DETERMINATION OF MINIMAL CLINICALLY IMPORTANT DIFFERENCES (MCID) AND PATIENT ACCEPTABLE SYMPTOMATIC STATE (PASS) IN MAXILLOFACIAL TRAUMA PATIENTS: A PROSPECTIVE OBSERVATIONAL STUDY

THESIS

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AIIMS, Jodhpur **DR. APARNA G**

ALL INDIA INSTITUTE OF MEDICAL SCIENCES

JODHPUR

CERTIFICATE

This is to certify that thesis entitled "Minimal Clinically Important Differences (MCID) and Patient Acceptable Symptomatic State (PASS) in Maxillofacial Trauma Patients: A Prospective Observational Study" is an original work of **Dr. Aparna G** carried out under our direct supervision and guidance at Department of Dentistry, All India Institute of Medical Sciences, Jodhpur.

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DECLARATION

I, hereby declare that the work reported in the thesis titled "Minimal Clinically Important Differences (MCID) and Patient Acceptable Symptomatic State (PASS) in Maxillofacial Trauma Patients: A Prospective Observational Study" embodies the result of original research work carried out by me in the Department of Dentistry, All India Institute of Medical Sciences, Jodhpur.

I further state that no part of the thesis has been submitted either in part or in full for any other degree of All India Institute of Medical Sciences or any other Institution / University.

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Alone we can do so little; together we can do so much

- Helen Keller

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-Aparna G


Dedicated
To
My Teachers
and
My Family…

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LIST OF ABBREVIATIONS

MCID	*Minimal Clinically Important Difference*
PASS	*Patient Acceptable Symptomatic State*
ORIF	*Open Reduction & Internal Fixation*
PRO	*Patient Reported Outcome*
PROM	*Patient Reported Outcome Measure*
QoL	*Quality of life*
VAS-NRS	*Visual Analog Scale – Numeric Rating Scale*
ATLS	*Advanced Trauma Life Support*
TMD	*Temporomandibular Disorders*
ROC Curve	*Receiver Operator Characteristic Curve*
AUC	*Area under the Curve*

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Summary

SUMMARY

Background

Maxillofacial trauma being a thoroughly researched area has enabled maxillofacial surgeons to have clearly defined surgical success criteria. However, these criteria are based on surgeons' clinical and radiographic evaluation with a clear lacuna existing in the research pertaining to Patient Reported Outcomes (PROs) in maxillofacial trauma. It is high time that PROs are used to augment the surgeons' criteria for providing best clinical care. With this aim, the present study was planned to establish the Patient Acceptable Symptomatic State (PASS) and Minimum Clinically Important Difference (MCID) of pain and function (bite force) in maxillofacial trauma patients.

Aim

To estimate the MCID and PASS levels for patients treated for maxillofacial trauma.

Methodology

A prospective observational study on 95 patients with maxillofacial trauma was conducted at a tertiary health care centre after applying the inclusion and exclusion criteria. Patients were alienated into two groups based on the type of standard of care given in the form of closed reduction or open reduction and internal fixation (ORIF) for maxillofacial fractures. Irrespective of the type of treatment provided all the patients were closely followed up for any discrepancy. In addition, preoperative and 4 weeks postoperative pain scores in terms of VAS-NRS and bite force assessing function were recorded. All the patients were evaluated by a 4-item question assessing the pain improvement after treatment on a Likert scale, which served as an anchor instrument to determine MCID and a 2-item question reporting satisfaction. MCID of pain and bite force were calculated using change difference method and ROC curve method of the anchor-based approach. PASS score was calculated as the 75^{th} percentile of score for patients who deemed themselves satisfied with treatment.

Results

The mean age of the study participants was 31.71 ± 12.34 years. The study participants comprised of 90 males (94.73%) and 5 females (5.27%). The mean VAS NRS was 8.21

± 1.23 preoperatively which improved to 1.53 ± 0.94 at 4 weeks postoperatively. The preoperative mean bite force was 18.06 ± 51.56N which increased to 186.34 ± 79.78N. The MCID of pain on VAS-NRS was found to be 6.68 by change difference method and 6.5 by ROC curve method. The MCID of mean bite force was found to be 186.14N by change difference method and 134.27N by ROC curve method. The PASS was calculated as the 75^{th} percentile of pain on VAS-NRS and bite force. The estimated PASS was 2 on VAS-NRS and 220.92N for bite force.

Conclusion

A plethora of literature is available delineating the surgical success by surgeon's objective parameters like occlusion, pain, restoration of form, function and post-surgical complications. However, with this study we tried to determine the treatment success through PROMs and established that patients considered a reduction of pain score on VAS-NRS by 6.5 and gain in mean bite force by 134.27N as clinically important. With this research, authors would like to convey that it is high time for maxillofacial surgeons to move beyond the physical, biochemical and radiological end points to meaningful PROs like PASS and MCID to ascertain clinically relevant changes rather than statistically significant changes.

Introduction

INTRODUCTION

Maxillofacial trauma has been ever increasing due to the increased incidence of motor vehicle accidents along with other aetiologies like sports injuries, industrial injuries and interpersonal violence (1). Trauma sustained to the face, which is a pivot facet of one's identity and characterised as the organ of emotion, adversely affects the patients' self-esteem and can cause long-lasting physical, psychological, functional and social disability (2).

To minimise these long-lasting morbid effects, early diagnosis and treatment planning with emphasis on adequate restoration of pain free masticatory function and facial aesthetics is mandatory. Even the best form of traditional research in maxillofacial trauma have focused on randomised controlled trials (RCTs) demonstrating statistically significant improvement in pain, activity, recreation, disfigurement, chewing and swallowing, etc as measures for gauging treatment success (2). As health care professionals, our treatment regimen, treatment assessment and follow ups are guided by these statistical significances ("p values"). Following which healthcare professionals across globe take these statistically significant results to their own practice irrespective of its actual clinical relevance. Unexpectedly, sample size is a paramount feature which can give statistically significant importance to seemingly clinically important feature and vice versa.

Laskin opined that the patient's independent acuity is an imperative element of alteration to facial trauma than any other outcome measured objectively (3). Further it is well established that patients psychological and genetic attributes effect overall patients' well-being and thus needs addressal. Accordingly, there is an escalated focus of laying patients at the core of clinical trials in order to evaluate the quality of clinical care (4) (5). PROMs promote patient and value-based care by measuring health or wellbeing outcomes in patients' perspective. The use of these PROMs to assess health status has clear-cut advantage over traditional research-based outcome measures and enable to establish a "patient-centred care" with better clinical outcomes and doctor patient relationship as well (4).

To avoid all sorts of discordance between the physician's and patient's perspectives it is imperative to use categorical end points to define the improvement in the clinical

state of the patient. Consequently, two different concepts that have been put forth to understand the outcome scores are (1) MCID and (2) PASS.

The MCID reflects the patient's perception of improvement or worsening of clinical state with regard to a received treatment (6). This measure has been widely used in varied medical specialities viz orthopaedics, neurosurgery, otorhinolaryngology, etc. (7–13). In the literature, various approaches have been employed for estimation of MCID reporting different values, thus rising a speculation on choosing the appropriate method (14). Moreover, MCID, being a patient-based establishment, fluctuates based upon patient characteristics such as age, gender, sociodemographic factors. With these drawbacks of the MCID, there was the emergence of PASS which is defined as "*the highest level of symptoms beyond which patients consider themselves well i.e., the outcome score that a patient needs to have in order to* ***feel good****"*. Certainly, it has been observed that PASS scores are stable over time and do not vary upon external patient factors (15).

In the maxillofacial speciality, there is meagre evidence related to MCID in the viewpoint of temporomandibular disorders and rhinosinusitis (13,16,17). There is an absolute scarcity of literature for determining PROMs like MCID and PASS in maxillofacial trauma. As pain free restoration of function is the primary aim for any treatment for both the surgeon and the patient, through this prospective observational study, we tried to determine the PASS and MCID of pain and bite force (as a marker of functional rehabilitation) for patients treated for maxillofacial trauma.

Review of Literature

REVIEW OF LITERATURE

Literature related to MCID of Pain and Disability

Laigaard J et al (18) in 2021 systematically reviewed 570 trials investigating analgesic interventions after total hip or knee arthroplasty calculating MCID of pain score and cumulated rescue opioid consumption. Median MCIDs for pain scores were absolute 15 mm at rest and 18 mm during movement on a VAS of 0-100mm. They recommended that MCID can be used for sample size calculations. Also, the systematic review revealed that in 46% of the trials with statistically significant outcomes, the differences did not reach the predetermined MCID.

Sutton et al (7) in 2019 determined the MCID in VAS assessing Pain and Foot and Ankle Ability Measure Scores in 170 patients who underwent Hallux valgus surgery. Pain satisfaction surveys were collected preoperatively and minimum 1-year postoperatively. Distribution-based method and anchor-based methods were used to calculate MCID. Calculated MCID scores ranged from 1.8 to 5.2 points for VAS pain and 11.1 to 22.7 points for FAAM-ADL implying that pain improvement of 1.8 to 5.2 points and FAAM-ADL improvement of 11.1 to 22.7 points indicates clinically significant improvement in patient's pain and function after hallux valgus surgery.

Asher et al (19) in 2018 calculated and defined the minimum clinically important difference for grade I degenerative lumbar spondylolisthesis by inquiring the Quality Outcomes Database registry. PROMs were the Oswestry Disability Index (ODI), numeric rating scale for leg pain (NRS-LP) and back pain (NRS-BP). Anchor-based and distribution-based methods were used to calculate the MCID for each PRO. The MCID values obtained were 14.3 points for ODI, 1.7 and 1.6 for NRS-LP and NRS-BP respectively and the percentage of patients who achieved MCID at 1 year was 71%, 79% and 76% for ODI, NRS-LP, NRS-BP respectively. The clinical implication of the study is that the percentage of patients reaching MCID can serve as an apposite indicator for screening surgical interventions that are unproductive thus regulating quality of surgical interventions.

Copay G A et al (11) in 2018 conducted a systematic review highlighting the use of MCID of pain and function in the orthopaedic literature from 2014-2016, focusing on upper extremities. The MCID was quoted in 129 (7.5%) of 1,709 clinical articles that

applied PROMs: 52 (40.3%) of 129 were related to the upper extremity, 5 (9.6%) of 52 calculated MCID values, and 47 (90.4%) of 52 used the established MCID values as a gauge of their own results. They inferred that MCID values may vary considerably on the basis of abundant factors, including the characteristics of study population, treatment modality, follow-up intervals, and approach used to calculate the MCID.

Olsen FM et al (20) in 2017 systematically reviewed experimental studies of MCID in acute pain by including 37 studies. They reported absolute MCID values between 8 to 40 mm (standardized to a 100 mm scale) and the relative MCID values of 13% to 85%. Patients with higher pain prior to intervention necessitated larger pain reduction for remarkable pain relief. MCID values were influenced by definition of improved patients and design of the study.

Simovitch et al (12) in 2017 quantified the success of total shoulder arthroplasty for pathologies of glenohumeral joint with MCID scores of pain scores and scales assessing range of motion. A total of 466 surgeries performed by 13 surgeons were included in the study. The MCID for the American Shoulder and Elbow Surgeons, Constant, University of California Los Angeles Shoulder Rating Scale, Simple Shoulder Test, Shoulder Pain and Disability Index, global shoulder function, and visual analog scale for pain scores, as well as active abduction, forward flexion, and external rotation, were calculated for different prosthesis types and patient cohorts using an anchor-based method. The results showed that females and reverse TSA were associated with lower MCID values as compared with males and anatomic TSA patients.

Torrens et al (21) in 2016 also utilised anchor-based methods to measure the MCID for the Constant score from 60 reverse total shoulder arthroplasty patients with 1-year minimum follow-up. The results obtained were mean Constant score of 30.1 before surgery and was 58.4 at the 1-year follow-up. Only 46.7% of patients for overall function and 33.3% patients for strength of Constant score exceeded the MCID after surgery. They also stated that the validity of such calculation techniques and low values of MCID is questionable.

Sandhu K S et al (22) in 2015 conducted a retrospective study of 234 patients with trigeminal neuralgia. The MCID was calculated using the 7-point patient global impression of change (PGIC) as an anchor. The results depicted that a 75% improvement in interference with general activities and a 62% improvement in

interference with facial activities were needed in order to attain an MCID. Interference of pain with activities was considered more important for patient outcomes when planning or assessing interventions for Trigeminal neuralgia.

Parker S L et al (23) in 2012 calculated MCID for pain and disability in 47 patients undergoing revision fusion for pseudoarthrosis-associated back pain. MCID was suggested to be as low as 2 points for ODI (disability) and 3 points for SF-12 (Physical component).

Tashijan et al (8) in 2009 conducted a study in which 81 patients with rotator cuff disease were evaluated after 6 weeks of non-surgical treatment with pain on VAS and two transition questions utilized in determining the MCID and PASS. The MCID and PASS were estimated to be 1.4 cm and 3 cm on a 10 cm VAS for pain, respectively. The study estimated that 1.4cm improvement on 10cm VAS measuring pain indicates minimal clinically important change and 0-3cm score implies an acceptable symptomatic state for patients with rotator cuff disease.

Copay G A et al (10) in 2008 calculated MCID for pain and disability in patients who underwent lumbar spine surgery. They found that the MCID values were 12.8 points for Oswestry Disability Index, 4.9 points for Physical Component Summary, 1.2 points for back pain, and 1.6 points for leg pain.

Tubach et al (9) in 2006 measured PASS in 330 patients with ankylosing spondylitis to assess symptom effects after 2 doses of celecoxib versus diclofenac. PASS estimates were obtained for 5 clinical domains namely, Global pain, nocturnal pain, patient's global assessment of disease activity, BASDAI, BASFI. 52% of patients considered their state to be satisfactory. At week 12, patients considered their state satisfactory if the estimates of PASS were 33.5mm for global pain, 28.0mm for nocturnal pain, 35.7mm for global disease assessment, 34.5 for BASDAI and 34.1 for BASFI.

Tubach et al (24) in 2006 assessed the treatment response in terms of function and pain by measuring PASS and MCID in patients treated for knee osteoarthritis and rotator cuff syndrome. They inferred that the acceptable state for pain was higher for chronic than acute conditions. The level of functional impairment considered acceptable by patients with knee osteoarthritis was more for disabled patients.

Tubach et al (25) in 2005 conducted a prospective study of 1362 patients with knee or hip osteoarthritis. Pain scores on VAS and functional impairment on WOMAC scale were assessed at 4 weeks after treatment. The scores of PASS were, respectively, 32.3 and 35.0 mm for pain, 32.0 and 34.6 mm for patient global assessment of disease activity, and 31.0 and 34.4 points for WOMAC function score. The PASS estimates did not depend age, gender or disease duration hence was considered more reliable than MCID.

Lee et al (26) in 2003 conducted a prospective, observational study in patients with acute pain of < 72 hours in the adult Emergency Department by recording VAS for Pain on 100mm scale on presentation and at discharge. The mean decrease in VAS was 30.0 mm for 81% of patients with adequate pain control at discharge as against 5.7 mm for the 19% with inadequate pain control. Post treatment the mean VAS was 31.3 mm for patients with tolerable pain and 55.1 for those without adequate pain control. The study thus concluded that a mean reduction in VAS of 30 mm represents a clinically important difference in pain severity that parallels to patients' discernment of acceptable pain control.

Jensen et al (27) in 2002 conducted a study to infer VAS ratings and change scores by reanalysing the data in 123 patients who underwent knee surgery and 123 patients who underwent laparotomy. The outcome measures included a VAS and a VRS of pain intensity and a VRS of pain relief. The findings suggested that 100-mm VAS ratings of 0 to 4 mm can be considered no pain; 5 to 44 mm, mild pain; 45 to 74 mm, moderate pain; and 75 to 100 mm, severe pain. The findings also suggested that a 33% decrease in pain represents a rational standard for pain relief that matters to the patients.

MCID Literature in Maxillofacial Speciality

Calixtre B L et al (17) in 2020 measured the MCID of outcomes related to TMD in 61 female patients using the Global Rating of Change Scale (GRCS) as an anchor. MCID was between 0 and 1.90 for orofacial pain, thus conveying that change in pain by 1.90 points was considered meaningful by the patients.

Chowdhury N et al (13) in 2017 estimated MCID for Sino Nasal Outcomes Test (SNOT-22) in 276 patients who underwent surgical management for chronic

rhinosinusitis. Their calculated MCID score was 9.0 and they concluded that it allows for enhanced clinical understanding of the results pertaining to rhinologic outcomes.

Ingram et al (16) in 2011 used the MCID for evaluating treatment outcomes with TMJMD patients. An anchor-based MCID approach was employed, with an objective chewing performance measure serving as the clinical outcome of interest. The MCID value was 2.745.

Peisker et al (28) in 2018 conducted a prospective cohort study in 95 adult patients who rated their pain on the first postoperative day after maxillofacial fracture repair by means of the questionnaire of the Quality Improvement in Postoperative Pain Management (QUIPS) project. The results obtained showed that the mean maximal pain and pain on activity were higher in patients with mandibular fractures than in patients with midface fractures and decreased mobility was observed with surgeries of longer duration.

Aim and Objectives

AIM & OBJECTIVES

Aim:

To estimate the minimal clinically important difference (MCID) and PASS levels for patients treated for maxillofacial trauma

Objectives:

Primary objective:

1. To calculate the MCID in VAS-NRS and bite force for maxillofacial trauma patients.

Secondary Objectives:

1. To establish a minimum threshold for successful treatment in terms of MCID for VAS-NRS
2. To establish a minimum threshold for successful treatment in terms of MCID for bite force.
3. To gauge PASS (Patient Acceptable Symptomatic State) in postoperative maxillofacial trauma patients
4. To assess and compare the preoperative and postoperative bite force as an outcome of functional restoration.

Research Question:

What is the PASS and MCID of pain and bite force in maxillofacial trauma patients after fracture treatment?

Materials and Methods

MATERIALS & METHODOLOGY

Study design:

A prospective observational study was conducted in the Department of Dentistry in AIIMS, Jodhpur after obtaining approval from the Institutional Ethical committee (AIIMS/IEC/2019-20/988). A total number of 124 maxillofacial trauma patients presenting to the Emergency & Trauma Centre and Department of Dentistry were scrutinized. Out of these, 95 maxillofacial trauma patients were enrolled in the study after taking written informed consent (Annexure IVA & IVB) and fulfilling the following selection criteria.

Inclusion Criteria:

- Patients who gave a written informed consent to be a part of the study.
- Patients in the age group between 18-65 years, of either sex.
- Patients with minimal comorbidities – ASA I, II.
- Absence of pre-existing maxillofacial pathologies especially any odontogenic tumor, cyst, neuralgias TMDs and MPDS.

Exclusion Criteria:

- Patients with severe debilitating conditions such as uncontrolled diabetes mellitus, uncontrolled hypertension, cardio respiratory conditions, previous history of cerebrovascular accidents, myocardial infarction, coronary artery disease
- Patients who were intubated / tracheostomized
- Patients with concomitant head injuries, cervical spine injuries or debilitating thoracic or abdominal trauma
- Patients with psychiatric illness
- Intoxicated patients
- Patients under the influence of central nervous system depressants such as fentanyl, morphine, codeine, pregabalin, gabapentin or any other drugs altering sensorium

- ❖ Patients with altered sensorium and having difficulty in comprehension and communication.

Sampling Frame:

Maximum possible number of patients were enrolled in the study in a stipulated time frame of 14 months in view of COVID-19 Pandemic.

Methodology:

In this study, all the 124 patients with maxillofacial trauma presenting to the Emergency and Trauma Centre and Department of Dentistry of AIIMS Jodhpur were screened for enrolment. Preceding enrolment, all patients were primarily assessed with routine history and physical examination under primary and secondary survey as per ATLS protocol (2017) (29). The primary stabilization was performed comprising of history, physical examination and initial imaging studies. Patients confirmed to have maxillofacial fractures were subsequently advised to enrol and participate in the study in accordance with inclusion and exclusion criteria after their written informed consent (n=95).

