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Angled implant brush for hygienic maintenance of full-arch fixed-implant rehabilitations: a pilot study

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ABSTRACT

Purpose: This pilot study was conducted to evaluate the cleaning efficacy of an angled implant brush for home oral hygiene of full-arch fixed-implant prostheses.
Methods: Forty-one patients treated with a full-arch implant rehabilitation in the maxilla or mandible (164 implants) for at least 4 months were enrolled. The screw-retained fixed prostheses were removed and baseline (T0) parameters were recorded, including plaque index (PI), probing depth (PD), and bleeding on probing (BOP). All patients completed a 5-item questionnaire on hygiene maintenance and received an implant brush for home hygiene. After 1 month (T1) PI, PD, and BOP were recorded again and patients completed a 7-item questionnaire to evaluate their satisfaction with the implant brush. One-way repeated-measures analysis of variance was conducted to evaluate the significance of changes in PI, PD, and BOP. A P value <0.05 was considered to indicate statistical significance.
Results: A statistically significant reduction of BOP (0.62±0.6 at T0 vs. 0.5±0.5 at T1; P=0.032) was found, while no statistically significant changes in PD (1.74±0.5 mm at T0 vs. 1.77±0.5 mm at T1; P=0.050) or PI (1.9±0.7 at T0 vs. 1.7±0.7 at T1; P=0.280) occurred. According to the 7-item questionnaire, patients reported no difficulty in using the angled brush (63.4%) and deemed it highly (46.3%) or very highly (4.8%) effective in improving their home oral hygiene.
Conclusions: Within the limits of the present pilot study, the patients experienced a reduction of BOP 1 month after being instructed to use the angled implant brush. The angled implant brush appeared to be a well-accepted device for home-care hygiene of full-arch fixed-implant rehabilitations.

Keywords: Dental implants; Implant-supported dental prosthesis; Oral hygiene; Dental plaque; Toothbrushing

INTRODUCTION

Immediate loading full-arch rehabilitations supported by dental implants have been demonstrated to be a predictable and effective approach to treat completely edentulous or seriously compromised dental arches [1-6]. However, early and late failures of implant

Author Contributions

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Conflict of Interest

No potential conflicts of interest relevant to this article was reported.

restorations have been reported in the literature. Implant failures have been attributed both to mechanical and biological complications, such as uncontrolled occlusal overload of the implants after prosthesis delivery and peri-implant infection induced by plaque accumulation [7-12].

Previous studies have investigated the relationship between the presence of inflammation at dental implant sites (i.e., peri-implant mucositis and peri-implantitis) and the presence of plaque [13-15]. Several authors have maintained that the effective removal of bacterial biofilm plays a pivotal role in promoting the long-term success of implant treatment [10,11,16-18].

Prevention and prompt treatment of peri-implant tissue inflammation includes a combination of both regular scheduled appointments for supportive therapy and proper daily oral hygiene performed at home by patient [19-21]. However, clearly defined protocols concerning the professional and home-care hygienic management of patients wearing a full-arch fixed-implant prosthesis are scarce in the literature [3,13,19,22,23]. The achievement of a satisfactory level of oral hygiene during post-implant rehabilitation may be influenced negatively by a series of factors relating to the patient and to the prosthodontic restoration. Patients who have been totally edentulous or with a compromised dentition for a long period of time before undergoing immediate-loading implant surgery might exhibit poor compliance with self-hygienic oral care [10,11,22,24]. Moreover, motivation to maintain adequate plaque control and manual dexterity tend to decrease with age [11,25].

As regards the prosthodontic restoration, acrylic resin and composite resin are commonly used as veneering materials for the fabrication of full-arch implant prostheses [1,9], since their shock-absorption properties allow them to reduce dangerous occlusal stresses and micro-motion on immediately loaded implants [26]. However, resinous materials retain more bacterial plaque [27] than other prosthetic materials that come into in contact with mucosal tissues, such as dental ceramics [28] or titanium [1]. Full-arch fixed-implant prostheses often contain sites where food debris may accumulate (e.g., the areas between peri-implant tissues and the prosthodontic bridge) and contours through which it is difficult to pass cleaning instruments [1,29,30], especially on the lingual surface of implant prostheses with artificial gum tissue [3].

The main cleaning devices for home oral hygiene of implant-supported fixed prostheses are manual and powered toothbrushes [10,11,23,31], inter-proximal brushes [21,32], and dental floss [3,16]. Some authors have proposed modifying the shape of conventional manual toothbrushes to enable patients to clean the entire implant prosthesis, even the most difficult areas, such as distal and lingual/palatal sites and underneath the artificial gum [33]. Although modern-designed implant brushes have been introduced to the market by many manufacturers, to the authors' knowledge, studies on the beneficial effects of these cleaning instruments are still lacking.

Therefore, the primary aim of the present pilot study was to assess the effectiveness of an angled implant brush to improve the hygiene of full-arch fixed implant prosthesis over a period of 1 month. Additionally, patients' satisfaction related to the use of the angled implant brush to accomplish daily oral hygiene was investigated. The null hypothesis tested was that there would be no differences in the plaque index (PI), probing depth (PD), and bleeding on probing (BOP) around implants before and after using the angled implant brush.

