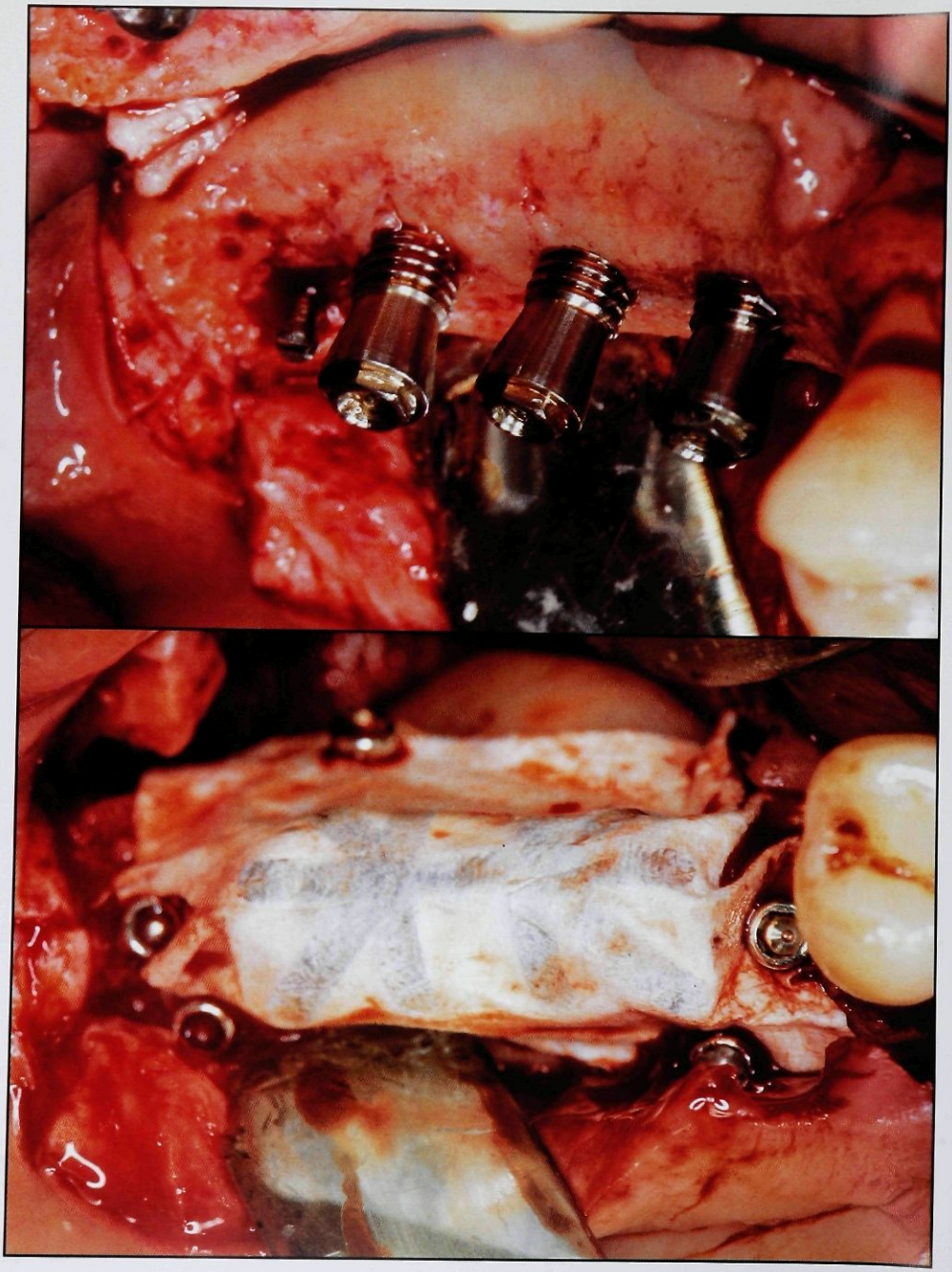
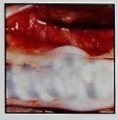


Vertical Ridge Augmentation Using a Membrane Technique Associated With Osseointegrated Implants



