

creos™ xenoprotect

Scientific evidence
January 2019

creos™ xenoprotect

Overview

creos xenoprotect is a resorbable collagen membrane for use in guided bone regeneration (GBR) and guided tissue regeneration (GTR) procedures.

- Natural collagen membrane^{1,2}
- Outstanding handling^{3,4} and mechanical strength^{1,2}
- Active role in bone-healing dynamics in vivo⁵
- Low rates of complications^{4,6,7}
- Good clinical results in the treatment of:
 - Dehiscence defects^{6,8}
 - Horizontal ridge augmentation⁷

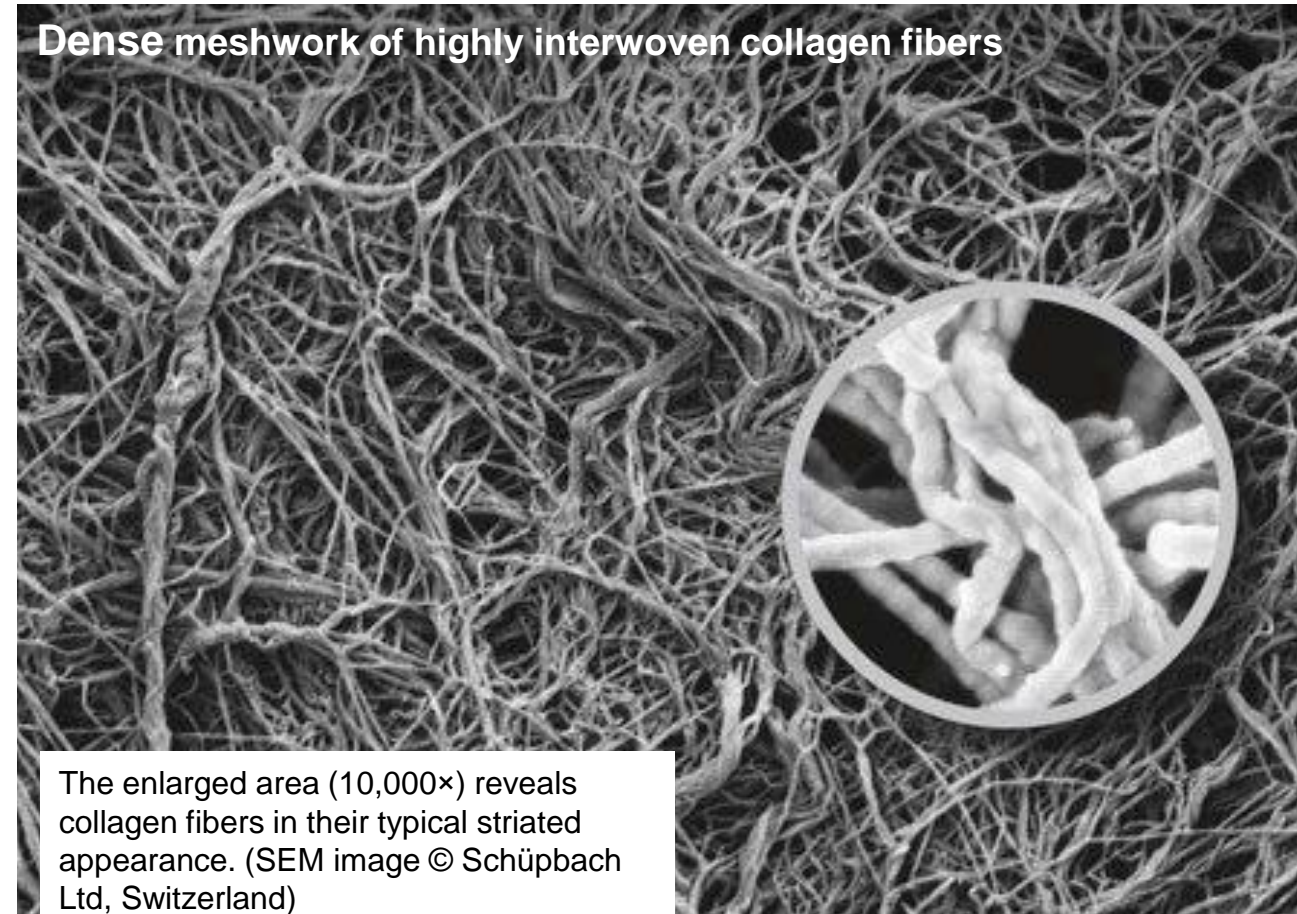


1. Bozkurt A, et al. Clin Oral Implants Res 2014;25(12):1403–1411. 2. Gasser A, et al. J Dent Res 2016;95(Spec Iss A):1683. 3. Arrighi I, et al. J Dent Res 2014;93(Spec Iss B):631. 4. Wessing B, et al. Int J Periodontics Restorative Dent 2016;36(2):179–187. 5. Omar O, et al. Clin Oral Implants Res 2018;29(1):7–19. 6. Wessing B, et al. Clin Oral Implants Res 2017;28(11):e218–e226. 7. Aleksic Z, et al. J Clin Periodontol 2018;45(S19):306. 8. Sanz-Sanchez I, et al. J Clin Periodontol 2018;45(S19):19–20.

creos™ xenoprotect: natural collagen membrane

- creos xenoprotect is composed of a network of interwoven, highly purified porcine collagen and elastin fibers, providing the membrane with high mechanical strength.¹
- The fiber mesh holds the bone graft material securely in place, preventing undesired soft tissue from migrating into the bone augmentation site during bone healing.²

1. Bozkurt A, et al. Clin Oral Implants Res 2014;25(12):1403–1411.
2. Gasser A, et al. J Dent Res 2016;95(Spec Iss A):1683.



creos™ xenoprotect: outstanding handling and mechanical strength

- creos xenoprotect shows low surface expansion when hydrated.¹
- creos xenoprotect can be stretched over the bone augmentation site and fixed with pins to stabilize the bone graft material in horizontal ridge augmentation procedures.²
- creos xenoprotect results in excellent suture retention due to high pull-out force.^{3,4}
- creos xenoprotect is highly tear resistant, making it easy to suture or fixate with pins.^{2,3}

1. Arrighi I, et al. J Dent Res 2014;93(Spec Iss B):631.

2. Wessing B, et al. Int J Periodontics Restorative Dent 2016;36(2):179–187.

3. Gasser A, et al. J Dent Res 2016;95(Spec Iss A):1683.

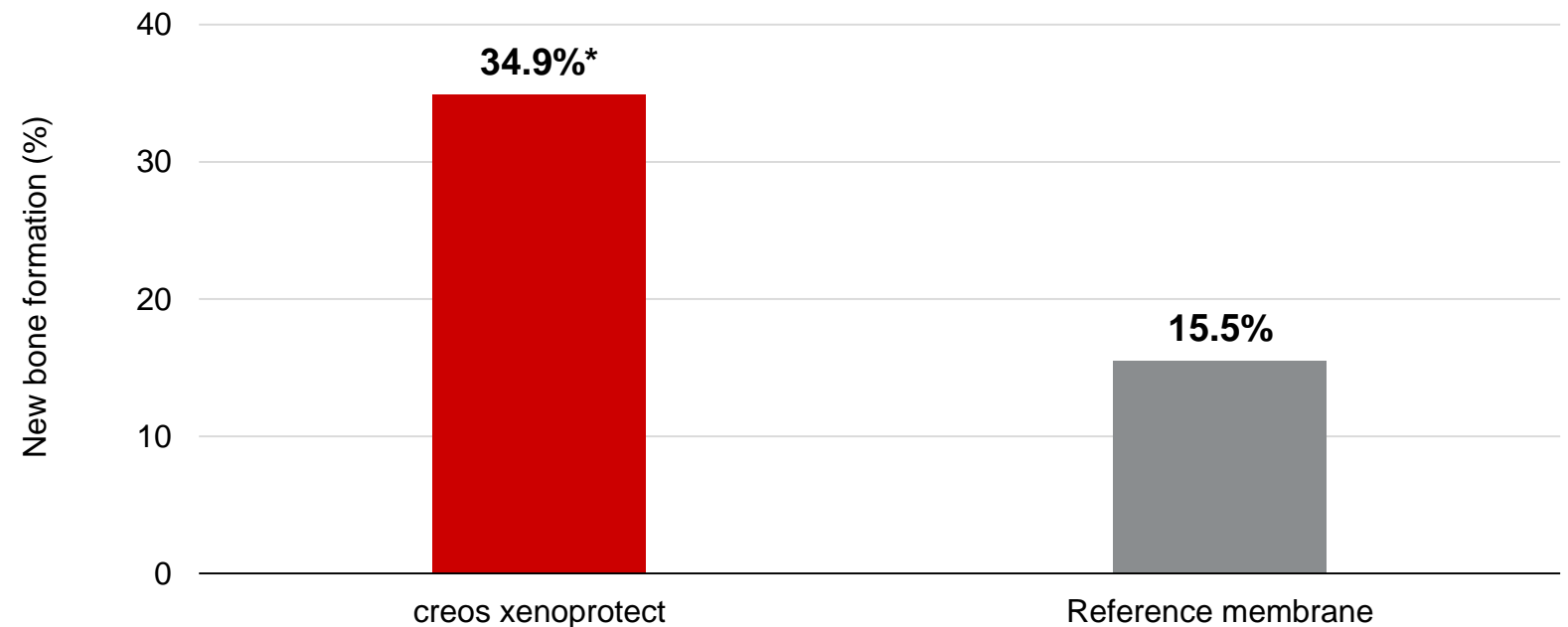
4. Bozkurt A, et al. Clin Oral Implants Res 2014; 25(12):1403–1411.



creos™ xenoprotect: active role in bone-healing dynamics in vivo

- creos xenoprotect plays an active role in regulating bone-healing dynamics *in vivo* in rats.¹
- In a preclinical model, creos xenoprotect is associated with formation of new bone in the center of an experimental defect.¹

creos xenoprotect facilitates the formation of new bone



Mean new bone formation at 21 days was 34.9% with creos xenoprotect and 15.5% with a reference membrane (Bio-Gide®). Measured by histomorphometric analysis of trabecular bone defects in rat femurs after filling with deproteinized bovine bone and covering with investigational membranes *p<0.05 vs reference membrane.¹

1. Omar O, et al. Clin Oral Implants Res 2018;29(1):7–19.

creos™ xenoprotect: low rates of complications

- In three clinical studies, rates of wound dehiscence and membrane exposure are low with creos xenoprotect.^{1,2,3}
- In clinical use, creos xenoprotect is associated with uneventful wound healing.¹

1. Aleksic Z, et al. J Clin Periodontol 2018;45(S19):306.
2. Wessing B, et al. Clin Oral Implants Res 2017;28(11):e218–e226.
3. Wessing B, et al. Int J Periodontics Restorative Dent 2016;36(2):179–187.
4. Wessing B, et al. Int J Oral Maxillofac Implants 2018;33:87–100.

Low* rates of wound dehiscence and membrane exposure with creos xenoprotect

	Severe horizontal bone defects (n=46) ¹	Single implant sites (n=24) ²	Horizontal bone defects (n=36) ³
Wound dehiscence (%)	19.5	16.7	12.2
Membrane exposure (%)	4.3	8.3	Not reported

*The overall estimated membrane exposure rate for non-cross-linked membranes was reported as 28.6% in a meta-analysis.⁴ Wound dehiscence was not reported.

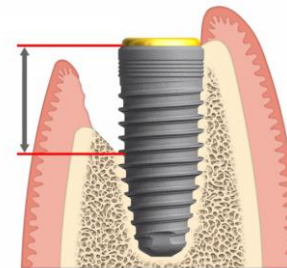
creos™ xenoprotect: good clinical results in dehiscence defects

- In a randomized clinical trial of 49 patients with dehiscence defects following implant placement, defect heights reduce after 6 months by 81% with creos xenoprotect.¹
- Bone gain after 6 months with creos xenoprotect is comparable to a reference membrane.¹
- Across both treatment groups, 1-year follow-up shows good clinical outcomes with 100% cumulative implant survival and success rates.²

High mean bone gain with creos xenoprotect

Defect height
at implant
insertion

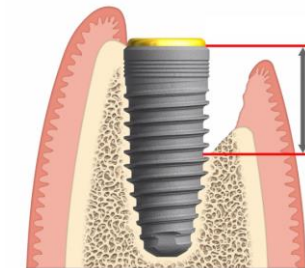
5.1 ± 2.1 mm



creos xenoprotect

Differences not
statistically
significant

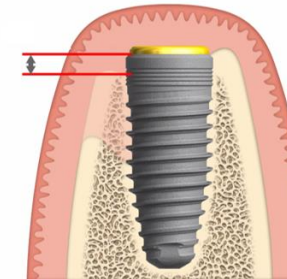
4.9 ± 1.9 mm



Reference membrane

Bone gain
at re-entry
6 months later

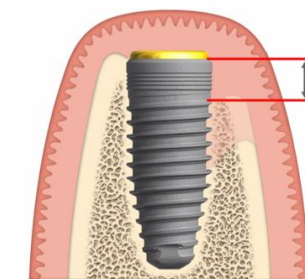
4.1 ± 2.2 mm



creos xenoprotect

Differences not
statistically
significant

3.3 ± 2.8 mm



Reference membrane

At implant insertion, the defect height was similar in the creos xenoprotect (n=24) and reference membrane (n=25; Bio-Gide) treatment groups. After 6 months, a comparable bone gain was seen in both treatment groups.²

