Pericardium Membrane and Xenograft Particulate Grafting Materials for Horizontal Alveolar Ridge Defects

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Purpose: *The purpose of this study was to evaluate the clinical feasibility of using a native collagen physical resorbable barrier made of bovine pericardium to augment localized alveolar ridge defects for the subsequent placement of dental implants.*

Materials & Methods: *There were 8 systemically healthy patients with 19 implant sites (aged 35 to 68 years), with inadequate dental alveolar ridge widths, selected for study. All patients completed initial therapy, which included scaling, root planning, and oral hygiene instruction. All ridge defects were augmented with bovine xenograft and a collagen pericardium membrane. Horizontal (width) hard tissue measurements were taken the day of ridge augmentation surgery, or implant placement and augmentation (baseline), and at the 6-month (reentry or uncovering) surgery.*

Results: *The change in ridge width varied from a loss of 0.2 mm to a gain of 7.8 mm, measured clinically with a mean value of 3.0368 and a median of 2.8 mm from baseline.*

Conclusions: *The results suggested that pericardium collagen membrane may be a suitable component for augmentation of localized alveolar ridge defects in conjunction with different xenografts.*
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Key Words: membrane resorption, bone regeneration, implant placement.

Membrane resorbtion,[1,2] biocompatibility, and space maintaining proprieties in guided bone regeneration (GBR) have proven to be significant. By excluding all nonosteogenic cells from the healing wound site, and by protecting and stabilizing the healing clot, it is possible to regenerate lost bone[3-8] and place implants for ideal prosthetic restorations. However, clinical outcome vary regarding the surgical procedure and materials.

Caries, trauma, or periodontal diseases frequently result in a decrease in alveolar ridge width. GBR is often the procedure of choice to augment deficient alveolar ridges.[3-6,9] Space for new bone provided by the membrane and bone replacement grafts are required for the GBR procedure. To reach a minimum bone width necessary for implant placement, a variety of bone materials are used in conjunction with GBR[4-7,9-11] with different membranes. One such membrane is the bovine pericardium (Tutodent® membrane; Tutogen Medical GmbH, Neunkirchen, Germany).

The purpose of this study was to evaluate clinically the clinical feasibility of using a native collagen physical resorbable barrier made of bovine pericardium to augment localized alveolar ridge defects for the subsequent placement of dental implants. There were 2 different xenograft materials used to augment localized alveolar ridge defects for the subsequent placement of dental implants.

Materials and Methods

There were 8 systemically healthy patients (2 men and 6 women), 35-68 years old, with inadequate alveolar ridge width and a need for dental implants, accepted for this study. Sites with localized pathology or previous augmentations were not accepted. All patients signed a consent form indicating their understanding of the study. Each patient agreed to make appointments as per the protocol time line. Bone width before augmentation was considered the baseline. Postoperative visits occurred at 3, 7, 14, and 30 days after surgery. Recall occurred at 12 weeks, and implant surgery was performed at 24 weeks for the staged cases. A medical history was taken. Soft and hard tissue examinations were performed. If indicated, patients were required to complete initial periodontal therapy. Initial therapy included scaling, root planning, oral hygiene instruction, placement of restorations, and occlusal adjustment as needed. The ridge augmentation (baseline) visit was scheduled after verifying completion of initial therapy. Preoperative radiographs were taken, including panoramic, standardized periapical films, and computer-assisted tomography for select cases.

Patients rinsed with 0.12% chlorhexidine gluconate for 1 minute before

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Table 1. Clinical Evaluation of Implant Width After Horizontal Augmentation With Collagen Membrane and 2 Different Xenografts*

Patient No.	Barrier	Bio-Oss®	Navigraft™	Implants
1	Pericardium membrane	x		3.75 10 mm
				3.75 10 mm
				3.75 8 mm
2	Pericardium membrane		x	3.75 10 mm, 3.75 10 mm
3	Pericardium membrane		x	3.75 13 mm, 3.75 10 mm, 2.8 13 mm
4	Pericardium membrane		x	3.75 10 mm
5	Pericardium membrane	x		3.75 13 mm
6	Pericardium membrane		x	3.75 13 mm, 3.75 13 mm, 3.75 13 mm, 3.75 10 mm
7	Pericardium membrane	x		3.75 13 mm, 3.75 13 mm, 3.75 10 mm
8	Pericardium membrane		x	4.7 10 mm, 3.75 10 mm

*Implant diameter is 3.75 for all cases, and lengths are 8 (1 implant), 0 (10 implants), and 13 mm (8 implants).

