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Peri-implant maintenance of immediate function implants: A randomized controlled clinical trial comparing hyaluronic acid and chlorhexidine.

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RUNNING TITLE: Evaluate an implant maintenance protocol

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ABSTRACT

Introduction: In implants, maintenance assumes an important role. The role of chlorhexidine is well known in maintenance, while only limited evidence exists about the practical use of hyaluronic acid. The objective of this study was to compare the healing of immediate function implants, inside a maintenance protocol using hyaluronic acid and chlorhexidine gels.

Study population and methodology: Thirty complete edentulous patients, with 4 immediate function Brånemark System implants placed in the mandible (total of 120 implants), were included in 2 groups (hyaluronic acid and chlorhexidine) using only these 2 chemicals in their daily implant self-care. Both groups were followed for 6 months, with clinical observations on the 10th day, 2 months, 4 months and 6 months post-surgically.

Results: No implant losses were registered at 6 months in both groups. Hyaluronic acid and chlorhexidine produced good results on maintenance of complete rehabilitations in the edentulous mandible with immediate function implants. Statistically significant differences were found in favour of the hyaluronic acid group in the Modified bleeding index on the 2nd observation (p=0.003). The difference was located in the the axial implants placed in the 5th sextant (p=0.05). Correlation coefficient between plaque and bleeding index revealed a potential better result for chlorhexidine at 6 months.

Conclusion: The findings point out the importance of a maintenance protocol in immediate function implants. Both chemicals are valid tools for implant maintenance, with a proper timing of administration (hyaluronic acid in the first 2 months; chlorhexidine between 2-6 months).

KEY WORDS: maintenance, oral implants, immediate function; hyaluronic acid; chlorhexidine, gel, tilted implants; axial implants, oral hygiene

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INTRODUCTION

In recent years more studies have been dealing with the concept of immediate function in implantology, which consists in the placement of the implant, abutment and crown on the same surgical step (1).

The maintenance phase of prosthetic rehabilitations with immediate function implants, assumes a role as important as the surgical phase, influencing the implants success rate (2, 3). The patient's oral hygiene has a significative impact on bone stability around osseointegrated implants, and even in complete edentulous patients, a bad oral hygiene relates to an increased bone loss (4). Moreover, the best way of treating peri-implant pathologies is still to prevent it (5, 6).

Hyaluronic acid (HA) is described as a natural organic substance, with physiological therapy activity, main component of the extracellular matrix of many tissues such as skin, synovial joints and periodontal tissues (7), with multi-functional role in healing of cronical lesions, including those that are observed in periodontal disease (8). Also in non-surgical treatment of periodontal disease, where the administration of high molecular weight HA proved to be effective in inducing tissue repair and healing in patients with inflammatory gingivitis and surgical wounds (7, 9, 10, 11).
Still, references in the literature for long-term use of hyaluronic acid in maintenance are sparse.

Chlorhexidine (CHX) represents the most efficient molecule of all antiseptic used in the oral cavity (12,13), with its efficacy attributed to the bactericide effect (the lethal effect of chlorhexidine is related to extensive intra-cellular damage inflicted in bacteria), to the bacteriostatic effect (which becomes lethal with the increasing concentration, causing

precipitation or coagulation of bacteria cytoplasm), and to its substantivity in the oral cavity, being its antimicrobial effect attributed to its di-cationic structure (14,15,16).

The aim of this randomized clinical controlled trial, was to compare the healing of the peri-implant complex in 2 groups of patients: 1- using 0.2% HA gel for daily implant self-care; 2- using 0.2% CHX gel for daily implant self-care; testing the hypothesis that healing of peri-implant mucosa would follow the same distribution for the implants in HA and CHX groups, tested by comparing the clinical and radiological evaluation parameters.

Study population and methofdology

This study was performed between January 2004 and December 2004 at a private practice, Clinica Maló in Lisbon, Portugal. The implants were placed and monitored by the same team.

The participants for this study were selected according to an inclusion criterion that consisted in patients submitted to a complete fixed prosthetic rehabilitation of the mandible with 4 immediate function implants: two anterior implants placed in axial position and two posterior implants tilted up to 40º distally, placed immediately in front of the mental foramens bilaterally (17). The implants consisted in Brånemark System™ Mk III Ti-Unite Ø 4X15mm (Nobel Biocare AB ™). The surgical, prosthetic and post-surgical protocols (medication) were followed according o the author's recommendations.

Other inclusion criteria consisted in the participants having to be present in the maintenance controls; and all participants needed to be followed for 6 months.

