

Sudan University of Science and Technology
Collage of Graduate Studies

Comparison of Diode Laser and Scalpel Technique in Frenectomy Procedure

مقارنه بين الليزر الثنائي و تقنيه المشرط في استئصال اللجام الشفوي

A Dissertation Submitted in Partial Fulfillment for the Requirement of the Degree of Higher
Diploma of Laser Application in Medicine (Dentistry)

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Declaration

I would like to declare that the work submitted is original and has not been submitted elsewhere.

Dedication

To my parents for their never ending support and encouragement. Everything that I am, I owe to them.

Acknowledgment

My deepest appreciation goes to my dissertation advisor Prof.Amna Algarrai and co-supervisor Prof.Sohad Elwaeel for their patient guidance, useful critique and most importantly for their unmatched generosity with their time.

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Abbreviations

Laser: light amplification by stimulated emission of radiation.

LLLT: low level laser therapy.

PBM: Photobiomodulation.

VAS: Visual Analog Scale.

CW: continuous wave.

Abstract

Background: The Frenum is a fold of mucous membrane that attaches the lips and cheeks to the alveolar mucosa and/or gingiva and underlying periosteum Labial frenum with an abnormal attachment can be termed an aberrant frenum which may interfere with many oral functions such as pronunciation and tongue movement. Interference may also occur with various therapeutic modalities in many dental departments such as in prosthodontics, orthodontics, and periodontal health, resulting in biofilm accumulation and may cause recession and contribute to diastema formation.

Objective: The aim of this study was to record and then compare the intra-operative and postoperative objective and subjective effects of Diode laser and conventional techniques after frenectomy surgery.

Methods: In this study, two patients were included where one received frenectomy procedure using Diode laser with wavelength of 980 nm, power of 2 watts and the other patient received scalpel frnectomy.

Results: The patient treated with Diode laser experienced no intra-operative pain, less local anesthetic was used, the surgical field was bloodless and no sutures

were needed. As for the patient treated via conventional scalpel technique, more local anesthetic was used, no intra-operative pain was experienced but mild pain was experienced post-operatively and more analgesics were used. Bleeding during the procedure was moderate and sutures were placed after completion of the procedure.

Conclusion: Diode laser showed superiority to scalpel technique due to reduced amount of anesthetic and analgesic used, the bloodless surgical field and no intraoperative pain.

المستخلص

خلفيه: اللجام الشفوي مكون من انسجه مخاطيه تربط الشفاه و الخدين بانسجه الفم المخاطيه و\او اللثه و الاغشه اللتي تغطي العظم الفكّي. اللجام الشفوي اللذي يرتبط ارتباط غير طبيعي يسمّى بلجام شاذ و اللّي يمكن ان يتعارض مع العديد م وظائف الفم مثل نطق الاحرف و حركه اللسان. يمكن ايضا ان يتعارض مع العديد من العلاجات المقدمه في العديد من اقسام طب الاسنان مثل قسم التركيبات, التقويم, و قسم اللثه و الانسجه المحيطه مما يمكن ان يؤدي الى تراكم الترسبات السنيه و انحسار اللثه و تكون الفلجه.

الهدف: الهدف من هذه الدراسه هو تسجيل ثم مقارنه الاعراض اثناء ثم بعد عمليه استئصال اللجام بالليزر و بالطريقه التقليديه.

الطريقه: في هذه الدراسه, تم ضم مريضين, تم استعمال جاز ليزر الدايدود بطول موجي 980 نانو متر وقوه 2. واط والمريض الاخر تم علاجه بالطريقه التقليديه باستعمال المشرط.

النتائج: المريض اللذي تم معالجته بالليزر لم يشعر باي الم اثناء العمليه, تم استعمال كميه اقل من البنج الموضعي, كان الموضع الجراحي خالي من الدم ولم يتم استعمال الخيوط الجراحيه بعد الانتهاء. اما المريض اللّي تم علاجه بالطريقه التقليديه تم استعمال كميه اكبر من البنج الموضعي, لم يكن هنالك الم اثناء العمليه, وبعد العمليه كان هنالك الم طفيف وتم استعمال كميه اكبر من المسكن, كان هنالك نزف ذو كميه متوسطه اثناء العمليه وتم وضع خيوط للجرح بعد الانتهاء.

الخلاصه: ليزر الدايدود اكثر تفوقا على تقنيه المشرط التقليديه لانه تم استعمال كميه اقل من البنج الموضعي والمسكنات, كما ان النزف اثناء العمليه لمن يكن موجودا ولم يكن هنالك الم اثناء العمليه.

Chapter One

Introduction

1.1 Introduction

The Frenum is a fold of mucous membrane that attaches the lips and cheeks to the alveolar mucosa and/or gingiva and underlying periosteum('Frenectomy : A Review with the Reports of Surgical Techniques', 2012). It consists of connective tissue, made of elastic and collagen fibers however it can also have muscular fibers. They have a physiological role as they limit and stabilize lingual and labial movements.(Tajasar *et al.*, 2021)(Haytac and Ozcelik, 2006)

Labial frenum with an abnormal attachment can be termed an aberrant frenum which may interfere with many oral functions such as pronunciation and tongue movement. Interference may also occur with various therapeutic modalities in many dental departments such as in prosthodontics, orthodontics, and periodontal health, resulting in biofilm accumulation(Journal and Stomatology, no date)('Prevalence of Types of Labial Frenum Attachment and Frenectomy with Conventional Scalpel Technique in a Sample of Iraqi Population', 2020). Moreover short lingual frenum can also be responsible of ankyloglossia (Ferrés-Amat *et al.*, 2016).

The frenum is characterized as pathogenic and is indicated for removal when an aberrant frenal attachment is present. There are various implications associated with that which may result in the formation of a midline diastema.(Tajasar *et al.*, 2021) In periodontics, if the frenum is closely attached to the gingival margin, the vestibule may become shallow leading to difficulties in maintenance of oral hygiene in the area, paired with pulling action of the frenum, this may contribute to gingival recession.(‘Frenectomy : A Review with the Reports of Surgical Techniques’, 2012).

1.2 Justification:

Due to the various complications that may be associated with scalpel frenectomies such as higher patient anxiety levels, longer appointment duration, risk of bleeding, more anesthetic required and the fact that scalpel procedure frenectomies always require the placement of sutures, it is crucial to use available alternatives that would help save time, reduced patient stress levels and minimize the various complications that might be associated with scalpel frenectomies for better intra-operative and post-operative outcomes.(Lebret *et al.*, 2021)(Khosraviani *et al.*, 2019)

Successful clinical outcomes using various types of lasers to manage oral soft tissue procedures are well described(Ozcelik *et al.*, 2008). Furthermore, several authors reported the benefit of laser assistance to perform oral frenectomies, such as shorter operative time, hemostasis and reduced postoperative pain.(Lebret *et al.*, 2021)(Azma and Safavi, 2013)

1.3.1 General objectives:

The aim was to study the effects of Diode laser in frenectomy procedure.

1.3.2 Specific objectives:

- To assess the amount of local anesthetic administered during the procedure.
- To assess the level of intra-operative bleeding using laser compared to scalpel frenectomy.
- To assess the level of post-operative pain one day post operatively and on day 7 and the amount of analgesics used after laser compared to scalpel frenectomy.

1.4 Comparison of Laser and scalpel techniques:

In 2007 in Sudan, a study was conducted using Diode Laser for frenectomy procedure using a glass fiber tip of 400 micrometer diameter, power setting of 20 watts, energy of 1.8 joules/sec, frequency of 10.000 Hz. Fourteen patients were included in the study and followed up after the procedure at three days, one week and four weeks. The results showed sufficient coagulation with no bleeding

during the operation, no pain during the procedure for all participants. One day after the procedure, all participants reported no pain with the exception of two participants that reported minimal pain or minimal discomfort. Good wound healing and fast epithelialization was reported as well.(Awooda, 2007)