Tutodent® pericardium membrane was used for horizontal bone augmentation in conjunction with different xenografts in 3 (7 implant sites with Bio-Oss®) and 5 patients (12 implant sites Navigraft™).

the surgical procedures. They were placed on 2000 mg of amoxicillin 2 hours before surgery. Local anesthetic was administered for pain control.

Flaps

Flaps with releasing incisions were raised after crestal or buccal incisions. In addition, the decision to place the implants or only graft the site was made at this time. Ridge width measurements were made using a periodontal probe. No decortication was made to expose additional bleeding. Bone substitute material (Navigraft 228; Zimmer Dental, Carlsbad, CA) or Bio-Oss® (Geistlich Pharma AG, Wolhusen, Switzerland) (Table 1) was placed to restore the ridge to an acceptable width (at least 6 mm) to allow the site to receive a dental implant (Figs. 1 and 2). A native collagen membrane barrier out of bovine pericardium (Tutogen Medical GmbH) was trimmed and placed over the graft material (Figs. 3 and 4). The flap lingual stabilized the barrier, and fixation tacks were used buccally. Approximately 1 mm of space was left between the barrier margin and adjacent teeth. A periosteal slit or split thickness flap, depending on the magnitude of the augmentation, was used to adjust the flap to provide tension-free primary closure. A combination of mattress and interrupted sutures were used.

No attempt was made to augment the ridges vertically above the height of the crest. Patients were seen for postoperative care at 3, 7, 14, and 30 days. Barrier coverage was evaluated for flap closure, and oral hygiene instructions were given. Flap sutures were removed at 15 days postoperatively. A recall appointment was scheduled 2 weeks following ridge augmentation. If a barrier membrane was exposed before the scheduled removal date, the patient was placed on twice-daily chlorhexidine gel and observed weekly (1 implant site). The membrane barrier was left in place in all cases, even if dehiscence occurred. No persistent infections were observed.

Clinical Measurements

According to the previously described technique, after flap elevation, ridge width was measured using a periodontal probe (Stoma Dentalsysteme, Emmingen-Liptingen, Germany) exactly at the midpoint of the programmed implant position. The probe was placed at the most coronal level of the crest, perpendicularly to the apico-coronal axis of the crest. One measure for each implant site was registered in each patient. At the implant placement surgical stage, the measurement of the crest width was performed exactly in the same manner as before for each programmed implant site, and the difference between before and after the augmentation procedure was calculated (Table 2). For the cases with simultaneous placement, measurements were made after uncovering.[1-4]

Implant Surgery

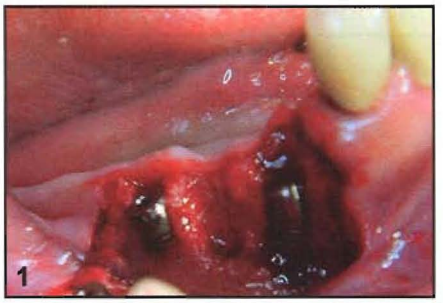
The implants were placed at 24 weeks following ridge exposure for the staged cases (Figs. 5–8). Suitability for placing implants was assessed based on sufficient ridge width. Any sites unsuitable for placement were recorded as failures. The changes in mean ridge height and mean ridge width were evaluated. All implants were submerged (Tapered ScrewVent®; Zimmer Dental). If threads were exposed in the staged case, they were regrafted. Flaps were sutured with nonresorbable interrupted sutures. Written and verbal postoperative instructions were provided. The implants were then allowed to osseointegrate. Implants were uncovered at 12 weeks following mandibular implant placement and 16 weeks following maxillary implant placement. The implants were surgically exposed, and healing abutments were connected to the implants.

