CLINICAL STUDY

Letters on Implant Dentistry 2022; 2: 62 – 66

Vertical and horizontal guided bone regeneration (GBR) using a Ti-reinforced non-resorbable e-PTFE membrane and simultaneous implant placement. A retrospective study

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This retrospective chart review of 903 sites treated according to a GBR protocol with simultaneous implant placement using NeoGen PTFE membranes and Neoss ProActive implants showed an implant survival rate of 99.8% after a follow-up of up to 5 years after membrane removal. Vertical ridge augmentation cases showed a mean bone fill of 86% Membrane related soft tissue complications occurred in 11% of the cases.

INTRODUCTION

Guided bone regeneration (GBR) is a treatment concept for bone augmentation where a membrane is placed between the soft tissue and the bone, to obstruct the soft tissue from growing into the bone defect. The membrane creates a space where the bone forming cells can generate new bone without the interference from soft tissue cells.

GBR can be performed in numerous ways: with resorbable or non-resorbable membranes, with or without grafting material, with or without structural reinforcement, in a staged approach or simultaneous with implant placement.[2]

The aim of the study was to retrospectively study the clinical outcome of a GBR procedure using a Ti-reinforced non-resorbable e-PTFE membrane and autogenous bone material with simultaneous implant placement. Results from this study cohort has previously been published.[1,2]

MATERIALS AND METHODS

Study design

This retrospective study reports on the clinical outcome of consecutive patients treated in the same clinic by one surgeon (NoH) using a surgical protocol where a guided bone regeneration (GBR) procedure using autogenous bone material and a non-resorbable e-PTFE membrane (NeoGen Ti-Reinforced PTFE Membrane, Neoss, Gothenburg, Sweden) was performed at time of implant placement.

All patients that underwent the clinical procedure were deemed appropriate through clinical and radiographic examination before treatment. The patients were informed of the procedures and gave their written consent before treatment.

All study data was collected through a retrospective chart review. All collected data was part of the patients files, therefore no additional treatments were performed as part of this study. The retrospective data collection was conducted in accordance with the World Medical Association Declaration of Helsinki and approved by the Ethics Committee of the Department of Medicine of the Justus Liebig University Giessen (AZ 222/19).

Treatment protocol

Antibiotic treatment was commenced the evening before surgery and lasted for 5 days. All surgeries were performed under local anesthesia.

A full thickness flap with releasing incisions was opened and the implant site was prepared (Figure 1B).