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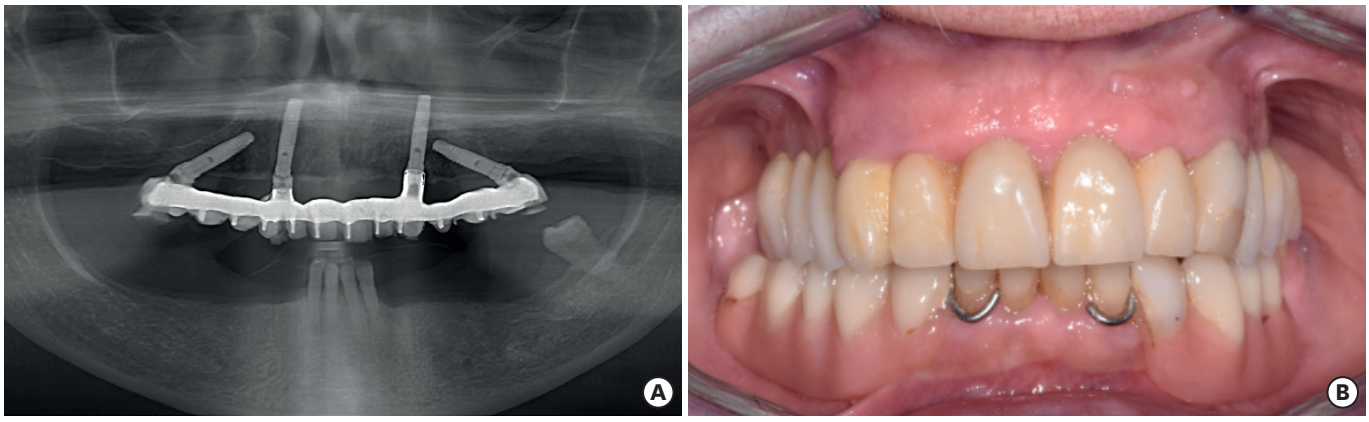

Figure 1. Immediate-loading full-arch implant fixed rehabilitation of the upper jaw following the Columbus Bridge Protocol. (A) Panoramic radiograph taken 1 month after delivery of the full-arch fixed implant prosthesis. (B) Clinical view of the implant rehabilitation on the upper arch at the time of the study (T0). T0: baseline evaluation.

MATERIALS AND METHODS

Study design and population

The present research was designed as a single-center, 1-month prospective study among patients treated with full-arch, screw-retained implant rehabilitations in the upper or lower jaw. Patients were enrolled if they met the following inclusion criteria:

(1) Age ≥18 years;
(2) Good general health, with an American Society of Anesthesiologists risk score<2;
(3) Patients provided with a screw-retained full-arch prosthesis supported by 4 to 6 implants in the upper or lower jaw according to the Columbus Bridge Protocol (CBP) [4,9] for at least 4 months (Figure 1A and B).

The exclusion criteria were:

(1) Heavy smokers (≥10 cigarettes/day);
(2) Pregnant or lactating women;
(3) Autoimmune mucosal diseases (e.g., lichen ruber planus, systemic lupus erythematosus, pemphigus, etc.);
(4) Diseases affecting the ability to use the dominant hand (e.g., recent traumatic injuries of the hand and/or the arm with or without bone fractures, autoimmune rheumatic diseases, peripheral neuropathy, etc.);
(5) Biological complications (e.g., failure of the osseointegration process, implant mobility, or implant loss) affecting at least 1of the implants after delivery of the implant-supported prosthesis;
(6) Mechanical complications (e.g., the fracture of implant prosthodontic components) affecting at least 1of the implants after delivery of the implant prosthesis;
(7) Treatment with medications associated with gingival tissue growth as a side effect (e.g., antiepileptic and immunosuppressant drugs or calcium channel antagonists);
(8) Use of cortisone or antibiotics within the previous 3 months or during the study period;
(9) Peri-implantitis affecting at least 1implant. Peri-implantitis was defined according to the criteria of Lindhe and Meyle [15] (PD ≥5 mm combined with positive BOP and suppuration, radiographic detection of marginal bone loss ≥2 mm measured from the implant shoulder, or implant thread exposure ≥1 mm compared with the bone level on a previous radiograph).

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Table 1. Patients' characteristics (n=41)

Characteristics	Values
Sex	
Male	20 (48.8)
Female	21 (51.2)
Age (years)	
Mean±SD	65.5±8.6
Range	50–85
Time of implant rehabilitation (years)	
Mean±SD	4.85±2.3
Range	1–10
Arch	
Lower dental	14 (34.1)
Upper dental	27 (65.9)
Tobacco smoking	
Yes	10 (24.4)
No	31 (75.6)

SD: standard deviation.

The study protocol followed the guidelines of the World Medical Association Declaration of Helsinki and was approved by the local Ethical Committee of the University of Genoa (authorization No. 528; Genoa, Italy). Between February and June 2019, 41 patients (20 men, 21 women) with a mean age of 65.5 years (range, 50–85 years) were enrolled in the study (Table 1). The participants had been in rehabilitation for a mean time period of 4.85 years (range, 1–10 years) after receiving full-arch immediate-loading fixed-implant prostheses according to the CBP (Figure 1A and B) [4,9].

