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# Bioequivalence study of two collagen membranes as part of dento-alveolar Guided Bone Regeneration (GBR)

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A number of collagen membranes with different manufacturing processes and properties are available in the field of GBR. The aim of this study was the evaluation and comparison of two different membranes (PARASORB RESODONT®, Resorba, Nuremberg, Germany and Bio-Gide®, Geistlich, Wolhusen, Switzerland) in clinical use.

## Materials and methods

The characteristics of the commonly used membranes are given in table 1:

| Characteristics | PARASORB RESODONT® | Bio-Gide® |
|---|---|---|
| Origin of collagen | equine | porcine |
| Cross-linking | yes; complete reconstitution<br>no chemical additives | none;<br>no chemical additives |
| Layered structure | single-layer | double-layer (porous, smooth) |
| Thickness | no data | no data |
| Density of collagen | 2.8 mg / 1 $cm^2$ | no data |
| Size | 35 x 30 mm | 25 x 25 mm |
| Absorption behaviour | complete | complete |
| Packaging | sterile single blister foil-sealed | sterile double blister |

*Tab. 1: membrane characteristics*

PARASORB RESODONT® Bio-Gide®

*Fig.1: front and rear of membranes*

## Application of the membranes was performed in accordance with the manufacturer's instructions for use:

PARASORB RESODONT®

Cut section with fine scissors in dry state – soak membrane in sterile NaCl solution for max. 3 seconds before placing - cover defect with excess of 2-3 mm – observe flush seal of edges – fixing with sutures or pins is possible but not necessarily required – cover membrane with mucoperiosteal flap.

Bio-Gide®:

Cut membrane to size with scissors – cover defect dry with excess of 2 mm – observe flush seal of edges - the smooth surface should face the soft tissue, the porous surface the bone – position membrane applying moderate pressure – attachment of membrane to bone via bleeding and exudation - fixing with sutures or pins is possible but not necessarily required – cover membrane with connective tissue flap.

The **spectrum of indications** included the following dento-alveolar surgical interventions and measures:

· external cover in sinus floor elevations

· cover of bony abutment in lateral augmentation simultaneous with implantation and

· cover of bony abutment in isolated augmentation without implantation.

The **augmentation material** used was exclusively autologous bone in form of bone meal (harvested from the drill site or during preparation of the bone blocks), bone chips (harvested with the Savescraper TWIST (Meta, Italy) from the retromolar region in the mandible) and cortico-spongeous bone blocks (harvested from the retromolar region of the mandible and fixed with 1.5 mm or 2.0 mm traction screws).

**The intra-operative assessment of the membranes included the following criteria:**

· Handling of packaging

· Handling of membrane

· Stability "in the hands" before and after wetting

· Application to the surgical area

· Positioning and fixation

**Postoperative observation** included the time points 1 week, 4 weeks and 3 - 4 months after application of the membrane. The last time point correlated in part with the uncovering of the surgical field for implantation purposes.

The assessment criteria were defined as

· wound healing,

· inflammatory reactions and

· the presentation of the membrane upon uncovering.

If the membrane is exposed during the healing process, surface cleaning and disinfection should be carried out with 0.2 % chlorhexidine solution, and waiting for possible reepithelialisation prior to removing the membrane and, if necessary, the graft.

A total of 20 patients received membranes from two different dental professionals, whereby 10 membranes of each type were used and evaluated.

# Summary and final assessment

Both membranes represent a safe and reliable solution for covering grafts in selected indications as part of GBR. The membranes can we well adapted to the desired shape and size, application and adaptation in the wound area do not present problems. In dry condition, both membranes tend to stick to wet gloves and should therefore only be handled and processed with instruments.

Wetting outside the wound area appears sensible to avoid tearing of the dry membrane during intra-oral adaptation. In the wetted version, both membranes can be well adapted to any anatomical situation.

## Intra-operative assessment

| Beurteilung | | PARASORB RESODONT® | | Bio-Gide® | |
|---|---|---|---|---|---|
| Handling of packaging and opening | + | 8 | + | 8 |
| | - | 0 | - | 0 |
| | 0 | 2 | 0 | 2 |
| Handling of membrane during cutting to size | + | 10 | + | 10 |
| | - | 0 | - | 0 |
| | 0 | 0 | 0 | 0 |
| Stability "in the hands" before wetting | + | 8 | + | 10 |
| | - | 0 | - | 0 |
| | 0 | 2 | 0 | 0 |
| Stability "in the hands" after wetting | + | 8 | + | 9 |
| | - | 0 | - | 0 |
| | 0 | 2 | 0 | 1 |
| Application to the surgical area (tweezers, periosteal elevator) | + | 10 | + | 7 |
| | - | 0 | - | 0 |
| | 0 | 0 | 0 | 3 |
| Positioning and fixation | + | 10 | + | 8 |
| | - | 0 | - | 0 |
| | 0 | 0 | 0 | 2 |

