THE EFFECT OF PRE-SURGICAL SUBMUCOSAL INJECTION OF DEXAMETHASONE ON POSTOPERATIVE OUTCOMES AFTER MANDIBULAR THIRD MOLAR SURGICAL DISIMPACTION AT MUHAS- DENTAL CLINIC.

Patrice Kuete Mekontchou, DDS

MDent (Oral and Maxillofacial Surgery) Dissertation

Muhimbili University of Health and Allied Sciences

October, 2024

Muhimbili University of Health and Allied Sciences School of Dentistry

Department of Oral and Maxillofacial Surgery

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By

Patrice Kuete Mekontchou

A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree of Master of Dentistry (Oral and Maxillofacial Surgery) of

Muhimbili University of Health and Allied Sciences

October, 2024.

CERTIFICATION

The undersigned certify thet they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation titled: "**The Effect Of Pre-Surgical Submucosal Injection Of Dexamethasone On Postoperative Outcomes After Mandibular Third Molar Surgical Disimpaction At Muhas- Dental Clinic**", in (partial) fulfilment of the requirements for the degree of Master of Dentistry (Oral and Maxillofacial surgery) of the Muhimbili of Health and Allied Sciences.

_____

Dr. Karpal Singh Sohal

(Supervisor)

_____

Date:

_____

Dr. Farrid M. SHUBI

(Co-Supervisor)

_____

Date:

DECLARATION AND COPYRIGHT

I, **Patrice KUETE MEKONTCHOU** declare that this **dissertation** is own original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

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ACKNOWLEDGEMENT

I am grateful to all those who contributed in one way or another in making the preparations of this dissertation report possible. Firstly, I thank GOD for granting me with life and health. I would like to send my sincere gratitude to my Family for funding this study. I would like to thank my supervisors Dr. Karpal SINGH SOHAL and Dr. Farrid M. SHUBI for sacrificing their valuable time to guide, encourage, correct and follow up this dissertation.

Additionally, I wat to express my gratitude to my mentors, Dr BARAKA, Dr. SHABAN, Dr. WILLIAM, Dr. ARNOLD, Dr. BEREGE, Dr. ABBAS, Dr. DORAH, Dr. DEOGLAS, Dr. LAIZER for their support and valuable guidance.

Thanks to the Muhimbili National Hospital and MUHAS Oral and maxillofacial surgery clinic for their permission to conduct this study. My sincere thanks to the staff members of MUHAS and MNH Oral and Maxillofacial Departments. Special thanks to Dr. SIRA S. OWIBINGIRE, and my classmate Dr. JESCA for their help during data collection, entry and analysis. My sincere gratitude to all patients who participated in this study, intern Doctors and residents who rotated in Oral and maxillofacial surgery department during the period of this study.

DEDICACE

I dedicate this work to my Father Mr MEKONTCHOU Samuel, who believed in me and stood by my side throughout this extended journey.

I want to express my gratitude to my siblings, Mr MEKONTCHOU Armel, Mr MEKONTCHOU Ludovic, Mrs MEKONTCHOU Aurelie, for your patience, your financial assistance, and your prayers.

I also want to thank my mother who is in heaven, Mama Brigitte for being my angel and for always keeping an eye on me.

ABSTRACT

Background: The impaction of a tooth is described as the failure of the tooth to appear in the mouth at the appropriate time and in the normal position. The surgical extraction of the impacted mandibular M3 molar is among the most performed surgeries by oral and maxillofacial surgeons. This routine procedure is linked to known post-operative complications described as trismus, pain and swelling of the face. To overcome the post-operative complications of third molar surgery, several medical interventions have been tried including drugs like corticosteroids, strong analgesics, and Non-Steroidal Anti-Inflammatory Drugs (NSAID). Despite carrying out the 3rd molar surgical disimpaction procedure on daily basis in our setting, pre-operative injection of submucosal dexamethasone is very rarely practiced despite its benefits noted elsewhere in the world. Moreover, the paucity of information has hindered the development of standardized surgical protocols for managing sequela associated with impacted third molars in our settings.

Aim of the study: To assess the effect of presurgical submucosal injection of dexamethasone on postoperative outcomes of surgical disimpaction of a mandibular third molar among patients treated at MUHAS Dental clinic, Oral and Maxillofacial clinic.

Materials and methods: This is a randomized case control study conducted at MUHAS-dental clinic. The study population included all adult patient with impacted mandibular third molar treated at MUHAS- Dental clinic. Patient were randomly assigned into two groups (control or case), followed by clinical examination with radiologic studies. Later, face measurements recorded and local anesthesia and submucosal injection of dexamethasone 8 mg for case or tumescent solution infiltration for control was carried out by the principal investigator or his assistant on the mucosa of the site of the surgery. Later, the surgery was carried by a non aware resident in maxillofacial surgery. On day 3 and day 7, patients were assessed for pain, swelling, trismus and comparative measurements were recorded. A level of difficulty was evaluated using a *Modified difficulty Index by Shubi singh&kuete for MM3*. All the data were encoded and entered into the Microsoft Excel 2022 spreadsheet and analyzed using the SPSS Statistical Package for the Social Sciences version 30. The level of

significance was set at $P < 0.05$. The significance of the differences in measurement between the preoperative and postoperative dexamethasone groups and control was assessed using paired t-test and Wilcoxon signed rank test.

Results: Preoperative administration of dexamethasone was found to reduce the sequalae related to surgical disimpaction of mandibular third molar. The pain was reduced through the VAS score pain from day3 with statistical significance ($p=0.025<0.05$). The patient were experiencing better mouth opening from day 3 and day7. And clinically, the facial edema was reduced considerably on day3 and day7. Using *Modified Difficulty level by Shubi Singh&kuete*, our surgeries ranged between low and moderate level. Also, during the surgery, minimal postoperative complications like alveolitis, dehiscence, nerve injury were reported.

Conclusion and recommendations: The findings of the present study showed that preoperative submucosal injection of dexamethasone is safe, cheap, and easy to apply. It also showed a statistical significant reduction of postoperative pain from day3, with observable reduction in the post operative swelling and better mouth opening. However, more studies with larger sample size and in multiple centers should further be carried. In addition, other studies involving the accessement of inferior alveolar nerve during surgery will also be needed to help in the improvement of patient care. Also, having a standard protocol for surgical disimpaction which is printed and made accessible to clinicians in all dental clinics would help to improve the quality of patient care.

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LIST OF ABBREVIATIONS

CBCT: Cone Beam Computed Tomograph

COX: Cyclo-Oxygenase

DNA: Deoxyribonucleic Acid

IV: Intra-Venous

IM: Intra-muscular

MDent: Master of Dentistry

Mg: milligram

MNH : Muhimbili National Hospital

MUHAS: Muhimbili University of Health and Allied Sciences

M2 molar: Second molar

M3 molar: Third molar

NSAID: Non-Steroidal Anti-Inflammatory Drugs

OPG: Orthopantomogram

SMI: SubMucosal Injection

TMJ: Temporo-Mandibular Joint

VAS: Visual Analogue Scale

DEFINITIONS OF TERMS

Corticosteroids: Class of steroid hormone that are produced in the adrenal cortex of vertebra.

Disimpaction : Surgical extraction of an impacted tooth.

Impacted molar : A molar tooth that failed to appear in the mouth at the respected time and in the normal position.

Post-operative outcomes : Complications related to the surgery.

Submucosal injection : Administration of the solution in the tissue covering the jaw.

Trismus: Tonic contraction in the masticatory muscle causing restriction to mouth opening, including restrictions due to Osteogenic, myogenic or neurogenic etiologies.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

The mandibular third molar is among the teeth that erupt late into the oral cavity and is the most commonly impacted tooth. The impaction of a tooth is described as the failure of the tooth to appear in the mouth at the respected time and in the normal position. (1).
The impacted third molar is usually associated with dental pathologies like periodontitis, dental caries, cysts, tumors, and resorption of the adjacent 2nd molar root (2).

The impacted tooth is assessed through physical and radiological examination. Through physical examination, the orientation and the caries status of the impacted tooth, the status of the surrounding structure, and the relation between the impacted 3rd molar and adjacent 2nd molar are assessed (3). The evaluation of the impaction of the mandibular 3rd molar is mostly done via Orthopanthomograph (OPG), though recently Cone beam computed tomography (CBCT) is designed as gold standard for diagnosis and surgery planning of impacted molar (4). X-ray is needed to assess the number and morphology of the root, the surrounding follicular sac, the density of the bone around it, the relation to the M2 molar, mandibular canal, the body, and the mandibular ramus (3).

The impacted tooth has been classified in several ways including the orientation of the tooth, and its relation to the second molar and the ascending ramus. Different orientations of impacted mandibular third molar can include mesioangular, horizontal, inverted, and distoangular (2,3).

Management of the impacted mandibular third molar depends on the patient's complaint, clinical and radiological evaluation, diagnosis, and prognosis. The treatment will vary from non-surgical observation to surgical like exposure transplantation and surgical removal (3).

The indications for removal of the M3 molar are the presence of pain or disease due to pericoronitis, dental periapical abscess, periodontitis, tumor/neoplasm/cyst, adjacent root resorption, malposition, reduced dental arch length, pretreatment for orthodontic treatment.

Other indications include related infections to the impacted tooth, crowding of the dental arch, pathologies like cysts and tumors, overcrowding teeth on the arch, pre-radiotherapy, pre-prosthodontic treatment, and the management of chronic facial pain (5).

Surgical removal of the impacted mandibular M3 molar is among the most performed surgery by oral and maxillofacial surgeons. This routine procedure is linked to known post-operative complications such as trismus, pain and swelling of the face (6). These complications negatively impact patients' well-being (7).

To overcome the post-operative complication of third molar surgery, several medical interventions have been tried including the use of drugs like corticosteroids, strong analgesics, and Non-Steroidal Anti-Inflammatory Drugs (NSAID). Corticosteroids act by inhibiting the release of arachidonic acid, therefore, suppressing the synthesis of leukotriene and prostaglandins. Among commonly used corticosteroids is dexamethasone, a long-acting glucocorticoid that can be effective for more than 36 hours in reducing inflammation (8).