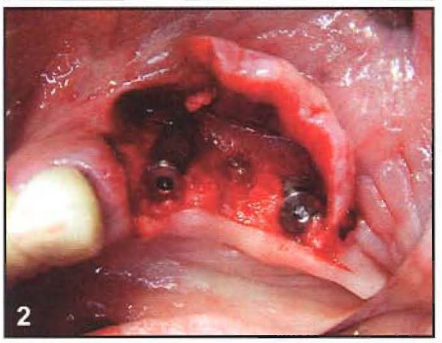
Results

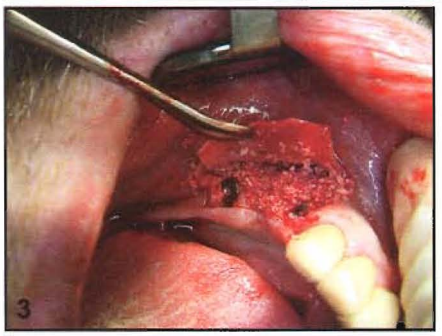
The change in alveolar ridge width varied from a loss of 0.2 mm to a gain of 5.8 mm, with a mean gain of 3.0364 mm (Table 2). Compared to the baseline measurement, the change was statistically significant $P < 0.001$ (t test). However, the number of sites is too limited for a real evaluation. There were 19 implant sites that gained ≤2 mm and 8 sites ≥3.0 mm. Seventeen mandibular and 1 maxillary localized alveolar ridge defect was treated (Table 2). There were 2 patients (7 implant sites) who received staged dental implants. Of those, 1 implant had exposed threads requiring regrafting at implant placement. All implants except 1 could be placed because of adequate ridge width. This site was treated with a small diameter implant.

Discussion

In a rat study by Schwarz,[1] in histologic and histometric analysis after 8 weeks following implantation, the pericardium membrane showed approximately 60% of membrane thickness measured after 2 weeks. The Tutodent® membrane body seemed to be structured like an interconnected porous







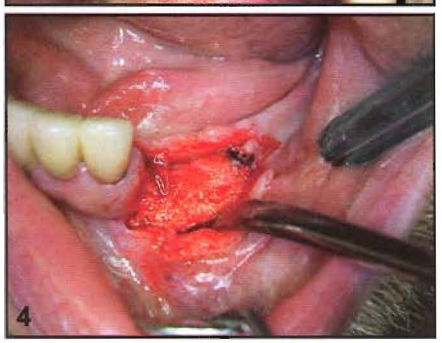


Fig. 1. Immediate implant placement. Bone dehiscence is noted at both implants. Ridge width at the crest of the bone was measured for each implant site.

Fig. 2. Occlusal view after flap preparation showing implant position in the remaining bone.

Fig. 3. Membrane (Tutodent® pericardium) is fixated with pins, and the defect is filled with xenograft (Bio-Oss®).

Fig. 4. After 6 months, partially regenerated bone is found. The entire dehiscence at both implant sites is covered.

Table 2. Clinical Evaluation of Horizontal Bone Augmentation With Tutodent® Membrane for Each Implant Site Before and After Augmentation

Measurement for Each Implant Position	No. Implants	Before Augmentation (staged procedure)	Before Augmentation (simultaneously implant placement)	After Augmentation	Ridge Width Change (mm)
1	3		2	7	5
			2.2	7.2	5
			2.4	7.2	4.8
2	2	2.4		7.6	5.4
		2.0		7.8	5.8
3	3	3.5		6.2	2.7
		3.2		5.5	2.3
		3.2		3.0	−02
4	1	3		6	3
5	1	4.3		6.6	2.3
6	4		4.2	6	1.8
			3.0	5.8	2.8
			3.2	5.8	2.6
			6.5	6.4	0.2
7	3	3		6.2	3.2
		2.8		6.0	3.8
		2.5		5.7	3.5
8	2	4.8		6.3	1.5
		5.0		7.2	2.2
				19 implants	57.9

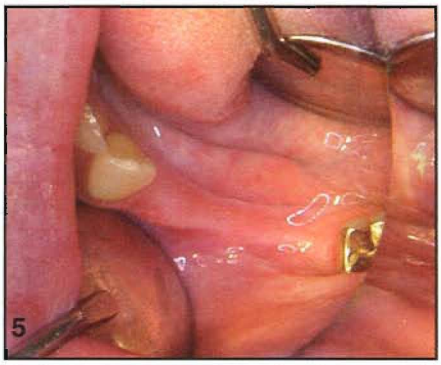
There were 6 patients (12 implants) treated with the staged GBR procedure. Placement was measured in 2 patients (7 implants) treated with simultaneously grafting and implant placement bone width at baseline and uncovering/implant. The change in alveolar ridge width varied from a loss of 0.2 mm to a gain of 5.8 mm, with a mean gain of 3.0364 mm.

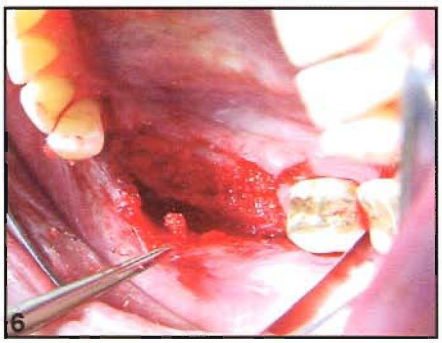
system. Histologic analysis 2 weeks following implantation revealed that merely half the Tutodent® membrane body was vascularized. After 16 weeks, the Tutodent® was almost entirely organized and replaced by newly formed connective tissue. After 24 weeks, a nearly complete biodegradation and substitution of the membrane by newly formed connective tissue was observed. The same investigator[1] describes the resorption time at 8–16 weeks. Another study from Rothamel *et al*[2] showed that the pericardium membrane promoted the attachment and proliferation of human periodontal ligament fibroblasts and human osteoblasts.

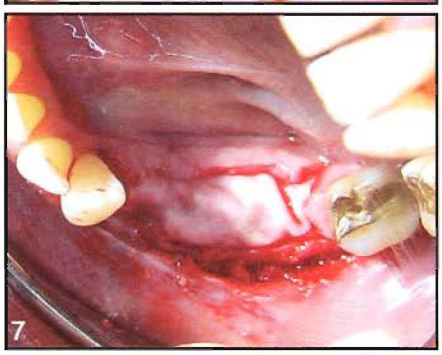
In a study of 66 sites in 40 patients with autogenous bone blocks and particles from the chin or retromolar regions, and having placed expanded polytetrafluoroethylene barrier membranes, Buser *et al*[3] reported a mean ridge width gain of 3.53 mm. In another study, Parodi *et al*[4] used bioresorbable collagen sponges with a bioresorbable collagen barrier in 16 sites in 16 patients to achieve a mean gain of 2.49 mm. Fugazzotto[5] performed 302 consecutive ridge augmentation procedures in 284 patients with Gore-Tex® (W.L. Gore & Assoc., Inc., Newark, DE) membranes in conjunction with various nonautogenous particulate materials. A total of 574 implants were placed in the augmented 279 buccolingual augmented ridges, which represented an overall success rate of 96%. The implant survival rate after augmentation was 97% for the uncovered implants.

Knapp *et al*[10] measured 12 patients with inadequate dental alveolar ridge widths using bioactive glass alloplast and a titanium-reinforced PTFE barrier. The change in ridge width varied in their study from a loss of 1 mm to a gain of 4.5 mm, with a mean gain of 1.1 mm ($P < 0.03$). Mean ridge width gain was 1.1 mm for both maxillary and mandibular sites. There was no measurement of success in cases of dehiscence.

The objective of this study was to evaluate the feasibility of using a pericardium collagen membrane in combination with 2 different xenograft grafting materials to augment localized deficient alveolar ridges in preparation for dental implants. To accomplish this objective, the changes in ridge width were measured. Collagen pericardium membranes were used in conjunction with various nonautogenous particulate







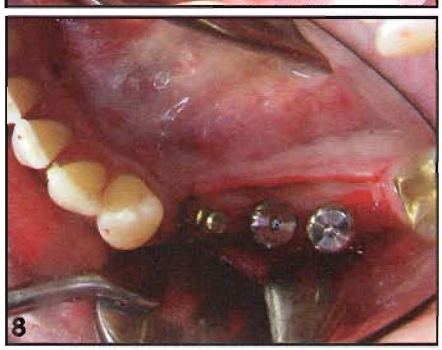


Fig. 5. Thin ridge is inadequate for implant placement. Staged procedure is needed.
Fig. 6. Membrane (Tutodent® pericardium) is fixated with pins, and the defect is filled with xenograft (Navigraft 228).
Fig. 7. Membrane is fixated labially only by the flap in position.
Fig. 8. Increased bone ridge with adequate bone for implant. Appropriate diameter is found after 6 months.

materials. Of 19 sites, 18 showed sufficient regenerated hard tissues for standard implant placement in ideal prosthetic positions. There was 1 site that did not show sufficient regenerated hard tissues for standard implant. In this case, a smaller diameter implant was used. The mean ridge width change of 3.0364 mm can be compared to changes in ridge width reported in other augmentation studies, keeping in mind that materials and methods vary. In this study, all implants were placed, and only 1 needed regrafting The change in ridge width varied in this study from a loss of 0.2, which was treated with a small diameter implant (described previously) connected to 2 standard implants, to a gain of 5.8 mm.

Conclusion

When used in conjunction with nonautogenous particulate materials, pericardium membranes (Tutodent®) have been successful in effecting bone regeneration in the treatment of 19 consecutive atrophic edentulous implant sites. Such augmentation showed clinical success in a buccolingual (horizontal) direction. There was 1 clinician that performed this study. Other studies involving more clinicians and histologic evaluations are necessary to evaluate the material combination presented in this study.

Disclosure

Dr. Marius Steigmann has a financial interest in terms of being a speaker for Tutogen®, Germany.

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ID Abstract Translations

GERMAN

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Perikard-Membrane und Partikelförmige Xenotransplantate zur Behandlung von Defekten des horizontalen Alveolarkamms

ZUSAMMENFASSUNG: **Zielsetzung:** Die Zielsetzung dieser Studie war auf eine Erhebung der klinischen Machbarkeit hinsichtlich der Verwendung einer natürlichen, physikalisch resorbierbaren Kollagenmembran aus Rinderperikard zur Anreicherung lokalisierter Defekte im Alveolarkamm zur anschließenden Zahnimplantierung ausgerichtet. **Materialien und Methoden:** Acht systemisch gesunde Patienten im Alter von 35 bis 68 Jahren mit insgesamt 19 Implantierungsbereichen und mit unzureichenden Werten bezüglich der Weite des alveolären Zahnkamms wurden für diese Studie als Testpersonen ausgewählt. Alle Patienten durchliefen die ersten Therapieschritte, zu denen Messung, Wurzelplanung und Anweisungen zur Mundhygiene gehörten. Alle Defekte im Kammbereich wurden mit Rinder-Xenotransplantat angereichert und mit einer Kollagen-Perikard-Membran abgedeckt. Am Tag der Anreicherungsprozedur, zum Zeitpunkt des Implantierung und Anreicherung (Basis) sowie bei der nach Ablauf von 6 Monaten vorgenommenen Operation (erneuter Eintritt oder Aufdeckung) wurden horizontale (Weiten-) Messungen des harten Gewebes vorgenommen. **Ergebnisse:** Die Veränderungen der Kammweite bewegten sich innerhalb eines Verlusts von 0.2 mm bis hin zu einer Anreicherung von 7.8 mm, alle Werte dabei klinisch erhoben mit einem Durchschnittswert von 3,0368 und einem Mittelwert von 2.8 mm von der Basis. **Schlussfolgerung:** Die Ergebnisse lassen den Schluss zu, dass sich Perikard-Kollagen-Membrane als Bestandteil zur Anreicherung lokalisierter Defekte des Alveolarkamms in Verbindung mit unterschiedlichen Xenotransplantaten eignen.

