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Effect of miswak-black silica toothbrush on the color stability and surface roughness of resin composite, resin-modified glass ionomer, and enamel surface, and its remineralization potential: an in vitro and in vivo study

Submission date 22/10/2025	**Recruitment status** Recruiting	[_] Prospectively registered [X] Protocol
Registration date 31/10/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 29/10/2025	**Condition category** Oral Health	[_] 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?
Dr Anfal Alqussier, aalqusayr@taibahu.edu.sa

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Effect of miswak-black silica toothbrush on the color stability and surface roughness of resin composite, resin-modified glass ionomer, and enamel surface, and its remineralization potential: an in vitro and in vivo study

Acronym
MIS-BLACK TB

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: TUCDREC202425/Alqussier

Study design
Single-centre clinical non-randomized and in vitro comparative laboratory study

Primary study design
Interventional

Study type(s)
Efficacy, Prevention, Other

Health condition(s) or problem(s) studied
Antibacterial effect, surface roughness and color stability of enamel, resin composite, and resin-modified glass ionomer

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)

Miswak-Black Silica toothbrush

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

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
20/04/2026

Eligibility

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
No

Age group
Adult

Lower age limit
18 years

Upper age limit
35 years

Sex
All

Total final enrolment
50

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
Al-Madinah Al-Munawwarah
Saudi Arabia
42353

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

The datasets generated during and/or analysed during the current study are not expected to be made available due to participant privacy

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
Protocol file			29/10/2025	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes