

# Randomised controlled clinical study evaluating two membranes for guided bone regeneration



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## Aim

The aim of the present study was to test whether or not one of two GBR membranes is superior to the other in terms of: i) vertical defect resolution and bucco-oral width of regenerated bone at the implant shoulder after 6 months ii) postoperative complications and during the 6-month follow-up and, iii) histologically assessed newly formed bone at 6 months.

## Hypotheses

The hypothesis of the study was that i) the augmented bone in respect to vertical defect resolution and bucco-oral width would show to remain closer to the original shape when covered by the resorbable membrane. ii) postoperative complications would occur more often in the non-resorbable group. iii) histology would not show differences in terms of newly formed bone.

## Material and Methods

This study was designed as a prospective randomised controlled clinical investigation. All procedures and materials were approved by the local ethical committee (2010-0051/5).

Twenty-seven patients with a single tooth gap (central incisor to premolar in the maxilla or mandible) in need of implant treatment were consecutively recruited at the Clinic for Fixed and Removable Prosthodontics and Dental Material Science, Center of Dental Medicine at the University of Zurich. In 27 patients, 27 implants were placed in single-tooth gaps.

The implant site was prepared according to the manufacturer's recommendations, and a screw type, rough surface two-piece dental implant (OsseospeedS, AstraTech, Mölndal, Sweden) was placed in a prosthetically ideal position using a surgical stent. Implants had to reach primary stability.

All implants had a buccal dehiscence defect that needed augmentation. These defect sizes were measured according to Fig.1 and augmented using demineralised bovine bone mineral. The augmented area was then randomly covered with either a resorbable membrane or a titanium-reinforced non-resorbable membrane (Fig.2)

- **Group 1:** resorbable membrane; DBBM+Collagen membrane (BioGide®) n=13
- **Group 2:** titanium-reinforced non-resorbable membrane; DBBM+ePTFE (Gore-Tex®) n=14

The buccal horizontal thickness of the augmented bone at the level of the implant shoulder was measured intra-surgically (baseline). After suturing, a CBCT was taken. Patients were then recalled at defined intervals for suture removal and assessment of the soft tissue condition.

After a healing phase of 6 months, a second CBCT was taken, and a re-entry surgery was performed in all patients by elevating a full-thickness flap: This in order to assess the resolution of the vertical defect and to measure the horizontal thickness of the bone at the buccal aspect of the implant at the level of the implant shoulder. Any remaining peri-implant osseous defect was recorded. In addition, core-biopsies were harvested at the height of the implant shoulder.

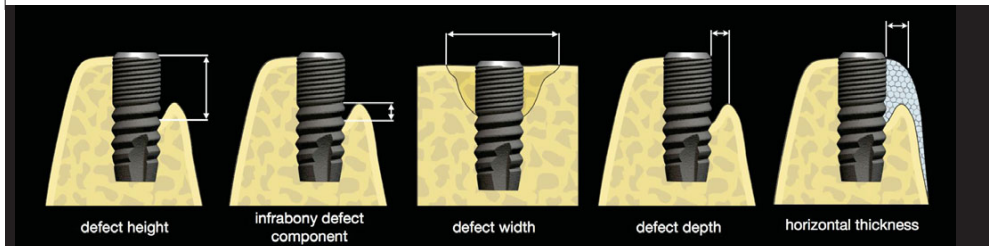


Fig.1: Clinically measured defect dimensions at time of implant placement.

