

A COMPARISON OF THE EFFICACY OF WATER FLOSSER TO INTERDENTAL FLOSS AROUND DENTAL IMPLANTS: A RANDOMIZED CONTROLLED TRIAL AND A QUALITATIVE STUDY OF PATIENTS' PERCEPTIONS

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Short informative title

A comparison of the efficacy of water flosser to interdental floss around dental implants: a randomized controlled trial and a qualitative study of patients' perceptions

Short running title

A comparison of water flosser to interdental floss around implants

Acknowledgments

Statistical analysis was conducted with the help of Dr. Loring Chuchmach. Funding for this study was provided by the Dr. Gerald Niznick College of Dentistry Endowment Fund, University of Manitoba. The water flossers units were donated to our clinic by WaterPik Inc., Fort Collins, Colorado (USA), but they were in no way involved in the protocol design or data analysis of the trial. The other authors report no conflicts of interest.

Author contributions:

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MeSH term keywords: water flosser, interdental floss, Dental Implants, Oral Hygiene, Dental Devices, Home Care, Qualitative Study, Patient Reported Outcome Measures

Word Count: 4275 | Tables: 5 | Figures:1| References: 45

ABSTRACT

AIM

The aim of this study was to determine the effectiveness of a water flosser device compared to flossing around implants in several clinical parameters and to investigate patients' perceptions and experiences of implant maintenance.

METHODS

This study comprised an initial quantitative study and follow-up qualitative study. Patients were randomly divided in two groups, group 1 (experiment) with water flosser and group 2 (control) with dental floss. At each appointment five clinical parameters were recorded: Full Mouth Plaque Score (FMPS), Quigley-Hein plaque index (QHI), Probing Depth (PD), Bleeding on Probing (BOP) and width of Keratinized Tissue (KT) around implants. Patients were then interviewed to investigate perceptions of implant care and maintenance.

RESULTS

Twenty-four patients with a total of 76 implants completed at least one follow-up appointment. No statistically significant differences were found for any of the investigated parameters. The qualitative data collected with the interviews were reorganized into main themes: implant versus natural tooth care routines and the 'impact' of the study intervention.

CONCLUSIONS

Based on this study, dental floss and water flosser are equally effective in maintaining peri-implant health. The majority of the patients in water flosser group were in favour of this device and willing to continue using it. Longer term follow-up with a larger sample size could help to demonstrate impact in oral hygiene behaviour and clinical outcomes.

BACKGROUND

LITERATURE REVIEW

Plaque accumulation and the inability to control biofilm around dental implants is a contributing factor in the development of inflammation around dental implants.¹⁻²⁻³ Optimizing the removal of plaque deposits is therefore considered an important aspect of prevention of peri-implant diseases and long-term maintenance. While there appears to be consensus in the literature about the need for optimal home plaque control, there are very few clinical trials that have examined different modalities of interdental cleaning around dental implants.⁴ Clinical experience and literature show that for patients interdental cleaning appears to be more difficult than brushing teeth and their compliance is lower.⁵⁻⁶ Poor access for adequate interproximal hygiene around implants has been shown to be related with a statistically significant higher occurrence of peri-implant disease.⁷

Very little is known about the effectiveness of different interproximal implant home care devices around dental implants. An observational study of van Velzen, Lang, Schulten, ten Bruggenkate, 2015⁸ and a case report of Montecvecchi, De Blasi, Checchi, 2016⁹ have shown that interproximal oral hygiene with dental floss can in some cases be detrimental. In these studies remnants of dental floss were found around the neck and coronal part of dental implants with rough surfaces. Remnants may have acted as ligatures and promoted plaque retention. According to van Velzen et al.⁸ the utilization of interproximal brushes or toothpicks may be preferred for daily home care practices to avoid the risk of remnants.

