

Chlorhexidine spray versus mouthwash in the control of dental plaque after implant surgery

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Abstract

Background/purpose: This randomized clinical trial was aimed at comparing two different means of delivering chlorhexidine digluconate (CHX) for plaque control during the 2 weeks following implant surgery.

Materials and Methods: Twenty patients selected for implant therapy were randomly divided into two groups: 10 subjects used 15 ml of 0.12% CHX mouthrinse (control group) and 10 used 0.2% CHX spray (test group). Professional oral hygiene was carried out immediately before surgery. During the 14 days following surgery mechanical oral hygiene was performed only at the teeth not surgically involved. Plaque index (PI), stain index (SI), modified gingival index and taste alteration were assessed on the 7th and 14th day after surgery. The clinical parameters were evaluated at four tooth surfaces by a single examiner. Teeth proximal to surgical site and teeth not involved were statistically compared.

Results: In both groups, the PI increased similarly, with respect to the baseline, at days 7 and 14. There was no significant difference between the two groups at either time point. On the contrary, in the control group, the SI increased significantly when compared with baseline over the 14 days both at teeth nearest to surgical sites and at not-involved sites. In the test group pigmentation was consistent only at teeth proximal to the surgical site. When considering not-involved sites, tooth staining was significantly lower in the test with respect to the control group.

Conclusions: The present study indicates that the efficacy of CHX spray in the postsurgical control of dental plaque is similar to that of CHX mouthwash. Tooth staining, however, is significantly lower in the spray group at sites not surgically involved. These effects might be related to the route of CHX delivery, as well as the total dose administered that was significantly lower in the spray group with respect to the rinse group.

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There is well-described clinical evidence showing that careful plaque control following oral surgery is essential for successful healing, thereby reducing the risk of wound infection (Nyman et al. 1975, Rosling et al. 1976).

Plaque control is also fundamental after implant therapy to achieve complete success of this rehabilitation procedure (Lang et al. 2000, Quirynen et al. 2002). In fact, a clinical trial conducted by Van Steenberghe et al. (1990) reported an increased incidence of early implant failure in patients with an high plaque score. It is well known that the presence of bacteria can interfere with the healing process following implant placement. The continuous inflammatory reaction, stimulated by pathogenic microorganisms, could induce peri-implant tissue infection, triggering a destructive process that may impair implant osseointegration. Bacterial activity around implanted biomaterials appears to be extremely resistant to antibiotics and, in the worst cases, may persist until the device is removed (Gristina et al. 1987). As suggested by Esposito et al. (1998) even if bacterial infections do not seem to be the main cause of implant integration failure, a strict plaque control protocol is recommended in the early days following oral implant surgery.

In such a period, it is extremely uncomfortable and difficult for the patient to perform mechanical oral hygiene at the healing site, which is fragile and must not be injured. Moreover, the presence of the suture allows the surgical wound to heal properly, but the suture may also retain plaque at this extremely delicate zone. For these reasons, agents that are able to potentially prevent the recolonization by periodontal pathogens may offer great therapeutic benefits (Newman et al. 1989).

The efficacy of chlorhexidine digluconate (CHX) as a bacteriostatic and bactericidal agent has long been demonstrated (Löe & Schiott 1970, Lang et al. 1982, Gjermo 1989). Several studies comparing CHX to other chemical agents have shown CHX to be the most effective in plaque control (Siegrist et al. 1986, Mankodi et al. 1990). This antiplaque activity of CHX seems to be due to high levels of adsorption in multiple sites in the oral cavity, and to its substantivity (Addy 1986, Kornman 1986, Mandel 1988).

Many clinical studies evaluating the effects of CHX showed that either 10 ml of 0.2% or 15 ml of 0.12% mouthwash used twice daily are equally effective therapies for plaque control during post-surgical period (Löe & Schiott 1970, Lang et al. 1982, Gjermo 1989, Jones 1997).

Nevertheless, these regimens present several side effects, including brown staining of teeth and restorations, unpleasant taste and an increase in calculus deposition, which limit patients' acceptance (Löe et al. 1976).