The CBP is an immediate-loading surgical and prosthodontic protocol developed for the rehabilitation of atrophic and edentulous maxillae and mandibles using distal tilted implants (upper jaw: implants placed parallel to the anterior sinus wall; lower jaw: implants placed obliquely angled above the mental foramen). The protocol requires sufficient bone volume to accommodate 4 to 6 implants with lengths ≥13 mm. All of the dental implants were tapered implants with an external hexagon connection (diameter, 4 mm; length ≥13 mm) (Full Osseotite implants; Biomet 3i, Palm Beach Gardens, FL, USA). Conical abutments (0°, 17°, 25°, and 45°) were used to optimize the position of the screw access openings of the tilted implants within the prostheses. The fixed screw-retained bridges delivered 24 hours after surgery were fabricated with metal frameworks in order to provide increased strength and rigidity to the prostheses. The occlusal surfaces of the prostheses were made of composite resin.

Ten patients (5 men, 5 women) who were current smokers (<10 cigarettes/day) were included within the sample (Table 1). After receiving a detailed explanation of the study protocol, all subjects signed a consent form to participate in the present research.

Baseline assessment

At the start of the study (T0), each patient answered a 5-item anonymous questionnaire on oral hygiene habits that was specifically developed for this study. In detail, patients were asked to indicate:

(1) How many times a day they performed home oral hygiene.
(2) What devices they used to clean their mouth and their implant prostheses (choosing among the following instruments: manual toothbrush with soft bristles, manual toothbrush with medium bristles, powered toothbrush, irrigator, angled implant brush, 0.12% chlorhexidine mouthwash, implant floss, inter-proximal brush, other cleaning

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means not included in the previous list).
(3) What degree of difficulty they encountered during home oral hygiene maneuvers (selecting 1of the following 5 descriptors: none, slight, medium, high, or very high).
(4) What degree of effectiveness they perceived relating to their own ability to keep their mouth in a healthy condition through their daily hygienic routine (selecting 1of the following 5 descriptors: none, slight, medium, high, very high).
(5) Whether they would have liked to receive more detailed hygienic and dietary advice for the home-care management of full-arch implant rehabilitations after the delivery of their implant prosthesis (yes or no).

Patients were left alone during the compilation of the questionnaire in order to avoid biasing their answers, and were given at least 5 minutes to complete the questionnaire. Upon request, a researcher provided further clarifications to help participants better understand 1or more items of the questionnaire.

Subsequently, a clinician removed the screw-retained full-arch implant prosthesis from the upper or lower jaw in order to record peri-implant tissue health parameters (PI, PD,and BOP) as described in a previous paper [13]. The presence of suppuration or calculus was also recorded. The majority of the patients presented conical abutments screwed onto the implants, so periodontal recording was performed at the abutment level.

PI was assessed at 4 sites (mesial, buccal, distal, lingual) on each implant/abutment with a disclosing solution (Butler GUM Red-Cote liquid; Sunstar Americas, Chicago, IL, USA) [13,34]. A PI value ranging from 0 (no presence of plaque) to 4 (all the implant/abutment surfaces covered by plaque) was recorded for each implant/abutment.The gum tissue around the abutments was softly dried with an air blast, and then the clinician applied the disclosing solution on each implant/abutment surface with a cotton swab, covering up to 5 mm of gum. Subsequently, patients rinsed their mouths with water and expectorated carefully.

PD was evaluated at 4 sites (mesial, buccal, distal, lingual) of each implant/abutment as the distance between the peri-implant mucosal margin and the bottom of the peri-implant sulcus. A manual plastic probe (UNC 12 Color Vue Probe; Hu-Friedy, Chicago, IL, USA) was used with a force of approximately 0.2 N, and PD measurements were rounded to the nearest millimeter [13].

BOP (yes/no) was recorded at 4sites (mesial, buccal, distal, lingual) on each implant/abutment immediately after PD evaluation, and values ranged from 0 (no presence of BOP) to 4 (all the implant/abutment surfaces presented BOP) [13,35]. In addition, global percentage values of PI and BOP were calculated at the patient level as the ratio between the number of implant/abutment surfaces (mesial, buccal, distal, lingual) presenting plaque or BOP and the total number of surfaces (i.e., 4 surfaces for each implant/abutment).

The tightening of each abutment and the immobility of each implant were evaluated, and the implants/abutments were not cleaned at T0.

Intervention

Once the clinical assessments were accomplished, all the implant prostheses were reinserted and patients received an angled implant brush (TePe Universal Care, TePe Oral Hygiene Products AB, Malmö, Sweden).

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Figure 2. Implant brush with angled neck used in the present study (Tepe Universal Care).

The implant brush used in this study hada small head and an angled neck, in order to allow easier access to implant abutment surfaces from the lingual/palatal side (Figure 2). According to patients' needs, the thermoplastic neck of the implant brush could be bent to several degrees of angulation after immersion in hot water for some minutes. The implant brush bristles were long, round-ended filaments with medium hardness. Patients were requested to use the implant brush after every meal (3 times a day) in order to clean the implant abutments and the areas between the prosthodontic bridge and the gum from the lingual/palatal side, brushing along the gum line after every meal, in addition to any other cleaning devices that they used (Figure 3A). Patients were instructed on how to use the implant brush and attended a short training session of 10 minutes that comprised a demonstration with models and in-mouth practice under the supervision of an expert dental hygienist (Figure 3A and B).

Follow-up assessment

After 1 month, patients were recalled for a check-up appointment (T1). PI, PD, and BOP were recorded, following the same procedural steps previously described for the assessment at T0. The tightening of each abutment and the immobility of each implant were verified again. After completing the clinical evaluation and screwing in the implant prostheses, patients were asked to fill in a 7-item anonymous questionnaire relating to their satisfaction with the implant brush.

(1) How many times per day they performed oral hygiene;
(2) How many times per day they used the implant brush during the study period;
(3) What devices they used to clean their mouth and their implant prosthesis during the study period (the list of instruments was the same as on the T0 questionnaire);
(4) The degree of difficulty they experienced when using the implant brush (selecting 1 of the 5 descriptors: none, slight, medium, high, very high);

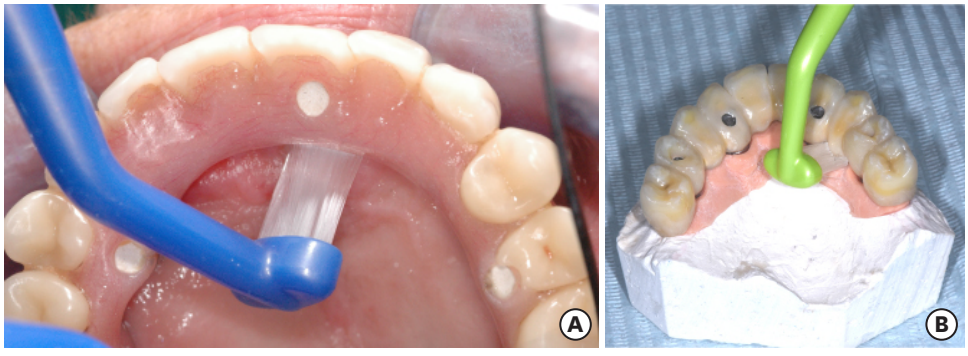

Figure 3. Training session with the angled implant brush. (A) In-mouth practice with the implant brush. (B) Demonstration of the correct use of the implant brush using a model.

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(5) The degree of effectiveness they felt relating to their own ability to keep their mouth in a healthy condition with the aid of the implant brush (marking 1 of the 5 descriptors: none, slight, medium, high, very high);
(6) Whether they were willing to continue to use the angled implant brush for daily oral hygiene (yes, no, maybe);
(7) Whether they would recommend it to their friends or family (yes, no, maybe).

Patients were left alone when they completed the questionnaire to prevent bias. Upon explicit request, further clarifications relating to 1 or more items of the questionnaire were given. The questionnaire also included a large space for free comments.

Statistical analysis

One-way repeated-measures analysis of variance was conducted to evaluate the significance of changes over time in PI, PD, and BOP. Differences between T0 and T1 in PI, PD, and BOP were evaluated at the patient level (n=41). The Kruskal-Wallis test was used to evaluate differences over time in PD, BOP, and PI among patients who performed oral hygiene once, twice, or three times a day. The Mann-Whitney test was used to analyze differences over time in PD, BOP, and PI between smokers and non-smokers, as well as between patients who used the angled implant brush once daily versus those who used it multiple times. *P* values <0.05 were considered to indicate statistical significance. SPSS version 20.0 (IBM Corp., Armonk, NY, USA) was used for the analysis.

RESULTS

Clinical evaluation

Data on 41 patients and 164 implants were collected and analyzed. Ten patients who met the inclusion and exclusion criteria did not agree to participate in the study because they were not willing to come back for the follow-up appointment after 1 month and/or because they refused to have the fixed prostheses removed for the recording of soft tissue health parameters. All the included patients (n=41) attended the scheduled follow-up appointment at 1 month, and all patients completed all the questions on the questionnaires.

At both T0 and T1, all the dental implants were stable and functional. No implants presented suppuration or calculus at any time point. All the original fixed prostheses were functional and did not need to be replaced, and no fractures of the veneering material occurred during the 1-month follow-up. Seven implant abutments were tightened at T0, while no abutments were found to be loose at T1.

No patients reported the need to bend further the plastic neck of the implant brush while immersing it in hot water to carry out hygienic procedures during the study period. Eleven patients (4 men, 7 women) reported having performed oral hygiene even on the buccal side of the full-arch implant prostheses with the aid of the angled implant brush.

Peri-implant health parameters are shown in Table 2. A statistically significant decrease (P=0.032) in BOP at the patient level was found between T0 and T1. The global BOP value calculated at the patient level for the 41 patients was 15.54% at T0 and 12.35% at T1. No statistically significant changes were found for PI (P=0.280) or PD (P=0.050). The global PI value calculated at the patient level for the 41 patients was 47.1% at T0 and 41.9% at T1.

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Table 2. Peri-implant health parameters

Parameters	T0		T1		*P* value
	Mean±SD	Min–Max	Mean±SD	Min–Max	
PD (mm)	1.74±0.5	1–4	1.77±0.5	1–4	0.05
BOP	0.62±0.6	0–4	0.5±0.5	0–3	0.032[a)]
PI	1.9±0.7	0–4	1.7±0.7	0–4	0.28

PI, PD and BOP were evaluated at the patient level (n=41). A statistically significant difference in BOP was found between T0 and T1, with a lower BOP value at T1 (n=41).
T0: baseline evaluation, T1: follow-up evaluation, PD: probing depth, BOP: bleeding on probing, PI: plaque index, SD: standard deviation, Min: minimum, Max: maximum.
[a)]Statistically significant difference.

No statistically significant difference between smokers and non-smokers was found in the changes from T0 to T1 of PD (P=0.200), BOP (P=0.314), and PI (P=0.988).

Questionnaire evaluation

Patients' answers to the 5-item baseline (Figure 4) and the 7-item follow-up (Figure 5) questionnaires were collected and analyzed.

For question 1 ("How many times per day do you perform home oral hygiene?"), 4.8% and 9.7% of the participants reported practicing oral hygiene only 1 time per day at T0 and T1,

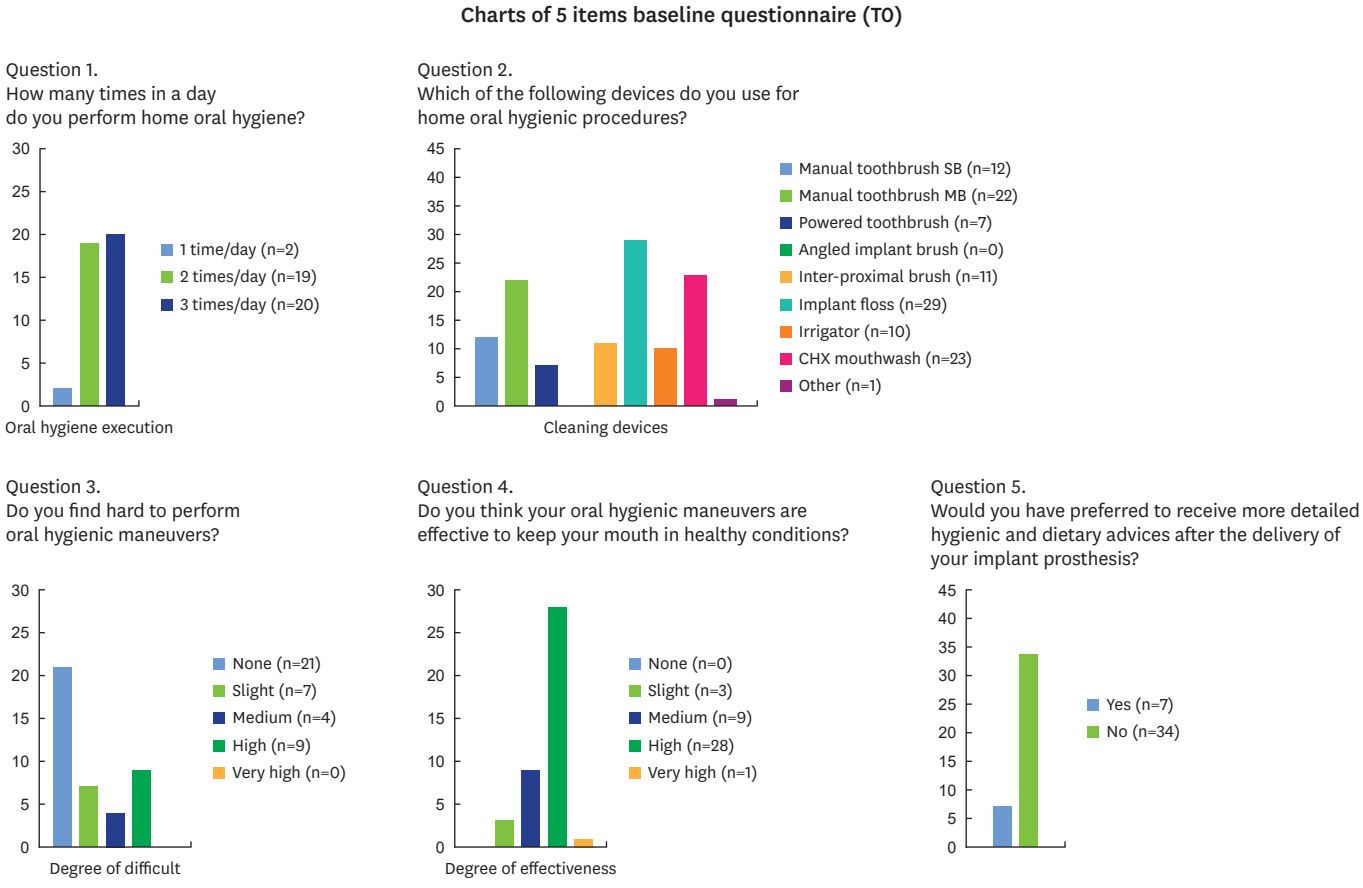

Figure 4. Responses to the 5-item baseline questionnaire (T0).
T0: baseline evaluation, SB: soft bristles, MB: medium bristles, CHX: 0.12% chlorhexidine.

