Date: 31 / 12 / 2024

The Effectiveness of Water Flossing Versus Regular Flossing for Oral Hygiene in Children Aged 10-15 Years: A Randomized Clinical Trial

2. Materials and Methods

2.1. Ethical Approval

The study protocol was reviewed and approved by the Research Ethics Committee of the Faculty of Dentistry, King Abdulaziz University, Jeddah, Saudi Arabia (Approval No. 169-11-24). Written informed consent was obtained from all parents or legal guardians prior to participation, in accordance with the Declaration of Helsinki.

2.2. Study Design

This study was designed as a randomized, controlled crossover clinical trial. Each participant used both interdental cleaning methods, water flossing and regular flossing, in two separate visits with a 14-day washout period between interventions to minimize carryover effects.

2.3. Study Setting

The study was conducted at the College of Dentistry and the University Dental Hospital, King Abdulaziz University, Jeddah, Saudi Arabia. Participant recruitment and data collection took place between November 2024 and April 2025.

2.4. Sample Selection

Participants were recruited using a convenience sampling approach from patients attending the College of Dentistry and the University Dental Hospital at King Abdulaziz University. Eligible participants who met the inclusion criteria were enrolled after obtaining informed parental consent.

2.5. Randomization

2.5.1. Sequence Generation

Random allocation sequences were generated using an online randomization tool (https://www.randomizer.org). Two sets of random numbers were created, corresponding to the two intervention orders.

2.5.2. Allocation Concealment

Each allocation code was printed, cut into identical slips, and sealed in opaque envelopes. The envelopes were placed in a single container. Upon recruitment, each participant selected one envelope to determine their assigned intervention sequence.

2.6. Blinding

Due to the nature of the interventions, blinding of the participants and operators was not feasible. However, the statistician responsible for data analysis was blinded to the group assignments to minimize analytical bias.

2.7. Inclusion and Exclusion Criteria

The inclusion criteria included children aged 10-15 years, medically fit and systemically healthy, with no active orthodontic treatment or space maintainer with no use of any type of dental floss within the previous 24 hours. Children with fewer than four posterior proximal contacts were excluded from the study.

2.8. Sample Size Calculation

The sample size was calculated using G*Power software (version 3.1.9.7), based on the findings of Abdellatif et al., who compared the efficacy of water flossers and regular floss in plaque removal [13]. Assuming a power of 80%, a two-tailed significance level (α) of 0.05, and an effect size derived from the cited study, a total of 44 participants (22 per group) were required to achieve sufficient statistical power.

2.9. Study Procedures

Participants were screened according to the inclusion and exclusion criteria. Parents were informed that participation was voluntary and that all collected data would remain confidential and accessible only to the research team.

Each participant was randomly assigned to start with one of the following:

- Group A: Unflavored, unwaxed regular dental floss (Oral-B, USA)(Figure 1a), or
- Group B: Water flosser (Waterpik Cordless Plus Water Flosser, USA)(Figure 1b).

After the first visit, a 14-day washout period was observed before the crossover intervention was applied.

At the first visit, demographic data (participant initials, age, and sex) and group allocation were recorded. A clinical examination was performed to assess the Plaque Index (PI) using the criteria of Silness and Löe (1964). All participants received standardized oral hygiene instructions, including brushing twice daily with the Modified Bass Technique using a soft-bristled toothbrush and fluoridated toothpaste. Participants received instructions on the proper use of the assigned interdental cleaning method and performed the procedure independently.

The Plaque Index (PI) was recorded for all teeth according to the following criteria:

- 0: No plaque in the gingival area.
- 1: A film of plaque adhering to the free gingival margin and adjacent tooth area, detectable only by a probe.
- 2: Moderate accumulation of soft deposits visible to the naked eye within the gingival margin.
- 3: Abundant soft matter within the gingival pocket and/or along the gingival margin.

At the second visit, participants switched to the opposite cleaning method (water flosser or regular floss), and plaque scores were reassessed using the same PI criteria.

2.10. Statistical Analysis

Descriptive statistics, including means, medians, standard deviations, interquartile ranges (IQRs), minima, and maxima, were calculated to summarize the data. Normality was assessed using the Kolmogorov-Smirnov test, and Levene's test was conducted to evaluate the assumption of equal variances. Due to the violation of the normality assumption, the Wilcoxon signed-rank test was used for the comparison of plaque scores between water floss and regular floss. This test was also used for additional paired comparisons, including before and after flossing, anterior versus posterior teeth, maxillary versus mandibular arches, and right versus left sides.

Linear regression analysis was used to assess the association between gender and plaque scores after flossing for each flossing method, with adjusted

models controlling for age and number of surfaces flossed. The significance level was set at p-value = 0.05. All analyses were performed using Stata version 16.1 (StataCorp, College Station, TX). (a)

(a) (b)

Figure 1. Oral hygiene aids used in the study: (a) Regular dental floss (Oral-B, USA); (b) Water flosser (Waterpik Cordless Plus Water Flosser, USA).

Consent Form

Title of Research:

The Effectiveness of Water Jet Floss and Interdental Flossing for Oral Hygiene in Children between 10 -15 Years Old: A Randomised Clinical Trial

Part I – Research Participant Information Sheet:

A. Purpose of the Research:

This study aims to evaluate the effect of water floss and traditional dental floss on children's oral health.

B. Description of the Research:

The process of cleaning teeth involves using a toothbrush with toothpaste. Some areas cannot be effectively cleaned using just a toothbrush, so it is necessary to use other tools like dental floss. There are devices that clean teeth in a manner similar to dental floss but use water, known as water flossers. These devices have proven effective in cleaning teeth for adults and orthodontic patients. The aim of this research is to present evidence-supported results regarding effective oral hygiene practices for children. By comparing the effectiveness of water flossing with traditional dental floss, this study helps identify the most effective method, which can influence recommendations for children's dental care.

C. Potential Risks and Discomforts:

Bleeding gums, mild pain, and discomfort.

D. Potential Benefits:

Cleaning teeth and teaching different methods for flossing, while choosing the most suitable one for the child.

E. Cost/s To participate in the research you will bear no additional costs or extra loss.

F. Compensation / Treatment:

In the event of injury resulting from participation in this research study, Researcher will make a treatment to you, its facilities and professional attention. Financial compensation from KAUFD is not available.

G. Voluntary Participation:

Participation in this study is voluntary. You will suffer no penalty nor loss of any benefits to which you are otherwise entitled should you decide not to participate. Withdrawal from this research study will not affect your ability to receive alternative methods of Dental care available at KAUFD.

Significant new findings developed during the course of the research study which might be reasonably expected to affect your willingness to continue to participate in the research study will be provided to you.

H. Confidentiality:

Your identity and medical record, as a participant in this research study, will remain confidential with respect to any publications that may result from this study. Furthermore, your Dental/medical record may be reviewed by the Research Advisory Council or the agency sponsoring this research in accordance with applicable laws and regulations.

I. Contact Person(s):

Dr. Abdalrahman M. Ainousa
amainousa@kau.edu.sa

A signed copy of the consent form will be given to you.

PART II - Authorization for performance of certain procedures:

1. I/surrogate authorize Dr. _____ and his/her associates to administer the following drugs, use the following devices or perform the following procedures during my treatment (or the treatment of the person named above for whom I am responsible)

_____

2. I acknowledge that I have read, or had explained to me in a language I understand, the attached Research Participant Information sheet and that Dr. _____ has explained to me the nature of the procedures described in the Research Participant Information Sheet as well as any benefits to be expected, possible alternative methods of treatment, the attendant discomforts and risks reasonably to be expected and the possibility that complications from both known and unknown causes may arise as a result thereof. I was given ample opportunity to comprehensively inquire about this study and procedures, and all my questions were answered to my satisfaction.

3. I understand that I am not entitled for reimbursement for expenses incurred as a result of my participation in this study

4. I voluntarily accept the risks associated with the above-mentioned procedures with the knowledge and understanding that the extent to which they may be effective in my treatment (or the treatment of the patient named above, as the case may be) has not been established, that there may be side effects and complications from both known and unknown causes and that these procedures may not result in cure or improvement.

5. I understand that I am free to withdraw this consent and discontinue treatment with the above procedures at any time. The consequences and risks, if any, which might be involved in the event I later decide to discontinue such treatment, have been explained to me adequately. I understand that such withdrawal will not affect my ability to receive any dental/medical care made necessary by the performance of such studies or to which I might be otherwise entitled.