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The role of ozone on gingival tissue healing after gingivectomy

Submission date 29/08/2024	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 05/09/2024	**Overall study status** Completed	
Last Edited 05/09/2024	**Condition category** Oral Health	

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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Prevention, Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
All

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
Mazzeh Highway
Damascus
Syria
4671

Sponsor information

Organisation
Damascus University

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

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