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KEY WORDS
3D-customized titanium grid, Vertical bone regeneration, Computer-guided bone regeneration

Case series

VERTICAL COMPUTER-GUIDED BONE REGENERATION OF SEVERELY RESORBED RIDGES WITH CUSTOMIZED TITANIUM GRID - ONE-YEAR FOLLOW-UP AFTER DEFINITIVE PROSTHESES DELIVERY: A RETROSPECTIVE CASE SERIES

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PURPOSE. The purpose of this report was to provide outcome data from a retrospective case series of vertical bone augmentation using 3D-customized titanium grids one year after fitting of definitive prostheses.

MATERIALS AND METHODS. Patients with severe vertical bone defects in the mandible or maxilla regenerated using titanium grids, previously customized via CBCT scan and pre-surgical virtual wax up, filled outside the mouth with 50% autologous bone and 50% deproteinized bovine bone were analysed. Eight to 9 months after regeneration, a second CBCT scan was performed to evaluate the regenerated bone, and implants were planned and placed.
Patients were monitored for one year after fitting of the definitive prostheses. Primary outcome measures were implant and prosthesis survival rates and complications. Secondary outcome measures were vertical dimensional changes, and peri-implant marginal bone loss.

RESULTS. Seven patients and eight procedures involving the insertion of a total of 22 implants were assessed. One-year after definitive prosthesis fitting, no patient had dropped out. No implant or prosthesis failed during follow-up. Three grid exposures were detected; one grid was removed two months after placement, while the other two were minimally exposed, which did not affect the outcome of the guided bone-regeneration (GBR) procedure, and were therefore not removed until implant placement. No other complication was recorded during the entire follow-up.
At implant placement, the mean maximum vertical augmentation was 7.38± 2.60 mm (95% CI: 5.578 to 9.182). One year after definitive prosthesis fitting, the mean marginal peri-implant bone loss at patient level was 0.98± 0.27 mm; 95% (CI: 0.78 to 1.18).

CONCLUSIONS. Within the limitations of this case series, the results recorded one year after definitive prosthesis fitting seem to validate the use of customized titanium grids for augmentation of major vertical bone defects.

CONFLICT OF INTEREST STATEMENT
This study was not supported by any company.
Silvio Mario Meloni and Milena Pisano are scientific consultants to 3P Implanfavourite company. Silvio Mario Meloni, Milena Pisano and Marco Tallarico are scientific consultants to the company Ubgen.
Computer-Guided Bone Regeneration is a registered trademark.

INTRODUCTION

It is well documented that after tooth loss, especially due to trauma or periodontal disease, or implant failure, bone resorption is inevitable, leading to horizontal and vertical alveolar crest defects[1]. In these scenarios, bone regeneration techniques such as guided bone regeneration (GBR) and bone grafting can be applied with the aim of achieving new bone formation for implant placement[2].

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GBR is based on particular surgical techniques that enable new bone formation by using barrier to protect the blood clot and isolate the defect from the overlying connective tissue[3-5]. This technique can be used for both vertical and horizontal regeneration[3,5-7]. Currently, titanium-reinforced polytetrafluoroethylene (PTFE) are still considered the best membranes for the vertical augmentation of bone volumes in large alveolar ridge defects[5-8]. However, several studies have recently underlined the limitations of PTFE membranes, leading to some discord in the literature[9]. As an alternative for horizontal bone augmentation, scientific support for resorbable membranes has been published during last decade[10]. However, these membranes are not currently considered suitable for major vertical augmentation[6] due to their limited capacity to preserve space, even though a recent report supports the use of slow-resorption pericardium for minor vertical augmentation[7].

To provide adequate bone regeneration a primary closure, angiogenesis, stability and space creation[9], it is necessary to use a resistant space-making structure filled with particulate bone, followed by careful soft tissue management[11].

Titanium grids have been used for this purpose, but they do have shortcomings. First and foremost, they cannot be resorbed by the body, which means that a second surgery to raise a large flap is necessary for their removal. Moreover, due to their stiffness, titanium grids need to be shaped during surgery to adapt to the profile of the alveolar ridges. These surgical steps are time-consuming, technical, and operator-sensitive; sharp edges could damage the covering soft tissue, leading to grid exposure[12].

That being said, the performance of the titanium grid has been significantly improved by new technologies, namely computer-aided design (CAD) and computer-aided manufacturing (CAM)[13-15], which enable their 3D-customization and thereby individualization of bone regeneration[16]. Moreover, the holes in the grid may allow early blood and cellular supply from the periosteum when covered with a resorbable membrane[17,18]. Another advantage of customized grids is the possibility to pre-plan the final bone position with a pre-surgical wax-up, in accordance with the computer guided bone regeneration approach described by Meloni et al.[3,7,19].

