano N. Amnion chorion allograft barrier: indications and techniques update. *J Imp Adv Clin Dent* 2012; 4(2):25-38. [6] Holtzclaw D, Cobb C. Extraction site preservation using new graft material that combines mineralized and demineralized allograft bone: a case series report with histology. *Compendium*. Feb 2014; 107-112. [7] Ashraf H, Font K, Powell C, et al. Anti-microbial Activity of an Amnion-Chorion Membrane to Oral Microbes. *International Journal of Dentistry*, vol. 2019, Article ID 1269534, 7 pages, 2019. [8] Palanker N, Lee C, Tribble G, et al. Anti-microbial efficacy assessment of human derived amnion-chorion. University of Texas at Houston Health Sciences Center Graduate Periodontics (Houston, TX). Poster presentation #27 at American Academy of Periodontology Meeting 2018, Vancouver, BC. Manuscript in preparation. [9] Hodde J. Naturally occurring scaffolds for soft tissue repair and regeneration. *Tiss Eng* 2002; 8(2): 295-308. [10] Niknejad H, Peirovi H, Jorjani M, et al. Properties of the amniotic membrane for potential use in tissue engineering. *Euro Cells Mat* 2008; 15: 88-89. [11] Holtzclaw D, Toscano N. BioClude™ placental allograft tissue membrane in combination with bone allograft for site preservation: A Case Series. *J Imp Adv Clin Dent* 2011; 3(3):35-50. [12] Wallace W, Cobb C. histological and computed tomography analysis of amnion chorion membrane in guided bone regeneration in socket augmentation. *J Imp Adv Clin Dent* 2011; 3(6):61-72. [13] 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. [14] Holtzclaw D, Toscano N. Amnion-chorion allograft barrier used for guided tissue regeneration treatment of periodontal intrabony defects: A retrospective observational report of 64 patients. *Clin Adv Perio* 2013; 3(3):131-137. [15] Chen A, Tofe A. A literature review of the safety and biocompatibility of amnion tissue. *J Imp Adv Clin Dent* 2010; 2(5):67-75. [16] MIMedex Research Report. MM-R0-00022: EpiFix and Amnionix Total Growth Factor Content. [17] Wallace W, Cobb C. Histological and computed tomography analysis of amnion chorion membrane in guided bone regeneration in socket augmentation. *J Imp Adv Clin Dent* 2011; 3(6):61-72. [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.

VINAY BHIDE, DDS, MSc

@DRBHIDEPERIO | TORONTO, ON

"BioXclude® has been a game changer for me in practice. The biological properties, handling, versatility for multiple therapeutic indications, and consistency of results is second to none!"

**Michael Block, DMD**

CENTER FOR DENTAL RECONSTRUCTION | METAIRIE, LA

"I have been using BioXclude® to cover my extraction site grafts and to cover larger grafts for ridge augmentation. My incision dehiscence rate is almost zero. The soft tissue healing using this material is very strong. I recommend it without reservations."

**Matthew Fien, DDS**


@FIENODONTICS | PLANTATION, FL

"BioXclude® is an incredible biomaterial and it has changed the way I practice. The applications are endless"

**Dan Holtzclaw, DDS, MS**

DENTAL IMPLANT CENTER | AUSTIN, TX

"I have used it thousands and thousands of times - I have used it on family members, I have used it on friends. I know that it works. Now, there are many, many, published studies that also show that this material works and there are histological studies to back it up."

Proudly  Owned & Operated