Several different interproximal implant home care devices are commercially available: dental floss, interproximal brushes, tooth cleaning picks and oral irrigators but available evidence is limited regarding their comparative effectiveness.¹⁰⁻¹¹ The history of dental floss dates back to ancient times with reports of interdental teeth cleaning using natural products, however a silk dental floss was introduced in 1815 by Levi Spear Parmly, a dentist in New Orleans.¹²⁻¹³ A dental water jet (now known as water flosser) was developed in Colorado in the 60's by a hydraulic engineer, John Mattingly, and a dentist, Gerald Moyer who introduced this device in dentistry in 1962.¹²⁻¹⁴

There have been only a few studies evaluating the effectiveness of water flossers. A four-week evaluation showed that the daily use of water flosser combined with manual toothbrush is significantly more effective in reducing gingival bleeding scores than the use of dental floss¹⁵

around teeth. A 2008 systematic review¹⁶ reported that water flosser did not have a beneficial effect on reducing plaque scores, however a positive tendency in improving gingival health compared with regular oral hygiene practices was found. Similarly, a 30-day clinical trial of Magnuson, Harsono, Lyle, Kugel, Perry, 2013¹⁷ showed that a water flosser was more effective at reducing bleeding around implants than string floss with no adverse events reported, however this clinical trial was very short in duration and the long term sustainability of this effect could not be determined. These findings align with a long standing hypothesis to explain the bleeding reduction; water pulsations alter host–microbial interactions in the subgingival environment and the inflammation is reduced independently of plaque removal.¹⁸

Based on the literature available, there is still no consensus regarding which interproximal implant home care device is the safest and most effective for long term implant maintenance. Another area in the literature that has not been fully explored yet is patients’ perceptions of implant maintenance. Several studies have investigated patient’s perception of dental implants but mostly from a surgical perspective,¹⁹⁻²⁰ with a focus on prevention and complications²¹ or with attention to patient’s expectations²²⁻²³ but there is little known about patients’ perception of maintenance of dental implants. This aspect is particularly important because the literature reports that a good plaque control is essential for implant success.²⁴

STUDY AIM

The primary objective of this study was to compare two different interproximal devices, water flosser and dental floss around implants in several clinical parameters. The second focus was to investigate patients’ experiences and perceptions of implant care, specifically maintenance with particular attention on the use of interproximal implant home care devices.

METHODS

STUDY DESIGN

This study is a multi-method approach²⁵ using a randomized, controlled clinical trial in a single center to determine effectiveness of two different interproximal implant home care devices and a qualitative approach to explore patients’ experiences and feedback regarding implant hygiene and maintenance at home.

This study was registered on the clinical trial register clinicaltrials.gov with number H2019:298 and was approved from the Research Ethic Board of the University of Manitoba [HS23066 (2019:298)]. The CONSORT checklist was followed in the development of the study.

PATIENT RECRUITMENT

This trial involved study population with previously placed and restored dental implants. All the participants were maintenance patients of the Dr. Sam Borden Graduate Periodontics Clinic, Dr. Gerald Niznick College of Dentistry, University of Manitoba with at least a single implant with a screw retained crown. All participants were properly informed about both phases of the study and gave verbal and written consent prior to their inclusion in the study.

INCLUSION/EXCLUSION CRITERIA

Inclusion Criteria:

- Male or female, 18 years of age and over
- Patients that presented with at least a single implant with a screw-retained crown and a diagnosis of peri-implant health or peri-implant mucositis (defined according to the 2017 World Workshop²⁶)
- Patients with general good health that did not have a condition contra-indicating routine dental treatment

Exclusion Criteria:

- Patients younger than 18 years of age
- Patients with implants with cemented crowns
- Patients with diagnosis of peri-implantitis (defined according to the 2017 World Workshop²⁶)
- Patients with any contact hypersensitivity to the related materials used in the study
- Tobacco users (vaping included)

RANDOMIZATION PROCESS

After recruitment, the patients were randomly assigned to one of the two groups, group 1 water flosser and group 2 conventional flossing. A computerized randomization scheme using the tool

available on the website (<https://en.calc-site.com/randoms/grouping>) was used to achieve simple randomization between the 2 groups. Each number was randomly linked with 'W' standing for water flosser or 'F' for flosser. Following a 1:1 allocation ratio a key-sheet with a progressive numeration 1 to 40 was generated. Allocation was based on recruitment. The dental hygienist (MD) generated the key-sheet, the principal investigator was blind to the assigned device.

PROCEDURES

Phase I (Quantitative)

The initial protocol consisted in five appointments and all participants were expected to be seen every 3 months for a one-year period: baseline, 3 months, 6 months, 9 months and 12 months.