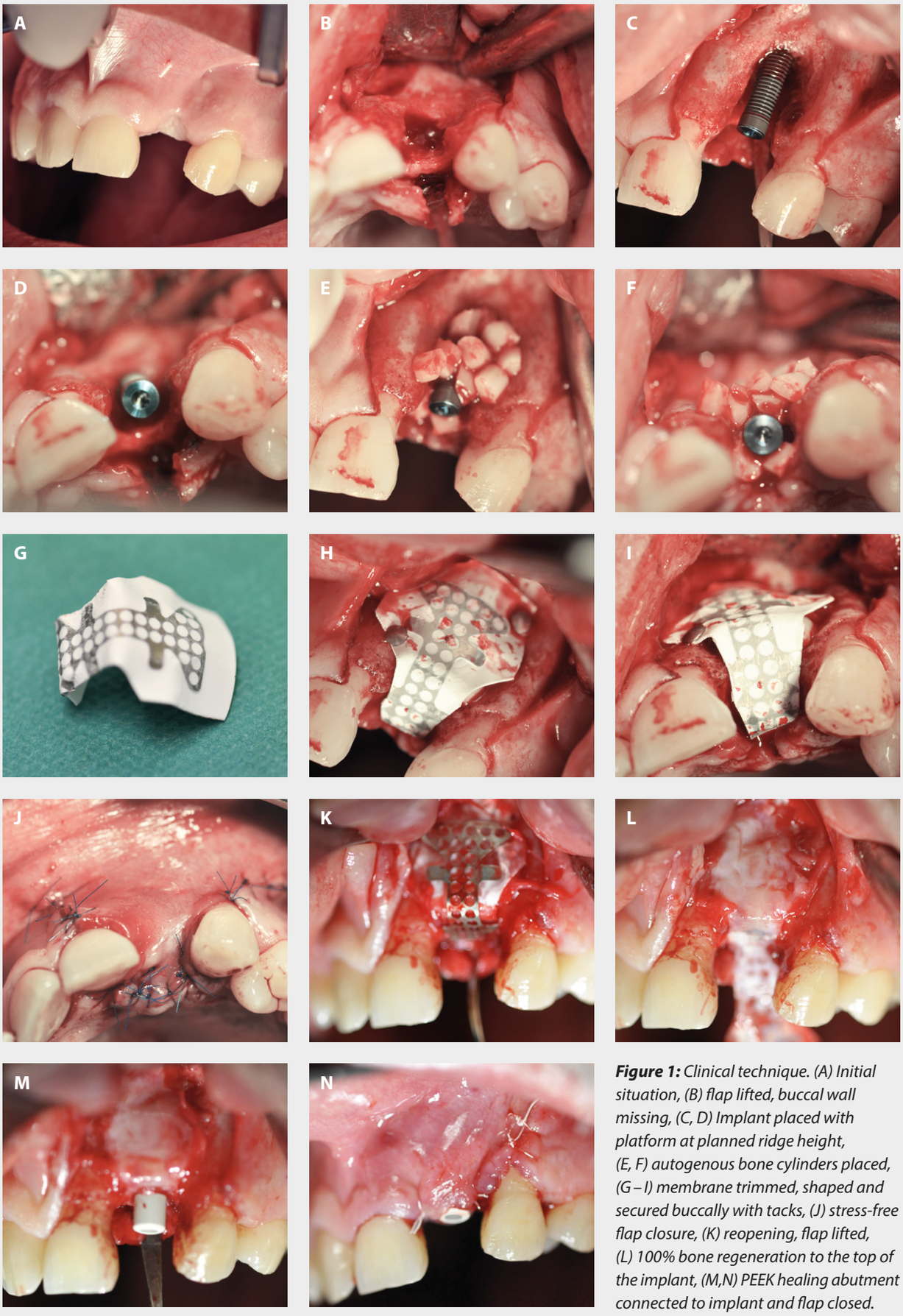


Figure 1: *Clinical technique. (A) Initial situation, (B) flap lifted, buccal wall missing, (C, D) Implant placed with platform at planned ridge height, (E, F) autogenous bone cylinders placed, (G – I) membrane trimmed, shaped and secured buccally with tacks, (J) stress-free flap closure, (K) reopening, flap lifted, (L) 100% bone regeneration to the top of the implant, (M,N) PEEK healing abutment connected to implant and flap closed.*

Implant osteotomies were drilled according to the manufacturer's guidelines to achieve good primary stability.

Autogenous bone chips were collected during preparation of the implant osteotomies using a bone collecting device connected to the suction system.

One or more dental implants (Neoss ProActive Straight, Neoss, Sweden) were placed with the implant-abutment connection at planned future bone level and a cover screw was connected (Figure 1C – D)

In larger defect cases, autogenous bone cylinders were used together with the autogenous bone chips to accelerate regeneration and to act as space fillers (Figure 1E – F). The bone cylinders (height up to 5 mm) were harvested from the oblique line of the mandible in the molar region using a 3.4 mm trephine drill. In smaller defect cases, only autogenous bone chips were used. No additional bone substitutes were used.

A Ti-reinforced e-PTFE membrane (NeoGen Ti-Reinforced PTFE Membrane, Neoss, Gothenburg, Sweden) was trimmed, shaped (Figure 1G), and fitted at the surgical site and secured buccally using membrane tacks (Figure 1H – I). A stable membrane configuration was achieved using the implants as tent posts.