The purpose of this report is to document outcomes of a retrospective series of vertical and horizontal bone augmentation cases treated using 3D customized titanium grids based on a pre-surgical prosthesis plan one year after definitive prosthesis fitting. This study is reported according to the STROBE guidelines (https://www.strobe-statement.org/checklists/).

MATERIALS AND METHODS

This is a retrospective case series based on an accurate chart review of all consecutive patients treated via computer guided vertical augmentation using customized titanium grids between February 2018 to July 2019 was implemented. Surgical procedures were performed by two oral surgeons (S.M, M.T). Restorations were performed by two dentists (M.P., P.R.).

Inclusion criteria were:

- patients aged over 18;
- partial or total edentulism;
- vertical defects greater than 4 mm;
- patients able to understand and sign informed consent.

Exclusion criteria were:

- American Society of Anesthesiology (ASA) class III or IV;
- psychiatric contraindications;
- pregnancy or breastfeeding;
- addiction to alcohol or drugs;

- smoking;
- head or neck radiotherapy in preceding 5 years;
- moderate or high parafunctional activity;
- untreated periodontitis;
- immediate post-extraction implants;
- bleeding index and plaque index >25%;
- lack of follow-up.

Surgical protocol

Clinical patient histories were collected, and study models made. Pre-operative photographs and radiographs (**FIGS. 1, 2**), including cone-beam CT (**FIG. 3A**) were taken. A virtual wax-up was generated to evaluate the ideal bone volumes to be regenerated (**FIG. 3B**) and plan implant positions. Then, in accordance with the pre-surgical wax up[7], a virtual titanium grid (myReOss system, ReOss, Filderstadt, Germany) was 3D-designed and manufactured.

Before fitting, patients were pre-medicated with 2 g amoxicillin plus clavulanic acid (Augmentin GlaxoSmithKline, Verona, Italy) one hour before the intervention and 1 g twice daily for one week, while allergic patients were treated with 600 mg clindamycin one hour before surgery and then 300 mg four times a day for one week. Patients were sedated with 0.50 mg triazolam (Triazolam Ratiopharm, Asiago, Italy), and rinsed their mouths with 0.2% chlorhexidine mouthwash (Curasept, Curadent Health Care, Saronno, Italy) for one minute before local anaesthesia (Septanest with adrenalin 1/10,0000, Septodont, Mataró, Spain) was administered (**FIG. 4**).

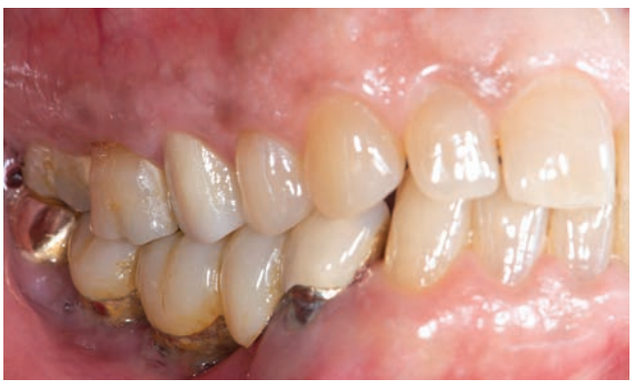

FIG. 1: *Failed implant-supported prosthesis*

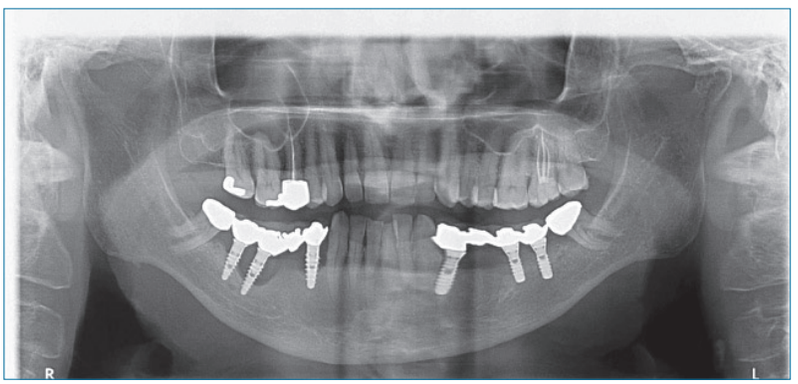

FIG. 2: *Panoramic x-ray showing failed implant-supported prosthesis in right lower jaw*

