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*Prospective Comparative Study*

# PROSPECTIVE COMPARATIVE STUDY OF CSR IMPLANTS PROSTHESIZED WITH CONOMETRIC TECHNIQUE: ANALOG VS DIGITAL TECHNIQUE

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## ABSTRACT

The growing interest in digital technologies has affected, in recent years, many areas of various fields of work, and dentistry is one of them; in fact, implantology and modern prosthetics are increasingly turning to digital technology. Both the traditional and digital impressions are operator dependent, so it is necessary that each prosthodontist, or rather any dentist, knows how to best capture the anatomical/mechanical details, in the case of implants, of each patient treated. Failure to do so would mean sending into production an artifact that already has underlying defects inherent in the impression taken poorly by the dentist or cast incorrectly by the dental technician. The purpose of this study is to compare analog and digital work-flow, in the design of the surgical and prosthetic procedures using CSR implants (CSR Implant System, Sweden&Martina, Due Carrare, Padua, Italy) associated with conometric technique. The innovative part of the CSR implants (CSR Implant System, Sweden&Martina, Due Carrare, Padua, Italy) lies in the DAT connection: a double internal conical contact interface between the abutment and the implant and between the screw and the abutment. In fact, the tapered technique that we find in the DAT connection just mentioned allows to obtain an implant-supported fixed prosthesis without the use of cement or screws fixation between abutment and prosthesis which, at the same time, is easily removable by the clinician, while still being a fixed prosthesis. The aim of this study is to evaluate the stability of implant prostheses rehabilitation, comparing the traditional technique (control group) with the digital technique (test group).

**KEYWORDS:** *digital impression, digital workflow, implant-prosthodontic restoration, intraoral scanner, full archrehabilitation, digital dentistry*

## INTRODUCTION

Nowadays in the digital age, the reading precision and accuracy of the scanners is becoming increasingly reliable and accurate, resulting in a precise and reliable fit of prosthetic artifact on abutments (1-7).

According to a recent study conducted by Peter Gehrke et al. in 2021 (8,9,10), it is inferred that the use of a cone-in-cone interface, analyzed by SEM analysis, avoids the creation of a micro gap at the cone-in-cone junction itself allowing a clinically and statistically optimal seal to avoid bacterial infiltration (Fig.1).

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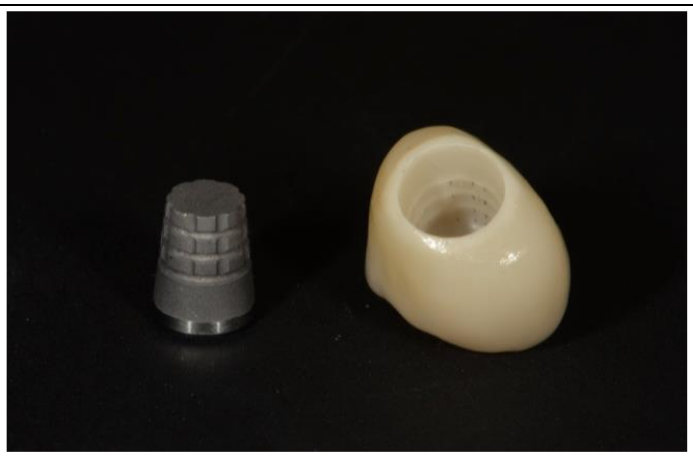

**Fig. 1.** *Cone-in-cone interface.*

According to various studies by Degidi M. et al. (11,12) the use of the conometric connection allows a fixation of the crown on the abutment without the use of screws and cement; this feature allows a lower percentage of bacterial infiltrate and a better accuracy of positioning, subsequently confirmed by endoral radiography. Moreover, the method of conometric prosthesis allows easier access in case of problematic situations, this is achievable by disassembling the crown using a dedicated clamp and repositioned with a fixation tool that exerts an axial force on the crown itself.

## MATERIALS AND METHODS

50 patients were enrolled in the study, 25 digital cases (DIG group) and 25 traditional cases (AN group). All the patients in the sample were treated at the Operating Unit of Dentistry and Dental Prosthetics of San Raffaele Hospital in Milan, Italy.

