

# The role of ozone on gingival tissue healing after gingivectomy

<b>Submission date</b> 29/08/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/09/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/09/2024	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Background and study aims:

Gingival enlargement is an oral condition that causes the gums to overgrow. It results from several factors, including inflammatory factors. Gingival enlargement can affect function, leading to difficulty speaking and chewing, which makes patients vulnerable to periodontal (gum) disease and halitosis (bad breath) and negatively affects their quality of life. Traditional periodontal treatment may not help in reducing gingival enlargement, so another option may be necessary, which is gingival resection. Traditional surgical resection with a scalpel (gingivectomy) is the standard method for treating gingival enlargement. Laser surgical resection is one of the modern treatment options, as the laser has the ability to reduce complications after surgery. Ozone treatment has been considered as a disinfectant aid due to its immunostimulating, antimicrobial and antioxidant effects. This study aims to test the effectiveness of applying ozone on wound healing and the extent of recurrence after traditional surgical cutting compared to laser cutting.

Who can participate?

Patients aged between 18 and 50 years with inflammatory gingival overgrowth that does not heal after 15 days of professional and individual care

What does the study involve?

In the first session, all patients will be prepared and educated on oral hygiene instructions. In the second session, 15 days after the patient has been prepared, if gingival overgrowth did not heal, a gingivectomy will be performed with a random choice of the traditional or laser surgical method. Participants are randomly allocated to the two treatment methods. (surgical method or laser method). Immediately after resection, ozone gas will be applied to the wound. At the follow-up sessions, pain, healing, gingival enlargement and patient satisfaction will be measured.

What are the possible benefits and risks of participating?

Benefits may include periodontal health improvement and patients will become more aware of the importance of oral care in addition to improving the patient's aesthetic and psychological aspects, reducing inflammation and thus improving their quality of life. Possible risks might include some pain and discomfort after the procedure.

Where is the study run from?  
Damascus University (Syria)

When is the study starting and how long is it expected to run for?  
March 2022 to October 2024

Who is funding the study?  
Damascus University (Syria)

Who is the main contact?  
Dr Dana Hussen, danahussen95@gmail.com, dana.hussen@damascusuniversity.edu.sy

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

Dr Dana Hussen

### Contact details

Mashrou'a Dummar  
Damascus  
Syria  
4671  
+963 (0)992185672  
dana.hussen@damascusuniversity.edu.sy

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

3035

## Study information

### Scientific Title

Evaluation of the efficacy of ozone in healing of inflammatory gingival enlargements after resection by traditional method or by diode laser

### Study objectives

h0: There are no statistically significant differences between all treatment groups regarding the clinical studies indices.

h1: There are statistically significant differences between all treatment groups regarding the clinical studies indices.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

Approved 20/06/2022, Scientific ethics committee at Damascus University (Baramkeh, Damascus, 4671, Syria; +963 (0)1133923223; ap.srd@damascusuniversity.edu.sy), ref: 2722

## **Study design**

Single-blinded randomized controlled clinical trial

## **Primary study design**

Interventional

## **Secondary study design**

Randomised controlled trial

## **Study setting(s)**

University/medical school/dental school

## **Study type(s)**

Prevention, Treatment

## **Participant information sheet**

Not available in web format, please use the contact details to request a participant information sheet

## **Health condition(s) or problem(s) studied**

Inflammatory gingival overgrowth

## **Interventions**

The study aims to compare the surgical method and the laser method of gingivectomy and to compare applying ozone after gingivectomy or not applying it in both treatment groups.

The patients are randomly allocated into each group using a paper envelope and letting the patient choose the envelope (each envelope contains a treatment group).

The surgery treatment group is split into two groups (split-mouth technique): with ozone application or without ozone application. A Kirkland scalpel is used on the buccal and lingual surfaces of the gingival tissue. An Orban scalpel is used on interdental papillae. Ozone is then applied to interdental papillae on one side of the oral cavity and then gingival dressing is applied.

