One-Stage Full Mouth Instrumentation (OSFMI): Clinical Outcomes of an Innovative Protocol for the Treatment of Severe Periodontitis

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ABSTRACT

Aims: This case series study aimed to assess the clinical outcomes of a novel protocol for the treatment of patients with severe periodontitis.

Materials and Methods: Twenty (20) patients with severe periodontitis underwent a single session of One-Stage Full-Mouth Instrumentation (OSFMI) involving supra- and sub-gingival air-polishing with erythritol and chlorhexidine powder and ultrasonic root surface debridement and calculus removal, in association with systemic amoxicillin and metronidazole. Pocket Probing Depth (PPD), Clinical Attachment Level (CAL), Recession (REC), Bleeding on Probing (BOP) and Plaque Index (PI) were collected at baseline (T0), 6 weeks (T1), 3 months (T2) and 6 months (T3).

Results: At 6 months, 30% of subjects reached the primary clinical endpoint (≤ 4 sites with PD ≥ 5 mm). The percentage of BOP decreased from 49.08 (CI95% 36.06; 62.1) at T0 to 12.97 (CI95% 7.57; 18.37) at T3. The mean number pockets with PPD≥ 5 mm and PPD≥ 7 mm decreased significantly, from 46.0 and 20.6 at T0 to 11.5 and 2.8 at T3 respectively ($p < 0.001$).

Conclusions: The OSFMI protocol led to clinical results comparable to those obtained with traditional SRP. Researchers are encouraged to test this protocol in randomized clinical trials with longer periods of observation.

Keywords: Severe Generalized Periodontitis, Active treatment, Air-polishing, Non-surgical therapy, Periodontal treatment

Introduction

Severe periodontitis represents the sixth most prevalent disease worldwide (Kassebaum *et al.*, 2014). It is characterized by an exaggerated, ineffective and self-sustaining inflammation of the connective tissue, causing the destruction of tooth-supporting structures (Meyle and Chapple, 2015). In the long term, periodontitis can lead to critical functional and aesthetic impairment, i.e. tooth mobility, altered occlusion, occasional pain, and eventually, tooth loss with a negative impact on quality of life (Pihlstrom *et al.*, 2005). Periodontal treatment aims to stop disease progression, minimize symptoms and- possibly restore lost tissues (Graziani *et al.*, 2018).

At present, the gold standard mechanical treatment for periodontitis consists of supra- and sub-gingival biofilm and calculus removal by means of mechanical and manual instruments, traditionally defined as scaling and root planing (SRP) (Cobb, 1996; Tunkel *at al.*, 2002). Moreover, there is good evidence in the literature

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to support the notion that the most effective treatment for severe periodontitis is the combination of SRP and systemic metronidazole (MTZ) and amoxicillin (AMX) (Feres *et al.,* 2015). The benefits of this treatment protocol over SRP-only has been supported by five systematic reviews (Sgolastra *et al.*, 2012a; Sgolastra *et al.*, 2012b; Zandbergen *et al.*, 2013; Rabelo *et al.* 2015; Zandbergen *et al.*, 2016), and eight randomized clinical trials (RCTs) of 1 to 2 years of follow-up (Goodson *et al.*, 2012; Mestnik *et al.*, 2012; Feres *et al.*, 2012; Harks *et al.*, 2015; Mombelli *et al.*, 2015; Tamashiro *et al.*, 2016; Borges *et al.*, 2017; Cosgarea *et al.*, 2017).

SRP with manual instruments can be a time-consuming process (Moëne *et al.*, 2010; Wennström *et al.*, 2011) and can produce side-effects such as over removal of root cementum (Bozbay *et al.*, 2018), roughening of hard surfaces (Flemmig *et al.*, 1998), gingival recession and hypersensitivity (Von Troil *et al.*, 2002; Sin *et al.*, 2013). In addition, recent clinical evidence has made it clear that deliberate removal of root cementum through root planing was no longer justified, advocating the implementation a more minimally invasive approach such as the ultrasonic root surface debridement (Ciantar, 2014). Air-polishing with low-abrasiveness powders has been identified as a possible means of performing and improving supra- and sub-gingival biofilm removal, in conjunction with mechanical instrumentation on mineralized deposits only (Sculean *et al.*, 2013). Supragingival air-polishing, considered an excellent tool for plaque and stain removal (Weaks *et al.*, 1984), with well tolerated sub-gingival application, can be more effective in removing biofilm than traditional SRP (Petersilka *et al.*, 2003a; Petersilka *et al.*, 2003b; Flemmig *et al.*, 2007; Flemmig *et al.*, 2012) while minimizing hard and soft tissue trauma. (Bozbay *et al.*, 2018; Petersilka *et al.*, 2018). Regular sub-gingival air-polishing with low-abrasiveness powders during supportive periodontal therapy has been proven to be time-efficient and more comfortable to the patients, and leads to clinical results comparable to those obtained with traditional SRP (Moëne *et al.*, 2010; Wennström *et al.*, 2011; Flemmig *et al.*, 2012; Hägi *et al.*, 2015). To date, only two studies have investigated the application of air-polishing during active treatment of periodontal patients, used subsequently to traditional SRP (Park *et al.*, 2018; Tsang *et al.*, 2018).

Given the advantages aforementioned, the aim of the present case series study was to evaluate the short-term clinical outcomes of a novel protocol (One-Stage Full Mouth Instrumentation, OSFMI) for the treatment of patients with severe periodontitis. The protocol involved supra- and sub-gingival tooth cleaning by means of air-polishing with low-abrasiveness erythritol + chlorhexidine (CHX) powder followed by ultrasonic root surface debridement, and the adjunctive use of MTZ+AMX.

Materials and Methods

Study design and Ethical Approval

This single-center, case series report was conducted at the University of Brescia Dental School, Department of Radiological Science and Public Health (Brescia, Italy). The study protocol was reviewed and approved by the Ethics Committee of the Civil Hospital of Brescia (protocol number 1473). All participants signed written informed consent before the beginning of the study. All procedures performed in human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards

Patient Selection

Twenty subjects (7 males, 13 females) diagnosed with severe periodontitis (Armitage, 1999) were selected from the population referred to the First Aid Unit of the Dental School. The inclusion criteria were as follows: ≥18 years of age and <70 years, ≥15 teeth, at least 30% of the sites with PPD and clinical attachment level (CAL) ≥4 mm and bleeding on probing (BOP) and ≥6 teeth with at least one site each with PPD and CAL ≥ 5 mm. The exclusion criteria were as follows: pregnancy, breastfeeding, asthma, lung diseases, systemic diseases that could affect the progression of periodontitis (e.g. diabetes), systemic diseases that could compromise the host response to infection, antibiotic therapy in the previous 6 months, long-term intake of anti-inflammatory agents, need for antibiotic pre-medication for dental treatment and allergy to MTZ and/or AMX and/or CHX.

Clinical Assessment

Age, gender, smoking status, clinical and dental history were collected before treatment. One calibrated examiner (M.M.) assessed Pocket Probing Depth (PPD), Clinical Attachment Loss (CAL), Recession (REC), Bleeding on Probing (BOP), Plaque Index (PI) at baseline (T0), 6 weeks (T1), 3 months (T2) and 6 months (T3) with a periodontal probe 0.5 mm in diameter (UNC 15, Hu-Friedy). A radiographic assessment was completed and the need for non-surgical periodontal therapy determined. The study examiner (M.M.) participated in a calibration exercise and the standard error of measurements was calculated: intra-examiner variability was 0.23mm for PPD and 0.28 for CAL. Categorical variables was 92% (Kappa-light-test)