Another study in 2014 in Iraq included 25 patients, Diode Laser was used to conduct frenectomy procedure with a wavelength of 980 nm in Continuous Wave mode and power of 20 watts, 400 micrometer fiber optic with a spot size of 0.9 mm. The clinical findings of the study included sufficient hemostasis, coagulation and precise incision margin with all of the surgical procedures. The postoperative advantages included lack of swelling, bleeding, pain or scar tissue formation. Good wound healing and overall patient satisfaction were observed in the clinical application of laser-assisted frenectomy.(Aldelaimi and Mahmood, 2014)

In 2018 a study was conducted in Nepal, where a total of 20 patients who exhibited papillary and papilla penetrating labial frenal attachments requiring frenectomy were randomly assigned to two groups, Group A: Comprised of 10 patients selected for diode laser frenectomy and Group B: Comprised of 10 patients selected for scalpel frenectomy. The postoperative pain of each patient was assessed using a Visual Analog Scale and the number of analgesic used was

recorded on postoperative days one and seven. Diode laser (iLase™) emitting 940 nm was used in Group A, where preset value was adjusted: Power of 2.00 watt, pulsed contact mode, continuous pulse duration, and pulse interval of 1.00ms. The entire procedure was painless with no bleeding and lesser intra-operative time. No sutures were placed in this group. Patients treated with the diode laser had significantly less postoperative pain at day one and used less number of analgesic (2.30 ± 0.94) as compared to scalpel surgery (4.40 ± 1.07). (Bista *et al.*, 2018).

Chapter two

Literature review and theoretical background

Placek et al. have classified the frenum depending on the extension of attachment of fibers into:

1. Mucosal: when the frenal fibers are attached up to mucogingival junction.
2. Gingival: when fibers are inserted within attached gingiva.
3. Papillary: when fibers are extending into interdental papilla.
4. Papilla penetrating: when the frenal fibers cross the alveolar process and extend up to palatine papilla.(Mirko, Miroslav and Lubor, 1974a)

Several procedures have been suggested, to eliminate aberrant frenal attachments including frenectomy (excision of the frenum) and frenotomy (relocating the frenulum attachment). Frenectomy is the elemention of the frenum completely, including its attachment to the alveolar bone. ('Frenectomy : A Review with the Reports of Surgical Techniques', 2012)

Various techniques have been used for performing Frenectomy procedures such as the conventional scalpel technique. However, there are many new surgical techniques and modifications that have been used such as:

1. The Miller technique.

2. V-Y plasty and Z-plasty have been developed to solve the problems which are caused by an abnormal labial frenum.

Other techniques such as electro cautery, and recently lasers such as erbium (Er): yttrium aluminum garnet (YAG), and neodymium-doped YAG (Nd:YAG), Diode laser and CO2 laser have been used.(Verma *et al.*, 2012)

The selection of frenectomy technique depends on the operator in accordance with the patient's socio-economic status, chair time, patient's medical status and the effectiveness of the procedure of choice. ('Prevalence of Types of Labial Frenum Attachment and Frenectomy with Conventional Scalpel Technique in a Sample of Iraqi Population', 2020)

Diode lasers, which first appeared in 1962, are still the most energy efficient and cost effective lasers. Therefore, they have found more and more applications in the field of medical therapies.(Report, 2015) Diode lasers were used mainly for photobiomodulation (PBM)—previously also known as biostimulation or low-level laser therapy (LLLT) where the wavelength is more detrimental than high power.

After the discovery of the role of cytochrome c oxidase in the mitochondria as primary chromophore and the introduction of the concept of “retrograde mitochondrial signaling”, the uses for diode lasers expanded. The significance of

PBM in cell culture studies, resistance to fungal infections, mitigation of the side-effects of cancer therapy, pain and inflammation therapies, wound healing, muscle performance, etc. has become clearer. It has been used for wound and ulcer healing applications, the treatment enhanced wound healing and improved patient satisfaction and overall wellbeing.(Pié-sánchez, Arnabat-domínguez and Gay-escoda, 2012)(Ozcelik *et al.*, 2008)

The term "laser" is a contraction of "light amplification by stimulated emission of radiation. Laser devices emit light that is spatially coherent and collimated meaning that a laser beam can remain narrow and confined over a long distance with minimal convergence, and it can be highly focused in a point. (Awooda, 2007)