Dexamethasone can be administered through different routes, that is intraoral (submucosal, intramuscular, intra-alveolar) and extraoral (intramuscular, intravenous)(9). In Tanzania, there is a scarcity of studies that assess the effectiveness of the pre-surgical administration of dexamethasone on the post-operative sequela of surgical removal of the lower M3 (10).

Our study was conducted to assess the effect of pre-surgical submucosal injection of dexamethasone on post-operative outcomes of surgical disimpaction of mandibular third molar among patients treated at MUHAS DENTAL CLINIC – Tanzania.

1.2 Problem Statement

Surgical disimpaction of the mandibular third molar is often related to post-operative sequela including trismus, pain, and swelling, which are managed by different methods including the administration of dexamethasone. Despite carrying out the 3rd molar surgical disimpaction procedure on daily basis in our setting, pre-operative injection of submucosal dexamethasone is very rarely practiced despite its benefits noted elsewhere in the world. This lack of information renders it difficult for surgeons to present evidence-based treatment plans for their patients, including post-operation follow-up time. Moreover, the paucity of information has hindered the development of standardized surgical protocols for managing sequela associated with impacted third molars in our settings.

1.3 Rationale:

Through this study, the effect of preoperative submucosal injection of dexamethasone on post-operative outcomes of surgical disimpaction of the lower third molar was assessed. To reduce inflammation postoperatively, dexamethasone administration has been used in many surgeries. This study will provide evidence-based information about the effect of pre-operative submucosal injection of dexamethasone on the post-operative outcomes of mandibular third molar surgical disimpaction. This will help to develop a guideline on dexamethasone usage on surgical disimpaction of the lower third molar.

Our study is part of the Master of Dentistry degree in Oral and Maxillofacial Surgery at the Muhimbili University of Health and Allied Sciences (MUHAS).

1.4 Research Question

1. What is the effect of presurgical submucosal injection of dexamethasone on postoperative pain after surgical disimpaction of the mandibular third molar?
2. What is the effect of presurgical submucosal injection of dexamethasone on postoperative swelling after surgical disimpaction of the mandibular third molar?
3. What is the effect of presurgical submucosal injection of dexamethasone on postoperative trismus after surgical disimpaction of the mandibular third molar?

1.5 Objectives

1.5.1 Broad objective

To assess the effect of presurgical submucosal injection of dexamethasone on postoperative outcomes among patients undergoing surgical disimpaction of a mandibular third molar at MUHAS Dental clinic.

1.5.2 Specific objectives

1. To determine the relationships between the sociodemographic characteristics and the general outcomes following surgical disimpaction of mandibular third molar treated at MUHAS Dental Clinic - Tanzania.
2. To assess the clinical factors associated with surgical disimpaction of mandibular third molar among patients treated with and without dexamethasone injection at MUHAS Dental Clinic - Tanzania.
3. To compare the measurement of pain, swelling, and trismus after surgical disimpaction of mandibular third molar among the groups of patient (case and control) treated at MUHAS Dental Clinic– Tanzania.

1.6 Conceptional Framework:

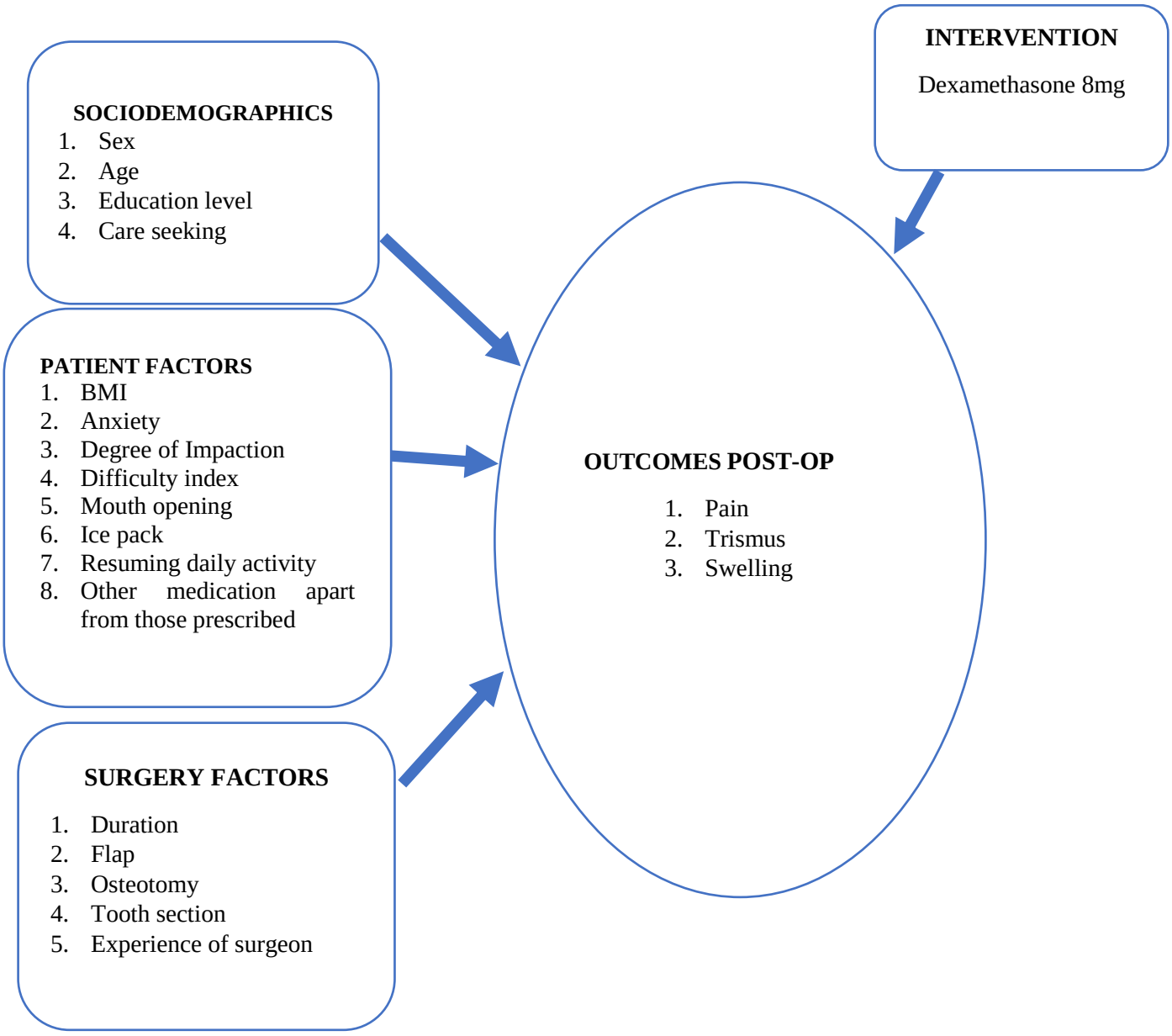


Figure 1: Conceptional Framework

Conceptional framework description:

The outcomes of the impacted mandibular M3 molar surgery, pain, swelling, and trismus can be affected by the patient's socio-demographic characteristics. It is believed that females develop more pain and swelling after surgery than males. Young patients have less calcified bone than adults, therefore the surgical procedure will be for less duration, involving less bone cutting and giving less postoperative sequelae. Education level and marital status do not directly affect sequelae, but indirectly modify health-seeking behavior and acquiring medications.

The development of post-operative outcomes after surgery is affected by patient factors. An anxious patient will put more stress to the surgeon, be less cooperative, extend the duration of the surgery, and increase the chance of post-operative complications. Index of difficulty helps to anticipate the complexity of the surgery. The higher the difficulty index the more severe post-operative complications.

It is true that surgery has postoperative sequelae, but the duration and technique used can predispose to greater pain, swelling, and trismus based on the amount of tissue dissected and the amount of inflammation generated.

A surgeon with more experience will approach the case differently, be more conscious of the damage, and will be able to effectively handle the pressure. All this will affect the surgery outcomes.

1.7 Literature Review:

The mandibular third molar (M3) is usually diagnosed as impacted when it fails to appear fully in the mouth despite being present in the mandibular arch. It may be partially visible or totally invisible in the oral cavity (due to bone and or the mucosa covering). Among the Tanzanian population, the mandibular M3 is the most commonly impacted tooth (11).

1.7.1 Relationship between sociodemographic characteristics and sequelae

Regarding post-operative sequela following third molar disimpaction, a study from Iraq showed that females experienced more pain and swelling than males after surgery, whereas there was no difference between old and youth age concerning post-operative pain and swelling (12). Also, age is a risk factor for post-operative complaints such as swelling, edema, and trismus (13).

In Japan, they found a significant correlation between surgical difficulty level and post-operative complications including swelling, pain, trismus during the first week postoperative (14). A Researcher in Belgium found that postoperative persistent pain was associated with female gender and an increase in age. Also, female gender was associated with persistent trismus (15).

In Nigeria, they found there is no statistical difference in patient age and the pain level, with no correlation between sex, difficulty index, and pain. Sex, age, and difficulty index do not have statistical significance on pain and trismus. Also, there was no correlation between post-operative swelling and patient gender (16).

1.7.2 Clinical factors associated with mandibular third molar disimpaction sequelae

From the study conducted at Leuven, the most common post-operative complaints were pain, trismus, and swelling. Also, patients were able to resume work, studies and daily activities 3 to 10 days after surgery (15). In a previous study from Tanzania, the post-operative complaints were severe pain, swelling, and trismus (11).

A study by Andra Rizqiawan found more impacted teeth on the left side with half impaction type. Impaction level position is IIA, on mesio-angular and advanced retention type (14).

