

GEM 21S[®]

GROWTH-FACTOR ENHANCED MATRIX



LYNCH
BIOLOGICS
Helping You Heal

GEM 21S®

GROWTH-FACTOR ENHANCED MATRIX

GEM 21S® Growth-factor Enhanced Matrix is designed to enhance the patient's natural ability to heal and restore their bone and gingiva that has been lost as a result of periodontal disease.

What is **GEM 21S®**?

GEM 21S® Growth-Factor Enhanced Matrix is a synthetic bone graft composed of purified, sterile recombinant (bioengineered) platelet-derived growth factor (rhPDGF) and a bone graft. PDGF is naturally found in our bodies (present in the platelets in your blood) and is often referred to as *nature's wound healing protein*. Whenever a patient experiences a wound or surgery, their blood clots and platelets release PDGF (along with other proteins), stimulating the healing process. Unfortunately, as we grow older and with certain conditions, the amount of naturally occurring PDGF declines so we no longer heal as we did previously. GEM 21S® replenishes the amount of PDGF at the grafted site to aid in faster, better healing.

(Refer to Package Insert: lynchbiologics.com/products/gem-21s/)

GEM 21S® is engineered to take advantage of tissue engineering principles combining purified, potent rhPDGF with an osteoconductive matrix (beta tricalcium phosphate, β -TCP).

Powerful Stimulator of Angiogenesis

An adequate blood supply is critical to the success of any grafting procedure. Extensive in vitro and in vivo studies have demonstrated that rhPDGF-BB is a powerful stimulant of angiogenesis that also stabilizes newly formed blood vessels.

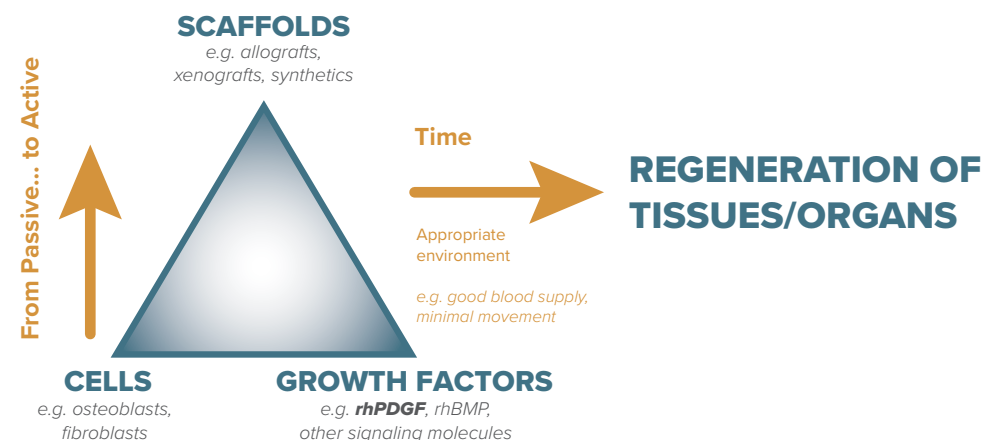
How will your patients benefit from treatment with **GEM 21S®**?

GEM 21S® promotes faster, better healing and a more predictable outcome of your oral regenerative procedures. GEM 21S® is the only product available for use in dental surgery that contains purified rhPDGF to improve healing.

“PDGF significantly increases the proliferation and migration of osteoblasts and other cells of the periodontum”^{1, 2, 3}