As laser beam is directed to tissues, various interactions take place which are grouped under the term laser tissue interactions. Each tissue component interacts differently with laser beam; each tissue has different characteristics and therefore, absorb, scatter, reflect and transmit laser beams differently at different wavelengths.(Khosraviani *et al.*, 2019)(Lebret *et al.*, 2021)

In periodontology, Lasers have various applications including soft tissue excision, ablation, various incisions, dental calculus removal using (Er: YAG, Er, Cr: YSGG lasers), Decontamination of root surfaces affected by periodontal disease and

implant surfaces as well, also, biostimulation therapy can be used to fasten wound healing, reduce bacterial count and it can also be used to assist in periodontal osseous surgery. Certain laser wavelengths (i.e. Er: YAG, Er, Cr: YSGG) are highly absorbed by hydroxyapatite and can be used for bone removal more efficiently than others. In contrast, diode and Nd: YAG lasers are more highly absorbed by hemoglobin and thus should be used when coagulation is desired.

In addition, due to the effect that these wavelengths (diode and Nd: YAG lasers) have on pigmented tissues, they can be used by periodontists for removal of gingival pigmentation and reduction of periodontopathogenic bacteria.(Lebret *et al.*, 2021)(Azma and Safavi, 2013)

In the last few years, the CO2 laser has been successfully used in oral soft tissue surgery procedures, such as gingival resections, gingivoplasties, soft tissue biopsy samples, frenectomies, treatment of lymphangiomas, and crown lengthening procedures.(Azma and Safavi, 2013)(Aldelaimi and Mahmood, 2014)

There are various advantages to using lasers such as reduced pain, less need for local anesthetics which is especially advantageous for patients who are medically compromised, reduced risk of bacteremia, better wound healing, with various wavelengths that can help with control of bleeding during surgery. (Ozcelik *et al.*,

2008) Usually there is no need for sutures, fewer instruments and materials are required, therefore, less need for sterilization. With the ability of lasers to remove both hard and soft tissues, they can be used in combination with scalpels.(Xie *et al.*, 2022)

Despite the varied advantages, Lasers can have disadvantages such as their relative high device cost, various hazards and need for eye protection for physician, dental assistant and patient. It requires an additional level of knowledge, education and an understanding of different properties of different wavelengths.(Article, 2019)

Laser in dentistry can be classified according to multiple parameters, such as:

1. Applicability to hard and soft tissues.
2. According to active medium of the laser into liquid state lasers, solid state lasers, semi-conductors lasers and gas lasers.
3. According to lasing medium into solid or gas laser medium.(Verma *et al.*, 2012)

The first gas laser was the helium neon laser which was promoted by a green wavelength and several infrared wavelengths. Carbon dioxide, NdYAG, and Er:YAG (erbium-doped yttrium aluminium garnet) can be used for both hard and soft

tissue applications but they have limitations as they are expensive and cause thermal injury to the tooth pulp. Cold lasers, also known as soft lasers, which are based on the diode device are compact and have low costs. The mixture of some noble gases such as argon, krypton, and xenon with reactive gases produce a special type of gas discharge which is called the excimer laser.

The diode laser is primarily absorbed by tissue pigment and haemoglobin. On the other hand, it is poorly absorbed by hydroxyapatite and water. Hence, it has been used in aesthetic gingival surgery such as gingivoplasty and gingivectomy, the removal of inflamed and hypertrophic tissue, soft tissue crown lengthening, frenectomies, gingival depigmentation and photo-stimulation of aphthous and herpetic lesions.⁴

Chapter three

Materials and Methods

3.1 Study design

Health care facility based Randomized controlled trial.

3.2 Study area and study population

The present study was carried out on patients attending the Periodontology department at Khartoum University dental clinics complex, Department of Periodontology.

3.3 Methodology

Cases satisfying the eligibility criteria were asked to participate in the study after reviewing and signing an informed written consent.

The participants were divided randomly using coin technique into two groups:

Group A: Patient who received frenectomy procedure using conventional scalpel technique.

