Vertical Ridge Augmentation Using Reinforced Ptfe Meshes Versus Customized Titanium Meshes. Preliminary Results Of A Randomized Clinical Trial.

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BACKGROUND

Guided bone regeneration (GBR) is the most advanced surgical technique available in the 3D reconstruction of atrophic jaws, in order to guarantee effective and predictable prosthetic-implant rehabilitation. The manual intra-operative modelling of a titanium-reinforced PTFE mesh is operator-dependent, difficult, inaccurate and slow. The use of custom-made meshes with bevel margins and a morphology adapted to the bone defect reduces these drawbacks.

AIM

The aim of the study was to compare the results obtained with GBR using titanium-reinforced PTFE mesh versus GBR using customized mesh, both covered with resorbable collagen membrane. In particular, healing complications and benefits for the patient and the operator were evaluated.

MATERIALS AND METHODS

The preliminary data included 10 patients: 6 patients (control group) were treated by means of titanium-reinforced PTFE mesh (RPM); 4 patients (test group) were treated by means of customized titanium mesh (Yxoss CBR). During reconstructive surgery (t0), the device filled with the grafting material was placed and primary closure of surgical sites was obtained. The PROMs were observed and self-reported by each patient on a daily questionnaire, while anxiety and stress levels of the operator were evaluated both with subjective and objective measures, using visual analogue scale (VAS) and electrocardiography (ECG). Finally preparation time, operative time and costs were compared.

RESULTS

The healing complication rate was 17% in the control group and 25% in the test group. The mean time for surgery preparation was 18 mins in the control group and 103 mins in the test group, while the mean duration of surgery was 110 mins and 107 mins, and the mean total cost of surgery was 830€ and 1.112€, respectively. No difference was found between study groups, neither in level of anxiety of the operator nor in level of postoperative pain and mean dosage of anti-inflammatory. Finally a high incidence of swelling was reported, followed by “difficulty in opening the mouth” in the control group and “neuro-sensory alterations” in the test group.

CONCLUSIONS

The preliminary results of this RCT showed that GBR using both devices is a reliable and predictable solution for bone augmentation of atrophic ridges. In fact, healing complication rates are in accordance with the mean values reported in the literature. Preparation time and surgery costs revealed a significant difference between study groups, while operative time was similar. Moreover a different patient distribution according to postoperative symptoms between study groups was reported. In conclusion, within the limits of this preliminary study, both techniques could be used successfully for bone augmentation. Further studies are required regarding patient and operator benefits/drawbacks.

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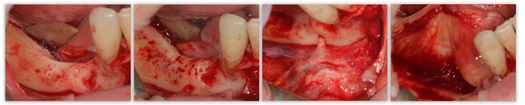
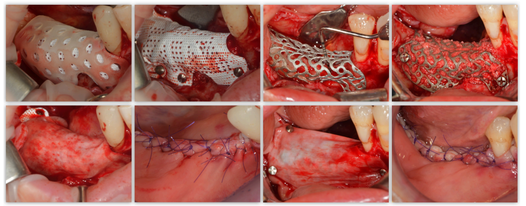
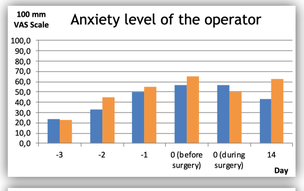
Surgical Protocol

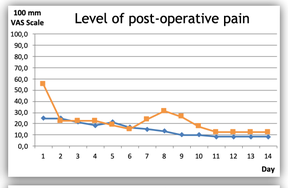


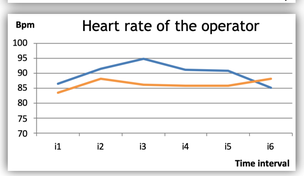
Control Group | Test Group

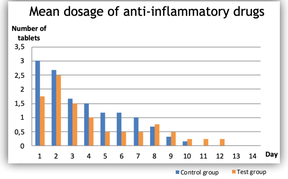


Patient no.	Sex	Age	Surgical site	Type of defect	Randomization group	Healing complications
1	F	68	46-47	V	Control	-
2	M	61	16-17	V	Control	-
3	F	53	35-37	HV	Test	-
4	F	64	44-47	V	Control	-
5	M	64	44-46	V	Control	Abscess
6	F	36	36-37	HV	Control	-
7	M	33	11-12	V	Control	-
8	F	62	45-47	HV	Test	-
9	F	70	44-47	V	Test	-
10	F	30	21-25	V	Test	Exposure









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