Ozone is applied on every interdental papilla for 20 seconds after isolation with cotton rolls. The surgical procedure takes nearly 30 minutes and the ozone application with the gingival dressing takes nearly 30 minutes so the whole working time is nearly 1 hour.

The laser group is split into two groups (split-mouth technique): with ozone application or without ozone application.

Laser parameters: Power: 2 W; Wavelength: 980 nm; Continuous mode CW.

The laser cutting session takes approximately 20 minutes, the ozone application takes nearly 15 minutes (no gingival dressing is applied) and the whole working time is approximately 35 minutes.

The follow-up appointments:

Clinical parameters and measures are re-evaluated in these sessions. Intra-oral photographs are taken. They take nearly 20 minutes.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

Gingival tissue enlargement measured using Gingival Overgrowth (GO), which has three degrees (0, 1, 2, 3), at baseline and after 15 days (immediately before gingival resection), 1 month and 3 months after resection

## **Secondary outcome measures**

1. Periodontal probing depth (PPD), defined as the distance from the free gingival margin to the bottom of the periodontal pocket. Measured using a periodontal probe (Williams) at baseline and after 15 days (immediately before gingival resection), 1 month and 3 months after resection.
2. Level of gingival inflammation is measured using the Gingival Index (GI) at baseline and after 15 days (immediately before gingival resection), 1 week, 2 weeks, 1 month and 3 months after resection.
3. Pain is measured using a visual analogue scale (VAS) on day 1, day 3, 1 week and 2 weeks after resection
4. Level of healing is measured using the Healing Index (HI), which has five degrees (1, 2, 3, 4, 5) at 1 week, 2 weeks and 1 month after resection

## **Overall study start date**

15/03/2022

## **Completion date**

25/10/2024

# **Eligibility**

## **Key inclusion criteria**

1. Grade II-III inflammatory gingival hyperplasia that has not been improved after 15 days of professional and individual periodontal care
2. Pseudo-gingival pockets with a depth of 2 mm and above
3. Patient aged between 18-50 years old
4. Healthy patients without systemic diseases

## **Participant type(s)**

Patient

## **Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

50 Years

**Sex**

Both

**Target number of participants**

30

**Total final enrolment**

40

**Key exclusion criteria**

1. Pregnant women or those using oral contraceptives
2. Breastfeeding women
3. Smokers
4. Patients treated with nonsteroidal anti-inflammatory drugs and analgesics for 1 month
5. Patients prohibited from undergoing surgery or anesthesia, or patients that have uncontrolled systemic diseases
6. Bad restorations or prosthodontics in the gingival area
7. Localized gingival hyperplasia
8. Patients with drug or hormonal hyperplasia

**Date of first enrolment**

14/07/2022

**Date of final enrolment**

29/08/2024

**Locations****Countries of recruitment**

Syria

**Study participating centre**

**Damascus University**

Faculty of Dental Medicine

Oral Medicine Department

Mazzeah Highway

Damascus

Syria

4671

**Sponsor information**

**Organisation**

Damascus University

**Sponsor details**

Baramkeh

Damascus

Syria

4671

+963 (0)1133923223

ap.srd@damascusuniversity.edu.sy

**Sponsor type**

University/education

**Website**

<http://www.damascusuniversity.edu.sy>

**ROR**

<https://ror.org/03m098d13>

**Funder(s)****Funder type**

University/education

**Funder Name**

Damascus University

**Alternative Name(s)**

University of Damascus, , DU

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Syria

**Results and Publications****Publication and dissemination plan**

Planned publication in a peer-reviewed journal

**Intention to publish date**

03/02/2025

**Individual participant data (IPD) sharing plan**

The datasets will be generated and analyzed during the current study and will be available upon request from Dr Dana Hussen (danahussen95@gmail.com)

**IPD sharing plan summary**

Available on request