Group B: Patient who received frenectomy procedure using diode laser 810 nm.

3.4.1 Inclusion criteria

- Subjects who were diagnosed as having a papillary or papilla penetrating frenal attachment in accordance with the Placek classification of frenal attachments. (Mirko, Miroslav and Lubor, 1974b)

3.4.2 Exclusion criteria

- Patients with periodontitis.
- Patients with Any systemic diseases or conditions that may affect the periodontal health.
- Patients on medications that may affect periodontal health.
- Patients whose labial frenum and adjacent mucosa was affected by trauma.
- Subjects whose upper or lower frenum has been subjected to surgery.
- Patients with any abnormal upper or lower frenum or premaxilla due to developmental or congenital deformity; Patients with cleft lip or palate.

3.5 Data collection tools and techniques

- Demographic data included age, gender and educational status in addition to medical history were recorded for each subject.
- The clinical examination was performed by an examiner of an adequate level of accuracy and reproducibility in recording the clinical parameters and indices.
- Safety measures were taken for operator, patients and assistant. For laser patient the recommended laser protective eyewear was used as well. High speed suction and clinical masks were used. Chlorhexidine mouth wash with a percentage of 0.12% was used for pre-procedural rinsing in both patients.
- In Group A, conventional classical technique was used for frenectomy. Topical anesthetic was applied followed by local infiltration anesthesia using 2% Lignocaine with adrenaline 1:200,000 adjacent to the frenum attachment, the aberrant frenum was held with a pair of hemostats, and the whole band of tissue together with its alveolar attachment was excised with a No.15 blade. Any remaining fibrous adhesions to the underlying periosteum were removed. After the bleeding was controlled, the wound was closed with 4-0 silk sutures.

- In group B, Diode laser was used for the patient. After application of topical anesthetic, two carpules of local anesthetic infiltration using 2% Lignocaine with adrenaline 1:200,000 was administered adjacent to the frenum attachment. Blunt end of the probe was used to check for the objective symptoms. After the area was anesthetized, the incision was carried out using laser tip. The intervening labial frenum was released from its apex to the base in a brushing stroke. After excision, the surgical site was wiped off with cotton pellet soaked in normal saline. The entire procedure was painless with no bleeding and lesser intra-operative time. No sutures were placed.
- At 1st and 7th day postoperatively, patients were recalled and assessed for pain perception. The patients were asked to mark their pain perception on a 10 cm long Visual Analog Scale (VAS) having two endpoints ranging from 0 to 10 where 0 designates no pain and 10 designates unbearable pain.
- Similarly, the number of analgesic consumed by each patient was recorded. After completion, all recordings were analyzed, which included comparison of postoperative pain and their number of analgesics taken after the procedure in both the groups.

3.6 Study variables

Independent variables: Type of frenal attachment.

Dependent variables: Intra-operative bleeding, amount of local anesthetic used, post-operative pain, amount of analgesics taken.

3.7 Study duration

The study was conducted between January and March of 2022.

3.8 Data collection tools:

- Pair of examination gloves, face mask and face shield were used for each participant and discarded after use.
- An examination set composed of a mirror, tweezers and an explorer.
- Surgical instrument set composed of local anesthetic syringe, hemostat, tissue forceps, No:15 scalpel, blade holder, periosteal elevator, needle holder, scissors.
- Diode laser device of wavelength of 810 nm, 2 watt power, continuous mode.
- Visual analog scale (VAS) for post-operative pain assessment.

3.9 Ethical consideration

- Ethical clearance was obtained from Sudan University of Science and Technology research ethics board.
- Before performing the starting the procedures, a written informed consent was obtained after explaining the nature and purpose of the study declaring that participation is voluntary and that refusal will not affect patient's right to receive treatment. Patients were informed that they may withdraw their participation even during data collection procedure without suffering any penalty of loss of privilege.
- Patient's right to confidentiality and anonymity was protected.
- The collected data was coded and saved in password protected laptop.