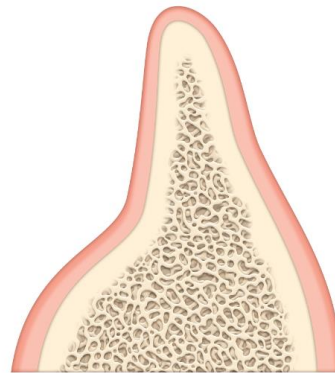
1. Wessing B, et al. Clin Oral Implants Res 2017;28(11):e218–e226.
2. Sanz-Sanchez I, et al. J Clin Periodontol 2018;45(S19):19–20.

creos™ xenoprotect: good clinical results in horizontal ridge augmentation

In a multicenter, prospective study of 46 patients with moderate to severe horizontal bone defects, creos xenoprotect demonstrates good healing and bone regeneration.¹

Increased mean horizontal bone width with creos xenoprotect

Initial situation before GBR

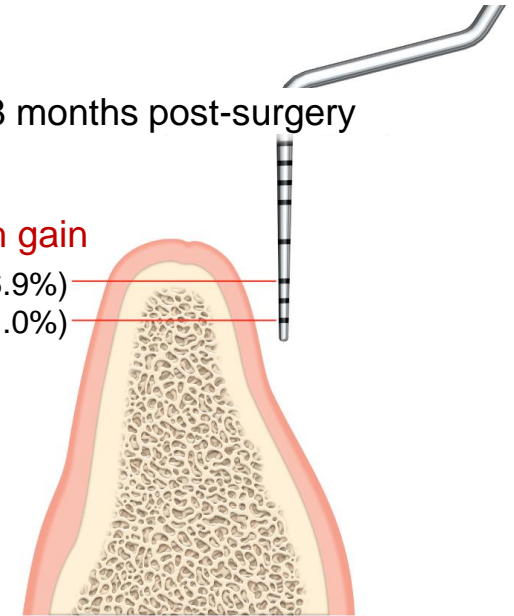


8 months post-surgery

Bone width gain

+4.0 mm (56.9%)

+4.7 mm (51.0%)



Schematic cross-section showing that prior to GBR, the mean defect size was 4.4 ± 2.6 mm wide. After 8 months, the mean horizontal bone increase was 4.0 mm (56.9% gain) and 4.7 mm (51.0% gain) at 1 mm and 3 mm from the top of the crest, respectively.¹

1. Aleksic Z, et al. J Clin Periodontol 2018;45(S19):306.

References

- Aleksic Z, Milinkovic I, Lazic Z, et al. A multicenter clinical investigation demonstrates bone regeneration in severe horizontal defects in the posterior mandible using creos xenoprotect: interim results [PR546]. J Clin Periodontol 2018;45(S19):306. [poster presentation].
- Arrighi I, Wessing B, Rieben A, et al. Resorbable collagen membranes expansion in vitro. J Dent Res 2014;93 (Spec Iss B):631. [poster presentation].
- Bozkurt A, Apel C, Sellhaus B, et al. Differences in degradation behavior of two non-cross-linked collagen barrier membranes: an in vitro and in vivo study. Clin Oral Implants Res 2014; 25(12):1403-1411.
- Gasser A, Wessing B, Eummelen L, et al. Mechanical stability of collagen membranes: an in vitro study. J Dent Res 2016;95(Spec Iss A): 1683. [poster presentation].
- Omar O, Dahlin A, Gasser A, et al. Tissue dynamics and regenerative outcome in two resorbable non-cross-linked collagen membranes for guided bone regeneration: A preclinical molecular and histological study in vivo. Clin Oral Implants Res 2018;29(1):7–19.
- Sanz-Sanchez I, Wessing B, Polizzi G, et al. Randomized clinical trial comparing two resorbable collagen membranes demonstrates good bone formation and soft tissue healing with GBR at single implant sites with dehiscence defects [O040]. J Clin Periodontol 2018;45(S19):19–20. [oral presentation].
- Wessing B, Emmerich M, Bozkurt A. Horizontal ridge augmentation with a novel resorbable collagen membrane: a retrospective analysis of 36 consecutive patients. Int J Periodontics Restorative Dent 2016;36(2):179–187.
- Wessing B, Urban I, Montero E, et al. A multicenter randomized controlled clinical trial using a new resorbable non-cross-linked collagen membrane for guided bone regeneration at dehiscence single implant sites: interim results of a bone augmentation procedure. Clin Oral Implants Res 2017;28(11):e218–e226.
- Wessing B, Zechner W. Guided bone regeneration with collagen membranes and particulate graft materials: a systematic review and met-analysis. Int J Oral Maxillofac Implants 2018;33:87–100.

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