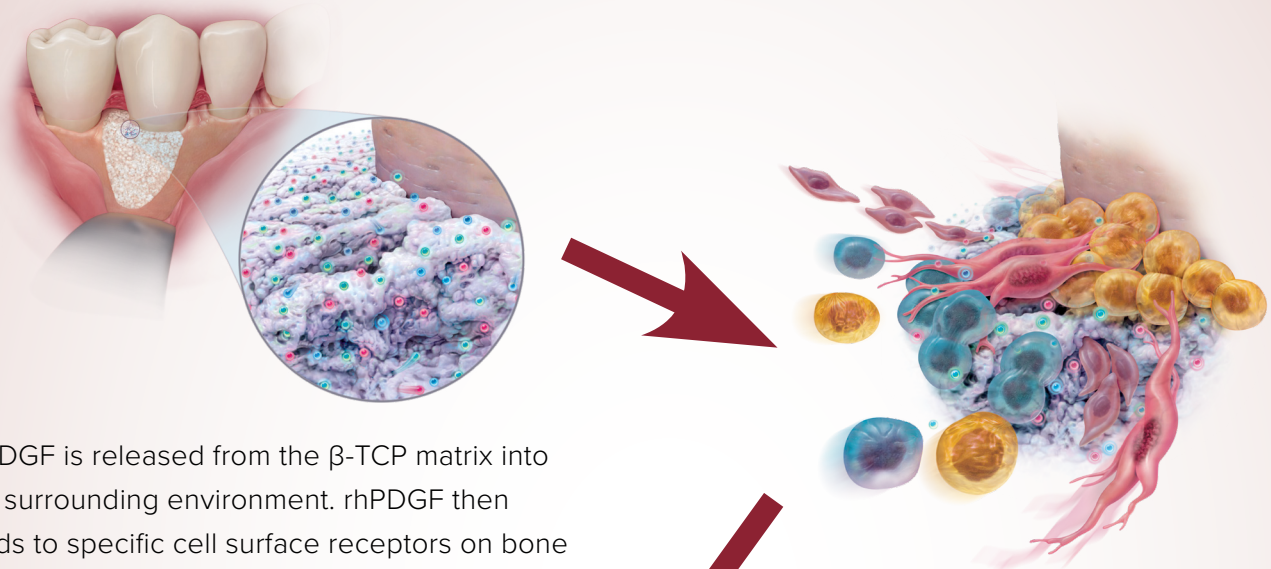
The Tissue Engineering Paradigm

It takes all 3 components to optimize regenerative outcomes... if you're only using scaffolds, you're only 1/3 as effective as you could be in many defects!



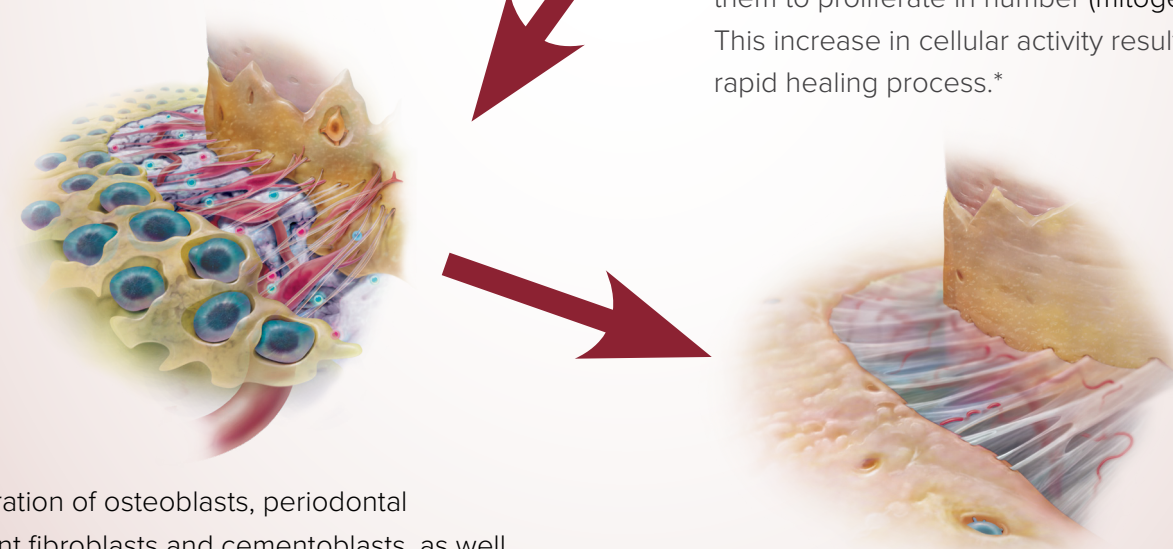
Mechanism of Action

The illustrations below describe how GEM 21S® speeds up your body's natural healing process. Once GEM 21S® is properly prepared by mixing the powerful growth-factor with the osteoconductive scaffold and the product is allowed to sit for at least 10 minutes, GEM 21S® is used to fill the area where bone and other supporting structures have been lost.



rhPDGF is released from the β -TCP matrix into the surrounding environment. rhPDGF then binds to specific cell surface receptors on bone and soft tissue healing cells, GEM 21S® acts by signaling your body to actively begin to heal and regenerate healthy bone and soft tissues.

GEM 21S® attracts the specific cells that your body needs to regenerate bone and the surrounding tissues (chemotaxis), and causes them to proliferate in number (mitogenesis). This increase in cellular activity results in a more rapid healing process.*



Proliferation of osteoblasts, periodontal ligament fibroblasts and cementoblasts, as well as new blood vessel formation (angiogenesis), leads to increased matrix synthesis, resulting in formation of new alveolar bone, periodontal ligament and cementum.*

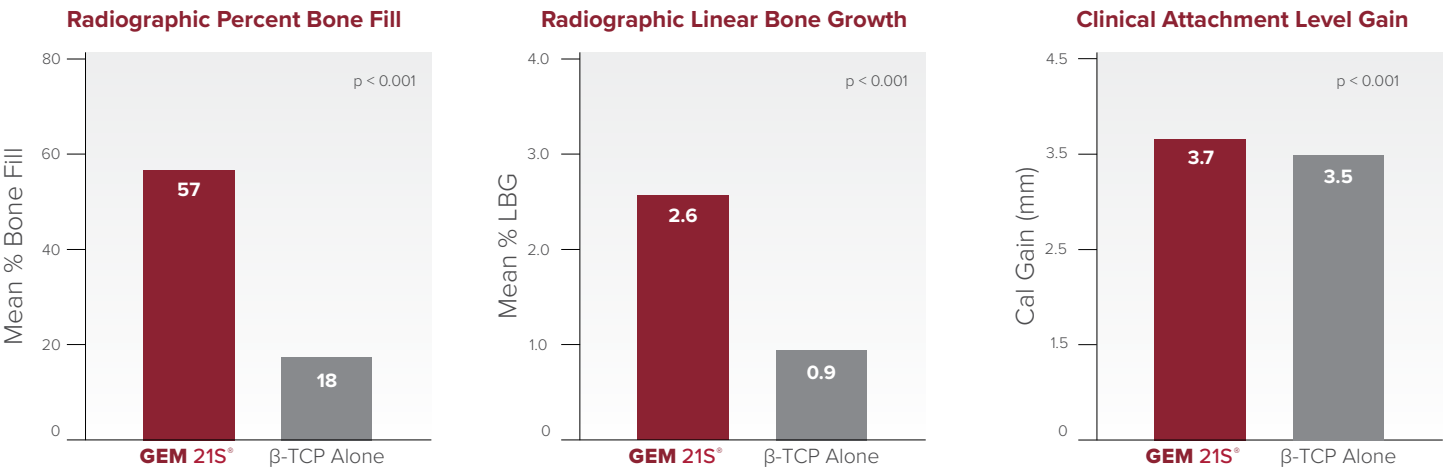
Clinical data shows that over time (approximately 6 months), GEM 21S® is gradually replaced with your patient's own bone and other normal tissues. The end result is enhanced bone and periodontal regeneration.

CLINICALLY RELIABLE

INTRABONY AND FURCATION DEFECTS

The results of the largest prospective, randomized, triple-blinded and controlled pivotal clinical trial reported to date that assessed a putative periodontal regenerative and wound healing therapy demonstrated the following:

- ▶ The use of GEM 21S® was safe and effective in the treatment of periodontal osseous defects
- ▶ Treatment with GEM 21S®
 - Stimulated a significant increase in the rate of CAL gain
 - Reduced gingival recession at 3 months post-surgery
 - Improved bone fill and linear bone gain as compared to a B-TCP bone substitute at 6 months



Nevins M, Giannobile WV, McGuire MK, Kao RT et al. Platelet-derived growth factor stimulates bone fill and rate of attachment level gain: results of a large multicenter randomized controlled trial. J Periodontol 2005; 76:2205-2215.

Indications

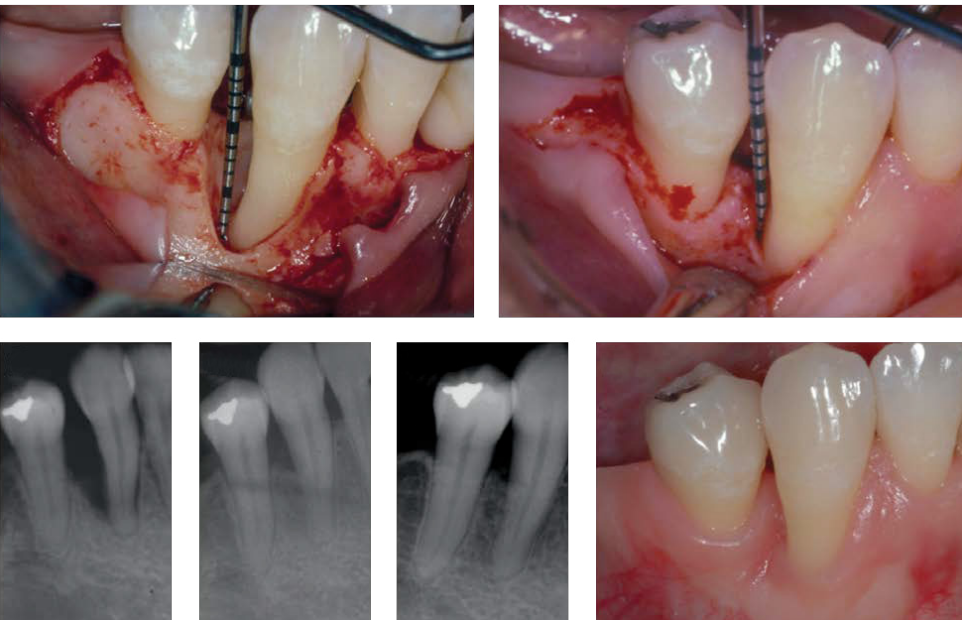
GEM 21S® is indicated to treat the following periodontally related defects:

- ▶ Intrabony periodontal defects
- ▶ Furcation periodontal defects
- ▶ Gingival recession associated with periodontal defects

CASES BY MASTER CLINICIANS



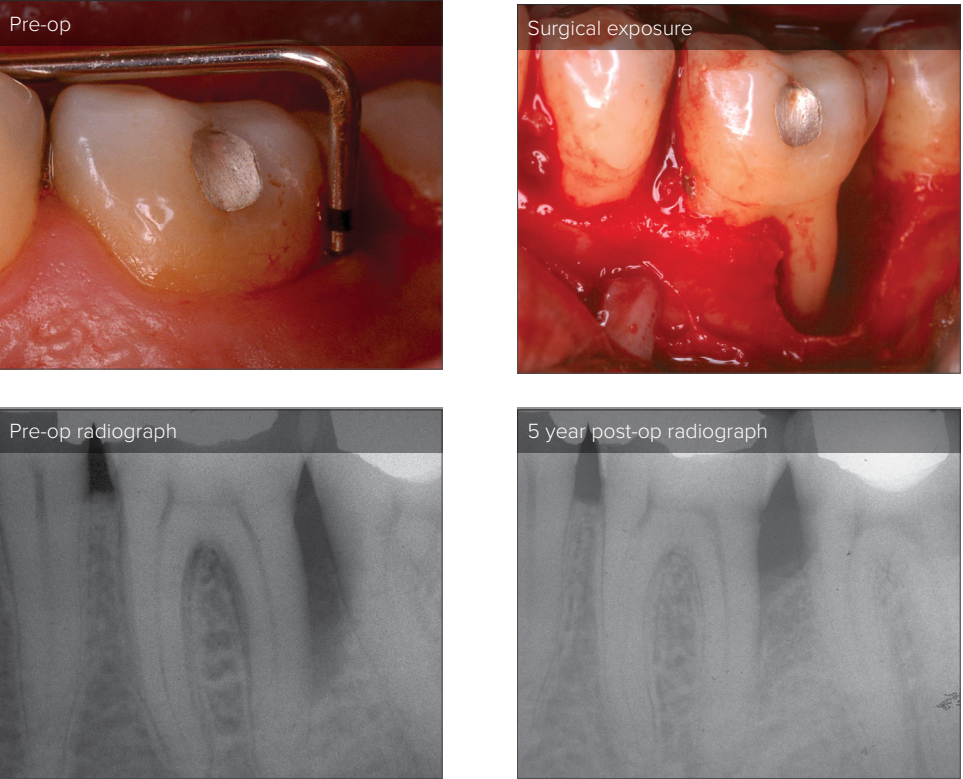
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From: Nevins, M., Kao, R. T., McGuire, M. K., McClain, P. K., Hinrichs, J. E., McAllister, B. S., Reddy, M. S., Nevins, M. L., Genco, R. J., Lynch, S. E., & Giannobile, W. V. (2013). Platelet-derived growth factor promotes periodontal regeneration in localized osseous defects: 36-month extension results from a randomized, controlled, double-masked clinical trial. Journal of periodontology, 84(4), 456–464.



Dr. Richard Kao
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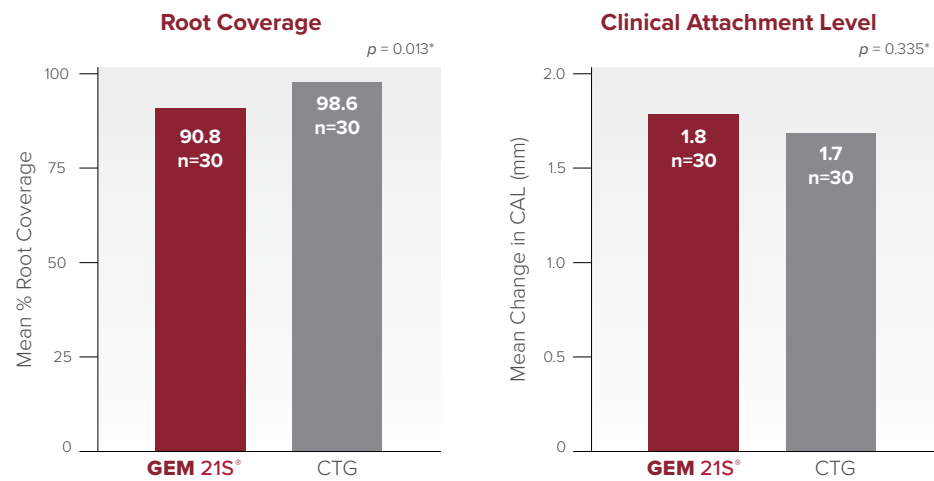


Richard T. Kao and Samuel E. Lynch. Stability of Recombinant Human Platelet-Derived Growth Factor-BB—Regenerated Periodontal Defects: Sixty-Month Clinical and Radiographic Observations. Clinical Advances In Periodontics. 2011; 1:132-141.

GINGIVAL RECESSION DEFECTS

Clinical Performance

A randomized controlled clinical trial compared GEM 21S® Growth-factor Enhanced Matrix to Subepithelial Connective Tissue Grafts (CTG).^{*} Investigators concluded that both the CTG and GEM 21S® treatments resulted in clinically significant improvements over the six month evaluation periods and were effective treatments for the correction of recession defects.



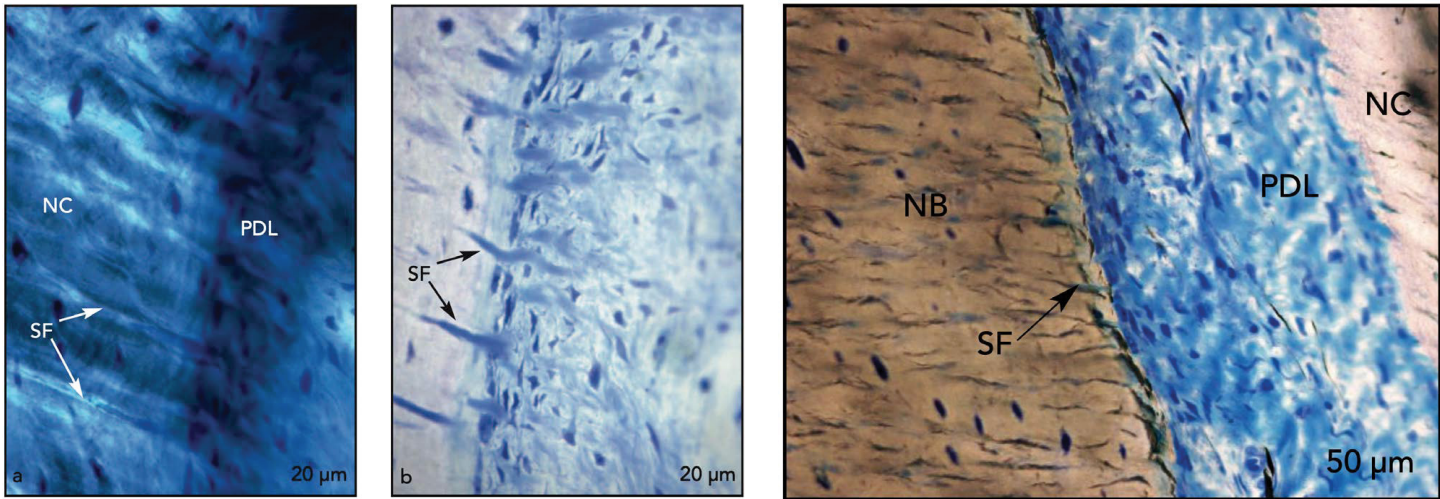
^{*}Results obtained in this trial are based on a technique that includes methods not included in approved insert.

McGuire MK, Scheyer ET, Nevins M, Schupbach P. Evaluation of a Human Recession Defects Treated with Coronally Advanced Flaps and Either Purified Recombinant Human Platelet-Derived Growth Factor-BB with Beta Triacalcium Phosphate or Connective Tissue: A Histologic and Microcomputed Tomographic Examination. *Int J Periodontics Restorative Dent.* 2009; 29:7-21.

Patient Satisfaction

At the conclusion of the trial, patients who were in need of additional surgery unanimously stated that they would prefer treatment with GEM 21S® over a CTG because they were satisfied with the esthetic results and could avoid the harvesting of a palatal graft.

Histologic Evidence



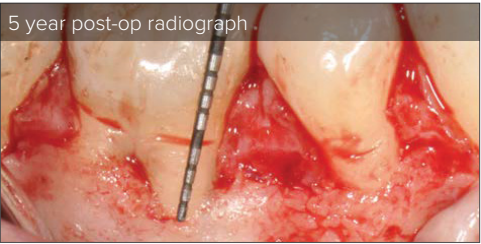
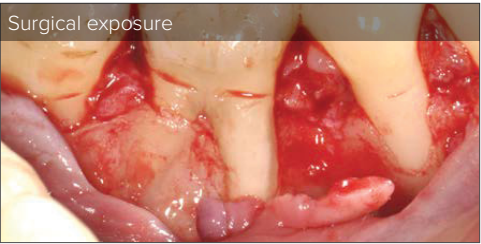
Under polarized light, Sharpey Fibers (SF) are seen inserting into newly regenerated bone (NB) and cementum (NC). In the ground section, well defined connective tissue fibers are also seen inserting into regenerated cementum. PDL = periodontal ligament.

CASES BY MASTER CLINICIANS



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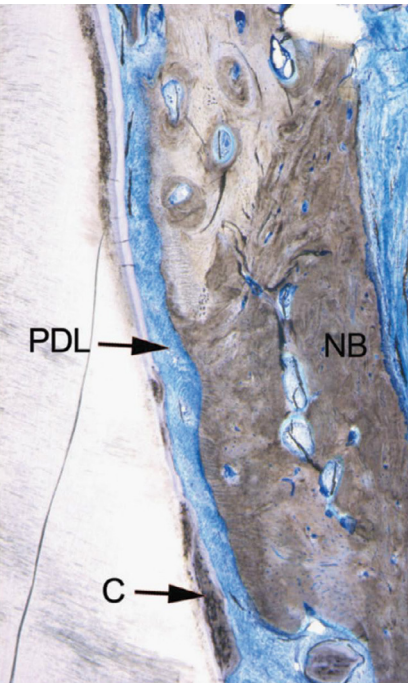


Ganeles J, Pette GA. Regenerative Treatment for Recession Defects Using Purified Human Platelet-Derived Growth Factor-BB, Particulate Grafts, and Coronally Repositioned Flaps. *Clin Adv Periodontics.* 2012 May;2(2):57-64. doi: 10.1902/cap.2011.110024. PMID: 32781816.



Dr. Michael McGuire

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From: McGuire MK, Scheyer T, Nevins M, Schupbach P. Evaluation of human recession defects treated with coronally advanced flaps and either purified recombinant human platelet-derived growth factor-BB with beta tricalcium phosphate or connective tissue: a histologic and microcomputed tomographic examination. *Int J Periodontics Restorative Dent.* 2009 Feb;29(1):7-21.