All clinical measurements were taken by a single blinded investigator (CS) while a single dental hygienist was responsible for prophylaxis and delivery of oral hygiene instructions to the study participants. At the baseline and at each further appointment five clinical parameters were recorded: Full Mouth Plaque Score (FMPS)²⁷ recorded at four sites around each tooth or implant and Quigley-Hein plaque index (QHI)²⁸ of the implants after the use of a disclosing solution, Probing Depth (PD)²⁹, Bleeding on Probing (BOP)³⁰ of the study implants recorded at six sites (distobuccal, mid-buccal, mesiobuccal, distolingual, mid-lingual and mesiolingual) using a UNC 12 Colorvue probe and the width of the keratinized tissue (KT)³¹ at the buccal surface of the study implants.

During each appointment the study investigator measured clinical parameters, described above, and participants received reinforcement of the oral hygiene instructions (OHI) and supportive periodontal therapy (SPT) with scaling with hand instruments by a single dental hygienist (MD).

Group 1 (experimental): patients were provided with water flosser (*Waterpik Water Flosser WP-600, Water Pik, Inc, Fort Collins, CO, USA*) and were asked to refill it with tap water. The recommended tip was the standard JTR tip set in floss mode with the power button set at 5. Patients were also asked to change the water daily and to clean each implant for 30 seconds. Instructions on how to properly use the device were provided by the dental hygienist and the patient was asked to try the device in the clinic.

Group 2 (control): patients were provided with multiple packages of dental floss (*TePe Bridge and Implant Floss, TePe Munhygienprodukter, Malmö, Sweden*) in order to be able to floss daily for 12 months. Patients were instructed to floss once a day, preferably at nighttime. A demonstration

of how to properly use the dental floss was done by the dental hygienist with the help of a hand mirror and patients were asked to replicate the same procedure in front of the hygienist.

Both groups also received a research bag comprising manual toothbrushes (*TePe soft toothbrush, TePe Munhygienprodukter, Malmö, Sweden*) and toothpastes (*Colgate Cavity Protection, Colgate-Palmolive, New York, USA*).

Once the study was concluded patients were asked to fill-out an emoji rating scale 1 – 5 questionnaire with two questions 1) how much they liked their interproximal device and 2) how easy it was to use.

Phase II (Qualitative)

The second part of this research consisted of a qualitative study conducted by phone interviews. The questions were provided to the patients prior to the interview for the purpose of familiarizing them with the topic. The interviews were conducted following a semi-structured outline (table 1). All the phone interviews were recorded and the answers were summarized and transcribed.

STUDY DURATION

The clinical trial lasted for a period of 11 months. The COVID-19 pandemic and closure of the clinic required an adjustment of the initial protocol and the interval of the follow-up appointments ranged between three and six months.

The enrolled patients were recalled by phone six months after the conclusion of the trial and asked to participate in a phone interview to collect additional qualitative data and to investigate patient's perception of dental implants and maintenance. These interviews were conducted between February and March 2021.

STATISTICAL METHODS

The primary outcome to evaluate was differences in BOP, the other 4 clinical parameters were secondary outcomes. The biostatistician was blind to the treatment group definitions. A two-Sample T-Test assuming unequal variances was used to evaluate statistical differences between the groups at follow-up 1 for the five clinical parameters investigated (table 4). A Whitney U test was used to analyze two answers from a questionnaire that was given to the patients at the end of the study to compare differences in how the two groups ranked the interproximal devices. Analyses

were conducted with the software IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp with a level of significance set at 0.05.

DESCRIPTIVE ANALYSIS

Qualitative descriptive methods were used to analyze participants' reports of implant care and maintenance. The interview responses were organized using a coding method focused on main themes: implant versus natural tooth care routines and integration of the study intervention into their oral hygiene routines. The thematic approach described by Braun & Clarke³² was used to produce a report. Qualitative analysis was conducted by CS and verified separately by GH in order to enhance the trustworthiness of the analysis and findings.³³