Although many indications suggest that the staining of teeth may depend directly on eating, drinking and smoking habits (Addy et al. 1991), some alternative routes of CHX delivery have been recently developed in order to target CHX locally and minimize side effects. These systems include the use of devices allowing for subgingival CHX irrigation (Lavigne et al. 1994, Felo et al. 1997), or different formulations such as gel and spray.

The gel form generally contains 1% of CHX and can be directly delivered to the target area using a finger or a toothbrush. In particular, during the full-mouth disinfection procedure, the gel is used for brushing and cleaning of the tongue (Mongardini et al. 1999). The efficacy of the gel, however, seems to be greatly dependent on the ability of the patient to properly deliver the gel to specific areas of the mouth and to comply with the treatment regimen. Moreover, during tooth brushing, the gel is easily

spread all over the mouth and therefore minimizes the advantages of local treatment (Addy & Moran 1997).

The spray formulation allows for the focusing of the treatment to specific regions, thereby drastically reducing the total dose of drug given to a patient, as well as specifically targeting the zones needing treatment. The effectiveness of this delivery system in preventing plaque accumulation and gingivitis has been already demonstrated and in those studies involving handicapped children and adults, the possibility of obtaining good plaque control even when both the level of oral hygiene and the compliance of the patient are poor is demonstrated (Dever 1979, Francis et al. 1987, Kalaga et al. 1989).

Recently, our group published a clinical trial comparing the effectiveness of 0.12% CHS mouthwash and 0.2% CHX spray in the plaque control after periodontal surgery (Francetti et al. 2000). The results of the study suggest that the efficacy of the CHX spray in the post-surgical control of dental plaque was similar to that seen with CHX mouthwash. Tooth staining, on the contrary, was highly influenced by the CHX delivery system, which is most likely due to the total dose administered, about 80% lower in the spray group.

Moving from the observations of the latter study, we aimed at testing the null hypothesis of equivalence between the two ways of delivering CHX (mouthrinse and spray) in the plaque control and occurrence of side effects like tooth staining after implant therapy in partially edentulous patients.

Material and Methods

Enrolment

A total of 20 patients (nine males and 11 females) have been enrolled in the study. Their mean age was 50.6 ± 14.2 (SD) years (range 35-68 years). All the patients were partially edentulous in either mandible or maxilla and needed rehabilitation by implant supported prosthesis. Exclusion criteria were: (1) presence of severe systemic diseases, such as poorly controlled or uncontrolled diabetes; (2) presence of chronic diseases requiring antibiotic prophylaxis: (3) smokers that reported consuming more than 10 cigarettes a day; (4) presence of parafunction such as bruxism or clenching; (5) need for bone augmentation at the intended implant site; (6) known allergy to CHX.

Voluntary informed consent was obtained from each patient.

In a preliminary visit, about 1 month before the day of implant placement, detailed information concerning proper oral hygiene procedure was given to all patients. In the same session any required periodontal treatment was performed.

The patients were randomly assigned to either control (using CHX mouthwash) or test (using CHX spray) groups, by means of a computer generated 1:1 randomization list.

Three patients of the control group and three of the test group were smokers and reported consuming less than 10 cigarettes a day.

Immediately prior to the surgical procedure, professional operators polished the patient's teeth using prophylactic paste and rubber cup.

One to five submerged fixtures (3i, West Palm Beach, FL, USA) were placed in the patients' jaws and the wounds were sutured with minimally plaque-retentive materials, such as ePTFE or polyester.

A total of 45 implants were placed: 21 in the patients of the control group and 24 in the patients of the test group.