Dr. E. Todd Scheyer

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GEM 21S®



ONE OF THE BEST STUDIED
BIOLOGICS IN DENTISTRY

500+
60+
1,650
~11 months

PUBLICATIONS
CLINICAL STUDIES
DEFECTS ANALYZED
MEAN FOLLOW-UP

Comparison of GEM 21S® and Emdogain®

Improvements in clinical and radiographic parameters in the GEM 21S® pivotal trial compare favorably with, documented outcomes for other regenerative therapies in studies examining defects with similar baseline characteristics.^{4,5}

		
Product Description	GEM 21S® GEM 21S® growth-factor enhanced matrix is a combination of highly purified recombinant human platelet derived growth factor-BB (rhPDGF-BB) and an osteoconductive matrix (beta-tricalcium phosphate, β -TCP).	Emdogain® Emdogain® consists of a number of hydrophobic proteins that self assemble to form a matrix layer on the root surface. The primary protein is amelogenin. These proteins are delivered in a propylene glycol alginate carrier solution. ⁵
Source	Synthetic (engineered through recombinant technology)	Xenograft (porcine origin)
Amount of Growth Factor	PDGF = 300,000 ng/ml	NONE
Primary Mode of Action	Extensive in vitro and in vivo studies have demonstrated that rhPDGF-BB is a powerful stimulant of angiogenesis and significantly increases the proliferation and migration of osteoblasts and other cells of the periodontium.	Amelogenin and the other proteins in Emdogain® mediate the formation of acellular cementum on the roots of teeth and provide a matrix for tissues associated with the attachment apparatus. ⁵
Radiographic Bone Fill (%)*	57% (6 months)	14% (8 months)
Radiographic Linear Bone Growth (mm)*	2.6 mm (6 months)	1.1 mm (8 months)
Clinical Attachment Level Gain*	3.7 mm (6 months)	2.7 mm (8 months)

Additional References

1. Wang HL, Pappert TD, Castelli WA, Chiego DJ Jr., Shyr Y, Smith BA, The Effect of Platelet-Derived Growth Factor on the Cellular Response of the Periodontium: An Autradiographic Study on Dogs. J Periodontol. 1994 May; 65 (5): 429-36.
2. Graves DT. The Use of Biologic Response Modifiers in Human Clinical Trials. Ann Periodontol. 1997; 2: 259-267.
3. Piche JE, Graves DT. Study of the Growth Factor Requirements of Human Bone-Derived Cells: a Comparison with Human Fibroblasts. Bone. 1989; 10(2): 131-189.
4. Heijl L, Heden G, Svardstrom G, Ostgren A. Enamel matrix derivative (EMDOGAIN) in the treatment of intrabony periodontal defects. J Clin Periodontol. 1997;24:705-714.
5. Zetterstrom O, Andersson C, Driksson L et al. Clinical safety of enamel matrix derivative (EMDOGAIN) in the treatment of periodontal defects. J Clin Periodontol. 1997;24:697-704.

Important Safety Information

GEM 21S® Growth-Factor Enhanced Matrix is intended for use by periodontists/ dentists/ oral surgeons familiar with periodontal surgical techniques. It should not

be used in the presence of untreated acute infections or untreated malignant cancerous growth at the site of use, where bone grafting is not advisable or tissue coverage is not possible and, in patients with a known hypersensitivity to one of its components. It must not be injected into your body, only placed into a defect around your teeth.

The safety and effectiveness of GEM 21S® has not been established in patients with an active malignant cancerous growth, in other non-periodontal bony locations, in patients less than 18 years old, in pregnant or nursing women, in patients with frequent/excessive tobacco use (e.g. smoking more than one pack per day). In a 180 patient clinical trial, there were no serious adverse events related to GEM 21S®. Adverse events that may occur are those associated with periodontal surgical procedures in general, including swelling; pain; bleeding; dizziness; fainting; difficulty breathing; eating or speaking; sinus problems; headaches; loose teeth; infection; loss of feeling; and shock. Should any of these occur, an additional surgical procedure and/or removal of the product may be required.

See Full Prescribing Information: <https://www.lynchbiologics.com/products/gem-21s/>



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