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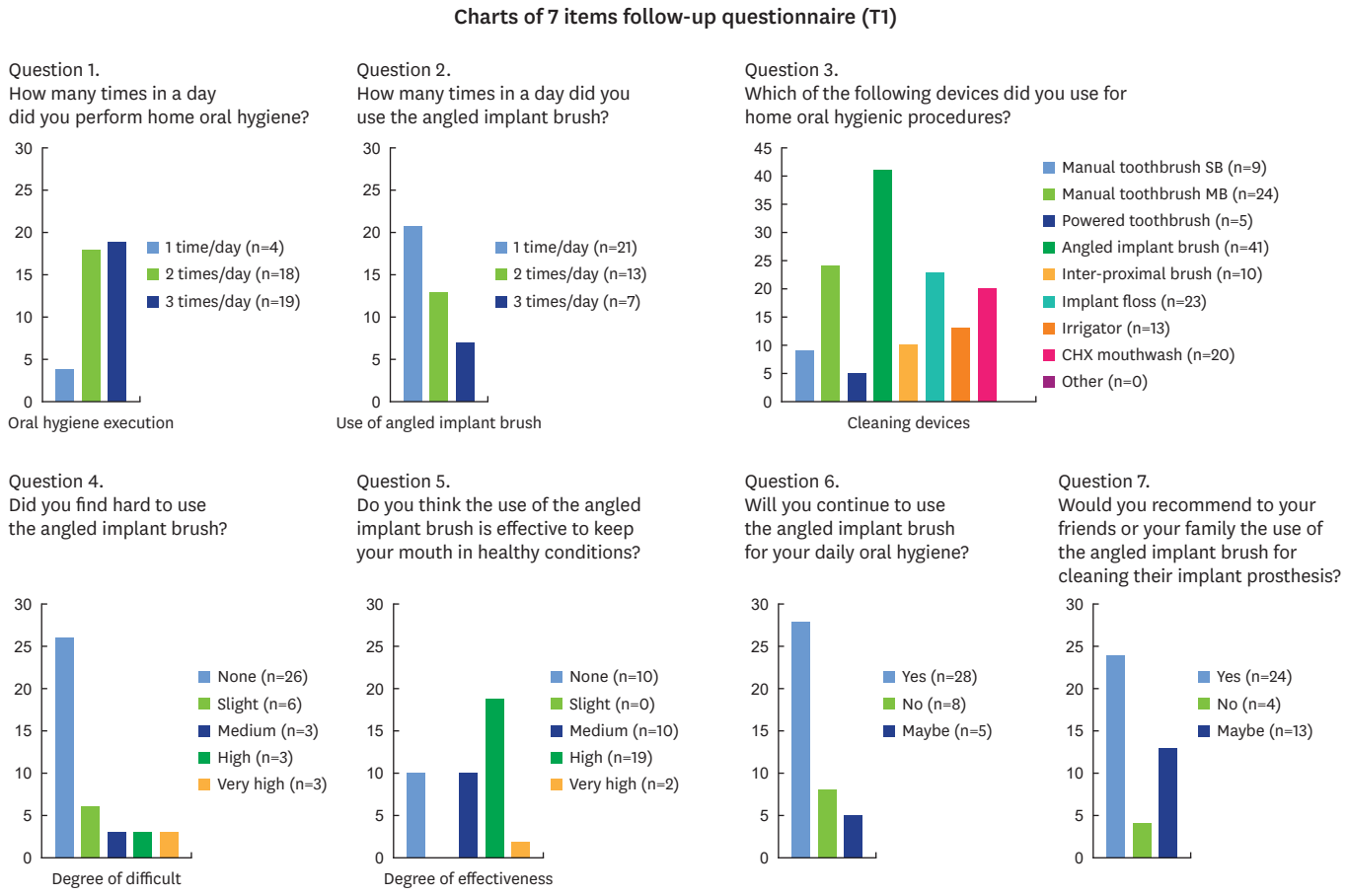

Figure 5. Responses to the 7-item follow-up questionnaire (T1).
T1: follow-up evaluation, SB: soft bristles, MB: medium bristles, CHX: 0.12% chlorhexidine.

respectively. At T0, 46.3% of the patients performed home oral hygiene twice daily, and the corresponding percentage was 43.9% at T1.

No statistically significant differences in the change of PD (P=0.165), BOP (P=0.213), and PI (P=0.699) from T0 to T1 was found according to whether patients performed oral hygiene once, twice, or 3 times a day.

The instruments and materials used for home oral hygiene are presented in Figures 4 and 5. Only 1 patient reported using a cleaning device not included in the questionnaire (a mouthwash containing essential oils) at T0 (Figure 4), but not at T1. The instruments that the patients declared they used at T1 were similar to those reported at T0 (Figure 5).

No difficulty during hygienic maneuvers was reported by 51.2% of the subjects, while the rest of the patients stated that they experienced high (21.9%), medium (17%) and slight (9.7%) levels of difficulty when performing daily oral hygiene with their usual cleaning devices (Figure 4). According to the T0 questionnaire, 68.2% of the patients considered the hygienic maneuvers accomplished with the usual cleaning devices to be highly effective for maintaining their mouth and the implant prosthesis in a healthy condition (Figure 4). Seventeen percent of the subjects indicated that would have preferred to receive further information about hygienic and dietary advice to correctly manage their implant prosthesis (Figure 4).

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In total, 51.2% of the patients used the angled implant brush only 1 time per day, while the rest of the patients used it 2 times per day (31.7%) or 3 times per day (17.1%) (Figure 5). No statistically significant difference was found in the change from T0 to T1 of PD (P=0.441), BOP (P=0.530), and PI (P=0.339) between patients that used the angled brush once daily versus patients that used it more frequently.

The majority of the patients reported no difficulties (63.4%) using the angled implant brush to clean the prosthesis during the study period, and the majority of them thought that it was effective for keeping their mouth in a healthy condition (very high effectiveness, 4.8%; high effectiveness, 46.3%) (Figure 5). Furthermore, 68.2% of the patients reported that they would continue to use the angled implant brush for their daily oral hygiene, 19.5% answered "maybe," and only 12.1% were not willing to continue to use the implant brush. In total, 58.5% of the patients stated that they would recommend the implant brush to friends or family members to clean their implant fixed prostheses (Figure 5). Only 1 patient responded in the space for open-ended comments, and wrote that she was very satisfied with the angled implant brush.

DISCUSSION

The present research evaluated the cleaning efficacy of an angled implant brush designed for fixed implant prostheses and patients' satisfaction with its use. The null hypothesis could be rejected only for the BOP parameter (Table 2).

Various authors have suggested that manual dexterity, motivation, and compliance with oral hygienic maintenance are subjective factors that could be negatively influenced by age [10,11]. Moreover, plaque removal strongly depends on the type of instrument and the way in which it is used [36]. The patients in the present study were aged over 50 years (Table 1) and did not have good oral hygiene, with high values of PI both at T0 (47.1%) and T1 (41.9%). These high levels of PI underscore the difficulties that these patients experienced in performing adequate home hygienic maintenance of their implant-supported full-arch fixed prostheses. Consequently, specific solutions must be developed to increase the likelihood of a satisfactory level of cleaning for this kind of rehabilitation.

PI scores decreased during the 1-month period of this study, but not to a statistically significant extent (P=0.280) (Table 2). A statistically significant improvement in BOP values was found after 1 month of using the angled implant brush (P=0.032), while no significant changes were reported for PD (P=0.050). However, the BOP reduction at T1 was not particularly relevant from a clinical standpoint, since BOP was already low at baseline (Table 2). Specifically, despite the high values of PI, BOP (15.54% at T0 and 12.35% at T1) and PD (mean, 1.74 mm at T0 and 1.77 mm at T1) values were within the normal limits. The majority of the patients did not present BOP and the maximum value of PD recorded was 4 mm (Table 2).

Patients' oral hygiene habits and satisfaction with the angled implant brush were evaluated on the basis of 2 anonymous brief questionnaires that were specifically developed for this investigation. Although a general psychometric principle is that instruments with fewer items have lower reliability [37], according to Preciado et al. [38] and Berretin-Felix et al. [39], customized (or focal) indices have demonstrated higher reliability than general questions. Thus, questionnaires with 5 items and 7 items were adopted for the baseline assessment

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(T0) and the follow-up evaluation (T1), respectively, in order to provide concise forms with specific questions focused on the relevant subject.

Questionnaires have certain limitations, such as dishonest and non-conscientious responses, differences in understanding and interpreting item prompts, subjective affective differences, difficulties in analyzing responses to the prompts, respondents' hidden agenda, missed and/or skipped item prompts, accessibility issues (reading level, vocabulary, vision, time, cognitive restrictions, etc.), and the possibility that respondents might provide responses believed to reflect what the examiner wants or responses to end the questionnaire session without focused thought about the prompts. Several countermeasures were taken to minimize the impact of potential confounding factors in the present study. The questionnaires were anonymous and each patient was left alone and provided with at least 5 minutes to complete the short questionnaires in order to prevent biased answers due to a perceived lack of time and the risk that subjects might provide responses believed to reflect what the examiner wants. Further clarifications relating to 1 or more items were provided only in response to patients' explicit request to prevent limitations due to reading levels and cognitive restrictions. No items of the T0 and T1 questionnaires were skipped or missed, as all patients responded to all questions.

The clinical data recorded at T0, reporting high PI, are consistent with the answers to the 5-item baseline questionnaire, since 51.2% of the subjects performed home oral hygiene fewer than 3 times per day at T0 (Figure 4), suggesting the need to improve patients' motivation and understanding regarding home oral hygiene.