From the study done in Bangkok, horizontal angulation was the most encountered, followed by mesial and vertical. According to Pell and Gregory's classification and the Winter classification, Class IA was leading, followed by class IB, class IIB, IIC, and IIIB (6). A study from Nepal showed that this impaction was predominant on the left side. The type of impaction was predominantly the vertical type, and the horizontally impacted molar is the one taking more time for surgery (17). In Nigeria, impacted mandibular third molar were more commonly found on the left side, with a majority being mesio-angular, followed by disto-angular and vertical (16). A study by Msagati et al. depicted that most of the impacted mandibular M3 were on the right side and the majority had mesio-angular inclination, followed by the horizontal type and disto-angular orientation (11).

According to a study conducted in India, the Lingual split technique gave less postoperative pain and swelling compared with the buccal approach using a chisel and mallet and even less than the buccal approach using a rotary instrument (18). It has also been shown in the same study that using a ligual based triangular flap result in a lower incidence of trismus, swelling and pain as compared to a buccal based triangular flap (19).

A recent study conducted in Belgium revealed that patients operated on by residents experienced less pain, trismus, and swelling than those operated on by senior surgeons (15). In addition, patients operated by residents were able to resume daily activities and stop analgesics earlier than patients operated on by senior surgeons (15).

1.7.3 Action of dexamethasone related to sequalae after mandibular m3 disimpaction

Dexamethasone is the most commonly used steroidal anti-inflammatory drug. It is a synthetic glucocorticosteroid with no mineralocorticoid effect and minimal adverse effect on leukocyte chemotaxis. It is used to manage allergies and inflammation following surgery (10). Dexamethasone, as an anti-inflammatory drug has a plasma half-life of 100-300 minutes with a biological half-life of 36-72 hours and an onset of action between 1-2 hours (20). It has a greater glucocorticoid action 25 times more potent than hydrocortisone, 6 times more than prednisolone, and 4 times more than methylprednisolone and is equipotent to betamethasone (21). Dexamethasone acts via two mechanisms to inhibit inflammation. The genomic

mechanism is the slow-acting by which corticosteroid molecules diffuse in the membranous cell bind to the cytosolic receptors GR, and get transported to the nucleus where they bind to specific band DNA sequences and cause the mRNA expression as well as the anti-inflammatory proteins synthesis. The other-one, a non-genomic or fast-acting, where dexamethasone molecules bind to cell membrane and inhibit the expression of phospholipase A2 and COX-2 enzymes (22).

Dexamethasone is known as one of the most commonly used corticosteroids in oral surgery to relieve pain and edema (23). In India, a study showed that by giving an injection of dexamethasone submucosally, significant swelling reduction on days 1, 3, and 7 post-operative was observed (23). After third molar surgery, swelling was greatly reduced in patients with IV and IM injections compared to IM and oral tablets on the 3^{rd} and 7^{th} day post-operatively (21).

A study conducted in Pakistan showed that patients receiving a submucosal injection of dexamethasone had a lower mean score for pain with a lower maximum pain. This was compared to patients who did not get dexamethasone. Also, swelling was minimal in patients on dexamethasone compared to patients not receiving dexamethasone. And finally, the trismus was lesser within the group receiving dexamethasone against the controls. They conclude that the submucosal injection of dexamethasone pre-operatively significantly reduces the post-operative sequelae related to mandibular third molar surgery (24). According to the results of a study conducted in Japan, giving a single dose of dexamethasone 8mg an hour before the surgery was effective in controlling swelling, pain, and trismus after the next day of surgery (25). A study conducted in Thailand shows that injecting dexamethasone 8 mg pre-operatively into the pterygomandibular space is more efficient to reduce swelling and pain than 4 mg (26).

According to a study conducted in Nepal 8mg of dexamethasone helps to reduce significantly the degree of swelling and trismus compared to 4mg (27).

CHAPTER TWO

2.0 METHODOLOGY

2.1 Study setting

The research was conducted at the Muhimbili University of Health and Allied Sciences (MUHAS) Dental clinic, Oral and Maxillofacial Surgery department.

2.2 Study design

In this study, a double blinded randomized case control study design was used.

2.3 Study duration

The study period was 10 months, from June 2023 to March 2024.

2.4 Study population

For our study, we included all adult patients with impacted mandibular M3 treated at the Oral and Maxillofacial surgery clinic - MUHAS.

2.4.1 Inclusion criteria

- All patients above 18 years with impacted mandibular M3.
- Patients who have given their consent.

2.4.2 Exclusion criteria

- Existing active infections and trismus
- Malignant or benign tumour associated with an impacted molar
- Mental or physical disability (TMJ ankylosis)
- History of long-term using steroids.

2.5 Sampling method and procedure:

We used a simple randomized assignment method, from the list of patients scheduled for the day. The patients were randomly assigned into two groups: control and intervention.
Measurements were done on the day of the surgery (before the surgery), and post surgery on day 3, and day 7.

2.5.1 Procedure:

Patients were randomly grouped into 2:
Group A: Intervention- pre-operative submucosal injection of 8 mg dexamethasone, with 2 ml volume. Injections were done on the submucosal tissue atleast 1 hour before the surgery.
Group B: Control- pre-operative submucosal injection of Lidocaine 2%, with 2 ml volume. Injection was done around the submucosal tissue atleast 1hour before surgery.
Site: The injections were done adjacent to the impacted tooth (buccal and lingual) submucosal area on all patients.

2.5.2 Surgical procedure:

Impacted mandibular M3 surgery was performed by surgeons and residents in maxillofacial surgery. They used the standardized surgical technique and with the awarness of the status of patients (whether in the control or case group).

Standardized surgical technique:

- Starting with extraoral disinfection of the head by using povidone-iodine and spirit.
- The mouth was cleaned with hydrogen peroxide 3%-mouthwash.
- Local anesthesia was administered using a solution with 2% lidocaine with 1:80.000 epinephrine (DENTOX Standard), a truncal technique for the inferior and lingual dental nerves, and an infiltrating technique for the buccal nerve.
- An incision was made on the marginal sulcular with a surgical blade No.15 (*starting time*), and the mucoperiosteal flap lifted. Afterwards, osteotomy and luxation of the tooth was done using handpiece + surgical fissure drill with profuse irrigation with saline solution, tooth removed, subsequently repositioning the flap. At the end,

hemostasis was achieved, the surgical site was curetted and rinsed and soft tissue repair was done with 3-0 sharp tip with black silk suture (*ending time*).

- Post-surgery, patients received verbal and written instructions, along with post-surgical medications.
- All patients received a prescription of antibiotics (Amoxicillin 625mg twice daily, Metronidazole 500mg three times/day for 5 days) and paracetamol (1gram thrice a day for 3 days).
- Post-operative, all patients were followed-up on day 3 and 7.
  Sutures were removed on the 7^{th} post-operative day.

Sample size

The sample size for the present study was calculated using the statistical software OpenEpi, version 3, an open-source calculator. Based on comparing the difference between the means of pain on day 3 after administration of an injection of dexamethasone from the previous study, $\propto$ error 0.05, power 80%, confidence interval 95%. We enrolled 160 patients allocated in two groups of **60** patients each.

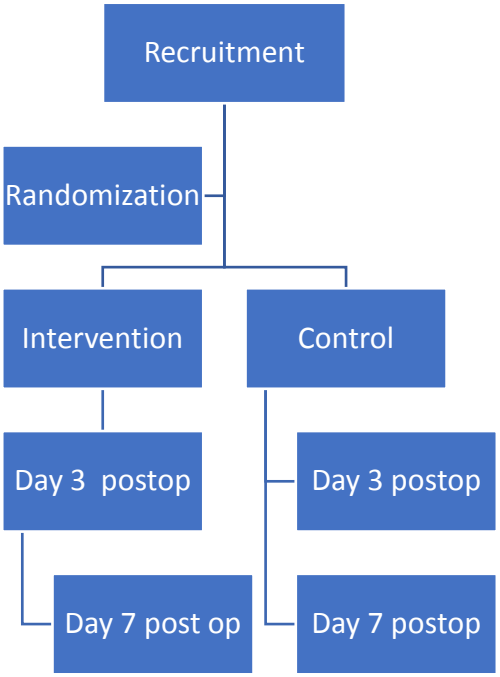


Figure 2: Patient Recruitment

2.6 Patient recruitment and data collection

Identification

The principal investigator and the research assistant participated in the identification of patients scheduled for mandibular M3 surgery at the MUHAS Oral and MaxilloFacial Surgery clinic. Patients were approached, detailed information about the study were given and informed consent was sought. Patients were interviewed whereby informations on demographic data and clinical history were recorded. Through clinical and physical examination, the classification of the impaction was done. A radiological examination of the patient was also done. Pre-operative facial measurement and interincisal measurement was recorded.

Randomization:

Simple random sampling was used, preferably by lottery on flipping coin for every first patient. And the following patients were assigned to the other group. The daily list of the patients was obtained and patient's allocation to each of the two groups.

The operating surgeon and the patient were both blinded, meaning they did not know the patient group. The Injection was done by the research team and the surgery by a different member of the clinic.

Data collection tool

Data was collected from participants undergoing surgical extraction of mandibular M3 surgery at MUHAS- Oral and MaxilloFacial Surgery clinic. This was done with the help of a trained research assistant. A radiological analysis of the impaction was done every morning for the planned patients with the assistance of one supervisor being a specialist in oral and maxillofacial surgery. We used a plastic tape, a body weight machine, a standiometer for anthropometry measurement.

In order to ensure clarity and a common understanding of the checklist, a pilot study was conducted before the study.

Data collection

The patient were assigned a daily appointment for disimpaction.

A clinical examination, diagnosis and treatment plan was proposed.

On the day of surgery, the patient presented himself at the reception. After registration, the patient was taken to the allocated clinic cube for the surgery.

The patient was invited to participate in our study. After a clear explanation, patients who agreed to participate was randomly assigned to one of the two groups: the control group and the intervention group.

