Scientific & Clinical Evidence

Jason® membrane
Pericardium GBR/GTR Membrane

Facts
- CE since 2009
- so far no serious clinical complication or objection
- approx. 250,000 successful clinical treatments (09/2014)
- no product related recall or remark
Preclinical studies

1.

**Keywords:** morphologic structure; biodegradation; pericardium membrane; Jason membrane® vs. BioGide


**Biocompatibility and Biodegradation of a native porcine pericardium membrane: results of in vitro and in vivo examinations**


The objective of this pilot study was to examine, in vitro and in vivo, a novel native collagen membrane extracted from porcine pericardium. The morphologic structure of two different native collagen membranes (Remotis=Jason® membrane and BioGide) was examined.

**Results for Jason® membrane:**

**Scanning Electron Microscopy:** Jason® membrane showed multi-layered collagen matrix structure with an interconnected system of pores.

**Biocompatibility:** 24 samples of Jason® membrane and BioGide; SaOS-2 osteoblastlike cells for 2h, 3 days and 7 days: Jason® membrane 3x higher cell numbers after 7 days incubation with cells.

**Biodegradation, barrier function and bone formation:** dog model (beagle dogs) socket extraction, 4 months healing time: comparison of cerabone®/Jason® membrane vs. BioOss/BioGide. For BioGide considerable degradation was noted after 4 to 8 weeks, for Jason® membrane after 8 to 12 weeks. Follow up period 4, 8, 16 and 24 weeks. After 24 weeks, defects with cerabone® and covered by Jason® membrane were completely organized with newly formed bone. New bone matrix was localized on the surface of the bone substitute particles or bridging two or more particles, leading to a 3D mineralized network.
Clinical aspects of novel types of collagen membranes and matrices: Current issues in soft- and hard- tissue augmentation


Guided bone regeneration and guided tissue regeneration are based on the isolation of potentially regenerative cell types such as periodontal ligament fibroblasts and osteoblasts on the one hand from rapidly proliferating epithelial and connective tissues on the other. The objective of these procedures is the predictable regeneration of lost tissue. Mechanical barriers play an important role in regeneration processes.

The possible use of Jason® membrane and collprotect® membrane as a barrier membrane is supported by the fact that native collagen is transferable from animals to humans and plays an active role in the formation of blood clots, promoting rapid stabilization of the wound area. In addition, collagen has a chemotactic effect on the fibroblasts of the periodontal ligament. In case of exposure to the oral cavity, certain periodontal pathogens appear to contribute to the biodegradation of collagen membranes. The resorption of collagen membranes exposed to the resident biota of the oral cavity is significantly accelerated.

Results for Jason® membrane: The pericardium membrane, still exhibits a pronounced barrier function after eight weeks. The thin multilayer structure and good tissue integration are readily discernible. Jason® membrane reveals a wide branching structure consisting of individual collagen layers forming an interconnected system of pores. Due to their different morphology, Jason® membrane takes significantly longer to biodegrade than BioGide.
3.

**Keywords:** pericardium; biodegradation; canine model; horizontal augmentation GBR; Jason\textsuperscript{®} membrane vs. BioGide

Sztuka Implantologii 2/2009

**Biocompatibility and biodegradation of native, porcine pericardial membrane. Results of in vivo/in vitro studies.**

D. Rothamel

Three different native collagen membranes: Jason\textsuperscript{®} membrane, BioGide and CopiOs were tested in vitro and in vivo.

**Results for Jason\textsuperscript{®} membrane:** In vivo studies showed massive cell proliferation on Jason\textsuperscript{®} membrane, which was statistically significant when comparing with BioGide. The surface of Jason\textsuperscript{®} membrane was tightly covered with SaOs-2 cells. The animal trial showed that Jason\textsuperscript{®} membrane was integrated with surrounding tissue without irritation. Resorption of Jason\textsuperscript{®} membrane was constantly occurring during first 2-3 months.

**Conclusion:** It can be assumed that Jason\textsuperscript{®} membrane present high biocompatibility. Jason\textsuperscript{®} membrane undergo resorption during 3 months without any signs of tissue irritation.