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The purpose of this study was to evaluate: (1) the surgical protocol, effectiveness, and reliability for vertical ridge augmentation using a new titanium-reinforced membrane and osseointegrated implants; and (2) the histologic characteristics of the interface between a pure titanium implant and newly regenerated human bone. Five patients received 15 conical Brånemark-type implants in six different surgical sites requiring vertical augmentation. The implants protruded 4 to 7 mm from the bone crest. Pure titanium miniscrews (1.3 × 10 mm) were positioned distally to the implants, protruding 3 to 4 mm from the bone level. The implants and the miniscrews were covered with a titanium-reinforced membrane, and the flaps were sutured. Membranes were removed at the stage 2 surgery after 9 months of healing. Measurements of biopsy specimens showed a gain in bone height from 3 to 4 mm. Histologic examination showed that all retrieved miniscrews were in direct contact with bone. Histomorphometric analysis of bone contact gave a mean value of 42.5 ± 3.6% for five of the six examined miniscrews. The results suggest that the placement of implants protruding 3 to 4 mm from the top of resorbed bone surfaces may result in vertical bone regeneration to the top of the implant cylinder and that the regenerated bone is able to osseointegrate pure titanium implants.
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Treatment of patients with severely resorbed edentulous jaws using osseointegrated dental implants remains one of the most challenging goals in implant dentistry. To obtain predictable long-term results, a sufficient amount of bone should be present at the recipient site for complete circumferential coverage of the implant.[1,2] The minimum amount of bone required to meet this condition when using the shortest standard (3.75-mm diameter) Brånemark implant is 4 mm horizontally and 7 mm vertically.[3] Resorption patterns following tooth extraction greatly alter the width and height of residual ridges, especially when tooth loss results from maxillofacial trauma, vertical root fractures, or severe periodontal involvement, or when the buccal plate of the jaw has been lost through traumatic extractions. Jaw bone atrophy and anatomic aberrations may also complicate correct implant placement with

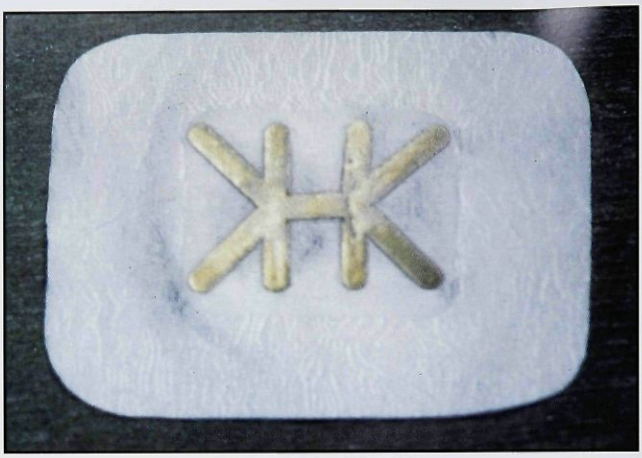


Fig 1 *TR GTAM, a new type of e-PTFE membrane that can be bent and shaped, maintaining the desired form due to the titanium mesh included in its construction.*

respect to location and angulation. Malpositioned implants may affect the coronal form, the emergence profile, embrasure spaces, establishment of physiologic buccal-lingual relationship, and the esthetics and function of the final implant-supported restoration.[4]

The application of the principle of guided tissue regeneration (GTR) to dental implant procedures provided the clinicians with the ability to: *(1)* augment the width of deficient alveolar ridges[5-9]; *(2)* cover implant fenestrations[10] and dehiscences[11-14] with newly regenerated bone; *(3)* allow immediate implant placement in residual osseous defect and large post-extractive sites[7,11,14,15]; and *(4)* treat angular bony defects around "failing implants."[14,16] The principles of guided tissue regeneration in natural tooth and dental implant have been extensively described in previous articles.[5,17-20]

Despite the encouraging results obtained with GTR in horizontal ridge augmentation and self-spacemaking bone defect treatment, there is a lack of data concerning jaw bone augmentation in the vertical dimension. The vertical dimension of the edentulous jaw is critical for implant placement in lateral areas of partially edentulous patients of Applegate-Kennedy class I and class II, where anatomic structures such as the maxillary sinus or the alveolar nerve may limit the bone height available for implant stability and load-bearing capability.

Several techniques have been proposed for sinus elevation with different bone graft materials[21-23] and alveolar nerve transposition in the mandible[24,25] to allow the placement of implants of adequate length. However, all of these techniques present negative side effects. They maintain a wide interarch space that alters the coronal length and form, the embrasure spaces, and the esthetics of the final prosthesis, and they produce a crown-root ratio unfavorable for the occlusal stress-bearing capability of the implants. In addition, nerve transposition procedures present a consistent risk of long-lasting temporary or permanent mental nerve disorders.