In the 2 weeks following surgical operation the patients belonging to the control group rinsed with 15 ml of 0.12% CHX mouthwash (EBUR-OS[®], Dentsply Italia, Roma, Italy) twice daily for at least 1 min. The amount of CHX contained in 15 ml of rinse is 18 mg. The patients allocated to the test group used a spray administration of 0.2% CHX (EBUR-OS Spray[®]) twice daily at sites involved in surgical treatment. In the latter group, each administration consisted of four consecutive sprays at the implant site. Each single spray released 0.13 ml of solution, corresponding to 0.26 mg of CHX (Francetti et al. 1996). On the average, each patient belonging to the spray group assumed 5 mg of CHX per day, namely a dose over 85% lower when compared with patients using rinse.

Antibiotics (amoxicillin+clavulanic acid) and Nimesulide (Aulin[®], Böehringer-Mannheim, Germany) 100 mg twice daily for 2 days were prescribed to all patients as pharmacological post-surgical therapy.

In the 2 weeks following surgery, all the patients suspended mechanical oral hygiene in correspondence with surgical sites, in order not to interfere with the wound-healing process. Usual oral hygiene procedure was maintained at teeth not involved with the surgery, by using a medium density toothbrush. Patients were also advised to avoid tough food, as well as any hot food and beverage during the first day. A cold and soft diet was suggested, in order to reduce the risk of bleeding and wound dehiscence. On day 14 after surgery, sutures were removed and patients resumed their usual oral hygiene procedure.

Clinical evaluation

Several clinicians performed surgical procedures of implant placement. Conversely, a single examiner, blind to the group allocation, assessed the clinical parameters.

The following parameters were evaluated at both days 7 and 14 post surgery: (A) plaque index of Silness & Löe (1964), (B) stain index (SI) (Soskolne et al. 1997), (C) modified gingival index (MGI), (D) taste alteration. Four hundred and ninety five teeth have been examined, 253 for the control group and 242 for the test group, corresponding to a total of 1012 and 968 tooth sites analysed, respectively.

The consumption of any other medication in addition to those prescribed was recorded.

Since a session of professional oral hygiene was performed immediately prior to surgery, PI, SI and MGI were assumed to be equal to zero at baseline.

The examiner evaluated PI and SI at four tooth surfaces: mesial, distal, palatal/lingual and vestibular.

The PI consisted of the detection of plaque thickness at the tooth surface, according to a scale ranging from 0 to 3, as described in the literature (Silness & Löe 1964). A Michigan O Probe with Williams markings was used in this study to evaluate PI.

The SI was measured using a scale ranging from 0 to 3, where absence of tooth pigmentation was scored as 0 and values of 1, 2 and 3 were used to identify light, moderate and heavy pigmentation, respectively (Soskolne et al. 1997).

In this study, a MGI was assessed for the whole mouth according to a scale ranging from 0 to 3. The modification respect to the gingival index of Löe & Silness (1963) consisted of avoiding probing at all sites.

Using a scale ranging from 0 (no modification) to 5 (severe modification),

Finally, the integrity of gingival epithelium was checked during each control, in order to promptly recognize undesired reactions such as gingival erythema or disepithelialization.

Statistical analysis

Teeth of different areas of the jaws were separately considered for the statistical analysis concerning PI and SI. We aimed at comparing the regions proximal to the surgical site and the regions of the jaws not surgically involved. The following two subgroups of teeth were identified: (1) the nearest involved teeth, namely the tooth mesial and, if present, the one distal to the surgical area; (2) the teeth not involved in surgery, namely all teeth excluding those proximal to the surgical site.

Given the interdependence between the different sites in the same mouth, the patient was considered as the unit of analysis for all statistical comparisons. For PI and SI we calculated the mean values at days 7 and 14 for each patient by averaging site-specific evaluations belonging to each region of the jaws, as defined above. The difference between rinse and spray group was evaluated by the non-parametric Mann–Whitney test. The non-parametric Wilcoxon test was used to compare observations at days 7 and 14 within each group, and to evaluate differences in PI and SI between nearest and not-involved teeth. The level of significance was considered

Results

p = 0.05.

The results of the site-specific evaluation of PI on days 7 and 14 for both groups are illustrated in Table 1. The percentage of observations corresponding to each score for total sites, control and test group, is reported for each group.