Chapter Four

Results and Discussion

4.1 Results

In this study, the amount of local anesthetic used was one carpule for the patient treated using Diode Laser, no bleeding was observed during the procedure and no sutures were placed. The patient used one analgesic tablet; 400 mg of ibuprofen on the first postoperative day reporting a score 2 on the Visual Analog Scale, by the seventh day the patient had a visual analog scale of zero and did not use any more analgesic.

For the patient treated with scalpel, the amount local anesthetic used was two carpules, with sutures placed after completion of the procedure. Bleeding during the procedure was moderate and given a score of 2, the patient used two analgesic tablets of 400 mg of ibuprofen on the first postoperative day reporting a score 4 on the Visual Analog Scale, by the seventh day the patient used two more Ibuprofen tablets with visual analog scale of 2 but only to touch and attempted lip movement.

4.2 Discussion

Photothermal interaction with tissue is the basic concept of surgical laser. In this process, radiant light is absorbed by the tissue and transformed to heat energy changing tissue structure. Laser light within is converted to thermal energy on contact with the tissue, causing laser tissue interaction, that when appropriately applied, can produce reactions ranging from incision, vaporization, to coagulation. Diode Lasers wavelength has affinity for melanin or dark pigments, and is strongly absorbed by the blood hemoglobin, which contributes to their thermal effect. Therefore, this laser works more efficiently when the energy applied in the presence of pigments. This was the reason that homeostasis occurs with this wavelength. The results of this study showed bloodless surgical field in the Diode Laser patient and no need for sutures and only mild post-operative pain was experienced in the laser treated patient which is in agreement with Tahir N Aldelaimi (Aldelaimi and Mahmood, 2014)

Regarding the amount of local anesthetic used, a smaller amount was used in Diode laser treated patient, only one carpule was used compared to two carpules in the patient treated with conventional technique, also less post-operative pain was experienced in the Diode laser patient which is in agreement with the study

conducted by Do Hang Viet et al (Viet DH, Ngoc VTN, Anh LQ, Son LH,Chu DT, Ha PTT, 2019)

4.3 Conclusion:

It can be concluded that both techniques show good results in terms of final healing but it can be seen that laser technique provides much higher patient comfort due to bloodless field, no sutures placement required and less analgesic required. The use of laser was easy and time efficient reducing the need for large amounts of local anesthetics and less post-operative pain and therefore it's easy to be accepted by patient and operator.

4.4 Recommendations and limitations:

It is recommended to increase the sample size and study follow up duration for future studies. Greater care should be exercised when it comes to patient awareness regarding knowledge of laser uses in dentistry, the various benefits and options that accompany it and finally the advantages that come with choosing laser technology for dental procedures.

Appendix I

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Appendix II
Sudan University of Science and Technology
Laser Institute
Graduate college

DATA COLLECTION SHEET

1. Patient code: _____
2. Contact number: _____
3. Age in years _____
4. Type of procedure: Frenectomy.
5. Technique: laser scalpel

6. Gender : Female Male

7. Past medical history:
8. Past dental history:
9. Clinical intra oral examination of the frenum and type:

10. Number of local anesthetic carpules used:

11. Intra-operative pain experienced: Yes No

12. Score for amount of bleeding during procedure:
 - Mild: 0
 - Moderate: 2
 - Severe: 3

Appendix III

إستمارة موافقة مستنيرة للمشاركة في بحث بعنوان :

استئصال لجام الشفه باستعمال المشروط و جهاز دايود ليزر الطبي والمقارنه بينهما

مقدمة:

ندعوك للمشاركة في هذه الدراسة البحثية حيث تشكل استمارة الموافقة هذه جزءاً من عملية قبورك و موافقتك عل المشاركة والاستمارة مصممة بحيث تمنحك فكرة عامة عن هذه الدراسة وعن ما سيحدث لك اذا قررت المشاركة فيها. اذا رغبت في معرفة المزيد عن اي شيء ورد في هذه الاستمارة نرجو ان لا تتردد في الاتصال برئيس فريق البحث.

الغرض من البحث:

المقارنه بين جهاز الدايدود ليزر و استعمال المشروط لازاله لجام الشفه من حيث كميّه البنج الموضعي المستعمله, مستوى الالم بعد العمليه, كميّه المسكن اللتي استعملها المريض بعد العمليه.

