

# What's new for the clinician?

Summaries of and excerpts from recently published papers

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## 1. The efficacy of 0.12% chlorhexidine versus 0.12% chlorhexidine plus hyaluronic acid mouthwash on healing of submerged single implant insertion areas.

Genovesi A, Barone A, Toti P, Covani U. *Int J Dent Hygiene* 2017; 15: 65–72

Two modalities of implant insertion are possible: Submerged implant insertion and non-submerged implant insertion. Osseointegration follows insertion of the implant. This process is characterized by the development of an intimate bone contact with the implant surface.<sup>1</sup> To minimize the risk of impaired osseointegration it has historically been recommended that the implant be inserted into the bone (submerged implant) and allow for submerged healing for three months in the lower jaw. After that time, during a second surgery, the implants are uncovered.<sup>1</sup>

Maintaining a high level of oral hygiene is a very important factor for the success of any dental implant insertion technique.<sup>1</sup>

Several topical antimicrobial substances used as an adjunct to mechanical cleaning procedures, such as essential oils, metal salts, oxygenating agents and others, have been employed generally in plaque control but the gold standard remains chlorhexidine (CHX) either at a concentration of 0.12% or 0.2%.<sup>1</sup> CHX showed substantivity (i.e. its binding) in the oral cavity, to both hard and soft tissues, producing a very durable effect, including long after (7–12 h) the moment of its application. This characteristic contributes to its antiplaque effect and has been shown to be effective against peri-implantitis that may affect the soft tissues around the implant.<sup>1</sup>

More recently a commercial product (Plac Away) has been introduced into the market for the treatment of gingivitis. It contains 0.12% chlorhexidine plus hyaluronic acid (CHX+HYL). The linear polymer of glucuronic acid N-acetylglucosamine disaccharide (hyaluronic acid, HYL) seems to be involved in both the reduction in inflammatory responses, due to its anti-oedematogenous and bacteriostatic effects, and in the promotion of a re-epithelization phenomenon.<sup>1</sup>

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### ACRONYMS

|                 |                                    |
|-----------------|------------------------------------|
| <b>CHX:</b>     | chlorhexidine                      |
| <b>CHX+HYL:</b> | chlorhexidine plus hyaluronic acid |
| <b>HYL:</b>     | hyaluronic acid                    |

Genovesi and colleagues (2017)<sup>1</sup> reported on a randomized clinical trial that sought to compare, over a two-week period, the efficacy of the two types of mouthwash, both being 0.12% chlorhexidine mouthwashes, one with hyaluronic acid (CHX+HYL) and the other without hyaluronic acid (CHX). An analysis was undertaken of the assessments of the clinical outcome parameters, which included oedema, inflammation around the suture area and granulation tissue in areas where submerged dental implants were placed; patient compliance was also followed up.

The secondary aim was to assess the effectiveness on plaque, bleeding, and staining index reduction in the two mouth-rinses (CHX+HYL versus CHX); a correlation analysis was also performed between the levels of consumption of coloured beverages and the staining index.

### MATERIALS AND METHODS

This double-masked parallel-arm randomized controlled clinical trial was conducted among 40 patients, all of whom had undergone a dental implant insertion for fixed prosthetic rehabilitation. The following criteria were employed:

#### Inclusion criteria:

- At least 18 years of age.
- Patients requiring dental implant insertion in a single-tooth edentulous area with the presence of healthy teeth adjacent to the healed extracted site (tooth without fixed prosthetic restoration, without failed dental restorative materials or restored cervical abrasion, abfraction, resorption lesion).
- A maximum of two dental implant placements per patient. If two implants were placed (with an adjunctive implant positioned in a different side or arch), just one site, following all inclusion criteria, was considered.

**Exclusion criteria:**

- General contraindication to dental implant treatment (uncontrolled diabetes and severe cardiovascular or infectious diseases).
- Intravenous and oral bisphosphonate therapy.
- Presence of severe, moderate or mild untreated periodontal disease.
- Unwillingness to return for the follow-up examination.
- Use of more than 10 cigarettes per day (being a risk factor for failure of dental implants).

Two types of mouthwash were labelled with an X (CHX, 0.12% chlorhexidine, 15 ml Dentosan®) or a Y (CHX+HYL, 0.12% chlorhexidine mouthwash plus 0.1% hyaluronic acid, 9ml Dentosan®chlorhexidine 0.2% plus 6ml Aftamed® 25mg/100g). Patients were assigned to one of the two mouthwash groups, X and Y, using an exactly symmetric binomial random binary sequence (X or Y), which had been generated prior to patient selection; Additionally, once scaling had been completed, patients were trained in the modified Bass brushing technique, using a manual toothbrush and a toothpaste having no influence on CHX effects, as well as in the use of dental floss.

The collection of clinical data was carried out by a blinded and calibrated researcher, who was unaware of the particular mouthrinse used by the participants. Data were collected for each patient: age, gender and location of dental implant placement. Details of the daily consumption of wine, tea and coffee were recorded during the observation period.

All patients were subjected to an oral hygiene session prior to the surgery in order to provide a more favourable oral environment for wound healing: all stain, calculus and plaque were removed. All the participants in the study remained blinded until the end of the study. For the surgery (placement of implants), patients received prophylactic antibiotic therapy (2g amoxicillin or, if allergic to penicillin, 600mg clindamycin) one hour before the procedure. All surgical procedures were performed by a single surgeon. The implants used for this study were all of the same brand and type.

Patients were treated under local anaesthesia using lidocaine with adrenaline 1:50 000. After a mid-crestal incision, a full thickness mucoperiosteal flap was minimally elevated and osteotomy for each site was prepared according to the procedures recommended by the manufacturer. The initial guide drill was used to perforate the cortex, followed by the use of the 2mm twist drill in accordance with the position and angulation planned by the implant surgical guide. The osteotomy was subsequently widened according to the manufacturer's indication. A final countersink was used to prepare the 2mm coronal part of the ridge to the same diameter of the implant. Subsequently, the implants were inserted, using the prescribed unit, to a calibrated maximum torque of 40 Ncm at predetermined 30 rpm. All titanium dental implants, root form, internal hex, rough-surfaced screws were inserted with the implant platform at the bone crest level. Cover screws were placed and flaps were closed over the implant with simple interrupted sutures. All patients were instructed to continue with prophylactic antibiotic therapy (1g amoxicillin or 300mg clindamycin) two times a day for 4 days, and naproxen sodium 550mg tablets were prescribed as an anti-inflammatory to be taken twice for the first day, but only if it was required.

Following the surgical procedure, each patient rinsed their whole oral cavity with mouthwash twice a day (in the morning and in the evening) for 1 min, using the sample solution, which was supplied for 15 days, and which was then expectorated. All participants were instructed to refrain from using water mouthrinse for one hour. Around the site of dental implant placement, toothbrushing was not allowed, and mouthwashing was the only choice. Compliance was checked by gathering a rinsing calendar which had been directly self-recorded by the patients.

Three hours after surgery, at two and at fifteen days, oedema, inflammation around the suture area and granulation tissue were recorded as binary events (presence versus absence) using the following scale: 0 = absence and 1 = presence.

At baseline (before surgery), and at 2 and 15 days after surgery, a comprehensive mouth plaque, bleeding and staining index was computed by means of the data acquired for the three standard indices.

- Plaque index (PI): plaque was revealed by plaque-disclosing tablets (two per patient). Six surfaces were examined per tooth (disto-buccal, mid-buccal, mesio-buccal, disto-lingual, mid-lingual and mesio-lingual). The absence or presence of plaque was recorded for each surface.
- Bleeding index on marginal probing (BIMP): bleeding on marginal probing was examined for six surfaces per tooth (disto-buccal, mid-buccal, mesio-buccal, disto-lingual, mid-lingual and mesio-lingual); the presence of bleeding was tested within 1 min after the gingival margin had been probed at an angle of approximately 60° to the longitudinal axis of the tooth. The record was noted on a scale from 0 to 2 (0 = non-bleeding; 1 = pinprick bleeding; 2 = excessive bleeding).
- Staining index (SI): four areas were examined per tooth: one incisal, one gingival and two approximals. Intensity of staining was scored as 0 = no stain; 1 = light stain; 2 = moderate stain; 3 = heavy stain).