RESULTS

QUANTITATIVE RESULTS

Thirty-three patients, seventeen male and sixteen female completed the baseline appointment. The study was conducted from October 2019 to September 2020. The age of the patients' population ranged between 46 and 85 years old with a mean age of 68 (table 2). All these patients were followed for SPT in our clinic for an average of 8.5 years. Four patients could not complete their first follow up because the study was interrupted by the COVID-19 pandemic before their first recall appointment, one patient did not want to return to the clinic because she was worried about COVID-19 while the study was still ongoing and four patients were dismissed because they were not compliant with the study protocol because they stopped using the assigned device or because they used non prescribed aids such as electric toothbrushes. The final sample of twenty-four patients were equally distributed between the two groups who were fully compliant and completed at least one follow-up appointment (figure 1); a total of ten compliant patients completed two follow-ups appointments before the study was interrupted due to the COVID-19 pandemic. Among these 24 patients 13 had more than one implant (2 to 7) with a total of 76 implants included in the study measures.

In table 3 descriptive methods were used for presentation of clinical parameters from baseline to follow-up. Table 4 reports differences at follow-up 1 between the treatment group (water flosser)

and the control group (dental floss). The sample size of patients who completed at least two follow-ups (10 patients) was considered too small to be used for statistical analysis.

The feedback questionnaire also did not produce statistically significant differences in the mean rankings provided by the two groups (table 5).

QUALITATIVE RESULTS

Twenty five patients (75% of patients recruited for phase I) consented to participate in Phase II. Twelve patients were in group 1 and 13 in group 2. The duration of the telephone interviews ranged between 8 and 20 minutes with an average length of 12 minutes.

Implant versus natural tooth care routines

The majority of the patients (17 patients) reported no differences in maintaining implants compared to natural teeth; for some of them implants felt exactly the same as natural teeth and in their daily routines they were almost unaware of the presence of the implants. On the other hand, according to five patients, implants were more difficult to be maintained and require additional time and particular attention. ***“I certainly found with the floss it was more difficult. Maybe it’s because I was made aware it was very important I get into there to clean” (patient #8).*** Two patients with more than one implant in their mouths reported that in their experience there were differences between different implants and particularly splinted implants were more difficult to maintain clean. ***“It depends on the type of implant. I have one implant that has two screws in one tooth and I have to make sure I clean that and it’s a little more trouble” (patient #26).*** Overall, all patients reported to have well structured oral hygiene routines. The majority reported to take care of implants and tooth hygiene at least twice a day specifically morning and evening. Six reported to limit their oral hygiene practices to one single intervention and only one patient described cleaning implants and teeth less than once a day. In addition to the frequency of cleaning, the majority also reported using an interproximal implant home care device, ranging from floss, proxabrushes or interdental picks to clean around the implants as well as between their natural teeth.

Integration of study intervention into oral care routines

The majority of the interviewed patients (13 patients) explained that the main change generated after their involvement in the research was introducing in their oral hygiene routine a different interproximal implant home care device. This outcome appears to be more evident for the water flosser group rather than for the floss group (10 vs 3). Seven patients reported that being involved in this research project made them more aware of oral hygiene and cleaning practices ***“I’m more vigilant about flossing than I was before” (patient #9)***. On the other hand, for eight patients the participation in the clinical trial did not determine a significant change in their routine.

In the water flosser group, more than six months after the conclusion of the research, almost the totality of the patients (11/12), reported they kept using the water flosser as an adjunctive device for their routine oral hygiene practices. The patient that decided to discontinue the use of the water flosser reported that she did not find it as effective as the dental floss. The majority of the water flosser users (8/12) expressed their willingness to repurchase a new unit if their device broke. Most of the patients (75%) appreciated the fact that the water flosser was easy to use. Four patients reported a pleasant sensation of feeling clean after use. A relative common complaint (5 out of 12 patients) was considering the water flosser unit somehow “messy” with water wetting patients’ faces and going around the room. ***“The water was going on my face or all over the sink. I don’t know if I’m not smart with it. At first it was difficult, but I figured it was worth keeping it up and now it’s much easier” (patient #7)***. ***“At first it’s difficult to not get water on your face. The water was spraying around before I got used to using it. It takes a little bit of time to get used to it” (patient #24)***. A patient reported that in her experience a limitation of the water flosser was the limited portability of this device and her inability to bring this device to work. Another patient mentioned that filling up the device with warm water made the experience more pleasant.

The dental floss group presents a quite large spectrum of opinions. Five patients reported to really like the floss. Two patients appreciated the rigid end of the floss that made it easier to pass through the interdental contact point or between splinted implants. The characteristics of this floss were considered negative by seven patients that found it too thick and difficult to be used. ***“What I didn’t like it was hard to push it through. If you didn’t do it on the first try, it would get wet and be difficult to be used” (patient #26)***. One patient added that he found the floss hard on his gums and traumatic. Three patients reported that the floss used to get stuck around the implants which made use unpleasant.

DISCUSSION

QUANTITATIVE STUDY

According to this randomized, controlled clinical trial in a single center it appears that in a short-term interval, ranging between three to seven months, water flosser and dental floss are equally effective around implants in maintaining similar clinical parameters.

The tendency of water flosser to produce a greater BOP reduction compared to dental floss, even if not statistically significant is consistent with the finding of the 30-day clinical trial of Magnuson¹⁷ that shows that water flosser is more effective at reducing bleeding around implants than string floss with no adverse events reported. Similar findings but around natural teeth are reported in the study of Chaves, Kornman, Manwell, Jones, Newbold, Wood, 1994¹⁸ and in the systematic review of Husseini, Slot, Van der Weijden, 2008¹⁶ that reports that oral irrigators do not have a beneficial effect in reducing visible plaque but show a positive trend in improving gingival health as an adjunctive device to tooth brushing.

In order to standardize the teeth brushing procedures patients were all equipped with the same manual toothbrush (*TePe soft toothbrush, TePe Munhygienprodukter, Malmö, Sweden*), it is reported in the literature that manual and powered toothbrushes achieve different results. With power brushes reducing plaque and gingivitis more than manual toothbrushing in the short and long term.³⁴ The toothpaste chosen for this study (*Colgate Cavity Protection, Colgate-Palmolive, New York, USA*) has as active ingredient Sodium Monofluorophosphate, without antimicrobial activity³⁵ that could have interfered with the action of the interproximal devices. The allocated dental floss (*TePe Bridge and Implant Floss, TePe Munhygienprodukter, Malmö, Sweden*) is a spongy floss with stiff plastic ends. The choice of this interproximal device was to standardize the control group even if in the literature the relationship between type of dental floss and differences in plaque removal is controversial. The study of Wong and Wade 1985³⁶ found that super floss was superior than conventional floss in plaque removal. On the other hand the study of Ong 1990³⁷ found that the differences between three types of dental floss were not statistically significant.

Four out of 28 patients that returned for the follow-up 1 reported to have not been compliant with the protocol and were then dismissed from the research. The drop-off rate was about 14% that is a value that could have been anticipated due to the length and the strictness of the protocol. The

overall high rate of compliant patients could be explained by the fact that all the participants have been maintenance patients of the periodontology clinic of the University of Manitoba and the importance of periodontal maintenance and oral hygiene practices were stressed during the time by the treating resident and by the dental hygienist who built a trusting relationship with her patients. It is well known that patients' compliance plays a crucial role for implants success and from the literature it appears that patients who are compliant in the first few years tend to continue long-term supportive periodontal therapy.³⁸ However a systematic literature review found that overall implant patients have an unsatisfactory compliance for supportive periodontal therapy and that dentists should reinforce the importance of maintenance.³⁹

QUALITATIVE STUDY

A qualitative approach was used to explore patients' experiences and feedback regarding implant hygiene and maintenance at home. The answers grouped in the first theme about implant versus natural tooth care routines show that the majority of the interviewed patients treated implants exactly as natural teeth and that 2/3 of them used to brush their teeth at least twice a day in accordance with American Dental Association recommendations. These findings can be partially explained considering that all the interviewed patients have been long term SPT patients of our clinic and oral hygiene instructions have been reinforced at each appointment by the treating oral hygienist.