Smokers, patients with systemic and/or local contra-indications; patients with bruxism; patients with generalized oral inflammation/ infection; diagnosis of an oral pathology that would be impeditive of continuing the study; the use of antibiotics beyond the first 10 days after surgery; and patients that did not complete the follow-up were excluded from this study.

Clinical evaluation parameters:

The clinical evaluation parameters performed for monitoring of healing consisted in: Modified plaque index (mPlI) (18); Modified bleeding index (mBI) (18); Probing pocket depth (PPD) in millimetres (19), assessed with a calibrated Kerr-Hawe ® Perio-probe; Suppuration (Sup), observed after applying finger pressure to the peri-implant complex and registered as present or absent (20); Clinical implant mobility (Mob) accessed manually and registered as present or absent (19).

Radiological evaluation parameters

The radiological evaluation consisted in observations of periapical x-rays (x-ray) registering radiolucent areas around the implant as present or absent (19). The radiographs were taken at the 3rd observation, around 4 months, using a Trophy® x-ray; Kodak® pellicles and anterior/posterior film holders Superbite Hawe-Neos®, to secure an orthognatic position of the film.

Methodology for data collection

The patients were randomly assigned to each group. An organized index was built to collect all clinical and radiological parameters from patients. Table 1, illustrates the clinical sequence of the study. One day before surgery (Day-1), the study design was explained to patients and a written consent was requested. On the day of surgery, an oral

hygiene clinical appointment was performed on the patient, where besides the prophylactic procedures, oral hygiene instructions were given about the tooth brush (7/100®, Pierre-Fabre Dermo-Cosmétique, Lda, Portugal) and the gel used: 0.2% HA gel (Gengigel®, Ricerfarma rfa, Italy) for group 1, or 0.2% CHX gel (Elugel®, Pierre-Fabre Dermo-Cosmétique Lda, Portugal) for group 2. The patients were instructed to abdicate from using any other mechanical or chemical means of removing dental plaque besides the toothbrush and the HA or CHX gel.

At day 10 post-surgically, the prosthesis was removed, followed by suture removal and initial clinical indexes assessment. The patients were re-instructed about their self care, and another tooth brush was delivered (15/100®, Pierre-Fabre Dermo-Cosmétique, Lda) to substitute the one delivered at day -1. At 2, 4 and 6 months post-surgically, the clinical sequence was repeated, adding a peri-apical x-ray at 4 months for monitoring radiolucent areas around the implant. In between the maintenance appointments, the patients maintained their rehabilitation using just the toothbrush and either the HA or CHX gels.

Statistical analysis

Descriptive and inferential statistics for all clinical and radiological parameters were performed, to evaluate the results of the two therapies, using a significance level of 5%.

Two statistical approaches were used. The first, on patient level, analysed 30 participants, divided in two groups of 15. The second approach (at implant level), analysed the mBI at 2 months, to compare data from the position of the implant, comparing each of the four implants within the two groups, with a total of 8 groups with 15 implants.

Spearman correlation coefficients were used to establish the degree of association between dental plaque (mPlI) and peri-implant mucosal bleeding (mBI).

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RESULTS

The sample was represented by 30 individuals, of both genders with ages between 44 and 80 years (mean 58.6 +/- 9.51). Age did not differ between the 2 groups (p=0.346 > 0.05) (t-test).

A total of 120 implants were placed in these 30 patients, 4 on each patient, and all patients were followed for the proposed time in this study.

Clinical evaluation parameters on patient level

(A) mPlI

The general level of mPlI was average, with a median of 1.5 and 1 in the first three observations, and in the 4th observation respectively. The observed means for the 4 observations were 1.4 (+/-0.9 in the 1st observation); 1.3 (+/-0.8 in the 2nd observation); 1.5 (+/-0.6 in the 3rd observation); 1.2 (+/- 0.9 in the 4th observation).

The difference in mPlI between the 2 groups was found not to be statistically significant in any of the 4 observations (p>0.05).

(B) mBI

On a general level, the mBI values were very low, with a median of 0 and 1 at the first three observations and 4th observation respectively. The observed means for the 4 observations were 0.35 (+/- 0.53 in the 1st observation); 0.18 (+/- 0.36 in the 2nd observation; 0.13 (+/- 0.26 in the 3rd observation); 0.97 (+/- 0.67 in the 4th observation).

There were no statistical significant differences in the mBI of the 2 groups in the 1st, 3rd and 4th observations. A statistical significant difference was found between the 2 groups, in the mBI of the 2nd observation in favour of the hialuronic acid gel (p=0.003 < 0.05).