Diverse answers emerged for question 2, regarding the cleaning devices that patients used for their daily oral hygiene. This variety might reflect the lack of defined guidelines in the dental literature concerning hygienic maintenance for full-arch fixed restorations on dental implants [3,13,19] when the patients were rehabilitated, especially regarding recall regimens and the types of cleaning devices that are preferable in this clinical setting. Menini et al. [40] proposed a dietary and hygienic protocol designed for patients treated with full-arch immediate-loading implant rehabilitation, according to the CBP [4,9]. These hygienic recommendations include specific cleaning devices depending on the time elapsed since surgery, such as 0.5% chlorhexidine periodontal gel, 0.2% and 0.12% chlorhexidine rinsing solutions, soft and medium bristled toothbrushes, inter-proximal brushes, and implant floss, which should be implemented at precise time periods from the time of implant surgery onwards. Although this protocol needs to be validated by prospective clinical trials, in the authors' experience it was beneficial [40].

Nearly 50% of patients reported no difficulties in accomplishing their daily oral hygiene using conventional cleaning devices, and the majority of the study participants considered their hygienic maneuvers to be highly effective, despite the high PI values recorded at T0 (Figure 4). The vast majority (82.9%) of patients did not report the need to receive further suggestions regarding the hygienic and dietary management of their full-arch implant rehabilitations (Figure 4). These factors might have influenced the high levels of plaque accumulation observed at both T0 and T1.

Similarly to the T0 evaluation (Figure 4), 53.6% of the subjects performed oral hygiene fewer than 3 times per day at T1. Slightly more than 50% of the study participants used the angled implant brush less than 2 times per day to clean the implant prosthesis, even though

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it was recommended to use the brush after every meal (3 times per day) (Figure 5). This data appears to contrast with patients' responses that they experienced no difficulties using the angled brush and considered it highly effective for improving their home oral hygiene. The poor compliance of these patients suggests that a greater effort should be made by the dental team to instruct and motivate the patients.

The answers to question 3 ("Which of the following devices did you use for home oral hygienic procedures?") on theT1 questionnaire were similar to those of question 2 on the T0 questionnaire, although fewer patients reported using implant floss (56% at T1 vs. 70.7% at T0) (Figure 5). This result might have been due to the use of the implant brush as an alternative to implant floss to clean the most difficult sites of the implant prostheses.

The T1 questionnaire outcomes reflected a generally high level of satisfaction regarding the angled implant brush. Although 24.3% of the subjects thought that it was not effective for improving plaque removal, the majority of them stated that they would both continue to use it and would recommend it to other patients (Figure 5).

The finding that PI remained high at the T1 evaluation is in contrast with patients' answers to the 7-item follow-up questionnaire, on which patients reported a generally high level of satisfaction regarding the effectiveness of the angled brush (Figure 5). The patients' perceptions of the brush's effectiveness were therefore not reflected by PI values, and this discrepancy may partially be explained by the fact that the patients generally did not perform oral hygiene 3 times per day as recommended. Our findings also underscore the need to monitor and improve patients' learning curve in the use of the new angled brush, even if they felt that the brush was effective and they considered themselves able to perform satisfactory oral hygiene.

There are some limitations regarding the research protocol of this study, such as the lack of a control group, the variability of home hygienic procedures reported by patients at baseline and at the follow-up evaluation, and the short observation period of 1 month. The inclusion of only 41 subjects in this study may have led them to exhibit effective brushing for a short-term period as a result of the Hawthorne effect [41], according to which subjects' behavior changes due to the awareness that their actions are monitored by examiners. Indeed, at the T0 visit, the prostheses were removed and even if the abutments did not receive any debridement, the adjunctive oral hygiene instructions may have increased the patients' motivation for that month. However, the PI did not significantly change between baseline and the T1 assessment, which conflicts with what would have happened if the study outcomes had been significantly impacted by the Hawthorne effect. A merit of this study is that it dealt with an important topic in implant dentistry, namely the hygienic management of full-arch fixed-implant prostheses, by testing the clinical effectiveness of a specific implant brush (in terms of improvements in PI, BOP, and PD) together with patients' degree of acceptance of this hygienic device.

The lack of data in the dental literature on patients' compliance with home hygienic maintenance of full-arch implant-supported fixed rehabilitations does not allow a direct comparison of the outcomes of the present study with other previous publications. However, Corbella et al. [3] carried out a prospective study on 61 patients to investigate the efficacy of an implant maintenance protocol for full-arch restorations over a mean observation period of 18.3 months (range, 6 months to 5 years), and concluded that the adoption of a systematic

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hygienic care program can reduce the incidence of peri-implant mucositis, clinical peri-implant attachment loss, and plaque accumulation.

Future research should seek to establish long-term validated protocols concerning the home-care hygienic management of patients with full-arch fixed-implant rehabilitations. The clinical effectiveness of the angled implant brush and patients' compliance need to be assessed throughout a medium- to long-term period of follow-up, and a larger sample size should be compared with a control group. Within the limitations of the present study, the angled implant brush appears to be a well-tolerated hygienic instrument and it can be used, in combination with other conventional cleaning devices, to improve the home oral hygiene of patients wearing full-arch implant-supported fixed rehabilitations.

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