الطريقة:

بعد قبورك للمشاركة في هذه الدراسة سيقم طبيبك حالتك لتحديد ما اذا كانت تطابق متطلبات الدراسة. وهذا يتطلب مراجعة تاريخك المرضي واخذ معلوماتك الشخصية وإجراء كشف طبي للجام الشفه ونوعه ثم تحديد عشوائي للتقنيه اللتي سوف يتم استعمالها اما بالليزر او بالمشروط.

الآثار الجانبية:

توجد احتماليه نزييف اثناء او بعد العمليه, كما توجد احتماليه انسداد بعض الغدد اللعابيه الضيره بالقرب من الجرح. احتماليه الم بعد العمليه.

الفوائد الممكنة :

لا توجد فوائد قد تعود اليك بشكل مباشر.

التكلفة/استعادة التكلفة:

لن تكلفك الدراسة اي رسوم نقدية.

انهاء المشاركة:

مشاركتك في هذه الدراسة عمل طوعي. ولن تؤثر في سير علاجك اذا قررت عدم المشاركة.

السرية:

لك كل الحق في التمتع بخصوصيتك ونؤكد لك في هذا السياق ان كل المعلومات التي تجمع في اطار هذه الدراسة ستظل سرية وللاستخدام العلمي فقط.

الاتصال بفريق الدراسة:

د/ مروه محمد سيداحمد

رقم الهاتف 0915561742

البريد الالكتروني: Marwa.mohamed.abdulrahem@gmail.com

الموافقة:

أقر بالآتي:

1. قرأت المعلومات اعلاه وشرح لي كل ما يتعلق بهذه الدراسة البحثية.
2. كان لدي فرصة في طرح الاسئلة وقد تمت الاجابة على كل الاسئلة التي طرحتها.
3. مشاركتي في هذه الدراسة البحثية عمل طوعي.
4. يمكنني الانسحاب من هذه الدراسة في اي وقت دون ان يؤثر ذلك في امكانية حصولي على علاج بديل متوفر.

5. ادرك تماماً انه قد لا تكون لي فائدة طبية مباشرة من المشاركة في هذه الدراسة البحثية.

6. ستقدم نسخة موقعة من استمارة الموافقة هذه.

التاريخ:.....

التوقيع:.....

Appendix V

Consent

Title of proposal:

Comparison of Diode Laser and Scalpel Technique for Frenectomy Procedure.

Purpose of the research:

To compare between diode laser and scalpel frenectomy in terms of amount of local anesthetic used, amount of bleeding during the procedure, pain level after the procedure. The amount of analgesic taken after the procedure.

Conflict of interest:

This research will be conducted by Dr. Marwa Mohamed in partial fulfillment for the requirement of the degree of Higher Diploma of Laser in Medicine.

Confidentiality:

The information about you will be kept confidential and it will not be disclosed to any one apart from the researcher

Potential Benefits:

If you participate in this research, you will benefit from investigations also your participation may help others in the future by the results.

Potential Risks:

some of the risks of the surgical procedure include the possibility of bleeding during the operation, trauma to minor salivary gland in the area on incision.

Contact Person:

If you have any questions you may ask them now or later, even after the study has started.

If you have any inquiries please call Dr.Marwa Mohamed .

Contact number: 0915561742

Email: marwa.mohamed.abdulrahem@gmail.com

Participation in this study is voluntary. You will suffer no penalty or loss of any benefits to which you are otherwise entitled should you decide not to participate. Significant new findings developed during the course of the research study, which might be expected to affect your willingness to continue to participate in the research study, will be provided to you.

Consent: I acknowledge:

1. That I have read this consent and that the above information regarding this research study have been explained to me.

2. I had an opportunity ask questions and that all my questions have been answered to my satisfaction.

3. My participation in this research is voluntary.

4. I may withdraw from the study at any time without affecting my ability to receive alternative medical care available.

5. I fully understand that there may not be any direct medical benefit to me by participating in this research study.

6. I will be given a signed copy of this consent.

Patient signature.....

Date.....