Every recruited patient underwent placement of an osseointegrated implant, and subsequently prosthesized either with a conometric technique using digital work-flow (DIG Group) or traditional one (AN GROUP) (Fig.2,3).

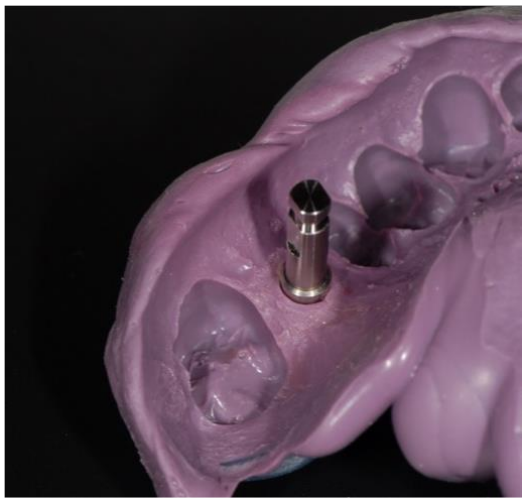

**Fig. 2.** *Analogical impression.*

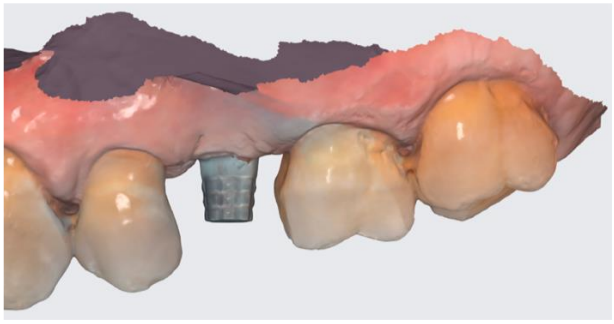

**Fig. 3.** *Digital impression.*

Once they receive the scan (whether it is in .stl or analog format), the dental technician proceeds to design and fabricate the shelled prosthetic construct within which he will then, using a direct method, cement the conometry coping using dual composite self-adhesive cement. Once the coping is cemented inside the prosthetic framework directly in the oral cavity, it is finished in the laboratory and the conometry is reactivated (Fig.4-9).