Table 2 reports the analogous score evaluation for the SI. In the rinse group, staining was observed in 46.2% and in

Table 1. Evaluation of the plaque index (PI) at days 7 and 14 after implant surgery

	PI	Rinse group		Spray group	
		N	%	N	%
7 days	0	811	80.1	810	83.7
	1	199	19.7	132	13.6
	2	2	0.2	26	2.7
	3	0	0	0	0
	Total	1012	100	968	100
14 days	0	792	53.8	763	78.8
	1	217	40.2	459	16.4
	2	3	6	46	4.8
	3	0	0	0	0
	Total	1012	100	968	100

<i>Tuble 2.</i> Evaluation of the stant much (SI) at uays / and 14 after implant surgery	Table 2.	Evaluation	of the stai	n index (S	I) at da	vs 7 and	14 after	implant surgery
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	SI	Rinse group		Spray group	
		N	%	N	%
7 days	0	544	53.8	888	91.7
	1	407	40.2	78	8.1
	2	61	6	2	0.2
	3	0	0	0	0
	Total	1012	100	968	100
14 days	0	396	39.1	864	89.3
	1	475	46.9	85	8.8
	2	141	14	19	1.9
	3	0	0	0	0
	Total	1012	100	968	100



Fig. 1. Mean values of the plaque index at days 7 and 14 in the two groups for teeth proximal to surgical site and not-involved teeth.



Fig. 2. Mean values of the stain index at days 7 and 14 in the two groups for teeth proximal to surgical site and not-involved teeth.

60.9% of the examined sites at days 7 and 14, respectively. Staining was present especially at teeth proximal to surgical sites (80% and 85% of sites belonging to this subgroup at 7 and 14 days, respectively). In patients of the spray group, staining was observed in 8.3% and 10.7% of the total sites examined at days 7 and 14, respectively. Pigmentation was observed mainly at the level of the teeth adjacent to surgical site. The mean values of the PI at days 7 and 14 within each subgroup of teeth are shown in Fig. 1. Fig. 2 shows the analogous outcome for the SI. The results of the statistical comparison between the rinse and spray group for PI and SI are reported in Table 3.

The PI was maintained at excellent levels in both groups throughout the observational period. No significant difference was detected between rinse and spray group at both days 7 and 14. Conversely, the SI was significantly lower in the test group with respect to the control group, at both days 7 and 14, when considering not-involved teeth. Table 4 shows the results of the comparison between days 7 and 14 for PI and SI. During the observational period the SI increased significantly in both groups. Slight variations between 7 and 14 days were detected for the PI.

Table 5 reports the results of the statistical comparison between proximal and not-involved teeth for PI and SI. No significant differences were detected for the PI. On the other hand, tooth staining was significantly lower in regions not involved from surgery when compared with sites proximal to the surgical area in patients belonging to the spray group. No difference was detected between different regions in patients using rinse.

Patients using CHX mouthwash reported significantly higher taste alteration with respect to patients using CHX spray, which did not result in any taste alteration.

Table 6 reports the results of the evaluation of the other parameters considered. The MGI was not significantly different between the two groups at days 7 and 14; moreover, these values did not statistically differ from baseline. The above observations suggested that both spray and mouthwash delivery forms were equally effective in preventing inflammation, as well as in the plaque control. There was a slight (but not statistically significant) taste alteration in the group using CHX mouthwash.

Finally, no disepithelization was detected in the 20 patients both at days 7 and 14. No other side effects were reported. Patients reported assuming no concomitant medications.

Discussion

The control of plaque accumulation is of extreme importance for the success of both periodontal and implant surgical treatment. Lambert et al. (1997) showed that 0.12% CHX rinses reduce the incidence of infectious complications after implant therapy. In the present clinical trial, the authors compared two different means of delivering CHX after implant therapy. A substantial equivalence of rinse and spray in the control of dental plaque was observed. The value of PI was extremely low throughout the observational period in all the regions of

Table 3. Results of the statistical comparison between rinse and spray groups

	Plaque index		Stain index	
	p, 7 days	p, 14 days	p, 7 days	p, 14 days
nearest teeth not-involved teeth	0.40 0.80	0.94 0.24	0.25 <0.001*	0.06 <0.001*

*Significant difference; p, probability value.