The possibility of using GTR principles for vertical ridge augmentation has been questioned because of the high tendency of the membrane to collapse toward the bony ridge under the pressure of the soft tissues in a non-spacemaking situation. As a result of this complication, an insufficient amount of bone, or even no bone at all, may regenerate from the procedure. Nevertheless, the availability of a new type of expanded polytetrafluoroethylene (e-PTFE) membrane reinforced with a pure titanium structure (TR GTAM, WL Gore) (Fig 1) together with recent membrane fixation devices[6-9] (Memfix System, Straumann) create new opportunities for space maintenance using membranes and new possibilities for vertical ridge augmentation using GTR techniques. The TR GTAM membrane can be bent and shaped and will maintain a desired form, due to the titanium mesh included in its construction. This characteristic should allow the creation and the preservation of a sufficient space between the membrane and the bone defect. Thus, regeneration could be obtained in situations in which the anatomy of the defect is non-self-spacemaking.

The protocol of this clinical study was designed to achieve the following purposes: (a) to present the surgical protocol for a new application of the principles of guided tissue regeneration: the vertical ridge augmentation using a membrane technique associated with osseointegrated implant; (b) to evaluate the effectiveness and the reliability of the TR GTAM membrane; and (c) to assess histologically the characteristics of the interface between a pure titanium implant and newly regenerated bone in humans.

Method and materials

Patients

Five patients, aged between 42 and 60 years (average age: 51.6) participated in the study. Patients showed excellent general health at the medical examinations, with no detectable systemic contraindications to surgical treatment. Patient selection was made on the basis of the presence of Applegate-Kennedy class I or class II partial edentulism. Patients had to be highly motivated to undergo the implant procedure, wanting to avoid at all costs treatment with removable partial dentures. They were informed that a new application of a well-known and predictable technique was going to be applied during their therapy.

Implant sites were selected on the basis of the following anatomic conditions:

1. Sufficient bone width (greater than 6 mm)
2. The top of the edentulous ridge located at least 4 to 5 mm lower than the gingival margin of the residual natural teeth
3. Interarch space too wide to be compatible with an esthetic and functional fixed prosthetic restoration

In all patients, the implant sites were assessed with clinical intraoral examination, orthopantomograms, and computerized axial tomographic examination with Dentascan (GE Medical Systems) reconstruction of the profiles.

Surgical technique

The surgical protocol was the same in all five patients (Figs 2a to 2g and 3a to 3g). The implant surgery was performed under the hygienic conditions adequate for implant surgery. After perioral skin disinfection and 2-minute mouthrinses with 0.2% chlorhexidine gluconate solution (Corsodyl, ICI Pharmaceuticals, Macclesfield, Cheshire, England), the patients were covered with sterile sheets to minimize bacterial contamination. The patients received antibiotic prophylaxis for 10 days (amoxicillin, 1 g, 12 and 2 hours preoperatively and every 12 hours postoperatively) and an anti-inflammatory agent (ketoprofen, 50 mg every 12 hours) for 7 days. The surgery was carried out after administering local anesthesia (Ultracain DS Forte, Hoechst) which was combined with a sedative premedication (diazepam, 5 mg orally 30 minutes before surgery).

A full-thickness crestal incision was made within the keratinized gingiva from the distal aspect of the last residual tooth to the distal end of the edentulous ridge. The incision was extended intrasulcularly and anteriorly to the mesial aspect of the adjacent tooth. Vertical releasing incisions were made at the mesiobuccal and mesiopalatal line angles and at the distal aspect of the crestal incision. The buccal and palatal flaps were widely reflected with a periosteum elevator (Pritchard 1-2, Hu-Friedy) so as to gain a sufficient access for implant and membrane placement. Care was taken not to damage the palatine arteria and the mental nerve in severely resorbed maxillae and mandibles. The flaps were handled gently to minimize soft tissue trauma and to avoid flap perforations. Once exposed, the cortical bone was curetted with a back-action chisel to remove all residual connective tissue and the periosteum.

Fifteen conical Brånemark implants (Nobelpharma AB, Gothenburg, Sweden) were placed in six surgical sites requiring vertical augmentation. Conical implants were chosen to avoid exposure of the implant threads above the bone and the gingival tissues in cases with only partial success or complete failure of the regenerative technique. In fact, in such cases, the smooth collar of the conical implants would facilitate the maintenance and health of the peri-implant soft tissues. The implant surgery was performed according to the standard procedure described by Adell et al,[26] except for some details. To improve primary stability, the recipient sites were not pretapped, and the implants were allowed to protrude 4 to 7 mm from the bone crest. Countersinks were not used.

