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Microbial contamination and surface effects of a salvadora persica–black silica toothbrush: a clinical and in vitro study

Submission date
22/10/2025

Recruitment status
No longer recruiting

Registration date
31/10/2025

Overall study status
Completed

Last Edited
14/10/2026

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
This study investigates the antibacterial efficacy of a newly designed Miswak-Black Silica toothbrush and its effects on the color stability, surface roughness, and remineralization potential of enamel and restorative materials compared to a conventional soft manual toothbrush.

Who can participate?
Healthy volunteers aged 18–35 years with good oral hygiene

What does the study involve?
Participants will use two different toothbrushes — Miswak-Black Silica and Colgate soft manual toothbrush — each for 1 week, separated by a 1-week washout period. Used brushes will be collected for bacterial culture testing. Laboratory tests will evaluate surface roughness, color change, and remineralization potential.

What are the possible benefits and risks of participating?
There are no direct personal benefits but participation may enhance oral health awareness. Risks are minimal, limited to temporary discomfort, potential mild abrasion or rare allergic reaction.

Where is the study run from?
College of Dentistry, Taibah University, Al-Madinah Al-Munawarah (Saudi Arabia)

When is the study starting and how long is it expected to run for?
May 2025 to April 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Microbial contamination and surface effects of a salvadora persica–black silica toothbrush: a clinical and in vitro study

Acronym
MIS-BLACK TB

Study objectives
Current study objectives as of 14/10/2026:

1. To clinically evaluate and compare bacterial presence and quantitative bacterial load (CFU counts) on used toothbrush bristles following a 5-week cross-over clinical trial in 51 systemically healthy adults
2. To quantitatively assess the in vitro physical effects of these protocols on surface roughness (ΔRa) and color stability (ΔE00) of human enamel and three esthetic restorative materials, including resin composite, resin-modified glass ionomer cement (RMGIC), and conventional glass ionomer cement (CGIC)

Previous study objectives:

1. To measure the antibacterial effect of Miswak-black Silica toothbrush compared to a soft manual toothbrush (combined in vivo and in vitro)
2. To evaluate the surface roughness of human enamel, resin composite, and resin-modified glass ionomer samples after toothbrushing simulation with Miswak-black Silica toothbrush or Colgate soft manual toothbrush (in vitro)

3. To investigate the color stability of human enamel, resin composite and resin-modified glass ionomer samples after toothbrushing simulation with Miswak-black Silica toothbrush or Colgate soft manual toothbrush (in vitro)
4. To assess the remineralization potential of Miswak-Black Silica Toothbrush on tooth structure (in vitro)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 13/05/2025, Taibah University College of Dentistry Research Ethics Committee (TUCD-REC) (College of Dentistry, Taibah University, Al-Madinah Al-Munawarah, 0000, Saudi Arabia; +966 (0)14 861 8888; tucdrec@taibahu.edu.sa), ref: TUCDREC/202425/AAlqussier

Primary study design
Interventional

Allocation
Non-randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Crossover

Purpose
Prevention

Study type(s)
Efficacy, Prevention, Other

Health condition(s) or problem(s) studied
Toothbrush microbial contamination; color stability and surface roughness of enamel, resin composite, resin-modified glass ionomer cement, and conventional glass ionomer cement

Interventions
Current interventions as of 14/10/2026:

Clinical component (fixed-sequence, non-randomized crossover; 5 weeks):
Week 1 – Protocol A: Silver-ion antibacterial soft manual toothbrush (Colgate Zig-Zag, Colgate-Palmolive) with a standardized fluoride toothpaste (Colgate Maximum Cavity Protection), twice daily for 2 minutes.
Week 2 – Washout: participants' own toothbrush with the standardized toothpaste.
Week 3 – Protocol B: Salvadora persica (Miswak)–black silica toothbrush (Shinyei Kaisha, Kobe, Japan) used without toothpaste, twice daily for 2 minutes.

Week 4 – Washout: participants' own toothbrush with the standardized toothpaste.
Week 5 – Protocol C (control): Conventional soft manual toothbrush (Sensodyne, GlaxoSmithKline) with the standardized toothpaste, twice daily for 2 minutes.
Used toothbrushes were collected at the end of each intervention week for microbiological analysis.

In vitro component: Enamel, resin composite, resin-modified glass ionomer cement, and conventional glass ionomer cement specimens were brushed with each of the three protocols for 10,000 cycles (≈1 year simulation) in a toothbrush simulator.

Note: Prior to the first enrolment, the protocol was amended to: (1) add a Sensodyne conventional toothbrush with fluoride toothpaste as a control arm; (2) extend the upper age limit to 45 years; and (3) revise the microbiological outcome from Streptococcus mutans CFU (48-hour incubation) to total cultivable bacterial presence and load (24-hour aerobic incubation), to assess overall toothbrush contamination. In vitro, conventional glass ionomer cement was added, and measurements used a contact profilometer (Mitutoyo SJ-210) and Vita Easyshade V. All participants followed the amended protocol. The registered Colgate toothbrush is the Colgate Zig-Zag silver-ion antibacterial toothbrush. The registry was not updated at the time; this update corrects that omission.

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Previous interventions:

Group 1: Miswak-Black Silica toothbrush (Shinyei Kaisha, Japan) used twice daily for 2 minutes without toothpaste for 1 week.
Group 2: Colgate soft manual toothbrush used with fluoride toothpaste twice daily for 2 minutes for 1 week.

All participants will be instructed to use the conventional (soft) toothbrush with fluoride-containing toothpaste for the first week. Then, after a week washout period, they will be instructed to use the smart toothbrush (miswak/black silica-based toothbrush) for another week (non-randomized study).

In vitro component: Enamel and restorative samples brushed for 10,000 cycles (≈1 year simulation).

Intervention Type
Device

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Salvadora persica (Miswak)–black silica toothbrush; Colgate Zig-Zag silver-ion antibacterial toothbrush; Sensodyne conventional soft toothbrush

Primary outcome(s)
Current primary outcome(s) as of 14/10/2026:

1. Bacterial presence (presence/absence of cultivable bacterial growth) on used toothbrush bristles measured using culture on Brain Heart Infusion agar after 24-hour aerobic incubation at the end of each 1-week intervention phase (weeks 1, 3, and 5)
2. Bacterial load (colony-forming units, CFU) on used toothbrush bristles measured using culture on Brain Heart Infusion agar after 24-hour aerobic incubation at the end of each 1-week intervention phase (weeks 1, 3, and 5)

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Previous primary outcome(s):

Bacterial colony-forming units (CFUs) on toothbrush bristles after 48-hour incubation (Streptococcus mutans)

Key secondary outcome(s)
Current key secondary outcome(s) as of 14/10/2026:

1. Color change (ΔE00) of enamel, resin composite, resin-modified glass ionomer cement, and conventional glass ionomer cement specimens measured using a spectrophotometer (Vita Easyshade V) and the CIEDE2000 formula at baseline and after 10,000 simulated brushing cycles
2. Surface roughness change (ΔRa) of the same specimens measured using a contact profilometer (Mitutoyo SJ-210) at baseline and after 10,000 simulated brushing cycles
3. Enamel remineralization potential measured using scanning electron microscopy (SEM) following demineralization and brushing simulation (not yet performed; deferred to a separate in vitro investigation)

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Previous key secondary outcome(s):

1. Mean surface roughness change (ΔRa) measured with a 3D profilometer before and after brushing simulation
2. Color variation (ΔE00) measured with a Vita Easyshade III spectrophotometer before and after brushing
3. Enamel remineralization examined via scanning electron microscopy (SEM) following demineralization and brushing simulation

Completion date
29/04/2026

Eligibility

Key inclusion criteria
Current key inclusion criteria as of 14/10/2026:

1. Age of 18–45 years
2. Tooth brushing frequency of two times daily
3. Systemically healthy individuals
4. Good oral hygiene status

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Previous key inclusion criteria:

1. Adults aged 18–35 years
2. Brushes teeth twice daily
3. Plaque index ≤2

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
All

Total final enrolment
51

Key exclusion criteria
1. Open carious lesions
2. Plaque index >2
3. Severe gingivitis (score >2)
4. Throat infection
5. Irregular brushing habits
6. Smoking
7. Medically compromised condition

Date of first enrolment
20/10/2025

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
Saudi Arabia

Study participating centre

Taibah University
College of Dentistry
PO Box 344
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Sponsor information

Organisation
Taibah University

ROR
https://ror.org/01xv1nn60

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			29/10/2025	No	Yes
Participant information sheet			14/10/2026	No	Yes
Protocol file			29/10/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes