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Original Article

COMPARISON OF CHLORHEXIDINE AND IALUNVANCE COMPLEX IN THE POST-SURGICAL MANAGEMENT OF PATIENTS FOLLOWING ORAL AND IMPLANT SURGERY: PROSPECTIVE CLINICAL STUDY

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ABSTRACT

Aim: The aim of this prospective clinical study was to compare Chlorhexidine 0.20% and Ialunvance Complex (Euchlorine) in the post-operative management of patients undergoing oral and implant surgery, and to evaluate Placque Index and Bleeding on Probing values according to type of mouthwash, patient age, systemic diseases, smoking and surgical procedure. *Materials and methods:* This study included patients who required oral and implant surgery procedures. Post-operative therapy involved the use of Chlorhexidine 0.20% or Euchlorine mouthwash. The clinical outcomes analyzed were Plaque Index and Bleeding on Probing. These parameters were measured immediately before surgery, seven and 30 days after the surgical procedure. The study assessed the influence of type of mouthwash, patient age, systemic diseases, smoking habits and surgical procedure performed on the analysed parameters. *Results:* The t-test analysis revealed that Bleeding on Probing was significantly higher after third molar extractions, in females, and in smokers, with Euchlorine mouthwash showing significant improvement over Chlorhexidine. The Plaque Index was significantly higher following full-arch implant-prosthetic rehabilitations, but showed no significant differences between genders, smokers, and the type of mouthwash used ($p > 0.5$). Systemic diseases did not significantly affect either Bleeding on Probing or Plaque Index. *Conclusion:* Ialuvance Complex mouthwash is more effective than Chlorhexidine 0.20% in reducing Bleeding on Probing. The Plaque Index was higher in full-arch implant-prosthetic rehabilitations but was not influenced by gender, smoking, or mouthwash type. Systemic diseases did not affect Bleeding on Probing or Plaque Index. Further studies are needed to confirm these findings.

KEYWORDS: *Oral Hygiene, Mouthwashes, Oral Surgery, Dental Implants, Chlorhexidine*

INTRODUCTION

Recent developments in dental practice have led to a growing interest in optimizing post-operative protocols for oral surgery and implant procedures (1,2).

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Avulsions of dental elements, as well as implant placement, could be marred by phenomena of infectious origin that could cause the following complications: local infections, alveolitis, failure of osseointegration due to bacterial proliferation, peri-implantitis, cellulitis and osteomyelitis (3-5).

Among the most frequently used protocols, the use of mouthrinses has attracted considerable attention due to their crucial role in promoting tissue healing and preventing the risk of infection by reducing intra-oral bacterial load (6,7).

In the context of post-operative oral hygiene, chemical plaque control could represent a valuable support to the extent that the patient, due to pain and oedema, is unable to remove supragingival biofilm by the sole use of mechanical devices (8).

In the current scenario, mouthwashes based on Chlorhexidine (CHX) and Ialunvance Complex (Euchlorine) could be considered as reference antiseptic agents (9-11).

Chlorhexidine is a cationic bis-biguanide, i.e. a class of compounds that are chemically related and known for their bactericidal properties (12). The antimicrobial effect of CHX is dose-dependent: at low concentration levels (0.02%-0.06%), a bacteriostatic action is obtained, conversely, at higher concentrations (> 0.12%), bactericidal (13,14).

The use of CHX in oral surgery could be crucial in preventing the accumulation of biofilm and accelerating the wound healing process, as well as in implant surgery as an antiseptic against bacteria responsible for peri-implant disease (15-17).

Ialunvance Complex (Euchlorine), considered as a possible alternative to CHX, consists of three main substances: Hydrogen Peroxide (H2O2), Hyaluronic Acid (HA) and Glycine.

Concerning H2O2, the main mechanism associated with it is its ability to neutralize volatile sulphury compounds (VSC), which are volatile sulphury compounds related to halitosis problems (18,19).

Another property of this chemical compound, when applied at a percentage between 0.5 and 3%, is its anti-inflammatory action. During wound healing, hydrogen peroxide induces chemotaxis and the adhesion of antibodies such as macrophages and neutrophils, which, through the release of proteases and elastases, determine the bactericidal activity of the solution (20).

In addition, H2O2 promotes the migration of keratinocytes to the surgical site, which promotes epithelial healing (21,22).

HA, a member of the glincosaminoglycan family, plays a significant role in tissue regeneration by promoting the development of granulation tissue; it also has an inflammatory effect and inhibits biofilm growth. Because its constituent molecules penetrate oral mucous membranes allowing a long-lasting effect, it is present at all stages of the wound healing process (23,24).

Glycine is the smallest non-essential amino acid and consists of a carbon molecule linked to an amine group and a carboxyl group. Due to its small size, it is able to form helices in proteins and act as an extracellular signaling molecule. Recently, in a study by T. Schaumann et al., it was shown that the amino acid glycine possesses anti-inflammatory and immunomodulatory properties in oral tissues and acts both by reducing the inflammatory state and by inhibiting macrophages and preventing the formation of free radicals (25,26).

The aim of this prospective clinical study was to compare Chlorhexidine 0.20% and Euchlorine in the post-operative management of patients undergoing oral and implant surgery, and to evaluate Placque Index (PI) and Bleeding on Probing (BoP) values according to type of mouthwash used, patient age, systemic diseases, smoking and surgical procedure.

MATERIALS AND METHODS

The current prospective clinical trial has been undertaken to systematically explore the efficacy of Chlorhexidine and Ialunvance Complex (Euchlorine) as post-surgical interventions. The methodology and reporting of this study followed the Strengthening the Reporting of Observational Studies in Epidemiology for Clinical Trials (STROBE-CT) guidelines.

Participants were recruited from the Department of Dentistry at San Raffaele Hospital in Milan, Italy, between January and September 2023. All procedures conducted on the enrolled patients adhered to ethical standards set by institutional and national research committees, as well as the principles outlined in the 1964 Declaration of Helsinki and its subsequent amendments. The study received approval from the ethics committee under approval number 190/INT/2021.

Partecipants

Inclusion criteria:

- Age > 18 years old;
- Patients subjected to implant or extractive surgery procedures;
- Subjects who were eligible for immediate loading and did not require regenerative surgical procedures for dental implant placement;

- Smokers;
- Affected by balanced systemic diseases.

Exclusion criteria:

- Absolute contraindications to implant-prosthetic rehabilitation or extractive procedures;
- Allergy to the tested substances;
- Inability to adhere to monitoring checks and professional hygiene maintenance protocols planned during the follow-up;
- Involvement in concurrent clinical trials that could interfere with the present protocol.

Surgical procedures

- Extraction of single extruded tooth
- Extraction of third molar in partial bone impaction;
- Extraction of third molar in total bone impaction;
- Placement of single immediate load dental implant;
- Placement of axial dental implants supporting immediate load bridges;
- Placement of axial dental implants supporting full-arch immediate load prostheses.

The surgical procedures were performed by three oral surgeons with at least 5 years of professional experience.

Antibiotic therapy (amoxicillin and clavulanic acid 1 g or clarithromycin 1 g in case of allergy, twice daily for 6 days after surgery) was prescribed and had to be taken from the day before surgery. Analgesic therapy (non-steroidal anti-inflammatory drugs, as needed) were provided for each patient. Chlorhexidine 0.20% or Ialunvance Complex (Euchlorine) (Fig.1) mouthwash were prescribed. The rinses had been done with 10 ml solution for about 1 minute each, twice a day for one week. An ultrasoft-bristled surgical toothbrush was recommended for the first three days after surgery, taking care not to brush the surgical area. Smoking patients were advised to abstain from smoking for 48 hours after the procedure.

Composition Aqua, hydrogen peroxide, PEG-40 hydrogenated castor oil, xanthan gum, VP/dimethiconylacrylate/polycarbamyl polyglycol ester, glycine, sodium hyaluronate, sodium saccharin, aroma, oxyquinoline sulfate, limonene, phenoxyethanol, caprylyl glycol, hexylene glycol.