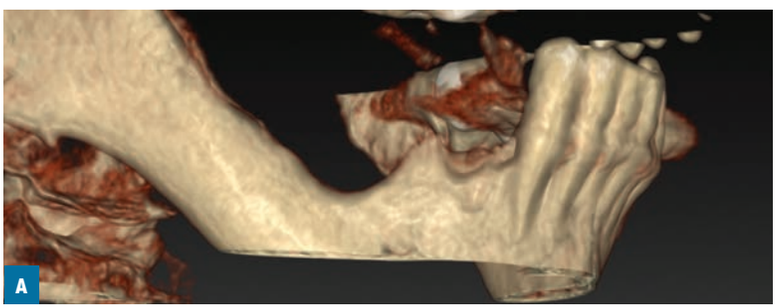

FIG. 3A: *Pre-operative 3D reconstruction showing the vertical bone defect*

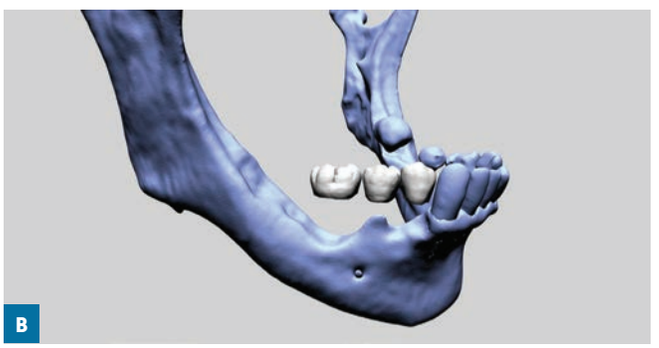

FIG. 3B: *Pre-surgical virtual wax-up to visualize the bone augmentation requirement*

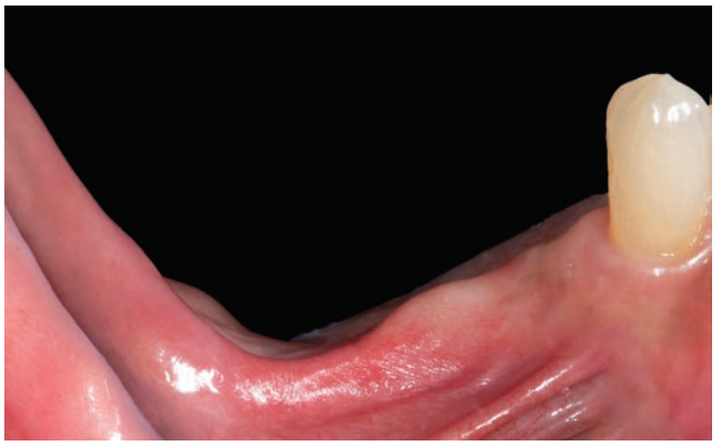

FIG. 4: *Pre-operative lateral clinical view*

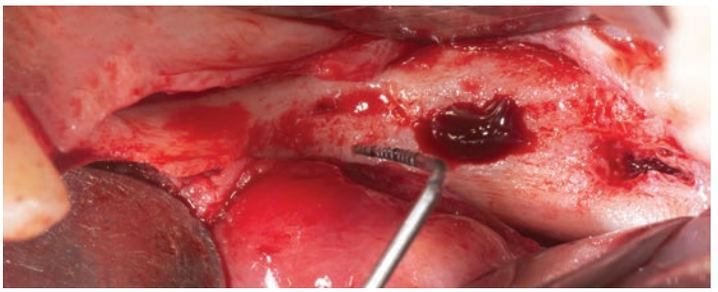

FIG. 5: *Intra-operative view of the vertical defect*

A mid-crestal incision was made into the residual keratinized tissue using a scalpel, and a full-thickness flap was raised over the mucogingival junction and extending 5 mm beyond the bone defect (**FIG. 5**). Two vertical incisions were made at least one tooth distant from the area to be augmented, or at least 5 mm from the surgical site in edentulous zones. Lingual and vestibular flaps were raised in posterior mandibles, and vestibular and palatal flaps in maxillae.

During these phases, the delicate anatomical structures were protected. Before harvesting autologous bone, the recipient site was cleaned of soft tissue. Immediately thereafter, a minimally invasive scraper (Micross, Meta technologies, Reggio Emilia, Italy) was used to harvest autologous bone from retromolar mandible regions. In maxillary sites, an additional mandibular flap was necessary to harvest the bone. Multiple holes were made at the recipient site using a ball drill of 2 mm diameter.

The custom-made titanium grid was filled, outside the mouth, with 50% autologous bone and 50% deproteinized bovine bone (Bio-Oss, Geistlich Biomaterials, Thiene, Italy), positioned in the atrophic zone, and fixed with titanium pins or microscrews (3P Implantfavourite, Scalenghe Italy, and Mcbio, Lomazzo, Italy) (**FIGS. 5-7**).

The grid was covered with bovine pericardium membranes (Ubgen, Vigonza, Italy) (**FIG. 8**), and a periosteal releasing incision was made to achieve tension-free closure between the two vertical incisions. In mandibles, various techniques were used at the vestibular and lingual flaps, such as periosteal incision of collagen fibres, debundling, and elastic fibre separation using the so-called brushing technique.

Flaps were sutured in two layers to minimize the risk of membrane exposure; horizontal mattress suturing (4-0 Vycril, Ethicon, Jonson & Jonson, USA or 4-0 PTFE Elastin, Braun Italia, Milan, Italy) was performed 4 mm from the incision line, while simple sutures were used to close the flaps and vertical incisions. Post-operatively, 80 mg of ketoprofen (Oki, Dompé, Milan, Italy) as needed was prescribed. A 4 mg/day regime of betamethasone (Bentelan, Glaxo, Verona, Italy) was administered for two days. The patient was instructed to rinse with 0.2% chlorhexidine (Curasept) three times per day for two weeks, and to eat only soft food for 30 days. Sutures were removed after two to three weeks.

Eight to nine months after augmentation, new CBCTs were performed to evaluate the graft integration and vertical bone augmentation, and to make virtual or cast models as well as final dental wax-ups (**FIG. 9**). Full-thickness flaps were raised to enable removal of the tita-

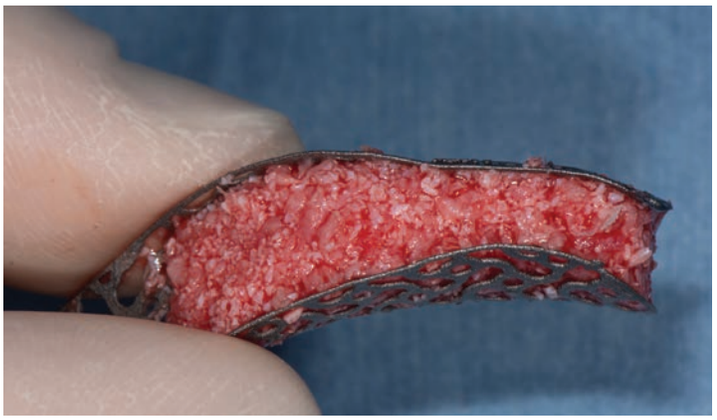

FIG. 6: *Customized titanium grid extra-orally filled with 50% autologous bone and 50% anorganic bovine bone*

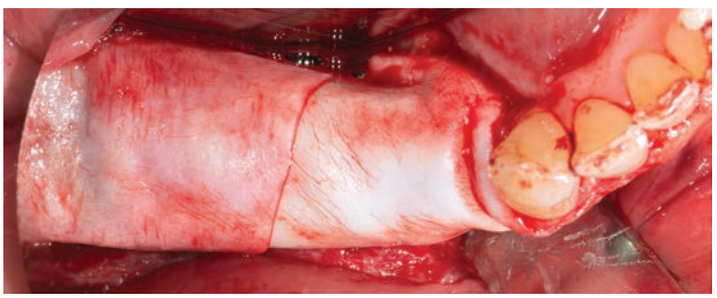

FIG. 8: *Titanium grid covered with two pericardium membranes*

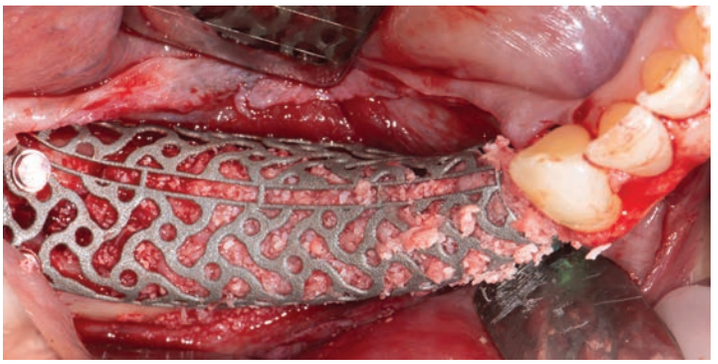

FIG. 7: *Customized titanium grid fixed to the bone*

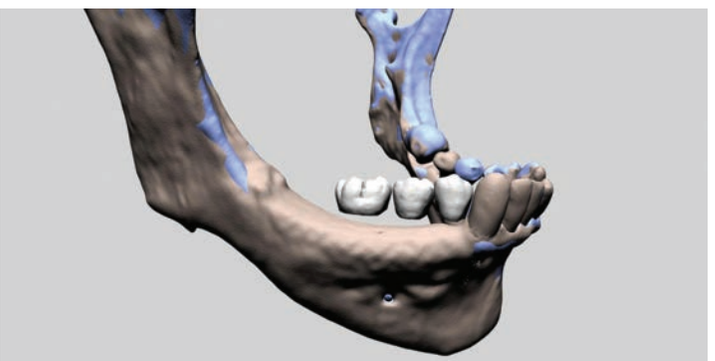

FIG. 9: *Virtual wax-up, nine months after bone regeneration, to determine the correct implant position*

nium grids, and implants were inserted with the aid of pilot drills or fully computer-guided templates (**FIGS. 10-13**). Flaps were then sutured in place, submerging the implants.
Three to six months thereafter, free gingival grafts, bilaminar sliding split-thickness flaps or strip techniques were performed to increase the amount of keratinized gingiva (**FIGS. 14-16**). Three months later, impressions were taken, and temporary screw-retained acrylic prostheses were fitted. Three to nine months later, final screw-retained zirconia-ceramic prostheses were fitted. Follow-up visits were scheduled every 3 months up to 12 months after fitting of the definitive prostheses (**FIGS. 17, 18**).