A pure titanium miniscrew (1.3 × 10 mm) was positioned distally to the implants in each surgical site to serve as a "tent pole" for the membrane. Following recipient-site preparation with a 0.9-mm-diameter drill under sterile saline irrigation, the miniscrews were inserted with a low-speed (1 rpm) handpiece. The miniscrews were allowed to protrude 3 to 4 mm from the bone level (Figs 2b and 3b). The protruding portions of the implants and of the miniscrews were measured at their mesial and distal aspects for biometric analysis before and after treatment. Before membrane placement, the cortical bone was perforated with a round bur to expose the cancellous bone and favor bleeding. The titanium structures of GTAM membranes were bent with pliers to obtain proper membrane shape, and later the external portions were trimmed with scissors so that they extended at least 4 to 5 mm beyond the defect margins. The membranes were tried in and reshaped several times until a close adaptation to the underlying bone and to the implants was achieved.

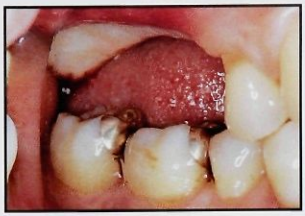


Fig 2a *Typical implant site selected for study. The sites were characterized by sufficient bone width (greater than 6 mm); the top of the edentulous ridge located at a level at least 4 to 5 mm lower than the gingival margin of the residual natural teeth; and interarch space too wide to be compatible with an esthetic and functional fixed prosthetic rehabilitation.*

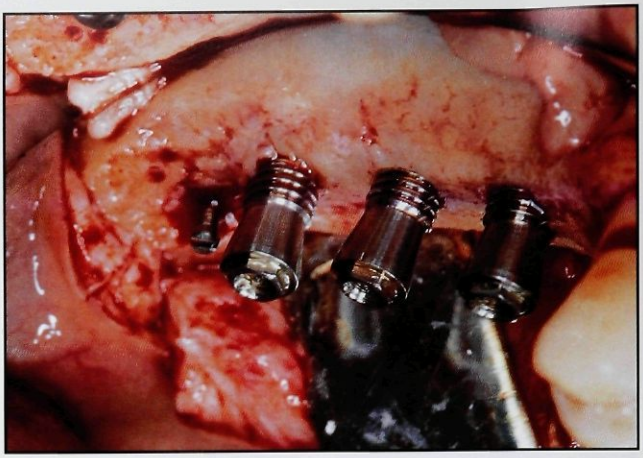


Fig 2b *Three conical Brånemark implants placed in the maxilla, protruding 6 to 7 mm from the bone crest. A pure titanium miniscrew protruding 3 mm from the bone level is visible in the third molar region.*

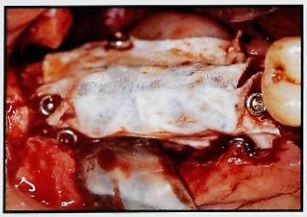


Fig 2c *TR GTAM membrane positioned in the surgical site and fixed to the bone with five Memfix fixation screws.*

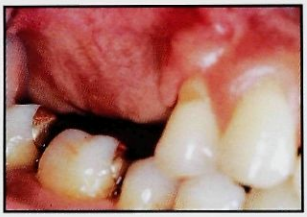


Fig 2d *Implant site just prior to stage 2 surgery after 9 months of uneventful healing.*

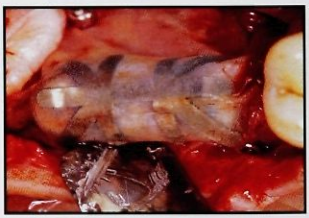


Fig 2e *After 9 months of healing, the membrane and the fixation screws are in proper position with no clinical signs of inflammation.*