A careful analysis of the second theme about the impact of the study intervention shows that 1/4 of the patients reported that the participation in this study made them more aware of their oral hygiene practices. These findings suggest that oral hygiene education and motivation can also play a role for a significant percentage of diligent and well-informed patients. This outcome is in accordance with the literature that underlines the importance of reinforcing oral hygiene instructions frequently even if there is not enough evidence to support which oral hygiene device is the most effective.⁴⁰

Patient's feedback for the water flosser was generally positive. All but one patient liked this device and kept using it even six months after the conclusion of the clinical trial when they were free to go back to the oral hygiene practices that they preferred and considered most effective. The enthusiasm of the majority of the interviewed patients could have positive clinical implications. It can be speculated that appreciation for the interproximal device and simplicity of use could play a

key role in patient's compliance.⁴¹ According to the literature oral irrigation devices can be effectively used even by children below 6–7 years that are still developing the fine motor skills needed for manual brushing and dental flossing.⁴²

Patient's opinion about the allocated dental floss were not unanimous. Less than half of the patients reported really liking the device but for the other half the characteristics of this floss were negative and they mentioned bad experiences such as having the floss stuck between implants or finding it hard to use. A single patient described this floss as traumatic. The literature reports that uncontrolled or too vigorous dental flossing may lead to irritation, ulceration, or defects on the gingiva.⁴³ However, it is important to highlight that on the market there are available many different dental flosses with different designs and patient's experience with different products can vary significantly. The literature reports no differences between waxed and non waxed flosses⁴⁴ and a study Wong and Wade³⁶ reported that super floss, a dental floss with design similar to the dental floss used in this study was found to be slightly superior to conventional waxed floss in plaque removal.

STRENGTHS AND LIMITATIONS

This is a randomized controlled clinical trial covering an area in which there is a lack of previous research combining quantitative and qualitative data to investigate impact and patients' perceptions about water flosser around dental implants.

The present study was impacted by the COVID-19 pandemic. The clinic was shut down in March 2020, cutting short the opportunity to complete follow up measures; at that time only 11 patients had completed at least one follow-up. The clinic was reopened in August 2020 and all patients willing to attend the clinic were booked for a final follow-up between August and September 2020. The clinical trial was then permanently interrupted due to university restrictions linked to the code red status of the Province of Manitoba. Patients were free to return to the oral hygiene practices that they preferred. The early closure of the trial and some patient drop-offs determined a small sample size and that may have influenced the study results and an overall lack of statistical significance. The COVID-19 related clinic closures also contributed to another limitation of this study, the uneven interval in the recall appointments ranging between three to six months and that could have had an effect in both Hawthorne effect and compliance. It is in fact reported in the

literature that patients tend over time to forget oral hygiene instructions and that compliance decreases.⁴⁵

Even though all the measurements were taken by one investigator (CS), another possible limitation is the non-calibration of the examiner.

CONCLUSION

Based on the results of this clinical trial, dental floss and water flosser are equally effective in maintaining clinical parameters around dental implants. Due to limitations and disruptions of this clinical trial by the COVID19 pandemic, further research is needed to corroborate this outcome. If these findings were to be confirmed, water flosser could be considered the first-choice device for implant maintenance, after the rising concerns in the literature involving the use of dental floss around implants. The qualitative study shows that despite minor concerns in learning how to use the water flosser, the majority of the patients in the water flosser group were in favour of this device and willing to continue using it. The adoption of an interproximal implant home care device well liked by patients may have a positive behavioural impact on patients' adherence to home oral hygiene.

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Table 1: Interview outline

<ol style="list-style-type: none"> 1. How easy or difficult is it to maintain a dental implant compared to natural teeth? 2. Did being involved in this research change your cleaning habits? <ol style="list-style-type: none"> a. Before entering the study how did you clean around your dental implant(s)? 3. What is your cleaning routine around dental implant(s) now? <ol style="list-style-type: none"> a. How often do you clean around dental implant(s)? 4. Are you still using the interproximal device (water flossing or dental floss) that was provided in the study? <ol style="list-style-type: none"> a. Please tell us what you liked or did not like about the cleaning device? 5. What, if any, kinds of differences do you notice between your implant(s) and your natural teeth? 6. Do you treat implant(s) any differently than your natural teeth? 7. What would you consider as signs that the implant is not healthy? 8. I'd like to ask you to report on anything you've noticed regarding your implant(s) <ol style="list-style-type: none"> a. First: Have you noticed any bleeding when you are cleaning around the implant? b. Have you noticed any sensitivity to hot or cold or touch? c. Have you noticed any movement around the implant? d. Have you noticed anything unusual when you bite down normally on the implant or when you are chewing food? 9. If you noticed any changes to the implant, how might that affect your cleaning routine? 10. Would you consider having another implant if needed? 11. Was maintaining the implant a concern for you? Would it impact your decision to have another implant, if needed? <p>FOR WATER FLOSSERS:</p> <ol style="list-style-type: none"> 1. Will you be using the water flosser on an ongoing basis (long term)? For implants only or for all of your teeth? 2. Water flossers has a considerable cost compared to dental floss, is this something you would purchase for cleaning around implants if it was the most effective method? 3. Was the water flosser easy to use? What were the challenges or downside to the water flosser? <p>Is anything else you would like to add about your implant maintenance?</p>
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Table 2: Baseline demographic characteristics