Fig. 1. *Ialuvance Complex (Euclorina Gengive, Dompé S.p.A, Milan, Italy).*

Data collection and clinical outcomes

The clinical outcomes analysed were PI and BoP, recorded by two dental hygienists. The considered indices were initially measured at time 0 (T0), i.e. the day of the surgical procedure immediately prior to commencement; subsequently, they were detected at the following post-surgical stages:

- Time 1 (T1) = seven days after surgery, at the same time as suture removal;
- Time 2 (T2) = 30 days after the surgical procedure.

For each procedure, the PI and BoP parameters were measured at relevant sites according to the following chart (Table I).

Table I. *Recording sites of PI and BoP parameters according to type of surgical procedure performed.*

Surgical procedure	Recording sites
Extraction of single extruded tooth	Adjacent tooth/teeth
Extraction of third molar in partial bone impaction	Adjacent tooth (upper or lower second molar)
Extraction of third molar in total bone impaction	Adjacent tooth (upper or lower second molar)
Placement of single immediate load dental implant	Adjacent tooth/teeth
Placement of axial dental implants supporting immediate load bridges	Adjacent tooth/teeth and dental implants placed
Placement of axial dental implants supporting full-arch immediate load prostheses	Dental implants placed

PI

An erythrosine-based plaque detector was used to highlight surfaces prone to bacterial biofilm. The Williams periodontal probe was inserted into the gingival sulcus at the buccal, lingual/palatal, mesial and distal points.

Each surface was evaluated and ranked according to the amount of plaque present using a four-point scale:

- 0: Absence of plaque;
- 1: Slight plaque deposit perceptible only by passing the probe over the gingival margin;
- 2: Moderate plaque accumulation visible on objective examination;
- 3: Abundant plaque accumulation within the gingival sulcus and on the tooth surface.

The sum of all scores obtained was divided by the number of surfaces analysed and multiplied by 100 to obtain the percentage. Based on the score obtained, a diagnosis was made:

- 0-10%: Good oral hygiene;
- 10-20%: Moderate amount of plaque;
- 20-30%: High amount of plaque;
- 30%: High amount of plaque.

BoP

The Williams periodontal probe was inserted into the gingival sulcus at the mesial, medial, distal vestibular and lingual/palatal points. A force of 0.2 to 0.6 Newton was applied (28). Each probing point was given a score of 0 for no bleeding and 1 for no bleeding. The following formula was applied to calculate the BoP percentage: BoP (%) = (Number of positive bleeding sites/Total number of sites probed) x 100.

The reference values for diagnostic purposes were as follows:

- 0-10%: Good gingival health;
- 10-25%: Mild gingivitis;
- 25-50%: Moderate gingivitis;
- 50%: Severe gingivitis.

STATISTICAL ANALYSIS

The statistical analysis was conducted using Python 3.10.6 and the following packages: math, scipy, statsmodels, and pandas. Initially, a two-sample t-test was performed to assess differences in independent variables (Plaque Index and Bleeding on Probing) based on factors such as type of surgery, mouthwash usage, gender, systemic diseases, and smoking habits. For this analysis, systemic diseases and smoking behavior were one-hot encoded and treated as binary variables, distinguishing patients with or without any systemic disease or smoking habits. We computed effect size using Cohen's D. Normality and equality of variance of the independent variables were assessed using the Shapiro-Wilk test and Levene's test, respectively. The null hypothesis tested was that the two independent samples (Patients treated with Euclorin vs. subjects treated with Chlorhexidine) have identical average values. Throughout all analyses, p-values < 0.05 were deemed statistically significant.

