

Internal offprint

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 no chemical additives	none; 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

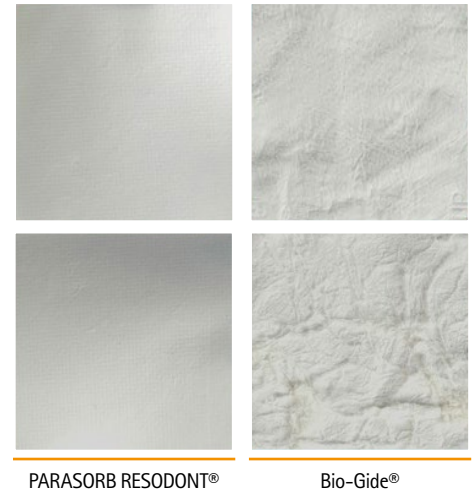


Fig.1: front and rear of membranes

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-spongy 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 be 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

- ➔ PARASORB RESODONT®: opening tab too small, better on one side only and larger
- ➔ Bio-Gide®: double blister too elaborate and unwieldy

Handling of membrane during cutting to size	PARASORB RESODONT®		Bio-Gide®	
	+	10	+	10
-	0	-	0	
0	0	0	0	

- ➔ PARASORB RESODONT® appears somewhat more dimensionally stable than Bio-Gide®

Stability "in the hands" before wetting	PARASORB RESODONT®		Bio-Gide®	
	+	8	+	10
-	0	-	0	
0	2	0	0	

- ➔ 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

Stability "in the hands" after wetting	PARASORB RESODONT®		Bio-Gide®	
	+	8	+	9
-	0	-	0	
0	2	0	1	

- ➔ 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

Application to the surgical area (tweezers, periosteal elevator)	PARASORB RESODONT®		Bio-Gide®	
	+	10	+	7
-	0	-	0	
0	0	0	3	

- ➔ 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

Positioning and fixation	PARASORB RESODONT®		Bio-Gide®	
	+	10	+	8
-	0	-	0	
0	0	0	2	

- ➔ 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 exudate in the wound, no additional fixation required

Tab. 2: Results of intra-operative assessment

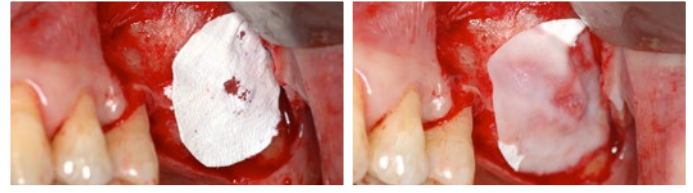


Fig. 2: Bio-Gide® membrane after dry application and secondary wetting

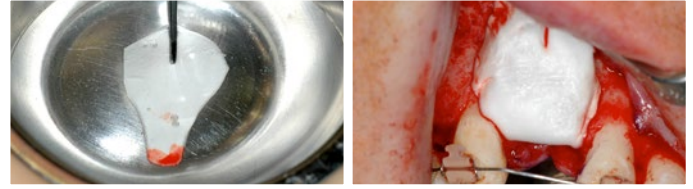


Fig. 3: PARASORB RESODONT® membrane after primary wetting and subsequent application

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 uncoverly	no evidence of membrane remains or reaction to foreign matter, smooth on implant bone surface during uncoverly

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	∅	∅

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.