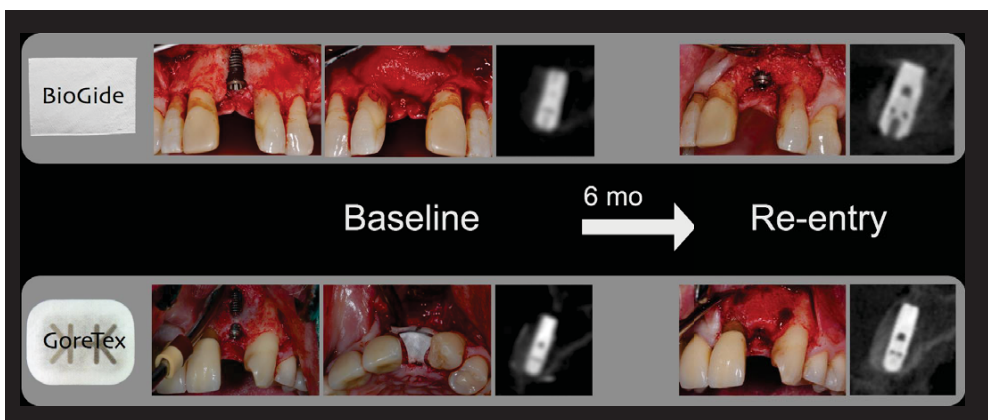


Fig.2: Randomisation and groups with respective membranes. CBCTs were taken at the time of surgery and again after 6 months.

## Results

### Clinical parameters

No significant differences in pocket probing depth and plaque indices were found between the two groups and time points.

There was a significant reduction in bleeding on probing over time, but no difference between the groups.

Regarding the amount of keratinised tissue, there was a significant reduction over time without a significant intergroup difference.

A total of six dehiscences were recorded (4 in Group 1 and 2 in Group 2); all but one of them healed by 3 months post-surgery.

### Histological analysis

The density of the DBBM particles and the newly formed bone as well as the density of the connective tissue demonstrated great variation within the groups. The differences between the two groups were not statistically significantly different for any of the outcomes measures ( $p > 0.05$ ).

### Bone dimensions (clinical)

The clinically measured defect height showed a significant reduction in both groups over time without significant intergroup differences.

At baseline, the clinical horizontal thickness at the implant shoulder had mean values of 3.38mm (SD=0.51; RES) and 2.85mm (SD=0.63; N-RES). At 6 months, these values amounted to 1.95mm (SD=0.88; RES) and 2.85mm (SD=1.16; N-RES). These changes were statistically significant ( $p < 0.001$  Kenward-Roger).

### Bone dimensions (CBCT)

High resolution CBCT analyses revealed a median decrease from baseline to 6 months at the implant shoulder of -0.72mm (mean=-0.83; SD=0.82; RES) and -0.07mm (mean:-0.15; SD 0.37; N-RES). These changes were statistically significant between the groups ( $p = 0.009$ , Wilcoxon).

| Clinical parameters                                                                                                                                                                                                                                            | Histological analysis                                                                                                                                                   | Bone dimension (CBCT)                                                                                                                     |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> <li>- Periodontal parameters (PI, BOP, PPD, Kerat.)</li> <li>- Soft tissue condition (Dehiscence, Inflammation)</li> <li>- Bone dimensions of GBR (Horizontal thickness, Defect height, width, depth, Infrabony)</li> </ul> | <ul style="list-style-type: none"> <li>- Tissue composition [%] (Substitute, New Bone, Soft tissue)</li> <li>- Bone-to-graft contact [<math>\mu</math>m] [%]</li> </ul> | <ul style="list-style-type: none"> <li>- Horizontal thickness [mm] (0-1-2-3mm from shoulder)</li> <li>- Vertical defect height</li> </ul> |

Fig.3: Overview of the measured parameters clinically, histologically and radiographically

## Conclusion

Both treatment modalities were clinically and radiologically effective in regenerating bone on the buccal aspect of single tooth dental implants showing dehiscence-type defects. Despite a higher initial horizontal thickness, sites with the resorbable membrane experienced a significantly higher reduction in bone thickness after 6 months compared to the non-resorbable membrane.

## Contact

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## References

Resorbable versus nonresorbable membranes in combination with Bio-Oss for guided bone regeneration. **Zitzmann NU, Naef R, Schärer P. Int J Oral Maxillofac Implants 1997 Nov-Dec;12(6):844-52.**  
 Healing of dehiscence-type defects in implants placed together with different barrier membranes: a comparative clinical study. **Moses O, Pitaru S, Artzi Z, Nemcovsky CE. Clin Oral Implants Res. 2005 Apr;16(2):210-9.**  
 Clinical outcomes of GBR procedures to correct peri-implant dehiscences and fenestrations: a systematic review. **Chiapasco M, Zaniboni M. Clin Oral Implants Res. 2009 Sep;20 Suppl 4:113-23.**