All the 95 patients were given standard treatment depending upon the type of fracture and patients systemic condition. Depending on this, patients were divided into two groups based on the operative intervention (closed versus open):

Group I: Closed Reduction

Group II: Open Reduction and Internal Fixation (ORIF)

Closed reduction was done in the form of arch bar fixation under LA and nasal splints. Patients with nasal bone fractures, isolated zygomatic arch fractures, undisplaced fracture, those who were unfit for surgery or tested positive for Covid 19 during admission, or denied surgery due to financial reasons were treated with closed reduction. Open reduction and internal fixation (ORIF) was done under general anaesthesia after appropriate preoperative work up following the standard protocol. Fixation was done with titanium miniplates and screws, customized for every case.

However, irrespective of the treatment group to which they belonged, all the patients were keenly followed up for pain, mouth opening, unassisted functional jaw

movements, paraesthesia and aesthetics and any discrepancy in the anatomical or functional restoration was corrected at the point of first contact. In addition to this as a part of the study, the following parameters were assessed:

I. At first contact – immediately after primary and secondary survey and stabilization (T1)

1. VAS-NRS for pain
2. Bite force for function

II. Post operative (4 weeks) (T2)

1. VAS-NRS for pain
2. Bite force for function
3. Rating of response to treatment as None/Poor/Good/Excellent (Table 2)
4. Satisfaction score was assessed by a standard question with *"Taking into account all the activities you have during your daily life, your level of pain, and also your functional impairment, do you consider that your current state is satisfactory?"*

Study Tools

The following scales were used for assessment

1. VAS-NRS (Visual Analog Scale – Numeric Rating Scale)

Pain was measured during unassisted jaw movements using VAS (NRS) on mouth opening, protrusive and lateral excursive movements. A Visual Analog Scale is a 10 cm horizontal line with "0" marked on the left extreme and "10" marked on the right extreme. Patients' rating of overall current level of pain on mouth opening and unassisted jaw movements from *"none – 0" to "disabling -10"* was recorded. The pain was classified as Mild (0-3), Moderate (4-6), Severe (7-10) based on VAS NRS score. The VAS-NRS scale was augmented with customized pictographic representation for easy comprehension considering the varied social and linguistic background of our patient population.

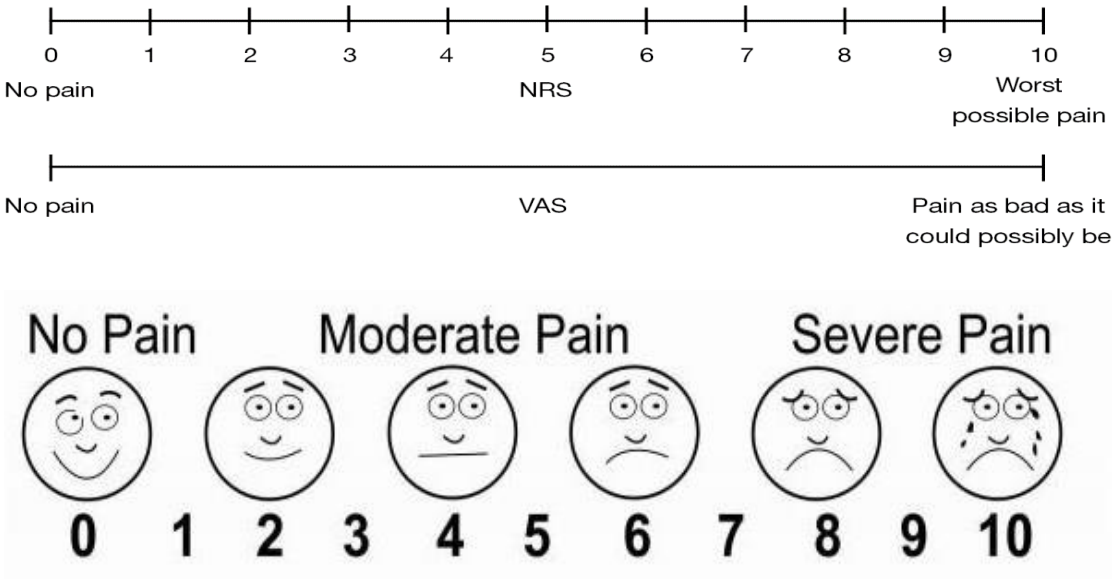

Figure 1: VAS -NRS for pain assessment

2. Bite Force

Jaw function was assessed by measuring bite force in the molar region using Flexi force sensor which works as a force sensing resistor in an electrical circuit. The force generated was converted into numerical values. All the study subjects were made to sit erect with a relaxed head position ensuring that the Frankfurt horizontal plane is parallel to the ground and then were asked to occlude on the Flexi force sensor at the right and left molar region for 5 seconds.

Although the literature suggests the normal range of bite force to be 200-300N in the incisor region and 500-700N in the molar region, but the bite force recorded may vary with the type of instruments used. Thus, it becomes prudent to standardize the instrument before use. The normal human bite force was assessed and standardized in 150 healthy individuals.

The control population were age and sex matched according to the study population and had no history of TMDs, MPDS and no maxillofacial pathology affecting the patient's bite.

The obtained value of bite force of the patients on the sensor was graded according to the scale given below:

Bite Force Grading (Function):

Table 1: Grading of Bite Force

Grade I	0-25% of the normal human bite force
Grade II	>25-50% of the normal human bite force
Grade III	>50-75% of the normal human bite force
Grade IV	>75% of the normal human bite force

Figure 2: Flexi force sensor

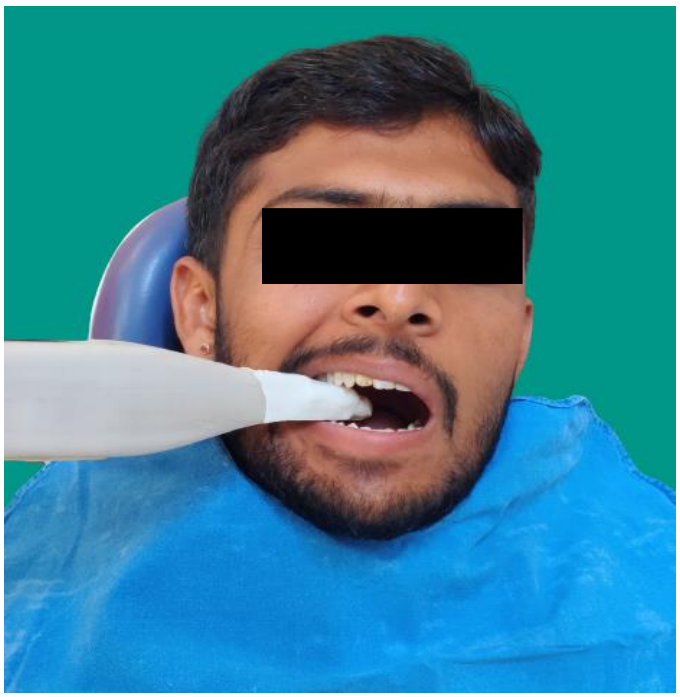

Figure 3: Flexi force sensor placed on human subject for assessment of bite force

3. Anchor instrument for MCID

The MCID was quantified as the minimal change from the preoperative to post-operative outcome, that resulted in patients rating their treatment as None/Poor compared with Good/Excellent. The MCID was calculated by anchor-based approach using change difference method and ROC curve method.

The patients were followed up till 4 weeks postoperatively and reassessed using the VAS-NRS for pain and bite force for function. The follow up examination additionally included a 4-item question assessing the pain improvement after treatment and is the anchor that was used to determine MCID.

Four **Item Anchor Instrument** used was

Table 2: Rating of response to treatment

"None"	"No good at all, ineffective treatment"
"Poor"	"Some effect but unsatisfactory"
"Good"	"Satisfactory effect with occasional episodes of pain and stiffness"
"Excellent"	"Ideal response, virtually pain free"

4. Satisfaction question for PASS.

The PASS was determined utilizing a 2-item question asking patient's their opinion of their current state. The question is a *''yes/no''* question i.e.; "*Taking into account all the activities you have during your daily life, your level of pain, and also your functional impairment, do you consider that your current state is satisfactory?"*

The 4-item and 2-item questions employed to estimate MCID and PASS were designed by Tubach et al (25).

STUDY FLOW CHART

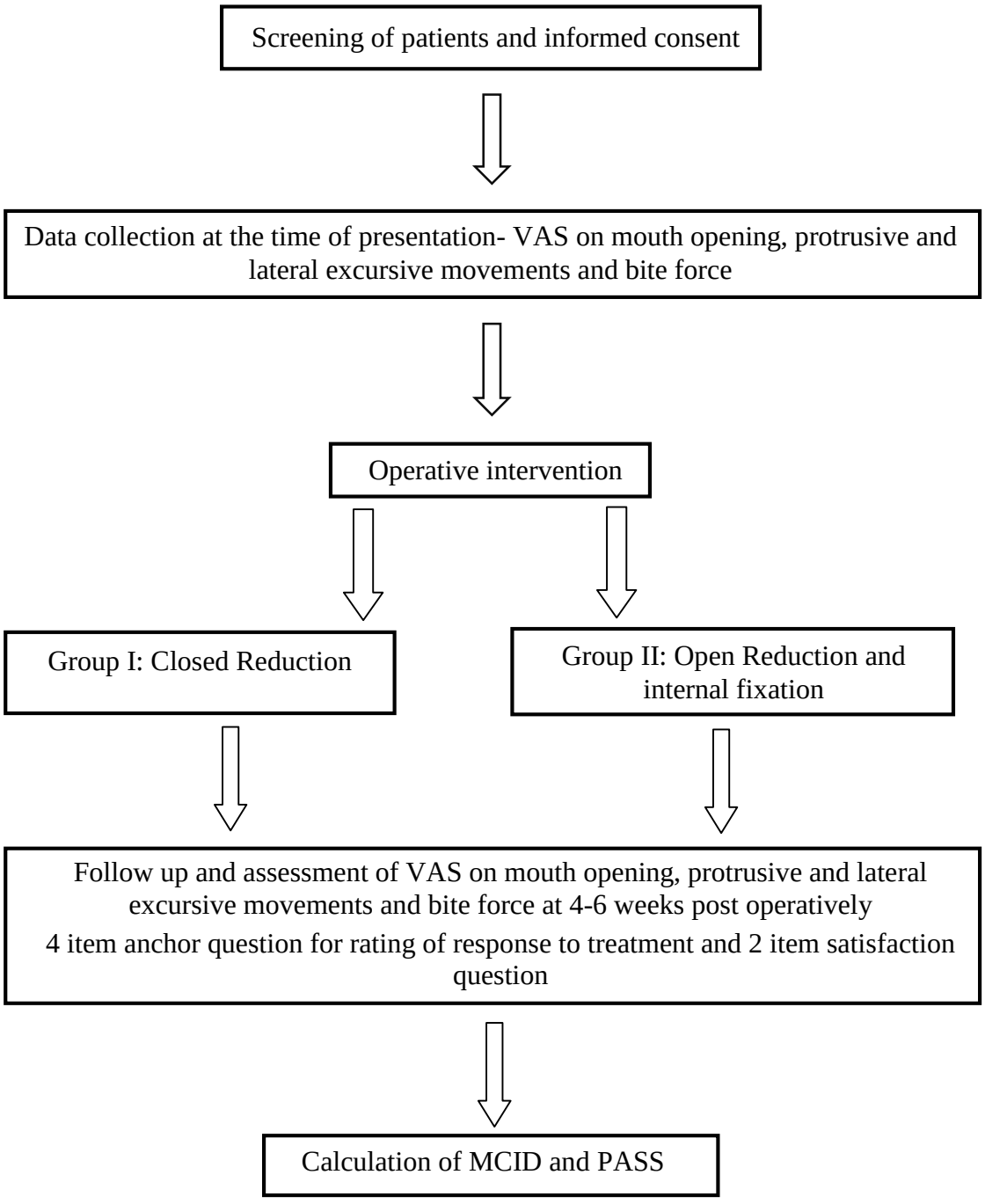

Figure 4: Study Flow Chart

STATISTICAL ANALYSIS

Data was collected in a Microsoft Excel sheet and the demographic data of the patients (Age, Gender, Socio-economic status, Education and Occupation) was expressed in percentages. Preoperative and postoperative parameters (Pain and Bite force) were expressed as Mean ± standard deviation. The correlation among change in right, left and mean bite forces, age and pain scores were assessed using Pearson's Correlation Coefficient test. MCID was calculated by utilizing two anchor-based methods- change difference method and ROC curve method.

Change difference method - The MCID for VAS NRS scores; and change in mean bite force was calculated by deriving differences between the mean change score of all patients classified as ''excellent'' from the mean change score of all patients who were classified as ''good''. A statistical test (Mann Whitney U test and t test) was performed between "unchanged" and "minimal important difference" means. p values less than 0.05 were considered significant.

ROC curve method - A receiver operator characteristic curve was drawn between the specificity (x-axis) and sensitivity (y-axis). Change in VAS NRS scores and mean bite force was plotted for groups reporting satisfaction with treatment (good versus excellent). The sensitivity and specificity of the MCID values thus obtained was evaluated and the area under the curve (AUC) was calculated which indicated the proportion of patients getting detected who have experienced change in VAS NRS scores and bite force. AUC >0.5 was considered to be satisfactory.

PASS score was calculated as the 75^{th} percentile of scores signifying that PASS level or a better score was attained by 75% of patients (8).

The Mean ± SD of bite force of right and left molar regions and mean bite force of 150 healthy controls was calculated and compared with the postoperative bite forces of the study sample. A Z test was applied for comparing the mean bite force of 95 patients at 4 weeks post operatively with the mean bite force of healthy population to detect whether there is any significant difference between mean bite force of normal healthy controls and participants in the study sample.

CLINICAL CASES

A. MIDFACE FRACTURES

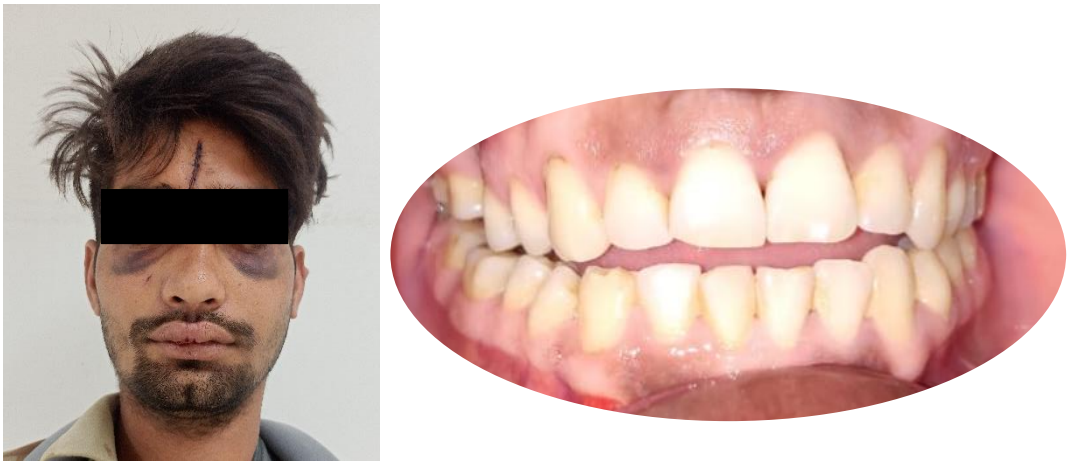

Figure 5: Preoperative clinical photograph and occlusion of patient with midface fracture

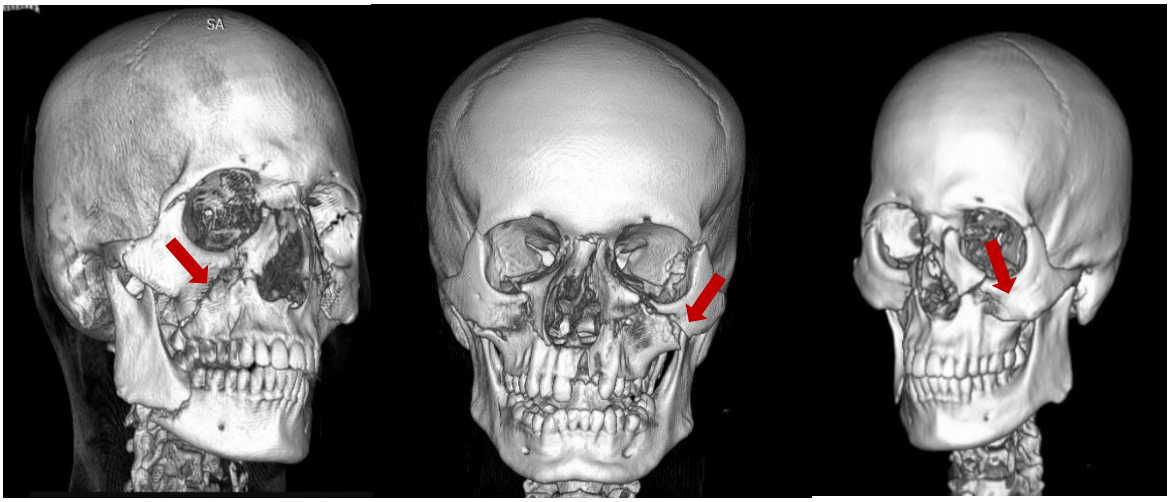

Figure 6: 3D reconstruction of CT scan images depicting midface fracture at various sites

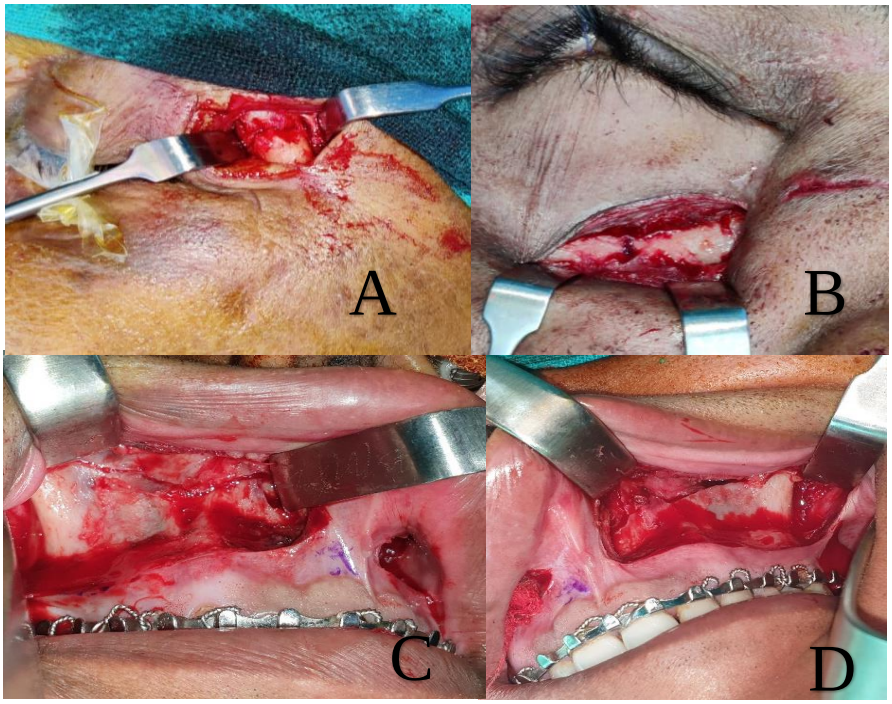

Figure 7: Intraoperative fracture site exposure; A- Frontozygomatic, B-Infraorbital rim, C & D – Right and Left zygomaticomaxillary and Nasomaxillary buttresses respectively

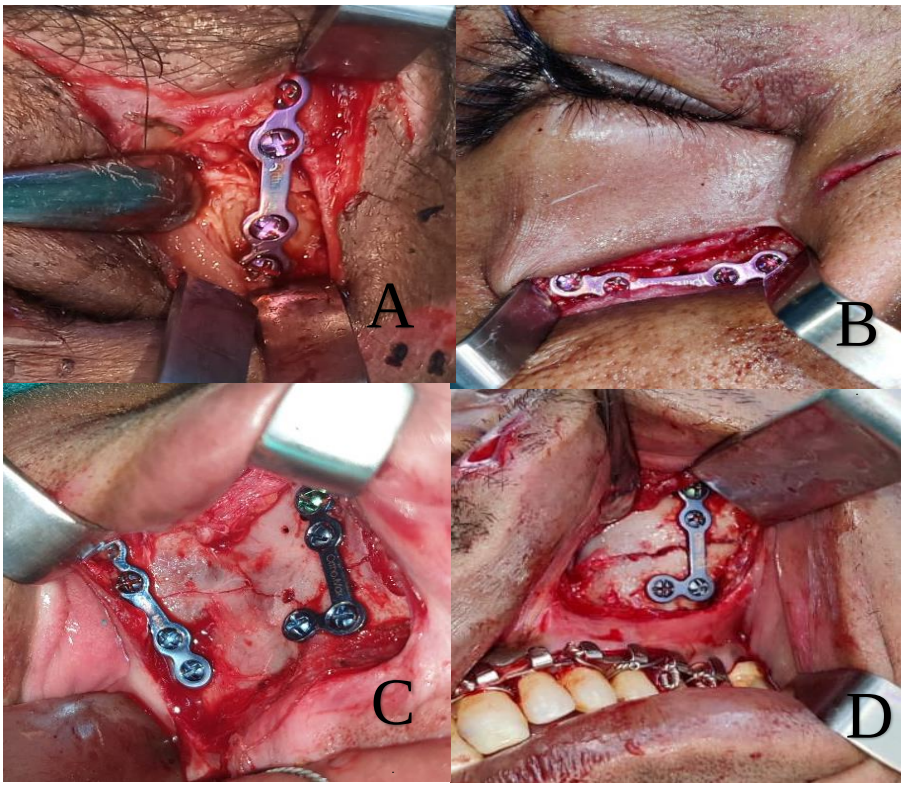

Figure 8: Intraoperative fracture site plating; A- Frontozygomatic, B-Infraorbital rim, C & D – Right and Left zygomaticomaxillary and Nasomaxillary buttresses respectively

B. MANDIBULAR FRACTURES

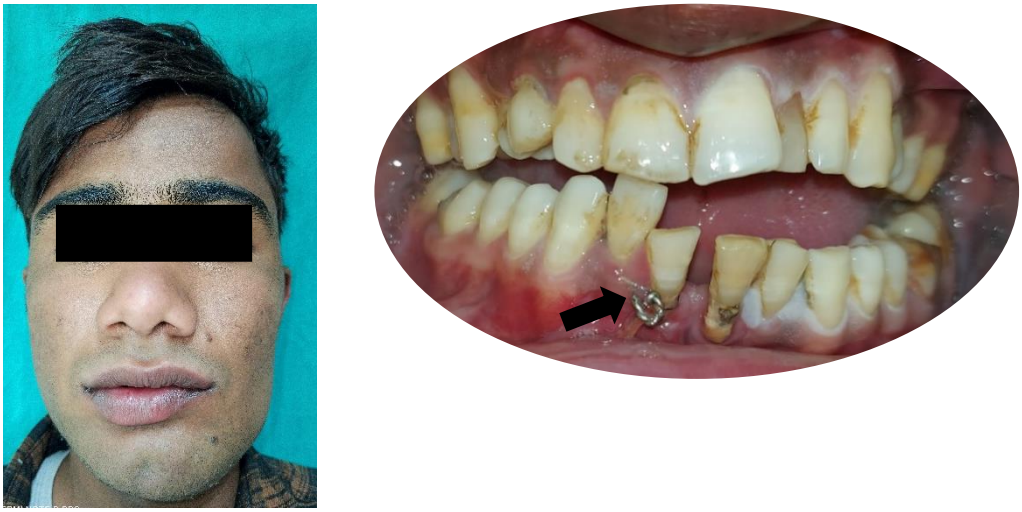

Figure 9: Preoperative clinical photograph and occlusion of patient with mandibular fracture

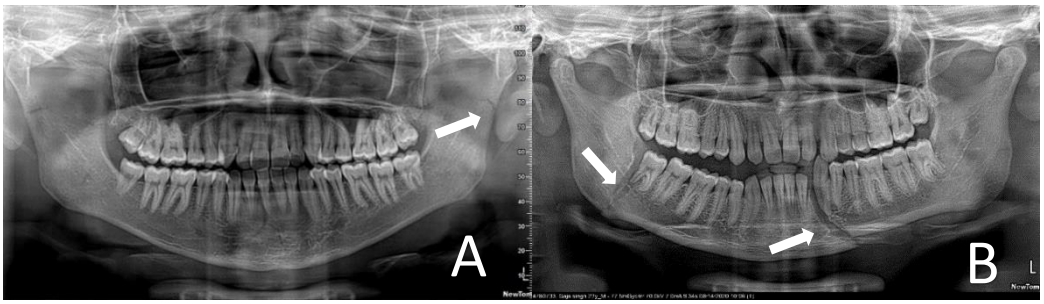

Figure 10: Orthopantomogram depicting mandibular fracture at various sites

A – Left subcondylar fracture, B- Right angle and left parasymphysis fracture

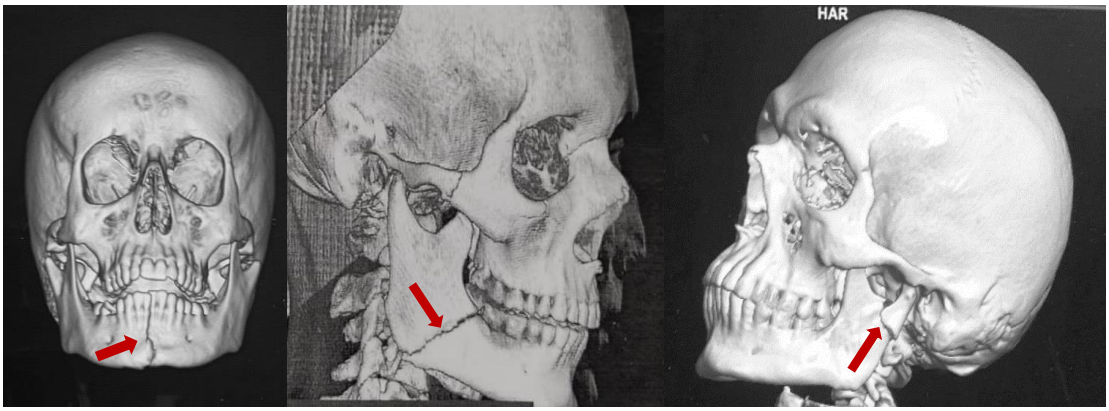

Figure 11: 3D reconstruction of CT scan images depicting mandibular fracture at various sites

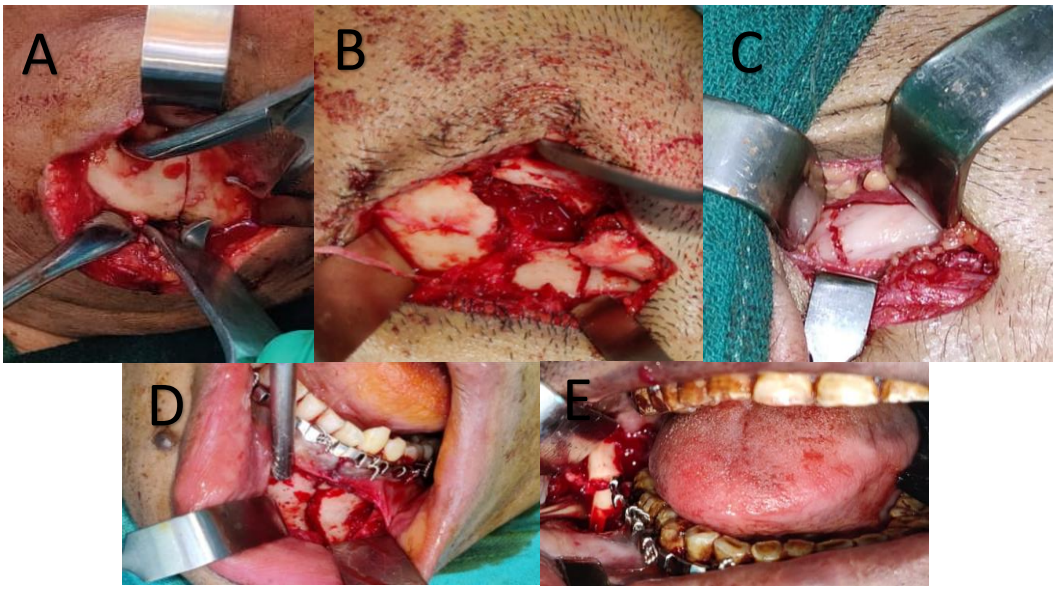

Figure 12: Intraoperative fracture site exposure
A- Symphysis, B-Body, C- Subcondyle, D- Parasymphysis, E-Angle

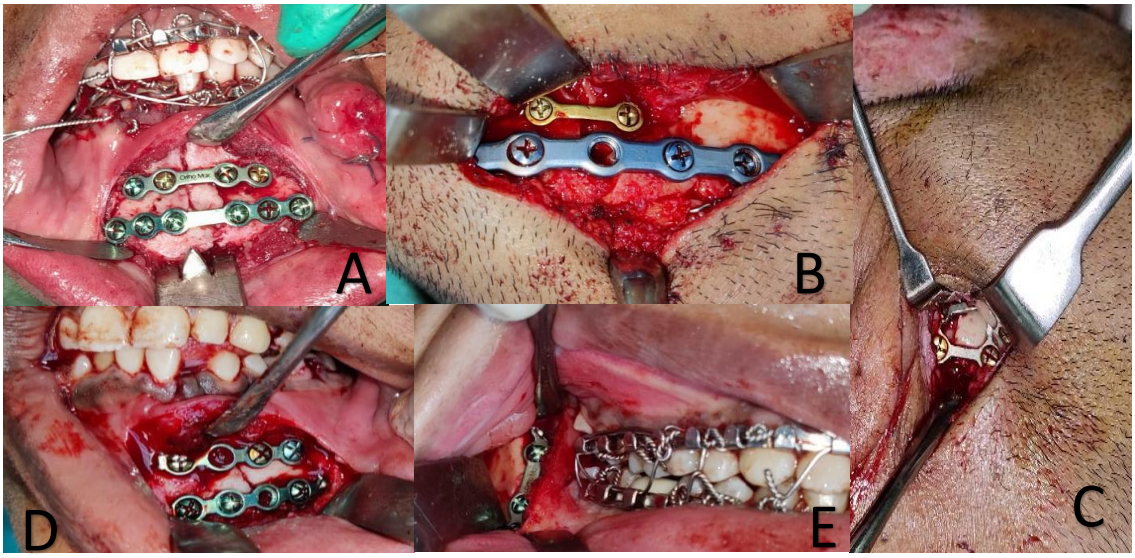

Figure 13: Intraoperative fracture site plating
A- Symphysis, B-Body, C- Subcondyle, D- Parasymphysis, E-Angle

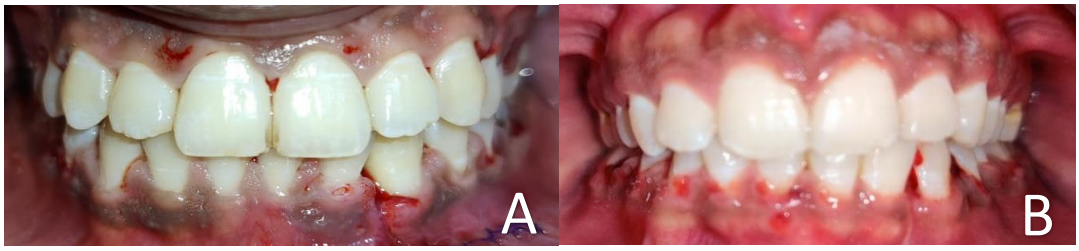

Figure 14: Postoperative Occlusion of patients A- Midface Fracture, B-Mandibular fracture

Results

RESULTS

A total of 124 patients with maxillofacial fractures who had presented to the Emergency and Trauma Centre the Department of Dentistry, AIIMS Jodhpur from September 2020 to November 2021 (14 months) were analysed as per the inclusion and exclusion criteria. Twenty- nine patients were excluded from the study due to intoxication, presence of other distracting thoracic, abdominal or head injuries or were intubated on presentation. Thus, 95 patients were finally recruited in the study without any attrition in the follow up period. The STROBE ("Strengthening the Reporting of Observational Studies in Epidemiology") flowchart of this study is shown in Figure 15.

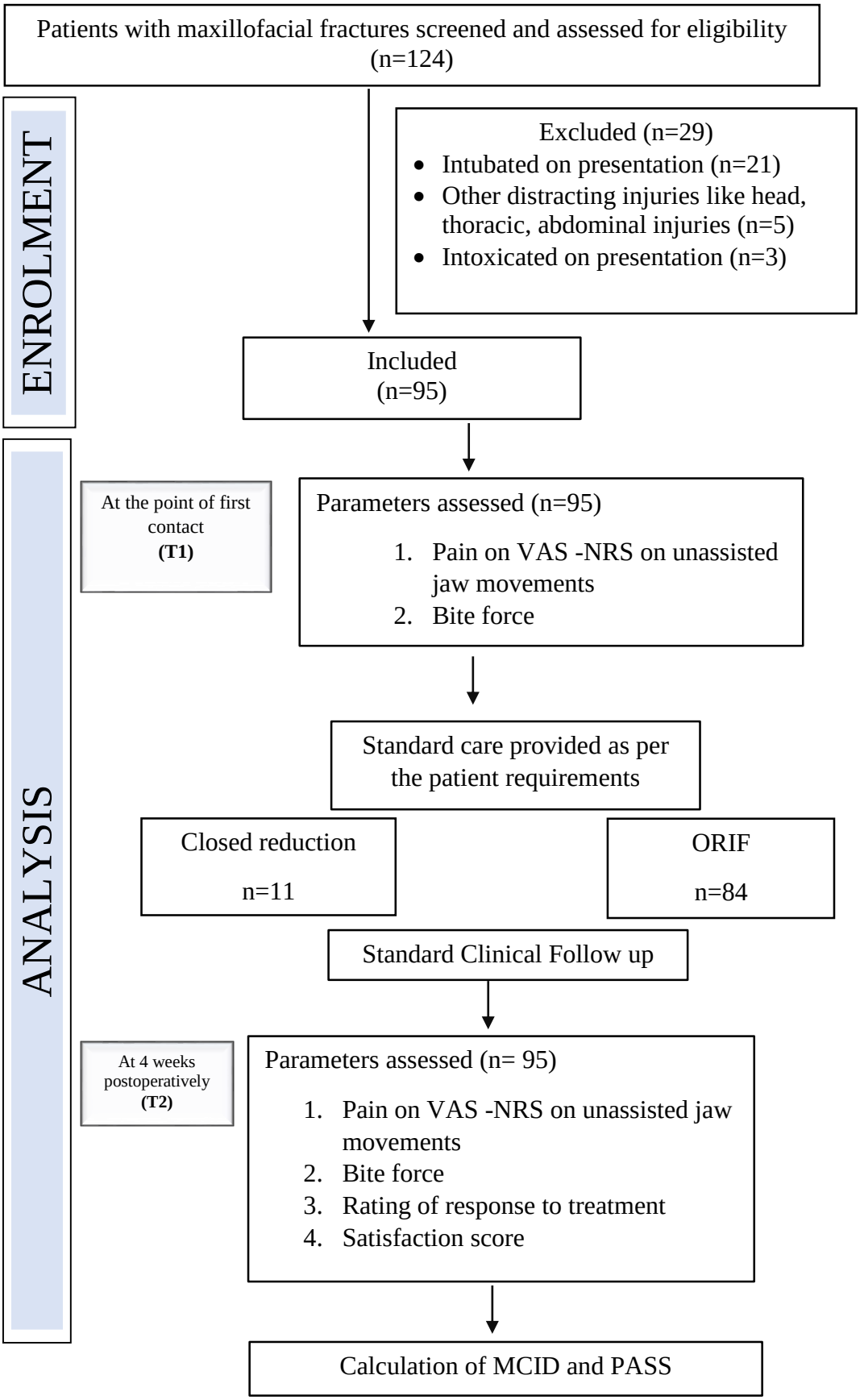

Figure 15: STROBE Flow Diagram

A. Demographic Data

The mean age of the study participants (n=95) was 31.71 ± 12.34 years. The study participants comprised of 90 males (94.73%) and 5 females (5.27%) as shown in Table 3. Among the 95 study participants, 56 males and 2 females were in the age group of 18-30 years, 21 males were in the age group of 31-45 years and only 13 males and 3 females were between 46-65 years of age as depicted in Figure 16.

Table 3: Age and Gender distribution of study participants

	Males	**Females**	**Total**
N (%)	90 (94.73)	5 (5.27)	95 (100)
Mean age ±SD (in years)	31.4 ± 12.08	37.4 ± 16.93	31.71 ± 12.34

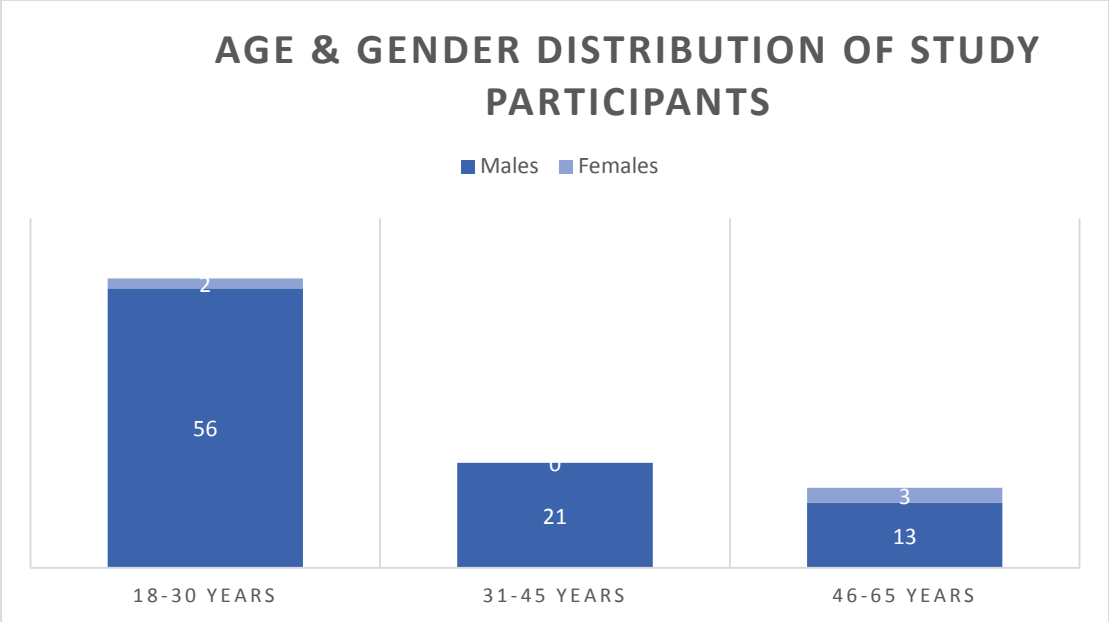

Figure 16: Bar diagram showing Age and Gender Distribution of Study Participants

B. Sociodemographic Data

Table 4 depicts the sociodemographic data of the patients. Most of the study participants in our study were educated till 12th standard (93.68%), followed by equal distribution of graduates and illiterates (3.16% each) as shown in Figure 17. A majority of them (94.74%) were from middle socioeconomic strata, 3.16% from upper socioeconomic strata and 2.10% were from lower socioeconomic strata as illustrated in Figure 18. Among the 95 study participants, 89.47% were skilled workers, 7.37% were unemployed and only 3.16% were professionals as shown in Figure 19.

Table 4: Sociodemographic Data of Study Participants

S. No	Sociodemographic Parameter		Study Participants N (%)	Total
1.	Educational Qualifications	Illiterate	3(3.16)	95
		Educated till 12th Standard	89(93.68)	
		Graduates	3(3.16)	
2.	Socioeconomic status	Lower	2(2.10)	95
		Middle	90(94.74)	
		Upper	3(3.16)	
3.	Occupation	Unemployed	7(7.37)	95
		Skilled Workers	85(89.47)	
		Professionals	3(3.16)	

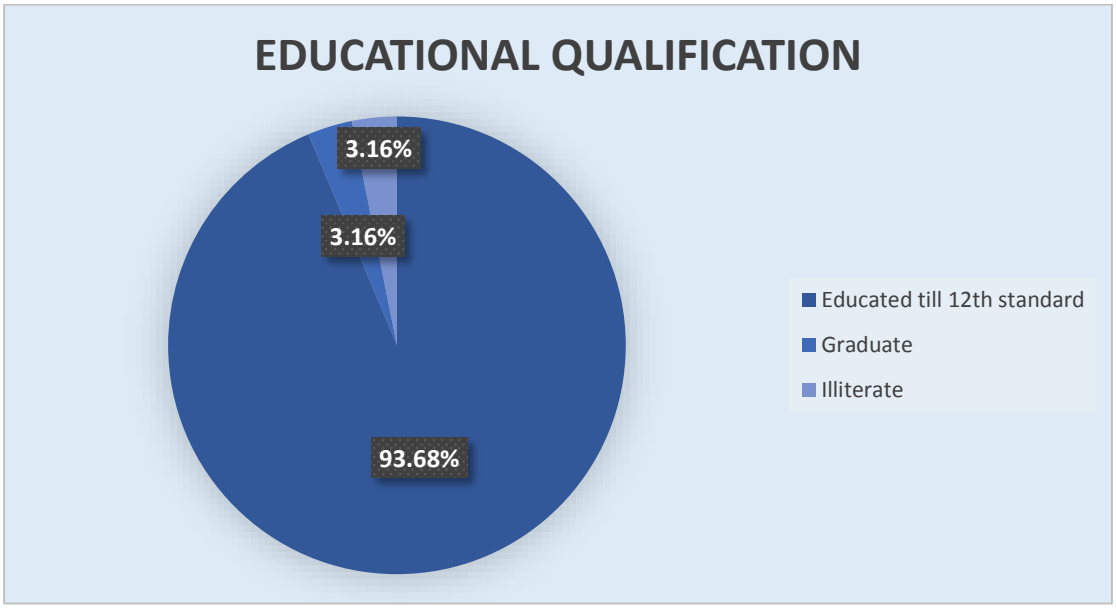

Figure 17: Pie chart depicting distribution of Educational Qualification of Study Participants

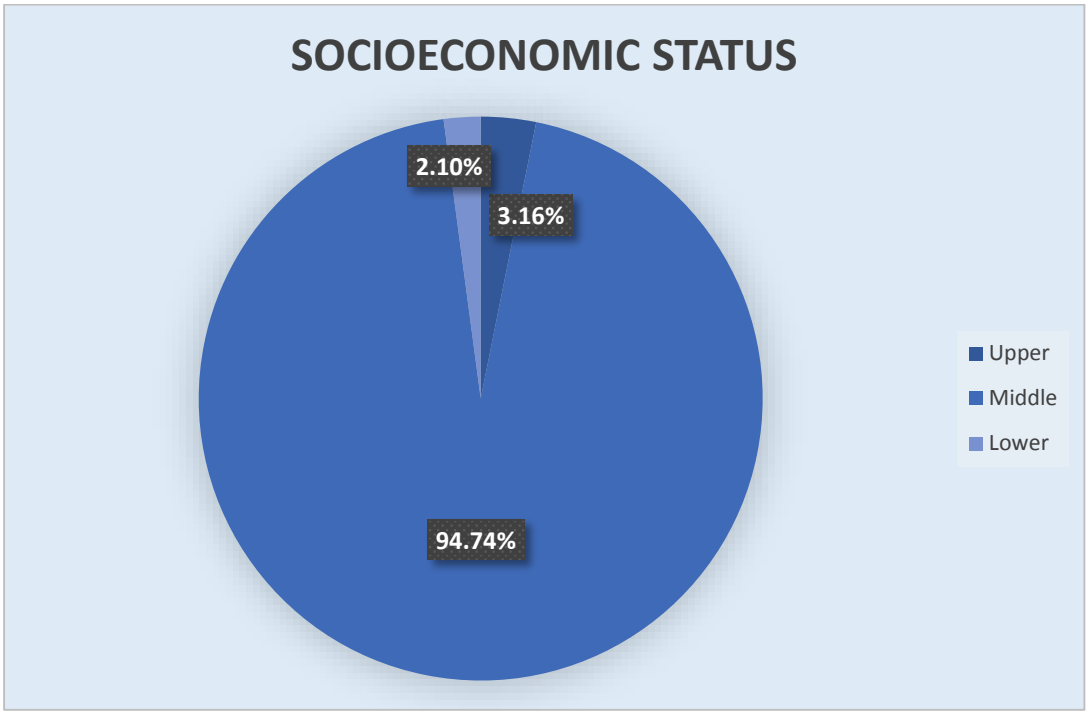

Figure 18: Pie chart depicting distribution of Socioeconomic status of Study Participants

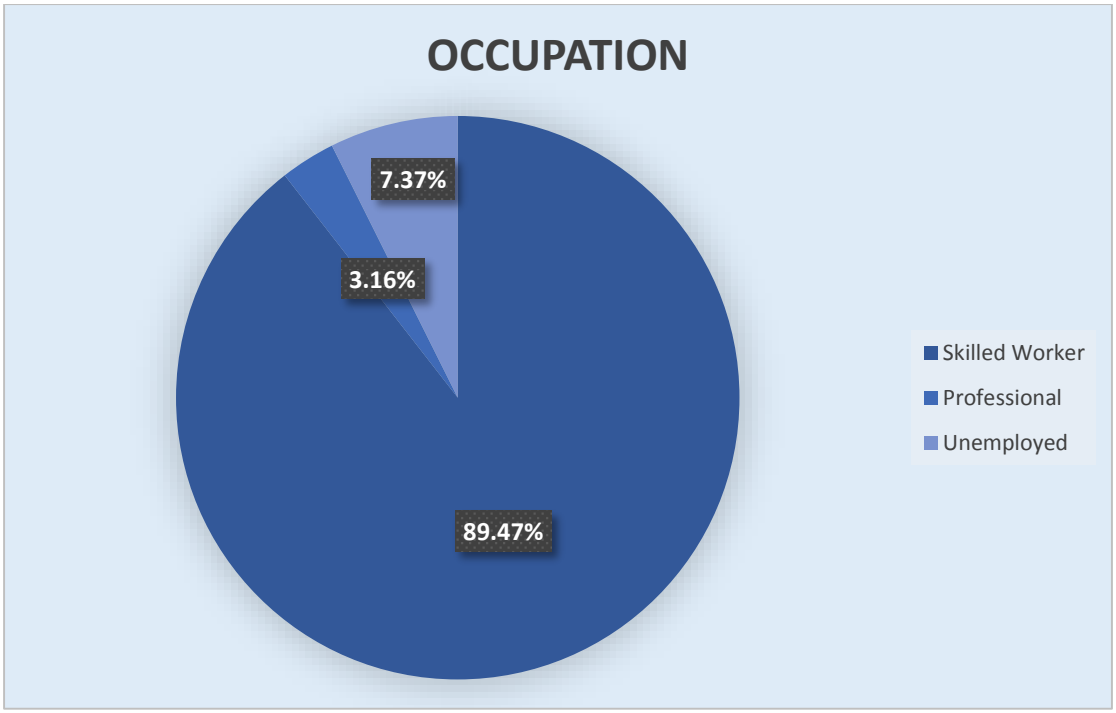

Figure 19: Pie chart depicting distribution of Occupation of Study Participants

C. Maxillofacial Trauma Characteristics

1. Mechanism of Injury

The mechanism of injury was RTI in 90.53% of the cases, fall from height in 4.21% of patients and the remaining 5.26 % had reported other mechanisms of injury such as machinery injury, gunshot wounds, physical assault, etc as presented in Figure 20

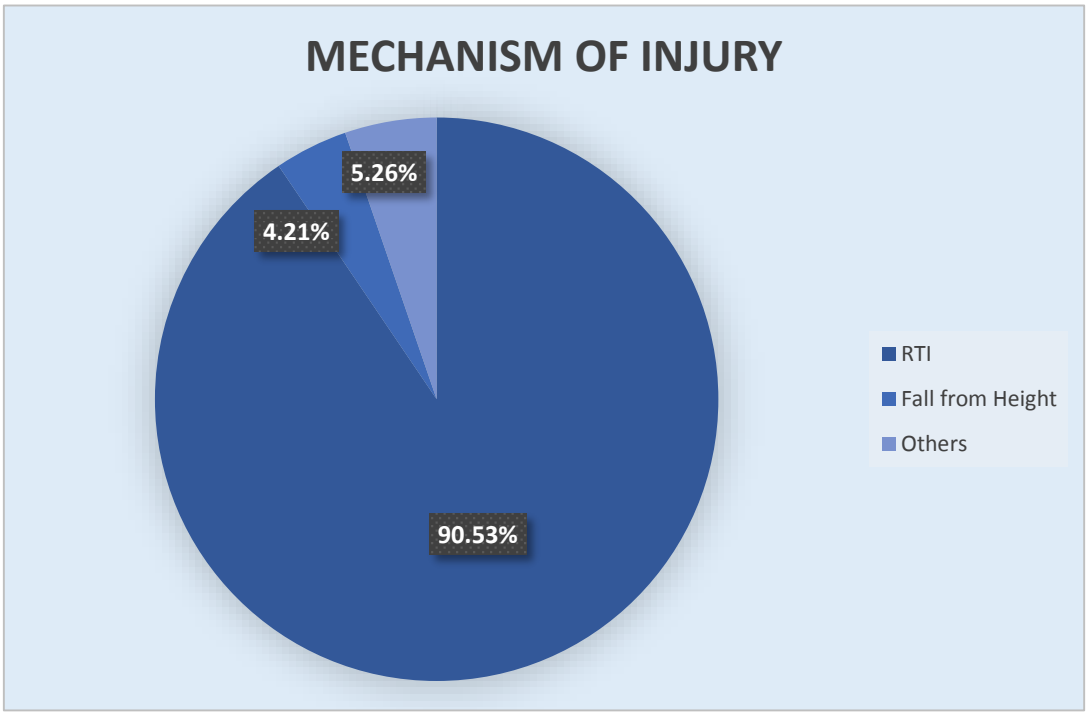

Figure 20: Pie chart depicting the distribution of mechanism of injury

2. Types of Injury

Among the 95 study participants, 11.58% had concomitant injuries such as undisplaced fractures of upper or lower extremities while 88.42% presented with isolated maxillofacial injuries as illustrated in Figure 21

3. Types of Maxillofacial Fractures

Of the 95 patients, 50.53% were diagnosed with midface fractures, 33.68% with mandibular fractures and 15.79% of the patients had fractures involving both the midface and mandible as shown in Figure 22

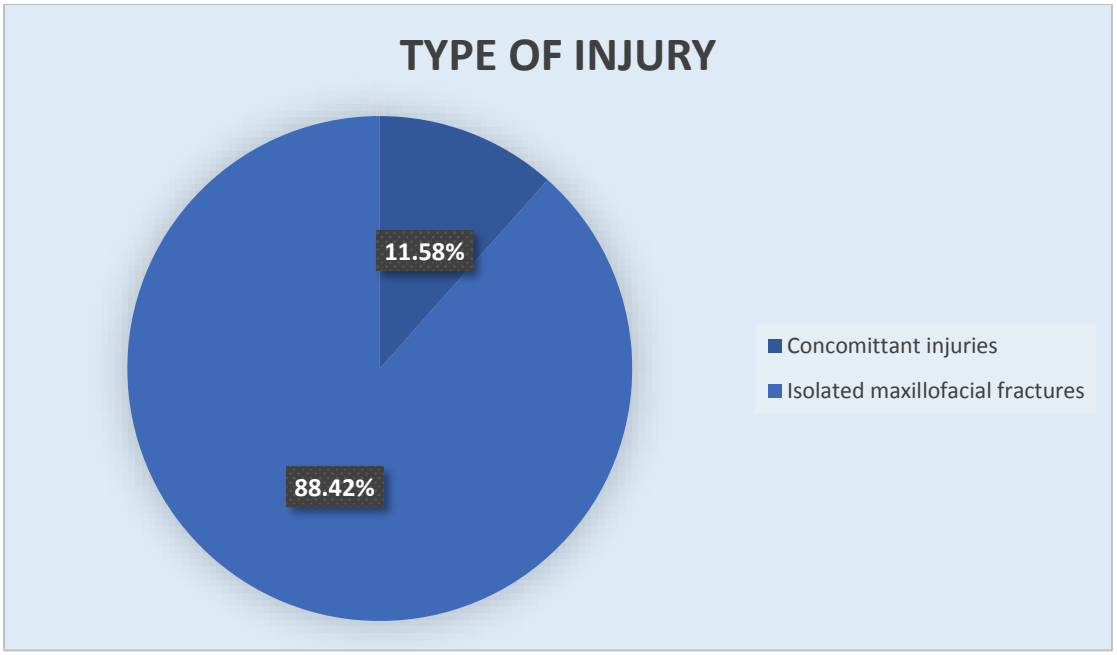

Figure 21: Pie chart depicting the distribution of type of injury

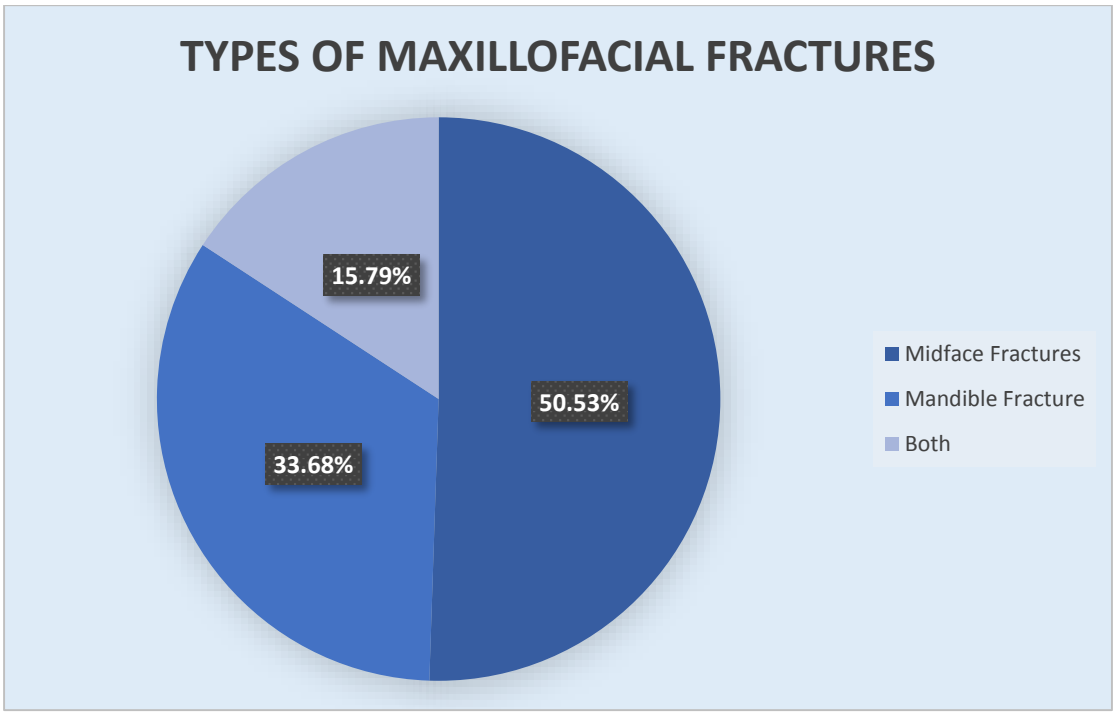

Figure 22: Pie chart depicting the distribution of types of Maxillofacial Fractures

4. Treatment

Of all the 95 included patients, 88.42 % of the participants underwent open reduction and internal fixation, whereas 11.58% of the patients underwent closed reduction as shown in Figure 23

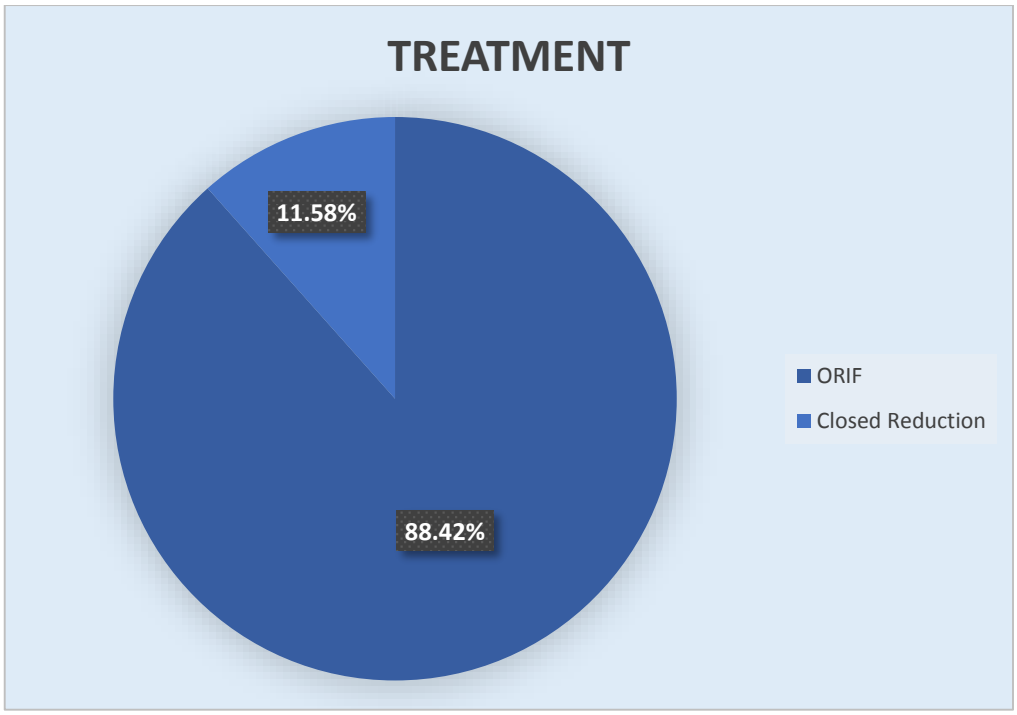

Figure 23: Pie chart depicting distribution of treatment modalities in study participants

D. Parameters Assessed

1. VAS-NRS

The mean preoperative (T1) VAS-NRS was found to be 8.21 ± 1.23 which improved to 1.53 ± 0.94 at 4 weeks postoperatively (T2). On a gender- based comparison of the VAS-NRS scores at T1 and T2, it was found that males had a slightly lower score of 8.18 at T1 as compared to females who reported 8.6 at T1. Post-operative (T2) VAS-NRS scores were also comparable between males (1.52) and females (1.6) as portrayed in Figure 24 and Table 5

On comparing the VAS-NRS scores of the study participants sustaining different types of maxillofacial fracture, at T1, highest pain scores of 8.87 was found in those sustaining fractures of both midface and mandible, followed by 8.16 in those with only

mandibular fractures and 8.04 in those with only midface fractures. Similar observation was made at 4th postoperative week (T2), with a score of 1.67 in patients with panfacial fracture, followed by 1.56 in patients with isolated fractures of midface and 1.4 in patients with isolated fractures of mandible as illustrated in Figure 25.

Table 5: Preoperative and Postoperative VAS-NRS pain scores and bite force

Time	**VAS – NRS (n=95)** **(Mean ± SD)**	**Bite Force (in Newtons)** **(Mean ± SD)**		
		Right	Left	Mean
T1	8.21 ± 1.23	16.75 ± 50.9	19.38 ± 56.16	18.06 ± 51.56
T2	1.53 ± 0.94	182.02 ± 76.14	190.80 ± 96.67	186.34 ± 79.78

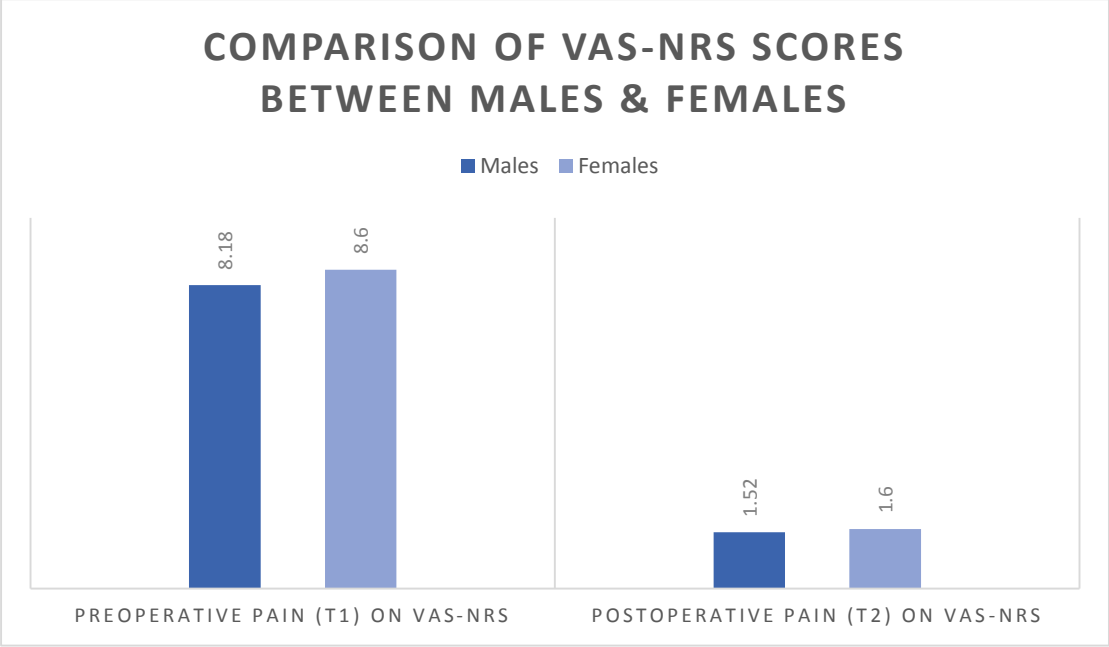

Figure 24: Bar chart depicting Gender-wise comparison of preoperative and postoperative VAS-NRS

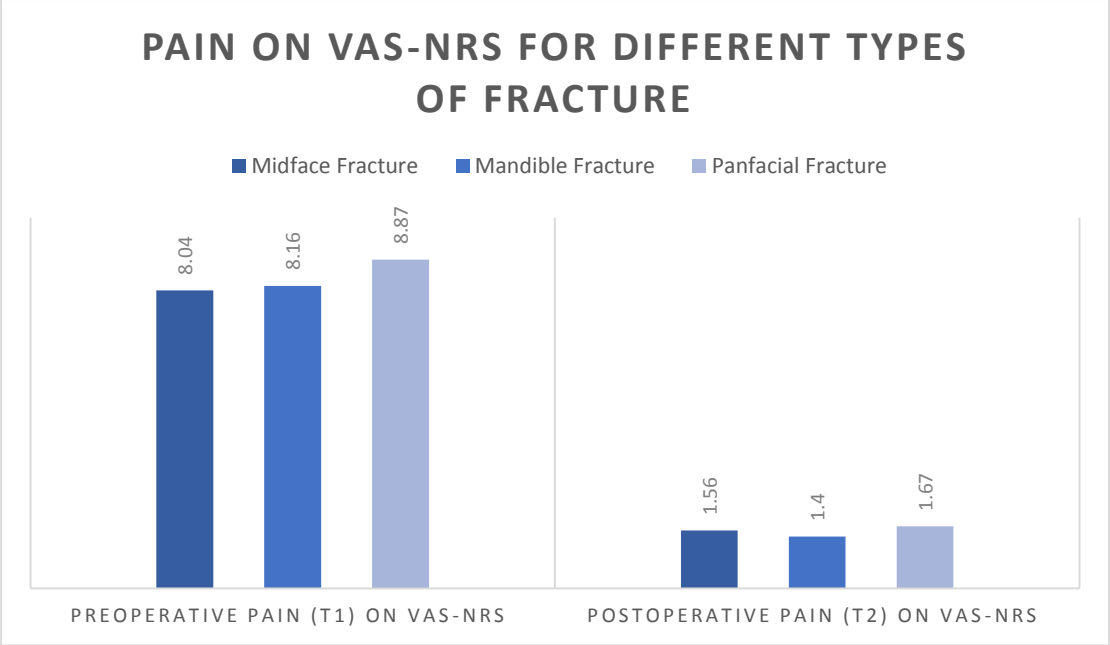

Figure 25: Comparison of pain scores on VAS-NRS based on type of fracture

2. Bite Force

The bite force assessed on the right molar region was 16.75 ± 50.9 N and 19.38 ± 56.16N on the left molar region. The mean preoperative (T1) bite force was 18.06 ± 51.56 N. The bite force values statistically significantly increased ($p<0.01$) at 4th postoperative week to 182.02 ± 76.14 on the right molar region and 190.80 ± 96.67 at the left molar region with a mean postoperative bite force (T2) of 186.34 ± 79.78 as depicted in Figure 26 and Table 5. Based on the type of maxillofacial fracture the mean postoperative bite forces were assessed to be 189.36N in midface fracture, 185.83N in mandible fractures and the least, 177.75N in fractures involving both midface and mandible as shown in Figure 27

The mean postoperative bite force of study population achieved was compared with the mean bite force of healthy controls and were classified into four grades. Majority of patients (60%) had achieved Grade II bite strength followed by 21.05% patients with Grade I bite force, 15.79% patients with Grade III and only 3.16% with Grade IV bite force as depicted in Figure 28 and Table 6.

Table 6: Grading of postoperative bite force(T2) of study participants

Grade	Description	Number of patients (%)
Grade I	0-25% of normal bite force	20 (21.05)
Grade II	25- 50% of normal bite force	57 (60)
Grade III	50- 75% of normal bite force	15 (16.79)
Grade IV	>75% of normal bite force	3 (3.16)
	Total	**95**

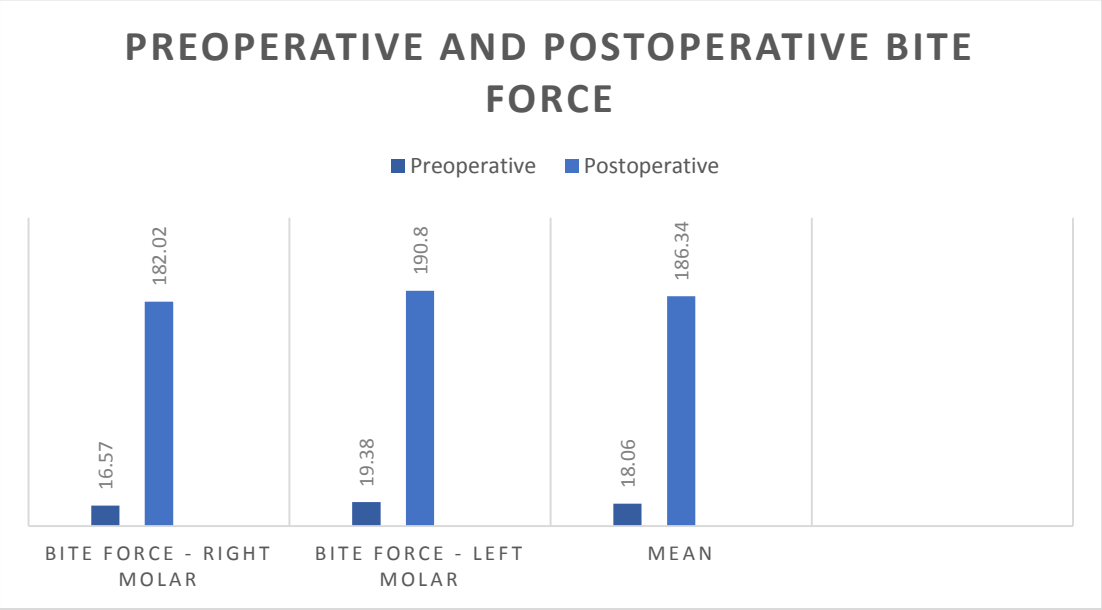

Figure 26: Bar chart comparing preoperative and postoperative bite force

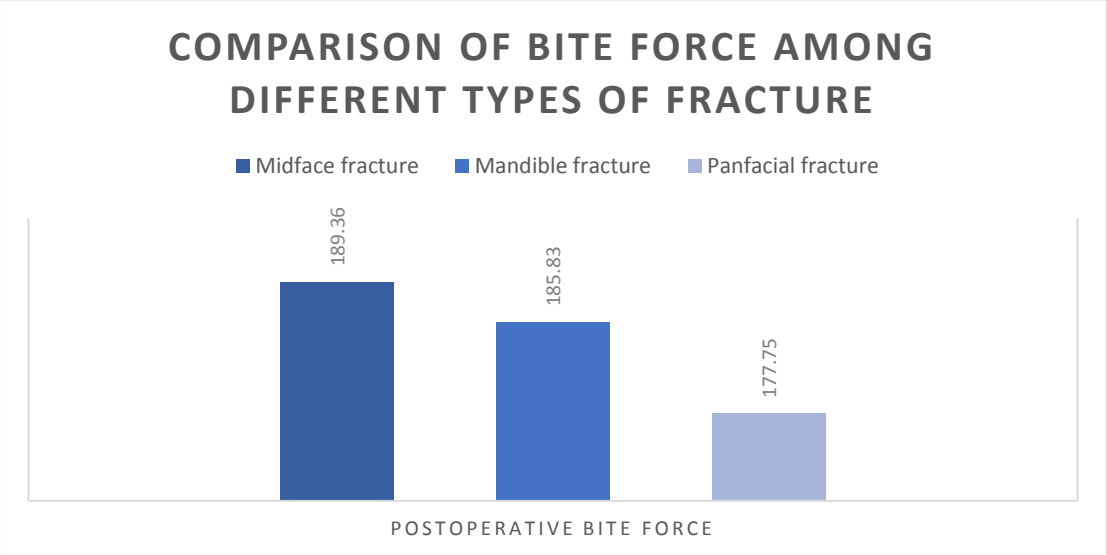

Figure 27: Bar chart comparing postoperative bite force among different types of fracture

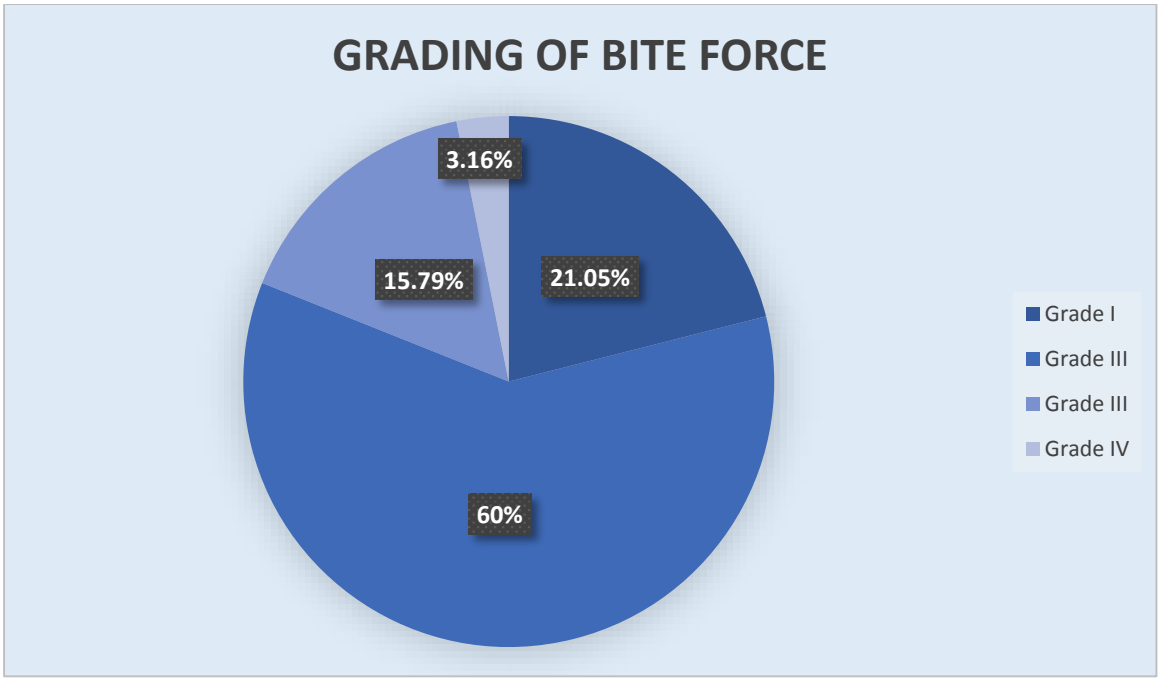

Figure 28: Pie chart depicting various grades of postoperative bite force achieved in study participants

3. Bite force standardization

Bite force was standardized using a healthy control group of 150 patients (105 males and 45 females) with a mean age of 32.65 ± 8.94 years (age range 18-50 years). The mean bite force on the right side was 468.95 ± 82.88N and on the left side was 470.21 ± 73.72N as shown in Table 7 and Figure 29

Table 7: Demographic data of Healthy Controls

Total number of controls	**Gender**		**Mean Age ± SD (in years)**	**Mean Bite Force Right (in N)**	**Mean Bite Force Left (in N)**	**Mean Bite Force (in N)**
	Males	Females				
150	105	45	32.65 ± 8.94	468.95 ± 82.88	470.21 ± 73.72	469.58 ± 76.43

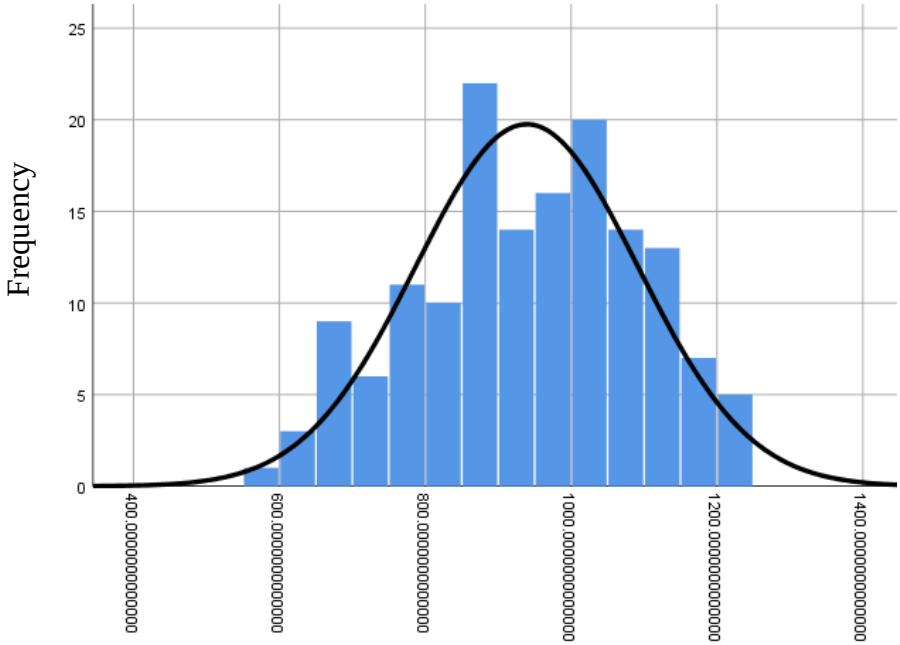

Figure 29: Mean Bite Force of Healthy Controls

4. Rating of Response to Treatment

The 4-tem standard anchor instrument was used to assess the rating of response to treatment at T2 (4 weeks follow up) which stated that 31.58% (30/95) of the patients rated the treatment as "Good" whereas 68.42% (65/95) rated the treatment as "Excellent" and no patient reported "None" or "Good" as presented in Table 8.

Table 8: Rating of response to treatment by study population

Rating of Response to Treatment		**Number of patients n (%)**
"None"	*"No good at all, ineffective treatment"*	0 (0)
"Poor"	*"Some effect but unsatisfactory"*	0 (0)
"Good"	*"Satisfactory effect with occasional episodes of pain and stiffness"*	30 (31.58)
"Excellent"	*"Ideal response, virtually pain free"*	65 (68.42)
	Total	95

5. PASS and Satisfaction Score

All the patients (95/95) reported satisfaction with the treatment on the two-item (Yes/No) question assessing satisfaction score as described in Table 9. The PASS score was calculated as 75th percentile of VAS-NRS score and was found to be 2. The PASS score of mean bite force was calculated to be 220.92N.

Table 9: Satisfaction score assessment of study participants

Satisfaction Score Assessment Question	**Response**	**Number of patients n(%)**
*"*Taking into account all the activities you have during your daily life, your level of pain, and also your functional impairment, do you consider that your current state is satisfactory*?"*	Yes	95(100)
	No	0(0)
	Total	95

6. Correlation of parameters

The correlation among change in right, left and mean bite forces, age and pain scores were assessed using Pearson's Correlation Coefficient test. There was a significant correlation between the change in right and change in left bite force (p=0.00). There was an increase in right bite force with an increase in left bite force as shown in Figure 30. Also, there was a statistically significant correlation between the change in bite force with age (p=0.01). With an increase in age there was a decrease in change in bite force values on right (p=0.004) and left (p=0.04) sides as depicted in Figures 31 & 32. However, there was no correlation of the change in pain scores with age (p=0.563) and change in bite force (p=0.88). (Table 10).