Table 4. Results of the statistical comparison between days 7 and 14

	Plaque	e index	Stain index	
	p, rinse group	p, spray group	p, rinse group	p, spray group
nearest teeth not-involved teeth	0.20 0.26	0.71 0.03*	0.05 0.005*	0.005* 0.04*

*Significant difference; p, probability value.

Table 5. Results of the statistical comparison between teeth proximal to the surgical site and teeth not surgically involved

	Plaque index	Stain index
	P	P
rinse group day 7	0.39	0.72
rinse group day 14	0.24	0.26
spray group day 7	0.09	0.005*
spray group day 14	0.26	0.005*

*Significant difference; p, probability value.

Table 6. Results of the evaluation of secondary variables collected in this study

Parameter	7 day	s	14 0	lays
	Rinse	Spray	Rinse	Spray
MGI taste alteration	$\begin{array}{c} 0.1 \pm 0.32 \\ 0.5 \pm 0.52 \end{array}$	$egin{array}{c} 0 \pm 0 \ 0 \pm 0 \end{array}$	$\begin{array}{c} 0.1 \pm 0.32 \\ 0.3 \pm 0.47 \end{array}$	$0.4 \pm 0.52 \\ 0 \pm 0$

Data are expressed as mean value ± 1 SD.

the jaws. At the level of the teeth nearest to the surgical area, the protection from plaque accumulation was effected only by the action of CHX, while in the other regions of the jaws, mechanical oral hygiene contributed to plaque control in both groups.

On the other hand, at least at teeth not proximal to the surgical site, the tooth pigmentation was significantly lower in patients using spray when compared with those using rinse.

Considering the different nature of the two delivery systems, it may be hypothesised that when CHX is delivered by means of mouthwash, it can be adsorbed not only at the surface of teeth adjacent to implant site and at periimplant tissues, but also on surrounding oral surfaces, which do not necessitate antimicrobial treatment. This could explain the higher SI observed in patients belonging to the rinse group when compared with the spray group at regions not proximal to surgical site. It is likely that the diffusion of CHX to those surfaces not requiring the drug cannot be entirely avoided even with the spray, as suggested by the occurrence of slight tooth staining on several surfaces belonging to not surgically involved teeth in the spray group. However, the local delivery of CHX should minimize its spreading to the tongue and the other oral tissues, thereby avoiding alteration of taste. Indeed, the taste sensation disturbance was comparable in both groups, being totally absent in patients using spray and, negligible in those using rinse.

It is of important note that tooth staining might also depend on many other factors not investigated in the present study, such as smoking and diet habits, or individual susceptibility (Eriksen et al. 1985, Leard & Addy 1997, Watts & Addy 2001). Anyway, given the high statistical difference between the two groups, it seems unlikely that the different staining levels are obtained by chance leading us to the conclusion that the method itself of delivering CHX is responsible for the observed difference.

Similar to previous studies concerning plaque control after periodontal surgery (Francetti et al. 2000), CHX, in the spray form, has been shown to be an efficient therapeutic tool, when applied after implant surgery. This alternative delivery system minimizes side effects and also drastically reduces the total dose of drug given to the patient.

After completion of this clinical study, the null hypothesis of equivalence between mouthrinse and spray was accepted for the efficacy of the treatment, but was rejected regarding the staining effect. The latter in fact was lower in the spray group with respect to mouthrinse group, especially at the level of not-involved teeth, that amounted to 94.2% and 93.2% of the teeth examined in the two groups, respectively.

Because of the fact that the efficacy of CHX spray in the control of dental plaque is very similar to that of CHX mouthwash, while side effects are reduced when using the spray form, the latter should be the preferred delivery system when plaque control in restricted areas is needed.

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