To examine changes over time while considering within-subject correlations, repeated measures ANOVA (Analysis of Variance) with type II sum of squares was employed. This statistical method compares means of a variable across different time points and determines whether there are statistically significant differences over time. With type II sum of squares, each term's contribution to the sum of squares is calculated after adjusting for other terms in the model, independent of their order. The results of this analysis were evaluated using effect size, specifically partial eta squared, a variant of the eta squared effect size measure commonly used in ANOVA. Both eta squared and partial eta squared

quantify the proportion of variance explained by a particular independent variable in the total variance of the dependent variable.

Power Analysis/Sample Size/Normality Check

Power analysis on the sample size was performed using the following formula: $n = (Z\alpha/2+Z\beta)2\times\sigma 2\ ES2$, where σ is the estimated standard deviation, Zα/2 and Zβ are critical values for the chosen significance level and power, and delta is the effect size.

In our preliminary analysis, we have calculated the effect size, power, and significance of the sample size. These metrics collectively provide insights into whether the sample size is sufficiently large to support reliable statistical analysis. With a sample size of 60 participants, a significance level (alpha) of 0.05, and an effect size of 0.5, our power analysis indicates a power of 0.78 (1-beta). This suggests a high likelihood of detecting significant effects if they truly exist, maintaining a commonly accepted balance between Type I and Type II errors in our analysis.

Concerning power analysis, with a sample size of 60 participants, we obtained a significance level (alpha) of 0.05; the effect size, representing the magnitude of the observed difference, was estimated to be 0.5. Additionally, our analysis was powered at 0.78 (1-beta). That ensured a sufficient probability of detecting significant effects if they exist and a commonly accepted balance between Type I and Type II errors.

RESULTS

Sixty patients were included in the study. Sample features were as follows (Table II). Incidence of systemic diseases in the sample surveyed was as follows (Fig.2). A single surgery was performed for each patient. The surgical procedures were summarised as follows (Table III).

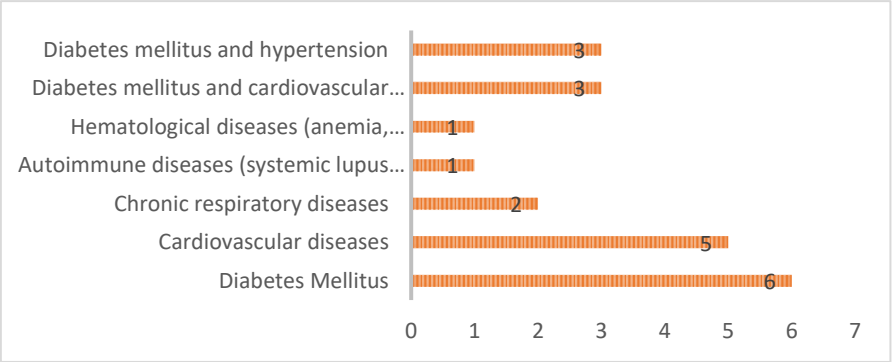

Fig. 2. *Incidence of systemic diseases in the sample surveyed.*

Table II. *Sample features according to gender, age, systemic diseases and smoking.*

	Sample features	
Gender	Female	31
	Males	29
Age	Average	46.5 years
	Range	21-72 years
Systemic diseases	Yes	24
	No	36
Smoking	Yes	16
	No	44

Table III. *Surgical procedures.*

Surgery	**Number of procedures**
Extraction of single extruded tooth	12
Extraction of third molar in partial bone impaction	10
Extraction of third molar in total bone impaction	12
Placement of single immediate load dental implant	10
Placement of axial dental implants supporting immediate load bridges	10
Placement of axial dental implants supporting full-arch immediate load prostheses.	9

Twenty-eight patients were prescribed chlorhexidine 0.20%, 32 with Ialunvance Complex. The results of the statistical analyses revealed notable findings regarding the factors influencing periodontal health outcomes.

BoP

The t-test analysis showed that bleeding on probing (BoP) after third molar extractions was significantly higher compared to other surgical procedures. The mean and standard deviation of BoP for third molar extractions were 3.5 ± 0.4, whereas for other surgical procedures they were 1.8 ± 0.2 ($p < 0.01$).

Gender differences were observed, with females exhibiting higher levels of BoP than males. The mean and standard deviation of BoP for females were 2.9 ± 0.3, while for males they were 2.1 ± 0.2 ($p < 0.05$). Smokers were found to have significantly higher BoP compared to non-smokers. The mean and standard deviation of BoP for smokers were 4.0 ± 0.5, while for non-smokers they were 2.2 ± 0.3 ($p < 0.01$).

The presence of systemic diseases did not yield significant differences in BoP. The mean and standard deviation of BoP for patients with systemic diseases were 2.7 ± 0.4, while for patients without systemic diseases they were 2.6 ± 0.3 ($p = 0.8$).

Statistically significant differences were found in BoP concerning the use of Ialunvance Complex versus Chlorhexidine mouthwash. The mean and standard deviation of BoP for Ialunvance Complex were 2.2 ± 0.2, whereas for Chlorhexidine they were 2.6 ± 0.4, demonstrating a significant improvement with the use of Ialunvance Complex ($p < 0.05$).

The results of Bleeding on Probing according to each category and related to each variable were summarized as follows (Fig.3).

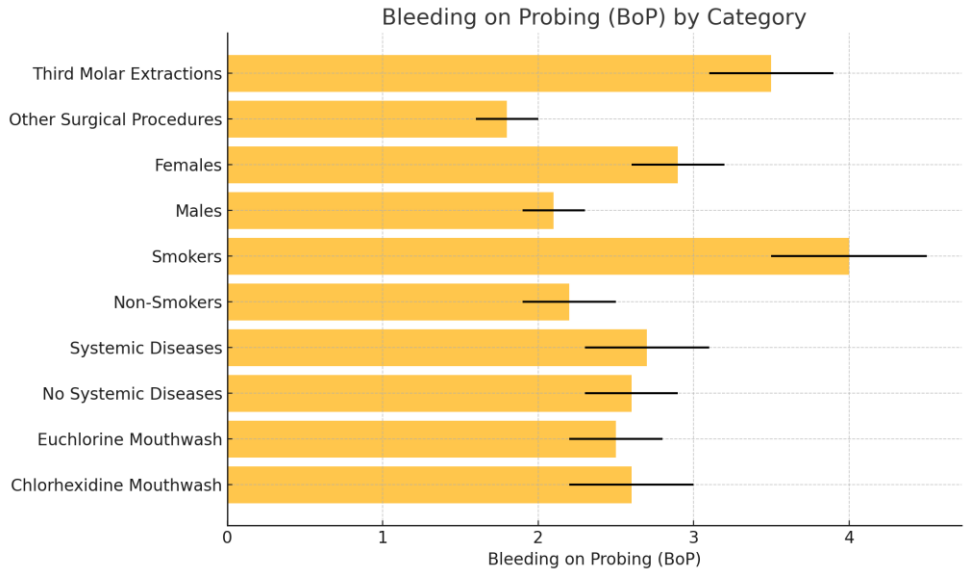

Fig. 3. *Mean BoP values and their standard deviations (represented by the error bars) for each category.*

The t-test analysis indicated that the Plaque Index (PI) following full-arch implant-prosthetic rehabilitations was significantly higher compared to other surgical procedures. The mean and standard deviation of PI for full-arch implant-prosthetic rehabilitations were 2.8 ± 0.5, whereas for other surgical procedures they were 1.6 ± 0.3 ($p < 0.01$).

No significant differences were noted in PI between genders. The mean and standard deviation of PI for females were 2.5 ± 0.4, while for males they were 2.4 ± 0.3 ($p = 0.5$). Smoking did not yield significant differences in PI. The mean and standard deviation of PI for smokers were 2.7 ± 0.4, while for non-smokers they were 2.6 ± 0.3 ($p = 0.6$).

The presence of systemic diseases did not yield significant differences in PI. The mean and standard deviation of PI for patients with systemic diseases were 2.7 ± 0.5, while for patients without systemic diseases they were 2.6 ± 0.3 ($p = 0.7$).

Furthermore, no statistically significant differences were found in PI concerning the use of Ialuvance Complex versus Chlorhexidine mouthwash. The mean and standard deviation of PI for Euchlorine were 2.6 ± 0.4, while for Chlorhexidine they were 2.7 ± 0.3 ($p = 0.8$).

The results of Plaque Index according to each category and related to each variable were summarized as follows (Fig.4).

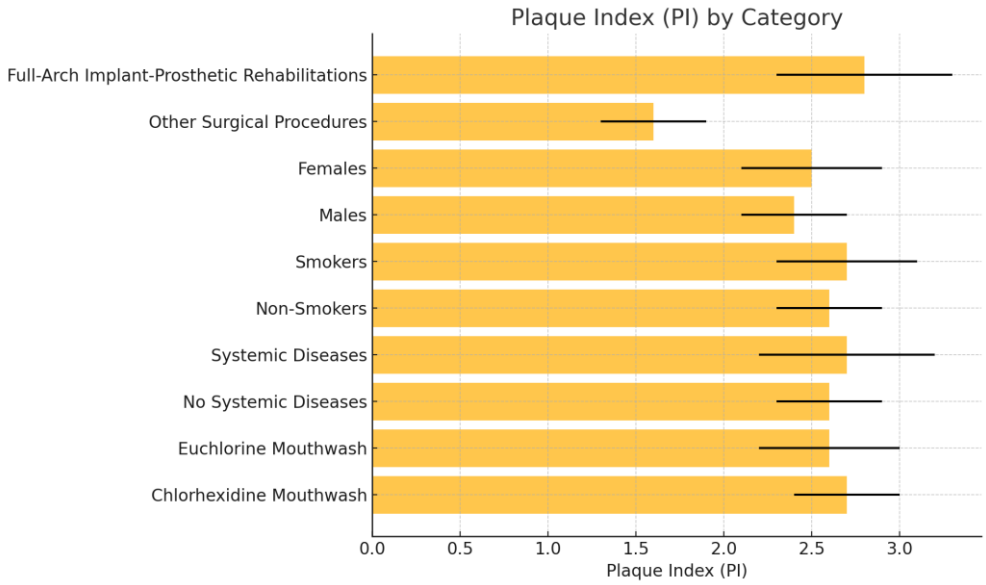

Fig. 4. *Mean PI values and their standard deviations (represented by the error bars) for each category.*

DISCUSSION

The aim of study was to compare Chlorhexidine 0.20% and Ialunvance Complex in the post-operative management of patients undergoing oral and implant surgery, and to evaluate Placque Index (PI) and Bleeding on Probing (BoP) values according to type of mouthwash used, patient age, systemic diseases, smoking and surgical procedure.

Concerning BoP the obtained results suggest that, after third molar extractions, it was significantly higher compared to other surgical procedures. Similar results were reported by Stella et al. (27) who, in their clinical study of 23 patients, evaluated the periodontal parameters of second molars following third molar avulsion and reported a significantly higher BoP. Contrasting results were reported by Pham et al. (28) who reported that, following avulsion of impacted third molars, the periodontal parameters of second molars, including BoP, were significantly lower and continuously improving.

With respect to gender, females exhibited higher levels of BoP than males. In this regard, the multicentre study by Zimmermann et al. (29) evaluated the possible impact of dental, socioeconomic, blood and biochemical factors on periodontal parameters and reported that there were no statistically significant differences between the sexes in terms of BoP. As stated by several studies (30-33), BoP values were also reported to be significantly higher in smoking than in non-smoking patients.

About the role of systemic diseases on BoP, the results obtained in the present study show no association. Contrasting results were reported by Herrera et al. (34) who reported a correlation between periodontal diseases and certain systemic diseases such as cardiovascular diseases, diabetes and respiratory diseases. These findings were confirmed by Ko et al. (35-36) and Schwarz et al. (37). In contrast, in accordance with our results, other authors have reported that systemic diseases, provided they are compensating, do not affect periodontal and peri-implant parameters (38).

The comparison of BoP indices between the use of Ialunvance Complex and Chlorhexidine mouthwashes revealed statistically significant differences favoring Ialuvance Complex. These findings align with recent research suggesting that different antiseptic agents can have varying degrees of effectiveness in reducing gingival inflammation and bleeding. Studies have demonstrated that Chlorhexidine, despite its well-documented efficacy in controlling plaque and gingivitis, can cause adverse effects such as tooth staining and taste alteration, which might influence patient compliance and ultimately its effectiveness in clinical practice. A systematic review highlighted that Chlorhexidine's side effects necessitate the exploration of alternative agents that could provide similar or enhanced benefits without the associated drawbacks (39).

On the other hand, Ialuvance Complex, which is less commonly discussed in the literature, appears to offer a comparable or even superior alternative to Chlorhexidine. The lower BoP indices associated with Ialunvance Complex suggest that it could be more effective in promoting periodontal health, potentially due to its different mode of action or patient tolerability. Recent studies have shown that herbal-based and alternative mouthwashes, like those containing Euchlorine, can be effective against common oral bacteria and reduce gingival inflammation, supporting the potential benefits observed in this study (40).

Concerning PI, following full-arch implant-prosthetic rehabilitations was significantly higher compared to other surgical procedures. Similar results were obtained in a six-year retrospective clinical study evaluating full-arch implant prosthetic rehabilitations. The study indicated that posterior sites exhibited greater plaque accumulation compared to anterior sites, likely due to the difficulty in maintaining hygiene in these areas (41).

No significant differences were noted in PI between genders, suggesting that gender does not play a substantial role in influencing plaque accumulation around dental implants. One possible explanation for this finding is that both males and females in these studies were subjected to similar oral hygiene protocols and follow-up care, which likely minimized any gender-based disparities in plaque control. Consistent and thorough oral hygiene practices are essential for all patients regardless of gender to maintain low PI levels and prevent peri-implant complications (41).

In contrast to what has been reported by other authors (42,43), in our study, smoking and systemic diseases did not yield significant differences in PI.

In addition, no statistically significant differences were found in the PI about the use of Ialunvance Complex mouthwashes compared to chlorhexidine-based ones.

Studies have shown that Ialunvance Complex, with its oxidizing action, effectively reduces bacterial load without the common side effects associated with chlorhexidine, such as tooth staining and taste alteration. This makes it an available alternative for patients who might experience adverse reactions to chlorhexidine (14). Furthermore, research has confirmed that both mouthwashes maintain similar efficacy in controlling plaque accumulation, ensuring that patients receive adequate protection against peri-implant diseases regardless of the mouthwash used (44).

CONCLUSIONS

Within the limitations of this study, Ialuvance Complex mouthwash could be considered more effective than Chlorhexidine 0.20% in reducing Bleeding on Probing. Although the Plaque Index was significantly higher in full-arch implant-prosthetic rehabilitations, it was not influenced by gender, smoking status, or the type of mouthwash used. Systemic diseases did not significantly impact either Bleeding on Probing or Plaque Index, suggesting that the choice of mouthwash and surgical procedure are more critical factors in post-operative management. Further clinical studies may be necessary to confirm the obtained results.

Author Contributions

Conceptualization, E.P. and R.V.; methodology, R.V.; software, A.B.; validation, E.P., R.V; formal analysis, S.S.; investigation, R.V.; resources, A.B.; data curation, B.D.; writing—original draft preparation, G.T.; writing—review and editing, X.X.; visualization, E.P.; supervision, E.P. All authors have read and agreed to the published version of the manuscript.

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Institutional Review Board Statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Ethics Committee of Vita-Salute San Raffaele University n.180/INT/2021, Dental School Department of Dentistry IRCCS San Raffaele Hospital, Milan, 20132, Italy.

Informed Consent Statement

Informed consent was obtained from all subjects involved in the study.

Conflict of interest

The authors declare that they have no conflict of interest.

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