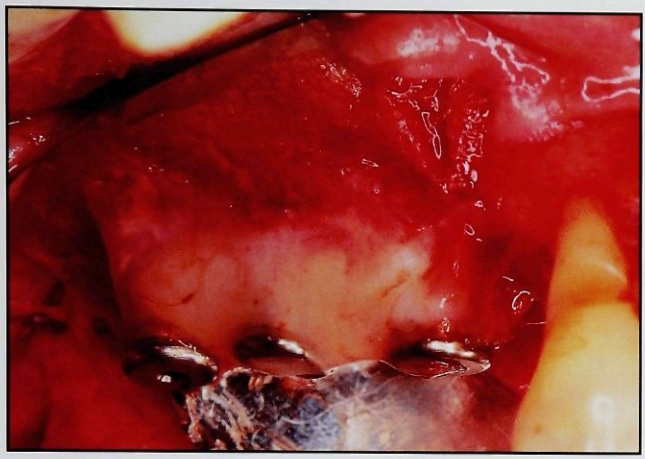
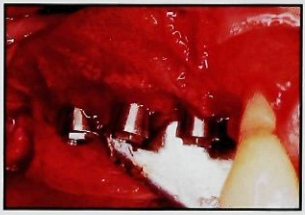


Fig 2f (left) *The membrane gently dissected from the underlying newly formed tissue. At the surface, a whitish and scarcely bleeding soft tissue is visible.*

Fig 2g (below) *The soft tissue was removed and scratched out with curettes until the newly formed hard bone was evident. A maximum of 3 to 4 mm of bone was regenerated.*



Once positioned in the surgical site, the membranes were fixed to the bone with 3 to 5 Memfix fixation screws.[9] The fixation screws were applied at the mesiobuccal, mesiopalatal, and distal edges of the membranes to achieve optimal stabilization (Figs 2c and 3c). Where the augmentation material was next to natural teeth, 2 mm of crestal bone was left uncovered, so as not to interfere with the healing process of the periodontal tissues. Releasing incisions in the periosteum were made at the base of the buccal flaps to enhance the elasticity of the flaps and to achieve a tension-free adaptation at closure. Closure was performed with vertical mattress sutures alternated with interrupted sutures. Patients were not allowed to wear a partial denture on the surgical site until stage 2 surgery to avoid any pressure on the wound area. Chemical plaque control with chlorhexidine (0.12% solution twice a day) was instituted for 15 days. The sutures were removed after 10 days, following topical application of 0.2% chlorhexidine gel (Corsodyl Gel) for 2 minutes to reduce bacterial contamination of the wound. After suture removal, the patients were checked once a week for the first month and then once a month until stage 2 surgery.

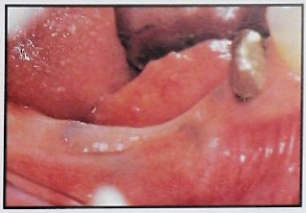


Fig 3a (above) *Atrophic edentulous ridge in the mandible characterized by the anatomic conditions required for participation in the study.*

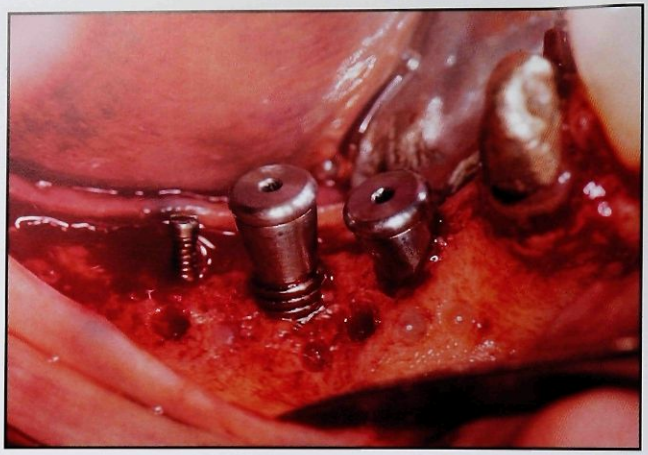


Fig 3b (right) *The implants and the pure titanium miniscrew are positioned in accordance with the study protocol. Perforations of the cortical bone are evident.*

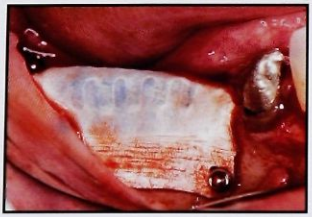


Fig 3c *The TR GTAM membrane is in position and stabilized with Memfix fixation screws.*

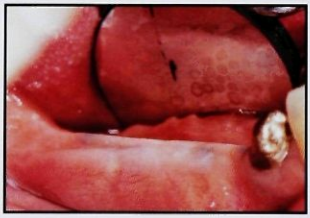


Fig 3d *Healing was uneventful and no dehiscences of the membrane occurred. The vertical augmentation of the edentulous ridge is evident.*

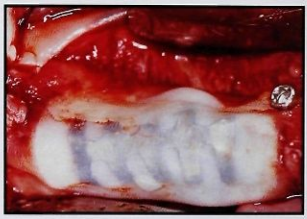


Fig 3e *At removal, the membrane adhered to the newly formed tissues and no clinical signs of inflammation were present.*

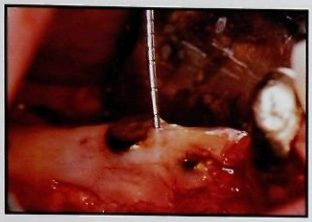


Fig 3f (above) *Newly formed tissue was inspected and probed following dissection of the membrane.*

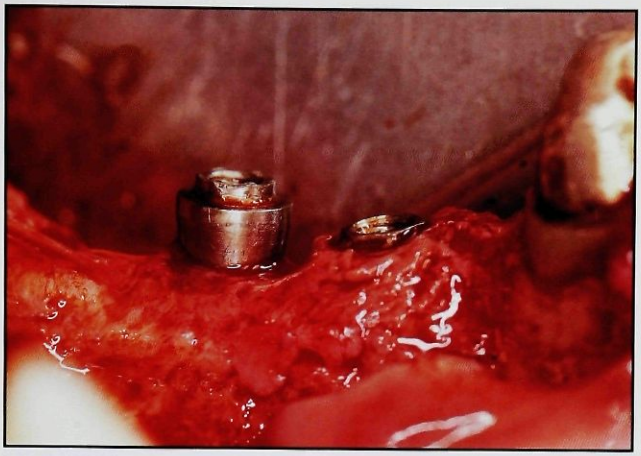


Fig 3g (right) *The soft tissue was removed to assess the regenerated hard bone. The implant in site 45 was completely covered by newly formed bone.*

After 9 months of healing, membranes were removed at stage 2 surgery. Following membrane removal, the pure titanium miniscrews were removed with a small trephine so that a small biopsy specimen of preexisting and newly formed tissue was collected from each site to be processed for histologic examinations. The specimens were fixed in 10% neutral buffered formalin for 24 hours. They were dehydrated in an ascending series of alcohol rinses and embedded in methylmethacrylate resin (Technovit 7200 VLC, Kulzer). After polymerization, the blocks were sectioned with a diamond saw to a thickness of 200 µm and ground down to 40 µm according to the technique of Donath and Breuner.[27] The slides were routinely stained with basic fuchsin-methylene blue. Histologic analysis was performed under a Laborlux S microscope (Leitz) and histomorphometric measurements were made by a Microvid Computer (Leitz) connected to an IBM personal computer to assess the length of the screws protruding from the crestal level and the percentage of regenerated bone–titanium contact.

Table 1 Implant placement and alveolar ridge height gains resulting from augmentation

Patient	Healing	Site (tooth no.)	Implant exposure (mm)		Gain of ridge height (mm)
			Stage 1 surgery	Stage 2 surgery	
1	Uneventful	35	4.5	1.5	3
	Uneventful	36	5	2	3
	Uneventful	37 (pin)	4	1	3
	Uneventful	45	4	0	4
	Uneventful	46	7	3	4
	Uneventful	47 (pin)	4	1.5	2.5
2	Uneventful	15	6	2	4
	Uneventful	16	7	3.5	3.5
	Uneventful	17	7	3	4
	Uneventful	18 (pin)	3	2	1
3	Uneventful	34	3	0	3
	Uneventful	35	3	0	3
	Uneventful	36	3	0	3
	Uneventful	37 (pin)	3	0.5	2.5
4	Uneventful	36	3	0	3
	Uneventful	37	3	0	3
	Uneventful	38	3	0	3
	Uneventful	38 (pin)	2	0	2
5	Abscess	45	6	5.5	0.5
	Abscess	46	5.5	5	0.5
	Abscess	47 (pin)	2	2	0

Results

The results of the present study are summarized in Table 1. All patients recovered well and no signs of infection were noted at the surgical sites. Only one patient (patient 5) developed an abscess involving the entire surgical site after 1 month of healing. The abscess probably derived from a periodontally involved third molar, present at the distal aspect of the surgical site. The membrane was immediately removed, the third molar was extracted, and the patient underwent antibiotic therapy (tetracycline, 250 mg 4 times a day) for 7 days. At the membrane removal, a hyperemic, heavily inflamed soft tissue was evident under the membrane. The flap was sutured again and left to heal for 8 additional months.