Interventions

The active periodontal therapy was performed for all patients by the same experienced operator (E.S.) following

the OSFMI protocol and accomplished in around 3-4 hours. Amoxicillin 500 mg plus Metronidazole 250 mg was prescribed for all subjects every 8 hours for 7 days. The antibiotic therapy started on the same day as the OSFMI protocol was performed. After a one-minute rinse with 0.12% CHX (Sunstar Gum 0.12%) a lip/cheek retractor was inserted in the oral cavity of the subjects (OptraGate, Ivoclar Vivadent), and a plaque disclosing agent was applied to all teeth (MIRA-2-TON Plaque Disclosing Solution, HAGER WERKEN). Removal of plaque from the attached gingiva, the dorsal surface of the tongue and from dental supra- and sub-gingival areas was performed using an air-polishing device with regular handpiece (Air-flow Master Piezon, EMS, Nyon, Switzerland) and a low abrasiveness erythritol + CHX powder (PLUS powder, EMS, Nyon, Switzerland). After this step, any visible or detectable calculus was removed with ultrasonic instrumentation (PS tip, Air-flow Master Piezon, EMS, Nyon, Switzerland) and root surface debridement was performed in all pockets ≥ 5 mm using the same ultrasonic tip. Brushing with a soft manual toothbrush (TePe, Malmö, Sweden) according to the Bass technique and interdental cleaning with floss and/or interdental brushes (TePe, Malmö, Sweden) were reviewed and reinforced.

Six weeks after the initial treatment the subjects were re-evaluated and answered a questionnaire to evaluate antibiotic side-effects (Table 1). All patients were included in a 3-monthly recalls maintenance program. The maintenance appointments included supra- and sub-gingival plaque removal using the same air-polishing device, regular handpiece and the low abrasiveness erythritol + CHX powder, with the addition of a specially-designed sub-gingival nozzle (Perio-Flow nozzle, EMS, Nyon, Switzerland) for the debridement of residual pockets, as previously described by Hägi *et al.* (2015). The ultrasonic tip (PS tip, Air-flow Master Piezon, EMS, Nyon, Switzerland) was used only where calculus was visible or detectable.

Clinical Endpoint for Treatment and Statistical Analysis

The primary clinical endpoint of the study was reduction in mean number of sites with PPD ≥ 5 mm between baseline and 6 months (Feres et al., 2012). The term "pocket closure" was used for sites with PPD≥5 mm at baseline that were reduced to PPD ≤ 4 mm post-treatment.

Secondary outcomes were as follows: percentage of subjects reaching the clinical endpoint for treatment according to Feres *et al.*, 2012 and Borges *et al.,* 2017 (i.e. ≤4 sites with PD ≥5 mm) and mean changes from baseline to 6 months in mean PPD, CAL, BOP, PI and reduction in mean number of sites with PPD ≥6 mm and PD ≥7 mm over time. Data were aggregated within patient averaging or summing measurements at site level, then at patient level, and the patient was used as a statistical unit. All data were modelled using Generalized Estimating Equations (GEE) using the patients as clusters and assuming an exchangeable correlation structure. Both PPD and CAL were modelled assuming a Gaussian distribution. Binary data were analyzed as counts and by assuming a Poisson distribution for counts with an identity link and setting the total number of sites within patient as an offset. All analyses were performed using R (version 3.5.1) and assumed a significance level of 5%. P-values were adjusted using Dunnett algorithm, accounting for group treatment versus baseline comparisons.

Results

This study was conducted between January 2014 and November 2016. Twenty patients (7 males, 13 females) were included in the study and their demographic characteristics and baseline clinical parameters are presented in Table 1. The mean full-mouth PPD and CAL of the subject included were 3.85 (1.17) and 4.32 (1.51) respectively.

Table 2 presents the means and the 95% confidence interval (CI) of each variable over the course of the study. All clinical parameters showed a statistically significant reduction from baseline to all subsequent time points. From baseline to 6 months after treatment, PPD showed a reduction of -1.46 mm, CAL of -0.97 mm and BOP of 36,10%. The % of sites with BOP decreased from 49.98% (CI95%: 36.06; 62.1) at baseline to 12.97 (CI95%: 7.57 ; 18.37) at 6 months ($p<0.01$). In addition, 76.39% (CI95%: 68.04% ; 84.753%) of the sites with PPD≥5 mm were reduced to PPD ≤ 4 mm at 6 months post-treatment.