SPANISH

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Membrana del pericardio y materiales para injertos de partículas de xenoinjerto para defectos horizontales de la cresta alveolar

ABSTRACTO: **Propósito:** El propósito de este estudio fue evaluar la factibilidad clínica del uso de una barrera reabsorvible física de colágeno nativo hecha de pericardio bovino para aumentar los defectos localizados de la cresta alveolar para la colocación posterior de implantes dentales. **Materiales y métodos:** Ocho pacientes sistémicamente saludables con 19 lugares para implantes (de 35 a 68 años) con anchos inadecuados de la cresta alveolar dental fueron seleccionados para el estudio. Todos los pacientes completaron la terapia inicial, que incluyó el raspaje, alisado radicular e instrucciones sobre la higiene oral. Todos los defectos de la cresta fueron aumentados con un xenoinjerto bovino y una membrana de pericardio de colágeno. Se midió el tejido duro horizontal (ancho) el día de la cirugía para aumentar la cresta o la colocación del implante y el aumento (base) y en la cirugía a los 6 meses (reingreso o descubrimiento). **Resultados:** El cambio en el ancho de la cresta varió desde una pérdida de 0.2 mm hasta una ganancia de 7.8 mm medidos clínicamente con un valor medio de 3,0368 y una mediana de 2.8 mm de la base. **Conclusión:** Los resultados sugirieron que una membrana de colágeno de pericardio podría ser un componente útil para aumentar defectos localizados de la cresta alveolar junto con diferentes xenoinjertos.

PORTUGESE

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Membrana do Pericárdio e Materiais de Enxerto de Particulado de Xenoenxerto para Defeitos do Rebordo Alveolar Horizontal

RESUMO: **Propósito:** O propósito deste estudo era avaliar a viabilidade clínica de usar uma barreira reabsorvível física de colágeno nativo feita de pericárdio bovino para aumentar os defeitos localizados do rebordo alveolar para a subseqüente colocação de implantes dentários. **Materiais e Métodos:** Oito pacientes sistematicamente saudáveis com 19 locais de implantes (com idade entre 35 e 68 anos) com largura dentárias inadequadas de rebordo alveolar foram selecionados para o estudo. Todos os pacientes completaram terapia ini-

cial, que incluía raspagem, planejamento radicular e instrução sobre higiene oral. Todos os defeitos do rebordo foram aumentados com xenoenxerto bovino e uma membrana do pericárdio de colágeno. Medições de tecido duro (de largura) horizontal foram tomadas no dias da cirurgia de aumento do rebordo, ou colocação e aumento do implante (linha de base), e na cirurgia (de reentrada). **Resultados:** A mudança na largura do rebordo variou de uma perda de 0.2 mm a um ganho de 7.7 mm, medidos clinicamente com um valor médio de 3,0368 e uma mediana de 2.8 mm a partir da linha de base. **Conclusão:** Os resultados sugeriram que a membrana de colágeno do pericárdio pode ser um componente adequado para aumento de defeitos localizados do rebordo alveolar juntamente com diferentes xenoenxertos.

JAPANESE

水平歯槽堤欠陥のためのPericardium MembraneとXenograft Particulate Grafting Material

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要約：

目的：本研究の目的は、ウシ心膜で作られたnative collagen physical resorbable barrierによるデンタルインプラント装着前の局部的歯槽堤欠損増大法の臨床可能性を評価することにあった。

素材と方法：全身的に健康で歯槽堤幅が不全であり19のインプラント部位を持つ8人の患者(年齢35歳～68歳)が、本研究のために選ばれた。患者はすべて、スケーリング、ルートプランニング、口腔衛生指導を含む初期治療を完了した。歯槽堤不全はすべてウシ異種移植による増大処置を受け、歯槽堤手術またはインプラント装着／増大(ベースライン)時と6ヶ月後のre-entryまたはuncovering surgery時に、pericardium membrane Horizontal (hard) tissueの計測が行われた。

結果：歯槽堤幅の変化には0.2mmの損失から7.8mmの増大までの幅があり、ベースラインからの臨床平均値は3.0368mm、中央値は2.8mmであった。

結論：この結果は、異なる異種移植を伴うpericardium collagen membraneの使用が、局部的歯槽堤欠損増大法の良好な一部を構成しうることを示している。

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