	Water Flosser	Dental Floss	Total
Baseline Participants	16	17	33

Age, Categorical Measure Types	≤18 years: 0 (0%) 18-65 years: 7 (43.75%) ≥65 years: 9 (56.25%)	≤18 years: 0 (0%) 18-65 years: 5 (29.41%) ≥65 years: 12 (70.59%)	≤18 years: 0 (0%) 18-65 years: 12 (36.36%) ≥65 years: 21 (63.64%)
Age, Mean and full range	67 (54-85)	68 (46-80)	68 (46-85)
Race Measure Type: Count of Participants	American Indian or Alaska Native: 0 (0%) Asian: 1 (6.25%) Native Hawaiian or Other Pacific Islander: 0 (0%) Black or African American: 1 (6.25%) More than one race White: 15 (87.5%) Unknown or Not Reported: 0 (0%)	American Indian or Alaska Native: 0 (0%) Asian: 1 (5.88%) Native Hawaiian or Other Pacific Islander: 0 (0%) Black or African American: 0 (0%) More than one race White: 16 (94.12%) Unknown or Not Reported: 0 (0%)	American Indian or Alaska Native: 0 (0%) Asian: 2 (6.06%) Native Hawaiian or Other Pacific Islander: 0 (0%) Black or African American: 1 (3.03%) More than one race White: 31 (90.91%) Unknown or Not Reported: 0 (0%)

Table 3: Clinical measures across baseline and follow-ups in experimental and control group

Clinical Measures	Baseline means shown (n = 24) Control n = 12 Treatment n = 12	Follow-up 1 means shown (n = 24) Control n = 12 Treatment n = 12
BOP [†] Control Treatment	7.52 14.82	9.68 8.83
QHI [‡] Control Treatment	0.70 0.47	0.65 0.31
MAX PD [§] Control Treatment	3.31 3.61	3.28 2.94
KT [¶] Control Treatment	1.98 2.29	2.02 2.33

FMPS#		
Control	40.08	33.92
Treatment	42.50	38.75

- † Bleeding on Probing
‡ Quigley-Hein plaque index
§ Probing Depth
¶ Keratinized Tissue
Full Mouth Plaque Score

Table 4: Comparison of changes from control to treatment group at follow-up 1

Clinical Measures	Treatment n=12	Control n=12	T value (p-value)
BOP†	8.83 (12.39)	9.68 (12.67)	0.17 (0.87)
QHI‡	0.31 (0.46)	0.65 (0.62)	1.5 (0.14)
MAX PD§	2.94 (0.82)	3.28 (1.09)	0.86 (0.40)
KT¶	2.33 (1.16)	2.02 (0.63)	-0.83 (0.42)
FMP#	38.75 (20.00)	33.92 (21.88)	-0.57 (0.58)

A two-Sample T-Test assuming unequal variances

- † Bleeding on Probing
‡ Quigley-Hein plaque index
§ Probing Depth
¶ Keratinized Tissue
Full Mouth Plaque Score

Table 5: Comparison of responses to Feedback Questionnaire

Clinical Measure		Control n = 12	Treatment N = 12	Sig
Liked interproximal device –	mean	3.75	4.25	.53
	mean rank	11.33	13.67	
Easy using interproximal device –	mean	3.42	3.83	.41
	mean rank	11.46	13.54	

Mann Whitney U test

Figure 1: CONSORT Flow Chart

