Dear Sir/Madam, 01-18-2026

I am writing to submit our study protocol for registration in the Protocol Registration and Results System (PRS).

The submitted protocol is entitled:

**“Effect of Water Flossing on Gingival Inflammation Around Single Implants: A Randomized Clinical Trial.”**

This study is a randomized, parallel clinical trial designed to evaluate the effectiveness of adjunctive water flossing, compared with toothbrushing &using the string floss, on peri-implant soft tissue health around single implant-supported crowns. The primary outcome is bleeding on probing, with secondary outcomes including plaque presence and probing depth.

The study will be conducted at the Department of Periodontics, King Abdulaziz University Dental Hospital, Jeddah, Saudi Arabia. Ethical approval has been obtained from the Institutional Review Board of King Abdulaziz University (Proposal No. 129-11-24), and all participants will provide written informed consent prior to enrollment.

This trial has not been previously registered in any other clinical trial registry, and the information provided in the PRS submission is accurate and complete to the best of our knowledge. The study will be conducted in accordance with the Declaration of Helsinki and applicable local regulations.

We kindly request your review and approval of this protocol for registration. Please do not hesitate to contact us should any additional information or clarification be required.

Thank you for your time and consideration.

Sincerely,

**Dr. Amal Ghazi Jamjoom**
Department of Periodontics
Faculty of Dentistry
King Abdulaziz University
Jeddah, Saudi Arabia

# Effect of Water Flossing on Gingival Inflammation Around Single Implants: Randomized Clinical Trial

## Introduction:

Dental implants are increasingly utilized in modern dentistry as practical solutions for functional and aesthetic tooth replacement. Their long-term success relies on comprehensive professional care, patient compliance, and individualized oral hygiene practices. Poor plaque control remains the principal risk factor for the development and progression of peri-implant diseases (19).

The primary objective of oral hygiene around dental implants is to minimize bacterial biofilm accumulation, which can lead to inflammation and infection. Failure to manage this effectively can result in peri-implant mucositis, characterized by inflammation of the soft tissues surrounding implants. If left untreated, this may progress to peri-implantitis, a more severe condition that involves bone loss and may ultimately cause implant failure. (1, 2). Home care recommendations are similar to those for individuals with natural teeth, involving brushing, flossing, and rinsing. Cheung et al. conducted a study to explore potential implant hygiene risk factors and outcomes in a community-based cohort. Among the 78 implants assessed, implant success was evaluated according to the criteria set by Karoussis et al. (2004), while peri-implant health was measured according to the requirements set by Renvert et al. (2018). The results showed that lower levels of plaque and calculus around implants were significantly associated with higher implant success (P = 0.005 [95% CI: 6.0–32.3%]). Additionally, patients with poor oral hygiene habits before implant placement were more prone to implant failure and peri-implant diseases. Notably, only half of the patients remembered the oral hygiene instructions (OHI) they received post-treatment, likely due to either lack of recall or the absence of instructions provided by their dentist. (3). This should highlight the importance of reinforcing OHI during routine maintenance visits. Although a fundamental component of oral hygiene, brushing is often insufficient to maintain optimal oral health. A toothbrush is not fully capable of cleaning inter-proximal tight areas, where food impaction and plaque accumulation endanger periodontal health. As a result, a growing number of studies are investigating the efficacy of supplemental interdental cleaning techniques, including flossers and interdental brushes (IDB). IDB is effective in plaque reduction (4), and patients tend to prefer it over regular floss due to its ease of use. (5)A randomized controlled study tested four floss products, three regular types (unwaxed, shred-resistant, and woven), and a powered one. All of them have removed plaque effectively when used in addition to a manual toothbrush, rather than alone, with better results than the power floss (Oral-B Hummingbird) (6). Oral irrigators, often termed waterjet or water flossers, were first discovered in the early 1960s. Their efficacy and safety have been proven over decades of use, considering it as an alternative to string floss and IDBs . The mechanism of action for pulsating oral irrigators, which use a water stream to flush out

plaque and debris, including loosely attached bacteria, were linked to a qualitative change in microbiota, even when the supragingival plaque levels were not altered (7). The biochemical improvements translate directly into better clinical outcomes, such as reduced pocket depth and less bleeding on probing. A study at the University of Nebraska Medical Center compared the effectiveness of oral irrigation versus regular flossing as an addition to tooth brushing. Participants, aged 19 to 70, were selected without regard to sex or ethnicity. To qualify, individuals needed a minimum mean plaque score of 2.0, 50% bleeding, at least 20 evaluable teeth (excluding third molars), and satisfactory general health. Subjects were divided into three groups based on their oral hygiene routines: one group used regular floss with a manual toothbrush, while the other two groups used a water flosser with either a manual or sonic toothbrush. Data were collected at 14 and 28 days. All three groups showed reductions in mean bleeding, gingival, and plaque indices from baseline. The oral irrigation groups demonstrated significantly better reductions in bleeding and gingivitis than the regular floss group, when used with both sonic and manual toothbrushes. Notably, the irrigation group experienced a nearly twofold decrease in bleeding incidence compared with those using regular floss. (8) Altalhi et al. conducted a comprehensive review of the effectiveness of water flossers in periodontal therapy. When combined with brushing, water flossers can help remove biofilm and reduce bleeding on probing (BOP) (9). Barnes et al. reported reductions of 40% to 93% in bleeding and 51% to 53% in gingivitis when using a water flosser alongside brushing. Methods of application could significantly affect plaque removal, Water Flosser can be easily used following manufacturer's recommendations with less subjective variations, when it was applied by a trained dentist, nonsignificant difference was found between regular and water floss in plaque percentage after single use (10). And due to their ease of use, water flossers can be especially helpful for people with limited dexterity, such as elderly and arthritis patients (9, 10). In the literature, only a few studies investigated oral hygiene practices among implant patients. Mohapatra et al. conducted a systematic review comparing water flossers and traditional dental floss for plaque reduction in adults. Interproximal plaque reduction is a crucial component of peri-implant health, and the study sought to determine which approach reduced it more successfully. Given their ability to reach hard-to-reach areas and encourage long-term compliance, the authors concluded that water flossers would be a more practical and effective alternative for patients, especially those with dental implants (11). This can be particularly significant for patients who struggle with peri-implant mucositis, as reducing plaque is critical in preventing the progression to peri-implantitis (12). In a crossover randomized clinical trial, Bevilacqua et al. evaluated the effectiveness of interdental brushes (IDBs) and dental floss in managing peri-implant mucositis. The study aimed to compare these two traditional cleaning methods in terms of their ability to reduce plaque and prevent inflammation around implant sites. The crossover trial’s findings are relevant when considering alternative methods like water flossers, as both IDBs and dental floss require precise manual manipulation, which can be

challenging for some patients. Water flossers, on the other hand, offer a less technique-sensitive option, potentially providing more consistent results in plaque control around implants. Magnuson et al. observed that using a water flosser at medium pressure with tap water around implants resulted in less bleeding than string floss. In a study by Mahajani et al., the primary outcome was a reduction in bleeding on probing incidence at 30 days. It was anticipated that at least 50% of participants in the water floss group would have bleeding at no more than one site per implant by day 30, compared to only 10% in the string floss group. These findings were consistent with other studies comparing water flossers to string floss on natural teeth. (13). AlMohariband colleagues investigated the efficacy of water floss, interdental brush, and dental floss on gingival health, plaque, and interleukin-6 (IL-6) levels around single implant-supported crowns in two weeks. Plaque and bleeding were improved with all three methods. Although the difference was not statistically significant, the water floss group showed a decrease in IL-6 levels, a mediator of inflammatory diseases such as peri-implantitis. The other two methods showed increased IL-6 levels with a statistical significance found in the interproximal brush group, this could be due to local inflammatory response caused by mechanical action of both IDB and dental floss (14). According to Tütüncüoğlu's study, daily use of oral irrigators led to a significant reduction in inflammatory markers, including interleukin-1 beta (IL-1β) and transforming growth factor-beta (TGF-β) (1). Similar anti-inflammatory effects have been discussed in previous studies (1,15,16). In conclusion, oral irrigation has proven to be a reliable tool for dental implant hygiene. Several studies show that combining it with regular brushing significantly increases implant health by reducing biofilm and controlling inflammation. By keeping biofilm levels low, growing evidence indicates that regular oral irrigation can prevent peri-implant mucositis from evolving into peri-implantitis. In the long run, incorporating oral irrigation into a daily routine seems beneficial for people with implants. While most studies focus on short-term gains, typically around 12 weeks, long-term studies to fully understand the impact of oral irrigation on preventing more severe peri-implant diseases and improving implant longevity are needed. To summarize, oral irrigation emerges as a valuable addition to the oral care routine of patients with dental implants. It offers several benefits, such as reducing plaque, managing inflammation, and even lowering the level of inflammatory markers that drive peri-implant disease. Both short- and mid-term studies indicate that oral irrigation is adequate for managing peri-implant mucositis and maintaining long-term implant health. Future studies should concentrate on whether regular use of oral irrigation can truly protect implants over the long haul. Water flossers could be more significant for patients who struggle with traditional flossing methods due to limited dexterity. Inadequate oral hygiene, the use of a prosthesis that cannot be easily cleaned, or the application of ineffective implant care guidelines can all contribute to peri-implant disease. Therefore, following a proper care routine is crucial to the long-term

health of an implant. This review was focused on water floss efficacy regarding the periodontium of natural teeth and single implant-supported crowns among adult patients.

**Objectives:**

This study aims to evaluate the effect of water floss in reversing peri- implant mucositis around dental implants

**Material & Method:**

- Ethical Approval

Ethical approval for this study was obtained from the Institutional Review Board of King Abdulaziz University, Jeddah, Saudi Arabia (Proposal No.129-11-24). All participants will sign an informed-consent form at the beginning of the study.

- Patient population

Twenty patients were selected from the Department of Periodontics at King Abdulaziz University Dental Hospital in Jeddah, Saudi Arabia. To evaluate the effectiveness of water flossing around dental implants compared to brushing alone. To be included, participants must be 18 years of age or older, medically cleared, and have at least one implant-supported crown. To reduce the confounders that could influence the soft tissue parameters being studied, patients were excluded if they met any of the following criteria:

1. Smoking
2. Any systemic or localized illness that would interfere with dental implant therapy
3. On medications
4. Pregnancy
5. History of periodontitis/ or peri-implant disease
6. Poor oral hygiene
7. Probing depth is >5

- Study design:

The research will be conducted as a two-group parallel randomized clinical trial to evaluate the effectiveness of the cordless water flosser H2O floss (China) in improving peri-implant health parameters in patients with implant-supported single crowns. The study participants will be assigned to one of two groups via computer-generated randomization. Randomization will be carried out at both the individual-subject and implant levels, resulting in 10 implants per group. The allocation ratio will be 1:1, ensuring equal representation of each group. The study incorporated two main phases: an initial recruitment stage, followed by an evaluation stage. The primary outcome in this study is the presence or absence of bleeding. In contrast, the secondary outcomes include plaque presence or absence, probing depth differences, and evaluation of the patient's keratinized tissue. The study incorporated two main phases: an initial recruitment stage, followed by an evaluation stage.

- Procedure:

Patients will be assigned for two clinical appointments, the first visit is for baseline charting, probing depth will be recorded on six sites per implant, using a standardized periodontal probe and the presence or absence of bleeding will be recorded. Disclosing tablets will be utilized to

Confirm the presence or absence of plaque around teeth and the implant. Patients (Group A) will be given a water floss, with verbal and written instructions to use the water floss, twice daily for 2 minutes, along with brushing, while Group B will be instructed to brush with a manual brush and use the string floss, twice daily for 2 minutes. After two weeks, in the second visit, the implant site is re-evaluated to monitor the outcomes.

- Statistical analysis:

1. Between-group comparison:
2. Chi-square test of association or Fisher's exact test for categorical data (bleeding and plaque), independent sample T-tests or ANOVA for continuous data (probing depth and keratinized gingiva)

3. Within-group comparison: McNemar's test for categorical data (Bleeding and plaque), paired T-tests for continuous data (probing depth and keratinized gingiva)

**Reference:**


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