Stress free flap closure was achieved by releasing the periosteum on the buccal side (Figure 1J).

The augmented sites were typically allowed to heal for 4 – 7 months, depending on clinical situation. After the healing period, second stage surgery was performed. A mid-crestal incision with releasing incisions was used. The flap was lifted to expose the membrane (Figure 1K) and the membrane was removed. If needed, excess bone on top of the cover screw (Figure 1L) was removed to get access to the implant. PEEK healing abutments (Neoss, Sweden) were connected to the implants for transgingival healing (Figure 1M) and the flap was closed (Figure 1N).

The definitive prostheses were delivered 0 – 18 months (average 2.8 months) after membrane removal.

Baseline parameters

Baseline parameters (age, gender, smoking habits, diabetes, tooth status, defect type, type of bone transplant, bone quality, and primary stability) were retrieved from the patient files (Table 1).

Follow-up

All information on membrane complications, such as infection and membrane exposure, were compiled from the patient records. The influence of the recorded baseline parameters on complication rate was evaluated.

Parameter	Group	n	%
Gender	Female	322	50.1
	Male	321	49.9
Age	10 – 19	11	1.7
	20 – 29	19	3.0
	30 – 39	37	5.8
	40 – 49	77	12.0
	50 – 59	207	32.2
	60 – 69	189	29.4
	70 – 79	95	14.8
	80 – 89	7	1.1
	90 – 99	1	0.2
Smoker	No	496	77.1
	Yes	147	22.9
Diabetes	No	628	97.7
	Yes	15	2.3
Defect type	Fenestration defect	36	5.6
	Intra-alveolar defect	12	1.9
	Horizontal defect < 50%	217	33.8
	Horizontal defect > 50%	254	39.5
	Horizontal defect buccal and oral	24	3.7
	Vertical defect ≤ 3 mm	62	9.6
	Vertical defect > 3 mm	38	5.9
Tooth status	Edentulous jaw	29	4.5
	Free-end gap	166	25.8
	Single-tooth gap, anterior	131	20.4
	Single-tooth gap, posterior	133	20.7
	Interdental gaps, anterior	49	7.6
	Interdental gaps, posterior	121	18.8
	Reduced residual dentition	14	2.2
Type of bone transplant	None	4	4.0
	Bone chips	34	34.3
	Bone cylinders	12	12.1
	Bone chips + Bone cylinders	49	49.5
Bone quality	D1	120	18.7
	D2	194	30.2
	D3	150	23.3
	D4	179	27.8
Primary Stability	High (> 30 Ncm)	448	69.7
	Poor (8 – 30 Ncm)	154	24.0
	Spinner (< 8 Ncm)	39	6.1
	None (extraaxial movement)	2	0.3

Table 1: *Baseline parameters*

The latest time-point registered in the patient's file was used for the implant follow-up. Implant follow-up time was calculated from time of membrane removal.

Vertical ridge augmentation

In sites where vertical ridge augmentation was performed (n = 95), the vertical bone level was assessed at time of surgery and at membrane removal. The change in bone level as well as the percentage bone gain was assessed (0% = no bone gain, 100% = bone regenerated to level of implant platform). One implant from each augmentation was chosen for analysis.

Parameter	All sites	Vertical ridge augmentation sites
Number of implants	903	95
Early exposure rate	7%	11%
Infection rate	4%	10%
Overall membrane complication rate	11%	21%
Implant restorability rate	100%	100%

Table 2: *Membrane complication rates*

Time interval	Implants	Failed	Withdrawn / Not followed	CSR
Insert. – 1 year	903	0	332	100%
1 – 2 years	571	0	139	100%
2 – 3 years	432	1	194	99.8%
3 – 4 years	237	0	166	99.8%
4 – 5 years	71	0	67	99.8%
5 years	4	–	–	–

Table 3: *Life table analysis. Dental implant survival.*

RESULTS

Overall outcome

The chart review identified 903 sites where a GBR procedure using a NeoGen PTFE membrane was performed simultaneous with implant placement. Vertical rigde augmentation was performed in 95 of these sites.

