Minimally Invasive Treatment of Periodontal Infrabony Defects – Pilot Randomized Clinical Trial

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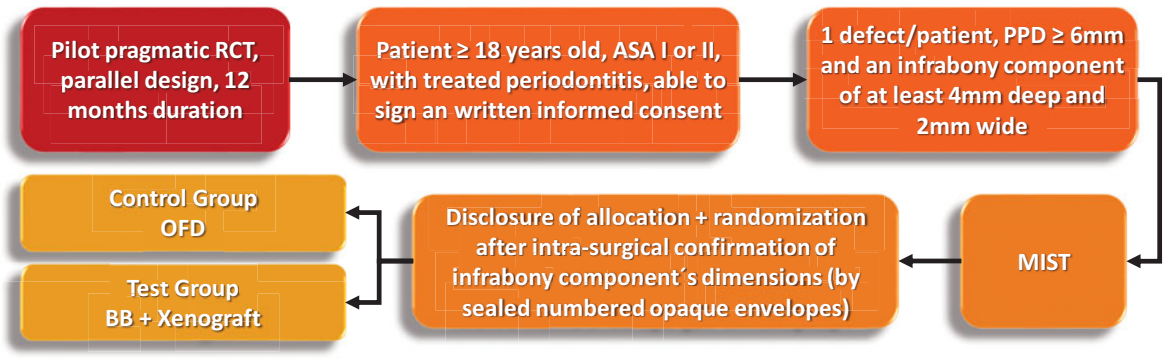
Introduction

The maintenance of graft stability and grafted anatomy during healing, due to the pressure exerted by soft tissues and the possible migration of particles, remains an issue when using particulate bone substitutes (Matos *et al.* 2012). Biphasic calcium sulphate is a bioresorbable, osteoconductive, fast setting synthetic bone grafting material, with physical properties not affected by the presence of blood or saliva, which can act as a binder when combined with other granulated bone graft substitutes (Horowitz *et al.* 2012). Minimally invasive surgical technique (MIST) has been proposed for the regeneration of periodontal infrabony defects (Cortellini & Tonetti 2007a), in order to minimize the surgical trauma and the tendency for collapse of interproximal tissues, enhance flap stability and wound healing, reduce surgical chair time and patient morbidity (Cortellini & Tonetti 2007b, Cortellini *et al.* 2008).

Aim

To evaluate the efficacy of a combination of a fast setting synthetic bone substitute with binding capacities (biphasic calcium sulphate (BondBone™, MIS Implant Technologies, Israel) - BB) and a xenograft (Bio-Oss™, Geistlich, Switzerland) versus open flap debridment, through a minimally invasive surgical technique (MIST), for the treatment of periodontal infrabony defects.

Material & Methods



- Protocol approved by the Ethical Commitee of the Faculty of Medicine – University of Coimbra (Portugal) and in accordance with Helsinski's Declaration for human clinical research.
- Digital standardized intraoral radiographs were obtained using an acrylic customized x-ray positioning stent combined with Dentsply Rinn XCP-DS® system, built for Gendex® Visualix® eHD 37.5 × 25.5 mm sensor (Gendex Dental Systems, IL, EUA) and calibrated with a 2mm metal sphere. X-ray tube stabilization was achieved with polyvinylsiloxane (Messias *et al.* 2013).
- Outcomes measured by 2 independent blind assessors at 0, 6 and 12 months.
- **Primary outcome measure:** Changes in clinical attachment level (CAL).
- **Secondary outcomes measures:** Changes in probing pocket depth (PPD), gingival recession (Re) and in radiographic marginal bone levels (RAD) (distance from CEJ to base of defect (CEJ_BD), distance from alveolar crest to base of defect (AC_BD), defect´s angle (angle)). Post-operative complications and adverse events. Patient's evaluation of treatment and aesthetics by anonymous questionnaire.

Results

Table 1 - Patient´s baseline characteristics.