- PARASORB RESODONT®: opening tab too small, better on one side only and larger
- Bio-Gide®: double blister too elaborate and unwieldy
- PARASORB RESODONT® appears somewhat more dimensionally stable than Bio-Gide®
- PARASORB RESODONT®: smooth surface, uniform thickness, sticks to wet gloves, easy to shape, tear strength comparable to paper, optimal application not possible in dry form
- Bio-Gide®: wavy surface, uneven thickness, sticks less to wet gloves, easy to shape, tear strength comparable to paper, can also be applied dry
- PARASORB RESODONT®: membrane folds quickly and is self-adhesive, should then only be handled with instruments, tear strength also remains good in wet condition
- Bio-Gide®: loses its visible surface structure, is more stable dimensionally and fully retains tear strength
- PARASORB RESODONT®: can be placed and smoothed easily over the graft using tweezers or a fine periosteal elevator, acts like a "second skin" on the graft, adapts precisely to all contours, hardly any voids between membrane and graft
- Bio-Gide®: allows for good placement, position easy to correct, does not fit very tightly to the graft, permits small voids between membrane and graft
- PARASORB RESODONT®: Positioning and adjustability on the graft is good, adjustment and modelling with moist swab, no additional fixation required
- Bio-Gide®: Positioning and adjustability on the graft is good, upon dry application adhesion of the membrane on the graft is via absorption of rinsing fluid, blood and exsudate in the wound, no additional fixation required

*Tab. 2: Results of intra-operative assessment*

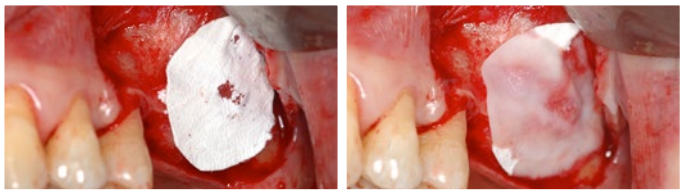

*Fig. 2: Bio-Gide® membrane after dry application and secondary wetting*

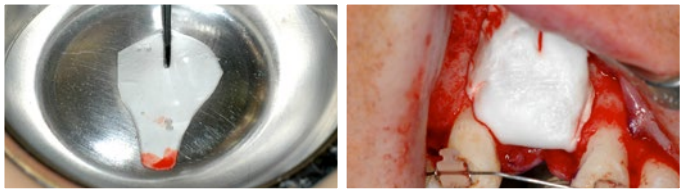

*Fig. 3: PARASORB RESODONT® membrane after primary wetting and subsequent application*

## Postoperative monitoring

| Monitoring | PARASORB RESODONT® | Bio-Gide® |
|---|---|---|
| 1 week | wound healing possible without difficulties, no inflammatory reactions detected at the wound edges, no swelling observed | wound healing possible without difficulties, no inflammatory reactions detected at the wound edges, no swelling observed |
| 4 weeks | covering soft tissue inconspicuous in colour, form and structure, no swelling | covering soft tissue inconspicuous in colour, form and structure, no swelling |
| 3 months (for implantation) | no evidence of membrane remains or reaction to foreign matter, smooth on implant bone surface during uncovery | no evidence of membrane remains or reaction to foreign matter, smooth on implant bone surface during uncovery |

| Course during exposition | PARASORB RESODONT® | Bio-Gide® |
|---|---|---|
| Occurrence | 1 x suture dehiscence | 2 x suture dehiscence |
| Reason | Tension at wound edge | Tension at wound edge, sharp bone edge |
| Signs of inflammation | none | none |
| Disinfection with chlorhexidine | can be done for patients without difficulty | can be done for patients without difficulty |
| Re-epithelisation | after approx. 14 days | after approx. 14 days |
| Total loss with removal | Ø | Ø |

Additional fixation with sutures or pins does not seem necessary as both membranes adapt tightly to the underlying graft after wetting and dislocations hardly occur. So far no membrane-associated changes such as dehiscence, bacterial infection, swelling or reactions to foreign matter have been observed during the postoperative process, wound healing was primary in most cases.

Based on the observations and experiences made, there is no principal difference between the two membranes.

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