Outcome measures

Implant and prosthesis survival rates and complications were the primary outcome measures. Implant failure was defined as any removal of implants dictated by implant mobility, progressive marginal bone loss, infection, or implant fracture. The stability of individual implants was measured by the prosthodontist at the time of definitive prosthesis fitting, applying a removal torque of 35 Ncm. After loading, implant stability was tested manually, with two dental mirror handles, by the same prosthodontist.
Prosthesis failure was defined as any prosthesis which had to be replaced for any reason, and any surgical, prosthetic, or biological complications were assessed, recorded, and treated by the same clinicians who performed the implant rehabilitation procedures, as applicable. Specifically, potential complications included grid exposure, subsequent infection, and/or morbidity associated with the donor site, any fracture or chipping of the provisional or definitive prostheses, abutment mobility, wound or implant infection, mucositis, abscess, or peri-implantitis.

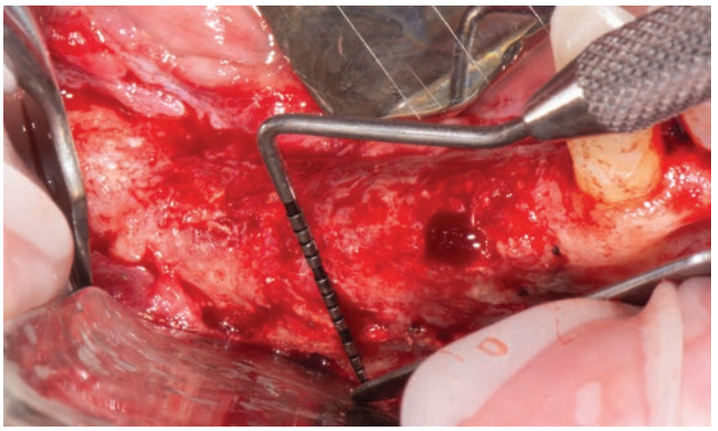

FIG. 10: *Amount of regenerated bone after titanium grid removal*