(C) PPD

The mean PPD was 2mm for both groups. The difference was found not statistically significant between the 2 groups at any observation ($p>0.05$).

(D) Mob

No differences were found between the two groups, as no implant was found mobile when clinically tested.

(E) Sup

No differences were found between the 2 groups, as no implant presented suppuration when clinically tested.

Radiological evaluation parameter

No differences were found between the 2 groups, as no implant presented radioluscency around it when radiologically tested.

Clinical evaluation parameters on implant level

This approach was applied to the mBI on the 2nd observation period, to assess the nature of the difference between the 2 groups (site related or a sum of small differences).

For the tilted implants localized in the posterior region (bilateral 3rd and 4th quadrant), no statistical significant difference was found between the 2 groups.

For the axial implants localized anteriorly in the 3rd and 4th quadrant, a statistical significant difference was found between the 2 groups, in favour of the HA group ($p=0.050$).

Correlation coefficient between MPlI and MBI

The Spearman correlation coefficient was analyzed for the 2 groups in the 3 observations between mPlI and mBI (Figure 1).

Regarding the HA group, coefficient correlation between mPlI and mBI for the 1st observation was a negative weak not statistically significant (r= -.328; p=0.232); at the 3rd observation it was observed a positive yet not statistically significant correlation (r= .481; p= 0.070); while at the 4th observation it was observed a positive strong statistically significant correlation (r= .716; p= 0.003). The correlation for the 2nd observation did not make sense because the variance of that sample was 0.

Regarding the CHX group, coefficient correlation was characterized by a positive weak and not statistically significant in the 1st observation (r= .191; p=0.495) and 2nd observation, (r= .024; p=0.932); a negative weak not statistically significant correlation in the 3rd observation, (r= -.379; p= 0.164); and a negative strong statistically significant correlation in the 4th observation (r= -. 625; p= 0.013).

DISCUSSION

In a general way, HA and CHX produced very positive results in the maintenance of complete edentulous mandible rehabilitations with fixed prostheses supported by immediate function implants.

Maintenance is key if one aims at implant success, having been observed in this study that having a maintenance strategy for implants, accounts for good clinical outcomes up to 6 months post-surgically. These results can be supported in the literature, where oral hygiene's significant impact on bone stability around osseointegrated implants was verified (2,3); moreover in complete edentulous patients rehabilitated prosthetically, where an insufficient oral hygiene related to a higher bone loss (4).

The gel as mean of chemical administration has proved valid (21), as its specific action together with mechanical stimulation of the tissues when used as a main therapy in conjunction with brushing (22,23,24), allows achieving better results than with a mouthwash (25).

In this study, the main comparison between the peri-implant complexes of the 2 groups was the relation between the mPlI and the mBI, in which is found the key to maintenance, as both plaque and bleeding indexes are reliable parameters for evaluating the patient's home care and the health of the peri-implant mucosa, respectively (19). During the course of the study, the plaque indexes never differed significantly between both groups. This implies that oral hygiene practice did not differ between the participants, therefore simplifying the analysis of the bleeding index, meaning that a higher or lower result in the two groups would not have been directly related to the dental hygiene abilities but to the chemicals in test.

The mPlI level was generally average, meaning that dental plaque was always present around the implants, being possible to be observed by the naked eye. This presence of dental plaque means that the patients didn't achieve high levels of dental hygiene self-care, fact that could be explained by the lack of compliance or ability to perform self care (26), by difficult prosthetic design not making it simple for the patient to maintain it (27), or by the fact that the patients only maintenance tool was the tooth brush, without other supportive mechanical means of dental plaque removal.

The presence of dental plaque, represents an etiological factor for the development of peri-implant disease (28).

In our study, despite the plaque indexes were average (establishing good conditions for the development of peri-implant pathology), the bleeding index was extremely low (mean: 1st observation= 0.350; 2nd observation= 0.183; 3rd observation= 0.133; 4th

observation= 0.967), indicating excellent peri-implant health and suggesting that the pathological effect of dental plaque was inhibited.

These results were also observed in the literature, as several studies observed an improvement in gingival patterns for HA (10) as well as for CHX therapy, but the later, along with a constant dental plaque index level, or an increase of supra-gingival calculus (29,30).

For HA, the possible mechanisms for these results include the bacteriostatic effect patterns (observed *in vitro)*, on microorganisms such as *Porphyromonas gingivalis, Actinobacillus actinomycetemcomitans, Staphylococcus aureus*, leading to a decrease in the risk of post-surgical infection and promoting a more predictable regeneration (31).

