

3. METHODOLOGY

3.1 Study area

This study was conducted in the oral surgery clinic, Dental and Maxillofacial Surgery department of Usmanu Dan Fodiyo University Teaching Hospital (UDUTH) Sokoto State. The state is located in North Western zone of Nigeria covering an area of 25,973km² with an estimated population of over 4.2million in 2005¹⁷² and a population density of 170/km².¹⁷² Sokoto state is located in the dry sahel region and surrounded by savannah vegetations. The state is bordered by Republic of Niger, Kebbi and Zamfara states. The inhabitants are mainly Hausa and Fulani ethnic groups.¹⁷² Other major and minor ethnic groups also reside in the state. The main economic activities in the area are farming, trading and cattle rearing. There are 23 local government areas (LGA) in Sokoto state. UDUTH is the main tertiary hospital located in the heart of the Sokoto metropolis and serves as the referral centre for patients requiring specialist care within the state and its neighbouring states. The Dental and maxillofacial surgery department of UDUTH provides all levels of care – from primary to tertiary, as it offers the most affordable and comprehensive dental service in the region.

3.2 Study Design

This was a prospective randomized control study

3.3 Study period

This study was conducted between 17th December, 2019 and 22nd November 2020.

3.4 Patient selection

Patients were selected from those who presented to or referred to the Dental & Maxillofacial surgery department, UDUTH, and who after assessment required the removal of their impacted M3. They were invited to take part in the study. Patients who accepted the invitation were assessed to know whether they met the selection criteria. An informed consent was obtained from each patient that met these criteria and they were then requested to sign a written consent before taking part in the study.

3.4.1 Inclusion criteria

1. ASA I patients at least age 18years with an indication for extraction of any impacted M3 under local anaesthesia.

3.4.2 Exclusion criteria

1. Patients who did not require a full thickness mucoperiosteal flap or bone removal.
2. Patients with difficulty index greater than or equal to 8 according to Pederson index.
3. Presence of symptoms such as severe pain, facial swelling or limited mouth opening from any cause within 10 days preceding surgery.
4. Patients who had allergy to the local anaesthetic agent, and to the study drugs.
5. Patients with peptic ulcer disease.
6. Habitual smokers
7. Pregnant and lactating mothers
8. Patients on medications that interfere with healing after surgery – steroids, oral contraceptives, other anti-inflammatory drugs for other reasons
9. Patients who could not read, understand or write in English language
10. Patients who did not provide informed consent

3.5 Sample size determination

The sample size in previous published similar studies have ranged from nineteen to fifty patients, with average of seventy-four surgical removal of M3.^{11, 16, 131, 134-136}

This study was a comparative study with quantitative endpoint. Sample size was determined using the following formula

$$\text{Sample size} = 2SD^2 (Z_{\alpha/2} + Z_{\beta})^2 / d^2$$

Where SD is the standard deviation from previous studies

$Z_{\alpha/2}$ is the standard normal variate set at 1.96 at 5% type I error

Z_{β} is set at 0.842 from Z table at 80% power

D is the effect size, difference in the mean values

Previous study on quality of life on third molar surgery by Braimah et al¹⁷³ reported a SD of 1.24 with a mean of 14.91 in the perception of impact on body function level at after follow up of 7days, and a mean difference of 0.93 from the baseline value

$$\text{Therefore sample size} = 2(1.24)^2 \times (1.96 + 0.84)^2 / 0.93^2 = 27.976$$

Approximately 28 participants

To make room for attrition, a 10% of sample size was added

Total sample size now $28+3 = 31$ participants per group

This amounts to a total of **62** subjects for this study.

3.6 Randomization

Patients that met the selection criteria (now henceforth referred to as participants) were randomly allocated into 2 groups using computer generated tables of random numbers into;

The suture less group (group 1) and the complete suture group (group 2)

An online randomization tool was used to generate a set of numbers used to allocate subjects into groups 1 and 2.¹⁷⁴ The number of groups and sample size was inputted into the dialog boxes in the online computer program and a group listing was generated by this program. This group listing was printed out and sealed in serially consecutive numbered envelopes and subjects were assigned to the next numbered envelope on presentation by the research assistant.¹⁷⁵

3.7 Pre-Surgical protocol

A written informed consent was obtained from each subject after the subjects had been fully informed about the procedure and purpose of the study.

