

# 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

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|----------------------------------------|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>22/10/2025   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol                       |
| <b>Registration date</b><br>31/10/2025 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                                  |
| <b>Last Edited</b><br>09/04/2026       | <b>Condition category</b><br>Oral Health          | <input type="checkbox"/> Individual participant data<br><input checked="" type="checkbox"/> 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

### Contact name

Dr Anfal Alqussier

### ORCID ID

<https://orcid.org/0000-0001-7149-8529>

### Contact details

KSA, Madinah

Madina

Saudi Arabia

00000

+966 (0)556622191

aalqusayr@taibahu.edu.sa

## Additional identifiers

## 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 ( $\approx$ 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 ( $\Delta R_a$ ) measured with a 3D profilometer before and after brushing simulation
2. Color variation ( $\Delta E_{00}$ ) 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**

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

**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

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type

[Participant information sheet](#)

Details

Date created

Date added

29/10/2025

Peer reviewed?

No

Patient-facing?

Yes

[Protocol file](#)

29/10/2025 No

No

[Study website](#)

Study website 11/11/2025

11/11/2025 No

Yes