Any side effects encountered by patients during mouthwash treatment, such as a lesion in the oral mucosa or taste modification, were also documented. For the final time point (15 days), pairwise linear correlations between the variables related to each patient's beverage consumption and the three indices were performed employing the Spearman's rank correlation test.

The submerged implants included in this study were restored three to four months after implant placement.

**RESULTS**

A total of 40 patients (24 men and 16 women, aged 54.7 ± 12.1 years) completed this trial. All patients certified in their rinsing calendars that they meticulously followed indications of the present paper, giving a 100% compliance. No patient dropout occurred.

Neither allergic reactions to CHX and/or HYL or antibiotics nor major complications were recorded in the subjects. Two patients (belonging to CHX group) continued analgesic therapy till the third day. These two patients were

excluded from statistical analysis due to the prospective cumulative effects of the analgesic/anti-inflammatory drug on surgical outcomes: however, these patients had shown inflammation around sutures and oedema both at baseline and at two days after surgery. During the mouthwash treatment, no minor side effects, such as burning mouth or taste modification, were reported by any of the patients.

For between group comparisons, the incidence of oedema showed significant differences between the two groups within two days after surgery (with 9 and 15 events at the 3-h control, respectively, for the CHX+HYL and CHX groups, with a P-value of 0.0205; and with 4 and 14 events at the two-day control, respectively, for the CHX+HYL and CHX groups, with a P-value of 0.0009). Significant differences between the two groups were displayed neither for variables related to inflammation around the suture area nor for that related to the granulation tissue. Significant differences were not found for any of the indices (PI, BIMP and SI), nor for the percentages of colonized sites, between the two mouthwash groups at any of the time points of the survey, whereas a similarity between indices and percentage of colonized sites was shown when intragroup significances were investigated.

For within group comparisons, the plaque index revealed significant differences for both the CHX+HYL and CHX groups, except for the comparison between two- and 15-day time. Regarding the BIMPs, the pre-operative values ( $0.14 \pm 0.10$  and  $0.13 \pm 0.11$  for the CHX+HYL and CHX groups, respectively) were different from those at the two-day stage ( $0.09 \pm 0.08$  and  $0.09 \pm 0.09$  for rinses in the CHX+HYL and CHX groups, respectively) and 15-day time point ( $0.07 \pm 0.04$ ) for the CHX+HYL mouthwash type, all with significant P-values less than 0.008. The distribution of the staining index seemed

to increase for both mouthwash types, from  $0.14 \pm 0.17$  to  $0.19 \pm 0.14$  in the CHX+HYL group, and from  $0.12 \pm 0.19$  to  $0.31 \pm 0.34$  in the CHX group, but with no significance.

No significant correlations were found between the staining index and the consumption of any of the coloured beverages for either type of rinse.

## CONCLUSIONS

In the healing site of patients subjected to dental implant placements, no difference between groups was observed at 15 days post-surgery; however, an anti-oedematogenous additional effect in early healing seemed to be disclosed for 0.12% CHX+HYL mouthwash. No significant differences in antiplaque, antigingivitis and antistaining effects were revealed by the comparison between the two rinses; however, when either 0.12% CHX+HYL or 0.12% CHX mouthwash was employed, significant reductions in plaque and bleeding were observed; moreover, both the rinses seemed to exhibit a tooth-staining effect.

## IMPLICATIONS FOR PRACTICE

Significant results were obtained for the chlorhexidine mouthwash plus hyaluronic acid, yielding anti-oedematogenous additional effects on surgically treated sites compared with chlorhexidine alone. Both rinses performed equally well for all the other variables investigated.

### Reference

1. Genovesi A, Barone A, Toti P, Covani U. The efficacy of 0.12% chlorhexidine versus 0.12% chlorhexidine plus hyaluronic acid mouthwash on healing of submerged single implant insertion areas: a short-term randomized controlled clinical trial. *Int J Dent Hygiene* 2017; 15: 65–72.

## 2. Alcohol-free 0.2% chlorhexidine oral rinse versus 0.2% chlorhexidine rinse with alcohol for the control of dental plaque accumulation.

Papaioannou W, Vassilopoulos S, Vrotsos I, Margaritis V, Panis V. *Int J Dent Hygiene* 2016; 14: 272–7.

Plaque control using mechanical means (toothbrush and interdental cleaning aids), when practiced successfully and on a daily basis, is usually sufficient for the preservation of healthy dental and periodontal tissues.<sup>1</sup> The majority of patients, however, do not succeed in effectively removing plaque, especially in the interdental areas and other hard-to-reach surfaces, hence, adjunctive use of antiseptics in the form of mouthwashes has been shown to be effective in successfully controlling plaque and gingival inflammation.<sup>1</sup>

Chlorhexidine digluconate (CHX) is a powerful antimicrobial substance that chemically belongs to the bisguanides family. Mouthwashes that contain CHX in different concentrations (0.1–0.2%) are considered to be

### ACRONYMS

- CHX:** chlorhexidine  
**DI:** discolouration index  
**GI:** gingival index  
**PI:** Silness and Løe plaque index

the most effective in reduction of plaque accumulation and gingival inflammation.<sup>1</sup> This is due to the action of CHX, which primarily strikes the bacterial cell membrane causing leakage of cell components of Gram-positive bacteria, Gram-negative bacteria, fungi and viruses (HSV1, HSV2, Influenza A).<sup>1</sup> CHX can also penetrate into the plaque biofilm and act against the already incorporated bacteria.<sup>1</sup> CHX preserves its antimicrobial action for more than 12 h due to its supragingival substantivity. It has both a bactericidal

and bacteriostatic effect dependent on the available concentration. Resistant microbial strains do not develop, even after prolonged use of CHX.

Papaiouannou *et al* (2016) reported on a trial that sought to compare the clinical efficacy of two formulations, both containing the same concentration of active ingredient in the solution (CHX 0.2% w/v) but having different content of excipients, on a) the formation of plaque, b) gingival inflammation and c) the discoloration of the dental tissues.

## MATERIALS AND METHODS

This was a double-blind crossover study. Ten healthy volunteers who were non-smokers, had a high level of oral health (Community Periodontal Index <2), no active dental caries, no allergies to the medication and had no removable dental prostheses or fixed or removable orthodontic appliances were included in this trial.

The clinical measurements were performed by a calibrated examiner at the beginning (baseline) and at the end of each study stage. The examiner was blinded to the solution used as well as to the previous measurements. The presence and the amount of plaque were recorded using the Silness and Løe plaque index (PI). More specifically, this index was measured on the mesial, middle and distal of both the buccal and lingual surface of all teeth except for the third molar and with a 0–3 gradation (0 = absence of plaque, 1 = no visible plaque detected by periodontal probe, 2 = moderate accumulation along the gingival margin of the tooth, 3 = abundant accumulation on the gums and on the dental surface).

On the same surfaces and with the same 0–3 grading, gum inflammation was also assessed with the help of the gingival index (GI) by Løe and Silness (0 = lack of inflammation, 1 = light discoloration and light swelling but lack of bleeding during probing, 2 = redness, swelling and bleeding during probing, 3 = intense redness, swelling and tendency to bleed automatically).

Finally, the discoloration index (DI) was recorded on the buccal and lingual surfaces, directly without the use of photographs, for the six anterior teeth of both the mandible and maxilla. This index records the discoloration both qualitatively (colour intensity: 0 = lack of stain, 1 = light stain – yellow to brown, slightly visible, 2 = medium stain – medium brown colour, 3 = dark stain – dark brown to black colour) and quantitatively (amount: 0 = lack of stain, 1 = thin stain line (<1 mm width), 2 = moderate band of stain (1–2 mm), 3 = wide band of stain (>2 mm).

These scores are combined into a single overall score according to the formula:  $1.5 \times \text{stain intensity} + 1 \times \text{stain amount}$ , resulting in a final DI rate for the mouth, which was a mean for all examined surfaces. The formula was developed taking into consideration that even a small amount of black stain can be more aesthetically annoying for the patient than a wider amount of light discoloration.

The 10 volunteers followed a two-week preparation programme that included plaque removal through a professional prophylaxis – as thoroughly as possible – and repeated instructions on oral hygiene. The objective was that the subjects taking part in the study were free of

microbial plaque and gingivitis at the end of this time period. This study consisted of only one group that followed two 21-day experimental gingivitis test periods. During these time periods, the study subjects abstained from every kind of oral hygiene with mechanical or other means except by the oral rinse provided. The products under investigation, CHLOREL® 0.2% w/v and CORSODYL® 0.2% w/v Mint Mouthwash were given to the study subjects at the respective time period, in identical packaging with only the following indications: Bottle A, Bottle B. The 10 volunteers rinsed every morning and evening and for a duration of 1 min with a) 10 ml solution from Bottle A for period 1 and b) 10 ml solution from Bottle B for period 2. This was a double-blind study. The contents of the bottles were revealed to the investigators after completion of the study.

After the end of the first test period, a 14-day washout period followed, during which the study subjects resumed oral hygiene with mechanical means at home, while plaque removal, tooth scaling and polishing were repeated at the clinic. Both at the beginning and at the end of each test period, the same examiner obtained and analysed the clinical measurements.

Briefly, the stages were the following:

1. Initial clinical measures (Day 0 – Baseline: PI, GI, DI, CPI)
2. Two-week preparation programme: Repeated instructions on oral hygiene, plaque removal, tooth scaling and polishing at the clinic.
3. First test period lasting three weeks: clinical examinations at the start (PI, GI, DI)

The subject abstains from all means of oral hygiene; rinses every morning and evening with 10 ml of solution A for 1 min. Clinical examinations repeated (PI, GI, DI) at the end of the period.

4. Washout period and 14-day preparation: The use of mouthwash is ended and daily oral hygiene using mechanical means is started. Repeated instructions on oral hygiene, plaque removal, tooth scaling and polishing.
5. Second test period lasting three weeks: clinical examinations at the start (PI, GI, DI). The subject abstains again from all other means of oral hygiene; rinses every morning and evening with 10 ml of solution B for 1 min. Clinical examinations repeated (PI, GI, DI) at the end of the test period.
6. Completion of study: subjects have plaque removed by scaling and polishing at the clinic.

## RESULTS

The group of volunteers comprised six females and four male students with a mean age of 23.4 years (SD 3.9). All had very good or excellent oral health. Mean values (standard deviations) of PI increased similarly for both solutions; however, these differences between initial and final values were statistically significant only for CHLOREL® (0.52 [0.15] to 0.75 [0.19]), respectively). Similarly, the mean values for the GI showed small increases over the course of the study periods, but these differences were not found to be statistically significant for either solution. The mean values of DI for CORSODYL® and CHLOREL®, which were at 0 at the beginning of each study period increased significantly for both solutions, with the former showing the highest mean final score, that is 0.20 (0.30). These differences were statistically significant for both solutions.

Mean values (standard deviations) of the percentage of surfaces free of plaque for the solution CORSODYL® initially and finally were 52.55 (19.50) and 36.95 (18.17), respectively, while for the solution CHLOREL® the figures were 51.28 (11.82) and 32.62 (16.80), respectively. However, these differences were statistically significant only for CHLOREL®.

Regarding the comparison of the initial and final values between the solutions, per index, no statistically significant differences was observed.

No adverse events occurred in any of the participants during the study.

### CONCLUSIONS

No statistically significant difference in any tested parameter was observed between the two antiseptic solutions. The non-alcoholic chlorhexidine rinse (CHLOREL®) had

levels of action comparable to the generally recognized gold standard alcoholic rinse (CORSODYL®). The two formulations are equally effective and safe to use.

### IMPLICATIONS FOR PRACTICE

The present study found that an alcohol-free 0.2% CHX mouthrinse had very acceptable clinical effectiveness on *de novo* plaque growth and gingival inflammation, in the absence of mechanical plaque control, and suggests that clinicians can prescribe such a rinse with confidence in its efficacy in the indicated cases.

### Reference

1. Papaioannou W, Vassilopoulos S, Vrotsos I, Margaritis V, Panis V. A comparison of a new alcohol-free 0.2% chlorhexidine oral rinse to an established 0.2% chlorhexidine rinse with alcohol for the control of dental plaque accumulation. *Int J Dent Hygiene* 2016; 14: 272–7.





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