For CHX, the possible explanation mechanisms for the reduction of bleeding indexes include a possible reduction of pathogenic bacteria in dental plaque and/or a reduction of plaque metabolism (29); its the bactericide and substantivity effect (32); its bacteriostatic effect, by reducing the amount of active cultures of gram + microorganisms (*Staphylococcus aureus*) and gram - (*Porphyromona/Prevotella spp* e *Fusobacterium spp*) after 3 months (33); by its particular effect on the neutralization of pathogenic agents such as *Staphylococcus aureus*, *Porphyromona gingivalis* e *Prevotella intermédia* (observed *in vitro*) (34); or by a decrease on the oedema, vasodilatation and presence of pro-inflammatory citoquine interleuquine-8 (based on a inflammation model) (35).

In our study however, despite having proved that the use of these chemicals induced an inhibition of the dental plaque pathological effect over peri-implant tissues (due to the presence of dental plaque and the extremely low bleeding index), it was not possible to determine with assurance this mechanism of inhibition, and because no microbiological tests were performed, this question remains open.

The statistical significant difference favourable to the HA on the modified bleeding index in the 2nd observation (around 2 months post-surgically), rejects the hypothesis that healing of the peri-implant mucosa follows the same distribution for the implants in HA and CHX groups. Regarding the implant level analysis, a statistically significant difference was found in favour of HA localized on the anterior implants (the 5th sextant axial implants). These differences were observed at a time interval where the soft tissue finalized its healing, and therefore, the HA acted as a healing agent. This healing effect is related to the modulation and acceleration of the host response by the HA, as a consequence of its numerous biochemical and biophysical properties, it's non- toxic effect, and its biocompatibility (36).

Complementing the results, there is the correlation between mPlI and mBI (Figure 1). In this evaluation, we can observe a pattern in the association between mPlI and mBI, where in HA came from a negative correlation in the 1st observations to a positive correlation in the 4th observation (r= .716; p= 0.003); while an opposite correlation occurred for CHX, coming from a positive correlation in the 1st observation to a negative correlation on the 4th observation (r= -. 625; p= 0.013), demonstrating a tendency to potenciate the CHX effect in detrimental to HA on a long term. These results find parallel in the literature, where significant positive changes in gingival health are reported, as for the increasing of supra-gingival calculus, in patients submitted to a CHX therapy for 6 months (22,37).

Taking into consideration these results, the authors suggest an optimal period for HA administration in the first 2 months post-surgically, due to this time frame representing a healing period; while CHX administration should be used for the remaining period (between 2 and 6 months post-surgically), since this time frame represents an exclusively maintenance period.

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More and larger randomized controlled trials are needed so to explore the effect of these agents over implants on both the clinical and microbiological levels, generating efficient maintenance protocols, with the objective of increasing the success in implantology.

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TABLES INDEX

Table 1: Clinical chronology regarding professional procedure, diagnosis methods and patient procedures in the study

Professional procedures	Study information; Written informed consent	Oral Hygiene clinical appointment; Oral hygiene instructions; Surgery	Suture removal; Oral hygiene clinical appointment; Oral hygiene instructions; New toothbrush	Oral hygiene clinical appointment; Oral hygiene instructions;	Oral hygiene clinical appointment; Oral hygiene instructions;	Final diagnosis
Diagnosis methods			mPlI; Sup; mBI; Mob	mPlI; Sup; mBI; Mob; PPD	mPlI; Sup; mBI; Mob; PPD; Periapical X-ray	mPlI; Sup; mBI; Mob; PPD
Time elapsed	Day -1	Day 0	Day 10	Month 2	Month 4	Month 6
Patient's procedures		Day of the surgery; Beginning of gel therapy	Gel therapy with HA or CHX	Gel therapy with HA or CHX	Gel therapy with HA or CHX	Gel therapy with HA or CHX