4.

**Keywords:** histological evaluation; experimental study rats; native collagen matrices; pericardium; biodegradation; tissue integration; cell invasion; Jason\textsuperscript{®} membrane

20\textsuperscript{th} Annual Scientific meeting of the European Association of Osseointegration 2011, Athens, Greece, Poster 449

**Biodegradation pattern of native and cross-linked porcine collagen matrices- an experimental study in rats**

D. Rothamel, T. Fienitz, M. Benner, A. Happe, M. Kreppel, M. Scheer, J. Zöller
The aim of the present study was to compare the biodegradation and tissue integration of two novel native collagen membranes (Jason® membrane and collprotect® membrane) for GTR and GBR, harvested from porcine pericardium and dermis.

40 rats, 5 groups, 1, 2, 4, 8 and 12 weeks

Results for Jason® membrane and collprotect® membrane: Healing was uneventful in all animals. For GBR membranes, histological evaluation revealed significant differences regarding resorption time and tissue integration. Jason® membrane was integrated within the first week and remained stable for a healing period of 8-12 weeks. Tissue integration and cell invasion took longer for collprotect® membrane, however dermal collagen of collprotect® membrane was resorbed faster within the first 4-8 weeks.

Conclusion: The present animal study showed that Jason® membrane shows significant longer resorption time than collprotect® membrane.

5.

Keywords: surface morphology; biocompatibility; Jason® membrane; maxresorb®

Academy of Osseointegration Orlando USA 2010, #248


The aim of the present study was to investigate surface morphology, biocompatibility and osseous organisation of a new biphasic bone substitute maxresorb® (MR), 60% HA/40% ß-TCP.

For biocompatibility testing, granules were incubated with human osteoblast-like cells (SaOs2).

In the in-vivo part, MR was used for lateral augmentation in dogs. Three months after tooth extraction full-thickness flaps were raised in the premolar
region on both sides of the maxilla and 0.5 g of MR (0.5 - 1 mm size) was placed on the respective jaw sites. Grafts were covered with a rehydrated collagen membrane (Jason® Membrane). After surgical flap elevation, wounds were closed using resorbable single sutures. After an uneventful healing period of 4, 8, 12, and 16 weeks (n = 2, respectively) the animals were sacrificed.

Results for maxresorb®:
Histologically, an initial new bone formation (blue) arising from the basal bone bed (lilac) was observed for the 4-week specimens. The MR granules (grey) appeared surrounded by blood vessels (blue) and embedded in a loose regenerative matrix. After a healing period of eight weeks, the entire augmentation material was dominated by newly formed hard tissue. The individual MR granules (grey) appeared largely encapsulated in woven bone or joined to each other in a kind of network via hard tissue bridges. The transition between the bone substitute material and the woven bone was very accentuated. A sporadic initial growing of hard substance into the porous parts of the granules could be seen. A partly moniliform arrangement of osteoblasts could be seen on the surface of the trabeculae. Actual bone marrow with fat cells and blood vessels was identified in the non-mineralised parts. An inflammatory reaction could not be detected. After 24 weeks, the augmentation materials appeared for the most part regenerated with lamellar bone tissue. Whereas most MR particles could still be clearly distinguished from the surrounding hard tissue, under greater magnification others showed only rudimentary borders with the vital bone tissue. In many places, clear indications of functional transformation in the sense of bone resorption and apposition could be seen.

Conclusion: Within the limits of the present study it was concluded that MR is a porous, nanostructured bone substitute with high biocompatibility, fast osseous organisation, good volume maintenance and slow resorption.
Clinical results

6.

**Keywords:** Case series, GBR, GTR, bone substitutes, collagen membranes, alveolar bone defects, Jason® membrane

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**Comparison of allogenic and xenogenic bone substitutes with pericardium membrane for guided bone augmentation of alveolar defects**

N. Papagiannoulis, O. Daum, D. Tadic, M. Steigmann

The aim of the present case series study was to evaluate the barrier function of pericardium collagen membrane during alveolar augmentation.

8 patients, age range 35-68 years, post op control 3, 7, 14 and 30 days, recall 12 weeks after surgery, augmentation with maxgraft® and cerabone® 19 implants successful inserted. Average bone width gain with cerabone® 4.96 mm and average bone width gain with maxgraft® 2.69 mm.

**Results with Jason® membrane:** bone gain after augmentation from 0.6 mm to 6.6 mm in average the bone gain was 3.78 mm. In total 18 mandible defects and 1 maxilla defect was treated.

**Conclusion:** This case series have shown that the use of Jason® membrane for guided bone regeneration e.g. lateral augmentation, socket preservation, horizontal ridge augmentation and sinus elevation was suitable.
7.

**Keywords:** sinus floor elevation; sintered natural bovine bone mineral; histological case report study; pericardium membrane; cerabone® and Jason® membrane

zzi 2011; 27 (1)

**Sinus floor elevation using a sintered, natural bone mineral**  
D. Rothamel, R. Smeets, A. Happe, T. Fienitz, F. Schwarz, J. Zöller

The aim of the present study was the histological and clinical evaluation of the xenogenic bone substitute material cerabone® for the indications one stage and two stage sinus floor elevation.  
12 patients; average age of patients 54.4 years; 15 Sinus lifts; histologically and histomorphometrically; 6 two stage procedures; lateral window covered with Jason® membrane; six months radiological control or biopsy was taken

**Results for cerabone® and Jason® membrane:** All patients showed good hard tissue regeneration of the sinus. Neither resorption nor dislocation of the cerabone® was observed. Radiologically, good volume stability of the graft was observed. Histologically, cerabone® was complete osseous integrated in newly formed bone matrix.  
Newly formed bone 25.8-49.6%; Remaining cerabone® 28.6-38.5%; in the two stage procedures, all implants achieved adequate primary stability.

**Conclusion:** After a healing period of six months, good bony consolidation of the augmentation was seen clinically and histologically in all patients.

8.

**Keywords:** sinus lift; synthetic bone graft; implant stability; Jason® membrane; maxresorb®

Assessment of Implant Stability Following Sinus Lift Procedures with Different Grafting Materials

Damir Jelušić, Ivan Puhar, Darije Plančak

The objective of this research was to evaluate implant stability following sinus lift with two grafting materials (maxresorb®), and to compare it with the results obtained for the implants placed in a pristine posterior maxilla. The study included 44 healthy patients with an existing indication for sinus lift procedure (test group). 46 implants were placed following sinus lift with a pure-phase beta-tricalcium phosphate, while 39 implants were placed following augmentation with 60% hydroxyapatite with 40% beta-tricalcium phosphate material (maxresorb®). The control group consisted of 48 healthy patients who were treated with 85 implants but without bone augmentation in posterior maxilla. Astra Tech OsseoSpeed implants were placed in all subjects. Resonance frequency analysis was used in both groups for determining implant stability 4 months after insertion. A mean implant stability quotient (ISQ) was calculated on the basis of 3 measurements.

After lifting the Schneiderian membrane from the sinus floor, depending on the randomization, a pure-phase β-TCP bone grafting material or a 60% HA with 40% β-TCP material (maxresorb®) was applied after previous rehydration with 1-5 mL of sterile saline. Buccal window was covered with rehydrated collagen membrane (Jason® membrane). A full thickness flap was adapted and the wound was sutured. Control conebeam computed tomography (CBCT) scan was recorded to exclude dislocation of the bone grafting material.

Results for maxresorb®:

No statistical difference was observed in ISQ values of implants placed with and without augmentation procedure (p=0.789). Statistically significant difference was not found when ISQ values of implants placed following particular grafting material were compared with ISQ values of corresponding implants in a pristine bone (p=0.697 and p=0.402). Implants placed following HA/β-TCP maxresorb® showed higher ISQ values, but statistical significance was not observed (p=0.402).

Conclusion: This study demonstrated that the implant stability is comparable among implants placed in the posterior maxilla regardless of sinus lift and
grafting procedure. Implants placed in the grafted posterior maxilla can be predictably loaded as the implants placed in a non-grafted, pristine maxilla.