	Control (10)	Test (10)	p
Age	52.10 ± 13.44	50.70 ± 13.63	0.820 [1]
Sex (F/M)	6 (60%) / 4 (40%)	6 (60%) / 4 (40%)	1.000 [2]
Smokers (<10 cig/day)	2 (20%)	1 (10%)	1.000 [2]
ASA Classification			
ASA I	5 (50%)	3 (30%)	0.650 [2]
ASA II	5 (50%)	7 (70%)	
Full mouth plaque score	15.53 ± 3.64	14.49 ± 4.35	0.436 [1]
Full mouth marginal bleeding score	0.30 ± 0.74	1.08 ± 1.25	0.739 [1]
Full mouth bleeding on probing score	7.38 ± 2.48	6.37 ± 3.11	0.393 [1]
Intrabony defect depth	6.700 ± 2.003	6.700 ± 1.829	0.969[1]
Predominantly 2, 3 walls & combined defects in both groups.			0.221[2]

[1] t-Student Test; [2] Fisher´s Exact Test

Table 2 – Post-operative complications & adverse events

	Complications	1st week	2nd week	3rd week	4th week	6th week
Control Group	Uneventfull	9 (90%)	9 (90%)	10 (100%)	10 (100%)	10 (100%)
	Dehiscence (minor)	1 (10%)	1 (10%)	0 (0%)	0 (0%)	0 (0%)
	Suppuration	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Test Group	Uneventfull	7 (70%)	5 (50%)	7 (70%)	10 (100%)	10 (100%)
	Dehiscence (minor)	3 (30%)	5 (50%)	3 (30%)	0 (0%)	0 (0%)
	Suppuration	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Table 3 – Patient self-reported post-operative pain & medication

	Control (10)	Test (10)	p [1]
Post-operative pain VAS 0-10 scale	2.30 ± 2.50	1.60 ± 1.65	0.469
Nº anti-inflamatory pills intake	2.90 ± 2.23	2.50 ± 2.32	0.763

[1] t-Student Test

Tables 4, 5, 6 – Post-operative changes in clinical periodontal parameters (PPD, Re, CAL)

	PPD_0M Mean ± SD (mm)	PPD_6M Mean ± SD (mm)	PPD_12M Mean ± SD (mm)	ΔPPD_0 - 12M Mean ± SD (mm)	p [1]
Control	6,8 ± 0,919	4,2 ± 1,135	3,7 ± 1,337	**3,1 ± 1,37**	0.142
Test	7,1 ± 1,287	3,7 ± 0,483	3,1 ± 0,994	**4,0 ± 1,25**	

	Re_0M Mean ± SD (mm)	Re_6M Mean ± SD (mm)	Re_12M Mean ± SD (mm)	ΔRe_0 - 12M Mean ± SD (mm)	p [1]
Control	1,7 ± 2,003	2,4 ± 2,221	2,4 ± 2,221	**-0,70 ± 0,67**	1
Test	1,0 ± 0,943	1,7 ± 1,703	1,7 ± 1,703	**-0,70 ± 0,95**	

	CAL_0M Mean ± SD (mm)	CAL_6M Mean ± SD (mm)	CAL_12M Mean ± SD (mm)	ΔCAL_0 - 12M Mean ± SD (mm)	p [1]
Control	8,5 ± 2,273	6,6 ± 1,776	6,1 ± 2,132	**2,4 ± 1,17**	0.089
Test	8,1 ± 1,792	5,4 ± 1,506	4,8 ± 2,150	**3,3 ± 1,06**	

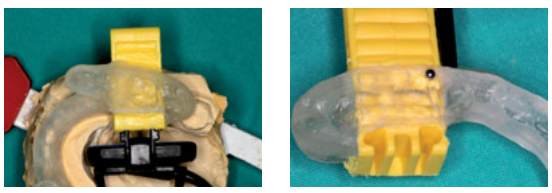
[1] t-Student Test between groups

Table 7 – Post-operative changes in radiographic parameters

Control Group						
Variable	ΔBaseline – 6 Months			ΔBaseline – 12 Months		
	$\bar{x}$	s	IC 95%	$\bar{x}$	s	IC 95%
CEJ_BD	1.09	1.52	[0.01;2.18]	**1.35**	1.65	[0,17;2.52]
AC_BD	1.38	1.72	[0.15;2.61]	**1.69**	1.74	[0.44;2.93]
Angle	-12.60	16.69	[-24.54;-0.66]	-14.90	16.31	[-26.57;-3.23]
Bone fill at 12 months: 32,13%						

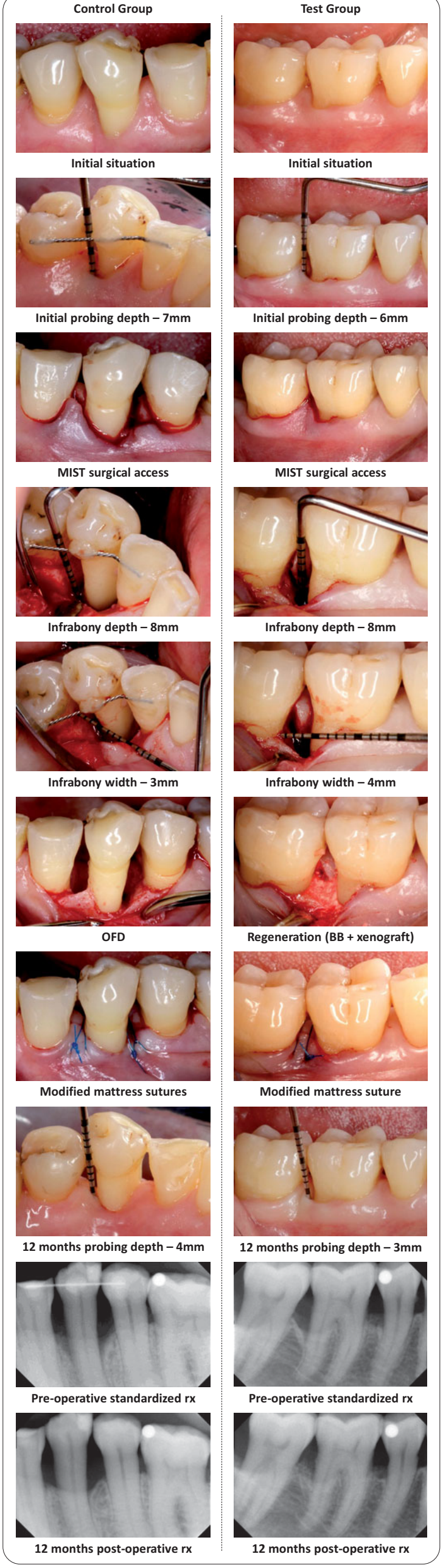
Test Group						
Variable	ΔBaseline – 6 Months			ΔBaseline – 12 Months		
	$\bar{x}$	s	IC 95%	$\bar{x}$	s	IC 95%
CEJ_BD	2.30	1.34	[1.34;3.26]	**2.62**	1.42	[1.60;3.63]
AC_BD	2.65	1.22	[1.78;3.53]	**2.95**	1.18	[2.10;3.80]
Angle	-20.08	6.88	[-25.01;-15.16]	-23.31	7.04	[-28.35;-18.27]
Bone fill at 12 months: 60,58%						

t-Student Test



Acrylic customized and calibrated x-ray positioning stent

Clinical Protocol



Discussion

Post-operative healing was achieved uneventfully in the majority of cases. The test group reported a higher frequency of minor dehiscences, mainly with modified papilla preservation flap, which self-resolved in the first 3 post-operative weeks. Factors like the apico-coronal location of the first incision or the macro and micro-porosity of the combined regenerative materials could compromise the revascularization of the papilla or of the defect and/or the stability of the initial blood clot. Regarding main clinical periodontal parameters, both groups showed significant improvements after 12 months. Intergroup comparison evidenced a tendency for better outcomes for the test group vs control group, regarding average PPD reduction (4.0±1.25mm vs 3.1±1.37mm, respectively) and CAL gain (3.3±1.06mm vs 2.4±1.06mm), despite not reaching statistically significant differences. Radiographically, the test group showed a significant superior result in terms of defect bone fill. These results are in accordance with the published literature on minimally invasive surgical technique (Trombelli *et al.* 2010, Cortellini & Tonetti 2011, Ribeiro *et al.* 2011, Mishra *et al.* 2013, Ghezzi *et al.* 2016).

Conclusions

1- Within the limits of this pilot study, both MIST and MIST with the combined regenerative materials resulted in significant improvements in terms of soft and hard tissues outcomes at 12 months.
2- This initial study was not able to detect a significant difference between treatments. Nevertheless, in spite of some minor adverse post-operative reaction, it is suggested that in more challenging defects, as for non-contained morphology, the combination of MIST approach with the tested biomaterials can have a beneficial added effect in terms of improving PPD reduction and CAL gain.

Conflict of interest disclosure

This study was supported by MIS Implant Technologies (Israel). All the authors disclaim to have no conflict of interest with the funding entity of this study, nor with any of the manufacturers of the materials used in this clinical trial.

Bibliography