In the remaining four patients, no dehiscence of the membranes occurred during the entire healing period (Figs 2d and 3d). At the membrane removal after 9 months, all membranes and fixation screws were found in proper position with no clinical signs of inflammation (Figs 2e and 3e). The fixation screws were removed with a screwdriver and the membranes were gently dissected from the underlying newly formed tissue. At the surface, a whitish and scarcely bleeding soft tissue was present in all sites (Figs 2f and 3f). The soft tissue was removed and scratched out with curettes until the newly formed hard bone was evident (Figs 2g and 3g).

Fig 4 *Histologic sections of the retrieved miniscrew in site 47 (patient 1).*

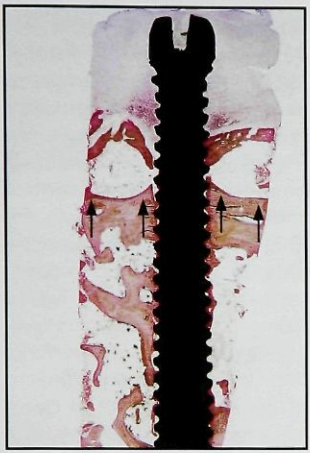


Fig 4a *Old bone is distinguishable, as it had a lower staining affinity for basic fuchsin. Arrows indicate the position of the preexisting bone level. (Original magnification × 10.)*

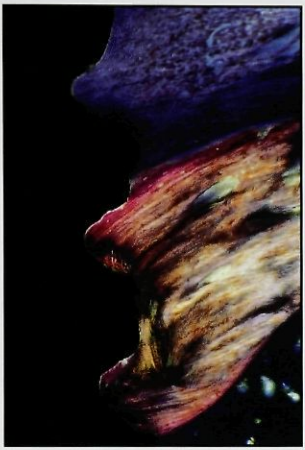


Fig 4b *Regenerated bone is in direct contact with the titanium surface. Polarized light microscopy shows a bone pattern of spongious lamellar bone. (Original magnification × 100.)*

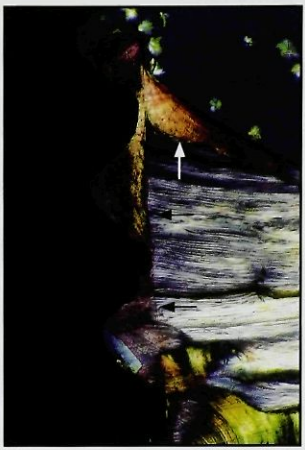


Fig 4c *Polarized light microscopy shows the lamellae present in the pre-existing bone has a different direction than those in the new bone (arrows). Osseointegration is evident. (Original magnification × 100.)*

Biometric measurements were taken mesially and distally from the top of each implant cylinder to the exposed newly formed hard bone. The measurements showed a gain in bone height varying from 3 to 4 mm (Table 1). Patient 5, in whom an abscess occurred and the membrane was prematurely removed, did not show any new bone formation at the implant sites.

Histologic examination of the bone biopsies showed that all retrieved miniscrews were in direct contact with bone. The most coronal portions of the screws, however, were over the crestal level of the bone, immersed in a dense fibrous tissue. The histomorphometric analysis of the percentage of bone contact gave a mean value of 42.5 ± 3.6% for five of the six examined miniscrews. The remaining miniscrew (patient 2), which was positioned in the tuberosity of the upper jaw, showed only 21.6% of the surface in contact with bone. In the majority of cases, histologic examination did not distinguish the newly formed bone from the old bone, but in some cases the old bone was distinguishable, as it had a lower staining affinity for basic fuchsin (Fig 4a). Polarized light microscopy showed a bone pattern of spongious lamellar bone (Figs 4b and 4c). In the most coronal part of the bone surrounding the miniscrews, direct contact with the titanium surface was detectable in some cases, and osteoblastic bone formation activity was present near the screw surface.

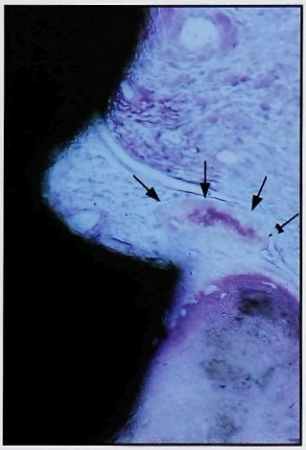


Fig 5 *Bone formation activity present at the top of the regenerating bone around a miniscrew (site 37, patient 1). Islands of osteoid tissue with ongoing intramembranous ossification are visible (arrows). (Original magnification × 100.)*

At this level, bone formation activity was present mainly at the most coronal portions of the miniscrews, where islands of osteoid tissue, with ongoing intramembranous ossification, were visible (Fig 5). The apical portions were in contact with a mature bone without signs of bone apposition. The portion of the miniscrews surrounded by supracrestal connective tissue had a mean value of 2.2 + 0.46 mm.

In the connective tissue overlying the crestal bone, no inflammatory reaction was present, and no macrophages were visible at the implant surface. This tissue consisted of densely packed collagen fibers with few cells and scarce blood vessels. No epithelial tissue was present.

Discussion

In this controlled study in humans, a guided tissue regeneration technique was tested for its capability of promoting vertical ridge augmentation in severely atrophic partially edentulous ridges. Vertical bone formation was tested at surgical sites in which implants were inserted and left protruding from flat atrophic edentulous ridges. In this way, the possibility of circumferential bone formation in vertical direction from flat cortical bone surfaces around titanium implants was verified. Vertical bone augmentation from flat cortical bone surfaces has been previously demonstrated by Dahlin et al[27] in rat calvaria and by Schmid et al[28] in rabbits, but a lack of investigations exists demonstrating this possibility in humans. This study clearly demonstrated that, with the surgical protocol described, it is possible to obtain up to 4 mm of vertical jawbone augmentation with a high degree of predictability. On the other hand, this investigation failed to demonstrate vertical bone regeneration greater than 4 mm. In fact, the most coronal portions of the implants protruding more than 4 mm from the bone crest were always surrounded by dense fibrous tissue.

The retrieved titanium miniscrews showed a mean gain in vertical direction of approximately 2.2 mm. The apical portion of the bone in contact with the screws showed an advanced stage of bone maturation, while the most coronal bone showed bone-forming activity. This observation substantiates the hypothesis that bone regeneration was still in progress at the time of membrane removal, after nine months of healing.

The theoretical basis for the use of titanium reinforced e-PTFE membranes in vertical augmentation would suggest the complete filling of the space under the membrane with newly formed bone. The lack, in our cases, of a complete bone regeneration over the 4-mm limit could be explained with different hypotheses:

1. The adaptation of a flat membrane to a three-dimensional curved anatomy caused different amounts of folds at the membrane borders. The folds may become "leaky spots," partially reducing the mechanical barrier effect of the membrane. Such leaky spots could have a limited effect when a small volume of bone has to be regenerated, but might hinder complete bone regeneration when considerable vertical augmentation is required. From this point of view, the e-PTFE membrane could be considered capable of retarding the penetration of connective tissue for a period long enough to allow the vertical regeneration of a maximum of 3 to 4 mm of bone.
2. The large blood clot under the membrane could undergo a certain amount of shrinkage during the early stage of healing, thus reducing the amount of bone regeneration. In this case, some filling material able to stabilize the blood clot could be helpful in augmenting the formation of new bone. This hypothesis is in accordance with previous studies[29] showing greater amount of bone regeneration when grafting materials are used under the membranes.
3. Blood supply in the most coronal portion of the space, secluded under the membrane, could be insufficient to allow osteogenic activity.
4. A longer period might be necessary to achieve complete bone regeneration up to the internal surface of the membrane. This is supported by the histologic finding in this study of bone-forming activity in the most coronal portion of bone regenerated around the titanium miniscrews, which demonstrated that bone regeneration was still in progress after nine months of healing.

The aim of this study was also to assess the possibility for regenerated bone to grow in direct contact with the surface of a titanium implant. Histologic results from the retrieved miniscrews have shown that the regenerated bone is able to osseointegrate titanium implants in humans, even though the percentage of direct bone-titanium contact in the regenerated bone (42.5 ± 3.6%) was consistently less than those reported in implants inserted in regular conditions.

In conclusion, the results of this study suggest that the placement of implants protruding 3 to 4 mm out from the top of resorbed bone surfaces may result in vertical bone regeneration up to the top of the implant cylinder, and that regenerated bone is able to osseointegrate pure titanium implants. Further research is needed to evaluate the load-bearing capability and long-term results of newly formed bone.

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