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CLINICAL RESEARCH – SURGERY

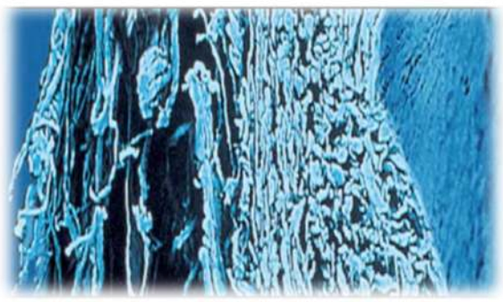
CROSS-LINKED COLLAGEN MEMBRANE FOR SIMULTANEOUS BONE REGENERATION: A RANDOMIZED CONTROLLED TRIAL

Rioboo M. Pousa X. Llanes M. Bravo M. Llanes F.
Periodontology department of the Complutense, Madrid Spain
Anatomopathology department of Hospital Clinico, Madrid Spain

Abstract

Background: Among the bioabsorbable membranes used in bone augmentation procedures, the literature has shown heterogeneous results when comparing cross-linked to native collagen membranes. **Aim**: to evaluate the safety and efficacy of a cross-linked membrane by glycation and compare it to a native collagen membrane. Material and method: This study was designed as a split-mouth randomized controlled clinical trial. 53 dental implants were placed 2 mm sub-crestally. The peri-implant defects in both sites were filled with the same bone substitute and randomization took place immediately. The test sits received a cross-link membrane (CLM) and the control sites a native collagen membrane (NCM). 4 months after submerged healing, biopsies from the soft tissue and the bone above the implant shoulder were obtained. Clinical and histological/histomorphometric outcomes were compared between the two types of membranes. **Results:** The histomorphometric analysis revealed a percentage of new bone formation and residual bone substitute particles of 2,71% and 2,96% in the control group and 14,71% and 13,16% in the test group, without significant differences between groups (p).Slight soft tissue dehiscence occurred in 52% of the test sites and 34,5% of the control sites. The implant survival rate was 96,2%, without differences between the two types of membranes. Patient reported outcomes, such as pain, inflammation or bleeding after surgery were similar in both groups.
Conclusion: Both types of collagen membranes showed a similar clinical and histological behaviour when used for simultaneous bone regeneration. The higher exposure rate in the test group did not interfere with the histological outcome.
Clinical implications: The election of a specific membrane should be based of the ability to provide reasonable clinical results, even with the presence of adverse events related to surgery.

Test: **Ossix Plus®**
Cross Linked membrane (CLM)



Control: **Geistlich Bio-Gide®**
Native collagen membrane (NCM)

Results

Day 0 — 16 patients, 53 implants
2 implants lost
4months — 16 patients, 51 implant, 53 biopsies
7 biopsies lost (transport and processing)
6 months — 16 satisfied patients, 51 restored implants, 46 analysed biopsies

Hematoxylin- eosin x240 OX: Ossix membrabne OB: osteoblast CH: Haversian conducts

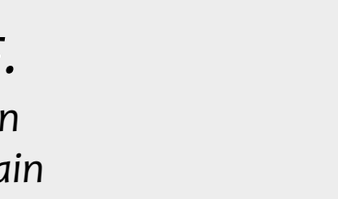


Table 3. Comparition between groups Ossix and Bioguide in implants (n=53) at 4 months.

Variable	Ossix [O] (n=24)	Bioguide [B] (n=29)	p[b]Value
	n (%)	n (%)	O *vs* B
% new bone tissue, mean±sd	2.71±8.78[c]	2.96±6.63[d]	0.918
% osseous substitute, mean±sd	14.71±16.35[c]	13.16±15.54[d]	0.537
Presence of membrane	c	d	0.333
No	17 (81.0)	17 (68.0)	
yes	4 (19.0)	8 (32.0)	

Table 2. Comparison at initial between groups Ossix and Bioguide in implants (n=53).

Variable	Ossix (n=24)	Bioguide (n=29)	p[a] Value
	n (%)	n (%)	
Primary closure. yes	24 (100)	29 (100)	-
Membrane exposure (1 week)			0.315
No	20 (83.3)	27 (93.1)	
yes	4 (16.7)	2 (6.9)	

Background and Aim

Bone augmentation procedures are often needed, simultaneous or prior to implant placement. Among the bioabsorbable membranes used in bone augmentation procedures, the literature has shown heterogeneous results when comparing cross-linked to native collagen membranes.

AIM: To evaluate the safety and efficacy of a cross-linked membrane by glycation and compare it to a native collagen membrane

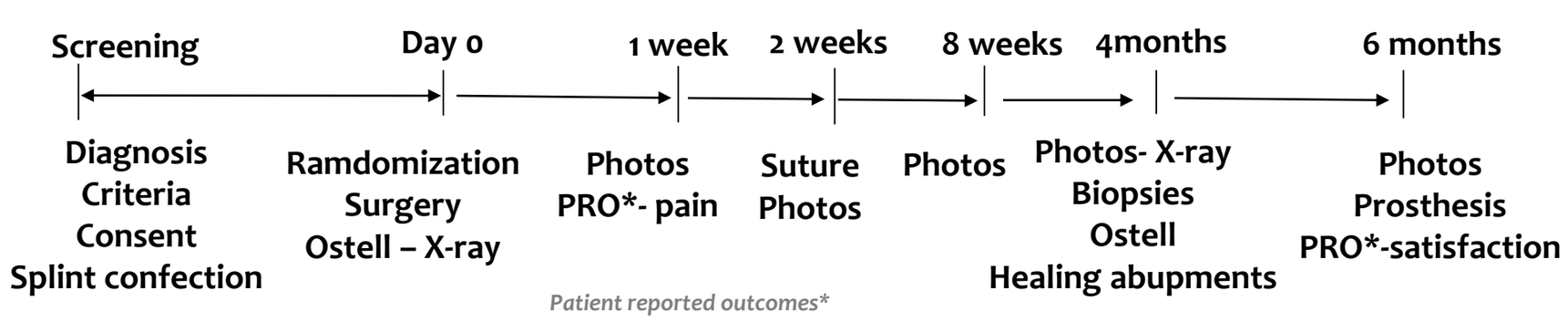
Conclusion

Both types of collagen membranes showed a similar clinical and histological behaviour when used for simultaneous bone regeneration.

The higher exposure rate in the test group did not interfere with the histological outcome.

Methods and Materials

Split-mouth randomized controlled clinical trial



*Patient reported outcomes**

References

Annen BM, Ramel CF, Hammerle CH, Jung RE. European journal of oral implantology. 2011;4(2):87-100.
Tal H, Kozlovsky A, Artzi Z, Nemocovsky CE, Moses O. Clinical OralImplant Research 19, 2008, 295-302.)
Rothamel D, Schwarz F, Sager M, Herten M, Sculean A, Becker J. Clinical oral implants research. 2005;16:369-78. , Moses O, Pitaru S, Artzi Z, Nemcovsky CE. Clinical oral implants research. 2005;16(2):210-9.
Brunel G, Piantoni P, Elharar F, Benque E, Marin P, Zahedi S. Journal of periodontology. 1996;67(12):1342-8.
Sela, M.N, Kohavi, D, Krausz E, Steinberg D & Rosen G. Clinical Oral Implants Research 2003 14: 263-268.

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