Mean changes at initially deep sites over the course of the study are described in Table 3. Subjects had an average of 46.0 ±30.0 sites with PPD ≥ 5 mm, 30.057±25.0 ≥ 6 mm and 20.06±19.7 ≥ 7 mm at baseline. These sites all showed statistically significant reduction at post-treatment. At 6 months, subject had an average of 11.5 ±13.1, 4.8 ±8.5 and 2.8±5.2 of sites with PPD ≥ 5, 6, and 7 mm, respectively.

The number and percentage of subjects reaching the clinical endpoint of ≤ 4 sites with PPD ≥ 5 mm is presented in Table 4. Of the subjects 20.0%, 25.0% and 30.0% achieved this clinical endpoint for treatment at 6 weeks, 3 months, to 6 months, respectively.

Two patients experienced a metallic taste during the antibiotic course. No other side effects were reported in the 6-weeks questionnaire.

Table 1. Demographic characteristics of the study population, means (± Standard Deviation, SD) and median (± Interquartile Range, IQR) of full-mouth clinical parameters at baseline and self-perceived side effects reported at 6 weeks (T1) evaluation.

N° subjects completing the study		20
Gender (% males)		35
Age (years)		50.3 (9.2)
PPD (mm)		
mean (sd)	3.85 (1.17)	
median (iqr)	3.48 (0.92)	
CAL (mm)		
mean (sd)	4.32 (1.51)	
median (iqr)	3.86 (1.94)	
REC (mm)		
mean (sd)	0.66 (0.68)	
median (iqr)	0.33 (0.94)	
BOP (%)		49.08
PI (%)		51.02
PPD min (mm)		2.33
PPD max (mm)		16.89
% of sites with PPD <4		76.2
% of sites with PPD 4-6		18.2
% of sites with PPD >6		5.6
Number of subjects reporting:		
Nausea or Vomiting ±sd		0 ±0.00
Diarrhoea ±sd		0 ±0.00
Metallic taste ±sd		2 ±4.54
Headache or dizziness ±sd		0 ±0.00
Irritability or bad mood ±sd		0 ±0.00
Weakness ±sd		0 ±0.00
Excessive Sleep ±sd		0 ±0.00

PPD: Pocket Probing Depth, CAL: Clinical Attachment Level, REC: Recession, BOP: Bleeding on Probing, PI: Plaque Index.

Discussion

The promising *in-vitro* and clinical outcomes of air-polishing and ultrasonic root surface debridement available in literature are attracting attention to the possible applications of these techniques in periodontology. The protocol presented in this case series (OSFMI) was developed on the author's hypothesis that full-mouth supra- and sub-gingival air-polishing combined with ultrasonic debridement can be a valid tool for the active treatment of periodontitis, leading to clinical results similar to the ones obtained with traditional SRP present in literature.

The data collected suggest that the OSFMI protocol was indeed effective in the active treatment of patients with severe periodontitis and resulted in improved clinical parameters in the short-term.

Twenty subjects with severe periodontitis treated by means of OSFMI and adjunctive use of MTZ+AMX showed statistically significant reductions in the mean number of sites with PPD ≥5 mm (primary outcome variable). Residual Sites within this PPD category have been used to determine treatment efficacy by different groups of investigators (Cionca *et* al., 2009; Feres *et al.*, 2012; Mombelli *et al.*, 2015; Borges *et al.*, 2017; Mombelli *et al.* 2017). In the present cases, the treatment protocol used was able to eliminate an average of 34.5 sites with PPD ≥5mm per patient in the 6 months after the treatment ($p<0.05$). It is important to highlight that the subjects selected for this study were diagnosed with severe periodontitis. At baseline, they presented an average of ~46 sites with PPD ≥5 mm, ~30.5 sites ≥6 mm and ~20.6 sites ≥7 mm. After treatment, the mean number of sites within these categories of PPD had decreased to 11.5, 4.8 and 2.8, respectively. These are considered positive results, since robust risk assessment studies have shown that the presence of residual sites after treatment is an important risk indicator for periodontal disease recurrence (Matuliene *et al.*, 2008). Interestingly, all the other clinical parameters evaluated significantly improved post-treatment too, such as mean PPD, CAL and BOP. The improvements in PPD and CAL were beyond the expected changes for SRP, according to a meta-analysis (Cionca *et* al., 2009) and a comprehensive review (Cobb, 1996), both used as benchmark studies to determine the ideal and expected effects of an efficient SRP procedure. Despite the good results obtained with the protocol tested in the present case series, the number of residual pathological sites is still considerable and would probably require further intervention. This may be explained by the severity of the disease in the population selected.