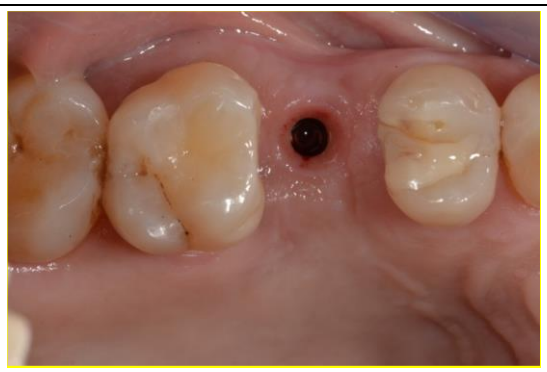

**Fig. 4.** *Perimplant tissues.*

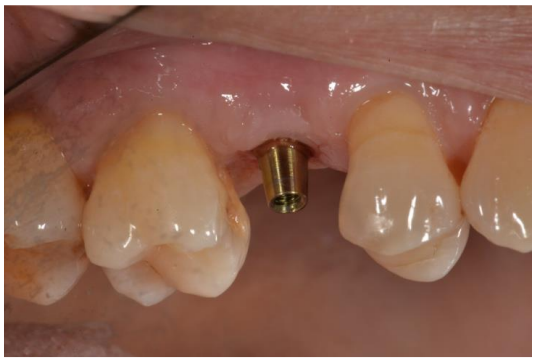

**Fig. 5.** *Vestibular view of the abutment.*

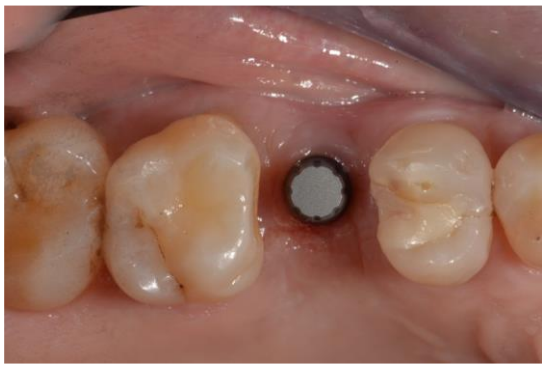

**Fig. 6.** *Occlusal view of the abutment with the cap in position.*

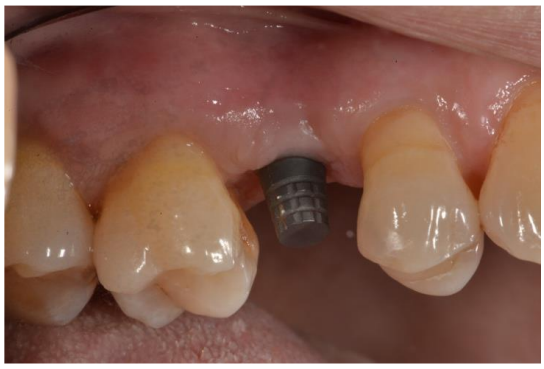

**Fig. 7.** *Vestibular view of the abutment with the cap in position.*

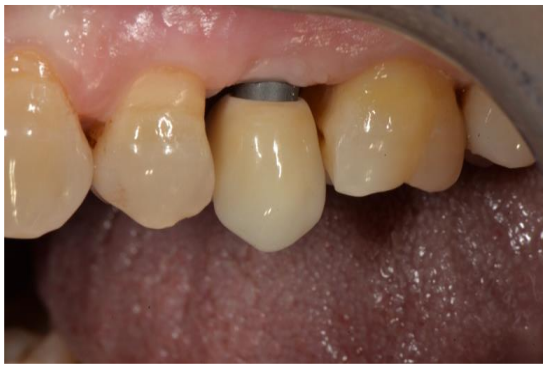

**Fig. 8.** *Crown in position over the cap.*

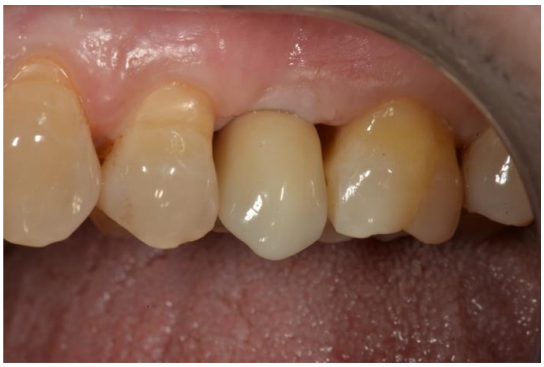

**Fig. 9.** *Final result.*

A sample size of 25 subjects in each group (DIG and AN, total of 50 patients) allows a test power of 1 - # = 0.95 and 1 - # = 0.79 for independent and paired comparisons, respectively, corresponding to a significance level of 0.05 and a Cohen's Effect Size d = 0.8 referring to the duration of prosthesis in relation to the loss or non-loss of the prosthetic artifact. Given a drop-out probability, estimated from previous clinical experience, of 0.15, the total initial number of patients to be recruited was 60 subjects (30+30).

Aesthetic assessment by a "blinded" clinician and patient satisfaction were measured during follow-up performed on the day of the placement of the tapered crown on CSR implant, at 3 (T1), 6 (T2) and 12 (T3) months after completion of the prosthetic phase.