***Table 2**: Clinical and radiological evaluation parameters for the 2 groups*

	Group HA			Group CHX			Statistical test	p value
	Mean	SD	Median	Mean	SD	Median		
mPlI 1	1.38	0.73	1.75	1.45	0.88	1.5	Kruskal-Wallis	0.597
mBI 1	0.27	0.36	0.25	0.52	0.53	0.50	Kruskal-Wallis	0.131
Mob	No	--	--	No	--	--	N/A	N/A
Sup	No	--	--	No	--	--	N/A	N/A
mPlI 2	1.03	0.71	1	1.6	0.55	1.75	Kruskal-Wallis	0.061
mBI 2	0.10	0.13	0	0.37	0.23	0.25	Kruskal-Wallis	0.003*
PPD 1	1.7	0.62	2	1.8	0.56	2	Kruskal-Wallis	0.502
Mob	No	--	--	No	--	--	N/A	N/A
Sup	No	--	--	No	--	--	N/A	N/A
mPlI 3	1.4	0.66	1.5	1.42	0.52	1.5	Kruskal-Wallis	0.966
mBI 3	0.18	0.20	0.25	0.23	0.28	0.25	Kruskal-Wallis	0.612
PPD 2	1.6	0.63	2	1.7	0.68	2	Kruskal-Wallis	0.638
Mob	No	--	--	No	--	--	N/A	N/A
Sup	No	--	--	No	--	--	N/A	N/A
x-ray	No	--	--	No	--	--	N/A	N/A
mPlI 4	0.93	1.03	1	1.4	0.63	1	Kruskal-Wallis	0.071
mBI 4	1.07	0.70	1	0.87	0.64	1	Kruskal-Wallis	0.417
PPD 3	1.6	0.72	2	1.7	0.64	2	Kruskal-Wallis	0.625
Mob	No	--	--	No	--	--	N/A	N/A
Sup	No	--	--	No	--	--	N/A	N/A

*** = statistically significant;**
N/A=not accessed due to all implants had no mobility (Mob), no suppuration (Sup) and no radioluscency around the implant visible in x-ray (x-ray).

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***Table 3**: Modified bleeding index in the second observation for the 2 groups. Comparative evaluation at implant level: tilted implant of the 3rd quadrant; axial implant of the 3rd quadrant; tilted implant on the 4th quadrant; axial implant on the 4th quadrant.*

	Group HA			Group CHX			Statistical test	p value
	Mean	SD	Median	Mean	SD	Median		
mBI tilted 3rd quadrant	0.07	0.26	0	0.27	0.59	0	Kruskal-Wallis	0.276
mBI axial 3rd quadrant	0.13	0.35	0	0.53	0.52	1	Kruskal-Wallis	**0.05***
mBI tilted 4th quadrant	0	0	0	0.27	0.46	0	Kruskal-Wallis	0.369
mBI axial 4th quadrant	0.20	0.41	0	0.47	0.52	0	Kruskal-Wallis	**0.05***

*** = statistically significant**

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FIGURE LEGEND

Figure 1

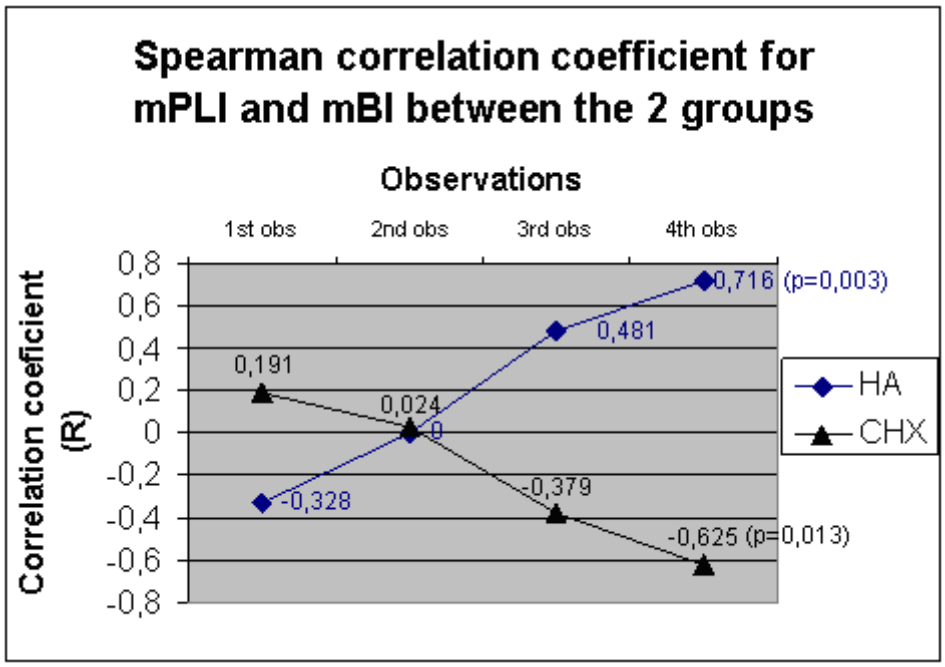

Figure 1: Correlation coefficient between the modified plaque index (mPlI) and modified bleeding index (mBI). Note the inverse relation between hyaluronic acid and chlorhexidine groups.