An interesting parallel may be drawn between the results of the present study and the one of Borges *et al.* (2017), which compared different dosages of MTZ (250 and 400 mg) and duration of administration of MTZ+AMX (7 and 14 days). Although Borges *et al.* (2017) followed the patients for 1 year, as opposed to the 6 months of follow-up period in this study, the severity of the disease was very similar between the population of Borges *et al.* (2017) and the present trial, allowing a comparison between the studies. The baseline parameters in Borges *et al.* (2017) and the present study were, respectively, as follows: mean number of sites with PPD ≥5 mm: 35.6 ± 20,7 and 46.0 ± 30.0, full mouth PPD:

Table 2. Full mouth clinical parameters estimates and % of pocket closure over time.

Clinical parameter	Estimate (CI 95%)	delta	pvalue
PPD (mm)			
Baseline	3.87 [3.35 ; 4.4] (+/- 1.17)		
6 weeks	2.66 [2.43 ; 2.9] (+/- 0.55)	-1.21 (-1.70;-0.72)	<0.01
3 months	2.56 [2.31 ; 2.81] (+/- 0.58)	-1.32 (-1.85;-0.78)	<0.01
6 months	2.42 [2.16 ; 2.68] (+/- 0.60)	-1.46 (-1.88;-1.03)	<0.01
CAL (mm)			
Baseline	4.51 [3.84 ; 5.19] (+/- 1.51)		
6 weeks	3.86 [3.3 ; 4.41] (+/- 1.30)	-0.66 (-1.00;-0.31)	<0.01
3 months	3.69 [3.13 ; 4.26] (+/- 1.33)	-0.82 (-1.31;-0.33)	<0.01
6 months	3.55 [2.93 ; 4.16] (+/- 1.44)	-0.97 (-1.32;-0.61)	<0.01
BOP (%)			
Baseline	49.08 (36.06 ; 62.1)		
6 weeks	8.21 (5.03 ; 11.38)	-40.87 (-56.03;-25.71)	<0.01
3 months	15.69 (10.28 ; 21.1)	-33.38 (-47.79;-18.98)	<0.01
6 months	12.97 (7.57 ; 18.37)	-36.10 (-48.59;-23.61)	<0.01
PI (%)			
Baseline	51 (35.21 ; 66.78)		
6 weeks	11.19 (7.04 ; 15.34)	-39.81 (-58.26;-21.36)	<0.01
3 months	24.05 (15.5 ; 32.59)	-26.95 (-45.50;-8.40)	<0.01
6 months	20.78 (14.27 ; 27.29)	-30.22 (-46.44;-13.99)	<0.01
Pocket closure (%)			
Baseline	0		
6 months	76.39 (68.04 ; 84.75)		<0.01
3 months	76.82 (68.52 ; 85.13)		<0.01
6 months	73.39 (66.18 ; 80.6)		<0.01

PPD: Pocket Probing Depth, CAL: Clinical Attachment Level, BOP: Bleeding on Probing, PI: Plaque Index.

3.8 ± 0.7 and 3.87 ± 1.17, and CAL: 4.4 ± 10 and 4.51 ± 1.51. Looking at the results and taking into consideration the main clinical endpoint for treatment proposed by Feres *et al.* (2012) and Borges *et al.* (2017), i.e. presence of ≤4 sites with PPD ≥5 mm, in the study from Borges *et al.* (2017) 31.8% of the subjects who received 7 days of adjunctive systemic MTZ+AMX achieved the end-point at 1 year. Noteworthy is that 30% of the subjects from the present case series also achieved the clinical endpoint. On the other hand, ~60% of those patients taking the antibiotics for 14 days in the study of Borges *et al.* (2017) achieved this clinical endpoint. Therefore, future studies testing the OSFMI protocol and longer periods of antibiotic administration may bring further

Table 3. Mean (±SD) in the number of sites with PD ≥ 5 mm, PD ≥ 6 mm and PD ≥ 7 mm

TIME	>=5	>=6	>=7
Baseline	46.0 (30.0)	30.5 (25.0)	20.6 (19.7)
6 weeks	13.8 (12.5)	6.1 (7.0)	4.2 (5.1)
3 months	13.5 (12.5)	5.6 (7.1)	3.6 (5.5)
6 months	11.5 (13.1)	4.8 (8.5)	2.8 (5.2)
delta (6 months vs baseline)	-34.5	-25.7	-17.8
pvalue (6 months vs baseline)	< 0.001	< 0.001	< 0.001

Table 4. Number and percentage of subjects with Low (i.e. ≤4 sites with PD ≥5 mm - acording to Feres (2012) or High risk, at baseline, 6 weeks, 3 and 6 months

Time	Low Risk (%)	N patients	N Low risk	N High risk
Baseline	0.0	20	0	20
6 weeks	20.0	20	4	16
3 months	25	20	5	15
6 months	30.0	20	6	14

important insights regarding the treatment of patients with severe periodontitis. Regarding the effect of the treatment in very deep pockets, the subjects of the present case series showed a mean reduction of ~17.8 sites with initial PPD ≥7 mm between baseline and 6 months, an even slightly higher value than that observed in the 7-day MTZ+AMX group of Borges *et al.* (2017) at 1 year after treatment.

Furthermore, at 6 months after therapy the subjects in the present series showed a lower prevalence of BOP-positive sites (12.97% at 6 months) than those taking 7 days of antibiotic in the study of Borges *et al.* (2017) (24% at 1 year). The lower prevalence of bleeding sites observed in this study is very close to the 10% cut-off point set by Lang and Tonetti (2003) as one of the criteria to define patients with low risk of presenting disease recurrence post-treatment. Furthermore, the BOP prevalence achieved is very similar to the one obtained by Flemmig *et al.* (2012), who applied the full-mouth Glycine Powder Air Polishing (GPAP) protocol, involving traditional mechanical instrumentation in the active phase and a supra- and sub-gingival application of air-polishing with glycine powder followed by ultrasonic and manual removal of hard deposits during the maintenance phase. Other protocols involving the application of air-polishing in residual pockets did not seem to lead to the same benefits (Wennström *et al.*, 2011; Hägi *et al.*, 2015).

Only two other studies have used an air-polishing device during active periodontal treatment, but as an adjunct to traditional SRP and limited to sub-gingival areas (Tsang *et al.,* 2018 and Park *et al.,* 2018). The authors were unable to show any statistically significant differences between the test (SRP + air-polishing) and the control (SRP) groups. One hypothesis that could help to explain the lack of differences between test and control groups is the fact that the air-polishing was used only in the subgingival area and the powder used did not contain an effective antibacterial agent, such as chlorhexidine.

The main strength of this study is that it is the first to apply the OSFMI protocol in the treatment of a group of individuals with severe periodontitis. The main limitations include the descriptive nature of the case series, the lack of a control group, the small sample size, the short-term follow up (6 months) and the lack of microbiological data that could support the clinical outcomes of treatment. Nonetheless, the data presented here may guide future studies in the field.

In conclusion, the data obtained from this case series study suggest that the OSFMI protocol can be used in the treatment of patients with severe periodontitis and, in the short term, could lead to clinical results comparable to those obtained with traditional SRP procedure. Researchers are encouraged to test this protocol in randomized clinical trials with longer periods of observation.

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