Two sets of syringes were used,

One with dexamethasone 8mg (2ml) and the second with lidocaine 2%(2ml)

Another with 2 serringes of lidocaine solution 2%(2ml).

The injections were done according to the respective group. And the injection was done by a blinded doctor.

Collection tools

A checklist was used to record patient's medical details and sociodemographic data. Also, patient's factors regarding the difficulty level, and degree of impaction. Postoperatively, data like swelling, pain, trismus, complains, extramedication used, capacity to resume normal eating were obtained.

Measurements:

Surgical disimpaction of the mandibular third molar started with a mucosal incision, flap reflection, bone removal, tooth sectioning, and luxation. All these caused an exaggerated inflammation reaction marked by pain, edema, and trismus in the post-operative period (20). Assessment and measurement on specific anatomic point was carried out preoperatively, on day 3 and day 7. Measurement was done by the investigator or a trained assistant. All the measurements were taken in millimeters.

Modified difficulty Index by Shubi Singh & Kuete : The difficulty index for the removal of impacted 3rd molar as described by Pederson is a universally accepted standardized and validated difficulty index scores of 7-10 indicating very difficult; 5-7 denoting moderately difficult and 3-4 indicating minimally difficulty while removal of impacted mandibular third molars.

We decided to modified this index by adding more clinical factors so that:

Level of occlusion (1-Level A, 2-Level B, 3- Level C), Impaction angle (1-Vertical, 2-Mesio-angular, 3-Horizontal, 4-Distoangular), Flap design (1-envelope, 2-Vestibular triangle, 3-Vestibular trapezoidal), Age (1-<25, 2->25), Extraction difficulty (1-Elevator/forcep alone, 2-Bone removal/tooth sectioning, Bone removal + tooth/root sectioning), Proximity to IAN (1-sufficient >3mm, 2-Reduced, 3-space absent), Surgical technique (1-flap, luxation, 2-flap, osteotomy, 3-flap, osteotomy, tooth section), Available retromolar space (1-class1, 2-class2, 3-class3), Root curvature (1-non-dilacerated, 2-dilacerated), Number of root (1-One fused root, 2-More than1, 3- tooth germ), BMI (1-ideal, 2-overweight), Relation to second molar (1-No contact, 2-contact with crown, 3-contact with root), Periodontal space (1-Normal, 2-Increased, 3-Pocket), Completed the procedure (1-Resident, 2-Specialist).

Overall score: Low difficulty (11-17), Moderate difficulty (18-24), High difficulty (25-31).

Here score varied from low difficulty (11-17), Moderate difficulty (18-24), to High difficult (25-31). Majority of our surgery was under Moderate and low difficulty index.

Swelling:

Edema is caused by extravasation of fluid after tissue injury related to laceration and obliteration of lymphatic vessels, alteration of lymphatic drainage, and fluid accumulation into tissue (23). To evaluate the effect of dexamethasone on swelling postoperatively, six anatomical points with linear measurement are done along the mandibular angle, commissure of the lip, border of the nose, pogonion, and canthus of the eye (20).

In order to measure facial edema, tapes was used to follow the trajectories described by Schultze-Mosgau et al:

Lateral canthus of the eye - the gonion angle
Tragus - the commissure of the mouth
Tragus - the soft tissue pogonion

Before surgery, measurements were taken. Post-surgical measurements were taken on the third and seventh days after surgery.

For this purpose, we were using a rubber meter to measure the distance between two points. These measurements were transferred to a millimeter ruler. The arithmetic mean values of these three variables were calculated for each patient.

Afterward, measurements were made using a caliper. The sum of all differences in post-surgical and pre-surgical measurements were considered for the overall facial edema assessment.

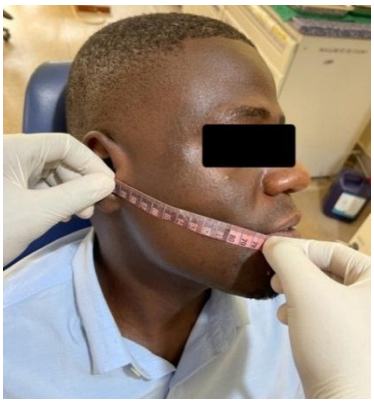


Figure 4: Lateral canthus of the eye – Gonion angle



Figure 3: Interincisal distance



Figure 5: Tragu commissure ofthemouth

Trismus:

The trismus is also one of the post-operative sequelae, and to study the effect of dexamethasone, the interincisal distance was measured using a ruler or caliper. Measuring the difference in maximal mouth opening in millimeter (distance between the incisal border of upper and lower central incisors) post-surgical and pre-surgical measurement differences.

Pain:

The corticosteroid has an analgesic property. Tissue injury caused post-operative pain, anxiety and delayed wound healing. This pain were measured by using the visual analogue scale (VAS).

In order to quantify the level of pain present, the patients were asked to give a specific number from 0 (Zero) to 10 (Ten), corresponding with the absence of pain to the maximum of pain imaginable. This evaluation was carried out before surgery, in the post-operative on the third and seventh post-operative days.

2.7 Data Analysis

All the data was encoded and entered into the Microsoft Excel 2022 spreadsheet and analyzed using the SPSS Statistical Package for the Social Sciences (SPSS Version 30 for Macbook, Chicago, IL, USA). The level of significance was set at $P < 0.05$. The significance of the differences in measurement between the preoperative and postoperative dexamethasone groups and control was assessed via paired t-test and Wilcoxon signed rank test. The Friedman two-way analysis of variance was used to analyze the significance of the differences between the dependent variables.

Frequency distributions were generated to describe the sociodemographic characteristics of the study population. We also described the different impacted teeth and types of mandibular 3rd molar impactions and complications after treatment.

A modified difficulty index was developed, using clinical and radiological characterictics. A value was given to each and the end score was calculated, raging from 11-17(low difficulty level); 18-24(Moderate difficulty level); 25-31(High difficulty level).

Continuous variables like age, pain, swelling, trismus was calculated as the mean.

Qualitative variables were expressed as frequency and percentages while quantitative variables were expressed as mean and standard deviation. Independent sample t test and one-way ANOVA were used as appropriate. A p-value of 0.05 or less was considered significant.

The results of the Pearson Chi-Square test was used to determine the relationship between patient factors; age, gender, side and impaction type with duration of surgery or surgical difficulty as the dependent variable. Statistically significant level will be set at $p \leq 0.05$.

2.8 Ethical Consideration

Ethical clearance was obtained from MUHAS Senate of Research and Publication Committee of MUHAS.

The approval for data collection was obtained from the Dean of School of Dentistry. Authorization was gotten from the head of department of oral and maxillofacial surgery– School of Dentistry, MUHAS – Dental clinic.

After obtaining their signed infromed consent, all eligible patients present at Muhas Dental clinic were enrolled in the study. Note that all participants were free to participate in our study and were allowed to withdraw at any time without panalities. Identification numbers were used instead of names to hide the patients' identity. The checklist informations were coded and saved in a computer for records keeping purposes. In order to ensure data security, researchers were using a password that is only known to them. A safe cabinet was used for storing the printed copies of the forms and only accessed by them.

2.9 Dissemination Plan

As part of the completion of the Masters degree program of Oral and Maxillofacial surgery, the final report will be submitted to the Head od Department of Oral and Maxillofacial Surgery, the Dean of the School of Dentistry, and the Director of Postgraduate studies, MUHAS.

Besides being presented at scientific conferences, this report will be published in scientific journals as well.

CHAPTER THREE

3.0 RESULTS

3.1 Sociodemographic Characteristics

In this study, a total of 130 patients were enrolled, 74 (56.9%) were female and 56 (43.1%) were male giving a males to females ratio of 1:1.3. The age range of patients was from 18 to 57 years, with a mean age of 26.8 +/-6.23 years. Majority 125 (96.6%) were from urban area. Most patients were student 53 (41%), and the majority of them was single 91 (70%). Generaly, there was equal distribution of patients in cases and controls groups. And the difference between the groups with relation to various variables (SD) was statistically not significant (p>0.005) (Table1).

Table 1: Sociodemographic characteristic of patients

		CASES	**CONTROL**	p-value
SEX	female	41(63.1%)	33(50.8%)	
	Male	24(36.9%)	32(49.2%)	0.157
AGE GROUP	18-25	33(50.8%)	31(47.7%)	
	26+	32((49.2%)	34(52.3%)	0.726
EDUCATION LEVEL	No formal education	0	1(1.5%)	
	Primary level	1(1.5%)	2(3.1%)	
	Secondary level	12(18.5%)	18(27.7%)	
	Tertiary level	52(80.0%)	44(67.7%)	0.362
MARITAL STATUS	Single	41(63.1)	50(76.9%)	
	Cohabiting	1(1.5%)	0	
	Married	23(35.4%)	15(23.1)	0.167

OCCUPATION	Student	25(38.5%)	28(43.1%)	
	No formal employment	7(10.8%)	3(4.6%)	
	Self-employment	7(10.8%)	8(12.3%)	
	Entrepreneur	6(9.2%)	5(7.7%)	
	Private sector	8(12.3%)	7(10.8%)	
	Public sector	12(18.5%)	14(21.5%)	0.828
LOCALITY	rural	2(3.1%)	3(3.8%)	
	urban	63(96.9%)	62(96.2%)	0.648
SMOKING	No	63(96.9%)	63(96.9%)	
	Yes	2(3.1%)	2(3.1%)	1
ALCOHOL CONSUMPTION	No	54(83.1%)	48(73.8%)	
	Yes	11(16.9%)	17(26.2%)	0.201

PRECLINICAL EVALUATION:

Very few patients had been premedicated prior to undergoing disimpaction of lower last impacted molars, with antibiotics accounting for 35(27%) and analgesics 27(21%). The frequent indications for disimpaction included Malposition 28(21.5%) and orthodontic treatment 27(20.7%). In general, most surgery 73(56.15%) was done on the right side. Patient with previous dental extraction were 62(47.69%), and 49(37.69%) had good experience with previous tooth extraction.

There was equal distribution of patients in cases and controls groups. And the difference between the groups with relation to various presurgical variables (SD) was statistically not significant ($p>0.05$) (Table 2).

Table 2: The presurgical status of the patient for surgery

		CASES	**CONTROLS**
Site	Left	35(53.8%)	22(33.8%)
	Right	30(46.2%)	43(66.2%)
Reason	Caries M2	3(4.6%)	3(4.6%)
	Recurrent pericoronitis	7(10.8%)	5(7.7%)
	Caries M3	9(13.8%)	6(9.2%)
	Irreversible pulpitis	8(12.3%)	10(15.4%)
	Oral pain	13(20%)	11(24.6%)
	Malposition	12(18.5%)	16(24.6%)
	Orthodontic	13(20.0%)	14(21.5%)
Antibiotic prophylaxis	No	52(80%)	43(66.2%)
	Yes	13(20%)	22(33.8%)
Previous extraction	No	32(49.2%)	36(55.4%)
	Yes	33(50.8%)	29(44.6%)
Extraction experience	Bad	6(9.2%)	7(10.8%)
	Good	27(41.5%)	22(33.8%)
	No	32(49.2%)	36(55.4%)

PRE-OPERATIVE ASSESSMENT:

In our study, patients in majority had adequate mouth opening 123(94.62%), and retractable cheek 129(99.23%). The second molar was less carious 25(19.23%), than the third molar 40(30.77%). Almost all the procedures were performeded by an oral and maxillofacial sugery resident 127(97.69%).

There was equal distribution of patients in cases and controls groups. And the difference between the groups with relation to various clinical parameters (SD) was statistically not significant (p>0.005) (Table 3).

Table 3: Clinical parameters of patient with impacted third molar

		CASES	**CONTROLS**	p-value
Mouth opening	Adequate	62(95.4%)	61(93.8%)	
	Reduced	3(4.6%)	4(6.2%)	0.698
Cheek flexibility	Non-retractable	0	1(1.5%)	
	Retractable	65(100%)	64(98.5%)	0.315
M2 relation	Absent	1(1.5%)	3(4.6%)	
	Present	64(98.5%)	62(95.4%)	0.310
Carious M2	Carious	13(20.0%)	12(18.5%)	
	Non-carious	52(80.0%)	53(81.5%)	0.824
Carious M3	Carious	26(40.0%)	17(26.2%)	
	Non-carious	39(60.0%)	48(73.8%)	0.093
Completed procedure	Specialist	2(3.1%)	1(1.5%)	
	Resident	63(96.9%)	64(98.5%)	0.559

RADIOLOGICAL EVALUATION:

During the evaluation of the patient, the most common ramus relationship was Class 2 ramus relation with proportion of 78 (60%), followed by class 1 47 (36.15%) and class 3 5 (3.84%). For Pell and Gregory level of occlusion, level A was the most frequent 97 (74.62%). Majority of the impacted teeth had Mesioangular orientation 105(80.77%), and high number of patients with non-dilacerated roots 106 (81.54%). Also, 113 (86.92%) of patient with more than one root on the last molar.

Using our Modified difficulty index from Shubi Singh and Kuete, our surgical extraction were high for Moderate difficulty 80 (61.54%), followed by Low difficulty level 50 (38.46%), and there was no high difficulty level.

There was equal distribution of patients in cases and controls groups. And the difference between the groups with relation to various variables (SD) was statistically not significant ($p>0.005$) (Table 4).

Table 4: Radiological characteristic of the impacted third molar

		CASES	**CONTROLS**	p-value
Ramus relation	Class1	19(29.2%)	28(43.1%)	
	Class2	44(67.7%)	34(52.3%)	
	Class3	2(3.1%)	3(4.6%)	0.201
Level of occlusal plane	Level A	50(76.9%)	47(72.3%)	
	Level B	13(20.0%)	15(23.1%)	
	Level C	2(3.1%)	3(4.6%)	0.804
Available retromolar	Class1	17(26.2%)	29(44.6%)	
	Class 2	45(69.2%)	35(53.8%)	
	Class 3	3(4.6%)	1(1.5%)	0.068
Impaction angle	Horizontal	0	1(1.5%)	
	Mesioangular	52(80.0%)	53(81.5%)	
	Vertical	13(20.0%)	11(16.9%)	0.555

Root curvature	Dilacerated	14(21.5%)	10(15.4%)	
	Non-dilacerated	51(78.5%)	55(84.6%)	0.498
Number of roots	One fused	7(10.8%)	10(15.4%)	
	More than 1	58(89.2%)	55(84.6%)	0.604
Relation to M2	Contact with crown	28(43.1%)	37(56.9%)	
	Contact with root	35(53.8%)	25(38.5%)	
	No contact	2(3.1%)	3(4.6%)	0.211
Periodontal space	Increased	35(53.8%)	33(50.8%)	
	Normal	20(30.8%)	22(33.8%)	
	Pocket	10(15.4%)	10(15.4%)	0.926
Modified difficulty level by Shubi, Singh & Kuete	Low difficulty	22	28	0.279
	Moderate difficulty	43	37	
	High difficulty	0	0	

POST-OPERATIVE EVALUATION:

On day 3 post-operative, patients who were in the case group had lower mean VAS score of Pain 2.48 (+/-1.97) compare to those in control groups 3.26 (+/-1.97) with a statistical significance p=0.025.

Similarly, the ability of opening the mouth after the surgery was better in the case group on day3 34.85 (+/-10.17) mm and on day7 42.51 (+/-7.95) mm comparing to the control on day3 31.46 (+/-9.92) mm and day7 40.37 (+/-8.71) mm but with no statistical significance difference p>0.05.

Also, the swelling was decreasing more on the different points of the face from day 3 to day 7 in the cases group than in the control groups, but with no statistical difference (Table 5).

Table 5: Measurements of Pain, mouth opening and facial swelling (in millimeters): mean values and difference from preoperative baseline values in the study groups

		CASES	**CONTROLS**	p-values / F/Anova
Pain- VAS mean	Day 0	2.05 +/-2.88	2.34 +/- 2.71	0.552
	Day 3	2.48 +/- 1.97	3.26 +/-1.97	0.025
	Day 7	0.86 +/- 1.18	1.28 +/- 1.28	0.057
Mouth opening	Day 0	46.78 +/-8.13	47.4 +/-8.85	0.68
Mean	Day 3	34.85 +/-10.17	31.46 +/-9.92	0.057
	Day 7	42.51 +/-7.95	40.37 +/-8.71	0.146
Swelling				
Tri-Pog	Day 0	150.83 +/-11.03	151.63 +/-11.88	0.691
	Day 3	152.78 +/-11.63	153.77 +/-1187	0.633
	Day 7	151.4 +/-11.42	152.22 +/-11.76	0.681
Tri-Bcom	Day 0	114.86 +/-8.74	115.31 +/-6.57	0.743
	Day 3	116.83 +/-8.34	118.06 +/-6.9	0.361
	Day 7	115.17 +/-8.3	116.63 +/-6.58	0.268
Go-CoEye	Day 0	104.6 +/-8.4	104.95 +/-11.12	0.838
	Day 3	108.57 +/-9.23	108.82 +/-11.75	0.895
	Day 7	105.49 +/-8.95	106.14 +/-11.13	0.716

COMPLICATIONS RELATED TO THE SURGERY

Post operative complications like alveolitis, dehiscence were minimal on day7 4 (3.07%), edema was less in the case group on day3 23(35.38%), than control group day3 32 (49.23%). Additional medications were taken in the equal proportion in both group 11 (16.92%). Very few patients were able to resume normal eating 7 days after surgical extraction of mandibular 3rd molar 24 (18.46%).

There was equal distribution of patients in cases and controls groups. And the difference between the groups with relation to various variables (SD) has no statistically not difference ($p>0.005$) (Table 6).

Table 6: Post operative complications observed after the surgery.

Bleeding		**CASES**	**CONTROLS**	**p-value**
	Day 3	None		
	Day 7	None		
Edema	Day 3	23(35.38%)	32(49.23%)	0.1
	Day 7	9(13.85%)	9(13.85%)	1
Alveolitis	Day 3	None		
	Day 7	1(1.53%)	none	0.315
Dehiscence	Day 3	None		
	Day 7	1(1.53%)	3(4.62%)	0.559
Extra Pain killers	Yes	11(16.92%)	11(16.92%)	0.469
	No	54(83.08%)	54(83.08%)	
Chewing on the operated side	Day 3	0	1(1.53%)	0.315
	Day 7	11(11.92%)	13(20%)	0.651

CHAPTER FOUR

4.0 DISCUSSION

4.1 Socio-demographic characteristics

The great majority of impacted mandibular third molars are discovered and removed between the second and third decade of life, ccording to statistics (28). In this study, it was found that participants were aged from 18 to 57 years. With a mean age of 26.8 +/- 6.23. For Mehdi, the patient undergoing disimpaction were older with a mean age of 28 +/-9.47 in India (28). The effect of age on postoperative Pain, Swelling, and Trismus was not significant.

In our study, students were more represented, followed by employees of public sector with majority of them single. Note that the MUHAS-dental clinic is located inside the MUHAS university campus and thus majority of people who attend this clinic are students. Most of these students are insured and young. This explains why most of our study participants were young.

We also found that females (57.69%) than were more than males(42.31%). This result were in concordance with Etetafia (1) in brazil, but different from Msangati (11), who found that males were most commomly affected than females. This difference could be due to the fact that probably males are usually more careless with their health challenges than females who sought for a solution early after being diagnosed with impaction in order to prevent related pathologies and esthetic discrepencies. Looking at the postoperative pain, swelling and trismus, there was no statistical significance. This was also reported by Osunde that there were no statistical significant differences in the level of pain score between males and females (16) .

4.2 Clinical factors associated with mandibular third molar disimpaction

In this study it was found that majority of the patient presented with impacted mandibular third molar with mesioangular orientation (80.77%). Rizqiawan in Indonesia found a high number of mesioangular position of mandibular third molar in his study (13). Wanithanont doing a same study, found that Horizontal angulation was the patient in Thailand (26).

Also, patients presented with impacted mandibular third molar more common on the right side (56.15%). Urechescu found that impacted third molar was more common in the right side (9). Rizqiawan in Indonesia found that surgeries for impacted left mandibular third molar were slightly more than those of the right side (13).

Looking at the indication for surgery, it was found that, the patients presenting for surgical extraction of impacted mandibular third molar were complaining more of malposition and neuralgic pain. Osunde found that in Nigeria, the patients attending the clinic for disimpaction were complaining more of recurrent pericoronitis and apical periodontitis (16).

Moreover, on radiological examination ramus relation was high for the class 2, followed by class1. Jamila in Tunisia found that ramus relation class 3 was majoritary represented followed by class 2 (29). In addition, the majority of this patients were having Non-dilacerated root curvature with more than one root.

In this study, we decided to modify the difficulty index for the removal of impacted 3rd molar as described by Pederson, and using a ***Modified difficulty Index by Shubi Singh&kuete***, we found that scores varied from low difficulty (11-17), Moderate difficulty (18-24), to High difficult (25-31). The majority of the surgeries were under moderate and low difficulty index. And it was found that there was no statistical significance between the level of difficulty and the postoperative pain, swelling and trismus**.**

4.3 Pain, swelling, and trismus associated to surgical disimpaction of mandibular third molar

Generally maximum pain intensity was seen at 3–5h post-surgery, which continues for 2–3 days, and gradually diminishes by the 7^{th} day (30). The postextraction facial swelling assessment described by Ustun et al. involved measurement of three lines, i.e., line joining outer canthus to gonion, tragus to commissure line, and tragus to soft tissue pogonion line (31). In the current study, the pain was evaluated using the VAS score on the day of the surgery, and postoperatively, day 3 and day 7. On both groups, the level of pain was high on post operative day 3 and was significant less $p<0.05$, and continued to decrease on day 7 in our case group. Maung in Thailand found that the meand value of VAS scores was lower in the study group compared with the control groupat all postoperative evaluations (32). This was contracdictory with Virkar in India who found that there was not association between submucosal injection of dexamethasone and reduction of the pain after mandibular third molar extraction even though the reduction of the VAS score was statistical important (23). From Saudi Arabia Wanithanont in his study found that the 4mg dexamethasone had a significantly higher VAS pain score than 8mg dexamethasone group on the 2^{nd} and 3^{rd} post-surgical days (26).

Edema:

Dexamethasone works to suppress edema by hydrolysing bradykinin and actin as an antihistamine and anti-inflamatory (23). Swelling reaches peak intensity within 12–48 h, resolving between the 5th and 7th POD (30).In this study, swelling was assessed on the face by measuring the distance between different points. Three measurements were done from the tragus-pogonion, tragus-Bicommisure of the mouth, Goniac angle-coner of the eye. There was an increase during the first 3 days following the surgery, and the swelling was subsiding on day 7. This variation of the measurement was observable through the measurement but with no statistical significance to prove that it was related to the injection of Dexamethasone. Garpar showed that there were no significant differences in the cumulative effects of swelling (33). But for Virkar in India, there was statiscally significant difference in postoperative edema on days 1, 3, and 7 between the control and test group (23).

Trismus:

Trismus measured as a reduction in width of the mouth opening is due to fluid accumulation in the fascia of masticatory muscles which compresses the neural structure (31). Trismus assessment is conducted by measuring the change in the maximal interincisal distance (MID) or maximal interincisal opening (MIO) from the preoperative value to the subsequent measurements at follow-up visits after tooth extraction (31). Laureano Filho et al, indicated that 8 mg dexamethasone is more efficient in minimizing trismus and swelling compared to the lower dose 4mg (20). In this study, the trismus was evaluated as reduction of mouth opening and we found that on day 3 post surgery, patients who received dexamethasone were having less limited mouth opening from day 3 than others. With a p-value of 0.057, non statistically significant. Al-Shamiri in his study indicate that trismus reaches a maximum on Day 1 and Day 2 postoperatively, and generally resolve by day 7 (34). From Romania, Urechescu found that there were a statistically significant differences in pain and trismus in favour of patients who were administred dexamethasone postoperatively (9). This can also be due to the fact that less pain will allow the patient to open widely. In Thailand, Wanithanont found that no statistical difference was observed between the groups regarding the maximum mouth opening on any postoperative day (26).

CHAPTER FIVE

5.0 CONCLUSION, LIMITATIONS AN D RECOMMENDATIONS

5.1 Conclusion

Patients undergoing surgical extraction of mandibular third molar will have clears complaints and are afraid of postoperative sequalae like pain, swelling, trismus. Preoperative administration of submucosal injection of 8mg dexamethasone is one of the safest and easy method used to reduce post operative sequalae. The present study showed that there was a statistical significance in reduction of pain from day 3 post operation with observable reduction of swelling and better mouth opening the day following surgical disimpaction of mandibular third molar under local anesthesia on patients at the dental clinic.

5.2 Limitations

The present study had certain limitations that should be acknowledged. Firstly, the integrity of the inferior alveolar nerve during and after the surgical procedure could not be guaranteed for all the patients. This could have influenced the outcomes.

Secondly, this study was conducted solely within the confines of a single institution, (MUHAS- Dental clinic). Therefore, the generalizability of the findings to other institutions or settings may be limited. Different institutions may have varying patient populations, surgical practices, resources, and healthcare systems, which could lead to observed variations in surgical outcomes.

Despite these limitations, the strengths of this study were firstly the fact that this study was a Randomized Control Trial study. Secondly, during this study a new approach on management of impacted mandibular third molar by preoperative submucosal injection of dexamethasone which was not practice in our setting. Lastly, the calibration of our clinicians with our standardized surgical procedure helps clinicians to improve their technical skills.

5.3 Recommendations

Based on the findings of this study, the following recommendations can be made:

1 Emphasize the presurgical submucosal injection of dexamethasone during surgical disimpaction of mamdibular third molar in the Dental clinic.

2 Define a standard surgical protocol, printed and available for clinicians in the dental clinic. This will help to assess the surgical performance of surgeons and ensure the quality of the service for the patients.

3 Design a time table for follow of post-operative patients to be seen in the clinic on day3 and day 7 post operative. This close follow up will give the opportunity to the clinicians to assess early the patient, to diagnose early any complication and to manage efficiently the patient.

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APPENDICES

Appendix I: Informed Consent Form (English Version)

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

DIRECTORATE OF RESEARCH AND PUBLICATION

MUHAS INFORMED CONSENT. ID-NO. :

Consent to Participate in a Study: Greetings! I am Dr. Patrice M. KUETE, I am working on this research to investigate the effect of presurgical submucosal injection of dexamethasone on post-operative outcomes of surgical disimpaction of a mandibular third molar at MUHAS Dental clinic-Tanzania.

Purpose of the study: The study is conducted in partial fulfilment of the requirements for the degree of Master of Dentistry in Oral and Maxillofacial Surgery at MUHAS. This study aims to determine the effect of presurgical submucosal injection of dexamethasone on postoperative outcomes like swelling, trismus and pain after surgical disimpaction of a mandibular third molar among patients treated at MUHAS Dental clinic. You are asked to participate in this study because you have this particular condition. We would appreciate it if could be honest and true for the betterment of the results that could lead to better intervention and recommendations for the future.

What Participation Involves: If you agree to join the study, you will first be interviewed to answer a series of questions in the questionnaire prepared for the study. Secondly, we shall take some measurements and the findings will be recorded down. Before the surgery, you will receive an injection of a solution before surgery that may include Dexamethasone 8 mg in the submucosal region. Thirdly, we shall take some measurements and the findings will be recorded down on day 3 and day 7 after surgery.

Confidentiality: I assure you that all information collected will be kept confidential. Your name will not be written on any questionnaire or in any report/document that might identify you. Your name will not be linked to research information in any way. Information collected

on the forms will be entered into a computer with only the study identification number included in the data. Confidentiality will be observed and unauthorized persons will have no access to the data collected.

Risks: We do not expect that any harm will happen to you because of participating in this study. Injection of submucosal Dexamethasone is not harmful; you will receive a single dose of 8 mg and this is mostly used in surgery. The injection could make you feel uncomfortable. You may be anxious.

Right to Withdraw and Alternatives: Participation in this study is completely voluntary. You can stop participating in this study at any time, even if you have already consented. Refusal to participate or withdrawal from the study will not incur a penalty.

Benefits: The information you provide shall help to determine the effect of presurgical submucosal injection of dexamethasone on post-operative outcomes of surgical disimpaction of a mandibular third molar at MUHAS Dental clinic- Tanzania.

Who to Contact: If you have questions about this study, you should contact the

Principal Investigator, Dr. Patrice KUETE M. of Muhimbili University of Health and Allied Sciences, P. O. Box 65014, Dar es Salaam. Telephone: **0766795017**

If you ever have questions about your rights as a participant, you may the Director of Research and Publication, **DR NAHYA SALIM MASOUD**, P. O. Box 65001, Telephone: +255-22-2152489, +255 0713250074

Dar es Salaam and Dr. Karpal SINGH SOHAL who is the Supervisor. Tel.: **0712723917**

Do you agree?

Participant agrees …… Participant does NOT agree……

I ……. have read the contents in this form. My questions have been answered. I agree to participate in this study.

Signature of participant ……

Signature of Principal Investigator ……

Date of signed consent ……

Appendix II: Checklist English version

Case: ☐ **Control:** ☐

Date: _____ Month _____ Year ___ **Questionnaire number: _____i**

PATIENT CHARACTERISTICS: **Registration number: _____f**

Sex: Male ☐ Female ☐		
Age (years):	Weight (Kg):	Height(m):
Phone:	Address:	Locality: Urban ___Rural ___d

Education level:
- ☐ 1. No formal education
- ☐ 2. Primary education
- ☐ 3. Secondary education
- ☐ 4. Tertiary education

Marital status:
- ☐ 1. Single
- ☐ 2. Married
- ☐ 3. Widow/widower
- ☐ 4. Divorced
- ☐ 5. Cohabiting

Occupation:
- ☐ 1. No formal employment
- ☐ 2. Public sector employee
- ☐ 3. Private sector employee
- ☐ 4. Entrepreneur
- ☐ 5. Self employed
- ☐ 6. Student
- ☐ 7. Peasant

Reason for extraction:
- ☐ 1. Dental caries on M3
- ☐ 2. Dental caries on M2
- ☐ 3. Orthodontic treatment
- ☐ 4. Malposition
- ☐ 5. Recurrent pericoronitis
- ☐ 6. Irreversible pulpitis
- ☐ 7. Neuralgic pain
- ☐ 8. others

Do you smoke? ☐ Yes. No ☐

Do you take alcohol? ☐ Yes No ☐

Antibiotic prophylaxis: ☐ Yes. No ☐

Anlagesic prophylaxis: ☐ Yes No ☐

Clinical form

Site of the impaction:
- 1. Right
- 2. Left

Clinical visibility
- 1. Fully impacted
- 2. Partial-impacted

Tongue size
1. cm

Mouth opening
- 1. Reduced
- 2. Adequated

Relation
- 1. M2 present
- 2. M2 absent

Cheek flexibility
- 1. Retractable
- 2. Non retractable

Carious state
- 1. M3 carious
- 2. M3 non carious

Adjacent tooth
- 1. M2 carious
- 2. M2 non carious

Operation time: min

Antibiotic prophylaxis
- 1. Yes
- 2. No

Ramus relationship/ space available
- 1. Class I- sufficient
- 2. Class II- reduced
- 3. Class III- none

Removed the tooth fully
- 1. Yes
- 2. No

Previous Teeth extraction experience
- 1. Yes. Good. Bad
- 2. No

MODIFIED INDEX EVALUATION:

Level of occlusal plane (Pell and Gregory)
- 1. Level A: high occlusal level
- 2. Level B: medium occlusal level
- 3. Level C: deep occlusal level

Available retromolar (Pell and Gregory)
- 1. Class I: sufficient space
- 2. Class II: reduced space
- 3. Class III: no space

Impaction angle (Winter)
- 1. Vertical
- 2. Mesioangular
- 3. Horizontal
- 4. Distoangular
- 5. Transverse

Root curvature
- 1. Non-dilacerated
- 2. Dilacerated

Number of roots
- 1. One fused root
- 2. More than 1
- 3. Tooth germ

Flap design
- Envelope
- Vestibular triangular
- Vestibular trapezoidal flap

Age/Year
- 1. <25
- 2. >=25

BMI (kg/m2)
- 1. 18.5-24.9 (ideal weight range)
- 2. >=25 (overweight)

Extraction difficulty
- 1. Elevator/forceps alone
- 2. Bone removal/tooth sectioning
- 3. Bone removal +tooth/root sectioning

Relationship to the second molar
- 1. No contact
- 2. Contact with crown alone
- 3. Contact with root

Proximity to inferior alveolar canal
- 1. I sufficient space >3mm
- 2. II reduced space 1-3mm
- 3. III space absent/ direct contact

Periodontal space
- 1. I Normal
- 2. II increased
- 3. III

Pocket

Surgical technique
- 1. I flap, luxation
- 2. II flap, osteotomy
- 3. III flap, osteotomy, tooth section

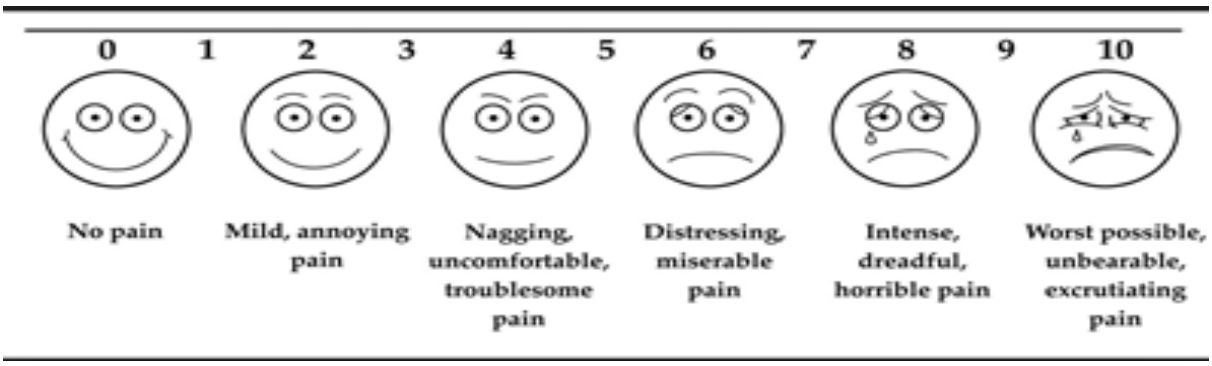
3.

Completed the procedure
- 1. Resident
- 2. Specialist

Total score		

Surgical characteristics:

Outcomes: MEASUREMENTS: Pre-op, immediate post-op, day 3, day 7
Pain: VAS



	Day 0	Day3	Day7
VAS score			

Trismus
Mesial incisal corner of the upper-lower right central incisor at maximum opening in centimeters



	Day 0	Day 3	Day 7
Trismus			

Swelling
Outer/lateral canthus of the eye- mandibular angle (Go-CoEye)
Tragus of the ear- corner of the mouth (Tr-Bcom)
Tragus of the ear – soft tissue pogonion (Tr-Pog)



	Tr - Pog	**Tr – Bcom**	**Go – CoEye**
Day 0			
Day 3			
Day 7			

Post-Operative follow-up time table

Post-op		**Day 0**	**Day 3**	**Day 7**
Bleeding	**No**			
	Yes			
Edema	**No**			
	Yes			
Alveolitis	**No**			
	Yes			
Dehiscence	**No**			
	Yes			
Nevralgic injury	**No**			
	Yes			
Suppuration	**No**			
	Yes			
Others medications				

Use of ice pack				
Eating on that side				

Appendix III: Follow-Up Table For Patient Enrolled

Date	Patient number	OPG number	Day 3	Day 7	GROUP

Appendix IV: Approval for ethical clearance

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATION

Ref. No.DA.282/298/01.C/1841 Date: 06/08/2023

MUHAS-REC-08-2023-1841
Patrice MEKONTCHOU KUETE
SCHOOL OF DENTISTRY
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: THE EFFECT OF PRE-SURGICAL SUBMUCOSAL INJECTION OF DEXAMETHASONE ON POSTOPERATIVE OUTCOMES AFTER MANDIBULAR THIRD MOLAR SURGICAL DISIMPACTION AT MUHASDENTAL CLINIC

Reference is made to the above heading,
I am pleased to inform you that the Chairperson has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 06/08/2023
EXPIRATION DATE OF APPROVAL: 06/08/2024

STUDY DESCRIPTION:
Purpose:
The purpose of this randomized controlled double-blind study is to assess the effect of presurgical submucosal injection of Dexamenthasone on postoperative outcomes of surgical disimpaction of a mandibular third molar among patients treated at MUHAS dental clinic.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:
https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2014844.pdf and in the MUHAS archives.

The PI is required to:

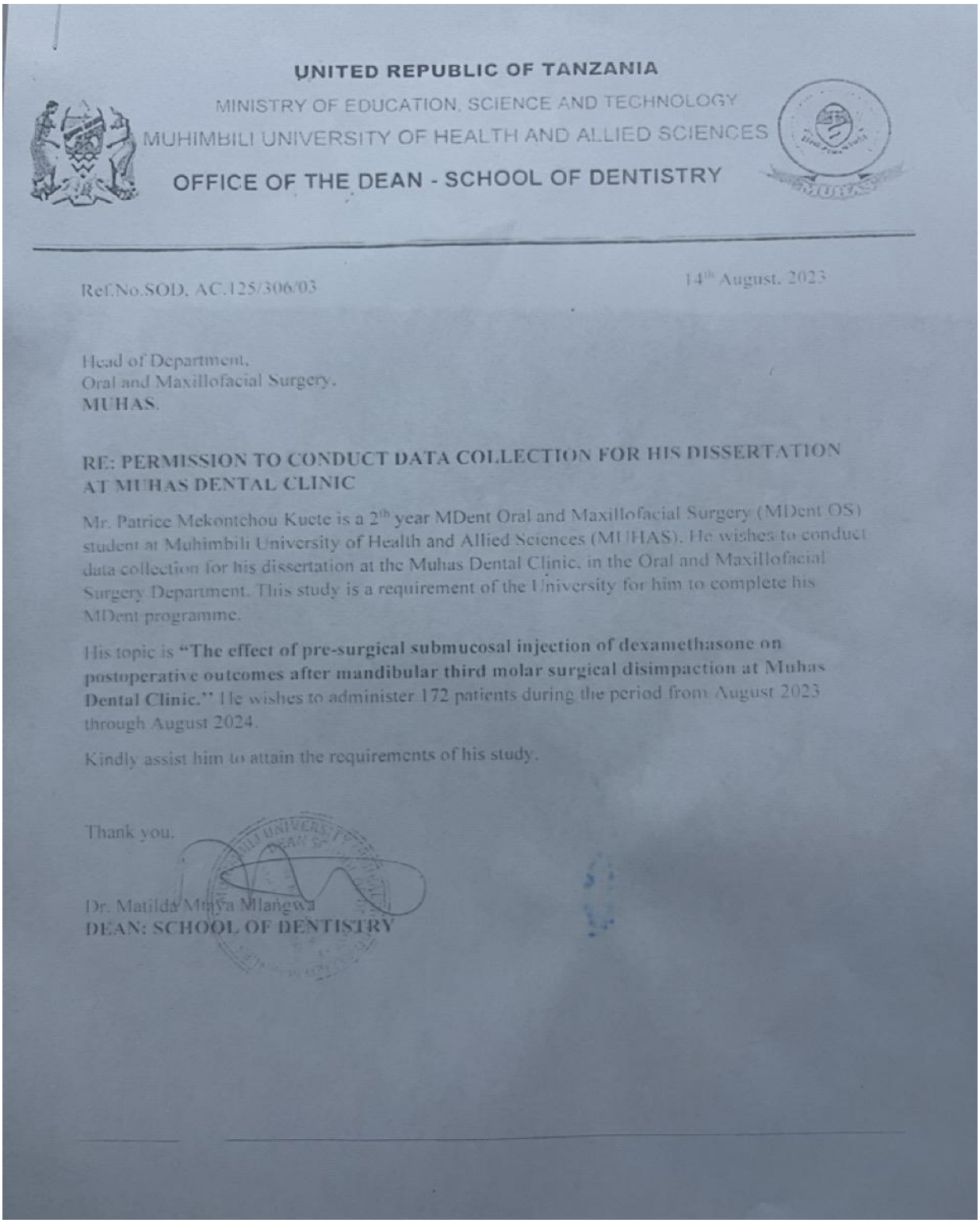
1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
8. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
9. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
10. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Nahya Salim Masoud,

Chairperson, MUHAS Research and Ethics Committee

Muhimbili University of Health and Allied Sciences
DIRECTOR
Research, Publications & Innovations
Box 65001

Appendix V: Approval for Data collection



UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DEAN - SCHOOL OF DENTISTRY

Ref.No.SOD. AC.125/306/03

14th August, 2023

Head of Department,
Oral and Maxillofacial Surgery.
MUHAS.

RE: PERMISSION TO CONDUCT DATA COLLECTION FOR HIS DISSERTATION AT MUHAS DENTAL CLINIC

Mr. Patrice Mekontchou Kuete is a 2th year MDent Oral and Maxillofacial Surgery (MDent OS) student at Muhimbili University of Health and Allied Sciences (MUHAS). He wishes to conduct data collection for his dissertation at the Muhas Dental Clinic, in the Oral and Maxillofacial Surgery Department. This study is a requirement of the University for him to complete his MDent programme.

His topic is **"The effect of pre-surgical submucosal injection of dexamethasone on postoperative outcomes after mandibular third molar surgical disimpaction at Muhas Dental Clinic."** He wishes to administer 172 patients during the period from August 2023 through August 2024.

Kindly assist him to attain the requirements of his study.

Thank you.

Dr. Matilda Mnya Mlangwa
DEAN: SCHOOL OF DENTISTRY

Appendix VI: Introduction letter

UNITED REPUBLIC OF TANZANIA
MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY
MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR – POSTGRADUATE STUDIES

In reply quote;
Ref. No. HD/MUH/C.362/2021

11th August 2023

The Dean,
School of Dentistry,
P.O. Box 65014
MUHAS

Re: INTRODUCTION LETTER

We would like to inform you that the bearer of this letter is **Patrice Mekontchou Kuete** with Reg. No. **HD/MUH/C.362/2021** is a student at Muhimbili University of Health and Allied Sciences (MUHAS) "pursuing **MDENT. Oral and Maxillofacial Surgery.**

As part of his studies, he will be doing an elective research titled: "**The Effect of Pre-Surgical Submucosal Injection of Dexamethasone on Postoperative Outcomes After Mandibular Third Molar Surgical Disimpaction at MUHAS Dental Clinic.**"

The research has been approved by the Chairman of University Senate.

Kindly provide him the necessary assistance to facilitate the conduct of his research.

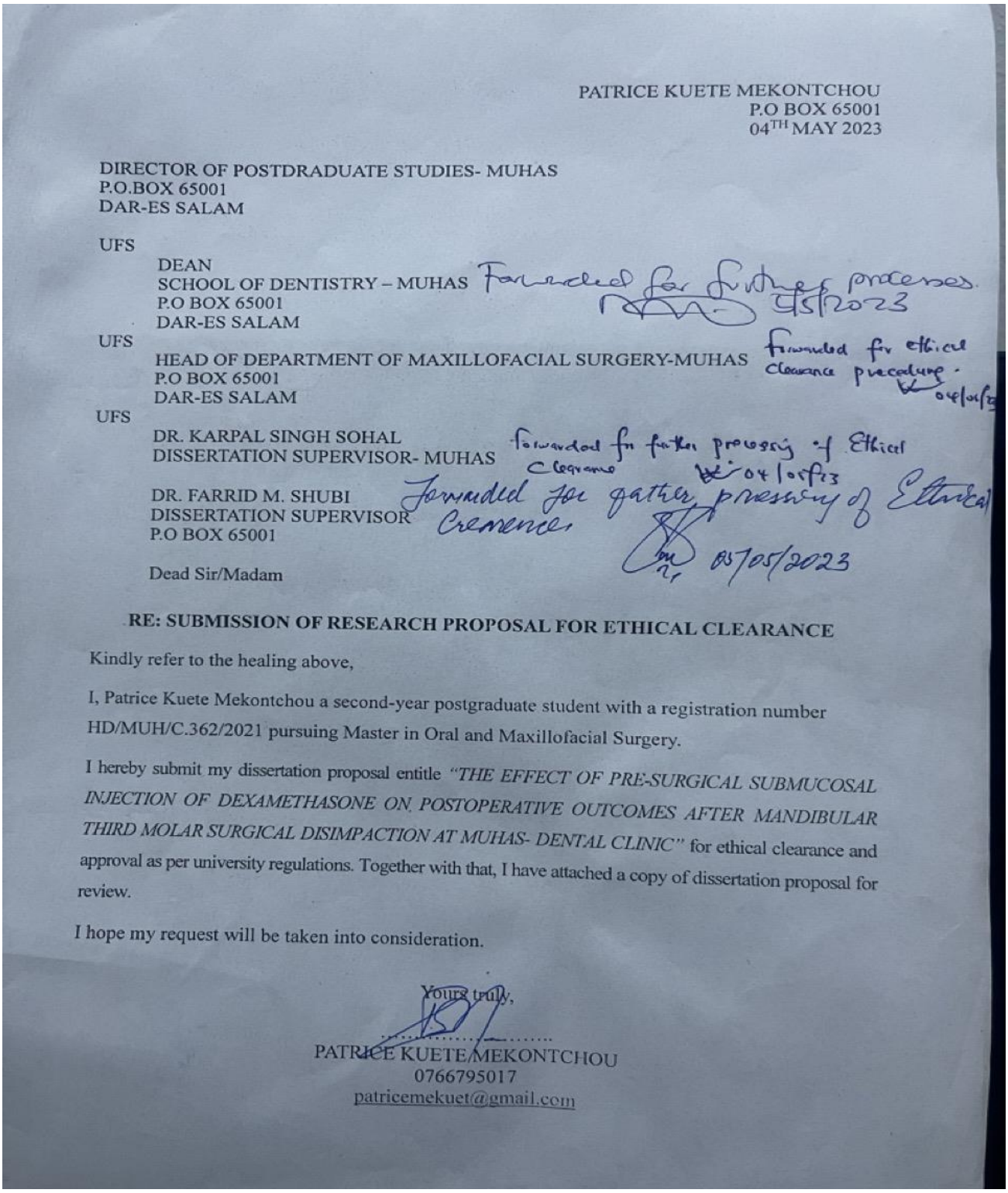
We thank you for your cooperation.

Ms. Victoria Mwanilwa
For: DIRECTOR, POSTGRADUATE STUDIES

c.c **Patrice mekontchou Kuete**

9 United Nations Road; Upanga West; P.O. Box 65001, Dar Es Salaam: Tel. G/Line: +255-22-2150302/6; Ext. 1015; Direct Line:+255-22-2151378;Telefax:+255-22-2150465;E-mail:dpgs@muhas.ac.tz;Web:https://www.muhas.ac.tz

Appendix VII: Submission letter



PATRICE KUETE MEKONTCHOU
P.O BOX 65001
04TH MAY 2023

DIRECTOR OF POSTDRADUATE STUDIES- MUHAS
P.O.BOX 65001
DAR-ES SALAM

UFS
DEAN
SCHOOL OF DENTISTRY – MUHAS Forwarded for further process. 05/2023
P.O BOX 65001
DAR-ES SALAM

UFS
HEAD OF DEPARTMENT OF MAXILLOFACIAL SURGERY-MUHAS forwarded for ethical Clearance procedure. 04/05/23
P.O BOX 65001
DAR-ES SALAM

UFS
DR. KARPAL SINGH SOHAL forwarded for further process of Ethical Clearance 04/05/23
DISSERTATION SUPERVISOR- MUHAS

DR. FARRID M. SHUBI Forwarded for gather pressing of Ethical Clearance 05/05/2023
DISSERTATION SUPERVISOR
P.O BOX 65001

Dead Sir/Madam

RE: SUBMISSION OF RESEARCH PROPOSAL FOR ETHICAL CLEARANCE

Kindly refer to the healing above,

I, Patrice Kuete Mekontchou a second-year postgraduate student with a registration number HD/MUH/C.362/2021 pursuing Master in Oral and Maxillofacial Surgery.

I hereby submit my dissertation proposal entitle *"THE EFFECT OF PRE-SURGICAL SUBMUCOSAL INJECTION OF DEXAMETHASONE ON POSTOPERATIVE OUTCOMES AFTER MANDIBULAR THIRD MOLAR SURGICAL DISIMPACTION AT MUHAS- DENTAL CLINIC"* for ethical clearance and approval as per university regulations. Together with that, I have attached a copy of dissertation proposal for review.

I hope my request will be taken into consideration.

Yours truly,

.....

PATRICE KUETE MEKONTCHOU
0766795017
patricemekuet@gmail.com