Eleven percent (11%) of the membrane sites experienced complications that required intervention, 7% were early exposures and 4% were infections. The corresponding complication rates in vertical ridge augmentations was slightly increased, 11% and 10% respectively (Table 2). Although some membranes had to be removed early, all placed implants could be restored. One implant failed after 2 years, resulting in an cumulative implant survival rate of 99.8% (Table 3).

Vertical ridge augmentation

The mean vertical defect size at surgery was 3.9 ± 2.3 mm, measured with the implant as reference. After augmentation the mean marginal bone level was 0.5 ± 0.9 mm. This represents a mean bone gain of 87.5%. Bone regeneration up to or above the implant platform was achieved in 51% of the sites.

Evaluation of risk factors

For three parameters (defect type, tooth status and smoking) there was a significant impact on complication rate. The impact of each parameters as well as a proposed risk classification is given in Table 4. For all other investigated parameters, there was no significant difference in complication rate between groups, and thus not considered risk factors for the procedure.

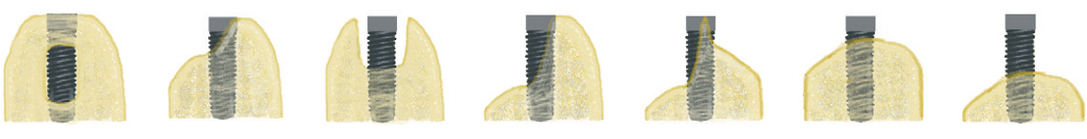
	Low risk		Decreased risk		Increased risk		High risk
Defect type							
	Fenestration defect	Horizontal defect < 50% of the implant length	Intra-alveolar defect	Horizontal defect > 50% of the implant length	Horizontal defect buccal and oral	Vertical defect ≤ 3 mm	Vertical defect > 3 mm
Risk ratio	***0.4***	***0.8***	***0.9***	***1.2***	***1.6***	***1.6***	***2.4***
Tooth status	Edentulous jaw	Free-end gap	Single-tooth gap posterior region	Interdental gaps posterior region	Single-tooth gap anterior region	Interdental gaps anterior region	Reduced residual dentition
Risk ratio	***0.5***	***1.0***	***1.1***	***1.3***	***1.3***	***1.6***	***1.7***
Smoking	Non-smoker					Smoker	
Risk ratio	***0.9***					***1.4***	
Examples: *Based on an average risk of 11% in the population*	A non-smoking patient with a small horizontal defect in the toothless-jaw has a risk of membrane complication of 4%: (11% × 0.8 × 0.5 × 0.9 = 4%)						
	A smoking patient with a large vertical defect with reduced residual dentition has a risk of membrane complication of 63%: (11% × 2.4 × 1.7 × 1.4 = 63%)						

Table 4: *Risk classification for e-PTFE membrane complication in relation to average risk.*

DISCUSSION

In the present study, membrane complications occured in 11% of the membrane sites. This is well in line with what is reported in a recent systematic review by Lim et al that reported an average complication rate of 17.6% for non-resorbable membranes and 18.3% for resorbable membranes.[3]

Membrane complications do occur, but it is not an event that automatically result in a failed treatment. On the contrary, all complications in the present study were resolved and all implants could be restored. This is in line with the results of Lim et al. They reported that the majority of studies in their systematic review achieved complete healing of the sites that had experienced complications without significant impact on the bone augmentation procedure.[3]

The risk classification given in Table 4, shows how different parameters influence the risk of complications. It should not be used as a formula to calculate exact risk ratios, but more as a tool to see how combining different indications and parameters can lead too higher risk and thereby identifying if a patient is at risk for the procedure.

It is concluded that guided bone regeneration (GBR) using the Ti-reinforced NeoGen PTFE membrane and simultaneous implant placement is a reliable and time efficient treatment in cases where bone augmentation is needed for implant placement.

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