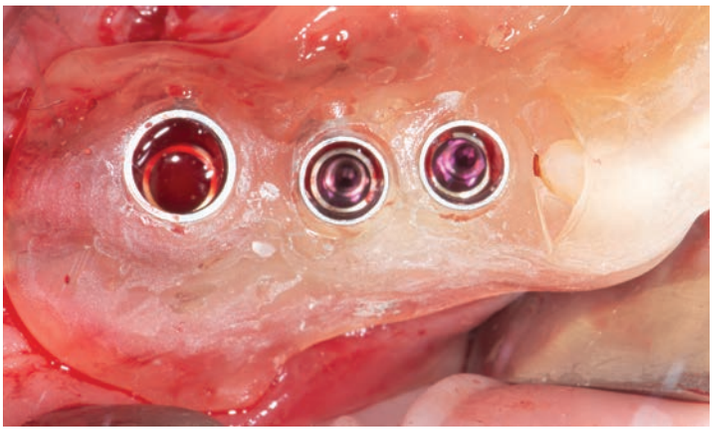

FIG. 11: *Computer-guided implant installation*

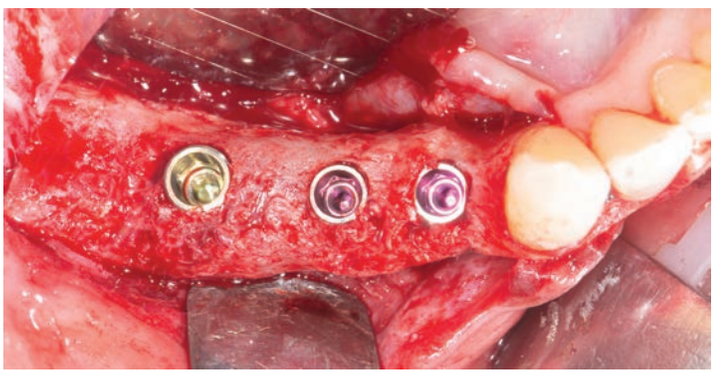

FIG. 12: *Implant installed*

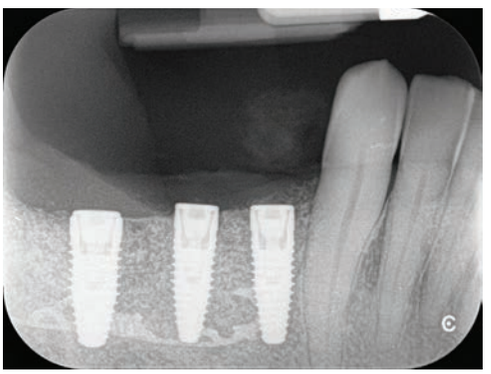

FIG. 13: *Peri-apical x-ray at implant installation*

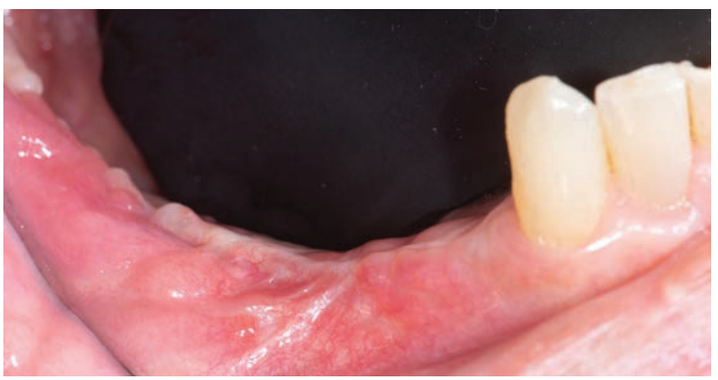

FIG. 14: *Soft tissue healing after implant installation; note the complete absence of keratinized tissue*

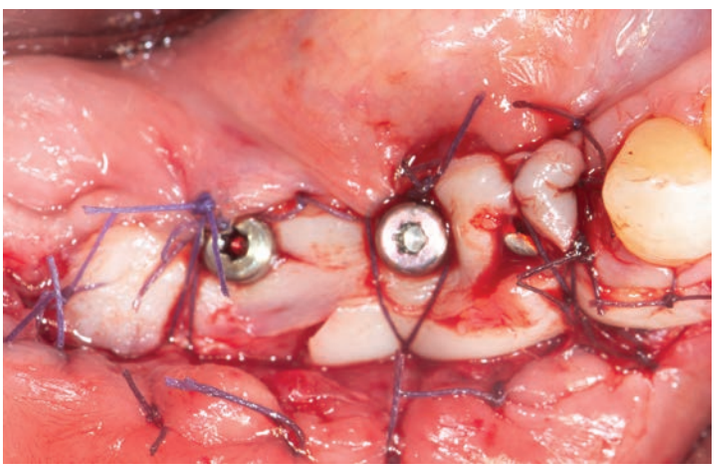

FIG. 15: *Double-layer gingival graft*

Secondary outcome measures were vertical dimensional changes and peri-implant marginal bone loss. As regards the former, bone augmentation was measured by superimposition of two CBCT scans, one taken before the surgery and the other 8 to 9 months later. The DICOM files were imported into dedicated software (Relu BV, Leuven, Belgium). Segmentation of the

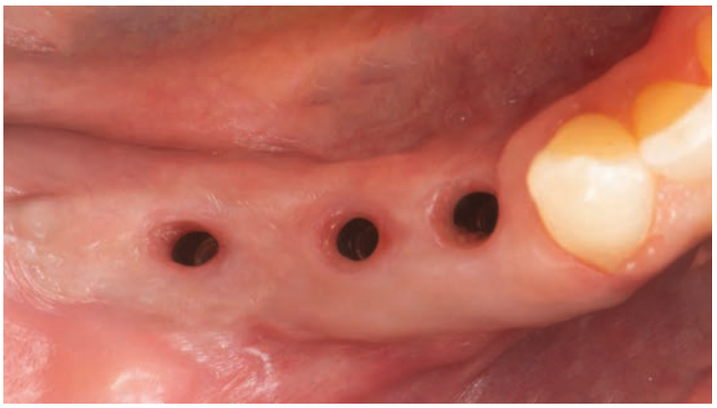

FIG. 16: *Soft tissue healing two months after gingival graft surgery; note the large amount of keratinized tissue*

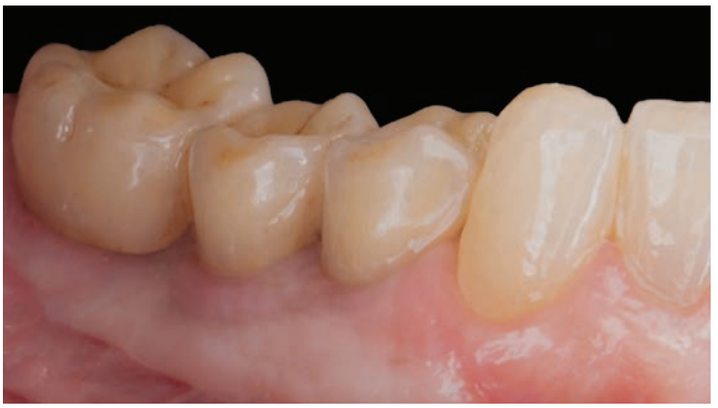

FIG. 17: *Screw-retained zirconia-ceramic definitive prosthesis, one year after fitting*

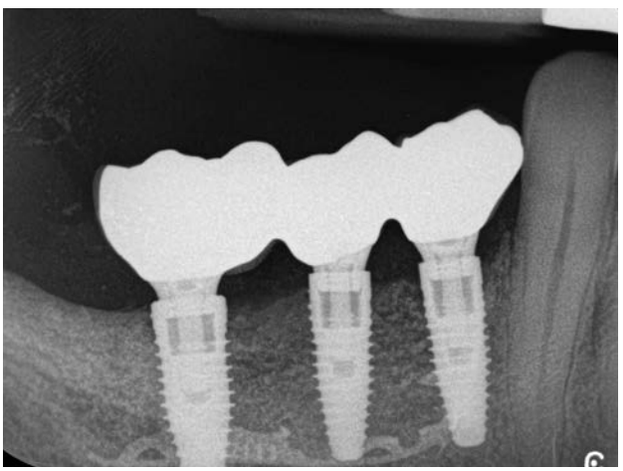

FIG. 18: *Peri-apical x-ray one year after definitive prosthesis fitting*

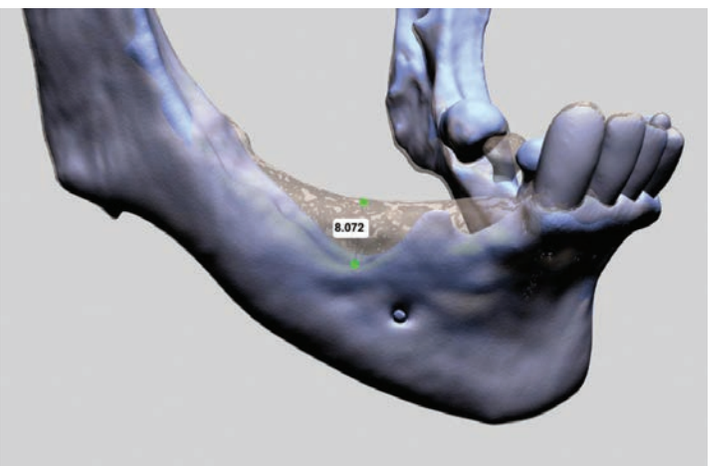

FIG. 19: *3D reconstruction of vertical bone augmentation, maximum value measurement*

DICOM data was performed to create STL files. Then, the 3D grids generated were matched point-by-point using the same regions of interest. The matching was then improved using a best-fit algorithm (Ortogonblender, Blender, Amsterdam, Netherlands). Finally, maximum vertical augmentation was measured at the highest point (**FIG. 19**).

Peri-implant marginal bone loss was calculated on periapical digital radiographs taken using a film-holder (Rinn XCP, Dentsply, Elgin, Illinois, USA) via the paralleling technique, first at implant placement (baseline) and then at one year after placement of the definitive prostheses. The radiographs were accepted or rejected for evaluation based on the clarity of the implant threads. The distance from the most coronal margin of the implant collar to the most coronal point of bone-to-implant contact was calculated. All readable radiographs were displayed by image analysis software (DFW2.8 for windows, Soredex, Tuusula, Finland) on a 24-inch LCD screen (iMac, Apple, Cupertino, CA, USA) and evaluated under standardized conditions (ISO 12646:2004). The software was calibrated for each single image using the known distance between two adjacent implant threads. Measurements of the mesial and distal bone crest level adjacent to each implant were made to the nearest 0.01 mm, and averaged at patient level.

Statistical analysis

All analysis was carried out using SPSS software for Mac OS X (version 22.0; SPSS, Chicago, Illinois, USA). Two dentists (M.T., M.D.) analysed the data. Descriptive analysis was performed for numeric parameters using mean ± SD and 95% confidence interval (CI). The differences in mean marginal bone levels over time were compared using paired t-tests.

RESULTS

Seven patients (1 male and 6 females) with a mean age of 55±3 years received eight GBR procedures with custom titanium grids. Overall, 22 implants were inserted, specifically six implants of length 10 mm and diameter 4.5 or 3.8 mm (Cono-in 3P Implafavourite), and 16 implants of length 8 or 10 mm and diameter 4.3 or 3.5 mm (Nobel Replace Tapered cc pmc, Nobel Biocare, Kloten, Switzerland) in one and six patients, respectively.

At the follow-up one year after definitive prosthesis fitting, no patient had dropped out. No implant or prosthesis failed. However, three (37.5%) of the customized grids became exposed. One grid was removed two months after its placement, while the other two did not affect the outcome of the GBR procedure and were therefore not removed until implant placement. No other complications were recorded during the entire follow-up period.

The mean maximum vertical augmentation achieved was 7.38±2.60 mm (95% CI: 5.57-9.18), and one year after final loading, the mean marginal peri-implant bone loss was 0.98±0.27; (95% CI: 0.78-1.18) at patient level (**TABLE 1**).

TABLE 1 PERI-IMPLANT MARGINAL BONE LEVELS AT PATIENT LEVEL

	Implant placement (baseline) (n = 7)	1 year (n = 7)
Marginal bone levels (mm)	0.16±0.06; 95% CI: 0.11 to 0.20	1.14±0.31;95%CI: 0.91 to 1.37
Marginal bone loss compared with baseline (mm)		0.98±0.27; 95%CI: 0.78 to 1.18
P Value		0.0001

DISCUSSION

The objective of reporting this retrospective case series was to provide preliminary data, gathered at one year after definitive prosthesis fitting, on vertical bone augmentation using a 3D-customized titanium grid prior to implant-supported rehabilitation. The outcomes of the procedure in our series, in particular a mean maximum vertical bone augmentation of 7.4 mm, appear to support this approach, despite a 37.5% intra-oral grid exposure rate.

The presence of a severe bone defect represents a challenging condition for implant supported rehabilitations[20,21]. Large bone defect regeneration is still a difficult surgical process, especially in severely atrophic ridges[22]. Furthermore, the use of resorbable membranes may not be suitable for large vertical defects due to their limited capacity to preserve space[23]. In severe defects with complex morphology, the GBR approach relying on non-resorbable membranes represent a better alternative, thanks to the greater space-maintaining capacity of the latter[24].

The use of titanium grids for bone regeneration is widely supported by the literature[25-27], and Miyamoto et al.[27], in 27 combined vertical and horizontal defects, reported a mean horizontal and vertical gain of 3.7 mm and 5.4 mm, respectively. Although titanium grids are a valid device for bone regeneration, some drawbacks have to be underlined. The grids are typically rectangular sheets that require cutting and shaping to fit the defect to be augemented[13]. This is time-consuming and requires clinical skill, experience, and the resulting shape may not be perfect[14]. In addition, if the corners and edges created during shaping are sharp, they could expose soft tissues to mechanical damage, causing flap perforation[15].

However, customized titanium grids were recently introduced as an alternative to conventional titanium grids. These have various potential benefits, including no need for modelling or trimming *in situ*, and the possibility of filling the grid with graft material outside of the oral cavity, thereby reducing the risk of intra-oral graft dispersion/contamination[28-30].

Sagheb et al.[28] in a retrospective study involving 17 patients and 21 atrophic sites. reported a 100% success rate for the regeneration procedure, despite a significant incidence of titanium grid exposures (33% of the sites between 5 and 12 weeks after surgery), with a mean vertical augmentation of 6.5±1.7 mm, and a mean horizontal augmentation of 5.5±1.9 mm.

More favourable results were reported by Sumida et al.[30], in their comparative study of conventional (13 sites) *versus* customized titanium grids (13 sites), with customized titanium grids proving superior in terms of both operating time (75 *versus* 112 minutes) and exposure/infection rate (7.7% *vs*. 23.1%).

CAD-CAM customized titanium grids, can, in our experience, facilitate the treatment of very large defects, especially when combined with careful digital planning of prosthetics and aesthetics involving a virtual wax up, as described herein and in other studies on computer guided bone regeneration[3,7,19].

The main drawbacks of customized titanium grid are high rate of exposure, and the time required for grid removal[28-30]. Nonetheless, in our experience, the surgical and prosthetics approach described in this article simplifies vertical bone regeneration, and could be applied by clinicians after proper training.

Despite the good results achieved in term of vertical bone augmentation, this case series presents several limitations, including a lack of suitable controls, a low number of patients treated, and the lack of independent outcome assessment. Hence, these results need to be validated by randomized controlled trials.

CONCLUSIONS

Within the limitations of this study, the results obtained one year after definitive prosthesis fitting seem to support the use of customized titanium grids for vertical bone augmentation in severely atrophic ridges.

Acknowledgements

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Figures 1, 2, 3, 4, 5, 7, 8, 11, 12, 14, 15 and 16 have been also published in: Dalla diagnosi al piano di trattamento. La chirurgia computer assistita e inserimento implantare protesicamente guidato come chiavi del successo. Tallarico M, Meloni SM. Teamwork media 2022. Villa Carcina (BS), Italy.

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