Table 10: Correlation of parameters

		Change in left bite force	**Change in right bite force**	**Change in mean bite force**	**Change in Pain Score**	**Age**
Change in left bite force	Pearson Correlation	1	.726	--	-.003	-.208
	Sig. (2-tailed)		.000*	--	.976	.043*
Change in right bite force	Pearson Correlation	.726	1	--	.035	-.291
	Sig. (2-tailed)	.000*		--	.733	.004*
Change in Pain Score	Pearson Correlation	-.003	.035	.015	1	-.060
	Sig. (2-tailed)	.976	.733	.888		.563
Age	Pearson Correlation	-.208	-.291	-.262	-.060	1
	Sig. (2-tailed)	.043*	.004*	.010*	.563	
* Statistically significant						

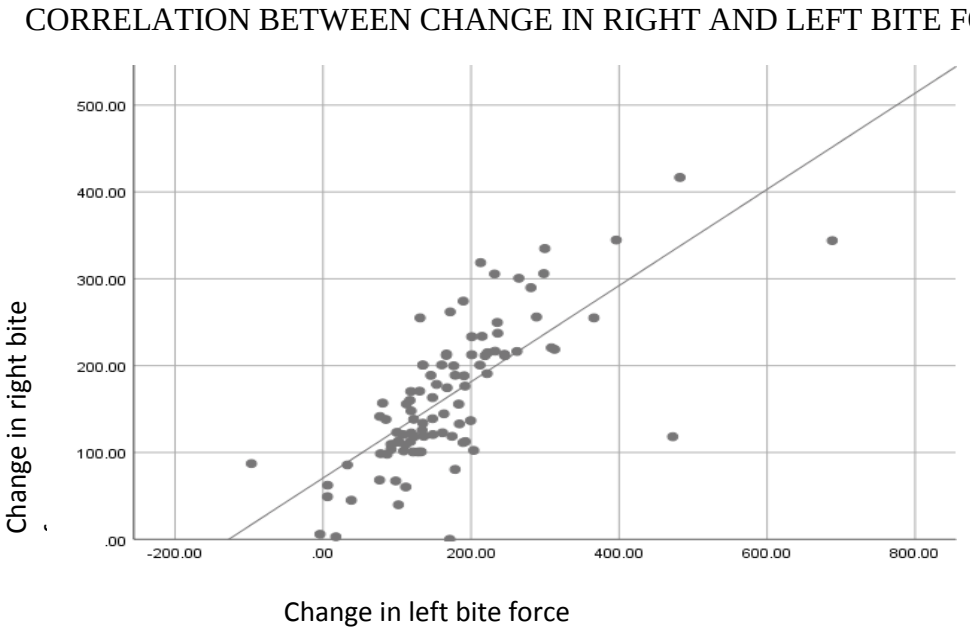

Figure 30: Scatter plot depicting correlation between change in right and left bite forces

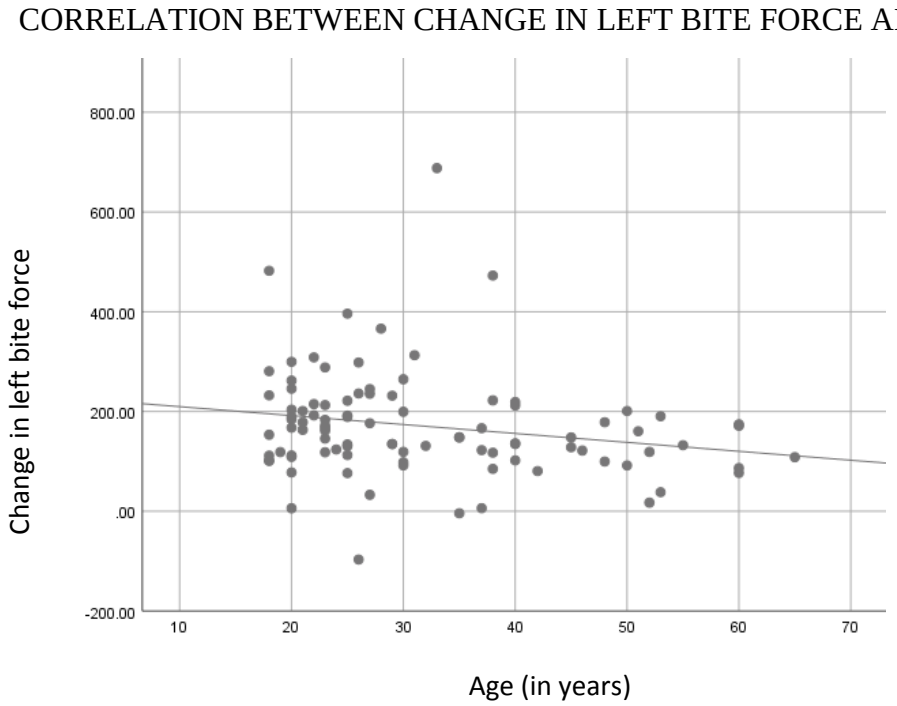

Figure 31: Scatter plot depicting correlation between change in left bite force and age

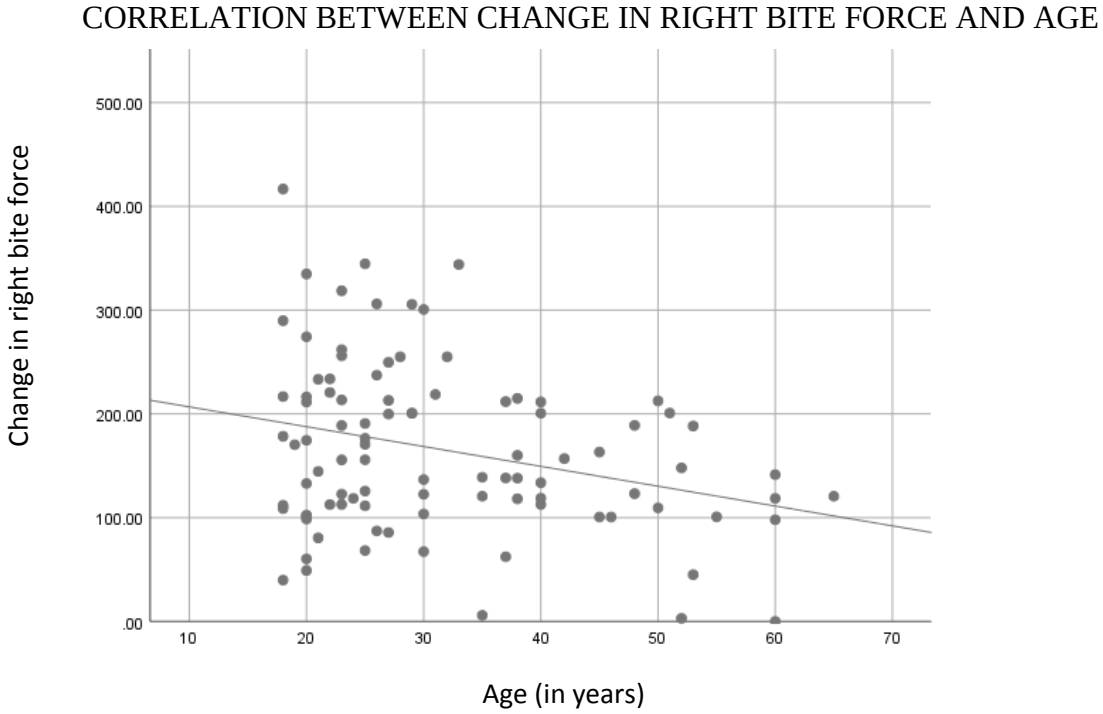

Figure 32: Scatter plot depicting correlation between change in right bite force and age

7. Minimal Clinically Important Difference (MCID)

a. MCID of pain on VAS-NRS by Change difference method

MCID of pain on VAS-NRS by change difference method was found to be 6.68.

Mean Change in pain scores of those who reported "good" treatment (30 /95) was 6.26 (1.36) as compared to 6.87 (1.19) for patients who reported excellent treatment (65/95). On applying Mann Whitney U test, this difference was not found to be statistically significant between both groups. ($p<0.05$) as presented in Table 11

b. MCID of pain on VAS-NRS by ROC curve method

Based on the ROC curve plotted between sensitivity and 1-specificity, the MCID of pain on VAS-NRS was found to be 6.5 and the AUC was 0.62 with a sensitivity of 65.6% and specificity of 55.2% as represented in Figure 33.

c. MCID of Bite Force by Change difference method

MCID of mean bite force by change difference method was found to be 186.14 N.

Mean Change in bite force scores of those who reported "good" treatment (30 /95) was 148.56 (47.82) as compared to 203.48(85.76) for patients who reported excellent treatment. On applying t test, this difference was found to be statistically significant between both groups. ($p< 0.05$) as presented in Table 11.

d. MCID of Bite Force by ROC curve method

Based on the ROC curve, the MCID of mean bite force was found to be 134.27N and the AUC was 0.69 with a sensitivity of 72.3% and specificity of 63.3% as represented in Figure 34.

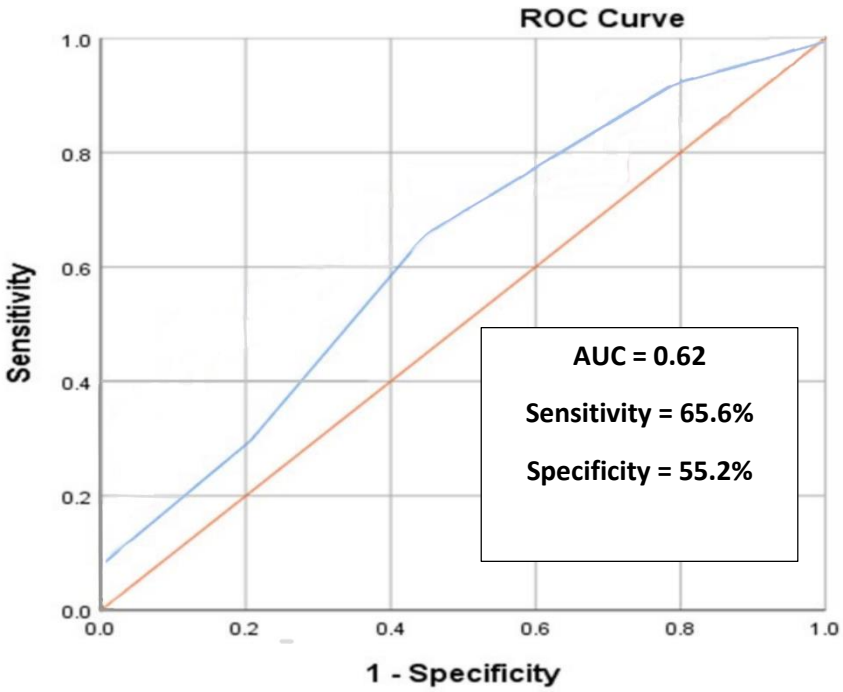

Figure 33: ROC Curve signifying MCID of pain on VAS-NRS

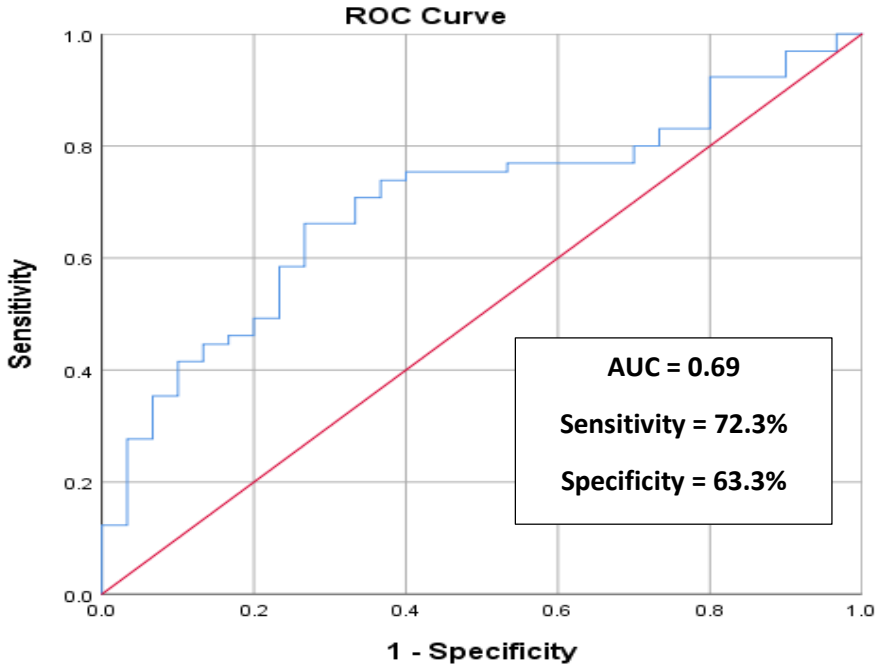

Figure 34: ROC Curve signifying MCID of mean bite force

Table 11: Change difference score of pain and bite force in "Good" and "Excellent" Groups

	Change Difference		
	Patient reporting "Good" treatment $	**Patient reporting "Excellent" treatment $**	**p value**
Pain Score (VAS-NRS)	6.26	6.87	<0.05*
Mean Bite Force (in Newtons)	148.56	203.47	<0.05*

* - statistically significant
$ - Refer Table 2

Table 12 depicts a summary of MCID of pain on VAS NRS and bite force derived by Change difference and ROC curve methods with the percentage of patients who have obtained the MCID

Table 12: MCID of pain on VAS-NRS and bite force by various methods

MCID Method	**MCID of Pain in VAS-NRS**	**MCID of mean bite force (in N)**
Change Difference	6.68	186.14
ROC curve	6.5	134.27
Area under the curve	0.62	0.69
Sensitivity	65.6%	72.3%
Specificity	55.2%	63.3%

Discussion

DISCUSSION

According to WHO news report 2021, global burden of non-fatal injuries due to trauma is between 20-50 million people every year. Although the countries with low and middle economic status have roughly 60% of the world's vehicles, 93% of the world's death toll occur in these countries (1). Majority of trauma victims incur significant disabilities as a result of injury. Notwithstanding physical trauma and environmental stresses are adverse life events that may further affect the physical, psychological, economic and social well-being of the patients in unexpected ways, the cumulative consequence of which can be damaging to the overall health (2).

Facial disfigurement, independent of whether it is congenital or traumatic is still a taboo in the general public leading to low self-esteem and varied psychological challenges (2). Bisson et al confirmed that patients who had facial trauma had a high probability (27%) of developing post-traumatic stress disorder (PTSD) by 7 weeks after trauma (30). Conforte J et al have reported that in patients sustaining facial injuries, the major decline in quality of life occurs immediately after trauma and improves over 30-90 days after surgery (2). As surgeons we put in all efforts to restore the patients' form and function with minimal complications. Assessment of this restoration, is done with well researched designated subjective and objective varied clinical, radiographic and psychosocial parameters as a marker of treatment success. Until time, these studies assessing the surgical management outcomes tend to disregard the salient patient's perspectives that can impact health aftermaths.

In the recent decade, the efforts from some researches have increasingly sensitised the surgical community to the obscure social and psychological aspects of patients on treatment outcome. There is enough literature evidence that gauged the psychosocial domain in the form of QoL, PTSD and varied questionnaires that have found to unfavourably impact response to treatment and may even intensify the risk of re-injury (30). Effective surgical repair, undoubtedly is a crucial aspect of recovery, but meeting the patients' perspective in treatment planning for better surgical outcome is equally important. Further, there is an urgent need to evaluate if the successful treatment for the surgeon actually corroborates with the patients' evaluation of successful treatment. It is every clinician's or surgeon's experience, that despite improved treatment outcomes

patients may be dissatisfied and vice versa, now it has found a literature support as well (31).

PROMs (Patient reported outcome measures) record the patients' perception of their own health through questionnaires. These measures intend to seal the lacuna in the surgeons' knowledge regarding the outcomes that concerns the patients in their purview (4,5). Research on PROMs have evolved over the last three decades. While scrutinising MEDSCAPE, it was found that there is no mention of PROMs before 2003 and there has been 178 studies from 2003 to 2010 and about 10,320 studies from 2011 -20, which shows about 60-fold increase than the last decade. PROMs offer resourceful and standardised methods of accumulating information on complex outcomes of daily functioning (4,5). PROMs help to provide person centred care and promotes standard decision making. It is being increasingly used in clinical registries and quality improvement activities.

MCID of PROMs signifies a threshold value of change in the PROM score adjudged to have an implication in clinical management. A thorough search in PUBMED revealed that there is no mention of MCID before 1987, with 15 studies available in the literature between 1987 and 2000. Through the first decade of the 21st century, there has been a rising trend with 163 studies reported in the literature. However, there has been a steep, dramatic increase in the past decade with 1714 studies available in the literature. An interesting fact to focus upon is that, out of these studies only 70 studies have actually calculated MCID in various fields like orthopaedics & neurosurgery (7,12,19,22,25). The scenario in maxillofacial region is even worse wherein, the MCID has been calculated only in 3 studies (13,16,17). Thus, it is high time for our fraternity to incorporate the standard PROs (MCID and PASS) as powerful patient based surgical outcome tools, to gauge our treatment success as clinical significance is far more relevant than the statistical significance.

Maxillofacial trauma has been reported in the young adults (18-30 years) in the literature. Similarly, our study population showed a preponderance of young adults (61.05%) being affected by trauma. This can be elucidated by the fact that this age group of population is the most socially active and interactive as compared to the other age groups. Comparable findings with respect to occurrence of maxillofacial trauma in young adults have been reported in the literature (32,33).

The predominance of male gender (94.74%) in the occurrence of maxillofacial fractures in the present study can be ascribed to the fact that men are involved in the outdoor events and are bread-winners of the family, as compared to women in Western India posing them at a greater risk. This is in accordance with the findings reported in the literature (32,34) . More so, the number of male drivers exceed the female drivers, eventually increasing the incidence of RTIs in males (32,34).

With only 1% of world's vehicles, India accounts for 11% of global death in road accidents, the highest in the world (35). In a developing country like India, the road safety laws are not under strict implementation, hence RTIs (90.53%) still remain the leading cause for facial trauma in our study followed by fall from height (4.21%) and other causes like interpersonal violence and machinery injuries. This is in accordance with the literature as per the study done by Sawhney and Ahuja and Gandhi et al (32,36).

Maxillofacial fractures have found to occur with concomitant injuries like head injuries, thoraco-abdominal injuries or long bone injuries. 88.42% of patients in the present study had isolated maxillofacial fractures. The various associated injuries with maxillofacial fractures as documented by Subhasraj et al are head injury (39%), orthopaedic injury (23%), cervical spine injury (3%), abdominal and thoracic injury (3%) (34). In the present study as well, a total of 11 (11.58%) patients had associated injuries. Of which 8 (8.42%) patients had orthopaedic injuries and 3 (3.16%) patients had head injuries.

Among the facial fractures, midface fractures (50.53%) were the most common followed by fractures of mandible (33.68%). Only 16.42% of patients had fractured the entire facial skeleton. These results are coherent with the study done by Agarwal P et al who reported 55.5% midface fractures and 44.5% of mandibular fractures (37). Subhasraj et al and Gandhi et al also stated similar results in their respective studies (32,34) . However, there was a slight variation found in the study conducted by Bakardjiev et al and Kieser et al, who have reported mandible to be more commonly fractured than maxilla (38,39).

The sociodemographic attributes of the study population included educational qualifications, socioeconomic status based on per capita income and the occupation. A majority of the study population (93.68%) were educated till 12^{th} standard and the remaining were illiterates (3.16%) or graduates (3.16%). Middle socioeconomic strata

(94.74%) of population comprised a major fraction, followed by upper socioeconomic strata (3.16%) and lower socioeconomic strata (2.10%). Maximum study population was employed with a skilled job (89.47%), 7.37% were unemployed and a meagre of 3.16% were professionals. Goodfellow M et al have reported a strong association between facial fractures and socioeconomic deprivation and have ascribed the cause to increased incidence of substance abuse and interpersonal violence (40). Further Juncar et al supported the association of maxillofacial injuries with lower educational qualification as it predisposes to unemployment and in turn low socioeconomic status, consequently affecting the mental health leading to substance abuse and aggression (41). Therefore, sociodemographic characteristics significantly impact the epidemiology of maxillofacial fractures.

All the patients received standard surgical care either in the form of open reduction and internal fixation or closed reduction with a stringent follow up. Closed reduction was performed in a total of 11 patients for isolated fractures of nasal bone (6.31%) and isolated zygomatic arch fractures (2.10%) and bilateral high condylar fracture (1.05%). Also, two patients with midface and mandibular fractures underwent closed reduction in the Covid-19 pandemic.

Pain which was the first parameter assessed is defined by the IASP as "*an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage*". Acute pain is triggered by a specific injury, and involves skeletal muscle spasm and activation of the sympathetic nervous system. However, with time it is self-limiting. Conversely, chronic pain resembles a diseased state. Chronic pain is a matter of concern to patients as it has no detectable end point and it outlasts the healing time (26,28,42).

As clinicians we have a duty to provide effective pain management with competent medical care, as pain adversely impacts the physical function, reduces quality of life and sleep, hampers treatment outcome and doctor-patient relationship as well (43).

Highest pain scores have been reported in the field of traumatology and orthopaedics, thus increasing the importance of pain assessment in maxillofacial trauma (28). In a study by McCarty C J et al patients with fractures of mandible (63%) and midfacial skeleton (29%) reported pain score of greater than 4 on VAS-NRS (44). To reduce subjective evaluation of pain based on the difference in the patient's perception several

scales were introduced in the clinical practice to objectify the pain. Tools assessing pain are mentioned in the literature like Visual analogue scale (VAS), Wong-Baker Faces Pain Scale, Comfort scale, McGill Pain Scale, Numeric Rating Scale (NRS), Colour Analog Scale and Mankoski Pain Scale (45,46). Mc Gill pain scale and Brief Pain inventory scale, most of which are complex and are difficult to understand. Faces Pain Scale, which displays facial expressions ranging from the state of well-being to worst pain possible, is chosen in young children. VAS is a single-dimensional pain evaluation scale that was developed by Freyd in 1923 (47). It is of two types, a 10-point scale, and a 100-point scale. 10-point VAS scale (modified NRS scale) which quantifies pain from "not at all" (zero) to worst terrible pain (ten) and is one of the most commonly used scales because of its simplicity, reproducibility, and easy comprehensibility. Moreover, Breivik at al confirmed its sensitivity to detect small changes in acute pain after surgery (42). In our study, pain was assessed during movement to assess pain free musculoskeletal rehabilitation. Also, assessment of acute pain on movement (dynamic pain) is more imperative than pain at rest (42). In this study pain that occured during unassisted jaw movements immediately post trauma and 4-6 weeks post operatively was measured on VAS-NRS thus minimising the effect of concomitant injuries on maxillofacial pain. The present study participants have rooted from diverse cultural and linguistic backgrounds. Hence, we augmented the VAS-NRS with pictographic representation for enhanced comprehension. The pain experienced by the patients was further categorized by using the NRS scale into "*mild" (0-3), "moderate" (4-6) and "severe" (7-10).*

The mean pain score immediately post trauma was found to be 8.21 ± 1.23. Such high pain scores could be due to the increased inflammatory response of the body immediately post trauma. This is in accordance with Singer et al who reported a high pain score between 7 and 8 (48). At the 4^{th} postoperative week, the pain scores reduced drastically to 1.53 ± 0.94. On a gender-wise comparison of the preoperative and postoperative pain scores, we observed a slightly higher reporting of pain in the females i.e., 8.6 and 1.6 as compared to 8.18 and 1.52 in males at T1 and T2 respectively, although this difference was found to be statistically insignificant. The literature also evidences a higher reporting of pain in female patients as compared to male patients (49). Also, patients with fractures of midface and mandible reported highest pain scores of 8.87 at T1 and 1.67 at T2, followed by patients with mandibular fractures with 8.16

at T1 and 1.4 at T2 and midface fractures with 8.04 at T1 and 1.56 at T2. This difference of pain scores depending on the site of fracture was also found to be statistically insignificant.

Apart from pain control, the second most important expectation from any treatment would be to have functional rehabilitation (50). Our treatment emphasis extended beyond the fracture reduction and stabilisation to rehabilitate the patient functionally at the earliest. In addition to occlusion and chewing ability being monitored regularly, occlusal bite force was used as an objective, consistent indicator for refurbishment of the skeletal framework and soft tissue healing in our patients. Clinically all our patients had a regular follow up during which occlusal discrepancy or postoperative complications if any, were identified and corrected at the earliest.

Functional rehabilitation after trauma ensures boosted QoL of patients (28). Masticatory function alludes to the ability of a person to chew without any interference. Occlusal forces and mandibular movements are key predictors of masticatory function (51). The entire masticatory system works as a single functional unit consisting of the maxilla, mandible, soft tissue attachments, muscles of mastication and the dentition. Any disturbance in this circuit of the apparatus can lead to an alteration in the occlusal bite force, thus hampering the mastication. This is the reason why authors firmly believed that bite force of entire maxillomandibular complex should be measured at different regions (right anterior and posterior and left anterior and posterior) but depicted as a single value in toto in the form of mean bite force.

As it is impossible to assess patients' pre-trauma bite force, for comparison, the bite force of age, sex and weight matched healthy controls was taken for reference. As females had a skewed representation (5.26%) in our study, only 45 females were enrolled in the control group and the mean bite force was not calculated separately for females both in controls and patient population. The age range of healthy controls was 18-50 years and body weight ranged between 45-75 kgs. The average bite force of healthy controls on the right and left sides were found to be 468.95N and 470.21N and the mean bite force was 469.58N. As illustrated in Figure 29, the bite force of healthy controls follows a characteristic Gaussian/Bell shaped curve. This signifies that the bite force of healthy controls follows a normal distribution implying that this cohort of healthy individuals is representative of the populace of Western zone of Rajasthan. In

the Indian population the mean maximum bite force on either side at the molar region was estimated as 448.47 ± 191.82N and 296.31 ± 116.79N in males and females respectively (52). According to Spiessl, maximum biting force in males is 750N and in females is 500N at the molar region (53).

In our study population, immediately after trauma, the right molar bite force was 16.75 ± 50.9N and left molar bite force was 19.38 ± 56.16N with a mean bite force of 18.06 ± 51.56N. This could be due to severe pain and bony discontinuity not allowing the patients to bite properly. At the 4^{th} week follow up post-surgery, the right molar bite force improved to 182.02 ± 76.14N and the left molar bite force improved to 190.80 ± 96.67N with a mean bite force of 186.34 ± 79.78N. There was a consistent progressive increase in bite force as the time progressed after fracture reduction. For the purpose of evaluating the bite force achieved at 4^{th} week post fracture reduction grading of bite force as per Table 1 was used. It was found that Grade I bite force was achieved in 21.05% of patients, Grade II in 60%, Grade III in 15.79 and Grade IV in 3.16% of patients. Thus, maximum number of patients (>75%) were able to reach mid quartile range signifying good functional restoration post surgically. Proper fracture reduction, good occlusion and mild pain experienced by the patient could be the contributory reasons.

On correlating the studied parameters, we inferred that there was a significant correlation ($p < 0.05$) between change in right and left bite force from preoperative to postoperative states with age; i.e.; with an increase in age, it was found that there was a less change (gain) in the bite force. However, literature has reported that age has very minor effect on bite force (54). This seems a logical stance as increasing age may slow down the patients' pace to reach the healthy level. There was no statistical correlation found between change in pain and bite force from preoperative to postoperative periods. This could be due to the fact that pain was assessed during function i.e., mouth opening and lateral excursions, and not on occlusion.

In the recent times, PROs seem to be a potent marker to assess the clinical efficacy of the provided treatment. A PRO is defined as *"any report coming directly from patients about how they function or feel in relation to a health condition and its therapy"*. PROs are questionnaires completed by patients which can be used to measure symptom burden and treatment and its impact on their sense of wellbeing and QoL. However, the

next crucial step would be to identify the minimal clinically relevant change in these PROs in the form of MCIDs as a decision maker for treatment and its follow up. The calculation of MCID is regarded beneficial as it is based upon PROs and can be applied to compare treatment modalities and can be relied upon to alter the treatment. In brief, MCID may help us to quantify the treatment outcome as it aids in assessment of the actual effect of treatment as perceived by the patient.

MCID was defined by Jaeshcke et al in 1989 as *"the smallest difference in score in the domain of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management"* (6). In simpler terms, it is minimally perceptible change in clinical condition that would be important to the patient. MCID plays a key role as the numerator of the value equation in the evolution to value-based care. Jaeshcke R et al argued that some cases of statistically significant treatment outcomes actually lacked clinical significance and relevance (6). This is more so experienced with chronic conditions. MCID may improve the clinician's ability to determine methods of care that provide better results in a homogenous population or may even indicate a point, for treatment regimen alteration in patient management (19).

MCID of pain is the subjective assertion of minimal change in pain score which is detectable as a meaningful change in pain status by patients. As reported by various authors the patients' positive outlooks for treatment are correlated with pain reduction after treatment (50,56,57). Perception of pain is a complex phenomenon and may vary depending on the gender, racial, social and cultural background of patients. Quantification of pain reduction or change in pain is necessary in order to gauge the beneficial effect of the intervention. MCID for chronic pain and function has been used extensively in orthopaedic literature to assess of success of surgical and non-surgical treatments (7,8,11,12). MCID has also found its role in assessing treatment of relevance in lumbar spine surgeries by assessment of chronic pain (10,19). In the purview of maxillofacial speciality MCID has been elaborated only for chewing efficiency in TMDs (16,17). Maxillofacial trauma being the major cause of pain and functional disability in the maxillofacial region, this study aimed to estimate the MCID of pain and bite force (as a marker of functional rehabilitation).

The MCID can be calculated by anchor based or distributive based approaches. In the anchor-based approach the difference in the PRO is linked to an eloquent external anchor that reflects the patient's perspective of the treatment. Clinical outcomes, laboratory values or Patient-Reported Outcomes (PRO) can serve as anchors. The most extensively utilised anchor is the patient's global rating of change, which is a transition rating evaluating the change in any selected parameter from pre to post intervention (58). The number of responses on the transition rating is tailored according to the disease studied or the outcome assessment tool. However, such transition ratings have been reported to have a high rate of recall bias. Despite the spontaneous response of transition questions, patients have substantial strain in recollecting former health states and this difficulty increases if patient has to remember for longer duration. It has been reported that as time progresses, patients are more probable to confuse change over time with current status (14,58).

According to an extensive review by Copay et al, 4 different methods of the anchor-based approach can be applied (55)

(a) the '*within-patients*' score change or mean change method. In this method, the MCID is considered as the difference of mean score of patients who improved.

(b) the '*between-patients*' score change or change difference method. In contrast the MCID calculated by the change difference method represents the difference between the mean score of improved patients and those who did not (59).

(c) ROC curve-based sensitivity- and specificity-based approach. This method of calculating MCID is by the ROC curve (the sensitivity- and specificity-based approach) which is used to recognize MCID thresholds on gauges that quantify an alteration in health status. While few studies specified the MCID as the upper end of the arc, and other studies denoted the MCID as that point on the ROC curve at which the sensitivity and specificity are maximum. The area under the curve (AUC) is derived which signifies the probability of detecting the proportion of patients who have experienced a change. The ROC curve is generated by plotting the sensitivity of the instrument (the true positive rate) against the specificity (the false positive rate) (60).

(d) the social comparison approach. Here, patients collate themselves with other patients and discuss regarding their health status, after which the patients perceive their

current health status themselves as the same or worse or better than their counterpart (59,60).

In lieu of the limited sample size in our study, MCID was calculated only by anchor-based approaches. We applied the change difference method and ROC curve method of the anchor-based approach in our study, while the other two methods, viz, mean change and social comparison methods could not be used as they were not compatible with our study design. The four-item anchor instrument used in the study for calculating MCID of pain and bite force was derived from standard anchor question designed by Tubach et al (25). This anchor instrument assessed the existing condition of the patients thus eliminating the concern of recall bias. Further we insisted repeatedly that the patient responds to the questions based on the current state and perspective.

In the change difference method, the MCID is ideally calculated and interpreted as the difference between scores of patients who rated themselves as *"a little better" or "a little worse"* as compared to the other patients. But as none of our patients scored themselves as "poor" or "none" on the anchor instrument, a comparison was drawn between patients rating themselves as "good" or "excellent". In our study the MCID of pain on VAS-NRS by change difference method was 6.68 and the MCID of mean bite force was 186.14N. The difference in pain scores on VAS-NRS and bite between the "Good" and "Excellent" cohorts were statistically significant ($p<0.05$). Thus, any comparison drawn between the two groups would give statistically valid results.

According to the ROC curve, the MCID of pain on VAS NRS derived was 6.5 with a sensitivity of 65.6% and a specificity of 55.2%. and the MCID of mean bite force was 134.27N with a sensitivity of 71.3% and specificity of 63.3%. The obtained MCID values by two different methods are quite nearby, thus proving its validity.

The MCID values obtained in our study implied that at 4 weeks follow up, if there is an improvement of pain on VAS NRS by a score of 6.5, then the treatment is clinically relevant to the patients. In a systematic review on acute pain on 100mm VAS scale, MCID has been found in a range of 11-40mm (20). On the other hand, in chronic pain MCID has been found in the range of 1.6 to 4.1 on VAS-NRS, scale (8,11,19,24). In our study MCID has been found to be 6.5 on a VAS-NRS score, which is actually a pretty high value obtained. Compounding observation here is that our anchor question was rated as "Good" or "Excellent" by 100% of our patients. Combined implication

could be that an MCID of 6.5 score on 10mm VAS-NRS has actually signified 100% treatment success in terms of pain relief. Also, a gain in mean bite force by a minimum of 134.27N is considered clinically relevant by the patients.

But, the point to be pondered upon in our study is the low sensitivity and specificity of the MCID values. The reason for low sensitivity could be due to the fact that none of our patients reported the treatment outcome as "Poor" or "None" with our used standard anchor instrument. 31.58% of patients reported the treatment outcome to be good and the rest 68.42% of patients reported the treatment outcome to be excellent. Conventionally patients who fall in the "None" and "Poor" cohorts are compared with those in "Good" and "Excellent" cohort. But in our study, comparison was drawn between "Good" and "Excellent" cohort of patients and as both the cohorts were statistically different, authors propose that result would be more acceptable.

On the other hand, distribution-based approaches for calculating MCID could not be used in our study due to smaller sample size. These are constructed upon the statistical characteristics of the study population and consequently on statistically significant changes. The distribution methods may use methods based on Standard Error of Measurement (SEM), Standard Deviation (SD), Effect Size (ES), Standardized Response Mean (SRM), Minimal Detectable Change (MDC), or Reliable Change Index (RCI) (14). This approach is capable of detecting change beyond some level of random variation, hence is regarded better statistically. However, it fails to validate the interrogation of the patient's outlook of clinically relevant change which is essentially distinguishable from statistical significance. Also, the distribution-based method solely relies on the sample and has been reported to be highly sample specific (61).

Using the type of methods to determine MCID is multifactorial and no single method can actually determine the MCID of any PROM. Further it has been proposed that in quasi-continuous PROMs, such as those that assess improvement with treatment in chronic diseases, sensitivity and specificity are often valued alike, thus different approaches should be used to derive at a particular value of MCID for a specific disease state (62).

The availability of various anchors and application of multiple methods for calculation of MCID always results in a range of numerical for a given scale. In order to derive at a single value, it has been recommended that anchor-based approaches should be

weighted more and clinical trial experience should be used to narrow down the MCID values. Revicki et al further endorsed the application of the anchor-based approaches to derive the prime evidence for MCID of any outcome and the distribution-based approaches as secondary or augmented evidences for that MCID value (14). A systematic consensus including multiple clinicians and researchers with a huge data with multiple patient-based and clinical outcomes is recommended to arrive at a single or a narrower range of MCID value.

The foremost constraint of the MCID is the availability of plentiful methods for its calculation, which produce a manifold of MCID scores for a solitary outcome. The application of innumerable of methods leads to controversies in determining which of the proposed MCID values is most accurate. Moreover, the MCID is not a universally constant measure and hence cannot be externally validated to varied population and disease states (63).

Another, PROM which can be a potentially clinically relevant concept, thus assessed in our study is the patient acceptable symptom state (PASS). This has been defined as "the highest level of symptom beyond which patients consider themselves well". The most extensively used anchoring question to identify PASS cut-off points is, *"Taking into account all the activities you have during your daily life, your level of pain, and also your functional impairment, do you consider that your current state is satisfactory?"*, which has been used in this study (25). The response options are ''yes'' or ''no''. It has been found that the robustness of PASS cut-off points is that they are constant with time and are unaltered by age, sex and duration of disease (15).

As per the PASS question assessing the satisfaction score, 100% of our patients were satisfied with the rendered treatment. The PASS levels were calculated as the 75^{th} percentile of scores and was found to be 2 on VAS-NRS for pain and 220.92N for mean bite force. There is a paucity of literature estimating PASS levels in the maxillofacial speciality. Orthopaedic literature has estimated PASS as the 75^{th} centile of patients with improvement and the scores ranged between 2 and 3.5 cm on a 10-cm VAS scale for chronic rotator cuff diseases (8,9). Myles et al estimated PASS as the 25^{th} centile of patients having a positive response and obtained a score of 33 on a 100-point VAS scale for patients with acute postoperative pain (64).

This high satisfaction rate in the form of "Good", or "Excellent" rating of anchor instrument for MCID and 100% satisfaction on PASS question is actually a very high target achieved. This could be a confluence of multiple factors involving patients' sociodemographic determinants, scrupulous treatment planning and a thorough treatment follow up. There could be a possibility that the stringent inclusion and exclusion criteria allowed only those patients with maxillofacial fractures who could be intervened at the appropriate time with apposite standard treatment, to be enrolled in the study. All those patients, where any form of deviation from standard fracture treatment with respect to site of reduction, timing of treatment or inoperability under general anaesthesia were excluded. Further it was found that study population basically consisted of 94.73% males, 96.74% of patients being literates, 92.63% of employed and 94.47% belonging to the middle socioeconomic strata. This sociodemographic background of the patients could be an important determinant for high treatment satisfaction. The literature evinces that increased pain perception and resulting disability have been reported more in the unemployed and low socioeconomic population (65,66). According to Sikora M et al, male patients stated a better improvement in the QoL than female patients after maxillofacial trauma (67).

Another contributing factor for very high treatment success could be definitive, standard surgical treatment that was given diligently abiding by the surgical protocols which comprised of informed surgical consents with in depth discussion on possible complications, perioperative antibiotic administration and aesthetic surgical approaches. A strict follow up allowed us to identify and address postoperative complications promptly and any subtle disturbances in function and occlusion were identified early and corrected with guiding elastics probably giving early and complete rehabilitation. Ergo, all these factors, one over the other might have contributed to the surprisingly 100% satisfaction score and high score response of our anchor instrument.

STRENGTHS:

Although this study is an analytical prospective which lies lower in the hierarchy of evidence pyramid of research (68), every attempt has been made to strengthen this study by using appropriate statistical tools and minimizing maximum possible biases.

1. This study was conducted strictly as per protocol. We tried to include maximum possible number of maxillofacial trauma patients (95) for calculating the MCID and PASS of pain and bite force.
2. Appropriate statistical tools (Microsoft Excel, t-test, Mann Whitney U test, Z-test) were used to calculate MCID and PASS values. MCID of both pain and bite force was calculated by change difference and ROC curve methods of anchor-based approach. And the values came out to be nearby.
3. All the patients who presented immediately with maxillofacial injuries or those who reported within 72 hours of trauma to our tertiary care center, i.e.; only the incident cases and not the prevalent cases were evaluated thus minimizing the selection biases.
4. Further all the screened patients were analyzed based upon the previously drafted stringent inclusion and exclusion criteria prior to enrolment into the study, thus minimizing the channeling bias.
5. To reduce the observer bias, the data collection was carried out by a single observer.
6. This study is of PROMS which are subjective variables. Thorough attention has been put forth to objectify it by using standardized study assessment tools viz VAS-NRS for pain, anchor question for rating of response to treatment and satisfaction question for PASS. The Flexi force sensor used for quantifying the bite force was also standardized in 150 healthy individuals. Thus, every possible step was taken for curtailing the detection bias of the study.
7. This prospective study was designed with the assessment parameters involving questions pertaining to the existing condition of the patient thus decreasing recall or responder bias.
8. Absence of any retrospective data collection ablated the chronology bias in our study.
9. All the 95 patients enrolled in the study were followed up to a period of 4 weeks and none of the patients were lost to follow up thus curbing attrition bias.

LIMITATIONS:

1. The sample size of our study was deficient for the application of the distribution-based approach for calculating the MCID of pain and bite force.
2. The sociodemographic distribution of the study participants was skewed with a majority of them being males, educationally qualified and belonging to middle socioeconomic strata due to which the stratification of MCID on the basis of sociodemographic variables could not be accomplished.
3. Since, none of the patients reported dissatisfaction with the treatment, the MCID was calculated between the "Good" and "Excellent" cohorts which could be a salient contributory factor for low sensitivity and specificity of the derived MCID value.

Conclusion

CONCLUSION

Although, traditional researchers have evaluated and weighted surgical success based on statistical significance, it is time that we shift our focus to the patients' perception of their own health state in order to fathom the clinical relevance of the rendered treatment. PROMs such as MCID and PASS are key metrics to solve the enigma of whether these statistically significant results prove clinically beneficial to patients or not.

In this study, we estimated the PASS and MCID of pain on VAS-NRS and bite force as a measure of functional restoration in maxillofacial trauma patients. Pain and function are the two most important maxillofacial treatment outcomes that need to be dealt with. Until recently all the studies have focussed on the statistically significant physical, psychological, biochemical and radiological end points for evaluating treatment success. This study is the first of its kind to attempt to calculate PASS and MCID of pain and bite force (restoration of function) after maxillofacial trauma fractures. The MCID of pain on VAS-NRS was found to be 6.5, suggesting that any patient with a decrease in VAS-NRS score, i.e., improvement of pain by a score of 6.5 is minimally satisfied with the treatment. The gain in mean bite force by 134.27N was clinically acceptable to the patients after treatment of maxillofacial fractures. The PASS estimates revealed a score of 2 on VAS-NRS and 220.92N of mean bite force as an acceptable level of symptomatic state for patients. All the patients were 100% satisfied in our study. Through this study we would like to highlight the importance and role of PROMs as part of surgical treatment success, which would further enhance the quality of health care delivery.

Implications And Future Recommendations

1. This study emphasizes the importance of the PROMs (MCID and PASS) in research to establish a threshold for successful treatment. But this is a single Centre study and calculation of MCID and PASS is basically a statistical exercise. A larger sample size would allow application and comparison of different methods of calculating the MCID. Thus, this study should be considered as a stepping stone for calculating MCID and PROs in a multicentric study with greater sample size, wider socioeconomic patient distribution for generalizability and external validity of the results.
2. MCID and PASS should depend on patient's sociodemographic factors like socioeconomic status, education, age and gender. Hence, stratification of MCID on the basis of these above-mentioned factors is altogether an elaborate area of research.
3. Our study demonstrated a very high satisfaction score, thus implying that appropriate treatment planning, pre-operative patient counselling, stringent surgical protocols and strict follow up can generate a positive effect of treatment even in patients' perspective. With this study authors put forth that 100% patient satisfaction in their perspective is an achievable target. Although, this model requires extrapolation to multiple centers.
4. Duration of follow up does not have a clear-cut guideline in maxillofacial trauma. Patients of midface fractures are routinely followed for 6 months and those with mandible fractures are followed up till a period of 3 months. Authors firmly believe that PROMs like PASS, MCID for pain and function could best establish the patients' recovery pace thus should be used to frame patient centric follow up protocol. This may require to generate a PROM based metric for deciding the follow up intervals and duration for maxillofacial trauma. This may aim towards reducing the number or rescheduling of follow up visits and further reduce the economic burden of the patients as well as the health care system.
5. There is a severe dearth in literature related to MCID and PASS in the maxillofacial region, however, these being important PROMs guiding treatment decisions and effective surgical outcomes, there is a felt need for estimation of MCID and PASS in other oral diseases affecting the maxillofacial region like TMDs, MPDS, oral mucosal lesions etc. Authors firmly believe that these PROMs would be more applicable in chronic diseases.

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Annexures

Annexure I: Institutional Ethics Committee Certificate

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2020/3226 **Date: 14/10/2020**

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2019-20/988**

Project title: **"Determination of Minimal Clinically Important Differences (MCID) and Patient Acceptable Symptomatic State (PASS) in Maxillofacial Trauma patients: A Prospective Observational Study"**

Nature of Project:	**Research Project**
Submitted as:	**M.D.S. Dissertation**
Student Name:	**Dr.Aparna G**
Guide:	**Dr.Kirti Chaudhary Dutt**
Co-Guide:	**Dr. Neeti Rustagi, Dr. Ankita Chugh & Dr.Pravin Kumar**

Institutional Ethics Committee after thorough consideration accorded its approval on above project.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

Please Note that this approval will be rectified whenever it is possible to hold a meeting in person of the Institutional Ethics Committee. It is possible that the PI may be asked to give more clarifications or the Institutional Ethics Committee may withhold the project. The Institutional Ethics Committee is adopting this procedure due to COVID-19 (Corona Virus) situation.

If the Institutional Ethics Committee does not get back to you, this means your project has been cleared by the IEC.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member Secretary

Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

Basni Phase-2, Jodhpur, Rajasthan-342005; **Website:** www.aiimsjodhpur.edu.in; **Phone:** 0291-2740741 Extn. 3109
E-mail : ethicscommittee@aiimsjodhpur.edu.in; ethicscommitteeaiimsjdh@gmail.com

Annexure II: Case Record Form

CASE RECORD FORM

SERIAL NO:	

NAME :

AGE/SEX :

OCCUPATION : Professional / Skilled worker / Unemployed

EDUCATIONAL QUALIFICATION : Graduate / Literate / Illiterate

SOCIOECONOMIC STATUS : Upper / Middle / Lower

AIIMS REGISTRATION ID :

CONTACT NUMBER :

MODE OF INJURY :

DATE OF INJURY :

Inclusion Criteria:	**YES**	**NO**
❖ Patients who have given written informed consent to be a part of the study		
❖ Patients in the age group between 18-65 years, of either sex		
❖ Patients with maxillofacial trauma		
❖ Patients with minimal comorbidities – ASA I,II		
❖ Absence of pre-existing maxillofacial pathologies especially tumors, cysts, TMDs and MPDS		

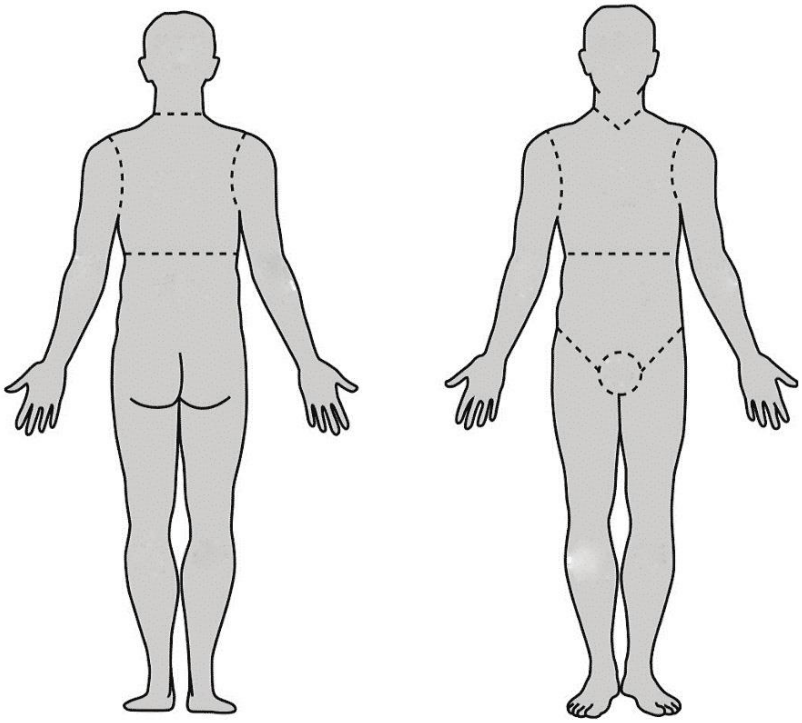
Exclusion Criteria:

- Patients in age range <18 years and>65 years
- Patients with severe debilitating conditions such as uncontrolled diabetes

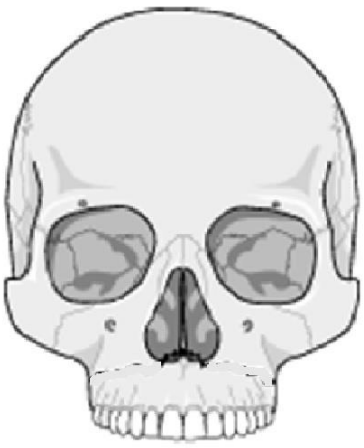
  mellitus, uncontrolled hypertension, cardio respiratory conditions, previous

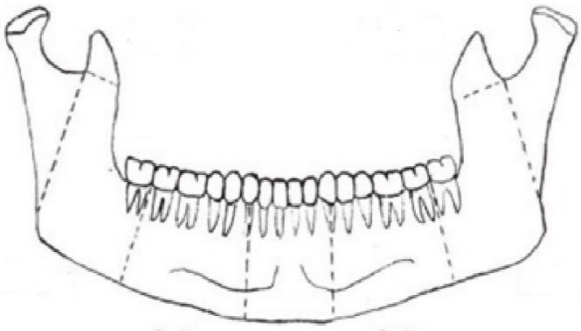
  history of cerebrovascular accidents, myocardial infarction,

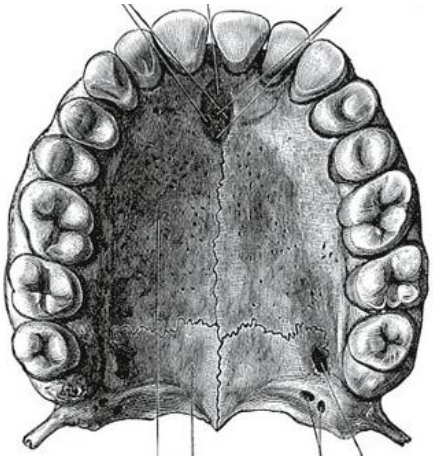
  coronary artery disease.
- Patients who are intubated / tracheostomized
- Patients with concomitant head injuries, cervical spine injuries or debilitating thoracic or abdominal trauma
- Patients with psychiatric illness
- Intoxicated patients
- Patients under central nervous system depressants such as fentanyl, morphine, codeine, pregabalin, gabapentin
- Patients with altered sensorium



Maxillofacial Fractures







Provisional Diagnosis

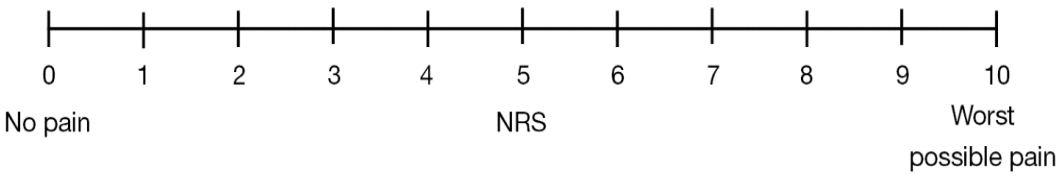
Radiographic Findings

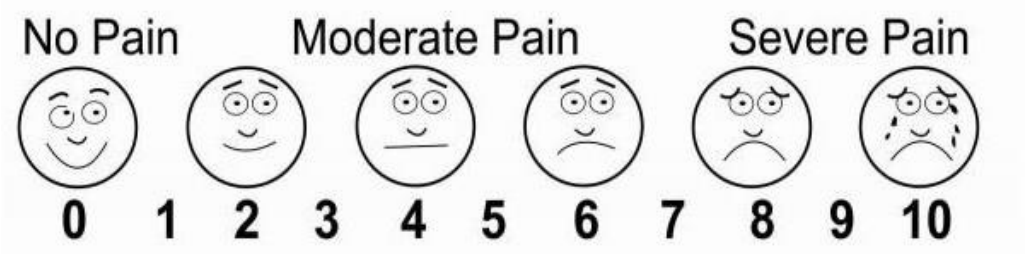
Final Diagnosis

Drugs administered

Visual Analogue Scale (VAS) used in this study for Pain assessment

Function	**VAS Score for Pain**
Mouth opening, Protrusion, lateral excursion	





Bite Force:

Operative Intervention:

Closed Reduction / ORIF

Post operatively (4weeks):

Function	**VAS Score for Pain**
Mouth opening, Protrusive, Lateral excursive	

Bite Force:

Rating of response to treatment

- None	No good at all, ineffective treatment
- Poor	Some effect but unsatisfactory
- Good	Satisfactory effect with occasional episodes of pain and stiffness
- Excellent	Ideal response, virtually pain free

Satisfaction with symptom state:

Taking into account all the activities you have during your daily life, your level of pain, and also your functional impairment, do you consider that your current state is satisfactory?

YES/NO

Annexure IIIA: Patient Information Sheet (English)

Oral and Maxillofacial Surgery

Department of Dentistry

All India Institute of Medical Sciences, Jodhpur

TITLE: "Determination of Minimal Clinically Important Differences (MCID) And Patient Acceptable Symptomatic State (PASS) in Maxillofacial Trauma patients: A Prospective Observational Study"

You have been requested to volunteer for a research study, in which data would be collected from patients with maxillofacial fractures. The data collected will include personal details such as address, contact numbers, educational qualification, socioeconomic status.

Once the diagnosis of maxillofacial fractures has been established, pain on performing various jaw movements will be assessed and recorded.

The surgical treatment will be provided as per requirement, and would carry its own risks and benefits. The risks and benefits of the treatment provided do not have any correlation with this study.

Post operatively pain on performing the jaw movements will be assessed again and questions evaluating the satisfaction with symptom state will be put forth.

This study will not require any additional follow up visits/expenses/invasive procedures.

All the data collected shall be kept confidential and will be used only for the purpose of research.

For further queries, contact:

Dr. Aparna G
Post graduate student
Department of Dentistry,
AIIMS, Jodhpur
Mobile no: 9003201443

Annexure IIIB: Patient Information Sheet (Hindi)

ओरल एंड मैक्सिलोफ़ेसियल सर्जरी

दंत चिकित्सा विभाग

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर

रोगी सूचना पत्र

TITLE: "Determination of Minimal Clinically Important Differences (MCID) And Patient Acceptable Symptomatic State (PASS) in Maxillofacial Trauma patients: A Prospective Observational Study"

आपको एक शोध अध्ययन के लिए भाग लेने के लिए अनुरोध किया गया है, जिसमें मैक्सिलोफेशियल फ्रैक्चर वाले रोगियों से डेटा एकत्र किया जाएगा। एकत्र किए गए डेटा में पता, संपर्क नंबर, शैक्षिक योग्यता, सामाजिक आर्थिक स्थिति जैसे व्यक्तिगत विवरण शामिल होंगे ।

एक बार जब मैक्सिलोफेशियल फ्रैक्चर का निदान स्थापित करने पर , विभिन्न जबड़े के हिलने डुलने पर दर्द का आकलन किया जाएगा और रिकॉर्ड किया जाएगा।

सर्जिकल उपचार आवश्यकता के अनुसार प्रदान किया जाएगा जिसमे, जोखिम और लाभ संभव है । प्रदान किए गए उपचार के जोखिम और लाभों का इस अध्ययन के साथ कोई संबंध नहीं है।

ऑपरेशन के बाद जबड़े की क्रियाओं को करने पर दर्द का फिर से मूल्यांकन किया जाएगा और संतुष्टि का मूल्यांकन करने वाले प्रश्नों को सामने रखा जाएगा।

इस अध्ययन में किसी भी अतिरिक्त अनुवर्ती यात्राओं / खर्चों / इनवेसिव प्रक्रियाओं की आवश्यकता नहीं है।

एकत्र किए गए सभी डेटा को गोपनीय रखा जाएगा और इसका उपयोग केवल अनुसंधान के उद्देश्य के लिए किया जाएगा।

अधिक प्रश्नों के लिए, संपर्क करें:

डॉ अपर्णा जी

स्नातकोत्तर छात्र

दंत चिकित्सा विभाग

एम्स, जोधपुर

मोबाइल नंबर: 9003201443

Annexure IVA: Informed Consent Form (English)

INFORMED CONSENT FORM

All India Institute of Medical Sciences, Jodhpur

The attached information sheet dated .....has elaborate details in the language that I can fully comprehend. I have read the said contents in detail and have fully understood the same. I also confirm that I was provided the requisite opportunity to ask questions for better conception.

The nature and purpose of the study and the relevant risks/benefits attached, the duration and all other necessary information has been clearly put forth. I declare that my participation is purely voluntary and that I am free to withdraw at any time without assigning any reason and that my medical care or legal rights shall not be affected in any way.

I am aware that information collected about me upon my participation in this research and the relevant section of medical notes shall be looked at by any responsible individual from AIIMS JODHPUR.

I hereby accord my permission for the undersigned individuals to access my records. I hereby give my consent to take part in the study.

Signature/Left Thumb Impression: ----------
Name of the Participant: ----------
Son/Daughter/Spouse of: ----------
Postal Address: ----------
Date: ----------
Place: ----------

This is to certify that the above consent has been obtained in my presence.

Signature of Principal Investigator

Date:

Place:

Witness 1	***Witness 2***
----------	----------
Signature/Left Thumb Impression	*Signature/Left Thumb Impression*
----------	----------
Name	*Name*
----------	----------
Postal Address	*Postal Address*
----------	----------

Annexure IVB: Informed Consent Form (Hindi)

Serial no: ----------

सूचित सहमति प्रपत्र

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर

संलग्न सूचना पत्र में भाषा में जो विस्तृत विवरण है मैं पूरी तरह से समझ सकता हूं। मैंने उक्त सामग्री को विस्तार से पढ़ा है और इसे पूरी तरह से समझा है। मैं यह भी पुष्टि करता हूं कि मुझे बेहतर समझने के लिए प्रश्न पूछने का अपेक्षित अवसर प्रदान किया गया था।

अध्ययन की प्रकृति और उद्देश्य और संबंधित जोखिम / लाभ, अवधि और अन्य सभी आवश्यक जानकारी स्पष्ट रूप से सामने रखी गई है। मैं घोषणा करता हूं कि मेरी भागीदारी विशुद्ध रूप से स्वैच्छिक है और मैं बिना किसी कारण बताए किसी भी समय अपनी भागीदारी वापस लेने के लिए स्वतंत्र हूं और मेरी चिकित्सा देखभाल या कानूनी अधिकार किसी भी तरह से प्रभावित नहीं होंगे।

मुझे पता है कि इस शोध में मेरी भागीदारी और चिकित्सा नोटों के संबंधित अनुभाग पर मेरे से एकत्र की गई जानकारी को एम्स जोधपुर के किसी भी जिम्मेदार व्यक्ति द्वारा देखा जाएगा।

मैं अपने रिकॉर्ड को एक्सेस करने के लिए अधोहस्ताक्षरी व्यक्तियों के लिए अपनी अनुमति देता हूं। मैं इस अध्ययन में भाग लेने के लिए अपनी सहमति देता हूं।

हस्ताक्षर / बाएं अंगूठे का निशान : _____

प्रतिभागी का नाम : _____

पुत्र / पुत्री / पति / पत्नी : _____

डाक पता : _____

तारीख : _____

जगह : _____

यह प्रमाणित करना है कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त हुई है।

प्रधान अन्वेषक का हस्ताक्षर

तारीख : _____

जगह : _____

गवाह 1:

हस्ताक्षर / बाएं अंगूठे का निशान : _____

नाम :_____

डाक पता :_____

गवाह 2:

हस्ताक्षर / बाएं अंगूठे का निशान : _____

नाम :_____

डाक पता :_____

Annexure V: STROBE Checklist

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Annexure VI: Plagiarism Report

ORIGINALITY REPORT

7%
SIMILARITY INDEX

PRIMARY SOURCES

1	Robert Z. Tashjian, Julia Deloach, Christina A. Porucznik, Amy P. Powell. "Minimal clinically important differences (MCID) and patient acceptable symptomatic state (PASS) for visual analog scales (VAS) measuring pain in patients treated for rotator cuff disease", Journal of Shoulder and Elbow Surgery, 2009 Crossref	100 words — 1%
2	www.ncbi.nlm.nih.gov Internet	80 words — 1%
3	"44th National AOMSI Conference", Journal of Maxillofacial and Oral Surgery, 2019 Crossref	57 words — < 1%
4	Deborah Sybil, K. Gopalkrishnan. "Assessment of Masticatory Function Using Bite Force Measurements in Patients Treated for Mandibular Fractures", Craniomaxillofacial Trauma & Reconstruction, 2020 Crossref	52 words — < 1%
5	hqlo.biomedcentral.com Internet	44 words — < 1%
6	"Spinal Disorders", Springer Science and Business Media LLC, 2008 Crossref	30 words — < 1%