The following assessments were performed:

1. Keratinized mucosal height (KM): measured from the mucogingival junction to the coronal margin of the free gengiva;
2. Disto Vestibular Probing Depth (PD-DL): the distance between the gingival margin and the bottom of the pocket on the disto-vestibular side;
3. Disto Lingual Probing Depth (PD-DL): the distance between the gingival margin and the bottom of the pocket on the disto-lingual side;
4. Radiographic bone loss around the implant, measured by monitoring changes in marginal bone level through

radiographs; a healthy implant should have less than 0.2mm of bone loss during the first year;

5. Patient satisfaction: measured by a satisfaction questionnaire.

## STATISTICS ANALYSIS

Prosthesis longevity will be analyzed using a Cox proportional hazards model. Considering an overall probability of failure of ! =0.20 (estimated from clinical experience) and a significance level " = 0.05, the expected sample size (# = 25 + 25) will allow a test power 1 - $ = 0.85 corresponding to an ln %% = 1.9.

A prosthesis is considered failed if it does not meet one or more of the reliability criteria that a dental prosthesis necessarily has: stability, function, aesthetics. A prosthesis, therefore, can be considered failed (0) or not failed (X).

## RESULTS

All patients included in this study completed surgical-prosthetic treatment by participating in all follow-ups required by this study; specifically, 14 male and 17 female patients were included for a total of 54 implants. At the time of implant placement, patients ranged in age from 25 to 70 years (50.5 ± 13.9).

During the predetermined follow-up period, there were 2 failed implants that were replaced after a period of bone regeneration and a prosthetic survival rate of 100%.

Values for each parameter were assessed by the same operator and with the same techniques to avoid errors in measurements.

*Keratinized mucosal height*

In the AN group, mean KM values were 2.90 mm; 3 mm; 3.27 mm respectively in a follow-up of 3, 6 and 12 months. In the DIG group, mean KM values were 2.51 mm; 3 mm; 3 mm respectively in a follow-up of 3, 6 and 12 months. Descriptive statistical analysis regarding mean KM values is shown in the table below (Fig.10).

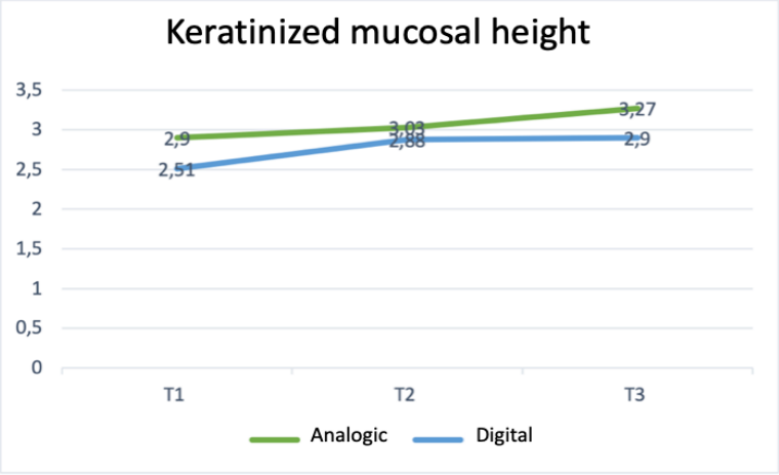


**Fig. 10.** *Keratinized mucosal height.*

*Disto-vestibular Probing Depth*

In the AN group, the mean PD DV values were 2.43mm; 1.95mm ;1.81mm respectively in a follow-up of 3, 6 and 12 months. In the DIG group, the mean PD DV values were 2.14 mm; 1.88mm ;1.7 mm in a follow-up of 3, 6 and 12 months, respectively. The descriptive statistical analysis regarding the mean PD DV values is shown in table below.

*Disto Lingual Probing Depth (PD-DL)*

In the AN group, the mean values of PD DL were 1.68 mm; 1.50 mm ;1.59 mm respectively in a follow-up of 3, 6 and 12 months. In the DIG group, the mean values of PD DL were 1.684 mm; 1.69 mm ;1.76 mm respectively in a follow-up of 3, 6 and 12 months. (Fig.11, Table I)

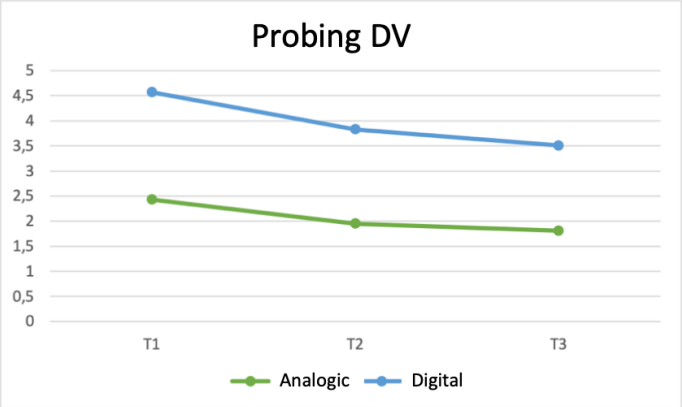


**Fig. 11.** *Probing DV.*

**Table I.** *Probing DV during T1; T2; T3.*

| PD DV | GROUP | MEAN (mm) | STAND DEV |
|---|---|---|---|
| **T1** | AN | 2,43 mm | 0,54 |
| | DIG | 2,14 mm | 0,59 |
| **T2** | AN | 1,95 mm | 0,50 |
| | DIG | 1,88 mm | 0,55 |
| **T3** | AN | 1,81 mm | 0,47 |
| | DIG | 1,7 mm | 0,45 |

The descriptive statistical analysis regarding the mean PD DV values is shown in table below (Table II, Fig.12).

**Table II.** *Probing DL during T1; T2; T3.*

| PD DL | GROUP | MEAN (mm) | STAND DEV |
|---|---|---|---|
| **T1** | AN | 1,68 mm | 0,33 |
| | DIG | 1,684 mm | 0,59 |
| **T2** | AN | 1,50 mm | 0,28 |
| | DIG | 1,69 mm | 0,51 |
| **T3** | AN | 1,59 mm | 0,22 |
| | DIG | 1,76 mm | 0,75 |

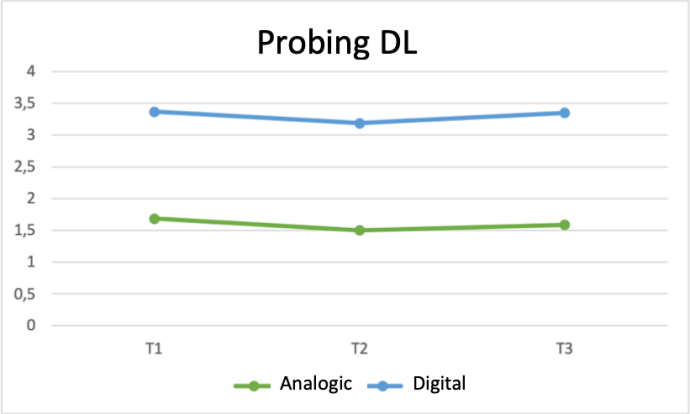


**Fig. 12.** *Probing DL.*

*Evaluation of Radiographic Parameters*

In the AN group, the mean marginal bone loss values were 1.50 mm; 1.64 mm; 1.72 mm in a follow-up of 3, 6 and 12 months, respectively. In the DIG group, the mean marginal bone loss values were 1.56 mm; 1.78 mm; 1.8 mm at a follow-up of 3, 6 and 12 months, respectively. Descriptive statistical analysis regarding the mean bone loss values is shown in the table below (Table III, Fig.13).

**Table III.** *Loss of bone in T1; T2; T3.*

| LOSS OF BONE | GROUP | MEAN (mm) | STAND DEV |
|---|---|---|---|
| **T1** | AN | 1,50 mm | 0,54 |
| | DIG | 1,56 mm | 0,55 |
| **T2** | AN | 1,64 mm | 0,534 |
| | DIG | 1,78 mm | 0,532 |
| **T3** | AN | 1,72 mm | 0,56 |
| | DIG | 1,80 mm | 0,53 |

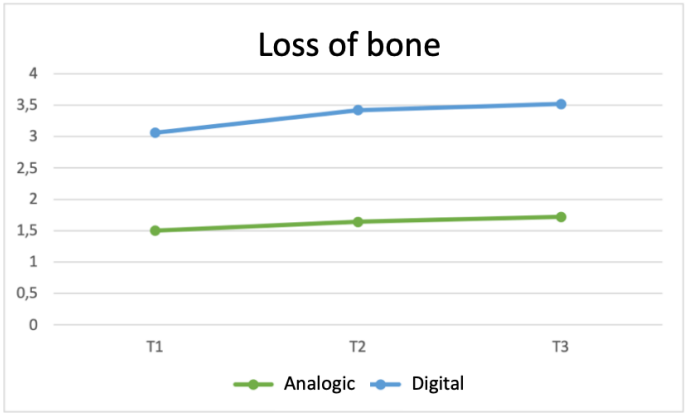


**Fig. 13.** *Loss of bone.*

*Patient Satisfaction*

The VAS scale score regarding patient satisfaction (digital vs. analog flow) is summarized in Table IV.

During impression taking, the digital group reported greater comfort with:

- Mean VAS value of 91±11.60 for the AN group and 98.61±2.72 for the DIG group.
- Gag reflex almost absent in the DIG group with mean values of 99.81±0.25 (vs. 85.73±6.57 for the AN group.
- Greater comfort for the DIG group during acquisition with mean value of 99.87±0.34, compared to the AN group in which we have as mean score 86.13±7.01.

- Overall, however, the two groups did not differ, from a clinical point of view, in terms of the patient's willingness to hypothetically undergo the procedure again (mean value AN group 97. 06 ± 10. 30 and DIG group 97.06±10.27).

On the other hand, regarding satisfaction in terms of cosmetic and functional outcome, for both AN and DIG groups, they were both above 95 score (Table IV).

**Table IV.** *Patient Satisfaction.*

| QUESTION | GROUP | MEAN + SD |
|---|---|---|
| **1** | AN | 95,13±3,37 |
| | DIG | 97,00±2,22 |
| **2** | AN | 93,53±7,83 |
| | DIG | 96,5±2,60 |
| **3** | AN | 98,4±2,69 |
| | DIG | 98,5±2,83 |
| **4** | AN | 86,13±7,01 |
| | DIG | 99,87±0,34 |
| **5** | AN | 85,73±6,57 |
| | DIG | 99,93±0,25 |
| **6** | AN | 76,86±13,73 |
| | DIG | 99,81±0,40 |
| **7** | AN | 85,66±17,54 |
| | DIG | 97,12±2,15 |
| **8** | AN | 98,66±5,16 |
| | DIG | 98,75±5,00 |
| **9** | AN | 97,06±10,30 |
| | DIG | 97,06±10,27 |
| **10** | AN | 97,00±10,30 |
| | DIG | 99,31±2,49 |

## DISCUSSION

Implant-prosthetic rehabilitations are playing an increasingly prominent role within the dental field both because of the patient's increasing desire to obtain fixed rehabilitation and because of the implementation of new techniques and technologies.

Traditional methods, whether in surgical or prosthetic, remain the reference procedures to evaluate efficacy and accuracy of new technologies and new workflows.

The best way to rehabilitate an edentulous area through implant- prosthetic treatment, whenever feasible, is also influenced by the superior survival rate compared to removable alternatives. This consideration was also confirmed by a 2021 study by Kurosaki et al. (13,14). This study demonstrated that 6 years after prosthetic rehabilitation, there was a survival rate of 94.7 percent for fixed implant- supported prosthetic rehabilitation, 77.4 percent for fixed prostheses and 33.3 percent for removable partial dentures. According to the results obtained in this study, 2 implant failures were recorded out of 54 implants placed.

Regarding implant failure, however, no significant differences were found between the two groups with a p value of 0.9979 at t1 and 0.9988 at time t2 with mean bone loss values of 1.5±0.54 for AN group and 1.56±0.55 for DIG group at time t1 and 1.64±0.534 for AN group and 1.78±0.532 for DIG group at t2, respectively.

Prosthetic rehabilitations, whether on implants or natural elements, must be meticulously planned and executed in order to achieve good prosthetic support that succeeds in adequately unloading the masticatory forces; for these purposes, certainly the digital technologies have been a major help. Indeed, with the introduction of digital technologies, great precision can be achieved in both implant and prosthetic placement.

Regarding the surgical phase through digital methods, the operator can plan implant placement through software that allows to simulate the size and position of the implant through the patient's CBCT, and also to mark reference anatomical points in order to avoid damage, and to make the procedure more predictable and reliable.

During the prosthetic phase, digital technology has taken an even more preponderant role. New technologies can be used in every phase of treatment such as planning, impression taking, design and follow-up.

During planning, digital technologies can be used for diagnosis, results preview and decision making. Then, moving on to impression taking, through intraoral scanners which allows to transfer or store information through ".stl" files; this guarantees clear communication between clinician and dental technician (15-17). Coming to the use of digital devices in design phase, it's possible to rely on dedicated software to design and produce a costumed prosthesis that fit perfectly, esthetically and functionally. Finally, intraoral scanners (I.O.S.) can also be used in follow-ups, where it can be seen if there are any changes that may affect both the soft tissues and the fit of the prosthetic artifacts (15-17).

However, regardless of the traditional or technological methods used, they must be accompanied by good professional and home oral hygiene with the dedicated aids recommended by the practitioner (18).

A study by Muhlemann et al. in 2018 (19) shows that when analyzing the advantages that are obtained through digital technologies for implant-supported rehabilitations, it's possible to evaluate better efficiency when designing prostheses through CAD/CAM methodologies compared to conventional workflow. Regarding the results obtained during this study, there were 2 prosthetic failures in the AN group due to disconnection of the conometric rehabilitation. This result, however, doesn't lead to a significant difference between the two groups evaluated, similarly to implant failure, with p values of 0.9989 at T1 and 0.9979 at T2.

According to a study by Oh T-J et al. in 2005, it was seen that commercially available implant systems recognized as medical devices have an implant-abutment connection accuracy of 1 to 10 μm. Taking into consideration that the average size of the most common bacteria colonizing the oral cavity is 0.3-5 μm it is predictable a fast and easy colonization of the implant connection surface.

According to a 2016 study by E.F. Gherlone and P. Capparè, 80 implants divided into 8 groups based on connection and implant type were considered; it was seen that the cone connection had a lower contamination rate than the other 7 types of implants (3). Specifically, bacteria being closely correlated with the presence of bleeding and plaque, we showed that 35.19% of patients had bleeding and the remaining 64.81% had no bleeding. Similarly, the presence of plaque was shown for 33.34% and the absence of plaque for the remaining 66.66%.

The presence of plaque and bleeding, and thus inflammation of the peri-implant soft tissues, also negatively affects the formation of new keratinized tissue around the implant itself. The bacteria colonization of the implant surface leads to the activation of chemotactic stimuli that brings to the recruitment of inflammatory cells and thus peri-implant inflammation that, if unchecked, leads to subsequent bone loss or even implant failure (20,21). In this study, the height of keratinized tissue (KM) was also evaluated, resulting in no statistically significant difference in the mean of KM at varying impression type (P=0.70) nor at varying time (p=0.19), nor that there is a different outcome comparing the impression method in different times, T1, T2 and T3(interaction, p=0.55).

Clinical and radiographic results in T3 show no significant differences between an analog and digital workflow in conometric implant prosthetic rehabilitations on CSR implants.

## CONCLUSIONS

The results of this prospective observational study with one year of follow-up and 54 implants placed showed that there are no statistically significant differences between an analog and a digital workflow in conometric prosthetic rehabilitations on CSR implants.

This type of implant has been demonstrated in the literature to be superior to traditional connections in terms of bacterial sealing and micromovements at the implant-abutment interface. Objective clinical and statistical evaluation demonstrated excellent survival in both implant and prosthetic phases. In addition, data acquired through a patient satisfaction questionnaire showed a preference for the digital protocol in terms of both comfort and timing.

In conclusion, the protocol of this prospective observational study will continue with further clinical studies to confirm the results obtained.

*Conflict of interest*

The authors declare that they have no conflict of interest.

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