The preoperative data obtained from each subject included: age, gender, ethnicity and body mass index (BMI). The indications for extraction, type of impaction and location of third molar (left or right) were also recorded in the proforma designed for this study

3.8 Surgical Procedure

Patients were scheduled to have only impacted M3 surgery on the appointment day. All surgical extractions were performed by the same surgeon (the researcher) under the supervision of the consultant, and under similar operative conditions. Surgeries were done within the period of 12noon and 3:00pm daily. Baseline pain, facial width, mouth opening, and quality of life score were obtained. Intravenous access was established using a 20G cannula (Hansel[®] by Ishwari Healthcare Ltd, India) as is the institutional protocol for M3 procedures. Anaesthesia was achieved by inferior alveolar nerve block (IAN) in addition to a buccal nerve block using lidocaine hydrochloride 2% with epinephrine 1:80,000 (FD[®] by Zeyco laboratories, Mexico). Two 1.8ml

cartridges were administered – one for the IAN and lingual nerves, and one for buccal nerve. Subjective and objective test of anaesthesia was done.

A triangular mucoperiosteal flap (Fig 4 and 5) was raised using an incision made just medial to the external oblique ridge and extended to the middle of the distal line angle of the second molar. The incision was then continued by a vertical incision line from the distobuccal line angle of the second molar apically over the mucogingival border line. Using a Howard periosteal elevator a full thickness mucoperiosteal flap was raised and retracted.

Bone removal was done using a low speed straight hand piece and No. 7/8 tungsten carbide round bur (with a speed range of 80,000 to 150,000rpm) to remove bone around the tooth under copious continuous irrigation with sterile normal saline. The buccal guttering technique was used. Suctioning was done using a high volume suction machine. Tooth sectioning of the crown and roots was done when necessary under continuous sterile saline irrigation using a fissure bur on a high speed hand piece. Once the tooth had been removed, gentle curettage of the socket was done, followed by a copious irrigation using sterile saline. The flap was then repositioned.

For patients in Group 1 – (SUTURELESS) No sutures were placed. Direct pressure was applied to the surgical site using sterile rolled gauze moistened with normal saline and patient was asked to clench for 30minutes to achieve haemostasis.

For patients in Group 2 – COMPLETE CLOSURE with at 3 interrupted sutures placed as follows; one on the extraction socket, the second posterior to the extraction socket and the third at the interdental papilla distal to the second molar. Additional sutures were placed if needed to ensure a hermetic seal. 3/0 Vicryl sutures (Becton®) were used.

Patients were then discharged home after extraction site was assessed for adequate hemostasis. The following data about the procedure were recorded:

- Amount of local anaesthetic given
- Whether the tooth was sectioned or not
- Bone operating time – the time from first application of bur for bone removal to the time the tooth is extracted.
- Total operative time - the time from the start of the first incision to the time the procedure is completed. The procedure is deemed to be completed once the surgeon asks the subject to clench on the moistened rolled gauze.
- Intra-operative complications

3.9 Postoperative protocol

Subjects received Caps Amoxicillin (GlaxoSmithKline®) 500mg orally 8hourly for 5 days and Tabs Metronidazole (Unigyl® from Unique pharmaceuticals) 400mg orally 8hourly for 5 days after surgery; and Tabs Ibuprofen 400mg (Brustan-N® from Ranbaxy-Sun pharmaceuticals) immediately after the surgery and then 8 hourly for 3 days. Instructions on warm saline rinses, to be done 8 times daily for 7 days was given.

3.10 EVALUATION PROCEDURE

The subjects were evaluated in a single-blinded manner by a single trained assistant. The assistant was blinded to the intervention type. All subjects were evaluated preoperatively and postoperatively using the same methods of evaluation stated below. The evaluation was done in a separate well lit room designated for research within the department by a registrar in oral and maxillofacial surgery.

3.10.1 Pain assessment

Baseline and post-operative pain were assessed using Visual Analogue Scale (VAS). The VAS has a reported cronbach α of 0.85 among dental patients presenting in Benin.¹⁷⁶ The VAS is a horizontal line, 10cm in length, anchored by word descriptors at each end. The left extreme of the line corresponds to “no pain”, while the right extreme corresponds to “extremely severe pain”. The subjects were asked to mark on the line, the point they felt represented their pain perception. This was done just prior to the procedure and on postoperative days 1-7. Thereafter, the VAS score for each subject was determined by measuring the length from the left extreme of the line to the point marked by the subject.

3.10.2 Swelling assessment

Baseline facial measurement was taken using a non-distensible measuring tape (Fig 2b). Three measurements were made in accordance with the following descriptions:

The first measurement is from the tip of the tragus to the soft tissue pogonion ipsilaterally, while the second is from the tip of the tragus to the ipsilateral oral commissure and the third is from the lateral canthus of the eye to the angle of the mandible ipsilaterally.¹⁵⁵ (Fig 2a) The measurements were taken thrice and the average was recorded in centimetres (cm). All measurements were done by the single trained assistant for all subjects and recorded in the proforma on day 1, 3 and 7. The facial swelling was then calculated as the difference between the value obtained on the review day and the baseline value.

3.10.3 Mouth opening assessment

This was obtained using a digital vernier calliper (Fig 3), as the maximum inter-incisal distance. These measurements were repeated thrice and the average was recorded in millimetres (mm). The mesial incisal edges of the upper and lower central incisors were used as reference points. All

measurements were done by the same trained assistant and recorded in the proforma on postoperative days 1, 3 and 7.

Trismus was computed as the difference between the value obtained on the review day and the baseline value.

3.10.4 Assessment of Oral Health-related quality of life

All subjects completed a quality of life questionnaire (OHIP-14) before commencement of the surgical procedure (Day 0) after due explanation on how to fill the questionnaires. Scores were derived by adding the responses to each question within a domain. Domain scores were computed as percentages of the total domain score. Total scores were also described in terms of “affected” if they were greater than 28 and “non-affected” if they were equal to or less than 28. This questionnaire was then applied on postop review day 7 and the differences in the scores were noted.



Fig 1: Mesioangular impaction

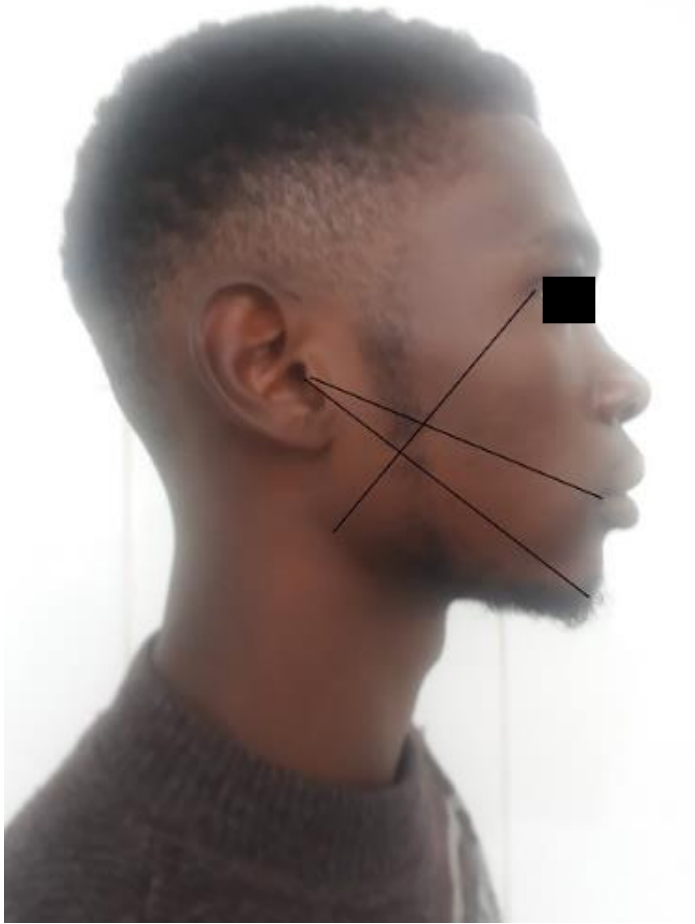


Fig 2a: Facial swelling measurements



Fig 2b: The use of non-distensible measuring tape across the face. Note that tape lies passively on face without compressing the tissues



Fig 3: Mouth opening measurement using a digital veneer calliper

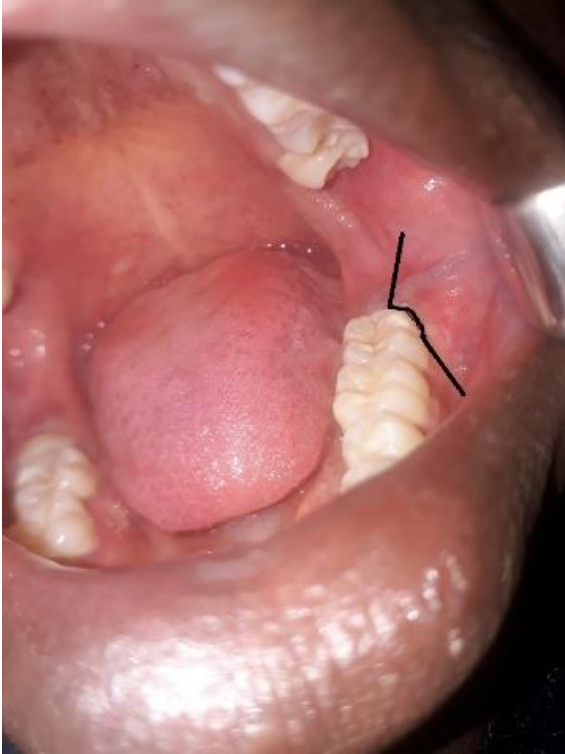


Fig 4: Outline of the triangular flap



Fig 5: Mucoperiosteal flap

3.10.5 Assessment of postoperative complications

The presence or absence of alveolar osteitis, infection, haemorrhage, paraesthesia in area of LN or IAN, soft tissue injury, TMJ pain dysfunction or any other complications were assessed and recorded on each appointment day. The management of the complications was appropriately done according to standard hospital protocol.

3.11 SUMMARY OF PARAMETERS RECORDED

- Pain evaluation using VAS at baseline (Day 0) and on days 1-7
- Subjective facial swelling evaluation, using a VAS as described by Berge.¹⁵⁹ Recorded at 6pm daily on postoperative days 1-7.
- Objective facial swelling evaluation, using three linear measurements of the face recorded in (mm). Recorded immediately pre-operatively, and on postoperative days 1, 3 and 7.
- Maximum interincisal distance measured using a Vernier calliper on postoperative days 1, 3 and 7
- Administration of OHIP14 Questionnaire on day 0 and day 7
- Details of the surgery that include: if tooth was sectioned, volume of local anaesthetic agents, occurrence of any complications, bone operating time and total operating time.
- Age, gender, ethnicity, body mass index (BMI), impaction type within the study population.

3.12 RESEARCH ASSISTANCE

I conducted the preoperative clinical evaluation of the participants and also trained the research assistants to measure variables and administer questionnaires. A dental surgery assistant was trained to be the timekeeper while a resident in oral and maxillofacial surgery unit was trained to measure the variables. I also conducted the third molar surgery under supervision of consultant. The data analysis was done by me with due consultation with medical statisticians.

3.13 ETHICAL CONSIDERATIONS

Approval for the study was obtained from the Health Research and Ethics Committee (HREC) of the Usmanu DanFodiyo University Teaching Hospital Sokoto (Appendix I). Prospective patients were provided with information on study objectives, methods, possible risks and benefits (Appendix II). Explanation was given on freedom not to participate, and how confidentiality will be ensured. Only those who consented to participate in the study were enrolled (Appendix III). A written and signed informed consent was obtained from all prospective patients participating in the study. The cost of sutures was waived for all study participants.

3.14 DATA ANALYSIS

All information were collected on a proforma which was designed for this study. Data was analysed using the Statistical Package for Social Sciences (SPSS) for Windows (IBM SPSS Statistics for Windows version 25.0, Chicago 1L, USA).

Means were used to describe parametric continuous variables while median was used for the nonparametric ones. Categorical variables were described using frequencies, percentages and charts where appropriate. The paired t-test was used to compare baseline values to the postoperative values of the variables. . A Kolmogov-Smirnov test of normality showed that the

outcome variables were normally distributed while the total operation time and bone cutting time were nonparametric. Therefore, the student t-test was used for comparing measures of pain, inter-incisal mouth opening, facial swelling and QoL scores in the two groups. The Chi-Square test was used for comparing the categorical variables between the two groups. The correlation tests were used to determine the association between the postoperative sequelae and the independent variables. Pearson correlation test was used for the parametric data while Spearman test was used for the nonparametric data. Inferential statistical analysis was done for postoperative variables using analysis of variance for repeated measures. The critical level of significance was set at $P < 0.05$.